Sl No. 03

Appendix-'1C(i)'

QRS/SPECIFICATIONS AND TRIAL DIRECTIVES OF MEDICAL EQUIPMENT OF PAEDIATRICDEPARTMENT :-

Sl. No	NAME OF THE EQUIPMENT	IS IT AVAILABLE IN PET (AS PER 100 BEDDED HOSPITAL)	IS QRs AVAILABLE	Remarks
1	INFANT OPEN CARE SYSTEM (RADIANT WARMER)	**YES** (Sr No.239)	**YES** FILE No 33(C) , APPROVED ON 18/05/2015	**Annexure-I**

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG(med)

Recommended / ~~Not Recommended~~

Appendix-1C (x)

1.QRS/SPECIFICATIONS AND TRIAL DIRECTIVES OF INFANT OPEN CARE SYSTEM(RADIANT WARMER)

SPECIFICATIONS	PROCEDURE SUGGESTED FOR TRIAL BY BOARD OF OFFICERS	RESULTS EXPECTED/ DESIRED
1. Essential parts a) Quartz/Ceramic/Calrod based warming system with microprocessor based controls, probes & alarms and has servo and manual temperature control facility b) Cart & bassinet c) Procedure & Examination light d) Facility of inbuilt baby weighing machine e) Facility for bed height adjustment which should be continuous and jerk free f) X-ray cassette holder g) Drawer h) IV stand (SS) i) Monitor shelves **2.** Should have a mechanism to provide continuous heat while doing any procedure like X-ray or even surgery to prevent hypothermia thus providing uninterrupted thermoregulation to the baby **3.** Should have two sensing probes to monitor Core and peripheral temperatures **4**. It should have twin thermistor probes to improve accuracy of temperature readings.	Board should check physically during demonstration. OEM should submit an undertaking and documents in this regard.	As per specification.

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG(Med)
Recommended / Not Recommended

Appendix-1C (xi)

SPECIFICATIONS	PROCEDURE SUGGESTED FOR TRIAL BY BOARD OF OFFICERS	RESULTS EXPECTED/ DESIRED
5. Cart a) Should swivel on 4 wheels of at least 4" (4 inch) diameter with foot operated brakes on at least 2 front wheels **6. Dimensions** a) Variable height - 180- 220 cms b) Width - 60-75 cms c) Depth - 100-135 cms **7. Bassinet** a) Collapsible transparent acrylic side walls b) Mattress material i. High quality & comfortable for the infant during prolonged period of treatment ii. Soft and easy to clean iii. X-ray transparent iv. Fire retardant v. Allows air to pass through but does not allow water to seep in **8. Bassinet tilt** a) Should allow tilt for Trendelenburg as well as reverse Trendelenburg position b) Should have continuous jerk free variable bed tilting mechanism for a bed tilt on either side to ±10-15 degree		

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG(med)

Recommended / Not Recommended

SPECIFICATIONS	PROCEDURE SUGGESTED FOR TRIAL BY BOARD OF OFFICERS	RESULTS EXPECTED/ DESIRED
c) Should have motorized variable height adjustment mechanism to vary the cradle/baby bed from the ground, should be able to adjust height of the bed from either side of the warmer d) Should have inbuilt weighing scale which can weigh up to 10 kg with facility for Tare facility and e) Good to have the facility for data storage of the baby's weight and temperature (optional) **9. Warming system** a) Quartz/Ceramic/Calrod based heating system b) Control - Microprocessor controlled with soft touch control panel c) Self test function performed at power on d) Digital display should show following parameters i. Set temperature ii. Present temperature of the baby iii. Heater output e) Mode - Manual & skin (servo) f) Manual mode i. Adjustable in steps from 0 to 100% in increments of 10% ii. Heater power should be reduced to 50 - 60% after 10-15 minutes in manual mode for baby safety		

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG (Med)

Recommended / Not Recommended

SPECIFICATIONS	PROCEDURE SUGGESTED FOR TRIAL BY BOARD OF OFFICERS	RESULTS EXPECTED/ DESIRED
g) Skin mode (servo mode) i. Set point range - 32 – 38 degrees C h) Skin temperature display i. Accuracy - ±0.1-0.3 degrees C ii. Resolution - 0.1 degree C i) Temperature probe-Only thermistor probes and wire should be easy to clean and long lasting j) No need of temperature probe calibration k) Control unit should have facility to convert Centigrade to Fahrenheit conversion l) Should have LCD graphical display with the facility of trending temperature (Optional) m) Text message to appear in the text display, if there is any alarm. n) Continuous measurement with Large easy to read display **10. Alarms** a) Audiovisual alarms with a display of text messages about the alarms i. Probe failure ii. Heater failure iii. High and low baby temperature (more than 0.5 degree C difference) iv. Power failure v. System failure vi. Silence/reset switch		

