सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

Ministry of Health & Family Welfare
Goverment of India

Technical Specifications of Medical Devices for EMERGENCY RESPONSE SYSTEMS

Ministry of Health & Family Welfare
Goverrntment of India

Technical Specifications of Medical Devices for EMERGENCY RESPONSE SYSTEMS

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन
भानु प्रताप शर्मा
सचिव
B.P. SHARMA
Secretary

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health and Family Welfare

Dated : 29th April, 2015

MESSAGE

Ministry of Health and Family Welfare in its endeavor to achieve highest standards of health for the people has undertaken several programmatic and institutional strengthening measures. National Health Mission is one such programmatic intervention aimed at improved overall health with special focus in energizing rural health infrastructure and services. Providing essential medical equipment is a critical component of strengthening health infrastructure. However, rapidly changing technologies, complexity associated with medical equipment and high costs of procurement - all these make selection of appropriate and cost effective equipment a challenging task. I am happy to note that National Health Systems Resource Centre (NHSRC) under the guidance of experts and with active participation of stakeholders have developed technical specifications of commonly procured medical devices to facilitate procurements by State / UT Governments. I am sure that you will find these very helpful. The specifications are suggestive and we have tried to keep them generic. However, we would welcome any suggestions for further improvement in these specifications.

(B.P. Sharma)

कमरा नं 156, ए-स्कंध, निर्माण भवन, नई दिल्ली-110011
Room No. 156, A-Wing, Nirman Bhawan, New Delhi-110011
Tele : (O) 011-23061863, Fax : 011-23061252, E-mail : secyhfw@gmail.com

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

C.K. Mishra, IAS
Additional Secretary &
Mission Director, NHM
Telefax : 23061066, 23063809
E-mail : asmd-mohfw@nic.in

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011
GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI-110011

MESSAGE

Under National Health Mission, support is being provided to all States/UTs for improving quality of health services and improving necessary infrastructure including medical equipment. Providing for adequate, safe and appropriate medical equipment at all levels of public health facilities remains a focus for the Government. Given the challenges of procurement it is necessary to have generic specifications for medical equipment. Cost, utility, availability in domestic market, maintenance and patient safety are crucial issues to be considered while procuring medical devices. I am pleased to note that these have been adequately considered by NHSRC while preparing the specifications. Keeping them as reference specifications while undertaking procurement will reduce costs of procurement, maintenance problems and procurement lead time. I am happy to note that NHSRC, has filled in an important technical gap by providing these specifications and I am sure that technical specifications suggested here will serve as a reference for procurement of medical devices under the National Health Mission.

We would be happy to have your valuable suggestion on improving these.

(C.K. Mishra)

New Delhi
29th April, 2015

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

Manoj Jhalani, IAS
Joint Secretary
Telefax : 23063687
E-mail : manoj.jhalani@nic.in

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली – 110011
GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI - 110011

31st April 2015

MESSAGE

National Health Systems Resource Centre which is also a WHO collaborating centre for priority medical devices & health technology policy; in consultation with users, care providers, engineers, medical technologists and representatives from medical devices manufacturers association has formulated technical specifications for commonly used medical devices. Specifications are suggestive in nature and any specific requirement needs to be incorporated at the time of procurement. However having well deliberated specification at one place should considerably reduce the procurement cost & time and improve quality of procurement.extensively. The specifications suggested herein are an outcome of several rounds of consultations with experts, user clinicians & care providers, medical technologists & engineers and industry stake holders. While effort has been made to make the specifications as generic as possible and consensus and technical appropriateness has been the corner stone of this technical exercise. We would welcome suggestions from the States.

(Manoj Jhalani)

Acknowledgement

Medical devices are a very important part of health care and their use is increasing by the day. Technical specifications play an important role in identification, selection and procurement of appropriate and cost effective medical devices. Consistency and standardization in technical specifications promotes positive competition and reduces effective costs. It also promotes uniformity in user training and smooth maintenance of equipment. In order to address the variation in technologies many of which could be add-ons, separate exercises were undertaken for specific categories of medical devices procured under National Health Mission. The experts consulted for specifications formulation exercises included clinicians, medical technologists, maintenance experts and also representatives from manufactures' industry associations. Specifications for medical devices for Special Neonatal Care Units, Neonatal and Pediatric Care Units, Ambulances, Operation Theatre for district sub-district levels, Rashtriya Bal Suraksha Karyakaram, Laboratory & Radiology equipment, Skill laboratory program are an outcome of intense participation, deliberation, technical research and inputs from experts. These include experts from prestigious institutions such as AIIMS, PGIMER-Chandigarh, RML Hospital, Safdarjung Hospital, Sree Chitra Institute of Medical Sciences & Technology, Central Scientific Instrument Organisation, Hindustan Life Care Limited, IITs, to name a few. Overall review by DGHS provided further validation to the technical work. Division of Healthcare Technology, NHSRC being the technical secretariat for this work played a pivotal role and names of following professionals deserve special mention: Jitendar Sharma, Mohammad Ameel, Anurag, Swati Barwala, Prabhat Arora, Kavita Kachroo, Akriti Chahar, Pankaj Parashar, Prashant Tiwari, Ashfaq Ashraf and Anjanaya. I am sure that specifications confirming to adequate standards of safety and accuracy shall be immensely useful for the states in undertaking appropriate and cost effective procurement of medical devices.

Dr. Sanjiv Kumar
Executive Director

SUCTION PUMP PORTABLE

Version no. :		1.0
Date:		5/8/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Suction systems
GMDN code		CT1272
GMDN definition		An assembly of devices designed to evacuate fluid, tissue, gas, or other foreign materials from a body cavity or lumen by means of suction. It generally consists of a mains electricity (AC-powered) suction pump, tubing, plastic/glass collection container(s), a vacuum gauge, a vacuum control knob, an overflow trap, a moisture filter, and possibly a microbial filter. The pump creates a vacuum in the suction tubing, which is inserted into the body for the removal of materials into the collection container. This system can be used in a wide variety of settings within healthcare facilities.
GENERAL		
1. USE		
1.1	**Clinical purpose**	To aspirate fluids, secretions, or other foreign materials from a patient's airway by means of suction.
1.2	**Used by clinical department/ ward**	All
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	0-760 mm Hg ± 10 regulable, 1/2 HP; single phase 1440 RPM motor; flutter free vacuum control knob,; Wide mouthed 2 x 2 LITRE (Polycarbonate) with self sealing bungs and mechanical over flow safety device.
2.2	**Settings**	Manual
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication (where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Max: 43 x 30 x 68 cms
3.2	**Weight (lBS, kg)**	Max: 27Kg
3.3	**Configuration**	NA
3.4	**Noise (in DBA)**	50 dB A ± 3
3.5	**Heat dissipation**	Should maintain upto 36.5 deg temp and the heat disbursed through a exhaust fan.
3.6	**Mobility, portability**	Yes
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	220 V, 50 Hz, 2 ± 0.5 Amps, 370 watts.

4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	Voltage corrector / stabilizer to allow operation at ± 30% of local rated voltage. Use of SMPS to correct voltage.
4.4	**Protection**	Electrical protection by resettable overcurrent breakers or replaceable fuses, fitted in both live and neutral lines.
4.5	**Power consumption**	200W
4.6	**Other energy supplies**	NA
	5. CCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & Spares**	Collection container & its cap, suctions tube tips, a vacuum gauge and control knob.
5.2	**Consumables / reagents (open, closed system)**	Tubing:8 mm ID x 2 mtr (PVC), 2x2 lt polycarbonate jar.
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.
	7. STANDARDS AND SAFETY	
7.1	**Certifications**	FDA /CE 1023, ISO 13485:2003; ISO 10079-1-1999; IEC 60601-1-8-2006; IEC 60601-1-SER-Ed 1.0-2011; IEC/TRF 60601-1-8-Ed 4.0-2010.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Avalability of 15 amp socket, safety and operation checks before handover.
8.2	**Requirements for sign-off**	Certificate of Calibration and inspection from the factory.
8.3	**Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)**	Training of users in operation and basic maintenance shall be provided
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	3 years
9.2	**Maintenance tasks**	Maintainance manual detailing complete maintaining schedule
9.3	**Service contract clauses, including prices**	Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented. User, technical and maintenance manuals to be supplied in english language along with machine diagrams. List to be provided of equipment and procedures required for local calibration and routine maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**	Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared

SUCTION PUMP, FOOT OPERATED

Version no. :		1.0
Date:		5/8/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Emergency suction systems
GMDN code		CT2180
GMDN definition		A portable assembly of devices primarily intended to be used by emergency medical services (EMS) to aspirate fluids, secretions, or other foreign materials from a patient's airway by means of suction. It typically consists of a manually-powered (hand or foot-operated) mechanism to drive the suction pump, tubing, a collection container, a vacuum gauge and control knob, and a microbial filter. The pump creates a vacuum in the suction tubing, which is used for the removal of materials into the collection container. This system is typically used during patient transport or for emergency situations.
GENERAL		
1. USE		
1.1	**Clinical purpose**	To aspirate fluids, secretions, or other foreign materials from a patient's airway by means of suction.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	0-600 mm Hg ± 10 mm regulable, flutter free vacuum control knob.
2.2	**Settings**	Manual
2.3	**User's interface**	Manual
2.4	**Software and/ or standard of communication (where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Max spec: 32 x 17 x 30 cms
3.2	**Weight (LBS, kg)**	2.5kg max
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	50 dB A ± 3
3.5	**Heat dissipation**	NA
3.6	**Mobility, portability**	Yes
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA

4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & spare parts**	Collection bottles, a vacuum gauge.
5.2	**Consumables / reagents (open, closed system)**	microbial filter, tubing.
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.
	7. STANDARDS AND SAFETY	
7.1	**Certifications**	FDA/CE 1023, ISO 13485:2003; ISO 10079-2-1999.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)**	Training of users in operation and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	3 years
9.2	**Maintenance tasks**	Maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation.
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented User, technical and maintenance manuals to be supplied in english language along with machine diagrams. List to be provided of equipment and procedures required for local calibration and routine maintenance
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared.

