OFFICE OF THE JOINT DIRECTOR OF HEALTH SERVICES (MALARIA), ASSAM
NATIONAL VECTOR BORNE DISEASE CONTROL PROGRAMME
SAIKIA COMMERCIAL COMPLEX, SRINAGAR PATH, CHRISTIANBASTI,
G.S. ROAD, GUWAHATI-781005,ASSAM
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No. NVBDCP/VII-2/PSCM/PICU/2014/2139 Date: 02-03-2015

CORRIGENDUM NO: 1
FOR SUPPLY OF HOSPITAL EQUIPMENTS

This is with reference to tender no : No. NVBDCP/VII-2/PSCM/PICU/2014/ ***910*** dated 29/01/15 , extension notice no : NVBDCP/VII-2/PSCM/PICU/2014/ ***1565*** dated 12/02/15 and extension notice No-2:- NVBDCP/VII-2/PSCM/PICU/2014/***1940*** dated 24/02/15 for supply of Hospital Equipments. The following amendments in the tender may be taken note of prior to submission of bids:-

1. The last date and time for receipt of tender is 10-03-2015 (up to 1.00 PM).
2. The tenders will be opened on 10-03-2015 by 3.15 P.M.
3. Sub Clause C under Clause 4 (ELIGIBILTY CRITERIA) is amended to read as follows:-

   Manufacturer participating as bidder or manufacturer from the Medical Equipments/Instruments would be sourced by the dealer should have average Annual Turnover of Rs 05(Five) crore in the last 3 financial years i.e 2011-12, 2012-13, 2013-14. For manufacturers of "Electric Suction Machine" and Electric Sterilser Seamless", should have average annual turnover of Rs 50 Lakhs in the last three financial years.
4. Sub clause M under Clause 6 (TECHNO-COMMERCIAL BID-COVER"A" is amended to read as follows:-

   The List of items quoted shall be furnished as per Annexure – VIII . The list shall specifically indicate manufacturer's name along with warranty period offered for each item. Item wise Technical Compliance Statement should also be submitted as per Annexure – XV which has to be declared by the manufacturer.
5. Annexure-XII (PRICE BID Format) is substituted with **Annexure-XII(Rev-I)**.
6. Annexure-XIII (Specification & details of items) is substituted with **Annexure-XIII(REV-I).**

   All other terms & conditions of the tender & extension notice shall remain unchanged.

Sd/-
Joint Director of Health Services (Malaria) cum
State Programme Officer, NVBDCP,ASSAM

SPECIFICATIONS & DETAILS OF ITEMS

Item No:-01

Item Name: Multi Parameter Monitor with Central Monitoring Station (set)

Tentative requirement:- 03 Sets

01 unit=Set of 10 nos Multi Parameter Monitor and 1 nos Central Monitoring Station)

Specifications:- As under....

- Should have facility to display ECG, RR, HR, Spo2, NIBP, single Temperature as standard parameters and with in built rechargeable battery back up of at least 2 hrs Operation
- Display: Color TFT display of size 12.1" or more
- ***Should display at least 08 or more waveforms of selected parameters simultaneously.***
- Should display 7 ECG waveforms at a time when selected for ECG view option.
- ***Should have facility to save ECG waveform for at least 30 minutes and be able to review the same in the Central Monitoring Station.***
- ***SpO2 technology (NELLCOR/MASIMO/Equivalent Technology) should sense the SPO2 in hypotensive, shivering & motion condition.***
- Should be able to analyze arrhythmia (18 types) & ST segments for all the leads
- Should have facility for displaying 6 different screen configurations.
- Should be able top store & display at least 72 hrs for graphical trends of all parameters
- Trends should also store ECG waveform of patient and can be previewed.
- Should be suitable for monitoring adult, pediatric & neonatal patients.
- Should be able to give visual & audible alarms with three levels of volume adjustment on violation of any monitored parameter
- Should have drug dose calculation software
- ***Should compulsorily have wired/wireless communication with central monitoring system***
- Nurse call function should be included as standard configuration
- Should store data in event of power – off or patient disconnection.
- Facility of bed to bed remote monitoring when connected via Ethernet to central monitoring
- Monitor should be **CE or US FDA** Certified.
- The scope of supply should be :
  SpO2 reusable probe -1 ; NIBP cuff for adult, children and neonates – 1 each
  ECG Cable – 1 ; Temperature probe – 1 ;Operating manual – English – 1

