



## TECHNICAL SPECIFICATIONS OF MEDCIAL DEVICES FOR RADIO IMAGING DEPARTMENT



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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 centre 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.

| Jorgia                       | on no. :                         | Ver_3   |
|------------------------------|----------------------------------|---|
| version<br>Date:             | -                                | 1/29/2019   |
| Done by : (name.institution) |                                  | HCT/NHSRC   |
| Done                         |                                  | TEGORY AND CODING   |
| JMD                          | NS name                          | 13267   |
|                              | NS code(s)                       | Radiographic Units  |
|                              | 110 000.0(0)                     | GENERAL   |
| 1. USI                       |                                  |   |
| 1.1                          | Clinical purpose                 | Units that include an x-ray source to irradiate the portion of the patient to be examined, and an image receptor that converts in some form of latent image the array of x-rays that were differentially attenuated within the patient. This latent image is converted, usually in another device (e.g., a film image processor), into a visible image (i.e., a radiograph) reflecting the internal structure of the irradiated patient region. The interpretation of these images by a physician contributes to a clinically useful diagnosis. |
| 1.2                          | Used by clinical department/ward | Radiology Department  |
|                              |                                  | TECHNICAL   |
| 2. TEC                       | CHNICAL CHARACTERISTICS          |   |
|                              | Technical characteristics        | X-ray Generator:  |
|                              | (specific to this type of        | High frequency X-Ray generator having frequency of 20 KHz or more suitable for  |
|                              | device)                          | radiography should be provided.   |
|                              |                                  | Power rating, 3 kW @ 100  |
|                              |                                  | kVp Maximum output, 100   |
|                              |                                  | kVp mAs 1-50 range  |
|                              |                                  | mA range (rad.) : 20 mA to 60 mA.<br>Control:   |
|                              |                                  | A very compact, Soft touch Control panel having following functions & indications   |
|                              |                                  | should be provided. The panel can be supplied in floor or wall mount with spill proof design following features should be on the control panel.   |
|                              |                                  | Machine ON/OFF switch, Digital display of KV & mAs, KV & mAs increase and   |
| 2.1                          |                                  | decrease switches. Tube focal spot selection switch, Ready and x-ray on switch ith indicators.  |
|                              |                                  | Bucky selection   |
|                              |                                  | switch. Self diagnostic programme with indicators for earth fault error, KV   |
|                              |                                  | error, filament error & Tube's thermal overload.  |
|                              |                                  | X-Ray Tube:   |
|                              |                                  | Tube should be one number Dual focus stationary anode,  |
|                              |                                  | BEL/Toshiba/Imported X-ray tube and thermally protected, having focal spot  |
|                              |                                  | 1.4 mm or less.   |
|                              |                                  | Anode heat storage capacity of tube should be more than   |
|                              |                                  | 140 KHU. One number manual collimator with aluminium filter & for   |
|                              |                                  | adjustment of exposure area. Coloumn  |
|                              |                                  | Stand: It should have floor to ceiling stand with vertical counter balanced   |
|                              |                                  | travel.   |

|        |                                      | lt should have 360 deg.   |
|--------|--------------------------------------|---|
|        |                                      | rotation. It should be provided one vertcal bucky                                     |
|        |                                      | stand with machine.   |
|        |                                      | Five position tilt table having bucky grid ration of 8:1 with 85 lines per inches     |
|        |                                      | should be provided. The bucky tray should accept cassette of 8"x10",10"x12" and       |
|        |                                      | 14"x17" size.   |
| 2.2    | User's interface                     | Manual  |
|        | Software and/ or standard of         | In built  |
| 2.3    | communication(where ever             |   |
|        | required                             |   |
| 3. PHY | SICAL CHARACTERISTICS                |   |
| 3.1    | Dimensions(metric)                   | NA  |
| 3.2    | Weight (lbs, kg)                     | NA  |
| 3.3    | Noise (in dBA)                       | Noise-free system   |
| 3.4    | •                                    | Should maintain nominal temp and the heat should be disbursed throgh a cooling        |
|        |                                      | mechanism   |
|        | ,, ,                                 | Stationary installation   |
| 4. ENE | RGY SOURCE (electricity, UPS, sol    |   |
| 4.1    | Power requirements                   | Power Supply:<br>230V, AC, 50 Hz, 15 Amps, three phase, Line resistance < 0.4 ohms.   |
| 4.2    | Battery operated                     | NO  |
| 4.3    | Protection                           | NA  |
| 4.4    | Power consumption                    | ???????   |
| 5. ACC | CESSORIES, SPARE PARTS, CONSUM       | MABLES  |
|        | Accessories, (mandatory,             | Machine should be provided with following accessories:                                |
|        | standard, optional);                 | 1) Two numbers of BARC approved whole body lead aprons with all attachments.          |
| 5.1    | Spare parts (main ones);             | 2) One pair of 8 meter HV Cable   |
|        | Consumables/reagents (open,          |   |
|        | closed                               |   |
| BIDDII | system <br>NG/PROCUREMENT TERMS/DON# | ITION REQUIREMENTS  |
|        | VIRONMENTAL AND DEPARTMENT           |   |
|        | Atmosphere/Ambience                  | 1 .Operating Condition: Capable of operating continuously in ambient temperture of    |
| 6.1    | (air conditioning,                   | 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances.              |
|        | humidity, dust)                      | 2. Storage condition: Capable of being stored continuosly in ambient temperature of   |
|        |                                      | 0 to 50 deg C and   |
|        |                                      | relative humidity of 15 to 90%  |
| 6.2    | User's care, Cleaning,               | Disinfection: Parts of the Device that are designed to come into contact with         |
| 0.2    | Disinfection & Sterility issues      | the patient or the operator should either be capable of easy disinfection or be       |
|        |                                      | protected by a single use/disposable cover.   |
| 7 CTA  | NDARDS AND SAFETY                    | 2. Sterilization not required.  |
| 7. 31A | Certificates (pre-market,            | Should be FDA/Europen CE/BIS approved product.  |
|        | sanitary,); Performance and          | Manufacturer and Supplier should have ISO 13485 certification for quality standards.  |
|        |                                      | Electrical safety conforms to the standards for electrical safety IEC 60601-1-General |
| 7.1    | safety standards (specific to        | requirements(or equivalent BIS Standard).   |
|        | the device type); Local and/or       |   |
|        | international                        | Shall meet internationally recognised standard for Electromagnetic                    |
|        |                                      | Compatability(EMI/EMC). for electromedical equipment: IEC 60601-1-2                   |
|        |                                      | Certified to be complaint with IEC 60601-1-3, IEC 60601-2-54<br>AERB type approved.   |

|                              | ocal and/or international   | Manufacturer/Supplier should have ISO 13485 certificate for quality standard.  |  |
|------------------------------|---|--|--|
| 8. TRAINING AND INSTALLATION |   |  |  |
|                              | Pre- installation requirements:<br>nature, values, quality,<br>olerance | Three phase stable power supply  |  |
| 8.2 R                        | Requirements for sign-off   | Certificate of calibration and inspection of parts from the manufacturer   |  |
| o.5                          | raining of staff (medical,<br>paramedical, technicians)                 | Training of users on operation and basic maintenance;     Advanced maintenance tasks required shall be documented;         |  |
| 9. WARR                      | ANTY AND MAINTENANCE  |  |  |
|                              | -   | 3 years, including all spares and caliberation.  |  |
| 10. DOCU                     | UMENTATION  |  |  |
| C                            | Operating manuals, set  | Should provide 2 sets(hard copy and soft copy) of:   |  |
| n                            | nanuals, other manuals  | User, technical and maintenance manuals should be supplied in english/Hindi  |  |
|                              |   | language along with machine diagrams;  |  |
| 10.1                         |   | List of equipment and procedures required for local calibration and routine  |  |
|                              |   | maintenance;   |  |
|                              |   | Service and operation manuals(original and Copy) to be provided;   |  |
|                              |   | Advanced maintenance tasks documntation;   |  |
|                              |   | Certificate of calibration and inspection, Satisfactory certificate for any existing installation from government hospial. |  |
| 10.2 C                       | Other accompanying  | List of essential spares and accessories, with their part number and cost;   |  |
|                              | locuments   |  |  |
| 11. Note                     |   |  |  |
| 1                            | Service Support Contact   | Contact details of manufacturer, supplier and local service agent to   |  |
| 11.1 d                       | letails (Hierarchy Wise;  | be provided; Any Contract(AMC/CMC/add-hoc) to be declared by   |  |
|                              | ncluding a toll<br>ree/landline number)                                 | the manufacturer.  |  |
| 11.2 R                       | Recommendations or  | Any warning sign would be adequaetly displayed.  |  |
| W                            | varnings  |  |  |

| 100                          | 100 mA X-Ray                     |  |  |  |
|------------------------------|----------------------------------|--|--|--|
| Versio                       | on no. :                         | Ver_1  |  |  |
| Date:                        |                                  | 15/02/2018   |  |  |
| Done by : (name.institution) |                                  | HCT/NHSRC  |  |  |
|                              | NAME, CATEG                      | ORY AND CODING   |  |  |
| UMDI                         | NS name                          | 13267  |  |  |
| UMDI                         | NS code(s)                       | Radiographic Units   |  |  |
|                              |                                  | ENERAL   |  |  |
| 1. USE                       |                                  |  |  |  |
|                              | Clinical purpose                 | Units that include an x-ray source to irradiate the portion of the patient to be   |  |  |
|                              |                                  | examined, and an image receptor that converts in some form of latent image   |  |  |
| l.,                          |                                  | the array of x-rays that were differentially attenuated within the patient. This   |  |  |
| 1.1                          |                                  | latent image is converted, usually in another device (e.g., a film image   |  |  |
|                              |                                  | processor), into a visible image (i.e., a radiograph) reflecting the internal  |  |  |
|                              |                                  | structure of the irradiated patient region. The interpretation of these images by  |  |  |
|                              |                                  | a physician contributes to a clinically useful diagnosis.  |  |  |
| 4.2                          | Handley distant                  |  |  |  |
| 1.2                          | Used by clinical department/ward | Radiology Department   |  |  |
|                              |                                  | CHNICAL  |  |  |
| 2. TEC                       | CHNICAL CHARACTERISTICS          | STATE OF THE PROPERTY OF THE P |  |  |
|                              | Technical characteristics        | X-ray Generator:   |  |  |
|                              | (specific to this type of        | High frequency X-Ray generator having frequency of 20 KHz or more suitable for   |  |  |
|                              | device)                          | radiography should be provided.  |  |  |
|                              | ,                                | Power output of generator should be 20 KW  |  |  |
|                              |                                  | Radiography KV range should be 40-120 KV   |  |  |
|                              |                                  | or more. mA range (rad.) : 100 mA or more.   |  |  |
|                              |                                  | Control:   |  |  |
|                              |                                  | A very compact, Soft touch Control panel having following functions & indications  |  |  |
|                              |                                  | should be provided. The panel can be supplied in floor or wall mount with spill proof  |  |  |
|                              |                                  |  |  |  |
|                              |                                  | design following features should be on the control panel.  |  |  |
|                              |                                  | Machine ON/OFF switch, Digital display of KV & mAs, KV & mAs increase and  |  |  |
|                              |                                  | decrease switches. Tube focal spot selection switch, Ready and x-ray on switch   |  |  |
| 2.1                          |                                  | ith indicators.  |  |  |
|                              |                                  | Bucky selection  |  |  |
|                              |                                  | switch. Self diagnostic programme with indicators for earth fault error, KV  |  |  |
|                              |                                  | error, filament error & Tube's thermal overload.   |  |  |
|                              |                                  | X-Ray Tube:  |  |  |
|                              |                                  | Tube should be one number Dual focus rotating anode, BEL/Toshiba/Imported X-ray  |  |  |
|                              |                                  | tube and thermally protected, having focal spot 2.8 mm or les.   |  |  |
|                              |                                  | Anode heat storage capacity of tube should be more than  |  |  |
|                              |                                  | 140 KHU. One number manual collimator with aluminium filter & for  |  |  |
|                              |                                  | adjustment of exposure area. Coloumn   |  |  |
|                              |                                  | Stand: It should have floor to ceiling stand with vertical counter balanced  |  |  |
|                              |                                  | travel.  |  |  |
|                              |                                  | It should have 360 deg.  |  |  |
|                              |                                  | rotation. It should be provided one vertcal bucky  |  |  |
|                              |                                  |  |  |  |

|  |   | the solution of the second transfer of  |
|--|---|---|
|  |   | stand with machine.   |
|  |   | Five position tilt table having bucky grid ration of 8:1 with 85 lines per inches   |
|  |   | should be provided. The bucky tray should accept cassette of 8"x10",10"x12" and   |
|  |   | 14"x17" size.   |
|  |   |   |
|  |   |   |
| 2.2  | User's interface  | Manual  |
|  | Software and/ or standard of  | In built  |
| 2.3  | communication(where ever  |   |
|  | required  |   |
| 3. PH  | IYSICAL 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 throgh a cooling  |
|  | ·   | mechanism   |
| 3.5  | Mobility, portability   | Stationary installation   |
|  | IERGY SOURCE (electricity, UPS, so  | · · · · · · · · · · · · · · · · · · ·   |
|  | Power requirements  | Power Supply:   |
| 4.1  | 1   | 230V, AC, 50 Hz, 15 Amps, three phase, Line resistance < 0.4 ohms.  |
| 4.2  | Battery operated  | NO  |
| 4.3  | Protection  | NA  |
| 4.4  | Power consumption   | ????????  |
| 5. AC  | CESSORIES, SPARE PARTS, CONSU   |   |
|  | Accessories, (mandatory, standard,  | Machine should be provided with following accessories:  |
| 5.1  | optional);  | 1) Two numbers of BARC approved whole body lead aprons with all attachments.  |
| 5.1  | Spare parts (main ones);<br>Consumables/reagents (open, closed  | 2) One pair of 8 meter HV Cable   |
|  | system)   |   |
| BIDD   | DING/PROCUREMENT TERMS/D  | ONATION REQUIREMENTS  |
| 6. EN  | VIRONMENTAL AND DEPARTMEN   | TAL CONSIDERATIONS  |
|  | Atmosphere/Ambience (air  | 1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and  |
| 6.1  | conditioning, humidity, dust)   | relative humidity of 15 to 80% in ideal circumstances.  |
|  |   | 2. Storage condition: Capable of being stored continuosly in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%  |
|  | User's care, Cleaning, Disinfection &   | Disinfection: Parts of the Device that are designed to come into contact with the patient or the  |
| c 2  | Sterility issues  | operator should either be capable of easy disinfection or be protected by a single use/disposable cover.  |
| 6.2  | 1   |   |
|  |   | 2. Sterilization not required.  |
| 7 07   | AND ARROGAND GARRON   |   |
| 7. STA   | ANDARDS AND SAFETY  | 2. Sterilization not required.  |
| 7. STA   | Certificates (pre-market, sanitary,);   | 2. Sterilization not required.  Should be FDA/Europen CE/BIS approved product.  |
| 7. STA   | Certificates (pre-market, sanitary,);<br>Performance and safety standards   | 2. Sterilization not required.  Should be FDA/Europen CE/BIS approved product.  Manufacturer and Supplier should have ISO 13485 certification for quality standards.  |
|  | Certificates (pre-market, sanitary,);   | 2. Sterilization not required.  Should be FDA/Europen CE/BIS approved product.  Manufacturer and Supplier should have ISO 13485 certification for quality standards.  Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or   |
| 7. STA   | Certificates (pre-market, sanitary,);<br>Performance and safety standards<br>(specific to the device type); Local   | 2. Sterilization not required.  Should be FDA/Europen CE/BIS approved product.  Manufacturer and Supplier should have ISO 13485 certification for quality standards.  Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard).   |
|  | Certificates (pre-market, sanitary,);<br>Performance and safety standards<br>(specific to the device type); Local   | 2. Sterilization not required.  Should be FDA/Europen CE/BIS approved product.  Manufacturer and Supplier should have ISO 13485 certification for quality standards.  Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or   |
|  | Certificates (pre-market, sanitary,);<br>Performance and safety standards<br>(specific to the device type); Local   | 2. Sterilization not required.  Should be FDA/Europen CE/BIS approved product.  Manufacturer and Supplier should have ISO 13485 certification for quality standards.  Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard).  Shall meet internationally recognised standard for Electromagnetic Compatability(EMI/EMC). for electromedical equipment:60601-1-2.  Certified to be complaint with IEC 60601-1-3, IEC 60601-2-54   |
| 7.1  | Certificates (pre-market, sanitary,);<br>Performance and safety standards<br>(specific to the device type); Local   | 2. Sterilization not required.  Should be FDA/Europen CE/BIS approved product.  Manufacturer and Supplier should have ISO 13485 certification for quality standards.  Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard).  Shall meet internationally recognised standard for Electromagnetic Compatability(EMI/EMC). for electromedical equipment:60601-1-2.  Certified to be complaint with IEC 60601-1-3, IEC 60601-2-54  AERB type approved.  |
| 7.1  | Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international  | 2. Sterilization not required.  Should be FDA/Europen CE/BIS approved product.  Manufacturer and Supplier should have ISO 13485 certification for quality standards.  Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard).  Shall meet internationally recognised standard for Electromagnetic Compatability(EMI/EMC). for electromedical equipment:60601-1-2.  Certified to be complaint with IEC 60601-1-3, IEC 60601-2-54   |
| 7.1<br>7.2<br>8. TR                                | Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international  Local and/or international  | 2. Sterilization not required.  Should be FDA/Europen CE/BIS approved product.  Manufacturer and Supplier should have ISO 13485 certification for quality standards.  Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard).  Shall meet internationally recognised standard for Electromagnetic Compatability(EMI/EMC). for electromedical equipment:60601-1-2.  Certified to be complaint with IEC 60601-1-3, IEC 60601-2-54  AERB type approved.  Manufacturer/Supplier should have ISO 13485 certificate for quality standard.   |
| 7.1  | Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international  Local and/or international  AINING AND INSTALLATION   | 2. Sterilization not required.  Should be FDA/Europen CE/BIS approved product.  Manufacturer and Supplier should have ISO 13485 certification for quality standards.  Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard).  Shall meet internationally recognised standard for Electromagnetic Compatability(EMI/EMC). for electromedical equipment:60601-1-2.  Certified to be complaint with IEC 60601-1-3, IEC 60601-2-54  AERB type approved.  |
| 7.1<br>7.2<br>8. TR                                | Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international  Local and/or international  AINING AND INSTALLATION  Pre- installation requirements:  | 2. Sterilization not required.  Should be FDA/Europen CE/BIS approved product.  Manufacturer and Supplier should have ISO 13485 certification for quality standards.  Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard).  Shall meet internationally recognised standard for Electromagnetic Compatability(EMI/EMC). for electromedical equipment:60601-1-2.  Certified to be complaint with IEC 60601-1-3, IEC 60601-2-54  AERB type approved.  Manufacturer/Supplier should have ISO 13485 certificate for quality standard.   |
| 7.1<br>7.2<br>8. TRA<br>8.1<br>8.2                 | Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international  Local and/or international  AINING AND INSTALLATION  Pre- installation requirements: nature, values, quality, tolerance Requirements for sign-off Training of staff (medical,   | 2. Sterilization not required.  Should be FDA/Europen CE/BIS approved product.  Manufacturer and Supplier should have ISO 13485 certification for quality standards.  Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard).  Shall meet internationally recognised standard for Electromagnetic Compatability(EMI/EMC). for electromedical equipment:60601-1-2.  Certified to be complaint with IEC 60601-1-3, IEC 60601-2-54  AERB type approved.  Manufacturer/Supplier should have ISO 13485 certificate for quality standard.  Three phase stable power supply  Certificate of calibration and inspection of parts from the manufacturer  1. Training of users on operation and basic maintenance;  |
| 7.1<br>7.2<br>8. TR.<br>8.1<br>8.2<br>8.3          | Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international  Local and/or international  AINING AND INSTALLATION  Pre- installation requirements: nature, values, quality, tolerance Requirements for sign-off  Training of staff (medical, paramedical, technicians)                          | 2. Sterilization not required.  Should be FDA/Europen CE/BIS approved product.  Manufacturer and Supplier should have ISO 13485 certification for quality standards.  Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard).  Shall meet internationally recognised standard for Electromagnetic Compatability(EMI/EMC). for electromedical equipment:60601-1-2.  Certified to be complaint with IEC 60601-1-3, IEC 60601-2-54  AERB type approved.  Manufacturer/Supplier should have ISO 13485 certificate for quality standard.  Three phase stable power supply  Certificate of calibration and inspection of parts from the manufacturer  |
| 7.1<br>7.2<br>8. TR.<br>8.1<br>8.2<br>8.3<br>9. WA | Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international  Local and/or international  AINING AND INSTALLATION  Pre- installation requirements: nature, values, quality, tolerance Requirements for sign-off  Training of staff (medical, paramedical, technicians)  ARRANTY AND MAINTENANCE | 2. Sterilization not required.  Should be FDA/Europen CE/BIS approved product.  Manufacturer and Supplier should have ISO 13485 certification for quality standards.  Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard).  Shall meet internationally recognised standard for Electromagnetic Compatability(EMI/EMC). for electromedical equipment:60601-1-2.  Certified to be complaint with IEC 60601-1-3, IEC 60601-2-54  AERB type approved.  Manufacturer/Supplier should have ISO 13485 certificate for quality standard.  Three phase stable power supply  Certificate of calibration and inspection of parts from the manufacturer  1. Training of users on operation and basic maintenance;  2. Advanced maintenance tasks required shall be documented; |
| 7.1  7.2  8. TR.  8.1  8.2  8.3  9. WA  9.1        | Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international  Local and/or international  AINING AND INSTALLATION  Pre- installation requirements: nature, values, quality, tolerance Requirements for sign-off  Training of staff (medical, paramedical, technicians)                          | 2. Sterilization not required.  Should be FDA/Europen CE/BIS approved product.  Manufacturer and Supplier should have ISO 13485 certification for quality standards.  Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard).  Shall meet internationally recognised standard for Electromagnetic Compatability(EMI/EMC). for electromedical equipment:60601-1-2.  Certified to be complaint with IEC 60601-1-3, IEC 60601-2-54  AERB type approved.  Manufacturer/Supplier should have ISO 13485 certificate for quality standard.  Three phase stable power supply  Certificate of calibration and inspection of parts from the manufacturer  1. Training of users on operation and basic maintenance;  |

