Amendment No.1

Date: 06.09.2018

Subject: Amendment no. 1 to the Tender Enquiry Document

Ref: (i) Tender Enquiry No.: HITES/PCD/PMSSY-III/35/ANST/18-19 dated 20.08.2018

The pre bid meeting of the above referred tender enquiry was held on 28.08.2018. Based on pre-bid discussions following amendments are being incorporated in the tender enquiry document.

Section VII
Technical Specifications

Sch. No.1: 12 Channel ECG Machine (Rfx No. 3000003308)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read As**
1	point 11,page 47	Equipment should be European CE with four digit notified body number or US FDA approved and certificate to be submitted.	**Amended as:** Equipment should be European CE with four digit notified body number or US FDA **or BIS** approved for the quoted model and certificate to be submitted.

Sch. No.2: Blood & fluid warmer (Rfx No. 3000003309)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read AS**
1	Point 6,Page 47	Should have US FDA or European CE with four digit notified body number certificate and certificate to be submitted	**Amended as:** Should have US FDA **or BIS** or European CE with four digit notified body number certificate for the quoted model and certificate to be submitted

Sch. No.3: Non Invasive Ventilator (Rfx No.3000003310)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read AS**
1	point 6,page 48	Should have US FDA or European CE with four digit notified body number certificate and certificate to be submitted	**Amended as:** Should have US FDA **or BIS** or European CE with four digit notified body number certificate for the quoted model and certificate to be submitted

Sch. No.4: High-end Monitor for ICU with CNS (Rfx No.3000003311)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read As**
1	Point 5, page 48	Monitor must be upgradable to connect for CO (Thermodilution), BIS/Entropy, Inbuilt NMT, four IBP, module. (Price to	**Amended as:** Monitor must be upgradable to connect for CO (Thermodilution), BIS/Entropy, **Inbuilt**

		be quoted separately)	**NMT along with display of Accelerograph,** four IBP, module. (Price to be quoted separately)
2	point 14,page 48	Monitor should have US FDA or European CE with four digit notified body number certificate and certificate to be submitted.	Amended as: Monitor should have US FDA **or BIS** or European CE with four digit notified body number certificate for the quoted model and certificate to be submitted.

Sch. No.5: Recovery Ward Modular Monitors with Central Nursing System (Rfx No.3000003312)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read As**
1	14	Should have inbuilt two channel recorder	**Deleted**
2	point 13	Should have US FDA or European CE with four digit notified body number certificate and certificate to be submitted.	**Amended as:** Should have US FDA **or BIS** or European CE with four digit notified body number certificate for the quoted model and certificate to be submitted.
3	BOQ I .2	2 channel recorder	**Deleted**

Sch. No.6: Ventilator-Portable (Rfx No.3000003313)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read As**
1	3.4 b	PEEP/CPAP- 0-25cm H2O	**Amended as:** PEEP/CPAP**- 0-20cm H2O**
2	7.1	Product Should have US FDA or European CE with four digit notified body number certificate and certificate to be submitted.	Amended as: Product Should have US FDA **or BIS** or European CE with four digit notified body number certificate for the quoted model and certificate to be submitted.

Sch. No.7: Transport Monitor (Rfx No.3000003314)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read As**
1	Point 16, page 52	Product should have Airworthiness RTCA DO-160 D, section 7,8,21 and Vibration standard MIL STD 810F, method 514.5 certifications.	**Amended as:** Product should have Airworthiness RTCA DO-160 D, section 7,8,21 and Vibration standard MIL STD 810F, method 514.5 certifications **(Preferable)**
2	point 15,page52	It should have US FDA or European CE with four digit notified body number certificate and certificate to be submitted.	**Amended as**: It should have US FDA **or BIS** or European CE with four digit notified body number certificate for the quoted model and certificate to be submitted.

