

महाराष्ट्र शासन

विविध-२०२०/प्र.क्र. १३८/प्रशासन-१  
वैद्यकीय शिक्षण व औषध द्रव्ये विभाग,  
गोकुळदास तेजपाल रुग्णालय आवार,  
नवीन मंत्रालय, मुंबई-०१  
दिनांक : २६.०३.२०२०

प्रति,

१. व्यवस्थापकीय संचालक, हाफकिन जीव औषध निर्माण महामंडळ, मुंबई
२. संचालक, वैद्यकीय शिक्षण संचालनालय, मुंबई.

विषय :- N---९५, PPE kit, Ventilator इत्यादींची सर्वसमावेशक विनिर्दिष्टे  
संदर्भ :- हाफकिन जीव औषध निर्माण महामंडळ यांचे दि. २४.०३.२०२० चे पत्र

सोबत N---९५, PPE kit, Ventilator इत्यादी बाबींच्या सर्वसमावेशक विनिर्दिष्टांची प्रत माहिती व उचित कार्यवाहीरतय जोडली आहे.

सदर पत्र सार्वजनिक आरोग्य विभागाच्या सहमतीने निर्गमित करण्यात येत आहे.

(अ.मु.डहाळ)

कार्यासन अधिकारी, वैद्यकीय शिक्षण व औषधी द्रव्ये

प्रत,

१. मा.मुख्य सचिव, महाराष्ट्र राज्य मुंबई
२. अपर मुख्य सचिव, गृह विभाग, मंत्रालय, मुंबई
३. प्रधान सचिव, नगर विकास विभाग, मंत्रालय, मुंबई
४. प्रधान सचिव, सार्वजनिक आरोग्य विभाग, मंत्रालय, मुंबई.
५. प्रधान सचिव, आदिवासी विकास विभाग, मंत्रालय, मुंबई
६. प्रधान सचिव, शालेय शिक्षण व क्रिडा विभाग
७. व्यवस्थापकीय संचालक, हाफकिन जीव औषध निर्माण महामंडळ, मुंबई
८. आयुक्त, आरोग्य सेवा व संचालक, रा. आ. अ. पुणे.
९. सर्व जिल्हाधिकारी
१०. सर्व मुख्य कार्यकारी अधिकारी
११. संचालक, आरोग्य सेवा, मुंबई.
१२. सर्व अधिष्ठाता, शासकीय वैद्यकीय महाविद्यालये व रुग्णालये
१३. सह संचालक, आरोग्य सेवा (खरेदी), मुंबई.
१४. अधिदान व लेखा अधिकारी, मुंबई
१५. निवासी लेखाधिकारी, मुंबई
१६. सर्व संबंधित जिल्हा कोषागार अधिकारी

E 115

**Ventilator Adult/ Ventilator Adult & Pediatric / Ventilator with accessories / Ventilator  
Invasive Ventilator / Mechanical Ventilator / High End Ventilator.**

1	General Description	Fully Microprocessor controlled having volume cycled & Time cycled with Volume & pressure preset with invasive and noninvasive modes & facility to monitor respiratory parameters including ETCO <sub>2</sub> .
2	Application	Adult as well as pediatric application up to minimum 5-6 K.G weight
3	Power supply & Operation mode	a) Electrical with only inbuilt battery backup for minimum 6 hrs. b) 220V $\pm$ 15%; 50Hz $\pm$ 3%, with inbuilt facility to work over a wide range of voltage fluctuations with True ONLINE UPS with isolation transformer.
4	Driving Gas.	a) In-built/external air source from same manufacturer as that of ventilator with USFDA or European CE approved and not OEM. b) It should either have facility to connect to external central medical compressed air line with auto switchover facility OR facility to connect to central oxygen pipeline through high pressure hose & low pressure oxygen source like O <sub>2</sub> cylinder through flow meter, which is appropriate to the source. c) The compressor based systems should have facility to connect to external central medical compressed air line with auto switchover facility d) Turbine based system must have both facility to connect to central oxygen pipeline through high pressure hose & low pressure oxygen source like O <sub>2</sub> cylinder through flow meter. An External Central UPS System of at least 3KV per unit with proper wiring to each bed for smooth operation (Specify for compressed air systems). e) Air source compressor based (in built/external) from same manufacturer as that of ventilator & not OEM and must be FDA approved. f) A trolley should be provided with each unit and the trolley should be of same make as the manufacturer.
5	Modes of ventilation	A. Invasive modes- a) Control (Volume & Pressure Controlled Ventilation) b) Assist - Control c) SIMV (Volume & Pressure Control) + PSV d) Spontaneous with CPAP + PSV e) PSV (with adjustable cycling time in percentage and max.insp.Time setting) f) Volume cycle with demand flow in control, A/C, SIMV modes g) PRVC or equivalent with control, A/C, SIMV & with volume limit.

*Forced*  
General Manager  
(Procurement)

*7/28*  
Director  
DME

*7/28*  
MANAGING DIRECTOR  
Hafkine Biopharmaceutical  
Corporation Ltd. (Procurement)



