सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

TECHNICAL SPECIFICATIONS OF MEDICAL DEVICES FOR
OPHTHALMOLOGY DEPARTMENT

Ministry of Health and Family Welfare
Government of India

DISCLAIMER

Please note the following points before using these technical specifications:

The specifications are suggestive in nature. State may adopt/adapt them as per context specific needs. These specifications may be tailored appropriately by users according to the specific situation, especially:
i. Local standards and legislation; local regulations and conditions; languages; installation conditions, technological levels, electrical range, capacities, utility environment, clinical procedures, personnel (users) experience and other local specific conditions.
ii. The number of accessories, consumables, spare parts and other components indicates usual and/or ideal number and is not a mandatory quantity. The user can determine this quantity according to a product's characteristics and frequency of use in the hospital.
iii. The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by NHM / NHSRC in preference to others of a similar nature that are not mentioned.
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PREETI SUDAN
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भारत सरकार
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स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health and Family Welfare

Date : 30.09.2019

MESSAGE

Various pioneering and innovative initiatives are being taken up by Government of India through National Health Mission (NHM) to provide affordable and effective healthcare to Indian Citizens. Substantial investments in the NHM have been made to strengthen Public Health System in the country.

Identifying vital medical devices is a critical part of strengthening health infrastructure. However rapidly changing technologies, complexity associated with medical devices, ensuring quality, safety performance and high costs of procurement - all these make selection of appropriate and cost effective devices a challenging task.

To address this need, the Ministry of Health and Family welfare, Government of India under the aegis of NHM formulated technical specifications of various medical devices as per Indian Public Health Standards. Cost, utility, availability in domestic market, maintenance and patient safety are crucial issues to be considered while procuring medical devices. I am delighted to note that these have been effectively considered by NHSRC under MoHFW while preparing the specifications.

Effort has been made to make the specifications as generic as possible and this has been the corner stone of this technical exercise. State may make appropriate modifications to suit their context specific requirements.

(Preeti Sudan)

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MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI - 110011

MESSAGE

National Health Mission is unique in such programmatic intervention envisioned at enrich largely on health with distinctive attention in vitalizing rural health infrastructure and services. Providing vital medical devices is a critical component of strengthening the health infrastructure.

Technical specifications play an important role in identification and procurement of appropriate cost effective medical devices. Factors to be considered include the type of health facility where the devices are to be used, the health work force available and the burden of disease experienced in the specific catchment area.

I am happy to note that, National Health System Resource Centre has filled an important technical gap by providing these specifications. The experts consulted for specification formulation exercises include experts from prestigious institutions such as AIIMS, PGIMER - Chandigarh, Ram Manohar Lohia Hospital, Safdarjung Hospital, Sree Chitra Institute of Medical Sciences & Technology, JIPMER, Hindustan Life Care Limited, Representatives from various state medical corporations to name a few. The specifications were also reviewed by Directorate General Health Services, Govt of india.

I am anticipating that using them as reference specifications while undertaking procurement will diminish costs of procurement, ensure the quality, standards, optimal performance of medical devices and reduce the procurement lead time. I am sure that technical specifications suggested here will serve as a reference for procurement of medical devices under the National Health Mission.

(Manoj Jhalani)

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INTRODUCTION

Medical devices are a very important part of health care and their use is increasing by the day. Technical specifications play an important role in identification, selection and procurement of appropriate and cost effective medical devices. Consistency and standardization in technical specifications promotes positive competition and reduces effective costs. It also promotes uniformity in user training and smooth maintenance of equipment. In order to address the variation in technologies many of which could be add-ons, separate exercises were undertaken for specific categories of medical devices procured under National Health Mission. The experts consulted for specifications formulation exercises included clinicians, medical technologists, maintenance experts and also representatives from manufactures' industry associations/government organizations.

National Health Systems Resource Centre which is also a WHO collaborating center for priority medical devices & health technology policy; in consultation with experts has formulated technical specifications for commonly used medical devices. Specifications are suggestive in nature and any specific requirement needs to be incorporated at the time of procurement. While effort has been made to make the specifications as generic as possible and consensus and technical appropriateness has been the corner stone of this technical exercise.

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

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

  (a) Proper grounding at electrical sockets,

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

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

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

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

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

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

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

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

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

CRYOSURGICAL UNITS, OPHTHALMIC (CO_2 and N_2O)

Version no. :		Ver_1
Date:		19/08/2018
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Cryosurgical Units, Ophthalmic
UMDNS code(s)		11068
GENERAL		
1. USE		
1.1	Clinical purpose	Cryosurgical units are designed for applying extreme cold to eye tissues to destroy abnormal cells. These units usually consist of a hollow probe (cryo probe) that circulates a cryogenic substance (e.g. liquid nitrogen) to form an ice crystal ball around the cells, which freezes the cells of the tissues with which it comes into contact. Ophthalmic cryosurgical units are used mainly to treat eye tumors (e.g., retinoblastoma), to relieve ingrown eyelashes (trachiasis), for cryo extraction of intra capsular cataracts, and/or to repair retinal detachment.
1.2	Used by clinical department/ward	Ophthalmology - Operating theater, Operating room.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Cryogen shall be CO_2 and N_2O. 2. Cryosurgical unit capable of achieving temperatures at the cryo tip below -79°C (-110.2°F) for CO_2, -89°C (-128.2°F) for N_2O. 3. Should have Active and Passive defrosting system. 4. Cryosurgical procedures require several different probe designs. Special probes are used based on the surgical procedures. Cryosurgical units with multiple probe tips can enable physicians to perform a number of specialized procedures. Should be supplied with all kinds of probes required for ophthalmology and all cryo probes must be autoclavable. 5. Operating pressure 400 to 850 psi. 6. The unit shall have a trigger mechanism to control the freeze/thaw cycle (active defrost preferred but not essential), removable circular, closed design cryo tips with flat surfaces or with a cone extrusion not exceeding 5 mm, insulated cryo shaft of length 170 mm to 200 mm, hose assembly (high pressure) with cylinder connector, pressure gauge and relief valve, and exhaust port to which a hose can be connected to safely vent the exhaust gas. 7. Due to the adverse effects of chronic exposure to waste anesthetic gases, nitrous oxide units should have scavenging ability.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required	NA