Sch. No.8: Anaesthesia Machine with Integrated Monitor & Ventilator (Rfx No.3000003315)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read As**
	point 4 ,page 55	Anesthesia workstation should be European CE with a four digit notified body number/US FDA certified and certificate to be submitted.	**Amended as:** Anesthesia workstation should be European CE with a four digit notified body number/US FDA **or BIS** certified for the quoted model and certificate to be submitted.
6	Point 8,page 53	Should be able to hold two seletatec vaporizers (Isoflurane, Sevoflurane & Desflurane) simultaneously. Vapourizers should be maintenance free. Cost of all vaporizers to be quoted separately. Isoflurane & Sevoflurane vaporizers will be supplied as standard	**Amended as:** Should be able to hold two **Seletatec or Electronic vaporizers** (Isoflurane, Sevoflurane & Desflurane) simultaneously. Vapourizers should be maintenance free. Cost of all vaporizers to be quoted separately. Isoflurane & Sevoflurane vaporizers will be supplied as standard
10	Point II .2 ,page 53	Should have atleast 15" or more TFT colour display with up to 10 waveforms at a time	**Amended as:** Should have atleast 15" or more TFT colour display with up to **8 waveforms** at a time
14	point 14 ,page 54	The quoted model (Both Anaesthesia and Monitor) should be European CE with four digit notified body number or US FDA approved and certificate to be submitted.	**Amended as :**The quoted model (Both Anaesthesia and Monitor) should be European CE with four digit notified body number or US FDAor **BIS** approved and certificate to be submitted.
16	Point II 12,page 54	Inbuilt Battery Back- up – 1 hour or more.	Amended as: Inbuilt Battery Back- up – **30 min or more.**
22		Suggested by bidder	**Added Para:** The machine should be supplied with active AGSS system with Jar & necessary components to connect with the central AGSS (Anesthetic Gas Scanvenging system) system

Sch. No.9: Anesthesia Workstation with monitor (Mid End) (RFX No.3000003316)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read As**
1	Point 9c,page 56	Modes: Volume controlled, manual / spont, pressure controlled mode, pressure support, SIMV	**Amended as:** Modes: Volume controlled, manual / spont, pressure controlled mode,pressure support (**or SIMV with PS),** SIMV

2	Point 10 a,page 56	Airway Monitoring Integrated monitor (7" or more color display/EL) for electronic monitoring and display of following set and measured values	**Amended as:** Airway Monitoring Integrated monitor (**6" or more** color display/EL) for electronic monitoring and display of following set and measured values
3	Point 13,page 56	Modular Monitor	**Amended as:** Modular Monitor (Module for ECG, SpO2, NIBP, Dual Temp, Resp (Combined or seperate or integrated))
4	point 14,page 54	The quoted model (Both Anaesthesia and Monitor) should be European CE with four digit notified body number or US FDA approved and certificate to be submitted.	**Amended as**: The quoted model (Both Anaesthesia and Monitor) should be European CE with four digit notified body number or US FDA **or BIS** approved for the quoted model and certificate to be submitted.
5	BOQ 4	Monitor without modules	**Amended As:** Module for ECG, SpO2, NIBP, Dual Temp, Resp (Combined or seperate or integrated)
6	BOQ 5	Module for ECG, SpO2, NIBP, Dual Temp, Resp (Combined or seperate)	
7	BOQ 6	Module for 2IBP if separate	
8			**Added Para:** The machine should be supplied with active AGSS system with Jar & necessary components to connect with the central AGSS system

Sch. No.10: Ventilator-High End (I.C.U.) (RFX No.3000003317)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read As**
7	Point 5i,page 58	Inspiratory flow and pressure Trigger Sensitivity	**Amended as:** Inspiratory flow **or** pressure Trigger Sensitivity
	point 18	Should have US FDA or European CE with four digit notified body number certificate and certificate to be submitted.	**Amended as:** Should have US FDA **or BIS** or European CE with four digit notified body number certificate for the quoted model and certificate to be submitted.
15	Point 20 ,page 59	Expiratory valve/cassette should be autoclavable and supply 2 no's with each unit.	**Amended as:** Expiratory valve/cassette/**expiratory filter should be autoclavable/sterilizable** and supply 2 no's with each unit.
16	Point 23,page 59	Compressor should be US-FDA or European CE approved.	**Amended as:** Compressor should be US-FDA or European CE **with 4 digit notified body or BIS** approved.
17	Point 24,page 59	Compressor, hinged arm and ventilator trolley should be from the same manufacturer	**Amended as:** Compressor, hinged arm **(or circuit support arm)** and ventilator trolley should be from the same manufacturer