LARYNGOSCOPE

Version no. :		Laryngoscope 2.0
Date:		5-Aug-13
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Laryngoscopes
GMDN code		CT1723
GMDN definition		A non-sterile, portable, battery-powered device intended to provide the light source for a laryngoscope (i.e., rigid intubation type) when fitted into the laryngoscope handle. It typically consists of a removable cylindrical cell that produces light which is emitted from the laryngoscope handle via a fibreoptic laryngoscope blade for airway illumination. The device may be kinetically or electrically recharged. This is a reusable device.
GENERAL		
1. USE		
1.1	**Clinical purpose**	For viewing vocal folds and glottis. Surgical and mechanical ventilation/ intubation.
1.2	**Used by clinical department/ward**	O.T / ICU / NICU/ Casuiality.
1.3	**Overview of functional requirements**	A light source on or via the blade illuminates the larynx to allow viewing and tube passage. The unit is handheld with internal batteries and has interchangeable, rigid blades of different sizes.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	Fiber optic Laryngoscope- preferably should be reusable using the latest LED technology. The main body of the handle should incorporate an excellent grip & should feel even wearing a glove. There should be a freely moving light intensifier of light from the light source through to the tip of the fiber optic blade to prevent any possibility of cross contamination. The unit should allow the blade to be inserted easily & should provide a positive locking mechanism when moved in to the closed position.
2.2	**Settings**	NA
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication(where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	Light weight (upto 500 gms)
3.3	**Configuration**	Handheld unit, single piece when in use; On/off switch to be robust and easy to use; External material to be non-ferrous; Blades to be surgical grade stainless steel; Supplied in protective, reclosable container

3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	Yes
3.6	**Others**	storage box should be provided
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	**Power Requirements**	Independent of external source
4.2	**Battery operated**	Internal batteries, rechargeable preferred Battery charger (if rechargeables), Battery compartment (if reusables) to be sealed against liquid ingress, yet easily opened.
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	3V lithium battery; 2nos.
4.6	**Other energy supplies**	
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)**	Batteries, blades of various neonatal sizes
5.2	**Spare parts (main ones)**	Handle
5.3	**Consumables / reagents (open, closed system)**	3 bulbs/3LED should be given as spare
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. Liquid splash resistant. Blades should be autoclavable.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Should be autoclavable
	7. STANDARDS AND SAFETY	
7.1	**Certificates**	FDA/CE; ISO 7376:2009 gives general requirements for laryngoscopes used for intubation, and specifies critical dimensions for the handle and lamp of hook-on type laryngoscopes. It also addresses the interchangeability of blades and handles.
7.3	**Local and/or international**	Manufacturer / supplier should have ISO certificate for quality standard.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	NA
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	3 years ; LED upto 6 months
9.2	**Maintenance tasks**	Autoclave

9.3	**Service contract clauses, including prices**	NA
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented. User, technical and maintenance manuals to be supplied in english language along with machine diagrams. List to be provided for procedures required for routine maintenance.
10.2	**Other accompanying documents**	NA
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared

FLOWMETER WITH HUMIDIFIER BOTTLE

Version no. :		1.0
Date:		6/8/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Flowmeter and associated device
GMDN code(s)		CT 623
GMDN definition		NA
GENERAL		
1.USE		
1.1	**Clinical purpose**	Flow meter unit is used for regulation and accurate measuring of flow of gasses
1.2	**Used by clinical department/ward**	All
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	Flowmeter: chromium plated brass body, metering tube and cover made of polycarbonate body, flow adjustment by needle valve equiped with inlet filter -100 um, flow rate 0-15 liters per minute, flush flow 60 litres per minute, flow read by the centre of the ball, inlet pressure 60psi; Humidifier bottle: lid made of ABS plastic, Jar made of unbreakable Poly carbonate, valve pressure brass cromium plated, it should be steam autoclaved/ gas sterilised
2.3	**Settings**	To manage flow of oxygen through the knob from 0 to 15 LPM
2.4	**User's interface**	Manual
2.5	**Software and/or standard of communication(where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	For 200ml
3.2	**Weight (lbs, kg)**	As per standard
3.3	**Configuration**	NA
3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	Yes
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA

4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & Spares**	Stainless steel or brass chromium needle valve and outlet flow control valve
5.3	**Consumables / reagents (open, closed system)**	Crack resistant transparent tube of 1.5 MT. length
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	NA
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.
	7. STANDARDS AND SAFETY	
7.1	**Certifications**	Complies with NFPA standard ; CE
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Availability of oxygen outlet points
8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	NA
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	One year
9.2	**Maintenance tasks**	Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.
9.3	**Service contract clauses, including prices**	NA
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	NA
10.2	**Other accompanying documents**	NA
10.3	**Recommendations for maintenance**	NA
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations or warnings**	NA

OXYGEN CYLINDER "B" TYPE

Version no. :		1.0
Date:		5/8/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Oxygen cylinder
GMDN code		CT 659
GMDN definition		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 O_2 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 O_2 content. The cylinder may be made of steel, aluminium (Al) or other ferrous or non-ferrous materials and must be used together with a pressure regulator in order to release the O_2 at the correct working pressure. O_2 is used as an essential life support gas, for anaesthesia, and for therapeutic purposes.
GENERAL		
1. USE		
1.1	**Clinical purpose**	A container designed as a refillable cylinder used to hold compressed medical oxygen (O_2) under safe conditions at high pressure; O_2 is used as an essential life support gas, for anaesthesia, and for therapeutic purposes.
1.2	**Used by clinical department/ward**	All
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Color coded, light weight. Aluminum alloy oxygen cylinder for providing oxygen therapy of total capacity of 4 cu M. 2. Mounted with pressure reducer and flow-meter provision of capacity upto 15 Liters per minutes and outlet for secretion aspiration. 4. Should have membrane pressure reducer with manometer complete with flow meter (0-15 liters /minute) and humidifier bottle. 5. should be seamless cylinder of water capacity 10 liters.
2.2	**Settings**	Flowmeter for controlling unflow of oxygen.
2.3	**User's interface**	Manual
2.4	**Software and/ or standard of communication(where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	To contain capacity of 4 cu M.
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	Yes; on its trolley; for Ambulances - to be supplied bare without trolley.

4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories & Spares**	humidifier, key and flow meter
5.3	**Consumables / reagents (open, closed system)**	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	NA
7. CERTIFICATES (pre-market, sanitary, ..)		
7.1	**Certifications**	Cylinder should have ISI mark and ISO certificate for quality standard or BIS equivalent; IS 3224. Cylinder should have explosive safety certificate and should be provided along with each cylinder during installation.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Certificate of Calibration,PESO Certificate and inspection from the factory.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	10 years
9.2	**Maintenance tasks**	NA
9.3	**Service contract clauses, including prices**	NA
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	NA
10.2	**Other accompanying documents**	NA
10.3	**Recommendations for maintenance**	NA
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations or warnings**	Color Codes to be displayed on the cylinders.

OXYGEN CYLINDER "D" TYPE

Version no. :		1.0
Date:		3/8/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Medical gas cylinders
GMDN category Code		CT 659
GMDN definition		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 O_2 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 O_2 content. The cylinder may be made of steel, aluminium (Al) or other ferrous or non-ferrous materials and must be used together with a pressure regulator in order to release the O_2 at the correct working pressure. O_2 is used as an essential life support gas, for anaesthesia, and for therapeutic purposes
GENERAL		
1. USE		
1.1	**Clinical purpose**	A container designed as a refillable cylinder used to hold compressed medical oxygen (O_2) under safe conditions at high pressure; O_2 is used as an essential life support gas, for anaesthesia, and for therapeutic purposes.
1.2	**Used by clinical department/ward**	All
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. It should be a standard 'D' type molybdenum steel cylinder. 2. The capacity should be of approx 7 cu mt. at pressure of 1800 - 2000ibs/square inch. 3. A pressure regulator/flow meter capable of reducing the pressure to appropriate level to run either a ventilator or provide oxygen therapy. 4. should be seamless.
2.2	**Settings**	flowmeter for controlling flow of oxygen.
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication(where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	The capacity should be of 5000 to 6000 Liters at pressure of 1800 - 2000ibs/ square inch.
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	Yes; on its trolley; for Ambulances - to be supplied bare without trolley.

4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories & Spares**	Humidifier, key and flow meter.
5.3	**Consumables / reagents (open, closed system)**	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	NA
7. CERTIFICATES (pre-market, sanitary, ..)		
7.1	**Certifications**	Cylinder should have ISI mark and ISO certificate for quality standard or BIS equivalent; IS 3224. Cylinder should have explosive safety certificate and should be provided along with each cylinder during installation
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Certificate of Calibration, PESO certificate and inspection from the factory.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	10 years
9.2	**Maintenance tasks**	NA
9.3	**Service contract clauses, including prices**	NA
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	NA
10.2	**Other accompanying documents**	NA
10.3	**Recommendations for maintenance**	NA
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations or warnings**	Color Codes to be displayed on the cylinders.

