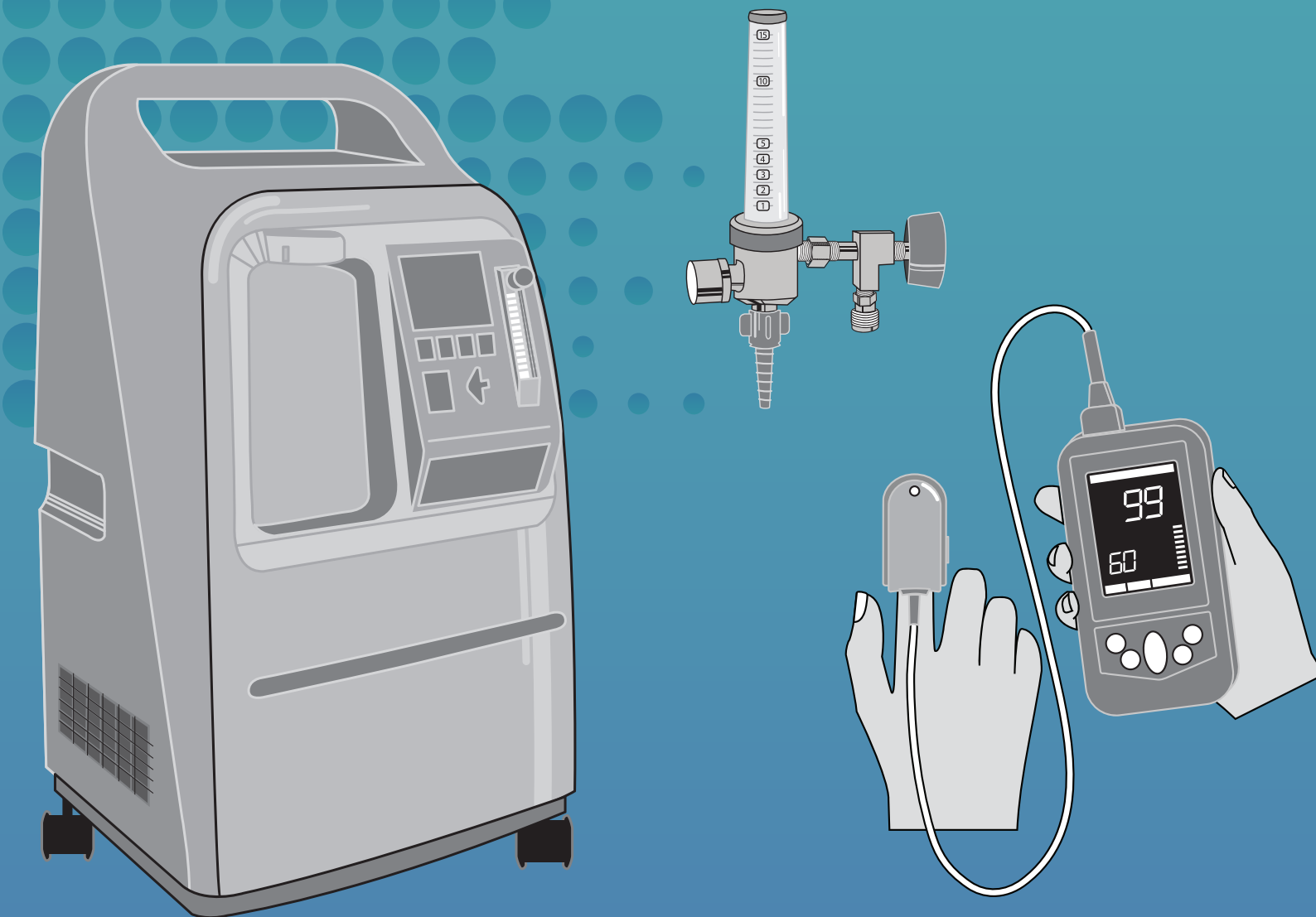
World Health Organization

unicef
for every child

WHO-UNICEF TECHNICAL SPECIFICATIONS AND GUIDANCE FOR OXYGEN THERAPY DEVICES

WHO MEDICAL DEVICE TECHNICAL SERIES



World Health Organization

unicef
for every child

WHO-UNICEF TECHNICAL SPECIFICATIONS AND GUIDANCE FOR OXYGEN THERAPY DEVICES

WHO MEDICAL DEVICE TECHNICAL SERIES

WHO-UNICEF technical specifications and guidance for oxygen therapy devices

(WHO medical device technical series)

ISBN 978-92-4-151691-4 (WHO)

Suggested citation. WHO-UNICEF technical specifications and guidance for oxygen therapy devices. Geneva: World Health Organization and the United Nations Children's Fund (UNICEF), 2019 (WHO medical device technical series). Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

Illustrations by Margot Steiner

Design and layout by L'IV Com Sàrl

Contents

Acknowledgements v

Abbreviations vii

Executive summary viii

1 Introduction 2
1.1 Background 2
1.2 Purpose of the manual 3
1.3 How to read this document 4
1.4 Target audience 5
1.5 Development process 6
References 6

2 Overview of oxygen therapy products 10
2.1 Landscape of oxygen therapy products 10
2.2 Scope of this publication 13
Reference 13

3 Oxygen sources 16
3.1 Overview of different oxygen sources 16
3.2 Technical specifications for oxygen cylinders 21
3.3 Technical specifications for oxygen concentrators 25
References 25

4 Devices for oxygen regulation and conditioning 28
4.1 Overview of flowmeters 28
4.2 Technical specifications for Thorpe tube flowmeters 31
4.3 Overview of flow-splitting devices 34
4.4 Technical specifications for flowmeter stands 36
4.5 Overview of humidifiers 38
4.6 Technical specifications for reusable non-heated bubble humidifiers 39
References 42

5 Oxygen delivery devices 44
5.1 Overview of oxygen delivery devices 44
5.2 Technical specifications for nasal cannulae, nasal catheters and oxygen tubing 45
References 50

6 Pulse oximetry 52
6.1 Overview of pulse oximeters 52
6.2 Overview of pulse oximeter probes 55
6.3 Technical specifications for self-contained fingertip pulse oximeters 57
6.4 Technical specifications for handheld pulse oximeters 60
6.5 Technical specifications for tabletop pulse oximeters 63
References 65

7 Devices for quality power supply **68**
7.1 Overview of devices for quality power supply 68
7.2 Technical specifications for solid-state voltage stabilizers 71
7.3 Technical specifications for surge suppressors 73
References 75

8 Oxygen analysers **78**
8.1 Overview of oxygen analysers 78
8.2 Technical specifications for electrochemical (galvanic cell) oxygen analysers 81
8.3 Technical specifications for ultrasonic oxygen analysers 83
Reference 84

Annex 1: Technical specifications for oxygen therapy devices **86**
Table A1.1: Technical specifications for oxygen cylinders 87
Table A1.2: Technical specifications for oxygen concentrators 93
Table A1.3: Technical specifications for Thorpe tube flowmeters 97
Table A1.4: Technical specifications for flowmeter stands 101
Table A1.5: Technical specifications for reusable non-heated bubble humidifiers 105
Table A1.6: Technical specifications for nasal cannulae 109
Table A1.7: Technical specifications for nasal catheters 113
Table A1.8: Technical specifications for oxygen tubing 117
Table A1.9: Technical specifications for self-contained fingertip pulse oximeters 121
Table A1.10: Technical specifications for handheld pulse oximeters 125
Table A1.11: Technical specifications for tabletop pulse oximeters 129
Table A1.12: Technical specifications for solid-state voltage stabilizers 133
Table A1.13: Technical specifications for surge suppressors 137
Table A1.14: Technical specifications for electrochemical (galvanic cell) oxygen analysers 141
Table A1.15: Technical specifications for ultrasonic oxygen analysers 145

Annex 2: Comparison of pulse oximetry and blood gas analysis **149**

Acknowledgements

The *WHO-UNICEF Technical specifications and guidance for oxygen therapy devices* publication has been developed by the United Nations Children's Fund (UNICEF) in collaboration with the World Health Organization (WHO) to help increase access to and utilization of life-saving oxygen therapy systems in low-resource settings.

Mulugeta Mideksa Amene and Beverly Bradley (Product Innovation Centre, UNICEF, Copenhagen, Denmark) drafted this document with input from Jonas Karlstrom (Product Innovation Centre, UNICEF) and Andrew Gammie (Fishtail Consulting Ltd, Chippenham, United Kingdom of Great Britain and Northern Ireland [United Kingdom]). Umberto Vitale (Product Innovation Centre, UNICEF) developed the first draft of the interagency technical specifications.

Adriana Velazquez Berumen (Senior advisor on medical devices, Essential Medicines and Health Products Department, WHO, Geneva, Switzerland) provided technical input during the preparation of this document and coordinated the input from the following WHO staff: Shamim Ahmad Qazi, Walter Johnson and Wilson Were; WHO consultant, Alejandra Velez; and interns, Joshua Daniel and Karen Kulp.

This document, and the broader WHO-UNICEF collaboration to improve access to and utilization of oxygen therapy systems, which began in 2017 and continues into 2019, has benefited from technical and strategic advice from two expert groups: the Technical Review Group (TRG) and the Advisory Committee (AC). The members of these committees are listed below. All committee members submitted a declaration of interest form.

Technical Review Group members: Roberto Ayala (CENETEC-Salud, Mexico City, Mexico), Audrey Battu (Clinton Health Access Initiative [CHAI], Boston, MA, United States of America), Jim Black (FREO2 Foundation Australia, Melbourne, Australia), Michael Dobson (University of Oxford, United Kingdom), Mike Eisenstein (PATH, Seattle, WA, United States of America), Adegoke G Falade (University of Ibadan, Nigeria), Martha Gartley (CHAI), Hamish Graham (University of Melbourne, Australia), Stephen Howie (University of Auckland, New Zealand), Fyezah Jehan (Aga Khan University, Karachi, Pakistan), Ameel Mohammad (National Health Systems Resource Centre, New Delhi, India), Valentino Mvanga (Ministry of Health and Social Welfare, Dar Es Salaam, United Republic of Tanzania), Susan Niermeyer (University of Colorado, Denver, CO, United States of America), Tayo Olaleye (CHAI), David Peel (Ashdown Consultants, Uckfield, United Kingdom), Shamim Ahmad Qazi (Department of Maternal, Newborn, Child and Adolescent Health, WHO, Geneva, Switzerland), Iain Wilson (Lifebox, London, United Kingdom), Anna Worm (Anna Worm Ltd, France).

Advisory Committee members: Trevor Duke (University of Melbourne, Australia), Mike English (KEMRI-Wellcome Trust, University of Oxford, United Kingdom), Amy Ginsburg (Save the Children, Seattle, WA, United States of America), Jessica Jones (Bill & Melinda Gates Foundation, Seattle, WA, United States of America), Sushil Kabra (All India Institute of Medical Sciences, New Delhi, India), Smita Kumar (United States Agency for International Development [USAID], Washington, DC, United States of America), Abadi Leul (Mekelle University, Tigray, Ethiopia), Kathy Mellor (BirthLink, Ickenham, United Kingdom), Bernard Olayo (Centre for Public Health and Development, Nairobi, Kenya), Kate Schroder (CHAI), Lisa Smith (PATH), Martin Weber (Child and Adolescent Health, WHO Regional Office for Europe, Copenhagen, Denmark).

The following individuals from the TRG and AC are gratefully acknowledged for their direct contribution in reviewing and commenting on the interagency specifications and/or drafts of the technical guidance document: Roberto Ayala, Audrey Battu, Jim Black, Michael Dobson, Trevor Duke, Adegoke G Falade, Martha Gartley, Stephen Howie, Fyezah Jehan, Jessica Jones, Abadi Leul, Ameel Mohammad, Kathy Mellor, Susan Niermeyer, Tayo Olaleye, David Peel, Shamim Ahmad Qazi, Kate Schroder, Lisa Smith, Martin Weber, Iain Wilson and Anna Worm.

In addition to the above committee members, the following individuals are also acknowledged for their input to the draft: Pawan Kumar (National Health Systems Resource Centre, New Delhi, India), Grace Irimu-Thinwa (University of Nairobi, Kenya), Annamarie Saarinen (Newborn Foundation, Washington, DC, United States of America), Michael Ruffo (PATH) and Cindy McWhorter (Product Innovation Centre, UNICEF).

Paul LaBarre and Kristoffer Gandrup-Marino (Product Innovation Centre, UNICEF), along with Abdallah Makhlof (Health Technology Centre, UNICEF), have been instrumental in providing leadership and guidance throughout the many stages of this project.

We would like to acknowledge Vivien Stone (Etchingham, United Kingdom) for assistance in editing and Margot Steiner (Morges, Switzerland) for the illustrations. Federica Gabellini (Product Innovation Centre, UNICEF) is acknowledged for her communications coordination and support throughout the development of this publication.

Funding for this project was provided by the Bill & Melinda Gates Foundation.

Abbreviations

A	ampere
AC	Advisory Committee/alternating current
ANSI	American National Standards Institute
bpm	beats per minute
BS	British Standards
CE	Conformité Européenne (European Conformity)
CGA	Compressed Gas Association (USA)
CHAI	Clinton Health Access Initiative
CPAP	continuous positive airway pressure
CSA	Canadian Standards Association
dB	decibel
DC	direct current
DEHP	di(2-ethylhexyl) phthalate
DISS	Diameter Index Safety System
EML	*WHO Model list of essential medicines*
EU	European Union
FDA	Food and Drug Administration (USA)
FiO_2	fraction of inspired oxygen
Fr	French or Charrière (Ch) (catheter sizing system)
GAPPD	Global Action Plan for Pneumonia and Diarrhoea
HbO_2	oxyhaemoglobin
HFNC	high-flow nasal cannula
Hz	hertz
ICRC	International Committee of the Red Cross
ICU	intensive care unit
IEC	International Electrotechnical Commission
IMDRF	International Medical Device Regulators Forum
IPC	infection prevention and control
ISO	International Organization for Standardization
J	joule(s)
kPa	kilopascal
kVA	kilo-volt-ampere
LED	light-emitting diode
LMIC	low- and middle-income countries
L/min	litres per minute
LRS	low-resource settings
MRI	magnetic resonance imaging
NFPA	National Fire Protection Association (USA)
NGO	nongovernmental organization
NICU	neonatal intensive care unit
ns	nanosecond(s)
PISS	Pin Index Safety System
PSA	pressure swing adsorption
psi	pounds per square inch absolute
psig	pounds per square inch gauge
s	second(s)
SpO_2	peripheral capillary oxygen saturation or oxygen saturation of peripheral capillaries
TRG	Technical Review Group
UL	Underwriters Laboratories (global certification mark)
UNICEF	United Nations Children's Fund
UPS	uninterruptible power supply
USA	United States of America
USAID	United States Agency for International Development
VAC	volts of alternating current
VPSA	vacuum pressure swing adsorption
V/s	volts per second
W	watt(s)
WHO	World Health Organization

Executive summary

Oxygen is an essential medicine that is used to treat hypoxaemia at all levels of the health care system. It is required for surgery, acute respiratory illnesses such as severe pneumonia, chronic pulmonary diseases, emergencies and cardiovascular diseases, among others. Yet in the 21st century many patients require oxygen and it is not available, especially in low-resource settings.

Through a strategic collaboration to increase access to and utilization of oxygen therapy systems, UNICEF and WHO, with support from the Bill & Melinda Gates Foundation, developed the present guidance, which includes technical specifications for a set of essential oxygen therapy devices, to support the procurement and supply of oxygen delivery systems. These devices include oxygen sources, technologies to monitor oxygen concentration in the patient and in the distribution system, as well as devices required to regulate flow and deliver oxygen to the patient. This document is intended to be used by planners, managers, procurement officers, and biomedical engineers and technicians.

This book was drafted by UNICEF with technical support from WHO. A technical advisory group of experts in the field was convened to review all the contents of the book and provide feedback in every aspect. UNICEF and WHO staff considered all inputs in drafting the final version.

The present publication has eight chapters. The first describes the need for oxygen and introduces the technologies and the structure of the document. The second chapter describes the landscape of the products required to deliver oxygen and a general overview of their use at different tiers of the health care system. The list of products covered in the remaining chapters was chosen carefully to represent technologies needed to provide, regulate, deliver and monitor basic oxygen therapy. Detailed specifications are provided for cylinders, flowmeters, flowmeter stands for splitting flow, bubble humidifiers, nasal cannulae and catheters and three types of pulse oximeters. In addition, specifications for other essential supporting technologies – voltage stabilizers, surge suppressors and oxygen analysers for biomedical maintenance – are provided in order to ensure correct operation of oxygen systems.

The technical specifications, provided as overviews in the text and complete tables in Annex 1, include name, coding, technical characteristics and requirements, regulatory aspects, warranties and guidance for appropriate use.

The purpose of this document is to increase access to quality products to ensure the supply of oxygen, especially in low- and middle-income countries and low-resource settings within countries from all income groupings. This project is one of many related to improving oxygen supply that other stakeholders are working on. These efforts aim to support ministries of health to ensure oxygen supply is available, as well as raise awareness of the importance of appropriate selection, procurement, maintenance and use of medical devices, both capital equipment and single-use devices.

This book is complementary to other WHO guidelines and publications on medical devices and on oxygen therapy for children, surgery and emergencies, and will become part of a package of tools to support oxygen delivery to those who need it.

The objectives of the collaboration between UNICEF and WHO have been presented at various workshops, including the Accelerating Access to Oxygen (A2O2), which convened in Dubai in November 2017, and the 4th WHO Global Forum on Medical Devices in India in December 2018. The goal of the information disseminated as part of this joint effort is to guide better selection and procurement of the technologies needed to ensure oxygen supply to those in need, specifically in low-resource settings.

These specifications and accompanying guidance will need to be updated and reviewed as existing technologies are modified and new technologies are developed, to match the needs in countries and in different health care settings, including emergency transportation and community use. UNICEF and WHO will remain committed to improving access to and utilization of oxygen therapy systems through technical resources and procurement mechanisms.

1 INTRODUCTION

1 Introduction

1.1 Background

Oxygen is a life-saving therapeutic medical gas used for the management of hypoxaemia – an abnormally low level of oxygen in the blood that is caused by disease, trauma or other health conditions. In June 2017, the World Health Organization (WHO) included oxygen on the *WHO Model list of essential medicines* (EML) beyond use during anaesthesia, due to its proven life-saving properties, safety and cost–effectiveness *(1)*. Oxygen is an essential element of basic emergency care *(2)* and is required for surgery *(3)* and the treatment of several respiratory diseases, both chronic and acute. For adults and children alike, oxygen is an essential and cross-cutting resource for health delivery systems.

Of the respiratory diseases treated with oxygen, lower respiratory tract infections, defined as pneumonia or bronchiolitis, are a leading cause of mortality and morbidity worldwide, causing an estimated 2.38 million deaths in people of all ages in 2016 *(4)*. In children under 5 years, pneumonia is the single largest infectious cause of death worldwide, killing around 880 000 children in 2016 *(5)*. About 13% of children hospitalized for pneumonia have hypoxaemia *(6,7)*, which increases the risk of death by up to five times *(8)*. It is estimated that every year about 1.5 million children admitted with severe pneumonia need oxygen treatment *(7)*. Childhood deaths from pneumonia are largely preventable, making pneumonia-related deaths a profound inequity affecting the poorest populations around the globe.

The WHO and UNICEF integrated Global Action Plan for Pneumonia and Diarrhoea (GAPPD) aims to accelerate pneumonia control with an integrated framework of key interventions to protect, prevent and treat pneumonia in children, including efforts to improve hypoxaemia management and access to oxygen *(9)*.

Having the ability to properly detect and diagnose hypoxaemia, and having a reliable supply of oxygen to treat hypoxaemia, are crucial elements of ending preventable deaths among adults and children globally. Achieving this requires a holistic and integrated system of technologies that includes everything from the oxygen source (either produced locally at a health facility or delivered and stored) and devices for flow regulation and conditioning, to consumables for oxygen delivery to the patient. In addition, pulse oximetry is used to detect hypoxaemia and monitor oxygen saturation during oxygen therapy for respiratory diseases, anaesthesia, emergency obstetric care, surgery, trauma or any other cause of respiratory difficulty. Finally, devices for continuity of power and power quality, devices for monitoring oxygen concentration, and spare parts for equipment maintenance, along with the capacity to maintain them, are also essential components of effective oxygen systems.

Several studies have shown that improving oxygen systems can improve clinical outcomes for children suffering from severe pneumonia and other respiratory diseases. In Papua New Guinea, improved oxygen systems reduced the risk of death by 35% *(10)*. In Malawi, the introduction of oxygen concentrators in all district hospitals resulted in a decline in pneumonia case fatality rates from 18.6% to 8.4% among total admitted pneumonia patients *(11)*. Several international

initiatives involving national governments, implementing partners and researchers are increasing the availability and use of pulse oximetry, growing the evidence-base for this technology *(12,13,14)*. A recent systematic review suggested that, when combined with improved oxygen administration, pulse oximetry can reduce mortality and improve admission practices of children with hypoxaemia *(15)*. However, implementation research is needed to better understand how pulse oximeter use affects resource utilization and health outcomes in routine programme settings.

Although there are commercially available oxygen technologies that can be used at most levels of the health system, there are inherent complexities in the selection, procurement, distribution and safe utilization of appropriate oxygen systems that make providing a reliable oxygen supply a challenge. The market for oxygen therapy products is diverse in terms of both cost and quality, leading to a high degree of demand-side confusion when selecting and procuring devices. Sometimes, even if oxygen is available, supplies are often unreliable, equipment is poorly maintained, and users and technicians do not have adequate training to use and maintain the equipment effectively *(16)*. Due to these challenges, life-saving oxygen therapy remains inaccessible or unreliable for many severely ill children admitted to hospitals in low-resource settings (LRS).

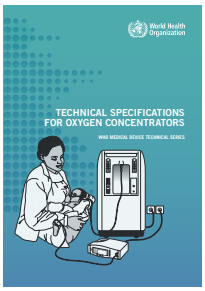
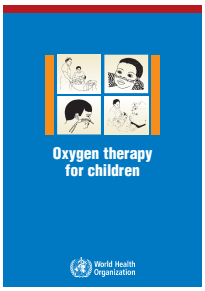
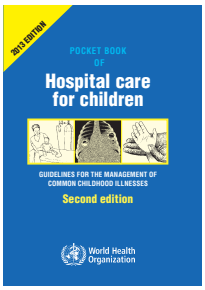
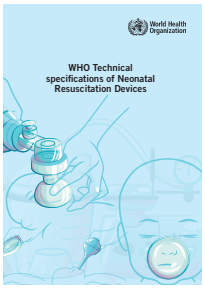
Through a grant from the Bill & Melinda Gates Foundation, WHO and UNICEF formed a strategic collaboration to improve access to and utilization of oxygen therapy systems in LRS. This collaboration aims to reduce information asymmetry and bottlenecks in the accessibility of products through the development and promotion of interagency specifications, as well as through procurement mechanisms in the form of product tenders and inclusion of new products in the UNICEF supply catalogue (https://supply.unicef.org) and in the WHO technical specifications of medical devices (https://www.who.int/medical_devices/management_use/mde_tech_spec/en/). This publication is one element of this collaborative effort.

1.2 Purpose of the manual

In order to meet the growing demand from countries to increase the availability of good quality, affordable, safe and appropriate oxygen therapy systems, the purpose of this interagency publication is to provide harmonized product specifications for a wide range of oxygen products, and to provide guidance on the selection, procurement, use and maintenance of these products.

This guide is complementary to a series of resources for improving the quality of care for severely ill patients in health facilities. In particular, the resources that follow specifically support the improved use and availability of oxygen therapy in LRS (see Table 1.1). As such, this document will not include detailed guidance for oxygen concentrators, for which WHO published *Technical specifications for oxygen concentrators* in 2015. This document will also not cover clinical guidance in detail; for clinical guidance related to oxygen therapy systems refer to *Oxygen therapy for children* (WHO, 2016).

Table 1.1 Other resources complementary to this technical guide

	***Technical specifications for oxygen concentrators* (2015)** provides an overview of oxygen concentrators and technical specifications to aid in the selection, procurement and quality assurance of these devices for the treatment of hypoxaemia in developing country settings. Recognizing the need to increase the quality, accessibility and availability of oxygen concentrators in LRS, this document highlights the minimum performance requirements and technical characteristics for oxygen concentrators and related equipment that are suitable for the use scenarios and climates in LRS (https://www.who.int/medical_devices/publications/tech_specs_oxygen-concentrators/en/) *(17)*.
	***Oxygen therapy for children* (2016)** is a bedside manual for health workers to guide the provision of oxygen therapy for children. The manual focuses on the availability and clinical use of oxygen therapy in children in health facilities by providing practical aspects for health workers, biomedical engineers and administrators. It addresses the need for appropriate detection of hypoxaemia, use of pulse oximetry, clinical use of oxygen and delivery systems and monitoring of patients on oxygen therapy. In addition, the manual addresses the practical use of pulse oximetry, and oxygen concentrators and cylinders, in an effort to improve oxygen systems worldwide (http://www.who.int/maternal_child_adolescent/documents/child-oxygen-therapy/en/) *(18)*.
	***WHO Pocketbook of hospital care for children: guidelines for the management of common illnesses with limited resources* (second edition, 2013)** is for use by doctors, nurses and other health workers who are responsible for the care of young children at first-level referral hospitals with basic laboratory facilities and essential medicines. These guidelines focus on the management of the major causes of childhood mortality in most developing countries, and also cover common procedures, patient monitoring and supportive care on wards, and some common surgical conditions that can be managed in small hospitals (https://www.who.int/maternal_child_adolescent/documents/child_hospital_care/en/) *(19)*.
	***WHO Technical specifications of neonatal resuscitation devices* (2016)** provides a minimum standard baseline to meet the increasing demand to procure good quality, affordable, accessible and appropriate neonatal resuscitation devices. The specifications are intended to support policy-makers, managers, procurement officers, manufacturers, regulators and nongovernmental agencies, especially in low- and middle-income countries (LMIC) to select, procure, use, reprocess and decommission appropriate neonatal resuscitation equipment (https://www.who.int/medical_devices/publications/neonatal-resuscitation/en/) *(20)*.

1.3 How to read this document

Chapter 2 provides a landscape overview of oxygen therapy products, oxygen systems and a framework to guide the appropriate level of the health system for these products. Subsequent chapters present technical guidance according to different product categories as follows:

- Chapter 3: Oxygen sources
- Chapter 4: Devices for oxygen regulation and conditioning
- Chapter 5: Oxygen delivery devices
- Chapter 6: Pulse oximetry
- Chapter 7: Devices for quality power supply
- Chapter 8: Oxygen analysers

Each chapter gives an overview of the product category and a comparison of the different device options in that category. The product overview may contain special boxes with highlighted information in one of three categories: important notes; considerations for neonates; and total cost of ownership considerations *(21,22)*.

Following the product overview is a summary of specifications for select products, including regulations and standards. Detailed WHO templates of the technical specifications for each product are presented in the tables in Annex 1 at the end of the document. Note that these technical specifications require adaptation to create procurement specifications for purchasing in a local setting.

The specifications provided in this guidance focus on commercially available technologies; however, they were written with the understanding that innovations in manufacturing, products, infrastructure and clinical practice will advance the field of oxygen supply and delivery. The specifications do not preclude appropriate upcoming products and/or technologies.

In addition to specifications, notes on installation, safety and handling, and maintenance are also provided. The goal of these sections is not to necessarily give comprehensive instructions (the user and service manuals should always be the primary source for this information), but rather to give users of this guidance document an idea of the level of expertise required to install the devices and the types and frequency of maintenance interventions that might be needed for them. The aim is to help decision-makers, planners and procurers gauge whether the necessary skills and resources are available in the settings where these devices are intended to be used.

The **important note** box highlights scope limitations of the information or guidance provided, or cases where readers should consult additional resources.

The **considerations for neonates** box summarizes additional information, caveats or nuanced guidance for the neonatal patient population when the general guidance may not apply. The neonatal period is the first 4 weeks after birth (27 completed days); whereas "infant" is between 28 days up to the first year; and "child" is after the first year of life.

The **total cost of ownership considerations** box summarizes important notes and trade-offs related to the lifetime costs of oxygen devices and their accessories, including capital expenditure and ongoing operating costs, that may not be apparent from the technical specifications alone. It is important that procurement decisions take these costs into consideration. Additional resources related to planning, managing and budgeting for the care and maintenance of medical devices throughout their life cycle include: *Medical equipment maintenance programme overview* (WHO Medical device technical series) *(21)* and *Guide 2: how to plan and budget for your healthcare technology* (How to manage series for healthcare technology) *(22)*.

1.4 Target audience

The specifications and technical guidance given are intended to support health facility administrators, clinical decision-makers, procurement officers, planning officers, biomedical engineers, infrastructure engineers and policy-makers to select, procure, use and maintain appropriate oxygen therapy system equipment, especially in LMIC. This document may also be of interest to health care workers, academics/researchers, development agencies, nongovernmental organizations (NGOs), device manufacturers, regulators and others involved in planning oxygen systems in LRS.

1.5 Development process

This guide and the associated product specifications have been developed jointly by the UNICEF Supply Division and WHO with inputs from several experts in the areas of childhood pneumonia, oxygen therapy technologies, pulse oximetry and biomedical engineering.

The development process started with a desk review of commercially available oxygen therapy products. A consultative process with project stakeholders and experts was used to identify those products essential to providing basic oxygen therapy;[1] the focus and scope of this first phase of work. Products essential for more *advanced* oxygen therapy, including respiratory support, are not covered in this guide.

Two expert groups informed and provided feedback on the content. The Technical Review Group (TRG) – an interdisciplinary group of expert clinicians, engineers, etc. – provided input on early drafts of the technical specifications and chapters of this guidance document. An Advisory Committee (AC), with representation from a broad spectrum of stakeholder organizations working in the field of pneumonia and oxygen therapy technologies, including the Clinton Health Access Initiative (CHAI), PATH, United States Agency for International Development (USAID), academia and others, provided technical and strategic advice on the project and had the opportunity to comment on later drafts of the technical specifications and this guidance document.

Please see the Acknowledgements for a list of all those who contributed.

References

1. WHO Model list of essential medicines (20th list, March 2017). Geneva: World Health Organization; 2017 (http://www.who.int/medicines/publications/essentialmedicines/20th_EML2017.pdf?ua=1, accessed 25 April 2019).
2. WHO/ICRC. Basic emergency care: approach to the acutely ill and injured. Module 3: approach to difficulty in breathing. Geneva: World Health Organization and International Committee of the Red Cross; 2018.
3. Gleb AW, Morriss WW, Johnson W, Merry AF, Abayadeera A, Belîi N et al. World Health Organization-World Federation of Societies of Anaesthesiologists (WHO-WFSA) International Standards for a Safe Practice of Anesthesia. Anesth Analg. 2018;126(6):2047–2055.
4. GBD 2016 Lower Respiratory Infections Collaborators. Estimates of the global, regional, and national morbidity, mortality, and aetiologies of lower respiratory infections in 195 countries, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet Infect Dis. 2018;18(11):1191–210.
5. Pneumonia [website]. UNICEF; 2019 (https://data.unicef.org/topic/child-health/pneumonia/, accessed 25 April 2019).
6. Subhi R, Adamson M, Campbell H, Weber M, Smith K, Duke T, Hypoxaemia in Developing Countries Study Group. The prevalence of hypoxaemia among ill children in developing countries: a systematic review. Lancet Infect Dis. 2009;9(4):219–27.
7. Nair H, Simões EAF, Rudan I, Gessner BD, Azziz-Baumgartner E, Zhang JSF et al. Global and regional burden of hospital admissions for severe acute lower respiratory infections in young children in 2010: a systematic analysis. Lancet. 2013;381(9875):1380–90.

[1] *Basic* oxygen therapy in this publication refers to the administration of oxygen by nasal cannula, nasal catheter or face mask. Basic oxygen therapy does not involve heated humidification, a blender or advanced respiratory support via the use of bubble continuous positive airway pressure (CPAP), CPAP or mechanical ventilation, which are beyond the scope of this publication.

8. Lazzerini M, Sonego M, Pellegrin MC. Hypoxaemia as a mortality risk factor in acute lower respiratory infections in children in low and middle-income countries: systematic review and meta-analysis. PLoS ONE. 2015;10(9):e0136166.

9. WHO/UNICEF. Ending preventable child deaths from pneumonia and diarrhoea by 2025. The integrated Global Action Plan for Pneumonia and Diarrhoea (GAPPD). Geneva: World Health Organization and the United Nations Children's Fund; 2013 (http://www.who.int/maternal_child_adolescent/documents/global_action_plan_pneumonia_diarrhoea/en/, accessed 25 April 2019).

10. Duke T, Wandi F, Jonathan M, Matai S, Kaupa M, Saavu M et al. Improved oxygen systems for childhood pneumonia: a multihospital effectiveness study in Papua New Guinea. Lancet. 2008;372(9646):1328–1333.

11. Enarson M, Gie R, Enarson DA, Mwansambo C. Development and implementation of a national programme for the management of severe and very severe pneumonia in children in Malawi. PLoS Med. 2009;6(11):e1000137.

12. Graham HR, Bakare AA, Gray A, Ayede AI, Qazi S, McPake B et al. Adoption of paediatric and neonatal pulse oximetry by 12 hospitals in Nigeria: a mixed-methods realist evaluation. BMJ Global Health. 2018;3:e000812.

13. McCollum ED, King C, Deula R, Zadutsa B, Mankhambo L, Nambiar B et al. Pulse oximetry for children with pneumonia treated as outpatients in rural Malawi. Bull World Health Organ. 2016;94(12):893–902.

14. Emdin CA, Mir F, Sultana S Kazi AM, Zaidi AKM, Dimitris MC et al. Utility and feasibility of integrating pulse oximetry into the routine assessment of young infants at primary care clinics in Karachi, Pakistan: a cross-sectional study. BMC Pediatr. 2015;15:141.

15. Enoch AJ, English M, Shepperd S. Does pulse oximeter use impact health outcomes? A systematic review. Arch Dis Child. 2016;101:694–700.

16. Graham H, Tosif S, Gray A, Qazi S, Campbell H, Peel D et al. Providing oxygen to children in hospitals: a realist review. Bull World Health Organ. 2017;95:288–302.

17. WHO. Technical specifications for oxygen concentrators. WHO Medical device technical series. Geneva: World Health Organization; 2015 (https://www.who.int/medical_devices/publications/tech_specs_oxygen-concentrators/en/, accessed 25 April 2019).

18. WHO. Oxygen therapy for children: a manual for health workers. Geneva: World Health Organization; 2016 (http://www.who.int/maternal_child_adolescent/documents/child-oxygen-therapy/en/, accessed 25 April 2019).

19. WHO. Pocket book of hospital care for children: guidelines for the management of common childhood illnesses (second edition). Geneva: World Health Organization; 2013 (https://www.who.int/maternal_child_adolescent/documents/child_hospital_care/en/, accessed 25 April 2019).

20. WHO. WHO Technical specifications of neonatal resuscitation devices. Geneva: World Health Organization; 2016 (https://www.who.int/medical_devices/publications/neonatal-resuscitation/en/, accessed 25 April 2019).

21. WHO. Medical equipment maintenance programme overview. WHO Medical device technical series. Geneva: World Health Organization; 2011 (https://www.who.int/medical_devices/publications/medical-equipment-maintenance/en/, accessed 25 April 2019).

22. Temple-Bird C, Kawohl W, Lenel A, Kaur M. Guide 2: how to plan and budget for your healthcare technology. How to manage series for healthcare technology. Healthcare Technology. Lewes, East Sussex, United Kingdom: Ziken International; 2005 (http://apps.who.int/medicinedocs/en/m/abstract/Js17710en/, accessed 25 April 2019).

2

OVERVIEW OF OXYGEN THERAPY PRODUCTS

2 Overview of oxygen therapy products

2.1 Landscape of oxygen therapy products

Medical oxygen is required across many levels of the health system, for various medical units and services ranging from primary health care, general wards and emergency transport, to delivery rooms, operating theatres, intensive care units (ICUs) and specialized hospital and outpatient units (Fig. 2.1). The oxygen systems required to meet needs at these different levels of the health system are varied.

First and foremost, oxygen systems must consist of an oxygen source, i.e. equipment for oxygen production or oxygen storage. Common sources of oxygen are compressed gas cylinders, oxygen concentrators, oxygen generating plants and liquid oxygen in bulk storage tanks.

The appropriate choice of oxygen source is multifactorial; it is important to take into consideration the amount of oxygen needed at the health facility, available infrastructure, cost, capacity and supply chain for local production of medicinal gases, reliability of electricity, access to maintenance services and spare parts, etc. More details about these different oxygen source options, and the merits and drawbacks of each, are provided in Chapter 3.

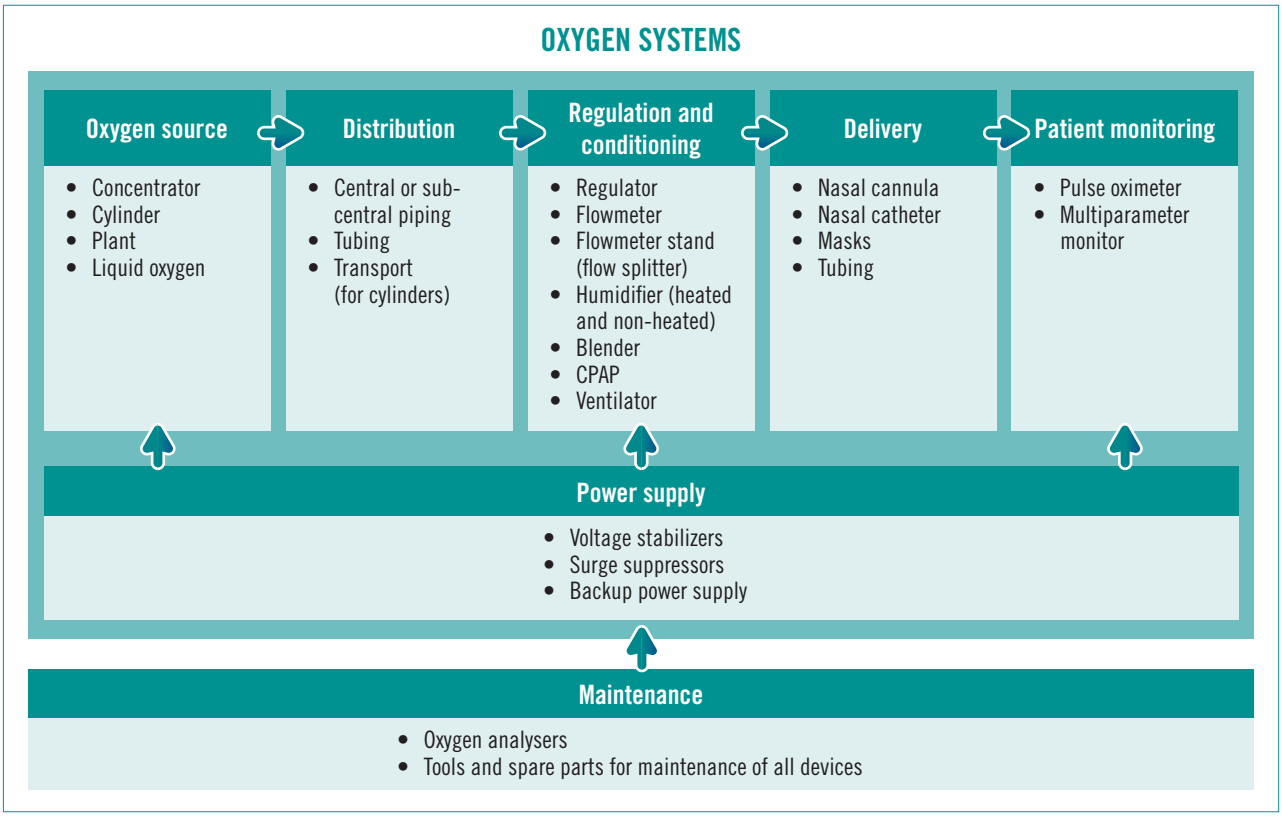
Fig. 2.1 Medical units at various levels of the health system where oxygen or pulse oximetry is needed

Primary level (e.g. home, community care, health post, health centre)	Secondary level (e.g. district hospital)	Tertiary level (e.g. regional, specialized hospital, specialized outpatient clinics)
		
• General ward • Labour unit • Neonatal resuscitation corner • Emergency triage • Transport to referral	• Emergency triage • Labour and delivery room • Neonatal care • Paediatric and/or adult ward • ICU • Operating theatre	• Emergency triage • Labour and delivery room • ICU (neonatal, paediatric, adult) • Paediatric and adult wards • Surgery and recovery wards • Cardiopulmonary ward • Emergency ward

Note: Archetypal examples only; not necessarily representative of all locations.

In addition to the oxygen source, many other oxygen system components are required to get oxygen to patients who need it (Fig. 2.2). This includes mechanisms for oxygen distribution, apparatuses to control pressure, flow, humidity and concentration, and devices for delivering oxygen to patients. Pulse oximetry is also required for measuring a patient's oxygen saturation level (SpO_2) to detect hypoxaemia, and for monitoring their oxygen status while receiving oxygen therapy. For those devices that are electrically powered, devices are needed to protect equipment from poor-quality mains electricity or provide continuity of power during mains power interruptions. Underpinning all of this is the need for maintenance, which, in addition to available expertise, requires tools to test the functionality of the oxygen therapy equipment as well as spare parts to keep it functioning (Fig. 2.2).

Fig. 2.2 Oxygen systems components



A complete oxygen system consists of elements from *all* categories shown in Fig. 2.2; however, not all products in each category are always necessary or appropriate in different contexts. As depicted in Table 2.1, the selection of many of these products depends on both the oxygen source used and the level of the health system where they are to be used. For example, at the primary level, only the most basic equipment is likely to be needed for oxygen delivery (e.g. concentrator and/or cylinders as the source, flowmeters, nasal cannulae and portable pulse oximeters). At higher tiers of the health system, additional products will be needed to support a fuller and more complex range of medical services. A plant may not be an appropriate source of oxygen at the primary level due to its high capital cost and large oxygen output volume, whereas it might be an economical solution for a large hospital. Similar considerations would apply for liquid oxygen, which may be cost-effective at larger hospitals given the volumes required, but not at primary level facilities.

What comprises a complete oxygen system also varies by source (as depicted vertically in Table 2.1). For example, tubing rather than piping is needed for distributing oxygen from a concentrator. Flowmeters are not required as a separate device when using concentrators for a single patient, as they already have built-in flowmeters. If, however, the concentrator needs to be used for multiple patients, it is possible to use a flow-splitting device (referred to as a flowmeter stand in Chapter 4) to split the output flow across multiple outlets. For facilities that use a mix of oxygen sources (e.g. concentrators and cylinders), then the devices listed in the columns for each of these sources are recommended.

Table 2.1 is a general guide to demonstrate how the components of oxygen systems can vary according to oxygen source and health system level. Depending on national policy and local capacity, this may not be representative of all settings.

Table 2.1 Devices required as part of a complete oxygen system, according to type of oxygen source (vertical) and level of the health system (horizontal)

	Oxygen sources		
	Concentrators	**Cylinders** (stand-alone or with manifold systems)	**Oxygen plant** (with central piping)
Devices for distribution			
Primary level	• Tubing	• Tubing	*(Plants may not be suitable as primary level oxygen source)*[a]
Secondary level and above (includes all primary level devices, plus…)		• Central or sub-central piping	• Central or sub-central piping
Devices for oxygen regulation and conditioning			
Primary level	• Flowmeter stand (flow splitter)	• Flowmeter • Humidifier (non-heated)	*(Plants may not be suitable as primary level oxygen source)*[a]
Secondary level and above (includes all primary level devices, plus…)		• Humidifier (heated) • Blender • CPAP	• Flowmeter (wall-mounted) • Humidifier (non-heated) • Humidifier (heated) • Blender • CPAP • Ventilator
Oxygen delivery devices			
Primary level	• Nasal cannula • Masks • Tubing	• Nasal cannula • Masks • Tubing	*(Plants may not be suitable as primary level oxygen source)*[a]
Secondary level and above (includes all primary level devices, plus…)	• Nasal catheter	• Nasal catheter • High-flow nasal cannula (HFNC)	• Nasal cannula • Masks • Tubing • Nasal catheter • HFNC
Pulse oximeters and patient monitoring devices			
Primary level	• Self-contained fingertip • Handheld	• Self-contained fingertip • Handheld	*(Plants may not be suitable as primary level oxygen source)*[a]
Secondary level and above (includes all primary level devices, plus…)	• Tabletop	• Tabletop	• Self-contained fingertip • Handheld • Tabletop • Multiparameter devices
Devices for quality power supply and oxygen analysis			
Primary level	• Voltage stabilizer • Surge suppressor • Oxygen analyser • Backup power supply • Tools and spare parts	• Oxygen analyser	*(Plants may not be suitable as primary level oxygen source)*[a]
Secondary level and above (includes all primary level devices, plus…)			• Voltage stabilizer • Surge suppressor • Backup power supply • Tools and spare parts

Notes: Health system levels are as described in Fig. 2.1, which may not be applicable across all settings. All products listed at the primary level are also desirable at the secondary level and above.

[a] Some primary level health facilities offer a wide variety of services and could benefit from an onsite plant. However, such a plant should only be considered if there is enough need for oxygen, and if there is appropriate capacity to use and maintain it.

2.2 Scope of this publication

In this publication, only those products required to deliver basic oxygen therapy[1] are described; some with detailed technical specifications provided in Annex 1. Devices required for respiratory support or surgical environments are not within the scope of this guidance document. Table 2.2 summarizes which products are discussed, denoting those that have detailed accompanying technical specifications.

