सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

TECHNICAL SPECIFICATIONS OF MEDICAL DEVICES FOR DENTAL DEPARTMENT

Ministry of Health and Family Welfare
Government of India

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Ministry of Health and Family Welfare
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DISCLAIMER

Please note the following points before using these technical specifications:

The specifications are suggestive in nature. State may adopt/adapt them as per context specific needs. These specifications may be tailored appropriately by users according to the specific situation, especially:

i. Local standards and legislation; local regulations and conditions; languages; installation conditions, technological levels, electrical range, capacities, utility environment, clinical procedures, personnel (users) experience and other local specific conditions.

ii. The number of accessories, consumables, spare parts and other components indicates usual and/or ideal number and is not a mandatory quantity. The user can determine this quantity according to a product's characteristics and frequency of use in the hospital.

iii. The mention of specific companies or of certain manufacturer's products does not imply that they are endorsed or recommended by NHM / NHSRC in preference to others of a similar nature that are not mentioned.

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MESSAGE

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INTRODUCTION

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/government organizations.

National Health Systems Resource Centre which is also a WHO collaborating center for priority medical devices & health technology policy; in consultation with experts 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. 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.

In the consultative meeting experts has mentioned the following activities needs to be considered wisely while procuring medical devices.

(1) The public health facility that intend to house medical devices (especially electrical/electronic based) must ensure before installation ,

(a) Proper grounding at electrical sockets,

(b) Wherever generator or UPS or solar power is used as back up energy source, should ensure the stabilizer/surge protector to prevent malfunction of medical devices. The same may be undertaken at facilities having voltage/energy fluctuations.

(2) Procurer may form rate contract on reagents/consumables anticipating yearly demand, on Medical devices which require periodic supply of reagents/consumables for its day to day operation.

(3) Appropriate filtering mechanism to be housed at public facility to ensure maximum longevity on Medical devices which operates efficiently depending on quality of pneumatics/water supply source.

(4) Ensure compliance for Medical devices which are regulated under various laws/regulatory body like CDSCO, AERB, Pollution control Board, PC PNDT, PESO etc.

(5) Procurer/public health facility must ensure scheduling calibration and preventive maintenance (incl. replacement of parts that are expected to be worn out after certain operation) as recommended in Medical device manufactures operational/service manual.

(6) Wherever necessary warning/safety information required, has to be placed at public health facilities.

(7) User/ In-house service training to be procured along with Medical devices for effective utilization.

(8) Public health facility may actively engage with MoHFW initiative, Post market surveillance/ Materiovigilance program of India.

(9) Public health facility have to rely on manpower availability or utilization or IPD/OPD load factor to decide on quantity of medical devices to be procured and not just on number of bed at each level.

DENTAL X-RAY-INTRA ORAL WITH RVG

Version no. :		Ver_1
Date:		12/07/2018
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Radiographic Units, Dental, Intraoral
UMDNS code(s)		18426
GENERAL		
1. USE		
1.1	Clinical purpose	Dental radiographic units for which the dental film is placed inside the patient's mouth. These units are used for imaging of crowns and the upper third of the roots of both upper and lower teeth (bitewing image), the full tooth structure (periapical image), or the masticating surface of the premolars and molars (occlusal image). In these units, the x-ray tube is usually located in a cylindrical tube head mounted on an articulating arm positioned according to the view desired.
1.2	Used by clinical department/ward	Dental Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	**SPECIFICATION FOR DENTAL X-RAY:** 1. Operation should be conventional as well as automatic. 2. Completely micro controller based digital timer assuring the accuracy of the exposure time selected. 3. Ease of operation as all the functions can be selected from the remote control as well as timer. 4. Feather touch keypad and length of exposure cable should be 5 to 6 meters. 5. Digital timer with the accuracy of 0.01 Sec (0.01 Sec to 4.00 Sec). 6. Patient selection Switches (Thin, Normal and Obese) 7. Film Speed selection switches (3 Speeds) 8. RVG mode for RVG sensor. 9. An excellent output of 65 kV to 70 kV, 7mAs to 10 mAs. 10. Audible and Visual indication of “X-Ray On” (Radiation indications). 11. Should provide compatible voltage stabilizer (Built in/External). 12. Collimating device should be 20 cm in length and parallel/square in a lead shield should also be provided. 13. Excellent, Mechanical maneuverability, long reach scissor arm. **SPECIFICATION FOR RVG:** 1. SUPER CMOS/CCD Technology 2. Sensor Size No.1 (universal)/ Size No.0 (pediatrics)/Size No.0 (optional). 3. No. of Pixels 16 LP/mm – 24LP/mm (true solution). 4. Pixel size is 18.5 x 18.5 micron. 5. Should provide compatible software with Image capture, enhancement and manipulation tools. 6. Sensor cable length should be 3 meters and reinforced for durability and reliability (Fiber optic and scintillator tech).