Specification of Central Monitoring Station

- Display: Color TFT display of size 19" or more
- ***Should compulsorily have wired/wireless communication with minimum 10 nos of Multi Para Monitors***
- Should be compatible with the above Multi Para Monitors
- ***Should be supplied with Genuine Windows and Anti Virus (minimum one year validity)***

Warranty (For both Multi Para Monitor & Central Monitoring Station):-

- ***Comprehensive warranty for 02 years***
- ***Comprehensive Maintenance for 03 Years***

Quality Certification /Safety certification (*For both Multi Para Monitor & Central Monitoring Station):-* to be met as follows:-

(Copy of the certifications must be submitted along with the bids)

a. US FDA certificate /CE certificate for the product.

b. ISO certificate of the manufacturer.

Item No:-02
Item Name: Defibrillator
Tentative requirement:- 03 Nos
Specifications:- As under....

1. The defibrillator should be latest, lightweight, small size with bright colored display.
2. The defibrillator should be Biphasic waveform with 3 wave form display with screen size minimum 6.5 inches diagonal.
3. It should display of both selected and delivered energy.
4. The machine should have facility to increase/decrease energy selection on paddles as well as on unit.
5. In manual mode the unit should provide energy selection at (1-10, 15, 20,30, 50,70,85,100,150,200) joules.
6. It should have ability to measure chest compression rate and depth in real time with both visual & audible feedback for rate and depth with CPR INDEX for adult and pediatric patients.
7. The unit should have transcutaneous external pacing with 40 milli-second pulse width.
8. The unit should do self test daily with facility to give print out of defibrillator testing report and also have code ready indicator on unit.
9. It should have ability to filter out CPR artifacts and allowing person to see organized filtered rhythms without interrupting chest compressions.
10. The Unit should be supplied with following accessories

a) Li-Ion smart battery -1 nos
b) 3-lead ECG cable- 1 nos
c) External defibrillator paddles (pediatric inbuilt in adult)- 1 nos
d) CPR feedback sensor with defibrillation padz for adult/pediatric patients – 2 nos

11. The unit should be upgradable to Spo2 , NIBP & ETCO2 and to internal defibrillation facility if required .

12. **The Unit should be U.S F.D.A & CE approved**

Warranty:-

- ***Comprehensive warranty for 02 years***
- ***Comprehensive Maintenance for 03 Years***

Quality Certification /Safety certification to be met as follows:-
(Copy of the certifications must be submitted along with the bids)

a. US FDA certificate and CE certificate for the product.
b. ISO certificate of the manufacturer.

Item No:-03
Item Name: Blood Gas and Electrolyte & Metabolite Analyzer (ABG Analyser)
Tentative requirement:- 03 Nos
Specifications:- As under....

1. Small, easy to operate and portable system capable of measuring pH, PCo2, Po2, Na+, K+, Ca++, Glucose, Lactate, Hematocrit.
2. All the tests blood gases/electrolytes/glucose/lactate should be performed simultaneously on a single-use disposable cartridge.
3. Upgradeable to future parameters like Cl^-, Creatinine on the same card.
4. The system should be USFDA or CE certified.
5. Sample requirement - not more than 100 µl.
6. The system should be capable of storing 2000 patient results
7. The single-use test cartridges should be self contained with all the reagents, sensors & calibrating solutions required for running.
8. Tests cartridges should be stored at room temperature without any requirement for refrigeration.
9. System should be provided along with a dedicated wireless (IR/Bluetooth) Thermal Printer.
10. System should be capable of recharging during operation.
11. System should use Amperometric, Potentiometric, Conductimetric sensors for measurement.
12. OPERATION: AC adapter or rechargeable Li-Ion battery
13. The system should have at least 6 hours of standby time.
14. System should come along with a Windows based Personal Digital Assistant to control the entire system & printer.

Warranty :-

- ***Comprehensive warranty for 02 years***
- ***Comprehensive Maintenance for 03 Years***

Quality Certification /Safety certification to be met as follows:-
(Copy of the certifications must be submitted along with the bids)

a. US FDA certificate / CE certificate for the product.
b. ISO certificate of the manufacturer.

