HLL INFRA TECH SERVICES LIMITED
(Subsidiary of HLL Lifecare Ltd., a Govt. of India Enterprise)
B-14 A, Sector-62, Noida-201 307
Phone: 0120 - 4071500
URL: www.hllhites.com

HITES/BME/PRE-TENDER/01/OPH/2022-23 **Date: 06.03.2023**

NOTICE OF INVITATION FOR PRE-TENDER MEETING

Biomedical Engineering Division of HLL INFRA TECH SERVICES LIMITED (a fully owned subsidiary of HLL Lifecare Limited, a Govt. of India Enterprise) is in the process of finalising technical specifications for various Medical/Laboratory/Scientific equipment. In this context, HITES is organising an ONLINE PRE-TENDER MEETING with prospective vendors for the following items to acquire further insight to make technical specification in general without compromising the quality:

SN	Item Name	Department
	Vitreo-Retina & Uvea Services	
1	Fundus fluorescein angiography (FFA)/ICG	**Ophthalmology**
2	Electroretinogram ERG, Multifocal ERG,	
3	Micro Perimetry	
4	Vitrectomy machine High End with Endolaser	
5	Vitrectomy machine Basic with Endolaser	
6	Yellow Laser multispot with micropulse	
7	Cryophotocoagulation	
8	OCT angiography with Multimodal Imaging	
	Glaucoma Services	
9	Goniolens	**Ophthalmology**
10	Tonopen	
11	Fundus camera (Non Mydriatic)	
	Cornea and refractive surgery services	
12	Ultrasonic Pachymeter	**Ophthalmology**
13	Specular microscope (Clinical)	
14	Corneal Topography system	
15	Operating Microscope Markerless Surgery	
16	Tear Lab Osmolarity system	

All the interested prospective vendors are invited to participate in the online pretender meeting and requested to please send their suggestions with respect to the specifications of above items (**Enclosed in Annexure I_Technical Specification**) to the below mentioned e-mail IDs on or before 09.03.2023, 04:00 PM. The details of the Pre-Tender meeting are detailed below:

Date & time of the Pre-Tender meeting	10.03.2023 at 3: 00 PM
Details of meeting	The meeting shall be conducted through following Google meet Link: Video call link: https://meet.google.com/tap-kaub-pgx
Last date for submitting suggestions with respect to the technical specifications	09.03.2023 at 04:00 PM
Contact Details	Ph: 0120-4071500/ 609/577 Email: bmenoida@hllhites.com

Disclaimer: This notification is not a tender or does not construe that participating vendors shall be qualified for prospective tender in this matter.

For HLL Infra Tech Services Limited

Deputy Vice President (BME)

ANNEXURE 1 _ TECHNICAL SPECIFICATIONS

1. Fundus fluorescein angiography (FFA)/ICG

1	Field angle	20-50 degrees
2	Capture modes	Color, red-free and red pictures and pictures of the anterior segment, as well as Flourescein angiography . Live visualization, Automatic multi image montage
3	Filters Optical filters for capture modes	Filters for green and blue pictures, filters for fundus autofluorescence images, UV / IR barrier filters
4	Compensation for ametropia	+35 D … -35 D, continuous
5	Capture sequence	1.5-2 seconds (depends on flash energy)
6	Pupil diameter	≥ 4.0 mm ≥ 3.3 mm (30° small pupil mode)
7	Working distance	35-40 mm (patient's eye – front lens)
8	Monitor	32" LCD/LED display
9	Fixation targets	External and internal
10	Flash energy	Xenon flash lamp, 24 flash levels
11	Database	Patient information and images with field angle, FA time, R / L recognition and date of visit are stored
12	Operating system	Latest Generation Operating System
13	Hard drive	6 TB SSD
14	Interfaces	USB/RS232
15	Instrument table from OEM	Asymmetric, suitable for wheelchair
16	Accessories	Network printer, monitor bracket, sliding keyboard shelf for instrument table
17	Certification	Should be BIS or European CE wirh 4 digit notified body no or USFDA certified

