

HSCC (I) Ltd

Amendment –I Dated 17.12.2019

Tender Ref : HSCC/AIIMS-RAEBARELI/Hospital/2/2019 Dated : 28.11.2019

Department : Urology

Item No.1 : Pneumatic lithotripter

Sl. No	Tendered Specification	READ AS
2	Digitally Controlled flow and pressure device generates highly accurate pulses in the form of single pulse operating mode and continuous pulse operating mode	Controlled flow and pressure device generates highly accurate pulses in the form of single pulse operating mode and continuous pulse operating mode
3	It should be able to control power to the hand piece for better stone fragmentation	It should be able to control pressure to the hand piece for better stone fragmentation
4	Design of master hand piece and digitally controlled flow should be in a way that provides minimum excursion and bilateral movement of the probe, so it gives safety to endoscope and avoid possible stone migrations	Design of master hand piece and controlled flow should be in a way that provides minimum excursion and bilateral movement of the probe, so it gives safety to endoscope and avoid possible stone migrations
10	In Let Pressure (Minimum) (To Control Unit) 4 Kg /cm2 & (Maximum) (To Control Unit) 6 Kg /cm2 12. Out Let Pressure: 0 - 5 Kg /cm2	In Let Pressure (Minimum) (To Control Unit) 4 Kg /cm2 & (Maximum) (To Control Unit) 6 Kg /cm2 . Out Let Pressure: 0 - 3 Kg /cm2
11	Digital display Freq. of Impacts Single Pulse Mode, Continuous Pulse Mode with twelve selectable options.	Should have Single Pulse Mode and Continuous Pulse Mode
12	Control Unit (Made from rust free molded ABS plastic body), Hand Piece (Made from Aluminum Alloy, should be sealed and airtight), Probe (Made from S.S. Alloy)	Control Unit (Rust free body), Hand Piece (Made from Aluminum Alloy, should be sealed and airtight), Probe (Made from S.S. Alloy)
13	Uretereroscopy: Probe Size : 0.8mm, 1mm, 1.4mm Length : 600-610mm	Uretereroscopy: Probe Size : 0.8mm, 1mm, 1.6mm Length : 600-610mm Flexible probe: 0.8 - 0.9mm length 940mm
14	Probe size 2-2.5mm, 3.0mm Length 425-450mm	PCNL Probe size 2-2.5mm, 3.2mm Length 425-450mm
15	Lithobridge Probe: 1.5mm Length 450 – 460mm	Blader Stone Probe: 1.5mm Length 450 – 460mm
18		Added Para: Manual override to operate the machine in case of electronic failure of the controll unit should be available
19		Added Para: The offered model should be European CE with 4 digit notified body number or USFDA or BIS approved for the quoted model
S. No.	BOQ	

2	Ureterenoscropy: Probe Size : 0.8mm, 1mm, 1.4mm Length : 600-610mm	Ureterenoscropy: Probe Size : 0.8mm, 1mm, 1.6mm Length : 600-610mm Flexible probe: 0.8 - 0.9mm length 940mm	5 Nos. Each
3	Probe: size 2-2.5mm, 3.0 mm Length 425-450mm.	PCNL Probe: size 2-2.5mm, 3.2mm Length 425-450mm.	2 No. Each
4	Lithobridge Probe: 1.5mm Length 450 – 460mm	Blader Stone Probe: 1.5mm Length 450 – 460mm	5 Nos.