21	BOQ point 9,Page 59	Hinged Arm	**Amended as:** **Hinged Arm/**Circuit support arm
22	BOQ point 10 ,Page 59	Proximal flow sensor (with necessary hardwarr and software required in the machine)	**Amended as:** Proximal flow sensor (with necessary hardwar**e** and software required in the machine)

Sch. No.11: Blood Gas Analyser (RFX No.3000003318)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read As**
1	Point 2 ,Page 59	Essential Measured parameters; pH, pCO2, pO2, SaO2 with co-oximetry, tHb, Lactates, Glucose, Na+, K+, Ca++, Cl-. All these parameters should be measured simultaneously.	**Amended as:** Essential Measured parameters; pH, pCO2, pO2, SaO2, **co-oximetry (optional), Hb,** Lactates, Glucose, Na+, K+, Ca++, Cl-. All these parameters should be measured simultaneously.
2	point 7,page 59	Fully automatic liquid calibration of all parameters at user-defined intervals without the use of Gas calibrated reagents, external gases, tanks or regulators.	**Amended as:** Fully automatic liquid calibration of all parameters at user-defined intervals without the use of Gas calibrated reagents, **external gas cylinders in case reagent based system**
3	point 8,page 59	**Continuous reagent level monitoring with graphic display/alarm .**	**Amended as:** Continuous reagent level monitoring with graphic display/alarm **in case reagent based system**
4	point 17,page 59	It must be UF-FDA /European CE with four digit notified body number approved and certificate to be submitted.	Amended as: It must be UF-FDA **/BIS**/European CE with four digit notified body number approved for the quoted model and certificate to be submitted.

Sch. No.12: Deep Vein Thrombosis (DVT) Pump (Rfx No.3000003319)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read As**
1	5	Should deliver constant pre-set pressure ranges – Distal 40 - 160 mm Hg	**Amended as:** Should deliver constant pre-set pressure ranges – **Distal 40 - 130 mm Hg**
2	12	US-FDA/ European CE approved product	**Amended as:** US-FDA/ European CE/**BIS** approved product for the quoted model

Sch. No.13: Video Laryngoscope (Rfx No.3000003320)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read As**
1	Point 4	Blade size: 2, 3, 4 and Difficult airway blade – 1 no. each size reusable should be quoted.	**Amended as:** Blade size: 2, 3, 4 **(Pediatric, adult small size and adult large size) and Difficult airway blade – 1 no.** each size reusable should be quoted.
2	Point 5	ET tube insertion dia: 6mm-8mm	**Deleted**
3	Point 6	Operates either on rechargeable lithium battery or on AAA batteries	**Amended as:** Operates either on **rechargeable or AAA batteries**
4	point 7,page 60	Offered model should be European CE or USFDA approved.	**Amended as:** Offered model should be European CE or USFDA **or BIS** approved for the quoted model.

Sch. No.14: Peripheral Nerve Stimulator (RFX No.3000003321)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read As**
1	point 12,page 61	Machine should be USFDA/European CE with four digit notified body number certified	**Amended as:** Equipment should be European CE with four digit notified body number or US FDA **or BIS** approved for the quoted model and certificate to be submitted.