Item No:-04
Item Name: High Frequency mobile X Ray Unit
Tentative requirement:- 03 Nos
Specifications:- As under....

- State of Art, High frequency microprocessor controlled Portable X Ray having following features:
    - Compact, lightweight, easily transportable mobile X Ray unit suitable for Pediatric / Neonatal applications, bedside x-rays, trauma, Intensive care units. The unit should occupy minimum floor area and should be capable to be taken through elevators with ease.
- The unit should be fully counterbalanced and can be positioned to suit different bed heights. The unit should have facility of vertical swing and horizontal rotation of the tube head to ensure X Ray of any anatomy even within limited space.
- The unit must have an effective braking system for parking and transport. The tube stand must be fully counterbalanced.
- The unit must have intelligent graphical LCD display with atleast 60 user- configurable anatomy presets for ease of operation to the operator.
- The exposure release switch should be detachable with a cord of sufficient length (atleast 3 m)
- The unit should have integrated Battery pack in order to take atleast 80 X – Ray exposures in case of electricity failure at site.
- **The Generator:**

a. Microprocessor controlled high frequency / inverter type of high frequency (40 KHz or more) for constant output. Higher Frequency will be preferred.
b. It should have power rating of 2.5 kW or more
c. It should have a digital display of mAs and kV.
d. KV range : 40 kv to 100 kV or wider range
e. mA range: 10mA to 100 mA or more
f. Exposure time of 40 ms to 3.5 s or less
g. KV selection: 40 kV to 100 kv, selectable in 1 kV steps h. mAS selection: 0.4 mAs to 140 mAs or more

- **X-Ray Tube and Collimator:**

a. Stationary anode having focal spot size less than 1.4mm.
b. Output of tube should match with that of generator.
c. Light Beam diaphragm / Double layer Collimator with auto cut off switch.
d. Collimator rotation +/- 90 degrees and Tube Head rotation – Vertical – at least 280 degrees, Horizontal – atleast 350 degrees should be possible

- ***The unit should operate on single phase power supply and should have plug in facility to any standard wall outlet with automatic adaptation to line voltage 160 to 250 volts, 15 Amp plug.The Leakage radiation level at 1 meter from the focus should be less than 70 mR. Products having minimal leakage radiation level will be preferred. (Please attach relevant test report). The weight of unit with inbuilt battery pack should not be more than 250 kg The Systems should be fully safe with respect to:-***
    - ***a.*** Over current
    - ***b.*** Over Voltage
    - ***c.*** Maximum loading of tube
- Manufacturer / supplier should have ISO 13485 certification.
- Should be an AERB approved product.
- User/Technical/Maintenance manuals to be supplied in English.

Warranty:-

- ***Comprehensive warranty for 02 years***
- ***Comprehensive Maintenance for 03 Years***

Quality Certification /Safety certification to be met as follows:-
(Copy of the certifications must be submitted along with the bids)

a. ISO 13485 certificate of the product.
b. AERB approval certificate of the product.

Item No:-05
Item Name: Portable ECG : 12 channel ECG Machine
Tentative requirement:- 03 Nos
Specifications:- As under....

- Should have 8" high resolution color touch-screen
- Should have alphanumeric keyboard and one touch operation
- Should have 12 leads simultaneously
- Should be Automatic measurement and interpretation tested with authoritative CSE/AHA/MIT database
- Should be Built in rechargeable Li-ion battery for 300 ECG report printing
- Should have minimum 200 ECG recordings storage capacity
- Rhythm should be Single or Three channel selectable
- Support external printer via USB port
- Should have Auto/Manual/Rhythm/R-R/off
- Should have inbuilt Thermal Printer
- Record speed should 5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s (+_ 3%)
- Should have Display size 320X240 dots single color /multicolor LCD Screen
- Should have Automatic Baseline Adjustment
- AC : 100V-115V/220V, 50/60 Hz, built-in rechargeable Li-ion battery; voltage =14.8V
- Weight should be max. 5kg
- Should have 420mm* 330mm* 105mm dimension
- Should be USFDA or CE Certified Quality approved

Warranty:-

- ***Comprehensive warranty for 02 years***
- ***Comprehensive Maintenance for 03 Years***

Quality Certification /Safety certification to be met as follows:-
(Copy of the certifications must be submitted along with the bids)

a. US FDA certificate / CE certificate for the product.
b. ISO certificate of the manufacturer.