3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Cryo probes to according the specific use (Preferably 3 sizes (1.5 mm, 2 mm, 3 mm)). 2. Integral timer and temperature indicator. 3. Should be supplied with rolling cart. 4. Should be supplied with unfilled cylinder for N_2O or CO_2.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	1. Operating Condition: Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	1. Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/ sterile disposable cover. 2. Sterilization required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO/ approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available.) 2. Manufacturer should have ISO 13485 certification for quality standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	Requirements for sign-off	Manufacturer and authorized supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.

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

CRYOSURGICAL UNITS, OPHTHALMIC (LIQUID NITROGEN)

Version no. :		Ver_1
Date:		19/08/2018
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Cryosurgical Units, Ophthalmic
UMDNS code(s)		11068
GENERAL		
1. USE		
1.1	Clinical purpose	Cryosurgical units designed for applying extreme cold to eye tissues to destroy abnormal cells. These units usually consist of a hollow probe (cryo probe) that circulates a cryogenic substance (e.g. liquid nitrogen) to form an ice crystal ball around the cells, which freezes the cells of the tissues with which it comes into contact. Ophthalmic cryosurgical units are used mainly to treat eye tumors (e.g., retinoblastoma), to relieve ingrown eyelashes (trachiasis), for cryo extraction of intra capsular cataracts, and/or to repair retinal detachment.
1.2	Used by clinical department/ward	Ophthalmology - Operating theater, Operating room.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Cryogen shall be Liquid Nitrogen. 2. Cryosurgical unit capable of achieving temperatures at the cryo tip below --196°C (-320.8°F). 3. Should have Active and Passive defrosting system. 4. Cryosurgical procedures require several different probe designs. Special probes are used based on the surgical procedures. Cryosurgical units with multiple probe tips can enable physicians to perform a number of specialized procedures. Should be supplied with all kinds of probes required for ophthalmology and all cryo probes must be autoclavable. 5. Operating pressure 400 to 850 psi. 6. The unit shall have a trigger mechanism to control the freeze/thaw cycle (active defrost preferred but not essential), removable circular, closed design cryo tips with flat surfaces or with a cone extrusion not exceeding 5 mm, insulated cryo shaft of length 170 mm to 200 mm, hose assembly (high pressure) with cylinder connector, pressure gauge and relief valve, and exhaust port to which a hose can be connected to safely vent the exhaust gas.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required)	NA

3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Cryo probes to according the specific use (Preferably 3 sizes (1.5 mm, 2 mm, 3 mm)). 2. Integral timer and temperature indicator. 3. Should be supplied with rolling cart. 4. Should be supplied with unfilled cylinder for N_2O or CO_2.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	1. **Operating Condition:** Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances
6.2	User's care, Cleaning, Disinfection & Sterility issues	1. **Disinfection:** Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/ sterile disposable cover. 2. Sterilization required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO/ approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available.) 2. Manufacturer should have ISO 13485 certification for quality standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including for all spares and calibration work.

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

OPHTHALMOSCOPE – DIRECT

Version no. :		Ver_1
Date:		19/08/2018
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Ophthalmo scopes, Direct
UMDNS code(s)		12817
GENERAL		
1. USE		
1.1	Clinical purpose	Hand held ophthalmoscopes designed for examining the eye (mostly the back of the eye, the funds) by providing a non inverted image of the eye. The instruments usually consist of a light source to project the light into the eye through the pupil, a mirror, and a wheel of lenses of varying strength to provide a magnified view of the eye and to adjust the focus of the view. They produce an upright, or un reversed, magnified image of the eye, at approximately 15 times magnification. Direct ophthalmoscopes are used mainly to detect eye conditions or eye diseases.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Available with LED/Halogen light source. 2. Magnification up to x15 from direct vision to maximum magnification. 3. Red-free, blue and polarization filters and Anti-reflection lens. 4. Should have small and large spot sizes, fixation targets, slit aperture, hemi-spot and cobalt blue filter. 5. Should be rechargeable battery with Charger / battery/ mains operated. 6. At least 3 apertures and fixation star. 7. Range of lenses not smaller than -30D to +20D with steps not greater than 1D. 8. Dust free sealed optics and aspherical optical system.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	220 to 240V, 50 Hz

4.2	Battery operated	Internal batteries, rechargeable preferred compatible with both 2.5 V and 3.5 V batteries or handles provided; Led display indicating the charging status.
4.3	Protection	Yes
4.4	Power consumption	To be specified by Vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)	a. Bulb – 2 nos
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/ambiance (air conditioning, humidity, dust …)	1. **Operating Condition:** Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	1. **Disinfection:** Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/ sterile disposable cover
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO/ approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available.) 2. Manufacturer should have ISO 13485 certification for quality standards. 3. ISO 10942:2006 Ophthalmic instruments -- Direct ophthalmoscopes.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including for all spares and calibration work.