ARTIFICIAL MANUAL BREATHING UNIT (ADULT)

Version no. :		1.0
Date:		6/8/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Resuscitators
GMDN code		CT 1899
GMDN definition		A hand-operated device designed to provide or assist ventilation in patients who are apnoeic or exhibit inadequate respiration. It typically employs entrained ambient air and includes a large flexible chamber that is hand-ventilated, a gas reservoir, tubing, and a connector for attachment to a mask or endotracheal (ET) tube; oxygen (O_2) from an O_2 source may also be connected when necessary. It is used by emergency medical services (EMS) in ambulances, intensive care units (ICU), during internal patient transfer, accident and emergency (A&E), mass casualty incidents (MCI), and is generally placed strategically throughout a hospital. This is a reusable device.
GENERAL		
1. USE		
1.1	**Clinical purpose**	to provide or assist ventilation in a patient who is apnoeic or exhibits inadequate respiration through manual pulmonar-driven pressure cycle functions.
1.2	**Used by clinical department/ward**	It is used in ambulances, intensive care units (ICU), during internal patient transfer, accident and emergency (A&E), and mass casualty incidents (MCI).
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1. Easy Grip manual resuscitator with transparent face-mask; 2. Adult models (1500 to 2000ml bag capacity); 3. Standard 15-22 mm Swivel connector allows connections to all common masks Endotracheal Tubes; 4. Provision to give supplemented oxygen-by-oxygen reservoir providing 100% oxygen; 5. Non-re breathing valve enabling the patient to inspire oxygen from the reservoir bag.
2.2	**Settings**	Manual
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication(where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Hanheld
3.2	**Weight (lbs, kg)**	light enough to be operated by hand/palm for long duration.
3.3	**Configuration**	NA
3.4	**Noise (in dBA), heat dissipation**	NA

3.5	**Mobility, portability**	Handheld
3.6	**Others**	
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & Spares**	Silicon bellow, Non Rebreathing Valve,
5.2	**Consumables / reagents (open, closed system)**	Adult Mask, 1 meter oxygen tube, Guedel Airway, Oxygen Reservoir bag.
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.
	7. STANDARDS AND SAFETY	
7.1	**Certifications**	ISO 13485; CE Certified product.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	1 Year
9.2	**Maintenance tasks**	NA
9.3	**Service contract clauses, including prices**	NA
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	NA
10.2	**Other accompanying documents**	NA
10.3	**Recommendations for maintenance**	NA
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations or warnings**	NA

ARTIFICIAL MANUAL BREATHING UNIT (CHILD & NEONATAL)

Version no. :		1.0
Date:		6/8/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Resuscitators
GMDN code		CT1899
GMDN definition		A hand-operated device designed to provide or assist ventilation in patients who are apnoeic or exhibit inadequate respiration. It typically employs entrained ambient air and includes a large flexible chamber that is hand-ventilated, a gas reservoir, tubing, and a connector for attachment to a mask or endotracheal (ET) tube; oxygen (O_2) from an O_2 source may also be connected when necessary. It is used by emergency medical services (EMS) in ambulances, intensive care units (ICU), during internal patient transfer, accident and emergency (A&E), mass casualty incidents (MCI), and is generally placed strategically throughout a hospital. This is a reusable device.
GENERAL		
1. USE		
1.1	**Clinical purpose**	To provide or assist ventilation in a patient who is apnoeic or exhibits inadequate respiration through manual pulmonar-driven pressure cycle functions.
1.2	**Used by clinical department/ward**	It is used in ambulances, intensive care units (ICU), during internal patient transfer, accident and emergency (A&E), and mass casualty incidents (MCI).
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1. Easy Grip manual resuscitator with transparent face-mask; 2. Child models (500 to 250ml bag capacity); 3. Standard 15-22 mm Swivel connector allows connections to all common masks Endotracheal Tubes; 4. Provision to give supplemented oxygen-by-oxygen reservoir providing 100% oxygen; 5. Non-re breathing valve enabling the patient to inspire oxygen from the reservoir bag.
2.2	**Settings**	Manual
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication(where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Handheld
3.2	**Weight (lbs, kg)**	Light enough to be operated by hand/palm for long duration.
3.3	**Configuration**	NA

3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	Handheld
3.6	**Others**	
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & Spares**	Silicon bellow, Non Rebreathing Valve.
5.2	**Consumables / reagents (open, closed system)**	Adult Mask, Oxygen Reservoir bag, 1 meter oxygen tube, Guedel Airway.
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.
	7. STANDARDS AND SAFETY	
7.1	**Certifications**	ISO 13485; CE Certified product.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform installation, safety and operation checks before handover.
8.2	**Requirements for sign-off**	Certificate of Calibration and inspection from the factory.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	1 Year
9.2	**Maintenance tasks**	NA
9.3	**Service contract clauses, including prices**	NA
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	NA

10.2	**Other accompanying documents**	NA
10.3	**Recommendations for maintenance**	NA
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations or warnings**	NA

TROLLEY STRETCHER- WITH BACK TILT FACILITY AND COLLAPSIBLE WHEELS FOR UPLOADING INTO THE TROLLEY

Version no. :		1.0
Date:		8/11/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Ambulance stretcher, manual
GMDN code(s)		CT1934
GMDN definition		A manually-operated device consisting of a platform mounted on a wheeled frame designed for use by emergency medical services (EMS) primarily to facilitate easy transport of a recumbent patient to and from ambulance vehicles (e.g., automobiles, aeroplanes, helicopters, boats). It is typically constructed of lightweight materials and has an undercarriage that opens and folds when it is removed from or pushed into the ambulance; it also usually includes locking devices that match with the locking/docking devices in the ambulance.
GENERAL		
1. USE		
1.1	**Clinical purpose**	It is designed for use by emergency medical services (EMS) primarily to facilitate easy transport of a recumbent patient to and from ambulance vehicles.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Automatic loading stretcher with capability to convert into wheelchair. 2. Built with anodized aluminum lightweight / stainless steel. 3. Adjustable back rest 0 dg -90 dg which allows to fix the back rest safety in any position. 4. Side protections completely overturn able with easy locking safety belts flap type. 5. Safety lever for the legs positioned near the unlocking device allowing thus the release operation for the loading, keeping the hands on the stretcher. 6. Vertical legs protected by nylon wedges. 7. Automatic centering device mounted on rotating wheels. This system automatically blocks the back wheels in the central position during the loading of the stretcher on the ambulance without having turn the wheels manually. 8. Stand for automatic loading stretcher with locking facility for quick fixing system with handle to mount the stand in very position on the stretcher. 9. One number of IV pole of adjustable height should be provided.
2.2	**Settings**	NA
2.3	**User's interface**	NA

2.4	**Software and/or standard of communication(where ever required)**	NA
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	Length; 190-210 cm; Width: 50-60cm; Height: 80-85cm.
3.2	**Weight (lbs, kg)**	Weight 35-45 kg; Load bearing Capacity: upto 200 kgs.
3.3	**Configuration**	NA
3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	yes on castors
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)**	Stand for loading stretcher
5.2	**Spare parts (main ones)**	Castors,Safety lever
5.3	**Consumables / reagents (open, closed system)**	NA
5.4	**Others**	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	NA
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..)Performance and safety standards (specific to the device type);Local and/or international**	ISO 13485, CE;Manufacturer / supplier should have ISO certificate for quality standard or BIS equivalent. CE certified product. The stretcher shall not fail or release when subjected to a force of 2200 pounds applied in logitudinal. Lateral or vertical direction. The fixation system shall hold the device to withstand accelerations or decelerations of 10 g longitudinal (forward, backward), 10 g, transverse (left, right) and 10 g vertical. Rails if used should comply with ISO 19054.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform safety and operation checks before handover.
8.2	**Requirements for sign-off**	Certificate of inspection from the factory.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.

9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years + 3 years CAMC
9.2	**Maintenance tasks**	Maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Required- alongwith diagramatic maintainance manual.
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	Should provide complete contact details of sales and service departments.
11.2	**Recommendations or warnings**	Any warning should be displayed.

CANVAS STRETCHER FOLDING

Version no. :		1.0
Date:		6/8/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Stretchers and associated devices.
GMDN category		CT 674
GMDN definition		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	It is designed for use by emergency medical services (EMS) primarily to facilitate easy transport of a recumbent patient to and from ambulance vehicles.
1.2	**Used by clinical department/ward**	All
1.4	**Overview of functional requirements**	
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Should be lightweight and made up of tubular alluminium alloy. 2. Should be easy to carry. 3. Should be rugged. 4. Should be compact & foldable. 5. Should have automatic locking, which does not fold in automatically.
2.2	**Settings**	NA
2.3	**User's interface**	NA
2.4	**Software and/or standard of communication(where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Length: 190-210 cm; Width: 50-60cm; Height: 13-20cm from the base level.
3.2	**Weight (lbs, kg)**	5 kg. to 6 kg.
3.3	**Configuration**	NA
3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	Yes
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA

4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)**	None
5.2	**Spare parts (main ones)**	None
5.3	**Consumables / reagents (open, closed system)**	None
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	NA
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ...); Performance and safety standards (specific to the device type); Local and/or international**	ISO 13485; CE
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform safety and operation checks before handover.
8.2	**Requirements for sign-off**	Certificate of inspection from the factory.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	1 years
9.2	**Maintenance tasks**	Maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented. User, technical and maintenance manuals to be supplied in english language along with machine diagrams. List to be provided for procedures required for routine maintenance.
10.2	**Other accompanying documents**	
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared.