2. Ophthalmic electrophysiology unit (ERG, EOG, VEP)

1	Multiple function system for all type of ERG,EOG,VEP
2	Automatic recording processing of Multifocal and conventional ERG and VEP data
3	Topographic analysis of response densities ,peak implicit times using comparison with normal reference data
4	Fast low Resolution test of screening high resolution test for precise localization of dysfunction
5	Effective elimination of blink of eye movements artefacts without test prolongation
6	First and higher order response analysis
7	Quality control, Fixation control through infrared eye with/without fundus monitoring recording with fixation artefact rejection
8	High brightness high resolution stimulus display
9	4-5 channel amplifier and filter setting remote controlled by the selected recording protocol
10	Inter ocular comparison of mfVEP records
11	mfVEP and mfERG should be essential integral part of the Electro Physiology unit
12	MfVEP testing of both eyes by mean of dichoptic stimulation
13	ISCEV protocol for conventional ERG and VEP recording and possibility also to have the advised/Extended draft and ISCEV protocol
14	Special mfERG and analysis protocol enhance response contribution form the inner retina and ganglion cells
15	Gaan/Fled should be for adult and paediatric use and separate BABY flash for infant
16	EOG test and analysis
17	Visual Acuity test
18	S Cone ERG testing and analysis
19	Dark Adaptometry test/ pupillometer
20	Contrast sensitivity test/Nystagmograpgy test/FST
21	Colour printer
22	Motorized table for both Ganzfled and monitor
23	**Accessories (Price of electrodes to be quoted sepaately and will be frozen during warranty period)**
a	Electrodes EEG Reusable Cup Electrodes set with sockets - 25 nos
b	ERG –jet Electrode - 25 nos
c	DTL Electrode with connection Cables - 25 nos
d	Ten 20 Conductive and Adhesive plates - 25 nos
e	Nu Prep Gel for Skin preparation - 10 nos
24	Should be BIS or European CE wirh 4 digit notified body no or USFDA certified

3. Microperimetry

1	Visual field should be 40 deg
2	Max stimulus luminance: 10000 asb
3	Background luminance: 30 asb
4	Stimulus size: Goldman I/II/III/IV/V compatible
5	Threshold stratety: 4-2/4-2-1
6	Fixation target: single cross, circle, four crosses
7	Color: white/yellow/red/blue

4. Vitrectomy with Endolaser (High end)

1	**Cutter** Should have ability to drive vitrectomy cutter to go upto 10000 cuts/minute or better Should have simultaneous & dual linear control of cut rate and vacuum. Should have 3D technology linearly control vacuum and cut rate simultaneously in vitrectomy mode
2	**Vacuum** Both Peristaltic &Venturi pump with ability to achieve vacuum upto 600 mm of Hg through a common cassette system.
3	**IOP Control** Should have the capacity to monitor infusion pressure.
4	**Illumination** Dual LED/ Xenon endolight sources for simultaneous use with independent controls. Should self adjust the illumination according to the selected gauge of endo-illuminator being used within phototoxicity limits
5	**Endolaser**
a	Should have an integrated Endolaser. Endol LASER should be integrated with body and LASER Parameters should be controlled on Vitrectomy Interface
b	532 nm endophotocoagulation facility
c	Should have the capacity to support 23G and 25G vitrectomy.
6	**Other Features**
a	Should have automated Silicon Oil injection and removal facility.
b	Should have Auto fluid/ air exchange.
c	Should have Fully programmable footswitch with facility to change modes through footswitch.
d	Should have facility of Diathermy (Retinal)
e	Should have Facility to toggle between a regular infusion pressure and higher alternate pressure (to achieve tamponade effect) with footswitch.
f	Should have facility of Extrusion of subretinal fluid.
g	Should have facility of Voice reconfirmation.
h	Programmability to store various parameters.
i	Phacofragmentation with ultrasound hand piece.
7	Phaco system integrated with the vitrectomy machine with the following fatures:
a	Facility to use variety of phacotips of different vendors.
b	Linear, pulse, burst , 3D modes should be available for Phaco and Dual Linear Mode for vitrectomy should be available.
8	Preferably inbuilt or external, noiseless compressor must be provided.
9	Should be BIS or European CE wirh 4 digit notified body no or USFDA certified
10	Accessories (Price of electrodes to be quoted sepaately and will be frozen during warranty period)
	23G pack - 50 nos

