OFFICE OF THE JOINT DIRECTOR OF HEALTH SERVICES (MALARIA), ASSAM
NATIONAL VECTOR BORNE DISEASE CONTROL PROGRAMME
SAIKIA COMMERCIAL COMPLEX, SRINAGAR PATH, CHRISTIANBASTI,
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No. NVBDCP/VII-2/PSCM/PICU/2014/2144 Date: 02-03-2015

CORRIGENDUM NO: 1
FOR SUPPLY OF ICU VENTILATORS

This is with reference to tender no : No. NVBDCP/VII-2/PSCM/PICU/2014/ ***905*** dated 29/01/15 , extension notice no : NVBDCP/VII-2/PSCM/PICU/2014/***1568*** dated 12/02/15 and extension notice No2:- NVBDCP/VII-2/PSCM/PICU/2014/***1945*** dated 24/02/15 for supply of ICU Ventilators. The following amendments in the tender may be taken note of prior to submission of bids:-

1. The last date and time for receipt of tender is 10-03-2015 (up to 1.00 PM).
2. The tenders will be opened on 10-03-2015 by 2.15 P.M.
3. Sub clause M under Clause 6 (TECHNO-COMMERCIAL BID-COVER"A" is amended to read as follows:-

   The List of items quoted shall be furnished as per Annexure – VIII. The list shall specifically indicate manufacturer's name along with warranty period offered for each item. Item wise Technical Compliance Statement should also be submitted as per Annexure – XV which has to be declared by the manufacturer.
4. Annexure-XII (PRICE BID Format) is substituted with **Annexure-XII(Rev-I)**
5. Annexure-XIII (Specification & details of items) is substituted with **Annexure-XIII(Rev-I).**

   All other terms & conditions of the tender & extension notice shall remain unchanged.

Sd/-
Joint Director of Health Services (Malaria) cum
State Programme Officer, NVBDCP,ASSAM

SPECIFICATIONS & DETAILS OF ITEMS

Item No:-01
Item:- Ventilator (Neonates to adults)
Tentative requirement:- 09 Nos
Specifications:- As under....

- ICU ventilators provide artificial respiratory support to the critical patients in all the types of Intensive Care Units with altitude compensation for volume and BTPS correction for monitoring.
- ***Advanced Microprocessor Controlled ICU Ventilator –Useful from infant to adult with invasive and non-invasive ventilation with internal/external air source based on external compressor Technology (No turbine or blower or piston).***
- Integrated Multicolor Touch Screen Display of minimum 12" size for Pressure-Time, Flow-Time, Volume-Time waveform display. Loops of Volume pressure, flow volume, facility to display two loops on one screen.
- Graphic display to have automatic scaling facility for waves.
- ***Direct access to all the vital parameter in the control panel should be restrictive***
- Hinged arm holder for holding the circuit.
- Should have Ideal Body Weight facility.
- Should have Trending facility for 24 hours.
- Should record up to 1000 episodes of alarms.
- Should have Automatic compliance & Leakage compensation for circuit.
- Ventilator should have following patient selection: Infant , Paediatric, Adult
- Should have following Modes of ventilation
  a. Breath Type: Volume control (VC), Pressure Control (PC)
  b. Modes (in each type): Assist/ Control Mandatory Ventilation
  c. SIMV, Spontaneous (SPONT), PSV, CPAP
  d. Should have Back up Ventilation : All Modes
  e. Frequency : 1 – 150 breath / Mnt
  f. Tidal Volume : 5ml to 3000 ml & Minute Volume: 1 LPM to 99 LPM
  g. PEEP/ CPAP: 0 to 45 cm H_2O
  h. Pressure Support: 0 –60 cm H2O
  i. PRESSURE CONTROL : 0- 80 cm H20
  j. Inspiratory Flow : 1 to 180 LPM
  k. I:E Ratio : Max. inverse: 4:1 to 1:9
  l. FIO2 setting : 21% to 100%
  m. Inspiratory Time : 0.1 sec to 5 sec
  n. Should have Triggering : Both pressure Triggering – 0.1 to – 05 cm /
  o. Flow Triggering 0.1 LPM to 2.0 LPM .
  p. Inspiratory Hold (Maximum 15 seconds) and Expiratory Hold.
  q. Dual mode / VTPC/PRVC
  r. Dual mode in pressure support (VTPS)
  s. BPRV or Bilevel or BiPAP
- Inspiratory flow setting should be directly available and a must criteria.
- Flow patter should be user selectable and must be available.
- Should have Monitoring of the following parameters
  a. Airway Pressure (Peak & Mean)
  b. Tidal volume (Inspired & Expired)
  c. Minute volume (Expired)
  d. Spontaneous Minute Volume
  e. Total Frequency

f. FIO2 dynamic
g. Intrinsic PEEP
h. Plateau Pressure
i. Resistance (Rinsp & Rexp) & Compliance (Cdyn & Cstat)
j. Use selector Alarms for all measured & monitored parameters.

