

Rajasthan Medical Services Corporation Limited, Jaipur

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No. F-8() RMSC/EPM/M-2/2015-16/NIB-159/ 1907

Dated: 18/9/16

CLARIFICATION/CORRIGENDUM/ADDENDUM

Sub:- Revised Technical Specifications and revised bid submission date of item Transport Incubator under NIB No. F-8() RMSC/EPM/M-2/2015-16/NIB-159/1181 dated 11.03.16

In Reference to subject cited above and NIB-159, the various representations received from the firms and issues raised by the Bidders are examined by the competent Authorities and technical committee. The following Clarification/Corrigendum/Addendum is issued for inclusion in Bid document & Technical Specification of items as below:-

A. Amended Technical Specifications of item Transport Incubator:-

NAME AND CODING		
Definition	Transport Incubator An electrically-powered unit designed to provide an enclosed controlled environment to maintain appropriate temperature and humidity levels mainly for premature infants and other newborns who cannot effectively regulate their body temperature; it is typically on wheels and also designed for transporting infants either outside or within the healthcare facility. It typically consists of a clear removable plastic hood with a mattress and operates using mains electricity (AC-powered) when not in use for transportation. During transport, it is connected to an ambulance electrical outlet or is battery-powered from a battery pack.	
General		
1. USE		
1.1	Clinical Purpose	Designed to provide an enclosed controlled environment to maintain appropriate temperature and humidity level mainly for premature infants and other newborns who cannot effectively regulate their body temperature.
1.2	Used by clinical department/ ward	(Ex : Intensive care unit (ICU), radiology department, orthopedics, emergency, ...)
1.3	Overview of functional requirements	Control of air temperature and infant skin temperature. Clear, hard cabinet for infant viewing Easy access control panel, with light touch operation switches. Facility to elevate base, adjustable range. Self-test functions are performed. Built for transport of infants between wards or health facilities, including by vehicle. Must have skin temperature display.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	<ol style="list-style-type: none"> 1. Visual and audible alarms for : <ol style="list-style-type: none"> (i) Patient and air high/low temperature alarm. (ii) Air circulation / probe / system / power failure alarm. 2. Heater power indicator. 3. Air velocity < 20cm/sec 4. Oxygen input flow rate 0 to 25 liters/min or oxygen concentration range 21 to 70%. 5. CO2 concentration within the hood of incubator should be less than 0.5% 6. Internal noise level < 60 dB. 7. Mode of operation should be properly displayed. 8. Green indicator light should be provided for its ready to be in normal use. 9. Infants straps should be provided to restrict the baby movement. 10. Skin temperature probe should be small in size to fix the probe firmly on the infant. Baby contact material should be biocompatible . 11. Infant bed should be drawable. Mattress foam should be available and infant bed mattress cover should be biocompatible material. 12. Examination light should be provided for inspection. 13. Should have heater power indicator. 14. Warmup time 30-40 minutes and shall not differ by more than 20%. 15. Shall be equipped with a thermal cut-out. It shall be so arranged that the