5. Vitrectomy machine Basic with Endolaser/ Phacoemulsification Machine

1	It should have rotatable touch screen display of at least 15 inch x 15 inch .
2	It should have foot pedal control **preferably wireless**
3	It should have disposable cassette (fluid management system) system for better phacodynamics.
4	Ultrasound phaco probe should have longitudinal and also should have other lesser energy dissipating movements like torsional or elliptical or orbital etc.
5	Ultrasound Phaco probe should be 6crystal , light weight, autoclavable, should have high oscillating frequency of 40 ± 10 KHz .
6	Ultrasound phaco probe should have built in IOP (Intraocular pressure) sensor which alerts the active fluidics system .
7	Ultrasound phaco probe should have a balanced tip (rounded) to prevent capsular tear, least heat generation at the wound site to improve patient's safety.
8	Ultrasound phaco probe should be compatible with 2.2 mm standard Phacotips like Kelman, flared, aspiration bypass system (ABS) and other advanced tips
9	Facility for ultrasound power control in various sub modes like continuous, pulsed and burst modes
10	It should have occlusion mode
11	It should have peristaltic and/orventuri vacuum system
12	It should be able to generate vacuum of atleast 500mmHg and aspiration flow rate of upto 60 cc/min atleast
13	It should be able to drive anterior vitrectomy cutter :of sizes 20G, 23G, and 25G with cut rates upto5000 cuts/min.
	a. Sub modes to be present like i)Irrigation aspiration cut mode and ii) Cut Irrigation aspiration mode.
13	It should have Bipolar diathermy.
14	There should be facility for constant IOP(Intraocular pressure) monitoring andhave technology for automatic IOP compensation to maintain stable IOP.
15	Infusion should be fed by pressurized air/gas system
16	Should have the ability to be controlled by front panel & foot switch and **by remote if available**
17	It should be provided with suitable UPS
18	Should be BIS or European CE wirh 4 digit notified body no or USFDA certified
19	Accessories and consumables to be provided:
a	Phaco hand pieces - 3
b	Phaco test chamber - 10
c	Phaco sleeve for 2.2mm - 50

d	Phaco tips 2.2mm (30 degree, 45 degree, Kelman) - 10 each
e	I/A handpiece bimanual / co axial - 5
f	Phaco FMS/ cassette - 50
20	The Equipment including all accessories and bought out items should be covered under warranty.
21	Warranty and CMC should be quoted as per tender conditions.
22	Should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for Medical Devices and copy of valid license should be submitted for the quoted model. In case the vendor has not yet obtained import/manufacturing license from CDSCO for the quoted model, proof of application for CDSCO medical device license to be submitted in the bid document and valid CDSCO license to be produced at the time of award of NOA for the quoted model.

6. Yellow Laser multispot with micropulse

1	Solid state diode pumped and continuous wave laser
2	Wavelength should be 577nm yellow having two delivery ports
3	Should have adequate cooling facility
4	Power output upto 2000mW
5	Exposure duration: 10-3000 ms
6	Aiming beam 635nm diode laser
7	Should be quoted with slit lamp having minimum 3 step magnification and slit lamp delivery should be capable of delivery multi spot pattern laser
8	Patterns: Grid, circle, triple arc pattern
9	Spacing: 0,1-,2-, 3- spot spacing in 0.25 diameter increments
10	Laser delivery must have a spot size of 50- 500 microns and continuously adjustable
11	Should be supplied with suitable motorised table
12	Should be supplied with wireless foor pedal and laser safety glass
13	Should be BIS or European CE wirh 4 digit notified body no or USFDA certified