- Should have below advanced monitoring
  a. Occlusion Pressure (P0.1), Max Inspiratory pressure (pi max).
  b. RSBI, Imposed work of Breathing (WOBi) and Expiratory Time constant (Tcexp)
  c. Facility to calculate lower and upper inflection point (P/V Flex points)
- Should have Slope / Rise (Manual and Automatic must) setting as in-built facility.
- Flex cycle / expiratory threshold setting (Manual and Automatic must) for pressure supported breaths as in-built facility.
- Apnea / backup ventilation
- Ultrasonic nebulizer which can < 3 micron particle size to be provided with the ventilator.
- Should have RS 232C interface for communications with networked devices.
- Servo Controlled Heated Humidifier useful for all patient category to be provided with the ventilator.
- **US FDA Ventilator and US FDA Internal/External Medical air compressor of the same make as of ventilator to be provided with ventilator.**
- VGA port for slave display and USB port for data downloading.
- Gas Supply Requirement: Air and O2 supply, Inlet Pressure should between 30 to 90 psig.
- Power Supply : 100-240 CAC, 250 VA max., 50/60 Hz/ battery back up for 60 min.
- The manufacturer must be ISO certified company.
- System configuration, scope of supply:
  a. Ventilator with Compressor – 1
  b. Adult, Paediatric and Neonatal Reusable Circuit – 1 each
  c. Servo Controlled Heated humidifier with Adult and Neonatal chamber – 1
  d. Nebulizer – 1
  e. Reusable Masks(Small, Medium and Large) – 1 each
  f. Reusable Bacteria filter – 2
  g. Test Lung – 1

Warranty:-

- ***Comprehensive warranty for 02 years***
- ***Comprehensive Maintenance for 03 Years***

Quality Certification /Safety certification to be met as follows:-

(Copy of the certifications must be submitted along with the bids)

a. US FDA certificate and CE certificate for the main ventilator unit.
b. US FDA certificate and CE certificate for the Internal/External Medical Air Compressor.
c. ISO certificate of the manufacturer.

Item No:-02
Item:- NIV / Bi-Level Ventilator
Tentative requirement:- 06 Nos
Specifications:- As under....

1. Non Invasive Ventilator having invasive application capabilities for Adult and Paediatric usage (above 15 Kgs).
2. It should be a light & compact device combining unique latest NIV features with simplicity in use.
3. ***Modes of Ventilation: CPAP (Continuous Positive Airway Pressure), S(Spontaneous), with PS, PC-BIPAP, PC-AC,VC-SIMV,VC-AC & Apnea Ventilation. All the modes should be available in Non-Invasive modes.***
4. Should incorporate latest algorithms for leak compensation and synchronization. Both should work together to provide control and flexibility to improve ventilation, comfort and sleep; better disease management, increased patient comfort and therapy acceptance (patient's breathing 'in sync' with their device.
5. ***It should have colour minimum 5inch colour screen for real-time monitoring to provide essential information including simultaneously viewed flow and pressure curves, the Ti-bar graph to fine-tune ventilation, and FiO2 settings.***
6. ***The machine should have only single limb breathing system(mandatory). Dual limb circuit system will not be accepted***.
7. ***Should have built in internal battery for minimum 45 minutes of back up time.***
8. Should include user adjustable alarms and essential non-adjustable, fixed alarms for patient safety
9. ***Should have oxygen inlet port to accept higher flow up to 120 L/min of oxygen to achieve a high FiO2 with built in FiO2 settings.***
10. ***Should have separate low pressure O2 port to accept low flow up to 10L/min of oxygen.***
11. ***The NIV should comply with following technical specifications***

Tidal Volume	***:***	***100-2000ml***
Ti-Control setting	***:***	***Ti Max 0.1–4 sec & Ti Min 0.1–Ti Max***
Respiratory Rate	***:***	***5–50 bpm***
Rise Time	***:***	***Min. 150–900 m.sec (approx.)***
Trigger and Cycle	***:***	***Sensitivity settings.***
Adjustable alarms	***:***	***High Leak, Low Minute Ventilation, High Pressure, Low Pressure, Low / High Respiratory Rate, Apnea, Low / High FiO2, Non-vented mask***
Weight	***:***	***Less than 8 Kgs.***
Air outlets	***:***	***Compatible with ISO 5356–1:2004***
Power supply	***:***	***AC 100–240V 50–60Hz,***
Device DC Input	***:***	***24 V / 3A***

12. ***Should be US FDA & CE certified (both).***
13. Should be supplied with autoclavable patient circuit, Oxygen connector, disposable full face mask (small & medium) 1 each, Reusable mask (small & medium) 1 each.
14. Company has to provide training to all the staff, as & when required.