Item No. 2 : ESWL

Sr. No.	TENDERED SPECIFICATION	READ AS
5	Site medication required for the installation of the complete system will be done by the supplier. Price to be quoted for 1000 square ft area. Added Para : Suitable Online UPS should be supplied with 1 hrs backup approx. 15 KVA Capacity.	Site modification required for the installation of the complete system will be done by the supplier. Price to be quoted for 1000 square ft area. Suitable Online UPS should be supplied with 1 hrs backup approx. 10 KVA Capacity.
6		Added Para : The offered model should be European CE with 4 digit notified body number or USFDA or BIS approved for the quoted model.
BOQ Point 2	Coupling Jelly 100 Liters	Coupling Jelly 100 Litres- If required for system
BOQ Point 4	Lead apron with thyroid shield -10 nos.	Lead apron with thyroid shield -10 nos. each
BOQ Point 6	ECG Electrodes 100 Nos.	Deleted
BOQ Point 7	Large Register for record keeping	Deleted

Item No.3 : Urodynamic System

Sl. No	TENDERED SPECIFICATION	READ AS
1	The unit should be able to perform CMG, Pressure flow, EMG ,EMG with biofeedback,Video Urodynamics, Uroflowmetry (with one wired and one wireless uroflowmeter).	The unit should be able to perform CMG, Pressure flow, EMG ,EMG with biofeedback,Video Urodynamics, Uroflowmetry (with one wired and one wireless uroflowmeter). For biofeedback , either software or separate module with wired/wireless EMG should be provided which has animated games incorporated. Probes for biofeedback should be provided (1 anal probe, 1 vaginal probe)
12	All in one PC computer Windows 7 or more, i5 processor, at least 4 GB RAM, 1 TB HDD with color laser printer, should have facility for USB port	All in one PC / computer Windows 7 or more, i5 processor, at least 4 GB RAM, 1 TB HDD with color laser printer, should have facility for USB port
16	Should have Bluetooth data transfer facility for CMG, Pressure flow and other Urodynamic studies.	Should have wireless data transfer facility for CMG, Pressure flow and other Urodynamic studies.
20	2 Lumen Catheter 8 Fr.-50 pcs	2 Lumen Catheter 8 Fr.-50 pcs ; 5-6 Fr. - 50 pcs
24	pressure transducers - 3 pcs	Reusable pressure transducers - 3 pcs(to be covered under both warranty & CMC) ; Domes: 50 pieces
30		Added Para: Price of accessories and consumables should be quoted separately
31		Added Para: Should have USFDA/European CE with 4 digit notified body number or BIS approved for the quoted model.

Item No. 4 : PCNL Set

Sr. No.	Tendered Specification	To be Read As
G		Added Para: The Equipment Should be USFDA / European CE with 4 digit notified body number/BIS approved for the quoted model

Item No. 5 : Holmium Laser 100 W

Sr. No.	Tendered Specification	To be Read As
7	It should be supplied with twin/double foot pedal	It should be supplied with single/double foot pedal
17		Added Para: It should be US FDA or European CE (with 4 digit notified body number) or BIS approved for the quoted model

Item No. 6 : Tissue Morcellator

Sr. No.	Tendered Specification	To be Read As
B.1	One Control Box,	Suction & Shaver system incorporated through Control Box.
B.4. b	Inner Blade –Outer dia 0.39cm or less, length 51 cm or more	Inner Blade –Outer dia 0.40 cm or less, length 40cm or more
13	Laser bridge- 2	Laser bridge/Laser Guide Rod- 2
20		Added Para: It should be US FDA or European CE (with 4 digit notified body number) or BIS approved for the quoted model

Item No. 7 : Digital Flexible Ureteroscope

Sr. No.	Tendered Specification	To be Read As
Name of Item	Digital Flexible Ureteroscope	Flexible Ureteroscope
15		Added Para: It should be US FDA or European CE (with 4 digit notified body number) or BIS approved for the quoted model

