

17.12.2021

**Pre- Bid Query Reply****Sub: Pre Bid Query Reply to the bidders for referred tender enquiry****Ref.: Tender Enquiry HITES/PCD/AIIMS-IV/46/CTVS/21-22 dated 26.10.2021 and Pre Bid Meeting Held on 15.11.2021.****Technical Specification Query Reply**

| <b>Response To Pre-Bid Queries</b>                                |   |  |   |   |
|---|---|--|---|---|
| <b>HITES/PCD/AIIMS-IV/46/CTVS/21-22</b>                           |   |  |   |   |
| <b>Item No 1: Electro hydraulic OT Table with all accessories</b> |   |  |   |   |
| <b>Tender Para</b>  | <b>TENDER SPECIFICATION</b>   | <b>RESPRESENTATION RECEIVED FROM THE FIRMS</b>   | <b>COMMITTEE RECOMMENDATION</b>   | <b>JUSTIFICATION</b>  |
| 2.1   | 2.1 OT Table is required for general surgery and should have X-Ray translucent tops.  | As per prebid discussion   | OT Table is required for <b>hybrid CTVS</b> surgery and should have X-Ray translucent tops. | For better clarity in specification                                       |
| 3   | Technical Specifications  |  |   |   |
| b.  | Table top should permit x-ray penetration and fluoroscopy with full length X-ray cassette tunnel accessible from either end.                            | TABLE TOP SHOULD PERMIT X-RAY PENETRATION AND FLUOROSCOPY WITH X-RAY CASSETTE TUNNEL FOR BACK SECTION ACCESSIBLE FROM HEAD END.<br>TABLE TOP SHOULD PERMIT X-RAY PENETRATION AND FLUOROSCOPY WITH X-RAY CASSETTE TUNNEL FOR BACK SECTION ACCESSIBLE FROM HEAD END. | No change   | As it is required for the hybrid procedures.                              |
| j.  | Should have built in electronic controlled kidney position with additional manual / electronic control Kidney Bridge for better positioning if required | TO BE DELETED<br>100% Kidney Bridge position should be obtained without moving the patient, through remote control by using extension / break function.  | No change   | Essential feature   |
| 3.2   | Measurements (Approx):<br>a. Height: 650-1100mm with  | Measurements (Approx) :<br>(+/- 10% tolerance allowed in the sizes/measurements/angles/dimensions)   | No change   | Required minimum measurements are already specified in the specification. |
| 4.2   | All accessories including the following should be quoted. The specific accessories and their quantity will be decided                                   | NOTE: Clarification required for accessories required as per tender specifications. Kindly note that in tender specification   | <b>4.2 All accessories including the following should be quoted (Price to be</b>            | For better clarity in specification for quoting.                          |

|  |   |  |   |  |
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|  | <p>on the basis of actual requirement:-</p> <p>a. Padded arm rest with straps - pair with damp</p> <p>b. Anesthesia screen with clamps</p> <p>c. Side supports: pair with clamps</p> <p>d. Shoulder supports: pair with clamps</p> <p>e. Knee crutches: pair with damp</p> <p>f. X-ray cassette tray with pushing rod</p> | <p>accessories are asked at S.No. 4.2 (a to f), 4.2 g (a to c) &amp; 4.2 h (A to G). Accessories asked at S.No. 4.2 (a to f) are standard accessories required mandatory with every OT Table so these accessories are included with each table and hence rates for these accessories should not be asked to quote separately as mentioned in tender specifications. All other accessories 4.2 g (a to c) &amp; 4.2 h (A to G) are optional for which rates should be quoted separately. We request you to look into this matter, do needful &amp; confirm/ clarify back to us.</p> <p>NOTE: Clarification required for accessories required as per tender specifications. Kindly note that in tender specification accessories are asked at S.No. 4.2 (a to f), 4.2 g (a to c) &amp; 4.2 h (A to G). Accessories asked at S.No. 4.2 (a to f) are standard accessories required mandatory with every OT Table so these accessories are included with each table and hence rates for these accessories should not be asked to quote separately as mentioned in tender specifications. All other accessories 4.2 g (a to c) &amp; 4.2 h (A to G) are optional for which rates should be quoted separately. We request you to look into this matter, do needful &amp; confirm/ clarify back to us.</p> <p>Please confirm whether the price of these accessories has to be included along with the OT Table price Or need to quote OT table without accessories separately and cost of individual accessories separately.</p> | <p><b>quoted separately for Para 4.2 a to f).</b></p> <p>The specific accessories and their <b>additional quantity</b> will be decided on the basis of actual requirement:-</p> <p>a. Padded arm rest with straps - <b>1 pair with damp</b></p> <p>b. Anesthesia screen with clamps - <b>1 pair</b></p> <p>c. Side supports: <b>1 pair with clamps</b></p> <p>d. Shoulder supports: <b>1 pair with clamps</b></p> <p>e. Knee crutches: <b>1 pair with damp</b></p> <p>f. X-ray cassette tray with pushing rod - <b>1</b></p> <p><b>No</b></p> |  |
|--|---|--|---|--|