Warranty:-

- ***Comprehensive warranty for 02 years***
- ***Comprehensive Maintenance for 03 Years***

Quality Certification /Safety certification to be met as follows:-
(Copy of the certifications must be submitted along with the bids)

a. US FDA certificate and CE certificate for the product.
b. ISO Certificate of the manufacturer.

ANNEXURE XII (Rev-I)

PRICE BID

(To be submitted in a separate sealed envelope)

TENDER NO.....

Sl	Brief Description of items	Basic Rate Per Unit	Tax/VAT per unit	Total Rs ***(3+4)***	CAMC charge/unit (for 03 years) inclusive of all taxes Rs	**Total** (Rate + CAMC) Rs (5+6)
1	***2***	***3***	***4***	***5***	***6***	***7***
1						
2						

SIGNATURE :

NAME & DESIGNATION :

DATE :

NAME & ADDRESS OF THE FIRM :

ANNEXURE-XV
Item No: 1

TECHNICAL SPECIFICATION COMPLIANCE STATEMENT

(Note:- Compliance Report to be submitted in a tabulated and point wise manner clearly mentioning the page/ para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered)

Name of Item:- ICU Ventilator (Neonate to Adult)

Sl	Parameters	Quoted Specification (To be filled by the manufacturer)	Deviations, if any
1	Ventilators to provide artificial respiratory support to the critical patients in all the types of Intensive Care Units with altitude compensation for volume and BTPS correction for monitoring.		
2	Advanced Microprocessor Controlled ICU Ventilator – Useful from infant to adult with invasive and non-invasive ventilation with internal/external air source based on external compressor Technology		
3	Integrated Multicolor Touch Screen Display of minimum 12" size for Pressure-Time, Flow-Time, Volume-Time waveform display. Loops of Volume pressure, flow volume, facility to display two loops on one screen.		
4	Graphic display to have automatic scaling facility for waves.		
5	***Direct access to all the vital parameter in the control panel should be restrictive***		
6	Hinged arm holder for holding the circuit.		
7	Should have Ideal Body Weight facility.		
8	Should have Trending facility for 24 hours.		
9	Should record up to 1000 episodes of alarms.		
10	Should have Automatic compliance & Leakage compensation for circuit.		
11	Ventilator should have following patient selection: Infant , Paediatric, Adult		

12	Breath Type: Volume control (VC), Pressure Control (PC)		
13	Modes (in each type): Assist/ Control Mandatory Ventilation		
14	SIMV, Spontaneous (SPONT), PSV, CPAP		
15	Should have Back up Ventilation : All Modes		
16	Frequency : 1 – 150 breath / Mnt		
17	Tidal Volume : 5ml to 3000 ml		
18	Minute Volume 1 LPM to 99 LPM		
19	PEEP/ CPAP: 0 to 45 cm H_2O		
20	Pressure Support: 0 –60 cm H2O		
21	PRESSURE CONTROL : 0- 80 cm H20		
22	Inspiratory Flow : 1 to 180 LPM		
23	I:E Ratio : Max. inverse: 4:1 to 1:9		
24	FIO2 setting : 21% to 100%		
25	Inspiratory Time : 0.1 sec to 5 sec		
26	Should have Triggering : Both pressure Triggering – 0.1 to – 05 cm /		
27	Flow Triggering 0.1 LPM to 2.0 LPM .		
28	Inspiratory Hold (Maximum 15 Seconds) Hold and Expiratory Hold.		
29	Dual mode / VTPC/PRVC		
30	Dual mode in pressure support (VTPS)		
31	BPRV or Bilevel or BiPAP		

32	Inspiratory flow setting should be directly available and a must criteria.		
33	Flow patter should be user selectable and must be available		
34	Should have Monitoring of the following parameters k. Airway Pressure (Peak & Mean) l. Tidal volume (Inspired & Expired) m. Minute volume (Expired) n. Spontaneous Minute Volume o. Total Frequency p. FIO2 dynamic q. Intrinsic PEEP r. Plateau Pressure s. Resistance (Rinsp & Rexp) & Compliance (Cdyn & Cstat) t. Use selector Alarms for all measured & monitored parameters.		
35	Should have below advanced monitoring d. Occlusion Pressure (P0.1), Max Inspiratory pressure (pi max). e. RSBI, Imposed work of Breathing (WOBi) and Expiratory Time constant (Tcexp) f. Facility to calculate lower and upper inflection point (P/V Flex points)		
36	Should have Slope / Rise (Manual and Automatic must) setting as in-built facility.		
37	Flex cycle / expiratory threshold setting (Manual and Automatic must) for pressure supported breaths as in-built facility.		
38	Apnea / backup ventilation		
39	Ultrasonic nebulizer which can < 3 micron particle size to be provided with the ventilator.		
40	Should have RS 232C interface for communications with networked devices.		