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

OPHTHALMOSCOPE – INDIRECT

Version no. :		Ver_1
Date:		19/08/2018
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Ophthalmoscopes, Indirect
UMDNS code(s)		12818
GENERAL		
1. USE		
1.1	Clinical purpose	Head-worn ophthalmoscopes designed for examining the eye (mostly the back of the eye, the fundus) by providing an inverted image of the funds. These instruments usually consist of a light source attached to a headband to project the light into the eye through the pupil and a converging lens placed in front of the patient's eye. They produce an inverted, or reversed, image of 2 to 5 times magnification of the entire retina, a field of view much larger than that of direct ophthalmoscopes. Indirect ophthalmoscopes are used mainly to detect eye conditions or eye diseases.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Available with LED/Halogen light source. (Desirably LED). 2. Magnification up to 5x. 3. Red-free, blue and polarization filters. 4. Should have stereo optical system with small pupil feature. 5. Should have synchronized adjustment of convergence parallax.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	220 to 240V, 50 Hz
4.2	Battery operated	Internal batteries, rechargeable preferred compatible with both 2.5 V and 3.5 V batteries or handles provided; Led display indicating the charging status.
4.3	Protection	Yes
4.4	Power consumption	To be specified by Vendor

5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	a. Three pencils, b. Funds chart, c. Sclera depressor, d. 20D condensing lens with anti reflecting coating. e. Bulb – 2 nos, Bulb holder, Bulb cover.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	1. **Operating Condition:** Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	1. **Disinfection:** Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/ sterile disposable cover.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO/ approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available.) 2. Manufacturer should have ISO 13485 certification for quality standards. 3. ISO 10942:2006 Ophthalmic instruments -- Direct ophthalmoscopes.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including for all spares and calibration work.
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;

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

SLIT LAMP

Version no. :		Ver.-1
Date:		19/08/2018
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Slit Lamp
UMDNS code(s)		12281
GENERAL		
1. USE		
1.1	Clinical purpose	Ophthalmic diagnostic instruments designed for examining the eye (mostly the anterior part of the eye) using an illumination system combined with a binocular microscope. The instruments usually consist of illumination sources with a mechanism that provides a slit beam of light into the eye with different types of illumination (e.g., direct or indirect, focal or diffuse, background illumination), a binocular microscope for viewing the magnified slit image, and a control component for adjusting the focus of the microscope and the slit (e.g., slit rotation, slit width); some also have refraction mirrors to direct light to a camera mounted above the microscope. Slit lamps provide a magnified view of eye structures (e.g., eyelid, sclera, iris, crystalline lens and cornea); some instruments can also examine the retina using specific lenses. Slit lamps are used mainly in the diagnosis of eye conditions.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Should have LED with adjustable and good illumination. 2. Should have facility for applanationtono meter if required. 3. Type of microscope: Binocular 4. Should have 3 step magnification and total magnification is grater than 10x. 5. Should have slit width ≥ 0-10 mm, adjustable. 6. Should have slit length ≥ 0-10 mm, adjustable. 7. Should have standard filters: Minimum: blue, green (red-free), heat absorption. A broader selection of filters increases the functionality of the slit lamp. 8. Rotation is between 0-180°. 9. Should be supplied with motorized table. 10. Should have a longitudinal movement of at least 90mm 11. Should have a lateral movement of at least 95mm. 12. Should have a vertical movement of at least 30mm. 13. Should have a chin rest vertical movement of at least 55mm.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required)	NA

3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	<50 dB
3.4	Heat dissipation	NA
3.5	Mobility, portability	NA
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	Should operate from 200 to 240Vac, 50 Hz input supply.
4.2	Battery operated	Should be supplied with suitable online UPS with at least half an hour backup.
4.3	Protection	Yes
4.4	Power consumption	To be specified by Vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Focusing Test rod & dust cover; 2. Slit lamp dust cover, 3. Rack, manual and motorized guard, 4. 90D/70D Lens
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	1. **Operating Condition:** Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	1. **Disinfection:** Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/ sterile disposable cover.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available.) 2. Manufacturer should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard).
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including for all spares and calibration work.

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

RETINOSCOPE

Version no. :		Ver_1
Date:		19/08/2018
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Retinoscopes
UMDNS code(s)		23679
GENERAL		
1. USE		
1.1	Clinical purpose	Retinoscopy is a technique to obtain an objective measurement of the refractive error of a patient's eyes. The examiner uses a retinoscope to shine light into the patient's eye and observes the reflection (reflex) of the patient's retina.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Available with LED light source. 2. Should be interchangeable to plane mirror and concave mirror mode by sleeve movement 3. Should have an external focusing sleeve which is easy to grip. 4. Should have crossed-linear polarizing filter. 5. Should allow one-hand operation for streak focus. 6. Available with 360º streak rotation. 7. Should have 100% dust proof housing and multi-coated optics.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	<50 dB
3.4	Heat dissipation	NA.
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	Should operate from 200 to 240Vac, 50 Hz input supply.
4.2	Battery operated	Yes, Should be rechargeable battery with Charger.
4.3	Protection	Yes
4.4	Power consumption	To be specified by Vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Should have a carrying case. 2. Bulb – 2 nos 3. Rechargeable battery – 1 no

BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	1. **Operating Condition:** Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	1. **Disinfection:** Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/ sterile disposable cover.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available.) 2. Manufacturer should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard).
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including for all spares and calibration work.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

OPHTHALMIC LASERS - PHOTO COAGULATING
(ARGON, DYE, KRYPTON AND FREQUENCY-DOUBLED ND:YAG)

Version no. :		Ver_1
Date:		19/08/2018
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Lasers, Nd:YAG, Frequency-Doubled, Ophthalmic
UMDNS code(s)		18217
GENERAL		
1. USE		
1.1	Clinical purpose	Nd:YAG frequency-doubled lasers, usually operated in pulsed modes, used to coagulate abnormal vascular tissue in the retina and other photo coagulation procedures in the eye. They are typically coupled to a bio microscope slit lamp or an indirect ophthalmoscope.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	**BEAM CHARACTERISTICS:** 1. Should have treatment laser type Argon, Dye, Krypton, and Frequency-Doubled Nd: YAG. 2. Principal wavelengths shall be 530-540 nm. 3. Delivered power of different lasers shall be as i. Argon blue-green 3 W, ii. Argon green 1 W, iii. Dye 1 W, iv. Krypton green 1.5 W, v. Krypton yellow 1.5 W, vi. Krypton red 1 W, vii. Nd: YAG 1 W. 4. Delivery Mode - Single, repeat. 5. The amount of time the patient is exposed to activated laser energy shall be 0.01-2 Sec. 6. Repeat time shall be 0.1-2 Sec 7. Spot diameter @ retina shall be 50-1,000μm **AIMING BEAM:** 1. Wavelength shall be 630 nm 2. Power shall be <1 mW. **DELIVERY SYSTEM TYPE:** 1. Slit lamp is required. 2. Intraocular probe is required. 3. Hand piece(s) is required.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	As Applicable