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| 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)<br>a. Gel Flat buttock chest roll (medium)<br>b. Gel prone positioner<br>c. Gel prone head rest (large)   | As per prebid discussion   | 4.2 g. The machines should be supplied with the following accessories for operating prone position (Price of each item should be mentioned separately)<br>a. Gel Flat buttock chest roll ( <b>Small, medium, and Large</b> ) - <b>2 Nos each</b><br>b. Gel prone positioner - <b>2 Nos</b><br>c. Gel prone head rest (large) - <b>2 Nos</b><br><b>Added Para : d.Light weight transfer board - 2 Nos</b> | For better clarity in specification for quoting.     |
| 4.2 h | Optional accessories (Price of each item should be mentioned separately)<br>A. X-Ray Top for 9" Urology extension<br>B. Metal Drain pan<br>C. Power lift stirrup set with side rail clamp<br>D. Foot control<br>E. Split leg pair<br>F. Reverse Trendelburg restraint strap<br>G. Light weight transfer board. | As per prebid discussion   | Optional accessories (Price of each item should be mentioned separately)<br>A. X-Ray Top for 9" Urology extension<br>B. Metal Drain pan<br>C. Power lift stirrup set with side rail clamp<br>D. Foot control<br>E. Split leg pair<br>F. Reverse Trendelburg restraint strap<br><b>G. Deleted.</b>  | For better clarity in specification for quoting.     |
| 7.2   | Electrical safety conforms to standards for electrical safety IEC 60601-1 General Requirements (or equivalent BIS Standard)  | TO BE DELETED. Also find enclosed the Office Memorandum from Ministry of Health & Family Welfare, Govt. of India which clearly states that intending organization shall not insist on specifications and standards like US-FDA or CE.<br><br>TO BE DELETED. Also find enclosed the Office Memorandum from Ministry of Health & Family Welfare, Govt. of India which clearly states that intending organization shall not insist on specifications and standards like US-FDA or CE. | Electrical safety conforms to standards for electrical safety IEC 60601-1 General Requirements (or equivalent BIS Standard / <b>NABL accredited lab certified</b> )<br><br><b>Test report for the quoted model should be submitted.</b>  | For wider participation and better quality assurance |

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| 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 | TO BE DELETED. Also find enclosed the Office Memorandum from Ministry of Health & Family Welfare, Govt. of India which clearly states that intending organization shall not insist on specifications and standards like US-FDA or CE. | Shall meet internationally recognised standard for Electro Magnetic Compatibility (EMC) for electromedical equipment: IEC-60601-1-2 :latest edition Or Equivalent BIS / <b>NABL accredited lab certified</b> ) or should comply with 89/366/EEC; EMC-directive as amended.<br><br><b>Test report for the quoted model should be submitted.</b> | For wider participation and better quality assurance |
|     |   | TO BE DELETED. Also find enclosed the Office Memorandum from Ministry of Health & Family Welfare, Govt. of India which clearly states that intending organization shall not insist on specifications and standards like US-FDA or CE. |  |  |
| 7.4 | Certified to be compliant with IEC 60601-2-46 : Particular requirements for the safety of Operating Tables: latest edition or equivalent  | TO BE DELETED. Also find enclosed the Office Memorandum from Ministry of Health & Family Welfare, Govt. of India which clearly states that intending organization shall not insist on specifications and standards like US-FDA or CE. | Certified to be compliant with IEC 60601-2-46 : Particular requirements for the safety of Operating Tables: latest edition or equivalent <b>Or Equivalent BIS / NABL accredited lab certified.</b><br><br><b>Test report for the quoted model should be submitted.</b>   | For wider participation and better quality assurance |
|     |   | TO BE DELETED. Also find enclosed the Office Memorandum from Ministry of Health & Family Welfare, Govt. of India which clearly states that intending organization shall not insist on specifications and standards like US-FDA or CE. |  |  |