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG(Med)

Recommended / Not Recommended

Appendix-1C (xiv)

SPECIFICATIONS	PROCEDURE SUGGESTED FOR TRIAL BY BOARD OF OFFICERS	RESULTS EXPECTED/ DESIRED
11. Heating unit - Should be swivel (if required) for accommodating X-Ray unit and should have self lock facility. **12.** It should have inbuilt X Ray tray to allow taking X-Rays without disturbing baby **13. Integrated procedure light**: Should have an integrated procedure light with intensity of atleast 1500 lux **14. Integrated examination light** (different from procedure light) a) Illuminance - at least75 foot candles at mattress centre b) Good to have dual examination lamp with dimming facility **15. Apgar Timer** a) Timer with stopwatch facility b) Reset facility **16. I.V. stand** a) Strong IV stand (S.S) with height adjustable and facility to fix large number of infusion pumps **17.** Integrated monitor shelves - Two in number **18**. Should have integrated atleast one large size drawer to keep articles		

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG(Med)
Recommended / Not Recommended

SPECIFICATIONS	PROCEDURE SUGGESTED FOR TRIAL BY BOARD OF OFFICERS	RESULTS EXPECTED/ DESIRED
19. Integrated X- Ray cassette holder a) Sliding holder located just below under surface of bassinet, with markings to help placement of cassette **20. Power consumption** - Less than 1 K.W **21**. Should have RS232 Port for data / Network connection. **22**. All metal parts of the equipment should be corrosion resistant and Epoxy/Powder coated **23.** All consumables required for installation and standardization of system to be given free of cost **24**. Availability of spares for at least 7 years after date of installation **25. Standards, safety and training** a) Should be US FDA or European CE approved product b) Manufacturer should be ISO certified for quality standards c) Electrical safety conforms to standards for electrical safety IEC 60601-1 (OR EQUIVALENT international / national standard) General requirement for Electrical safety of Medical Equipment		

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADs (med)

Recommended/Not Recommended

SPECIFICATIONS	PROCEDURE SUGGESTED FOR TRIAL BY BOARD OF OFFICERS	RESULTS EXPECTED/ DESIRED
d) Should have local service facility. The service provider should have the necessary equipments recommended by the manufacturer to carry out preventive maintenance test as per guidelines provided in the service/maintenance manual **26. Warranty for 5 years & provision of CMC for next five years** **27. Items covered under warranty/CMC** a) Warranty and CMC must include (but not limited to) the following: all electrical and electronic parts, weighing, heating parts and casings thereof; cart and bassinet b) Consumable accessories, if any, not covered in warranty/CMC should be clearly specified. c) Prices of consumables and accessories should be quoted separately and frozen for the period of warranty and CMC. **28. Power supply** a) Power input to be 220-240VAC, 50Hz b) Suitable Autovoltage corrector with spike protector should be available **29. Environmental factors** a) Shall meet IEC-60601-1-2 :2001 General Requirements of Safety for Electromagnetic Compatibility or should comply with 89/366/EEC; EMC-directive		

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADGs (Med)
Recommended / Not Recommended

SPECIFICATIONS	PROCEDURE SUGGESTED FOR TRIAL BY BOARD OF OFFICERS	RESULTS EXPECTED/ DESIRED
b) The unit shall be capable of being stored continuously in ambient temperature of 0-50deg C and relative humidity of 15-90% c) The unit shall be capable of operating continuously in ambient temperature of 20-40 deg C and relative humidity of 15-90% **30. Documentation** a) User/Technical/Maintenance manuals to be supplied in English b) Certificate of calibration and inspection from factory c) List of important spares and accessories with their part number and costing d) 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 **31. Essential accessories to be supplied at initial purchase with each piece of equipment** a) Reusable thermistor temperature probes (For measuring core temperature): 05 (Five) per radiant warmer b) Reusable thermistor temperature probes (For measuring periphery temperature): 05 (Five) per radiant warmer c) Integrated RS232C output: One		

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.C.

Recommendation of ADs (med)
Recommended / Not Recommended

Appendix-1C (xvii)

SPECIFICATIONS	PROCEDURE SUGGESTED FOR TRIAL BY BOARD OF OFFICERS	RESULTS EXPECTED/ DESIRED
32. The rates of consumable accessories should also be quoted separately Onsite physical demonstration/training of the equipment to all the end users with all the requested facilities will be mandatory		

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Presiding Officer

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Recommendation of ADG (Med)

Recommended / Not Recommended

Appendix-'24(i)'

QRS/SPECIFICATIONS AND TRIAL DIRECTIVES OF MEDICAL EQUIPMENT OF PAEDIATRICDEPARTMENT :-

Sl. No	NAME OF THE EQUIPMENT	IS IT AVAILABLE IN PET (AS PER 100 BEDDED HOSPITAL)	IS QRs AVAILABLE	Remarks
1	BUBBLE CPAP	**NO.** NOT AVAILABLE IN PET OF 100 BEDDED HOSPITAL BUT IT IS AVAILABLE IN PET OF 200 BEDDED HOSPITAL (Dept of Paediatrics. Sr No.21)	**NO**	**Annexure-II**
2	NON-INVASIVE BILIRUBINOMETER	**NO**	**NO**	**Annexure-III**

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	PCO

Recommendation of ADG (Med).