2.2	User's interface	Manual, English Menu
2.3	Software and/ or standard of communication(where ever required	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise-free system
3.4	Heat dissipation	Should maintain nominal temp and the heat should be disbursed through a cooling mechanism
3.5	Mobility, portability	Should provide a pedestal stand with freely movable round wheels with locking devices to prevent unusual and excessive movement/ System should be wall mounted. It has to be set as per the requirement of the facility.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	230V, AC, 50 Hz, 15 Amps,
4.2	Battery operated	No
4.3	Protection	Suitable stabilizer to be provided. High voltage protection for X-ray tube.
4.4	Power consumption	To be specified by vendor.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Machine should be provided with following items, 1. Two numbers of BARC approved whole body lead aprons with all attachments and thyroid colors. 2. RVG (with Software) should be supplied with adequate and compatible computer system with latest operating system i.e desktop of latest version (i5 processor with 500 GB or more Hard disk drive and RAM approx 4 GB) and suitable laser printer.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	1. **Operating Condition:** Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. **Storage condition:** Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	1. Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.

7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO/AERB approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO/AERB is not available.) 2. The unit should be AERB approved. 3. Manufacturer and Supplier should have ISO 13485 certification for quality standards 4. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard). 5. History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of product should be continued to be provided to purchaser till manufacturing of same type product is curtailed.
7.2	Local and/or international	Manufacturer/Supplier should have ISO 13485 certificate for quality standard.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: (nature, values, quality)	Stable power supply
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users on operation and basic maintenance; 2. Advanced maintenance tasks required shall be documented;
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares parts and accessories or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

DENTAL X-RAY – EXTRA ORAL (O.P.G) – DIGITAL

Version no. :		Ver_1
Date:		12/07/2018
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Radiographic Units, Dental, Extra oral
UMDNS code(s)		18427
GENERAL		
1. USE		
1.1	Clinical purpose	Dental radiographic units in which the dental film is placed in an external film cassette. These units are designed for imaging the maxillofacial region using a rotating x-ray beam (panoramic radiography), which produces a single image of the dental arch as a fixed elliptical shape; and/or to obtain images of the complete skull (cephalometric radiography) or of a region of interest from various angles. Some extra oral units can produce multilayered transverse images of the maxillary and mandibular jaws (cross-sectional tomography).
1.2	Used by clinical department/ward	Dental Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. It should be digital. 2. Suitable for Adult and Pediatrics. 3. Minimum total filtration shall be 2.5 mm Al. 4. Heat capacity shall be ≥20,000 HU. 5. Focal spot size should be 0.6 mm. 6. Constant potential; high-frequency required. 7. Automatic Exposure Control (AEC) is required which is used to control the length of x-ray exposure. The exposure timer controls the length of the x-ray exposure; typical exposure times are 0.1 to 5 seconds for cephalometric radiography and 5 to 20 seconds for panoramic radiography. Patient selection Switches (Thin, Normal and Obese) 8. Feather touch keypad and length of exposure cable should be 5 to 6 meters. 9. Ease of operation as all the functions can be selected from the remote control as well as timer. 10. An excellent output of 60 kV to 80 kV, 0 mAs to 15 mAs. 11. Exposure time shall be ≤ 15 sec 12. Audible and Visual indication of “X-Ray On” (Radiation indications). 13. Should provide compatible voltage stabilizer (Built in/External). 14. Source to Image Distance(SID) 400-500 mm 15. Magnification : 1.2-1.5x
2.2	User's interface	Manual, English Menu
2.3	Software and/or standard of communication(where ever required	In built