|         | Operating manuals, set manuals,                         | Should provide 2 sets(hard copy and soft copy) of:   |
|---------|---|--|
|         | other manuals   | User, technical and maintenance manuals should be supplied in english/Hindi language along with                            |
|         |   | machine diagrams;  |
| 10.1    |   | List of equipment and procedures required for local calibration and routine maintenance;                                   |
|         |   | Service and operation manuals(original and Copy) to be provided;   |
|         |   | Advanced maintenance tasks documntation;   |
|         |   | Certificate of calibration and inspection, Satisfactory certificate for any existing installation from government hospial. |
| 10.2    | Other accompanying documents                            | List of essential spares and accessories, with their part number and cost;   |
| 11. Not | es  |  |
|         | Service Support Contact details                         | Contact details of manufacturer, supplier and local service agent to be provided; Any                                      |
|         | (Hierarchy Wise; including a toll free/landline number) | Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.  |
| 11.2    | Recommendations or warnings                             | Any warning sign would be adequaetly displayed.  |

| 100     | 00 mA X-Ray - Mobile   |   |  |  |
|---------|--|---|--|--|
| Version | no.:   | Ver_1   |  |  |
| Date:   |  | 15/02/2018  |  |  |
| Done by | : (name.institution)   | HCT/NHSRC   |  |  |
|         | NAME, CAT  | TEGORY AND CODING   |  |  |
| UMDN:   | S name   | 13272   |  |  |
| UMDN    | S code(s)  | Radiographic Units, Mobile  |  |  |
|         |  | GENERAL   |  |  |
| 1. USE  |  |   |  |  |
| 1.1     | Clinical purpose   | Radiographic units consisting of a manually driven or motor-driven wheeled cart that transports an x-ray generator, an x-ray tube and tube stand, collimators, and a film cassette or flat-panel detector storage drawer (for film and digital units respectively). There are three different types of mobile radiographic units, which are categorized according to the generator: line-powered transformers, capacitor-discharge generators, and battery-powered transformers. Most mobile radiographic units utilize one of several types of digital imaging; advantages of digital imaging over film include greater dynamic range, reduced patient radiation exposure, and the ability to integrate with digital picture archiving and communication systems (PACS). Mobile radiographic units are used for imaging patients who cannot be moved to the radiology department or when patient transport is contraindicated, such as for patients in intensive care and critical care units or operating and emergency rooms.  |  |  |
| 1.2     | Used by clinical department/ward                               | Radiology Department  |  |  |
| 1.2     |  | TECHNICAL   |  |  |
| 2 TEC   | HNICAL CHARACTERISTICS   | TECHNOLIE   |  |  |
|         | Technical characteristics (specific to                         | X-ray Generator:  |  |  |
| 2.1     | this type of device)   | High frequency X-Ray generator having frequency of 20 KHz or more suitable for radiography should be provided. Power output of generator should be 20 KW Radiography KV range should be 40-120 KV or more. mA range (rad.): 100 mA or more.  Control:  A very compact, Soft touch Control panel having following functions & indications should be provided. The panel can be supplied in floor or wall mount with spill proof design following features should be on the control panel.  Machine ON/OFF switch, Digital display of KV & mAs, KV & mAs increase and decrease switches. Tube focal spot selection switch, Ready and x-ray on switch ith indicators.  Bucky selection switch. Self diagnostic programme with indicators for earth fault error, KV error, filament error & Tube's thermal overload.  X-Ray Tube:  Tube should be one number Dual focus rotating anode, BEL/Toshiba/Imported X-ray tube and thermally protected, having focal spot 2.8 mm or les.  Anode heat storage capacity of tube should be more than 140 KHU. One number manual collimator with aluminium filter & for adjustment of exposure area. |  |  |
| 2.2     | User's interface   | Manual  |  |  |
| 2.3     | Software and/ or standard of communication(where ever required | In built  |  |  |
| 3. PHY  | SICAL 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  | Mobile CO2  |  |  |
| 4. ENE  | RGY SOURCE (electricity, UPS, solar, gas,                      |   |  |  |
| 4.1     | Power requirements   | Power Supply:<br>230V, AC, 50 Hz, 15 Amps, three phase, Line resistance < 0.4 ohms.   |  |  |
| 4.2     | Battery operated Protection                                    | NA  |  |  |
| 4.3     | Power consumption  | NA<br>????????  |  |  |
|         | ESSORIES, SPARE PARTS, CONSUMABLES                             |   |  |  |
| 5. ACC  |  | Machine should be provided with following accessories:  1) Two numbers of BARC approved whole body lead aprons with all attachments.  2) One pair of 8 meter HV Cable   |  |  |
|         |  |   |  |  |

| 6. ENVIRON                              | THE PARTY OF THE P |  |  |  |
|---|--|--|--|--|
|   | 5. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS   |  |  |  |
|   | nidity, dust)  | <ol> <li>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.</li> <li>Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%</li> </ol>  |  |  |
| 6.2 User                                | es   | 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 not required.  |  |  |
| 1 | ARDS AND SAFETY  |  |  |  |
| Perfe                                   | formance and safety standards (specific to device type); Local and/or international  | Should be FDA/Europen CE/BIS approved product.  Manufacturer and Supplier should have ISO 13485 certification for quality standards.  Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard).  Shall meet internationally recognised standard for Electromagnetic Compatability(EMI/EMC). for electromedical equipment:60601-1-2  Certified to be complaint with IEC 60601-1-3, IEC 60601-2-54 |  |  |
| 7.2 Loca                                | al and/or international  | Manufacturer/Supplier should have ISO 13485 certificate for quality standard.  |  |  |
| 8. TRAININ                              | NG AND INSTALLATION  |  |  |  |
|   | - installation requirements:<br>ure, values, quality, tolerance  | Three phase stable power supply  |  |  |
| 8.2 Requ                                | uirements for sign-off   | Certificate of calibration and inspection of parts from the manufacturer   |  |  |
|   |  | Training of users on operation and basic maintenance;     Advanced maintenance tasks required shall be documented;   |  |  |
| 9. WARRAN                               | NTY AND MAINTENANCE  |  |  |  |
| 9.1 War                                 | rranty   | 3 years, including all spares and caliberation.  |  |  |
| 10. DOCUM                               | MENTATION  |  |  |  |
| 1 -                                     | nuals  | Should provide 2 sets(hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals(original and Copy) to be provided; Advanced maintenance tasks documntation; Certificate of calibration and inspection,   |  |  |
| 10.2 Othe                               | er accompanying documents  | List of essential spares and accessories, with their part number and cost;   |  |  |
| 11. Notes                               |  |  |  |  |
| 11.1 Wise<br>free/                      | e; including a toll<br>/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 Reco                               | commendations or warnings  | Any warning sign would be adequaetly displayed.  |  |  |

| CT      | CT Scan - 64 Slice                |  |  |  |
|---------|-----------------------------------|--|--|--|
| Version | no.:                              | Ver_1  |  |  |
| Date:   |                                   | 15/02/2018   |  |  |
| Done by | y: (name.institution)             | HCT/NHSRC  |  |  |
|         | NAME, CATEGORY AND CODING         |  |  |  |
| UMDN    | MDNS name 13267                   |  |  |  |
| UMDN    | UMDNS code(s) Radiographic Units  |  |  |  |
|         | G                                 | ENERAL   |  |  |
| 1. USE  |                                   |  |  |  |
| 1.1     | Clinical purpose                  | Computed Tomography scanners are used for a wide variety of diagnostic procedures, including spine and head injuries, lesions, and abdominal and pelvic malignancies; to examine the cerebral ventricles, the chest wall, and the large blood vessels; and to assess musculoskeletal degeneration.   |  |  |
| 1.2     | Used by clinical department/ward  | Radiology Department   |  |  |
|         | TE                                | CHNICAL  |  |  |
| 2. TEC  | HNICAL CHARACTERISTICS            |  |  |  |
|         | Technical characteristics         | 1. Gantry  |  |  |
| 2.1     | (specific to this type of device) | Should incorporate low Voltage SlipRings b) Minimum scan time for a 360° rotation should be less than or equal to 0.35 sec. (350 mili sec.) c) Should have minimum tilt of 30 degrees on either side and remote tilt should be available as standard Gantry should be provided with remote/user control panels on either side for positioning of the patient The sub millimeter slice @0.63 mm or less in 64 row 64 slice acquisition acquisitions should be available. The system should be in position to perform 64 slices / rotation for general, cardiac and vascular applications f) Should have 3D positioning laserlights The scan FOV in acquisition mode be at least 50 cm with intermediate steps for scanning different anatomies h) Gantry aperture should be at least 70 cm. in diameter Integrated Display Panel - Gantry front showing current scan parameters such as kV, mA, ECG trace etc. for easy set up for ECG gated studies. 2. X-Ray Generator Should be compact and in-built in the gantry b) Should be high frequency having at least 70 kW output or more The mA range available should be between 20 to 600 or more, with increment steps of not more than 10 mA. d) Tube Voltage: 80-140 kV 3. X-Ray Tube The X-ray tube should be dual focus with heat storage capacity of 6 MHU or more, with effective storage of at least 15 MHU. b) Peak heat dissipation rate of anode should be at least 750 KHU/min c) X-ray tube cooler unit should be inside the gantry d) Focal spots, and type of X-ray tube should be specified as per IEC Recommendations. e) Filter and beam limiting devices should be quoted as standard. 4. Detectors a) These should be of solid state type |  |  |
| 2.2     | User's interface                  | Patient Communication System: An integrated intercom and automated patient instruction system (API) should be provided.  |  |  |

|        | Software and/ or standard of                  | Workstations:  |
|--------|---|--|
| 2.3    | communication(where ever required             | A client server architecture based solution (Intellispace Portal 6/ Dexus-AW server 2/ Syngo Via 30A or equivalent.) with minimum concurrent 24,000 slices rendering capacity, with storage of minimum 1TB having following client hardware specifications-Workstation: Z820 or equivalent CPU, dual quad core processor, 16 GB RAM, 1TB hard drive, DVD Writing with clinical grade monitor of minimum 2 MP.A reputed Anti-Virus Solution for Server should be in place.  The Server should be with minimum three user (Three Hardware's) facility Fully DICOM 3.0 Compliant and PACS Interface ready.  The workstation should have following processing tools/software's Available as standard: Multi planar reconstruction(MPR), Minimum and Maximum intensity projection 3D Volume rendering , • 3D SSD (Shaded Surface Display).  Advance Vessel Analysis with plaque visualization, • Auto Bone Removal.  Volume measurement,  • Lung Nodule analysis.  Liver lesion analysis.  Colonography.  Perfusion CT.  Image Fusion of CT, MR & PET Data  Neuro DSA.  Coronary tree analysis: automated 3D processing of coronary arteries, calcium scoring, stent analysis, LV analysis  Multi-modality automatic tumour tracking & Automatic measurements in RECIST, WHO, Volume & Choi criteria calculation. |
|        |   | Choi criteria calculation.   |
|        | SICAL CHARACTERISTICS                         | her.   |
| 3.1    | Dimensions(metric)                            | NA<br>NA   |
| 3.2    | Weight (lbs, kg)                              | NA<br>Noise free system  |
| 3.3    | Noise (in dBA) Heat dissipation               | Noise-free system  Should maintain nominal temp and the heat should be disbursed through a cooling mechanism   |
| 3.4    | ricat dissipation                             | Should maintain nominal temp and the neat should be disbursed through a cooling mechanism  |
| 3.5    | Mobility, portability                         | Stationary installation  |
| 4. ENI | ERGY SOURCE (electricity, UPS, solar          |  |
| 4.1    | Power requirements                            | 3 phase power supply   |
| 4.2    | Battery operated                              | NO   |
| 4.3    | Protection                                    | •  |
| 4.4    | Power consumption                             | TANK FOR   |
| 5. AC( | CESSORIES, SPARE PARTS, CONSU                 |  |
|        | Accessories, (mandatory, standard, optional); | Dry Chemistry Laser Imager (dpi 500 or more) of a reputed make: Integrated with main console and workstation   |
|        | Spare parts (main ones);                      | b) Color Laser Printer (High Resolution) for color coaded images   |
|        | Consumables/reagents (open, closed            | C) UPS with half hour 'back-up' to run entire CT system, Workstations and Laser Imager   |
|        | system)                                       | d) Dual – Head Pressure injector of reputed make (100 syringes)  |
| 5.1    |   | e) 160 KVA Silent DG Set with AMF panel  |
|        |   | f) Two LED based view boxes with adjustable illumination to view 3 films of 14" x 17" in each view box.  |
|        |   | g) Thyroid Collars -2 No. h) Gonadal Shields- 2 each for male and female(Total 4)  |
|        |   | i) Lead Apron Hanger with 2 light weight Lead Aprons   |
|        |   | j) Lead glass  |
| BIDD   | ING/PROCUREMENT TERMS/D                       | ONATION REQUIREMENTS   |
|        | VIRONMENTAL AND DEPARTMEN                     | <u> </u>   |
|        | Atmosphere/Ambience (air                      | 1 .Operating Condition: Capable of operating continuously in ambient temperture of 18 to 30 deg C and  |
| 6.1    | conditioning, humidity, dust)                 | relative humidity of 20 to 75% in ideal circumstances.   |
|        |   | 2. Storage condition: Capable of being stored continuosly in ambient temperature of 18 to 30 deg C and   |
|        | User's care, Cleaning, Disinfection &         | relative humidity of 20 to 75%  Disinfection: Parts of the Device that are designed to come into contact with the patient or the   |
| 6.2    | Sterility issues                              | operator should either be capable of easy disinfection or be protected by a single use/disposable cover.   |
| 6.2    |   | 2. Sterilization not required.   |
| 7 070  | NIDADDO AND CAPETY                            |  |
| 1. STA | ANDARDS AND SAFETY                            |  |

|        | Certificates (pre-market, sanitary,);                              | Should be FDA/Europen CE/BIS approved product.  |  |
|--------|--|---|--|
|        | Performance and safety standards                                   | Manufacturer and Supplier should have ISO 13485 certification for quality standards.  |  |
|        | (specific to the device type); Local                               | Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or                         |  |
| 7.1    | and/or international   | equivalent BIS Standard).   |  |
|        |  | Shall meet internationally recognised standard for Electromagnetic Compatability(EMI/EMC). for                                |  |
|        |  | electromedical equipment:IEC 60601-1-2  |  |
|        |  | Certified to be complaint with IEC 60601-1-3, IEC 61010-2-44 or equivalent BIS AERB type approved.                            |  |
| 7.2    | Local and/or international   | Manufacturer/Supplier should have ISO 13485 certificate for quality standard.   |  |
| 8. TR  | AINING AND INSTALLATION  |   |  |
| 8.1    | Pre- installation requirements: nature, values, quality, tolerance | lead glass, door shields  |  |
| 8.2    | Requirements for sign-off  | Certificate of calibration and inspection of parts from the manufacturer  |  |
| 8.3    | Training of staff (medical,  | 1. Training of users on operation and basic maintenance;  |  |
|        | paramedical, technicians)  | 2. Advanced maintenance tasks required shall be documented;   |  |
| 9. WA  | ARRANTY AND MAINTENANCE  |   |  |
| 9.1    | Warranty   | 5 years, including all spares and caliberation.   |  |
| 10. DO | OCUMENTATION   |   |  |
|        | Operating manuals, set manuals,                                    | Should provide 2 sets(hard copy and soft copy) of:  |  |
|        | other manuals  | User, technical and maintenance manuals should be supplied in english/Hindi language along with                               |  |
|        |  | machine diagrams;   |  |
| 10.1   |  | List of equipment and procedures required for local calibration and routine maintenance;                                      |  |
|        |  | Service and operation manuals(original and Copy) to be provided;  |  |
|        |  | Advanced maintenance tasks documntation;  |  |
|        |  | Certificate of calibration and inspection,<br>Satisfactory certificate for any existing installation from government hospial. |  |
| 10.2   | Other accompanying documents                                       | List of essential spares and accessories, with their part number and cost;  |  |
| 11. N  | 11. Notes  |   |  |
|        | Service Support Contact details                                    | Contact details of manufacturer, supplier and local service agent to be provided; Any   |  |
| 11.1   | (Hierarchy Wise; including a toll free/landline number)            | Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.   |  |
| 11.2   | Recommendations or warnings  | Any warning sign would be adequaetly displayed.   |  |

