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F-8() RMSC/EPM/M-5/NIB-703/ 60

Date:- 10/11/22

Clarification/Corrigendum/Addendum

Subject:-Revised Technical Specifications and Revised bid submission date of the rate contract for Radiant Warmer UNIT for under NIB No. F-8() RMSC/EPM/M-5/NIB-703/2022-23/465 Date 21.09.2022

In Reference to subject cited above and NIB-703, the various representations received from the firms and issues raised by the Bidders are examined by the competent Authorities and technical committee. The following Corrigendum/Addendum is issued for inclusion in bid document as below:-

1. Revised Technical Specifications of Radiant Warmer:-

- 1. It should be fixed height microprocessor controller radiant warmer with manual mode, servo mode & Pre Heat/ Pre Warm mode options with mode settings.
- 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. Mode of operation should be clearly displayed.
- 5. In servo mode, baby set temperature should be 32 to 38°C.
- 6. The desired temperature range from 25 to 40 degree C and settable temperature can be from 32 to 38°C.
- 7. The resolution should be 0.1 degree C and accuracy should be ± -0.2 °C.
- 8. 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.
- 9. 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.
- 10. It should have Calrod/Ceramic infrared heater.
- 11. Should have a facility to lock the keyboard to avoid unwanted user modification of the set parameters.
- 12. 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.
- 13. It should have audiovisual alarm facility for overheating beyond set temperature range. Auditory alarm shall have a sound level of at least 65dBA at a distance of 3 meter and shold not exceed 80dBA.
- 14. 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.

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- 15. Once the skin probe gets off from the patient for more than 10 minutes but less than 15minutes to avoid overheating of patient, if the heater output is more than 60% it will automatically cut off to 25-30% and should alarm continuously for check sensor.
- 16. Warmer head should be rotatable in different directions, so as to allow taking X-Ray.
- 17. It should have alarm for probe failure, power failure, system failure and heater failure.
- 18. It should have inbuilt internal battery to indicate power failure indication at least ½ hour during power failure.
- 19. Integrated basinet trolley & wheel base should be made of corrosion free material.
- 20. LED observation light should be provided for observing the baby. Observation light of 90to100 foot candles or1000 LUX (Color tem range 3700k to 5100k).
- 21. It should have facility to auto reset the system in case of hang up caused by power fluctuation.
- 22. Should be supplied with good quality thermal sealed & water proof Mattress. Transparent collapsible unbreakable polycarbonate side walls easily detachable for cleaning Mattress size should be minimum 20"X 30".

Matters should have density approx. 20-25 kg/m3.

- 23. 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.
- 24. Bed should be about 80-100 cms from the floor and 80-90 cms from the heat source, as per international guidelines.
- 25. Should have lockable castor (at least 4" size) wheels.
- 26. Indicator light shall be provided to indicate that warmer is ready for normal use/ or better technology through display.
- 27. Markings on the bassinet and X-ray cassette holder are mandatory to enable proper positioning of the baby while doing the X-Ray.
- 28. The size of the drop down side should above the mattress surface and should be at least 6 mm thick; clear and transparent.
- 29. Should have an inbuilt logic in the software to ensure there is no overheating of baby skin at any point of time.
- 30. 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.
- 31. Skin temperature probe should be small in size to fix the probe firmly on the infant.
- 32. Should be supplied with User/Technical/Maintenance manuals to be supplied in English and additional User manual in Hindi language.
- 33. 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 fixed/swivel and drawer/platform for storage.
- 34. For the purpose of cable management there should be atleast two number of ports(edges covered by silicon rings) on the side of walls.
- 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 /BIS. (Certificate should be attach in Technical Bid).
- 37. Equipment should meet IEC 60601-2-21, Report should be issued from Accrediated NABL Laboratory or equivalent foreign Laboratory Internationally, Accrediated for Testing Medical Devices under Scope of Accreditation should be submitted in Technical Bid.

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- 38. Manufacturer should have ISO 13485 certified from IAF accredited Certification Body (Certificate should be attach in Technical Bid).
- 39. Warranty: Three years on equipment from the date of installation.
- 40. 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.
- 41. Device should be supplied with extra 02 nos. of temperature sensors.

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2. Revised Date extension of Bid:-

Existing Dates				Extended Dates			
Last Date for sale of Bid Form	Last Date for Receipt of Bid Form	Last Date of Submission of bid document fees	Date & time of online opening of technical bid	Last Date for sale of Bid Form	Last Date for Receipt of Bid Form	Last Date of Submission of bid document fees	Date & time of online opening of technical bid
10.11.2022 11:00 AM	10.11.2022 06:00 PM	11.11.2022 02:00 PM	11.11.2022 03:00 PM	23.11.2022 11:00 AM	23.11.2022 06:00 PM	24.11.2022 02:00 PM	24.11.2022 03:00 PM

Please note that all clarification/amendment/corrigendum in technical specifications/bid conditions is the integral part of the bid document. This corrigendum/ addendum should be signed and annexed with bid document.

All other terms & conditions remains the same.

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