STRETCHER SCOOP

Version no. :		1.0
Date:		6/8/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Stretchers and associated devices
GMDN code(s)		CT 674
GMDN definition		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	It is most frequently used to lift supine patients from the ground, either due to unconsciousness or in order to maintain stability in the case of trauma, especially spinal injury, where it is used as an intermediate step between the ground and a restraining device such as a long spine board or vacuum mattress.
1.2	**Used by clinical department/ward**	Emergency.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. The equipment shall be lightweight aluminum/Polymer stretcher, which folds into two and separates for application and removal, locking adjustable length with latches-with nylon-straps 2. Narrow foot end frame for handling in confined areas. 3. Should be X-ray and MRI Compatible.
2.3	**Settings**	NA
2.4	**User's interface**	Manual
2.5	**Software and/or standard of communication(where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Length: 160 to 200 cms; Width: 42 cm (Minimum);
3.2	**Weight (lbs, kg)**	Weight: < 11 kg; Load bearing capacity - upto 150 kg.
3.3	**Configuration**	NA
3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	Yes
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA

4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)**	NA
5.2	**Spare parts (main ones)**	NA
5.3	**Consumables / reagents (open, closed system)**	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	NA
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	NA
	7. STANDARDS AND SAFETY	
7.1	**Certifications**	ISO 13485; FDA/CE
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform safety and operation checks before handover.
8.2	**Requirements for sign-off**	Certificate of inspection from the factory.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	5 years
9.2	**Maintenance tasks**	Maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented. User, technical and maintenance manuals to be supplied in english language along with machine diagrams. List to be provided for procedures required for routine maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost.
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared.

BP INSTRUMENT ANEROID

Version no. :		1.0
Date:		8/5/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Sphygmomanometers
GMDN code(s)		CT1677
GMDN definition		A device designed to measure blood pressure consisting of an inflatable cuff that fits around a limb (arm or thigh), an inflation bulb for controlling the air pressure within the cuff, an aneroid manometer, and tubing. The aneroid manometer consists of a metal bellows, which expands as the pressure in the cuff increases, and a mechanical amplifier that transmits this expansion through a lever to an indicator needle, which rotates around a circular, calibrated scale. The manometer may be mounted to a wall, placed on a table, or hand held (portable); blood pressure measurement is taken in conjunction with a stethoscope.
GENERAL		
1. USE		
1.1	**Clinical purpose**	To measure non invasive blood pressure.
1.2	**Used by clinical department/ward**	All
1.4	**Overview of functional requirements**	
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	Scale 0-300 mm hg. Air release at closed lap with maximum 4mmHg/Minute. Manual setting of deflation possible upto 2/3mm Hg/sec. From 260mmHg. To 15mm Hg in a maxium deflation time of 10 seconds. Gauge's background in white colour. Graduated scale for ever/ 2mmhg, every 10 units and every 20 units. Nylon straps cuff with pouch, latex bulb with completely chromium plated valve with regulation of vent-hole air by screw valve.
2.2	**Settings**	The cuff is inflated just to fit in the limb for which an inflation bulb is used to control the air pressure within the cuff.
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication(where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	The rubber tubes used should have an internal diameter of 3 ± 0.5mm and the external diameter should not be less than 8mm; The dial mano meter with minimum diameter of 160 mm.
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	Yes

4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional)**	Adult arm cuffs of size medium & large and paediatric size, inflation bulb, tubing.
5.2	**Spare parts (main ones)**	Dial mano meter.
5.3	**Consumables / reagents (open, closed system)**	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	NA
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ...); Performance and safety standards (specific to the device type); Local and/or international**	ISO 13485;
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform safety and operation checks before handover.
8.2	**Requirements for sign-off**	Certificate of inspection from the factory.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1 years
9.2	**Maintenance tasks**	Maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	User, technical and maintenance manuals to be supplied in english language along with machine diagrams. List to be provided for procedures required for routine maintenance.
10.2	**Other accompanying documents**	
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations or warnings**	Any recommendations for best use and supplimentary warning for safety should be declared.

STETHOSCOPE

Version no. :		1.0
Date:		8/5/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Stethoscopes
GMDN code(s)		CT1930
GMDN definition		A mechanical listening device designed for listening to sounds from the heart, lungs, and/or gastrointestinal tract. It typically comprises a membrane at the listening head connected by a split "Y" tube to the headgear with ear olives that are placed into the users ears. Mechanical stethoscopes are typically found in two variants 1) a general-purpose stethoscope used for clinical/ward activities; or 2) a reinforced stethoscope used by cardiologists.
GENERAL		
1. USE		
1.1	**Clinical purpose**	Listening to sounds from the heart, lungs, and/or gastrointestinal tract.
1.2	**Used by clinical department/ward**	All
1.3	**Overview of functional requirements**	
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	Stethoscope of standard size, chromium plated metal binaural, V rubber tube in one piece. Rotating piper fitting for both flip functions.
2.2	**Settings**	NA
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication(where ever required)**	NA
2.5	**Others**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Diaphragm approx: 20 mm.
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA

4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories& Spares**	1 x spare set of earpiece, 1 x spare diaphram.
5.2	**Consumables / reagents (open, closed system)**	NA
5.3	**Others**	NA
	BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	NA
6.3	**Others**	NA
	7. STANDARDS AND SAFETY	
7.1	**Certifications**	By ISO 9001 certified manufacturer.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	NA
8.4	**Others**	NA
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	1 year
9.2	**Maintenance tasks**	NA
9.3	**Service contract clauses, including prices**	NA
9.4	**Others**	NA
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	NA
10.2	**Other accompanying documents**	NA
10.3	**Recommendations for maintenance**	NA
10.4	**Others**	NA
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations or warnings**	NA

PNEUMATIC SPLINTS

Version no. :		1.0
Date:		8/5/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Splints
GMDN code(s)		CT665
GMDN definition		A non-sterile sleeve intended to be placed around an arm or leg and inflated to immobilize and protect the limb. It is typically used by Emergency Medical Services (EMS) as a temporary measure in emergencies, e.g., accidents and motor vehicle crashes, to stabilize the limb for transport to a hospital. This is a reusable device.
GENERAL		
1. USE		
1.1	**Clinical purpose**	To Immobalize the limb for transport to a hospital.
1.2	**Used by clinical department/ward**	Emergency Services.
1.3	**Overview of functional requirements**	
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. X-ray should be possible through the splints (Radio-tranparency); 2. Inflatory tubes' extension with dosing damp makes dosing easy and quick after inflation; 3. Fixing of splint is by zipper or belt; 4. Distal end left open to expose toes; 5. Should be washable and reusable;
2.3	**Settings**	Fixing of splint is by zipper or belt.
2.4	**User's interface**	Manual
2.5	**Software and/or standard of communication(where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Set of 6 adult sizes with carrying case: 1. Hand & Wrist. 2. Half arm. 3. Full arm. 4. Foot and ankle. 5. Half leg. 6. Full leg.

3.2	**Weight (lbs, kg)**	Light
3.3	**Configuration**	NA
3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	Yes
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)**	Inflatory tubes' extension.
5.2	**Spare parts (main ones)**	NA
5.3	**Consumables / reagents (open, closed system)**	NA
5.4	**Others**	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Should be washable and reusable
6.3	**Others**	Should be washable and reusable.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ...); Performance and safety standards (specific to the device type); Local and/or international**	ISO 9001
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	NA
8.4	**Others**	NA
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	1 year
9.2	**Maintenance tasks**	NA
9.3	**Service contract clauses, including prices**	NA
9.4	**Others**	NA

10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	NA
10.2	**Other accompanying documents**	NA
10.3	**Recommendations for maintenance**	NA
10.4	**Others**	NA
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations or warnings**	NA

GAUZE CUTTER

Version no. :		1.0
Date:		8/5/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Not found
GMDN code(s)		CT 2127
GMDN definition		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	To cut gauze lenghts for preparing bandages.
1.2	**Used by clinical department/ward**	All
1.4	**Overview of functional requirements**	
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	Scissors with thermoplastic handle and steel blade to cut clothes like materials; should be corrosion free.
2.3	**Settings**	NA
2.4	**User's interface**	Manual
2.5	**Software and/or standard of communication(where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Length: 18cm.
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	Yes
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA

5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional)**	NA
5.2	**Spare parts (main ones)**	NA
5.3	**Consumables / reagents (open, closed system)**	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	NA
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ...); Performance and safety standards (specific to the device type); Local and/or international**	ISO 9001
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform safety and operation checks before handover.
8.2	**Requirements for sign-off**	
8.3	**Training of staff (medical, paramedical, technicians)**	
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1 years
9.2	**Maintenance tasks**	NA
9.3	**Service contract clauses, including prices**	NA
9.4	**Others**	
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	NA
10.2	**Other accompanying documents**	NA
10.3	**Recommendations for maintenance**	NA
10.4	**Others**	
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations or warnings**	NA