		B. Non-invasive modes (NIV) with mask – must be available independent and separate mode.
		a) Control, Assist control, SIMV + PSV, CPAP + PSV
		b) Biphasic with PSV on both levels & with adjustable patient synchrony.
6	Parameter settings with respective ranges	a) Fio <sub>2</sub> : Adjustable (21-100%) with 100% oxygen flush b) ETCO <sub>2</sub> with digital value & waveforms c) I:E Ratio : Adjustable (1:4 – 4:1) d) Insp. Tidal Volume : 50-1500ml e) Resp. Rate : 5 to 70 BPM. f) Inspiratory Time : 0.3-7 sec f) Insp. pause time for X-ray facility : 0.1-2sec. (Auto) & max 6sec (Manual) b) Insp. Flow rate : 10 to 130 LPM & demand flow upto 180 LPM h) Insp. Flow waveform : User selectable. square & decelerating. i) Pressure control : 0-80 cmH <sub>2</sub> O j) Pressure support : 0-60 cmH <sub>2</sub> O k) Flow cycled ventilation : Adjustable for pressure control, PRVC, PSV & Non-invasive modes. l) Flow cycle for PSV & PC : 0.5 to 30% 5-70 m) Bias flow : User adjustable (10-20 LPM) pressure n) Trigger Sensitivity : Flow adjustable (1-20 LPM) o) Apnea Back-up : Automatic & Interactive, user adjustable with selectable apnea back up time & rate. p) Apnea time : 10 to 40 sec q) Apnea Back Rate : 12 BPM onwards. r) PEEP : 0-35 cm H <sub>2</sub> O s) Sigh Rate & Volume : 1 per 100 breaths & 1.5 times the set T.V. t) Pressure limit : (pop off) : 20-120 cm H <sub>2</sub> O
	Ventilatory Maneuvers	a) Expiratory hold b) Manual Breath c) Negative Inspiratory Force Maneuver.
8	Monitored Parameters & Trends on Display	a) Driving gas supply pressure (Air/Oxygen) b) Fio <sub>2</sub> c) EtCO <sub>2</sub> d) Resp. Rate: Ventilator & Patient e) Time: Inspiratory, Expiratory, I:E Ratio f) Inspired Tidal Volume: Ventilator & Patient g) Expired Tidal Volume: Ventilator & Patient h) Minute Volume: Ventilator & Patient i) Airway Pressures: P <sub>max</sub> , P <sub>mean</sub> & P <sub>plateau</sub> . j) PEEP k) Auto PEEP l) Apnea m) Sigh n) Compliance - Static o) Circuit Resistance

*Prakash*

*CAJ*

*Worm*

Manager

8/28

Director  
DME R





*Bhuit*  
General Manager  
(Procurement)  
HBCL Mumbai

*Je* Ventilator

Lower End (Price Range 10 Lakh)

*Je*  
MANAGING DIRECTOR  
Hafkine Biopharmaceuticals  
Corporation Ltd. (Procurement)

Sr. No.	General Description	
1	General Description	Fully Microprocessor controlled having volume cycled & Time cycled with Volume & pressure preset with invasive and noninvasive modes & facility to monitor respiratory parameters including ETCO <sub>2</sub> .
2	Application	Adult as well as pediatric application up to minimum 5-6 KG weight.
3	Power Supply and Operation Mode	a) Electrical with only inbuilt battery backup for minimum 5-6hrs. b) 220V +/-15%; 50Hz+/-3%. With inbuilt facility to work over a wide range of voltage fluctuations with True ONLINE UPS with isolation transformer.
4	Driving Gas	a) In-built/external air source from same manufacturer as that of ventilator with USFDA or European CE approved and not OEM. b) It should either have facility to connect to external central medical compressed air line with auto switchover facility OR facility to connect to central oxygen pipeline through high pressure hose & low pressure oxygen source like O <sub>2</sub> cylinder through flow meter, which is appropriate to the source. c) The compressor based systems should have facility to connect to external central medical compressed air line with auto switchover facility. d) Turbine based system must have both facility to connect to central oxygen pipeline through high pressure hose & low pressure oxygen source like O <sub>2</sub> cylinder through flowmeter. An External central UPS system of at least 3KV per unit with proper wiring to each bed for smooth operation (specific for compressed air systems). e) Air source compressor based (inbuilt/external) from same manufacturer that of ventilator & not OEM and must be FDA approved. f) A trolley should be provided with each unit and the trolley should be of same make as the manufacturer.
5	Modes of Ventilation.	A) Invasive modes- a) Control (volume & pressure controlled ventilation) b) Assist-control c) SIMV (volume & pressure control)+PSV d) Spontaneous with CPAP + PSV e) PSV (with adjustable cycling time in percentage and max.insp. Time setting) f) Volume cycle with demand flow in control, A/C, SIMV modes

		<p>g) PRVC or equivalent with control, A/C, SIMV &amp; with volume limit.</p> <p>B) Non-invasive modes (NIV) with mask-must be available independent and separate mode.</p> <p>a) Control, Assist control, SIMV + PSV, CPAP + PSV</p> <p>b) Biphasic with PSV on both levels &amp; with adjustable patient synchrony.</p>
6	Parameter settings with respective ranges.	<p>a) Fio<sub>2</sub>: Adjustable (21-100%) with 100% oxygen flush</p> <p>b) ET CO<sub>2</sub> with digital value &amp; waveforms</p> <p>c) I:E Ratio: Adjustable (1:4 -4:1)</p> <p>d) Insp. Tidal Volume :50-1500ml</p> <p>e) Resp. Rate: 5 to 70 BPM.</p> <p>f) Inspiratory Time: 0.3-7 sec</p> <p>g) Insp. pause time for X-ray facility: 0.1-2 sec. (Auto) &amp; max 6sec (Manual)</p> <p>h) Insp. Flow rate: 10 to 130 LPM &amp; demand flow upto 180 LPM</p> <p>i) Insp. Flow waveform: User selectable square &amp; decelerating.</p> <p>j) Pressure control: 0-80 cmH<sub>2</sub>O</p> <p>k) Pressure support : 0-60 cmH<sub>2</sub>O</p> <p>l) Flow cycled ventilation: Adjustable for pressure control, PRVC, PSV, &amp; Non-invasive modes.</p> <p>m) Flow cycle for PSC &amp; PC : 0.5 to 30% 5-70</p> <p>n) Bias flow: User adjustable (10-20 LPM)</p> <p>o) Apnea Back-up: Automatic &amp; Interactive, user adjustable with selectable apnea back up time &amp; rate</p> <p>p) Apnea time: 10 to 40 sec</p> <p>q) Apnea Back Rate: 12 BPM onwards</p> <p>r) PEEP: 0-35 cm H<sub>2</sub>O</p> <p>s) Sigh Rate &amp; Volume: 1 per 100 breaths &amp; 1.5 times the set V.</p> <p>t) Pressure limit: (pop off): 20-120 cm H<sub>2</sub>O</p>
7	Ventilatory Maneuvers.	<p>a) Expiratory hold</p> <p>b) Manual Breath</p> <p>c) Negative Inspiratory Force Maneuver.</p>
8	Monitored parameters & Trends on Display.	<p>a) Driving gas supply pressure (Air Maneuver)</p> <p>b) FiO<sub>2</sub></p> <p>c) EtCO<sub>2</sub></p> <p>d) Resp. Rate: Ventilator &amp; Patient</p> <p>e) Time: Inspiratory, Expiratory, I:E Ratio</p> <p>f) Inspired Tidal Volume : Ventilator &amp; Patient</p> <p>g) Expired Tidal Volume : Ventilator &amp; Patient</p> <p>h) Minute Volume : Ventilator &amp; Patient</p> <p>i) Airway Pressures : P<sub>max</sub>, P<sub>mean</sub> &amp; P<sub>plateau</sub>.</p> <p>j) PEEP</p> <p>k) Auto PEEP</p> <p>l) Apnea</p> <p>m) Sigh</p>