Item No:-06

Item Name: ELECTRIC SUCTION MACHINE

Tentative requirement:- 03 Nos

Specifications:- As under....

1 Description of Function	
1.1	To extract fluid from the body during surgery or emergency treatment
2 Operational Requirements	
2.1	• Shall have Motor of minimum ¼ H.P. capacity The machine should be portable on four wheels and handle for transportation
3 Technical Specifications	
3.1	• Cabinet to be made of mild steel with epoxy powder coated finish. • It should have two graduated polycarbonate jars of 1.5 liters capacity with synthetic rubber lids. The bottle shall be fitted with the arrangement to prevent overflow of fluid. • The suction machine should be capable of producing minimum vacuum of 700 (+/-10 mm Hg) approx mm Hg which should be adjustable and monitored by vacuum gauge of 100 mm. • Free air displacement 30 ~ 35 ltrs/min. • Noise level 50 dB +/- 03 dB. • Non collapsible silicon tubing Bacterial filter fitted on top.
4 System Configuration Accessories, spares and consumables	
4.1	• Following accessories should include a. Bottles 2 Nos. b. Lids 2 Nos. C. Rubber Seals 2 Nos..d. Suction Tubing set 1 No Any other standard accessories desired for proper functioning of the machine.
5 Environmental factors	
5.1	• The unit shall be capable of being stored continuously in ambient temperature of 0-50deg C and relative humidity of 15-90% The unit shall be capable of operating continuously in ambient temperature of 10 - 40deg C and relative humidity of 15-90%
6 Power Supply	
6.1	• Power input to be 220-240VAC, 50Hz fitted with Indian plug A fuse or a resettable circuit breaker of a appropriate capacity should be incorporated for protection of motor
7 Standards, Safety and Training	
	• Should be FDA/CE approved product. • Manufacturer should have ISO 9001:2008 & ISO 13485:2003 certification for quality standards. • Comprehensive training for lab staff and support services till familiarity with the system on site.
8 Documentation	
	• Service manual in English. • Certificate of calibration and inspection • Log book with instructions for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and company service engineer should be clearly spelt out. Compliance Report to be submitted in a tabulated and point wise manner clearly mentioning the page/ para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered.

Warranty:-

- ***Comprehensive warranty for 02 years***
- ***Comprehensive Maintenance for 03 Years***

Quality Certification /Safety certification to be met as follows:-

(Copy of the certifications must be submitted along with the bids)

a. US FDA certificate or CE certificate for the product.

b. ISO9001:2008 & ISO 13485:2003 certificate.

Item No:-07
Item Name: Electric Sterilizer Seamless shell, with automatic lifting handle with tray all supplied with power cord
Tentative requirement:- 03 Nos
Specifications:- As under....

Electric Sterilizer – Medium

–Should be IS : 5022–1989
Made of Seamless S.S. Sheet of grade-304 (18 Cr-8 Ni).
Suitable for 220V, 50 Hz, Single Phase, AC Supply.
L: 430, W: 200, H: 150mm, Power: 1.50 Kw

Warranty:-

- ***Comprehensive warranty for 02 years***
- ***Comprehensive Maintenance for 03 Years***

Quality Certification /Safety certification to be met as follows:-
(Copy of the certifications must be submitted along with the bids)

a. IS 5022-1989 certificate.

Item No:-08
Item Name: Oxygen Cylinder B Type with flow meter and wrench
Tentative requirement:- 06 Nos
Specifications:- As under....

- The oxygen cylinder should confirming to IS : 7285 (Part 1) – 2004 and with appropriate valves confirming to IS: 3224-2002 for Medical oxygen gas service Cylinders subjected to hydrostatic stretch test at pressure of 250 Bar as required under rule 35 of the Gas Cylinder Rules , 2004.
- 10 ltrs water capacity. Supplied with Flow meter and wrench.

Quality Certification /Safety certification to be met as follows:-
(Copy of the certifications must be submitted along with the bids)

a. IS:7285(Part-I)-2004 certificate for the cylinder.
b. IS:3224-2002 certificate for the valves.