3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise-free system
3.4	Heat dissipation	Should maintain nominal temp and the heat should be disbursed through a cooling mechanism
3.5	Mobility, portability	Stationary.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	Electrical Requirement : 200-230 VAC 50/60 Hz single phase
4.2	Battery operated	Online UPS shall be Provided
4.3	Protection	Stabilizer to be provided
4.4	Power consumption	To be specified by vendor.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Dust covers- 1 2. Allen Key - 1 set 3. spare bulb - 2 Nos 4. Should be supplied with motorized table 5. Should provide protective goggles to be exclusive for ND-Yag Laser 6. iridotomy and capsulotomy lens,(2 each) 7. Appropriate UPS backup
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	1. Operating Condition: Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 40 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	Sterilization not required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available.) 2. Manufacturer should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard).
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.

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

OPHTHALMIC LASERS - PHOTO DISRUPTING
(Q-SWITCHED ND:YAG)

Version no. :		Ver.-1
Date:		19/08/2018
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Lasers, Nd:YAG, Ophthalmic
UMDNS code(s)		16947
GENERAL		
1. USE		
1.1	Clinical purpose	Neodymium-doped yttrium-aluminum-garnet (Nd:YAG) lasers, usually Q-switched, used to cause a photo disruptive effect in the eye (e.g., posterior capsulotomy), forming a plasma and generating immense localized mechanical shock waves (micro explosions) that, when highly focused, can destroy tissue. These lasers have built-in slit-lamp bio microscopes or are coupled to a slit-lamp or indirect ophthalmoscope by fixed mirrors.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	**1. BEAM CHARACTERISTICS:** i. Operating mode: Q-switched ii. Mode structure: Fundamental iii. Energy range: Single pulse, 0.3-10mJ iv. Pulse width shall be 4 n sec v. Burst shall be 1-3 pulses/burst vi. Repetition rate a. Single pulse shall be 1-2 Hz b. Burst shall be 1 Hz. vii. Spot size shall be 10 μm viii. Cone angle shall be 16 deg **2. AIMING BEAM:** i. Type: Dual Laser ii. It should have variable intensity **3. COMPATIBLE SLIT LAMP** i. Magnification shall be $\leq$25x ii. Working distance shall be 100 mm **4. DISPLAYS/CONTROLS** i. Selected energy is required ii. Shot selection is required iii. Power output is required iv. Shot counter is required 5. Calibration method shall be automatic. **6. COOLING REQUIREMENTS:** Air
2.2	User's interface	Manual
2.3	Software and or standard of communication(where ever required)	As Applicable

3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise-free system
3.4	Heat dissipation	Should maintain nominal temp and the heat should be disbursed through a cooling mechanism
3.5	Mobility, portability	Stationary.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	Electrical Requirement : 200-230 VAC 50/60 Hz single phase
4.2	Battery operated	Online UPS shall be Provided
4.3	Protection	Stabilizer to be provided
4.4	Power consumption	To be specified by vendor.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	i. Contact lens ii. TV, 35 mm adapter iii. Head restraint iv. Tonometer v. Dust covers- 1 vi. Allen Key - 1 set vii. Spare bulb - 2 Nos
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	1. Operating Condition: Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 40 deg C and relative humidity of 15 to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Sterilization not required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available.) 2. Manufacturer should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard).
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.

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

PHOTOABLATING OPHTHALMIC LASERS

(EXCIMER OPHTHALMIC LASERS)

Version no. :		Ver.-1
Date:		19/08/2018
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Lasers, Excimer, Ophthalmic
UMDNS code(s)		17702
GENERAL		
1. USE		
1.1	Clinical purpose	Excimer lasers, usually Q-switched, used for corneal ablation (i.e., photorefractive keratectomy) and other ophthalmologic procedures (e.g., surgical creation of a communication between the lacrimal sac and the nasal cavity). A typical system incorporates a patient table, physician's chair, and computer system. Some systems have built-in slit lamps.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	**1. BEAM CHARACTERISTICS:** i. Wave length shall be 193 nm ii. Power output at tissue shall be 0-3 W iii. Energy should be 10 mJ/pulse iv. Energy density shall be 150-200 mJ/cm^2 v. Delivery modes shall be Continuous, pulsed vi. Beam diameter shall be 1-5mm vii. Pulse repetition frequency shall be 10-200 Hz viii. Pulse width should be 10-15 nsec **2. AIMING BEAM:** i. Wave length shall be 630 nm **3. COMPATIBLE SLIT LAMP** i. Magnification shall be ≤25x ii. Working distance shall be 100 mm **4. DISPLAYS/CONTROLS** i. Selected energy is required ii. Shot selection is required iii. Power output is required iv. Shot counter is required 5. Calibration method shall be automatic. 6. Cooling Requirements: Air 7. Computer system is required with optimal configuration. 8. Type of Laser Gas Cylinders Halogen gas
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required)	As Applicable