| Item No 2: Heart lung machine |   |  |   |                         |
|-------------------------------|---|--|---|-------------------------|
| Tender Para                   | TENDER SPECIFICATION  | RESPRESENTATION RECEIVED FROM THE FIRMS  | COMMITTEE RECOMMENDATION  | JUSTIFICATION           |
| 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. | The unit should have 5 pump <b>head</b> compactly arranged with <b>Single/separate</b> power supply and control modules. Should have easy access connectors for | For wider participation |

|      |   |  |   |                                     |
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|      |   |  | interchanging the pump.   |                                     |
| 2    | Each individual roller pump should be capable of running independently at available voltage.  | Request for Deletion of this point/bid not to be rejected with refer to our above request in point No 3.1(1) above   | <b>Deleted</b>  | For wider participation             |
| 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 OR ONLY ROLLER PUMP with facility for tubing to be used adjustable from X" to 5/*; through 3/8" and in" by easily changeable mechanism | "Individual pump heads should have Harvey / <b>horse shoe</b> 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."       | For wider participation             |
| 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  | Individual pump heads should have display of infusion volume in <b>LPM &amp; RPM</b>  | For wider participation             |
| 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 inbuilt/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. <b>Pulsatile module can be in built/ which can be mounted on any of the blood pump.</b> | For wider participation             |
| 3.2  | Should have a venous control module with single pole mast with electronic venous line occluder (Rate to be offered if available).   | Is this product price to be included of the final bidding price or is it optional and the price should not be inclusive of this product  | <b>Should have a venous control module with single pole mast with electronic venous line occluder</b>   | For wider participation             |
| 2.1  | 4.a Air- Oxygen Blender with hoses and Flow meter   |  | 4.a <b>Electronic</b> Air-Oxygen Blender with hoses and Flow meter  | For better clarity in specification |
| 3.11 | Accessories:  |  |   |                                     |
| 5    | Compatible Co2 Blender should be supplied as standard   | Pts clarify if you Require Electronic or Manual Gas Blender  | <b>Compatible Electronic Co2 Blender should be supplied as standard</b>   | For better clarity in specification |

| Item No 3 : Electric operated sternum saw system |                      |   |                          |               |
|--|----------------------|---|--------------------------|---------------|
| Tender Para                                      | TENDER SPECIFICATION | RESPRESENTATION RECEIVED FROM THE FIRMS   | COMMITTEE RECOMMENDATION | JUSTIFICATION |
|  | Suggested by bidder  | Please include battery operated Sternum Saw System in the specification as this is easier for the surgeon and in better handling. Also no Threatening of cables required. | No change                |               |

| Item No 4 : Electro Cautery Machine |   |  |                          |               |
|-------------------------------------|---|--|--------------------------|---------------|
| Tender Para                         | TENDER SPECIFICATION  | RESPRESENTATION RECEIVED FROM THE FIRMS  | COMMITTEE RECOMMENDATION | JUSTIFICATION |
| 0                                   | The equipment should be BIS or European CE with 4 digit notified body no or US FDA certified.   | Changes Required<br>Should be US-FDA or European CE with 4 digit notified body number<br>OR<br>Declaration of conformity for quoted model along with 150 3485, 150 9001 and IEC 60601-1-2:2014, IEC 60601-2-2:2017, or BIS certified   | No Change                |               |
|                                     | IEC 60101-1 Medical Electrical Equipment, General Requirements for safety 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 | <b>Reason:</b><br>To promote the Indian manufacturers and Make in India initiative the Declaration of conformity for quoted model along with ISO 13485, 150 9001 and IEC 60601-1- 2:2014, IEC 60601-2-2:2017 should also be asked as requested. IEC 60601-1-2:2014, IEC 60601-2-2:2017 insures the quality standard of the equipment which is equivalent to other quality standards and safety of the equipment.<br><br>Hence, Declaration of conformity for quoted model along with 150 |                          |               |