Item No. 8, Semi Rigid Uretero-Renoscope

Revised Technical Specification

Sl. No	Semi Rigid Uretero renoscope
1	Description of Function Minimally invasive Fibre optic, endoscopic instrument for diagnosis and treatment of diseases of ureter and kidney.
2	Operational Requirements Integrated fibre optic ureteroscope for using in adult and pediatrics upper urinary tract endoscopic surgery
3	Technical Specifications
3.1	Long Arm (Working Length – 430 mm or more) Autoclave with offset Eyepiece, Distal sheath tip 6 Fr. – 6.5 Fr. Atraumatic Viewing angle 5 -10 degree with laterally placed eyepiece. - 1 no. Channel size 4Fr or more
3.2	Long Arm (Working Length – 430 mm or more) Autoclave with offset Eyepiece, Distal sheath tip 7.5-9Fr. Atraumatic Viewing angle 5 -10 degree with laterally placed eyepiece. - 1 no. Channel size 5 fr or more
3.3	Autoclable Chamber/Tray of suitable size
4	System Configuration Accessories, spares and consumable
4.1	System as specified
4.2	URS alligator forceps (largest compatible with each ureteroscope) – 2nos. for each ureteroscope (should be European CE or USFDA or BIS approved, can be from the other manufacturer)
4.3	URS triprong forceps (largest compatible with each ureteroscope) – 2nos. for each ureteroscope (should be European CE or USFDA or BIS approved, can be from the other manufacturer)
4.4	Compatible balloon ureteral dilator - 2 nos.(should be European CE or USFDA or BIS approved, can be from the other manufacturer)
4.5	Path finder - 4 no (should be European CE or USFDA or BIS approved, can be from the other manufacturer)
4.6	All adapters required for smooth functioning of system to be supplied as standard
5	Standards, Safety and Training
5.1	Should be European CE with 4 digit notified body no or USFDA or BIS approved for the quoted model
5.2	Manufacturer/Supplier should have ISO certification for quality standards.

Item No. 9, Cystoscope & Resectoscope

Revised Technical Specification

Sl. No	<u>Cystoscope & Resectoscope</u>
1	Cystoscope
	30 degree Telescope of size: 4mm, length 28-30cm - 2 Nos
	0 degree Telescope of size: 4mm, length 28-30cm - 1 Nos
	70 degree Telescope of size: 4mm, length 28-30cm - 1 Nos
	Should have very high quality of rod lens system
	Should have fiber optic light transmission incorporated.
	The Telescope should be autoclavable.
2	Cystoscope Sheath
	Cystoscope sheath with leur lock connection of two different size should be provided - 1 no. Each
	21-22 FR and 17-18 FR sheath one each with slot for instrument
	The sheath should be marked and graduated
3	Telescope bridge
	Telescope bridge with two instrument channel to fit with the cystoscope - 2 no.
4	Flexible Grasping forceps
	Compatible Grasping forceps 33cm or more to be provided to fit the purpose - 4 nos.
5	Flexible cup biopsy forcep
	Compatible cup biopsy forceps 33cm or more to be provided to fit the purpose - 2 no.
6	Rigid Biopsy and Grasping Forcep
	Optical Rigid Biopsy forcep compatible with Cystoscope sheath to be provided - 1 no.
	Toomey glass syringe 100 -150 CC - 1 no
	Toomey glass syringe of 100-150 cc with adaptor to fit with sheath - 1 no.
7	ELLIK Evacuator
	ELLIK Evacuator with 2 bulb and adaptor to be provided - 2 sets.
8	Urethrotome sheath with 1 working element
	20-21 FR optical Urethrotome sheath with one channel to be provided -1 no.
	Straight cold knife 5 nos.
9	Resectoscope sheath
	26 FR continuous irrigation resectoscope sheath (inner & outer sheath) with ceramic beak to be provided to fit the purpose with set of silicon tube. Sheath should be provided with deflecting obturator & visual obturator - 1 no. each
10	Working Element set