Table 2.2 Overview of oxygen therapy products covered in this publication

Product category	Products covered	Technical specifications
Chapter 3 Oxygen sources	**Cylinders** **Concentrators**[a] **Plants**	✓ ✓ —
Chapter 4 Devices for oxygen regulation and conditioning	**Flowmeter:** • Thorpe tube • Bourdon gauge • Dial click **Flowmeter stand (flow splitter)** **Humidifier:** • Non-heated, bubble bottle • Heated	 ✓ — — ✓ ✓ —
Chapter 5 Oxygen delivery devices	**Nasal cannula** **Nasal catheter** **Non-invasive (e.g. masks)** **Tubing**	✓ ✓ — ✓
Chapter 6 Pulse oximetry	**Pulse oximeter:** • Self-contained fingertip • Handheld • Tabletop	 ✓ ✓ ✓
Chapter 7 Devices for quality power supply	**Voltage stabilizer:** • Solid-state • Servo-electronic **Surge suppressor**	 ✓ — ✓
Chapter 8 Oxygen analysers	**Oxygen analyser:** • Electrochemical (galvanic cell) • Ultrasonic	 ✓ ✓

Note:
[a] Guidance on concentrators is not covered in this publication, see *Technical specifications for oxygen concentrators (1).*

Reference

1. WHO. Technical specifications for oxygen concentrators. WHO Medical device technical series. Geneva: World Health Organization; 2015 (https://www.who.int/medical_devices/publications/tech_specs_oxygen-concentrators/en/, accessed 25 April 2019).

[1] *Basic* oxygen therapy in this publication refers to the administration of oxygen by nasal cannula, nasal catheter or face mask. Basic oxygen therapy does not involve heated humidification, a blender or advanced respiratory support via the use of bubble CPAP, CPAP or mechanical ventilation, which are beyond the scope of this publication.

3

OXYGEN SOURCES

3 Oxygen sources

3.1 Overview of different oxygen sources

Oxygen therapy, or supplemental oxygen, is the use of medical oxygen as a medicine in health care. Medical oxygen is oxygen that is (as a minimum) 82% pure oxygen and free from any contamination, generated by an oil-free compressor. In LRS, the three most common sources of medical oxygen in health care facilities are: compressed gas cylinders, oxygen concentrators and oxygen plants. A fourth oxygen source, though less common in LRS, is bulk-stored liquid oxygen.

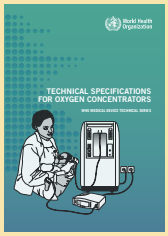
The appropriate choice of oxygen source is multifactorial; it is important to take into consideration the amount of oxygen needed at the health facility, available infrastructure, cost, capacity and supply chain for local production (and delivery) of medicinal gases, reliability of electricity, access to maintenance services and spare parts, etc. In addition, the level of the health system at which these different sources might be used will depend on local policy, training and capacity at the different levels of care. Table 3.1 provides a comparison of these different oxygen source options. This chapter will focus on oxygen cylinders in more detail, with technical specifications provided in section 3.2.

Oxygen cylinders: Oxygen gas can be compressed and stored in cylinders. These cylinders are filled at a gas manufacturing plant, either via a cryogenic distillation or a process known as pressure swing adsorption (PSA),[1] and transported to health facilities to be connected to manifold systems (groups of cylinders linked in parallel) that are piped to areas of the health facility; or cylinders can be used directly within patient areas. The use of cylinders typically involves transport to and from the bulk supply depot for regular refilling, which could have logistical challenges and ongoing cost implications, often leading to unreliable supply in many settings *(1)*. While less common, cylinders can also be filled by a PSA oxygen plant that is co-located with a health facility and that has a high-pressure compressor for cylinder filling purposes.

Cylinders do not require electricity, but they do require several accessories and fittings to deliver oxygen, such as pressure gauges, regulators, flowmeters, and, in some cases, humidifiers. Cylinders also require periodic maintenance, commonly provided by gas suppliers at the point of refilling.

Box 3.1 Important note

Technical specifications for oxygen concentrators were published by WHO in 2015 *(1)*; thus, detailed guidance on concentrators is not included in this publication.



Oxygen concentrators: An oxygen concentrator is a self-contained, electrically powered medical device designed to concentrate oxygen from ambient air. Utilizing PSA technology, an oxygen concentrator draws in air from the environment, extracts the nitrogen, and can produce a continuous source of 95.5% concentrated oxygen *(1)*.

Oxygen concentrators are portable and can be moved between clinical areas, but they are also often set up to be stationary fixtures in patient areas. Concentrators designed for home care or bedside use are available in models that can deliver maximum flow rates between 5 and 10 L/min.[2] When used with a flowmeter stand for splitting flow (see Chapter 4), concentrators can provide a continuous supply of oxygen to multiple patients at the same time. Concentrators can provide a safe and cost-efficient source of oxygen, but they do require a source of continuous and reliable power (see Chapter 7) and regular preventive maintenance (see Chapter 8) to ensure proper functioning *(1)*. It is best practice to also have cylinders as a backup supply.

[1] Note that vacuum pressure swing adsorption (VPSA) is another, newer, technology for oxygen generation that works at much lower pressure and is more energy efficient. Its use in LRS is currently unknown.

[2] Smaller concentrators are also available for ambulatory or patient transport applications.

Oxygen plant (central oxygen supply system): An oxygen plant is a large, onsite, central source of oxygen that is piped directly to terminal units within patient areas. Plants can generate oxygen using PSA technology (similar to concentrators) or by cryogenic distillation. Plants can also be set up to refill cylinders for oxygen distribution or backup oxygen supply; these cylinders can be connected to sub-central manifold systems at the health facility or transported to neighbouring health facilities. Note that oxygen plants require a reliable source of power. It is best practice to also have cylinders as a backup supply.

Pipeline systems supply oxygen at high pressure to equipment such as anaesthetic machines and ventilators. A key advantage of pipeline systems is that they obviate the need for handling and transporting heavy cylinders between hospital wards. The high cost of installing centralized oxygen sources with copper pipelines and the high level of specialized maintenance required currently make these systems of oxygen delivery unsuitable for many district-level hospitals in LRS *(1)*.

Box 3.2 Total cost of ownership considerations

- Initial upfront costs and ongoing operating costs can vary considerably between oxygen sources.
- Factors affecting initial costs of equipment, spare parts and accessories include purchasing versus leasing agreements, and shipping, delivery and installation costs.
- Ongoing costs must also be considered:
  - expected life span of device, and replacement parts, refill and consumable costs;
  - shipping and local distribution costs;
  - training costs;
  - annual maintenance (parts and labour) costs;
  - energy costs;
  - annual operation costs.
- Income potential:
  - patient treatment fees;
  - sale of oxygen to other facilities.

Table 3.1 Description and comparison of oxygen sources

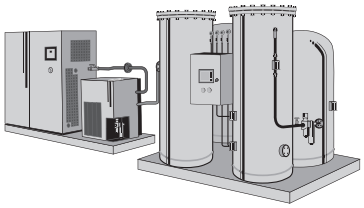
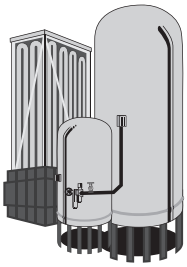
	Cylinders	Concentrators (PSA)	Oxygen plant (PSA)	Liquid oxygen
General characteristics				
Illustration/ image				
Description	A refillable cylindrical storage vessel used to store and transport oxygen in compressed gas form. Cylinders are refilled at a gas generating plant and thus require transportation to and from the plant.	A self-contained, electrically powered medical device designed to concentrate oxygen from ambient air, using PSA technology.	An onsite oxygen generating system using PSA technology, which supplies high-pressure oxygen throughout a facility via a central pipeline system, or via cylinders refilled by the plant.	Bulk liquid oxygen generated off-site and stored in a large tank and supplied throughout a health facility via a central pipeline system. Tank requires refilling by liquid oxygen supplier.
Clinical application and/or use case	Can be used for all oxygen needs, including high-pressure supply and in facilities where power supply is intermittent or unreliable. Also used for ambulatory service or patient transport. Used as a backup for other systems.	Used to deliver oxygen at the bedside or within close proximity to patient areas. A single concentrator can service several beds with the use of a flowmeter stand to split output flow.	Can be used for all oxygen needs, including high-pressure supply.	Can be used for all oxygen needs, including high-pressure supply and in facilities where power supply is intermittent or unreliable.
Appropriate level of health system	Primary, secondary, possibly tertiary (any medical unit requiring oxygen).	Primary, secondary, possibly tertiary (any medical unit requiring oxygen).	Secondary and tertiary.	Secondary and tertiary.

Table 3.1 Description and comparison of oxygen sources (continued)

	Cylinders	Concentrators (PSA)	Oxygen plant (PSA)	Liquid oxygen
Product-specific characteristics				
Distribution mechanism	Connected to manifold of central/sub-central pipeline distribution system, or directly connected to patient with flowmeter and tubing.	Direct to patient with tubing or through a flowmeter stand.	Central/ sub-central pipeline distribution system, or can be used to refill cylinders that can be connected to manifold systems in the facility.	Central pipeline distribution system.
Electricity requirement	No.	Yes.	Yes.	No.
Initial costs	Moderate; cylinder, regulator, flowmeter, installation, training.	Moderate; concentrator, spares, installation, training.	High; plant and pipeline distribution system, installation, training.	Can be high; tank, pipeline installation, training.
Ongoing operating costs	High; cylinder deposit and leasing fees, refill costs, transportation from refilling station to health facility.	Low; electricity and maintenance (spare parts and labour).	Low/moderate; electricity and maintenance (spare parts and labour). May require additional staff to operate/manage if not operated by third party.	Moderate (can be high if tank is leased); refill costs, maintenance.
Maintenance requirement	Limited maintenance required by trained technicians.	Moderate maintenance required by trained technicians *(1)*, who could be in-house.	Significant maintenance of system and piping required by highly trained technicians and engineers, can be provided as part of contract.	Significant maintenance of system and piping required by highly trained technicians and engineers, can be provided as part of contract.
User care	Moderate; regular checks of fittings and connections, regular checks of oxygen levels, cleaning exterior.	Moderate; cleaning of filters and device exterior.	Minimal; at terminal unit only.	Minimal; at terminal unit only.
Merits	• No power source needed.	• Continuous oxygen supply (if power available) at low running cost. • Output flow can be split among multiple patients.	• Can be cost-effective for large facilities. • Continuous oxygen supply.	• 99% oxygen obtained. • High oxygen output for small space requirement.
Drawbacks	• Requires transport/ supply chain. • Exhaustible supply. • Highly reliant upon supplier. • Risk of gas leakage. • Risk of unwanted relocation.	• Low pressure output, usually not suitable for CPAP or ventilators. • Requires uninterrupted power. • Requires backup cylinder supply. • Requires maintenance.	• High capital investments. • Requires uninterrupted power. • Needs adequate infrastructure. • High maintenance for piping. • Requires backup cylinder supply. • Risk of gas leakage from piping system.	• Requires transport/ supply chain. • Exhaustible supply. • High maintenance for piping. • High total cost. • Needs adequate infrastructure. • Requires backup cylinder supply. • Risk of gas leakage from piping system.
Is this product available in the UNICEF catalogue?	No.	Yes.	No.	No.

Sources: Adapted from: *Technical specifications for oxygen concentrators*. Geneva: World Health Organization; 2015. Table 1. p. 8 *(1);* and National Strategy for the Scale-up of Medical Oxygen in Health Facilities (2017–2022). Annex A. Overview of oxygen delivery systems. Federal Ministry of Health, Federal Republic of Nigeria.

Liquid oxygen: Facilities can be equipped with large bulk liquid oxygen tanks that are refilled periodically by a truck from a supplier. The liquid oxygen tank supplies a centrally piped system throughout the health facility by self-vapourization, meaning that a power supply is not required. Although currently an economical option in some locations, liquid oxygen requires high technical knowledge and large, well-ventilated spaces, and can introduce risks in settings with extreme temperature and humidity. It is best practice to also have cylinders as a backup supply.

3.1.1 Additional information on cylinders

Cylinder naming and sizing

Oxygen cylinders come in many different sizes. Cylinder sizes for medical gases are named alphabetically, unlike industrial cylinders which are numbered. Table 3.2 summarizes the key features of cylinder sizes commonly used in health care facilities. Unlike liquids, gases can be compressed, and doing so increases their density. That is why a gas cylinder of 47 L volume under pressure can contain gas that expands to 6800 L of volume when released into normal atmospheric pressure.

Cylinders are fitted with customized valves (either pin index or bullnose type) that are opened with valve keys, and with valve guards for safety. The Pin Index Safety System (PISS) is designed to ensure the correct gas is connected to the regulator or other equipment. The arrangement of the pins is unique for each gas, and the positions of the holes on the cylinder valve must correspond with the pins to prevent the use of the wrong gas.

Some cylinders have built-in, integral pressure regulators, which do not require a separate pressure regulator to be fitted to the cylinder valve before use.

Table 3.2 Cylinder sizes common in health facilities

Cylinder size	D	E	F	G	J
Nominal content/oxygen capacity (L)	340	680	1360	3400	6800
Water capacity (L)	2.3	4.7	9.4	23.6	47.2
Dimensions (height × diameter) (mm)	535 × 102	865 × 102	930 × 140	1320 × 178	1520 × 229
Approximate full weight (kg)	3.9	6.5	17	39	78
Valve outlet connection (and specification)	Pin index (ISO 407)	Pin index (ISO 407)	Bullnose (BS 341)	Bullnose (BS 341)	Pin index side spindle (ISO 407)
Nominal service pressure (kPa/bar/psi)	13 700 kPa (137 bar/1987 psi)	13 700 kPa (137 bar/1987 psi)	13 700 kPa (137 bar/1987 psi)	13 700 kPa (137 bar/1987 psi)	13 700 kPa (137 bar/1987 psi)
Health facility use	Emergency and ambulance transport	Emergency and ambulance transport	Stand-alone	Stand-alone	Manifold connection and stand-alone

Notes: BS – British Standard; ISO – International Organization for Standardization; psi – pounds per square inch absolute.
Source: BOC Healthcare (https://www.bochealthcare.co.uk/en/images/cylinder_data_med309965_2011_tcm409-54065.pdf, accessed 12 June 2019).

Colour coding for gases

The international standard for the colour coding of gas cylinders is ISO 32: 1977 Gas cylinders for medical use – Marking for identification of content. According to the ISO standard, oxygen should be labelled as white. Fig. 3.1 shows differences in gas cylinder colour coding between ISO and US standards.

Fig. 3.1 Differences in colour coding of different gases between ISO colour coding standard and United States convention

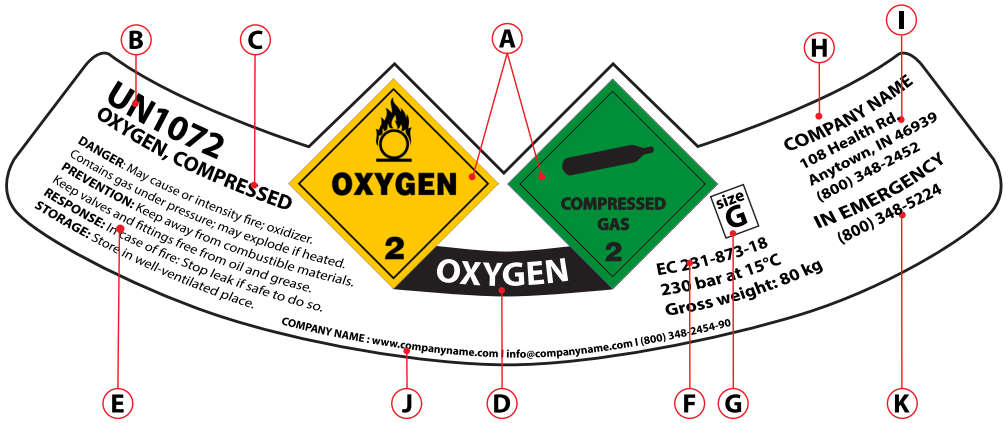
Gas	ISO colour code	US colour code
Carbon dioxide	Grey	Grey
He-O_2	Brown and white	Brown and green
Instrument air		Red (USA only)
Medical air	Black and white	Yellow
Nitrogen	Black	Black
Nitrous oxide	Blue	Blue
O_2-He	White and brown	Green and brown
Oxygen	White	Green
Vacuum (suction)	Yellow	White
WAGD (evac)	Purple	Purple

Notes: He – helium; evac – evacuation; WAGD – waste anaesthesia gas disposal.

Cylinder labelling

Medical gas cylinders are required to be labelled, as the primary means of identifying the contents of the cylinder. The colour of the cylinder is only a guide. Labels for gas cylinders can be reduced in size and shape to the dimensions specified in ISO 7225 – Gas cylinders – Precautionary labels. Fig. 3.2 is an example of a typical label.

Fig. 3.2 Example of a gas cylinder label



A. **Diamond hazard label:** displaying the primary hazard with additional hazard labels displaying any subsidiary hazards. These labels will display the dangerous goods classification number.

B. **UN number:** preceded by the letters UN. The UN number is a number assigned by the United Nations Committee of Experts on the Transport of Dangerous Goods. The UN number for compressed oxygen is UN 1072.

C. **Proper shipping name.**

D. **Product name** (may be omitted if the proper shipping name is identical).

E. **Signal word, hazard and precautionary statements.**

F. **EC number** (if applicable).

G. **Package size and pressure.**

H. **Company name.**

I. **Address of the gas company.**

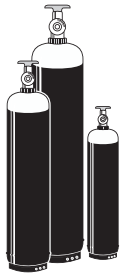
J. **Additional company information.**

K. **Contact telephone number.**

Note: See British Compressed Gases Association. Technical information sheet 6. Revision 2: 2012. Cylinder identification. Colour coding and labelling requirements; 2012 *(2)*.

3.2 Technical specifications for oxygen cylinders

3.2.1 Overview of specifications



For complete specifications see Annex 1, Table A1.1. The content in the specifications focuses on commercially available technologies; however, it was written with the understanding that innovations in manufacturing, products, infrastructure and clinical practice will advance the field of oxygen supply and delivery. The specifications do not preclude appropriate upcoming products and/or technologies.

Cylinders:

- ISO standard (size, labelling and colour), refillable cylinders for medical grade compressed oxygen or air.
- Fitted with a primary valve, standard (pin index or bullnose) or integral.
- Nominal pressure 13 700 kPa (137 bar, 1987 psi), for standard valve cylinders, or 23 000–30 000 kPa (230–300 bar, 3336–4351 psi) depending on the cylinder model, for integral valve cylinders. Maximum pressure capacity should be stated.

Primary valve and pressure regulator assemblies:

- Pin index or bullnose primary valve and compatible pressure regulators, providing pressure-regulated supply.
- Steel/plated brass/aluminium casing, brass valve.
- Handle/key operated, supplied with tool as required.
- Nominal inlet pressure 13 700 kPa (137 bar, 1987 psi), maximum 20 000 kPa (200 bar, 2901 psi).
- Outlet pressure 345 kPa (3.45 bar, 50 psi).
- Integrated manometer, 0–20 000 kPa (0–200 bar, 0–2901 psi).
- Safety over-pressure release valve.
- Supplied with flowmeter (see configurations/options for specifications in Annex 1, Table A1.1).

Integral valves:

- All-in-one cylinder valve providing direct attachment to the cylinder with adjustable flow rate.
- Steel/plated brass/aluminium casing, brass valve.
- 6 mm barbed and BS 5682 Schrader (if applicable depending on the size of the cylinder) outlets.
- Integrated open/close valve, outlet nominal pressure 400 kPa (4 bar, 58 psi).
- Inlet pressure 23 000–30 000 kPa (230–300 bar, 3336–4351 psi), depending on the cylinder model.
- Integrated refill valve ISO 5145/CGA (Compressed Gas Association) 540 compliant.
- Integrated manometer, covering the full nominal pressure range of the cylinder, e.g. standard 23 000–30 000 kPa (230–300 bar, 3336–4351 psi) for integral valve cylinders.
- Integrated flowmeter.
- Safety over-pressure release valve.

3.2.2 Regulatory approval, standards and compliance

Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of the International Medical Device Regulators Forum (IMDRF) – EU, USA, Canada, Australia, Japan).

International standards applicable to the manufacturer and the manufacturing process are listed below. Compliance to the latest available version is recommended.

- ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes.
- ISO 14971 Medical devices – Application of risk management to medical devices.
- ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

International standards applicable to the product are listed below. Compliance to the latest available version is recommended.

- ISO 10524 Pressure regulators for use with medical gases.
- ISO 15002 Flow-metering devices for connection to terminal units of medical gas pipeline systems.
- ISO 32 Gas cylinders for medical use – Marking for identification of content.

3.2.3 Installation and use

When installing an oxygen cylinder:

- Ensure the quality of the oxygen is assured, either by supplier quality certificate, PSA plant logbook or onsite analyser testing.
- Oxygen cylinders should be prepared for use and set up in a secure position; vigilance by the operator during preparation is of critical importance.
- Tighten all the connections (between the cylinder and the regulator and between the regulator and the flowmeter), so that oxygen does not leak out.
- Before assembling regulators and fittings, it is extremely important to ensure there are no particles of dirt in the cylinder outlet. Use clean compressed air or nitrogen to blow out any loose particles of dirt from the valve sockets.
- Where clean compressed air or nitrogen is not available, particles of dirt and residual moisture can be removed by quickly opening and immediately closing the valve (otherwise known as “snifting”).
- No one should attempt to connect a regulator and/or accessory equipment using improvised hookups or adapters. Neither should plastic tape be used on a regulator.

When using an oxygen cylinder:

- All gas cylinders should be equipped with a functioning gas regulator while in use.
- Check the contents gauge on the cylinder before starting to be sure there is enough gas available. Open the regulator and check the amount of oxygen in the cylinder on the pressure gauge. If the needle is in the red zone, the cylinder is nearly empty and should not be used.
- Valve protection caps are required on all cylinders that are threaded to accommodate a cap, unless the cylinder valve is connected for use to a regulator or manifold.
- When personnel have finished using a compressed gas cylinder, the cylinder valve should be closed and the pressure in the regulator and associated equipment released.

3.2.4 Safety and handling

General handling

- Personal protective equipment, such as eye and hand protection, should be worn when handling oxygen cylinders.
- All compressed medical oxygen gas cylinders (regardless of size) should be secured to racks, walls, work benches or hand trolleys by a strong chain or strap, capable of preventing the cylinder from falling or being knocked over.
- Secure in an upright position. Note that small cylinders (e.g. E size), when used for patient transport, may be laid flat, but still need to be firmly secured.
- Do not drop cylinders or allow sharp impacts on cylinders.
- Cover the top of the oxygen cylinder with the cap when it is not in use or when being transported for delivery.

- Set up the cylinder for patient use a safe distance from the patient.
- After connecting the appropriate equipment, turn the flow control off; carefully open the main valve, then turn up the flow slowly to the desired rate.
- Do not place the cylinder on a patient's bed.
- Before moving cylinders, they must be disconnected from any regulators or manifolds, applying any protective valve caps before the cylinders are released.
- Cylinders should be moved only on a hand truck or other cart designed for handling gas cylinders.
- No more than one cylinder should be handled at a time except on carts designed to transport more than one cylinder.
- All medical gas cylinders should be clearly labelled to identify the contents. A cylinder without a readable product label should not be used and should be returned to the supplier.
- All defective gas cylinders or equipment should be reported immediately to the supplier for correction or replacement.

Box 3.3 Important note

This publication does not provide comprehensive guidance on the safety and handling of oxygen cylinders. Anyone having contact with oxygen, including by, and not limited to, technicians and health workers, must undertake comprehensive training on the safe handling of cylinders. Only personnel trained in the proper transportation and safe use of gas cylinders should handle cylinders.

Storage

- Always physically separate full and empty medical gas cylinders. Ambulatory organizations can do this by using separate racks, physical barriers or by colour coding the storage rack.
- Label the cylinders clearly (open/empty or full/unopened), to avoid confusion and delay selecting between full, partial and empty cylinders.
- Store in well-ventilated, clean, dry conditions, not exposed to extremes of heat or cold.
- Protect cylinder and all other fittings from contamination by oil and grease.
- Never use a single-use and/or re-use an industrial gas cylinder for refilling medical oxygen.

Fire safety

- Ensure appropriate fire extinguishers are kept nearby and are regularly inspected.
- Keep oxygen cylinders at least several metres from a heat source, open flames, electrical devices, or other possible sources of ignition.
- Put a "no smoking" sign near oxygen sources in the hospital.
- Check that all nearby electrical circuit breakers and devices are in safe working condition and free from sparking to prevent a serious fire occurrence.

Disposal

- Cylinders and unwanted product should be returned to the vendor, not vented into the environment.
- Obsolete cylinders must be disposed of based on local regulations.

Other

- Use aluminium alloy cylinders with compatible accessories in magnetic resonance imaging (MRI) procedure rooms.

3.2.5 Maintenance

User care and preventive maintenance

Table 3.3 provides daily and weekly guidance for user care and routine maintenance of oxygen cylinders and associated accessories. However, preventive maintenance of the cylinders should be carried out periodically (e.g. every 5–10 years) by the gas supplier, and a coloured cylinder test ring may be fitted around the cylinder neck indicating the next due date for testing.

Troubleshooting and corrective maintenance

Table 3.4 provides some troubleshooting tips for common issues with oxygen cylinders and associated accessories. Refer to user and service manuals for more guidance.

Table 3.3 User care and preventive maintenance recommendations for oxygen cylinders (and associated accessories)

Schedule period	Activities	Check
Daily	Cleaning	✓ Ensure delivery tubes and masks are decontaminated. ✓ If humidifier bottle is used, disinfect and refill with clean water.
	Visual checks	✓ Check cylinder is correct type and correctly labelled. ✓ Check all parts are fitted tightly and correctly.
	Function	✓ Before use, ensure cylinder has sufficient pressure. ✓ Ensure flow is sufficient for intended use. ✓ Close cylinder valve after each use.
Weekly	Cleaning	✓ Clean cylinder, valve and flowmeter with damp cloth.
	Visual checks	✓ Check for leakage: hissing sound or reduction in pressure.
	Function	✓ Remove valve dust with brief, fast oxygen flow checks. ✓ Check flow can be varied using flow control.

Source: Adapted from *User care of medical equipment: a first line maintenance guide for end users. Strengthening Specialised Clinical Services in the Pacific*; 2015 (https://bmet.ewh.org/handle/20.500.12091/83, accessed 26 April 2019).

Table 3.4 Troubleshooting for oxygen cylinders (and associated accessories)

Problem or fault	Possible cause	Solution
No oxygen is flowing	• Empty cylinder.	• Replace cylinder.
	• Flowmeter knob or cylinder flow valve is closed.	• Open valves, and then check meter registers flow.
	• Faulty regulator.	• Close all valves and replace regulator.
Leakage from cylinder or flowmeter	• Cylinder is not connected to pressure regulator properly.	• Tighten all fittings.
	• Faulty or missing washer between regulator and cylinder.	• Replace washer.
	• Flowmeter seal damaged or loose.	• Replace sealing washer and realign flowmeter.
	• Cylinder faulty.	• Label faulty and take appropriate action.
Leakage cannot be located	• Leakage too small to be heard.	• Apply detergent solution (NOT oily soap) to joints. Bubbles will show at leak point. • Clean/replace washer and tighten at that joint.
Flowmeter ball not moving, yet oxygen is flowing	• Faulty flowmeter.	• Close all valves, disconnect flowmeter and clean inside. Reconnect and test. • If problem persists, replace flowmeter.
Pressure gauge does not show pressure, yet oxygen is flowing	• Faulty pressure gauge.	• Replace pressure gauge.

Source: Adapted from *User care of medical equipment: a first line maintenance guide for end users. Strengthening Specialised Clinical Services in the Pacific;* 2015 (https://bmet.ewh.org/handle/20.500.12091/83, accessed 26 April 2019).

3.3 Technical specifications for oxygen concentrators

3.3.1 Overview of specifications

For complete specifications see Annex 1, Table A1.2. The content in the specifications focuses on commercially available technologies; however, it was written with the understanding that innovations in manufacturing, products, infrastructure and clinical practice will advance the field of oxygen supply and delivery. The specifications do not preclude appropriate upcoming products and/or technologies.

Full details regarding technical specifications and guidance and information on related equipment, handling and procurement, as well as the previous version of the technical specification (v1, 2015), can be found in the WHO *Technical specifications for oxygen concentrators (1)*.

References

1. WHO. Technical specifications for oxygen concentrators. WHO Medical device technical series. Geneva: World Health Organization; 2015 (https://www.who.int/medical_devices/publications/tech_specs_oxygen-concentrators/en/, accessed 25 April 2019).
2. British Compressed Gases Association. Technical information sheet 6. Revision 2: Cylinder identification. Colour coding and labelling requirements; 2012.

4

DEVICES FOR OXYGEN REGULATION AND CONDITIONING

4 Devices for oxygen regulation and conditioning

The oxygen therapy products covered in this chapter include flowmeters, flow-splitting devices and humidifiers. These devices play different roles in the regulation and conditioning of oxygen gas for the delivery of oxygen therapy to patients. This chapter will describe when it is appropriate to use these devices, and with which oxygen sources – either high-pressure cylinders, oxygen concentrators or from the terminal unit (i.e. medical gas outlet) of a central piped system.

4.1 Overview of flowmeters

In oxygen therapy systems, flowmeters are needed to measure and control the rate of oxygen flow to a patient, either from a concentrator, a high-pressure cylinder or a terminal unit of a piped system. Concentrators have built-in flowmeters so there is no need to purchase them separately. When using oxygen sources with varying pressures (e.g. oxygen cylinders or terminal units), it is important that flowmeters are placed on the low-pressure side, downstream of a pressure-reducing valve.

Three types of gas flowmeters are described in this overview: Thorpe tube, Bourdon gauge and dial/click. All three types come in various flow ranges. The choice of appropriate flowmeter will depend on clinical needs and device capabilities. Table 4.1 provides a comparison of these three device types. As Thorpe tube flowmeters are commonly used globally, technical specifications are provided for this type only in section 4.2.

Thorpe tube flowmeter: Also known as a rotameter, this variable orifice flowmeter consists of a connection to a gas source, a distal valve to control gas flow rate, an upright clear tube containing a float (which rises and falls in relation to gas flow) and an outlet port. The valve is opened and closed by turning an attached dial. This type of flowmeter must be used in a vertical position.

Box 4.1 Important note

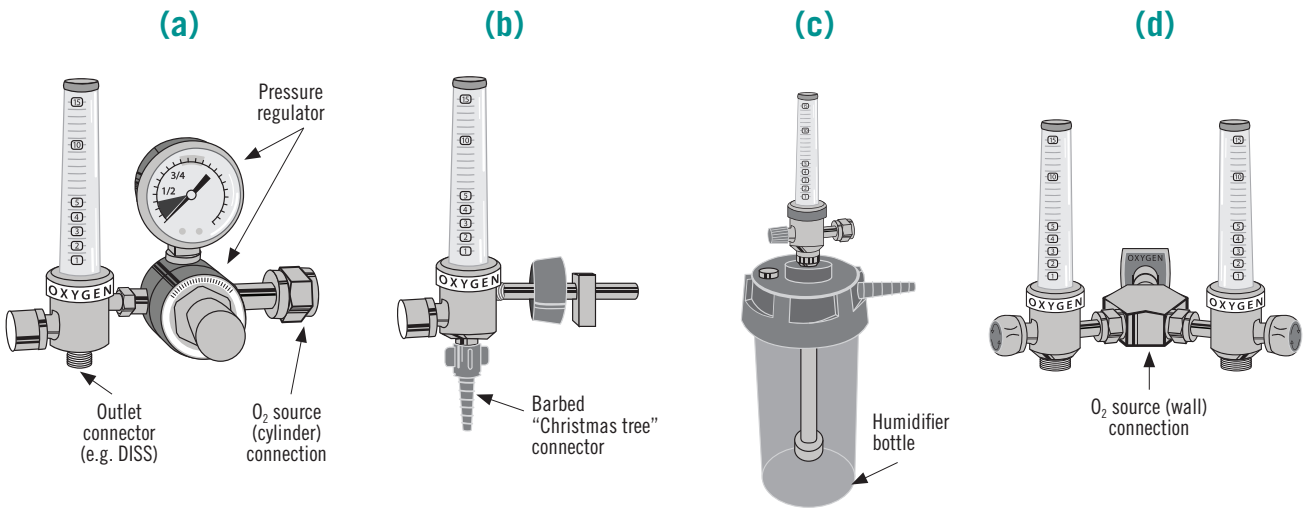
DISS connectors are threaded and have a unique diameter for each type of gas to prevent the wrong connection. Other connector types may be used, thus it is important that the required compatible connector type is specified when procuring for existing equipment and systems (see *Additional configurations and options to be specified* in section 4.2).

This type of flowmeter is used only with a 345 kPa (3.45 bar, 50 psig)[1] gas source – either a terminal unit from a piped oxygen system or a pressure-reducing valve (regulator)[2] when using a high-pressure cylinder as the source (Fig. 4.1a). The outlet port, commonly a Diameter Index Safety System (DISS) connector (see Box 4.1 and Fig. 4.1a), can be connected to a barbed conical connector (sometimes called a "Christmas tree" connector) for oxygen tubing to a delivery device such as nasal prongs (Fig. 4.1b), or a humidifier (Fig. 4.1c). See section 4.5 for more information on humidifiers. Thorpe tube flowmeters can also come in a twin configuration to allow for independent gas supply to two patients from a single gas source (Fig. 4.1d). See section 4.3 for other devices for splitting flow.

[1] psig refers to the pressure specified by a gauge, hence the name – pounds per square inch, gauge. It is a unit of pressure relative to the ambient pressure or atmospheric pressure.

[2] The preset regulator with one low-pressure gauge indicator is recommended as the first choice in LRS. The adjustable regulator with double gauge, which displays both the high and low oxygen pressure, gives additional treatment options but also adds complexity. For central pipeline oxygen supply systems, quick-connectors are recommended.

Fig. 4.1 Thorpe tube flowmeter with (a) pressure regulator and outlet connector (e.g. DISS) (male). Connector (DISS or other convention) can be connected to (b) a barbed "Christmas tree" connector for oxygen tubing or (c) a humidifier bottle. Also shown is (d) an example of a dual flowmeter from a single wall source for use with two patients



Thorpe tube flowmeters are calibrated to a specific medical gas (e.g. oxygen or medical air) and come in dedicated flow rate ranges appropriate for different patient groups (e.g. neonate, infant, child, adult) (see Box 4.2 and Table 4.2 for more guidance on flow rate ranges).

Thorpe tube flowmeters can be pressure compensated or uncompensated. A *compensated* flowmeter has a float that is upstream from the valve so that the float is in contact with the source pressure rather than atmospheric pressure. This offers the advantage that if pressure is applied distally to the tube, e.g. flow-restricting equipment or kinked tubing, it will have no effect on the flowmeter's performance. The flow displayed is accurate in the face of an obstruction downstream. As the flow is restricted, the flowmeter will display lower and lower flows, down to zero if there is a complete blockage. If the resistance is removed, the flow will increase.

An *uncompensated* flowmeter will have a float that is downstream from the valve, and this float is subjected to atmospheric pressure. In this case, if pressure is applied distally to the tube, e.g. kinked tubing, the back pressure builds up and affects the float. It will rise and display an erroneously high flow rate because the density of the gas under the float has been increased.

A *compensated* flowmeter is preferred because it can indicate when the system is delivering insufficient oxygen if the line becomes obstructed or pinched. The compensated flowmeter would show that the flow rate is low whereas the uncompensated flowmeter would display an erroneously high flow rate. This aids in troubleshooting and may help detect situations that put patients at risk.

Box 4.2 Considerations for neonates

- For neonatal applications, especially with premature babies, flows as low as 20–30 mL/min may be required.
- Ultra-low flowmeters are available for this patient group, with a range up to 150–200 mL/min and very small graduations.
- When procuring flowmeters for neonatal patients, be sure to specify the desired flow range (see Table 4.2).

Box 4.3 Total cost of ownership considerations

- When purchasing flowmeters, it is essential to consider all required accessories as well:
  - pressure-reducing valve (required for Thorpe tube flowmeters);
  - outlet adapters for connecting tubing;
  - humidifiers (if required).
- Consider standardizing connection types across health facilities to ensure compatibility and facilitate procurement.
- Other ongoing costs throughout the life of the device must also be considered:
  - expected life of device and replacement costs;
  - shipping and local distribution costs;
  - training costs;
  - maintenance (parts and labour) costs.

Bourdon gauge: A Bourdon gauge is a fixed-orifice device with an adjustable valve that controls the gas flow rate. It consists of inlet and outlet ports, a dial regulator and a valve, and a pressure gauge that reads as flow rate. Gas enters a chamber that has a fixed-orifice outlet. As the pressure is increased, a coiled copper tube straightens out and the needle valve turns to read a higher unit. Bourdon gauges are calibrated to a specific medical gas and have a dedicated flow rate range. An advantage of fixed-orifice flowmeters is that they are unaffected by gravity and can operate at any angle. This makes them ideal for emergency medicine and transport. Bourdon gauges are not back pressure compensated; as resistance to flow increases, the indicated flow reading becomes inaccurate. They are also less accurate at low-flow ranges.

Dial/click flowmeter: A dial/click or flow restrictor flowmeter is a fixed-orifice device calibrated to deliver a specific flow at a constant pressure – 345 kPa (3.45 bar, 50 psig). It consists of inlet and outlet ports, an integrated reducing valve, and an adjustable dial that provides specific flow rate settings, which are indicated in a small display window. As such, dial flowmeters regulate but do not measure the flow of gas. Like Thorpe tube flowmeters, dial/click flowmeters come in dedicated flow rate ranges appropriate for different patient groups (e.g. neonate, infant, child, adult). These devices are simple to operate but are only accurate at their rated pressure.

Table 4.1 Description and comparison of flowmeters

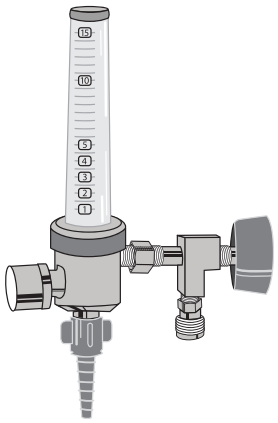
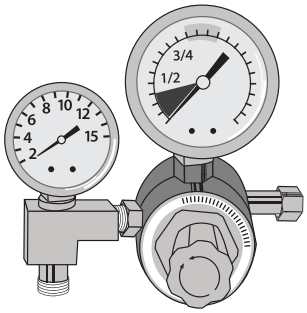
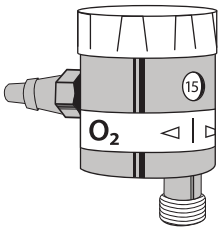
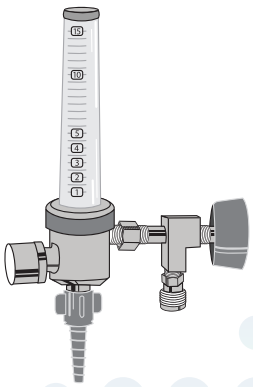
	Thorpe tube (rotameter)	Bourdon gauge (single and multiple stage)	Dial/click (flow restrictor)
General characteristics			
Illustration/image			
Description	A variable orifice flowmeter consisting of an upright clear tube containing a float, which rises and falls in relation to gas flow. There are two types: uncompensated and compensated for back pressure. Requires a separate pressure-reducing valve.	A fixed-orifice flowmeter, whereby gas enters a chamber and as the pressure is increased, a coiled copper tube straightens out and the needle valve turns to read a higher unit. This device integrates a pressure-reducing valve.	A fixed-orifice flowmeter calibrated to deliver flow in specific increments, adjusted with a click dial. This device integrates a pressure-reducing valve.
Clinical application and/or use case	• For all inpatient clinical areas in health care facilities where oxygen therapy is provided. • Recommended for use with terminal units (wall outlets) of piped distribution systems or for large stand-alone cylinders.[a]	• Ideal for ambulance transportation. • Recommended for use with smaller portable cylinders common for emergency and ambulance transportation.[a]	• For all inpatient clinical areas in health care facilities where oxygen therapy is provided (terminal units – either wall outlets or ceiling mount drops of piped oxygen distribution systems in hospitals). Also common with portable cylinders for intrafacility, interfacility or air transport.

Table 4.1 Description and comparison of flowmeters (continued)

	Thorpe tube (rotameter)	Bourdon gauge (single and multiple stage)	Dial/click (flow restrictor)
Appropriate level of health system (and relevant medical units)	Primary, secondary, tertiary (all health care facilities where oxygen therapy is provided).	Primary, secondary, tertiary (emergency medical service and patient or ambulance transport).	Primary, secondary, tertiary (for intra-facility, interfacility and air transport, and ambulatory oxygen with portable cylinders).
Product-specific characteristics			
Integrates a pressure-reducing valve	No.	Yes.	Yes.
Inlet pressure	Always attached to a 345 kPa (3.45 bar, 50 psig) source.	Variable.	Variable.
Oxygen source	Terminal unit (wall outlet) or cylinder with pressure-reducing valve.	Cylinder.	Terminal unit (wall outlet or ceiling mount drop), or cylinder.
Merits	• Simple. • Cost-effective. • Wide variety of flow ranges available. • Provides visual feedback of actual flow measurement. • Can fine-tune flow rate. • Pressure compensated: flow is accurate in the face of an obstruction downstream.	• Unaffected by gravity; works in any position. • Inbuilt with regulator and gauge.	• Simple to operate. • Unaffected by gravity; works in any position. • Inbuilt with regulator and gauge. • Compact.
Drawbacks	• Affected by gravity; works in a vertical position only. • Needs additional pressure regulator and gauge. • Fragile. • Uncompensated: can display an erroneously high flow rate.	• Not back pressure-compensated. • As flow increases, the indicated flow reading becomes inaccurate.	• Can only choose flow rates in fixed increments. • Regulates but does not measure flow. • Expensive. • Accurate only at rated pressure.
Is this product available in the UNICEF catalogue?	Yes.[b]	No.	No.

Notes:
[a] See Chapter 3 for more information on cylinder sizes.
[b] Thorpe tube flowmeters are available in three flow ranges: 0–3 L/min, 0–5 L/min, 0–15 L/min. An ultra-low flow option may be added in the future if there is sufficient demand.

4.2 Technical specifications for Thorpe tube flowmeters



For complete specifications see Annex 1, Table A1.3. The content in the specifications focuses on commercially available technologies; however, it was written with the understanding that innovations in manufacturing, products, infrastructure and clinical practice will advance the field of oxygen supply and delivery. The specifications do not preclude appropriate upcoming products and/or technologies.

4.2.1 Overview of specifications

Technical requirements

- Transparent, clearly readable and graduated (metric system) column, shatter resistant polymer certified for medical use.
- Clearly visible permanent graduation with 270 or more degrees of visibility.
- Needle valve and body constructed of brass or aluminium.

- Calibrated at 345–380 kPa (3.4–3.8 bar, 50–55 psi) inlet gauge pressure.
- Inlet gauge pressure (nominal) > 380–413 kPa (3.8–4.1 bar, 55–60 psi), peak inlet gauge pressure 690 kPa (6.9 bar, 100 psi).
- Built-in inlet filter replaceable by user.
- Minimum flow rate to be 0 L/min (fully closed).
- Maximum flow rate when fully open to be stated.
- Anti-slip knob.
- Suitable for cleaning and disinfection.
- ISO 32 colour coded for medical gases.
- DISS style inlet and outlet (or other required versions for local setting – see *Additional configurations and options to be specified*).
- Accuracy: +/- 10% (or better) of maximum flow.

Additional configurations and options to be specified

The following is a list of important questions to consider when selecting and procuring Thorpe tube flowmeters:

- What medical gas will be delivered with the flowmeter?
  - Oxygen or medical air needs to be specified.
- What flow range is required for the desired application (see Table 4.2)?
- What is the connector type to the oxygen source?
  - What type of terminal unit is installed? Or what type of regulator is attached to the cylinder?
  - Will an adapter be needed for this connection?
- Outlet pressure needed.
- Will there be a risk of back pressure?
  - If yes, choose a pressure-compensated flowmeter.
- What additional accessories are needed for the desired application?
  - DISS female/male connector (or other) and adapter to connect with regulator.
  - Barbed green "Christmas tree" connector to connect to tubing/patient delivery device.
  - DISS male/female connector (or other) and adapter to connect with a humidifier.

Table 4.2 Typical flow ranges available and their clinical applications

Example flow ranges	Graduations	Clinical application
0–200 mL/min or 0–1 L/min	20 mL/min or less 0.1 L/min or less	Ultra-low flow applications; appropriate for neonatal care.
0–3 L/min	0.25 L/min or less	Low-flow applications; appropriate for neonatal and paediatric care.
0–5 L/min	0.5 L/min or less	Low to medium flow; appropriate for paediatric oxygen therapy.
0–15 L/min	1 L/min or less	Versatile, for low- to high-flow applications.

4.2.2 Regulatory approval, standards and compliance

Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).

International standards applicable to the manufacturer and the manufacturing process are listed below. Compliance to the latest available version is recommended.

- ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes.
- ISO 14971 Medical devices – Application of risk management to medical devices.

International standards applicable to the product are listed below. Compliance to the latest available version is recommended.

- Colour coding ISO 32 or American National Standards Institute (ANSI) for medical gases.
- Conforms to ISO, National Fire Protection Association (NFPA) and/or CGA standards, and/or UL (global certification mark) and/or Canadian Standards Association (CSA) approved.

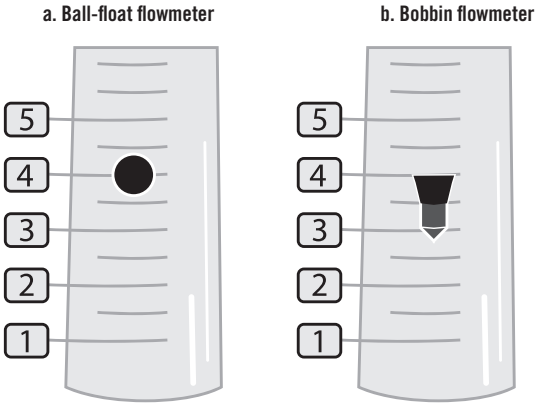
4.2.3 Installation

- Attach the flowmeter to a 345 kPa (3.45 bar, 50 psig) source. Thorpe tubes will have a DISS or quick-connect fitting.
- Attach the required oxygen delivery device to the DISS fitting on the flowmeter, for example attach nasal prongs via a barbed "Christmas tree" connector or via a humidifier (see Fig. 4.1).
- Note that for pressure-compensated flowmeters, the float will "jump" when first connected to a source and the tube is pressurized.
- Adjust the flow to the desired setting.
- To read accurately, a Thorpe tube must be vertical.