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|  | <p>Certified to be compliant with IEC 60601-2-2 Medical Electrical Equipment Part 2-2: Particular requirements for the safety of High Frequency Surgical Equipments: latest edition</p> | <p>13485, 150 9001 and IEC 60601-1 2:2014, IEC 60601-2-2:2017 should be also added in the requirement of the quality standards. It will allow the maximum participation from Indian bidders under make in India policy.</p> |  |  |
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| Item No 5 : Colour Doppler Echocardiography System (Mid End) |  |   |  |                                     |
|--|--|---|--|-------------------------------------|
| Tender Para  | TENDER SPECIFICATION   | RESPRESENTATION RECEIVED FROM THE FIRMS             | COMMITTEE RECOMMENDATION   | JUSTIFICATION                       |
| 2.2  | Should be field up gradable to 4D TEE & <b>Transthoracic echo imaging</b>                          | Should be field up gradable to 4D TEE echo imaging. | Should be field up gradable to 4D TEE echo imaging.  | For wider participation             |
| 3.8  | Frame rate should be 2500 FPS or more  | Frame rate should be 1900 FPS or more.              | Frame rate should be <b>1900 FPS or more.</b>  | For wider participation             |
| 4.6  | DVD/CD Recorder with 100 CDs and 100 DVDs  | As per prebid discussion                            | DVD/CD Recorder with 100 CDs and 100 DVDs <b>with cover</b>  | For better clarity in specification |
| 4.7  | High end color laser printer with auto duplexing, scanning facility - 1 no & 2 sets of cartridges. | As per prebid discussion                            | High end color laser printer with auto duplexing, scanning facility - 1 no & 2 <b>additional</b> sets of cartridges. | For better clarity in specification |

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| 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) | As per prebid discussion | System should provide with Latest PC (off-line licensed workstation) with minimum 2TB Hard drive <b>(1TB in computer and 1TB Portable Hard Drive) and 512GB flash drive</b> , 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, <b>latest Windows 11 professional OS &amp; licensed MS office</b> 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) | For better specification |
|------|--|--------------------------|--|--------------------------|

| Item No 6 : Instrument Set for Cardio-Vascular & Thoracic Surgery- Low End |   |   |   |                    |
|--|---|---|---|--------------------|
| Tender Para  | TENDER SPECIFICATION  | RESPRESENTATION RECEIVED FROM THE FIRMS   | COMMITTEE RECOMMENDATION  | JUSTIFICATION      |
| Item Name  | Item Name : Instrument Set for Cardio-Vascular & Thoracic Surgery- <b>Low End</b> | Please clarify the word "Low End" in Nomenclature of item No.6 Instrument Set for Cardio-Vascular & | Item Name : Instrument Set for Cardio-Vascular & Thoracic Surgery | For better clarity |



|    |   |   |  |                    |
|----|---|---|--|--------------------|
|    |   | Thoracic Surgery- Low End   |  |                    |
| 51 | Morse Sternal retractor — double blade Aluminium  | Qty not mentioned<br>Please mentioned qty minimum 2 each for use bilaterally<br>Kindly clarify the quantity of both A&B.  | Morse Sternal retractor —double blade Aluminium - <b>2 each</b>  | For better clarity |
| 58 | <b>58.</b> Langenbeck's retractors - 2 each   | In technical specification 58 is wrongly mentioned before Langenbeck<br>Please delete 58  | Langenbeck's retractors -2 each  | For better clarity |
| 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 reusable sternal spreader for disposable sternal blades of same OEM) – 2 Nos.<br>This is the only disposable item in the entire set, for which the drug license is mandatory, Hence we are not able to participate. So humbly request to you kindly remove the asked item in the serial. | <b>Disposable</b> Cardiac tissue stabilizer with enhanced stability and flexibility <b>with OEM, Stainless Steel, reusable sternal spreader</b> —2 No. | For better clarity |
|    |   | Certification not mentioned please add required certification<br>(i)Manufacturer should be ISO13485/CE/BIS/USFDA certified. Copy of certificate to be closed  | No change  |                    |
| 80 | Cardiac apex vacuum stabiliser/positioner - 2nos  | Please clarify whether the asked item is disposable or reusable. If it is disposable request to kindly remove this item as for this Drug license is mandatory   | Cardiac apex vacuum stabiliser/positioner ( <b>Disposable</b> ) - 2nos   | For better clarity |

