

07.12.2021

Amendment No. 2**Sub: Technical amendment to the referred tender enquiry****Ref.: HITES/PCD/AIIMS-IV/46/CTVS/21-22 dated 26.10.2021 read with its Amendment No 1 dated 26.11.2021**

The following changes are being incorporated in the above referred Tender Enquiry Document.

**SECTION VII
TECHNICAL SPECIFICATIONS**

Tender Ref No. HITES/PCD/AIIMS-IV/46/CTVS/21-22		
Item No 1: Electro hydraulic OT Table with all accessories(2021_HLL_92629_1)		
Tender Para	TENDER SPECIFICATION	AMENDED AS
2.1	2.1 OT Table is required for general surgery and should have X-Ray translucent tops.	OT Table is required for hybrid CTVS surgery and should have X-Ray translucent tops.
4.2	All accessories including the following should be quoted. The specific accessories and their quantity will be decided on the basis of actual requirement:- a. Padded arm rest with straps - pair with damps b. Anesthesia screen with clamps c. Side supports: pair with clamps d. Shoulder supports: pair with clamps e. Knee crutches: pair with damps f. X-ray cassette tray with pushing rod	4.2 All accessories including the following should be quoted (Price to be quoted separately for Para 4.2 a to f). The specific accessories and their additional quantity will be decided on the basis of actual requirement:- a. Padded arm rest with straps - 1 pair with damps b. Anesthesia screen with clamps - 1 pair c. Side supports: 1 pair with clamps d. Shoulder supports: 1 pair with clamps e. Knee crutches: 1 pair with damps f. X-ray cassette tray with pushing rod - 1 No
4.2 g	4.2 g. The machines should be supplied with the following accessories for operating prone position (Price of each item should be mentioned separately) a. Gel Flat bottom chest roll (medium) b. Gel prone positioner c. Gel prone head rest (large)	4.2 g. The machines should be supplied with the following accessories for operating prone position (Price of each item should be mentioned separately) a. Gel Flat bottom chest roll (Small, medium, and Large) - 2 Nos each b. Gel prone positioner - 2 Nos c. Gel prone head rest (large) - 2 Nos Added Para : d.Light weight transfer board - 2 Nos
4.2 h	Optional accessories (Price of each item should be mentioned separately) A. X-Ray Top for 9" Urology extension B. Metal Drain pan C. Power lift stirrup set with side rail clamp	Optional accessories (Price of each item should be mentioned separately) A. X-Ray Top for 9" Urology extension B. Metal Drain pan C. Power lift stirrup set with side rail clamp

	D. Foot control E. Split leg pair F. Reverse Trendelburg restraint strap G. Light weight transfer board.	D. Foot control E. Split leg pair F. Reverse Trendelburg restraint strap G. Deleted.
7.2	Electrical safety conforms to standards for electrical safety IEC 60601-1 General Requirements (or equivalent BIS Standard)	Electrical safety conforms to standards for electrical safety IEC 60601-1 General Requirements (or equivalent BIS Standard / NABL accredited lab certified) Test report for the quoted model should be submitted.
7.3	Shall meet internationally recognised standard for Electro Magnetic Compatibility (EMC) for electromedical equipment: IEC-60601-1-2 :latest edition Or Equivalent BIS) or should comply with 89/366/EEC; EMC-directive as amended	Shall meet internationally recognised standard for Electro Magnetic Compatibility (EMC) for electromedical equipment: IEC-60601-1-2 :latest edition Or Equivalent BIS / NABL accredited lab certified) or should comply with 89/366/EEC; EMC-directive as amended. Test report for the quoted model should be submitted.
7.4	Certified to be compliant with IEC 60601-2-46 : Particular requirements for the safety of Operating Tables: latest edition or equivalent	Certified to be compliant with IEC 60601-2-46 : Particular requirements for the safety of Operating Tables: latest edition or equivalent Or Equivalent BIS / NABL accredited lab certified. Test report for the quoted model should be submitted.

Item No 2: Heart lung machine (2021_HLL_92629_2)

Tender Para	TENDER SPECIFICATION	AMENDED AS
3.1	5- Pump Console	
1	The unit should have 5 pump console compactly arranged with separate power supply and control modules. Should have easy access connectors for interchanging the pump.	The unit should have 5 pump head compactly arranged with Single/separate power supply and control modules. Should have easy access connectors for interchanging the pump.
2	Each individual roller pump should be capable of running independently at available voltage.	Deleted
5	"Individual pump heads should have Harvey Roller pumps with facility for tubing to be used adjustable from 1/4" to 1/16" through 3/8" and 1/2" by easily changeable mechanism."	"Individual pump heads should have Harvey /horse shoe Roller pumps with facility for tubing to be used adjustable from 1/4" to 1/16" through 3/8" and 1/2" by easily changeable mechanism."
6	Individual pump heads should have display in digital —The total infusion volume in litres and delivery time, the flow rates in LPM and in RPM	Individual pump heads should have display of infusion volume in LPM & RPM
12	Roller pump should have a self diagnostic circuit with provision to detect and display critical alarm conditions. Pulsatile module which can be mounted on any of the blood pump.	Roller pump should have a self diagnostic circuit with provision to detect and display critical alarm conditions. Pulsatile module can be in built/ which can be mounted on any of the blood pump.

