

12.04.2021

Amendment No. 4**Sub: Amendment to the referred tender enquiry**

Ref.: Tender Enquiry HITES/PCD/AIIMS-IV/32/Pulmo/19-20 Dated 11-03-2020 read with Notice on Extension of Due Dates dated 25.03.2020 read with Amendment no 1,2 &3 dated 03.03.2021, 25.03.2021 & 09.04.2021 respectively

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

SECTION VII**Technical Specifications**

TECHNICAL AMENDMENT-01		
NIB Ref: HITES/PCD/AIIMS-IV/32/Pulmo/19-20 dated 11.03.2020		
Item No. 1 Body Plethysmograph with Diffusion Study (2021_HLL_72086_1)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
Pg 47 Para II	Test and minimum set of parameter required: Respiratory Mechanics - MIP/MEP and Respiratory Drive (P0.1)	Test and minimum set of parameter required: Respiratory Mechanics - MIP/MEP and Respiratory Drive (P0.1) The system preferably have SNIP & NEP tests
Pg 48 Para	Quality assurance: The system should have European CE, US FDA, ISO certifications and should meet ATS/ERS 2005 standardization guidelines	Quality assurance: 1. The system should have European CE with 4 digit notified body or US FDA or BIS certified. 2. System should meet ATS/ERS 2005 standardization guidelines
Item No. 2 - Multiparameter Monitor-5 Para (2021_HLL_72086_2)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
Pg 48 Para 3.1	Minimum 10 inches or more multicoloured TFT display	12 inches or more multicoloured Touch screen display
Pg 48 Para 3.2	Should have facility to monitor and display - ECG, NIBP, SpO2 (Nellcor/Masimo), Temperature, Respiration and upgradable to ETCO2 (Sidestream or Microstream) & IBP.	Should have facility to monitor and display - ECG, NIBP, SpO2 (Nellcor/Masimo), Temperature, Respiration, ETCO2 (Mainstream) & IBP

Pg 48 Para 3.3	Digital and 4 waveforms/traces display of all parameters. Specification include – monitoring of heart rate & respiratory rate in addition to above to make it a complete monitor	Digital and 6 waveforms/traces or more display of all parameters. Specification include – monitoring of heart rate & respiratory rate in addition to above to make it a complete monitor
Pg 47 Para 3.5	Automatic arrhythmia detection & alarm for standard arrhythmia	Automatic arrhythmia detection & alarm for standard arrhythmia (preferable with advanced arrhythmia detection)
Pg 49 Para 3.11	Trend of at least 48 hours.	Trend of at least 48 hours and full disclosure of atleast 36 hrs.
Pg 49 Para 3.13	Should have inbuilt 2 Ch thermal recorder with selectable recording speed of 25 & 50 mm /sec.	Should have inbuilt/ modular 2 Ch thermal recorder with selectable recording speed of 25 & 50 mm /sec.
Pg 49 Para 7.1	It should have US FDA or European CE with four digit notified body number certificate and certificate to be submitted	It should have US FDA or European CE with four digit notified body number or BIS certified and certificate should be submitted along with the bid
		Added Para: System should be HL7 compatible
		Added Para in BOQ: ETCO2 (Mainstream) - 1 no Reusable Low flow mainstream ET Co2 sensors with cable (adult) & adaptors - 02 nos
		Added Para in BOQ: IBP connection cables (reusable)- 2 nos IBP disposable kits - 10 nos
Item No. 3 - Ventilator-High End (I.C.U) (2021_HLL_72086_3)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
Pg 50 Para 3	Compressed air /oxygen driven/integrated non removable turbine based	Should run on Compressor as well as central air supply. Should work with the compressor of OEM in the event of failure of central gas supply.
Pg 50 Para 4	Should have the following modes.	Added para: 4.h High flow Nasal Cannula (HFNC) therapy 4.i. Should have facility to measure Trans Pulmonary Pressure (TPP)