41	Servo Controlled Heated Humidifier useful for all patient category to be provided with the ventilator.		
42	**US FDA Ventilator and US FDA Internal/External Medical air compressor of the same make as of ventilator to be provided with ventilator.**		
43	VGA port for slave display and USB port for data downloading.		
44	• Gas Supply Requirement: Air and O2 supply, Inlet Pressure should between 30 to 90 psig. • Power Supply : 100-240 CAC, 250 VA max., 50/60 Hz/ battery back up for 60 min.		
45	The manufacturer must be ISO certified company.		
46	System configuration, scope of supply: h. Ventilator with Compressor – 1 i. Adult, Paediatric and Neonatal Reusable Circuit – 1 each j. Servo Controlled Heated humidifier with Adult and Neonatal chamber – 1 k. Nebulizer – 1 l. Reusable Masks(Small, Medium and Large) – 1 each m. Reusable Bacteria filter – 2 n. Test Lung – 1		
47	***Warranty:-*** • ***Comprehensive warranty for 02 years*** • ***Comprehensive Maintenance for 03 Years***		
48	US FDA certificate and CE certificate for the main ventilator unit.		
49	US FDA certificate and CE certificate for the External Medical Air Compressor.		
50	ISO certificate of the manufacturer.		

(Note:- Signature by authorized official of the manufacturer on all the pages of the compliance statement is must)

ANNEXURE-XV
Item No: 2

TECHNICAL SPECIFICATION COMPLIANCE STATEMENT

(Note:- Compliance Report to be submitted in a tabulated and point wise manner clearly mentioning the page/ para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered)

Name of Item:- NIV/Bi-Level Ventilator

Sl	Parameters	Quoted Specification (***To be filled by the manufacturer***)	Deviations, if any
1	Non Invasive Ventilator having invasive application capabilities for Adult and Paediatric usage (above 15 Kgs).		
2	Whether light & compact device combining unique latest NIV features with simplicity in use.		
3	***Modes of Ventilation:*** • ***CPAP (Continuous Positive Airway Pressure),*** • ***S(Spontaneous) with PS,*** • ***PC-BIPAP,*** • ***PC-AC,*** • ***VC-SIMV,*** • ***VC-AC &*** • ***Apnea Ventilation.*** ***All the modes should be available in Non-Invasive modes.***		
4	Should incorporate latest algorithms for leak compensation and synchronization. Both should work together to provide control and flexibility to improve ventilation, comfort and sleep; better disease management, increased patient comfort and therapy acceptance (patient's breathing 'in sync' with their device.		
5	***It should have colour minimum 5inch colour screen for real-time monitoring to provide essential information including simultaneously viewed flow and pressure curves, the Ti-bar graph to fine-tune ventilation, and FiO2 settings.***		
6	***The machine should have only single limb breathing system(mandatory). Dual limb circuit system will not be accepted***.		
7	***Should have built in internal battery for minimum 45 minutes of back up time.***		

8	Should include user adjustable alarms and essential non-adjustable, fixed alarms for patient safety		
9	***Should have oxygen inlet port to accept higher flow up to 120 L/min of oxygen to achieve a high FiO2 with built in FiO2 settings.***		
10	***Should have separate low pressure O2 port to accept low flow up to 10L/min of oxygen.***		
11	***Tidal Volume :100-2000ml***		
12	***Ti-Control setting :Ti Max 0.1–4 sec & Ti Min 0.1–Ti Max***		
13	***Respiratory Rate :5–50 bpm***		
14	***Rise Time :*** ***Min. 150–900 m.sec (approx.)***		
15	***Trigger and Cycle :*** ***Sensitivity settings.***		
16	***Adjustable alarms:*** ***High Leak, Low Minute Ventilation, High Pressure, Low Pressure, Low / High Respiratory Rate, Apnea, Low / High FiO2, Non-vented mask***		
17	***Weight : Less than 8 Kgs.***		
18	***Air outlets : Compatible with ISO 5356–1:2004***		
19	***Power supply :AC 100–240V 50–60Hz,***		
20	***Device DC Input : 24 V / 3A***		
21	***Should be US FDA & CE certified (both).***		
22	Should be supplied with autoclavable patient circuit, Oxygen connector, disposable full face mask (small & medium) 1 each, Reusable mask (small & medium) 1 each.		
23	Company has to provide training to all the staff, as & when required.		
24	***Warranty:-*** • ***Comprehensive warranty for 02 years*** • ***Comprehensive Maintenance for 03 Years***		

25	US FDA certificate and CE certificate for the product.		
26	ISO Certificate of the manufacturer.		

(Note:- Signature by authorized official of the manufacturer on all the pages of the compliance statement is must)