WEST BENGAL MEDICAL SERVICES CORPORATION LIMITED Through United Nations Development Programme, New Delhi.

Invitation to Bid (ITB)

SUPPLY OF NEONATAL VENTILATORS FOR HOSPITALS AND MEDICAL COLLEGES OF THE GOVERNMENT OF WEST BENGAL

ITB: UNDP-WBMSC-08-2014

Amendment-II, dated 14 May, 2014

The following amendments are hereby made to the Bid document for the SUPPLY OF NEONATAL VENTILATORS FOR HOSPITALS AND MEDICAL COLLEGES OF THE GOVERNMENT OF WEST BENGAL, with reference to above ITB:

Reference:Wherever appearing in the bid document, the date, time and venue for receiving opening of bids shall be read as:					
Last Date, Time and Place of Receiving of Bids	1300 Hrs. (IST) on May 23, 2014 at United Nations Development Programme (UNDP), 55, Lodhi Estate, New Delhi-110003.				
Date, Time and Place of Bid Opening	1430 Hrs. (IST) on May 23, 2014 at United Nations Development Programme (UNDP), 55, Lodhi Estate, New Delhi-110003.				

Section 3a - Schedule of Requirements and Technical Specifications are hereby replaced
as in Annexure below of this Amendment.
Section 7 – Price Schedule form is hereby replaced as in annexure below of this
amendment

All other terms and conditions of the bid document, except as amended herein above, remain unaltered.

United Nations Development Programme, 55, Lodhi Estate, New Delhi – 110 003. Tel: 91 11 2462 8877 Email : procurement.dsc@undp.org

Annexure

Section 3a: Schedule of Requirements and Technical Specifications

List of Goods and Consignee:

Schedule No.	Description of Goods	Quantity (in number)	Bid Security in INR	Bid Security in USD
1	Neonatal Ventilator	52	10,00,000.00	16,000

Consignee - Hospitals and Medical Colleges of Govt. of West Bengal

i. Delivery to Consignee within 30 days from the date of issue of the Purchase Order-Contract.

ii. Installation, Training & Commissioning:

Satisfactory Installation, Training & Commissioning as per the Consignee list above within **15 days** from the respective dates of delivery of the goods.

<u>Note</u>: While installation at the designated site/location and commissioning will be the responsibility of the supplier, basic readiness of the site enabling such installation will be the responsibility of the consignee

Supplier should provide onsite training, monitor effectiveness of training and take corrective actions as and when required by WBMSCL / end user during the warranty period after the installation of the equipment.

The successful bidder will have to set up service centre in West Bengal and submit proper document in support within 15 days of receipt of Award of Contract (AOC).

Technical Specifications

Schedule - 1

Neonatal Ventilator

A. ESSENTIAL

1. A neonatal ventilator must have all these components below:

- Ventilator
- Integrated display unit and user interface
- Air Compressor (Ventilator should be compressor driven).
- Reusable Circuit
- Servo Humidifier
- Nebulizer (integrated or standalone)
- Proximal flow / volume sensor
- Stand for circuits
- External battery backup (for ventilator, monitor, humidifier and compressor)
- Operator manual
- Service Manual

2. Type of ventilator:

Advanced microprocessor based Continuous flow, time cycled, pressure limited ventilator capable of ventilating Newborns weighing ≤ 500 grams.

3. Modes

Nasal CPAP, Non-invasive ventilation, IMV (IPPV), SIMV, Assist/Control (A/C), pressure supported ventilation (with backup ventilation).

4. Range of set parameters

Parameters	Essential						
Non-invasive modes							
NCPAP pressure / PEEP	3 - 10						
Apnea alarm while on NCPAP	Must						
• PIP (NIV) – cm of H_2O	10 - 50						
• Inspiratory time (NIV) – sec	0.2 - 2.0						
Invasive Modes							
• Peak inspiratory pressure (cm of H ₂ O)	10-50						
• Positive and expiratory pressure (cm of H ₂ O)	3 - 10						

• Fraction of inspired oxygen (%):	21-100%
• Inspiratory time (sec)	0.2 - 2.0
• Rate (per min)	20-120
• Tidal volume (ml)	2-100
• Trigger	Flow

5. Display unit / User interface:

LED/LCD - TFT monitor with 10" or higher digital display

Display of following set parameters:

- Airway pressures(PIP, PEEP)
- FiO2
- Rate
- Ti, Te, I:E ratio
- Tidal Volume
- Minute Volume

Display of following measured parameters:

- Airway pressures (PIP, PEEP, MAP)
- FiO₂
- Ti, Te, I:E ratio
- Tidal Volume
- Minute Volume
- Compliance
- Resistance
- Leak percentage
- Alarm message
- Graphics Scalars (pressure, volume, flow)/
 - Loop (pressure-volume, flow volume)
 - a) 3 waves-Pressure, volume and flow with time,
 - b) 2 loops P-V, F-V with facility of saving of 1 (one) Loop for reference

6. Alarms (Audio & Visual)

- Power / mains failure
- Compressor failure
- O2 not connected / pressure low
- Air not connected
- MV low / high
- Leak alarm / low tidal volume
- Flow sensor not connected

- Flow sensor not calibrated
- Oxygen too high
- Oxygen too low
- Low & High pressure
- High / low respiratory rate
- Apnea alarm

7. Humidifier

- i. Capable of working with both invasive and non-invasive mode
- ii. Must conform to ISO 8185
- iii. Should be capable of always supplying fully saturated gas at 37°C
- iv. Flow resistance $\leq 20 \text{ cm H}_2\text{O/L/sec}(\text{Ins R} \leq 12, \text{Exp R} \leq 8)$
- v. Temperature range $31-40^{\circ}$ C
- vi. Temperature control $\pm 2^{\circ}$ C
- vii. Digital display of temperature 5-80°C
- viii. Capable of ambient humidity compensation
- ix. Should be compatible with both reusable & disposable chambers and circuits
- x. Must have water level indicator
- xi. Minimum Warm up time (<30 min)

8. Medical Air Compressor

- a) Imported standalone or in-built or integrated, USFDA and CE approved.
- b) Oil free Medical Air Compressor, not turbine generator
- c) Air quality should comply with ISO 8573.1 compressed air purity class 1.4.1
- d) Air Compressor should automatically be activated in the event of wall air supply loss
- e) Replacement of filters should be performed without removing the compressor (inbuilt)
- f) Low noise

9. Nebulizer

- (i) Purpose : aerosolized drug delivery while intubated.
- (ii) Technique : Ultrasonic / vibrating mesh technology
- (iii) Standalone / Integrated with pre-installed software and to be supplied with required reusable nebulization chamber or unit along with tubing, cable and adapter / accessories for nebulization.
- (iv) Particle size (MMD): $\geq 2\mu m \leq 5\mu m$

10. Proximal flow / volume sensor

- (i) Type : flow sensor / volume sensor
- (ii) Dead space :≤1 ml
- (iii) TV : 0.5 200 ml

(iv) If reusable, costs for required sensors and cable for a total of 5 years are to be included in the quoted price of the equipment. Quoted CMC price should include cost for required sensors and cable during CMC period.

(v) If disposable, costs of required units for a total of 5 years (approx.. minimum 150 per year) are to be included in the quoted price of the equipment. Quoted CMC price should include cost of required units (approx. 150 per year) during CMC period. Supply of disposables will be in a staggered manner as per the demand of the end – user.

11. FiO₂ / Oxygen cell

Cost of the cells during the warranty period should be included in the quoted price of the equipment and that during the CMC period should include in the quoted CMC price.

12. Environmental factors

- 1. The unit shall be capable of being stored continuously in ambient temperature of 0-60 deg C and relative humidity of <95%.
- 2. The unit should be capable of operating continuously in ambient temperature of 10-40 deg C and relative humidity of 15-90%.
- 3. Shall meet IEC-60601-1-2:2001 (Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility.

13. Power supply with back-up power

- 1. Power input to be 220-240VAC, 50Hz
- 2. Resettable over current breaker shall be fitted for protection
- 3. Suitable UPS (for humidifier, Compressor and Ventilators) with maintenance free batteries for minimum one-hour back-up should be supplied with the system.

14. Standards, safety and training

- a) Certified to be compliant with ANS/IEC 60601.2.12-01 Medical Electrical Equipment Part 2-12. Should be US FDA and CE approved product.
- b) Certified to be compliant with ISO-7767 for Oxygen monitoring.
- c) Should meet IEC 529 Level 3 (IP3X) (spraying water) for enclosure protection, water ingress.
- d) Demonstration of quoted equipment model is a must.
- e) Should have local service facility. The service provider should have the necessary equipment recommended by the manufacturer to carry out preventive maintenance test as per guidelines provided in the service/maintenance manual.
- f) Warranty for 5 years and provision of CMC for next 5 years

15. Spares with each Ventilator*

* Price of the spares listed below are to be quoted separately along with the bid. The bidder should ensure the availability of spares for another 5 years after the completion of warranty & CMC.