Recommended / Not Recommended

Appendix-'26(ii)'

1.QRS/SPECIFICATIONS AND TRIAL DIRECTIVES OF BUBBLE CPAP

SPECIFICATIONS	PROCEDURE SUGGESTED FOR TRIAL BY BOARD OF OFFICERS	RESULTS EXPECTED/ DESIRED
BCPAP machine should have the following components: 1. CPAP generator 2. Servo humidifier including reusable chamber, temperature probe, heater wire with adaptor 3. Air-oxygen blender 4. Single equipment mounting stand with swivel brake casters (four) 5. Reusable bubble CPAP circuits 6. Nasal interface including nasal prongs, and masks of different sizes. 7. Head bonnet of different sizes 8. User manual (English) **CPAP Generator :** 1. Capable to deliver nasal/ nasopharyngeal CPAP and heated humidified high gas flow through nasal cannula/ mask (>2 LPM). 2. Circuits (reusable) should be compatible with different nasal interfaces 3. CPAP range: 1 – 10 cm of H2O 4. Accuracy: ±1 cm of H2O. 5. Gas flow range: 1 – 12 LPM. 6. Pressure release valve: safety valve mechanism to release excessive pressure	Board should check physically during demonstration. OEM should submit an undertaking and documents in this regard.	As per specification.

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG (med)

Recommended / Not Recommended

Appendix-2C (iii)

SPECIFICATIONS	PROCEDURE SUGGESTED FOR TRIAL BY BOARD OF OFFICERS	RESULTS EXPECTED/ DESIRED
7. Reservoir (Bubble chamber) capacity: >300 ml. 8. Generator tube: graduations in the tube should be clearly readable from a distance of 6 feet, and it should be snugly fitting into the chamber and the chamber should be transparent for checking water level. 9. Equipment mounting stand: should be supplied with a stand with clamps for mounting blender, bubble chamber and humidifier **Servo Controlled Humidifier** : 1. Capable of working with both CPAP and HHHFNC 2. Should be capable of supplying fully saturated gas at 37^0C. 3. Flow resistance <20 cm H2O/ L/ sec (Ins R <12, Exp R <8) 4. Temperature range: 31^0C – 40^0 C 5. Temperature control: ± 20C 6. Digital display of temperature: 5^0 C – 80 ^{0} C 7. Range of working room temperature: 20^0 C – 30^0 C 8. Capable of ambient humidity compensation 9. Should be compatible with both reusable & disposable chambers and circuits.		

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG (Med)

Recommended/Not Recommended

SPECIFICATIONS	PROCEDURE SUGGESTED FOR TRIAL BY BOARD OF OFFICERS	RESULTS EXPECTED/ DESIRED
10. Must have water level indicator in the chamber. 11. Minimum warm up time: <30 min 12. Servo humidifier should be US FDA or CE or BIS certified. **Air-oxygen blender** 1. Oxygen concentration range should be 21 – 100%. 2. Number of ports should be two (02). 3. Accuracy: ±3% full scale 4. Weight: should be less than 2 kilograms 5. It Should work with gas supply pressure: 30 – 75 PSIG 6. Primary outlet flow range: 1 – 15 L/ min 7. Auxiliary outlet flow range: 1 – 15 L/ min 8. External calibration should be done at least once in six months. 9. It should be supplied with air & oxygen hose at least 5 metres in length with suitable adaptors for wall oxygen and gas panel. 10. Blender should be US FDA or CE or BIS certified **Power Supply** 1.Power input to the Servo Humidifier to be 220 – 240 VAC, 50 Hz		

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG(med)

Recommended / Not Recommended

Appendix-2C (v)