Pg 50 Para 5.a	Tidal Volume: Minimum 5ml or less and maximum of 1500 ml or more in Volume control	Tidal Volume: Minimum 20 ml or less and maximum of 1500 ml or more in Volume control
Pg 50 Para 5.b	PEEP upto 30 cmH2O or more	PEEP upto 35 cmH2O or more
Pg 51 Para 18	Should have US FDA or European CE with four digit notified body number certificate and certificate to be submitted	Should have US FDA or European CE with four digit notified body number or BIS certificate to be submitted
Item No. 4 - High Resolution Video Bronchoscopy system (2021_HLL_72086_4)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
Pg 52 Para A.4	Should have High Defination image	Should have High resolution image
Pg 52 Para A.5	Scope should have rotation function by left/right 120degree	Deleted
Pg 52 Para B.1	Should be compatible with Analog, HD-SDI and DVI output & 16:9 & 16:10 output for a HDTV monitor should be available	Should be compatible with HD-SDI and DVI output & 16:9 & 16:10 output for a HDTV monitor should be available (No adaptors/converters are acceptable)
Pg 52 Para B.5	Narrow Band Imaging capacity for compatibility with NBI Videoscopes	Real time optical Chrome endoscopy imaging should be available
Pg 52 Para C	Light Source (Xenon short arc Ozone free 300 Watt lamp) :	Light Source (Xenon short arc Ozone free 300 Watt lamp) or LED (Intensity equivalent to 300W Xenon):
Pg 53 Para C.1	Equipped with Narrow Band Imaging capability with high intensity Xenon Light source (300W) with 500 hours life	Equipped with Real time optical Chrome endoscopy imaging capability with high intensity Xenon Light source (300W) with 500 hours life or LED (Intensity equivalent to 300W Xenon)
Pg 53 Para C.3	Equipped with special filter for Narrow Band Imaging	Equipped with filter for Real time optical Chrome endoscopy imaging
Pg 53 Para C.5	Emergency halogen light for backup	Emergency halogen light for backup (incase of Xenon Light source)
Pg 53 Para	19" — 26" High resolution LCD medical grade color monitor. HD Compatible	26" or more High resolution LCD medical grade color monitor. HD Compatible

D.1		
Pg 53 Para D.3	Recording & Reporting software with suitable computer system and color laser printer should be supplied	Recording & Reporting software with suitable computer system with latest windows 10 or above and color laser printer should be supplied. The software should be upgradable during warranty and CMC period free of cost
Pg 53 Para D	All quoted product should be US FDA approved and/or have CE certified	All quoted product should be US FDA or European CE with four digit notified body number or BIS certified
Item No. 5 - POLYSOMNOGRAPHY (SLEEP STUDY) (2021_HLL_72086_5)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
Pg 53 Para 2.1	Polysomnography System must have integrated ZRIP driver allows to setup the patient faster and easier by reducing the no. of connection during hook-up	Polysomnography System must have integrated RIP driver allows to setup the patient faster and easier by reducing the no. of connection during hook-up
Pg 53 Para 3.1	Total Number of Channels should be: More than 60	Total Number of Channels should be: 55 or more
Pg 53 Para 3.1 a	EEG input should be: 32	EEG input should be: 25 or more
Pg 53 Para 3.1 d	The machine should have ECG: 7 (3 Physical and 4 derived)	The machine should have ECG: Second lead ECG
Pg 53 Para 3.1 o	Sensors: 2	Deleted
Pg 54 Para 3.2	Sensor- pediatric and adult, microphone, pulse Oximeter sensor and leads) of ECG, EEG, Leg & chin EMG, EOG	Sensor- microphone - 2 nos, pulse Oximeter sensor (adult & pediatric) -2 nos each ECG leads (adult & pediatric)- 2 nos each EEG (adult & pediatric)- 2 nos each, Leg & chin EMG (adult & pediatric)- 2 nos each EOG (adult & pediatric)- 2 nos each