Modular corrosion free original trolley	1 unit
Silicon patient circuit with WYE piece for neonates	5 sets
Servo controlled humidifier, with digital temperature display reusable chamber and capable of working in both invasive and non-invasive modes	1 unit
Reusable humidifier chamber	5 such
Nasal CPAP Disposable Circuit	10sets
Temperature probe & adaptor (Humidifier)	5 such
Heater wire (Humidifier)	5 such
Heater wire adaptor (Humidifier)	5 such
Flow sensor cable if reusable	3 such
Flow sensor if reusable	3 such
Flow sensor if disposable (number per year at least)	150 sets
Nebulizer – Integrated / standalone	1set
Stand for patient circuit	2 such
Test lung for each ventilator	1 set
Hose for O ₂ connection (for wall connection)	5 metres
Hose for compressed air (for wall connection)	5 metres
Nasal mask and prongs (three different sizes)	2 sets each
Expiratory valve / block per ventilator	2 units
Low noise air compressor	1 unit
Washable external air filters for compressor	2 sets
Expiratory Cassette / membrane	10 units

16. Documentation

- (i) Certified of calibration and inspection from factory
- (ii) List of Equipment available for providing calibration and routine maintenance support as per manufacturer documentation in service/technical manual
- (iii) User Manual in English
- (iv) Service manual in English
- (v) 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.
- (vi) List of important spare parts and accessories with their part number and costing.
- (vii) Compliance Report to be submitted in a tabulated and point wise manner clearly mentioning the page/para number of original catalogue/date sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered.
- (viii) Must submit user list and performance report within last 5 years from major hospitals.

B. <u>DESIRABLES</u>

17. Desirable Parameter versus allotted marks

Parameters	Maximum allotted	Range versus allotted marks		
	marks	Range of parameters	Allotted marks	
		Available & integrated	5	
Volume ventilation*	5	Upgradable	3	
		Not upgradable	1	
High frequency ventilation*	5	Upgradable	5	
Then nequency ventilation	5	Not upgradable	1	
Oxygen sensor (longer life at least > 5 years)	5	Available & integrated	5	
Oxygen sensor (longer me at least > 5 years)	5	Not available	1	
Record / trends saving	3	≤24 hours	1	
	5	> 48 hours & integrated	3	
		3 to 15	3	
NCPAP pressure / PEEP (cm of H2O)	3	3 to 25	2	
		3 to > 25	1	
		0.10 to 2.0	7	
Inspiratory time (sec) in TCPL	7	0.10 to > 2.0	3	
		$0.20 \text{ to} \ge 3.0$	1	
		2 to 100	15	
Tidal volume (ml)	15	2 to 150	10	
		2 to 200	5	
		2 to > 200	1	
User friendliness	12	User interface & ease in operation. Compactness of whole system including compressor, Graphics etc.	12	

Parameters		kimum otted	Range versus allotted marks		
		arks			
			Range of parameters	Allotted marks	
Proximal flow / volume sensor		7	Reusable & autoclavable	7	
r toxiniqi now / volume sensor		7	Disposable	1	
Air compressor	5		Integrated / In-built	5	
in compressor			Imported standalone	1	
Nebulizer		3	Vibrating mesh technique	3	
		5	Ultrasonic	1	
			± 3 %	6	
	6	PIP	± 5 %	3	
			>±5%	1	
			± 3 %	6	
	6	PEEP	± 5 %	3	
Accuracy			> ± 5 %	1	
			± 3 %	6	
	6	FiO2	± 5 %	3	
			>±5%	1	
	6	TV	± 0.5 ml (< 5 ml)	6	
	0	IV	± 1.0 ml (<5 ml)	1	
		3	FiO2 (±4%) < 30 sec	3	
Alarm delay (support with manual)		5	FiO2 (±4%) > 30 sec	1	
Alarm delay (support with manual)		3	Circuit disconnection < 0.1 sec	3	
		5	Circuit disconnection > 0.1 sec	1	
Total	1	100			

• Bidders will have to quote the cost for up-gradation separately. The same shall be considered during bid evaluation.