3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise-free system
3.4	Heat dissipation	Should maintain nominal temp and the heat should be disbursed through a cooling mechanism
3.5	Mobility, portability	Stationary Installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	230V, AC, 50 Hz, 15 Amps, Line resistance < 0.4 ohms.
4.2	Battery operated	No
4.3	Protection	High voltage protection for X-ray tube.
4.4	Power consumption	To be specified by vendor.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)	Machine should be provided with following items, 1. Two numbers of BARC approved whole body lead aprons with all attachments and thyroid color.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	1. **Operating Condition:** Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. **Storage condition:** Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	1. **Disinfection:** Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/ disposable cover.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO/AERB approved (USFDA/ CE requirements will be applicable only when the Indian standards like BIS/CDSCO/AERB is not available.) 2. The unit should be AERB approved. 3. Manufacturer and Supplier should have ISO 13485 certification for quality standards 4. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard). 5. History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of product should be continued to be provided to purchaser till manufacturing of same type product is curtailed.
7.2	Local and/or international	Manufacturer/Supplier should have ISO 13485 certificate for quality standard.

8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: (nature, values, quality)	Stable power supply
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users on operation and basic maintenance; 2. Advanced maintenance tasks required shall be documented;
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares parts and accessories or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

FULLY LOADED DENTAL CHAIR ELECTRICALLY OPERATED

Version no. :		Ver_1
Date:		12/07/2018
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Chairs, Examination/Treatment, Dentistry
UMDNS code(s)		10792
GENERAL		
1. USE		
1.1	Clinical purpose	Examination/treatment chairs designed to facilitate dental examination, treatment, and/or minor surgical procedures. These chairs are typically adjustable up to a height that allows the healthcare staff to perform procedures while standing; the chairs usually include head and armrests, a reclining back that may be tilted from a vertical to a horizontal or near-horizontal position, and rotating capabilities to facilitate examination and/or treatment.
1.2	Used by clinical department/ward	Dental Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. It should have double articulating headrest with seesaw movement. 2. It should be provided with soft cervical support. 3. Dental unit should have latest overhead delivery system. 4. It should have two 3 way syringes (Tip autoclavable, with spare tips) one on unit side and other on the assistant side. 5. It should have two high speed Air rotor terminals with two rotor hand pieces and accessories and one terminal for fiber optic. One for air motor/micro motor having straight and contra angle hand pieces and other for air rotor terminal with two air rotor hand pieces with two spare cartridges. 6. It should have LED light cure unit with minimum intensity 1200 mW/cm^2. 7. It should have infection control system with non-retraction valves (Bio system/equivalent). 8. All hand pieces/terminals should be kept on Autoclavable pads. 8 spare autoclavable pads should be supplied. 9. Arm of unit should be pneumatically locked. 10. All air tubing of the delivery system can be disinfected internally after every dental procedure. 11. It should have one in built piezo ultrasonic scalar (max frequency should be 36 kHz) 12. Removable auxiliary tray (autoclavable) shall be supplied – 10 sets. 13. It should have integrated latest foot operated LED light (30000 - 50000 Lux). 14. It should have rotatable water system with removable spittoon. 15. It should have Medium Vacuum Suction and high suction (Motorized Suction).