| CT      | CT Scan - 128 Slice               |  |  |
|---------|-----------------------------------|--|--|
| Version | no.:                              | Ver_1  |  |
| Date:   |                                   | 15/02/2018   |  |
| Done by | y: (name.institution)             | HCT/NHSRC  |  |
|         | NAME, CATE                        | GORY AND CODING  |  |
| UMDN    | S name                            | 13267  |  |
| UMDN    | S code(s)                         | Radiographic Units   |  |
|         | G                                 | ENERAL   |  |
| 1. USE  |                                   |  |  |
| 1.1     | Clinical purpose                  | Computed Tomography scanners are used for a wide variety of diagnostic procedures, including spine and head injuries, lesions, and abdominal and pelvic malignancies; to examine the cerebral ventricles, the chest wall, and the large blood vessels; and to assess musculoskeletal degeneration.   |  |
| 1.2     | Used by clinical department/ward  | Radiology Department   |  |
|         | TE                                | CHNICAL  |  |
| 2. TEC  | HNICAL CHARACTERISTICS            |  |  |
|         | Technical characteristics         | 1. Gantry  |  |
| 2.1     | (specific to this type of device) | Should incorporate low Voltage SlipRings b) Minimum scan time for a 360° rotation should be less than or equal to 0.35 sec. (350 mili sec.) c) Should have minimum tilt of 30 degrees on either side and remote tilt should be available as standard Gantry should be provided with remote control/user control panels on either side for positioning of the patient The sub millimeter slice @0.63 mm or less in 64 row 128 slice acquisitions should be available. The system should be in position to perform 256 slices / rotation for general, cardiac and vascular applications f) Should have 3D positioning laserlights The scan FOV in acquisition mode be at least 200 mm to 500 mm with intermediate steps for scanning different anatomies h) Gantry aperture should be at least 70 cm. in diameter Integrated Display Panel - Gantry front showing current scan parameters such as kV, mA, ECG trace etc. for easy set up for ECG gated studies. 2. X-Ray Generator Should be compact and in-built in the gantry b) Should be high frequency having at least 100 kW output or more The mA range available should be between 20 to 800 or more, with increment steps of not more than 10 mA. d) Tube Voltage: 80-140 kV 3. X-Ray Tube The X-ray tube should be dual focus with heat storage capacity of 8 MHU or more, with effective storage of at least 25MHU. b) Peak heat dissipation rate of anode should be at least 1600 KHU/min c) X-ray tube cooler unit should be inside the gantry d) Focal spots, and type of X-ray tube should be specified as per IEC Recommendations. e) Filter and beam limiting devices should be quoted as standard. 4. Detectors a) These should be of solid state type |  |
| 2.2     | User's interface                  | Patient Communication System: An integrated intercom and automated patient instruction system (API) should be provided.  |  |

|        | Software and/ or standard of  | Workstations:  |
|--------|---|--|
| 2.3    | communication(where ever required   | A client server architecture based solution (Intellispace Portal 6/ Dexus-AW server 2/ Syngo Via 30A or equivalent.) with minimum concurrent 24,000 slices rendering capacity, with storage of minimum 1TB having following client hardware specifications-Workstation: Z820 or equivalent CPU, dual quad core processor, 16 GB RAM, 1TB hard drive, DVD Writing with clinical grade monitor of minimum 2 MP.A reputed Anti-Virus Solution for Server should be in place.  The Server should be with minimum three user (Three Hardware's) facility Fully DICOM 3.0 Compliant and PACS Interface ready.  The workstation should have following processing tools/software's Available as standard: Multi planar reconstruction(MPR),  Minimum and Maximum intensity projection 3D Volume rendering, • 3D SSD (Shaded Surface Display).  Advance Vessel Analysis with plaque visualization, • Auto Bone Removal.  Volume measurement,  • Lung Nodule analysis.  Liver lesion analysis.  Colonography.  Perfusion CT.  Image Fusion of CT, MR & PET Data  Neuro DSA.  Coronary tree analysis: automated 3D processing of coronary arteries, calcium scoring, stent analysis, LV analysis  Multi-modality automatic tumour tracking & Automatic measurements in RECIST, WHO, Volume & Choi criteria calculation. |
|        |   | Choi Chena Calculation.  |
|        | YSICAL CHARACTERISTICS  | h  |
| 3.1    | Dimensions(metric)  | NA<br>NA   |
| 3.2    | Weight (lbs, kg)  | NA<br>Naise free system  |
| 3.3    | Noise (in dBA) Heat dissipation   | Noise-free system Should maintain nominal temp and the heat should be disbursed throgh a cooling mechanism   |
| 3.4    | ireat dissipation   | Should maintain hominal temp and the heat should be disoursed throgh a cooling mechanism   |
| 3.5    | Mobility, portability   | Stationary installation  |
| 4. ENI | ERGY SOURCE (electricity, UPS, solar  | gas, water, CO2)   |
| 4.1    | Power requirements  | Three phase stable power supply  |
| 4.2    | Battery operated  | NO   |
| 4.3    | Protection  | -  |
| 4.4    | Power consumption   | -  |
| 5. AC  | CESSORIES, SPARE PARTS, CONSU   |  |
|        | Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system) | Dry Chemistry Laser Imager (dpi 500 or more) of a reputed make: Integrated with main console and workstation b) Color Laser Printer (High Resolution) for color coaded images C) UPS with half hour 'back-up' to run entire CT system, Workstations and Laser Imager d) Dual – Head Pressure injector of reputed make (100 syringes) e) 160 KVA Silent DG Set with AMF panel   |
| 5.1    |   | f) Two LED based view boxes with adjustable illumination to view 3 films of 14" x 17" in each view box. g) Thyroid Collars -2 No. h) Gonadal Shields- 2 each for male and female(Total 4) i) Lead Apron Hanger with 2 light weight Lead Aprons j) Lead glass   |
|        | ING/PROCUREMENT TERMS/D   | •  |
| 6. ENV | VIRONMENTAL AND DEPARTMENT  |  |
| 6.1    | Atmosphere/Ambience (air conditioning, humidity, dust)  | Operating Condition: Capable of operating continuously in ambient temperture of 18 to 30 deg C and relative humidity of 20 to 75% in ideal circumstances.      Storage condition: Capable of being stored continuously in ambient temperature of 18 to 30 deg C and relative humidity of 20 to 75%   |
| 6.2    | User's care, Cleaning, Disinfection &<br>Sterility issues   | 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 not required.  |

| 7. STA         | 7. STANDARDS AND SAFETY   |   |  |
|----------------|---|---|--|
|                | Certificates (pre-market, sanitary,);                                 | Should be FDA/Europen CE/BIS approved product.  |  |
|                | Performance and safety standards                                      | Manufacturer and Supplier should have ISO 13485 certification for quality standards.  |  |
|                | (specific to the device type); Local                                  | Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or                         |  |
| 7.1            | and/or international  | equivalent BIS Standard).   |  |
|                |   | Shall meet internationally recognised standard for Electromagnetic Compatability(EMI/EMC). for                                |  |
|                |   | electromedical equipment:IEC 60601-1-2  |  |
|                |   | Certified to be complaint with IEC 60601-1-3, IEC 61010-2-44 or equivalent BIS standard AERB type approved.                   |  |
| 7.2            | Local and/or international  | Manufacturer/Supplier should have ISO 13485 certificate for quality standard.   |  |
| 8. TR <i>A</i> | AINING AND INSTALLATION   |   |  |
| 8.1            | Pre- installation requirements:<br>nature, values, quality, tolerance | Lead Glass, Door Sheild   |  |
| 8.2            | Requirements for sign-off   | Certificate of calibration and inspection of parts from the manufacturer  |  |
| 0.2            | Training of staff (medical,   | 1. Training of users on operation and basic maintenance;  |  |
| 8.3            | paramedical, technicians)   | 2. Advanced maintenance tasks required shall be documented;   |  |
| 9. WA          | RRANTY AND MAINTENANCE  |   |  |
| 9.1            | Warranty  | 3 years, including all spares and caliberation.   |  |
| 10. DC         | OCUMENTATION  |   |  |
|                | Operating manuals, set manuals,                                       | Should provide 2 sets(hard copy and soft copy) of:  |  |
|                | other manuals   | User, technical and maintenance manuals should be supplied in english/Hindi language along with                               |  |
|                |   | machine diagrams;   |  |
| 10.1           |   | List of equipment and procedures required for local calibration and routine maintenance;                                      |  |
|                |   | Service and operation manuals(original and Copy) to be provided;  |  |
|                |   | Advanced maintenance tasks documntation;  |  |
|                |   | Certificate of calibration and inspection,<br>Satisfactory certificate for any existing installation from government hospial. |  |
| 10.2           | Other accompanying documents  | List of essential spares and accessories, with their part number and cost;  |  |
| 11. No         | 11. Notes   |   |  |
|                | Service Support Contact details                                       | Contact details of manufacturer, supplier and local service agent to be provided; Any   |  |
| 11.1           | (Hierarchy Wise; including a toll free/landline number)               | Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.   |  |
| 11.2           | Recommendations or warnings   | Any warning sign would be adequaetly displayed.   |  |

| Ful     | Full Body MRI System - 1.5 tesla  |   |  |
|---------|-----------------------------------|---|--|
| Version | no.:                              | Ver_1   |  |
| Date:   |                                   | 15/02/2018  |  |
| Done by | y: (name.institution)             | HCT/NHSRC   |  |
|         |                                   | GORY AND CODING   |  |
| UMDN    | S name                            | 16260   |  |
|         | S code(s)                         | Magnetic Resonance Imaging (MRI) Units  |  |
| CIVIDI  |                                   | ENERAL  |  |
| 1. USE  |                                   | ENERAL  |  |
| I. USE  | Clinical purpose                  | MRI is primarily used to identify diseases of the central nervous system, brain, and spine and to detect  |  |
| 1.1     | Chinicai puipose                  | musculoskeletal disorders. It is also used to view cartilage, tendons, and ligaments. MRI can also be used to image the eyes and the sinuses. MRI can be used to help diagnose infectious diseases; to detect metastatic liver disease; to display heart-wall structure; to stage prostate, bladder, and uterine cancer. MRI can also be used as a functional imaging tool. |  |
| 1.2     | Used by clinical department/ward  | Radiology Department  |  |
|         | TE                                | CHNICAL   |  |
| 2. TEC  | HNICAL CHARACTERISTICS            |   |  |
|         | Technical characteristics         | 1. MAGNET   |  |
|         | (specific to this type of device) | Whole Body 1.5Tesla Magnetic Resonance Imaging System optimized for higher performance in Whole Body and Vascular examinations with superconducting magnet, high performance gradients and digital Radio Frequency System.  |  |
|         |                                   | b. 1.5T active shielded super conductive magnet should be short and non-claustrophobic.   |  |
|         |                                   | c. It should have at least 70 cm patient bore with flared opening.  |  |
|         |                                   | d. Magnet length should be less than 200cm.   |  |
|         |                                   | e. Homogeneity of magnet should be less than 3.5 ppm over 45cm DSV  |  |
|         |                                   | The magnet should be well ventilated and illuminated with built in 2 way intercom for communication with patient.   |  |
|         |                                   | g. It should have a built in cryo-cooler such that helium consumption does not exceed $0.01\mathrm{lit/hour.}$  |  |
|         |                                   | h. Emergency Rundown Control at both operator console room and Gantary Room is a must.  |  |
|         |                                   | i. Fringe Field 0.5 Gauss line radius is essential.   |  |
| 2.1     |                                   | <ul><li>j. Front Panel of gantry should display table and patient position.</li><li>2. SHIM SYSTEM</li></ul>  |  |
| 2.1     |                                   | High performance, highly stable shim system with global and localized automated shimming for high   |  |
|         |                                   | homogeneity magnetic field for imaging and spectroscopy.  |  |
|         |                                   | b. Auto shim should be available to shim the magnet with patient in position.   |  |
|         |                                   | 3. GRADIENT SYSTEM  |  |
|         |                                   | Actively shielded Gradient system   |  |
|         |                                   | The gradient should be actively shielded with each axis having independently a slew rate of at least 200 T/m/s and a peak amplitude of 33mT/m.  |  |
|         |                                   | c. The system should have efficient and adequate Eddy current compensation  |  |
|         |                                   | d. Effective cooling system for gradient coil and power supply  |  |
|         |                                   | e. Duty Cycle- 100% the gradient power amplifier.   |  |
|         |                                   | f. Usable over 45 cm of FOV in all directions. 4. RF SYSTEM   |  |
|         |                                   | A fully digital RF system capable of transmitting power of at least 15kw.   |  |
|         |                                   | It should also have at least 32 independent RF receiver channels with each having bandwidth of 1 MHz  |  |
|         |                                   | or more along with necessary hardware to support quadrature ICP array/Matrix coils. c. It should  |  |

|             | 1   | <del>,</del>  |
|-------------|---|---|
| 2.2         | User's interface  | The main Host computer should have a 19 inches or more high resolution LCD TFT color monitor with 1024 x 1024 matrix display  The system should have image storage capacity of 100 GB for at least 2,00,000 images in 256x256 matrix.  c. The reconstruction speed should be at least 1300 or more for full FOV 256 matrix.  The main console should have facility for music system for patient in the magnet room. The system should have DVD / CD / flash drive archiving facility. The system should be provided with auto DVD writer.  e. Two way intercom system for patient communication.  MRI System should be DICOM ready in all parameters with no additional requirement of licence for connectivity to any PACS/HIS and Radiotherapy treatment planning system. |
| 2.3         | Software and/ or standard of communication(where ever required  | a. A workstation with same user interface as of main console is required with the availability of all necessary software including:  Basic post-processing software including MIP, MPR, surface reconstruction and volume rendering technique.  Advanced post-processing offered applications perfusion quantification, advanced diffusion and DTI, processing of 2D/3D CSI data, with color metabolite mapping, quantification of CSF flow data, vascular analysis package.  It should have at least 19 inch color monitor, with hard disk of at least 120 GB for at least 250,000 image storage in 256 matrix, and 4 GB RAM capacity or more, with self playing DVD/CD archiving facility.  c. Seperate viewing station should be provided.                               |
| 3. PHY      | SICAL CHARACTERISTICS   |   |
| 3.1         | Dimensions(metric)  | NA  |
| 3.2         | Weight (lbs, kg)  | NA  |
| 3.3         | Noise (in dBA)  | Maximum 120 dBA   |
| 3.4         | Heat dissipation  | Should maintain nominal temp and the heat should be disbursed throgh a cooling mechanismwith less than 1° c change during scan  |
| 3.5         | Mobility, portability   | Stationary installation   |
| 4. ENE      | ERGY SOURCE (electricity, UPS, solar,   | gas, water, CO2)  |
|             | Power requirements  | 3 phase power supply  |
|             | Battery operated  | -   |
| 4.3         | Protection  | _   |
|             | Power consumption   | _   |
|             | CESSORIES, SPARE PARTS, CONSU   | MARLES  |
| 5.1<br>BIDD | Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)  ING/PROCUREMENT TERMS/DO/IRONMENTAL AND DEPARTMENT | Dual Head MRI Compatible Pressure Injector with 100 sets of syringes.  b. Water Chiller for Cold Head I Gradients  c. 2 Non-ferromagnetic patient transfer trolley should be provided.  d. Fire Fighting System, Detectors and 6 Fire Extinguishers - MR compatible/ MR safe Hand held metal detectors and two mental detector doors to be installed at the entrance point as will be intimated.  f. Closed circuit CCD camera g. Phantoms for image quality audits.  MRI compatible Anaesthesia machine (for paediatric and adult use) with dual vaporisers i.Suction and O2 pipeline and manifold to be provided inside the RF enclosure. j. Suitable RF Enclosure k. UPS for entire system for backup of 30 minutes. l. DG set  DNATION REQUIREMENTS                     |
|             |   | ,   |
| 6.1         | Atmosphere/Ambience (air conditioning, humidity, dust)  | Operating Condition: Capable of operating continuously in ambient temperture of 18 to 30 deg C and relative humidity of 20 to 75% in ideal circumstances.      Storage condition: Capable of being stored continuously in ambient temperature of 18 to 30 deg C and relative humidity of 20 to 75%  |
|             | User's care, Cleaning, Disinfection &<br>Sterility issues   | 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 not required.   |

| 7. STA | 7. STANDARDS AND SAFETY   |   |  |
|--------|---|---|--|
|        | Certificates (pre-market, sanitary,);                                 | Should be FDA/Europen CE/BIS approved product.  |  |
|        | Performance and safety standards                                      | Manufacturer and Supplier should have ISO 13485 certification for quality standards.  |  |
|        | (specific to the device type); Local                                  | Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or                         |  |
| 7.1    | and/or international  | equivalent BIS Standard).   |  |
| ,,,    |   | Shall meet internationally recognised standard for Electromagnetic Compatability(EMI/EMC). for                                |  |
|        |   | electromedical equipment:IEC 60601-1-2  |  |
|        |   | Certified to be complaint with IEC 61010-2-33<br>AERB type approved.  |  |
| 7.2    | Local and/or international  | Manufacturer/Supplier should have ISO 13485 certificate for quality standard.   |  |
| 8. TRA | AINING AND INSTALLATION   |   |  |
| 8.1    | Pre- installation requirements:<br>nature, values, quality, tolerance | Turnkey Project only space to be provided.?????   |  |
| 8.2    | Requirements for sign-off   | Certificate of calibration and inspection of parts from the manufacturer  |  |
| 8.3    | Training of staff (medical,   | 1. Training of users on operation and basic maintenance;  |  |
|        | paramedical, technicians)   | 2. Advanced maintenance tasks required shall be documented;   |  |
| 9. WA  | RRANTY AND MAINTENANCE  |   |  |
| 9.1    | Warranty  | 5 years, including all spares and caliberation.   |  |
| 10. DC | CUMENTATION   |   |  |
|        | Operating manuals, set manuals,                                       | Should provide 2 sets(hard copy and soft copy) of:  |  |
|        | other manuals   | User, technical and maintenance manuals should be supplied in english/Hindi language along with                               |  |
|        |   | machine diagrams;   |  |
| 10.1   |   | List of equipment and procedures required for local calibration and routine maintenance;                                      |  |
|        |   | Service and operation manuals(original and Copy) to be provided;  |  |
|        |   | Advanced maintenance tasks documntation;  |  |
|        |   | Certificate of calibration and inspection,<br>Satisfactory certificate for any existing installation from government hospial. |  |
| 10.2   | Other accompanying documents  | List of essential spares and accessories, with their part number and cost;  |  |
| 11. No | 11. Notes   |   |  |
|        | Service Support Contact details                                       | Contact details of manufacturer, supplier and local service agent to be provided; Any   |  |
| 11.1   | (Hierarchy Wise; including a toll                                     | Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.   |  |
|        | free/landline number)   |   |  |
| 11.2   | Recommendations or warnings   | Any warning sign would be adequaetly displayed.   |  |