Pg 54 Para 3.3. b	Automatic chin EMG referencing	Automatic chin EMG referencing through software
Pg 54 Para 3.4 d	on screen impedance check	Real Time Impedance display for Continuous display of actual numeric impedance value on each ECG channel and oximetry of impedance/signal quality
Pg 54 Para 3.4 m	Portable recording workstations can operate anywhere/on standalone basis	Portable recording workstations can operate anywhere/on standalone basis (OS: Windows 10 or above, Core i5, 1 TB Hard Disk and 8 GB RAM)
Pg 54 Para 3.4 p	User configurable reports-All night dump sleep stage summary, Arousal summary etc.	User configurable reports-All night sleep stage summary, Arousal summary etc.
Pg 54 Para 3.4 t	Titration device should be as follows:- Modes: CPAP, Auto CPAP, S, Auto Bi-level, S/T, T, PC, AutoSV, AVAPS-AE . Weight Approximately: less than 2.5 kg	Titration device should be as follows:- Modes: CPAP, Auto CPAP, S, Auto Bi-level, S/T, T, PC, AutoSV, AVAPS-AE/ iVAPS . Weight Approximately: less than 2.5 kg
Pg 54 Para 3.4 t	AutoSV : EPAP: 4-30 cm H2O, Pressure Support: 0- 26 cm H2O AVAPS	AutoSV : EPAP: 4-30 cm H2O, Pressure Support: 0- 26 cm H2O AVAPS/ iVAPS
Pg 54 Para	It should have integrated Humidifier	It should have integrated/ compatible Humidifier
Pg 54 Para	It should be USFDA approved or European CE with 4 digit notified body number	It should be USFDA approved or European CE with 4 digit notified body number / BIS approved
Item No. 06 - Semi-Rigid Video Thoracoscope System (2021_HLL_72086_6)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
Pg 56 Para 3.1.3	Built-in CCD chip for unprecedented image quality	Built-in CCD chip/CMOS for unprecedented image quality
Pg 56 Para 3.1.4	Adaptor-Free system with direct connection to CCD Camera control unit	Adaptor-Free system with direct connection to CCD/CMOS Camera control unit
Pg 56 Para 3.1.6	Equipped with a compatible CCD Camera Unit	Equipped with a compatible CCD/CMOS Cameral Unit

Pg 56 Para 3.1.7	Optical System- Field of view -90-100 degrees; Directional of view- 0 degree (forward viewing); Depth of field- 18 to 100 mm; Chip-1/4" CCD	Optical System- Field of view -90-100 degrees; Directional of view- 0 degree (forward viewing); Depth of field- 18 to 100 mm; Chip-1/4" CCD/CMOS
Pg 56 Para 3.1.8	Insertion Portion- Distal end outer diameter <.=10 mm approximately; Rigid portion outer diameter-<= 10 mm approximately; Working Length-270-350 mm	Insertion Portion- Distal end outer diameter <.=10 mm approximately; Rigid portion outer diameter-<= 10 mm approximately; Working Length-270-350 mm, working channel : 2.8 mm or more for biopsy and other routine work
Pg 56 Para 3.1.9	Bending Section- Angulation range- Up 100-110 degree; Down 100-110 degree. Additional angulation if any available pls specify and highlight	Bending Section- Angulation range- Up 100 degree or more; Down 100 degree or more. Additional angulation if any available pls specify and highlight
Pg 56 Para 3.2	Video processor with light source, Monitor and Recording system with capacity of 5TB	Video processor with light source, Monitor and Recording system with capacity of minimum 2 TB (internal) and minimum 5 TB (external) hard disk
Pg 56 Para 3.2.7	Emergency lamp(Halogen).	Emergency lamp(Halogen) - incase of Xenon light source
Pg 56 Para 3.2.8	Compatibility with the gastro scope and colonoscope duodenoscope and Enteroscope	Deleted
Pg 56 Para 3.2.9	Minimum 23" LCD/LED Medical Grade colour monitor with Full HD resolution	Minimum 27" LCD/LED Medical Grade colour monitor with Full HD resolution
Item No. 07 - Ultra Sonic Nebulizer (2021_HLL_72086_7)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
Pg 57 Para 5	Nebulizer performance 0.5 -1 ml/minute with control dose	Nebulizer performance 0.2 -1 ml/minute with control dose
		Added Para: It should be USFDA approved or European CE with 4 digit notified body number / BIS approved
Item No. 8 Syringe Infusion Pump (2021_HLL_72086_8)		

Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
Pg 57 Para 3	Should have US FDA or European CE with four digit notified body number certificate and certificate to be submitted.	Should have US FDA or European CE with four digit notified body number / BIS certified and certificate to be submitted.
Pg 57 Para 6	Display of Drug directory of more than 50 drugs , customized and adjustable	Display of Drug Directory of upto 500 drugs , customized and adjustable for maintaining the quality of product and increase the efficiency
Pg 57 Para 15	Mounting device/ Docking Station for at least four pumps as per requirement so as to enable to power up to 4 pumps with one power cord when mounted on IV pole (Price to be quoted separately)	Rack mounted with facility of data transfer to EMR (HPL-7), The racks should be able to mount atleast 3-5 infusion pumps
Pg 57 Para 16	The unit shall be capable of stored and operating continuously in ambient temperature of 10 - 50deg C and relative humidity of 15-90%	The unit shall be capable of stored (-5 to 50 degree C) and operate continuously in ambient temp 10 to40 degree C and relative humidity of 15-90%
Item No. 9 - 12 Channel ECG Machine (2021_HLL_72086_9)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
Pg 58 Para 3	Recording speed selection of 5, 10/ 12.5, 25 and 50 mm/sec.	Recording speed selection of 10/ 12.5, 25 and 50 mm/sec.
Pg 58 Para 4	Sensitivity of 2.5,5,10,20 mm /mV . It should also have AGC (Automatic Gain Control)	Sensitivity of 5,10,20 mm /mV. It should also have AGC (Automatic Gain Control)
Pg 58 Para 6	Patient memory function 20 patients or more	Patient memory function 40 patients or more
Pg 58 Para 11	Equipment should be European CE with four digit notified body number or US FDA approved and certificate to be submitted	Equipment should be European CE with four digit notified body number or US FDA approved / BIS and certificate to be submitted
Item No. 10 - Argon Plasma Coagulation System (2021_HLL_72086_10)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
Pg 59 Para 4.1	Patient plate with compatible cords — reusable(2Nos) and Disposable with cable (5Nos.)	Patient plate with compatible cords — reusable(2Nos) and Disposable with cable (50 Nos.)

Item No. 11 - Colour Doppler - 2D (2021_HLL_72086_11)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
Pg 61 Para 13	The unit should have US FDA or European CE with four digit notified body number certificate and certificate to be submitted	The unit should have US FDA or European CE with four digit notified body number certificate/ BIS approved and certificate to be submitted
Item No. 12 - Cardiopulmonary Exercising Test Machine (2021_HLL_72086_12)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
Pg 62 Para 6	The system should have a bidirectional volume sensor with the following specifications:- (i) Volume: 0 to 10 lit. (ii) Accuracy: 50 ml or 2% (iii) Resolution: 3 ml (iv) Flow: 0 to 15 l/s	The system should have a bidirectional volume sensor with the following specifications:- (i) Volume: 0 to 10 lit. (ii) Accuracy: 50 ml or 2.5% (iii) Resolution: 3 ml (iv) Flow: 0 to 15 l/s
Pg 62 Para B.2.iii	Motor power: 2 kW	Motor power: 2 kW or more
Pg 62 Para C.1	Should be US FDA/ European CE with 4 digit notified body approved product	Should be US FDA/ European CE with 4 digit notified body number / BIS approved product
Item No. 13 - Video Assisted Thoracoscope system (2021_HLL_72086_13)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
Pg 64 Para 3	26" FULL HD FLAT SCREEN QTY 1 no.	26" or more FULL HD FLAT SCREEN QTY 1 no.
Pg 65 Para 4. xiii	Medical grade unit with CE mark	Deleted
Pg 65 Para xv	xv. Hard disk: 500 GB SATA 3.5"	xv. Hard disk: 1TB or more
Pg 67 Para xxiv	xxiv. Dissecting Forceps, insulated, curved jaws, double action jaws, size 5 mm, length 28 cm, with connector pin for unipolar coagulation, consisting of: Insulated Metal Handle with 4 locking positions, Insulated	xxiv. Dissecting Forceps, insulated, curved jaws, double action jaws, size 5 mm, length 28 cm, with connector pin for unipolar coagulation, consisting of: Insulated Metal/ Plastic Handle with 4 locking positions, Insulated Outer Tube with Working Insert—Qty 1