4.2.4 Safety and handling

- Always keep the Thorpe tube flowmeter in a vertical position.
- A Thorpe tube flowmeter should be read at the largest diameter of the float as follows (see Fig. 4.2):
  – a ball-float should be read from the middle of the ball;
  – a bobbin should be read from the top of the bobbin.
- The eye should be parallel to the float when reading.

Fig. 4.2 How to read a Thorpe tube flowmeter



A ball-float is read from the centre of the ball, whereas a bobbin is read from the top of the bobbin. Each example depicts 4 L/min.

4.2.5 Maintenance

User care and preventive maintenance

Cleaning instructions:

- Disconnect all connections before cleaning.
- Clean and disinfect exterior surfaces of the flowmeter according to the manufacturer's instructions and infection prevention and control (IPC) protocol specific to the setting.
- Never use lubricants as they are flammable.

A trained biomedical engineer or technician should perform regular inspections and calibration checks with an oxygen flow analyser (as per the service manual and/or the biomedical engineering unit's preventive maintenance schedule).

Refer to user and service manuals for more guidance.

Troubleshooting and corrective maintenance

Table 4.3 provides some troubleshooting tips for flowmeters (see also Table 3.4). Refer to user and service manuals for more guidance.

Table 4.3 Troubleshooting for flowmeters (and associated accessories)

Problem or fault	Possible cause	Solution
No oxygen is flowing	• Flowmeter knob or cylinder flow valve is closed.	• Open valves, and then check meter registers flow.
Leakage from cylinder or flowmeter	• Flowmeter seal damaged or loose.	• Check for leaks at the connection between the flowmeter and the oxygen source, at the connection between the oxygen flowmeter and the oxygen delivery device, and along the oxygen delivery device to the patient. • If leak occurs at the regulator, try tightening the connection. • If leak occurs at the terminal unit, try another flowmeter. If a different flowmeter still leaks, the leak is probably at the terminal unit.
Leakage cannot be located	• Leakage too small to be heard.	• Apply detergent solution (NOT oily soap) to joints. Bubbles will show at leak point. • Clean/replace washer and tighten at that joint.
Flowmeter ball not moving, yet oxygen is flowing	• Faulty flowmeter.	• Close all valves, disconnect flowmeter and clean inside. Reconnect and test. • If problem persists, replace flowmeter.
Flowmeter fails to deliver expected flow or behaves erratically	• Faulty flowmeter.	• Check the output with a calibrated flow analyser. • If necessary, send it for repair to a biomedical engineering unit or replace the flowmeter.
Patient is on oxygen and the patient's oxygen saturation is declining	• Patient is not getting oxygen flow.	• Check that oxygen is flowing from the delivery device. • Check that the oxygen tubing is connected to the flowmeter. • Check that the correct oxygen flow is set.

Source: Adapted from *User care of medical equipment: a first line maintenance guide for end users. Strengthening Specialised Clinical Services in the Pacific;* 2015 (https://bmet.ewh.org/handle/20.500.12091/83, accessed 26 April 2019).

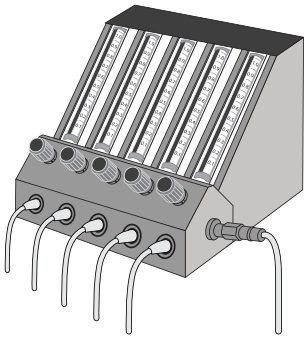
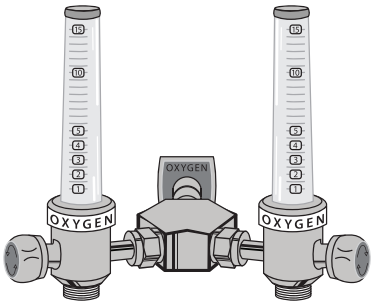
4.3 Overview of flow-splitting devices

A flow-splitting device can provide an effective and efficient means of economically administering medical oxygen to multiple patients from a single source, when supply permits. Flow-splitting devices may be used with concentrators, cylinders and centralized systems for both paediatric and adult patients. The two main devices for splitting oxygen flow discussed here are the flowmeter stand and the dual flowmeter.

Flowmeter stand: A flowmeter stand, also referred to as flowmeter station or assembly, is a device that distributes medical oxygen, in a controlled manner, from a single source to multiple (up to five) outlets through independent flowmeters, to meet individual patient needs. It is most commonly used with concentrators or in settings where there are few oxygen sources.

The flowmeter stand is equipped with independent pressure-compensated Thorpe tube flowmeters to measure and regulate the flow at each outlet. Each flowmeter is adjusted separately to ensure precise control with a visual indication of flow for safety. The ability of the

Table 4.4 Description and comparison of flow-splitting devices

	Flowmeter stand	Dual flowmeter
General characteristics		
Illustration/image		
Description	A device that distributes medical oxygen by splitting output flow from a single oxygen source across multiple outlets through independently regulated flowmeters, to meet individual patient needs.	A device that distributes medical oxygen by splitting output flow from a terminal unit (wall outlet) oxygen source through two independently regulated flowmeters, to meet individual patient needs.
Clinical application and/or use case	Splitting oxygen flow for inpatient oxygen therapy, particularly paediatric or neonatal wards where lower flow rates are used. One inlet can be divided into several independently regulated outlets for up to five patients. Set flow rates cannot exceed output flow rate of the concentrator.	Splitting oxygen flow for inpatient oxygen therapy. One inlet can be divided into two independently regulated outlets for up to two patients.
Appropriate level of health system (and relevant medical units)	Primary, secondary, tertiary (anywhere oxygen therapy is provided; health centre, general hospital, district hospital, provincial hospital, regional hospital, specialized hospital).	Secondary, tertiary (requires piped terminal unit).
Product-specific characteristics		
Flow regulation	Yes; via the mounted flowmeters.	Yes; via the two flowmeters.
Oxygen source	Concentrator or cylinder (on the downstream side of a pressure regulator at 345 kPa (3.45 bar, 50 psig)).	Terminal unit of centralized piped system.
Merits	• Simple. • Can serve multiple patients who need oxygen therapy at different flow rates. • Can be securely mounted to a terminal unit within easy reach of health care workers and out of the way of disturbances. • Flowmeters are generally easy for health care workers to read. • Suitable for primary care settings without centralized piped oxygen.	• Simple. • Can serve two patients who need oxygen therapy at different flow rates. • Can be securely mounted to a terminal unit within easy reach of health care workers and out of the way of disturbances. • Less costly than flowmeter stand, in general. • Easier installation.
Drawbacks	• Costly. • Require space for health care workers to easily access the flowmeters. • Usually mounted in a fixed position, which may restrict where patients can be placed. • A clear outlet-to-bedside identification system must be established, otherwise there can be confusion about which outlet serves which bedside.	• Requires centralized piped system and terminal unit adapter (which is not available in many primary care settings). • Can only divide flow for up to two patients.
Is this product available in the UNICEF catalogue?	Yes.	No.

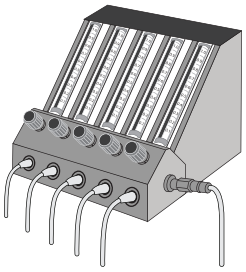
flowmeter stand to deliver indicated flow rates is limited by the flow and pressure provided by the oxygen source. For example, when used with an oxygen concentrator, the combined flow rates of individual outlets cannot exceed the output flow rate of the concentrator. Because of this combined flow limitation, the flowmeter stand is recommended for paediatric or neonatal use where lower flow rates are required *(1)*.

Dual flowmeter: This is a twin configuration of a Thorpe tube flowmeter to allow for independent gas supply to two patients from a single gas source (see section 4.1 and Fig. 4.1d). This device is most suitable for connection to a terminal unit oxygen source.

Plastic flow splitter: These are devices that distribute medical oxygen from a single source to multiple outlets. For example, Y connectors divide flow into two outlets. These devices, however, are not recommended to be used alone because the flow may not be divided equally and there is no indicator of actual flow from each outlet.

Flow-splitting devices are also discussed in the WHO *Technical specifications for oxygen concentrators* (section 3.4 *Accessories to divide flow to multiple patients*) *(1)*.

4.4 Technical specifications for flowmeter stands



For complete specifications see Annex 1, Table A1.4. The content in the specifications focuses on commercially available technologies; however, it was written with the understanding that innovations in manufacturing, products, infrastructure and clinical practice will advance the field of oxygen supply and delivery. The specifications do not preclude appropriate upcoming products and/or technologies.

4.4.1 Overview of specifications

- Tabletop device, suitable also for wall mounting.
- Equipped with up to five independent, pressure-compensated Thorpe tube flowmeters, to measure and regulate the flow of medical gas.
- Suitable for cleaning and disinfection.
- Inlet port compatible with all the international standards for oxygen fittings, including DISS, threaded and non-threaded, 6 mm barbed.
- 6 mm barbed outlet as standard – availability of adapters and outlet options to match all the international standards for oxygen fittings to be stated.
- Flowmeter range 0–2 L/min, accuracy better than 10%, graduation 0.125 L/min or lower.

Additional requirements for the flowmeters

- Transparent, clearly readable and graduated (metric system) column, shatter resistant polymer certified for medical use.
- Needle valve and body constructed of brass or aluminium.
- Inlet pressure at least 138 kPa (1.38 bar, 20 psig).
- Adjustment knobs to have rough surface to prevent slipping.
- Preferably colour coded flowmeter, e.g. to ISO 32.
- Internal parts (e.g. valve, inlet filter if present), replaceable by user.

4.4.2 Regulatory approval, standards and compliance

Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).

International standards applicable to the manufacturer and the manufacturing process are listed below. Compliance to the latest available version is recommended.

- ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes.
- ISO 14971 Medical devices – Application of risk management to medical devices.

International standards applicable to the product are listed below. Compliance to the latest available version is recommended.

- Colour coding ISO or ANSI for medical gases.
- Conforms to ISO, NFPA and/or CGA standards, and/or UL and/or CSA approved.

4.4.3 Installation

- The flowmeter stand can be used on a table or can be wall mounted, depending on the environment and where space is available. As Thorpe tube flowmeters are sensitive to vibration and positioning, the flowmeter stand should be kept in a vertical position.
- The flowmeter stand should be mounted at an appropriate level so that the health care provider can easily read the flowmeters and adjust the flows accurately.
- It is very important that each of the knobs/tubes be labelled such that it is clear which flowmeter/outlet is serving which bed, especially if tubing extends for some distance from the flowmeter stand.
- If oxygen is being provided by an oxygen concentrator through a flowmeter stand, the total distance from the concentrator to the patient's bedside should not exceed 15 m. Flow rate can be affected over long distances.
- During installation, be careful to avoid kinks in tubing, especially around sharp bends. Tubing can be fixed to the wall with cable clips or encased in trunking, a system of plastic or metal shafts that cover tubing, which gives more protection and avoids the use of cable clips.
- If humidification is required, flows must be humidified at the bedside, downstream of the flowmeter stand.

4.4.4 Safety and handling

- Whenever an outlet is not in use, the flowmeter must be turned to a closed position. This is especially important if connected to a cylinder, which may empty prematurely.

4.4.5 Maintenance

The following lists offer user care, preventive maintenance and troubleshooting tips for the flowmeter stand. Refer to user and service manuals for more guidance.

User care and preventive maintenance

- Clean and disinfect exterior surfaces of the flowmeter stand according to the manufacturer's instructions and IPC protocol specific to the setting.
- Periodically check for kinks in tubing; the flow of oxygen can be blocked by twisted tubing.
- Periodically inspect for leaks in each flowmeter, and the tubing from the source and to the patient.
- The biomedical engineering unit should frequently inspect the flow and pressure at the patient end with a calibrated oxygen flowmeter and oxygen analyser.
- Periodically inspect the vertical position of the flowmeter stand and all individual flowmeters.

Troubleshooting and corrective maintenance

- If the reading is inaccurate, it may be the position of the flowmeter. Adjust the flowmeter stand to be in vertical position.
- Replace any broken flowmeters and/or knobs.

4.5 Overview of humidifiers

Oxygen humidifiers: These are medical devices that can be integrated into oxygen delivery systems to humidify supplemental oxygen. Humidification is generally not necessary when oxygen is delivered at relatively low flow rates through nasal prongs or nasal catheters. When oxygen is delivered at higher-than-standard flow rates, or when methods of oxygen delivery bypass the nose, such as when nasopharyngeal catheters are used, humidification is needed – especially when cold oxygen is delivered from a cylinder. Refer to the WHO publication *Oxygen therapy for children* for clinical guidelines around when humidification is required *(2)*.

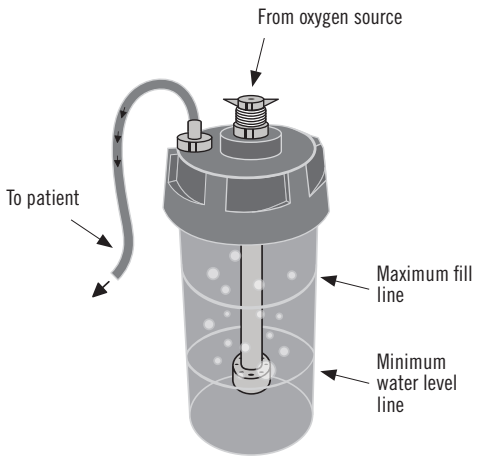
There are various types of humidifiers, and their designs differ in how they apply three main principles related to humidification:

- **Temperature:** As the temperature of gas increases, its ability to hold water vapour increases.
- **Surface area:** There is more opportunity for evaporation to occur with greater surface area of contact between water and gas.
- **Time of contact:** There is more opportunity for evaporation to occur when a gas remains in contact with water for long duration.

In this section, we distinguish between non-heated bubble humidifiers and heated humidifiers.

Non-heated bubble humidifiers: Non-heated bubble humidifiers are simple, low-cost devices that add water to oxygen gas by bubbling the gas through water at room temperature. These humidifiers function by allowing pressurized oxygen gas to flow down a tube into the bottom of a water container. The gas escapes from the distal end of the tube forming bubbles that gain water vapour as they rise to the surface (see Fig. 4.3). The bubble humidifier must be filled with clean water (distilled water or tap water that has been boiled and cooled), and then firmly attached to the oxygen outlet *(2)*. They are appropriate to use if a nasopharyngeal catheter is used to deliver oxygen or if a higher-than-standard flow is used *(2)*.

Fig. 4.3 Non-heated bubble humidifier – principles of operation



Bubble humidifiers can be reusable bottles or single-use bottles that come either empty or pre-filled with distilled water. Reusable bottles introduce a risk of bacterial contamination if the water in the bottle is not changed regularly, whereas single-use bottles reduce this risk. Bubble humidifiers are less efficient than heated humidifiers because unheated gas is less able to hold water vapour.

Heated humidifiers: Heated humidifiers consist of a heat source and a humidification chamber (a refillable transparent container). The built-in heater warms the water in the chamber to add

moisture to the airstream as it passes over the water surface. The heat is adjustable for more or less moisture. Heated humidification is needed for CPAP and for high-flow nasal cannula (HFNC) oxygen therapy (see Box 4.4) *(3)*. (Note that some CPAP devices have built-in humidification.)

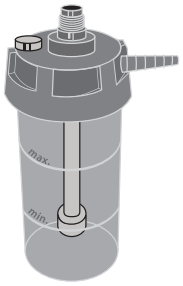
Heated humidifiers are more effective at humidifying gas than non-heated ones. However, heated humidifiers are moderately expensive compared with non-heated humidifiers and require a continuous power supply *(2)*. The downside of this type of device is that the heat tends to cause "rainout" – the accumulation of water in tubing due to moist warm air cooling and condensing on its way to the patient – which can disrupt CPAP therapy. Rainout can be minimized with the use of a special type of tubing or hose cover. With heated humidifiers, the water in the reservoir must be changed regularly to prevent bacterial contamination.

Box 4.4 Important note

Both CPAP and HFNC oxygen therapy require *heated* humidification and a blender. This publication does not give procurement guidance for all of the products required for providing CPAP and HFNC oxygen therapy. Heated humidifiers are discussed here as a comparison with non-heated humidifiers used for regular oxygen therapy; however, technical specifications for heated humidifiers are not provided. See *Oxygen therapy for children (2)* and other latest clinical guidelines for more information on CPAP and HFNC.

These different types of humidifiers differ in efficiency, cost, clinical application and risk of contamination. The choice of appropriate humidifier will depend on clinical needs and device capabilities. Table 4.5 provides a comparison of these device types. Technical specifications are provided only for non-heated bubble humidifiers.

4.6 Technical specifications for reusable non-heated bubble humidifiers



For complete specifications see Annex 1, Table A1.5. The content in the specifications focuses on commercially available technologies; however, it was written with the understanding that innovations in manufacturing, products, infrastructure and clinical practice will advance the field of oxygen supply and delivery. The specifications do not preclude appropriate upcoming products and/or technologies.

4.6.1 Overview of specifications

- Graduated, transparent humidification bottle; shatter resistant.
- Graduation should show minimum and maximum water level.
- Detachable metal or rigid durable polymer cap with gas connectors.
- DISS (or specify alternate style) inlet connector.
- 6 mm barbed (or specify alternate style) outlet.
- Must be capable of disinfection. Supplier must define decontamination procedure.
- Humidification chamber working volume available between 150 mL and 500 mL.
- Graduation options available in metric, imperial and both units.
- Flow rate capacity up to 15 L/min.
- Pressure relief safety valve ≥ 14 kPa (0.14 bar, 2 psig).
- Threadings and adapters available for other international standards for fittings.

4.6.2 Regulatory approval, standards and compliance

Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).

International standards applicable to the manufacturer and the manufacturing process are listed below. Compliance to the latest available version is recommended.

- ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes.
- ISO 14971 Medical devices – Application of risk management to medical devices.
- ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

International standards applicable to the product are listed below. Compliance to the latest available version is recommended.

- Conforms to ISO, NFPA and/or CGA standards, and/or UL and/or CSA approved.

4.6.3 Installation

If humidification is required:

- Humidifiers typically have threads for direct attachment to concentrators or flowmeters with threaded outputs, or require a humidifier adapter for barbed outlets.
- Connect the humidifier to the concentrator or flowmeter and ensure a tight seal.
- Ensure the humidifier bottle is securely and stably mounted.
- Take care to avoid oxygen leaks and make sure that it is bubbling before use with a patient.

4.6.4 Safety and handling

- Always use distilled or sterile water. Never use unboiled tap water (even if it is safe drinkable water) nor non-carbonated mineral water. In some hospitals, tap water may be contaminated and increase the risk for hospital-acquired (nosocomial) infection *(2)*.
- Do not fill the bottle above the maximum fill line. It is recommended that the humidifier be filled up to about 10 mm (1/2 inch) below the maximum fill line.
- Do not let the water level of the humidifier pass below the minimum fill line.

4.6.5 Maintenance

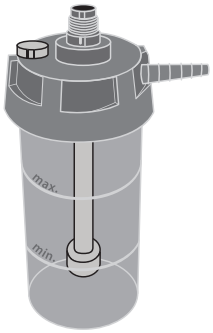
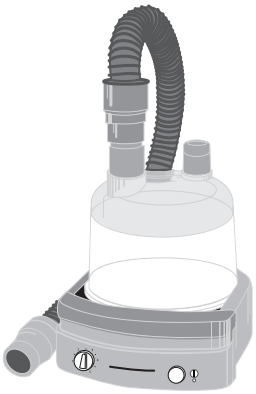
The following lists offer user care, preventive maintenance and troubleshooting tips for bubble humidifiers. Refer to user and service manuals for more guidance.

User care and preventive maintenance

- The water level in the humidifier should be checked twice daily and topped up as necessary.
- Humidifier equipment must be washed and disinfected regularly to prevent bacterial colonization according to the manufacturer's instructions and IPC protocol specific to the setting:[1]
  - The water in the humidifier should be changed daily, and the humidifier, water jar and catheter should be washed in mild soapy water, rinsed with clean water and dried in air before reuse.
  - Once a week (for the same patient) and in between patients, all the components of the humidifier should be soaked in a mild antiseptic solution for 30 minutes, rinsed with clean water and dried in air. Allowing the humidifier to dry completely will discourage bacterial colonization *(2,4)*.
- At every change, check for leakages between the flowmeter and humidifier and between the humidifier and oxygen delivery device.
- A spare, clean humidifier filled with clean water should always be available, so that oxygen therapy is not interrupted while the humidifier is being cleaned *(2)*.

[1] In situations where the IPC protocol for the setting warrants sterilization or other decontamination process beyond disinfection, more research is needed to demonstrate the effectiveness of reprocessing procedures to decontaminate bubble humidifiers to be safely reused and to demonstrate how many times bubble humidifiers can be safely decontaminated and reused before disposal is necessary.

Table 4.5 Description and comparison of humidifiers

	Bubble humidifier (non-heated)		Heated
	Reusable	Single-use (empty or pre-filled)[a]	
General characteristics			
Illustration/image			
Description	A reusable bottle that reduces the dryness of oxygen by bubbling the gas through distilled water (or water that has been boiled and cooled) at room temperature.	A single-use bottle that reduces the dryness of oxygen by bubbling the gas through distilled water at room temperature.	A device consisting of a heat source and a humidification chamber whereby the built-in heater warms the water in the chamber to add moisture to the airstream as it passes over the surface.
Clinical application and/or use case	• Reduces drying of the nasal passages during oxygen therapy. • Used when oxygen is delivered at higher-than-standard flow rates, or when methods of oxygen delivery bypass the nose, such as when nasopharyngeal catheters are used.		• Heated humidification is needed for CPAP and for HFNC oxygen therapy.
Appropriate level of health system (and relevant medical units)	Primary, secondary and tertiary level.		Secondary and tertiary level.
Product-specific characteristics			
Merits	• Simple. • No power required. • Low cost. • Reusable.	• Simple. • No power required. • Less risk of contamination.	• Adjustable heat for more or less moisture. • More efficient at humidifying gas.
Drawbacks	• High risk of contamination (reduced by changing the water frequently).[b] • Decontamination required.	• Disposable/single-use. • More costly.	• Risk of "rainout". • High risk of contamination (reduced by changing the water frequently).[b] • Needs power source.
General comments	• Works best at a water temperature of at least 30 °C.	• Works best at a water temperature of at least 30 °C.	• Works best at a water temperature of at least 37 °C.
Is this product available in the UNICEF catalogue?	Yes.	No.	No.

Notes:
[a] Only single-use pre-filled is depicted.
[b] See sections 4.6.4 and 4.6.5 for water replacement guidance.

Troubleshooting and corrective maintenance

There is no specific corrective maintenance for reusable bubble humidifiers. The following list indicates when the device should be replaced:

- Replace cracked/leaking reservoir or lid seal.
- Replace damaged threaded connecter to the flowmeter or concentrator outlet.
- Replace the reservoir or lid if there is any sediment or scaling that is not possible to clean out.

References

1. WHO. Technical specifications for oxygen concentrators. WHO Medical device technical series. Geneva: World Health Organization; 2015 (https://www.who.int/medical_devices/publications/tech_specs_oxygen-concentrators/en/, accessed 25 April 2019).
2. WHO. Oxygen therapy for children: a manual for health workers. Geneva: World Health Organization; 2016 (http://www.who.int/maternal_child_adolescent/documents/child-oxygen-therapy/en/, accessed 25 April 2019).
3. Every Preemie–SCALE and USAID. Safe and effective oxygen use for inpatient care of newborns. Do no harm technical series. United States Agency for International Development; 2017 (https://www.everypreemie.org/donoharmbriefs/, accessed 27 April 2019).
4. WHO. Decontamination and reprocessing of medical devices for health-care facilities. Geneva: World Health Organization; 2016; 107–109 (http://apps.who.int/iris/bitstream/handle/10665/250232/9789241549851-eng.pdf?sequence=1, accessed 27 April 2019).

5

OXYGEN DELIVERY DEVICES

5 Oxygen delivery devices

5.1 Overview of oxygen delivery devices

This chapter describes the devices that connect an oxygen source to a patient, for the delivery of oxygen therapy. These delivery methods can be used regardless of what source of oxygen is used (cylinder, concentrator or piped system).

Devices for oxygen delivery differ in cost, efficiency of oxygen use, and ability to provide the requisite fraction of inspired oxygen (FiO_2) (i.e. the percentage or concentration of oxygen that a patient inhales). The choice of appropriate delivery device will thus depend on clinical needs and device capabilities.

Nasal cannula: Nasal cannulae, also called nasal prongs, are the preferred method for delivering oxygen to infants and children under 5 years of age with hypoxaemia, according to the WHO *(1)*. Nasal cannulae consist of plastic tubes that end in two short tapered prongs that are placed in the nostrils. When delivering standard flow rates with this delivery method, the flow of oxygen typically does not meet the patient's full inspiratory demand so ambient air mixes with the delivered oxygen (see Box 5.1). The prongs should not fill the nostrils completely to allow ambient room air in around the prongs, thus different sizes are available to meet the needs of different patient groups – typically neonate, infant, child and adult. The nasal cannula should be secured with a piece of tape on the cheeks near the nose to avoid displacement or dislodgement *(2)*. Note that poor-quality tape can cause skin trauma, particularly in neonates, causing the skin to break and thus become open to infection. The FiO_2 when using nasal cannulae depends on the flow rate, prong diameter in relation to nostril diameter, and the patient's body weight (which is related to tidal volume, the total volume of gas moved per inspiration) *(3)*.

Box 5.1 Important note

Note that higher flows of an air-oxygen mix through nasal cannulae can be used in preterm neonates and infants with respiratory distress who have a need for distending airway pressure. This HFNC oxygen therapy requires heated humidification and a blender, to ensure the right percentage of oxygen is provided. This publication does not provide procurement guidance for all the products required for HFNC oxygen therapy. See *Oxygen therapy for children (1)* (p. 37) for more information.

Box 5.2 Considerations for neonates

- Nasal cannulae should always be the preferred option for neonates. However, they must be used with high-quality tape to avoid skin trauma, which can cause the skin to break and thus become open to infection.
- If there is no alternative, size 6 Fr nasal catheter or smaller should be used for neonates.
- Note that nasal catheters can lead to trauma, dryness and increased risk of mucus build up causing airway obstruction. Extra care must be taken when using nasal catheters for neonates.

Nasal catheter: This is a thin, flexible tube that is passed into the nose and ends with its tip in the nasal cavity. Catheters are sized according to the French gauge system (Fr), also known as Charrière (Ch), where the gauge is three times the external tubing diameter. Nasal catheters are less costly than nasal cannulae and are recommended as an alternative where nasal cannulae are not available (see Boxes 5.2 and 5.3) *(4)*. Nasal catheters are usually well tolerated, and they are unlikely to be dislodged.

Both nasal cannulae and nasal catheters provide an optimal balance between safety, efficacy and efficiency *(3)*.

Non-invasive methods: Non-invasive methods of oxygen delivery include head boxes, face masks (simple, partial rebreathing and non-rebreathing), incubators and tents. With these methods, the FiO_2 can be determined more precisely by an oxygen analyser placed near the patient's mouth *(5)*. For neonates, infants and children, however, the use of head boxes, face masks, incubators and tents to deliver oxygen is generally

discouraged, as they are wasteful of oxygen and potentially harmful due to the risk of carbon dioxide accumulation *(6)*.

Table 5.1 provides a comparison of nasal cannulae and nasal catheters (WHO-recommended methods) versus other non-invasive options. More detailed information and specifications for nasal cannulae and nasal catheters are provided in sections 5.2.1 and 5.2.2, respectively.

Technical specifications for bulk **oxygen tubing** are also provided in section 5.2.3. Oxygen tubing is soft, flexible plastic tubing of small diameter and thick walls that is required to help bridge the distance between an oxygen source and the device used to deliver oxygen to a patient (e.g. nasal prongs, nasal catheter). If oxygen is being provided by an oxygen concentrator connected to a flowmeter stand that is some distance from the patient (see Chapter 4), a conduit to fix oxygen tubing against the wall can be installed to deliver oxygen to individual patient beds *(7)*. The length of tubing and cannulae from the flowmeter stand to the patient should not exceed 15 m *(8)*. Flow rate can be affected over long distances.

Box 5.3 Total cost of ownership considerations

- Nasal cannulae and nasal catheters are consumables, intended for single patient use. Sufficient quantities should be procured for the needs of different patient groups.
- Nasal cannulae come in different sizes; these are not one-size-fits-all products.
- Be mindful of the shelf life (typically up to 5 years).
- Other ongoing costs to consider:
  - shipping and local distribution costs.

5.1.1 Procurement and selection considerations

The following is a list of important factors to consider when selecting and procuring an appropriate oxygen delivery device:

- Sizing appropriate for the patient, i.e. neonate, infant, child or adult (see Box 5.4).
- Oxygen flow rate (L/min) prescribed: high/low oxygen flow.
- FiO_2 required by patient: high/low FiO_2.
- Oxygen concentration (FiO_2) and oxygen flow rate achievable by delivery devices.
- Risk of harm to the patient.
- Required duration of oxygen treatment: long-term or short-term oxygen therapy.
- Patient comfort, mobility and safety: vomiting, eating, speaking, drinking.

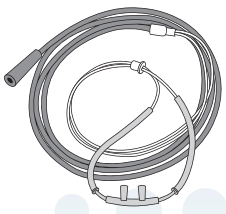
Box 5.4 Important note

Sizing of nasal cannulae will be manufacturer specific. There is no standard for the sizing of nasal cannulae. An ISO standard is currently under development (ISO/CD 23368 Anaesthetic and respiratory equipment – Low flow nasal cannulae for oxygen therapy) (see https://www.iso.org/standard/75350.html for progress).

5.2 Technical specifications for nasal cannulae, nasal catheters and oxygen tubing

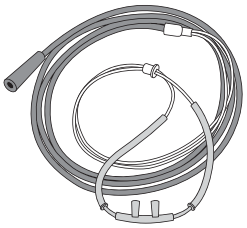
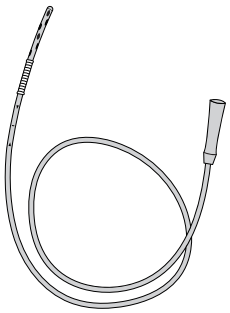
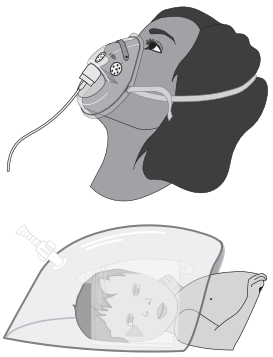
5.2.1 Overview of specifications for nasal cannulae

For complete specifications see Annex 1, Table A1.6. The content in the specifications focuses on commercially available technologies; however, it was written with the understanding that innovations in manufacturing, products, infrastructure and clinical practice will advance the field of oxygen supply and delivery. The specifications do not preclude appropriate upcoming products and/or technologies.



- Nasal cannulae (prongs) suitable for delivering air/oxygen mixture into the nasal cavities.
- Oxygen and air/oxygen mixture compatibility.
- Sizing appropriate for the patient, i.e. neonate, infant, child or adult.

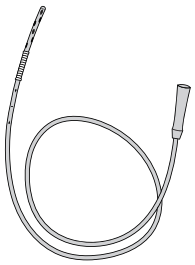
Table 5.1 Description and comparison of oxygen delivery options

	Nasal cannula (prongs)	Nasal catheter	Other non-invasive options (face mask, head box, incubator, tent)
General characteristics			
Illustration/image			
Description	Plastic tubes that end in two short tapered prongs that are placed in the nostrils.	Thin, flexible tube that is passed into the nose and ends with its tip in the nasal cavity.	Various non-invasive methods of oxygen delivery are available, including head boxes, face masks (simple, partial rebreathing and non-rebreathing), incubators and tents.
Clinical application and/or use case	Low-flow oxygen therapy for the treatment of hypoxaemia.	Low-flow oxygen therapy for the treatment of hypoxaemia.	Applications where FiO_2 needs to be tightly controlled. Typically, higher flows are required to achieve adequate concentration of oxygen and prevent carbon dioxide accumulation.
Appropriate level of health system (and relevant medical units)	All levels. All departments where oxygen therapy is delivered, including, but not limited to, ICUs, inpatient ward, emergency, operating theatre, recovery room, observation, emergency vehicles, etc.		(Note: Not recommended for neonates, infants and children *(1)*. For risks, see Drawbacks below.)
Product-specific characteristics			
Achievable FiO_2 (%)	Depends on the patient, but up to 50–55% can be achieved.		Depending on the device, can be varied from 21–100%.
Merits	• Causes less interference with eating, drinking, speaking.	• Lower cost alternative to nasal cannulae.[a] • Less likely to be dislodged.	• Non-invasive. • No increased risk of airway obstruction by mucus or of gastric distention.
Drawbacks	• More costly than nasal catheters.[a] • Risk of dislodgement. • Poor-quality tape can cause skin trauma, particularly in neonates, causing the skin to break and thus become open to infection.	• More invasive than nasal cannulae. • Insertion requires skilled trained nurse. • Can become blocked with mucus.	• Can interfere with eating, drinking and speaking. • Wasteful of oxygen. • Potentially harmful due to risk of carbon dioxide accumulation (hypercapnia).
Is this product available in the UNICEF catalogue?	Yes. (Three sizes of nasal cannula are available: neonate, child and adult.)	Yes. (Size 8 Fr available.)	No.

Note:
[a] See Box 5.3 *Total cost of ownership considerations.*
Source: Some content adapted from *Oxygen therapy for children (1)*, Table 2, p. 28.

- Transparent tubing with prongs included, suitable for low-pressure gas supply (345–380 kPa, 3.4–3.8 bar, 50–55 psi).
- Rubber or soft plastic tubing and prongs, semi-rigid and allowing freedom of movement.
- Tubing wall thickness 1.58–2.38 mm (1/16–3/32 inches).
- Anti-kink tubing, non-permanent deformation if kinked or bent too tight.
- Low-resistance tubing, round shape section, designed for low-flow procedures, typically 0–15 L/min where the delivered gas does not meet all the inspiratory demand and entrains with ambient air.
- Single patient use.
- Soft twin prongs nasal tips to ensure equal oxygen flow to both.
- Non sterile.

5.2.2 Overview of specifications for nasal catheters



For complete specifications see Annex 1, Table A1.7. The content in the specifications focuses on commercially available technologies; however, it was written with the understanding that innovations in manufacturing, products, infrastructure and clinical practice will advance the field of oxygen supply and delivery. The specifications do not preclude appropriate upcoming products and/or technologies.

- Flexible nasal catheter with holes at distal end for delivering air/oxygen mixture.
- Oxygen and air/oxygen mixture compatibility.
- Sizing appropriate for the patient, e.g. 8 Fr for infants.
- Transparent tubing, suitable for low-pressure gas supply 345–380 kPa (3.4–3.8 bar, 50–55 psi).
- Rubber or soft plastic tubing and catheter, semi-rigid and allowing freedom of movement.
- Connecting tubing internal diameter of 3–6 mm (1/8–1/4 inches).
- Open distal end with multiple lateral eyes for even dispersion of oxygen.
- Anti-kink tubing, non-permanent deformation if kinked or bent too tight.
- Single patient use.
- Non sterile.

5.2.3 Overview of specifications for oxygen tubing

For complete specifications see Annex 1, Table A1.8. The content in the specifications focuses on commercially available technologies; however, it was written with the understanding that innovations in manufacturing, products, infrastructure and clinical practice will advance the field of oxygen supply and delivery. The specifications do not preclude appropriate upcoming products and/or technologies.

Detailed requirements

- Tubing suitable for delivering air/oxygen mixture into the nasal cavities, connected to oxygen sources, medical equipment, oxygen administration devices and patient circuits.
- Oxygen and air/oxygen mixture compatibility.
- Rubber or soft plastic transparent tubing, semi-rigid, polyvinyl chloride or other material, FDA Title 21/USP VI compliant and certified for medical use, hardness > 60 Shore A (ASTM D-2240).
- Tubing wall thickness between 1.58–2.38 mm (1/16–3/32 inches).
- Round shape section, internal diameter ranges from 3–5 mm (1/8–3/16 inches), compatible with standard 6 mm barbed (ribbed and tapered) fitting.
- Anti-kink tubing, non-permanent deformation if kinked or bent too tight.
- Non sterile.

Configurations/options

- Thick wall tube: 5 mm internal diameter; and bubble tube: 3–4 mm internal diameter.
- Multiple anti-kink options (star lumen and other designs).
- Bulk coil lengths, for example (but not limited to): 25 m and 50 m coils.
- Standard, latex free and phthalate/di(2-ethylhexyl) phthalate (DEHP)-free versions.
- Various pre-cut lengths, with or without connectors, for example (but not limited to): standard and wide, and ready to use in most common procedures, for example (but not limited to): 210 cm, 420 cm, 760 cm.
- Connectors and adapters to connect the oxygen delivery device with all standard breathing circuits and air/oxygen tubing, for example (but not limited to): 6 mm tube fitting and 15/22 mm breathing circuits.

5.2.4 Regulatory approval, standards and compliance (applicable to nasal cannula, nasal catheter and oxygen tubing)

Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).

International standards applicable to the manufacturer and the manufacturing process are listed below. Compliance to the latest available version is recommended.

- ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes.
- ISO 14971 Medical devices – Application of risk management to medical devices.
- ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

International standards applicable to the product are listed below. Compliance to the latest available version is recommended.

- ISO, NFPA and/or CGA standards and/or UL and/or CSA approved.
- ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen.
- ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications.
- ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
- ISO 18190 Anaesthetic and respiratory equipment – General requirements for airways and related equipment.
- ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process.

5.2.5 Installation

- From a technical perspective, no installation is required other than to ensure proper connection and that the environment where these devices are to be used offers minimal risk of kinking or accidental disconnection.
- Refer to *Oxygen therapy for children (1)* for guidance on how to safely secure these devices to a patient.

5.2.6 Safety and handling

- Be mindful of product shelf life.
- Be mindful of the manufacturer's storage requirements (typically, storage conditions should be below 40 °C and less than 90% humidity).

- Ensure environment offers minimal risk of kinking or accidental disconnection.
- Ensure tubing is positioned so that it is not wrapped tightly around any part of the patient's body or likely to entangle the patient with movement.
- When not in use, do not leave nasal catheters or cannulae in contact with bed sheets or blankets – this is an infection control hazard as well as a fire hazard if the concentrator is turned on, as the oxygen will make the bedding material much more flammable.
- Tubing can also be a tripping hazard, so it should be kept safely out of the way during use or patient ambulation.

5.2.7 Maintenance

User care and preventive maintenance

- Nasal cannulae and catheters are single-use products and should be disposed of after each patient (see Box 5.5 and the WHO's *Decontamination and reprocessing of medical devices for health-care facilities*) *(9)*.

Troubleshooting and corrective maintenance

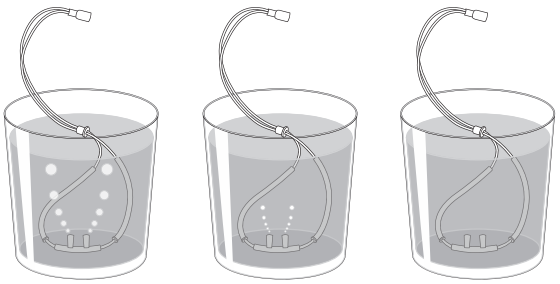
There is no corrective maintenance for single-use products.

- Replacement is required if broken (e.g. visible cracks, holes, deformations, discolouration) or malfunctioning (e.g. occluded and no air flow is coming through).
- To check for gross leaks in the oxygen connections to the patient's air flow, a bubble test can be conducted (see the WHO *Technical specifications for oxygen concentrators*) *(10)*.
  - To perform this test, the distal end of the nasal prongs or catheters is submerged into a beaker of clean water (see Fig. 5.1). Bubbles will appear if gas is flowing through the nasal prongs. If not, all oxygen delivery connections should be checked.

Box 5.5 Important note

Manufacturers' recommendations are that nasal cannulae and catheters are not to be reused. However, this may not be practical in some settings. More research is needed to demonstrate the effectiveness of reprocessing procedures to decontaminate these devices to be safely reused. Research is also needed to demonstrate how many times these devices can be safely decontaminated and reused before disposal is necessary.

Fig. 5.1 Bubble test to check for flowing oxygen and leaks



References

1. WHO. Oxygen therapy for children: a manual for health workers. Geneva: World Health Organization; 2016 (http://www.who.int/maternal_child_adolescent/documents/child-oxygen-therapy/en/, accessed 25 April 2019).
2. WHO. Oxygen therapy for children; 2016; p. 24.
3. WHO. Oxygen therapy for children; 2016; p. 23.
4. WHO. Oxygen therapy for children; 2016; p. 22.
5. WHO. Oxygen therapy for children; 2016; p. 26
6. WHO. Oxygen therapy for children; 2016; p. 27.
7. WHO. Oxygen therapy for children; 2016; p. 28.
8. WHO. Technical specifications for oxygen concentrators. Geneva: World Health Organization; 2015 (http://www.who.int/medical_devices/publications/tech_specs_oxygen-concentrators/en/, accessed 28 April 2019); p. 46.
9. WHO. Decontamination and reprocessing of medical devices for health-care facilities. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/bitstream/handle/10665/250232/9789241549851-eng.pdf?sequence=1, accessed 29 April 2019); pp. 107–109.
10. WHO. Technical specifications for oxygen concentrators; 2015; p. 29.

6

PULSE OXIMETRY

6 Pulse oximetry

6.1 Overview of pulse oximeters

Pulse oximetry is a simple and non-invasive method to indirectly measure the oxygen saturation of haemoglobin in arterial blood (SpO_2). Pulse oximeters are the accepted global standard for detecting and monitoring hypoxaemia, which is an abnormally low level of oxygen in the blood *(1)*. Hypoxaemia can occur with conditions primarily affecting the lungs, such as pneumonia, bronchiolitis, asthma and neonatal respiratory distress, but also systemic illnesses such as sepsis and trauma. Pulse oximetry is also used during anaesthesia in surgery *(2)* and for monitoring patient response to oxygen therapy. Together with an appropriate oxygen supply, pulse oximetry is necessary for the efficient and safe use of oxygen.

Pulse oximeters use the principle of differential light absorption to determine SpO_2. A sensor (also called a probe) is applied to an area of the body (e.g. a finger, toe or earlobe) and transmits different wavelengths of light from light-emitting diodes (LEDs) through the skin and into the tissue. These wavelengths are differentially absorbed by the blood's oxyhaemoglobin (HbO_2), which is red, and deoxyhaemoglobin, which is blue. A photodetector in the sensor (opposite to the LED) converts the transmitted light into electrical signals proportional to the absorbance. The pulse oximeter's microprocessor processes these signals and derives a SpO_2 reading *(3)*.

Although pulse oximetry is an important medical technology that has existed for over 30 years, it is often not available or functional in many LRS. Challenges related to the availability of pulse oximetry include low prioritization by countries and governments regarding its utility due to competing needs and limited health care spending. Where it is available, lack of functionality is common due to inadequate procurement and maintenance systems for the replacement of probes and batteries, and for repairs. Adoption into routine clinical practice may also be a challenge for widespread use *(4)*.

This chapter provides guidance on the selection and procurement of pulse oximeters to address some of these challenges.

A pulse oximeter can serve as either a spot checking device or can be used for continuous monitoring:

- A **spot check** is a single SpO_2 reading that is taken in order to detect if a patient is hypoxaemic and therefore qualifies for oxygen therapy.
- For **continuous monitoring**, the probe remains fixed to the patient and a continuous reading of SpO_2 is provided by the device.

Pulse oximeter probes should be chosen appropriately for the desired mode of use (see section 6.2 for more details on probes).

Continuous monitoring is required during surgery as the condition of the patient could shift rapidly, particularly under anaesthesia *(5)*. When oxygen therapy is given, particularly during intensive or emergency care, a pulse oximeter is beneficial for measuring the ongoing success of the therapy and can be used as a screening or warning to predict arterial haemoglobin oxygen desaturation. In premature neonates, continuous monitoring helps avoid hyperoxaemia, which is a risk factor for retinopathy of prematurity, a developmental disorder of the retina that may result in blindness. Pulse oximetry is also essential during attempts to wean oxygen therapy to determine whether a patient can maintain SpO_2 within the target range. Because pulse oximeters detect pulsatile blood flow, most devices will also display pulse rate.

Since pulse oximeters provide a non-invasive and continuous means of monitoring SpO_2, they reduce the need for arterial puncture and laboratory blood gas analysis. For a comparison of pulse oximetry to blood gas analysers, see Annex 2. Blood gas analysers are not specifically covered in this publication.

Based on application and design sophistication, pulse oximeters fall into three distinct groups:
Self-contained fingertip or finger clip oximeter: Fingertip oximeters are ultra-compact, battery-powered pulse oximeters integrated into a finger/toe clip mounted directly on the patient, typically intended for personal use. Fingertip oximeters have the lowest upfront cost of the three types (see Box 6.1) and are suitable for spot checking.

Portable handheld oximeter: This is a portable unit with a display screen and attached cable and probes, which come in varied sizes for neonates, infants, children and adults (see section 6.2 for more details on probes). The display screen typically shows a numeric digital display and a waveform and may include alarm settings. Handheld pulse oximeters can be used for spot checking or continuous monitoring. If used for continuous monitoring the alarm function must be activated.

Tabletop or stand-alone oximeter:[1] A stationary (e.g. tabletop, wall- or pole-mounted) device that may monitor oxygen saturation only or may incorporate other physiological parameters such as capnography, blood pressure monitoring and temperature. Well suited for a variety of applications, these devices normally include alarm settings and trends and are normally used for continuous monitoring in secondary and tertiary health care settings.

These three distinct types of pulse oximeter differ in cost, durability and the variety of information they are able to provide. The choice of appropriate pulse oximeter will depend on clinical needs and device capabilities. In addition, the level of the health system at which these devices could be used will depend on local policy, training and capacity at the different levels of care level. Table 6.1 provides a comparison of these three device types.