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|---------|---|--|--|---|
|         | Note: Bidder should quote all the instruments specified above | Kindly change as the bidders should quote all the items, 80% from the same manufacturer & remaining 20% can be sourced from a reputable manufacturer.  | Note: Bidder should quote all the instruments specified above <b>(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.)</b> | For wider participation                     |
| II      | Bidder has to provide the demonstration of the item           | CTVS surgery is delicate suggested to provide demonstration of all items Bidder has to provide the demonstration of all items qty 1 each   | Bidder has to provide the demonstration of <b>all the items including outsourced instruments</b>   | For better clarity and control the quality. |
|         | suggested by bidder   | Variation of Size of asked instruments.<br>Reason: Variation of ( $\pm 10\%$ ) is acceptable in all the sizes of asked instruments specification.  | <b>Added Para : Variation of sizes (<math>\pm 10\%</math>) is acceptable in all the sizes of asked instruments specification.</b>  | For wider participation                     |
| Page 56 | Instruments should be of high quality and standard            | Point No. 2 All the instruments should be made of high grade stainless steel.<br><br>Kindly change as All the instruments should be made of high grade stainless steel and relevant document of material certificates which Used to make Instruments, should be submitted. | Instruments should be of high quality and standard <b>medical grade Stainless Steel 400 grade</b>  | For better quality assurance                |

|    |                     |  |  |                              |
|----|---------------------|--|--|------------------------------|
| NA | Suggested by bidder | Please incorporate point for "The bidder must quote the 80% of tendered Quantity from same OEM and 20% of tendered Quantity can quote from other OEM. (As many items appearing in the tender are brought out items from 3rd party. It may please not be made obligatory to receive their authorisation letter, as there supply is restricted to their Dealer Network only. | Amended as above :   |                              |
|    |                     | As per prebid discussion   | <p><b>Added Para:</b><br/> <b>Curved Artery Forceps : 3", 4" and 6"- 30 nos. each</b><br/> <b>Straight Artery Forceps : 3", 4" and 6"- 30 nos. each</b><br/> <b>Curved Kocher forceps : 6" size - 30 nos.</b><br/> <b>Towel clips (4" size) with ratchet : 30 nos</b><br/> <b>Tooth forceps (6" size) : 10 nos</b><br/> <b>Skin non-tooth forceps (6" size) : 10 nos</b><br/> <b>Stainless Steel Bowl (250ml, 500ml and 1 litre) : 6 nos. Each</b><br/> <b>Kidney Tray (Small, Medium and Large) : 3 nos. Each</b><br/> <b>BP Handle no.3, no4 and no.7 : 6 Nos each</b><br/> <b>Czerney's retractor - 4 nos</b><br/> <b>Double ended retractor - 8 nos</b><br/> <b>Russian Forceps 8" - 4 nos</b><br/> <b>Scissors curved t.c. mayo. 7" - 8 nos</b><br/> <b>Scissors straight t.c. mayo. 7" - 4 nos</b><br/> <b>Sponge holder 10" - 4</b></p> | Essential items by the Dept. |