General Manager  
(Production)

12/11/17

Director

DMER Scanned with CamScanner

MANAGING DIRECTOR  
H. B. Biopharmaceuticals  
Corporation Ltd. (Pvt.)



*Brul*  
General Manager  
(Procurement)  
HBCL Mumbai

*De*  
DIRECTOR  
MER

MANAGING DIRECTOR  
Haffkine Biopharmaceuticals  
Corporation Ltd. (Procurement)

		<p>n) Compliance-Static o) Circuit Resistance p) Rapid/Shallow Breathing Index q) Events Log Sheet page. r) Each minute trend of all above mentioned parameters for last 24hrs s) Alarm log time &amp; date stamped</p>
9	Display Characteristics.	<p>a) In Built &amp; incorporated min.12"Active Touch Screen and with TFT 1) Color Graphics Display 2) Adjustable scales &amp; Sweep speed b) Simultaneous Display of Waveforms: Flow, Volume &amp; pressure c) Waveforms colour coded (for insp.Exp.spon.) and freezing with movable cursor facility. d) Loops: Flow-Volume &amp; Pressure-Volume, both simultaneous, color coded.</p>
10	Alarms/ Indicators.	<p>All Alarms &amp; Indicators should have luminous and audible signals priority wise and in display. a) Apnea b) Airway Pressure: High/Low c) Battery : Fully Charged/Low d) Breath Rate : High e) FiO2 : High/ Low (Preset) f) Gas supply Failure For : Oxygen and Air g) Minute Volume : Low h) Mode Of Operation : Mains/ Battery i) Pressure/ Flow Transducer (Sensor) Failure j) Power Failure k) Triggered Breath Indicator l) Unusual/ Incorrect settings m) Ventilator Inoperative</p>
11	Capnography.	<p>Capnography EtCO2 monitoring with High and Low EtCO2 alarm and EtCO2 Waveform. Inbuilt Capnography is with main stream/ side stream technology, tenderer will have to supply EtCo2 adaptor and main stream EtCO2 sensor.</p>
12	Nebulizer.	<p>Synchronized INBUILT Nebulizer with adjustable auto OFF timer from 1 to 30 mins.</p>
13	Standard Accessories and reusable breathing Circuit.	<p>a) Non Proprietary, chemically sterilizable and steam autoclavable (for minimum 20 cycles), reusable breathing circuit for <u>adult &amp; Paediatric 2 Nos. each.</u> b) Reusable flow sensor- Easily removable for sterilization by steam autoclaving 2 nos. (3 different sizes of small, medium &amp; large, <u>Qty. 2 of each</u>) c) Reusable &amp; Autoclavable Exhalation valve Body &amp;</p>

		Diaphragm (for min 30 Cycles) 2 Nos. each d) Should be supplied with 1 reusable EtCO2 sensor with cable and 1 reusable airway adaptors. e) Reusable and steam autoclavable bacteria filter (for min. 20 Cycles). f) Reusable, Autoclavable, Non- Invasive full face mask with harness separate – 1 No. of each 3 different sizes (total 3 mask) g) Stand for ventilator and breathing circuit support arm- 1 No. each.
14	Disposable circuits and accessories.	a) Dual Limb non proprietary disposable circuits to be used- <u>100 no. each.</u> b) Disposable <u>HEPA Filters with HME – 50Nos.</u> c) Disposable Airway adaptor for <u>EtCO2 sensor- 20 nos, sample line – 100 Nos with each sidestream EtCO2.</u>
15	UPS	True on line ups WITH Isolation Transformer for complete system including Air source for complete protection against all types of Input supply variations.
16	Approval & Certification.	Quoted model must be FDA (U.S.A.) and European CE Approved product – Mandatory & CE Marked.
17	Warranty.	Comprehensive Warranty : 2 years
18	CMC	After warranty period - 8 years
19	Post Record	It should be user friendly with good post sales service records
20	Demonstration	Physical Demonstration with complete system and all accessories to be provided.
21	Installation	As per Government Rules

arious accessories and their number varies as per user requirements

1	Reusable Patient Circuits
2	Disposable Patient Circuits.
3	Flow Sensors.
4	Exhalation Valves.
5	NIV Masks Sizes Adult, Pediatric and Neonatal.
6	EtCo2 Sensors and their adaptors.
7	Nebulizer and Humidifier.
8	Nasal Cannulas / Prongs, Water traps.
9	Trolley and Support Arm.