One of the main differences is in performance and accuracy due to different integrated hardware as well as signal processing algorithms. Some devices have integrated technology that helps overcome noise artefacts caused by patient motion, can detect sensor displacement, or can acquire readings even in conditions of low perfusion via signal amplification. Such algorithms are especially useful for monitoring neonates and trauma victims.

Box 6.1 Total cost of ownership considerations

- Initial upfront cost can vary considerably between pulse oximeter types.
- A lower initial device cost does not necessarily mean lower lifetime cost.
- Ongoing costs throughout the life of the device must also be considered:
  - reusable probes (require replacement every 6–12 months) versus single-use probes;
  - some reusable probes will require replacement sensor wraps or adhesives;
  - rechargeable versus single-use batteries;
  - expected life of device and replacement costs;
  - shipping and local distribution costs;
  - training costs;
  - maintenance (parts and labour) costs; and
  - energy costs.

[1] Note that pulse oximetry capabilities can be configured into physiologic monitoring systems or vital signs monitors. These types of devices are not discussed in this guidance document. The four primary vital signs are pulse rate, temperature, respiration rate and blood pressure. It is important to note that not all vital signs monitors will include SpO_2, and that tabletop SpO_2 monitors are not a replacement for vital signs monitors.

Table 6.1 Description and comparison of pulse oximeters

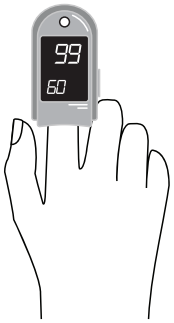
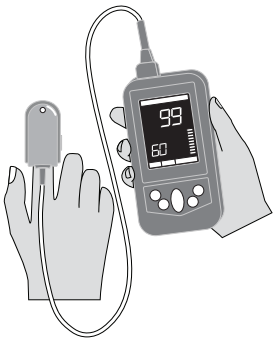
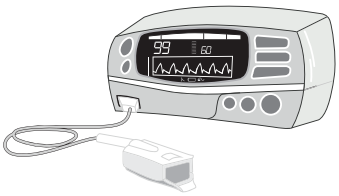
	Self-contained fingertip	Portable handheld	Tabletop
General characteristics			
Illustration/image			
Description	Portable device that has the sensor, analyser and display contained in a single unit.	Handheld portable device with display screen and attached sensor probe and cable.	Stationary device for continuous operation/monitoring. Some can be wall- or pole-mounted.
Clinical application and/or use case	Measurement of pulse rate and SpO_2 to detect hypoxaemia, supporting the diagnosis of respiratory disorders. Almost always designed for adults. Some paediatric models can be used on children (check weight range for device), but are not appropriate for use in neonates. Suitable for spot checks only.	Measurement and/or ongoing monitoring of pulse rate and SpO_2 to detect hypoxaemia, supporting the diagnosis of respiratory disorders. Most, but not all, will display a plethysmography waveform. Suitable for spot checks, or for continuous monitoring (if used for continuous monitoring, alarm feature must be available and activated, and device must be regulatory approved for continuous monitoring).	Monitoring of pulse rate, SpO_2 and plethysmography waveform to detect hypoxaemia, supporting the diagnosis of respiratory disorders. Suitable for longer term continuous monitoring.
Appropriate level of health system (and areas of use)	Primary,[a] secondary and tertiary level, but application dependent, i.e. where spot checking on adults (or children, if a paediatric model for an appropriate weight range is used) is the desired function.	Primary,[a] secondary, tertiary, e.g. health centres, general medical and outpatient areas, operating room, ICU, neonatal intensive care unit (NICU), recovery.	Secondary and tertiary, e.g. general medical and outpatient areas, operating room, ICU, NICU, recovery.
Product-specific characteristics			
Parameters monitored	SpO_2. Pulse rate.	SpO_2. Pulse rate (some may have additional features such as respiratory rate).	SpO_2. Pulse rate (some may have additional features).
Accessories required	• Replacement batteries. • May have USB cable for charging.	• Probes; size specific to the patient – adult, child, infant and neonate (reusable probes typically need replacing at least once per year). • Replacement batteries. • Charging/power cable.	• Probes; size specific to the patient – adult, child, infant and neonate (reusable probes typically need replacing at least once per a year). • Charging/power cable.
Merits	• Low upfront cost.[b] • Portable. • Self-contained unit; no external probes/cables.	• Multiple use-case options. • Portable. • More alarms and internal memory than fingertip devices. • Typically, have ≥ 12 hours' operational capacity on rechargeable built-in battery and take ≤ 4 hours to charge. • Ideally have a port (or Wi-Fi) for downloading and/or printing data.	• Multiple use-case options. • May be pole-mounted. • Large internal memory to store patient IDs and records. • Ideally have a port (or Wi-Fi) for downloading and/or printing data. • Most accurate, in general.

Table 6.1 Description and comparison of pulse oximeters (continued)

	Self-contained fingertip	Portable handheld	Tabletop
Drawbacks	• Not recommended for use in neonates. • No internal memory. • Can be sensitive to wear and tear. • Device failure likely requires complete replacement. • Can get lost easily. • Least accurate, in general.	• If single-use probes are used,[b] can be expensive and difficult to maintain supply, especially in remote areas. • Reusable probes can be sensitive to wear and tear.	• Highest upfront cost.[b] • Less portable than the other units. • If single-use probes are used,[b] can be expensive and difficult to maintain supply, especially in remote areas. • Reusable probes can be sensitive to wear and tear.
Power requirement	Usually single-use batteries, some devices may work with rechargeable batteries.	Battery (single-use or rechargeable) and/or electrical power.	Rechargeable battery and/or electrical power.
Is this product available in the UNICEF catalogue?	Yes.	Yes.	Yes.

Notes:
[a] Use of pulse oximetry at the primary level is country-specific, depending on policy, training and capacity at primary care level.
[b] See Box 6.1 and section 6.2 *Overview of pulse oximeter probes.*

6.2 Overview of pulse oximeter probes

Probes for pulse oximetry devices represent a significant ongoing cost. Their cables and connectors are fragile and susceptible to wear and tear, requiring frequent replacement. Both disposable (single patient) and reusable probes are available; however, the annual cost of disposable probes is likely to far exceed the cost of the instrument itself *(6)*. On the other hand, disposable probes may be essential for proper fit with small preterm infants or in situations involving life-threatening pathogens. Thus, when purchasing a pulse oximeter, it is important to consider the types and ongoing life cycle costs of appropriate cables and probes, and other supplies such as sensor wraps and adhesives for non clip-on probes.

There are two categories of probe sensor design: reflection sensors and transmission sensors. With reflection sensors, both the emitter and detector are on the same side. This can result in limited signal strength. With transmission sensors, the emitter and detector are on opposite sides. This is the more common design used in almost all pulse oximetry.

Pulse oximeter probes may be attached to the finger, nose, earlobe or forehead; the skin in these areas has a much higher vascular density than other areas (e.g. chest wall). Some models may also have multisite probes (for ear, finger or toe).

If important for the desired application, make sure probes are available in adult, child, infant and/or neonatal sizes (Fig. 6.1). Neonatal probes are often flexible bands designed for use on the forefoot, palm or wrist. Sizes for paediatrics are often based on weight ranges and are not standardized across manufacturers.[1] Probes should be specified and procured

Box 6.2 Considerations for neonates

- Continuous monitoring of neonates on oxygen and/or receiving respiratory therapies (e.g. CPAP) is essential (when possible), particularly for premature neonates.
- In premature neonates, continuous monitoring helps avoid hyperoxaemia, which is a risk factor for retinopathy of prematurity.
- Neonatal probes are often flexible bands, or sensors held on by a small wrap, designed for use preferably on the palm or outer fleshy aspect of the foot.
- Disposable probes may offer better fit with small preterm infants, but they incur high recurring costs and introduce the risk of infection if reused.
- The probe site should be repositioned every four hours, to check skin and avoid skin trauma and/or burns.

[1] *Note:* Some manufacturers distinguish between neonatal (up to ~ 3 kg), infant (~ 3–10 kg) and child (> 10 kg) probes, whereas others may only offer one or two size categories to cover these weight ranges. These weight ranges are examples only. Products should be specified and procured according to clinical needs.

according to clinical needs. It is important that the probe is a good fit for the patient and well positioned, so that it is not too tight (constricting circulation) or too loose (letting in too much light or falling off altogether) *(7)*.

Reusable probes come in both hard spring clip-style and soft flexible shell designs (Fig. 6.1). Both types must be disinfected before use on another patient. Common practice is that the soft shell version is used for ongoing monitoring, whereas the hard shell version is more for spot checking or short-term monitoring before the patient has been diagnosed. Hard shell probes should be avoided for long-term surveillance because they could result in skin breakdown (pressure necrosis) or burns if left on a patient for a long period of time. They are also sensitive to motion and hence generate more false alarms, which can be problematic in a continuous monitoring scenario. Soft shell probes on the other hand can offer a tighter fit, decreasing potential for ambient light interference, but they can be harder to disinfect. There are also Y-shaped multisite probes, which include reusable cables and sensors and single-use adhesive or non-adhesive attachment wraps (Fig. 6.1). Such multisite sensors fit various monitoring sites (finger, toe, thumb, hand, foot) for adults, children, infants and neonates.

There are also multiple pulse oximeter cable connector types, many of which are proprietary to the make and model of pulse oximeter (see Fig. 6.2). There may be commercial, non-proprietary (generic) probes available, but some manufacturers only assure accuracy when their devices are used with their probes. To ensure compatibility, it is recommended that only sensors specified by the manufacturer be used. If the users decide to use alternate-source pulse oximeter sensors, it is recommended that users obtain written confirmation of compatibility from the alternate-source supplier, stating that the sensors will provide adequate accuracy with the specific model of pulse oximeter *(3)*.

Fig. 6.1 SpO_2 sensor/probe cable types

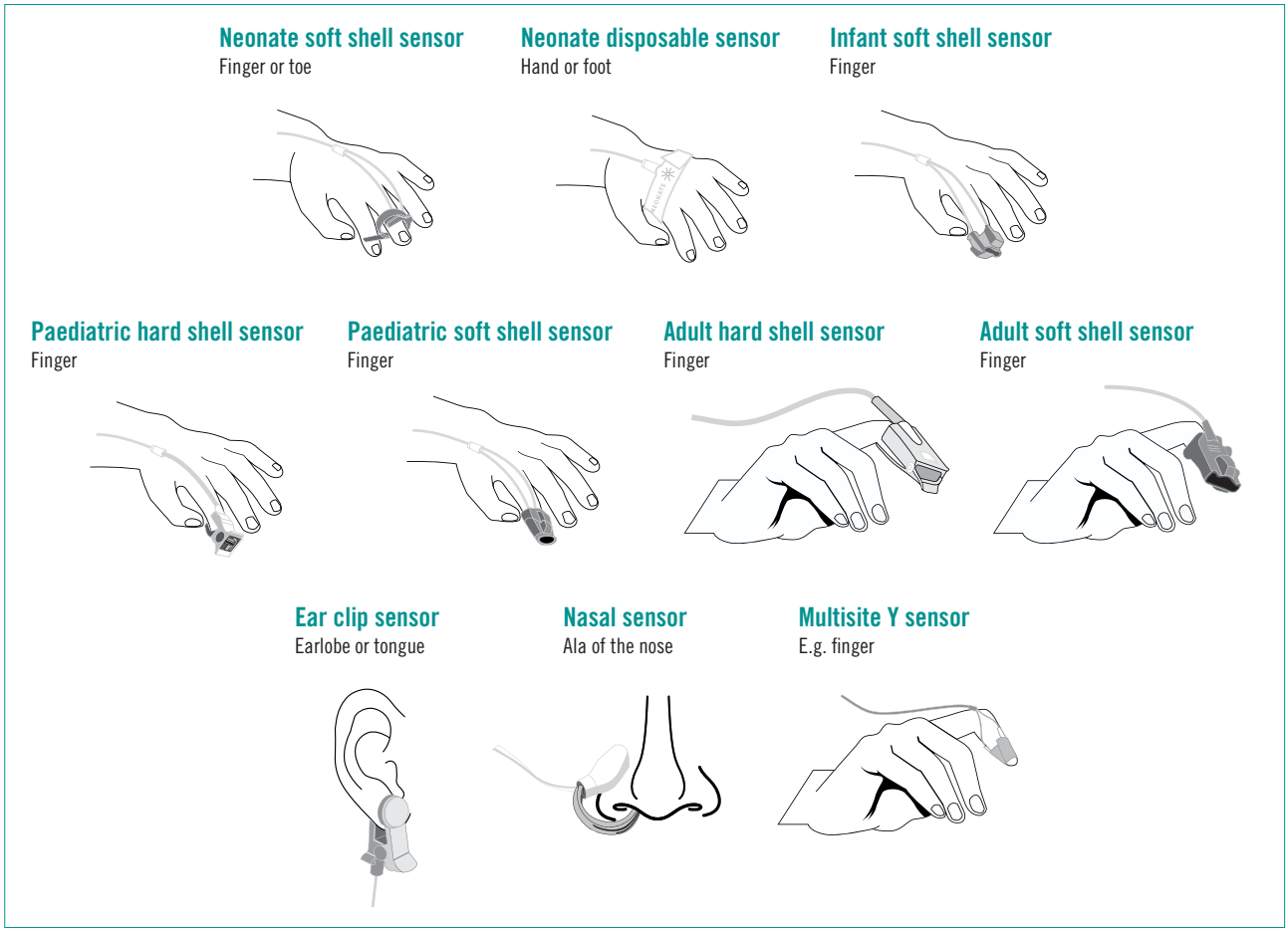


Fig. 6.2 Different types and brands of pulse oximeter probe connectors

Source: Pacific Medical. SpO_2 cables connectors: the 9 most common SpO_2 cable connectors. Pacific Medical; 2015 (http://pacificmedicalsupply.com/content/Common%20Sp02%20Connector%20Chart.pdf, accessed 13 September 2019).

6.3 Technical specifications for self-contained fingertip pulse oximeters

6.3.1 Overview of specifications

For complete specifications see Annex 1, Table A1.9. The content in the specifications focuses on commercially available technologies; however, it was written with the understanding that innovations in manufacturing, products, infrastructure and clinical practice will advance the field of oxygen supply and delivery. The specifications do not preclude appropriate upcoming products and/or technologies.

Operational characteristics

- SpO_2 and pulse rate monitor for adults and children, for all skin pigmentations. Weight range for each patient category must be stated.
- Suitable for spot checking.
- SpO_2 detection range to include: 70–99%.
- SpO_2 resolution: 1% or less.
- SpO_2 accuracy (in the range at least 70–99%): within ± 3%.
- If equipment is capable of a wider SpO_2 detection range, the accuracy over that wider range shall be stated.
- Pulse rate detection range to include: 30–240 beats per minute (bpm).
- Pulse rate resolution: 1 bpm or less.
- Pulse rate accuracy: within ± 3 bpm.
- Display shows SpO_2, pulse rate, signal quality, sensor error or disconnect and low battery status.
- Suitable for detection in low perfusion conditions (as per ISO 80601-2-61, test method must be described).

- Design must enable use in demanding environments, e.g. shock, vibration as per tests in ISO 80601-2-61, free fall tests equivalent to International Electrotechnical Commission (IEC) 60068-2-31.
- Available sizes must accommodate finger/toe thicknesses at least including the range 8–25 mm.
- Automatic correction for movement and ambient light artefacts (as per ISO 80601-2-61, test method must be described).
- Enclosure to have ingress protection level IPX2 or better.
- Any aspects of usability as per IEC 62366-1 must be described.
- Suitable for cleaning and disinfection.
- Continuous operation within specification in ambient temperature of between 5–40 °C.
- Continuous operation within specification in relative humidity of at least 10–90% non-condensing.

Electrical characteristics

- Operated by internal battery.
- Batteries may be single use or rechargeable by external alternating current (AC) battery charger or by USB connection. Rechargeable batteries are preferred.
- If rechargeable, operation must be possible while charging.
- Charger, if used, must have protection against over-voltage and over-current line conditions, and be certified to IEC 60601-1.
- If rechargeable batteries are used and the expected lifetime of unit is more than the expected lifetime of the batteries, rechargeable batteries must be replaceable by the user.
- Batteries must allow at least 2500 spot checks – calculated at 30 s (seconds) per spot check – or at least 21 hours of operation.
- Automatic power-off.

6.3.2 Regulatory approval, standards and compliance

Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).

International standards applicable to the manufacturer and the manufacturing process are listed below. Compliance to the latest available version is recommended.

- ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes.
- ISO 14971 Medical devices – Application of risk management to medical devices.

International standards applicable to the product are listed below. Compliance to the latest available version is recommended.

- ISO 80601-2-61 Medical electrical equipment – Part 2-61: Requirements for basic safety and essential performance of pulse oximeter equipment.

6.3.3 Installation

- Does not require any specific installation other than correct insertion of batteries and pre-use checks.

6.3.4 Safety and handling

- When not in use, the device should always be stored, within its storage case, in a secure and clean location with controlled temperature and humidity, and protected from dust and exposure to insects.

6.3.5 Maintenance

User care and preventive maintenance

- Run functionality tests before applying to the patient, e.g. displays and probe lights are illuminated.
- Clean and disinfect the fingertip oximeter after each patient tested, according to the manufacturer's instructions and IPC protocol specific to the setting.
- When it is not used, store in appropriate place (well ventilated and secured in storage case).
- Do not use expired or short life span batteries. Otherwise:
  - frequent battery replacements will be required, increasing running costs;
  - performance will be reduced when the battery is low; and
  - changing batteries will be a routine activity for the operator/nurses, when low battery indicator is displayed.

Refer to user and service manuals for more guidance.

Troubleshooting and corrective maintenance

Table 6.2 provides some troubleshooting tips for common issues with fingertip pulse oximeters. Refer to user and service manuals for more guidance.

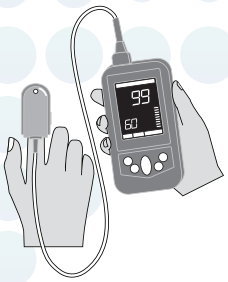
Table 6.2 Troubleshooting and repair or self-contained fingertip pulse oximeters

Problem or fault	Possible cause	Solution
Display suddenly turns off	• The oximeter is automatically powered off when no signal is detected (time to shut off may differ by model; consult user manual).	• Relocate the probe on another finger or restart the oximeter and be sure the signal strength is strong enough for stable display.
	• The power of the battery is too low.	• Replace the battery.
Display lockup	• Display does not appear to change (you should see a change to the pleth wave or pulse indicator if the device is on the finger).	• Reposition finger or relocate on another finger. Remove and replace battery. If the problem persists, contact technical service of the provider.
SpO_2 or pulse rate does not display	• Oximeter is not placed correctly on the finger.	• Reposition the device.
	• Patient's SpO_2 value is too low to be measured.	• Shield the probe from excessive ambient light. • Try device on another patient for comparison to ensure it is not a faulty device.
Unstable SpO_2 or pulse rate	• Finger might not be placed deep enough into the clamp probe.	• Retry by inserting the finger to the end.
	• Excessive movement.	• Prevent movement of the finger, hand or body.
No readings	• Low pulse quality (no reading).	• Reposition finger. • Warm finger by rubbing. • Select another finger.
The oximeter will not turn on or blank display	• No battery or low power of battery.	• Replace battery.
	• Battery installed incorrectly.	• Reinstall the battery or check the polarity/direction of the battery.
	• The display might be damaged.	• Replace with new device.
	• Dirty/corroded contact.	• Decontaminate the contact.
	• Finger positioned incorrectly.	• Shift finger to activate the device.
	• Device may be too cold.	• Allow device to sit at room temperature for at least 30 minutes.

Source: Adapted from various manufacturers' manuals. Refer to actual user and service manuals for more guidance.

6.4 Technical specifications for handheld pulse oximeters

6.4.1 Overview of specifications



For complete specifications see Annex 1, Table A1.10. The content in the specifications focuses on commercially available technologies; however, it was written with the understanding that innovations in manufacturing, products, infrastructure and clinical practice will advance the field of oxygen supply and delivery. The specifications do not preclude appropriate upcoming products and/or technologies. These specifications could also apply for the SpO_2 feature of a multiparameter device, for example, one that also measures respiratory rate.

Operational characteristics

- SpO_2 and pulse rate monitor, with plethysmography waveform, for adults, children, infants and neonates, for all skin pigmentations. Weight range for each patient category must be stated.
- SpO_2 detection range to include: 70–100%.
- SpO_2 resolution: 1% or less.
- SpO_2 accuracy (in the range at least 70–100%): within ± 2% under ideal conditions of use, and within ± 3% for all patients and perfusion/movement conditions.
- If equipment is capable of a wider SpO_2 detection range, the accuracy over that wider range should be stated.
- Pulse rate detection range to include: 30–240 bpm.
- Pulse rate resolution: 1 bpm or less.
- Pulse rate accuracy: within ± 3 bpm.
- Data update period for valid data displayed ≤ 10 s.
- Display with main parameters: SpO_2, pulse rate, plethysmographic waveform (and possibly other indicators of signal quality), alarm messages, battery state indication.
- Suitable for detection in low perfusion conditions (as per ISO 80601-2-61, test method must be described).
- Automatic correction for movement and ambient light artefacts (as per ISO 80601-2-61, test method must be described).
- Design must enable use in demanding environments (e.g. shock, vibration as per tests in ISO 80601-2-61, free fall tests equivalent to IEC 60068-2-31).
- Audible and visual alarms for low/high saturation and pulse rate, threshold set by user.
- Audible and visual alarms for sensor error or disconnected, system errors, low battery.
- Alarm override and temporary silencing function.
- Capable of working with, and supplied with, adult, child, infant and neonatal reusable probes.
- Enclosure to have ingress protection level IPX2 or better.
- Suitable for cleaning and disinfection.
- Overall device and probe weight < 400 g.
- Any aspects of usability as per IEC 62366-1 must be described.
- Continuous operation within specification in ambient temperature of between 5–40 °C.
- Continuous operation within specification in relative humidity of between 10–90% non-condensing.

Electrical characteristics

- Operated by replaceable battery power supply, either rechargeable or single use. Rechargeable batteries are preferred.
- External or built-in AC battery charger, if rechargeable type. Power connection requirements as per local power supply.
- Charger, if used, to have protection against over-voltage and over-current line conditions and be certified to IEC 60601-1.
- Protection against defibrillator discharges and electrosurgical units.

- Suitable for operation by battery and by mains power supply, if connected and/or recharging.
- Automatic switch between battery and mains powered modes, when recharging or in mains power failure.
- The display should show which power source is in use.
- Running time on battery only: ≥ 12 hours.

6.4.2 Regulatory approval, standards and compliance

Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).

International standards applicable to the manufacturer and the manufacturing process are listed below. Compliance to the latest available version is recommended.

- ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes.
- ISO 14971 Medical devices – Application of risk management to medical devices.

International standards applicable to the product are listed below. Compliance to the latest available version is recommended.

- IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems.
- IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.
- ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.
- ISO/IEEE 11073-10404 Health informatics – Personal health device communication – Part 10404: Device specialization – Pulse oximeter.

6.4.3 Installation

- Ensure correct insertion of batteries and placement of casing (if applicable).
- Ensure all cables and probes are connected properly.
- Functional checks.

6.4.4 Safety and handling

- When not in use, the device should always be stored, within its storage case, in a secure and clean location with controlled temperature and humidity, and protected from dust and exposure to insects.

6.4.5 Maintenance

User care and preventive maintenance

Table 6.3 provides daily, weekly and 6-monthly guidance for user care and preventive maintenance of both handheld and tabletop pulse oximeters. Refer to user and service manuals for more guidance.

Troubleshooting and corrective maintenance

Table 6.4 provides some troubleshooting tips for common issues with handheld and tabletop pulse oximeters. Refer to user and service manuals for more guidance.

Table 6.3 User care and preventive maintenance recommendations for handheld and tabletop pulse oximeters

Schedule period	Activities	Check
Daily	Cleaning	✓ Clean and disinfect exterior surfaces of the pulse oximeter according to the manufacturer's instructions and IPC protocol specific to the setting. ✓ Clean and disinfect the probe after each patient tested, according to the manufacturer's instructions and IPC protocol specific to the setting. ✓ Discard single-use probes after each use.
	Visual checks	✓ Check all parts are present and connected. ✓ Ensure that probes which are not in use are not left hanging or lying about where they can be damaged. ✓ Check cables are not twisted and remove from service if any damage is visible.
	Function	✓ Check operation on healthy subject if in doubt of function.
Weekly	Cleaning	✓ Unplug, remove equipment cover (if applicable), clean and disinfect exterior surfaces of the pulse oximeter according to the manufacturer's instructions and IPC protocol specific to the setting. Replace cover.
	Visual checks	✓ Tighten any loose screws and check parts are fitted tightly. ✓ If plug, cable or socket are damaged, replace.
	Function	✓ Check operation of all lights, indicators and visual displays. ✓ Check probe disconnection alarm.
Every 6 months		✓ Biomedical engineering unit preventive maintenance check required (refer to service manual).

Sources: Adapted from *User care of medical equipment: a first line maintenance guide for end users. Strengthening Specialised Clinical Services in the Pacific;* 2015 (https://bmet.ewh.org/handle/20.500.12091/83, accessed 26 April 2019); and *Pulse oximetry training manual.* Geneva: World Health Organization; 2011 (http://www.who.int/patientsafety/safesurgery/pulse_oximetry/who_ps_pulse_oxymetry_training_manual_en.pdf?ua=1, accessed 28 April 2019).

Table 6.4 Troubleshooting and repair of handheld and tabletop pulse oximeters

Problem or fault	Possible cause	Solution
Equipment is not running	• No power from mains socket.	• Check power switch is on. • Replace fuse with correct voltage and current if blown. • Check mains power is present at socket using equipment known to be working. • Contact electrician for rewiring if power not present.
	• Battery (if present) is discharged.	• Recharge or replace battery.
	• Power supply cable fault.	• Try cable on another piece of equipment to determine the power cable or the device is faulty. • Contact biomedical engineering unit for repair if required.
SpO_2 or pulse rate not displayed or unstable	• Probe is not mounted correctly.	• Connect probe and cable properly.
	• Probe is dirty.	• Remove grease, dirt, nail polish, etc. and clean probe.
	• Patient movement.	• Request patient to remain still. • For paediatric patients, try employing distraction/engagement of the apprehensive child or breastfeed (if still breastfeeding). • For neonates and infants, try locating the sensor on the foot.
	• Patient's SpO_2 value is too low to be measured.	• Re-site probe if necessary. Further clinical examination of patient.
	• Internal malfunction.	• Device may require replacement. Contact biomedical engineering unit.

Table 6.4 Troubleshooting and repair of handheld and tabletop pulse oximeters (continued)

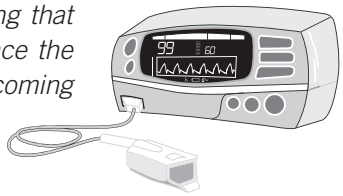
Problem or fault	Possible cause	Solution
"Probe off" displayed on screen	• Probe is not connected properly.	• Connect the probe properly. • Check the extension cable and probe.
	• The connection between the probe and oximeter is loose.	• Tighten the connection, or refer to biomedical engineering unit for repair.
"Error" displayed on screen	• Faulty probe.	• Replace the probe.
	• Faulty control circuit.	• Refer to biomedical engineering unit to replace control board if possible, or contact supplier.
Continuous alarm sounds	• Alarm limits set too low or high.	• Set appropriate alarm limits.
	• Power disconnected.	• Connect power cable.
	• Internal malfunction.	• Refer to biomedical engineering unit to replace the control board.
Electrical shocks	• Wiring fault.	• Remove from clinical use immediately. Re-wire the connection based on the manufacturer's schematic and circuit diagram.

Source: Adapted from *User care of medical equipment: a first line maintenance guide for end users. Strengthening Specialised Clinical Services in the Pacific;* 2015 (https://bmet.ewh.org/handle/20.500.12091/83, accessed 26 April 2019).

6.5 Technical specifications for tabletop pulse oximeters

6.5.1 Overview of specifications

For complete specifications see Annex 1, Table A1.11. The content in the specifications focuses on commercially available technologies; however, it was written with the understanding that innovations in manufacturing, products, infrastructure and clinical practice will advance the field of oxygen supply and delivery. The specifications do not preclude appropriate upcoming products and/or technologies.



Operational characteristics

- Continuously monitors SpO_2, plethysmography waveform and pulse rate for adults, children, infants and neonates, for all skin pigmentations. Weight range for each patient category must be stated.
- SpO_2 detection range to include: 70–100%.
- SpO_2 resolution: 1% or less.
- SpO_2 accuracy (in the range at least 70–100%): within ± 2% under ideal conditions of use, and within ± 3% for all patients and perfusion/movement conditions.
- If equipment is capable of a wider SpO_2 detection range, the accuracy over that wider range shall be stated.
- Pulse rate detection range: 30–240 bpm.
- Pulse rate resolution: 1 bpm or less.
- Pulse rate accuracy: within ± 3 bpm.
- Data update period for valid data display ≤ 10 s.
- Display with main parameters: SpO_2, pulse rate, plethysmographic waveform, signal quality, alarm messages, battery state indication.
- Suitable for detection in low perfusion conditions (as per ISO 80601-2-61, test method must be described).
- Automatic correction for movement and ambient light artefacts (as per ISO 80601-2-61, test method must be described).
- Design must enable use in demanding environments (e.g. shock, vibration as per tests in ISO 80601-2-61, free fall tests equivalent to IEC 60068-2-31).

- Internal data storage for patient data and trends and for event log.
- Audible and visual alarms for low/high saturation and pulse rate, threshold set by user.
- Audible and visual alarms for sensor error or disconnected, system errors, low battery.
- Alarm override and temporary silencing function.
- Capable of working with, and supplied with, adult, child, infant and neonatal reusable probes.
- Enclosure to have ingress protection level IPX2 or better.
- Suitable for cleaning and disinfection.
- Any aspects of usability as per IEC 62366-1 must be described.
- Continuous operation within specification in ambient temperature of between 5–40 °C.
- Continuous operation within specification in relative humidity of between 10–90% non-condensing.

Electrical characteristics

- Operated by local line electrical power supply and internal rechargeable backup battery.
- Protection against over-voltage and over-current line conditions and be certified to IEC 60601-1.
- Protection against defibrillator discharges and electrosurgical units.
- Battery charger integrated in the main unit.
- Automatic switch between battery and mains powered modes, when recharging or in mains power failure. The display shall show which power source is in use.
- Internal replaceable and rechargeable batteries.
- Running time on battery only: ≥ 6 hours.
- The power cable length ≥ 2.5 m.

6.5.2 Regulatory approval, standards and compliance

Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).

International standards applicable to the manufacturer and the manufacturing process are listed below. Compliance to the latest available version is recommended.

- ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes.
- ISO 14971 Medical devices – Application of risk management to medical devices.
- IEC 80001-5-1, Application of risk management for IT-networks incorporating medical device – Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software – Part 5-1: Activities in the product life cycle.

International standards applicable to the product are listed below. Compliance to the latest available version is recommended.

- IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems.
- IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.
- ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.
- ISO/IEEE 11073-10404 Health informatics – Personal health device communication – Part 10404: Device specialization – Pulse oximeter.

6.5.3 Installation

- Functional checks.
- Ensure proper connections.
- Ensure loose cables are secured and do not pose a risk to patients, health care workers or other equipment in the area.

6.5.4 Safety and handling

- When not in use, the device should always be stored in a secure and clean location with controlled temperature and humidity, and protected from dust and exposure to insects.

6.5.5 Maintenance

User care and preventive maintenance

See section 6.4.5 *User care and preventive maintenance* for both handheld and tabletop pulse oximeters.

Troubleshooting and corrective maintenance

See section 6.4.5 *Troubleshooting and corrective maintenance* for both handheld and tabletop pulse oximeters.

References

1. WHO. Technical specifications for oxygen concentrators. Geneva: World Health Organization; 2015 (http://www.who.int/medical_devices/publications/tech_specs_oxygen-concentrators/en/, accessed 28 April 2019).
2. WHO. Pulse oximetry training manual. Geneva: World Health Organization; 2011 (http://www.who.int/patientsafety/safesurgery/pulse_oximetry/who_ps_pulse_oxymetry_training_manual_en.pdf?ua=1, accessed 28 April 2019).
3. ECRI Institute. Pulse oximeters product comparison. Plymouth Meeting (PA): Emergency Care Research Institute; 4/1/2018.
4. Graham HR, Bakare AA, Gray A, Ayede AI, Qazi S, McPake B et al. Adoption of paediatric and neonatal pulse oximetry by 12 hospitals in Nigeria: a mixed-methods realist evaluation. BMJ Glob Health. 2018;26;3(3):e000812.
5. WHO/Patient Safety. WHO/Patient Safety Pulse Oximetry Project [website]. Geneva: World Health Organization; 2019 (http://www.who.int/patientsafety/safesurgery/pulse_oximetry/en/, accessed 28 April 2019).
6. WHO. Global Pulse Oximetry Project: background document for the First International Consultation Meeting WHO headquarters, Geneva, Switzerland 29 and 30 October 2008. Geneva: World Health Organization; 2008 (https://www.who.int/patientsafety/events/08/1st_pulse_oximetry_meeting_background_doc.pdf, accessed 20 September 2019).
7. WHO/Patient Safety. Using the pulse oximeter: Tutorial 2 – Advanced. 2011 (https://www.who.int/patientsafety/safesurgery/pulse_oximetry/who_ps_pulse_oxymetry_tutorial2_advanced_en.pdf?ua=1, accessed 28 April 2019).

7

DEVICES FOR QUALITY POWER SUPPLY

7 Devices for quality power supply

7.1 Overview of devices for quality power supply

Medical equipment operated by electricity demands a high-quality, reliable, regulated and safe power supply to operate correctly. In many LRS, known problems related to power include highly volatile or low supply voltage, as well as power surges *(1)*. In the case of oxygen therapy products, these poor power conditions can significantly harm electrically powered oxygen concentrators, as well as pulse oximeters that require power directly from a mains source, or require recharging from a mains source. While ISO-compliant concentrators include basic power protection, repeated exposure to such poor-quality power can cause shut down, underperformance or permanent damage that requires repair by a skilled technician earlier than expected *(2)*.

Two key devices that can help protect medical equipment from poor power are voltage stabilizers and surge suppressors. In fact, for oxygen concentrators, WHO recommends that both are used, as a minimum, to counter the poor-quality power that causes cumulative damage to devices over time *(2)* (see Box 7.1). Table 7.1 provides a comparison of these different devices.

Table 7.1 Description and comparison of power supply devices

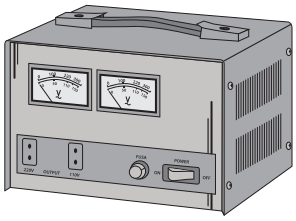
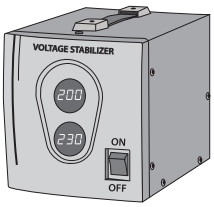
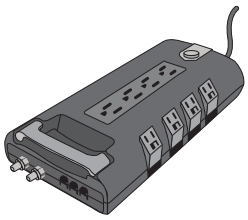
	Voltage stabilizer		Surge suppressor
	Servo-electronic	Solid-state	
General characteristics			
Illustration/image			
Description	Voltage stabilizer consisting of a servo-motor, control circuit, carbon brush and various other components, designed to compensate for voltage fluctuations in mains power, generating a more stable output voltage regardless of changes in input voltage.	A fully electronic voltage stabilizer, without any moving parts, designed to compensate for voltage fluctuations in mains power, generating a more stable output voltage regardless of changes in input voltage.	A device installed in the power distribution panel, or between the mains power supply and the electrical equipment, to prevent damage and provide protection against surges.
Clinical application and/or use case	Used to protect medical equipment from poor power (under and over voltage).	Used to protect medical equipment from poor power (under and over voltage).	Used to protect medical equipment from power surges.
Appropriate level of health system (and relevant medical units)	Primary, secondary and tertiary.	Primary, secondary and tertiary.	Primary, secondary and tertiary.
Product-specific characteristics			
Merits	• More accurate and resistant to input voltage and current fluctuations. • Less costly than solid-state stabilizers. • May also offer surge protection.	• No noise. • Low maintenance due to no moving parts. • May also offer surge protection.	• No noise. • Solid state. • Durable.

Table 7.1 Description and comparison of power supply devices (continued)

	Voltage stabilizer		Surge suppressor
	Servo-electronic	Solid-state	
Drawbacks	• High noise due to moving parts. • Highly vulnerable to dust due to wear of carbon brush. • Slow reset. • Higher maintenance needs; more prone to wear and tear due to moving internal parts, and wear of carbon brush.	• More costly than servo-electric stabilizers.	• Does not compensate for low-voltage conditions.
Is this product available in the UNICEF catalogue?	No.	Yes.	Yes.

Voltage stabilizer: Sometimes also referred to as a voltage regulator[1] a voltage stabilizer is designed to compensate for voltage fluctuations in mains power, generating a more stable output voltage regardless of changes in input voltage. Although the technology is often embedded within electrical devices or power distribution systems, small portable stabilizers are available that can be plugged in between sensitive equipment and a mains wall outlet. Some voltage stabilizers may also offer surge protection.

There are two different types of voltage stabilizers: servo-electronic (i.e. electromechanical) and solid-state.

- **Servo-electronic:** The servo-electronic voltage stabilizer consists of a servo-motor, control circuit, carbon brush and various other components. The automatic control circuit will send a signal to drive the servo-motor when the input voltage fluctuates or the load varies. This can then adjust the position of the carbon brush inside the automatic voltage stabilizer. The output voltage is then adjusted to the rated value and a steady state is maintained. The servo-electronic stabilizer is very accurate and resistant to input voltage and current fluctuations. However, since the motor's carbon brushes can get eroded, dust or other particles can interfere with normal operation. Thus, servo-electronic stabilizers require regular attention and maintenance. As such, it is not a recommended solution in LRS.
- **Solid-state:** The solid-state voltage stabilizer is fully electronic, without any moving parts. Compared with the servo-electronic type (which has motors and coiled transformers), the solid-state version is a smaller and lower maintenance device and, due to its fully electronic design, has a faster reaction time. Therefore, the solid-state stabilizers are recommended for LRS. A specification for this type only is provided in section 7.2.

Box 7.1 Important note

Note that voltage stabilizers and surge suppressors do not provide continuity of power during power interruptions, therefore it is recommended that backup power supplies are considered if power interruptions are a major problem. See WHO's *Technical specifications for oxygen concentrators (2)* for a discussion of options for supporting oxygen concentrators during power interruptions, including backup cylinders, uninterruptible power supply (UPS), battery backup systems and solar panels.

Box 7.2 Total cost of ownership considerations

- The initial upfront cost for servo-electronic stabilizers is likely lower than that for solid-state stabilizers.
- However, servo-electronic stabilizers require more maintenance due to more moving parts that can wear or fail over time.
- Costs throughout the life of power quality devices that must be considered include:
  - expected life of device and replacement costs (related to quality of mains voltage and frequency of major surges);
  - shipping and local distribution costs;
  - training costs; and
  - maintenance (parts and labour) costs.

[1] There are minor differences in the functionality of stabilizers and regulators; however, these terms are often used interchangeably. Regulators reduce variation in input voltage within a tolerance range to produce a constant output voltage; however, outside the regulation range, correction is not guaranteed, and the regulator will not cut off output voltage. Stabilizers maintain an output voltage within a given tolerance range when input voltage stays within the stated range but will cut off output outside of this range.

Surge suppressor: Also known as a surge protector or transient suppressor, a surge suppressor is a device installed in the power distribution panel, or between the mains power supply and the electrical equipment, to prevent damage and provide protection against surges, spikes and other dangerous voltage fluctuations. These "spikes" are of short duration (measured in microseconds – units of 10^{-6} second), but in that time, they can cause hardware to malfunction.

Spikes can be repeatable transients frequently caused by the operation of motors, generators or the switching of reactive circuit components, or by random transients, often caused by lightning and electrostatic discharge. The worst type of transient occurs when lightning strikes in the vicinity (it is not necessary for a power line to be directly hit). Such a "spike" can peak at thousands of volts and can cause permanent damage to equipment.

A surge suppressor is designed to prevent the peak AC voltage from going above a certain threshold. The device works by effectively short-circuiting to electrical ground for transient pulses exceeding the threshold, while the flow of normal current is unaffected. For the suppressor to work, a three-wire AC power connection must be used. Adapters, which allow three-wire appliances to be used with two-wire outlets or extension cords, defeat the electrical ground connection and render most surge suppressors ineffective and are therefore not acceptable. The use of a ground connection is very important for medical equipment in health care settings to avoid damage to patients, health care workers or the equipment itself.

A stand-alone surge suppressor can be easily installed between the electrical socket and the equipment, the latter plugging directly into the surge suppressor. These models of surge suppressor can be single or multisocket, providing adequate protection limited by the number of available sockets and total power rating of the suppressor device. Compared with a wired surge suppressor integrated into an electrical panel, the plugged models are not fixed and do not require specialized installation. In most cases, they are the best solution for protecting single electrical sockets or individual pieces of equipment.

After a power surge, internal protective components (e.g. fuse and/or metal oxide varistor) may need to be replaced if compromised, otherwise the surge protector may no longer provide protection.

7.1.1 Guidelines for sizing voltage stabilizers and surge suppressors

Voltage stabilizers and surge suppressors come in various capacities and configurations, thus it is important to properly specify these devices according to the need and desired application, taking into consideration factors such as, but not limited to, input voltage, number of devices, expected load, etc. Table 7.2 provides approximate quantities and sizing for a couple of load scenarios involving oxygen concentrators (typically < 600 W) and pulse oximeters.

See also *Additional configurations and options to be specified* in sections 7.2 and 7.3 for more options.

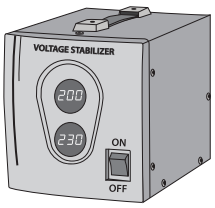
Table 7.2 Example sizing chart for combined use of voltage stabilizer(s) and surge suppressor(s)

Example load[a]	Voltage stabilizer: quantity and rating (kVA)	Surge suppressor: quantity and amperage (A)		Comments
		120 VAC	220 VAC	
One concentrator and one pulse oximeter	1 x 1.0 kVA (minimum)	1 x 25 A	1 x 16 A	
Two concentrators and two pulse oximeters	1 x 1.5 to 3.0 kVA	2 x 25 A	2 x 16 A	Due to start up current, it is not recommended that more than one concentrator is plugged into a single surge suppressor.

Notes: A – ampere; kVA – kilo-volt-ampere; VAC – volts of alternating current; W – watt.
[a] Assuming concentrator power consumption is < 600 W (0.6 kW) per concentrator, and charging pulse oximeter power consumption is ~ 15 W (0.015 kW). The kVA rating of the stabilizer normally needs to be 25% greater than the sum of the kW ratings of the devices. Thus 1 kVA is usually sufficient for one concentrator and one pulse oximeter.

7.2 Technical specifications for solid-state voltage stabilizers

7.2.1 Overview of specifications



For complete specifications see Annex 1, Table A1.12. The content in the specifications focuses on commercially available technologies; however, it was written with the understanding that innovations in manufacturing, products, infrastructure and clinical practice will advance the field of oxygen supply and delivery. The specifications do not preclude appropriate upcoming products and/or technologies.

Technical requirements

- Electronic, microprocessor-controlled voltage stabilizer.
- Solid-state tap-switching technology, without moving parts.
- Single phase.
- 110–120 VAC or 220–240 VAC nominal input voltage (see configurations/options below).
- Frequency range 50–60 Hz ± 10% at least.
- Voltage input and output indicators.
- Input circuit breaker.
- Spike, surge, transient and lightning protection.
- Built-in overload protection.
- Capacity for short-term overload working conditions, at least 135% for 4 minutes and 110% for 6 minutes.
- Independent and filtered (non-interfering) outlets (applicable to multiple outlet voltage stabilizers).
- Automatic voltage stabilization and regulation.
- Automatic over-voltage and under-voltage protection, with output power supply disconnection.
- Capacity for short-term extended under/over input voltage (at least additional ± 2%) without activation of the protection and with output swing < 10%.
- Automatic start-up after disconnection, with start-up delay between 2–10 s.
- Outlet voltage 110 VAC or 220 VAC (as per local requirement) ± 8% or narrower accuracy.
- Protection of the stabilizer and the load against switch on/off over-current and over-voltage.
- Manual bypass function.
- Visual and/or audible alarm for operational conditions and system status.
- Efficiency at least 80% at 25% load, 90% at 50% load and 95% at 75–100% load.
- Correction speed > 750 V/s.
- Unaffected by load power factor in order to allow use with all types of output load.

- Power cord length > 1.5 m (for plugged versions).
- Low noise < 45 decibels (dB).
- Hospital grade classification (preferred).

Additional configurations and options to be specified

The following is a list of additional considerations when procuring voltage stabilizers:

- Do you need indoor (at least IP20), outdoor (at least IP54) or rack-mount housings?
- What environmental conditions (e.g. temperature, humidity, altitude) will the device be operating in?
- Will it be used on grounded or non-grounded mains?
- Optional input and output power metering.
- Is it advantageous for either the input or output to have capacity for dual voltage range (i.e. both 110–120 VAC and 220–240 VAC)?
- What is the range of input voltage swing (e.g. within the range ± 15–20%, ± 20-25%, ± 25–30%)?
- Do you need single or multiple outlet sockets, rating from 2.5 A to 16 A?
- Optional built-in isolating transformer, available at least for capacity > 1.5 kVA.
- Optional built-in output circuit breaker, independent for each output.
- Do you want to also require output spike, surge and transient protection (including lightning), with availability of Type I and Type II IEC 62305 lightning surge protection?
- Availability of different delay on start-up and on automatic reconnection, including (but not limited to): 0 s/immediate on power reconnection or start-up, 3–4 minutes, or adjustable.
- Capacity range (depending on the models) must be specified (see Table 7.2):
  - models up to 1 kVA should be lightweight and portable (at least 0.5 and 1 kVA);
  - models from 1 kVA to 10 kVA should be mobile/wheeled (at least 1, 1.5–2, 2.5–3.5, 5, 7–10 kVA);
  - models from 10 kVA to 30 kVA should be available in wheeled and fixed version (at least 7–10, 10–15, 20–25, 30 kVA); and
  - wired and plugged version availability, with customizable plug (inlet) and sockets (outlets) matching all commercial electrical standards (at least, but not limited to, European/German, British, French, American, Australian, Indian).