ARTERY FORCEPS

Version no. :		1.0
Date:		8/5/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Forceps
GMDN code(s)		CT2065
GMDN definition		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	These are a handheld, hinged instrument used for grasping and holding objects.
1.2	**Used by clinical department/ward**	All
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	Standard instrument in stainless steel length 14 cm; corrosion free.
2.2	**Settings**	NA
2.3	**User's interface**	NA
2.4	**Software and/or standard of communication(where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Length 14 cm.
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	Yes
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional)**	NA

5.2	**Spare parts (main ones)**	NA
5.3	**Consumables / reagents (open, closed system)**	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	NA
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ...); Performance and safety standards (specific to the device type); Local and/or international**	ISO 9001
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform safety and operation checks before handover.
8.2	**Requirements for sign-off**	
8.3	**Training of staff (medical, paramedical, technicians)**	
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	1 years
9.2	**Maintenance tasks**	NA
9.3	**Service contract clauses, including prices**	NA
9.4	**Others**	
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	NA
10.2	**Other accompanying documents**	NA
10.3	**Recommendations for maintenance**	NA
10.4	**Others**	
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations or warnings**	NA

MAGILL'S FORCEP

Version no. :		1.0
Date:		6/8/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Forceps
GMDN code(s)		CT2065
GMDN definition		A hand-held instrument used for grasping a tube [e.g., a catheter or an endotracheal (ET) tube] for its insertion and/or extraction into/from the airways, or for grasping obstructive objects for their removal from the airways. Commonly known as a Magill's forceps, it typically has a scissors-like design with ring handles and is made of high-grade stainless steel. It is available in various sizes and the working end will typically have grasping blades that have small ringed loops or S-shaped distal working ends. The blades are serrated to provide extra grip. It is typically used by emergency medical services (EMS). This is a reusable device.
GENERAL		
1. USE		
1.1	**Clinical purpose**	Angled forceps used to guide a tracheal tube into the larynx or a nasogastric tube into the esophagus under direct vision. It is also used to place pharyngeal packs and remove foreign bodies.
1.2	**Used by clinical department/ward**	All
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	Standard instrument in stainless steel; corrosion free.
2.2	**Settings**	NA
2.3	**User's interface**	NA
2.4	**Software and/or standard of communication(where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	Yes
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA

4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)**	NA
5.2	**Spare parts (main ones)**	NA
5.3	**Consumables / reagents (open, closed system)**	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	NA
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ...); Performance and safety standards (specific to the device type); Local and/or international**	ISO 9001
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform safety and operation checks before handover.
8.2	**Requirements for sign-off**	
8.3	**Training of staff (medical, paramedical, technicians)**	
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	1 year
9.2	**Maintenance tasks**	NA
9.3	**Service contract clauses, including prices**	NA
9.4	**Others**	
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	NA
10.2	**Other accompanying documents**	NA
10.3	**Recommendations for maintenance**	NA
10.4	**Others**	
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations or warnings**	NA

CERVICAL COLLAR

Version no. :		1.0
Date:		8/5/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Disability-assistive products
GMDN code(s)		CT1000
GMDN definition		A padded device that is worn around the neck and used to support or immobilize the cervical spine to treat deformities, fractures, sprains, or strains (often to treat whiplash resulting from an automobile accident). This device will provide support to the head while limiting movement of the cervical vertebrae. It is available in a variety of sizes. This is a reusable device.
GENERAL		
1. USE		
1.1	**Clinical purpose**	Used to support or immobilize the cervical spine to treat deformities, fractures, sprains, or strains
1.2	**Used by clinical department/ward**	Trauma care; musculo-skeletal support
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Should be adjustable to 4 different sizes. Should be be rigid and not padded. 2. Should be pre-molded chin support, locking dips and rear ventilation panel, enlarged trachea opening. 3. Should be high-density polyethylene and foam padding with one piece design enables efficient storage where space is limited. 4. Should be X-ray lucent and easy to clean and disinfect.
2.3	**Settings**	Size adjustment.
2.4	**User's interface**	Manual
2.5	**Software and/or standard of communication(where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	As light as possible.
3.3	**Configuration**	NA
3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	NA

4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional)**	NA
5.2	**Spare parts (main ones)**	NA
5.3	**Consumables / reagents (open, closed system)**	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	NA
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	NA
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ...); Performance and safety standards (specific to the device type); Local and/or international**	ISO 9001
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform safety and operation checks before handover.
8.2	**Requirements for sign-off**	
8.3	**Training of staff (medical, paramedical, technicians)**	
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1 years
9.2	**Maintenance tasks**	NA
9.3	**Service contract clauses, including prices**	NA
9.4	**Others**	
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	NA
10.2	**Other accompanying documents**	NA

10.3	**Recommendations for maintenance**	NA
10.4	**Others**	
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations or warnings**	NA

FIRST AID BAG

Version no. :		1.0
Date:		6/8/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Emergency/First aid kits
GMDN code(s)		CT1279
GMDN definition		A portable, strong, hand-held container of plastic, fabric, or leather designed for transportation of small medical devices, instruments, and/or supplies. It typically includes attachments for easy handling and mechanisms for closure and/or locking; it may have the internal space appropriately configured according to the intended contents (e.g., stethoscopes, sphygmomanometers, drugs). It may be dedicated for a variety of purposes and/or users, including specialization for physicians, nurses, first aid providers, or paramedics. This is a reusable device.
GENERAL		
1. USE		
1.1	**Clinical purpose**	Used for transportation of small medical devices, instruments, and/or supplies.
1.2	**Used by clinical department/ward**	Emergency / First Aid.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	Bag with partitions for vials transport. Indispensable implement to protect and identify any kind of vials. Made with nylon, it should be provided with 2 compartments, of which one sub-divided in to 3 partitions and one divided in 2. Inside elastic band to fix the vials and accommodation for identification labels. Dimensions: 30x18 x 15 cm or Pre-packed kits as convenient as long as it contains the specified first aid items.
2.3	**Settings**	NA
2.4	**User's interface**	NA
2.5	**Software and/or standard of communication(where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Dimensions: 30x18 x 15 cm or Pre-packed kits as convenient as long as it contains the specified first aid items.
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	Yes
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA

4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)**	NA
5.2	**Spare parts (main ones)**	NA
5.3	**Consumables / reagents (open, closed system)**	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	NA
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	NA
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ...); Performance and safety standards (specific to the device type); Local and/or international**	ISO 9001:2008 supplier.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform safety and operation checks before handover.
8.2	**Requirements for sign-off**	
8.3	**Training of staff (medical, paramedical, technicians)**	
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	NA
9.2	**Maintenance tasks**	NA
9.3	**Service contract clauses, including prices**	NA
9.4	**Others**	
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	NA
10.2	**Other accompanying documents**	NA
10.3	**Recommendations for maintenance**	NA
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations or warnings**	NA

SPINAL BOARD

Version no. :		1.0
Date:		8/5/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Stretchers and associated devices
GMDN code(s)		CT674
GMDN definition		A flat, stiff device intended to be placed under a patient (the patient is usually strapped to this device) to ensure spinal immobilization when a spinal injury is suspected. This device is often used in combination with a head/neck immobilizing device that is also typically fixed or strapped to it. It is typically used after serious accidents and for transport of the patient on a stretcher. It is typically made of x-ray translucent/non-ferromagnetically active materials that allow x-ray and magnetic resonance imaging (MRI) and comes in various sizes. This is a reusable device.
GENERAL		
1. USE		
1.1	**Clinical purpose**	It is placed under a patient to ensure spinal immobilization when a spinal injury is suspected.
1.2	**Used by clinical department/ward**	Emergency/Trauma Care
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Should be in plastic material of high strength and waterproof. 2. It should be supplied with 3 belts with rapid unhooking buckle in all three belts. 3. Should have radio transparency to make radiologic examinations/x-rays without removing the patient from the board.
2.3	**Settings**	NA
2.4	**User's interface**	Manual
2.5	**Software and/or standard of communication(where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Length: 180 - 190cm; Breadth: 40 - 48cm ; Height: 5 to 7cm.
3.2	**Weight (lbs, kg)**	Weight: <6 kg; load bearing capacity: upto 150 kgs.
3.3	**Configuration**	NA
3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	Yes
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA

4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)**	NA
5.2	**Spare parts (main ones)**	NA
5.3	**Consumables / reagents (open, closed system)**	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	NA
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	NA
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ...); Performance and safety standards (specific to the device type); Local and/or international**	ISO 9001; FDA/CE
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform safety and operation checks before handover.
8.2	**Requirements for sign-off**	
8.3	**Training of staff (medical, paramedical, technicians)**	
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	1 year
9.2	**Maintenance tasks**	NA
9.3	**Service contract clauses, including prices**	NA
9.4	**Others**	
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	NA
10.2	**Other accompanying documents**	NA
10.3	**Recommendations for maintenance**	NA
10.4	**Others**	
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations or warnings**	NA