		16. Should have following multiple programmes i. Two programmable working positions. ii. Splitting and last working position with light ON and OFF automatically. iii. Return to Zero position with light OFF automatically. iv. It should have emergency stop control with luminous indication. v. Programmable bowl water and cup filler water. 17. It should have LED based X-ray viewer (For I.P.G/O.P.G films). 18. It should be provided with right arm. 19. It should have multi functional foot control base. 20. It should be provided with two stool with adjustable backrest tilt including an adjustable ring for foot rest 21. Oil free medical grade compressor of 1HP (fully imported)
2.2	User's interface	Manual, English Menu
2.3	Software and/or standard of communication(where ever required	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise-free system
3.4	Heat dissipation	Should maintain nominal temp and the heat should be disbursed through a cooling mechanism
3.5	Mobility, portability	Stationary Installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	230V, AC, 50 Hz, 15 Amps, Line resistance < 0.4 ohms.
4.2	Battery operated	No
4.3	Protection	Stabilizer or inbuilt protection to voltage fluctuation/current surge.
4.4	Power consumption	To be specified by vendor.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	**LED LIGHT CARE UNIT:** 1. Ensures up to 1200 mW/ sq.cm **ULTRASONIC SCALAR:** 1. Piezotronic Scalar with frequency of 28000-36000 Hz 2. Autoclavable hand piece, Total control is Micro processor based 3. Hand Pieces most sleek. 4. The scalar supplies with: Piezotronic scalar with 4 tips. **FOOT OPERATED LIGHT:** 1. LED light with 3 intensity with 3 axis movement. 2. Intensity is between 30000 - 50000 Lux 3. On/off Switch by sensor switch - non touch. 4. Step intensity control by non touch sensor. **AIR ROTOR:** 1. Air Rotor hand piece clean head with a speed of 350000 RPM 2. Supplies with a. Titanium/ SS Air rotor torque hand piece. b. Ultra push type non retraction valve.

		BRUSHLESS MICROMOTOR: 1. It should have digital display of speed. 2. High Torque Micro motor (Foot Controlled) with Speed range of 2000 -40000 RPM 3. It should have reverse and forward speed along. 4. It should have auto cut off system for over load. 5. It should be supplied with a. Contangle Hand piece (Autoclavable) : Speed : 40000 RPM b. Straight Hand Piece (Autoclavable): Speed 40000 RPM. **AIR COMPRESSOR:** 1. Medical grade, Oil free, Noise free at least 1 HP Compressor. 2. The compressor should be fitted with a. Built in thermo cut off to save motor during excess of heat b. auto head air release valve, c. Automatic cut off d. Safety release valve e. Drain Valve f. The inner surface of the compressor tank (at least 35 L) is coated with Epoxy to prevent rusting.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	1. Operating Condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	1. Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO/AERB approved (USFDA/ CE requirements will be applicable only when the Indian standards like BIS/CDSCO/AERB is not available.) 2. Manufacturer and Supplier should have ISO 13485 certification for quality standards 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard). 4. History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of product should be continued to be provided to purchaser till manufacturing of same type product is curtailed.
7.2	Local and/or international	Manufacturer/Supplier should have ISO 13485 certificate for quality standard.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: (nature, values, quality)	Stable power supply

8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users on operation and basic maintenance; 2. Advanced maintenance tasks required shall be documented;
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares parts and accessories or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

MINI AUTOCLAVE (VACUUM TYPE)

Version no. :		Ver_1
Date:		12/07/2018
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Sterilizing Units, Steam, Tabletop
UMDNS code(s)		16142
GENERAL		
1. USE		
1.1	Clinical purpose	a tabletop unit including a treatment with shelves on which the devices to be sterilized are placed, usually after being cleaned of gross debris and then packed;
1.2	Used by clinical department/ward	Dental Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device	1. The autoclave should provide sterilization at 121° C and 134° C for both wrapped and unwrapped tools and also a flash cycle for rapid sterilization. 2. The autoclave should be equipped with a powerful vacuum pump to eject air pockets from the chamber at the beginning and at the end of cycle (Pre-vacuum and Post vacuum) 3. It should have minimum four sterilization programs and two test programs. 4. Minimum volume at least 20 liters. 5. It should be class B autoclave so that hollow bodied instruments, hand pieces, and turbines can be fully autoclaved.
2.2	User's interface	Manual, English Menu
2.3	Software and/or standard of communication(where ever required	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise-free system
3.4	Heat dissipation	Should maintain nominal temp and the heat should be disbursed through a cooling mechanism
3.5	Mobility, portability	
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	230V, AC, 50 Hz, 15 Amps, Line resistance < 0.4 ohms.
4.2	Battery operated	No
4.3	Protection	Stabilizer or inbuilt protection to voltage fluctuation/current surge.
4.4	Power consumption	To be specified by vendor.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones);	All Accessories like water purification unit, sealing machine etc. should be of same manufacturer. All accessories should be supplied to make equipment fully functional as per user requirement.

BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	**1. Operating Condition:** Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. **2. Storage condition:** Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	**1. Disinfection:** Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO/AERB approved (USFDA/ CE requirements will be applicable only when the Indian standards like BIS/CDSCO/AERB is not available.) 2. Manufacturer and Supplier should have ISO 13485 certification for quality standards 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard). 4. History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of product should be continued to be provided to purchaser till manufacturing of same type product is curtailed.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: (nature, values, quality)	Stable power supply
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users on operation and basic maintenance; 2. Advanced maintenance tasks required shall be documented;
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares parts and accessories or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;

11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

DENTAL INSTRUMENTS

Version no. :		1
Date:		15/02/2018
Done by : (Name/institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		NA
UMDNS code(s)		NA
GENERAL		
1. USE		
1.1	Clinical purpose	Dental instruments are tools that dental professionals use to provide dental treatment. They include tools to examine, manipulate, treat, restore, remove teeth and surrounding oral structure.
1.2	Used by clinical department/ward	Dental
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	List of instruments	**DIAGNOSTIC INSTRUMENTS** 1. Mouth Mirror Handle with tops. – 1 No 2. Explorer – 1 No 3. Tweezers – 1 No 4. Straight Probe. – 1 No 5. Periodontal Probe. – 1 No 6. Kidney Tray 1 – No **RESTORATIVE INSTRUMENTS** 1. Spoon Excavator – 18/w Medium E-2 2. Cement Spatula – 1 No 3. Plastic filling instrument – 2 No 4. Burnisher Ball – 1 No 5. Smooth Plugger – 1 No 6. Matrix Band – 1 No 7. Matrix Retainer with band (50 nos) – Toffelmeir – 8 No 8. Cellophane Strips – 1No 9. Composite Filling Instrument – 2 No **ENDODONTIC INSTRUMENTS** 1. Endodontic No: D, G 16 / Equivalent endodontic explorer – 1 No 2. Endodontic Spreader, 0.2 mm tips (Nickel, Titanium) – 1No **MINOR SURGICAL INSTRUMENTS** 1. P-9 Elevators – 1 No 2. BEN-Q Perio steal Elevator – 1 No 3. Scissor – Goldman Fox Straight (13 cm) with Tungster cubicle tip – 1 No 4. Metal aspirator (23 cm)/ Cogswell -3 or equivalent – 1 No 5. No-2 Molt Surgical Curettes – 1 No 6. No – 6 R Molt Surgical Curettes – 1 No 7. Metal Mallet with silicon padding – 1 No

2.2	User's interface	NA
2.3	Software and/or standard of communication(where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective SS case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	1. Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/ disposable cover. 2. Sterilization required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO/AERB approved (USFDA/ CE requirements will be applicable only when the Indian standards like BIS/CDSCO/AERB is not available.) 2. Manufacturer and Supplier should have ISO 13485 certification for quality standards 3. The surgical instruments should be made using top quality medical grade hardened stainless steel with defined specifications like AISI-410, AISI-420, AISI-304, AISI-303, AISI-440 etc. using guidelines of ASTM standard F899-94 and ISO 7153 and with a dull finish.
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. Advanced maintenance tasks required shall be documented.

9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares parts and accessories or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

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3	Representatives from Federation of Indian Chambers of Commerce & Industry (FICCI) Association.		
4	Representatives from Medical Technology Association of India (MTaI) Association.		
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NOTES

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