7.2.2 Regulatory approval, standards and compliance

International standards applicable to the manufacturer and the manufacturing process are listed below. Compliance to the latest available version is recommended.

- ISO 9001 Quality management systems – Requirements.

International standards applicable to the product are listed below. Compliance to the latest available version is recommended.

- IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
- IEC 61000-6-3 Electromagnetic compatibility. Generic standards. Emission standard for residential, commercial and light-industrial environments.
- IEC 61000-6-1 Electromagnetic compatibility. Generic standards. Immunity for residential, commercial and light-industrial environments.
- IEC 50561-1 Power line communication apparatus used in low-voltage installations. Radio disturbance characteristics. Limits and methods of measurement. Apparatus for in-home use.
- IEC 60065 Audio, video and similar electronic apparatus – Safety requirements.
- IEC 61643 Low-voltage surge protective devices.

- IEEE-1100 Powering and grounding electronic equipment.
- UL 60950-1 Information technology equipment – Safety – Part 1: General requirements.
- UL 1449 Standard for surge protective devices.
- IEC/BS/EN 62305 Lightning protection or equivalent.

7.2.3 Installation

- Ensure the rated voltage of the voltage stabilizer is same as the rated mains voltage supply.
- The grounding connection must be separated from the supply's neutral conductor.
- Ensure loose cables are secured and do not pose a risk to patients, health care workers or other equipment in the area.
- The stabilizer should be installed in a cool and well-ventilated place to reduce overheating of the equipment.

7.2.4 Safety and handling

- When dealing with voltage stabilizers, always follow safe electrical work practices.
- Never connect to the voltage outlet if the rated voltage differs from the main source.
- Do not use the voltage stabilizer for a larger load than its rated power.

7.2.5 Maintenance

The following lists offer user care, preventive maintenance and troubleshooting tips for solid-state voltage stabilizers. Refer to user and service manuals for more guidance.

User care and preventive maintenance

- Periodically inspect the connection and properly tie down any loose cables.
- When cleaning, unplug the device first. Clean exterior surfaces using a cloth very lightly dampened with a mild detergent and water. Wipe dry with a clean cloth.

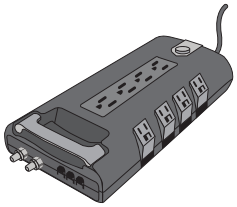
Troubleshooting and corrective maintenance

- A solid-state voltage stabilizer should require no scheduled maintenance.
- Check any externally visible components for damage after a surge; if components are visibly blown out, replace the fuse or other similar protective components if necessary, or replace the unit.

7.3 Technical specifications for surge suppressors

7.3.1 Overview of specifications

For complete specifications see Annex 1, Table A1.13. The content in the specifications focuses on commercially available technologies; however, it was written with the understanding that innovations in manufacturing, products, infrastructure and clinical practice will advance the field of oxygen supply and delivery. The specifications do not preclude appropriate upcoming products and/or technologies.



Technical requirements

- Solid-state electronic, secondary, plugged surge suppressor.
- Single phase, with grounding connection.
- 110–120 VAC or 220–240 VAC nominal input voltage.
- Frequency range 50–60 Hz ± 10% at least.
- Safety circuit breaker (thermal protection/fuse or equivalent protection) against catastrophic failure.

- Spike, surge, transient and lightning protection.
- Built-in overload protection.
- Capacity for short-term overload working conditions.
- Protective modes L-N, L-E and N-E.
- IEC rating lightning surge protection Type III or better.
- Hospital grade classification (preferred).
- Response time < 20 nanoseconds (ns).
- Maximum surge/spike current discharge > 6 kA.
- Energy rating > 400 joules (J).
- Power cord length > 1.5 m.
- Integrated overall power switch to cut power to all sockets.

Additional configurations and options to be specified

- Maximum current rating must be specified.
- Is a single or multisocket version required?
- Are individual socket power switches with indicator desired?
- Is radiofrequency and data/phone/network protection required (phone and cable lines can carry power spikes too)?
- What plug (inlet) and sockets (outlets) are required to match the local electrical standard?
- Is an enclosure that allows stand-alone floor mounting required?

7.3.2 Regulatory approval, standards and compliance

International standards applicable to the manufacturer and the manufacturing process are listed below. Compliance to the latest available version is recommended.

- ISO 9001 Quality management systems – Requirements.

International standards applicable to the product are listed below. Compliance to the latest available version is recommended.

- IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
- IEC 61643-11 Low-voltage surge protective devices – Part 11: Surge protective devices connected to low-voltage power systems – Requirements and test methods (replaces IEC 61643-1).
- Telcordia Technologies technical reference TR-NWT-001011.
- ANSI/IEEE C62.xx, including (but not limited to) C62.72 Application of surge devices for low-voltage AC circuits, C62.47 Electrostatic discharge, C62.41.2 Recommended practice on characterization of surges in low voltage.
- IEEE-1100 Powering and grounding electronic equipment.
- UL 1449 Standard for surge protective devices.
- UL 60950-1 Information technology equipment – Safety – Part 1: General requirements.
- IEC/BS/EN 62305 Lightning protection or equivalent.

7.3.3 Installation

- Ensure the rated voltage of the surge protector is same as the rated mains voltage supply.
- The grounding connection must be separated from the supply's neutral conductor.
- Ensure the surge suppressor is not in a location where it may get wet, especially multisocket devices with unused sockets.
- Do functionality checking (e.g. check that the device supplies power using a lamp or simple device) before connecting to the oxygen concentrator (or voltage stabilizer if used).

7.3.4 Safety and handling

- When dealing with surge suppressors, always follow safe electrical work practices.
- Never connect to the voltage outlet if the rated voltage differs from the main source.
- Do not overload beyond the rated amperage of the surge protection.

7.3.5 Maintenance

The following lists offer user care, preventive maintenance and troubleshooting tips for surge suppressors. Refer to user and service manuals for more guidance.

User care and preventive maintenance

- When cleaning, unplug the device first. Clean exterior surfaces using a cloth very lightly dampened with a mild detergent and water. Wipe dry with a clean cloth.

Troubleshooting and corrective maintenance

- Strictly follow the manufacturer's service manual.
- Check any externally visible components for damage after a surge; if components are visibly blown out, replace the fuse or other similar protective components if necessary, or replace the unit.

References

1. Peel D, Neighbour R, Eltringham RJ. Evaluation of oxygen concentrators for use in countries with limited resources. Anaesthesia. 2013;68(7):706–712.
2. WHO. Technical specifications for oxygen concentrators. Geneva: World Health Organization; 2015 (http://www.who.int/medical_devices/publications/tech_specs_oxygen-concentrators/en/, accessed 28 April 2019); section 3.5, p. 23.

8

OXYGEN ANALYSERS

8 Oxygen analysers

8.1 Overview of oxygen analysers

The proper functionality of medical devices has a direct impact on patient health and safety, but also plays a crucial role in the overall performance and effectiveness of health care institutions. To ensure patient safety, it is essential to monitor, test and calibrate (where necessary) medical equipment regularly.

For example, the performance of oxygen concentrators may degrade over time due to normal wear and tear, environmental changes and other factors. Regular inspection and measurement can identify issues so that corrective action can be taken.

In this chapter, we discuss analysers for monitoring and testing the concentration (purity), flow and pressure of oxygen from oxygen sources. Some analysers may offer functionality to test all three of the above parameters. Others may only measure oxygen concentration, and so separate devices would be needed to measure flow and pressure. Table 8.1 provides a comparison of these different technologies.

Oxygen analysers: Oxygen analysers, also referred to as oxygen monitors, are devices that measure and display the concentration of oxygen in patient breathing circuits, medical gas supply lines, compressed gas cylinders and oxygen concentrators. They are also used to check and adjust devices used to administer oxygen to patients.

Some oxygen analysers are designed to continuously measure oxygen concentration inspired by a patient in a respiratory therapy setting (e.g. in an anaesthesia or ventilator breathing circuit, infant oxygen hood, or oxygen therapy system tubing). Oxygen analysers can also be built into ventilators or anaesthesia units, where the oxygen sensor is automatically enabled when the system is in use. In a continuous patient monitoring application, an alarm is required to alert clinical personnel when the oxygen concentration reaches a dangerous level or goes beyond a predetermined range *(1)*.

Other analysers are intended to perform routine oxygen spot checks either at the oxygen source (e.g. an oxygen concentrator), in the environment (e.g. oxygen hood) or during equipment maintenance. In this case, alarms may not be necessary. In this chapter, the focus is on such portable handheld analysers that a biomedical engineering technician or health worker could use to test the concentration of oxygen from a concentrator or the low-pressure side of a compressed gas cylinder or terminal unit source.

Oxygen analysers use different sensing technologies for testing oxygen purity. Three common sensor technologies are: electrochemical (involving galvanic cells), ultrasonic and paramagnetic.

- **Electrochemical sensors:** These determine oxygen concentration using the conductivity of an electrochemical cell (e.g. galvanic cell). A galvanic cell is essentially an oxygen-powered battery in which the electrical potential (voltage) changes with the concentration of oxygen *(1)*. Galvanic cell analysers need to be calibrated; calibration is usually accomplished by exposing the electrode to room air (21% oxygen) and another source with known concentration (e.g. 100% oxygen from a cylinder). Note that calibration is dependent upon the gas pressure, so must be carried out at the pressure of the gas that will be measured. Inability to calibrate the analyser usually means that the sensor needs to be changed.

  Due to accumulation of electrolyte residue and oxidation over time, galvanic sensors also need to be periodically replaced. A sensor should typically last at least 12 months.

Table 8.1 Description and comparison of oxygen analysers

	Oxygen analysers for testing concentration		Multiparameter analysers (concentration, flow and pressure)
	Electrochemical (galvanic cell)	**Ultrasonic**	
General characteristics			
Illustration/image			
Description	A device that measures and displays oxygen concentration using electrochemical sensing technology.	A device that measures and displays the oxygen concentration using ultrasonic oxygen sensing technology.	A device designed to test all types of gas flow equipment especially those requiring high accuracy.
Clinical application and/or use case	Can be used for continuous monitoring and for spot checking at an oxygen source or in an environment. Al clinical departments that use oxygen should have an analyser and use it regularly.	Spot checking and servicing of PSA-generated oxygen, from concentrators or generators. All clinical departments that use concentrators should have an analyser and use it regularly.	Equipment spot checking and servicing.
Appropriate level of health system	Primary, secondary, tertiary.	Primary, secondary, tertiary.	Secondary, tertiary.
Product-specific characteristics			
Principle of operation	Electrochemical process whereby the electrical potential (voltage) changes with the concentration of oxygen.	Piezoelectric ceramics are used for ultrasonic transmission and reception. Ultrasonic technology accurately measures the speed of sound through the gas.	Varies depending on device.
Sensor material	Galvanic cell sensor consists of an anode, a cathode and an electrolyte.	Electronic sensor.	Varies depending on device.
Parameters measured	• Oxygen concentration.	• Oxygen concentration. • Flow rate (for some).	• Oxygen concentration. • Flow rate. • Pressure.
Detection range	0–99.9%	21–95.6%	0–99.9% depending on device.
Merits	• Works for concentrator and low-pressure side of cylinder supply. • Works for cryogenically generated cylinder oxygen. • Cheapest initial cost, in general.[a]	• Accurate and stable. • No need for calibration. • Compact and easy to use. • No need to replace sensor. • Can also measure flow rate. • Lifetime: ≥ 5 years.	• Multiple parameters measured by one device.
Drawbacks	• Lifetime: < 1–2 years. • Influenced by the temperature and pressure. • Needs calibration. • Needs sensor spare parts.	• Works only for PSA-generated oxygen (< 96%). • Higher initial purchase cost, in general.[a] • Can be damaged by humidity.	• High cost.
General comments	Recommended if the sensors are available and in proper supply.	Recommended for testing PSA-generated oxygen.	
Is this product available in the UNICEF catalogue?	Yes.	Yes.	No.

Note:
[a] See Box 8.1 *Total cost of ownership considerations.*

Oxygen analysers that use galvanic cell technology can be used for continuous monitoring and for spot checking at any oxygen source (e.g. a cylinder, concentrator or plant) or environment (e.g. an oxygen hood).

- **Ultrasonic oxygen sensors:** These are used to test oxygen concentration when the input is a mixture of other known gases. Gas flows through an ultrasonic chamber with an inlet and outlet. Due to molecular weight differences in the gases, sound travels at different speeds through the gas mixture, which is sensed by two ultrasound transducers (sending and receiving) that determine the percentage of oxygen.

  Because this technology requires some level of other trace gases (e.g. argon), ultrasonic analysers are appropriate for spot checking the output of PSA-generated oxygen, from concentrators or PSA oxygen generator, which provide < 96% pure oxygen. Ultrasonic technology cannot be used to test cryogenically generated oxygen in a cylinder because the percentage concentration of oxygen is too high. Ultrasonic sensors can be damaged by high humidity, therefore humidifiers should be removed before testing oxygen concentration from an oxygen source.

  Advantages of ultrasonic analysers are that they do not need calibration and the sensors do not need replacing. However, the initial cost may be more expensive than galvanic cell analysers.

Box 8.1 Total cost of ownership considerations

- Initial upfront cost can vary between the different types of oxygen analysers.
- A lower initial device cost does not necessarily mean lower lifetime cost (e.g. electrochemical analysers require periodic sensor replacements).
- Ongoing costs throughout the life of the device that should be considered include:
  - sensor replacement frequency and costs (electrochemical only);
  - expected life of device (may be less if used for continuous monitoring versus for spot checks);
  - rechargeable versus single-use (disposable) batteries;
  - shipping and local distribution costs;
  - training costs; and
  - maintenance (parts and labour) costs.

- **Paramagnetic sensors:** These are often used in oxygen analysers that are built into respiratory equipment and therefore are not compared in Table 8.1 as a tool for biomedical engineers. These sensors make use of the unique susceptibility of oxygen molecules to magnetic forces. Paramagnetic sensors consist of identical symmetrical chambers that are exposed to a magnetic field. Oxygen gas and a sample reference gas (e.g. air) are pumped through the chambers to a common outlet; the effect of the field on the oxygen creates a pressure difference between the two chambers. As a result of this difference, a differential pressure transducer generates a voltage in direct proportion to the oxygen concentration *(1)*.

8.2 Technical specifications for electrochemical (galvanic cell) oxygen analysers

8.2.1 Overview of specifications

For complete specifications see Annex 1, Table A1.14. The content in the specifications focuses on commercially available technologies; however, it was written with the understanding that innovations in manufacturing, products, infrastructure and clinical practice will advance the field of oxygen supply and delivery. The specifications do not preclude appropriate upcoming products and/or technologies.

Operational characteristics

- Portable handheld oxygen analyser for spot checking or continuous measurement of the oxygen concentration from a medical gas source and in an environment (e.g. oxygen hood).
- Electrochemical cell oxygen sensing technology.
- Oxygen measurement range to include: 15–99%.
- Oxygen resolution: 0.1%.
- Oxygen accuracy: within ± 3%.
- Suitable for measuring gas supply with pressure up to 345 kPa (3.45 bar, 50 psi).
- Response time ≤ 20 s.
- Warm-up time < 10 s.
- Replaceable galvanic cell (oxygen sensor), nominal operating life ≥ 1.5 years or 600 000 oxygen percentage hours, whichever is greater.
- Calibration and self-test mode, two-point calibration at ambient and 100% oxygen concentration.
- Internal calibration timer, with reminder (alarm and/or display message).
- Low and high oxygen concentration audible and visual alarms required.
- Display visualizing oxygen concentration, system messages and battery status.

Electrical characteristics

- Operated by battery power supply.
- Internal replaceable batteries, either rechargeable or single use.
- Battery life > 250 hours with continuous use.
- Automatic power-off when not in use.
- External or built-in AC battery charger, if rechargeable type.
- Charger, if used, to have protection against over-voltage and over-current line conditions and be certified to IEC 60601-1.

Casing and environmental requirements

- Enclosure to have ingress protection level IPX1 or better.
- Suitable for cleaning and disinfection.
- Capable of being stored continuously in ambient temperature from 0–40 °C, relative humidity from 15–95% and elevation from 0–2000 m.
- Capable of operating continuously in ambient temperature from 10–40 °C, relative humidity from 15–95%, simultaneously, and elevation from 0–2000 m.

8.2.2 Regulatory approval, standards and compliance

Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).

International standards applicable to the manufacturer and the manufacturing process are listed below. Compliance to the latest available version is recommended.

- ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes or ISO 9001 Quality management systems – Requirements.
- ISO 14971 Medical devices – Application of risk management to medical devices.

International standards applicable to the product are listed below. Compliance to the last available version is recommended.

- ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen.

8.2.3 Installation

- Strictly follow the manufacturer's instruction manual on installation.
- It is important to minimize the amount of time a trace oxygen sensor is exposed to air during the installation process. The quicker the sensor can be installed into the unit, the faster the sensor will recover to low oxygen measurement levels.

8.2.4 Safety and handling

- Do not connect the analyser to the high-pressure side of oxygen cylinder.
- While replacing the galvanic cell sensor it is recommended to wear rubber gloves.
- Do not remove the cell and expose to air unless you have indication that the cell is not performing.
- The cell comprises of thin sensing membranes. Be careful not to puncture with any sharp objects.
- When not in use, the device should always be stored in a secure and clean location, within its storage case, with controlled temperature and humidity, and protected from dust and exposure to insects.

8.2.5 Maintenance

User care and preventive maintenance

- Replace the sensor as per the manufacturer's recommendation (usually every 6–12 months).
- Calibrate your analyser after replacing the sensor with known oxygen concentration level (common practice is 21% from the air and/or 100% from cylinder filled by cryogenic plant).
- Clean exterior surfaces using a cloth very lightly dampened with a mild detergent and water. Wipe dry with a clean cloth.
- Functional test by users before using the device.

Troubleshooting and corrective maintenance

- Follow the manufacturer's service manual which shows the error code/probable cause and proposed remedial action.
- The sensor must be replaced if the galvanic cell membrane is non-functioning.
- Otherwise, contact the manufacturer's first-line support team.

8.3 Technical specifications for ultrasonic oxygen analysers

8.3.1 Overview of specifications

For complete specifications see Annex 1, Table A1.15. The content in the specifications focuses on commercially available technologies; however, it was written with the understanding that innovations in manufacturing, products, infrastructure and clinical practice will advance the field of oxygen supply and delivery. The specifications do not preclude appropriate upcoming products and/or technologies.

Operational characteristics

- Handheld oxygen analyser for spot checking or continuous measurement of the oxygen concentration from a medical gas source.
- Ultrasonic oxygen sensing technology, with permanent sensing chamber.
- Oxygen measurement range to include: 21–96%.
- Oxygen resolution: 0.1%.
- Oxygen accuracy: within ± 3%.
- Flow rate measurement: up to at least 10 L/min.
- Flow rate accuracy: within ± 3%.
- Flow rate resolution 0.1 L/min.
- Suitable for measuring gas supply with pressure up to 345 kPa (3.45 bar, 50 psi).
- Response time < 30 s.
- Warm-up time < 15 s.
- Display visualizing oxygen concentration, flow rate, system messages and battery status.

Electrical characteristics

- Operated by battery power supply.
- Internal replaceable batteries, either rechargeable or single use.
- Battery life > 250 hours continuous use.
- Automatic power-off when not in use.
- External or built-in AC battery charger, if rechargeable type.
- Charger, if used, to have protection against over-voltage and over-current line conditions and be certified to IEC 60601-1.

Casing and environmental requirements

- Enclosure to have ingress protection level IPX1 or better.
- Suitable for cleaning and disinfection.
- Capable of being stored continuously in ambient temperature from 0–40 °C, relative humidity from 15–95%, and elevation from 0–2000 m.
- Capable of operating continuously in ambient temperature from 10–40 °C, relative humidity from 15–95%, simultaneously, and elevation from 0–2000 m.

8.3.2 Regulatory approval, standards and compliance

Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).

International standards applicable to the manufacturer and the manufacturing process are listed below. Compliance to the latest available version is recommended.

- ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes or ISO 9001 Quality management systems – Requirements.
- ISO 14971 Medical devices – Application of risk management to medical devices.

International standards applicable to the product are listed below. Compliance to the latest available version is recommended.

- ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen.

8.3.3 Installation

- Strictly follow the manufacturer's instructions on installation in the manual.

8.3.4 Safety and handling

- When not in use, the device should always be stored in a secure and clean location, within its storage case, with controlled temperature and humidity, and protected from dust and exposure to insects.

8.3.5 Maintenance

User care and preventive maintenance

- Clean exterior surfaces using a cloth dampened with a mild detergent and water. Wipe dry with a clean cloth.
- Functional test by users before using the device.
- The ultrasonic sensor does not need to be replaced.

Troubleshooting and corrective maintenance

- An ultrasonic oxygen analyser should require no scheduled maintenance.
- Follow the manufacturer's service manual which shows the error code/probable cause and proposed remedial action.
- Otherwise, contact the manufacturer's first-line support.

Reference

1. ECRI Institute. Oxygen monitors, inspired. Health Product Comparison System. Plymouth Meeting (PA): Emergency Care Research Institute; 2018.

ANNEXES

Annex 1: Technical specifications for oxygen therapy devices

The tables in Annex 1 summarize technical specifications to guide the procurement and acquisition of oxygen therapy devices of high quality, safety and efficacy as well as other considerations for implementation, functioning and decommissioning. Similar specification sheets for other critical medical devices are available from the WHO. The template used to produce this table was developed by WHO and can be found at http://www.who.int/medical_devices/management_use/mde_tech_spec/en.

The content in the specifications focuses on commercially available technologies; however, it was written with the understanding that innovations in manufacturing, products, infrastructure and clinical practice will advance the field of oxygen supply and delivery. The specifications do not preclude appropriate upcoming products and/or technologies.

Table A1.1: Technical specifications for oxygen cylinders
Table A1.2: Technical specifications for oxygen concentrators
Table A1.3: Technical specifications for Thorpe tube flowmeters
Table A1.4: Technical specifications for flowmeter stands
Table A1.5: Technical specifications for reusable non-heated bubble humidifiers
Table A1.6: Technical specifications for nasal cannulae
Table A1.7: Technical specifications for nasal catheters
Table A1.8: Technical specifications for oxygen tubing
Table A1.9: Technical specifications for self-contained fingertip pulse oximeters
Table A1.10: Technical specifications for handheld pulse oximeters
Table A1.11: Technical specifications for tabletop pulse oximeters
Table A1.12: Technical specifications for solid-state voltage stabilizers
Table A1.13: Technical specifications for surge suppressors
Table A1.14: Technical specifications for electrochemical (galvanic cell) oxygen analysers
Table A1.15: Technical specifications for ultrasonic oxygen analysers

Table A1.1: Technical specifications for oxygen cylinders

MEDICAL DEVICE SPECIFICATION (These technical specifications are generic and have been developed according to the latest available commercial products. They should be adapted to the setting where the product will be used (voltage, language, accessories, connectors etc.)		
i	Version number	1
ii	Date of initial version	
iii	Date of last modification	
iv	Date of publication	September 2019
v	Completed/ submitted by	UNICEF, WHO
NAME, CATEGORY AND CODING		
1	WHO category/code	
2	Generic name	Medical gas cylinder, portable.
3	Specific type or variation (optional)	Compressed oxygen or compressed medical air, with valves and regulators.
4	GMDN name	Oxygen cylinder, Oxygen cylinder regulator, Medical air cylinder, Medical air cylinder regulator.
5	GMDN code	47225 (Oxygen cylinder), 43438 (Oxygen cylinder regulator), 46097 (Medical air cylinder), 60944 (Medical air cylinder regulator).
6	GMDN category	
7	UMDNS name	Medical gas cylinders, Regulators, High-pressure gas.
8	UMDNS code	16501 (Medical gas cylinders), 13323 (Regulators, High-pressure gas).
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Oxygen/medical air tank with valves and regulators.
11	Alternative code/s (optional)	N/A
12	Keywords (optional)	Cylinder, medical air, oxygen, tank, compressed, pressure regulator, valve, respiratory care, medical gas.

13	GMDN/UMDNS definition (optional)	GMDN 47225 Oxygen cylinder A container designed as a refillable cylinder used to hold compressed medical oxygen (O_2) under safe conditions at high pressure (e.g. 50–200 bar). It is typically filled with oxygen when delivered from the gas supplier and includes a valve stem, an opening/closing valve, and will be graded according to size (capacity) and colour-coded to denote oxygen content. The cylinder may be made of steel, aluminium or other ferrous or non-ferrous materials and must be used together with a pressure regulator in order to release the oxygen at the correct working pressure. Oxygen is used as an essential life support gas, for anaesthesia and for therapeutic purposes. 43438 Oxygen cylinder regulator A reduction valve designed to be attached through a gas-tight connector (e.g. a pin-index or bull-nosed screw thread connection) to the valve stem of an oxygen (O_2) cylinder to lower high, variable gas pressure (e.g. 50–250 bar) to a lower, constant working pressure, typically 3–5 bar. It can be a single- or a dual-stage regulator, usually of a piston or diaphragm design. It will have a safety relief valve to avoid excessive pressure due to increased ambient temperatures, and it may have associated devices, usually a manometer or manometers, to display the available gas reserve of a gas cylinder and the working pressure. 46097 Medical air cylinder A container designed as a refillable cylinder used to hold compressed medical air [a mixture of approximately 21% oxygen (O_2) and 78% nitrogen (N_2) and other inert gases] under safe conditions at high pressure (e.g. 50–200 bar). It is typically filled with medical air when delivered from the gas supplier and includes a valve stem, an opening/closing valve, and will be graded according to size (capacity) and colour-coded to denote medical air content. The cylinder is typically made of steel and must be used together with a pressure regulator in order to release the air at the correct working pressure. Medical air is used for life support, therapeutic purposes and in anaesthesia. 60944 Medical air cylinder regulator A reduction valve designed to be attached through a gas-tight connector (e.g. a pin index or bullnosed screw thread connection) to the valve stem of a medical air cylinder to lower high, variable gas pressure (e.g. 50–250 bar) to a lower, constant working pressure (typically 3–5 bar). It can be a single- or dual-stage regulator, usually of a piston or diaphragm design. It includes a safety relief valve to avoid excessive pressure due to increased ambient temperatures, and it may include associated devices, usually a manometer(s), to display the available gas reserve of the air cylinder and the working pressure. UMDNS 16501 Medical gas cylinders No UMDNS definition. 13323 Regulators, High-pressure gas Regulators designed to reduce the output pressure of gases stored in high-pressurized gas containters (e.g. medical gas cylinders) to provide a controlled pressure (typically 50 psi/3.5 bar) and flow rate appropriate for delivering gases to patients. These regulators include controllers and may also include a manometer to measure the output pressure of the gases. High-pressure gas regulators are placed between the output port of the high-pressure gas container at one end and the patient breathing circuit at the other end. The regulators are mainly used for delivery of respiratory (e.g. oxygen) and anaesthetic gases at an appropriate pressure.
PURPOSE OF USE		
14	Clinical or other purpose	Compressed oxygen and medical air cylinders are dedicated refillable containers for holding such medical gases in high-pressure, non-liquid state. They are fitted with a valve and a pressure regulator, that also includes a flow regulator in the integral valve version, for supplying 50 psi oxygen and medical air to other medical devices, or low-pressure supply to the patient if an integral valve is installed. The cylinders are available in various standard sizes and are supplied with regulators and fittings for all the international standards.
15	Level of use (if relevant)	Health post; health centre; district/general hospital; regional hospital, secondary care; specialized hospital, tertiary care; emergency vehicles; home care.
16	Clinical department/ ward (if relevant)	All sites where oxygen and/or medical air supply through cylinders are provided, including, but not limited to, intensive care units, inpatient ward, emergency, operating theatre, recovery room, observation, etc., and also emergency vehicles and home care.
17	Overview of functional requirements	Oxygen and medical air cylinders are refillable containers for such gas, in a compressed form, available in international standard capacity/pressure and dimensions. The cylinders can be made of steel, aluminium/alloy, carbon fibre or other composite material. Nominal pressure should be 13 700 kPa (137 bar, 1987 psi) for standard cylinders and 23 000 or 30 000 kPa (230 or 300 bar, 3336 or 4351 psi) for cylinders fitted with integral valves. Each cylinder is fitted and supplied with a valve. Multiple options for pressure regulators, various fitting and outlets, and integral valves should be available separately. Specific ISO, ANSI and other international colour coding for oxygen and medical air should be available. Accessories like holders, racks and trolleys should be available separately.

TECHNICAL CHARACTERISTICS		
18.1	Detailed requirements	**Oxygen cylinders:** Refillable cylinders for compressed oxygen (oil-free and compliant to ISO standards) or air (compliant to ISO standards) for medical use. Fitted with a primary valve, standard (pin index or bullnose) or integral, refillable. Nominal pressure 13 700 kPa (137 bar, 1987 psi), for standard valve cylinders, or 23 000–30 000 kPa (230–300 bar, 3336–4351 psi) depending on the cylinder model, for integral valve cylinders. CGA approved seamless steel/aluminum alloy/composite body, colour coding according to ISO/ANSI/CGA/NFPA, sizes ISO/US standard. Cylinders supplied with optional pressure regulators, multiple fitting according to all the international standards. Safety over-pressure release valve (if not built-in in the integral valve fitted cylinders). **Primary valve and pressure regulator assemblies:** Pin index or bullnose primary valve and compatible pressure regulators, providing pressure-regulated supply of oxygen (oil-free and compliant to ISO standards) or medical air (compliant to ISO standards). Steel/plated brass/aluminium casing, brass valve. Pin index and bullnose primary valve versions, handle/key operated, supplied with tools. Nominal inlet pressure 13 700 kPa (137 bar, 1987 psi), maximum 20 000 kPa (200 bar, 2901 psi). Outlet pressure 345 kPa (3.5 bar, 50 psi). Integrated manometer, 0–20 000 kPa (0–200 bar, 0–2901 psi). Safety over-pressure release valve. Pressure regulator supplied with flowmeter, if required – see configurations/options for specifications. **Integral valves:** All-in-one cylinder valve for oxygen (oil-free and compliant to ISO standards) or medical air (compliant to ISO standards), providing direct attachment to the cylinder, pressure regulation and supply of medical gas with adjustable flow rate. Steel/plated brass/aluminium casing, brass valve. 6 mm barbed and BS 5682 Schrader (if applicable depending on the size of the cylinder) outlets. Integrated open/close valve, outlet nominal pressure 400 kPa (4 bar, 58 psi). Inlet pressure 23 000–30 000 kPa (230–300 bar, 3336–4351 psi), depending on the cylinder model. Integrated refill valve ISO 5145/CGA 540 compliant. Integrated manometer, covering the full nominal pressure range of the cylinder (standard 23 000–30 000 kPa (230–300 bar, 3336–4351 psi), for integral valve cylinders, or whatever applicable). Integrated flowmeter. Safety over-pressure release valve.
18.2	Configurations/ options	**Oxygen cylinder configurations/versions/options:** Standard and MRI-compatible versions. Specific ISO/ANSI/CGA/NFPA colour coding for oxygen and medical air. Seamless cylinders made of steel, aluminium/alloy, carbon fibre or other composite material (CGA approved and compliant to ISO applicable standards). Pin index/bullnose and integral valve options. OXYGEN and MEDICAL AIR cylinders with STANDARD VALVE available in all the ISO international standard sizes, including size AZ, C, D, E, F, G, H, J, and also US sizes M2 to M 265 (not all sizes apply to both oxygen and medical air). The type of standard valve has to be compliant to international ISO and US standards, i.e. pin index ISO 407/BS 850/CGA 870 valve, CGA 540 valve, 5/8 inch BSP (F) Bullnose BS 341 valve, also according to the size/pressure of the cylinder and to any applicable regulation. OXYGEN cylinders should be available also with INTEGRAL VALVE (with manometer and flow regulator, 400 kPa (4 bar) nominal outlet pressure, 6 mm barbed and BS 5682 Schrader outlets), in all the ISO international standard sizes, including size ZA, CD, ZD, HX and ZX, and also US sizes in M coding system. **Regulator/integral valve configurations/versions:** Standard and MRI-compatible versions. Oxygen and medical air versions. Pressure regulators and integral valves should be available with DISS and 6 mm barbed outlet. Pressure regulators should be available in basic open/close model and fitted with integrated flowmeter, Thorpe tube or Bourdon gauge. *Pressure regulators and integral valves with dial style flowmeter should be available at least in the following flow ranges, for oxygen and medical air:* - Low flow 0–3 or 4 L/min (only for oxygen), discrete (dial) flow setting (indicative steps 0, 0.03, 0.06, 0.12, 0.25, 0.50, 0.75, 1.0, 1.5, 2.0, 3.0, 4.0), accuracy 10%. - Standard flow 0–15 L/min, discrete (dial) flow setting (indicative steps 0, 0.25, 0.5, 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 8.0, 10.0, 12.0, 15.0), accuracy 10%. - High flow 0–25 L/min minimum, discrete (dial) flow setting (indicative steps 0, 0.25, 0.50, 1.0, 2.0, 3.0, 4.0, 6.0, 8.0, 10.0, 15.0, 25.0), accuracy 10%. *Pressure regulators and integral valves with Thorpe or Bourdon flowmeter should be available at least in the following flow ranges, for oxygen and medical air:* - Low flow 0–3 or 4 L/min (only for oxygen), accuracy 10%, indicative graduation (L/min) 0.03, 0.06, 0.12, 0.25, 0.5, 0.75, 1.0, 1.5, 2.0, 3.0, 4.0. - Standard flow 0–7 or 8 and 0–15 or 16 L/min, accuracy 10%, graduation 0.5 L/min (0.5–3 range) and 1 L/min (3–max range). - High flow 0–25 L/min minimum, accuracy 10%, graduation 0.5 L/min first increment and 1 L/min full range.

19	Displayed parameters	Pressure and flow (for integral valve cylinders only).
20	User adjustable settings	Open/close control, pressure and flow (for integral valve cylinders only).
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components (if relevant)	Cylinder body, primary valve and pressure regulator or integral valve assembly, outlet connectors, safety pressure release valve, valve/regulator knob, manometer and flowmeter (for integral valve).
22	Mobility, portability (if relevant)	Portable or stationary (depending on the size of the cylinder).
23	Raw materials (if relevant)	Brass valve assemblies. Cylinders made of steel, aluminum/alloy, carbon fibre or compound material. Bronze/brass/ synthetic sealings. All materials in contact with air certified for medical use.
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	Availability of refill and maintenance service to be checked locally.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	Cylinder holding, carts, trolleys. Supplied with keys and tools to operate valves and regulators. Complete set of tubing and adapters to use the pressure regulator and the integral valve with all common international standard fittings, for medical gas sources, patient circuits and other medical devices.
26	Sterilization/ disinfection process for accessories (if relevant)	N/A
27	Consumables/ reagents (if relevant)	N/A
28	Spare parts (if relevant)	Common and frequently used spare parts, sensors/transducers/actuators, reusable probes/cables/patient connection accessories, periodic maintenance and calibration kits/materials, renewables that should be procured together with the equipment and in quantity sufficient for 2 years recommended (1 year at least) of typical use. These items should be supplied to each department where the equipment is installed and also to central and local maintenance department. Sealing set, maintenance kit, regulating unit (knob), adapters and connectors, keys and tools to operate the valves. Items in the above-mentioned categories that are not frequently needed or require specialized skills to be used/replaced. The need and the quantity of these items should be assessed by technical staff before procuring the main medical devices, and procured together. It is recommended to store and use them in central and local maintenance department. Primary valve assembly, regulator valve assembly, pressure safety valve, inlet/outlet connectors, full set of sealings, integral valve assembly, manometer and flowmeter (for integral valves).
29	Other components (if relevant)	N/A
PACKAGING		
30	Sterility status on delivery (if relevant)	Not sterile, suitable for storage and supply of medical grade oxygen and air. Supplied with certificate of cleanliness.
31	Shelf life (if relevant)	N/A
32	Transportation and storage (if relevant)	Applicable regulations on transport and storage of cylinders may vary if the cylinders are empty or partially/fully filled. Compliant with regulations on hazardous goods, flammable, explosive, compressed gas, according with GHS and international standards is mandatory. Sealed container. Capable of being transported and stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non condensing. Specific requirements for altitude may be required, depending on the installation site.

33	Labelling (if relevant)	Hazardous goods, flammable, explosive, compressed gas labelling according with GHS and international standards and regulations. Primary packaging: Unit of use: one (1) cylinder or valve/regulator in a box or case with manufacturer's instruction for use, spare parts and accessories (when applicable). Cylinder type and content in litres, tare weight (weight when empty), maximum cylinder pressure, cylinder size code. Labelling on the primary packaging: Name and/or trademark of the manufacturer; manufacturer's product reference; type of product and main characteristics; lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (if applicable); information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol); information for handling, if applicable (or equivalent harmonized symbol). Over packaging: Packaging unit. Labelling on the packaging unit: Labelling to be the same as primary packaging. Extra information required: number of units.
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Capable of being stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non condensing. Suitable for continuous operation in ambient temperature of at least 5–45 °C, relative humidity of at least 15–90% non condensing. Specific requirements for altitude may be required, depending on the installation site. Applicable regulations on transport and storage of cylinders may vary if the cylinders are empty or partially/fully filled. Compliance with regulations on hazardous goods, flammable, explosive, compressed gas, according with GHS and international standards is mandatory.
TRAINING, INSTALLATION AND UTILIZATION		
35	Pre-installation requirements (if relevant)	Verify medical air and oxygen fittings on the medical devices/equipment to be connected with the cylinders.
36	Requirements for commissioning (if relevant)	Local clinical and technical staff to affirm completion of installation. Supplier's or other third party technical support may be required for installation where local technical staff support was not suitable or in case of installation of bulk or central storage and supply systems based on cylinders.
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided upon request. Training of technical staff in advanced maintenance tasks shall be provided uopn request.
38	User care (if relevant)	Common user care tasks, other device-specific procedures may apply, according to the use and the manufacturer's instructions. Pre-use checks. Proper connection. Cleaning with compatible products, without oil and grease. Common maintenance tasks, other device-specific procedures may apply, according to the use and the manufacturer's instructions. Periodic functionality checks, calibration.
WARRANTY AND MAINTENANCE		
39	Warranty	5 years recommended for the cylinders, 3 years recommended for the pressure regulators and valves (2 years at least).
40	Maintenance tasks	Planned maintenance, with appropriate maintenance kit and materials, and regular cleaning and functionality checks, performed by a certified provider of service for compressed medical gases, or local technician if properly trained, certified and equipped. Valves and regulators may require periodic recalibration.
41	Type of service contract	Recommended for periodic maintenance and refill or for leasing.
42	Spare parts availability post-warranty	8 years at least, starting from the installation.
43	Software/hardware upgrade availability	N/A
DOCUMENTATION		
44	Documentation requirements	User and maintenance manuals, hard and soft copies, to be supplied in local language, or agreed other language if local not available. English version must also be available. Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration and routine maintenance. List to be provided of common spares and accessories, with part numbers. Contact details of manufacturer, supplier and local service agent to be provided.

DECOMMISSIONING		
45	Estimated life span	20–25 years for the cylinders, 10 years for the valves, 7 years for the flowmeters.
SAFETY AND STANDARDS		
46	Risk classification	Class A (GHTF), Class I (USA), Class IIa (Europe), Class IIb (Australia), Class II (Canada, Japan).
47	Regulatory approval/ certification	Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).
48	International standards	**Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is recommended, proof of compliance must be provided):** ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes. ISO 14971 Medical devices – Application of risk management to medical devices. ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. **Standards applicable to the product (where applicable, compliance to the last available version is recommended, proof of compliance must be provided):** Colour coding ISO or ANSI for medical gases. Conforms to ISO, NFPA and/or CGA standards, and/or UL or CSA approved. ISO 11114 Gas cylinders – Compatibility of cylinder and valve materials with gas contents. ISO 10524 Pressure regulators for use with medical gases. ISO 15002 Flow-metering devices for connection to terminal units of medical gas pipeline systems. ISO 15245 Gas cylinders – Parallel threads for connection of valves to gas cylinders. ISO 10297 Gas cylinders – Cylinder valves – Specification and type testing. ISO 17871 Gas cylinders – Quick-release cylinder valves – Specification and type testing. ISO 17879 Gas cylinders – Self-closing cylinder valves – Specification and type testing. ISO 407 Small medical gas cylinders – Pin-index yoke-type valve connections. ISO 5145 Cylinder valve outlets for gases and gas mixtures – Selection and dimensioning. ISO 11117 Gas cylinders – Valve protection caps and valve guards – Design, construction and tests. ISO 11363 Gas cylinders – 17E and 25E taper threads for connection of valves to gas cylinders. ISO 12209 Gas cylinders – Outlet connections for gas cylinder valves for compressed breathable air. ISO 14246 Gas cylinders – Cylinder valves – Manufacturing tests and examinations. ISO 22435 Gas cylinders – Cylinder valves with integrated pressure regulators. ISO 7866 Gas cylinders – Refillable seamless aluminium alloy gas cylinders – Design, construction and testing. ISO 20701 Gas cylinders – Refillable welded aluminium-alloy cylinders – Design, construction and testing. ISO 9809 Gas cylinders – Refillable seamless steel gas cylinders – Design, construction and testing. ISO 11119 Gas cylinders – Refillable composite gas cylinders and tubes – Design, construction and testing. ISO 13341 Gas cylinders – Fitting of valves to gas cylinders. ISO 32 Gas cylinders for medical use – Marking for identification of content. ISO 7225 Gas cylinders – Precautionary labels. ISO 10461 Gas cylinders – Seamless aluminium-alloy gas cylinders – Periodic inspection and testing. ISO 11623 Gas cylinders – Composite construction – Periodic inspection and testing. ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. ISO 15996 Gas cylinders – Residual pressure valves – Specification and type testing of cylinder valves incorporating residual pressure devices. ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen.
49	Regional/local standards	Country-specific and regional colour gas coding and other standards apply and must be listed.
50	Regulations	Country-specific and regional regulations apply and must be listed. Compliance to (where applicable, but not limited to, and last available version): **US regulations:** 21 CFR part 820. 21CFR 201.328 Labeling of medical gas containers. **EU regulations:** Regulation (EU) 2017/745. **Japan regulations:** MHLW Ordinance No. 169. 12855000 Oxygen administration kit.

Table A1.2: Technical specifications for oxygen concentrators

MEDICAL DEVICE SPECIFICATION (These technical specifications are generic and have been developed according to the latest available commercial products. They should be adapted to the setting where the product will be used (voltage, language, accessories, connectors etc.)		
i	Version number	3
ii	Date of initial version	2012
iii	Date of last modification	September 2015
iv	Date of publication	September 2019
v	Completed/ submitted by	UNICEF, WHO
NAME, CATEGORY AND CODING		
1	WHO category/code	
2	Generic name	Oxygen concentrator.
3	Specific type or variation (optional)	Stationary oxygen concentrator.
4	GMDN name	Stationary oxygen concentrator.
5	GMDN code	12873
6	GMDN category	
7	UMDNS name	02 Anaesthetic and respiratory devices, 04 Electro mechanical medical devices, 11 Assistive products for persons with disability.
8	UMDNS code	Oxygen concentrators.
9	UNSPS code (optional)	
10	Alternative name/s (optional)	12873
11	Alternative code/s (optional)	Concentrator, oxygen concentrator, oxygen enricher, stationary concentrator, bedside concentrator.
12	Keywords (optional)	Hypoxaemia, oxygen therapy.
13	GMDN/UMDNS definition (optional)	A stationary mains electricity (AC-powered) device designed to concentrate oxygen from ambient air and deliver the concentrated oxygen, typically through an attached nasal cannula (or prongs), to a patient requiring oxygen therapy. It processes the air through an internal filtration system (e.g. a molecular sieve [zeolite granules or membranes]), which has a large total surface area to separate N_2 from the air. It typically consists of an air compressor, filters, dual chambers, a reservoir and controls. The oxygen concentration is variable depending on the flow rate utilized. It is typically wheeled, but is designed to be placed in one location (e.g. an institution or a home setting).
PURPOSE OF USE		
14	Clinical or other purpose	Delivery of low-flow, continuous, clean and concentrated oxygen (> 82%) from room air (21%). With appropriate accessories, two or more hypoxaemic patients can be treated with one concentrator.
15	Level of use (if relevant)	Health centre, general hospital, district hospital, provincial hospital, regional hospital, specialized hospital.
16	Clinical department/ ward(if relevant)	Paediatric ward, surgical operating theatre.
17	Overview of functional requirements	1. Provides a continuous flow of concentrated oxygen (> 82%) from room air through one or more oxygen outlets; commonly between 5 and 10 L/min in total. 2. Contains oxygen monitor to verify concentration. 3. Delivers oxygen through a nasal prongs or nasal catheter. 4. Flow from one concentrator can be divided for at least two paediatric patients with (built-in or add-on) flowmeters that allow continuous flow rate control. 5. Requires continuous AC power source to operate, such as solar power, battery or mains electricity ± backup (e.g. generator, UPS or battery). (Maximum flow is chosen based on the expected patient load at any given time. Oxygen needs vary per by patient and application. In general, up to 2 L/min per patient under 5 years of age is needed.)