ANNEXURE XII(Rev-I)

PRICE BID
(To be submitted in a separate sealed envelope)

TENDER NO……

Sl	Brief Description of items	Basic Rate Per Unit	Tax/VAT per unit	Total ***Rs (3+4)***	CAMC charge/unit (for 03 years) inclusive of all taxes Rs	**Total** (Rate + CAMC) Rs (5+6)
1	***2***	***3***	***4***	***5***	***6***	***7***
1						
2						
3						
4						
5						
6						
7						
8						

Note:- 01 Unit = 1 no of equipment / 01 set of Multi Para Monitor(10 nos) with Central Monitoring Station (01 nos)

SIGNATURE :

NAME & DESIGNATION :
DATE :

NAME & ADDRESS OF THE FIRM :

ANNEXURE-XV
Item No:-1

TECHNICAL SPECIFICATION COMPLIANCE STATEMENT

(Note:- Compliance Report to be submitted in a tabulated and point wise manner clearly mentioning the page/ para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered)

Name of Item:- Multi Parameter Monitor with Central Monitoring Station (set of 10+1)

Sl	Parameters	Quoted Specification (To be filled by the manufacturer)	Deviations, if any
1	Should have facility to display ECG, RR, HR, Spo2, NIBP, single Temperature as standard parameters and with in built rechargeable battery back up of at least 2 hrs Operation		
2	Display: Color TFT display of size 12.1" or more		
3	***Should display at least 08 or more waveforms of selected parameters simultaneously.***		
4	Should display 7 ECG waveforms at a time when selected for ECG view option.		
5	***Should have facility to save ECG waveform for at least 30 minutes and be able to review the same in the Central Monitoring Station.***		
6	• ***SpO2 technology (NELLCOR/MASIMO/Equivalent Technology) should sense the SPO2 in hypotensive, shivering & motion condition.***		
7	• Should be able to analyze arrhythmia (18 types) & ST segments for all the leads		
8	• Should have facility for displaying 6 different screen configurations.		
9	• Should be able top store & display at least 72 hrs for graphical trends of all parameters		

10	• Trends should also store ECG waveform of patient and can be previewed.		
11	Should be suitable for monitoring adult, pediatric & neonatal patients.		
12	• Should be able to give visual & audible alarms with three levels of volume adjustment on violation of any monitored parameter		
13	• Should have drug dose calculation software		
14	• ***Should compulsorily have wired/wireless communication with central monitoring system***		
15	• Nurse call function should be included as standard configuration		
16	• Should store data in event of power – off or patient disconnection.		
17	• Facility of bed to bed remote monitoring when connected via Ethernet to central monitoring		
18	• **Whether the product is US FDA or CE Certified.**		
19	• The scope of supply should be : SpO2 reusable probe -1 ; NIBP cuff for adult, children and neonates – 1 each ECG Cable – 1 ; Temperature probe – 1 ;Operating manual – English – 1		
20	**<u>Specification of Central Monitoring Station</u>** • Display: Color TFT display of size 19" or more • ***Should compulsorily have wired/wireless communication with minimum 10 nos of Multi Para Monitors***		

	• Should be compatible with the above Multi Para Monitors • ***Should be supplied with Genuine Windows and Anti Virus (minimum one year validity)***		
21	***Warranty (For both Multi Para Monitor & Central Monitoring Station):-*** • ***Comprehensive warranty for 02 years*** • ***Comprehensive Maintenance for 03 Years***		
22	US FDA certificate / CE certificate for the product.		
23	ISO certificate of the manufacturer.		

(Note:- Signature by authorized official of the manufacturer on all the pages of the compliance statement is must)

ANNEXURE-XV
Item No:-2

TECHNICAL SPECIFICATION COMPLIANCE STATEMENT

(Note:- Compliance Report to be submitted in a tabulated and point wise manner clearly mentioning the page/ para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered)

Name of Item : Defibrillator

Sl	Parameters	Quoted Specification (***To be filled by the manufacturer***)	Deviations, if any
1	The defibrillator should be latest, lightweight, small size with bright colored display.		
2	The defibrillator should be Biphasic waveform with 3 wave form display with screen size minimum 6.5 inches diagonal.		
3	It should display of both selected and delivered energy.		
4	The machine should have facility to increase/decrease energy selection on paddles as well as on unit.		
5	In manual mode the unit should provide energy selection at (1-10, 15,20,30,50,70,85,100,150,200) joules.		
6	It should have ability to measure chest compression rate and depth in real time with both visual & audible feedback for rate and depth with CPR INDEX for adult and pediatric patients.		
7	The unit should have transcutaneous external pacing with 40 milli-second pulse width.		
8	The unit should do self test daily with facility to give print out of defibrillator testing report and also have code ready indicator on unit.		
9	It should have ability to filter out CPR artifacts and allowing person to see organized filtered rhythms without interrupting chest compressions.		