3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise-free system
3.4	Heat dissipation	Should maintain nominal temp and the heat should be disbursed through a cooling mechanism
3.5	Mobility, portability	Stationary.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ….)		
4.1	Power requirements	Electrical Requirement : 200-230 VAC 50/60 Hz single phase
4.2	Battery operated	Online UPS shall be Provided
4.3	Protection	Stabilizer to be provided
4.4	Power consumption	To be specified by vendor.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Contact lens 2. Head restraint 3. Dust covers- 1 4. Allen Key - 1 set 5. Spare bulb - 2 Nos
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	**1. Operating Condition:** Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 80% in ideal circumstances. **2. Storage condition:** Capable of being stored continuously in ambient temperature of 0 to 40 deg C and relative humidity of 15 to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Sterilization not required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	i. Should be US FDA/CE/BIS/CDSCO approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available.) ii. Manufacturer should have ISO 13485 certification for quality standards. iii. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard).
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Availability of 5 Amp/15 Amp. Electrical Socket.
8.1	Pre- installation requirements: nature, values, quality, tolerance	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.

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

KERATO METER - MANUAL

Version no. :		Ver.-1
Date:		19/08/2018
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Ophthalmometers
UMDNS code(s)		12811
GENERAL		
1. USE		
1.1	Clinical purpose	Ophthalmic measuring instruments designed for objectively determining the curvature of the anterior corneal surface and the refraction of the eye (e.g., diopter, cylinder axis) by projecting illuminated images onto the patient's cornea. The instruments usually consist of light sources, a pair of objects to be projected onto the cornea, a telescope with prisms and lenses for reflecting and observing images, a device for adjusting the positions of the reflected images, and the software appropriate to calculate the corneal curvature and the refractive power. Ophthalmometers are used mainly for pre assessment for refractive corneal surgery and for contact lens fitting.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Should have (15x / 10x) eye piece. 2. Should measure corneal refractive power measuring range from 36 to 52 D in steps of 0.25D steps. 3. Should measure corneal radius of curvature measuring range from 6.5 to 9.4 mm in steps of 0.05mm. 4. Should have high accuracy of measurements. 5. Should have dust cover and spare bulb. 6. Should be supplied with motorized table. 7. Should have well illuminated circular mires with + sign.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	NA
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	Electrical Requirement : 200-230 VAC 50/60 Hz single phase
4.2	Battery operated	No
4.3	Protection	NA
4.4	Power consumption	To be specified by service provider

5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Lamp (12v 10w): 5 No 2. Calibrating Device – 1 No
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	**1. Operating Condition:** Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 80% in ideal circumstances. **2. Storage condition:** Capable of being stored continuously in ambient temperature of 0 to 40 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	Sterilization not required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available.) 2. Manufacturer should have ISO 13485 certification for quality standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including for all spares and calibration work.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;

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

AUTO REFRACTOMETER

Version no. :		Ver.-1
Date:		19/08/2018
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Refractometers
UMDNS code(s)		15169
GENERAL		
1. USE		
1.1	Clinical purpose	Measuring instruments used to determine the ratio of the velocity of light in a vacuum to the velocity of light in another medium (i.e., index of refraction).
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Should have in the system. 2. Should have refractive measurement sphere from -25 to +22D in steps of 0.25D. 3. Should have refractive measurement cylinder from -10 to +10D in steps of 0.25D. 4. Should have refractive measurement axis angle from 1 to 180º in steps of 1º. 5. Should have at least 0, 12 and 13.5 vertex distance. 6. Should measure a minimum pupil diameter of 2.5mm. 7. Should have at least 5 inches LCD/LED display. 8. Should have vertically adjustable chin rest of at least ±25mm. 9. Should have motorized table.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required)	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	NA
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	Electrical Requirement : 200-230 VAC 50/60 Hz
4.2	Battery operated	No
4.3	Protection	NA
4.4	Power consumption	To be specified by service provider

5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Calibrating Device – 1 No.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	1. Operating Condition: Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 40 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	Sterilization not required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO/approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO /is not available.) 2. Manufacturer should have ISO 13485 certification for quality standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users in operation and basic maintenance shall be provided. 2. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including for all spares and calibration work.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.

10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	1. Contact details of manufacturer, supplier and local service agent to be provided; 2. Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

APPLANATION TONOMETER

Version no. :		Ver.-1
Date:		19/08/2018
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Ophthalmic Tono meters, Applanation
UMDNS code(s)		10168
GENERAL		
1. USE		
1.1	Clinical purpose	Ophthalmic tono meters designed to determine intraocular pressure by measuring the force required to flatten the cornea apex by a fixed amount. These instruments are typically small and reusable instruments and are attached to a slit lamp; the tono meter includes a tip to be applied to the cornea and a manually controlled spring that applies a variable force on the cornea through the tip.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Range of Measurement 0-80 mmHg 2. Movement of Light Circle 1.53 x 2 = 3.06mm 3. Prism Diameter 7mm 4. Prism Range of Movement 3mm 5. Should be compatible with all models of slit lamps.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise Free System
3.4	Heat dissipation	Should maintain nominal temperature and the heat should disbursed through a cooling mechanism.
3.5	Mobility, portability	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	Electrical Requirement : 200-230 VAC 50/60 Hz single phase
4.2	Battery operated	No
4.3	Protection	NA
4.4	Power consumption	To be specified by service provider
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Calibration Bar, 2. Prism 3. Tonometer Mount base to fix with optics.

BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	1. **Operating Condition:** Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. **Storage condition:** Capable of being stored continuously in ambient temperature of 0 to 40 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	Sterilization not required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO/approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO / is not available.) 2. Manufacturer should have ISO 13485 certification for quality standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users in operation and basic maintenance shall be provided. 2. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including for all spares and calibration work.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

PHACOMACHINE

Version no. :		Ver.-1
Date:		19/08/2018
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Phaco emulsification Units, Cataract Extraction
UMDNS code(s)		17596
GENERAL		
1. USE		
1.1	Clinical purpose	Ophthalmic surgery units designed for removal of cataractous lenses by the insertion of a probe that cuts and emulsifies the lenses using ultrasonic waves (phacoemulsification). These units consist of a hollow probe (i.e., a phaco probe) that includes an irrigation sleeve, an oscillating tip that converts electric energy into ultrasonic waves, and a channel for aspiration of lens fragments; the units also include a vacuum pump and controls for the output levels, irrigation rate, and mode of operation. Phacoemulsification units are used in ophthalmic offices for cataract extraction surgery.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	**1. OPERATIONAL MODES:** i. System should have following operation modes: Irrigation, Ultrasound, Irrigation/Aspiration (I/A) system, Diathermy and Vitrectomy. **2. ULTRA SOUND SYSTEM:** i. Hand Piece type: Piezoelectric, made up of Titanium. ii. Frequency: 25-80 kHz. iii. It should be autoclavable. **3. IRRIGATION/ASPIRATION (I/A)SYSTEM:** i. System should have dual pump (Peristaltic and Venturi) user can switch between the two pumps during surgery with Max. Vacuum (peristaltic: 500 mmHg) with 1 mmHg pump increment. ii. Reflux method: Gravity / Pump reversal. iii. Tubing shall be re usable. iv. I/A Hand pieces shall be autoclavable with port diameter of 0.2-0.5 mm. v. Collection container size shall be 1-60 cc. **4. ANTERIOR VITRECTOMY:** i. Guillotine type hand piece with variable speed shall be preferred. ii. Hand piece shall be re usable and autoclavable. iii. Control Panel or linear cut rate control by foot pedal.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required)	As Applicable.

3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise Free System
3.4	Heat dissipation	Should maintain nominal temperature and the heat should disbursed through a cooling mechanism.
3.5	Mobility, portability	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ….)		
4.1	Power requirements	Electrical Requirement : 200-230 VAC 50/60 Hz.
4.2	Battery operated	An UPS with 30 minutes back up shall be provided.
4.3	Protection	Stabilizer to be provided.
4.4	Power consumption	To be specified by service provider
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Phaco hand piece – 1no 2. Phaco tips -4 nos 3. Anterior vitrectomy packs including cutters and other disposables – 25 nos 4. Cassettes and disposables – 12 nos.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	1. Operating Condition: Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 40 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	5. Sterilization is required for hand piece, tips and forceps.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available.) 2. Manufacturer should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard).
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users in operation and basic maintenance shall be provided. 2. Advanced maintenance tasks required shall be documented.

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

MICROSURGERY SET - CATARACT

Version no. :		Ver.-1
Date:		19/08/2018
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		NA
UMDNS code(s)		NA
GENERAL		
1. USE		
1.1	Clinical purpose	Set of instruments which are used for cataract surgeries.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	List of instruments	1. Barraquer wire speculum, Large 2. Suture tying forceps curved 3. MC Pherson forceps 4. MC Pherson Corneal Forceps, 1X2 teeth 5. Sup. Rectus Forceps 6. Castroviejo Corneal Scissors, Universal 7. VannasCapsulotony Scissors, Angled 8. Barraquer Needle Holder, Microjous W/o Lock 9. Simcoe I/A Cannula, Direct 10. BP Handle – 11 no blade 11. Sinkey 11 lens Manipulating Hook 12. Phaco Chopper 13. Iris Repositor 14. Utrata Forceps 15. Sterilization Box 16. Tenotomy Scissors 17. Steel Bowl
2.2	User's interface	NA
2.3	Software and or standard of communication (where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective SS case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA

5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	MVR 2.8, 3.2 Blade 11,15.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	**Operating Condition:** Capable of operating continuously in ambient temperature of 5 to 40 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 40 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/sterile disposable cover. Sterilization required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available.) 2. Manufacturer should have ISO 13485 certification for quality standards. 3. The surgical instruments should be made using top quality medical grade hardened stainless steel with defined specifications like AISI-410, AISI-420, AISI-304, AISI-303, AISI- 440 etc. using guidelines of ASTM standard F899-94 and ISO 7153 and with a dull finish.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users in operation and basic maintenance shall be provided. 2. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.

10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/l andline 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.

MICROSURGERY LID SET

Version no. :		Ver.-1
Date:		19/08/2018
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		NA
UMDNS code(s)		NA
GENERAL		
1. USE		
1.1	Clinical purpose	Set of instruments are used for lid reconstruction, restore lid function, relieve symptoms, and improve the patient's appearance.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	List of instruments	1. Desmarres Lid Retractor, Size 0 2. Jaeger Lid Plate 3. Fixation Hook, 2.0X1.5m, Small 4. Graefe Muscle Hook, Size 3. 5. Meyerhoefer Chalazion Curette, Size 2. 6. St. Martin Suturing Forceps 1X2 teeth 7. Fixation forceps, 1X2 teeth 8. Beer Cilia, Forceps 9. Berke Ptosis Forceps 20 mm 10. Snellenentropium Forceps, Left, Small 11. Snellenentropium Forceps, Right, Small 12. McPherson Tying Forceps, Long Handle 13. Westcott Stitch Scissors 14. Eye Scissors, Curved, 4 1/2" Length 15. Stevens Tenotomy Scissors, Curved 16. Barraquer N. Holder, Short model, M. Jaws, w/o Lock. 17. Bard Parker Handle # 3 18. Castroviejo Caliper, Straight 19. Fixation Forceps, 2x3 Teeth, Angular. 20. Corneal Scissors
2.2	User's interface	NA
2.3	Software and/ or standard of communication (where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective SS case for clean storage and safe transport.