7. Cryophotocoagulation/Cryosurgical unit

1	Cryogen shall be CO2 and N2O
2	Cryosurgical unit capable of achieving temperatures at the cryo tip below -79°C (-110.2°F) for CO2, -89°C (-128.2°F) for N2O
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
8	Accessories
a	Cryo probes to according the specific use (Preferably 3 sizes (1.5 mm, 2 mm, 3 mm)).
b	Integral timer and temperature indicator
c	Should be supplied with rolling cart.
d	Should be supplied with unfilled cylinder for N2O or CO2
9	Should be BIS or European CE wirh 4 digit notified body no or USFDA certified

8. OCT angiography with Multimodal Imaging

1	Type	Spectral Domain3D OCT
2	Principle	Confocal Laser Scanning
3	LIVE Eye Tracking	Realtime DUAL beam Eye-tracking to eliminate motion artifacts or equivalent scanning speed of 6,50,000 A Scan/Sec
4	Lateral Resolution	Should be 6 microns or less
5	Axial Resolution	Should be 4 micron or less
6	Max A-Scan Rate	85,000A Scan/sec with LIVE Eye Tracking
7	Scan Depth	1.9 mm
8	Max Scan Size for OCT	55 º OCT should be there
9	Confocal Multi Colour Fundus Imaging	The machine should have Confocal Laser Multi Colour Fundus Imaging.
10	Full raster Averaging	The machine should have facility to do the Full raster averaging (at least 4images averaging for the whole area of the scan) for OCT Angio.
11	Dynamic Evaluation of Layers	The machine should have facility to do Dynamic Evaluation of Layers.
12	Focus Adjustment Range	-12 diopters to +12 diopters spherical with high myopia compensation software
13	Peripheral OCT	Should be included
14	Smallest measurable change	1 µm
15	Scan Patterns	Preset as well as User-defined, Circle and Volume scans
16	Pupil Diameter	Imaging/scan should be independent of pupil diameter
17	Separate EDI Mode or Swept Source OCT	Separate EDI mode or Swept Source (Enhanced depth Imaging) for deeper retinal layer scan (Choroid layer imaging)
18	All Layers Segmentation	The Machine should have facility to do the auto segmentation of all layers separately.
19	RNFL Thickness mapping	Separate thickness map for RNFL
20	Ganglion cell thickness mapping	Separate thickness map for Ganglion Cell only
21	Posterior Pole Asymmetry Analysis for Glaucoma	Machine should have imaging mode for Posterior Pole Asymmetry Analysis for Glaucoma
22	ONH Analysis	BMO-ILM Analysis for Glaucoma
23	Fixation	External and Internal Fixation lights

24	Image Displays	OCT B Scan taken in acquisition mode - RNFL in gray scale and colour
		3 D View with cube, surface, single slice, grid, Y-Scale, movie options
		Thickness profile with automatic as well as manually adjustable segmentation line
		Thickness Maps with overlay in Fundus images
25	3D Stereo Viewing	3D View with red – Cyan stereo mode
26	Progression	Should be possible to track by measuring the SAME section over a period of time. Comparison of 2 scans within a progression series
27	Image brightness	Automatic Control
28	Image rotation	180º
29	Built-in Reports	Patient Information, Diagnosis and comments
		Single visit reports with single OCT B scans
		Follow up reports showing progression and Retinal Thickness Change Analysis
		Thickness Map Reports
		3 D View Report
		RNFL Report
		Combined RNFL and Asymmetry Analysis
30	Additional Imaging	The single platform should able to take –Confocal ColourLaser Fundus, Fluorescence Angiogram,Blue Laser Autofluorescence, ICGA, Red Free, IR and OCT imaging
31	Blue Laser	The OCT should have facility of Non Invasive Blue Laser Auto Fluorescence facility
32	Movies mode for Fluorescence Angiogram and ICGA	The machine should have Movies mode for Fluorescence Angiogram and ICGA
33	Simultaneous fluorescence angiography and OCT	Machine should have Simultaneous fluorescence angiography and OCT
34	Simultaneous ICGA and OCT	Machine should have Simultaneous ICGA and OCT
35	Simultaneous Blue Laser Autofluorescence and OCT	Machine should have scanning mode of Simultaneous Blue Laser Autofluorescence and OCT
36	Simultaneous ICGA and FA	Machine should have Simultaneous ICGA and FA

