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F-8() RMSC/EPM/M-4/NIB-600/ 17-06

Date: 22/02/2022

Clarification/Corrigendum/Addendum

Subject:-Amendment in technical specification

"Foy1. Transport Incubator 2. Advance Transport Incubator for under NIB No. F-80 RMSC/EPM/M-4/NIB-600/2021-22/738 Date 26.05.2021

In Reference to subject cited above and NIB-600, 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:-

(A) Revised Technical Specification:-

Technical Specifications of Transport Incubator

- 1. Double wall Acrylic transparent canopy with mattress.
- 2. Size of the incubator canopy should not more than 900 mm (L) X 500mm (w) X 500mm (H) to baby bed Size. Baby bed should be 60 x 30 cm. (±5) cm with mattress thickness 25mm (±5mm).
- **3.** Front and head end access doors with access portholes with elbow operated flip doors and lock chips,cfff tubing access ports and iris port for ventilator tubing.
- **4.** Incubator should have sliding acrylic baby tray to resuscitate baby and to take X-rays.
- 5. Incubator should have re-usable mattress.
- 6. Should have a slide-out mattress tray with baby restraining Straps.
- 7. Should have humidification system, inlet for oxygen and intravenous tubing.
- 8. Should have soft-touch keys to set the desired parameter values.
- **9.** Should have inbuilt resuscitation console with suction unit for neonatal use.
- 10. Should have soft-touch keys to set the desired parameter values.
- 11. Should have microprocessor based servo control temperature control system with digital display of actual and set temperature of air and skin.
- 12. Range of temperature
 - i. For skin control:34°C to 38°C
 - ii. For air control: 22°C to 39°C
 - iii. Resolution: 0.1°C

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- iv. Accuracy: 0.2°C- 0.5°C within set temp
- v. Air / Skin temperature display range: 20°C to 45°C
- 13. Should have heater output display in %.
- **14.** Air velocity <20cm/sec. Oxygen input flow rate 0 to 25 liters/min or oxygen concentration range 21 to 60% or above.
- 15. Audio visual alarms: high/low air temperature (±0.1°C), high and low skin temperature (±0.5°C), temperature sensor failure, A.C. power failure and low battery, skin mode of + 0.5 C of temperature, system failure, air circulation, Skin probe.
- 16. Internal noise level <60dB.
- **17.** Green indicator light should be provided for its ready to be in normal use.
- 18. Infant's straps should be provided to rusticate baby movement.
- **19.** Skin temp probe should be small in size to fix the probes firmly on the infants. Baby contact material should be biocompatible.
- **20.** Safety cut off at 38°C for skin and 39 C for air with audio and visual alarms.
- 21. Examination light should be provided.
- 22. Should have heater power indication.
- **23.** Warm-up time should be 30-40 minute and shall not differ by more than 20%.
- **24.** Mounted on autoloading Collapsible stretcher trolley with adjustable height.
- **25.** Trolley should be light weight (40kg or less without cylinders) on four locking castors with handles.
- 26. System must be capable of being securely installed in ambulance.
- **27.** Should have forced air circulation system with be Medial filter to Remove air born particles.
- 28. Battery and AC supported.
- 29. Indicators for Mains and Battery Modes of Operation.
- 30. Indicators for Battery Power Capacity.
- 31. Should have internal light for illumination.
- **32.** Should have options of Wall Gas Supply or Cylinder Supply.
- 33. Should have inbuilt IV stand.
- **34.** Should gave space provision for mounting syringe pumps, multipara monitor and other patient monitoring and accessories.
- 35. Power requirements: 220v, 240v / 50Hz
- **36.** Built-in sealed rechargeable batteries capable of working for at least 2-4 hours when fully charged. (Protection for overcharging.)
- **37.** All metal parts of the equipment should be corrosion resistant and epoxy/power coated.
- **38.** All consumables required for installation and standardization of system to be given free of cost.
- 39. Should be European CE (Notified body)/USFDA approved.