*Pratik*  
General Manager  
(Procurement)  
HBCL Mumbai

*DL*  
Director  
DMER

*W. R. M.*  
MANAGING DIRECTOR  
Haffkine Biopharmaceutical  
Corporation Ltd. (Procurement)

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Bjclab2

51e Ventilator  
Direct Order  
Medium Range (Price Range 15 Lakh)

MANAGING DIRECTOR  
Haffkine Biopharmaceutical  
Corporation Ltd. (Procurement)

1	General Description	Fully Microprocessor controlled having volume controlled & Time cycled with Volume & pressure preset with invasive and non-invasive modes & facility to monitor respiratory parameters including ETCO2 <u>with inbuilt High Flow O2 Therapy through Nasal Cannula.</u>
2	Application	Adult as well as pediatric application up to minimum 5-6 KG weight.
3	Power Supply and Operation Mode	a) Electrical with only inbuilt battery backup for 5 to 6 hrs or more for the complete system. b) 220V +/- 15%; 50Hz +/- 3%. with inbuilt facility to work over a wide range of voltage fluctuations with True ONLINE Sine wave UPS. If the system can provide inbuilt battery backup of minimum 4 hrs, the online UPS is not compulsory. c) An External Central UPS System of appropriate rating which can provide uninterrupted supply of about 6 hrs with proper wiring to each bed for smooth operation.
4	Driving Gas	a) In-built/external air source from same manufacturer as that of ventilator with USFDA approved or European CE (Notified Body) Certified. b) It should either have facility to connect to external central medical compressed air line with auto switchover facility OR facility to connect to central oxygen pipeline through high pressure hose & low pressure oxygen source like O2 cylinder through flow meter, which is appropriate to the source. c) The compressor based systems should have facility to connect to external central medical compressed air line with auto switchover facility. d) Turbine based system must have both facility to connect to central oxygen pipeline through high pressure hose & low pressure oxygen source like O2 cylinder through flow meter. e) A trolley should be provided with each unit and the trolley should be rust free but not mandatorily from the same make as manufacturer. It should be warranted rust free for 8 years of installation.
5	Modes of Ventilation.	A. Invasive modes- a) Control (Volume & Pressure Controlled Ventilation) b) Assist - Control c) SIMV (Volume & Pressure Control) + PSV d) Spontaneous with CPAP + PSV e) PSV (with adjustable cycling time in percentage and max.insp. Time setting) f) Volume cycle with demand flow in control, A/C, SIMV

		<p>modes</p> <p>g) PRVC or equivalent with control, A/C, SIMV &amp; with volume limit.</p> <p>B. Non-invasive modes (NIV) with mask – must be available independent and separate mode with leakage compensation.</p> <p>a) Control, Assist control, SIMV + PSV, CPAP + PSV</p> <p>b) Biphasic / Bi-Level / Dual Level/ BIPAP or Equivalent.</p> <p><u>c) MMV/ Automode for smooth safe transition to spontaneous Ventilation.</u></p>
6	Parameter settings with respective ranges.	<p>a) FiO<sub>2</sub>: Adjustable (21-100%) with 100% oxygen flush</p> <p>b) Inbuilt EtCO<sub>2</sub> with digital value &amp; waveforms</p> <p>c) I:E Ratio : Adjustable (1:4 - 4:1)</p> <p>d) Insp. Tidal Volume : 30-1500ml</p> <p>e) Resp. Rate : 5 to 70 BPM</p> <p>f) Inspiratory Time : 0.3-7 sec</p> <p>g) Insp.pause time for X-ray facility : 0.1-2 sec. (Auto) &amp; 6sec (Manual)</p> <p>h) Insp.Flow rate : 10 to 130 LPM &amp; demand flow upto 180LPM</p> <p>i) Insp.Flow waveform: User selectable square &amp; decelerating.</p> <p>j) Pressure control : 5-80 cmH<sub>2</sub>O</p> <p>k) Pressure support : 5-40 cmH<sub>2</sub>O or more.</p> <p>l) Flow cycled ventilation: Adjustable for pressure control, PRVC, PSV &amp; Non-invasive modes.</p> <p>m) Flow cycle for PSV &amp; PC : 0.5 to 30% 5-70</p> <p>n) Bias flow : User adjustable (10-20 LPM) / Automatic.</p> <p>o) Trigger Sensitivity : Flow adjustable 1-10 LPM or more.</p> <p>p) Apnea Back-up: Automatic &amp; Interactive, user adjustable with selectable apnea back up time &amp; rate.</p> <p>q) Apnea time : 10 to 40 sec</p> <p>r) Apnea Back Rate: 12 BPM onwards.</p> <p>s) PEEP : 0-35 cm H<sub>2</sub>O</p> <p>t) Sigh Rate &amp; Volume : 1 per 100 breaths &amp; 1.5 times the set T.V.(Pressure or Volume Sigh)</p> <p>u) Pressure limit : (pop off) : 20-99 cm H<sub>2</sub>O or more</p>
7	Ventilatory Maneuvers.	<p>a) Expiratory hold</p> <p>b) Manual Breath</p> <p>c) Negative Inspiratory Force Maneuver or RSBI (Rapid Shallow Breathing Index).</p>
8	Monitored parameters & Trends on Display.	<p>a) FiO<sub>2</sub></p> <p>b) EtCO<sub>2</sub></p> <p>c) Resp.Rate: Ventilator &amp; Patient</p> <p>d) Time: Inspiratory, Expiratory, I:E Ratio</p> <p>e) Inspired Tidal Volume: Ventilator &amp; Patient</p> <p>f) Expired Tidal Volume: Ventilator &amp; Patient</p> <p>g) Minute Volume: Ventilator &amp; Patient</p>

General Manager  
(Procurement)

16/28

Director  
AMER

MANAGING DIRECTOR  
Haffkine Biopharmaceutical Corporation Ltd. (Private)

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*Apurva*  
General Manager  
(Procurement)  
HbCL Mumbai

*Al*  
Director  
OMER

*Sanjay*  
MANAGING DIRECTOR  
Haffkine Biopharmaceuticals  
Corporation Ltd. (Procurement)

### Display Characteristics

- g) Airway Pressure (High/Low & PEEP)
- h) PEEP
- i) A/V Ratio
- k) Apnea
- l) SpO<sub>2</sub>
- m) Compliance (Static, Dynamic)
- n) Circuit Resistance
- o) Rapid Shallow Breathing Index
- p) Evend - Log Sheet page
- q) Each minute trend of all above mentioned parameters for last 24 hr
- r) Alarm log time & date stamped