Sch. No.15: PCA PUMP (Rfx No.3000003322)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read As**
1	Point 6, page 61	Selectable Occlusion pressure trigger levels from 100 mmHg to 900 mmHg.	**Amended as:** Selectable Occlusion pressure trigger levels from **150 mmHg to 900 mmHg**
2	Point 8, page 61	Should have comprehensive alarm package including Occlusion pressure pre-alarm & alarm, End of infusion pre-alarm and alarm, Volume limit pre-alarm & alarm, KVO rate, Low battery pre-alarm and alarm, **Line disconnection alarm**, Syringe barrel & **clasp check,** Plunger detection, maintenance reminder alarm etc.	**Amended as:** Should have comprehensive alarm package including Occlusion pressure pre-alarm & alarm, End of infusion pre-alarm and alarm, Volume limit pre-alarm & alarm, KVO rate, Low battery pre-alarm and alarm, Syringe barrel, Plunger detection, maintenance reminder alarm etc.

3	Point 9,page 61	Battery back should be for about 6 ~ 7 hr at 5ml/hr for 50ml syringes with a provision to display residual battery life in hours and minutes	**Amended as:** Battery back should be for about 6 - 7 hr at 5ml/hr for 50ml syringes with a provision to **display (numeric or graphical) residual battery life**
4	point 10,page 61	Should meet the international safety standards US-FDA/ CE Certification	**Amended as:** Should meet the international safety standards US-FDA/ CE**/BIS** Certification for the quoted model

Sch. No.16: Patient Warming System (RFX No.3000003323)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read As**
1	Point 2, page 62	Should have **Two** Air flow setting for the air flow 30-50cfm for adult and infant patient in same machine	**Amended as** Should have air flow setting for the air flow **30-50cfm** for adult and infant patient in same machine
2	Point 7,page 68	Should have microprocessor control system to allow a multi-staged Heater.	**Amended as** Should have microprocessor control system
3	point 8, page 62	Three heater elements	**Deleted**
4	point 13, page 62	Blanket should not be more than 160 gm. Weight	**Amended as:** Blanket should be light weight
5	Point 18,page 62	Offered model should be USFDA or European CE with four digit notified body number approved	**Amended as:** Offered model should be USFDA or European CE with four digit notified body number or **BIS** approved for the quoted model

Sch. No.17: Suction Machine (RFX No.3000003324)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read As**
1	Point 5,Page 62	It should be heavy duty and noiseless, with piston/cylinder technology.	**Amended As:** It should be heavy duty and noiseless, with **piston/cylinder/Diaphragm technology.**
2	point 6,Page 62	Should be able to create desired maximum vacuum in least possible time, vacuum should be up to –90 K pascal with minimum capacity of 60L/min.	**Amended as:** Should be able to create desired maximum vacuum in least possible time, vacuum should be up to –90 K pascal with **minimum capacity of 45L/min**.

3	point 10,Page 62	Should be CE or USFDA for quality and safety purpose.	**Amended As:** Should be CE or USFDA or **BIS** for the quoted model for quality and safety purpose.

Sch. No.18: Fibre optic Bronchoscope (Rfx No.3000003325)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read As**
1		**Video Bronchoscope**	**Amended as:** **Fiber Optic** Bronchoscope
2	Point 1,page 63	Video Processor & Light source Outputs - RGB, Y/C, VBS Composite, XGA & DV simultaneous or DVI	**Amended as:** Video Processor & Light source **Outputs - suitable video output**
3	Point 8,page 63	Video Processor & Light source Electronic magnification up to 1.5X by a touch of scope remote switches	**Amended as:** Video Processor & Light source Electronic magnification up to 1.5X by a touch of scope **remote switches/adapters/coupler**
4	point 10,page 63	Should be European CE with 4 digit notified body number/US FDA approved.	**Amended as:** Should be European CE with 4 digit notified body number/US FDA **/BIS** approved for the quoted model

Sch. No.19: Defibrillator with CPR monitoring and TC pacing (RFX No.3000003326)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read As**
1	Point 4, page 64	It should display of both selected and delivered energy	**Amended as:** It should display selected energy**. Delivered energy either to be displayed or printed in the report**
2	Point 6,page 64	In manual mode the unit should provide energy selection at (1-200 J in variable step) and AED mode of upto minimum 150 Joules.	**Amended as:** In manual mode the unit should provide energy selection at **(2-200 J in variable step)** and AED mode of upto minimum 150 Joules.
3	point 13,page 64	Should have US FDA or European CE with four digit notified body number certificate and certificate to be submitted.	**Amended as:** Should have US FDA **or BIS** or European CE with four digit notified body number certificate for the quoted model and certificate to be submitted.