| Fu      | Full Body MRI System - 3 tesla    |   |  |
|---------|-----------------------------------|---|--|
| Version | no.:                              | Ver_1   |  |
| Date:   |                                   | 15/02/2018  |  |
| Done b  | y: (name.institution)             | HCT/NHSRC   |  |
|         | NAME, CATE                        | GORY AND CODING   |  |
| UMDN    | S name                            | 16260   |  |
|         | S code(s)                         | Magnetic Resonance Imaging (MRI) Units  |  |
| CIVIDI  |                                   | ENERAL  |  |
| 1. USE  |                                   | ENERAL  |  |
| I. USE  | Clinical purpose                  | MRI is primarily used to identify diseases of the central nervous system, brain, and spine and to detect  |  |
| 1.1     | Chinear purpose                   | musculoskeletal disorders. It is also used to view cartilage, tendons, and ligaments. MRI can also be used to image the eyes and the sinuses. MRI can be used to help diagnose infectious diseases; to detect metastatic liver disease; to display heart-wall structure; to stage prostate, bladder, and uterine cancer. MRI can also be used as a functional imaging tool. |  |
| 1.2     | Used by clinical department/ward  | Radiology Department  |  |
|         | TE                                | CHNICAL   |  |
| 2. TEC  | HNICAL CHARACTERISTICS            |   |  |
|         | Technical characteristics         | 1. MAGNET   |  |
|         | (specific to this type of device) | Whole Body 3 Tesla Magnetic Resonance Imaging System optimized for higher performance in Whole Body and Vascular examinations with superconducting magnet, high performance gradients and digital Radio Frequency System.   |  |
|         |                                   | b. 3T active shielded super conductive magnet should be short and non-claustrophobic.   |  |
|         |                                   | c. It should have at least 70 cm patient bore with flared opening.  |  |
|         |                                   | d. Magnet length should be less than 200cm.   |  |
|         |                                   | e. Homogeneity of magnet should be better than 1.5 ppm over 40 cm DSV   |  |
|         |                                   | The magnet should be well ventilated and illuminated with built in 2 way intercom for communication with patient.   |  |
|         |                                   | g. It should have a built in cryo-cooler such that helium consumption does not exceed 0.01 lit/hour. h. Emergency Rundown Control at both operator console room and Gantary Room is a must.   |  |
|         |                                   | i. Fringe Field 0.5 Gauss line radius is essential.   |  |
|         |                                   | <ul><li>j. Front Panel of gantry should display table and patient position.</li><li>2. SHIM SYSTEM</li></ul>  |  |
| 2.1     |                                   | High performance, highly stable shim system with global and localized automated shimming for high   |  |
|         |                                   | homogeneity magnetic field for imaging and spectroscopy.  |  |
|         |                                   | b. Auto shim should be available to shim the magnet with patient in position.   |  |
|         |                                   | 3. GRADIENT SYSTEM  |  |
|         |                                   | Actively shielded Gradient system   |  |
|         |                                   | The gradient should be actively shielded with each axis having independently a slew rate of at least 200 T/m/s and a peak amplitude of 40 mT/m.   |  |
|         |                                   | c. The system should have efficient and adequate Eddy current compensation  |  |
|         |                                   | d. Effective cooling system for gradient coil and power supply  |  |
|         |                                   | e. Duty Cycle- 100% the gradient power amplifier.  f. Usable over 45 cm of FOV in all directions.   |  |
|         |                                   | 4. RF SYSTEM  |  |
|         |                                   | A fully digital RF system capable of transmitting power of at least 15kw.   |  |
|         |                                   | It should also have at least 32 independent RF receiver channels with each having bandwidth of 1 MHz or more along with necessary hardware to support quadrature ICP array/Matrix coils. The highest  |  |

| 2.2    | User's interface   | The main Host computer should have a 19 inches or more high resolution LCD TFT color monitor with 1024 x 1024 matrix display  The system should have image storage capacity of 100 GB for at least 2,00,000 images in 256x256 matrix.  c. The reconstruction speed should be at least 1300 or more for full FOV 256 matrix.  The main console should have facility for music system for patient in the magnet room. The system should have DVD / CD / flash drive archiving facility. The system should be provided with auto DVD writer.  e. Two way intercom system for patient communication.  MRI System should be DICOM ready in all parameters with no additional requirement of licence for connectivity to any PACS/HIS and Radiotherapy treatment planning system. |
|--------|--|---|
| 2.3    | Software and/ or standard of communication(where ever required   | a. A workstation with same user interface as of main console is required with the availability of all necessary software including:  Basic post-processing software including MIP, MPR, surface reconstruction and volume rendering technique.  Advanced post-processing offered applications perfusion quantification, advanced diffusion and DTI, processing of 20/30 CSI data, with color metabolite mapping, quantification of CSF flow data, vascular analysis package.  It should have at least 19 inch LCD TFT color monitor, with hard disk of at least 120 GB for at least 250,000 image storage in 256 matrix, and 4 GB RAM capacity or more, with self playing DVD/CD archiving facility.  c. Seperate viewing station should be provided.                       |
|        | SICAL CHARACTERISTICS  |   |
| 3.1    | Dimensions(metric)   | NA  |
| 3.2    | Weight (lbs, kg)   | NA  |
| 3.3    | Noise (in dBA)   | Maximum 120 dBA   |
| 3.4    | Heat dissipation   | Should maintain nominal temp and the heat should be disbursed throgh a cooling mechanism with less than 1° c change during scan   |
| 3.5    | Mobility, portability  | Stationary installation   |
| 4. ENE | RGY SOURCE (electricity, UPS, solar,   | gas, water, CO2)  |
| 4.1    | Power requirements   |   |
| 4.2    | Battery operated   | NO  |
| 4.3    | Protection   |   |
| 4.4    | Power consumption  |   |
|        | CESSORIES, SPARE PARTS, CONSUI   | MABLES  |
| 5.1    | Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)  NG/PROCUREMENT TERMS/DO | Dual Head MRI Compatible Pressure Injector with 100 sets of syringes.  b. Water Chiller for Cold Head I Gradients  c. 2 Non-ferromagnetic patient transfer trolley of international make should be provided.  d. Fire Fighting System, Detectors and 6 Fire Extinguishers.  Hand held metal detectors and two mental detector doors to be installed at the entrance point as will be intimated.  f. Closed circuit CCD camera g. Phantoms for image quality audits.  MRI compatible Anaesthesia machine for paediatric and adult use) with dual vaporisers i.Suction and O2 pipeline and manifold to be provided inside the RF enclosure. j. Suitable RF Enclosure k. UPS for entire system for backup of 30 minutes. l. DG set   |
|        | TRONMENTAL AND DEPARTMENT  | •   |
| 6.1    | Atmosphere/Ambience (air conditioning, humidity, dust)   | Operating Condition: Capable of operating continuously in ambient temperture of 18 to 30 deg C and relative humidity of 20 to 75% in ideal circumstances.     Storage condition: Capable of being stored continuosly in ambient temperature of 18 to 30 deg C and relative humidity of 20 to 75%  |
|        | User's care, Cleaning, Disinfection &<br>Sterility issues  | 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 not required.   |

| 7. STA | 7. STANDARDS AND SAFETY   |   |  |
|--------|---|---|--|
|        | Certificates (pre-market, sanitary,);                                 | Should be FDA/Europen CE/BIS approved product.  |  |
|        | Performance and safety standards                                      | Manufacturer and Supplier should have ISO 13485 certification for quality standards.  |  |
|        | (specific to the device type); Local                                  | Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or                         |  |
| 7.1    | and/or international  | equivalent BIS Standard).   |  |
| ,,,    |   | Shall meet internationally recognised standard for Electromagnetic Compatability(EMI/EMC). for                                |  |
|        |   | electromedical equipment:IEC 60601-1-2.   |  |
|        |   | Certified to be complaint with IEC 61010-2-33<br>AERB type approved.  |  |
| 7.2    | Local and/or international  | Manufacturer/Supplier should have ISO 13485 certificate for quality standard.   |  |
| 8. TRA | AINING AND INSTALLATION   |   |  |
| 8.1    | Pre- installation requirements:<br>nature, values, quality, tolerance |   |  |
| 8.2    | Requirements for sign-off   | Certificate of calibration and inspection of parts from the manufacturer  |  |
| 8.3    | Training of staff (medical,   | 1. Training of users on operation and basic maintenance;  |  |
| 0.3    | paramedical, technicians)   | 2. Advanced maintenance tasks required shall be documented;   |  |
| 9. WA  | RRANTY AND MAINTENANCE  |   |  |
| 9.1    | Warranty  | 3 years, including all spares and caliberation.   |  |
| 10. DC | CUMENTATION   |   |  |
|        | Operating manuals, set manuals,                                       | Should provide 2 sets(hard copy and soft copy) of:  |  |
|        | other manuals   | User, technical and maintenance manuals should be supplied in english/Hindi language along with                               |  |
|        |   | machine diagrams;   |  |
| 10.1   |   | List of equipment and procedures required for local calibration and routine maintenance;                                      |  |
|        |   | Service and operation manuals(original and Copy) to be provided;  |  |
|        |   | Advanced maintenance tasks documntation;  |  |
|        |   | Certificate of calibration and inspection,<br>Satisfactory certificate for any existing installation from government hospial. |  |
| 10.2   | Other accompanying documents  | List of essential spares and accessories, with their part number and cost;  |  |
| 11. No | 11. Notes   |   |  |
|        | Service Support Contact details                                       | Contact details of manufacturer, supplier and local service agent to be provided; Any   |  |
| 11.1   | (Hierarchy Wise; including a toll                                     | Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.   |  |
| 11.0   | free/landline number)   |   |  |
| 11.2   | Recommendations or warnings   | Any warning sign would be adequaetly displayed.   |  |

| PO      | PORTABLE ULTRASOUND  |  |  |
|---------|--|--|--|
| Version | no.:   | Ver_1  |  |
| Date:   |  | 15/02/2018   |  |
| Done by | : (name.institution)   | HCT/NHSRC  |  |
|         | NAME, CAT  | EGORY AND CODING   |  |
| UMDNS   | name   | 17422  |  |
| UMDNS   | code(s)  | Scanning Systems, Ultrasonic, Cardiac, gynaological, General, Anaesthesia, vascular  |  |
|         |  | GENERAL  |  |
| 1. USE  |  |  |  |
| 1.1     | Clinical purpose   | An assembly of devices designed for extracorporeal and/or intracorporeal (endosonography or endoscopic) imaging procedures involving the heart and blood vessels. Included are software packages that support a variety of static or real-time cardiac specific imaging applications used to diagnose anatomical defects of the heart, determine blood flow characteristics and functional/anatomical problems associated with myocardial infarction. It is used to generate ultrasound pulses, direct them to a target area, detect the echoes, and process the resulting information to produce and display static or dynamic two or three-dimensional (3-D) images.   |  |
| 1.2     | Used by clinical department/ward                               | Radiology Department   |  |
|         |  | TECHNICAL  |  |
| 2. TECH | HNICAL CHARACTERISTICS   |  |  |
| 2.1     | Technical characteristics (specific to this type of device)    | A typical configuration for a cardiac ultrasound system consists of a scanner and software, several single- or multifrequency transducers, a TEE probe, color Doppler, M-mode, CFM, cardiac analysis software.  Phased array transducers required 3.Following transducers are to be supplied:  .A-2.0-5.0MHzMulti frequency Convex Transducer-One.  .B-5.0-12.0 MHz Multi frequency Linear transducer-One.  .C-5.0-8.0 MHz or more Endo Cavitory probe-One.  Transesophageal Echocardiogram - TEE scanning capability  Penetration depth of at least 30 cm  Digital and caliper measurement functions required for both distance and area  Alphanumeric annotation to be possible  Measurement accuracy to be better than 2% over 10cm distance  Doppler display to indicate blood flow both numerically and in colour.  . System that is DICOM compatible for communication efficiency. 3D or 2D image for cardiac studies in adults, children and infants  11. ZOOM in real time at least 4X and ZOOM for frozen image at least 20X.  12. Equipment dynamic range, at least, 180 dB. |  |
| 2.2     | User's interface   | Patient Communication System: An integrated intercom and automated patient instruction system (API) should be provided.  |  |
| 2.3     | Software and/ or standard of communication(where ever required | The hardware and software included will allow the following application: Cardiac and stress echo; tissue differentiation to clearly show the walls of the left ventricle and egional wall motion abnormalities.  Left ventricle wall abnormalities software; abdominal; obstetrical and gynecological; peripheral and deep vascular;   |  |
| 3 PHYS  | SICAL CHARACTERISTICS  |  |  |
|         | Dimensions(metric)   | NA   |  |
|         | Weight (lbs, kg)   | NA   |  |
|         | Noise (in dBA)   | Noise-free system  |  |
|         | Heat dissipation   | Should maintain nominal temp and the heat should be disbursed through a cooling mechanism  |  |
| 3.5     | Mobility, portability  | Trolley is mobile  |  |
| 4. ENEI | RGY SOURCE (electricity, UPS, solar, gas, v                    | water, CO2)  |  |
| 4.1     | Power requirements   | NA NA  |  |
| 4.2     | Battery operated   | 3 hours  |  |
|         | Protection   | Voltage corrector / stabilizer / UPS to allow operation at $\pm$ 30% of local rated voltage and one hour operation in the event of mains power failure.  |  |
| 4.4     | Power consumption  | ????????   |  |
| 5. ACCE | ESSORIES, SPARE PARTS, CONSUMABLES                             |  |  |
| 5.1     |  | All probes required for frequency range stated. It is recommended include the type of transducers and the minimum of transducers with harmonics.   |  |

| BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS  |   |  |  |
|--|---|--|--|
| 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS   |   |  |  |
|  | Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances.     Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%   |  |  |
| er's care, Cleaning, Disinfection & Sterility<br>nes   | 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 not required.   |  |  |
| ARDS AND SAFETY  |   |  |  |
| tificates (pre-market, sanitary,);<br>formance and safety standards (specific to<br>device type); Local and/or international | Should be FDA/Europen CE/BIS approved product.  Manufacturer and Supplier should have ISO 13485 certification for quality standards.  Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard).  Shall meet internationally recognised standard for Electromagnetic Compatability(EMI/EMC). for electromedical equipment: IEC 60601-1-2.  Certified to be complaint with IEC 61010-2-33 |  |  |
| cal and/or international   | Manufacturer/Supplier should have ISO 13485 certificate for quality standard.   |  |  |
| NG AND INSTALLATION  |   |  |  |
| - installation requirements:<br>ure, values, quality, tolerance  | Single phase stable power supply; PCPNDT Act clearance  |  |  |
| quirements for sign-off  | Certificate of calibration and inspection of parts from the manufacturer  |  |  |
| ining of staff (medical,<br>amedical, technicians)   | Training of users on operation and basic maintenance;     Advanced maintenance tasks required shall be documented;  |  |  |
| NTY AND MAINTENANCE  |   |  |  |
| 3  | 3 years, including all spares and caliberation.   |  |  |
| MENTATION  |   |  |  |
| erating manuals, set manuals, other<br>nuals   | Should provide 2 sets(hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals(original and Copy) to be provided; Advanced maintenance tasks documntation; Certificate of calibration and inspection,  |  |  |
| ner accompanying documents   | List of essential spares and accessories, with their part number and cost;  |  |  |
|  |   |  |  |
| e/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.  Any warning sign would be adequaetly displayed.  |  |  |
| se; inc<br>e/land  | luding a toll<br>line number)   |  |  |