- a) In Built & incorporated min 12" Active Touch Screen and with TFT
  - 1. Color Graphics Display
  - 2. Adjustable scales & sweep speed - Automatic
- b) Simultaneous Display Of Waveforms, Flow, Volume & pressure
- c) Waveforms color coded (for insp, Exp, Spon) and freezing with movable cursor facility
- d) Loops: Flow-Volume & Pressure-Volume, both simultaneous, color coded

10	Alarms/ Indicators.	<p>All alarms &amp; Indicators should have luminous and audible signals priority wise and messages in display.</p> <ul style="list-style-type: none"> <li>a) Apnea.</li> <li>b) Airway Pressure: High/Low</li> <li>c) Battery: Fully Charged/Low.</li> <li>d) Breath Rate: High.</li> <li>e) FiO<sub>2</sub>: High/Low (Preset).</li> <li>f) Gas Supply Failure For: Oxygen and air.</li> <li>g) Minute Volume: Low</li> <li>h) Mode of Operation: Mains / Battery.</li> <li>i) Pressure/ Flow Transducer [Sensor] Failure.</li> <li>j) Power Failure</li> <li>k) Triggered Breath Indicator.</li> <li>l) Unusual/ Incorrect settings.</li> <li>m) Ventilator Inoperative.</li> </ul>
11	Capnography.	<p>Capnography etCO<sub>2</sub> monitoring with High and Low etCO<sub>2</sub> alarm and etCO<sub>2</sub> waveform.</p> <p>Inbuilt Capnography is with main stream / side stream technology, tenderer will have to supply EtCO<sub>2</sub> adaptor and main stream etCO<sub>2</sub> sensor.</p>
12	Nebulizer.	Synchronized INBUILT Nebulizer with adjustable manual time or Auto OFF.
13	Standard Accessories and	a. Non Proprietary, chemically sterilizable and steam autoclavable (for minimum 20 cycles), reusable breathing

	reusable breathing Circuit.	<p>circuit for adult &amp; Pediatric 2 no.s each. (Total 4 No.s)</p> <p>b. Reusable flow sensor-Easily removable for sterilization by steam autoclaving <u>6 no.s</u></p> <p>c. Reusable &amp; Autoclavable Exhalation valve body &amp; Diaphragm, {for min. 30 cycles} 4 No.s each.</p> <p>d. Should be supplied with 2 reusable EtCo2 sensor with cable and 5 reusable airway adaptors for main stream.</p> <p>e. Servo controlled humidifier with Adult and pediatric chamber 1 No. each (total 2) along with 30 Adult and 20 Pediatric Cannulas.</p> <p>f. Stand for ventilator and breathing circuit support arm - 1 No. each. of same make and rust free.</p>
14	Disposable circuits and accessories.	<p>a) Dual Limb non proprietary disposable circuits to be used- <u>100 No. each</u></p> <p>b) Disposable HEPA Filters with HME- 100 No.s (70 Adult &amp; 30 Pediatric).</p> <p>c) Disposable Airway adaptor for EtCo2 Sensor- 20 no.s., sample line- 100 nos with each sidestream EtCO2 &amp; 50 Water traps.</p> <p>d) <u>Reusable masks of 3 sizes:- small, medium, large-5 nos. each (Total-15).</u></p>
15	UPS	TRUE ON LINE UPS for Complete system including Air source for complete protection against all types of Input supply variations.
16	Approval & Certification.	Quoted model must be FDA (U.S.A) and European CE Approved product - Mandatory & CE marked
17	Warranty.	Comprehensive Warranty : 2 years
18	CMC	After warranty period - 8 years
19	Post Record	It should be user friendly with good post sales service records
20	Demonstration	Physical Demonstration with complete system and all accessories to be provided.
21	Installation	As per Government Rules

Various accessories and their number varies as per user requirements

1	Reusable Patient Circuits
2	Disposable Patient Circuits.
3	Flow Sensors.
4	Exhalation Valves.
5	NIV Masks Sizes Adult, Pediatric and Neonatal.
6	EtCo2 Sensors and their adaptors.
7	Nebulizer and Humidifier.
8	Nasal Cannulas / Prongs, Water traps.
9	Trolley and Support Arm.

General Manager

18/28

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*Pratik*

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Ventilator  
Director  
OMER

High End (Price Range 20 Lakh)

*Team*  
MANAGING DIRECTOR  
Hafslund BioPharmaceuticals  
Corporation Ltd. (Procurement Cell)

1	General Description	Microprocessor based intensive care unit (ICU) Ventilator for Paediatrics & Neonates.
2	Application	It should be suitable for use on Adult, Paediatric & Neonatal patients (0.5 kg. to 145 kg.)
3	Power Supply and Operation Mode	Main Power: 100-240V/50-60Hz Battery back-up of <u>6 hr</u> for complete System Rechargeable battery, <u>battery backup for Ventilator &amp; compressor for 6 hours.</u>
4	Driving Gas	<u>Air source : Compressor of the same make and CE and USFDA approved.</u> <u>Medical grade compressor with facility to connect to external compressed air pipeline. Automatic changeover between compressor &amp; central compressed air line. The machine should have a automatic bias flow. The compressor should be of same company &amp; not OEM.</u> <u>The machine should have a non-consumable type 02 sensor. It need not be replaced/changed over a period of time. Data download via USB. log book entries via USB. If Galvanic sensors are provided then they should be covered under warranty and CMC.</u>
5	Modes of Ventilation.	Advance / Special Modes - MMV + PSV – Mandatory Minute Ventilation - PSV + Tidal Volume Assured - APRV – Airway Pressure Release ventilation - PRVC / Outflow / VC plus - NIV – Non-invasive Ventilation - Low flow PV loop maneuver to record the elastic ling properties & determine the opening & closing alveolar pressure. Automatic determination of inflection point. <u>TCPL – Time cycled pressure limited</u> - SIMV (TCPL) + PSV - <u>CPAP with Continuous Flow (with leak compensation for NIV)</u> - PRVC/Auto Flow / Equivalent - Possibility to optimizes peep, P insp. Or VT directly on the graphic display of low flow PV loop. NIV – Non – Invasive Ventilation measurement & display of the leakage min volume & relative leakage in percentage. Leakage corrected waveform. <u>NCPAP</u> <u>NEONATES INFANTS Ventilation Mode</u> - VCV – Volume Control (Assisted/Controlled)