Sch. No.20: Defibrillator with ECG monitor (Rfx No.3000003327)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read As**
1	Point 3.13, page 65	In manual mode the unit should provide energy selection at (1-200 J in variable step) joules and AED mode of upto minimum 150 Joules.	**Amended as:** In manual mode the unit should provide energy selection **at (2-200 J in variable step) joules** and AED mode of upto minimum 150 Joules.
2	point 7.1 page 66	Should have US FDA or European CE with four digit notified body number certificate and certificate to be submitted.	**Amended as:**Should have US FDA **or BIS** or European CE with four digit notified body number certificate for the quoted model and certificate to be submitted.
3	BOQ Sl.no.6	Internal paddle - 1 no.	**Deleted**

Sch. No.21: Infusion Pump (Volumetric) (RFX No.3000003328)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read As**
1	point 7.1,page 67	Should have US – FDA/European CE with four digit notified body number certificate for the product and certificate to be submitted.	**Amended as:** Should have US – FDA**/BIS**/European CE with four digit notified body number certificate for the quoted model and certificate to be submitted.

Sch. No.22: Syringe Infusion Pump (RFX No.3000003329)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read AS**
1	point 3 ,page 67	Should have US FDA or European CE with four digit notified body number certificate and certificate to be submitted.	**Amended as:** Should have US FDA **or BIS** or European CE with four digit notified body number certificate for the quoted model and certificate to be submitted.
2	Point 15 ,page 68	**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)	**Amended as:** 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)

Sch. No.23: Multiparameter Monitor- 5 Para (RFX No.3000003331)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read As**
1	Point 3.2, page 69	Should have facility to monitor and display - ECG, NIBP, SpO2(Nellcor/Masimo), Temperature, Respiration and upgradable to ETCO2(Sidestream or Microstream) & IBP.	**Amended as:** Should have facility to monitor and display - ECG, NIBP, SpO2(Nellcor/Masimo), Temperature, Respiration and upgradable to ETCO2(Sidestream or Microstream or **mainstream**) & IBP.
2	point 7.1,page69	It should have US FDA or European CE with four digit notified body number certificate and certificate to be submitted.	**Amended as:** It should have US FDA **orBIS** or European CE with four digit notified body number certificate for the quoted model and certificate to be submitted.

Sch. No.25: :-Paediatric Fibre optic Bronchoscope (RFX No.3000003333)			
Sl. No	**Tender Page & Para**	**TENDER SPECIFICATION**	**Read As**
1	point 7,page 70	**Upward bending capability of the tip should be 140 degrees or more**	**Amended as:** Upward bending capability of the tip should be **120 degrees or more**
2	point 8,page70	Downward bending capability of the tip should be 130 degrees	**Amended as:** Downward bending capability of the tip should be **120 degrees or more**
3	point 14,page 71	Should be European CE with 4 digit notified body number/US FDA approved.	**Amended as:** Should be European CE with 4 digit notified body number/US FDA **/BIS** approved for the quoted model

SECTION – IX
QUALIFICATION CRITERIA

NOTE:
Added Para:

7. The bidder or manufacturer should have registered office/registered service centre in the following regions in India:

North: Delhi/Noida/Gurgaon
South: Bangalore/Hyderabad/Chennai
East: Kolkata/Bhubaneswar/Guwahati
West: Mumbai/Pune

(Necessary documentations in this regard may please be submitted along with the tender)

All other terms and conditions of the tender enquiry remain unaltered.