4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	1. **Operating Condition:** Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. **Storage condition:** Capable of being stored continuously in ambient temperature of 0 to 40 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	1. **Disinfection:** Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/sterile disposable cover. 2. Sterilization required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available.) 2. Manufacturer should have ISO 13485 certification for quality standards. 3. The surgical instruments should be made using top quality medical grade hardened stainless steel with defined specifications like AISI-410, AISI-420, AISI-304, AISI-303, AISI- 440 etc. using guidelines of ASTM standard F899-94 and ISO 7153 and with a dull finish.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users in operation and basic maintenance shall be provided. 2. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years

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

FOREIGN BODY REMOVAL SET

Version no. :		Ver.-1
Date:		19/08/2018
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Spuds, Eye
UMDNS code(s)		16025
GENERAL		
1. USE		
1.1	Clinical purpose	A slender, probe-like device that is used to grasp and extract foreign bodies from superficial tissue of the eye with minimum trauma to that tissue.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	List of instruments	1. Barraquer wire speculum, Big 2. Desmarres Lid retractor, size 2 3. Golf club foreign body spud. 4. Beer Cilia forceps. 5. Jewelers forceps, standard 6. Castroviejo lacrimal Dilator, double end 7. Lacrimal canmula, straight, 23 G 8. Sterilization box, complete 9. Sterilization Box
2.2	User's interface	NA
2.3	Software and/ or standard of communication (where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective SS case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA

BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	1. **Operating Condition:** Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. **Storage condition:** Capable of being stored continuously in ambient temperature of 0 to 40 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	1. **Disinfection:** Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/sterile disposable cover. 2. Sterilization required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available.) 2. Manufacturer should have ISO 13485 certification for quality standards. 3. The surgical instruments should be made using top quality medical grade hardened stainless steel with defined specifications like AISI-410, AISI-420, AISI-304, AISI-303, AISI- 440 etc. using guidelines of ASTM standard F899-94 and ISO 7153 and with a dull finish.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users in operation and basic maintenance shall be provided. 2. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.

VISUAL ACUITY DRUM

Version no. :		Ver.-1
Date:		19/08/2018
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Opto kinetic Drums
UMDNS code(s)		16476
GENERAL		
1. USE		
1.1	Clinical purpose	Diagnostic ophthalmic devices designed to elicit and evaluate the regular, involuntary movement of the eyeball (i.e., nystagmus).
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	List of instruments	1. Four Sides - English, Hindi - C or Regional Language or 'E' Chart with inbuilt illumination 2. Friend Test/Duochrome 3. Worths Four dots test
2.2	User's interface	NA
2.3	Software and/ or standard of communication (where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	NA
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA

BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	1. **Operating Condition:** Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. **Storage condition:** Capable of being stored continuously in ambient temperature of 0 to 40 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	1. **Disinfection:** Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/ sterile disposable cover. 2. Sterilization required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO approved (USFDA/ CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available.) 2. Manufacturer should have ISO 13485 certification for quality standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users in operation and basic maintenance shall be provided. 2. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.

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

PERIMETER- AUTOMATED

Version no. :		Ver.-1
Date:		19/08/2018
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Ophthalmic Perimeters, Automated
UMDNS code(s)		16918
GENERAL		
1. USE		
1.1	Clinical purpose	Ophthalmic perimeters that perform visual field assessment with little operator involvement.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	It should have following features: 1. True Goldman Standard Perimeter with Integrated Hemispherical Bowl of 30cm radius with Touch screen. 2. Stimulus Type-LED 3. Stimulus Size-Goldman III 4. Stimulus Intensity-0-318cd/m2/≤1000asb 5. Stimulus Duration-adjustable from 0.2 second to more 6. Stimulus Colour-White to White and Blue-onWhite 7. Fixation Control-Video eye monitor and HeijlKraakau Blind Spot Monitor 8. Patient Positioning Motorized Chin rest with adjustable height and in depth adjustable head rest 9. Static Perimetry Programs- Glaucoma (Screening, Threshold, Localization), Macula (Screening, Threshold, Localization), User defined programs 10. Threshold Test Strategies-Fast Threshold, Full Threshold, Supra Threshold 11. Kinetic Perimetry Strategy-Automated Goldman Standard
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required	As Applicable.
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise Free System
3.4	Heat dissipation	Should maintain nominal temperature and the heat should disbursed through a cooling mechanism.
3.5	Mobility, portability	Portable

4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	Electrical Requirement : 200-230 VAC 50/60 Hz.
4.2	Battery operated	An UPS with 30 minutes back up shall be provided.
4.3	Protection	Stabilizer to be provided.
4.4	Power consumption	To be specified by service provider
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Standard Accessories: 1. PC with 40 GB Hard Drive, 512 MB 2. RAM, CPU-750MHz 3. Online UPS 4. Laser jet Compatible Printer 5. Response Button 6. Support for Correction Lenses and Full 7. Set of Thin Rim Lenses 8. Opaque Eye Patch 9. Automated Table/Stand 10. Protective Cover
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	1. **Operating Condition:** Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. **Storage condition:** Capable of being stored continuously in ambient temperature of 0 to 40 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	Sterilization is required for hand piece, tips and forceps.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available.) 2. Manufacturer should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard).
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users in operation and basic maintenance shall be provided. 2. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including for all spares and calibration work.