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- **40.** Manufacturer/ supplier should have ISO 13485 certificate for quality standards.
- **41.** Electrical safety confirms to standards for electrical safety IEC-60601-1.Shall meet IEC-60601-1-2(General requirements for safety electromagnetic compatibility, shall comply with IEC 60601-1-20 transport incubator standard requirement.)
- **42.** List of essential spares and expendables consumables should be provided and quoted separately. Prices so quoted to be frozen for 5 years.
- **43.** Guarantee should be provided for 3 years (starting from date of installation at hospital).
- **44.** Should be provided with original user manual and troubleshooting, certificates of calibration.
- **45.** At the time of installation training to the staff should be provided.
- **46.** Accessories to be supplied :
 - 1. Reusable skin temperature probes: 05 nos.
 - 2.5 Ltr. Oxygen cylinders: 2 nos. (with regulator and flow meter.)
 - 3. Reusable mattress: 2 nos.
 - 4. Washable and removable straps and binders. : 10 nos.
- **47.** Should be supplied with T-piece infant resuscitator with following specifications, along with reusable T-piece with tubes 10 nos., face masks 3size 5 sets, test lung-2 nos. gas supply hose pipe line with connector.
 - I. PIP at 8 Ltr/min: 4 to 75 cmH2O
 - II. PEEP at 8 Ltr/min: 0 to 9 cmH2O
 - III. Safety provision with adjustable pressure relief Valve (PRV) for maximum pressure relief at 8 Ltr/min: 5 to 70 cmH2O
 - **IV.** Resuscitator should be gas powered by flow source, no electrical/battery operation.

Revised Technical specification of Advance Transport Incubator:-

- 1. Double wall Acrylic transparent canopy with mattress.
- 2. Size of the incubator canopy should not more than 900 mm (L) X 500mm (w) X 500mm (H) to baby bed Size. Baby bed should be 60 x 30 cm. (±5) cm with mattress thickness 25mm (±5mm).
- 3. Front and head end access doors with access portholes with elbow operated flip doors and lock chips, tubing access ports and iris port for ventilator tubing.
- **4.** Incubator should have sliding acrylic baby tray to resuscitate baby and to take X-rays.
- 5. Incubator should have re-usable mattress.
- 6. Should have a slide-out mattress tray with baby restraining Straps.
- 7. Should have servo-control humidification system with humidity indicator, inlet for oxygen and intravenous tunings.



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- 8. Should have soft-touch keys to set the desired parameter values.
- 9. Should have resuscitation console with suction unit for neonatal use.
- 10. Should have soft-touch keys to set the desired parameter values.
- 11. Should have microprocessor based servo control temperature control system with digital display of actual and set temperature of air and skin.
- 12. Range of temperature
 - i. For skin control:34°C to 38°C
 - ii. For air control: 22°C to 39°C
 - iii. Resolution: 0.1°C
 - iv. Accuracy: 0.2°C 0.5°C within set temp
 - v. Air / Skin temperature display range: 20 to 45°C
- 13. Should have heater output display in %.
- 14. Air velocity <20cm/sec.

Oxygen input flow rate 0 to 25 liters/min or oxygen concentration range 21 to 60% or above.

- 15. Audio visual alarms: high/low air temperature (±0.1°C), high and low skin temperature (±0.5°C), temperature sensor failure, A.C. power failure and low battery, skin mode of + 0.5 C of temperature, system failure, air circulation, Skin probe.
- **16.** Internal noise level <60dB.
- 17. Green indicator light should be provided for its ready to be in normal use.
- 18. Infants straps should be provided to rusticate baby movement.
- **19.** Skin temp probe should be small in size to fix the probes firmly on the infants. Baby contact material should be biocompatible.
- 20. Safety cut off at 38°C for skin and 39°C for air with audio and visual alarms.
- 21. Examination light should be provided.
- **22.** Should have heater power indication.
- **23.** Warm-up time should be 30-40 minute and shall not differ by more than 20%.
- **24.** Mounted on auto loading Collapsible stretchable trolley with adjustable height.
- **25.** Trolley should be light weight (40 kg or less without cylinders) on four locking castors with handles.
- **26.** System must be capable of being securely installed in ambulance.
- **27.** Should have forced air circulation system with be Medial to remove air born particles.
- 28. Battery and AC supported.
- 29. Indicators for Mains and Battery Modes of Operation.
- 30. Indicators for Battery Power Capacity.
- 31. Should have internal light for illumination.
- **32.** Should have options of Wall Gas Supply or Cylinder Supply.