	Working element set passive type compatible with offered resectoscope sheath with standard accessories like, Collins knife, HF cord, Protection tube, cutting loop to be provided -1 set comprising of following
	Cutting loop single stem - 30 Nos.
	Collins knife - 5 nos.
	High Frequency cord - 5 Nos.
	Added para: Protection tube 1 no
11	OTIS Urethrotome parallel expanding (adjustable from 15-35 Fr) - 1 no
	Compatible double edged blade - 5 nos.
12	Coagulating Electrode, 5 Fr., unipolar, length 50-55 cm -2 nos.
13	Stone Punch with Sheath size 24-26Fr or less – One
	All above mentioned equipment should be European CE with 4 digit notified body number or USFDA or BIS certified.
	Added para: Declaration from principal manufacturer that quoted items are brand new and not refurbished
	Added para: There will be 95% uptime warranty during CMC period on 24 (hrs) X 7 (days) X 365 (days) basis, with penalty, to extend CMC period by double the downtime period. If non functioning period exceed 2 weeks at a stretch , a temporary standby equipment of same specification must be provided

Item No.10 : General Surgical Instrument Set

Sl. No.	TENDERED SPECIFICATION	READ AS
A2	BACKHAUS TOWEL HOLDING FORCEPS, 110MM	BACKHAUS TOWEL HOLDING FORCEPS, 110MM - 8 Nos
A3	TOWEL CLAMP, 115 MM LENGTH	TOWEL CLAMP, 115 MM LENGTH - 8 Nos
B	KIDNEY SET (TWO EACH)	KIDNEY SET (ONE SET)
50	MIKULICZ ABDOMINAL RETRACTOR	MIKULICZ ABDOMINAL RETRACTOR 90x50mm
51	MIKULICZ ABDOMINAL RETRACTOR	MIKULICZ ABDOMINAL RETRACTOR 95x35mm
52	MIKULICZ ABDOMINAL RETRACTOR	MIKULICZ ABDOMINAL RETRACTOR 150x50mm
16	Head light with light source	Head light with light source - 300 watt Xenon Dual port light source
17	300 watt Xenon Dual port light source	Deleted
E2	BACKHAUS TOWEL HOLDING FORCEPS, 110MM	BACKHAUS TOWEL HOLDING FORCEPS, 110MM - 6 nos
E3	TOWEL CLAMP, 115 MM LENGTH	TOWEL CLAMP, 115 MM LENGTH - 6 nos
L	Corrosion free surgical grade stainless steel (Stainless steel alloy of 350-450	Corrosion free surgical grade stainless steel SS 400 grade and bidder should submit original OEM certificate for the same

	grade)	
O		Added Para: All instruments should be US-FDA or European CE approved with 4 digit notified body number or BIS approved (copy of certificate have to be enclosed with the bid)
P		Added para: Bidder should submit country of origin certificate to be certified by chamber of commerce of that country
Q		Added para: Price of each item must also be quoted separately.

Item No.11 : Uroflowmetry

Sl. No	TENDERED SPECIFICATION	READ AS		
2	The Uroflowmetry sensor should be wired/Wireless to the main unit. The sensor should also be operable by wireless Bluetooth mode.	The Uroflowmetry sensor should be wireless to the main unit.		
3	Should have Database Software and Uroflow Software which includes extensive report printed by PC printer, possibility to add investigation comments and real time on line view of the investigation. Should have the facility of wireless transfer of data using Bluetooth Technology with automatic start. Automatic Investigation and Analysis.	Should have Database Software and Uroflow Software which includes extensive report printed by PC printer, possibility to add investigation comments and real time on line view of the investigation. Should have the facility of wireless transfer of data with automatic start. Automatic Investigation and Analysis.		
8	Beakers for Uroflow -5 Nos, Rechargeable Batteries 2set for each (Uroflo & Blader scan), Charger for Rechargeable Batteries 1set for each (Uroflo & Blader scan). Should be supplied as standard	Beakers for Uroflow -5 Nos, 1 set Rechargeable Batteries for Bladder scanner, 1 set batteries for Uroflow. Charger for Rechargeable Batteries 1set. Should be supplied as standard		
12		Added Para: Complete system except computer system should be European CE with 4 digit notified body number or USFDA or BIS approved for the quoted model		
SN		BOQ	Qty	UOM
3	Rechargeable Batteries (Uroflo & Blader scan)	Rechargeable Batteries (Blader scan); Batteries for Uroflow	1	set each
4	Charger for Rechargeable Batteries (Uroflo & Blader scan)	Charger for Rechargeable Batteries (Blader scan)	1	set