|    |  |                          |   |                        |
|----|--|--------------------------|---|------------------------|
|    |  |                          | <p><b>nos</b><br/> <b>Sponge holder 8" - 4</b><br/> <b>nos</b><br/> <b>Suction tip frazier 2 - 4</b><br/> <b>nos</b><br/> <b>Suction tip frazier 3 - 4</b><br/> <b>nos</b><br/> <b>Suction tip frazier 4 - 4</b><br/> <b>nos</b><br/> <b>Hegar dialator set 3 to</b><br/> <b>26 mm : 2 Sets each</b></p>                    |                        |
| 42 | Cushing nerve hooks 19cm / 7 ½" – 1No.   | As per prebid discussion | Cushing nerve hooks 19cm / 7 ½" – <b>4 Nos.</b>   | Requirement of theDept |
| 43 | Crile nerve hooks 14.5cm/ 5 ½" – 1 No.   | As per prebid discussion | Crile nerve hooks 14.5cm/ 5 ½" – <b>4 Nos.</b>  | Requirement of theDept |
|    | <p>7 HEAVY BARRY WIRE TWISTER with TC inserts<br/> a) Length 20 cm -2 no.<br/> b)Length 17cm -2 no.</p> <p>8 RUBIO MINI WIRE TWISTER with TC inserts<br/> a)Length 13 cm / 5" – 1</p> <p>9 Sternal Wire Cutter Pliers<br/> a) Length 21 cm – 1<br/> b) Length 17.5cm - 2</p> | As per prebid discussion | <p>7 HEAVY BARRY WIRE TWISTER with TC inserts<br/> a) Length 20 cm -<b>4 no.</b><br/> b)Length 17cm -<b>4 no.</b></p> <p>8 RUBIO MINI WIRE TWISTER with TC inserts<br/> a)Length 13 cm / 5" – <b>2 Nos</b></p> <p>9 Sternal Wire Cutter Pliers<br/> a) Length 21 cm – <b>2 Nos</b><br/> b) Length 17.5cm - <b>4 Nos</b></p> | Requirement of theDept |
|    | <p>11 DEBAKEY – GERALD – Atraumatic Tissue Forceps Titanium (2 each)<br/> a)Length 15 cm / 6" Jaw 1.5 mm<br/> b)Length 18 cm / 7" Jaw 1.5 mm<br/> c)Length 24cm Jaw 1.5mm</p>  | As per prebid discussion | <p>11 DEBAKEY – GERALD – Atraumatic Tissue Forceps Titanium (<b>3 each</b>)<br/> a) Length 15 cm / 6" Jaw 1.5 mm<br/> b) Length 18 cm / 7" Jaw 1.5 mm<br/> c) Length 24cm Jaw 1.5mm</p>   | Requirement of theDept |

| Item No 7 : IABP Machine |   |   |   |                         |
|--------------------------|---|---|---|-------------------------|
| Tender Para              | TENDER SPECIFICATION  | RESPRESENTATION RECEIVED FROM THE FIRMS   | COMMITTEE RECOMMENDATION  | JUSTIFICATION           |
| 3.10                     | <b>Optical</b> 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 and stopped pumping<br><br>Reason: "Optical blood leak detect system" term favoring a specific manufacturer. | Blood leak detect for early indication of blood coming into the balloon lumen due to IABC leak          | For wider participation |
| 3.16                     | Should have software which allows the user to monitor the IABP from any remote location via a modem           | Remove  | No change   |                         |
| 3.18                     | Should have capability to connect on the Hospital network   | Remove  | No change   |                         |
| 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   | Intra Aortic Balloon Catheter for Adults, Size: <b>30 / 34cc</b> - Qty: 3 Nos, Size: 40cc - Qty: 7 Nos. | For wider participation |
|                          | BOQ: 4<br>Intra Aortic Balloon Catheter for Adults, Size: 34cc  |   | BOQ: 4<br>Intra Aortic Balloon Catheter for Adults, Size: <b>30 / 34 cc</b>                             | For wider participation |

| Item No 8 : ACT Machine |   |   |                          |                   |
|-------------------------|---|---|--------------------------|-------------------|
| Tender Para             | TENDER SPECIFICATION                      | RESPRESENTATION RECEIVED FROM THE FIRMS   | COMMITTEE RECOMMENDATION | JUSTIFICATION     |
| 3.1                     | ACT machine having at least two test well | Please consider ACT Machine with one well as two tests well is manufactured by only one company, so you are requested to amend the specification with one test well which is standard worldwide | No change                | Essential feature |