Important Note:

Equipment will be considered technically qualified if,

- 1. Conform with all essential specifications mentioned in A (ESSENTIAL) ; and
- 2. Secure at least 80 marks out of 100 in B (DESIRABLES) of the technical specifications.

Bidders are requested to keep one unit of the offered model along with all the accessories ready for a functional demonstration to be scheduled at Kolkata immediately after the bid opening at a short notice. The exact date, venue and time will be intimated to all the preliminarily qualified bidders separately by the Bid Evaluation Committee.

Company should have local service facility (Details to be provided in following format)

Sl. No.	Name and address of the service center (s)	Phone Nos.	Fax No.	e-mail address	No. of Service engineers

Sl. No.	Name of Service Engineer	Mobile Number	Location

Toll Free No. (if any) : Name of Service Head : Mobile Number :

The service provider should have the necessary equipment recommended by the manufacturer to carry out preventive maintenance test as per guidelines provided in the service/maintenance manual, but at least once in three months during the warranty and CMC period.

One CD/DVD of demonstration video must be supplied with the equipment for end users.

Warranty for 5 years and CMC for 5 years after warranty. The prices for CMC shall be quoted at the time of tendering process. The Prices of CMC shall be considered for the evaluation process.

The offered Warranty includes the cost of labour for all repairs; all spares & accessories required for replacement during repairs which forms part of the equipment system, without which it cannot perform satisfactorily.

The successful bidder will have to set up its own service centre in West Bengal and submit proper documents in support within 15 days of receipt of Award of Contract (AOC). The manufacturer will also have to set up their regional office in West Bengal. The service provider should have the necessary equipment recommended by the manufacturer to carry out preventive maintenance test as per guidelines provided in the service/maintenance manual.

NOTE :

- 1) Reusable consumables should last during the warranty period.
- In case any additional reusable consumables are required during the warranty period those will be supplied free of charge by the supplier.
- The life expectancy of the reusable consumable is expected to be of at least one year from the date of purchase of the same. The reusable consumables will be procured at the prices accepted as per the contract.
- 4) Any reference to brand / product, in case it occurs anywhere in the technical specification is purely for indicative/illustrative purposes and should be read as including its equivalent.
- 5) Unless specified otherwise in the Technical Specifications, all offers should include UPS unit or battery backup of at least one hour, as the case may be, with each equipment.
- 6) Offered product catalogue to be attached in original (2 in nos.) with each bid.
- 7) Attach valid quality certification document(s); no self-certifications admissible.
- 8) Product quality standard (CE/US FDA) to be supported by authentic documents; Warranty, its scope and service facilities to be clearly indicated in the documents.
- 9) One CD/DVD of demonstration video must be supplied with the equipment for end users.
- 10) One CD/DVD of demonstration video must be submitted along with the bid.

Section 7: Price Schedule Form¹

The Bidder is required to prepare the Price Schedule as indicated in the Instruction to Bidders. The Bidders are requested to provide the **cost of the goods** (*inclusive of all tax/duty, excluding entry tax*) for each Schedule quoted in the following format.

SCH. No. (a)	BRIEF DESCRIPTION OF GOODS (b)	QTY. (c)	MAKE/MODEL NO. & COUNTRY OF ORIGIN (d)	CURRENCY (e)	UNIT PRICE DDP (Incoterm 2010) FINAL DESTINATION (all inclusive) (f)	TOTAL PRICE DDP (Incoterm 2010) FINAL DESTINATION (all inclusive) (g) = (c) x (f)
1	Neonatal Ventilator – Quoted price should include a) cost of Proximal flow / volume sensors & cable (if reusable) for a total of 5 years of warranty [OR] b) cost of Proximal flow / volume sensors & cable (if disposable) for a total of 5 years of warranty (approx. minimum 150 per year) AND c) cost of FiO2 / Oxygen cell for a total of 5 years of warranty	52				
	Cost for the up gradation of Volume ventilation, if applicable	52				
	Cost for the up gradation of High frequency ventilation, if applicable	52				
	Note: Quoted CMC price should include a) cost of Proximal flow / volume sensors & cable (if reusable) [OR] b) cost of Proximal flow / volume sensors & cable (if disposable, appro c) Cost of FiO2 / Oxygen cell	x. minimun	n 150 per year) AND			
	CMC Charges for Year1 after completion of 5 years warranty	52				
	CMC Charges for Year2 after completion of 5 years warranty	52				

¹No deletion or modification may be made in this form. Any such 1deletion or modification may lead to the rejection of the Bid.