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

BINOMAGS/ MAGNIFYING LOUPE

Version no. :		Ver.-1
Date:		19/08/2018
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Loupes, Binocular
UMDNS code(s)		25585
GENERAL		
1. USE		
1.1	Clinical purpose	Loupes designed to be worn close to the practitioner's eyes to provide stereo-optic (i.e., binocular) visual magnification of the patient during medical examinations or procedures. Binocular loupes are used by specialists such as ophthalmologists, surgeons, dermatologists, and dentists.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	List of instruments	1. Should have 2.5 x magnification. 2. Should made up of Plastic. 3. Atleast 40 mm x 40 mm x 45 mm dimension. 4. Head band Type
2.2	User's interface	NA
2.3	Software and/ or standard of communication (where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	NA
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA

BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	1. **Operating Condition:** Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. **Storage condition:** Capable of being stored continuously in ambient temperature of 0 to 40 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	1. **Disinfection:** Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/sterile disposable cover. 2. Sterilization required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available.) 2. Manufacturer should have ISO 13485 certification for quality standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users in operation and basic maintenance shall be provided. 2. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;

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

TRIAL FRAME SET (ADULT AND CHILD)

Version no. :		Ver.-1
Date:		19/08/2018
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Eyeglasses, Frames, Trial
UMDNS code(s)		34357
GENERAL		
1. USE		
1.1	Clinical purpose	Devices designed to hold lenses in an appropriate position in front of the eyes during an ophthalmic lens and frames trial procedure. Trial frames include graduated arcs and a linear rule to determine the lenses' angular positions and to measure the interpupillary distance; the frames usually allow the installation of several (e.g., 3) trial lenses simultaneously. Trial eyeglass frames are used in examination procedures to determine the lenses and eyeglass frame characteristics needed for a particular user, including a good frame adjustment to the nose and ears position.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Horizontal and Vertical bridge adjustment. 2. Adjustable Saddle Bridge. 3. Separate PD adjustment for each eye to compensate for asymmetrical factors in facial structure. 4. Individual adjustment for length and angle. 5. Adjustment for rotating cylinders to correct the axis. 6. Scale with large easy to read numerals. 7. The space for lens holder ensures accurate additive reading. 8. PD scale: 24 - 38 mm for both right and left. 9. Nose height adjustments : Movable up to 14.5 mm. 10. Temple length adjustment sit can be sided up to 37 mm (Approx.)
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA

4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	**Disinfection:** Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	NA
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	NA
9. WARRANTY AND MAINTENANCE		
9.1	Standards	Manufacturer should have ISO 13485 certification for quality standards.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	NA
10.2	Other accompanying documents	NA
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided;Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.

TRAIL LENS SET

Version no. :		Ver.-1
Date:		19/08/2018
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		NA
UMDNS code(s)		NA
GENERAL		
1. USE		
1.1	Clinical purpose	Trial frame designed to permit insertion of different lenses used in correcting refractive errors of vision.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. The lenses should be of 20 mm aperture fitted in aluminum mount of 38 mm diameter, anodized red/ gold for negative power and black/silver for positive power. 2. The Sphere lenses with handle and cylinder without handle. 3. The trial lenses should be good quality, the case made of melamine poised wood, sturdy and attractive finish. 4. Lenses - spheres + and -. a. 0.25 to 4.0 in 0.25 steps. b. 4.5 to 6.0 in 0.5 steps. c. 7.0 to 14.0 in 1.0 steps. d. 16.0 to 20.0 in 2.0 steps e. 0.25 to 3.5 in 0.25 steps f. 4.0 to 6.0 in 0.5 steps g. Prisms 1/2, 1, 2,3,4,5,6,8,10,12.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA

5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	a. Red Glass and Green Glass b. pin hole c. Slit d. Two back discs e. Cross Cylinder +/- 0.25 and +/- 0.5
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	**Disinfection:** Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	Standards	1. Manufacturer should have ISO 13485 certification for quality standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	NA
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	NA
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	NA
10.2	Other accompanying documents	NA
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

DIGITAL VISUAL ACUITY CHART SYSTEM

Version no. :		Ver.-1
Date:		19/08/2018
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		NA
UMDNS code(s)		NA
GENERAL		
1. USE		
1.1	Clinical purpose	A Snellen chart is an eye chart that can be used to measure visual acuity.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Vision testing by snellen vision chart at different distances. 2. C and E charts. 3. Logmar Charts 4. Testing Contrast Sensitivity. 5. Pediatric Vision Testing. 6. Educational Charts. 7. Red and Green Charts. 8. Ishihara Charts 9. Testing Peripheral Vision. 10. Astigmatic fan. 11. Should have functions in different languages. 12. Wide LED monitor.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	NA
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA

5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	NA
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.
7. STANDARDS AND SAFETY		
7.1	Standards	1. Manufacturer should have ISO 13485 certification for quality standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	NA
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	NA
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	NA
10.2	Other accompanying documents	NA
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

NEAR VISION CHART

Version no. :		Ver.-1
Date:		19/08/2018
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		NA
UMDNS code(s)		NA
GENERAL		
1. USE		
1.1	Clinical purpose	A Near Vision chart is used to screen uncorrected near visual acuity at 25 cm
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Animal Picture Chart for per-verbal children. 2. Self illuminated. 3. English, Hindi, Regional language, illiterate E and C Chart. 4. Plates made from high quality non reflective plastic.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)	a. Red Glass and Green Glass b. pin hole c. Slit d. Two baack discs e. Cross Cylinder +/- 0.25 and +/- 0.5
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	NA

6.2	User's care, Cleaning, Disinfection & Sterility issues	**Disinfection:** Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	NA
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	NA
9. WARRANTY AND MAINTENANCE		
9.1	Standards	Manufacturer should have ISO 13485 certification for quality standards.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	NA
10.2	Other accompanying documents	NA
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

COLOUR VISION CHART

Version no. :		Ver.-1
Date:		19/08/2018
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		NA
UMDNS code(s)		NA
GENERAL		
1. USE		
1.1	Clinical purpose	It is used to measures your ability to tell the difference among colors
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Animal Picture Chart for per-verbal children. 2. Ishiharas colour vision chart. 3. Standard ishiharas pseudo - isochromatic plates in booklet form, 4. standard key for interpretation.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	NA

6.2	User's care, Cleaning, Disinfection & Sterility issues	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	Standards	Manufacturer should have ISO 13485 certification for quality standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	NA
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	NA
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	NA
10.2	Other accompanying documents	NA
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

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