37	Scan Planning for OCT Angio	Machine should have facility to plan the OCT Angio position overlap on to Fluorescence Angiogram ,Blue Laser Autofluorescence and ICGA for best understanding of the pathology.
38	Real time composite	Machine should have real time composite mode for wide fundus imaging
39	UWF Lens (more than 100 deg)	Non-contact Ultra-Wide Field imaging for Angiogram , ICGA (more than 100 Deg with single image)
40	Anterior Segment	Should have anterior segment OCT (price to be quoted separately)
41	PC and Printer	Compatible Computer with required S/W and Photo Printer

9. Goniolens

	Should supply following lens set
1	2-sussmann lens
2	1-zeiss four mirror gonio lens
3	1-Four mirror goldmann lens
4	1-Abraham lens

10. Tonopen

1	Easy-to-use, hand-held instrument
2	IOP readings that correlate closely with Goldmann Tonometry.
3	Lightweight, ergonomic design and advanced electronic measurement technology
4	Should be capable of fast and accurate IOP measurements with minimal training
5	Transducer Micro Strain Gauge Measurement Range 5 - 80 mmHg
6	Should be battery operated

11. Fundus Camera (Non Mydriatic)

1	Type : Non-mydriatic Automated Fundus Camera
2	Field of view should be at least 120 deg
3	Image capture : Color, Auto fluroscence, green, blue and red
4	Sensor Resolution: 10-12 Megapixel
5	Touch screen monitor of at least 18" or more
6	Fixation Light Internal and External fixation light both
7	Exposure interval 0.5-1 sec
8	Facility for Data storage, data transfer, image archiving, image analysis
9	Instrument table Asymmetrical motorized suitable for patients in wheel chair
10	Should be supplied with computer & compatible software with following specification: Intel core i7 or better processor, 8GB RAM, 2 TB HDD and compatible windows OS. All the offered software should be upgradable
11	Should be USFDA or European CE with 4 digit notified body number approved product.
12	Online UPS with atleast 30 minutes backup.
13	Should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for Medical Devices and copy of valid license should be submitted for the quoted model. In case the vendor has not yet obtained import/manufacturing license from CDSCO for the quoted model, proof of application for CDSCO medical device license to be submitted in the bid document and valid CDSCO license to be produced at the time of award of NOA for the quoted model.

12. Ultrasonic Pachymeter

1	A pachymeter is a medical device used to measure the thickness of the eye's cornea.Modern design incorporates ultrasound technology for measurement of the thickness
2	Microprocessor based digital instrument with automatic probe alignment to measure corneal thickness.
3	Should have facility for printout of all measurements by locations
4	Measuring range 0.3 – 1.0cm with 1 micron increments
5	Measuring accuracy + /-5 microns
6	Should display current and average of all measurements

13. Clinical Specular Microscope

1	It should be used for in vivo, non-contact, endothelial cell count
2	It should be fast, able to capture and analyse the parameters within 2 sec
3	It should have both automatic and manual mode
4	The size of the photocapure should be at least 0.20 x 0.50 mm
5	It should be able to perform in the corneal with the corneal thickness range of 300-700 micrometer
6	It should able to capture the endothelial cell datas from both centre as well as periphery of the cornea
7	It should able to calculate approximately 300 cells
8	Analysis method: automated/ L-count/ core method/ center method/center-flex method
9	Analysis values: CD (cell density), AVG (average cell area), SD (standard deviation of cell area), CV (coefficient of variation of cell area), Cell size etc
10	There should be comparison feature between the two examinations
11	It should be provided with high speed computer system with 1 TB storage system for better data management and color printer
12	Machine should be provided with compatible combined motorized table and chair unit
13	It should be provided with motorized chair for examiner
14	It should be provided with UPS with 30 minutes backup
15	Should be BIS or European CE wirh 4 digit notified body no or USFDA certified