DOUBLE HEAD IMMOBILIZERS

Version no. :		1.0
Date:		6/8/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Immobilizers
GMDN code(s)		CT1818
GMDN definition		A rigid or non-rigid device, usually made of fabric and/or plastic materials, used to temporarily render the head/neck of a patient immovable to ensure immobilization when a head and/or spinal injury is suspected. It is used in conjunction with serious accidents and for transport of the patient on a stretcher and possibly in conjunction with a spinal board to which this device and the patient are strapped. It is typically made of x-ray translucent/non-ferromagnetically active materials that allow x-ray and magnetic resonance imaging (MRI) and comes in various sizes. This is a reusable device after appropriate cleaning.
GENERAL		
1. USE		
1.1	**Clinical purpose**	Used to temporarily render the head/neck of a patient immovable to ensure immobilization when a head and/or spinal injury is suspected.
1.2	**Used by clinical department/ward**	Emergency
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Head Immobilizer should be mountable and separable from the scoop stretcher. 2. Should be of standard side. 3. Should be with padded belts for the fixing. 4. It should be covered by a liquid proof and bacterial proof material.
2.2	**Settings**	NA
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication(where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Standard
3.2	**Weight (lbs, kg)**	Standard
3.3	**Configuration**	NA
3.4	**Noise (in dBA), heat dissipation**	NA

3.5	**Mobility, portability**	Yes
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)**	NA
5.2	**Spare parts (main ones)**	NA
5.3	**Consumables / reagents (open, closed system)**	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	NA
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	NA
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ...); Performance and safety standards (specific to the device type); Local and/or international**	ISO 9001; FDA/CE
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform safety and operation checks before handover.
8.2	**Requirements for sign-off**	
8.3	**Training of staff (medical, paramedical, technicians)**	
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	1 year
9.2	**Maintenance tasks**	NA
9.3	**Service contract clauses, including prices**	NA
9.4	**Others**	
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	NA
10.2	**Other accompanying documents**	NA

10.3	**Recommendations for maintenance**	NA
10.4	**Others**	
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations or warnings**	NA

FEOTAL DOPPLER

Version no. :		1.0
Date:		6/8/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Foetal Doppler system
GMDN code(s)		CT 2000
GMDN definition		A portable, hand-held, battery-powered device assembly consisting of a measuring and display unit and an attached probe or interchangeable probes designed to noninvasively detect foetal heart beats using ultrasound/Doppler technology. The heart beats are typically conveyed audibly via the measuring/ display unit and attached probe which is applied to the surface of the pregnant woman's abdomen. The device aids in determining foetal viability.
GENERAL		
1. USE		
1.1	**Clinical purpose**	To nonivasively detect foetal heart beats from the surface of the preganant women's abdomen.
1.2	**Used by clinical department/ward**	Emergency/gynae deptt.
1.3	**Overview of functional requirements**	
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	Water proof probes of 2MHz, 3MHz and 5 MHz frequency, Ultra sound Intensity ‹10mw/cm2, Auto Shut Off Facility to save Battery Power, Built-in Speaker, Volume Control Facility and Audio Output for Ear Phone, Heart Rate Range should be from 50 to 120 bpm with accuracy of + /-2%, Should be Water Proof Body, Should have Facility for FHR Data transfer to PC.
2.2	**Settings**	Setting of ultraound intensity.
2.3	**User's interface**	LCD display
2.4	**Software and/or standard of communication(where ever required)**	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Handheld
3.2	**Weight (lbs, kg)**	500 gm
3.3	**Configuration**	
3.4	**Noise (in dBA),**	Noise: <60dBA

3.5	**heat dissipation**	
3.6	**Mobility, portability**	Yes
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	**Power Requirements**	AA batteries
4.2	**Battery operated**	AA battery type; Minimum Battery Time of 300 minutes.
4.3	**Tolerance (to variations, shutdowns)**	± 10% of input AC.
4.4	**Protection**	Electrical protection by resettable overcurrent breakers or replaceable fuses, fitted in both live and neutral lines.
4.5	**Power consumption**	
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)**	Doppler probe, battery charger.
5.2	**Spare parts (main ones)**	
5.3	**Consumables / reagents (open, closed system)**	AA battery,
	BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..)**	FDA or CE or UL approved product. Type B or BF,
7.2	**Performance and safety standards (specific to the device type)**	Shall meet IEC-60601-1-2:2007 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Or Equivalent BIS).
7.3	**Local and/or international**	Manufacturer should be ISO 13485 certified
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform installation, safety and operation checks before handover.
8.2	**Requirements for sign-off**	Certificate of Calibration and inspection from the factory.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	Three years
9.2	**Maintenance tasks**	Maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	Local clinical staff to affirm completion of installation.

10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented. User, technical and maintenance manuals to be supplied in english language. List to be provided of equipment and procedures required for local calibration and routine maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	AMC/CAMC Details to be provided
11.2	**Recommendations or warnings**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.

PORTABLE HAND HELD GLUCOMETER

Version no. :		1.0
Date:		8/5/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Glucose self-testing
GMDN code(s)		CT296
GMDN definition		A collection of devices including a portable, battery-powered, semi-automated or automated instrument (self-testing meter), reagents, test strips and/or other associated materials and accessories [e.g., control solutions, lancets] intended to be used together for testing, either at the point-of-care or in self-testing by a layperson, for the quantitative measurement of glucose and/or ketones in a whole blood clinical specimen. Measured glucose values are used to manage blood glucose levels, primarily by persons with diabetes mellitus.
GENERAL		
1. USE		
1.1	**Clinical purpose**	It intended to be used together for testing, either at the point-of-care or in self-testing by a layperson, for the quantitative measurement of glucose and/or ketones in a whole blood clinical specimen.
1.2	**Used by clinical department/ward**	All
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	Should have reading range/linearity from 20 to 600 mg/dl; Should have a maximum reading time of less than 10 seconds; Should use a minimum blood sample less than 1.5µl; Should have a minimum memory of 50 tests;
2.2	**Settings**	Should have easy code entry technique and display of sugar in Mg/dl and NOT in mili moles.
2.3	**User's interface**	LCD display
2.4	**Software and/or standard of communication(where ever required)**	Inbulit; .Should have facility to ensure accuracy of measurements.
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Handheld device.
3.2	**Weight (lbs, kg)**	Handheld device.
3.3	**Configuration**	Should use electrochemical technology.
3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	Handheld.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	Battery powered.
4.2	**Battery operated**	3-volt lithium coin cell battery or 2 x (AAA) Alkaline Batteries.

4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	NA
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & Spare parts**	1 year
5.2	**Consumables / reagents (open, closed system)**	Glucose strips(able to use capillary blood samples) with availabilty in local market.
	BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS	
6	**ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS**	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	NA
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ...); Performance and safety standards (specific to the device type); Local and/or international**	FDA/CE
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	Required.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	1 year
9.2	**Maintenance tasks**	Should require no routine maintenance.
9.3	**Service contract clauses, including prices**	Should have life time replacement offer.
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Required
10.3	**Recommendations for maintenance**	to be provided during installation.
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	Should provide complete contact details of sales and service departments.
11.2	**Recommendations or warnings**	

NEBULIZER (ELECTRIC)

Version no. :		1.0
Date:		8/5/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Nebulizing systems
GMDN code(s)		CT1097
GMDN definition		An assembly of devices designed to generate warmed aerosolized medication/ fluids (finely dispersed airborne droplets in a liquid phase) intended to be inhaled by a patient with a respiratory disorder [e.g., chronic obstructive pulmonary disease (COPD), cystic fibrosis (CF)]. It will typically consist of an electrically-powered generator, a reservoir, a heating element, and a hand-held nebulizing chamber where the nebulization of the medicine usually takes place.
GENERAL		
1. USE		
1.1	**Clinical purpose**	Designed to generate warmed aerosolized medication/fluids (finely dispersed airborne droplets in a liquid phase) intended to be inhaled by a patient with a respiratory disorder.
1.2	**Used by clinical department/ward**	All
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	Medicine cup capacity of minimum 5 ml.
2.2	**Settings**	Manual
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication(where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Should be compact.
3.2	**Weight (lbs, kg)**	<2kg.
3.3	**Configuration**	
3.4	**Noise (in dBA), heat dissipation**	<60dBA
3.5	**Mobility, portability**	Yes
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	220 V AC + 10%, 50Hz power supply.
4.2	**Battery operated**	Rechargable battery (4.8 V nominal output).
4.3	**Tolerance (to variations, shutdowns)**	± 10% of input AC.

4.4	**Protection**	Electrical protection by resettable overcurrent breakers or replaceable fuses, fitted in both live and neutral lines
4.5	**Power consumption**	2Watt (nebulizing); 6.5 Watt (charging)
4.6	**Other energy supplies**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & Spares**	With necessary accessories- nebulization mask, tubing for nebulizer; cable cord
5.3	**Consumables / reagents (open, closed system)**	Aerosol/medicinal solutions
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary,)**	FDA/ CE ; ISO 27427-2010; IEC-60601-1-SER--Ed 1.0 - 2011
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform installation, safety and operation checks before handover.
8.2	**Requirements for sign-off**	Certificate of Calibration and inspection from the factory.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	3 Years
9.2	**Maintenance tasks**	Maintainance manual detailing complete maintaining schedule
9.3	**Service contract clauses, including prices**	Local clinical staff to affirm completion of installation
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented User, technical and maintenance manuals to be supplied in english language. List to be provided of equipment and procedures required for local calibration and routine maintenance
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.