3.2	Should have a venous control module with single pole mast with electronic venous line occluder (Rate to be offered if available).	Should have a venous control module with single pole mast with electronic venous line occluder
2.1	4.a Air- Oxygen Blender with hoses and Flow meter	4.a Electronic Air- Oxygen Blender with hoses and Flow meter
3.11	Accessories:	
5	Compatible Co2 Blender should be supplied as standard	Compatible Electronic Co2 Blender should be supplied as standard
Item No 5 : Colour Doppler Echocardiography System (Mid End) (2021_HLL_92629_5)		
Tender Para	TENDER SPECIFICATION	AMENDED AS
2.2	Should be field up gradable to 4D TEE & Transthoracic echo imaging	Should be field up gradable to 4D TEE echo imaging.
3.8	Frame rate should be 2500 FPS or more	Frame rate should be 1900 FPS or more.
4.6	DVD/CD Recorder with 100 CDs and 100 DVDs	DVD/CD Recorder with 100 CDs and 100 DVDs with cover
4.7	High end color laser printer with auto duplexing, scanning facility - 1 no & 2 sets of cartridges.	High end color laser printer with auto duplexing, scanning facility - 1 no & 2 additional sets of cartridges.
4.13	System should provide with Latest PC (off-line licensed workstation) with minimum 2TB Hard drive, 2x8 GB DDR 3 RAM, Intel i7- 3.5 GHz or higher processor, Two serial port, Minimum 4 nos USB C port, Inbuilt Bluetooth & Wi-Fi, 24" Medical grade Monitor, wireless Keyboard & mouse, latest Windows professional OS & licensed MS office of latest version, licensed software for analyzing and quantification of 2D and 3D data sets, CD/DVD writer with Image Management Software should be supplied. PC should be supplied with the licensed software to work on the below features. i. Strain and Strain rate imaging. ii. Semi-Automated Border Detection. iii. Tissue Motion Annular Displacement. iv. 2D speckle tracking (any other Hardware essential for OFFLINE Quantification)	System should provide with Latest PC (off-line licensed workstation) with minimum 2TB Hard drive (1TB in computer and 1TB Portable Hard Drive) and 512GB flash drive , 2x8 GB DDR 3 RAM, Intel i7- 3.5 GHz or higher processor, Two serial port, Minimum 4 nos USB C port, Inbuilt Bluetooth & Wi-Fi, 24" Medical grade Monitor, wireless Keyboard & mouse, latest Windows 11 professional OS & licensed MS office of latest version , licensed software for analyzing and quantification of 2D and 3D data sets, CD/DVD writer with Image Management Software should be supplied. PC should be supplied with the licensed software to work on the below features. i. Strain and Strain rate imaging. ii. Semi-Automated Border Detection. iii. Tissue Motion Annular Displacement. iv. 2D speckle tracking (any other Hardware essential for OFFLINE Quantification)
Item No 6 : Instrument Set for Cardio-Vascular & Thoracic Surgery- Low End (2021_HLL_92629_6)		
Tender Para	TENDER SPECIFICATION	AMENDED AS
Item Name	Item Name : Instrument Set for Cardio-Vascular & Thoracic Surgery- Low End	Item Name : Instrument Set for Cardio-Vascular & Thoracic Surgery
51	Morse Sternal retractor —double blade Aluminium	Morse Sternal retractor —double blade Aluminium - 2 each
58	58. Langenbeck's retractors -2 each	Langenbeck's retractors -2 each
79	Cardiac tissue stabilizer with enhanced stability and flexibility (disposable with sternal spreader) —2 No.	Disposable Cardiac tissue stabilizer with enhanced stability and flexibility with OEM, Stainless Steel, reusable sternal spreader —2 No.