		<ul style="list-style-type: none"> <li>- PCV – Pressure Control (Assisted/Controlled)</li> <li>- PSV – Pressure Support</li> <li>- CPAP – Continuous Positive Airway Pressure</li> <li>- SIMV (VCV) + PSV</li> <li>- SIMV (PCV) + PSV</li> <li>- Automatic adaption of leak compensation.</li> </ul>
6	Parameter settings with respective ranges.	<p>Ventilation Parameter Settings (According to operative more &amp; patient category)</p> <ul style="list-style-type: none"> <li>- Tidal volume : 3 ml. – 2000ml</li> <li>- Inspiratory Rate: 0 – 100 bpm (adult and paediatric), 0 – 150 (neonatal)</li> <li>- Inspiratory flow: 0 – 120 lpm</li> <li>- Peak Inspiratory Pressure: 1 – 95 cm H<sub>2</sub>O</li> <li>- CPAP/PEEP: 0- 50 cm H<sub>2</sub>O</li> <li>- Pressure support : 0-95 cm H<sub>2</sub>O above peep</li> <li>- Rise time/slope : 0 to 2 sec manual or automatic</li> <li>- Flow trigger : 0.2 – 15 lpm</li> <li>- FiO<sub>2</sub> : 21 – 100%</li> <li>- Manual Inspiratory / Expiratory hold : 0 – 15 sec</li> <li>- Sigh: Volume or Pressure Sigh Preferred for safety reasons</li> <li>- Inspiratory Termination criteria : 1 to 80%</li> <li>- O<sub>2</sub> therapy : Continuous flow of 2 to 50 l pm with varying FiO<sub>2</sub> from 21 to 100%</li> <li>- Tube compensation for Adult Paediatric &amp; Neonates</li> </ul>
7	Ventilatory Maneuvers.	<ul style="list-style-type: none"> <li>a) Expiratory hold</li> <li>b) Manual Breath</li> <li>c) Negative Inspiratory Force Maneuver or RSBI (Rapid Shallow Breathing Index).</li> </ul>
8	Monitored parameters & Trends on Display.	<p>Breath type – Control, Assist, Spontaneous Breaths</p> <p>Pressure – End expiratory pressure, end inspiratory pressure, maximum circuit pressure, mean circuit pressure, Peak, Mean, Plateau PEEP, Auto PEEP.</p> <p>Volume – Exp. Minute volume, Tidal Volume expired &amp; inspired, Spontaneous Minute volume</p> <p>Ventilation Frequency</p> <p>I:E ratio</p> <p>FiO<sub>2</sub></p> <p>Respiratory rate</p> <p>Resistance (Insp. &amp; Exp.), Compliance (Dynamic &amp; Static for paediatric ) (Dynamic for Neonate)</p> <p>Trends up to 72 hours</p>
9	Display Characteristics.	<p>It should have minimum 15" size TFT active matrix color screen with single device user interface.</p> <p>Loops</p> <ul style="list-style-type: none"> <li>- It should display Volume – time curve, Pressure – time</li> </ul>

General Manager  
(Management)

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Director

MANAGING DIRECTOR



		<p>curve, Flow - time curve, Pressure - Volume curve &amp; F<sub>50</sub> Volume Loop.</p> <ul style="list-style-type: none"> <li>- Curves of Insp., Exp., &amp; spontaneous &amp; both curve &amp; loops can be user-selectable to freeze with the flexibility to change scale horizontally or vertically or both with the adjustment facility of base line for analysis.</li> <li>- Sighs</li> <li>- Suction %O<sub>2</sub>: for suction sequence with variable FiO<sub>2</sub>; Nebulizer</li> <li>- 24-hour trend display of up to 24 parameters</li> <li>- Scroll &amp; zoom Functions.</li> <li>- Ability to display up to 10 mandatory or spontaneous loop.</li> <li>- Reference loop to measure the progress of ventilation treatment.</li> </ul>
10	Alarms/ Indicators.	<p>Alarm management.</p> <p>High &amp; Low Inspiratory Pressure</p> <p>Should have the gas flow from 0-31 L/s</p> <p>Low pressure of O<sub>2</sub> &amp; air, or one of them</p> <p>Main Power Loss, Low battery</p> <p>High &amp; Minute Volume</p> <p>High &amp; Low Tidal Volume</p> <p>High &amp; Low O<sub>2</sub> %</p> <p>Apnea</p> <p>High respiratory rate</p> <p>High circuit pressure</p> <p>Ventilator inoperative</p> <p>Pressure/flow transducer failure</p> <p>It should have trending (Both Numeric /Tabular &amp; Maneuver) for more than 50 parameters for 72 hours. at least</p>
11	Capnography.	<u>Volumetric Capnography integrated (Mainstream)</u>
12	Nebulizer.	The nebuliser should be inbuilt & inspiration synchronised .
13	Standard Accessories and reusable breathing Circuit.	<p>Accessories for NIV-</p> <p>a) Infant Bonnet sizes for head circumference ranging from 17cm to 36 cm. - 5 each</p> <p>b) Head gear for head circumference ranging from 29cm to 45cm. - 2 each</p> <p>c) Chin strap for face circumference ranging from 20 cm to 44 cm. - 2 each</p> <p>d) Reusable Nasal mask small, medium , large, Extra small. - 5 each</p> <p>e) Reusable Nasal Prongs for CPAP all sizes -5 each</p> <p>f) Circuits &amp; assembly with adapter for delivering NIV, length ranging from 50mm, 70mm, and 100mm - 5 each</p> <p>Reusable &amp; autoclavable Proximal Flow sensor for Neonatal Patients- 10 nos.</p> <p>MR850 or equivalent with CE &amp; FDA certification</p>