TECHNICAL CHARACTERISTICS		
18.1	Detailed requirements	One or two oxygen outlets, each to be provided with separate controllable flowmeter. Audible and/or visual alarms for low oxygen concentration (< 82%), low battery and power supply failure. Audible and/or visual alarms for high temperature, low/high/no-flow rate and/or low/high pressure. Power efficiency ≤ 70 W/L/min. User interface to be easy to operate; numbers and displays to be clearly visible. Digital or analogue meter that displays cumulative hours of device operation. Oxygen outlet(s) with 6 mm (1/4 inch) barbed fitting and DISS connector, or equivalent. Flowmeter minimum flow rate of 0.5 L/min or less. This may be achieved by a combination of concentrator and separately supplied flowmeter stand. Flowmeter continuously adjustable, with minimum markings at 0.5 L/min intervals (or lower for paediatrics). Noise level < 60 dB(A).
18.2	Configurations/ options	
19	Displayed parameters	Oxygen flow rate (on flowmeter). Cumulative hours of operation.
20	User adjustable settings	Oxygen flow rate.
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components (if relevant)	Case to be hard, cleanable with standard hospital cleaning materials. Oxygen outlet to be securely mounted and sheltered to reduce risk of being broken or bent.
22	Mobility, portability (if relevant)	Whole unit to be movable with wheels on at least two feet. Unit weight to be < 27 kg.
23	Raw materials (if relevant)	Water, detergent and/or mild cleaning solution to clean device exterior and gross particle filter (if applicable).
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	Electrical source requirements to be locally compatible (voltage and plug type need to be specified). Capacity for safe operation on at least ± 10% of local rated voltage. Mains power cable to have length ≥ 2.5 m. Electrical protection by resettable circuit breakers or replaceable fuses, fitted in both neutral and live lines.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	The unit shall include internally and externally mounted filters for cleaning the air intake. All user-removable filters shall be cleanable. Cleaning instructions for filters shall be included in the instructions for use. For two or more simultaneous paediatric patients: 1 x flowmeter stand with minimum range from 0 to 2 L/min. Kink-resistant oxygen tubing with standard connectors (15 m each). 2 x adult cannula with 2 m kink-resistant oxygen tubing with standard connectors. 4 x infant cannula with 2 m kink-resistant oxygen tubing with standard connectors. 4 x neonatal cannula with 2 m kink-resistant oxygen tubing with standard connectors.
26	Sterilization/ disinfection process for accessories (if relevant)	Disinfection for nasal prongs.
27	Consumables/ reagents (if relevant)	5-year supply recommended. 1-year supply (adjust quantities per patient load and usage frequency): nasal prongs or nasal catheters (each size for adult, child, infant); child nasal prongs: distal diameter: 1–2 mm; child/infant catheters: 6 or 8 French gauge.
28	Spare parts (if relevant)	Internal and external filters and spare parts for user fitting (as described in user manual), including: parts supply, including all necessary filters, for 2 years' operation at 15 hours per day. 1 x spare battery set for alarm system (if applicable). 1 x spare mains power cable, length ≥ 2.5 m. 2 x replacement sets of spare fuses (if non-resettable fuses are used). DISS to 6 mm barbed adaptor for each outlet (if relevant). Bidder must give a complete list of the specific spare parts included in their bid. Other spares that may be needed: circuit breaker, printed circuit board, sieve beds, compressor service kit, valves, wheels, motor capacitor, flowmeters and fan. (Spare parts are not interchangeable between devices of different brands and models, and can vary in their design and lifetime. Medical units to select spare parts ensuring compatibility with the brand and model of the equipment.)
29	Other components (if relevant)	N/A

PACKAGING		
30	Sterility status on delivery (if relevant)	N/A
31	Shelf life (if relevant)	N/A
32	Transportation and storage (if relevant)	Keep away from oil, grease and petroleum-based or flammable products as well as smoking or open flames.
33	Labelling (if relevant)	Electrical power input requirements (voltage, frequency and socket type).
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Capable of being stored continuously in ambient temperature from 0–40 °C, relative humidity of at least 15–95% and elevation from 0 to at least 2000 m. Capable of supplying the specified oxygen concentration continuously in ambient temperature from 10–40 °C, relative humidity of at least 15–95%, preferably simultaneously, and elevation from 0 to at least 2000 m. For operation at elevations higher than 2000 m, environmental requirements are less stringent; performance characteristics at such altitudes must be stated.
TRAINING, INSTALLATION AND UTILIZATION		
35	Pre-installation requirements (if relevant)	Verify plug electrical requirements with socket to be used. Clinical and staff training on device use. System for procuring spare parts.
36	Requirements for commissioning (if relevant)	Note and report any signs of external or internal damage upon device delivery. Record the number of hours on the hour meter. Verify oxygen concentration level is within specifications when device is operated with all tubing and flowmeters installed. Verify operation of oxygen concentration, battery and power failure alarms. Spare parts for 1 year or 5000 hours (5 years or 15 000 hours ideally) of use are arranged.
37	Training of user/s (if relevant)	Clinical staff training in oxygen therapy guidelines, device use and multiple-patient use. Technical staff training in device operation, safety and maintenance provided by manufacturer, supplier or experienced users. Advanced maintenance tasks required shall be documented.
38	User care (if relevant)	Device exterior to be wiped effectively with a mild solution of detergent or cleaning agent (weekly), without connection to mains power. Gross particle filter to be cleaned effectively when removed and washed with soap and water (weekly). Do not clean with alcohol. (User care needed more often in very dusty environments.)
WARRANTY AND MAINTENANCE		
39	Warranty	2 years or more (5 years ideally) to cover life span of equipment. Manufacturer/supplier ideally responsible for all costs for repairs and replacement covered under the warranty. Extended warranty options specified by manufacturer.
40	Maintenance tasks	Test power failure alarms. Measure operating pressure with pressure test gauge. Measure oxygen concentration with a calibrated oxygen analyser. Repair internal components as needed. Maintain spare-parts inventory.
41	Type of service contract	Service contract is recommended and includes technical support, spare parts, maintenance and repairs. Pricing for service contracts should be negotiated before the system is purchased.
42	Spare parts availability post-warranty	Less than 4 weeks after warranty end. 5 years of spare parts should be organized at the time of purchase and replaced when used.
43	Software/hardware upgrade availability	N/A
DOCUMENTATION		
44	Documentation requirements	1 x set user and maintenance manuals, hard and soft copies, in local language, or in agreed other language if local is not available. English version must also be available. 1 x certificate of calibration and inspection. 1 x list of equipment and procedures required for local cleaning, disinfection, troubleshooting, calibration and routine maintenance. 1 x list of all spares and accessories, with part numbers and contact details for parts supply. 1 x document with contact details of manufacturer, supplier and local service agent. List of all spare or replacement parts, their lifetime and costs for 5 years of operation.

DECOMMISSIONING		
45	Estimated life span	7 years; this can vary between brands.
SAFETY AND STANDARDS		
46	Risk classification	Class C (GHTF Rule 11); FDA Class II (USA); Class IIA (EU and Australia); Class II (Canada).
47	Regulatory approval/ certification	Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).
48	International standards	**Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is recommended, proof of compliance must be provided):** ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes. ISO 14971 Medical devices – Application of risk management to medical devices. **Standards applicable to the product (where applicable, compliance to the last available version is recommended, proof of compliance must be provided):** ISO 80601-2-69: 2014 Medical electrical equipment – Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment. IEC 60601-1: 2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-2: 2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests. IEC 60601-1-6: 2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability. IEC 60601-1-8: 2012 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. IEC 60601-1-9: 2013 Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design. IEC 60601-1-11: 2010 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home health-care environment. Compliance with ISO 8359 may be considered.
49	Regional/local standards	Country-specific and regional standards apply and must be listed.
50	Regulations	Country-specific and regional regulations apply and must be listed. Compliance to (where applicable, but not limited to, and last available version): **US regulations:** 21 CFR part 820 Quality System Regulation. 21 CFR section 868.5440 Portable oxygen generator. **EU regulations:** Regulation (EU) 2017/745. **Japan regulations:** MHLW Ordinance No. 169.

Table A1.3: Technical specifications for Thorpe tube flowmeters

MEDICAL DEVICE SPECIFICATION (These technical specifications are generic and have been developed according to the latest available commercial products. They should be adapted to the setting where the product will be used (voltage, language, accessories, connectors etc.)		
i	Version number	1
ii	Date of initial version	
iii	Date of last modification	
iv	Date of publication	September 2019
v	Completed/ submitted by	UNICEF, WHO
NAME, CATEGORY AND CODING		
1	WHO category/code	
2	Generic name	Medical gas flowmeter.
3	Specific type or variation (optional)	Thorpe tube, pressure-compensated.
4	GMDN name	Medical gas flowmeter, Thorpe tube.
5	GMDN code	61365
6	GMDN category	
7	UMDNS name	Flowmeters, Gas, Respiratory, Oxygen; Flowmeters, Gas, Respiratory, Medical air.
8	UMDNS code	24782 (Oxygen), 25074 (Medical air).
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Oxygen flowmeter, Medical air flowmeter.
11	Alternative code/s (optional)	N/A
12	Keywords (optional)	Flow meter, flowmeter, Thorpe, oxygen, medical air, regulator, repiratory care.
13	GMDN/UMDNS definition (optional)	GMDN A device intended to measure and regulate the flow of a medical gas [e.g. oxygen (O_2), carbon dioxide (CO_2), nitrous oxide (N_2O), helium/oxygen gas mixture (heliox), medical air] during various procedures (e.g. therapeutic administration, anaesthesia, insufflation during surgery). It consists of an upright tube containing a float, which rises and falls in relation to gas flow, and a distal valve (compensated flowmeter) to control gas flow rate. It will be calibrated to a specific medical gas and have a dedicated flow rate range, therefore some types may be dedicated to a specific patient group (e.g. neonate, infant, adult) or clinical use. UMDNS 24782, Flowmeters, Gas, Respiratory, Oxygen Respiratory flowmeters designed to measure the flow rate and amount of oxygen delivered to a patient from a medical gas system or oxygen cylinder via appropriate devices. Oxygen breathing flowmeters are typically mechanical or electromechanical instruments that are placed in the low-pressure section of the oxygen supply, usually after a pressure regulator in high-pressure oxygen supplies (e.g. high-pressure oxygen cylinders). Oxygen respiration flowmeters are intended for use with a variety of oxygen-delivery systems, including those that use nasal cannulae or face masks on the patient. Some flowmeters may include a control valve as an attachment that regulates the flow of oxygen (typically to provide a pre-established constant flow). 25074, Flowmeters, Gas, Respiratory, Medical air Respiratory flowmeters designed to measure the flow rate and volume of medical air delivered to a patient from a medical gas system or other appropriate supply source via appropriate devices. Medical air flowmeters are typically mechanical or electromechanical instruments that are placed in the low-pressure section of the medical air supply.

PURPOSE OF USE		
14	Clinical or other purpose	Flowmeters are devices designed to measure and regulate the flow of a medical gas. They connect the low-pressure medical gas source (up to 345–380 kPa, 3.5–3.8 bar, 50–55 psi), such as central system, cylinders valves, concentrators or another medical device, to a patient circuit or a medical device that uses or delivers the gas. The purpose of the flowmeters included in this description is to regulate and measure the flow of oxygen or medical air. Dedicated flowmeters, calibrated to specific gas and flow ranges, pressure-compensated, are covered.
15	Level of use (if relevant)	Health post; health centre; district/general hospital; regional hospital, secondary care; specialized hospital, tertiary care; emergency vehicles; home care.
16	Clinical department/ ward (if relevant)	All departments where oxygen and/or respiratory support/therapy is delivered, including, but not limited to, intensive care units, inpatient ward, emergency, operating theatre, recovery room, observation, etc., and also emergency vehicles and home care.
17	Overview of functional requirements	The Thorpe tube flowmeter is composed of inlet and outlet ports, a regulator, a valve and a clear tapared measuring tube. It regulates and measures the flow of oxygen or medical air, depending on the model, from the source to the patient or to another medical device. It is suitable for connection with various medical gas sources, such as centralized system, cylinders, concentrators or compressors. Standard (absolute, non-compensated) and pressure-compensated flowmeter versions, suitable for specific flow ranges.
TECHNICAL CHARACTERISTICS		
18.1	Detailed requirements	Thorpe tube flowmeter, to measure and regulate the flow of medical gas. Disinfectable with hospital grade detergents. Transparent, clearly readable and graduated (metric system) column, shatter resistant polymer certified for medical use. Clearly visible graduation, 270 or more degrees of visibility. Needle valve and body constructed of brass or aluminium. Calibrated at 345–380 kPa (3.4–3.8 bar, 50–55 psi) inlet gauge pressure. Inlet gauge pressure (nominal) > 380–413 kPa (3.8–4.1 bar, 55–60 psi), peak gauge inlet pressure 690 kPa (6.9 bar, 100 psi). Pressure-compensated design to give specified accuracy for whole range of input pressures. Built-in inlet filter, replaceable by user. Minimum flow rate to be zero, i.e. fully closed. Maximum flow rate when fully open to be stated. Anti-slip knob. ISO 32 colour-coded for medical gases. DISS style inlet and outlet.
18.2	Configurations/ options	**Oxygen and Medical air versions** Versions with absolute non-pressure compensated Thorpe tube (non-compensated) and with pressure-compensated column calibrated within the range (gauge) 345–380 kPa (3.4–3.8 bar, 50–55 psi). Available in international ISO and ANSI colour-coding systems for oxygen and medical air. Available in versions suitable for mounting on all the international standard fittings, like (but not limited to) 1/8 inch FNPT female, 3/8 inch BSP female, UNI EN 737, DIN, DISS, AFNOR, Ohmeda, Chemtron, Puritan Bennet, Schrader, etc. Mounting to be on panel, equipment or pressure regulator, as specified by purchaser. Availability of various outlet adapters (tubing nipples/Christmas trees), with ISO, ANSI and generic colour-coding and suitable for all international standard outlet fittings, including (but not limited to) threaded, non-threaded, 6 mm barbed and 9/16 inch UNF female thread for oxygen and medical air. **Oxygen models availability (minimum requirements for accuracy, graduation and flood flow):** 0–200 mL/min, accuracy 10%, single taper, graduations 25 mL/min in the range 25–200 mL/min, 0.5–1 L/min flood flow. 0–1000 mL/min, accuracy 10%, single taper, 0.1 L/min graduation in the range 0.1–1000 mL/min, 2.5–5 L/min flood flow. 0–3 or 3.5 L/min, accuracy 10%, dual taper graduations 0.25 L/min (0–1 L/min range) and 0.5 L/min (1 L/min – maximum range), or single taper graduations 0.25 L/min full range, 8–10 L/min flood flow. 0–7 or 8 L/min, accuracy 10%, dual taper graduations 0.5 L/min (0–5 L/min range) and 1 L/min (5 L/min – maximum range), 25 L/min flood flow. 0–16 L/min, accuracy 10%, dual taper graduations 0.5 L/min (0–5 L/min range) and 1 L/min (5 L/min – maximum range), 70 L/min flood flow. 0–70 L/min, accuracy 10%, single taper graduations 5 L/min full range, 85 L/min flood flow. **Medical air models availability (minimum requirements for accuracy, graduation and flood flow):** 0–3 or 3.5 L/min, accuracy 10%, dual taper graduations 0.25 L/min (0–1 L/min range) and 0.5 L/min (1 L/min – maximum range) or single taper graduations 0.25 L/min full range, 8–10 L/min flood flow. 0–7 or 8 L/min, accuracy 10%, dual taper graduations 0.5 L/min (0–5 L/min range) and 1 L/min (5 L/min – maximum range), 25 L/min flood flow. 0–16 L/min, accuracy 10%, dual taper graduations 0.5 L/min (0–5 L/min range) and 1 L/min (5 L/min – maximum range), 70 L/min flood flow. 0–70 L/min, accuracy 10%, single taper graduations 5 L/min full range, 85 L/min flood flow. Versions with central, bottom or top ball reading (shall be specified in product brochure and instructions for use).
19	Displayed parameters	Measured flow rate.
20	User adjustable settings	Flow rate.

PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components (if relevant)	Reusable components suitable for disinfection including (but not limited to): sealing set, flowmeter body, Thorpe (measuring) tube, valve and regulating knob, inlet and outlet connectors (different types) and tubing, pressure safety valve, bacteria filter, float ball, etc.
22	Mobility, portability (if relevant)	Portable.
23	Raw materials (if relevant)	Brass/steel/aluminium/polymers/hard plastic body and valve, certified for medical use. Polypropylene, polycarbonate, acrylic or transparent equivalent biocompatible plastic/polymer certified for medical use, unbreakable or shatter resistant, for the column.
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	Oxygen, Medical air (up to 345–380 kPa, 3.5–3.8 bar, 50–55 psi).
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	T-bar double fitting, complete set of adapters to use the flowmeter (inlet and outlet) with all common international standard fittings, for medical gas sources, patient circuits and other medical devices.
26	Sterilization/ disinfection process for accessories (if relevant)	Suitable for cleaning and disinfection.
27	Consumables/ reagents (if relevant)	N/A
28	Spare parts (if relevant)	Sealing set, regulating unit (knob), inlet filter, adapters and connectors. Needle valve, pressure safety valve, Thorpe column and float ball, flowmeter body.
29	Other components (if relevant)	N/A
PACKAGING		
30	Sterility status on delivery (if relevant)	Not sterile.
31	Shelf life (if relevant)	N/A
32	Transportation and storage (if relevant)	Sealed container. Capable of being transported and stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non condensing. Specific requirements for altitude may be required, depending on the installation site.
33	Labelling (if relevant)	Primary packaging: Unit of use: one (1) Thorpe tube flowmeter in a box or case or bag with manufacturer's instruction for use, spare parts and accessories (when applicable). Gas type, calibration temperature and pressure should be specified on the label. Labelling on the primary packaging: Name and/or trademark of the manufacturer; manufacturer's product reference; type of product and main characteristics; lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (if applicable); information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol); information for handling, if applicable (or equivalent harmonized symbol). Over packaging: Packaging unit. Labelling on the packaging unit: Labelling to be the same as primary packaging. Extra information required: number of units.
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Capable of being stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non condensing. Suitable for continuous operation in ambient temperature of at least 5–45 °C, relative humidity of at least 15–90% non condensing. Specific requirements for altitude may be required, depending on the installation site.
TRAINING, INSTALLATION AND UTILIZATION		
35	Pre-installation requirements (if relevant)	Verify fittings on medical air and oxygen sources (concentrator, cylinders, wall outlet/central supply, etc.) and on the medical devices/equipment working with the flowmeter.
36	Requirements for commissioning (if relevant)	Local clinical and technical staff to affirm completion of installation, proper operation, free from leaks. May require periodic recalibration.

37	Training (if relevant)	Training of users in operation and basic maintenance is not mandatory, but can be recommended, depending on the case, and shall be provided upon request. Training of technical staff in advanced maintenance tasks is not mandatory, but can be recommended, depending on the case, and shall be provided uopn request.
38	User and technical care (if relevant)	Pre-use checks. Proper connection. Cleaning with compatible products. Periodic functionality checks.
WARRANTY AND MAINTENANCE		
39	Warranty	5 years recommended (2 years at least), the product shall be in production and fully supported when procured.
40	Maintenance tasks	Regular cleaning and functionality checks, calibration.
41	Type of service contract	Not required.
42	Spare parts availability post-warranty	8 years at least, starting from the installation.
43	Software/hardware upgrade availability	N/A
DOCUMENTATION		
44	Documentation requirements	User and maintenance manuals, hard and soft copies, to be supplied in local language, or agreed other language if local not available. English version must also be available. Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration and routine maintenance. List to be provided of common spares and accessories, with part numbers. Contact details of manufacturer, supplier and local service agent to be provided.
DECOMMISSIONING		
45	Estimated life span	7 years.
SAFETY AND STANDARDS		
46	Risk classification	Class A (GHTF), Class I (USA), Class IIa (Europe, Australia), Class II (Canada, Japan).
47	Regulatory approval/ certification	Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).
48	International standards	**Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is recommended, proof of compliance must be provided):** ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes. ISO 14971 Medical devices – Application of risk management to medical devices. **Standards applicable to the product (where applicable, compliance to the last available version is recommended, proof of compliance must be provided):** Colour coding ISO or ANSI for medical gases. Conforms to ISO, NFPA, and/or CGA standards, and/or UL or CSA approved. ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen. ISO 15002 Flow-metering devices for connection to terminal units of medical gas pipeline systems. ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications. ISO 10524 Pressure regulators for use with medical gases. ISO 18082 Anaesthetic and respiratory equipment – Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases. ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. ISO 5359 Low-pressure hose assemblies for use with medical gases. ISO 32 Colour coding for medical gases.
49	Regional/local standards	Country-specific and regional colour gas coding and other standards apply and must be listed.
50	Regulations	Country-specific and regional regulations apply and must be listed. Compliance to (where applicable, but not limited to, and last available version): **US regulations:** 21 CFR part 820. 21CFR part 868.2320 – Uncompensated thorpe tube flowmeter. 21CFR part 868.2340 – Compensated thorpe tube flowmeter. **EU regulations:** Regulation (EU) 2017/745. **Japan regulations:** MHLW Ordinance No. 169. 37132000 Flowmeter, oxygen therapy.

Table A1.4: Technical specifications for flowmeter stands

MEDICAL DEVICE SPECIFICATION (These technical specifications are generic and have been developed according to the latest available commercial products. They should be adapted to the setting where the product will be used (voltage, language, accessories, connectors etc.)		
i	Version number	1
ii	Date of initial version	
iii	Date of last modification	
iv	Date of publication	September 2019
v	Completed/ submitted by	UNICEF, WHO
NAME, CATEGORY AND CODING		
1	WHO category/code	
2	Generic name	Flowmeter stand
3	Specific type or variation (optional)	Oxygen.
4	GMDN name	Not in GMDN database, applicable collective terms: flowmeters and associated devices (by name), anaesthesia and respiratory gas supply equipment (by use).
5	GMDN code	N/A
6	GMDN category	
7	UMDNS name	Not in UMDNS database.
8	UMDNS code	N/A
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Flow splitter.
11	Alternative code/s (optional)	N/A
12	Keywords (optional)	Flowmeter stand, flow splitter, oxygen, flowmeter, concentrator, regulator, respiratory care.
13	GMDN/UMDNS definition (optional)	N/A
PURPOSE OF USE		
14	Clinical or other purpose	The oxygen flowmeter stand is a device intended to distribute medical oxygen from a source to multiple independent outlets. The flowmeter stand, depending on the design, can be connected to concentrators (typically 138 kPa (1.4 bar, 20 psig) inlet) or to any low-pressure oxygen source (345–380 kPa, 3.5–3.8 bar, 50–55 psi), including concentrators, cylinders and a centralized system, and has dedicated flowmeters, calibrated to specific flow ranges. The ability of the flowmeter stand to deliver rates indicated by the flow settings for the outlets, is limited by the flow and pressure provided by the oxygen source.
15	Level of use (if relevant)	Health post; health centre; district/general hospital; regional hospital, secondary care; specialized hospital, tertiary care.
16	Clinical department/ ward (if relevant)	All departments where oxygen and/or respiratory support/therapy is delivered, including, but not limited to, intensive care units, inpatient ward, emergency, operating theatre, recovery room, observation, etc.
17	Overview of functional requirements	The flow spliter is a tabletop or wall-mounted device composed of an inlet valve that delivers oxygen to multiple independent flowmeters, each one providing an outlet. Up to five independent Thorpe tube pressure-compensated flowmeters, that can be calibrated to multiple flow ranges, are installed in the flowmeter stand housing. It can be connected to concentrators or to any standard pressure oxygen source, like cylinders and central system, according to device version.

TECHNICAL CHARACTERISTICS		
18.1	Detailed requirements	Device suitable to deliver oxygen from the source to multiple independent outlets. Tabletop device, suitable also for wall mounting. Equipped with four or five independent, pressure-compensated, Thorpe tube flowmeters, to measure and regulate the flow of medical gas. Disinfectable with hospital grade detergents. Inlet port to be compatible with all the international standards for oxygen fittings, included DISS, threaded and non-threaded, 6 mm barbed – availability of different ports and/or adapters to be stated. 6 mm barbed outlet as standard – availability of adapters and outlet options to match all the international standards for oxygen fittings to be stated. 0–2 L/min, accuracy better than 10%, graduation 0.125 L/min or lower. Transparent, clearly readable and graduated (metric system) column, shatter resistant polymer certified for medical use. Needle valve and body constructed of brass or aluminium. Inlet pressure up to at least 138 kPa (1.4 bar, 20 psi). Adjustment knobs to have rough surface to prevent slipping. Colour-coded flowmeter preferable, e.g. to ISO 32. Internal parts (e.g. valve, inlet filter if present), replaceable by user.
18.2	Configurations/ options	
19	Displayed parameters	Measured flow rate (on each independent flowmeter).
20	User adjustable settings	Flow rate (on each independent flowmeter).
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components (if relevant)	Reusable components suitable for disinfection with hospital grade detergents including (but not limited to): sealing set, flowmeter stand and flowmeter bodies, Thorpe (measuring) tube, valve and regulating knob, inlet and outlet connectors (different types) and tubing, pressure safety valve, bacteria filter, float ball, etc.
22	Mobility, portability (if relevant)	Portable.
23	Raw materials (if relevant)	Flowmeter stand hard plastic or metal epoxy painted, suitable for cleaning and disinfection with hospital grade cleaning products. For the flowmeters: Brass/steel/aluminium/polymers/hard plastic body and valve, all materials in contact with oxygen certified for medical use. Polypropylene, polycarbonate, acrylic or transparent equivalent biocompatible plastic/polymer certified for medical use, unbreakable or shatter resistant, for the column.
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	Oxygen, envisaged for use with oxygen concentrator.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	Wall mount accessories, additional power take off, T-bar double fitting, complete set of adapters and tubing to use the flowmeter stand (inlet and outlet) with all common international standard fittings, for medical gas sources, patient circuits and other medical devices.
26	Sterilization/ disinfection process for accessories (if relevant)	Suitable for cleaning and disinfection with hospital grade cleaning products.
27	Consumables/ reagents (if relevant)	N/A
28	Spare parts (if relevant)	Sealing set, regulating unit (knob), inlet filters, adapters and connectors. Needle valve, pressure safety valve, Thorpe column and float ball, flowmeter stand and flowmeter bodies.
29	Other components (if relevant)	N/A
PACKAGING		
30	Sterility status on delivery (if relevant)	Not sterile.
31	Shelf life (if relevant)	N/A
32	Transportation and storage (if relevant)	Sealed container. Capable of being transported and stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non condensing. Specific requirements for altitude may be required, depending on the installation site.

33	Labelling (if relevant)	Primary packaging: Unit of use: one (1) flowmeter stand in a box or case or bag with manufacturer's instruction for use, spare parts and accessories (when applicable). Gas type, calibration temperature and pressure should be specified on the label. Labelling on the primary packaging: Name and/or trademark of the manufacturer; manufacturer's product reference; type of product and main characteristics; lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (if applicable); information for particular storage conditions(temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol); information for handling, if applicable (or equivalent harmonized symbol). Over packaging: Packaging unit. Labelling on the packaging unit: Labelling to be the same as primary packaging. Extra information required: number of units.
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Capable of being stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non condensing. Suitable for continuous operation in ambient temperature of at least 5–45 °C, relative humidity of at least 15–90% non condensing. Specific requirements for altitude may be required, depending on the installation site.
TRAINING, INSTALLATION AND UTILIZATION		
35	Pre-installation requirements (if relevant)	Verify fittings on oxygen sources (concentrator, wall outlet/central supply, etc.) and on the medical devices/equipment working with the flowmeter stand.
36	Requirements for commissioning (if relevant)	Local clinical and technical staff to affirm completion of installation, proper operation, free from leaks. May require periodic recalibration.
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance is required. Training of technical staff in maintenance tasks is required.
38	User care (if relevant)	Pre-use checks. Proper connection. Cleaning with compatible products. Periodic functionality checks.
WARRANTY AND MAINTENANCE		
39	Warranty	5 years recommended (2 years at least), the product shall be in production and fully supported when procured.
40	Maintenance tasks	Regular cleaning and functionality checks, calibration.
41	Type of service contract	Not required.
42	Spare parts availability post-warranty	8 years at least, starting from the installation.
43	Software/hardware upgrade availability	N/A
DOCUMENTATION		
44	Documentation requirements	User and maintenance manuals, hard and soft copies, to be supplied in local language, or agreed other language if local not available. English version must also be available. Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration and routine maintenance. List to be provided of common spares and accessories, with part numbers. Contact details of manufacturer, supplier and local service agent to be provided.
DECOMMISSIONING		
45	Estimated life span	7 years.
SAFETY AND STANDARDS		
46	Risk classification	Class A (GHTF), Class I (USA), Class IIa (Europe, Australia), Class II (Canada, Japan).
47	Regulatory approval/ certification	Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).

48	International standards	**Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is recommended, proof of compliance must be provided):** ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes. ISO 14971 Medical devices – Application of risk management to medical devices. **Standards applicable to the product (where applicable, compliance to the last available version is recommended, proof of compliance must be provided):** Colour coding ISO or ANSI for medical gases. Conforms to ISO, NFPA, and/or CGA standards, and/or UL or CSA approved. ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen. ISO 15002 Flow-metering devices for connection to terminal units of medical gas pipeline systems. ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications. ISO 10524 Pressure regulators for use with medical gases. ISO 18082 Anaesthetic and respiratory equipment – Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases. ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. ISO 5359 Low-pressure hose assemblies for use with medical gases. ISO 32 Colour coding for medical gases.
49	Regional/local standards	Country-specific and regional colour gas coding and other standards apply and must be listed.
50	Regulations	Country-specific and regional regulations apply and must be listed. Compliance to (where applicable, but not limited to, and last available version): **US regulations:** 21 CFR part 820. 21CFR part 868.2320 – Uncompensated thorpe tube flowmeter. 21 CFR part 868.2340 – Compensated thorpe tube flowmeter. **EU regulations:** Regulation (EU) 2017/745. **Japan regulations:** MHLW Ordinance No. 169. 37132000 Flowmeter, oxygen therapy.

Table A1.5: Technical specifications for reusable non-heated bubble humidifiers

MEDICAL DEVICE SPECIFICATION (These technical specifications are generic and have been developed according to the latest available commercial products. They should be adapted to the setting where the product will be used (voltage, language, accessories, connectors etc.)		
i	Version number	1
ii	Date of initial version	
iii	Date of last modification	
iv	Date of publication	September 2019
v	Completed/ submitted by	UNICEF, WHO
NAME, CATEGORY AND CODING		
1	WHO category/code	
2	Generic name	Humidifier, non-heated, reusable.
3	Specific type or variation (optional)	Non-heated, reusable.
4	GMDN name	Non-heated respiratory humidifier.
5	GMDN code	35113
6	GMDN category	
7	UMDNS name	Humidifiers, non-heated.
8	UMDNS code	12051
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Oxygen humidifier, bubble humidifier, bubbling device.
11	Alternative code/s (optional)	N/A
12	Keywords (optional)	Humidifier, non-heated, respiratory, artificial airway, bubble, oxygen.
13	GMDN/UMDNS definition (optional)	GMDN A device designed to prevent the drying of airway passages associated with the inhalation of oxygen (O_2) by adding water vapour to the dry gas as it is passed through, or more seldom, over water. It typically consists of a graduated container (reservoir) for the water, a top piece that functions as a detachable lid (typically a screw lid with a gastight seal), and a tube that protrudes into the water to divert the gas below the water level. This device, commonly known as a bubble humidifier, does not heat the water. It has connectors: 1) one (e.g. a winged nut) that connects to an oxygen therapy flowmeter; and 2) one to which the patient tubing is connected. This is a reusable device. UMDNS Humidifiers designed to add moisture to the gases flowing in the inspiratory artificial airways, thus increasing the humidity of the gas delivered into the lungs. The humidifiers are inserted in the inspiratory lines typically leading from the outlet of a critical care or anaesthesia ventilator. These humidifiers can introduce moisture either by forcing the incoming gas through the water in a heated reservoir of sterile water (bubble-through units), or by passing the incoming gas over the surface of a water reservoir (pass-over humidifier) or over a wet wick (wick humidifier, a variation of the pass-over humidifier). Artificial airway humidifiers are intended mainly for use when an artificial airway supplies air through devices such as tracheostomy or endotracheal tubes, bypassing the normal humidification process for respired gases.
PURPOSE OF USE		
14	Clinical or other purpose	The humidifier is inserted in the inspiratory line of a breathing circuit to add moisture to the breathing gases for administration to a patient. The bubbling bottle humidifier is a sealed container filled with water and connected inline into the breathing circuit. The medical gas mixture flows through the water inside the bottle and is enriched in humidity. This type of humidier does not heat the gas.
15	Level of use (if relevant)	Health centre; district/general hospital; regional hospital, secondary care; specialized hospital, tertiary care; emergency vehicles; home care.
16	Clinical department/ ward (if relevant)	All departments where oxygen and/or respiratory support/therapy is delivered, including, but not limited to, intensive care units, inpatient ward, emergency, operating theatre, recovery room, observation, etc., and also emergency vehicles and home care.

17	Overview of functional requirements	The non-heated, reusable humidifier provides humidity to the gas in the inspiratory line of the breathing circuit. It is a bubbling air/water contact system, composed of a bottle filled with water and connected inline into the breathing circuit.
TECHNICAL CHARACTERISTICS		
18.1	Detailed requirements	Non-heated, reusable humidifier for oxygen therapy and ventilation/anaesthesia inspiratory lines. Bubble-through humidification system. Graduated, transparent humidification bottle, unbreakable or shatter resistant. Graduation shall show minimum and maximum water level. Detachable metal or rigid durable polymer cap with gas connectors. Pressure relief safety valve, ≥ 14 kPa (0.1 bar, 2 psi) rating. DISS connectors for inlet. 6 mm barbed connector for outlet. Humidification chamber working volume at least 150 mL, not greater than 500 mL. Flow rate capacity up to 15 L/min. Must be capable of disinfection. Supplier must define decontamination procedure.
18.2	Configurations/ options	Humidification chamber working volume available at least 150 mL, not greater than 500 mL. Graduation options available in metric, imperial and both units.
19	Displayed parameters	Graduated water level on the bottle.
20	User adjustable settings	N/A
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components (if relevant)	Bottle, diffuser, tubing, O-ring/seals, inlet and outlet connectors, cover lid.
22	Mobility, portability (if relevant)	Portable.
23	Raw materials (if relevant)	Cap and connectors made of brass/steel/other biocompatible metal or polymer certified for medical use. Bottle and tubes made of polypropylene, polycarbonate or equivalent biocompatible plastic/polymer certified for medical use, unbreakable or shatter resistant. Pressure valve made of brass chromium plated or equivalent metal certified for medical use.
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	Oxygen/other medical gas supply (centralized, cylinders or concentrators) and related equipment to deliver medical gas (mixer/blender, anaesthesia, ventilator, etc.).
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	Adapters and swivel hose nipple connectors to mount the humidifier in oxygen therapy/respiratory support circuits and in anaesthesia/ventilation circuits. Spare O-ring/seal. Outlet connector for 6 mm barbed connection to oxygen tubing included. Additional adaptors from DISS to required connector for each gas port, as specified by purchaser.
26	Sterilization/ disinfection process for accessories (if relevant)	Must be capable of disinfection. Supplier must define decontamination procedure.
27	Consumables/ reagents (if relevant)	N/A
28	Spare parts (if relevant)	N/A
29	Other components (if relevant)	N/A
PACKAGING		
30	Sterility status on delivery (if relevant)	Sterile or certified clean and ready for use.
31	Shelf life (if relevant)	At least 3 years (recommended 5 years) for sterility of the new unpacked product.
32	Transportation and storage (if relevant)	Sealed container. Capable of being transported and stored in ambient temperature of at least 0–50 °C, relative humidity of at least 15–95% non condensing. Specific requirements for altitude may be required, depending on the installation site.

33	Labelling (if relevant)	Primary packaging: Unit of use: one (1) humidifer in an individual sterilized or certified clan and ready for use peel pack (or equivalent packaging). Labelling on the primary packaging: Name and/or trademark of the manufacturer; manufacturer's product reference; type of product and main characteristics; if the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging; the word "sterile" (or equivalent harmonized symbol); sterilization method (or equivalent harmonized symbol); lot number prefixed by the word "LOT" (or equivalent harmonized symbol); expiry date by year and month, prefixed by the word "EXP" (or equivalent harmonized symbol); the words "for single use" (or equivalent harmonized symbol); the words "check the integrity of the individual sterilized pack before use" (if space allows); the words "destroy after use" (if space allows). Secondary packaging: Protected unit: one (1) box containing multiple items in primary in their primary packaging. Labelling on the secondary packaging: Labelling to be the same as primary packaging. Extra information required: Number of units per secondary packaging. Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol). Information for handling, if applicable (or equivalent harmonized symbol). Manufacturer's instruction for use. Alternatively, the instruction for use can be indicated on a separate insert.
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Capable of being stored in ambient temperature of at least 0–50 °C, relative humidity of at least 15–95% non condensing. Suitable for continuous operation in ambient temperature of at least 5–45 °C, relative humidity of at least 15–90% non condensing. Specific requirements for altitude may be required, depending on the installation site.
TRAINING, INSTALLATION AND UTILIZATION		
35	Pre-installation requirements (if relevant)	N/A
36	Requirements for commissioning (if relevant)	Local clinical and technical staff to affirm completion of installation and proper operation.
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance is not mandatory, but can be recommended, depending on the case, and shall be provided upon request. Training of technical staff in advanced maintenance tasks is not mandatory, but can be recommended, depending on the case, and shall be provided uopn request.
38	User care (if relevant)	Pre-use checks. Proper connection. Cleaning with compatible products, disinfect after each use.
WARRANTY AND MAINTENANCE		
39	Warranty	2 years recommended (1 year at least), the product shall be in production and fully supported when procured.
40	Maintenance tasks	Regular cleaning/sterilization and functionality checks.
41	Type of service contract	Not required.
42	Spare parts availability post-warranty	8 years at least, starting from the installation.
43	Software/hardware upgrade availability	N/A
DOCUMENTATION		
44	Documentation requirements	User and maintenance manuals, hard and soft copies, to be supplied in local language, or agreed other language if local not available. English version must also be available. List to be provided of common spares and accessories, with part numbers. Contact details of manufacturer, supplier and local service agent to be provided.

DECOMMISSIONING		
45	Estimated life span	Not exceeding shelf life.
SAFETY AND STANDARDS		
46	Risk classification	Class A (GHTF), Class I (USA), Class IIa (EU, Australia), Class II (Canada, Japan).
47	Regulatory approval/ certification	Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).
48	International standards	**Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is recommended, proof of compliance must be provided):** ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes. ISO 14971 Medical devices – Application of risk management to medical devices. ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. **Standards applicable to the product (where applicable, compliance to the last available version is recommended, proof of compliance must be provided):** Conforms to ISO, NFPA and/or CGA standards, and/or UL or CSA approved. ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen. ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications. ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. ISO 18190 Anaesthetic and respiratory equipment – General requirements for airways and related equipment ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process. ISO 8185 Respiratory tract humidifiers for medical use – Particular requirements for respiratory humidification systems.
49	Regional/local standards	Country-specific and regional standards apply and must be listed.
50	Regulations	Country-specific and regional regulations apply and must be listed. Compliance to (where applicable, but not limited to, and last available version): **US regulations:** 21 CFR part 820. 21CFR 868.5450 – Respiratory gas humidifier. **EU regulations:** Regulation (EU) 2017/745. **Japan regulations:** MHLW Ordinance No. 169.

Table A1.6: Technical specifications for nasal cannulae

MEDICAL DEVICE SPECIFICATION (These technical specifications are generic and have been developed according to the latest available commercial products. They should be adapted to the setting where the product will be used (voltage, language, accessories, connectors etc.)		
i	Version number	1
ii	Date of initial version	
iii	Date of last modification	
iv	Date of publication	September 2019
v	Completed/ submitted by	UNICEF, WHO
NAME, CATEGORY AND CODING		
1	WHO category/code	
2	Generic name	Cannula, oxygen.
3	Specific type or variation (optional)	Nasal prongs.
4	GMDN name	Basic nasal oxygen cannula.
5	GMDN code	35201
6	GMDN category	
7	UMDNS name	Cannulae, nasal oxygen.
8	UMDNS code	12700
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Nasal cannula, Oxygen supply cannula.
11	Alternative code/s (optional)	N/A
12	Keywords (optional)	Oxygen cannula, nasal prongs.
13	GMDN/UMDNS definition (optional)	GMDN A non-sterile, semi-rigid tube with nasal prongs designed to be inserted into the nostrils of a patient, and held in place with a headstrap, to administer oxygen (O_2). It is commonly known as "nasal prongs". This is a single-use device. UMDNS Nasal cannulae designed for delivery of oxygen into the nasal cavities. These cannulae typically consist of a plastic tube 6 mm (1/4 inch) in diameter that includes two prongs that project about 1 cm into the nose on both sides. Oxygen-supply nasal cannulae are used for short-term oxygen administration (e.g. in the immediate postoperative period); they are also used for long-term oxygen therapy in patients with chronic oxygen-dependent respiratory failure (e.g. chronic obstructive pulmonary disease, interstitial fibrosis, diffusion defect).
PURPOSE OF USE		
14	Clinical or other purpose	Oxygen cannulae are plastic tubes shaped as two prongs delivering air/oxygen mixture into the nasal cavities and connected with an oxygen administration circuit. Cannulae can be designed for low-flow applications (0–15 L/min range in general, not meeting all the inspiratory demand, ambient air mixes with the delivered gas) or high flow (> 15 L/min typically, the patient inspires mainly the delivered gas). Cannulae provide an altrenative to masks, causing less interference with eating, drinking, speaking/vocalization.
15	Level of use (if relevant)	Health post; health centre; district/general hospital; regional hospital, secondary care; specialized hospital, tertiary care; emergency vehicles; home care.
16	Clinical department/ ward (if relevant)	All departments where oxygen and/or respiratory therapy is delivered, including, but not limited to, intensive care units, inpatient ward, emergency, operating theatre, recovery room, observation, etc., and also emergency vehicles and home care.
17	Overview of functional requirements	Nasal cannulae (nasal prongs), device designed for easy administration of oxygen into the patient nose through two small prongs placed in the nostrils, providing comfort for the patient.

TECHNICAL CHARACTERISTICS		
18.1	Detailed requirements	Cannulae and nasal prongs suitable for delivering oxygen/air mixture into the nasal cavities. Oxygen and air/oxygen mixture compatibility, as per ISO 15001. Transparent tubing with prongs included, suitable for low-pressure gas supply. Rubber or soft plastic tubing and prongs, semi-rigid and allowing freedon of movement, PVC or other material, FDA Title 21/USP VI compliant and certified for medical use, hardness > 60 Shore A (ASTM D-2240). Tubing wall thickness between 1.58 mm (1/16 in) and 2.38 mm (3/32 in). Anti-kink tubing, non-permanent deformation if kinked or bent too tight. Low resistance tubing, round shape section, designed for low-flow procedures, typically 0–15 L/min range, where the delivered gas does not meet all the inspiratory demand and entrains with ambient air. Soft twin prongs nasal tips to ensure equal oxygen flow to both outlets. Non sterile.
18.2	Configurations/ options	Multiple anti-kink options (star lumen and other designs). Available with a catalogue of connectors and adapters for all standard fittings for oxygen sources and related equipment, administration devices and patient circuits. Standard, latex free and phthalate/DEHP-free versions, available for tubes and prongs. Straight, curved and flared tip prongs. Multiple sizes for neonates, infants, children and adult (spacing, diameter, length, flow capacity). Tubing and prong components sold both separately and as ready to use circuits. Tubing in various sizes, lengths (at least, but not limited to, 0.5 m, 1.5 m and 2 m). Tubing compatibility with standard oxygen connection tubing, 3–5 mm internal diameter and 7–8 mm external diameter, and 15/22 mm diameter ventilation tubing; available with “standard” and “universal” hose end connector. Tie sliding and over-the-ear tubing adjustable options, with or without ear guards.
19	Displayed parameters	N/A
20	User adjustable settings	N/A
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components (if relevant)	Nasal prongs, headset loop, adjuster, end connectors.
22	Mobility, portability (if relevant)	Portable.
23	Raw materials (if relevant)	Rubber or soft plastic transparent tubing and prongs, semi-rigid, PVC or other material, FDA Title 21/USP VI compliant and certified for medical use, hardness > 60 Shore A (ASTM D-2240).
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	Oxygen/other medical gas supply (centralized, cylinders or concentrators) and related equipment to deliver medical gas (mixer/blender, anaesthesia, ventilator, etc.).
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	Adapters and supply tubing to connect the cannula/prongs with oxygen therapy/respiratory support circuits and in anaesthesia/ventilation circuits.
26	Sterilization/ disinfection process for accessories (if relevant)	Suitable for cleaning and disinfection.
27	Consumables/ reagents (if relevant)	N/A
28	Spare parts (if relevant)	N/A
29	Other components (if relevant)	N/A
PACKAGING		
30	Sterility status on delivery (if relevant)	Non sterile.
31	Shelf life (if relevant)	At least 3 years (recommended 5 years).
32	Transportation and storage (if relevant)	Sealed container. Capable of being transported and stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non condensing. Specific requirements for altitude may be required, depending on the installation site.

33	Labelling (if relevant)	Primary packaging: Unit of use: one (1) set of nasal cannulae (prongs) in an individual pack. Labelling on the primary packaging: Name and/or trademark of the manufacturer; manufacturer's product reference; type of product and main characteristics; if the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging; lot number prefixed by the word "LOT" (or equivalent harmonized symbol); expiry date by year and month, prefixed by the word "EXP" (or equivalent harmonized symbol); the words "for single use" (or equivalent harmonized symbol); the words "check the integrity of the individual sterilized pack before use" (if space allows); the words "destroy after use" (if space allows). Secondary packaging: Protected unit: one (1) box containing multiple items in primary in their primary packaging. Labelling on the secondary packaging: Labelling to be the same as primary packaging. Extra information required: Number of units per secondary packaging. Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol). Information for handling, if applicable (or equivalent harmonized symbol). Manufacturer's instruction for use. Alternatively, the instruction for use can be indicated on a separate insert.
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Capable of being stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non condensing. Suitable for continuous operation in ambient temperature of at least 5–45 °C, relative humidity of at least 15–90% non condensing. Specific requirements for altitude may be required, depending on the installation site.
TRAINING, INSTALLATION AND UTILIZATION		
35	Pre-installation requirements (if relevant)	N/A
36	Requirements for commissioning (if relevant)	Local clinical and technical staff to affirm completion of installation and proper operation.
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance is not mandatory, but can be recommended, depending on the case, and shall be provided upon request.
38	User care (if relevant)	Common user care tasks, other device-specific procedures may apply, according to the use and the manufacturer's instructions. Pre-use checks. Proper connection. Cleaning and disinfection with compatible products.
WARRANTY AND MAINTENANCE		
39	Warranty	Shelf life.
40	Maintenance tasks	N/A
41	Type of service contract	N/A
42	Spare parts availability post-warranty	N/A
43	Software/hardware upgrade availability	N/A
DOCUMENTATION		
44	Documentation requirements	User and maintenance manuals, hard and soft copies, to be supplied in local language, or agreed other language if local not available. English version must also be available. List to be provided of common spares and accessories, with part numbers. Contact details of manufacturer, supplier and local service agent to be provided.

