RAJASTHAN MEDICAL SERVICES CORPORATION LTD.
D- Block, SwasthyaBhawan, TilakMarg, C-Scheme JAIPUR (Raj)
Ph. No. 0141-2223887, Fax No. 0141-2228065 CIN: U24232RJ2011SGC035067 E-Mail –edepmrmsc-rj@nic.in

No F-8(215) RMSC/EPM/M-4/NIB-579/2020-21/ 7545 **Dated:** 25.06.2021

CLARIFICATION/CORRIGENDUM/ADDENDUM

Subject: Amended technical specifications, of bid document of item 1. TRANSCUTANEOUS BILIRUBINOMETER 2.RADIANT WARMER 3. RADIANT WARMER WITH OXYGEN-PROVISION 4. LED PHOTOTHERAPY UNIT under No F-8(215) RMSC/EPM/M-4/NIB-579/2020-21/510 Dated: 22-03-21

In reference to subject cited above NIB-579, various representation received from the firms and issues raised by the bidder are examined by the competent authorities and technical committee. The following clarification/corrigendum/addendum is issued for inclusion in bid document of items as below:-

1. **Revised Technical Specification of 1.TRANSCUTANEOUS BILIRUBINOMETER 2.RADIANT WARMER 3. RADIANT WARMER WITH OXYGEN-PROVISION 4. LED PHOTOTHERAPY UNIT:-**

S.N	REVISED TECHNICAL SPECIFICATIONS OF TRANSCUTANEOUS BILIRUBINOMETER
1.	Intended Use For Preterm Fullterm And Post Term Babies Up To 20 Post Natal Days
2.	SERUM BILIRUBIN RANGE 0 TO 20mg/Dl
3.	Accuracy +/- 1 mg /dl
4.	Repeatability +/- 1 mg / dl
5.	Weight ≤250gm (with battery)
6.	Battery Type - Lithium ion
7.	Battery Life - Two Year Minimum
8.	Measurement With Fully Charge Battery - **minimum 100 single measurements**
9.	Power Supply (can be operated with A/C Adaptor/ Charger) Input- 100-240 VAC, 50/60Hz, **0.4-A-2A**
10.	Should have user friendly control panel
11.	It should have facility to displayed observed bilirubine in mg/dl
12.	Accessories Spare Parts Consumables • 1 Extra Charger • 1 Extra Battery • Tip Cover
13.	• Standards and Safety Should Be USFDA approval/CE (From Notified Body)/BIS. • Baby Contact Material Should Be Bio Compatible as Per relevant ISO Standard Requirement
14.	Should have reusable measuring probe which can be cleaned with disinfectant.
15.	Should have large easy to read display.
16.	**WARRANTY**
17.	Warranty of 3 years from the date of installation.
18.	**Documentation**
19.	User or Technical or Maintenance Manuals (In English) to be supplied.
20.	**Other General Term and Conditions**
21.	Installation will be done by supplier free of cost.

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22. The company shall maintain the make and model name/number of the quoted equipment and submit the technical brochure of the quoted model in the technical bid along with compliance sheet as per technical specification.
23. Preventive maintenance schedule – As per OEM (Mention PM Schedule)
24. Calibration Schedule – As per OEM (Mention Schedule)
25. Life of equipment – As per OEM