Item No.12: Laparoscopy Set

S.No	TENDERED SPECIFICATION	READ AS
6 f	The system should have digital zoom and integrated optical zoom with auto focus to enhance the quality of image size & cross speciality standardization of the camera system, regardless of the telescope used.	The system should have digital zoom and optical zoom to enhance the quality of image size & cross speciality standardization of the camera system, regardless of the telescope used.
6 k	Lens F14-30mm ± 10 %	Lens F16-30mm ± 10 %
7 b	26” full HD medical grade monitor in 16: 9/10 HDTV format, LED/LCD display	26” full HD medical grade monitor in 16: 9/10 HDTV format, LED /LED backlit display
7 f	TFT/LCD/LED screen stand/Fixtures for connecting to Pendant System/Ceiling Light Arm	LED screen stand/Fixtures for connecting to Pendant System/Ceiling Light Arm
8 b	Adjustable flow rate of 30 litres per minute or more and pressure range adjustable between 0 to 30 mm Hg	Adjustable flow rate of 45 litres per minute or more and pressure range adjustable between 0 to 30 mm Hg
8 h	Should have smoke evacuation available in the system or separate smoke evacuation system should be offered	Delete
8 j	Should include pin-index connection to small/big gas cylinder with regulator, high pressure hose, mains cord, silicone autoclavable tubing set, universal wrench and gas filter	Should include pin-index connection to small/big gas cylinder with regulator, high pressure hose, accessory to connect with central pipeline, mains cord, silicone autoclavable tubing set, universal wrench and gas filter
9	LIGHT SOURCE(Xenon 300) with TWO spare bulbs	LED LIGHT SOURCE
9a	Xenon cold light fountain with 300 watts xenon lamp	LED light source equivalent to 300 W Xenon having lamp life time of atleast 5000 hours
9 b	Colour temperature of at least 5800 °K	Delete
9 c	Manual and automatic adjustment of light intensity	Delete
9 d	Brightness control to be regulated manually or automatically via the output signal of a video camera	Delete
9 e	Lamp life 500 hrs or more	Delete
9 f	Display of lamp life/Bulb usage meter warning light	Delete
14		Added Para: The Laparoscopic system should have smoke evacuation available in the system or separate smoke evacuation system should be offered
15		Added Para: The telescopes, Camera, Monitor,Insufflator, Light Source and all their subparts must be from the same OEM
16		Added Para: The complete system should be European CE (with 4 digit notified body number.) or USFDA approved or BIS approved