10	The Unit should be supplied with following accessories e) Li-Ion smart battery -1 nos f) 3-lead ECG cable- 1 nos g) External defibrillator paddles (pediatric inbuilt in adult)- 1 nos h) CPR feedback sensor with defibrillation padz for adult/pediatric patients – 2 nos		
11	The unit should be upgradable to Spo2 , NIBP & ETCO2 and to internal defibrillation facility if required .		
12	The Unit should be **U.S F.D.A & CE** approved		
13	***Warranty:-*** • ***Comprehensive warranty for 02 years*** • ***Comprehensive Maintenance for 03 Years***		
14	**US FDA certificate and CE certificate for the product.**		
15	ISO certificate of the manufacturer.		

(Note:- Signature by authorized official of the manufacturer on all the pages of the compliance statement is must)

ANNEXURE-XV
Item No:-3

TECHNICAL SPECIFICATION COMPLIANCE STATEMENT

(Note:- Compliance Report to be submitted in a tabulated and point wise manner clearly mentioning the page/ para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered)

Name of Item : Blood Gas and Electrolyte & Metabolite Analyzer (ABG Analyser)

Sl	Parameters	Quoted Specification (***To be filled by the manufacturer***)	Deviations, if any
1	Small, easy to operate and portable system capable of measuring pH, PCo2, Po2, Na+, K+, Ca++, Glucose, Lactate, Hematocrit.		
2	All the tests blood gases /electrolytes/glucose/lactate should be performed simultaneously on a single-use disposable cartridge.		
3	Upgradeable to future parameters like Cl^-, Creatinine on the same card.		
4	The system should be USFDA or CE certified.		
5	Sample requirement - not more than 100 µl.		
6	The system should be capable of storing 2000 patient results		
7	The single-use test cartridges should be self contained with all the reagents, sensors & calibrating solutions required for running.		
8	Tests cartridges should be stored at room temperature without any requirement for refrigeration.		
9	System should be provided along with a dedicated wireless (IR/Bluetooth) Thermal Printer.		
10	System should be capable of recharging during operation.		
11	System should use Amperometric, Potentiometric, Conductimetric sensors for measurement.		

12	OPERATION: AC adapter or rechargeable Li-Ion battery		
13	The system should have at least 6 hours of standby time.		
14	System should come along with a Windows based Personal Digital Assistant to control the entire system & printer.		
15	***Warranty :-*** • ***Comprehensive warranty for 02 years*** • ***Comprehensive Maintenance for 03 Years***		
16	US FDA certificate /CE certificate for the product.		
17	ISO certificate of the manufacturer.		

(Note:- Signature by authorized official of the manufacturer on all the pages of the compliance statement is must)

ANNEXURE-XV
Item No:-4

TECHNICAL SPECIFICATION COMPLIANCE STATEMENT

(Note:- Compliance Report to be submitted in a tabulated and point wise manner clearly mentioning the page/ para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered)

Name of Item : High Frequency mobile X Ray Unit

Sl	Parameters	Quoted Specification (***To be filled by the manufacturer***)	Deviations, if any
1	State of Art, High frequency microprocessor controlled Portable X Ray having following features: Compact, lightweight, easily transportable mobile X Ray unit suitable for Pediatric / Neonatal applications, bedside x-rays, trauma, Intensive care units.		
2	The unit should occupy minimum floor area and should be capable to be taken through elevators with ease.		
3	The unit should be fully counterbalanced and can be positioned to suit different bed heights. The unit should have facility of vertical swing and horizontal rotation of the tube head to ensure X Ray of any anatomy even within limited space.		
4	The unit must have an effective braking system for parking and transport. The tube stand must be fully counterbalanced.		
5	The unit must have intelligent graphical LCD display with atleast 60 user-configurable anatomy presets for ease of operation to the operator.		
6	The exposure release switch should be detachable with a cord of sufficient length (atleast 3 m) The unit should have integrated Battery pack in order to take atleast 80 X – Ray exposures in case of electricity failure at site.		
7	**The Generator:** h. Microprocessor controlled high frequency / inverter type of high frequency (40 KHz or more) for constant output. Higher Frequency will be preferred. i. It should have power rating of		