14. Corneal Topography system

1	Measuring Technology should be based on Scheimpflug camera
2	Field of View 17 mm X 14.5 mm
3	Analysed Points over 100,000 or Measured points over 6200
4	Illumination Source - Non-visible infrared (950 nm) LED
5	Optics Digital CMOS camera with 1280x1024 pixel resolution
6	Curvature Measurement Range - 15 to 95 D (3.5 to 22.5 mm)
7	Accuracy - ± 0.05 D (± 0.01 mm)
8	Reproducibility ± 0.10 D (± 0.02 mm)
9	HVID (white to white) Measurement Range 10.0 to 14.0 mm
10	Pupillometry Acquired Images: Dynamic, mesopic, Scotopic and photopic (700 nm)
11	Measurement Range0.5 to 11.0 mm
12	Resolution0.1 mm
13	Views : Axial Curvature, Tangential Curvature
14	Videokeratoscopic (Rings, Scotopic, Photopic)
15	Keratometry, Refractive Power, Mean Curvature, Corneal Wavefront
16	OD/OS Comparison
17	Pathfinder for Corneal Analysis Software
18	MasterFit for Contact Lens Software

15. Operating Microscope Markerless Surgery

A	**Operating Microscope with assist microscope & wide angle viewing system**
1	Should have apochromatic optics
2	Should have motorized continuous magnification (zoom)
3	Should have working distance of objective lens F = 200mm
4	Eye piece should be minimum 10x or 12.5x wide with dioptre adjustments
5	Waterproof , wireless, freely programable foot control panel with focus , zoom, light intensity control & X Y coupling
6	Should have red reflex switching in/out facility
7	Should have 0-90 degree inclinable/tiltable binocular tube with integrated inverted tube from OEM
8	Should have total magnification range from 4.1x to 15x or more
9	Should have stereo coaxial illumination or equivalent technology by fiber optic light guide
10	Should provide assistant microscope from OEM with stereo co-observation tube with Beam splitter (80:20)/ (70:30)/(50:50) , 10x/12.5x eyepiece External/ integrated in the microscope body for additional Stereo co observation attachment/ documentation
11	Should be floor standing type with fibre wheels with brake.
12	It should have LED illumination OR Halogen illumination with integrated halogen backup lamp with automatic lamp changeover incase of failure of main lamp
13	Should have heat absorbing and UV filters, retina protection device/filter, contrast enhancement aperture/Blue blocking filter
14	Equipment should be supplied with an integrated/external single chip or more CCD/CMOS HD camera with HD video recording system including 32" or more HD LED/LCD monitor. Should have atleast 1TB image storage capacity.
15	Should have non contact wide angle viewing system from OEM, with quick interchangeable lenses for macula and peripheral view (120 deg or more) of the retina. Non contact lenses 60D & 128D – 2 sets to be supplied
B	**Markerless toric IOL alignment**
1	Markerless toric IOL alignment, Assistance Markerless License
2	Reference Axis, Capsulorhexis, Main Incision & Paracenthesis, LRI, Z ALIGN, Marker based & Markerless
3	Target axis for toric IOL alignment
4	Keratoscope function for intraoperative assessment of the corneal curvature
5	One or three lines, Position relative to yellow reference axis

16. Tear Lab Osmolarity system

1	Tear osmometer to measure the tear osmolarity
2	Should be able to measure osmolarity between 280 to 350 mosm/kg H2O with a standard deviation of 5 mosm/kg H2O and resolution of 1 mosm/kg H2O
3	The minimum sample required should be 500nl
4	The test should be complete in less than 15 minutes