BABY HYPOTHERMIA WRAP KIT

Version no. :		1.0
Date:		5/8/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Not found
GMDN code(s)		NA
GMDN definition		
GENERAL		
1. USE		
1.1	**Clinical purpose**	Low-birth-weight (LBW) premature infants are born without the adaptive mechanisms needed for survival outside of the womb. These fragile infants require thermoprotective interventions which is usually provided by hypothermia wrap kit.
1.2	**Used by clinical department/ward**	NICU/SNCU/Emergency
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	Light weight, AC/DC power driven heat generating kit with straps for holding the baby in position. Includes necessary protection in design for avoiding overheating. Should have temperature regulator.
2.3	**Settings**	Temperature range: from 35 to 38°C, accuracy +/- 0.5°C
2.4	**User's interface**	Safety alarms for high and low temperature DESIRABLE non-mandatory.
2.5	**Software and/or standard of communication(where ever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Just as to wrap the baby.
3.2	**Weight (lbs, kg)**	Minimum possible.
3.3	**Configuration**	NA
3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	Yes
3.6	**Others**	
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	220 to 240V, 50 Hz.
4.2	**Battery operated**	1 set of batteries (9 V type 6SR61) if DC compatible.
4.3	**Tolerance (to variations, shutdowns)**	± 10% of input AC.

4.4	**Protection**	Electrical protection by resettable overcurrent breakers or replaceable fuses, fitted in both live and neutral lines.
4.5	**Power consumption**	50 W
4.6	**Other energy supplies**	Can run on 12 - 24 volt battery or 110 - 240 volt AC.
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & Spares**	1 heating pad; 1 power cord main supply of length approximately 1m.
5.3	**Consumables / reagents (open, closed system)**	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Washable; could be cleaned using alcohol based disinfectant.
6.3	**Others**	
	7. STANDARDS AND SAFETY	
7.1	**Certifications**	FDA/CE/IEC 60601-1-2-2011 Part 1-2: General requirements for basic safety and essential performance.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform installation, safety and operation checks before handover.
8.2	**Requirements for sign-off**	Certificate of inspection from the factory.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	1 years
9.2	**Maintenance tasks**	Maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	Local clinical staff to affirm completion of installation.
9.4	**Others**	
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented. User, technical and maintenance manuals to be supplied in english language. List to be provided of equipment and procedures required for local calibration and routine maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.

DEFIBRILLATOR

Version no. :		1
Date:		5/8/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Automated external defibrillators
GMDN code(s)		CT269
GMDN definition		A portable electronic device designed to automatically detect cardiac arrhythmias (ventricular fibrillation/pulseless ventricular tachycardia) in a sudden cardiac arrest (SCA) patient, after which it audibly/visually instructs an operator to enable it to activate defibrillation of the heart through application of electrical shocks to the chest surface. The device is intended to be operated by healthcare professionals (e.g., paramedics, medical staff) in healthcare settings. It consists of an external pulse generator (EPG) and a pair of skin-adhesive electrodes to monitor the rhythm and deliver the shocks; it also includes internal rechargeable batteries that must be charged when not in use.
GENERAL		
1. USE		
1.1	**Clinical purpose**	To detect cardiac arrhythmias in a sudden cardiac arrest patient, and then audibly/visually instructs an operator to enable it to activate defibrillation of the heart through application of electrical shocks to the chest surface.
1.2	**Used by clinical department/ward**	Emergency/ICU/Cardiac care
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Unit should be lightweight compact and portable. 2. Unit should have facility for Automatic External Defibrillation and manual defibrillation. 3. Should be able to deliver shock from 50-200 joules in biphasic mode via metal chest pads. 4. Should having design protection to avoid passage of current to the user. 5. The whole system should have an inbuilt recorder; TELEMETRY NOT RECOMMENDED.
2.2	**Settings**	Manual AND Automatic.
2.3	**User's interface**	The monitor should have a TFT color display with a three channel display.
2.4	**Software and/or standard of communication(where ever required)**	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	Compact
3.2	**Weight (lbs, kg)**	<10kg
3.3	**Configuration**	

3.4	**Noise (in dBA), heat dissipation**	<60dBA; adjustable heart rate alarm as well as paddles & ECG cable disconnection alarms.
3.5	**Mobility, portability**	Yes
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	**Power Requirements**	220 to 240V, 50 Hz.
4.2	**Battery operated**	Rechargeable battery backup of approximately 5 hours.
4.3	**Tolerance (to variations, shutdowns)**	± 10% of input AC.
4.4	**Protection**	Electrical protection by resettable overcurrent breakers or replaceable fuses, fitted in both live and neutral lines.
4.5	**Power consumption**	Should not be more than 160 W.
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & Spares**	Chest paddles,
5.3	**Consumables / reagents (open, closed system)**	ECG cable; Recording paper rolls; Disposable pads;
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	NA
	7. STANDARDS AND SAFETY	
7.1	**Certifications**	FDA, CE ; IEC-60601-1-2:2007; IEC 60601-1-8-2006; IEC 60601-1-SER-Ed 1.0-2011; IEC/TRF 60601-1-8 Ed4.0-2010; ISO 13485.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform installation, safety and operation checks before handover.
8.2	**Requirements for sign-off**	Certificate of Calibration and inspection from the factory.
8.3	**Training of staff (medical, paramedical, technicians)**	NA
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	3 years
9.2	**Maintenance tasks**	Maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	Local clinical staff to affirm completion of installation.
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented. User, technical and maintenance manuals to be supplied in english language. List to be provided of equipment and procedures required for local calibration and routine maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
	11. NOTES	
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.

MONITOR

Version no. :		1.0
Date:		5/8/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Patient monitors/monitoring systems
GMDN code(s)		CT1444
GMDN category		Anaesthetic and respiratory devices , Electro mechanical medical devices
GMDN definition		A device assembly designed to continuously measure and display multiple vital physiological parameters of newborn and premature infants, especially those under critical care. It is typically capable of monitoring parameters such as electrocardiogram (ECG), respiration rate, heart rate, blood pressure, and body temperature; it may also assess haemoglobin oxygen saturation (SpO_2) through transcutaneous sensors that measure both transcutaneous oxygen ($tcpO_2$) and transcutaneous carbon dioxide ($tcpCO_2$) saturation. The system typically includes sensors with appropriate size and design for infant use.
GENERAL		
1. USE		
1.1	**Clinical purpose**	Designed to continuously measure and display multiple vital physiological parameters of newborn and premature infants, especially those under critical care.
1.2	**Used by clinical department/ward**	All
1.3	**Overview of functional requirements**	Operates from mains voltage or from internal rechargeable battery.Operator can set audio visual alarm levels for low or high levels of each parameter independently.Allows display of single, 3 lead ECG or simultaneous display of at least 5 waves ECG selected from up to 12 points.Display to be digital of all active parameters and trace display for at least three selectable parameters.Continuous display on screen of neonatal or infant ECG, respiration and heart rates, invasive / non-invasive blood pressure, body temperature and SpO_2.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Should have facility for printing ECG at 25mm/sec and 50mm/sec speed. 2. Should have facility for charging from both 12V DC & 220V AC. 3a. Should be supplied with. i. Pulse oximeter probe. ii. ECG cable -12 lead. iii. Temperature probe. iv. NIBP (non-invasive blood pressure) probe All probes should be supplied in 2 pairs, should be re-usable and should include adult, pediatric & neonatal size cuff/leads. 2. Capable of saving data for min 24 hrs. 3. Rates for consumables should be offered in price bid.

		4. Optional item to be quoted : invasive blood pressure-monitoring module complete with reusable transducer. 5. The monitor should have facility for transmission of data from ambulance to a receiving station (desirable NOT Mandatory) to be quoted separately.
2.2	**Settings**	User operated 1mV ECG test marker function required.
2.3	**User's interface**	Manual (touch screen or remote operated not mandatory).
2.4	**Software and/or standard of communication**	Audio Visual alarms required: high and low levels for each parameter (operator variable settings), sensor / wire / probe disconnected, low battery.
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	Screen size minimum: 8.4"
3.2	**Weight (lbs, kg)**	<6kg.
3.3	**Configuration**	Case is to be hard and splash proof. Display must allow easy viewing in all ambient light levels. Cable connectors to be designed so as fit correct socket only.
3.4	**Noise (in dBA)**	<50 dB; Lead disconnection Alarm > 65 dB.
3.5	**heat dissipation**	Should maitain nominal Temp and the heat should be disbursed through a exhaust cooling fan.
3.6	**Mobility, portability**	Supplied in protective case for clean storage and safe transport.
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	**Voltage (value, AC or DC, monophase or triphase)**	220 to 240V, 50 Hz.
4.2	**Battery operated**	Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit.Battery powered, silenceable alarm for power failure.Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure.
4.3	**Tolerance (to variations, shutdowns)**	Voltage corrector / stabilizer to allow operation at ± 30% of local rated voltage.
4.4	**Protection**	Electrical protection provided by fuses in both live and neutral supply lines.
4.5	**Power consumption**	<120Watt.
4.6	**Other energy supplies**	Mains cable.
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & Spares**	2 pairs, 12 lead ECG cable. 5 packs of 100 disposable ECG connection electrodes. Two sets of reusable SpO_2 probes ncluding adult, pediatric & neonatal probes. two sets of NIBP cuffs of each size.Two external skin temperature probes.
5.2	**Consumables / reagents (open, closed system)**	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	The case is to be cleanable with alcohol.
	7. STANDARDS AND SAFETY	
7.1	**Certifications**	FDA / CE ; IEC-60601-1-2:2007; IEC 60601-1-8-2006; IEC 60601-1-SER-Ed 1.0-2011; IEC/TRF 60601-1-8 Ed4.0-2010; ISO 13485; ISO 80601-2-56-2009 (Thermometer); ISO 80601-2-61-2011 (SpO_2)

8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform installation, safety and operation checks before handover.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
8.4	**Others**	
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years
9.2	**Maintenance tasks**	Maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	Warranty of 3 years with free servicing (min. 3/year) during warranty.
9.4	**Others**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Advanced maintenance tasks required shall be documented. User, technical and maintenance manuals to be supplied in English language. List to be provided of equipment and procedures required for local calibration and routine maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11. NOTES		
11.1	**Other information**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning signs would be adequately displayed.