| Item No 9 : Surgical Loupe |   |  |  |   |
|----------------------------|---|--|--|---|
| Tender Para                | TENDER SPECIFICATION  | RESPRESENTATION RECEIVED FROM THE FIRMS  | COMMITTEE RECOMMENDATION   | JUSTIFICATION   |
| 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. | As per prebid discussion   | The <b>customized</b> telescope to meet the inter pupillary distance of surgeons according to their working distance and pupil height and vertex distance. <b>The changes in customized specification can be made twice during warranty period at free of cost</b> | For better clarity in specification and better after sales service. |
| 3                          | Magnification of 3.5-4.5X with field of view and depth should be around 100mm calibrated at individual working distance of surgeon                            | As per prebid discussion   | Magnification of 3.5-4.5X with field of view <b>100mm (+/-5%) at working distance</b>  | For wider participation   |
| 4                          | Light weight frame not more than 90 gms   | As per prebid discussion   | Light weight frame not more than <b>100 gms.</b>   | For wider participation   |
| 6                          | Telescope to be of Keplerian Type with a prism contained internally in the magnifies offering high resolution   | The telescope manufacturer to have the facility to modify operating parameters as and when required by the surgeons for 2 times rework free of cost. | No change  |   |

| Item No 10 : Surgical xenon head light and light source |   |   |                          |   |
|---|---|---|--------------------------|---|
| Tender Para   | TENDER SPECIFICATION  | RESPRESENTATION RECEIVED FROM THE FIRMS                                     | COMMITTEE RECOMMENDATION | JUSTIFICATION                           |
| 1   | Surgical Xenon head light with light source on professional head band, headlight OEM Floor stand with 9ft (275cm) premium bifurcated cables, headlight module and gown clips , headband should be lightweight material that's washable and breathable | Pls. amend as LED Light source, as LED is having 10times the life of Xenon. | No change                | Specification is for Xenon Light source |
| 3   | Xenon bulb life should be min 1000hrs. If it stops  | In LED life is 40,000 Hours, where as u r asking for                        | No change                |   |

|   |  |   |           |  |
|---|--|---|-----------|--|
|   | working before 1000hrs then it should be replaced free of cost   | 1000Hours. We recommend to use LED.<br>LED Headlight bulb life is 50000hrs and it is cost effective.  |           |  |
| 8 | Continuously adjustable spot size and brightness control, super high output Xenon.,                    | Pls. amend as super high output LED   | No change |  |
| 9 | iii. Product should be BIS or European CE approved (with 4 digit notifying body no) or USFDA Approved. | Request to consider as CE approved.As this is a class I product and requirement of notified body is not mandatory. Moreover as per  | No change |  |
|   | BOQ  |   |           |  |
|   | Xenon Light source 1 no  | Pls. amend as LED Light source, as LED is having 10times the life of Xenon.   | No change |  |
| 2 | Head light band with fiber optic cable 2 nos   | In LED there is no requirement of fiber optic cable.  | No change |  |
| 3 | Spare bulb 1 no  | No spare bulb required, as LED has a life of more than 40,000 Hours   | No change |  |
|   | Suggested by bidder  | Please Include the LED Headlights specification because it allows the surgeon to move freely from one side of the OT table to the other side of table without disconnecting the light source. | No change |  |

| Item No 11 : Single Chamber Pacemaker |   |  |  |                         |
|---------------------------------------|---|--|--|-------------------------|
| Tender Para                           | TENDER SPECIFICATION  | RESPRESENTATION RECEIVED FROM THE FIRMS  | COMMITTEE RECOMMENDATION   | JUSTIFICATION           |
| 13                                    | Should be BIS or European CE with 4 digit notified body no. or US FDA approved. | <p>Modify the clause to "Should be BIS/ CDSCO/ ICMED or European CE or US FDA approved"</p> <p>Reason:<br/>You must know that the BIS standard for the category of devices (Pacemakers) referenced above is still under development (Annex 1). Hence, it is not possible to have BIS certification for the said devices. Furthermore, Both Government of India approved CDSCO and ICMED (Indian certification for Medical Devices have not been included as sufficient condition for eligibility. Documents attached</p> | <p>Should be BIS or European CE with 4 digit notified body no. or US FDA approved.</p> <p><b>OR</b><br/><b>Should meet IEC 60601-2-31 and test report should be submitted from any NABL accredited lab</b></p> | For wider participation |