Revised Technical Specification of Radiant Warmer

1. It should be fixed height microprocessor controller radiant warmer with manual mode, servo mode & Pre Heat options.
2. It should have facilities to display skin set, observed temperature in °C and heat power separately.
3. Should have user friendly touch panel control.
4. Should have manual mode and servo mode settings.
5. Mode of operation should be clearly displayed.
6. In servo mode, baby set temperature should be 32 to 38°C.
7. The desired temperature range from 25 to 40 degree C and settable temperature can be from 32 to 38°C.
8. The resolution should be 0.1 degree C and accuracy should be +/- 0.2 °C.
9. Manual Mode can adjust heater output 10-100% with 5-10% increment an auditory and visual alarm shall be given at least every 15 min.
10. In manual mode, heater cut off/switch off, if the maximum irradiance at any point of the mattress area exceeds a total irradiance level of 10mW/cm2.
11. It should have quartz/ Calrod infrared heater.
12. Should have a facility to lock the keyboard to avoid unwanted user modification of the set parameters.
13. It should have integrated basinet trolley; bed should be tilt able and have provision for x-ray cassette holder, should be tilt able and have provision for x-ray cassette holder.
14. It should have audiovisual alarm facility for overheating beyond set temperature range.
15. It should have alarm facility for patient temperature less than or greater than the required temperature i.e. above or below the set range. Machine should sense the skin probe failure and cut off the heater.
16. Once the skin probe gets off from the bed of the patient the Machine should alarm.
17. Warmer head should be rotatable in different directions, so as to allow taking X-Ray.
18. It should have alarm for probe failure, power failure, system failure and heater failure.
19. It should have inbuilt internal battery to indicate power failure indication at least ½ hour during power failure.
20. Integrated basinet trolley & wheel base should be made of corrosion free material.
21. LED observation light should be provided for observing the baby.
22. It should have facility to auto reset the system in case of hang up caused by power fluctuation.
23. Should be supplied with good quality thermal sealed & water proof Mattress. Transparent collapsible side walls easily detachable for cleaning Mattress size should be minimum 20"X 30".
24. Should have a feather touch operation with large digital display and comprehensive alarms. Control panel should be liquid proof and allow easy and hygienic disinfection.

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25. Bed should be about 80-100 cms from the floor and 80-90 cms from the heat source, as per international guidelines.
26. Should have lockable castor (atleast 4" size) wheels.
27. Indicator light shall be provided to indicate that warmer is ready for normal use/ or better technology through display.
28. Markings on the bassinet and X-ray cassette holder is mandatory to enable proper positioning of the baby while doing the X-Ray.
29. The size of the drop down side should above the mattress surface and should be at least 6 mm thick; clear and transparent.
30. Should have an inbuilt logic in the software to ensure there is no overheating of baby skin at any point of time.
31. X-Ray Cassette tray should be of optimum size and should adopt up to 20 mm thick X-Ray cassette. The baby bed should be crevice free for ease of cleaning, infection control.
32. Skin temperature probe should be small in size to fix the probe firmly on the infant.
33. Should be supplied with User/Technical/Maintenance manuals to be supplied in English and additional User manual in Hindi language.
34. Should have standard IV pole (sturdy; non rusting; medical grade stainless steel; adjustable to max height of 6 feet from the ground level), monitor tray (12X10 inches; 270 deg swivel; axed at level of warmer display) and storage drawer.
35. Power input to be 220-240 VAC, 50Hz fitted with Indian plug at least 3 mtr. Power Cable.
36. Equipment should be US FDA approved / CE certified from notified body registered in European commission/BIS.
37. Warranty: Three years on equipment from the date of installation.

38. The company should mention the make & model name/number of the quoted equipment and submit the technical brochure of the quoted model in the Technical bid along with compliance sheet as per technical specifications.

Revised Technical specification of Radiant Warmer with Oxygen-Provision

1. Mobile newborn resuscitation table with fixed-height radiant warmer.
2. Antistatic castors, 2 with breaks.
3. Table surface with mattress with infant head/shoulder support.
4. Mattress-padding: foam density approx. 21 - 25 kg/m3
5. Mattress cover should be thermal sealed and waterproof.
6. Side boards should be transparent with BPA free biocompatible material acryl/ Polycarbonate, drop down and lockable.
7. Under table 2 storage drawers.
8. Side rails allow for mounting of accessories.
9. Hood suspended above the table integrates heating element and overhead light.
10. Overhead light: LED Light or Halogen Light.
11. Provision for integration of two 5 L Aluminum oxygen bottles.
12. Control unit should have T-piece Resuscitator with blender and meconium aspirator suction (Electrical Suction) facility with knob facility.
13. 10 nos. T-pieces with 10 circuits and 15 nos. masks (5 each in three sizes) should be supplied with unit at the time of installation.
14. Heating element: quartz/ Calrod heating element with lifelong guarantee.
15. Control unit allow skin temperature preset indicator and drives radiant heater output in servo and manual mode.