SYRINGE PUMP

Version no. :		1.0
Date:		6/8/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Syringe pump
GMDN code(s)		CT111
GMDN definition		A device designed to precisely drive the plunger of a syringe down its barrel to infuse a solution when it must be administered with a high degree of volume accuracy and rate consistency. Because of the lower flow settings and flow resolution, it is especially appropriate for neonatal, infant, and critical care applications in which small volumes of concentrated drugs are to be delivered over an extended period. It can also be used to administer epidural analgesia.
GENERAL		
1. USE		
1.1	**Clinical purpose**	Designed to precisely drive the plunger of a syringe down its barrel to infuse a solution when it must be administered with a high degree of volume accuracy and rate consistency.
1.2	**Used by clinical department/ward**	Intensive care unit (ICU), radiology department, orthopaedics, emergencies, ...).
1.3	**Overview of functional requirements**	A syringe containing medication is securely mounted on the drive arm. Alarms indicate if any error situations occur. The drive arm infuses the medication at a steady, programmed rate.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.2	**Technical characteristics (specific to this type of device)**	Flow rate programmable range at least from 0.1 to 200 ml/hr, in steps of 0.1 ml/hr; and at least from 100 to 1200 ml/hr in steps of 1 ml/hr. Saves last infusion rate even when the AC power is switched off. Bolus rate should be programmable, with infused volume display. Selectable occlusion pressure trigger levels selectable from 300, 500 and 900 mmHg. Must work on commonly available 20, 50 and 60 ml syringes Accuracy of ±2% or better. Maximum pressure generated ≤ 20 psi. Automatic detection of syringe size and proper fixing. Must provide alarm for wrong loading of syringe. Anti-bolus system to reduce pressure on sudden release of occlusion. Pause infusion facility required. Self-check carried out on powering on.

		Comprehensive alarm package required including: occlusion alarm, near end of infusion pre-alarm and alarm, volume limit pre-alarm and alarm, low battery pre-alarm and alarm, AC power failure, drive disengaged, syringe loading error, maintenance required.
2.3	**Settings**	Double loadable with one syringe of minimum 20ml.
2.4	**User's interface**	Automatic.
2.5	**Software and/or standard of communication**	Inbuilt.
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	Max spec: 120 x 100 x 40mm.
3.2	**Weight (lbs, kg)**	<500gm
3.3	**Configuration**	Tamper-resistant case made of impact resistant material. Securely mountable on tabletop, IV stand or bed fitting.
3.4	**Noise (in dBA)**	<50 dB.
3.5	**heat dissipation**	NA
3.6	**Mobility, portability**	Yes
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	**Voltage (value, AC or DC, monophase or triphase)**	220 to 240V, 50 Hz.
4.2	**Battery operated**	Internal rechargeable battery having at least 5 hours backup for 10ml/hr flow rate with 50ml syringe.
4.3	**Tolerance (to variations, shutdowns)**	Voltage corrector/stabilizer to allow operation at ± 30% of local rated voltage.
4.4	**Protection**	Battery powered alarm for power failure or disconnection; Electrical protection provided by fuses in both live and neutral supply lines;
4.5	**Power consumption**	25W
4.6	**Other energy supplies**	Na
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories & Spares**	Clamp for mounting pump on IV stand.
5.2	**Consumables / reagents (open, closed system)**	Battery, syringe holder.
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. Enclosure to protect against water ingress; Possible to perform cleaning with alcohol or chlorine wipes.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	NA
	7. STANDARDS AND SAFETY	
7.1	**Certifications**	FDA / CE ; IEC-60601-1-2:2007; IEC 60601-1-8-2006; IEC 60601-1-SER-Ed 1.0-2011; IEC/TRF 60601-1-8 Ed4.0-2010; IEC-60601-2-24: Particular requirements for the safety of infusion pumps and controllers; ISO 13485.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform installation, safety and operation checks before handover.

8.2	**Requirements for sign-off**	As per requirement.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	3 years.
9.2	**Maintenance tasks**	Advanced maintenance and calibration tasks required shall be documented.
9.3	**Service contract clauses, including prices**	Local clinical staff to affirm completion of installation.
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	User, technical and maintenance manuals to be supplied in english language. List to be provided of equipment and procedures required for local calibration and routine maintenance.
10.2	**Other accompanying documents**	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
	11. NOTES	
11.1	**Other information**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	

TRANSPORT VENTILATOR

Version no. :		1.0
Date:		6/8/2013
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Intensive-care ventilators
GMDN code(s)		CT2175
GMDN definition		An electrically-powered device designed to provide automated, alveolar ventilatory support for patients during interhospital or intrahospital transport, and in emergency situations. It is typically a compact, lightweight, rugged device with internal batteries to power it during patient transport. It typically provides mandatory breaths at pre-set intervals (control mode), not allowing the patient to breathe spontaneously; operation in assist/control and/or synchronized intermittent mandatory ventilation (SIMV) modes is available in some types. It usually includes an airway pressure monitor and low and high pressure alarms; it may be used in ambulances, and in field hospitals.
GENERAL		
1. USE		
1.1	**Clinical purpose**	To provide automated, alveolar ventilatory support for patients during interhospital or intrahospital transport, and in emergency situations. It is typically a compact, lightweight, rugged device with internal batteries to power it during patient transport.
1.2	**Used by clinical department/ward**	Emergency /Critical Care.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Modes of ventilation: a) Volume controlled. b) Pressure controlled. c) Pressure support. d) Synchronized intermittent mandatory ventilation (SIMV). e) Assist/control mode. f) PEEP. 2. Alarms required: FiO_2, minute volume, pressure, PEEP, apnoea, occlusion, high respiration rate, disconnection. 3. System alarms required: power failure, gas disconnection, low battery, vent inoperative, self diagnostics. 4. If alarm silencing feature is incorporated, it must be temporary and clearly displayed when activated. 5. Air and externally supplied oxygen mixture ratios fully controllable. 6. Inlet gas supply (O_2) pressure range at least 35 to 65 psi. 7. Medical air compressor integral to unit, with inlet filter.

		8. Visual and audible alarms Accessories and tubing should be supplied for adult, pediatric & neo-natal size requirements.
2.3	**Settings**	1. The following variables should be controllable by the operator: a) Tidal volume up to 100 ml. b) Pressure (inspiratory) up to 80 cm H_2O. c) Volume (inspiratory) up to 120 l/min. d) Respiratory rate: up to 60 breaths per minute. e) SIMV Respiratory Rate: up to 40 breaths per minute. f) PEEP up to 20 cm H_2O. g) Pressure support up to 45 cm H_2O. h) FiO_2 between 21 to 100 %. i) Inspiratory and expiratory times up to at least 2 sec and 8 sec respectively.
2.4	**User's interface**	Manual and Automatic.
2.5	**Software and/or standard of communication(where ever required)**	Inbuilt
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	<5kgs
3.3	**Configuration**	NA
3.4	**Noise (in dBA), heat dissipation**	<60dB; Alarm > 65dB
3.5	**Mobility, portability**	Yes
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	**Power Requirements**	220 to 240V, 50 Hz.
4.2	**Battery operated**	With atleast 6 hours battery backup.
4.3	**Tolerance (to variations, shutdowns)**	± 10% of input.
4.4	**Protection**	OVP, earth leakage protection.
4.5	**Power consumption**	<140Watt
4.6	**Other energy supplies**	Gas/battery driven.
5	**ACCESSORIES, SPARE PARTS, CONSUMABLES**	
5.1	**Accessories & Spares**	Full face mask, breathing circuit, carry bag, filters.
5.3	**Consumables / reagents (open, closed system)**	Battery, leakage adapter.
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Cleanable with alcohol or chlorine wipes.
	7. STANDARDS AND SAFETY	
7.1	**Certifications**	FDA / CE ; IEC-60601-1-2:2007; IEC 60601-1-8-2006; IEC 60601-1-SER-Ed 1.0-2011; IEC/TRF 60601-1-8 Ed4.0-2010; ISO 13485; ISO 15001-2010 (Anestheric & respiratory equipment- compatibility with oxygen).

8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Electrical sockets; Oxygen supply.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years.
9.2	**Maintenance tasks**	Maintainance manual detailing complete maintaining schedule.
9.3	**Service contract clauses, including prices**	Warranty of three year with free servicing (min. 3) during warranty.
9.4	**Others**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	User and maintenance manuals to be supplied in English language. 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 important spares and accessories, with their part numbers and cost. Contact details of manufacturer, supplier and local service agent to be provided
10.2	**Other accompanying documents**	User/Technical/Maintenance manuals to be supplied in English.
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning signs would be adequately displayed .

NATIONAL HEALTH MISSION
Ministry of Health and Family Welfare
Government of India
website : www.nrhm.gov.in