CMC Charges for Year3 after completion of 5 years warranty	52		
CMC Charges for Year4 after completion of 5 years warranty	52		
CMC Charges for Year5 after completion of 5 years warranty	52		

* DDP Price final destination shall include all the cost incidental to delivery at final destination including all duties & taxes to be paid.

* DDP Price of the above equipment shall include Supply and Installation, Commissioning and warranty for Equipment.

** There shall be no exemption from any applicable tax or duty;

*** Entry tax @ 1% of cost of goods is applicable which will be reimbursed.

NOTE : The following points with regard to consumables should be noted while bidding for the schedule:-

- 1. Reusable consumables should last during the warranty period.
- 2. In case any additional reusable consumables are required during the warranty period those will be supplied free of charge by the supplier.
- 3. The life expectancy of the reusable consumable is expected to be of at least one year from the date of purchase of the same. The reusable consumables will be procured at the prices accepted as per the contract.
- 4. The price excluding CMC quoted in <u>one</u> schedule should be in <u>one</u> currency only.
- 5. If CMC column is left blank, then it will be assumed that the CMC is free of cost.

Important:-

• Bidders will have to quote the cost for up-gradation separately. The same shall be considered during bid evaluation. Proximal flow / volume sensor:

(i) If reusable, costs for required sensors and cable for a total of 5 years are to be included in the quoted price of the equipment. Quoted CMC price should include cost for required sensors and cable during CMC period.

(ii) If disposable, costs of required units for a total of 5 years (approx.. minimum 150 per year) are to be included in the quoted price of the equipment. Quoted CMC price should include cost of required units (approx. 150 per year) during CMC period. Supply of disposables will be in a staggered manner as per the demand of the end – user.

FiO2 / Oxygen cell:

Cost of the cells during the warranty period should be included in the quoted price of the equipment and that during the CMC period should include in the quoted CMC price.

Spares:

* Price of the spares listed below are to be quoted separately along with the bid. The bidder should ensure the availability of spares for another 5 years after the completion of warranty & CMC.

ltem	Unit Price
	(Delivery at final destination)
Modular corrosion free original trolley	
Silicon patient circuit with WYE piece for neonates	
Servo controlled humidifier, with digital temperature display reusable chamber and capable of working in both invasive and non-invasive modes	
Reusable humidifier chamber	
Nasal CPAP Disposable Circuit	
Temperature probe & adaptor (Humidifier)	
Heater wire (Humidifier)	
Heater wire adaptor (Humidifier)	
Flow sensor cable if reusable	
Flow sensor if reusable	
Flow sensor if disposable (number per year at least)	
Nebulizer – Integrated / standalone	
Stand for patient circuit	
Test lung for each ventilator	
Hose for O ₂ connection (for wall connection)	
Hose for compressed air (for wall connection)	
Nasal mask and prongs (three different sizes)	
Expiratory valve / block per ventilator	
Low noise air compressor	
Washable external air filters for compressor	
Expiratory Cassette / membrane	

__% of total firm price for each calendar day less than thirty (30) days

BIDDER'S SIGNATURE AND CONFIRMATION OF THE ITB		
PROVIDED THAT A PURCHASE ORDER IS ISSUED BY UNDP WITHIN THE REQUIRED BID VALIDITY PERIOD, THE UNDERSIGNED HEREBY		
COMMITS, SUBJECT TO THE TERMS OF SUCH PURCHASE ORDER, TO FURNISH ANY OR ALL ITEMS AT THE PRICES OFFERED AND TO DELIVER		
SAME TO THE DESIGNATED POINT(S) WITHIN THE DELIVERY TIME STATED IN SCHEDULE OF REQUIREMENT.		
Exact name and address of company		
COMPANY NAME		
ADDRESS	AUTHORIZED SIGNATURE DATE	
FAX NO	NAME OF AUTHORIZED SIGNATORY (TYPE OR PRINT)	
EMAIL ADDRESS OF CONTACT PERSON	FUNCTIONAL TITLE OF SIGNATORY	
OTHER EMAIL ADDRESSES	WEB SITE	