80	Cardiac apex vacuum stabiliser/positioner - 2nos	Cardiac apex vacuum stabiliser/positioner (Disposable) - 2nos
	Note: Bidder should quote all the instruments specified above	Note: Bidder should quote all the instruments specified above (The bidder should quote not less than 90% of instruments from the same manufacturer. If some instrument is not available with OEM, maximum of 10% instruments can be outsourced from any other reputed manufacturer. In this case, a declaration should be submitted from OEM for non-production of such items.)
II	Bidder has to provide the demonstration of the item	Bidder has to provide the demonstration of all the items including outsourced instruments
		Added Para : Variation of sizes ($\pm 10\%$) is acceptable in all the sizes of asked instruments specification.
Page 56	Instruments should be of high quality and standard	Instruments should be of high quality and standard medical grade Stainless Steel 400 grade
42	Cushing nerve hooks 19cm / 7 1/2" – 1No.	Cushing nerve hooks 19cm / 7 1/2" – 4 Nos.
43	Crile nerve hooks 14.5cm/ 5 1/2" – 1 No.	Crile nerve hooks 14.5cm/ 5 1/2" – 4 Nos.
	7 HEAVY BARRY WIRE TWISTER with TC inserts a) Length 20 cm -2 no. b)Length 17cm -2 no. 8 RUBIO MINI WIRE TWISTER with TC inserts a)Length 13 cm / 5" – 1 9 Sternal Wire Cutter Pliers a) Length 21 cm – 1 b) Length 17.5cm - 2	7 HEAVY BARRY WIRE TWISTER with TC inserts a) Length 20 cm - 4 no. b)Length 17cm - 4 no. 8 RUBIO MINI WIRE TWISTER with TC inserts a)Length 13 cm / 5" – 2 Nos 9 Sternal Wire Cutter Pliers a) Length 21 cm – 2 Nos b) Length 17.5cm - 4 Nos
	11 DEBAKEY – GERALD – Atraumatic Tissue Forceps Titanium (2 each) a)Length 15 cm / 6" Jaw 1.5 mm b)Length 18 cm / 7" Jaw 1.5 mm c)Length 24cm Jaw 1.5mm	11 DEBAKEY – GERALD – Atraumatic Tissue Forceps Titanium (3 each) a) Length 15 cm / 6" Jaw 1.5 mm b) Length 18 cm / 7" Jaw 1.5 mm c) Length 24cm Jaw 1.5mm
		Added Para: Curved Artery Forceps : 3", 4"and 6"- 30 nos. each Straight Artery Forceps : 3", 4"and 6"- 30 nos. each Curved kocher forceps : 6" size - 30 nos. Towel clips (4"size) with ratchet : 30 nos Tooth forceps (6" size) : 10 nos Skin non-tooth forceps (6" size) : 10 nos Stainless Steel Bowl (250ml, 500ml and 1 litre) : 6 nos. Each Kidney Tray (Small, Medium and Large) : 3 nos. Each BP Handle no.3, no4 and no.7 : 6 Nos each Czerney's retractor - 4 nos

		Double ended retractor - 8 nos Russian Forceps 8" - 4 nos Scissors curved t.c. mayo. 7" - 8 nos Scissors straight t.c. mayo. 7" - 4 nos Sponge holder 10" - 4 nos Sponge holder 8" - 4 nos Suction tip frazier 2 - 4 nos Suction tip frazier 3 - 4 nos Suction tip frazier 4 - 4 nos Hegar dialator set 3 to 26 mm : 2 Sets each
Item No 7 : IABP Machine (2021_HLL_92629_7)		
Tender Para	TENDER SPECIFICATION	COMMITTEE RECOMMENDATION
3.10	Optical Blood leak detect for early indication of blood coming into the balloon lumen due to IABC leak	Blood leak detect for early indication of blood coming into the balloon lumen due to IABC leak
4.3	Intra Aortic Balloon Catheter for Adults, Size: 34cc - Qty: 3 Nos, Size: 40cc - Qty: 7 Nos.	Intra Aortic Balloon Catheter for Adults, Size: 30 / 34cc - Qty: 3 Nos, Size: 40cc - Qty: 7 Nos.
	BOQ: 4 Intra Aortic Balloon Catheter for Adults, Size: 34cc	BOQ: 4 Intra Aortic Balloon Catheter for Adults, Size: 30 / 34 cc
Item No 9 : Surgical Loupe (2021_HLL_92629_9)		
Tender Para	TENDER SPECIFICATION	AMENDED AS
1	The telescope should be adjustable to meet the inter pupillary distance of surgeons according to their working distance and pupil height and vertex distance.	The customized telescope to meet the inter papillary distance of surgeons according to their working distance and pupil height and vertex distance. The changes in customized specification can be made twice during warranty period at free of cost
3	Magnification of 3.5-4.5X with field of view and depth should be around 100mm calibrated at individual working distance of surgeon	Magnification of 3.5-4.5X with field of view 100mm (+/-5%) at working distance
4	Light weight frame not more than 90 gms	Light weight frame not more than 100 gms.
Item No 11 : Single Chamber Pacemaker (2021_HLL_92629_11)		
Tender Para	TENDER SPECIFICATION	AMENDED AS
13	Should be BIS or European CE with 4 digit notified body no. or US FDA approved.	Should be BIS or European CE with 4 digit notified body no. or US FDA approved. OR Should meet IEC 60601-2-31 and test report should be submitted from any NABL accredited lab
Item No 12 : Dual chamber pacemaker (2021_HLL_92629_12)		
Tender Para	TENDER SPECIFICATION	AMENDED AS
15	Should be BIS or European CE with 4 digit notified body no. or US FDA approved.	Should be BIS or European CE with 4 digit notified body no. or US FDA approved. OR

		Should meet IEC 60601-2-31 and test report should be submitted from any NABL accredited lab
		Added Para : Should have both a auto and manual setting for AV-Delay
		Added Para : Should have automatic setting of Maximum tracking rate.
		Added Para : Should have auto sensing
		Added Para: Should display impedance to understand the pacing lead connection status and give alarm when lead gets disconnected.
		Added Para : Should display statistics of total no of cycles sensed and paced in a given time.

All other contents of the Tender enquiry including terms & conditions remain unaltered.

Note:

- I. Prospective Bidders are also advised to check the website regularly prior to the closing date and time of online submission of bids**