	Outer Tube with Working Insert—Qty 1	
Pg 67 Para xxv	xxv. Scissors, insulated, straight jaws, curved scissor-blades, double action jaws, size 5 mm, length 28 cm, with connector pin for unipolar coagulation, consisting of: Insulated Metal Handle with 4 locking positions, Insulated Outer Tube with Working Insert—Qty 1	xxv. Scissors, insulated, straight jaws, curved scissor-blades, double action jaws, size 5 mm, length 28 cm, with connector pin for unipolar coagulation, consisting of: Insulated Metal/ Plastic Handle with 4 locking positions, Insulated Outer Tube with Working Insert—Qty 1
Pg 67 Para xxvi	xxvi. Scissors, insulated, distally angled outer sheath, curved scissor-blades, scissor blades open horizontally to angulation, double action jaws, size 5 mm, length 28 cm, with connector pin for unipolar coagulation, consisting of: Insulated Metal Handle with 4 locking positions, Insulated Outer Tube with Working Insert—Qty 1	xxvi. Scissors, insulated, distally angled outer sheath, curved scissor-blades, scissor blades open horizontally to angulation, double action jaws, size 5 mm, length 28 cm, with connector pin for unipolar coagulation, consisting of: Insulated Metal / Plastic Handle with 4 locking positions, Insulated Outer Tube with Working Insert—Qty 1
Pg 67 Para xxvii	Scissors, insulated, distally angled outer sheath, straight scissor- blades, scissor blades open parallelly to angulation, single action jaws, size 5 mm, length 28 cm, with connector pin for unipolar coagulation, consisting of: Insulated Metal V- Handle with 4 locking positions, Insulated Outer Tube with Working Insert—Qty 1	Scissors, insulated, distally angled outer sheath, straight scissor- blades, scissor blades open parallelly to angulation, single action jaws, size 5 mm, length 28 cm, with connector pin for unipolar coagulation, consisting of: Insulated Metal/ Plastic V- Handle with 4 locking positions, Insulated Outer Tube with Working Insert—Qty 1
Pg 69 Para 27	BOQ for VATS & Recording device: Dissecting Forceps, insulated, curved jaws, double action jaws, size 5 mm, length 28 cm, with connector pin for unipolar coagulation, consisting of: Insulated Metal Handle with 4 locking positions, Insulated Outer Tube with Working Insert 1 no.	BOQ for VATS & Recording device: Dissecting Forceps, insulated, curved jaws, double action jaws, size 5 mm, length 28 cm, with connector pin for unipolar coagulation, consisting of: Insulated Metal / Plastic Handle with 4 locking positions, Insulated Outer Tube with Working Insert 1 no.

Pg 69 Para 28	BOQ for VATS & Recording device: Scissors, insulated, straight jaws, curved scissor-blades, double action jaws, size 5 mm, length 28 cm, with connector pin for unipolar coagulation, consisting of: Insulated Metal Handle with 4 locking positions, Insulated Outer Tube with Working Insert 1 no.	BOQ for VATS & Recording device: Scissors, insulated, straight jaws, curved scissor-blades, double action jaws, size 5 mm, length 28 cm, with connector pin for unipolar coagulation, consisting of: Insulated Metal/ Plastic Handle with 4 locking positions, Insulated Outer Tube with Working Insert 1 no.
Pg 70 Para 29	Scissors, insulated, distally angled outer sheath, curved scissor- blades, scissor blades open horizontally to angulation, double action jaws, size 5 mm, length 28 cm, with connector pin for unipolar coagulation, consisting of: Insulated Metal Handle with 4 locking positions, Insulated Outer Tube with Working Insert 1 no.	Scissors, insulated, distally angled outer sheath, curved scissor- blades, scissor blades open horizontally to angulation, double action jaws, size 5 mm, length 28 cm, with connector pin for unipolar coagulation, consisting of: Insulated Metal/ Plastic Handle with 4 locking positions, Insulated Outer Tube with Working Insert 1 no.
Pg 70 Para 30	Scissors, insulated, distally angled outer sheath, straight scissor- blades, scissor blades open parallelly to angulation, single action jaws, size 5 mm, length 28 cm, with connector pin for unipolar coagulation, consisting of: Insulated Metal Y-Handle with 4 locking positions, Insulated Outer Tube with Working Insert 1 no.	Scissors, insulated, distally angled outer sheath, straight scissor- blades, scissor blades open parallelly to angulation, single action jaws, size 5 mm, length 28 cm, with connector pin for unipolar coagulation, consisting of: Insulated Metal / Plastic Y- Handle with 4 locking positions, Insulated Outer Tube with Working Insert 1 no.
Pg 70 Para 31	Biopsy Forceps, insulated, distally angled outer sheath, single action jaws, size 5 mm, length 28 cm, with connector pin for unipolar coagulation, consisting of: Insulated Metal Y-Handle with 4 locking positions, Insulated Outer Tube with Working Insert 1 no	Biopsy Forceps, insulated, distally angled outer sheath, single action jaws, size 5 mm, length 28 cm, with connector pin for unipolar coagulation, consisting of: Insulated Metal/ Plastic Y-Handle with 4 locking positions, Insulated Outer Tube with Working Insert 1 no
Item No. 14 -Rigid Bronchoscope (2021_HLL_72086_14)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS

Pg 72 Para 5.a	26" High resolution LCD / LED medical grade color monitor.	26" or more High resolution LCD / LED medical grade color monitor.
Pg 72 Para 5.7	All the quoted items should be USFDA / European CE approved with 4 digit notified body number	All the quoted items should be USFDA / European CE approved with 4 digit notified body number / BIS approved

**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**