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		<p>heater is disconnected and an auditory and visual warning is given at an incubator temperature which does not exceed 39 deg C.</p> <p>16. It should not topple over at 10 deg inclined plane.</p> <p>17. Patient skin temperature range: 34 deg C to 37.5 deg C. over ride up to 39 deg C.</p> <p>18. Air temperature range: 25 deg C to 38 deg C; Temperature resolution ± 0.1 deg C; Temperature accuracy less than ± 0.2 deg C.</p> <p>19. should be supplied with T-piece Infant Resuscitator with following specification , along with reusable T-piece with Tubes – 10 No's , FACE MASKS 3 sizes – 5 Sets , Test lung -2 No's, gas supply hose pipe line.</p> <p>a) PIP at 8 L/min : 4 to 75 cmH₂o</p> <p>b) PEEP at 8 L/min : 0 to 9 cmH₂o</p> <p>c) Safety provision with adjustable Pressure Relief Valve (PRV) for maximum pressure relief at 8 L/min : 5 to 70 cmH₂o</p> <p>d) Resuscitator should be gas powered by flow source , No electrical / battery Operation.</p>
2.2	Setting	Patient skin temperature range: 25 deg C to 39 deg C. over ride upto 39 deg C Air temperature range : 21.5 deg C to 38 deg C. humidity : 50-70%.
2.3	User's interface	Display is to be backlit and allows easy viewing in all ambient light levels.
2.4	Software and /or standard of communication	In built
2.5	Others	<p>1. Temperature on the baby mattress should not exceed 40 deg C and 43 deg for other materials.</p> <p>2. The overshoot temperature shall not exceed 2 deg C.</p> <p>3. The stability of temperature during steady temperature shall not differ from the average temperature by more than 1 deg C.</p>
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	Baby bed should be atleast 60x30 cm and the canopy should be atleast 80x40 cm.
3.2	Weight (lbs, kg)	Not exceeding 40-60kg. (without cylinders).
3.3	Configuration	<p>Oxygen port with tubing, also mount for oxygen cylinder of 5 liter size.</p> <p>Accommodates shelves, suction unit and I/V poles.</p> <p>Double-walled cabinet with at least two hand ports.</p> <p>Should have collapsible trolley with lockable castors.</p> <p>Mounted on mobile base, lowest height setting of which is at least 80 cm high suitable size castor diameter, two castors must be fitted with brake facility . Castors must be made of conductive material and rotate (swivel) freely around the vertical axis. The canopy and infant bed should be crevice free for ease of cleaning.</p>
3.4	Noise (in dBA)	<60dBA; Audible sound level should be atleast 65 dBA at 3 meter distance from the device ; the alarm sound level in the compartment shall not exceed dBA.
3.5	Heat dissipation	Should maintain upto 37 deg temp.
3.6	Mobility, portability	Yes, on castors.
4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO2,		
4.1	Voltage (value, AC or DC, monophasic or triphase)	AC- 220 to 240 V, 50 Hz DC- 12V or 24 V POWER ON AMBULANCE
4.2	Battery operated	Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit. Battery backup of 3-4 hours for equipment operation. The battery should be protected from overcharging.
4.4	Power consumption	--
4.5	Other energy supplies	Mains cable to be at least 3 m length.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories (mandatory, standard, optional)	With washable and removable straps and binders.
5.2	Spare parts (main ones)	Two extra sets of all sensors.
5.3	Consumables/ reagents (open, closed system)	Two extra sets of filters, two extra sets of fuses (if replacable fuses used).
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/ Ambiance (air conditioning, humidity, dust	<p>Operating condition:</p> <ul style="list-style-type: none"> - Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances. - An ambient air velocity is less than 0.3 m/s.

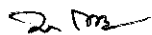
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6.2	User's care, Cleaning, Disinfection & Sterility issues	Unit layout to enable easy cleaning and sterilization of all surfaces, with no unreachable fluid traps. The case is to be cleanable with alcohol or chlorine wipes.
6.3	Others	--
7. STANDARDS AND SAFETY		
7.1	Certificate (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international	1.Should be FDA/EUROPEAN CE approved product 2. Manufacturer / supplier should have ISO 13485 certificate for quality standard. Electrical safety conforms 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.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Supplier to perform installation, safety and operation checks before handover.
8.2	Requirements for sign-off	Certificate of Calibration and inspection from the factory.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. GUARANTEE AND MAINTENANCE		
9.1	GUARANTEE	3 years
9.2	Maintenance tasks	Advanced maintenance tasks required shall be documented.
9.3	Service contract clauses, including prices	Local clinical staff to affirm completion of installation.
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	User, technical and maintenance manuals to be supplied in English language. Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration and routine maintenance list to be provided of important spares and accessories, with their part numbers and cost.
10.2	Other accompanying documents	User / Technical/ Maintenance manuals to be supplied in English.
11. NOTES		
11.1	Other information	Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared.

B. The bid is re-scheduled as follows:

Existing Dates			Extended Dates		
Last Date for Sale of Bid Form	Last Date of Receipt of Bid Form	Date of Opening of Technical Bid	Last Date for Sale of Bid Form	Last Date of Receipt of Bid Form	Date of Opening of Technical Bid
1	2	3	4	5	6
up to 11:00 A.M. 18.04.2016	up to 1.00 P.M. 18.04.2016	from 3.00 P.M. 18.04.2016	up to 11:00 A.M. 04.05.2016	up to 1.00 P.M. 04.05.2016	from 3.00 P.M. 04.05.2016

This corrigendum shall be signed and annexed with bid document. This bears an approval of Managing Director, Rajasthan Medical Services Corporation Limited, Jaipur.


Executive Director (EPM)
RMSCL, Jaipur