DECOMMISSIONING		
45	Estimated life span	Not exceeding shelf life.
SAFETY AND STANDARDS		
46	Risk classification	Class A (GHTF), Class I (USA), Class IIa (EU, Australia), Class II (Canada, Japan).
47	Regulatory approval/ certification	Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).
48	International standards	**Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is recommended, proof of compliance must be provided):** ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes. ISO 14971 Medical devices – Application of risk management to medical devices. ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. **Standards applicable to the product (where applicable, compliance to the last available version is recommended, proof of compliance must be provided):** Conforms to ISO, NFPA and/or CGA standards, and/or UL or CSA approved. ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen. ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications. ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. ISO 18190 Anaesthetic and respiratory equipment – General requirements for airways and related equipment.
49	Regional/local standards	Country-specific and regional standards apply and must be listed.
50	Regulations	Country-specific and regional regulations apply and must be listed. Compliance to (where applicable, but not limited to, and last available version): **US regulations:** 21 CFR part 820. 21CFR 868.5340 Nasal oxygen cannula. **EU regulations:** Regulation (EU) 2017/745. **Japan regulations:** MHLW Ordinance No. 169. 35201000 Cannula, nasal, oxygen.

Table A1.7: Technical specifications for nasal catheters

MEDICAL DEVICE SPECIFICATION (These technical specifications are generic and have been developed according to the latest available commercial products. They should be adapted to the setting where the product will be used (voltage, language, accessories, connectors etc.)		
i	Version number	1
ii	Date of initial version	
iii	Date of last modification	
iv	Date of publication	September 2019
v	Completed/ submitted by	UNICEF, WHO
NAME, CATEGORY AND CODING		
1	WHO category/code	
2	Generic name	Oxygen administration nasal catheter.
3	Specific type or variation (optional)	Nasal catheter.
4	GMDN name	Oxygen administration nasal catheter.
5	GMDN code	35203
6	GMDN category	
7	UMDNS name	Catheters, Nasal, Oxygen supply.
8	UMDNS code	12702
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Nasal catheter, Oxygen supply.
11	Alternative code/s (optional)	N/A
12	Keywords (optional)	Oxygen catheter, nasal catheter.
13	GMDN/UMDNS definition (optional)	GMDN A flexible tube, typically lubricated with a water-soluble gel, that is inserted through a naris to deliver supplemental oxygen to the nasopharynx. This is a single-use device. UMDNS Nasal catheters designed for delivery of oxygen into either of the nasal cavities. These catheters typically consist of a soft plastic tube with an internal diameter of 3–6 mm (1/8–1/4 inch); the distal tip is foam-collared and inserted into a nostril. Oxygen-supply nasal catheters are mostly used for short-term oxygen administration (e.g. in the immediate postoperative period); these catheters can be used in patients with a nasogastric tube in situ in the other nostril.
PURPOSE OF USE		
14	Clinical or other purpose	A nasal catheter is a thin, flexible tube for delivering oxygen that is passed into the nose and ends with its tip in the nasal cavity. Catheters can be designed for low-flow applications (0–15 L/min range; in general, not meeting all the inspiratory demand, ambient air mixes with the delivered gas) or high flow (> 15 L/min; typically, the patient inspires mainly the delivered gas). Like cannulae, catheters provide an altrenative to masks, causing less interference with eating, drinking, speaking/ vocalization.
15	Level of use (if relevant)	District/general hospital; regional hospital, secondary care; specialized hospital, tertiary care.
16	Clinical department/ ward (if relevant)	All departments where oxygen and/or respiratory therapy is delivered, including, but not limited to, intensive care units, inpatient ward, emergency, operating theatre, recovery room, observation, etc.
17	Overview of functional requirements	Where nasal prongs are not available, nasal catheters can be used as alternative delivery method for administration of oxygen into the patient nasal cavity, providing comfort for the patient. It involves inserting an oxygen catheter into the nasal cavities. It should be changed from one nostril to the second nostril after every 8 hours to avoid pain.

TECHNICAL CHARACTERISTICS		
18.1	Detailed requirements	Flexible nasal catheter with multiple holes at distal end. Oxygen and air/oxygen mixture compatibility, as per ISO 15001. Transparent tubing, suitable for low-pressure gas supply. Rubber or soft plastic tubing and catheter, semi-rigid and allowing freedom of movement, PVC or other material, FDA Title 21/USP VI compliant and certified for medical use, hardness > 60 Shore A (ASTM D-2240). Catheter length between 10 cm and 40 cm. Anti-kink tubing, non-permanent deformation if kinked or bent too tight. Non sterile.
18.2	Configurations/ options	Multiple anti-kink options (star lumen and other designs). Available with a catalogue of connectors and adapters for all standard fittings for oxygen sources and related equipment, administration devices and patient circuits. Standard, latex free and phthalate/DEHP-free versions, available for tubes and prongs. Multiple sizes for neonates, infants, children and adult (spacing, diameter, length) (e.g. for infants, the catheter should be 8 French (Fr) or 2.67 mm outer diameter or 8.34 mm circumference); Tubing in various sizes, lengths (at least, but not limited to, 0.5 m, 1.5 m and 2 m). Tubing compatibility with standard oxygen connection tubing, 3–5 mm internal diameter and 7–8 mm external diameter, and 15/22 mm diameter ventilation tubing; available with "standard" and "universal" hose end connector.
19	Displayed parameters	N/A
20	User adjustable settings	N/A
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components (if relevant)	End connectors.
22	Mobility, portability (if relevant)	Portable.
23	Raw materials (if relevant)	Soft plastic transparent tubing with several small holes at the nasal passage, or other material, FDA Title 21/USP VI compliant and certified for medical use, hardness > 60 Shore A (ASTM D-2240).
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	Oxygen/other medical gas supply (centralized, cylinders or concentrators) and related equipment to deliver medical gas.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	Adapters and supply tubing to connect the catheter with oxygen supply.
26	Sterilization/ disinfection process for accessories (if relevant)	Suitable for cleaning and disinfection.
27	Consumables/ reagents (if relevant)	N/A
28	Spare parts (if relevant)	N/A
29	Other components (if relevant)	N/A
PACKAGING		
30	Sterility status on delivery (if relevant)	Non sterile.
31	Shelf life (if relevant)	At least 3 years (recommended 5 years).
32	Transportation and storage (if relevant)	Sealed container. Capable of being transported and stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non condensing. Specific requirements for altitude may be required, depending on the installation site.

33	Labelling (if relevant)	Primary packaging: Unit of use: one (1) nasal catheter in an individual pack. Labelling on the primary packaging: Name and/or trademark of the manufacturer; manufacturer's product reference; type of product and main characteristics; if the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging; lot number prefixed by the word "LOT" (or equivalent harmonized symbol); expiry date by year and month, prefixed by the word "EXP" (or equivalent harmonized symbol); the words "for single use" (or equivalent harmonized symbol); the words "destroy after use" (if space allows). Secondary packaging: Protected unit: one (1) box containing multiple items in their primary packaging. Labelling on the secondary packaging: Labelling to be the same as primary packaging. Extra information required: Number of units per secondary packaging. Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol). Information for handling, if applicable (or equivalent harmonized symbol). Manufacturer's instruction for use. Alternatively, the instruction for use can be indicated on a separate insert.
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Capable of being stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non condensing. Suitable for continuous operation in ambient temperature of at least 5–45 °C, relative humidity of at least 15–90% non condensing. Specific requirements for altitude may be required, depending on the installation site.
TRAINING, INSTALLATION AND UTILIZATION		
35	Pre-installation requirements (if relevant)	N/A
36	Requirements for commissioning (if relevant)	N/A
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance is not mandatory, but can be recommended, depending on the case, and shall be provided upon request.
38	User care (if relevant)	Common user care tasks, other product-specific procedures may apply, according to the use and the manufacturer's instructions. Pre-use checks. Proper insertion. Cleaning and disinfection with compatible products.
WARRANTY AND MAINTENANCE		
39	Warranty	Shelf life.
40	Maintenance tasks	N/A
41	Type of service contract	N/A
42	Spare parts availability post-warranty	N/A
43	Software/hardware upgrade availability	N/A
DOCUMENTATION		
44	Documentation requirements	Contact details of manufacturer, supplier and local service agent to be provided with product description in local language, or agreed other language if local not available. English version must also be available.
DECOMMISSIONING		
45	Estimated life span	Not exceeding shelf life.

SAFETY AND STANDARDS		
46	Risk classification	Class A (GHTF), Class I (USA), Class IIa (EU, Australia), Class II (Canada, Japan).
47	Regulatory approval/ certification	Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).
48	International standards	**Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is recommended, proof of compliance must be provided):** ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes. ISO 14971 Medical devices – Application of risk management to medical devices. ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. **Standards applicable to the product (where applicable, compliance to the last available version is recommended, proof of compliance must be provided):** Conforms to ISO, NFPA and/or CGA standards, and/or UL or CSA approved. ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen. ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications. ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. ISO 18190 Anaesthetic and respiratory equipment – General requirements for airways and related equipment.
49	Regional/local standards	Country-specific and regional standards apply and must be listed.
50	Regulations	Country-specific and regional regulations apply and must be listed. Compliance to (where applicable, but not limited to, and last available version): **US regulations:** 21 CFR part 820. 21CFR 868.5350 Nasal oxygen catheter. **EU regulations:** Regulation (EU) 2017/745. **Japan regulations:** MHLW Ordinance No. 169. 35203000 Oxygen nasal catheter.

Table A1.8: Technical specifications for oxygen tubing

MEDICAL DEVICE SPECIFICATION (These technical specifications are generic and have been developed according to the latest available commercial products. They should be adapted to the setting where the product will be used (voltage, language, accessories, connectors etc.)		
i	Version number	1
ii	Date of initial version	
iii	Date of last modification	
iv	Date of publication	September 2019
v	Completed/ submitted by	UNICEF, WHO
NAME, CATEGORY AND CODING		
1	WHO category/code	
2	Generic name	Tubing, oxygen.
3	Specific type or variation (optional)	Oxygen connection, small bore.
4	GMDN name	Oxygen administration tubing.
5	GMDN code	12875
6	GMDN category	
7	UMDNS name	Tubing, Oxygen connecting.
8	UMDNS code	12875
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Tubing, oxygen supply.
11	Alternative code/s (optional)	N/A
12	Keywords (optional)	Oxygen tube, oxygen supply, connection tubing.
13	GMDN/UMDNS definition (optional)	GMDN A length of flexible tube, typically a small bore, thick-walled, anti-kink tubing (to prevent blockage) intended for the delivery of a pure oxygen (O_2) or an oxygen enriched gas to a mask or nasal cannula, typically during delivery of dry oxygen to the patient. The tubing is typically available in standard coil lengths and is cut by clinical staff to appropriate lengths to create an extension or connecting piece. This is a single-use device. UMDNS Tubing designed for external connection of an oxygen delivery source (e.g. hospital oxygen line, oxygen cylinder) at one end and, at the patient end, a device used to administer oxygen such as a nasal oxygen cannula; nasal, nasopharyngeal, or transtracheal oxygen catheter; or oxygen mask. This tubing is typically disposable (single-use) rubber or soft plastic tubing of small diameter (3–5 mm/1/8–3/16 inch), thick walls, and usually include tapered connectors with molded inner rings that hold securely when pressure is applied. Oxygen connection tubing is used in hospitals, in the field, and at home to administer oxygen to patients who need additional oxygen supply.
PURPOSE OF USE		
14	Clinical or other purpose	Tubing designed for external connection of an oxygen delivery source (i.e. oxygen concentrators or pressure regulators and flowmeters connected to oxygen cylinders or central supply system) at one end and, at the patient end, a device used to administer oxygen such as a nasal oxygen cannula or oxygen mask.
15	Level of use (if relevant)	Health post; health centre; district/general hospital; regional hospital, secondary care; specialized hospital, tertiary care; emergency vehicles; home care.
16	Clinical department/ ward (if relevant)	All departments where oxygen and/or respiratory support/therapy is delivered, including, but not limited to, intensive care units, inpatient ward, emergency, operating theatre, recovery room, observation, etc., and also emergency vehicles and home care.
17	Overview of functional requirements	Oxygen tubes connect an oxygen source to the patient delivery device for administration of oxygen. This tubing is typically rubber or soft plastic tubing of small diameter, thick walls, and usually includes tapered connectors with molded inner rings that hold securely when pressure is applied.

TECHNICAL CHARACTERISTICS		
18.1	Detailed requirements	Tubes suitable for delivering oxygen/air mixture into the nasal cavities, connected to oxygen sources, medical equipment, oxygen administration devices and patient circuits. Oxygen and air/oxygen mixture compatibility, as per ISO 15001. Rubber or soft plastic tubing, semi-rigid, PVC or other material, FDA Title 21/USP VI compliant and certified for medical use, hardness > 60 Shore A (ASTM D-2240). Tubing wall thickness between 1.58 mm (1/16 inch) and 2.38 (3/32 inch). Round shape section, internal diameter range 3–5 mm (1/8–3/16 inch), compatible with standard 6 mm barbed fitting. Anti-kink tubing, non-permanent deformation if kinked or bent too tight. Non sterile.
18.2	Configurations/ options	Rubber or soft plastic transparent tubing. Thick wall tube, 5 mm internal diameter, and bubble tube, 3–4 mm internal diameter. Multiple anti-kink options (star lumen and other designs). Bulk coils, for example (but not limited to): 25 m and 50 m coils. Standard, latex free and phthalate/DEHP-free versions. Various pre-cut lenghts, with or without connectors (for example, but not limited to, standard and wide) and ready to use in most common procedures, for example (but not limited to): 210 cm, 420 cm, 760 cm. Connectors and adapters to connect the mask with all standard breathing circuits and air/oxygen tubing, for example (but not limited to): 6 mm tube fitting and 15/22 mm breathing circuits.
19	Displayed parameters	N/A
20	User adjustable settings	N/A
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components (if relevant)	Tube body, connectors.
22	Mobility, portability (if relevant)	Portable.
23	Raw materials (if relevant)	Rubber or soft plastic transparent tubing, semi-rigid, PVC or other material, FDA Title 21/USP VI compliant and certified for medical use, hardness > 60 Shore A (ASTM D-2240).
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	Oxygen/other medical gas supply (centralized, cylinders or concentrators) and related equipment to deliver medical gas (mixer/blender, anaesthesia, ventilator, etc.).
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	Adapters to connect the tubing with oxygen therapy/respiratory support circuits and in anaesthesia/ventilation circuits.
26	Sterilization/ disinfection process for accessories (if relevant)	Suitable for cleaning and disinfection.
27	Consumables/ reagents (if relevant)	N/A
28	Spare parts (if relevant)	N/A
29	Other components (if relevant)	N/A
PACKAGING		
30	Sterility status on delivery (if relevant)	Non sterile.
31	Shelf life (if relevant)	At least 3 years (recommended 5 years).
32	Transportation and storage (if relevant)	Sealed container. Capable of being transported and stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non condensing. Specific requirements for altitude may be required, depending on the installation site.

33	Labelling (if relevant)	Primary packaging: Unit of use: one (1) oxygen tube set in an individual pack. Labelling on the primary packaging: Name and/or trademark of the manufacturer; manufacturer's product reference; type of product and main characteristics; if the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging; lot number prefixed by the word "LOT" (or equivalent harmonized symbol); expiry date by year and month, prefixed by the word "EXP" (or equivalent harmonized symbol); the words "for single use" (or equivalent harmonized symbol); the words "check the integrity of the individual sterilized pack before use" (if space allows); the words "destroy after use" (if space allows). Secondary packaging: Protected unit: one (1) box containing multiple items in primary in their primary packaging. Labelling on the secondary packaging: Labelling to be the same as primary packaging. Extra information required: Number of units per secondary packaging. Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol). Information for handling, if applicable (or equivalent harmonized symbol). Manufacturer's instruction for use. Alternatively, the instruction for use can be indicated on a separate insert.
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Capable of being stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non condensing. Suitable for continuous operation in ambient temperature of at least 5–50 °C, relative humidity of at least 15–90% non condensing. Specific requirements for altitude may be required, depending on the installation site.
TRAINING, INSTALLATION AND UTILIZATION		
35	Pre-installation requirements (if relevant)	N/A
36	Requirements for commissioning (if relevant)	Local clinical and technical staff to affirm completion of installation and proper operation.
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance is not mandatory, but can be recommended, depending on the case, and shall be provided upon request.
38	User care (if relevant)	Common user care tasks, other device-specific procedures may apply, according to the use and the manufacturer's instructions. Pre-use checks. Proper connection. Cleaning and disinfection with compatible products.
WARRANTY AND MAINTENANCE		
39	Warranty	Shelf life.
40	Maintenance tasks	N/A
41	Type of service contract	N/A
42	Spare parts availability post-warranty	N/A
43	Software/hardware upgrade availability	N/A
DOCUMENTATION		
44	Documentation requirements	List to be provided of common accessories and adapters, with part numbers. Contact details of manufacturer, supplier and local service agent to be provided in local language, or agreed other language if local not available. English version must also be available.

DECOMMISSIONING		
45	Estimated life span	Not exceeding shelf life.
SAFETY AND STANDARDS		
46	Risk classification	Class A (GHTF), Class I (USA), Class IIa (EU, Australia), Class II (Canada, Japan).
47	Regulatory approval/ certification	Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).
48	International standards	**Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is recommended, proof of compliance must be provided):** ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes. ISO 14971 Medical devices – Application of risk management to medical devices. ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. **Standards applicable to the product (where applicable, compliance to the last available version is recommended, proof of compliance must be provided):** Conforms to ISO, NFPA and/or CGA standards, and/or UL or CSA approved. ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen. ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications. ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. ISO 18190 Anaesthetic and respiratory equipment – General requirements for airways and related equipment. ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process.
49	Regional/local standards	Country-specific and regional standards apply and must be listed.
50	Regulations	Country-specific and regional regulations apply and must be listed. Compliance to (where applicable, but not limited to, and last available version): **US regulations:** 21 CFR part 820. **EU regulations:** Regulation (EU) 2017/745. **Japan regulations:** MHLW Ordinance No. 169.

Table A1.9: Technical specifications for self-contained fingertip pulse oximeters

MEDICAL DEVICE SPECIFICATION (These technical specifications are generic and have been developed according to the latest available commercial products. They should be adapted to the setting where the product will be used (voltage, language, accessories, connectors etc.)		
i	Version number	1
ii	Date of initial version	
iii	Date of last modification	
iv	Date of publication	September 2019
v	Completed/submitted by	UNICEF, WHO
NAME, CATEGORY AND CODING		
1	WHO category/code	
2	Generic name	Oxygen saturation monitor, self-contained fingertip.
3	Specific type or variation (optional)	Battery-powered, portable, self-contained.
4	GMDN name	Pulse oximeter, battery-powered.
5	GMDN code	45607
6	GMDN category	
7	UMDNS name	Oximeters, Pulse.
8	UMDNS code	17148
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Oximeter, pulse; oximeter, all-in-one pulse oximeter, finger clip pulse oximeter.
11	Alternative code/s (optional)	N/A
12	Keywords (optional)	SpO_2, oxygen, monitor, portable.
13	GMDN/UMDNS definition (optional)	GMDN A portable, battery-powered, photoelectric device intended for the transcutaneous measurement and display of haemoglobin oxygen saturation (SpO_2). The signals, typically produced by light-emitting diodes (LEDs) and a receiving detector in a probe, or directly built-in, are used to make the measurements using the principle of spectrophotometry. The oximeter displays the SpO_2 values and may calculate/display other parameters, e.g. pulse rate, electrocardiogram (ECG). The device is typically applied to the fingertip or around the wrist; it may be used by health care facilities, emergency services or in the home. UMDNS Oximeters designed primarily for determining the relative amount of oxygenated and deoxygenated haemoglobin (O_2Hb and HHb, respectively) by measuring light absorbence changes resulting from arterial blood flow pulsations and displaying the results as percentage saturation of haemoglobin in arterial blood (SpO_2). These oximeters include red and infrared light sources (typically LEDs of 660 and 940 nm), photodetectors, and probes that transmit light through a pulsating arterial bed, such as the finger tip, earlobe, or toe. Pulse oximeters are used in operating rooms, intensive care units, recovery rooms, and sometimes in emergency vehicles or for patient respiratory care at home.
PURPOSE OF USE		
14	Clinical or other purpose	Self-contained fingertip pulse oximeter is a small, lightweight, portable device indicated for use in measuring non-invasively and displaying functional oxygen saturation of arterial haemoglobin (%SpO_2) and pulse rate of patients. It is intended for spot checking of adult and paediatric patients with digital display. Supports the diagnosis for respiratory disorders.
15	Level of use (if relevant)	Health centre, district hospital, provincial hospital, specialized hospital, emergency vehicles.
16	Clinical department/ ward (if relevant)	For spot checks throughout the whole hospital, i.e. wards, operating theatre, ICU, recovery and emergency room in health care facilities.
17	Overview of functional requirements	Pulse oximeter contained in single small package, operated by placing on a patient's finger. The device is intended for spot checking adult and paediatric patients who are well or poorly perfused. The device measures and displays SpO_2 and pulse rate.

TECHNICAL CHARACTERISTICS		
18.1	Detailed requirements	**Operational characteristics:** SpO_2 and pulse rate monitor integrated into finger/toe clip. Specifications to apply to adults and children, and all skin pigmentations. Weight range for each patient category must be described. Suitable for spot check. SpO_2 detection to include the range: 70–99%. SpO_2 resolution: 1% or less. SpO_2 accuracy (in the range at least 70–99%): within ± 3%. If equipment is capable of a wider SpO_2 detection range, the accuracy over that wider range shall be stated. Pulse rate detection to include the range: 30–240 bpm. Pulse rate resolution: 1 bpm or less. Pulse rate accuracy within ± 3 bpm. Suitable for detection in low perfusion conditions (as per ISO 80601-2-61, test method must be described). Design must enable use in demanding environments, e.g. shock, vibration as per tests in ISO 80601-2-61, free fall tests equivalent to IEC 60068-2-31. Available probe sizes must accommodate finger/toe thicknesses at least including the range 8–25 mm. Automatic correction for movement, ambient light artefacts (as per ISO 80601-2-61, test method must be described). Display shows %SpO_2, pulse rate, signal quality, sensor error or disconnect and low battery status. Enclosure to have ingress protection level IPX2 or better. Any aspects of usabilty as per IEC 62366-1 must be described. Suitable for cleaning and disinfection. **Electrical characteristics:** Operated by internal battery. Batteries may be single use, or rechargeable with external AC battery charger, or by USB connection. Rechargeable batteries are preferred. If rechargeable, operation must be possible while charging. Charger, if used, must have protection against over-voltage and over-current line conditions, and be certified to IEC 60601-1. Automatic switch between mains and battery powered modes, when recharging, if relevant. If rechargeable batteries are used and expected lifetime of unit is more than expected lifetime of the batteries, rechargeable batteries must be replaceable by the user. Hours of continuous use, or number of tests, per battery set shall be stated. Batteries must allow at least 2500 spot checks calculated at 30 s per spot check, or at least 21 hours of operation. Automatic power-off.
18.2	Configurations/ options	Plethysmographic waveform visualization optional. Internal data storage, and/or external data download, for patient trends and event log optional. Adult, paediatric configurations required. Audible alarms optional.
19	Displayed parameters	SpO_2, pulse rate, battery and system status, signal quality, plethysmograpy waveform (optional).
20	User adjustable settings	N/A
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components (if relevant)	Oxygen saturation monitor in single self-contained package, battery charger (if relevant).
22	Mobility, portability (if relevant)	Portable.
23	Raw materials (if relevant)	N/A
UTILITY REQUIREMENTS		
24	Electrical, water and/ or gas supply (if relevant)	Battery power. If rechargeable, batteries may be charged via USB connector or by external AC charger.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	1 x carry/storage case. 2 x spare sets of batteries, if single use type (separately packed). 1 x neck lanyard for carrying. 1 x replacement flexible cover for patient finger contact (if removable).
26	Sterilization process for accessories (if relevant)	Suitable for cleaning and disinfection.
27	Consumables/ reagents (if relevant)	Batteries.

28	Spare parts (if relevant)	The following must be available from the supplier as and when required by the customer: Rechargeable or disposable batteries as described above. Replacement flexible cover for patient finger contact (if removable). 1 x replacement set of spare fuses (if non-resettable fuses are used).
29	Other components (if relevant)	N/A
PACKAGING		
30	Sterility status on delivery (if relevant)	Non sterile.
31	Shelf life (if relevant)	N/A
32	Transportation and storage (if relevant)	Sealed container. Capable of being transported and stored in ambient temperature of at least 5–50 °C, relative humidity of at least 10–95% non condensing. Specific requirements for altitude may be required, depending on the installation site.
33	Labelling (if relevant)	Primary packaging: Unit of use: one (1) pulse oximeter in a box or case or bag with manufacturer's instruction for use, spare parts and accessories (when applicable). Labelling on the primary packaging: Name and/or trademark of the manufacturer; manufacturer's product reference; type of product and main characteristics; lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (if applicable); information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol); information for handling, if applicable (or equivalent harmonized symbol). Over packaging: Packaging unit. Labelling on the packaging unit: Labelling to be the same as primary packaging. Extra information required: number of units.
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Capable of being stored in ambient temperature of at least 5–50 °C, relative humidity of at least 10–95% non condensing. Continuous operation within specification in ambient temperature of at least 5–40 °C, relative humidity of at least 10–90% non condensing. Specific requirements for altitude may be required, depending on the installation site. Display must allow easy viewing in all ambient light levels.
TRAINING, INSTALLATION AND UTILIZATION		
35	Pre-installation requirements (if relevant)	Electrical power supply (if battery charger is used). Check compatibility with the voltage and frequency of local setting.
36	Requirements for commissioning (if relevant)	Local clinical and technical staff to affirm function on arrival.
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance is required. This is preferably achieved by direct user training, or by training of trainers for several users. Clearly written instructions, with accompanying diagrams, is an acceptable but less preferred alternative.
38	User care (if relevant)	Pre-use checks. Proper connection, mounting and battery replacement/charging. Cleaning and disinfection with compatible products. Periodic functionality checks with appropriate testers. Periodic preventive maintenance checks and electrical safety checks (if charger used).
WARRANTY AND MAINTENANCE		
39	Warranty	2 years recommended, at least 1 year mandatory. The product shall be in production and fully supported when procured.
40	Maintenance tasks	Preventive maintenance, safety checks and functionality tests at least once per year shall be described in the instructions with each unit.
41	Type of service contract	Not required.
42	Spare parts availability post-warranty	All spare parts as listed above must be available for at least 5 years after supply.
43	Software/hardware upgrade availability	N/A

DOCUMENTATION		
44	Documentation requirements	Product description, operating and service manual, spare parts catalogue with part numbers and contact details for parts supply to be supplied in local language, or agreed other language if local not available. English version must also be available. Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration checks and routine maintenance. Contact details of manufacturer, supplier and local service agent to be provided.
DECOMMISSIONING		
45	Estimated life span	Expected lifetime of unit shall be stated, and shall be > 2 years.
SAFETY AND STANDARDS		
46	Risk classification	Class B (GHTF Rule 10), Class II (USA), Class IIb (EU, Japan, Canada and Australia).
47	Regulatory approval/ certification	Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).
48	International standards	**Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is recommended, proof of compliance must be provided):** ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes. ISO 14971 Medical devices – Application of risk management to medical devices. **Standards applicable to the product (where applicable, compliance to the last available version is recommended, proof of compliance must be provided):** IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems. IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment. ISO/IEEE 11073-10404 Health informatics – Personal health device communication – Part 10404: Device specialization – Pulse oximeter (if capacity for data connection to a computer is included) IEC 60068-2-31 Environmental testing – Part 2-31: Tests –Test Ec: Rough handling shocks, primarily for equipment-type specimens. IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices. IEC 62133 - Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells. Part 1: Nickel, Part 2: Lithium.
49	Regional/local standards	Country-specific and regional standards apply and must be listed.
50	Regulations	Country-specific and regional regulations apply and must be listed. Compliance to (where applicable, but not limited to, and last available version): **US regulations:** 21 CFR part 820. 21CFR part 870.2700 Oximeter. **EU regulations:** Regulation (EU) 2017/745. **Japan regulations:** MHLW Ordinance No. 169. 17148010 Pulse oximeter.

Table A1.10: Technical specifications for handheld pulse oximeters

MEDICAL DEVICE SPECIFICATION (These technical specifications are generic and have been developed according to the latest available commercial products. They should be adapted to the setting where the product will be used (voltage, language, accessories, connectors etc.)		
i	Version number	1
ii	Date of initial version	
iii	Date of last modification	
iv	Date of publication	September 2019
v	Completed/ submitted by	UNICEF, WHO
NAME, CATEGORY AND CODING		
1	WHO category/code	
2	Generic name	Oxygen saturation monitor, handheld.
3	Specific type or variation (optional)	Battery-powered, handheld, non-invasive.
4	GMDN name	Pulse oximeter, battery-powered.
5	GMDN code	45607
6	GMDN category	
7	UMDNS name	Oximeters, Pulse.
8	UMDNS code	17148
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Oximeter, pulse; oximeter.
11	Alternative code/s (optional)	N/A
12	Keywords (optional)	SpO_2, oxygen, pulse oximetry, monitor, portable.
13	GMDN/UMDNS definition (optional)	GMDN A portable, battery-powered, photoelectric device intended for the transcutaneous measurement and display of haemoglobin oxygen saturation (SpO_2). The signals, typically produced by light-emitting diodes (LEDs) and a receiving detector in a probe, or directly built-in, are used to make the measurements using the principle of spectrophotometry. The oximeter displays the SpO_2 values and may calculate/display other parameters, e.g. pulse rate, electrocardiogram (ECG). The device is typically applied to the fingertip or around the wrist; it may be used by health care facilities, emergency services, or in the home. UMDNS Oximeters designed primarily for determining the relative amount of oxygenated and deoxygenated haemoglobin (O_2Hb and HHb, respectively) by measuring light absorbence changes resulting from arterial blood flow pulsations and displaying the results as percent saturation of haemoglobin in arterial blood (SpO_2). These oximeters include red and infrared light sources (typically LEDs of 660 and 940 nm), photodetectors, and probes that transmit light through a pulsating arterial bed, such as the finger tip, earlobe or toe. Pulse oximeters are used in operating rooms, intensive care units, recovery rooms, and sometimes in emergency vehicles or for patient respiratory care at home.
PURPOSE OF USE		
14	Clinical or other purpose	To monitor the haemoglobin oxygen saturation and plethysmography waveform and to calculate the pulse rate for a patient, supporting the diagnosis of respiratory disorders.
15	Level of use (if relevant)	Health post; health centre; district/general hospital; regional hospital, secondary care; specialized hospital, tertiary care; emergency vehicles; home care.
16	Clinical department/ ward (if relevant)	All departments where diagnostics and patient monitoring are provided and departments where oxygen and/or respiratory support/therapy is delivered, including, but not limited to, intensive care units, inpatient and outpatient ward, emergency, operating theatre, recovery room, observation, etc., and also emergency vehicles and home care.

17	Overview of functional requirements	Portable pulse oximeter, handheld. Continuously displays patient oxygen saturation in real time using an external probe on the skin. Contains adjustable alarms to alert when either saturation or heart rate is high or low. Supplied with reusable probes. Settings and probes must be suitable for adult, paediatric and neonatal patients. Operates from rechargeable and/or disposable batteries; supplied with battery charger if rechargeable.
TECHNICAL CHARACTERISTICS		
18.1	Detailed requirements	**Operational characteristics:** SpO_2 and pulse rate monitor, with plethysmography waveform, for adults, children and neonates, for all skin pigmentations. Weight range for each patient category must be stated. SpO_2 detection to include the range: 70–100%. SpO_2 resolution: 1% or less. SpO_2 accuracy (in the range at least 70–100%): within ± 2% under ideal conditions of use, and within ± 3% for all patients and perfusion/movement conditions. If equipment is capable of a wider SpO_2 detection range, the accuracy over that wider range shall be stated. Pulse rate detection to include the range: 30–240 bpm. Pulse rate resolution: 1 bpm or less. Pulse rate accuracy within ± 3 bpm. Data update period for valid data displayed ≤ 10 s. Display with main parameters: $\%SpO_2$, pulse rate, plethysmographic waveform (and possibly other indicators of signal quality), alarm messages, battery state indication. Suitable for detection in low perfusion conditions (as per ISO 80601-2-61, test method must be described). Automatic correction for movement and ambient light artefacts (as per ISO 80601-2-61, test method must be described). Design must enable use in demanding environments, e.g. shock, vibration as per tests in ISO 80601-2-61, free fall tests equivalent to IEC 60068-2-31. Audible and visual alarms for low/high saturation and pulse rate, threshold set by user. Audible and visual alarms for sensor error or disconnected, system errors, low battery. Alarm override and temporary silencing function. Capable of working with, and supplied with, adult, paediatric and neonatal reusable probes. Enclosure to have ingress protection level IPX2 or better. Overall device and probe weight < 400 g. Any aspects of usabilty as per IEC 62366-1 must be described. Suitable for cleaning and disinfection. **Electrical characteristics:** Operated by replaceable battery power supply, either rechargeable or single use. Devices that operate from rechargeable or both battery types will be preferred. External or built-in AC battery charger, if rechargeable type. Plug style as per local supply. Charger, if used, to have protection against over-voltage and over-current line conditions and be certified to IEC 60601-1. Protection against defibrillator discharges and electrosurgical units. Suitable for operation by battery and by mains power supply, if connected and/or recharging. Automatic switch between battery and mains powered modes, when recharging or in mains power failure. The display shall show which power source is in use. Running time on battery only ≥ 12 hours.
18.2	Configurations/ options	Internal data storage for patient trends and event log (optional). Data interface, suitable for exporting data to external software (optional). Availability of adult, paediatric and neonatal reusable sensors of at least the following types: finger clip and neonatal/ infant foot clips (durable plastic built), silicone wrap, woven fabric, adhesive. Automatic power-off function enabling/disabling, to allow continuous monitoring use.
19	Displayed parameters	SpO_2, plethysmograpy waveform, pulse rate, battery and system messages, alarms.
20	User adjustable settings	Audiovisual adjustable alarms: high/low SpO_2 and high/low pulse rate (operator variable settings). Alarm override and temporary silencing.
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components (if relevant)	Oxygen saturation monitor body, plastic casing, removable battery cover, battery charger (separated or integrated component), probe connector, control panel, display, internal electronic board, reusable probes. Equipment and reusable accessories/probes suitable for cleaning and disinfection with hospital grade detergents.
22	Mobility, portability (if relevant)	Portable, handheld.
23	Raw materials (if relevant)	N/A

UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	Applicable to the battery charger or charging station. The requirements for power input voltage/frequency and plug type of the equipment must be chosen according to the local electrical supply. Depending on the local electrical supply availability and quality, voltage corrector/stabilizer/UPS can be recommended, in order to allow operation at ± 30% of local rated voltage, providing also protection for over current events. Electrical protection preferably by resettable circuit breakers in both live and neutral supply lines.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	Carry case. To be supplied with reusable probes, adult, paediatric and neonatal sizes (depending on the intended use), recommended 2 or 3 probes of the needed type, probe cable length (including extender if supplied) > 1 m. The catalogue shall include various sizes, fitting all patients, of clip and wrap-up (silicone, woven fabric, adhesive and other material/design) probes.
26	Sterilization/ disinfection process for accessories (if relevant)	Suitable for cleaning and disinfection.
27	Consumables/ reagents (if relevant)	Rechargeable and/or disposable batteries.
28	Spare parts (if relevant)	Spare sets of rechargeable or disposable batteries, reusable probes, extender cable. Replacement set of spare fuses (if non-resettable fuses are used), display, connectors, battery holder, control panel, casing, battery charger.
29	Other components (if relevant)	N/A
PACKAGING		
30	Sterility status on delivery (if relevant)	Non sterile.
31	Shelf life (if relevant)	N/A
32	Transportation and storage (if relevant)	Sealed container. Capable of being transported and stored in ambient temperature of at least 5–50 °C, relative humidity of at least 10–95% non condensing. Specific requirements for altitude may be required, depending on the installation site.
33	Labelling (if relevant)	Primary packaging: Unit of use: one (1) pulse oximeter in a box or case or bag with manufacturer's instruction for use, spare parts and accessories (when applicable). Labelling on the primary packaging: Name and/or trademark of the manufacturer; manufacturer's product reference; type of product and main characteristics; lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (if applicable); information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol); information for handling, if applicable (or equivalent harmonized symbol). Over packaging: Packaging unit. Labelling on the packaging unit: Labelling to be the same as primary packaging. Extra information required: number of units.
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Capable of being stored in ambient temperature of at least 5–50 °C, relative humidity of at least 10–95% non condensing. Continuous operation within specification in ambient temperature of at least 5–40 °C, relative humidity of at least 10–90% non-condensing. Specific requirements for altitude may be required, depending on the installation site. Display must allow easy viewing in all ambient light levels.
TRAINING, INSTALLATION AND UTILIZATION		
35	Pre-installation requirements (if relevant)	Electrical power supply (if battery charger is used). Check compatibility with the local voltage and frequency.
36	Requirements for commissioning (if relevant)	Supplier must perform installation, safety and operation checks before handover. Local clinical and technical staff to affirm completion of installation.
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance is mandatory. Training of technical staff in advanced maintenance tasks is not mandatory, but is recommended.

38	User care (if relevant)	Pre-use checks. Proper connection, probe mounting and battery replacement/charging. Cleaning and disinfection with compatible products. Periodic functionality checks with appropriate testers. Periodic preventive maintenance and electrical safety checks.
WARRANTY AND MAINTENANCE		
39	Warranty	2 years recommended, at least 1 year mandatory. The product shall be in production and fully supported when procured.
40	Maintenance tasks	Preventive maintenance, safety checks and functionality tests at least once per year shall be described in the instructions with each unit.
41	Type of service contract	Not required.
42	Spare parts availability post-warranty	8 years at least, starting from the installation.
43	Software/hardware upgrade availability	N/A
DOCUMENTATION		
44	Documentation requirements	User and maintenance manuals, hard and soft copies, to be supplied in local language, or agreed other language if local not available. English version must also be available. Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration and routine maintenance. List to be provided of common spares and accessories, with part numbers and contact details for parts supply. Contact details of manufacturer, supplier and local service agent to be provided.
DECOMMISSIONING		
45	Estimated life span	7 years.
SAFETY AND STANDARDS		
46	Risk classification	Class B (GHTF Rule 10), Class II (USA), Class IIb (EU, Japan, Canada and Australia).
47	Regulatory approval/ certification	Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).
48	International standards	**Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is recommended, proof of compliance must be provided):** ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes. ISO 14971 Medical devices – Application of risk management to medical devices. **Standards applicable to the product (where applicable, compliance to the last available version is recommended, proof of compliance must be provided):** IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems. IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment. ISO/IEEE 11073-10404 Health informatics – Personal health device communication – Part 10404: Device specialization – Pulse oximeter. IEC 60068-2-31 Environmental testing – Part 2-31: Tests – Test Ec: Rough handling shocks, primarily for equipment-type specimens. IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices. IEC 62133 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells. Part 1: Nickel, Part 2: Lithium.
49	Regional/local standards	Country-specific and regional standards apply and must be listed.
50	Regulations	Country-specific and regional regulations apply and must be listed. Compliance to (where applicable, but not limited to, and last available version): **US regulations:** 21 CFR part 820. 21CFR part 870.2700 Oximeter. **EU regulations:** Regulation (EU) 2017/745. **Japan regulations:** MHLW Ordinance No. 169. 17148010 Pulse oximeter.

Table A1.11: Technical specifications for tabletop pulse oximeters

MEDICAL DEVICE SPECIFICATION (These technical specifications are generic and have been developed according to the latest available commercial products. They should be adapted to the setting where the product will be used (voltage, language, accessories, connectors etc.)		
i	Version number	1
ii	Date of initial version	
iii	Date of last modification	
iv	Date of publication	September 2019
v	Completed/ submitted by	UNICEF, WHO
NAME, CATEGORY AND CODING		
1	WHO category/code	
2	Generic name	Oxygen saturation monitor, tabletop.
3	Specific type or variation (optional)	Line-powered, tabletop, non-invasive.
4	GMDN name	Pulse oximeter, line-powered.
5	GMDN code	17148
6	GMDN category	
7	UMDNS name	Oximeters, Pulse.
8	UMDNS code	17148
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Oximeter, pulse; oximeter.
11	Alternative code/s (optional)	N/A
12	Keywords (optional)	SpO_2, oxygen, pulse oximetry, monitor, tabletop.
13	GMDN/UMDNS definition (optional)	GMDN A mains electricity (AC-powered) photoelectric device intended for the continuous transcutaneous measurement and display of haemoglobin oxygen saturation (SpO_2). The signals, typically produced by light-emitting diodes (LEDs) and a receiving detector in a probe, or directly built-in, are used to make the measurements using the principle of spectrophotometry. The oximeter displays the SpO_2 values and may calculate/display other parameters, e.g. pulse rate, electrocardiogram (ECG). The device is typically used bedside. UMDNS Oximeters designed primarily for determining the relative amount of oxygenated and deoxygenated haemoglobin (O_2Hb and HHb, respectively) by measuring light absorbence changes resulting from arterial blood flow pulsations and displaying the results as percentage saturation of haemoglobin in arterial blood (SpO_2). These oximeters include red and infrared light sources (typically LEDs of 660 and 940 nm), photodetectors, and probes that transmit light through a pulsating arterial bed, such as the finger tip, earlobe or toe. Pulse oximeters are used in operating rooms, intensive care units, recovery rooms, and sometimes in emergency vehicles or for patient respiratory care at home.
PURPOSE OF USE		
14	Clinical or other purpose	To monitor the haemoglobin oxygen saturation and plethysmography waveform of the patient and to calculate the pulse rate, supporting the diagnosis for respiratory disorders. Suitable for continuous monitoring.
15	Level of use (if relevant)	District/general hospital; regional hospital, secondary care; specialized hospital, tertiary care.
16	Clinical department/ ward (if relevant)	All departments where diagnostics and patient monitoring are provided and departments where oxygen and/or respiratory support/therapy is delivered, including, but not limited to, intensive care units, inpatient ward, emergency, operating theatre, recovery room, observation, etc.

17	Overview of functional requirements	Tabletop pulse oximeter. Continuously displays patient oxygen saturation in real time using an external probe on the skin. Contains adjustable alarms to alert when either saturation or heart rate is high or low. Supplied with reusable probes. Settings and probes must be suitable for adult, paediatric and neonatal patients. Operates from mains voltage and from internal rechargeable battery.
TECHNICAL CHARACTERISTICS		
18.1	Detailed requirements	**Operational characteristics:** Continuously monitors SpO_2, plethysmography waveform and pulse rate for adults, children and neonates. Weight range for each patient category must be stated. SpO_2 detection to include the range: 70–100%. SpO_2 resolution: 1% or less. SpO_2 accuracy (in the range at least 70–100%): within ± 2% under ideal conditions of use, and within ± 3%, for all patients and perfusion/movement conditions. If equipment is capable of a wider SpO_2 detection range, the accuracy over that wider range shall be stated. Pulse rate detection to include the range: 30–240 bpm. Pulse rate resolution: 1 bpm or less. Pulse rate accuracy within ± 3 bpm. Data update period for valid data display ≤ 10 s. Suitable for detection in low perfusion conditions (as per ISO 80601-2-61, test method must be described). Automatic correction for movement, ambient light artefacts (as per ISO 80601-2-61, test method must be described). Design must enable use in demanding environments, e.g. shock, vibration as per tests in ISO 80601-2-61, free fall tests equivalent to IEC 60068-2-31. Internal data storage for patient data and trends and for event log. Audible and visual alarms for high/low saturation and pulse rate (thresholds to be easily settable by user), sensor error or disconnected, system errors, low battery. Alarm override and temporary silencing function. Display with main parameters: $\%SpO_2$, pulse rate, plethysmographic waveform, signal quality, alarm messages, battery state indication. Capable of working with, and supplied with, adult, paediatric and neonatal reusable probes. Enclosure to have ingress protection level IPX2 or better. Any aspects of usabilty as per IEC 62366-1 must be described. Suitable for cleaning and disinfection. **Electrical characteristics:** Operated by line electrical power supply with internal rechargeable battery backup. Protections against over-voltage and over-current line conditions. Protection against defibrillator discharges and electrosurgical units. Battery charger integrated in the main unit. Automatic switch between battery and mains powered modes, when recharging or in mains power failure. The display shall show which power source is in use. Internal replaceable, rechargeable batteries. Running time on battery only ≥ 6 hours. Mains power cable length ≥ 2.5 m.
18.2	Configurations/ options	Network and data interface, suitable for exporting data to external software (optional). Availability of adult, paediatric and neonatal reusable sensors of at least the following types: finger clip and neonatal/ infant foot clips (durable plastic built), silicone wrap, woven fabric, adhesive.
19	Displayed parameters	SpO_2, plethysmograpy waveform, pulse rate, battery and system messages, alarms.
20	User adjustable settings	Audiovisual adjustable alarms: high and low SpO_2 and pulse rate (operator variable settings). Alarm override and temporary silencing.
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components (if relevant)	Oxygen saturation monitor body, casing, probe connector, control panel, display, internal electronic board, reusable probes. Equipment and reusable accessories/probes suitable for cleaning and disinfection with hospital grade detergents.
22	Mobility, portability (if relevant)	Tabletop.
23	Raw materials (if relevant)	N/A
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	The requirements for power input voltage/frequency and plug type of the equipment must be chosen according to the local electrical supply. Depending on the local electrical supply availability and quality, voltage corrector/stabilizer/UPS can be recommended, in order to allow operation at ± 30% of local rated voltage, providing also protection for over current events. Electrical protection, preferably by resettable circuit breakers in both live and neutral supply lines.

ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	To be supplied with reusable probes, adult, paediatric and neonatal sizes depending on the intended use, recommended 2 or 3 probes of the needed type, probe cable length > 1 m. The catalogue shall include various sizes, fitting all patients, of clip and wrap-up (silicone, woven fabric, adhesive and other material/design) probes.
26	Sterilization/ disinfection process for accessories (if relevant)	Suitable for cleaning and disinfection.
27	Consumables/ reagents (if relevant)	Batteries.
28	Spare parts (if relevant)	Rechargeable batteries, reusable probes and extender cable, mains cable. Set of spare fuses (if non-resettable fuses are used), display, connectors, control panel, casing.
29	Other components (if relevant)	N/A
PACKAGING		
30	Sterility status on delivery (if relevant)	Non sterile.
31	Shelf life (if relevant)	N/A
32	Transportation and storage (if relevant)	Sealed container. Capable of being transported and stored in ambient temperature of at least 5–50 °C, relative humidity of at least 10–95% non condensing. Specific requirements for altitude may be required, depending on the installation site.
33	Labelling (if relevant)	Primary packaging: Unit of use: one (1) pulse oximeter in a box or case or bag with manufacturer's instruction for use, spare parts and accessories (when applicable). Labelling on the primary packaging: Name and/or trademark of the manufacturer; manufacturer's product reference; type of product and main characteristics; lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (if applicable); information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol); information for handling, if applicable (or equivalent harmonized symbol). Over packaging: Packaging unit. Labelling on the packaging unit: Labelling to be the same as primary packaging. Extra information required: number of units.
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Capable of being stored in ambient temperature of at least 5–50 °C, relative humidity of at least 10–95% non condensing. Continuous operation within specification in ambient temperature of at least 5–40 °C, relative humidity of at least 10–90% non condensing. Specific requirements for altitude may be required, depending on the installation site. Display must allow easy viewing in all ambient light levels.
TRAINING, INSTALLATION AND UTILIZATION		
35	Pre-installation requirements (if relevant)	Electrical power supply. Check compatibility with the local voltage and frequency.
36	Requirements for commissioning (if relevant)	Supplier must perform installation, safety and operation checks before handover. Local clinical and technical staff to affirm completion of installation.
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance is mandatory. Training of technical staff in advanced maintenance tasks is not mandatory, but is recommended.
38	User care (if relevant)	Pre-use checks. Proper connection, probe mounting and battery replacement/charging. Cleaning and disinfection with compatible products. Periodic functionality checks with appropriate testers. Periodic preventive maintenance and electrical safety checks.

WARRANTY AND MAINTENANCE		
39	Warranty	2 years recommended, at least 1 year mandatory. The product shall be in production and fully supported when procured.
40	Maintenance tasks	Preventive maintenance, safety checks and functionality tests at least once per year shall be described in the instructions with each unit.
41	Type of service contract	Not required.
42	Spare parts availability post-warranty	8 years at least, starting from the installation.
43	Software/hardware upgrade availability	N/A
DOCUMENTATION		
44	Documentation requirements	User and maintenance manuals, hard and soft copies, to be supplied in local language, or agreed other language if local not available. English version must also be available. Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration and routine maintenance. List to be provided of common spares and accessories, with part numbers and contact details for parts supply. Contact details of manufacturer, supplier and local service agent to be provided.
DECOMMISSIONING		
45	Estimated life span	7 years.
SAFETY AND STANDARDS		
46	Risk classification	Class B (GHTF Rule 10), Class II (USA), Class IIb (EU, Japan, Canada and Australia).
47	Regulatory approval/ certification	Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).
48	International standards	**Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is recommended, proof of compliance must be provided):** ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes. ISO 14971 Medical devices – Application of risk management to medical devices. **Standards applicable to the product (where applicable, compliance to the last available version is recommended, proof of compliance must be provided):** IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems. IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment. ISO/IEEE 11073-10404 Health informatics – Personal health device communication – Part 10404: Device specialization – Pulse oximeter. IEC 60068-2-31 Environmental testing – Part 2-31: Tests – Test Ec: Rough handling shocks, primarily for equipment-type specimens. IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices. IEC 62133 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells. Part 1: Nickel, Part 2: Lithium.
49	Regional/local standards	Country-specific and regional standards apply and must be listed.
50	Regulations	Country-specific and regional regulations apply and must be listed. Compliance to (where applicable, but not limited to, and last available version): **US regulations:** 21 CFR part 820. 21CFR part 870.2700 Oximeter. **EU regulations:** Regulation (EU) 2017/745. **Japan regulations:** MHLW Ordinance No. 169. 17148010 Pulse oximeter.

Table A1.12: Technical specifications for solid-state voltage stabilizers

MEDICAL DEVICE SPECIFICATION (These technical specifications are generic and have been developed according to the latest available commercial products. They should be adapted to the setting where the product will be used (voltage, language, accessories, connectors etc.)		
i	Version number	1
ii	Date of initial version	
iii	Date of last modification	
iv	Date of publication	September 2019
v	Completed/ submitted by	UNICEF, WHO
NAME, CATEGORY AND CODING		
1	WHO category/code	
2	Generic name	Voltage stabilizer.
3	Specific type or variation (optional)	Electronic, solid state.
4	GMDN name	Voltage regulator.
5	GMDN code	35934
6	GMDN category	
7	UMDNS name	Power supplies, Line-voltage stabilization.
8	UMDNS code	16934
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Voltage stabilizer, power conditioner.
11	Alternative code/s (optional)	N/A
12	Keywords (optional)	Voltage regulator, stabilizer, conditioner, power supply, electrical supply.
13	GMDN/UMDNS definition (optional)	GMDN A device that helps to maintain a stable mains voltage, i.e. with the help, or as part, of a suitable secondary power supply. Should the voltage drop below a pre-set limit the device will increases the voltage in correspondence with the particular type of device it is protecting. Some types may, when there is a sufficient reduction, automatically switch on a boost transformer. UMDNS Power supplies designed to deliver an almost steady, predetermined value of AC voltage (e.g. 120 V) for a limited range of input line voltage variations (e.g. plus or minus 10%). These devices typically include an electronic line voltage monitor to detect line voltage fluctuations and some electric or electronic stabilization circuit or device to compensate for these variations. Line voltage stabilizing power supplies are mostly used to maintain normal operation of electrical equipment (e.g. motors, pumps, lights, refrigerators) under reduced-voltage conditions (brownouts).
PURPOSE OF USE		
14	Clinical or other purpose	The voltage regulator is a power supply that is installed between the mains and the electrical medical equipment. It stabilizes the mains voltage to a pre-determined output, eliminating its fluctuations and protecting the electrical equipment also from surges. Various capacity and configurations of voltage regulators can be installed according to the needs. The solid state voltage regulator is fully electronic, without moving parts. Compared with the servo-electronic voltage regulator (which is electro-mechanic with motors and coiled transformers), the solid state version is a smaller and lower maintenance device, and, due to its full electronic design, it has faster reaction. On the other side, the servo-electronic regulator is more accurate and resistant to input voltage and current fluctuations. For equipping normal department, such as NICU, with no special requirements in terms of electrical supply, a solid state voltage regulator is the optimal solution. For high-demanding departments, such as radiology, that needs more accurate voltage stability and improved protection from external events, a servo-electronic voltage regulator may be the best solution. In harsh environments and with low maintenance resources, often found in low-resource settings, the solid state technology is more reliable and offers the best long-term performance and value for money.
15	Level of use (if relevant)	Health post; health centre; district/general hospital; regional hospital, secondary care; specialized hospital, tertiary care; emergency vehicles; home care.

16	Clinical department/ ward (if relevant)	All sites where electric equipment, requiring stable mains power supply and sensitive to voltage fluctuations and surges, is installed.
17	Overview of functional requirements	Electronic voltage regulator, solid state tap-switching technology, microprocessor controlled and without moving parts. Single phase, available for 110–120 VAC and 220–240 VAC networks, 50–60 Hz. Availability of multiple capacities and configurations, suitable for portable use and for fixed installations. Availability of models with built-in surge suppressor, circuit breakers and isolating transformer. Availability of various configurations and connections to fit all electrical standards for networks and equipment.
TECHNICAL CHARACTERISTICS		
18.1	Detailed requirements	Electronic, microprocessor controlled voltage stabilizer. Solid state tap-switching technology, without moving parts. Single phase, one or two output socket(s) of local standard design. If output is wired or IEC style, a convertor to local standard socket must be supplied. 110–120 VAC or 220–240 VAC ± 10% nominal input voltage, depending upon local requirement. Frequency range at least 50–60 Hz ± 10%, exact frequency will depend on local requirement. Load rating at least 1 kVA. Voltage input and output indicators. Input resettable circuit breaker for overload or short circuit. (Single-use fuses not acceptable.) Spike, surge, transient and lightning protection. Suitable for short term overload working conditions, at least 135% for 4 minutes and 110% for 6 minutes. Independent and filtered (non-interfering) outlets (applicable to multiple outlet voltage regulators). Automatic over-voltage and under-voltage protection, with output power supply disconnection. Suitable for short-term extended under/over input voltage (at least additional ± 2%) without activation of the protection and with output swing < 10%. Automatic start-up after disconnection, with start-up delay between 2 s and 10 s. Outlet voltage 110 VAC or 220 VAC (as per specified local requirement) ± 8% or narrower accuracy. Protection of the regulator and the load against switch on/off over current and over voltage. Manual bypass function. Visual and/or audible alarm for operational conditions and system status. Efficiency at least 80% at 25% load, 90% at 50% load and 95% at 75–100% load. Correction speed > 750 V/s. Unaffected by load power factor. Power cord length > 1.5 m. Low noise < 45 dB.
18.2	Configurations/ options	Indoor operation, enclosure protection at least IP20. Suitable for use on grounded and non-grounded mains, with the possibility to use an alternative grounding. Optional voltage and power input and output metering. Optional built-in isolating transformer (power conditioner), available at least for capacity > 1.5 kVA. Optional built-in output circuit breaker, independent for each output. Availability of versions with and without output circuit breaker, one for each output. Optional output spike, surge and transient protection (including lightning), with availability of Type I and Type II IEC rating lightning surge protection. Availability of different delay on start-up and on automatic reconnection, including (but not limited to): 0 s/immediate on power reconnection or start-up, 3–4 minutes, adjustable. Capacity range (depending on the models) 1–30 kVA: - models up to 1 kVA shall be lightweight and portable (at least 0.5 and 1 kVA); - models from 1 kVA to 10 kVA shall be mobile/wheeled (at least 1, 1.5–2, 2.5–3.5, 5, 7–10 kVA); - models from 10 kVA to 30 kVA shall be available in wheeled and fixed version (at least 7–10, 10–15, 20–25, 30 kVA); - wired and plugged version availability, with customizable plug (inlet) and sockets (outlets) matching all commercial electrical standards (at least, but not limited to, European/German, British, French, American, Australian, Indian).
19	Displayed parameters	Input and output voltage, load (indication/measurement/metering options depending on the configuration).
20	User adjustable settings	Input/output voltage (depending on the configuration).
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components (if relevant)	Voltage regulator body, sockets/plugs or wiring (fixed installations), switches, display, fuses and circuit breakers, electronic boards, solid state electronics for voltage regulation, isolating transformer (if applicable), surge protection electronics (if applicable).
22	Mobility, portability (if relevant)	Portable/mobile or fixed installation, depending on the configuration.
23	Raw materials (if relevant)	N/A
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	The requirements for power input voltage/frequency and plug type of the equipment must be chosen according to the local electrical supply. Electrical protection by resettable circuit breakers in both live and neutral supply lines.

ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	Power cables, plugs and sockets, matching the applicable electric standard in the installation site.
26	Sterilization/ disinfection process for accessories (if relevant)	N/A
27	Consumables/ reagents (if relevant)	N/A
28	Spare parts (if relevant)	Sockets/plugs and wiring, switches, fuses/circuit breakers, display, control panel, external housing, electronic boards, isolating transformer (if applicable).
29	Other components (if relevant)	N/A
PACKAGING		
30	Sterility status on delivery (if relevant)	Non sterile.
31	Shelf life (if relevant)	N/A
32	Transportation and storage (if relevant)	Sealed container. Capable of being transporterd and stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non condensing. Specific requirements for altitude may be required, depending on the installation site.
33	Labelling (if relevant)	Primary packaging: Unit of use: one (1) voltage regulator in a box or case with manufacturer's instruction for use, spare parts and accessories (when applicable). Labelling on the primary packaging: Name and/or trademark of the manufacturer; manufacturer's product reference; type of product and main characteristics; lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (if applicable); information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol); information for handling, if applicable (or equivalent harmonized symbol). Over packaging: Packaging unit. Labelling on the packaging unit: Labelling to be the same as primary packaging. Extra information required: number of units.
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Capable of being stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non condensing. Suitable for continuous operation in ambient temperature of at least 5–45 °C, relative humidity of at least 15–90% non condensing. Specific requirements for altitude may be required, depending on the installation site.
TRAINING, INSTALLATION AND UTILIZATION		
35	Pre-installation requirements (if relevant)	Compatibility with the electrical system (design and specifications).
36	Requirements for commissioning (if relevant)	Recommended that the supplier performs installation, safety and operation checks before handover. Local technical staff to affirm completion of installation.
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided upon request. Training of technical staff in advanced maintenance tasks shall be provided upon request.
38	User care (if relevant)	Pre-use checks (for portable and mobile versions). Proper connection, avoid ungrounded outlet, do not use with inappropriate extension cords or adapters (for portable and mobile versions). Avoid exceeding the maximum power output. Cleaning with compatible products. Periodic maintenance, functionality and electrical safety checks with electrical testers.
WARRANTY AND MAINTENANCE		
39	Warranty	3 years recommended (2 years at least), the product shall be in production and fully supported when procured.
40	Maintenance tasks	Preventive maintenance, safety checks and functionality tests at least once per year.

41	Type of service contract	Not required.
42	Spare parts availability post-warranty	8 years in total, including the warranty period.
43	Software/hardware upgrade availability	N/A
DOCUMENTATION		
44	Documentation requirements	User and maintenance manuals, hard and soft copies, to be supplied in local language, or agreed other language if local not available. English version must also be available. Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration and routine maintenance. List to be provided of common spares and accessories, with part numbers. Contact details of manufacturer, supplier and local service agent to be provided.
DECOMMISSIONING		
45	Estimated life span	10 years.
SAFETY AND STANDARDS		
46	Risk classification	N/A
47	Regulatory approval/ certification	Product must be approved by the FDA, CE, IEEE, NFPA, OSHA and/or other internationally recognized regulatory body.
48	International standards	**Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is recommended, proof of compliance must be provided):** ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes or ISO 9001 Quality management systems – Requirements **Standards applicable to the product (where applicable, compliance to the last available version is recommended, proof of compliance must be provided):** IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. EN 61000-6-3 Electromagnetic compatibility (EMC). Generic standards. Emission standard for residential, commercial and light-industrial environments. EN 61000-6-1 Electromagnetic compatibility (EMC). Generic standards. Immunity for residential, commercial and light-industrial environments. EN 50561-1 Power line communication apparatus used in low-voltage installations. Radio disturbance characteristics. Limits and methods of measurement. Apparatus for in-home use. EN 61558-2 Safety of transformers, reactors, power supply units and similar products for supply voltages up to 1100 V. IEC 60065 Audio, video and similar electronic apparatus – Safety requirements. IEC 61643-11 Low-voltage surge protective devices. Telcordia Technologies technical reference TR-NWT-001011. ANSI/IEEE C62.xx series. IEEE-1100 Powering and grounding electronic equipment. NFPA 780 Lightning protection systems. UL 1449 Standard for surge protective devices. EN 62305 Lightning protection. AS/NZS 1768 Lightning protection. UL 60950-1 Information technology equipment – Safety – Part 1: General requirements.
49	Regional/local standards	Country-specific and regional standards apply and must be listed.
50	Regulations	Country-specific and regional regulations apply and must be listed.

Table A1.13: Technical specifications for surge suppressors

MEDICAL DEVICE SPECIFICATION (These technical specifications are generic and have been developed according to the latest available commercial products. They should be adapted to the setting where the product will be used (voltage, language, accessories, connectors etc.)		
i	Version number	1
ii	Date of initial version	
iii	Date of last modification	
iv	Date of publication	September 2019
v	Completed/ submitted by	UNICEF, WHO
NAME, CATEGORY AND CODING		
1	WHO category/code	
2	Generic name	Surge suppressor.
3	Specific type or variation (optional)	Multiple socket.
4	GMDN name	Not in GMDN database.
5	GMDN code	Not in GMDN database.
6	GMDN category	
7	UMDNS name	Not in UMDNS database.
8	UMDNS code	Not in UMDNS database.
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Surge protector, surge diverter.
11	Alternative code/s (optional)	N/A
12	Keywords (optional)	Surge suppressor, spike, transient, noise, power supply, electrical supply.
13	GMDN/UMDNS definition (optional)	N/A
PURPOSE OF USE		
14	Clinical or other purpose	The surge suppressor, or surge protection, device is an electrical device installed in the power distribution panel, or between the mains power supply and the electrical equipment, to provide protection against surges, spikes and other dangerous voltage fluctuations, including lightnings. The device works absorbing or redirecting to the ground connection the energy, and protects the connected devices by cutting off the power supply. The secondary plugged surge suppressor is a device that can be easily installed between the electrical socket and the equipment, the latter plug in directly into the surge suppressor. These models of surge suppressor can be single or multisocket and provide adequate protection for few pieces of equipment plugged, limited by the number of available sockets and by the total power capacity of the device. Compared with the wired surge suppressor, integrated in the electrical panel, the plugged models are not fixed and do not require specialized installation. They are the best solution for protecting single electrical sockets or individual pieces of equipment in most cases.
15	Level of use (if relevant)	Health post; health centre; district/general hospital; regional hospital, secondary care; specialized hospital, tertiary care; home care.
16	Clinical department/ ward (if relevant)	All sites where electric equipment, requiring mains power supply and sensitive to surges, spikes and fluctuations, is installed.
17	Overview of functional requirements	Plugged surge suppressor, with multiple protected output sockets, hospital grade. Suitable for installation between the standard mains power supply and the connected electrical devices. Solid state electronics. Thermal protection/fuse against catastrophic failure. Single phase, available for 110–120 VAC and 220–240 VAC networks, 50–60 Hz. Availability of multiple capacities and configurations. Availability of various configurations and connections to fit all electrical standards for networks and equipment.

TECHNICAL CHARACTERISTICS		
18.1	Detailed requirements	Solid state electronic, plugged surge suppressor. Single phase, with grounding connection. Multiple socket type, (2, 3 or 4 sockets), with plug and socket designs locally compatible. 110–120 VAC and 220–240 VAC nominal input voltage (depending upon local requirements). Frequency range at least 50–60 Hz ± 10%. Safety circuit breaker (thermal protection/fuse or equivalent protection) against overload. Spike, surge, transient and lightning protection. Suitable for short-term overload working conditions. Maximum current rating > 13 A. Protective modes L-N, L-E and N-E. IEC rating lightning surge protection Type III or better. Hospital grade classification. Response time < 20 ns. Maximum surge/spike current discharge > 6 kA. Energy rating > 400 J. Power cord length > 1.5 m. Integrated overall power switch required to cut power to all sockets.
18.2	Configurations/ options	Multisocket version. Stand alone enclosure preferred, allowing free standing on table or floor. Optional radio frequency (RFI) and data/phone/network protection. Customizable plug (inlet) and sockets (outlets) matching all commercial electrical standards (i.e. but not limited to, European/German, British, French, American, Australian, Indian).
19	Displayed parameters	Optional voltage/current display.
20	User adjustable settings	Individual socket power switches (if applicable).
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components (if relevant)	Surge suppressor body, sockets, switches, fuses, power cable and plug.
22	Mobility, portability (if relevant)	Portable.
23	Raw materials (if relevant)	N/A
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	The requirements for power input voltage/frequency and plug type of the equipment must be chosen according to the local electrical supply. Electrical protection by resettable circuit breakers in both live and neutral supply lines. Grounding connection in the mains power network shall be assessed and verified, because it severely affects the surge suppressor efficacy.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	Power cables, plugs and sockets, matching the applicable electric standard in the installation site.
26	Sterilization/ disinfection process for accessories (if relevant)	N/A
27	Consumables/ reagents (if relevant)	N/A
28	Spare parts (if relevant)	Set of spare fuses and circuit breakers (if non-resettable fuses are used). Sockets, switches, fuses/circuit breakers, plug, power cable, external housing.
29	Other components (if relevant)	N/A
PACKAGING		
30	Sterility status on delivery (if relevant)	Non sterile.
31	Shelf life (if relevant)	N/A
32	Transportation and storage (if relevant)	Sealed container. Capable of being transported and stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non condensing. Specific requirements for altitude may be required, depending on the installation site.

33	Labelling (if relevant)	Primary packaging: Unit of use: one (1) surge suppressor in a box or case or bag with manufacturer's instruction for use, spare parts and accessories (when applicable). Labelling on the primary packaging: Name and/or trademark of the manufacturer; manufacturer's product reference; type of product and main characteristics; lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (if applicable); information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol); information for handling, if applicable(or equivalent harmonized symbol). Over packaging: Packaging unit. Labelling on the packaging unit: Labelling to be the same as primary packaging. Extra information required: number of units.
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Capable of being stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non condensing. Suitable for continuous operation in ambient temperature of at least 5–45 °C, relative humidity of at least 15–90% non condensing. Specific requirements for altitude may be required, depending on the installation site.
TRAINING, INSTALLATION AND UTILIZATION		
35	Pre-installation requirements (if relevant)	Compatibility with the electrical system (design and specifications).
36	Requirements for commissioning (if relevant)	Recommended that the supplier performs installation, safety and operation checks before handover. Local technical staff to affirm completion of installation.
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided upon request. Training of technical staff in advanced maintenance tasks shall be provided upon request.
38	User care (if relevant)	Pre-use checks. Proper connection, avoid ungrounded outlet, do not use with extension cords or adapters not providing connection to ground. Avoid exceeding the maximum power output. Cleaning with compatible products. Periodic functionality and electrical safety checks with electrical testers.
WARRANTY AND MAINTENANCE		
39	Warranty	3 years recommended (2 years at least), the product shall be in production and fully supported when procured.
40	Maintenance tasks	Preventive maintenance, safety checks and functionality tests at least once per year.
41	Type of service contract	Not required.
42	Spare parts availability post-warranty	8 years in total, including the warranty period.
43	Software/hardware upgrade availability	N/A
DOCUMENTATION		
44	Documentation requirements	User and maintenance manuals, hard and soft copies, to be supplied in local language, or agreed other language if local not available. English version must also be available. Certificate of inspection to be provided. List to be provided of equipment and procedures required for functionality and safety checks and for maintenance. List to be provided of common spares and accessories, with part numbers. Contact details of manufacturer, supplier and local service agent to be provided.
DECOMMISSIONING		
45	Estimated life span	10 years.

SAFETY AND STANDARDS		
46	Risk classification	N/A
47	Regulatory approval/ certification	Product must be approved by the FDA, CE, IEEE, NFPA, OSHA and/or other internationally recognized regulatory body.
48	International standards	**Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is recommended, proof of compliance must be provided):** ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes or ISO 9001 Quality management systems – Requirements. **Standards applicable to the product (where applicable, compliance to the last available version is recommended, proof of compliance must be provided):** IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 61643-11 Low-voltage surge protective devices – Part 11: Surge protective devices connected to low-voltage power systems – Requirements and test methods (replaces IEC 61643-1). IEC 61643-21 Low voltage surge protective devices – Part 21: Surge protective devices connected to telecommunications and signalling networks – Performance requirements and testing methods. IEC 61643-22 Low-voltage surge protective devices – Part 22: Surge protective devices connected to telecommunications and signalling networks – Selection and application principles. UL 1449 Standard for surge protective devices. Telcordia Technologies technical reference TR-NWT-001011. ANSI/IEEE C62.xx, including (but not limited to) C62.72 Application of surge devices for low voltage AC circuits, C62.47 Electrostatic discharge, C62.41.2 Recommended practice on characterization of surges in low voltage. IEEE-1100 Powering and grounding electronic equipment. NFPA 780 Lightning protection systems. EN 62305 Lightning protection. AS/NZS 1768 Lightning protection. UL 60950-1 Information technology equipment – Safety – Part 1: General requirements.
49	Regional/local standards	Country-specific and regional standards apply and must be listed.
50	Regulations	Country-specific and regional regulations apply and must be listed.

Table A1.14: Technical specifications for electrochemical (galvanic cell) oxygen analysers

MEDICAL DEVICE SPECIFICATION (These technical specifications are generic and have been developed according to the latest available commercial products. They should be adapted to the setting where the product will be used (voltage, language, accessories, connectors etc.)		
i	Version number	1
ii	Date of initial version	
iii	Date of last modification	
iv	Date of publication	September 2019
v	Completed/ submitted by	UNICEF, WHO
NAME, CATEGORY AND CODING		
1	WHO category/code	
2	Generic name	Oxygen analyser, electrochemical.
3	Specific type or variation (optional)	Battery-powered, handheld.
4	GMDN name	Respiratory oxygen monitor, battery-powered.
5	GMDN code	46049
6	GMDN category	
7	UMDNS name	Analysers, Environmental/gas system, Oxygen.
8	UMDNS code	23713
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Oxygen tester, oxygen monitor.
11	Alternative code/s (optional)	N/A
12	Keywords (optional)	Oxygen analyser, tester, medical gas, respiratory care.
13	GMDN/UMDNS definition (optional)	GMDN A battery-powered instrument designed to continuously measure the concentration of oxygen (O_2) inspired by a patient in a respiratory maintenance/therapy setting (e.g. oxygen in an anaesthesia or ventilator breathing circuit, oxygen tent, oxygen therapy device/system tubing). It typically consists of an electronic unit with a display to show actual values of percentage of oxygen concentration, a sensor to detect the oxygen values, control knobs or buttons, and an alarm to alert when oxygen values are beyond a predetermined range. UMDNS Environmental/gas system analysers designed to measure and display the concentration of oxygen in a sample of gas. These analysers are typically portable units based in one of several technologies, including the use of the paramagnetic properties of oxygen and in the creation of zirconia oxygen electrolytic cells. Oxygen environmental/gas system analysers are used to determine oxygen concentrations in closed and/or open air conditions, frequently in contaminated atmospheres; they can usually measure in a range from 0–100%, but devices intended only for accurate measuring of very small concentrations of oxygen are also available.
PURPOSE OF USE		
14	Clinical or other purpose	The oxygen analyser measures the oxygen concentration in a flow of gas from a medical gas source or, with adapters, through a medical gas flow device such as a ventilator or anaesthesia system, or within an environment such as oxygen hood and infant incubator.
15	Level of use (if relevant)	Health centre; district/general hospital; regional hospital, secondary care; specialized hospital, tertiary care; emergency vehicles; home care.
16	Clinical department/ ward (if relevant)	All departments where oxygen supply is available and oxygen/respiratory support and therapy are provided. The oxygen analyser should be provided also to technical/maintenance departments.
17	Overview of functional requirements	Handheld oxygen analyser, displays the oxygen concentration measured in the flow of gas or the environment. Electrochemical cell oxygen sensing technology. Some products or versions are suitable for pressure and flow measurements. Operates from commercial batteries.

TECHNICAL CHARACTERISTICS		
18.1	Detailed requirements	**Operational characteristics:** Handheld oxygen analyser for spot check and/or continuous measurement of the oxygen concentration from a medical gas source and in an environment (depending on the configuration or version of the analyser). Galvanic fuel cell (electro-chemical) oxygen sensing technology. Supplied with connectors and/or adapters suitable for measurement of various medical gas supply sources, for example (but not limited to) oxygen concentrators, ventilators/anaesthesia machines and patient circuits (T-piece and/or in-line adapters), wall/column/cylinder supplies (compliance with ISO 7396-1). Oxygen measurement to include the range: 15–99%. Oxygen resolution: 0.1%. Oxygen accuracy: within ± 3%. Suitable for measuring gas supply with pressure up to 345 kPa (3.5 bar, 50 psi). Performance and calbration requirements at different pressures to be stated. Response time ≤ 20 s. Warm-up time < 10 s. Replaceable galvanic fuel cell (oxygen sensor), nominal operating life ≥ 1.5 years or 600 000 %O_2-hours, whichever is greater. Calibration and self-test mode, two point calibration at ambient and 100% oxygen concentration. Internal calibration timer, with reminder (alarm and/or display message). Display visualizing oxygen concentration, system messages and battery status. Low and high oxygen concentration audible and visual alarms required. Automatic power-off when not in use. Enclosure to have ingress protection level IPX1 or better. **Electrical characteristics:** Operated by battery power supply. Internal replaceable batteries, either rechargeable or single use. Battery life > 250 hours continuous use.
18.2	Configurations/ options	Suitability for environmental measurements, such as oxygen hood or infant incubator, in addition to the measure of the oxygen concentration in a gas flow from a gas supply source. Suitability for continuous measurement (monitoring), with automatic power-off disabling. Suitability for rechargeable batteries (in this case the recharging unit shall be supplied together with the equipment).
19	Displayed parameters	Oxygen concentration, battery and system status, alarms.
20	User adjustable settings	Alarms.
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components (if relevant)	Casing, display, control panel, electronic board, battery holder and access door, connection ports, probe, battery charger. Equipment and reusable accessories/probes suitable for cleaning and disinfection with hospital grade detergents. Display must allow easy viewing in all ambient light levels.
22	Mobility, portability (if relevant)	Portable.
23	Raw materials (if relevant)	N/A
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	For the battery charger (if applicable). External or built-in AC battery charger, if rechargeable type. Charger, if used, to have protection against over-voltage and over-current line conditions, and be certified to IEC 60601-1. The requirements for power input voltage/frequency and plug type of the equipment must be chosen according to the local electrical supply. Depending on the local electrical supply availability and quality, voltage corrector/stabilizer/UPS can be recommended, in order to allow operation at ± 30% of local rated voltage, providing also protection for over current events. Electrical protection by resettable circuit breakers in both live and neutral supply lines.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	Carry case. Adapters for measuring various medical gas supply sources/ambient air (if applicable, depending on the models). Adapters for all available standards for fittings, including T-pieces and/or in-line adapters for various types and sizes of breathing circuits and adapters for central supply systems and cylinders.
26	Sterilization/ disinfection process for accessories (if relevant)	Suitable for cleaning and disinfection.
27	Consumables/ reagents (if relevant)	Oxygen galvanic fuel cell, batteries (disposable and/or rechargeable).

28	Spare parts (if relevant)	Oxygen cell/sensor, sample line (if applicable), rechargeable and disposable batteries. Sample line (if applicable) Set of spare fuses (if non-resettable fuses are used), display, connectors, battery holder, control panel, casing, battery charger.
29	Other components (if relevant)	N/A
PACKAGING		
30	Sterility status on delivery (if relevant)	Non sterile.
31	Shelf life (if relevant)	> 3 years for the oxygen galvanic fuel cell.
32	Transportation and storage (if relevant)	Sealed container. Capable of being transporterd and stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non condensing. Specific requirements for altitude may be required, depending on the installation site.
33	Labelling (if relevant)	Primary packaging: Unit of use: one (1) oxygen analyser in a box or case or bag with manufacturer's instruction for use, spare parts and accessories (when applicable). Labelling on the primary packaging: Name and/or trademark of the manufacturer; manufacturer's product reference; type of product and main characteristics; lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (if applicable); information for particular storage conditions(temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol); information for handling, if applicable (or equivalent harmonized symbol). Over packaging: Packaging unit. Labelling on the packaging unit: Labelling to be the same as primary packaging. Extra information required: number of units.
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Capable of being stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non condensing. Suitable for continuous operation in ambient temperature of at least 5–45 °C, relative humidity of at least 15–90% non condensing. Specific requirements for altitude may be required, depending on the installation site.
TRAINING, INSTALLATION AND UTILIZATION		
35	Pre-installation requirements (if relevant)	Electrical power supply (if battery charger is used). Check compatibility with the voltage and frequency.
36	Requirements for commissioning (if relevant)	Local clinical and technical staff to affirm completion of installation. Certificate if calibration supplied with the equipment.
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided upon request. Training of technical staff in advanced maintenance tasks shall be provided uopn request.
38	User care (if relevant)	Pre-use checks and calibration in ambient air. Proper connection. Cleaning with compatible products. Periodic functionality checks and preventive maintenance, certified calibration.
WARRANTY AND MAINTENANCE		
39	Warranty	2 years recommended (1 year at least), the product shall be in production and fully supported when procured.
40	Maintenance tasks	Preventive maintenance, functionality tests and calibration as per manufacturer's specifications and at least once per year.
41	Type of service contract	Not required.
42	Spare parts availability post-warranty	8 years at least, starting from the installation.
43	Software/hardware upgrade availability	N/A

DOCUMENTATION		
44	Documentation requirements	User and maintenance manuals, hard and soft copies, to be supplied in local language, or agreed other language if local not available. English version must also be available. Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration and routine maintenance. List to be provided of common spares and accessories, with part numbers. Contact details of manufacturer, supplier and local service agent to be provided.
DECOMMISSIONING		
45	Estimated life span	10 years.
SAFETY AND STANDARDS		
46	Risk classification	Class II (USA), Class IIa (EU), Class IIa or IIb (Australia).
47	Regulatory approval/ certification	Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).
48	International standards	**Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is recommended, proof of compliance must be provided):** ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes or ISO 9001 Quality management systems – Requirements. ISO 14971 Medical devices – Application of risk management to medical devices. **Standards applicable to the product (where applicable, compliance to the last available version is recommended, proof of compliance must be provided):** ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen. IEC 62133 – Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells. Part 1: Nickel, Part 2: Lithium.
49	Regional/local standards	Country-specific and regional standards apply and must be listed.
50	Regulations	Country-specific and regional regulations apply and must be listed. Compliance to (where applicable, but not limited to, and last available version): **US regulations:** 21 CFR part 820. 21CFR part 868.1720 Oxygen gas analyzer. **EU regulations:** Regulation (EU) 2017/745. **Japan regulations:** MHLW Ordinance No. 169. 12855000 Oxygen administration kit.

Table A1.15: Technical specifications for ultrasonic oxygen analysers

MEDICAL DEVICE SPECIFICATION (These technical specifications are generic and have been developed according to the latest available commercial products. They should be adapted to the setting where the product will be used (voltage, language, accessories, connectors etc.)		
i	Version number	1
ii	Date of initial version	
iii	Date of last modification	
iv	Date of publication	September 2019
v	Completed/ submitted by	UNICEF, WHO
NAME, CATEGORY AND CODING		
1	WHO category/code	
2	Generic name	Oxygen analyser, ultrasonic.
3	Specific type or variation (optional)	Battery-powered, handheld.
4	GMDN name	Respiratory oxygen monitor, battery-powered.
5	GMDN code	46049
6	GMDN category	
7	UMDNS name	Analysers, Environmental/gas system, Oxygen.
8	UMDNS code	23713
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Oxygen tester, oxygen monitor.
11	Alternative code/s (optional)	N/A
12	Keywords (optional)	Oxygen analyser, tester, medical gas, respiratory care.
13	GMDN/UMDNS definition (optional)	GMDN A battery-powered instrument designed to continuously measure the concentration of oxygen (O_2) inspired by a patient in a respiratory maintenance/therapy setting (e.g. oxygen in an anaesthesia or ventilator breathing circuit, oxygen tent, oxygen therapy device/system tubing). It typically consists of an electronic unit with a display to show actual values of percentage of oxygen concentration, a sensor to detect the oxygen values, control knobs or buttons, and an alarm to alert when oxygen values are beyond a predetermined range. UMDNS Environmental/gas system analysers designed to measure and display the concentration of oxygen in a sample of gas. These analysers are typically portable units based in one of several technologies, including the use of the paramagnetic properties of oxygen and in the creation of zirconia oxygen electrolytic cells. Oxygen environmental/gas system analysers are used to determine oxygen concentrations in closed and/or open air conditions, frequently in contaminated atmospheres; they can usually measure in a range from 0–100%, but devices intended only for accurate measuring of very small concentrations of oxygen are also available.
PURPOSE OF USE		
14	Clinical or other purpose	The oxygen analyser measures the oxygen concentration in a flow of gas from a medical gas source or, with adapters, through a medical gas flow device such as a ventilator or anaesthesia system.
15	Level of use (if relevant)	Health centre; district/general hospital; regional hospital, secondary care; epecialized hospital, tertiary care; emergency vehicles; home care.
16	Clinical department/ ward (if relevant)	All departments where oxygen supply is available and oxygen/respiratory support and therapy are provided. The oxygen analyser should be provided also to technical/maintenance departments.
17	Overview of functional requirements	Handheld oxygen analyser, displays the oxygen concentration measured in the flow of gas or the environment. Ultrasonic oxygen sensing technology. Some products or versions are suitable for pressure and flow measurements. Operates from commercial batteries.

TECHNICAL CHARACTERISTICS		
18.1	Detailed requirements	**Operational characteristics:** Handheld oxygen analyser for continuous measurement of the oxygen concentration from a medical gas source. Ultrasonic oxygen sensing technology. Supplied with connectors and/or adapters suitable for measurement of various medical gas supply sources, for example (but not limited to) oxygen concentrators, ventilators/anaesthesia machines and patient circuits (T-piece and/or in-line adapters), wall/column/cylinder supplies (compliance with ISO 7396–1). Oxygen measurement to include the range: 21–96%. Oxygen resolution: 0.1%. Oxygen accuracy: within ± 3%. Response time < 30 s. Warm-up time < 15 s. Suitable for measuring gas supply with pressure up to 345 kPa (3.5 bar, 50 psi). Self-calibration in typical conditions of use. Display visualizing oxygen concentration, flow rate, system messages and battery status. Automatic power-off when not in use. Enclosure to have ingress protection level IPX1 or better. **Electrical characteristics:** Operated by battery power supply. Internal replaceable batteries, either rechargeable or single use. Battery life > 250 hours continuous use.
18.2	Configurations/ options	Optional: measurement of the gas supply pressure (nominal values): Pressure range 0–345 kPa (0–3.5 bar, 0–50 psi). Pressure resolution 1 kPa (0.01 bar, 0.1 psi). Pressure accuracy within ± 3%. Suitability for measurement of the gas supply flow (nominal values): Flow range up to at least 10 L/min. Flow resolution 0.1 L/min. Flow accuracy within ± 3%.
19	Displayed parameters	Oxygen concentration, battery and system status, alarms, pressure and flow (depending on the product's configuration or version).
20	User adjustable settings	Alarms and units (depending on the product's configuration or version).
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components (if relevant)	Casing, display, control panel, electronic board, battery holder and access door, connection ports, probe, battery charger. Equipment and reusable accessories/probes suitable for cleaning and disinfection with hospital grade detergents. Display must allow easy viewing in all ambient light levels.
22	Mobility, portability (if relevant)	Portable.
23	Raw materials (if relevant)	N/A
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	For the battery charger (if applicable): External or built-in AC battery charger, if rechargeable type. Charger, if used, to have protection against over-voltage and over-current line conditions, and be certified to IEC 60601-1. The requirements for power input voltage/frequency and plug type of the equipment must be chosen according to the local electrical supply. Depending on the local electrical supply availability and quality, voltage corrector/stabilizer/UPS can be recommended, in order to allow operation at ± 30% of local rated voltage, providing also protection for over-current events. Electrical protection by resettable circuit breakers in both live and neutral supply lines.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	Carry case. Adapters for measuring various medical gas supply sources/ambient air (if applicable, depending on the models). Adapters for all available standards for fittings, including T-pieces and/or in-line adapters for various types and sizes of breathing circuits and adapters for central supply systems and cylinders.
26	Sterilization/ disinfection process for accessories (if relevant)	Suitable for cleaning and disinfection.
27	Consumables/ reagents (if relevant)	Batteries (disposable and/or rechargeable).

28	Spare parts (if relevant)	Sample line (if applicable), rechargeable and disposable batteries. Set of spare fuses (if non-resettable fuses are used), display, connectors, battery holder, control panel, casing, battery charger.
29	Other components (if relevant)	N/A
PACKAGING		
30	Sterility status on delivery (if relevant)	Non sterile.
31	Shelf life (if relevant)	N/A
32	Transportation and storage (if relevant)	Sealed container. Capable of being transported and stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non condensing. Specific requirements for altitude may be required, depending on the installation site.
33	Labelling (if relevant)	Primary packaging: Unit of use: one (1) oxygen analyser in a box or case or bag with manufacturer's instruction for use, spare parts and accessories (when applicable). Labelling on the primary packaging: Name and/or trademark of the manufacturer; manufacturer's product reference; type of product and main characteristics; lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (if applicable); information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol); information for handling, if applicable (or equivalent harmonized symbol). Over packaging: Packaging unit. Labelling on the packaging unit: Labelling to be the same as primary packaging. Extra information required: number of units.
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Capable of being stored in ambient temperature of at least 5–50 °C, relative humidity of at least 15–95% non condensing. Suitable for continuous operation in ambient temperature of at least 5–45 °C, relative humidity of at least 15–90% non condensing. Specific requirements for altitude may be required, depending on the installation site.
TRAINING, INSTALLATION AND UTILIZATION		
35	Pre-installation requirements (if relevant)	Electrical power supply (if battery charger is used). Check compatibility with the voltage and frequency.
36	Requirements for commissioning (if relevant)	Local clinical and technical staff to affirm completion of installation. Certificate if calibration supplied with the equipment.
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided upon request. Training of technical staff in advanced maintenance tasks shall be provided upon request.
38	User care (if relevant)	Pre-use checks and calibration in ambient air. Proper connection. Cleaning with compatible products. Periodic functionality checks and preventive maintenance, certified calibration.
WARRANTY AND MAINTENANCE		
39	Warranty	2 years recommended (1 year at least), the product shall be in production and fully supported when procured.
40	Maintenance tasks	Preventive maintenance, functionality tests and calibration as per manufacturer's specifications and at least once per year.
41	Type of service contract	Not required.
42	Spare parts availability post-warranty	8 years at least, starting from the installation.
43	Software/hardware upgrade availability	N/A

DOCUMENTATION		
44	Documentation requirements	User and maintenance manuals, hard and soft copies, to be supplied in local language, or agreed other language if local not available. English version must also be available. Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration and routine maintenance. List to be provided of common spares and accessories, with part numbers. Contact details of manufacturer, supplier and local service agent to be provided.
DECOMMISSIONING		
45	Estimated life span	10 years.
SAFETY AND STANDARDS		
46	Risk classification	Class II (USA), Class IIa (EU), Class IIa or IIb (Australia).
47	Regulatory approval/ certification	Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification (e.g. by a founding member of IMDRF – EU, USA, Canada, Australia, Japan).
48	International standards	**Standards applicable to the manufacturer and the manufacturing process (compliance to the last available version is recommended, proof of compliance must be provided):** ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes or ISO 9001 Quality management systems – Requirements. ISO 14971 Medical devices – Application of risk management to medical devices. **Standards applicable to the product (where applicable, compliance to the last available version is recommended, proof of compliance must be provided):** ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen. IEC 62133 – Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells. Part 1: Nickel, Part 2: Lithium.
49	Regional/local standards	Country-specific and regional standards apply and must be listed.
50	Regulations	Country-specific and regional regulations apply and must be listed. Compliance to (where applicable, but not limited to, and last available version): **US regulations:** 21 CFR part 820. 21CFR part 868.1720 Oxygen gas analyzer. **EU regulations:** Regulation (EU) 2017/745. **Japan regulations:** MHLW Ordinance No. 169. 12855000 Oxygen administration kit.

Annex 2: Comparison of pulse oximetry and blood gas analysis

Factor to be considered	Pulse oximetry	Arterial blood gas analyser (co-oximeter)
Pain and distress to patient.	Minor discomfort from sensor probe.	Needle prick for blood sample could be painful and distressing to patient.
Sampling procedure.	Non-invasive.	Invasive.
Risk to staff.	Nil.	Potential for needlestick injury.
Suitability for monitoring.	Continuous or regular spot checks. At bedside.	Not suitable/possible for continuous monitoring. Information for a single time point only.
Cost (initial, running and maintenance).	Low to moderately expensive plus moderate recurrent costs (sensor probes).	Moderately expensive plus high recurrent costs for reagents and maintenance.
Operator skill required.	Use and interpretation can be taught to trained nurses and health care workers.	High level of laboratory expertise and skill in clinical interpretation.
Indication of ventilation adequacy.	Does not provide information on alveolar ventilation nor oxygen delivery to the tissues.	Yes.
Indication of acid-base state or electrolytes.	No.	Yes.
Major sources of error.	• Poor perfusion. • Movement artefact. • Greater margin of machine error at lower SpO_2. • Cannot distinguish carboxyhaemoglobin from oxyhaemoglobin.	• Uncooperative patient. • Clotted specimen. • Air in syringe. • Laboratory handling.
Infrastructure and power requirement.	Handheld type is portable and DC powered (battery). AC power is required for tabletop type and for recharging batteries.	More space required. Reliable and continuous power source required.
Level of biomedical engineering maintenance required.	Low.	Medium.
Calibration requirement.	No.	Yes.

Notes

Notes

Notes

For further information contact:

Medical Devices
Medicines and Health Products Department
World Health Organization
20 Avenue Appia, 1211 Geneva 27, Switzerland
Tel +41 22 791 1239
Email medicaldevices@who.int
www.who.int/medical_devices

Product Innovation Centre
UNICEF Supply Division
United Nations Children's Fund
Oceanvej 10–12, 2150 Copenhagen, Denmark
Tel +45 45 33 55 00
Email innovateforchildren@unicef.org
www.unicef.org/supply

ISBN 978 92 4 151691 4