| Ver_1 Date: 15/02/2018 Done by: (name.institution) HCT/NHSRC  NAME, CATEGORY AND CODING  UMDNS name  UMDNS code(s)  GENERAL  1.1 Clinical purpose 1.2 Used by clinical department/ward Radiology Department  TECHNICAL  2. TECHNICAL CHARACTERISTICS  Technical characteristics (specific to this type of device)  Technical characteristics (specific to this type of device)  Manual film processing unit- with the tanks with lid shall be of capacities 13.5 liters for fixing and developing tanks, 22.5 liter for washing tank along withhangers.  Casing shall be of robust anti-corrosive material of stainless steel 316 grade.  Tanks to be made out of 23 SWG, 304 grade mirror finish, quality stainless steel sheet for developer, washchemicals.  Single welding joint in the body height of tank and polished to avoid corrosion. All welding joints are fold pressed welded to avoid leakage.  2.2 User's interface Manual  |                                 |
|---|---------------------------------|
| Done by: (name.institution)  HCT/NHSRC  NAME, CATEGORY AND CODING  UMDNS name  UMDNS code(s)  GENERAL  1. USE  1.1 Clinical purpose 1.2 Used by clinical department/ward  TECHNICAL  2. TECHNICAL CHARACTERISTICS  Technical characteristics (specific to this type of device)  Manual film processing unit- with the tanks with lid shall be of capacities 13.5 liters for fixing and developing tanks, 22.5 liter for washing tank along with hangers.  Casing shall be of robust anti-corrosive material of stainless steel 316 grade.  Tanks to be made out of 23 SWG, 304 grade mirror finish, quality stainless steel sheet for developer, washchemicals.  Single welding joint in the body height of tank and polished to avoid corrosion. All welding joints are fold pressed welded to avoid leakage.  |                                 |
| NAME, CATEGORY AND CODING  UMDNS code(s)  GENERAL  1. USE  1.1 Clinical purpose 1.2 Used by clinical department/ward  TECHNICAL  2. TECHNICAL CHARACTERISTICS  Technical characteristics (specific to this type of device)  Manual film processing unit- with the tanks with lid shall be of capacities 13.5 liters for fixing and developing tanks, 22.5 liter for washing tank along withhangers.  Casing shall be of robust anti-corrosive material of stainless steel 316 grade.  Tanks to be made out of 23 SWG, 304 grade mirror finish, quality stainless steel sheet for developer, washchemicals.  Single welding joint in the body height of tank and polished to avoid corrosion. All welding joints are fold pressed welded to avoid leakage.   |                                 |
| UMDNS code(s)  GENERAL  1. USE  1.1 Clinical purpose 1.2 Used by clinical department/ward Radiology Department TECHNICAL  2. TECHNICAL CHARACTERISTICS  Technical characteristics (specific to this type of device)  Manual film processing unit- with the tanks with lid shall be of capacities 13.5 liters for fixing and developing tanks, 22.5 liter for washing tank along withhangers. Casing shall be of robust anti-corrosive material of stainless steel 316 grade. Tanks to be made out of 23 SWG, 304 grade mirror finish, quality stainless steel for developer, washchemicals. Single welding joint in the body height of tank and polished to avoid corrosion. All welding joints are fold pressed welded to avoid leakage.   |                                 |
| UMDNS code(s)  GENERAL  1. USE  1.1 Clinical purpose 1.2 Used by clinical department/ward Radiology Department  TECHNICAL  2. TECHNICAL CHARACTERISTICS  Technical characteristics (specific to this type of device)  Manual film processing unit- with the tanks with lid shall be of capacities 13.5 liters for fixing and developing tanks, 22.5 liter for washing tank along with hangers.  Casing shall be of robust anti-corrosive material of stainless steel 316 grade.  Tanks to be made out of 23 SWG, 304 grade mirror finish, quality stainless steel sheet for developer, washchemicals.  Single welding joint in the body height of tank and polished to avoid corrosion. All welding joints are fold pressed welded to avoid leakage.  |                                 |
| I. USE  1.1 Clinical purpose 1.2 Used by clinical department/ward Radiology Department  TECHNICAL  2. TECHNICAL CHARACTERISTICS  Technical characteristics (specific to this type of device)  Manual film processing unit- with the tanks with lid shall be of capacities 13.5 liters for fixing and developing tanks, 22.5 liter for washing tank along withhangers.  Casing shall be of robust anti-corrosive material of stainless steel 316 grade.  Tanks to be made out of 23 SWG, 304 grade mirror finish, quality stainless steel sheet for developer, washchemicals.  Single welding joint in the body height of tank and polished to avoid corrosion. All welding joints are fold pressed welded to avoid leakage.   |                                 |
| I. USE  1.1 Clinical purpose 1.2 Used by clinical department/ward Radiology Department  TECHNICAL  2. TECHNICAL CHARACTERISTICS  Technical characteristics (specific to this type of device)  Manual film processing unit- with the tanks with lid shall be of capacities 13.5 liters for fixing and developing tanks, 22.5 liter for washing tank along withhangers.  Casing shall be of robust anti-corrosive material of stainless steel 316 grade.  Tanks to be made out of 23 SWG, 304 grade mirror finish, quality stainless steel sheet for developer, washchemicals.  Single welding joint in the body height of tank and polished to avoid corrosion. All welding joints are fold pressed welded to avoid leakage.   |                                 |
| 1.1   Clinical purpose  |                                 |
| 1.1 Clinical purpose 1.2 Used by clinical department/ward Radiology Department  TECHNICAL  2. TECHNICAL CHARACTERISTICS  Technical characteristics (specific to this type of device)  Manual film processing unit- with the tanks with lid shall be of capacities 13.5 liters for fixing and developing tanks, 22.5 liter for washing tank along with hangers.  Casing shall be of robust anti-corrosive material of stainless steel 316 grade.  Tanks to be made out of 23 SWG, 304 grade mirror finish, quality stainless steel sheet for developer, washchemicals.  Single welding joint in the body height of tank and polished to avoid corrosion. All welding joints are fold pressed welded to avoid leakage.  |                                 |
| 1.2 Used by clinical department/ward  Radiology Department  TECHNICAL  2. TECHNICAL CHARACTERISTICS  Technical characteristics (specific to this type of device)  Manual film processing unit- with the tanks with lid shall be of capacities 13.5 liters for fixing and developing tanks, 22.5 liter for washing tank along with hangers.  Casing shall be of robust anti-corrosive material of stainless steel 316 grade.  Tanks to be made out of 23 SWG, 304 grade mirror finish, quality stainless steel sheet for developer, washchemicals.  Single welding joint in the body height of tank and polished to avoid corrosion. All welding joints are fold pressed welded to avoid leakage.  |                                 |
| TECHNICAL  2. TECHNICAL CHARACTERISTICS  Technical characteristics (specific to this type of device)  Manual film processing unit- with the tanks with lid shall be of capacities 13.5 liters for fixing and developing tanks, 22.5 liter for washing tank along with hangers.  Casing shall be of robust anti-corrosive material of stainless steel 316 grade.  Tanks to be made out of 23 SWG, 304 grade mirror finish, quality stainless steel sheet for developer, washchemicals.  Single welding joint in the body height of tank and polished to avoid corrosion. All welding joints are fold pressed welded to avoid leakage.  |                                 |
| 2.1 Technical characteristics (specific to this type of device)  Manual film processing unit- with the tanks with lid shall be of capacities 13.5 liters for fixing and developing tanks, 22.5 liter for washing tank along with hangers.  Casing shall be of robust anti-corrosive material of stainless steel 316 grade.  Tanks to be made out of 23 SWG, 304 grade mirror finish, quality stainless steel sheet for developer, washchemicals.  Single welding joint in the body height of tank and polished to avoid corrosion. All welding joints are fold pressed welded to avoid leakage.   |                                 |
| Technical characteristics (specific to this type of device)  Manual film processing unit- with the tanks with lid shall be of capacities 13.5 liters for fixing and developing tanks, 22.5 liter for washing tank along with hangers.  Casing shall be of robust anti-corrosive material of stainless steel 316 grade.  Tanks to be made out of 23 SWG, 304 grade mirror finish, quality stainless steel sheet for developer, washchemicals.  Single welding joint in the body height of tank and polished to avoid corrosion. All welding joints are fold pressed welded to avoid leakage.   |                                 |
| this type of device)  for fixing and developing tanks, 22.5 liter for washing tank along with hangers.  Casing shall be of robust anti-corrosive material of stainless steel 316 grade.  Tanks to be made out of 23 SWG, 304 grade mirror finish, quality stainless steel sheet for developer, washchemicals.  Single welding joint in the body height of tank and polished to avoid corrosion. All welding joints are fold pressed welded to avoid leakage.  |                                 |
| Tanks to be made out of 23 SWG, 304 grade mirror finish, quality stainless steel sheet for developer, washchemicals.  Single welding joint in the body height of tank and polished to avoid corrosion. All welding joints are fold pressed welded to avoid leakage.   |                                 |
| Single welding joint in the body height of tank and polished to avoid corrosion. All welding joints are fold pressed welded to avoid leakage.   |                                 |
| welding joints are fold pressed welded to avoid leakage.  | 1                               |
|   | 1                               |
| 2.2 User's interface Manual   | !                               |
| 2.2 User's interface Manual   |                                 |
| 2.2 User's interface Manual   |                                 |
| 2.2 User's interface Manual   |                                 |
|   |                                 |
| Software and/ or standard of NA   |                                 |
| 2.3 communication(where ever required   |                                 |
|   |                                 |
| 3. PHYSICAL CHARACTERISTICS   |                                 |
| 3.1 Dimensions(metric) NA   |                                 |
| 3.2 Weight (lbs, kg) NA   |                                 |
| 3.3 Noise (in dBA) NA   |                                 |
| Heat discipation Should maintain nominal tamp and the heat should be disbursed through a cooling mechanism  |                                 |
| 3.4 Reat dissipation Should maintain nominar temp and the neat should be disoursed through a cooling mechanism  |                                 |
| 3.5 Mobility, portability   |                                 |
| 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)   |                                 |
| Power requirements Power Sundy  |                                 |
| 4.1 Fower requirements Fower Supplys: A.C., 50 Hz, 15 Amps, three phase, Line resistance < 0.4 ohms.  |                                 |
| 4.2 Battery operated NO   |                                 |
| 4.3 Protection NA   |                                 |
| 4.4 Power consumption ????????  |                                 |
| 5. ACCESSORIES, SPARE PARTS, CONSUMABLES  |                                 |
| Accessories, (mandatory, standard, optional); Machine should be provided with following accessories:  |                                 |
|   |                                 |
| Spare parts (main ones); 1) Two numbers of BARC approved whole body lead aprons with all attachments.  5.1 Consumables/reagents (open, closed 2) One pair of 8 meter HV Cable   |                                 |
| system)  2) One pair of 8 meter HV Cable  system)  3) 3 numbers of non corrosive tanks for solution   |                                 |
| 4) hanger of 10 clips and loose clips.  |                                 |
| BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS   |                                 |
| 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS  |                                 |
|   | C and relative humidity of      |
| humidity dust ) 15 to 2004 in ideal aircumstances   | C and relative littlifficity of |
| 1 0.1 1   | C and                           |
| 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg of relative humidity of 15 to 90%  | C allu                          |
| User's care, Cleaning, Disinfection & Sterility Disinfection: Parts of the Device that are designed to come into contact with the patient or the Device that are designed to come into contact with the patient or the Device that are designed to come into contact with the patient or the Device that are designed to come into contact with the patient or the Device that are designed to come into contact with the patient or the Device that are designed to come into contact with the patient or the Device that are designed to come into contact with the patient or the Device that are designed to come into contact with the patient or the Device that are designed to come into contact with the patient or the Device that are designed to come into contact with the patient or the Device that are designed to come into contact with the patient or the Device that are designed to come into contact with the Device that are designed to come into contact | the operator should             |
| issues aither he canable of easy disinfection or he protected by a single use/disposable cover  | operator snound                 |
| 6.2 Issues Child be capable of easy distinction of be protected by a single use/disposable cover.  2. Sterilization not required.   |                                 |
|   |                                 |
| 7. STANDARDS AND SAFETY   |                                 |
| Certificates (pre-market, sanitary,); Should be FDA/Europen CE/BIS approved product.  |                                 |
| Performance and safety standards (specific to Manufacturer and Supplier should have ISO 13485 certification for quality standards.  |                                 |
| the device type); Local and/or international Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirement.   | ts(or equivalent BIS            |
| Standard).  | -                               |
| 7.1 Shall meet internationally recognised standard for Electromagnetic Compatability(EMI/EMC). for  | r electromedical                |
| equipment:61326-1.  |                                 |
| Certified to be complaint with IEC 61010-1-3, IEC 61010-1-2, IEC 61010-2-54, IEC 61010-1-6 and IE   | EC 62304.                       |
|   |                                 |
| 7.0 1.01.04(0.50.00.50.51)  |                                 |
| 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:<br>nature, values, quality, tolerance                         | Three phase 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)   | Training of users on operation and basic maintenance;     Advanced maintenance tasks required shall be documented;   |  |
| 9. WAR  | 9. WARRANTY AND MAINTENANCE   |  |  |
| 9.1     | Warranty  | 3 years, including all spares and caliberation.  |  |
| 10. DO  | 10. DOCUMENTATION   |  |  |
| 10.1    | Operating manuals, set manuals, other manuals   | Should provide 2 sets(hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals(original and Copy) to be provided; Advanced maintenance tasks documntation; Certificate of calibration and inspection, |  |
| 10.2    | Other accompanying documents  | List of essential spares and accessories, with their part number and cost;   |  |
| 11. Not | 11. Notes   |  |  |
| 11.1    | Service Support Contact details (Hierarchy<br>Wise; including a toll<br>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 adequaetly displayed.  |  |

| CH      | CHEST STAND: Floor Model  |  |  |  |
|---------|---|--|--|--|
| Version | no.:  | Ver_1  |  |  |
| Date:   |   | 15/02/2018   |  |  |
| Done by | : (name.institution)  | HCT/NHSRC  |  |  |
|         | NAME, CATEGORY AND CODING   |  |  |  |
| UMDNS   | name  |  |  |  |
| UMDNS   | code(s)   |  |  |  |
|         |   | GENERAL  |  |  |
| 1. USE  |   |  |  |  |
| 1.1     | Clinical purpose  |  |  |  |
| 1.2     | * *   | Radiology Department   |  |  |
|         |   | TECHNICAL  |  |  |
| 2. TECH | HNICAL CHARACTERISTICS  |  |  |  |
|         | Technical characteristics (specific to  | Floor model vertical stand with rigid L channel structure on a stable platform for standing  |  |  |
|         | this type of device)  | patients.  |  |  |
|         | ,   | L channel to be made of 4 mm thick 50 mm sq. angle and approximately 180 cm height and   |  |  |
|         |   | fitted on patient platform.  |  |  |
| 2.1     |   | Cassette holder to take cassettes up to 14 x 17" to move vertically up and down on two SS  |  |  |
|         |   | guide rods with facility to lock cassette holder in any desired position for taking radiographs  |  |  |
|         |   | Cassette holder up and down movement to be approximately 60 cm.  |  |  |
|         |   |  |  |  |
| 2.2     | User's interface  | Manual   |  |  |
|         | Software and/ or standard of  | NA   |  |  |
| 2.3     | communication(where ever required   |  |  |  |
|         |   |  |  |  |
|         | SICAL CHARACTERISTICS   |  |  |  |
|         | Dimensions(metric)  | NA NA  |  |  |
|         | Weight (lbs, kg)  | NA NA  |  |  |
|         | Noise (in dBA)  | NA NA  |  |  |
| 3.4     | Heat dissipation  | Should maintain nominal temp and the heat should be disbursed through a cooling mechanism  |  |  |
| 3.5     | Mobility, portability   |  |  |  |
|         | RGY SOURCE (electricity, UPS, solar, gas, v   | untar CO2  |  |  |
|         | Power requirements  | NA   |  |  |
|         | Battery operated  | NA   |  |  |
|         | Protection  | NA   |  |  |
|         | Power consumption   | NA   |  |  |
|         | ESSORIES, SPARE PARTS, CONSUMABLES  |  |  |  |
| J. ACCI | Accessories, (mandatory, standard, optional);   |  |  |  |
|         | Spare parts (main ones);  |  |  |  |
|         | Consumables/reagents (open, closed  |  |  |  |
|         | system)   |  |  |  |
|         |   |  |  |  |
|         | NG/PROCUREMENT TERMS/DONATION   |  |  |  |
|         | RONMENTAL AND DEPARTMENTAL CON  |  |  |  |
|         | Atmosphere/Ambience (air conditioning,  | 1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity of  |  |  |
| 6.1     | humidity, dust)   | 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%  |  |  |
|         | User's care, Cleaning, Disinfection & Sterility   | Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should   |  |  |
|         | issues  | either be capable of easy disinfection or be protected by a single use/disposable cover.   |  |  |
| 0.2     |   | 2. Sterilization not required.   |  |  |
|         | VD + DDG + NVD G + VDC  |  |  |  |
| /. STAN | DARDS AND SAFETY  | OL THE PROPERTY OF THE PROPERT |  |  |
|         | Certificates (pre-market, sanitary,);   | Should be FDA/Europen CE/BIS approved product.   |  |  |
|         | Performance and safety standards (specific to<br>the device type); Local and/or international | Manufacturer and Supplier should have ISO 13485 certification for quality standards.   |  |  |
|         | the device type); Local and/or international  | Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard).  |  |  |
| 7.1     |   | Shall meet internationally recognised standard for Electromagnetic Compatability(EMI/EMC), for electromedical  |  |  |
|         |   | equipment:61326-1.   |  |  |
|         |   | Certified to be complaint with IEC 61010-1-3, IEC 61010-1-2, IEC 61010-2-54, IEC 61010-1-6 and IEC 62304.  |  |  |
|         |   | ,  |  |  |
| 7.2     | Local and/or international  | Manufacturer/Supplier should have ISO 13485 certificate for quality standard.  |  |  |
|         | NING AND INSTALLATION   | manufacture/Supplier should have 150-15465 certhicate for quality standard.  |  |  |
|         | Pre- installation requirements:   | Three phase stable power supply  |  |  |
|         | nature, values, quality, tolerance  | тиес риазе мане рожет вирргу   |  |  |
|         | Requirements for sign-off   | Certificate of calibration and inspection of parts from the manufacturer   |  |  |
| ь       | <u> </u>  | • •  |  |  |

| 8.3     | Training of staff (medical, paramedical, technicians)   | Training of users on operation and basic maintenance;     Advanced maintenance tasks required shall be documented;   |  |
|---------|---|--|--|
| 9. WAF  | parametrical, technicians) 2. Advanced maintenance tasks required snan de documented; 9. WARRANTY AND MAINTENANCE |  |  |
| 9.1     | Warranty  | 3 years, including all spares and caliberation.  |  |
| 10. DO  | 10. DOCUMENTATION   |  |  |
| 10.1    | Operating manuals, set manuals, other manuals   | Should provide 2 sets(hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals(original and Copy) to be provided; Advanced maintenance tasks documntation; Certificate of calibration and inspection, |  |
| 10.2    | Other accompanying documents  | List of essential spares and accessories, with their part number and cost;   |  |
| 11. Not | 11. Notes   |  |  |
| 11.1    | Service Support Contact details (Hierarchy<br>Wise; including a toll<br>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 adequaetly displayed.  |  |

| LEA                          | LEAD SCREEN BARRIER   |  |  |  |
|------------------------------|---|--|--|--|
| Version                      | Version no. : Ver_1   |  |  |  |
| Date:                        |   | 15/02/2018   |  |  |
| Done by : (name.institution) |   | HCT/NHSRC  |  |  |
| Bone of                      | NAME, CATEGORY AND CODING   |  |  |  |
| UMDNS                        | <u> </u>  | EGORI TILD CODITO  |  |  |
| UMDNS                        |   |  |  |  |
| CIMBINS                      | , code(3)   | GENERAL  |  |  |
| 1. USE                       |   | OLIVLICAL  |  |  |
| 1.1                          | Clinical purpose  |  |  |  |
|                              | Used by clinical department/ward                                      | Radiology Department   |  |  |
| 1.2                          |   | rechnical  |  |  |
| 2 TECI                       | HNICAL CHARACTERISTICS  | ICHINCAL   |  |  |
| Z. IECI                      | Technical characteristics (specific to                                | Triple fold type- Lead Screen movable on a sturdy, rust proof wheels with  |  |  |
|                              | this type of device)  | 1.5 mm lead sheet sandwiched between phenol bonded laminated sheet with teak wood  |  |  |
|                              |   | finishing.   |  |  |
|                              |   | Lead glass window (1.0 mm lead or equivalent) of minimum size 7" x 7" at a convenient height   |  |  |
|                              |   | to be provided.  |  |  |
|                              |   | Angle iron frame work for durability of screen to be provided.   |  |  |
|                              |   | Size of the screen: Central part 6 feet height x 2 feet width. Item to conform to IS 7620  |  |  |
|                              |   | orequivalent.  |  |  |
| 2.2                          | User's interface  | Manual   |  |  |
|                              | Software and/ or standard of  | NA   |  |  |
| 2.3                          | communication(where ever required                                     |  |  |  |
|                              |   |  |  |  |
|                              | SICAL CHARACTERISTICS   |  |  |  |
|                              | Dimensions(metric)  | NA   |  |  |
|                              | Weight (lbs, kg)  | NA .   |  |  |
|                              | Noise (in dBA)  | NA   |  |  |
| 3.4                          | Heat dissipation  | Should maintain nominal temp and the heat should be disbursed throgh a cooling mechanism   |  |  |
|                              | Mobility, portability   |  |  |  |
|                              | RGY SOURCE (electricity, UPS, solar, gas, v                           | vater, CO2)  |  |  |
|                              | Power requirements  |  |  |  |
|                              | Battery operated  | NO NO  |  |  |
|                              | Protection  | NA NA  |  |  |
|                              | Power consumption   |  |  |  |
| 5. ACCE                      | ESSORIES, SPARE PARTS, CONSUMABLES                                    |  |  |  |
|                              | Accessories, (mandatory, standard, optional);                         |  |  |  |
| 5.1                          | Spare parts (main ones);<br>Consumables/reagents (open, closed        |  |  |  |
|                              | system)   |  |  |  |
|                              |   |  |  |  |
|                              | NG/PROCUREMENT TERMS/DONATION   | <u> </u>   |  |  |
| 6. ENVI                      | RONMENTAL AND DEPARTMENTAL CON  |  |  |  |
|                              | Atmosphere/Ambience (air conditioning,                                | 1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity of  |  |  |
| 6.1                          | humidity, dust)   | 15 to 80% in ideal circumstances.  |  |  |
|                              |   | <ol> <li>Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and<br/>relative humidity of 15 to 90%</li> </ol>   |  |  |
|                              | User's care, Cleaning, Disinfection & Sterility                       | Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should   |  |  |
| 6.3                          | issues  | either be capable of easy disinfection or be protected by a single use/disposable cover.   |  |  |
| 6.2                          |   | 2. Sterilization not required.   |  |  |
|                              |   |  |  |  |
| 7. STAN                      | NDARDS AND SAFETY   |  |  |  |
|                              | Certificates (pre-market, sanitary,);                                 | Should be FDA/Europen CE/BIS approved product.   |  |  |
|                              | Performance and safety standards (specific to                         | Manufacturer and Supplier should have ISO 13485 certification for quality standards.   |  |  |
|                              | the device type); Local and/or international                          | Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard).  |  |  |
| 7.1                          |   | Standard). Shall meet internationally recognised standard for Electromagnetic Compatability(EMI/EMC), for electromedical   |  |  |
|                              |   | equipment:61326-1.   |  |  |
| 1                            |   | Certified to be complaint with IEC 61010-1-3, IEC 61010-1-2, IEC 61010-2-54, IEC 61010-1-6 and IEC 62304.  |  |  |
|                              |   | ·  |  |  |
| 7.3                          | Local and/or international  | Manufacturar/Sunniar should have ISO 13485 partificate for quality standard  |  |  |
|                              | Local and/or international  | Manufacturer/Supplier should have ISO 13485 certificate for quality standard.  |  |  |
|                              | NING AND INSTALLATION  Pro_inctellation_requirements:                 | Three phase stable nature supply   |  |  |
| 8.1                          | Pre- installation requirements:<br>nature, values, quality, tolerance | Three phase stable power supply  |  |  |
| 8.2                          | Requirements for sign-off   | Certificate of calibration and inspection of parts from the manufacturer   |  |  |
|                              |   | A AMERICAN SERVICE SER |  |  |