	2.5 kW or more j. It should have a digital display of mAs and kV. k. KV range : 40 kv to 100 kV or wider range l. mA range: 10mA-100 mA or more m. Exposure time of 40 ms to 3.5 s or less n. KV selection: 40 kV to 100 kv, selectable in 1 kV steps h. mAS selection: 0.4 mAs to 140 mAs or more		
8	**X-Ray Tube and Collimator:** e. Stationary anode having focal spot size less than 1.4mm. f. Output of tube should match with that of generator. g. Light Beam diaphragm / Double layer Collimator with auto cut off switch. h. Collimator rotation +/- 90 degrees and Tube Head rotation – Vertical – at least 280 degrees, Horizontal – atleast 350 degrees should be possible		
9	***The unit should operate on single phase power supply and should have plug in facility to any standard wall outlet with automatic adaptation to line voltage 160 to 250 volts, 15 Amp plug.The Leakage radiation level at 1 meter from the focus should be less than 70 mR. Products having minimal leakage radiation level will be preferred. (Please attach relevant test report). The weight of unit with inbuilt battery pack should not be more than 250 kg The Systems should be fully safe with respect to:-*** ***d.*** Over current ***e.*** Over Voltage ***f.*** Maximum loading of tube		
10	Manufacturer / supplier should have ISO 13485 certification.		
11	Should be an AERB approved product.		
12	User/Technical/Maintenance manuals to be supplied in English.		
13	***Warranty :-*** • ***Comprehensive warranty for 02 years***		

	• ***Comprehensive Maintenance for 03 Years***		
14	ISO 13485 certificate of the product.		
15	AERB approval certificate of the product.		

(Note:- Signature by authorized official of the manufacturer on all the pages of the compliance statement is must)

ANNEXURE-XV
Item No:-5

TECHNICAL SPECIFICATION COMPLIANCE STATEMENT

(Note:- Compliance Report to be submitted in a tabulated and point wise manner clearly mentioning the page/ para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered)

Name of Item : Portable ECG : 12 channel ECG Machine

Sl	Parameters	Quoted Specification (***To be filled by the manufacturer***)	Deviations, if any
1	Should have 8" high resolution color touch-screen		
2	Should have alphanumeric keyboard and one touch operation		
3	Should have 12 leads simultaneously		
4	Should be Automatic measurement and interpretation tested with authoritative CSE/AHA/MIT database		
5	Should be Built in rechargeable Li-ion battery for 300 ECG report printing		
6	Should have minimum 200 ECG recordings storage capacity		
7	Rhythm should be Single or Three channel selectable		
8	Support external printer via USB port		
9	Should have Auto/Manual/Rhythm/R-R/off		
10	Should have inbuilt Thermal Printer		
11	Record speed should 5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s (+_ 3%)		
12	Should have Display size 320X240 dots single color /multicolor LCD Screen		
13	Should have Automatic Baseline Adjustment		
14	AC : 100V-115V/220V, 50/60 Hz, built-in rechargeable Li-ion battery; voltage =14.8V		
15	Weight should be max. 5kg		

16	Should have 420mm* 330mm* 105mm dimension		
17	Should be USFDA or CE Certified Quality approved		
18	***Warranty :-*** • ***Comprehensive warranty for 02 years*** • ***Comprehensive Maintenance for 03 Years***		
19	US FDA certificate / CE certificate for the product.		
20	ISO certificate of the manufacturer.		