16. Unit should have pre-heating mode.
17. Integrated timer: 1 to 59 min with count-up feature.
18. Temperature range, skin: 34 to 38°C (user pre-settable)
19. Monitoring of skin temperature by means of sensor, range: 30 to 42°C
20. Heater output: 0 to 100% in increments of 5 to 10%.
21. Control unit: audiovisual alarms according to timer and temperature presets avoiding overheating.
22. Display reports systems errors, sensor failure. Once the skin probe gets off from the patient the machine should alarm.
23. Power requirement: 220 V/ 50 Hz
24. Power consumption not more than 800 W.
25. Equipment should be US FDA approved / CE certified from notified body registered in European commission/BIS.
26. Equipment should be supplied (free of cost) with:
    a. Mattress (1No.)
    b. Skin temperature probe including connection cable (1No.) :- Reusable
    c. Spare skin temperature probe including connection cable (10 No.) :- Reusable
    d. Aluminum Oxygen bottles 5 L (2 Nos.)
    e. Spare set of fuses (5 Set)
    f. Operating / user manual (1No)
27. Warranty: Three years on equipment from the date of installation.
28. The price of T-piece Resuscitator shall be quoted in BOQ separately .
29. T-Piece Resuscitator
    1. Infant resuscitator with Aluminum Metal or any sturdy material casing for durability.
    2. Should be provided with Metal Gas inlet (as per type of institution requirement) and patient outlet connectors.
    3. Gas inlet should fit standard oxygen line without require any special tubing.
    4. Standard 15mm Female Connector should accept standard Infant Resuscitator T-Piece Circuits without the need for an adapter.
    5. Manometer Range -20 to 80 cm H2O/mbar -2 to 7.8 kPa *Color coded.
    6. Circuit Cap Design should be with a friction fit.
    7. Silicon autoclavable transparent masks.
    8. Circuits with universal compatibility.
    9. Circuit protective Cap, covers patient end of circuit.
    10. Compact size ensuring convenience in transportation.
    11. This equipment should have blender and meconium aspirator suction (Electrical Suction) facility
    12. Equipment should be US FDA approved or CE certified from notified body registered in European commission.

Revised Technical Specification of LED Phototherapy Unit

1. Lifetime of LED 20,000 to 30,000 hours.
2. Spectral Irradiance from 30 to 60 $\mu W \cdot cm^{-2} \cdot nm^{-1}$ at 45 cm distance between bed and light
3. Should have multilevel intensity control from minimum to maximum
4. At the tilted position, the irradiance is 30 $\mu W \cdot cm^{-2} \cdot nm^{-1}$ at 45 cm distance between bed and light
5. Wavelength is 450 – 480 nm, and it's free from UV and IR radiation.
6. Effective surface area - 200 X 400 mm within a irradiance ratio of 0.4 (min/max irradiance)
7. Digital (LCD) Timer for monitoring therapy hours (resettable) & lamp usage hours (non resettable)

8. Have feather touch key pad
9. Cooling Fan/ heat sink is provided to dissipate the heat created by LED's
10. Light head should be compact to use along with the Radiant warmer & provided with tilting facility so that the unit is not coming directly under warmer.
11. Smooth Height adjustment mechanism & seamless height adjustment from minimum to maximum height
12. Minimum height – 1150 mm or less from the floor to use near the mother bed
13. Maximum height – 1500 mm or more from the floor to use with the incubator and Radiant warmer.
14. Coating: Epoxy/powder coated body for scratch and rust prevention and
15. PU (Poly Urethane)/ABS/Fiber coating for plastic
16. Mobility: Three/four castors; two rear castors provided with brakes
17. The base of the unit is such that it will go beneath any Incubator/bed/trolley, with minimum of 100 mm floor clearance
18. Should be supplied with white LED for patient examination
19. The unit should be supplied with reusable eye masks, Quantity: 10
20. Equipment should be US FDA approved / CE certified from notified body registered in European commission/BIS.
21. Warranty: Three years on equipment from the date of installation.

Note:- Please note that all above amendments/corrigendum in technical specifications/bid conditions is the integral part of (Section-V, Schedule of Supply, and Point no. 3) and the bid document. This corrigendum/ addendum should be signed and annexed with bid document. All other terms & conditions remains the same.

Executive Director (EPM)
RMSCL, Jaipur