| 8.3     | Training of staff (medical,                   | 1. Training of users on operation and basic maintenance;   |  |
|---------|---|--|--|
| 0.3     | paramedical, technicians)                     | 2. Advanced maintenance tasks required shall be documented;  |  |
| 9. WAF  | D. WARRANTY AND MAINTENANCE                   |  |  |
| 9.1     | Warranty                                      | 3 years, including all spares and caliberation.  |  |
| 10. DO  | CUMENTATION                                   |  |  |
|         | Operating manuals, set manuals, other manuals | Should provide 2 sets(hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams;                                 |  |
| 10.1    |   | List of equipment and procedures required for local calibration and routine maintenance;  Service and operation manuals(original and Copy) to be provided;  Advanced maintenance tasks documntation; |  |
|         |   | Certificate of calibration and inspection,   |  |
| 10.2    | Other accompanying documents                  | List of essential spares and accessories, with their part number and cost;   |  |
| 11. Not | 11. Notes                                     |  |  |
|         | Service Support Contact details (Hierarchy    | Contact details of manufacturer, supplier and local service agent to be provided; Any  |  |
| 11.1    | Wise; including a toll free/landline number)  | Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.  |  |
| 11.2    | Recommendations or warnings                   | Any warning sign would be adequaetly displayed.  |  |

| FIL                 | FILM HANGER  |  |  |
|---------------------|--|--|--|
| Version no. : Ver_1 |  |  |  |
| Date:               |  | 15/02/2018   |  |
| Done by             | : (name.institution)   | HCT/NHSRC  |  |
|                     | NAME, CAT  | EGORY AND CODING   |  |
| UMDNS               | S name   |  |  |
| UMDNS               | S code(s)  |  |  |
|                     |  | GENERAL  |  |
| 1. USE              |  |  |  |
| 1.1                 | Clinical purpose   |  |  |
| 1.2                 | Used by clinical department/ward   | Radiology Department   |  |
|                     | ·  | TECHNICAL TECHNICAL  |  |
| 2. TECI             | HNICAL CHARACTERISTICS   |  |  |
|                     | Technical characteristics (specific to this type of device)  | Stainless steel film hanger clip type or channel type to hang wet films. Sizes should be 8 "x 10", 10"x 12", 12"x 15" and 14"x 14", 14"x 17"(dimensions in inches)  The equipment should be suitable for operation in temperatures from 10° C to 45° C with a relative humidity of 100 %  Labels and markings should be clear and visible.  Equipment should be simple to use, operate and maintain. It should be designed for easy access to serviceable parts. |  |
| 2.2                 | User's interface   | Manual   |  |
|                     | Software and/ or standard of   | NA   |  |
| 2.3                 | communication(where ever required  |  |  |
|                     |  |  |  |
|                     | SICAL CHARACTERISTICS  |  |  |
|                     | Dimensions(metric)   | NA<br>No.  |  |
| 3.2                 | Weight (lbs, kg)   | NA<br>N.   |  |
| 3.3                 | Noise (in dBA)   | NA   |  |
| 3.4                 | Heat dissipation   | Should maintain nominal temp and the heat should be disbursed throgh a cooling mechanism   |  |
| 3.5                 | Mobility, portability  |  |  |
| 4. ENE              | RGY SOURCE (electricity, UPS, solar, gas, v<br>Power requirements  | NA   |  |
| 4.1                 | Battery operated   | NA   |  |
| 4.2                 | Protection   | NA   |  |
|                     | Power consumption  | NA   |  |
|                     | ESSORIES, SPARE PARTS, CONSUMABLES   |  |  |
| 5.1                 | Accessories, (mandatory, standard, optional);<br>Spare parts (main ones);<br>Consumables/reagents (open, closed<br>system)               |  |  |
| BIDDI               | NG/PROCUREMENT TERMS/DONATION  | ON REQUIREMENTS  |  |
| 6. ENVI             | RONMENTAL AND DEPARTMENTAL CON   |  |  |
| 6.1                 | Atmosphere/Ambience (air conditioning, humidity, dust)   | <ol> <li>Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances.</li> <li>Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%</li> </ol>   |  |
| 6.2                 | User's care, Cleaning, Disinfection & Sterility issues   | 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 not required.  |  |
| 7. STAI             | NDARDS AND SAFETY  |  |  |
| 7.1                 | Certificates (pre-market, sanitary);<br>Performance and safety standards (specific to<br>the device type); Local<br>and/or international | 3. AERB type approved.   |  |
| 7.2                 | Local and/or international   | Manufacturer/Supplier should have ISO 13485 certificate for quality standard.  |  |
|                     | INING AND INSTALLATION Pre- installation requirements:   | Three phase stable power supply  |  |
| 8.1                 | nature, values, quality, tolerance   |  |  |
| 8.2                 | Requirements for sign-off  | Certificate of calibration and inspection of parts from the manufacturer   |  |
| 8.3                 | Training of staff (medical, paramedical, technicians)  | Training of users on operation and basic maintenance;     Advanced maintenance tasks required shall be documented;   |  |
| 9. WAR              | RRANTY AND MAINTENANCE   |  |  |
| 9.1                 | Warranty   | 3 years, including all spares and caliberation.  |  |
|                     |  |  |  |

| 10. DO  | 10. DOCUMENTATION                            |   |  |
|---------|--|---|--|
|         | Operating manuals, set manuals, other        | Should provide 2 sets(hard copy and soft copy) of:  |  |
|         | manuals                                      | User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams; |  |
|         |  | List of equipment and procedures required for local calibration and routine maintenance;                          |  |
| 10.1    |  | Service and operation manuals(original and Copy) to be provided;  |  |
|         |  | Advanced maintenance tasks documntation;  |  |
|         |  | Certificate of calibration and inspection,  |  |
|         |  |   |  |
| 10.2    | Other accompanying documents                 | List of essential spares and accessories, with their part number and cost;  |  |
| 11. Not | es   |   |  |
|         | Service Support Contact details (Hierarchy   | Contact details of manufacturer, supplier and local service agent to be provided; Any                             |  |
|         | Wise; including a toll free/landline number) | Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.   |  |
| 11.2    | Recommendations or warnings                  | Any warning sign would be adequaetly displayed.   |  |

| Vision   V   | X-R     | RAY LOBBY- SING  | LE FILM   |
|--|---------|--|---|
| Jone      | Version | no.:   | Ver_1   |
| NAME, CATEGORY AND CODING  NAME, CATEGORY AND CODING  NAMES some  INDENS code(s)  GENERAL  1. Use  1. Characteristics operation  Technical gurpose  Technical department want  Radiology Department  Technical department want  Technical want to depart want  Technical department want  Technical want  Technical department | Date:   |  | 15/02/2018  |
| MMENS anno  INDENS code(s)  GENERAL  1. Use  Radiology Department  FERMICAL  1. Clinical purpose  Technical Characteristics (specific to this type of device)  Technical Characteristics (specific to this type of the type of type of the type of type of the type of type of type of type of type of the type of type o | Done by | : (name.institution)   | HCT/NHSRC   |
| SUBSECTION   Comment   |         |  | EGORY AND CODING  |
| Liste   Linical purpose   Radiology Department   | UMDNS   |  |   |
| Liste   Linical purpose   Radiology Department   | UMDNS   | code(s)  |   |
| 1.1   Clinical purpose   |         |  | GENERAL   |
| Time   Description   Radiology Department  | 1 USE   |  |   |
| Redicings Department   TECHNICAL CHARACTERISTICS   Technical characteristics (specific to this type of device)   Six per pert demain ones);   Six pert pert demain ones);   Six pert pert demain ones);   Six pert   |         | Clinical purpose   |   |
| TECHNICAL CHARACTERISTICS  |         |  | Radiology Department  |
| Technical characteristics (specific to his type of device)   I. For viewing single X-ray film having dimensions of 15"x 5"x 2"V(L x D x H) with 2 nos. of 20% floorescent tubes of 2 feet length each with necessary fittings in MS housing of 20 SWS and is oldy powder created. View box to be fitted with white acrylic sheet to reduce glare and provide uniform illumination. Origin claps gip rolled are to be provided to hold the film. Ventilation for cooling. Drip tray for wertlins   Ventilation for ventilation for punity standard, optionally   Ventilation for punity ventilation   Ventilation for punity ventilation   Ventilation for punity ventilation   Ventilation for punity ventilation   Ventilation for wertlins   Ventilation   Ventilation   Ventilation   Ventilation   Ventilation   Ventilation   Ventilation   Ve   | 1.2     |  | =   |
| Technical characteristics (specific to this type of device)   I. For viewing single X-ray fifth having dimensions of 15" N" 25"(1. 0) x   with 2 nos. of 20" Monoscent tubes of 2 feet length each with necessary fittings in MS housing of 20 SWG and is duly powder coated. View box to be fitted with white acrylic sheet to reduce glare and provide uniform illumination. Gip clips gip ropides are to be provided to hold the film. Ventilation for cooling. Dip tray for we refilms   Ventilation for cooling. Dip tray for we films   Ventilation for cooling. Dip tray for we film   Ventilation for cooling. Dip tray for we films   Ventilation for cooling. Dip tray for we film   Ventilation for cooling. Dip tray for we film   Ventilation for cooling. Dip tray for we film   Ventilation for cooling mechanism   Ventilation for ventilation for ventilation for ventilation for ventilation for ventilation for ventilation   Ventilation for ventilation for ventilation   Ventilation for particulation   Ventilation for ventilation   Ventilation for ventilation   Ventilation for    | 2 TECH  |  | rectified in  |
| this type of device)  ## with 2 nos. of 2009 floorscent tubes of 2 feet length each with necessary fittings in MS housing of 20 SWG and is duly powder coated.  View box to be fitted with white acrylic sheet to reduce glare and provide uniform illumination.  Grip clips' girp rollers are to be provided to hold the film.  Ventilation for cooling.  Drip trus for wet films  2.2 [Jiser's interface]  Manual  3. Physic CAL CHARACTERISTICS  3. Dimensions(metrix)  NA  3.2 Weight (Ms. kg)  NA  3.3 Noise (in dBA)  NA  3.4 Heat dissipation  3.5 Mobility, pontability  4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)  4.1 Power crugationens  4.2 Battery operated  NA  4.2 Pattery operated  NA  4.3 Procession  NA  4.4 Power consumption  NA  ACCESSORES SPARE PARTS, CONSUMABLES  Special Consumables/ reagents (open, closed system)  Special Consumables/ reagents (open, closed system)  Special Consumables/ reagents (open, closed system)  BIDDING/PROCUREMENT TERMS DONATION REQUIREMENTS  6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS  ### Antonopher's Ambience (air conditioning, unindiry, dust)  1. Special Consumables (open, closed system)  Port of the consumption of the process of the proce        |         |  | 1. For viewing cingle V ray film having dimensions of 15" v 5" v 25" (I v D v   |
| 2.2 User's interface   |         | this type of device)   | H) with 2 nos. of 20W fluorescent tubes of 2 feet length each with necessary fittings in MS housing of 20 SWG and is duly powder coated.  View box to be fitted with white acrylic sheet to reduce glare and provide uniform illumination.  Grip clips/ grip rollers are to be provided to hold the film.  Ventilation for cooling. |
| Software and/ or standard of communication(where ever required S. pHYSICAL CHARACTERISTICS 3.1 Dimensions(metric) NA 3.2 Weight (Ibs. kg) NA 3.3 Nose (in dBA) NA 3.4 Heat dissipation Should maintain nominal temp and the heat should be disbursed throgh a cooling mechanism Should maintain nominal temp and the heat should be disbursed throgh a cooling mechanism (S. physical Cooling and Cooling mechanism (S. physical Cooling NA) 3.4 Heat dissipation Should maintain nominal temp and the heat should be disbursed throgh a cooling mechanism (S. physical Cooling NA) 3.5 Mobility, portability 4.1 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. ACCESSORES, SPARE PARTS, CONSUMABLES ACCESSORES, CONSUMABLES ACCESSOR     |         |  |   |
| 2.3 communication(where ever required 3. PHYSICAL CHARACTERISTICS 3.1 Dimensions(metric) 3.2 Weight (lbs, kg) NA 3.3 Noise (in dBA) NA 3.4 Heat dissipation Should maintain nominal temp and the heat should be disbursed throgh a cooling mechanism 3.5 Mobility, portability 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. Protection NA 5. ACCESSORIES, SPARE PARTS, CONSUMABLES Accessories, (mandatory, standard, optional); Spare parts (main ones); 5.1 Consumables/reagents (open, closed system) BIDDING/PROCUREMENT-TERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS Amosphere/Ambience (air conditioning, loss of the consumption of the consum     |         |  |   |
| 3.1 Dimensions(metric) 3.2 Weight (file, kg) 3.3 Noise (in dBA) 3.4 Heat dissipation 3.5 Mobility, portability 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2) 4.1 Power requirements 4.2 Battery operated 5.3 Protection 5. NA 5. ACCESSORIES, SPARE PARTS, CONSUMABLES 6. Accessories, (mandatory, standard, optionall); 5. Local manubles/reagents (open, closed system)  3. In Consumables/reagents (open, closed system)  4. In John Consumables/reagents (open, closed system)  3. In John Correction 5. Local manubles/reagents (open, closed system)  4. Sprotection 5. Local manubles/reagents (open, closed system)  4. Sprotection 5. Local manubles/reagents (open, closed system)  5. Local manubles/reagents (open, closed system)  6. EVYRONMENTAL AND DEPARTMENTAL CONSIDERATIONS  6. Lover's care, Cleaning, Disinfection & Sterility 6. Lover's care, Cleaning, Disinfection & Sterility 6. Lover's care, Cleaning, Disinfection & Sterility 6. Local and/or international 6. Local and/or international 7. STANDARDS AND SAFETY  Certificates (pre-market, sanitary,); 7. Performance and safety standards (specific to the device type); Local and/or international 7. Local and/or international 7. Local and/or international 7. Local and/or international 8. RANINGS AND INSTALLATION 8. Ranings And Safery 8. Requirements for sign-off 9. Certificates (pre-market, sanitary,); 1. Training of staff (medical, local section) 1. Training of staff freedical, local sections and caliberation.  8. Paramed And District on the protection of parts from the manufacturer 1. Training of staff (medical, local section) 2. Advanced maintenance tasks required shall be documented; 3. WARRANTY AND MAINTENANCE 9. WARRANTY AND MAINTENANCE   |         |  | NA  |
| 3.1 Dimensions(metric) NA 3.2 Weight (bs, kg) NA 3.3 Noise (in dBA) NA 3.4 Heat dissipation Should maintain nominal temp and the heat should be disbursed throgh a cooling mechanism 3.5 Mobility, portability 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 Accessories, (mandatory, standard, optional); Spare parts (main ones); 5.1 Consumables/reagents (open, closed system)  Mandity, dust) 5.2 Consumbles/reagents (open, closed system)  Jopenting Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humber of the capable of cap          | 2.5     | communication(where ever required                              |   |
| 3.1 Dimensions(metric) NA 3.2 Weight (bs, kg) NA 3.3 Noise (in dBA) NA 3.4 Heat dissipation Should maintain nominal temp and the heat should be disbursed throgh a cooling mechanism 3.5 Mobility, portability 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 Accessories, (mandatory, standard, optional); Spare parts (main ones); 5.1 Consumables/reagents (open, closed system)  Mandity, dust) 5.2 Consumbles/reagents (open, closed system)  Jopenting Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humber of the capable of cap          | 3 PHYS  | SICAL CHARACTERISTICS  |   |
| 3.2   Weight (lbs, kg)   |         |  | NA  |
| 3.3 Noise (in dBA)  3.4 Heat dissipation  Should maintain nominal temp and the heat should be disbursed throgh a cooling mechanism  3.5 Mobility, portability  4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)  4.1 Power requirements  NA  4.2 Battery operated  NA  3.4 Power consumption  NA  5. ACCESSORIES, SPARE PARTS, CONSUMABLES  Accessories, (mandatory, standard, optional); Spare parts (main ones); Spar    |         | ` '  |   |
| 3.4 Heat dissipation Should maintain nominal temp and the heat should be disbursed throgh a cooling mechanism  3.5 Mobility, portability 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2) 4.1 Power requirements NA 4.2 Battery operated NA 4.3 Protection NA 5. ACCESSORIES, SPARE PARTS, CONSUMABLES Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)  BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS 1.5 Lose and the subspace of the su      |         | 0 1 2  |   |
| 3.5 Mobility, portability 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2) 4.1 Power requirements A.2 4.2 Battery operated NA 4.3 Protection NA 5. ACCESSORIES, SPARE PARTS, CONSUMABLES ACCESSORIES, SPARE PARTS, CONSUMABLES ACCESSORIES, Guandatory, standard, optional): Spare parts (main ones): 5. Consumables/reagents (open, closed system) Spare parts (main ones): 5. Lonsumables/reagents (open, closed system) Spare parts (main ones): 5. Lonsumables/reagents (open, closed system)  BIDDING/PROCUREMENT TERMIS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS Atmosphere/Ambience (air conditioning, humidity, dust) 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% User's care, Cleaning, Disinfection & Sterility sisues  1. Operating Condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% User's care, Cleaning, Disinfection & Sterility sisues  2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% Exertification or the protected by a single use/disposable cover. 2. Sterilization not required.  3. TANING AND SAFETY  Certificates (pre-market, sanitary); 7.1 Performance and safety standards (specific to an and/or international and/or internation             |         | 1 1  |   |
| 4.1 Power requirements NA 4.2 Battery operated NA 4.3 Protection NA 4.4 Power consumption NA 5. ACCESSORIES, SPARE PARTS, CONSUMABLES Accessories, (mandatory, standard, optional); Spare parts (main ones); 5.1 Consumables/reagents (open, closed system)  BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS  BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS    Atmosphere/Ambience (air conditioning, losinfection & Sterility susues   15 to 80% in ideal circumstances, 2. Storage condition: Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative hundridy of 15 to 50%    User's care, Cleaning, Disinfection & Sterility susues   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 hundridy of 15 to 50%    Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator shot either be capable of easy disinfection or be protected by a single use/disposable cover. 2. Sterilization not required.    STANDARDS AND SAFETY   | 3.4     | -  | Should mannain nominar temp and the neat should be disoursed through a cooming mechanism  |
| 4.1 Power requirements NA 4.2 Battery operated NA 4.3 Protection NA 4.4 Power consumption NA 5. ACCESSORIES, SPARE PARTS, CONSUMABLES Accessories, (mandatory, standard, optional); Spare parts (main ones); 5.1 Consumables/reagents (open, closed system)  BIDDING/PROCUREMENT/HERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS  Atmosphere/Ambience (air conditioning, lumidity, dust) 15 to 80% in ideal circumstances. 2. Storage condition: Capable of pering stored continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 90%  1. Operating Condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%  1. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%  1. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%  1. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%  1. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%  2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%  2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%  2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%  2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%  2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%  2. Storage condition: Capable of pering continuously in ambient temperature of 0 to 50 deg C and relative humidity     |         |  | tratay CO2  |
| 4.2 Battery operated NA 4.3 Protection NA 4.4 Power consumption NA 5. ACCESSORIES, SPARE PARTS, CONSUMABLES Accessories, (mandatory, standard, optional); Spare parts (main ones); 5.1 Consumables/reagents (open, closed system)  BIDDING-PROCUREMENT TERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS Atmosphere/Ambience (air conditioning, aumidity, dust)  1. Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative hundity of 15 to 90%;  1. Operating Condition: Capable of operating continuously in ambient temperture of 0 to 50 deg C and relative hundity of 15 to 90%;  1. Operating Condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative hundity of 15 to 90%;  1. Operating Condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative hundity of 15 to 90%;  1. Operating Condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative hundity of 15 to 90%;  1. Operating Condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative hundity of 15 to 90%;  2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative hundition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative hundition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative hundition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative hundition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative hundition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative hundition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative hundition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative hundition: Capable of being st    |         |  |   |
| 4.3 Protection NA  4.4 Power consumption NA  5. ACCESSORIES, SPARE PARTS, CONSUMABLES  Accessories, (maniatory, standard, optional); Spare parts (main ones); 5.1 Consumables/reagents (open, closed system)  BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS  6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS  Atmosphere/Ambience (air conditioning, 15 to 80% in ideal circumstances. 2. Storage condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative hum didity, dust)  1. Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative hum didity, dust)  5. to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative hum didity of 15 to 90%  1. Strandards And Department of the Device that are designed to come into contact with the patient or the operator shot either be capable of easy disinfection or be protected by a single use/disposable cover. 2. Sterilization not required.  7. STANDARDS AND SAFETY  Certificates (pre-market, sanitary); Performance and safety standards (specific to the device type); Local and/or international 3. AERB type approved. 3. AERB type approved product. 2. Free installation requirements: nature, values, quality, tolerance and safety standards. 4. Three phase stable power supply nature, values, quality, tolerance and safety standards. 4. Three phase stable power supply nature, values, quality, tolerance and safety standards. 4. Three phase stable power supply nature, values, quality, tolerance and safety standard. 4. Three phase stable power supply nature, values, quality, tolerance and safety standard. 5. Advanced maintenance tasks required shall be documented; 9. AWARANTY AND MAINTENANCE   |         | •  |   |
| 4.4 Power consumption NA  S. ACCESSORIES, SPARE PARTS, CONSUMABLES  Accessories, (mandatory, standard, optional); Spare parts (main ones); 5.1 Consumables/reagents (open, closed system)  BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS  6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS  Atmosphere/Ambience (air conditioning, humidity, dust)  15 to 80% in ideal circumstances. 2. Storage condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 90%  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%  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%  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%  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%  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%  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%  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%  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%  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%  15 to 80% in      |         |  |   |
| 5. ACCESSORIES, SPARE PARTS, CONSUMABLES    Accessories, (mandatory, standard, optional);  |         |  |   |
| Accessories, (mandatory, standard, optional); Spare parts (main ones); Spare parts (main one); Spare parts (main ones); S |         |  |   |
| Spare parts (main ones); Consumables/reagents (open, closed system)  BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS  6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS  Atmosphere/Ambience (air conditioning, humidity, dust)  1. Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity, dust)  1. Operating Condition: Capable of operating continuously in ambient temperture of 0 to 50 deg C and relative humidity of 15 to 90% 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% 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% is indeed in the patient of the operator show either be capable of easy disinfection or be protected by a single use/disposable cover.  7. STANDARDS AND SAFETY  Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international 3. AERB type approved. 3. AERB type approved. 3. AERB type approved.  7. Local and/or international 4. Training of not international 5. TRAINNG AND INSTALLATION  8.1 Pre- installation requirements: nature, values, quality, tolerance mature, values, quality, tolerance paramedical, technicians)  7. Warranty  3 years, including all spares and caliberation.   |         |  |   |
| 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS  Atmosphere/Ambience (air conditioning, humidity, dust)  Atmosphere/Ambience (air conditioning, humidity, dust)  User's care, Cleaning, Disinfection & Sterility issues  User's care, Cleaning, Disinfection & Sterility is to 90%  Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator shot either be capable of easy disinfection or be protected by a single use/disposable cover.  1. Should be FDA/Europen CE/BIS approved product.  2. Manufacturer and Supplier should have ISO 13485 certification for quality standards.  3. AERB type approved.  3. AERB type approved.  4. Training of variant is a stable power supply  All the part of the         | 5.1     | Spare parts (main ones);<br>Consumables/reagents (open, closed |   |
| 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS  Atmosphere/Ambience (air conditioning, humidity, dust)  Atmosphere/Ambience (air conditioning, humidity, dust)  User's care, Cleaning, Disinfection & Sterility issues  User's care, Cleaning, Disinfection & Sterility is indeal circumstances  2. Sterility humidity of 15 to 90%  Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator shot is designed to come into contact with the patient or the operator shot is designed to come into contact with the patient or the operator shot is designed to come into contact with the patient or the operator shot of easy disinfection or be protected by a single use/disposable cover.  1. Should be FDA/Europen CE/BIS approved product.  2. Manufacturer and Supplier should have ISO 13485 certification for quality standards.  3. AERB type approved.  3. AERB type approved.  4. Three phase stable power supply  Alternative Allows Autority         | BIDDIN  | NG/DDOCLIDEMENT TEDMS/DONATIO                                  | ON DECLUDEMENTS   |
| 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 90%  User's care, Cleaning, Disinfection & Sterility issues  Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator showeither be capable of easy disinfection or be protected by a single use/disposable cover.  2. Sterilization not required.  7. STANDARDS AND SAFETY  Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international  7. Local and/or international  Manufacturer and Supplier should have ISO 13485 certification for quality standards.  3. AERB type approved.  8. TRAINING AND INSTALLATION  8.1 Pre- installation requirements: nature, values, quality, tolerance  8.2 Requirements for sign-off Certificate of calibration and inspection of parts from the manufacturer  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 and caliberation.   |         |  |   |
| humidity, dust)    15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuosly in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%  |         |  |   |
| either be capable of easy disinfection or be protected by a single use/disposable cover.  2. Sterilization not required.  7. STANDARDS AND SAFETY  Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international  7.2 Local and/or international  Manufacturer/Supplier should have ISO 13485 certification for quality standards.  8. TRAINING AND INSTALLATION  8.1 Pre-installation requirements: nature, values, quality, tolerance  8.2 Requirements for sign-off  Certificate of calibration and inspection of parts from the manufacturer  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 and caliberation.  |         | humidity, dust)  | 15 to 80% in ideal circumstances.  2. Storage condition: Capable of being stored continuosly in ambient temperature of 0 to 50 deg C and  |
| Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international  7.2 Local and/or international  8. TRAINING AND INSTALLATION  8.1 Pre- installation requirements: ature, values, quality, tolerance  8.2 Requirements for sign-off  8.3 Training of staff (medical, paramedical, technicians)  7.4 Certificates (pre-market, sanitary,);  1. Should be FDA/Europen CE/BIS approved product.  2. Manufacturer and Supplier should have ISO 13485 certification for quality standards.  3. AERB type approved.  Manufacturer/Supplier should have ISO 13485 certificate for quality standard.  8. TRAINING AND INSTALLATION  8.1 Pre- installation requirements: ature, values, quality, tolerance  8.2 Requirements for sign-off  Certificate of calibration and inspection of parts from the manufacturer  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 and caliberation.  |         |  |   |
| Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international  7.2 Local and/or international  8. TRAINING AND INSTALLATION  8.1 Pre- installation requirements: arture, values, quality, tolerance  8.2 Requirements for sign-off  8.3 Training of staff (medical, paramedical, technicians)  7.4 Warranty  1. Should be FDA/Europen CE/BIS approved product.  2. Manufacturer and Supplier should have ISO 13485 certification for quality standards.  3. AERB type approved.  Manufacturer/Supplier should have ISO 13485 certificate for quality standard.  8. TRAINING AND INSTALLATION  8.1 Pre- installation requirements: arture, values, quality, tolerance  8.2 Requirements for sign-off  Certificate of calibration and inspection of parts from the manufacturer  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 and caliberation.   | 7. STAN | NDARDS AND SAFETY  |   |
| Performance and safety standards (specific to the device type); Local and/or international 3. AERB type approved.  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: Three phase stable power supply nature, values, quality, tolerance  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 and caliberation.   |         |  | 1. Should be FDA/Europen CE/BIS approved product.   |
| the device type); Local and/or international  7.2 Local and/or international  8. TRAINING AND INSTALLATION  8.1 Pre- installation requirements: nature, values, quality, tolerance  8.2 Requirements for sign-off  8.3 Training of staff (medical, paramedical, technicians)  9. WARRANTY AND MAINTENANCE  9.1 Warranty  3. AERB type approved.  4. Aunufacture r/Suplier should have ISO 13485 certificate for quality standard.  5. Training of using the manufacturer  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. AERB type approved.  4. AERB type approved.  5. AERB type approved.  6. AERB type approved.  6. AERB type approved.  6. AERB type approved.  8. AERB type approved.  9. AERB typ | 7.1     |  |   |
| 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, tolerance  8.2 Requirements for sign-off Certificate of calibration and inspection of parts from the manufacturer  8.3 Training of staff (medical, paramedical, technicians)  9. WARRANTY AND MAINTENANCE  9.1 Warranty  3 years, including all spares and caliberation.  |         |  | 3. AERB type approved.  |
| 8. TRAINING AND INSTALLATION  8.1 Pre- installation requirements: nature, values, quality, tolerance  8.2 Requirements for sign-off Certificate of calibration and inspection of parts from the manufacturer  8.3 Training of staff (medical, paramedical, technicians)  9. WARRANTY AND MAINTENANCE  9.1 Warranty  3 years, including all spares and caliberation.  |         |  | Manufacturar/Complianchauld have ICO 12405 contificate for any live standard  |
| 8.1 Pre- installation requirements: nature, values, quality, tolerance  8.2 Requirements for sign-off  8.3 Training of staff (medical, paramedical, technicians)  9. WARRANTY AND MAINTENANCE  9.1 Warranty  1. Training of users on operation and basic maintenance; 2. Advanced maintenance tasks required shall be documented;  3 years, including all spares and caliberation.   |         |  | pyranuracturer/Supplier snould have 180/15485 certificate for quality standard.   |
| 8.1 nature, values, quality, tolerance  8.2 Requirements for sign-off Certificate of calibration and inspection of parts from the manufacturer  8.3 Training of staff (medical, paramedical, technicians)  9. WARRANTY AND MAINTENANCE  9.1 Warranty  3 years, including all spares and caliberation.  |         |  | These abose stable across specify   |
| 8.3 Training of staff (medical, paramedical, technicians)  9. WARRANTY AND MAINTENANCE  9.1 Warranty  3 years, including all spares and caliberation.  | 8.1     | nature, values, quality, tolerance                             |   |
| 8.3 paramedical, technicians) 2. Advanced maintenance tasks required shall be documented; 9. WARRANTY AND MAINTENANCE 9.1 Warranty 3 years, including all spares and caliberation.   | 8.2     |  |   |
| 9. WARRANTY AND MAINTENANCE 9.1 Warranty 3 years, including all spares and caliberation.   | 8.3     |  |   |
| 9.1 Warranty 3 years, including all spares and caliberation.   |         | <u>r</u>   | 2. Advanced maintenance tasks required shall be documented;   |
|  |         |  | 2 years including all groups and saliboration   |
| IU. DOCUMENTATION  |         |  | p years, including all spares and camberation.  |
|  | 10. DOC | COMENTATION  |   |