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- 33. Should have inbuilt IV stand.
- **34.** Should have space provision for mounting syringe pumps, multipara monitor and other patient monitoring and accessories.
- 35. Power requirements: 220v, 240v / 50Hz
- **36.** Built-in sealed rechargeable batteries capable of working for at least 2-4 hours when fully charged. (Protection for overcharging.)
- **37.** All metal parts of the equipment should be corrosion resistant and epoxy/power coated.
- **38.** All consumables required for installation and standardization of system to be given free of cost.
- 39. Should be European CE (Notified body)/USFDA approved.
- **40.** Manufacturer/ supplier should have ISO 13485 certificate for quality standards.
- **41.** Electrical safety confirms to standards for electrical safety IEC-60601-1.Shall meet IEC-60601-1-2(General requirements for safety electromagnetic compatibility, shall comply with IEC 60601-1-20 transport incubator standard requirement.)
- **42.** List of essential spares and expendables consumables should be provided and quoted separately. Prices so quoted to be frozen for 5 years.
- **43.** Guarantee should be provided for 3 years (starting from date of installation at hospital).
- **44.** Should be provided with original user manual and troubleshooting, certificates of calibration.
- **45.** At the time of installation training to the staff should be provided.
- **46.** Accessories to be supplied :
 - 1. Reusable skin temperature probes: 05 nos.
 - 2.5 ltr. Oxygen cylinders: 2 nos. (with regulator and flow meter.)
 - 3. Reusable mattress: 2 nos.
 - **4.** Washable and removable straps and binders. :10 nos.
- 47. Should be supplied with Neonatal transport Ventilator
- 1. Basic compact neonatal ventilator unit well mounted in the system.
- 2. Turbine/Pneumatic based ventilator that does not require air cylinders to function.
- **3.** Should be able to run with oxygen cylinders to provide high FiO2 during transport.(21 to 100%)
- 4. Should have a independent battery backup of up to 3-4hours.
- **5.** Should have modes -Apnea, Assist Control-Pressure, Assist Control-Volume, CPAP-Pressure, Backup, SIMV-Pressure, SIMV-Volume
- 6. Other parameters- Rate (Neonatal) 10- 150 BPM, Expiratory Time 0.2 4.0 seconds, Inspiratory Time 0.2 3.0 seconds, Flow (Neonatal) 0.1 15 LPM, PEEP (Neonatal) 0 20 cmH2O, PIP (Neonatal) 3 60 cmH2O, Tidal Volume (Neonatal) 2- 200 ml.
- 7. Should have alarms for:- Rate, Oxygen (O2), PEEP, IPAP, Peak Pressure, Mean Pressure, Low Battery, I:E Rate

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- 8. Should be European CE (notified body)/usfda certified.
- 9. Should be supplied with following accessories
 - Re usable Infant Circuit
 - Infant Test Lung
 - Infant Flow Sensor
 - Disposable Patient Filter
 - O2 High Pressure Supply Hose
 - Device is safety certified according CE(Notified body)/USFDA certified.
 - Device is produced by ISO 9001 certified manufacturer
- **48.** Should be supplied with a well mounted neonatal multipara monitor with MESIMO/Nellcor/SET technology, battery operated for 3-4 hours (With neonatal Accessories each-2 Nos) .CE (Notified Body)/USFDA certified.
- **49.** Should be supplied with well mounted syringe pump battery operated for 3-4 hours. CE (Notified Body)/USFDA certified.

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.

Executive Director (EPM) RMSCL, Jaipur