Item No.13 : OT Table Electro Hydraulic

Sl. No	TENDERED SPECIFICATION	READ AS
	Multipurpose electro hydraulic with manual override /electromechanical with electrical override/ powered with powered override mobile Table with divided leg section suitable for all major surgical procedures complete with 5cm mattress and corded handset.	Multipurpose electro hydraulic /electromechanical / powered mobile Table with divided leg section suitable for all major surgical procedures complete with 5cm mattress and corded handset
A 3	Removable head and leg sections to suit different applications.	Removable and Interchangeable head/ leg sections to suit different applications with buttons on corded handset to detect orientation
A 8	The robust handset should offer controls namely Trend/ Reverse Trend, Lateral Tilt, Flexion/ Extension ,Height functions and slide. Auto levelling should be available.	The robust handset should offer controls namely Trendelenburg, Reverse Trendelenburg, Lateral Tilt, Flexion, Extension ,Height functions and slide. Auto levelling should be available
A 9	Brakes, 4Nos. Wheels and 5th wheel for 360° rotation.	Brakes, 4Nos. Wheels and preferably 5th wheel for 360° rotation.
A 10	Table should have a narrow and eccentric base allowing optimum access and greater stability	Table should have a narrow base allowing optimum access and greater stability
A 15		Added Para: Table should have a mechanism/sensor to prevent/detect collision
B 1	Special-design, maintenance-free rechargeable batteries with capacity for about a week's use in the operating room	Special-design, maintenance-free rechargeable batteries with capacity for about a day use in the operating room
C 1	Length : 2000 - 2100mm	Length : 1950 - 2100mm
C 2	Width : 500-600mm without side rail	Width : 500-550mm without side rail
C 4	Maximum height (without mattress): Minimum of 1040mm	Maximum height (without mattress): Minimum of 950mm
C 5	Maximum lateral tilt: 20-30deg. (either side)	Maximum lateral tilt: 18 deg or more. (either side)
C 7	Reverse Trendelenburg at least 25° deg	Reverse Trendelenburg at least 20° deg or more
C 8	Head section adjustment : - atleast +/-30degree	Head section adjustment : - atleast -30/+25 degree
C 12	Cranial & Caudal traversing :atleast 200mm	Longitudinal Slide: atleast 250 mm (125mm on each side)
C 14	Maximum patient weight : 450 kg or more at centered column and 270 kg in all articulations.	Maximum patient weight : 250 kgs
D 1	Arm board with clamp-02 nos.	Arm board with clamp-04 nos.
D 4	Side supports with clamps -02 Nos	Side supports with clamps -04 Nos
D 10	Lithotomy leg holders "Geopel type" -(Adult and paediatric)-1set each	Lithotomy leg holders "Geopel type" -1set
D 12		Added Para: Shoulder support- 2 nos

D 13		Added Para: Pneumatic lift stirrup set with side rail clamp - 1 set (price to be quoted separately)
D 14		Added Para: Extender for Urological surgeries with perineal cut with compatible drain tray
E	The table should be US-FDA or European CE (with four digit notified body number) approved product	Should be US-FDA or European CE with 4 digit notified body number or Declaration of conformity for quoted model along with ISO 13485 or BIS certified for the quoted model
F	For Electrical IEC 60101-1, medical /electrical equipment for safety , IEC 60601-2-46 for safety of OT Tables and IEC 60601-1-2 for Electromagnetic Compatibility.	The IEC certificate namely IEC 60601-1(electrical safety), IEC-60601-1-2 (electromagnetic compatability), IEC 60601-2-46(Particular requirements for the safety of Operating Tables) along with full test report as per IEC guideline for the quoted model should be submitted from anyone of the labs mentioned below TUV, SGS, Intertek, UL, SAMEER, Bharat Test House, Astute Labs or from the labs in their country of origin (incase of foreign manufacturers).
SI No	BOQ –Qty	BOQ -Qty.
2	Arm board with clamp – 2 Nos.	Arm board with clamp – 4 Nos.
5	Side supports with clamps -2 Nos.	Side supports with clamps -4 Nos.
11	Lithotomy leg holders “Geopel type” (adult and pediatric) : 1 set each	Lithotomy leg holders “Geopel type” -1 Set
12		Added Para: Shoulder support 2 Nos
13		Added Para: Pneumatic lift stirrup set with side rail clamp - 1 set (price to be quoted separately)1

Also please find attached Price Scheduled for quoting prices for the optional items/ prices of individual items to be quoted separately wherever as required. All other terms and conditions of the tender enquiry documents shall remain unchanged.

Prospective bidders are advised to regularly visit HSCC website/CPPP Website for the Corrigendum/amendments etc. if any, as these will be notified on these portals only. No separate advertisement will published in the newspaper in this regard.

CGM (Projects)
HSCC (I) Ltd.