|         | Operating manuals, set manuals, other        | Should provide 2 sets(hard copy and soft copy) of:  |
|---------|--|---|
|         | manuals                                      | User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams; |
|         |  | List of equipment and procedures required for local calibration and routine maintenance;                          |
| 10.1    |  | Service and operation manuals(original and Copy) to be provided;  |
|         |  | Advanced maintenance tasks documntation;  |
|         |  | Certificate of calibration and inspection,  |
|         |  |   |
| 10.2    | Other accompanying documents                 | List of essential spares and accessories, with their part number and cost;  |
| 11. Not | es   |   |
|         | Service Support Contact details (Hierarchy   | Contact details of manufacturer, supplier and local service agent to be provided; Any                             |
|         | Wise; including a toll free/landline number) | Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.   |
| 11.2    | Recommendations or warnings                  | Any warning sign would be adequaetly displayed.   |

| DA      | RK ROOM SAFET  | Y LIGHT   |
|---------|--|---|
| Version | no.:   | Ver_1   |
| Date:   |  | 15/02/2018  |
| Done by | : (name.institution)   | HCT/NHSRC   |
| J       |  | EGORY AND CODING  |
| UMDNS   | <u> </u>   |   |
| UMDNS   | S code(s)  |   |
|         |  | GENERAL   |
| 1. USE  |  |   |
| 1.1     | Clinical purpose   |   |
|         | Used by clinical department/ward   | Radiology Department  |
| 1.2     |  | TECHNICAL   |
| 2 TECI  | HNICAL CHARACTERISTICS   | rectified to  |
| Z. TECI | Technical characteristics (specific to   | Body to be made out of MS sheet with outside black coating and unbreakable red  |
|         | this type of device)   | plastic filter for satisfactory results Lamp holder to be included Size approximately 25 x 20 x 15 cm made of MS housing of 20 SWG epoxy powder coated Necessary electrical fittings are provided I the housing to fit a red colored 25W bulb along with mains cable and 3 pin plug with provision for switching ON/OFF |
| 2.2     | User's interface Software and/ or standard of  | Manual<br>NA  |
| 2.3     | communication(where ever required  | ina   |
|         | SICAL CHARACTERISTICS  |   |
| 3.1     | Dimensions(metric)   | NA NA   |
| 3.2     | Weight (lbs, kg)   | NA NA   |
| 3.3     | Noise (in dBA)   | NA NA   |
| 3.4     | Heat dissipation   | Should maintain nominal temp and the heat should be disbursed throgh a cooling mechanism  |
| 3.5     | Mobility, portability  |   |
|         | RGY SOURCE (electricity, UPS, solar, gas, v  | . ,   |
|         | Power requirements   | NA  |
| 4.2     | Battery operated   | NA  |
|         | Protection   | NA  |
|         | Power consumption  | NA NA   |
|         | ESSORIES, SPARE PARTS, CONSUMABLES   |   |
| 5.1     | Accessories, (mandatory, standard, optional);<br>Spare parts (main ones);<br>Consumables/reagents (open, closed<br>system) |   |
| DIDDI   | NG/DDOCLIDEMENT TEDMS/DONATIO  | NI DECLIDEMENTS   |
|         | NG/PROCUREMENT TERMS/DONATION<br>RONMENTAL AND DEPARTMENTAL CON  | · · · · · · · · · · · · · · · · · · ·   |
| O. ENVI | Atmosphere/Ambience (air conditioning,   | 1 Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity of  |
| 6.1     | humidity, dust)  | 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of left temperature of 0 to 50 deg C and relative humidity of 15 to 90%  |
| 6.2     | User's care, Cleaning, Disinfection & Sterility issues   | 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 not required.   |
| 7. STAI | I<br>NDARDS AND SAFETY   |   |
|         | Certificates (pre-market, sanitary,);  | 1. Should be FDA/Europen CE/BIS approved product.   |
| 7.1     |  |   |
| /.1     | the device type); Local  | 3. AERB type approved.  |
| 7.2     | and/or international  Local and/or international   | Manufacturer/Supplier should have ISO 13485 certificate for quality standard.   |
|         | INING AND INSTALLATION   | prantine ture 1/3 uppner should have 150/15465 certificate for quality standard.  |
| 8.1     | Pre- installation requirements:  | Three phase stable power supply   |
| 8.2     | nature, values, quality, tolerance Requirements for sign-off   | Certificate of calibration and inspection of parts from the manufacturer  |
|         | Training of staff(medical,   | 1. Training of users on operation and basic maintenance;  |
| 8.3     | paramedical, technicians)  | 2. Advanced maintenance tasks required shall be documented;   |
| 9. WAR  | RRANTY AND MAINTENANCE   |   |
| 9.1     | Warranty   | 3 years, including all spares and caliberation.   |
| 10. DO  | CUMENTATION  |   |
|         |  |   |

|         | Operating manuals, set manuals, other        | Should provide 2 sets(hard copy and soft copy) of:  |
|---------|--|---|
|         | manuals                                      | User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams; |
|         |  | List of equipment and procedures required for local calibration and routine maintenance;                          |
| 10.1    |  | Service and operation manuals(original and Copy) to be provided;  |
|         |  | Advanced maintenance tasks documntation;  |
|         |  | Certificate of calibration and inspection,  |
|         |  |   |
| 10.2    | Other accompanying documents                 | List of essential spares and accessories, with their part number and cost;  |
| 11. Not | es   |   |
|         | Service Support Contact details (Hierarchy   | Contact details of manufacturer, supplier and local service agent to be provided; Any                             |
| 11.1    | Wise; including a toll free/landline number) | Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.   |
| 11.2    | Recommendations or warnings                  | Any warning sign would be adequaetly displayed.   |

| DARK ROOM TIMER |   |  |  |
|-----------------|---|--|--|
| Version         | no :  | Ver_1  |  |
| Date:           | 10  | 15/02/2018   |  |
|                 | : (name.institution)  | HCT/NHSRC  |  |
| Bone of         |   | EGORY AND CODING   |  |
| UMDNS           |   |  |  |
| UMDNS           | S code(s)   |  |  |
|                 |   | GENERAL  |  |
| 1. USE          |   |  |  |
| 1.1             | Clinical purpose  |  |  |
| 1.2             | Used by clinical department/ward                                      | Radiology Department   |  |
|                 | ,   | TECHNICAL  |  |
| 2. TEC          | HNICAL CHARACTERISTICS  |  |  |
|                 | Technical characteristics (specific to                                | DARK ROOM TIMER  |  |
|                 | this type of device)  | 1. Electronic type in the range from 0.1 seconds   |  |
|                 |   | 2. Accuracy: ± .01 %   |  |
|                 |   | Digital display with audio signal.     Auto reset option.  |  |
|                 |   | 5. Power supply: 220-240 V AC, 50 Hz, Single phase.  |  |
|                 |   | 6. Easy to use indarkroom.   |  |
| 2.2             | User's interface  | Manual   |  |
| 2.3             | Software and/ or standard of  | NA NA  |  |
| 2.3             | communication(where ever required                                     |  |  |
| 3. PHY          | SICAL CHARACTERISTICS   |  |  |
| 3.1             | Dimensions(metric)  | NA   |  |
| 3.2             | Weight (lbs, kg)  | NA NA  |  |
| 3.3             | Noise (in dBA)  | NA NA  |  |
| 3.4             | Heat dissipation  | Should maintain nominal temp and the heat should be disbursed through a cooling mechanism  |  |
|                 | N. 199  |  |  |
| 3.5             | Mobility, portability   |  |  |
|                 | RGY SOURCE (electricity, UPS, solar, gas, v                           |  |  |
| 4.1             | Power requirements  Battery operated                                  | NA<br>NA   |  |
| 4.2             | Protection  | NA   |  |
| 4.4             | Power consumption   | NA   |  |
|                 | ESSORIES, SPARE PARTS, CONSUMABLES                                    |  |  |
|                 | Accessories, (mandatory, standard, optional);                         |  |  |
|                 | Spare parts (main ones);  |  |  |
| 5.1             | Consumables/reagents (open, closed                                    |  |  |
|                 | system)   |  |  |
| BIDDI           | I<br>NG/PROCUREMENT TERMS/DONATIO                                     | ON REQUIREMENTS  |  |
|                 | IRONMENTAL AND DEPARTMENTAL COM                                       |  |  |
| o. Ervi         | Atmosphere/Ambience (air conditioning,                                | 1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity of  |  |
| 6.1             | humidity, dust)   | 15 to 80% in ideal circumstances.  |  |
| 0.1             |   | 2. Storage condition: Capable of being stored continuosly in ambient temperature of 0 to 50 deg C and  |  |
| <u> </u>        | User's care, Cleaning, Disinfection & Sterility                       | relative humidity of 15 to 90%  Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should   |  |
|                 | issues  | either be capable of easy disinfection or be protected by a single use/disposable cover.   |  |
| 6.2             |   | 2. Sterilization not required.   |  |
|                 |   |  |  |
| 7. STA          | NDARDS AND SAFETY   |  |  |
|                 | Certificates (pre-market, sanitary,);                                 | Should be FDA/Europen CE/BIS approved product.      Mount of the product of |  |
| 7.1             | Performance and safety standards (specific to the device type); Local | <ol> <li>Manufacturer and Supplier should have ISO 13485 certification for quality standards.</li> <li>AERB type approved.</li> </ol>  |  |
| L               | and/or international  | υ. πελέν την αργιστού.   |  |
| 7.2             | Local and/or international  | Manufacturer/Supplier should have ISO 13485 certificate for quality standard.  |  |
| 8. TRA          | INING AND INSTALLATION  |  |  |
| 8.1             | Pre- installation requirements:                                       | Three phase stable power supply  |  |
| 8.2             | nature, values, quality, tolerance<br>Requirements for sign-off       | Cartificate of calibration and inspection of parts from the manufacturer   |  |
|                 | Training of staff (medical,   | Certificate of calibration and inspection of parts from the manufacturer  1. Training of users on operation and basic maintenance;   |  |
| 8.3             | paramedical, technicians)   | 2. Advanced maintenance tasks required shall be documented;  |  |
| 9. WAF          | 9. WARRANTY AND MAINTENANCE   |  |  |
| 9.1             | Warranty  | 3 years, including all spares and caliberation.  |  |
| 10. DO          | CUMENTATION   |  |  |
|                 |   |  |  |