| Item No 12 : Dual chamber pacemaker |   |  |  |                                 |
|-------------------------------------|---|--|--|---------------------------------|
| Tender Para                         | TENDER SPECIFICATION  | RESPRESENTATION RECEIVED FROM THE FIRMS  | COMMITTEE RECOMMENDATION   | JUSTIFICATION                   |
| 15                                  | Should be BIS or European CE with 4 digit notified body no. or US FDA approved. | <p>Modify the clause to "Should be BIS/ CDSCO/ ICMED or European CE or US FDA approved"</p> <p>Reason:<br/>You must know that the BIS standard for the category of devices (Pacemakers) referenced above is still under development (Annex 1). Hence, it is not possible to have BIS certification for the said devices. Furthermore, Both Government of India approved CDSCO and ICMED (Indian certification for Medical Devices have not been included as sufficient condition for eligibility. Documents attached</p> | <p>Should be BIS or European CE with 4 digit notified body no. or US FDA approved.</p> <p><b>OR</b><br/><b>Should meet IEC 60601-2-31 and test report should be submitted from any NABL accredited lab</b></p> | For wider participation         |
|                                     | suggested by bidder   | Should have both a auto and manual setting for AV-Delay  | <b>Added Para :<br/>Should have both a auto and manual setting for AV-Delay</b>  | To improve quality of equipment |



|  |                     |  |   |                                 |
|--|---------------------|--|---|---------------------------------|
|  | suggested by bidder | Should have automatic setting of Maximum tracking rate.  | <b>Added Para :<br/>Should have automatic setting of Maximum tracking rate.</b>   | To improve quality of equipment |
|  | suggested by bidder | Should have auto sensing   | <b>Added Para :<br/>Should have auto sensing</b>  | To improve quality of equipment |
|  | suggested by bidder | Should display impedance to understand the pacing lead connection status and give alarm when lead gets disconnected. | <b>Added Para:<br/>Should display impedance to understand the pacing lead connection status and give alarm when lead gets disconnected.</b> | To improve quality of equipment |
|  | suggested by bidder | Should display statistics of total no of cycles sensed and paced in a given time.                                    | <b>Added Para :<br/>Should display statistics of total no of cycles sensed and paced in a given time.</b>                                   | To improve quality of equipment |

### Commercial Query Reply

| S.N | Existing               | Commercial Representation  | HITES Reply   |
|-----|------------------------|--|---|
| 1   |                        | Heart and Lung machine is a life saving Product currently no bidder for this item is qualified to fulfill criteria of Class I and Class II Bidder. The machine is currently manufactured outside India only and is sold by the foreign company subsidiaries in India | No Change<br>please follow preference to Make in India order (PPO),2017 and its subsequent amendments |
| 2   | Qualification Criteria | 25% of tender quantity of same items of CTVS system must have supplied by the participating bidder   | No Change<br>please follow Qualification criteria Section IX 2(a) &(b)                                |
| 3   |                        | Request you to drop the MII Clause, since our Temporary Pacemakers are imported and there's no local content. As this is an emergency and live saving equipment if MII clause can be made optional and global bidders can quote                                      | No Change<br>please follow preference to Make in India order (PPO),2017 and its subsequent amendments |
| 4   |                        | Please Incorporate point for 25% of tender quantity satisfactory performance report of CTVS instruments or any other specialty from any govt hospital in specification   | No Change   |
|     |                        | Please Incorporate point for "The bidder must quote the 80% of tender quantity from same OEM and 20% of quantity can quote from other OEM  | No Change   |
| 5   | This bid is            | Please clarify the   | No Change   |

|   |  |  |
|---|--|--|
| reserved for Class I and Class II bidders only as per make in India Policy (DPIIT Order dated 16thSeptember 2020). Participating bidders need to submit relevant make in India authorization certificate. | product we intend to quote are all imported and they are not made in India. Please consider for the imported product for the same. | please follow preference to Make in India order (PPO),2017 and its subsequent amendments |
|---|--|--|

**Note:**

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