General Manager  
(Procurement)

*[Signature]*

Director

		<u>Humidifier which is Servo controlled with digital monitoring of inspired gas temperature complete with heating wire (reusable). Complete set off heater adapter, flow probe &amp; heating wire should be supplied. - 4 nos.</u>
14	Disposable circuits and accessories.	a) Disposable sensors 100 Nos. b) <u>The ventilator should be compatible to nay standard disposable or reusable patient breathing circuit.</u>
15	UPS	TRUE ON LINE UPS for Complete system including Air source for complete protection against all types of Input supply variations.
16	Approval & Certification.	The ventilator must have both US-FDA & European CE approval as a Class-I ICU/CCU ventilator
17	Warranty.	Comprehensive Warranty : 2 years
18	CMC	After warranty period - 8 years
19	Post Record	It should be user friendly with good post sales service records
20	Demonstration	Physical Demonstration with complete system and all accessories to be provided.
21	Installation	As per Government Rules

arious accessories and their number varies as per user requirements

1	Reusable Patient Circuits
2	Disposable Patient Circuits.
3	Flow Sensors.
4	Exhalation Valves.
5	NIV Masks Sizes Adult, Pediatric and Neonatal.
6	EtCo2 Sensors and their adaptors.
7	Nebulizer and Humidifier.
8	Nasal Cannulas / Prongs, Water traps.
9	Trolley and Support Arm.

*Pratik*  
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(Procurement)  
HECL Mumbai

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Director  
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*22/2/2018*  
MANAGING DIRECTOR  
Haffkine Biopharmaceutical  
Corporation Ltd. (Procurement Cell)  
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**Annexure-X**  
**Specification for Adult & Paediatric Ventilator**

1	General Description	Fully Microprocessor controlled having volume controlled & Time cycled with Volume & pressure preset with invasive and non-invasive modes & facility to monitor respiratory parameters including EtCO <sub>2</sub> with inbuilt High Flow O <sub>2</sub> Therapy through Nasal Cannula.
2	Application	Adult as well as pediatric application up to minimum 5-6KG weight.
3	Power supply & Operation mode	a) Electrical with only inbuilt battery backup for minimum 2hrs or more for the complete system. b) 220V $\pm$ 15%; 50Hz $\pm$ 3%, with inbuilt facility to work over a wide range of voltage fluctuations with True ONLINE Sine wave UPS. If the system can provide inbuilt battery backup of minimum 4 hrs, the online UPS is not compulsory. c) An External Central UPS System of appropriate rating which can provide uninterrupted supply of about 6 hrs with proper wiring to each bed for smooth operation.
4	Driving Gas.	a) In-built/external air source from same manufacturer as that of ventilator with USFDA approved or European CE (Notified Body) Certified. b) It should either have facility to connect to external central medical compressed air line with auto switchover facility OR facility to connect to central oxygen pipeline through high pressure hose & low pressure oxygen source like O <sub>2</sub> cylinder through flow meter, which is appropriate to the source. c) The compressor based systems should have facility to connect to external central medical compressed air line with auto switchover facility. d) Turbine based system must have both facility to connect to central oxygen pipeline through high pressure hose & low pressure oxygen source like O <sub>2</sub> cylinder through flow meter. e) A trolley should be provided with each unit and the trolley should be rust free but not mandatorily from the same make as manufacturer. It should be warranted rust free for 8 years of installation.
5	Modes of Ventilator	A. Invasive modes- a) Control (Volume & Pressure Controlled Ventilation) b) Assist - Control c) SIMV (Volume & Pressure Control) + PSV d) Spontaneous with CPAP + PSV e) PSV (with adjustable cycling time in percentage and max.insp. Time setting) f) Volume cycle with demand flow in control, A/C, SIMV modes g) PRVC or equivalent with control, A/C, SIMV & with volume limit. B. Non-invasive modes (NIV) with mask - must be available independent and separate mode with leakage compensation. a) Control, Assist control, SIMV + PSV, CPAP + PSV b) Biphasic / Bi-Level / Dual Level/ BIPAP or Equivalent. c) MMV/ Automode for smooth safe transition to spontaneous Ventilation.
	Parameter	a) FiO <sub>2</sub> : Adjustable (21-100%) with 100% oxygen flush b) Inbuilt EtCO <sub>2</sub> with digital value & waveforms c) I:E Ratio : Adjustable (1:4 - 4:1) d) Insp. Tidal Volume : 30-1500ml e) Resp. Rate : 5 to 70 BPM f) Inspiratory Time : 0.3-7 sec g) Insp pause time for X-ray facility : 0.1-2 sec. (Auto) & max 6sec (Manual) h) Insp Flow rate : 10 to 130 LPM & demand flow upto 180LPM