SPECIFICATIONS	PROCEDURE SUGGESTED FOR TRIAL BY BOARD OF OFFICERS	RESULTS EXPECTED/ DESIRED
2. Power cord for the humidifier should not be less than 3 metre and to be fitted with Indian plug **Documentation** 1.Certificate of calibration and inspection from factory 2.User manual in English 3. List of all spare parts and accessories with their part number and costing. 4. Must submit user list and performance report within last 3 years from major hospitals **Standards, Safety and Training** 1. Demonstration of quoted model is a must. 2. Should have local service facility. The service provider should have the necessary equipments recommended by the manufacturer to carry out preventive maintenance test as per guidelines provided in the service/maintenance manual 3. Warranty for 5 years and provision of CMC for next 5 years **Items to be supplied with each machine** 1. Equipment mounting stand (stainless steel) with clamps (three) and hanger (1) - 01 unit 2. Reusable patient circuit for all modes including HHHFNC - 02 sets 3. Servo controlled humidifier with digital temperature display - 01 set 4. Heater wire for servo humidifier for reusable circuits - 02 sets 5. Heater wire adaptor for servo humidifier - 02 sets 6. Temperature/ flow probe for servo humidifier - 02 sets		

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.C.

Recommendation of ADG(med)

Recommended / Not Recommended

Appendix-2C (vi)

SPECIFICATIONS			PROCEDURE SUGGESTED FOR TRIAL BY BOARD OF OFFICERS	RESULTS EXPECTED/ DESIRED
7. Reusable humidifier chamber	-	02 sets		
8. Nasal interface (disposable kit)	-	10 sets		
9. Nasal mask CPAP (small) (1 set contains 10 units)	-	01 set		
10. Nasal mask CPAP (medium)	-	01 set		
11. Nasal mask CPAP (large)	-	01 set		
12. Nasal prongs for CPAP- size '0'	-	10 sets		
13. Nasal prongs for CPAP- size '1'	-	10 sets		
14. Nasal prongs for CPAP- size '2'	-	10 sets		
15. Nasal prongs for CPAP- size '3'	-	10 sets		
16. Infant bonnet (17 cm- 22 cm)	-	10 pieces		
17. Infant bonnet (22 cm- 25 cm)	-	10 pieces		
16. Infant bonnet (25 cm- 29 cm)	-	10 pieces		
16. Infant bonnet (29 cm- 36 cm)	-	10 pieces		
17. Oxygen analyzer compatible with Bubble CPAP machine.	-	01 unit		
18. Air-oxygen blender	-	01 unit		
19. Hose for oxygen connection (for wall connection)	-	05 metres		
20. Hose for compressed air (for wall connection)	-	05 metres		
21. CPAP generator/ bubble chamber (Disposable).	-	02 sets		
Consumables other than those mentioned above required for smooth functioning of the equipment should be added with rates in the above-mentioned list.				

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG(med)

Recommended/ Not Recommended

Appendix-2C (vii)

2. QRS/SPECIFICATIONS AND TRIAL DIRECTIVES OF NON-INVASIVE BILIRUBIN-OMETER

SPECIFICATIONS	PROCEDURE SUGGESTED FOR TRIAL BY BOARD OF OFFICERS	RESULTS EXPECTED/ DESIRED
1. Measuring method should measure the optical density difference at two wavelengths to determine the yellowness of the subcutaneous tissue. 2. The instrument should be suitable for non-invasive bilirubin measurement of neonates with gestational age 27 — 42 weeks and 1- month post-natal age; body weight 900 grams to 4000 grams. 3. Measurement range: 0.0mg/dL to 20mg/dL or 0 µmol/L to 340 µmol/L 4. Error of estimate (SEE): ± 1.5mg/dL or ± 25.5µmol/L 5. It should measure readings at sternum and forehead. 6. Should have alarms when measurements are greater than 20mg/d1 or 340 µmol/L 7. Can be used in all skin colors, >35 weeks gestational age, pre- phototherapy. 8. Light source should be Pulse xenon arc lamp. 9. Light source should have life of more than 10000 measurements. 10. Light source checker should be built in to the charger base. 11. Should have detectors with Silicon photodiodes. 12. Should have Ni-MH battery as power source. 13. Protection type and level Internally-powered instrument, BF type 14. It should measure at least 400 single measurements when fully charged. 15. It should have operating temperature range from 10°C to 40°C.	Board should check physically during demonstration. OEM should submit an undertaking and documents in this regard.	As per specification.

Member-I	Member-II	Member-III	Member-IV	Member-V	Member-VI	Member-VII	Member-VIII	Member-IX	Member-X	Member-X	Member-XI	Member-XII	P.O.

Recommendation of ADG(med)

Recommended / Not Recommended

Appendix-2C (viii)

SPECIFICATIONS	PROCEDURE SUGGESTED FOR TRIAL BY BOARD OF OFFICERS	RESULTS EXPECTED/ DESIRED
16. It should be light weight; less than 250 g. 17. It should be supplied with: Charger unit with a checker, AC adapter, Carrying case and wrist strap, Power cable adapter set. It should be USFDA/ European CE from a notified body with a 4-digit notification number certified.		

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