(Note:- Signature by authorized official of the manufacturer on all the pages of the compliance statement is must)

ANNEXURE-XV
Item No:-6

TECHNICAL SPECIFICATION COMPLIANCE STATEMENT

(Note:- Compliance Report to be submitted in a tabulated and point wise manner clearly mentioning the page/ para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered)

Name of Item : ELECTRIC SUCTION MACHINE

Sl	**Name**	Quoted Specification (***To be filled by the manufacturer***)	**Deviation if any**
1 Description of Function			
1.1	To extract fluid from the body during surgery or emergency treatment		
2 Operational Requirements			
2.1	• Shall have Motor of minimum ¼ H.P. capacity • The machine should be portable on four wheels and handle for transportation		
3 Technical Specifications			
3.1	• Cabinet to be made of mild steel with epoxy powder coated finish. • It should have two graduated polycarbonate jars of 1.5 liters capacity with synthetic rubber lids. The bottle shall be fitted with the arrangement to prevent overflow of fluid. • The suction machine should be capable of producing minimum vacuum of 700 (+/- 10 mm Hg) approx mm Hg which should be adjustable and monitored by vacuum gauge of 100 mm. • Free air displacement 30 ~ 35 ltrs/min. • Noise level 50 dB +/- 03 dB. • Non collapsible silicon tubing • Bacterial filter fitted on top.		
4 System Configuration Accessories, spares and consumables			
4.1	• Following accessories should include b. Bottles 2 Nos. c. Lids 2 Nos. d. Rubber Seals 2 Nos.. e. Suction Tubing set 1 No • Any other standard accessories desired for proper functioning of the machine.		
5 Environmental factors			
5.1	• The unit shall be capable of being stored continuously in ambient temperature of 0-50deg C and relative humidity of 15-90% • The unit shall be capable of operating		

Sl	Name	Quoted Specification (*To be filled by the manufacturer*)	Deviation if any
	continuously in ambient temperature of 10 -40deg C and relative humidity of 15-90%		
6 Power Supply			
6.1	• Power input to be 220-240VAC, 50Hz fitted with Indian plug • A fuse or a resettable circuit breaker of a appropriate capacity should be incorporated for protection of motor		
7 Standards, Safety and Training			
	• Should be FDA/CE approved product. • Manufacturer should have ISO 9001:2008 & ISO 13485:2003 certification for quality standards. • Comprehensive training for lab staff and support services till familiarity with the system on site.		
8 Documentation			
	• Service manual in English. • Certificate of calibration and inspection • Log book with instructions for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and company service engineer should be clearly spelt out. • Compliance Report to be submitted in a tabulated and point wise manner clearly mentioning the page/ para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered.		

(Note:- Signature by authorized official of the manufacturer on all the pages of the compliance statement is must)

ANNEXURE-XV
Item No:-7

TECHNICAL SPECIFICATION COMPLIANCE STATEMENT

(Note:- Compliance Report to be submitted in a tabulated and point wise manner clearly mentioning the page/ para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered)

Name of Item : Electric Sterilizer Seamless shell, with automatic lifting handle with tray all supplied with power cord

Sl	Parameters	Quoted Specification (***To be filled by the manufacturer***)	Deviations, if any
1	Should be IS : 5022–1989		
2	Made of Seamless S.S. Sheet of grade-304 (18 Cr-8 Ni).Suitable for 220V, 50 Hz, Single Phase, AC Supply.		
3	L: 430, W: 200, H: 150mm, Power: 1.50 Kw		
4	***Warranty:-*** • ***Comprehensive warranty for 02 years*** • ***Comprehensive Maintenance for 03 Years***		
4	IS 5022-1989 certificate.		

(Note:- Signature by authorized official of the manufacturer on all the pages of the compliance statement is must)

ANNEXURE-XV
Item No:-8

TECHNICAL SPECIFICATION COMPLIANCE STATEMENT

(Note:- Compliance Report to be submitted in a tabulated and point wise manner clearly mentioning the page/ para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered)

Name of Item : Oxygen Cylinder B Type with flow meter and wrench

Sl	Parameters	Quoted Specification (***To be filled by the manufacturer***)	Deviations, if any
1	The oxygen cylinder should confirming to IS : 7285 (Part 1) – 2004 and with appropriate valves confirming to IS: 3224-2002 for Medical oxygen gas service Cylinders subjected to hydrostatic stretch test at pressure of 250 Bar as required under rule 35 of the Gas Cylinder Rules , 2004.		
2	10 ltrs water capacity. Supplied with Flow meter and wrench.		
3	IS:3224-2002 certificate for the valves.		
4	IS:3224-2002 certificate for the valves.		

(Note:- Signature by authorized official of the manufacturer on all the pages of the compliance statement is must)