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6	Settings with respective ranges	<ul style="list-style-type: none"> <li>i) Insp Flow waveform: User selectable square &amp; decelerating</li> <li>j) Pressure control : 5-80 cmH<sub>2</sub>O</li> <li>k) Pressure support : 5-40 cmH<sub>2</sub>O or more.</li> <li>l) Flow cycled ventilation: Adjustable for pressure control, PRVC, PSV &amp; Non-invasive modes.</li> <li>m) Flow cycle for PSV &amp; PC : 0.5 to 30% 5-70</li> <li>n) Bias flow : User adjustable (10-20 LPM) / Automatic.</li> <li>o) Trigger Sensitivity : Flow adjustable 1-10 LPM or more.</li> <li>p) Apnea Back-up: Automatic &amp; Interactive, user adjustable with selectable apnea back up time &amp; rate.</li> <li>q) Apnea time : 10 to 40 sec</li> <li>r) Apnea Back Rate: 12 BPM onwards.</li> <li>s) PEEP : 0-35 cm H<sub>2</sub>O</li> <li>t) Sigh Rate &amp; Volume : 1 per 100 breaths &amp; 1.5 times the set I.V. (Pressure or Volume Sigh)</li> <li>u) Pressure limit : (pop off) : 20-99 cm H<sub>2</sub>O or more</li> </ul>
7	Ventilatory Maneuvers	<ul style="list-style-type: none"> <li>a) Expiratory hold</li> <li>b) Manual Breath</li> <li>c) Negative Inspiratory Force Maneuver or RSBI (Rapid Shallow Breathing Index).</li> </ul>
8	Monitored Parameters & Trends on Display	<ul style="list-style-type: none"> <li>a) FiO<sub>2</sub></li> <li>b) EtCO<sub>2</sub></li> <li>c) Resp. Rate: Ventilator &amp; Patient</li> <li>d) Time: Inspiratory, Expiratory, I:E Ratio</li> <li>e) Inspired Tidal Volume: Ventilator &amp; Patient</li> <li>f) Expired Tidal Volume: Ventilator &amp; Patient</li> <li>g) Minute Volume: Ventilator &amp; Patient</li> <li>h) Airway Pressures: Pmax, Pmean &amp; Pplateau.</li> <li>i) PEEP</li> <li>j) Auto PEEP</li> <li>k) Apnea</li> <li>l) Sigh</li> <li>m) Compliance – Static / Dynamic.</li> <li>n) Circuit Resistance</li> <li>o) Rapid Shallow Breathing Index</li> <li>p) Events Log Sheet page.</li> <li>q) Each minute trend of all above mentioned parameters for last 24 hrs</li> <li>r) Alarm log time &amp; date stamped.</li> </ul>
9	Display Characteristics	<ul style="list-style-type: none"> <li>a) In Built &amp; incorporated min.12" Active Touch Screen and with TFT</li> <li>1. Color Graphics Display</li> <li>2. Adjustable scales &amp; sweep speed / Automatic.</li> <li>b) Simultaneous Display Of Waveforms: Flow, Volume &amp; pressure</li> <li>c) Waveforms color coded (for insp. Exp., Spon.) and freezing with movable cursor facility.</li> <li>d) Loops: Flow-Volume &amp; Pressure-Volume, both simultaneous, color coded.</li> </ul>
10	Alarms/Indicators	<p>All alarms &amp; Indicators should have luminous and audible signals priority wise and messages in display.</p> <ul style="list-style-type: none"> <li>a) Apnea.</li> <li>b) Airway Pressure: High/Low</li> <li>c) Battery: Fully Charged/low.</li> <li>d) Breath Rate: High.</li> <li>e) FiO<sub>2</sub>: High/Low (Preset).</li> <li>f) Gas Supply Failure For: Oxygen and air.</li> <li>g) Minute Volume: Low</li> <li>h) Mode of Operation: Mains / Battery.</li> <li>i) Pressure/ Flow Transducer [Sensor] Failure.</li> <li>j) Power Failure</li> </ul>

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HBCL Mumbai

*Pratik*  
MANAGING DIR  
Hafkine Biopharmaceuticals  
Corporation Ltd. CH



		k) Triggered Breath Indicator l) Unusual Incorrect settings m) Ventilator Inoperative
11	Capnography	Capnography etCO <sub>2</sub> monitoring with High and Low etCO <sub>2</sub> alarm and etCO <sub>2</sub> waveform Inbuilt Capnography is with main stream / side stream technology, tenderer will have to supply EtCO <sub>2</sub> adaptor and main stream etCO <sub>2</sub> sensor.
12	Nebulizer	Synchronized INBUILT Nebulizer with adjustable manual timer or Auto OFF.
13	Standard Accessories & Reusable Breathing Circuits.	a. Non Proprietary, chemically sterilizable and steam autoclavable (for minimum 20 cycles), reusable breathing circuit for adult & Paediatric 2 no.s each (Total 4 No.s) b. Reusable flow sensor-Easily removable for sterilization by steam autoclaving 6 no.s c. Reusable & Autoclavable Exhalation valve body & Diaphragm, {for min. 30 cycles} 4 No.s each. d. Should be supplied with 1 reusable EtCo <sub>2</sub> sensor with cable and 5 reusable airway adaptors for main stream. e. Servo controlled humidifier with Adult and pediatric chamber 1 No. each (total 2) along with 30 Adult and 20 Pediatric Cannulas. f. Stand for ventilator and breathing circuit support arm - 1 No. each. of same make and rust free.
14	Disposable circuits and accessories	a) Dual Limb non proprietary disposable circuits to be used- 100 No each b) Disposable HEPA Filters with HME- 100 No.s( 70 Adult & 30 Pediatric). c) Disposable Airway adaptor for EtCo <sub>2</sub> Sensor- 20 no.s., sample line- 100 nos with each sidestream EtCO <sub>2</sub> & 50 Water traps. d) Reusable masks of 3 sizes:- small,medium,large-5 nos each (Total- 15).
15	UPS	TRUE ON LINE UPS for Complete system including Air source for complete protection against all types of Input supply variations.
16	Approval & certification	Quoted model must be FDA (U.S.A) and European CE Approved product - Mandatory & CE marked
17	Literature	Operating manual, Service Manual and list of installations in state & country should be given.
18	Post Record	User friendly with good past record for after sales services in Government medical colleges & submission of 3 performance certificates.
19	Demonstration	Physical demonstration of complete system with all accessories as quoted must be given to technical committee well within the time limit prescribed.
20	Warranty	Comprehensive Warranty: 2 years
21	Comprehensive Maintenance contract	Should include comprehensive maintenance contract for 8 years.
22	Installation Base	Should have at least 20 installation of quoted model in use for last one year in India. Scope of supply should be written in details otherwise tender document remain incomplete. The same will be sent to the user with purchase order. For all imported Equipment the bidder has to submit bill of entry copy for equipment imported in last 02 years. Successful bidder will be required to submit Custom duty clearance copy along with supplies of equipment or else payment will not be released. Bidders should mention clearly those parts which are covered under warranty and those not covered under warranty in Envelope No. 1.

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