|         | Operating manuals, set manuals, other        | Should provide 2 sets(hard copy and soft copy) of:  |
|---------|--|---|
|         | manuals                                      | User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams; |
|         |  | List of equipment and procedures required for local calibration and routine maintenance;                          |
| 10.1    |  | Service and operation manuals(original and Copy) to be provided;  |
|         |  | Advanced maintenance tasks documntation;  |
|         |  | Certificate of calibration and inspection,  |
|         |  |   |
| 10.2    | Other accompanying documents                 | List of essential spares and accessories, with their part number and cost;  |
| 11. Not | es   |   |
|         | Service Support Contact details (Hierarchy   | Contact details of manufacturer, supplier and local service agent to be provided; Any                             |
| 11.1    | Wise; including a toll free/landline number) | Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.   |
| 11.2    | Recommendations or warnings                  | Any warning sign would be adequaetly displayed.   |

| X-F      | X-RAY CASSETTE  |  |  |
|----------|---|--|--|
| Version  | no. :   | Ver_1  |  |
| Date:    |   | 15/02/2018   |  |
| Done by  | : (name.institution)  | HCT/NHSRC  |  |
| ,        |   | EGORY AND CODING   |  |
| UMDNS    | · · · · · · · · · · · · · · · · · · ·                       |  |  |
| UMDNS    |   |  |  |
|          |   | GENERAL  |  |
| 1. USE   |   | GENERAL  |  |
| 1.1      | Clinical purpose  |  |  |
| 1.2      |   | Radiology Department   |  |
| 1.2      | , i   | TECHNICAL  |  |
| 2 TECI   |   | TECHNICAL  |  |
| Z. TECI  | HNICAL CHARACTERISTICS                                      |  |  |
|          | Technical characteristics (specific to this type of device) | A set of cassettes having system for indicating whether or not it is loaded and a slot for patient identity card.  |  |
|          | tins type of device)  | Cassettes to be compatible with the radiology equipment 3. Should include 14"x   |  |
|          |   | 17", 15"x 12", 12"x 10", 10"x 8"   |  |
|          |   | Cassettes to be made of Aluminium for light weight. 4 corners to be connected with non-  |  |
|          |   | metallic construction to give protection covers.   |  |
|          |   | Soft push button locking arrangement with stainless springs  |  |
|          |   | Suitable lead protection spray to be given on the inside rear flap of the cassette to eliminate  |  |
|          |   | fog effect on X-ray film   |  |
|          |   | 7. High grade foam material to be pasted inside to give the film a uniform contact with  |  |
|          |   | intensifying screens   |  |
| 2.2      | User's interface  | Manual   |  |
|          | Software and/ or standard of                                | NA   |  |
| 2.3      | communication(where ever required                           |  |  |
|          | ` 1   |  |  |
| 3. PHY:  | SICAL CHARACTERISTICS                                       |  |  |
| 3.1      | Dimensions(metric)  | NA NA  |  |
| 3.2      | Weight (lbs, kg)  | NA   |  |
| 3.3      | Noise (in dBA)  | NA NA  |  |
| 3.4      | Heat dissipation  | Should maintain nominal temp and the heat should be disbursed through a cooling mechanism  |  |
|          |   |  |  |
|          | Mobility, portability                                       |  |  |
|          | RGY SOURCE (electricity, UPS, solar, gas, v                 |  |  |
|          | •   | NA NA  |  |
| 4.2      | J 1   | NA NA  |  |
| 4.3      | Protection  | NA NA  |  |
|          | Power consumption   | NA NA  |  |
| 5. ACCI  | ESSORIES, SPARE PARTS, CONSUMABLES                          |  |  |
|          | Accessories, (mandatory, standard, optional);               |  |  |
|          | Spare parts (main ones);                                    |  |  |
| 5.1      | Consumables/reagents (open, closed                          |  |  |
|          | system)   |  |  |
| BIDDI    | NG/PROCUREMENT TERMS/DONATION                               | ON REQUIREMENTS  |  |
|          | RONMENTAL AND DEPARTMENTAL CON                              |  |  |
| J. LIVVI | Atmosphere/Ambience (air conditioning,                      | 1 Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity of   |  |
|          | humidity, dust)   | 1. Operating Condition: Capable of operating continuously in amolein temperatire of 3 to 30 deg C and relative numberly of 15 to 80% in ideal circumstances.   |  |
| 6.1      |   | 2. Storage condition: Capable of being stored continuosly in ambient temperature of 0 to 50 deg C and  |  |
|          |   | relative humidity of 15 to 90%   |  |
|          | User's care, Cleaning, Disinfection & Sterility             | Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should   |  |
| 6.2      | issues  | either be capable of easy disinfection or be protected by a single use/disposable cover.   |  |
| J.2      |   | 2. Sterilization not required.   |  |
| 7 074    | ND ADDC AND CAFEEY  |  |  |
| 7. STAI  | NDARDS AND SAFETY   | 1 CL 111 FDA/F   |  |
|          | Certificates (pre-market, sanitary,);                       | Should be FDA/Europen CE/BIS approved product.      Mount of the product of |  |
| 7.1      | Performance and safety standards (specific to               | * *  |  |
|          | the device type); Local<br>and/or international             | 3. AERB type approved.   |  |
| 7.2      | Local and/or international                                  | Manufacturer/Supplier should have ISO 13485 certificate for quality standard.  |  |
|          | INING AND INSTALLATION                                      |  |  |
|          | Pre- installation requirements:                             | Three phase stable power supply  |  |
| 8.1      | nature, values, quality, tolerance                          | ттее ришье вшоге рожет вирргу  |  |
| 8.2      | Requirements for sign-off                                   | Certificate of calibration and inspection of parts from the manufacturer   |  |
|          | Training of staff (medical,                                 | 1. Training of users on operation and basic maintenance;   |  |
| 8.3      | paramedical, technicians)                                   | 2. Advanced maintenance tasks required shall be documented;  |  |
|          |   |  |  |

| 9. WAR  | 9. WARRANTY AND MAINTENANCE   |   |  |
|---------|---|---|--|
| 9.1     | Warranty  | 3 years, including all spares and caliberation.   |  |
| 10. DO  | CUMENTATION   |   |  |
| 10.1    | Operating manuals, set manuals, other manuals   | Should provide 2 sets(hard copy and soft copy) of:  User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams;  List of equipment and procedures required for local calibration and routine maintenance;  Service and operation manuals(original and Copy) to be provided;  Advanced maintenance tasks documntation;  Certificate of calibration and inspection, |  |
| 10.2    | Other accompanying documents  | List of essential spares and accessories, with their part number and cost;  |  |
| 11. Not | 11. Notes   |   |  |
| 11.1    | Service Support Contact details (Hierarchy<br>Wise; including a toll<br>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 adequaetly displayed.   |  |

| Inte       | Intensifying Screens                            |  |  |
|------------|---|--|--|
| Version    | no.:  | Ver_1  |  |
| Date:      |   | 15/02/2018   |  |
| Done by    | : (name.institution)                            | HCT/NHSRC  |  |
| ,          |   | EGORY AND CODING   |  |
| UMDNS      |   |  |  |
| UMDNS      |   |  |  |
| CIVIDIAL   | , code(s)                                       | GENERAL  |  |
| 1. USE     |   | ULIVERAL   |  |
|            | Clinical purpose                                |  |  |
| 1.1        | 1 1   | Dudislam Dandungt  |  |
| 1.2        | Used by clinical department/ward                | Radiology Department   |  |
|            |   | TECHNICAL  |  |
| 2. TECI    | HNICAL CHARACTERISTICS                          |  |  |
|            | Technical characteristics (specific to          | High speed in class 100 to 160 in various sizes  |  |
|            | this type of device)                            | Calcium tungstate emulsion layer on polyester base   |  |
|            |   | Compatible with all X- ray films available 4. Sizes of screens:  |  |
| 2.2        | User's interface                                | 14"x 17", 15"x 12", 12"10", 10"x8" (5 nos. each) Manual  |  |
| 2.2        | Software and/ or standard of                    | NA   |  |
| 2.3        | communication(where ever required               | H 11.1   |  |
|            | Zommanioudon (where ever required               |  |  |
| 3. PHY     | SICAL CHARACTERISTICS                           |  |  |
|            | Dimensions(metric)                              | NA   |  |
| 3.2        | Weight (lbs, kg)                                | NA   |  |
| 3.3        | Noise (in dBA)                                  | NA   |  |
|            | Heat dissipation                                | Should maintain nominal temp and the heat should be disbursed through a cooling mechanism                                    |  |
| 3.4        | ricat dissipation                               | biodia mamaan nominan emp ana de near sibula de disbursea dinogri a coomig mechanism   |  |
| 3.5        | Mobility, portability                           |  |  |
| 4. ENEI    | RGY SOURCE (electricity, UPS, solar, gas, v     | water, CO2)  |  |
|            | Power requirements                              | NA NA  |  |
|            | Battery operated                                | NA   |  |
|            | Protection                                      | NA   |  |
|            | Power consumption                               | NA   |  |
|            | ESSORIES, SPARE PARTS, CONSUMABLES              |  |  |
| J. ACCI    | Accessories, (mandatory, standard, optional);   |  |  |
|            | Spare parts (main ones);                        |  |  |
| 5.1        | Consumables/reagents (open, closed              |  |  |
|            | system)   |  |  |
|            |   |  |  |
| BIDDI      | NG/PROCUREMENT TERMS/DONATION                   | ON REQUIREMENTS  |  |
| 6. ENVI    | RONMENTAL AND DEPARTMENTAL CON                  | NSIDERATIONS   |  |
|            | Atmosphere/Ambience (air conditioning,          | 1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity of    |  |
| 6.1        | humidity, dust)                                 | 15 to 80% in ideal circumstances.  |  |
| 0.1        |   | 2. Storage condition: Capable of being stored continuosly in ambient temperature of 0 to 50 deg C and                        |  |
| <u> </u>   |   | relative humidity of 15 to 90%   |  |
|            | User's care, Cleaning, Disinfection & Sterility | Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should             |  |
| 6.2        | issues  | either be capable of easy disinfection or be protected by a single use/disposable cover.  2. Sterilization not required.     |  |
|            |   | a. Sistinguitar nortoquitou.   |  |
| 7. STAN    | NDARDS AND SAFETY                               |  |  |
|            | Certificates (pre-market, sanitary,);           | Should be FDA/Europen CE/BIS approved product.   |  |
|            | Performance and safety standards (specific to   | Manufacturer and Supplier should have ISO 13485/ISO 9001 certification for quality standards.                                |  |
| 7.1        | the device type); Local and/or international    | Shall complaints to IEC 61262-7: Medical electrical equipment - Characteristics of electro-optical X- ray image intensifiers |  |
| 7.1        | 31.77   | - Part 7: Determination of the modulation transfer function  |  |
|            |   |  |  |
|            |   |  |  |
|            | Local and/or international                      | Manufacturer/Supplier should have ISO 13485 certificate for quality standard.  |  |
| 8. TRA     | NING AND INSTALLATION                           |  |  |
| 8.1        | Pre- installation requirements:                 | Three phase stable power supply  |  |
|            | nature, values, quality, tolerance              |  |  |
| 8.2        | Requirements for sign-off                       | Certificate of calibration and inspection of parts from the manufacturer   |  |
| 8.3        | Training of staff (medical,                     | 1. Training of users on operation and basic maintenance;   |  |
|            | paramedical, technicians)                       | 2. Advanced maintenance tasks required shall be documented;  |  |
|            | 9. WARRANTY AND MAINTENANCE                     |  |  |
| 9.1        | Warranty  | 3 years, including all spares and caliberation.  |  |
| $\Pi()$ DO | CUMENTATION                                     |  |  |

|         | Operating manuals, set manuals, other        | Should provide 2 sets(hard copy and soft copy) of:  |
|---------|--|---|
|         | manuals                                      | User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams; |
|         |  | List of equipment and procedures required for local calibration and routine maintenance;                          |
| 10.1    |  | Service and operation manuals(original and Copy) to be provided;  |
|         |  | Advanced maintenance tasks documntation;  |
|         |  | Certificate of calibration and inspection,  |
|         |  |   |
| 10.2    | Other accompanying documents                 | List of essential spares and accessories, with their part number and cost;  |
| 11. Not | es   |   |
|         | Service Support Contact details (Hierarchy   | Contact details of manufacturer, supplier and local service agent to be provided; Any                             |
| 11.1    | Wise; including a toll free/landline number) | Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.   |
| 11.2    | Recommendations or warnings                  | Any warning sign would be adequaetly displayed.   |

| LEAD APRON                   |  |  |  |  |
|------------------------------|--|--|--|--|
| Version no.                  | .:   | Ver_1  |  |  |
| Date:                        |  | 15/02/2018   |  |  |
| Done by : (name.institution) |  | HCT/NHSRC  |  |  |
|                              | NAME, CATEGOR  | Y AND CODING   |  |  |
| UMDNS na                     | ame  |  |  |  |
| UMDNS co                     | ode(s)   |  |  |  |
|                              | GENE   | RAL  |  |  |
| 1. USE                       |  |  |  |  |
| 1.1                          | Clinical purpose   |  |  |  |
| 1.2                          | Used by clinical department/ward   | Radiology Department   |  |  |
| TECHNICAL                    |  |  |  |  |
| 2. TECHNICAL CHARACTERISTICS |  |  |  |  |
|                              | Technical characteristics (specific to this  | Coat type aprons fabricated from multiple leaded vinyl fabric having minimum   |  |  |
|                              | type of device)  | 0.5 mm lead equivalent for protection from scattered radiation   |  |  |
|                              |  | Apron to cover over shoulders through upto knees   |  |  |
|                              |  | Item should be light in weight and durable   |  |  |
|                              |  | Necessary water proof cloth lining to be stitched on vinyl fabric.   |  |  |
|                              |  | Apron should have approval certificate of AERB   |  |  |
| 1                            |  | Suitable wooden hanger to be provided for hanging apron to avoid damage  |  |  |
|                              |  |  |  |  |
|                              |  |  |  |  |
| 2.2                          | User's interface   | Manual   |  |  |
|                              | Software and/ or standard of   | NA   |  |  |
| 2.3                          | communication(where ever required  |  |  |  |
| 3. PHYSICAL CHARACTERISTICS  |  |  |  |  |
| 3.1                          | Dimensions(metric)   | NA NA  |  |  |
|                              | 1 1  |  |  |  |
| 3.2                          | Weight (lbs, kg) Noise (in dBA)  | NA<br>NA   |  |  |
| 3.3                          | ` '  |  |  |  |
| 3.4                          | Heat dissipation   | Should maintain nominal temp and the heat should be disbursed throgh a cooling mechanism   |  |  |
| 3.5                          | Mobility, portability  |  |  |  |
|                              | GY SOURCE (electricity, UPS, solar, gas, water,  | ,  |  |  |
| 4.1                          | Power requirements   | NA   |  |  |
| 4.2                          | Battery operated   | NA   |  |  |
| 4.3                          | Protection   | NA   |  |  |
| 4.4                          | Power consumption  | NA   |  |  |
| 5. ACCESS                    | SORIES, SPARE PARTS, CONSUMABLES   |  |  |  |
|                              | Accessories, (mandatory, standard, optional);  |  |  |  |
| 5.1                          | Spare parts (main ones); Consumables/reagents (open, closed system)                              |  |  |  |
| BIDDING                      | G/PROCUREMENT TERMS/DONATION R   | EQUIREMENTS  |  |  |
|                              | ONMENTAL AND DEPARTMENTAL CONSIDE  |  |  |  |
|                              | Atmosphere/Ambience (air conditioning,   | Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative   |  |  |
| 6.1                          | humidity, dust)  | 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% |  |  |
|                              | User's care, Cleaning, Disinfection & Sterility  | Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator  |  |  |
| 6.2                          | issues   | should either be capable of easy disinfection or be protected by a single use/disposable cover.  2. Sterilization not required.  |  |  |
| 7. STAND                     | OARDS AND SAFETY   |  |  |  |
|                              | Certificates (pre-market, sanitary,);  | 1. Manufacturer and Supplier should have ISO 13485/ISO 9001 certification for quality standards  |  |  |
| 7.1                          | Performance and safety standards (specific to<br>the device type); Local<br>and/or international | 2. Shall be complaint to IEC61331-1  |  |  |
| 7.2                          | Local and/or international   | Manufacturer/Supplier should have ISO 13485 certificate for quality standard.  |  |  |
| 8. TRAIN                     | ING AND INSTALLATION   |  |  |  |
| 8.1                          | Pre- installation requirements:<br>nature, values, quality, tolerance                            | Three phase 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,  | 1. Training of users on operation and basic maintenance;   |  |  |
|                              | paramedical, technicians) ANTY AND MAINTENANCE   | 2. Advanced maintenance tasks required shall be documented;  |  |  |
|                              |  | 3 years including all energy and caliberation  |  |  |
| 9.1                          | Warranty   | 3 years, including all spares and caliberation.  |  |  |
| 10. DOCU                     | MENTATION  |  |  |  |

| 10.1      | Operating manuals, set manuals, other manuals   | Should provide 2 sets(hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals(original and Copy) to be provided; Advanced maintenance tasks documntation; Certificate of calibration and inspection, |  |
|-----------|---|--|--|
| 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<br>(Hierarchy Wise; including a toll<br>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 adequaetly displayed.  |  |