SEBUTHARGA MEMBEKAL, MENGHANTAR, MENGUJI DAN MENTAULIAH PERALATAN PERUBATAN BAGI SATU (1) UNIT VENTILATOR FOR NEONATAL AND INFANTS UNTUK JABATAN PEDIATRIK, HOSPITAL SIBU, SARAWAK BAGI TAHUN 2015.

NO. SEBUTHARGA: HS/Q026/2015

No	Specification	Qty	Compliance to Requirements: YES /NO	Remarks
1	**Standards, regulations, certificates of compliance**			
	The device is compliant with the basic requirements from Appendix 1 of the Guideline 93/42/EEC. It is CE marked according to Article 17, which requires that the product has undergone a conformity evaluation according to Article 11. 1.1 EN ISO 9001 1.2 EN ISO 13485			
2	**Application and operation area**			
	2.1 Intensive care units, sub acute care wards, recovery rooms 2.2 Pediatrics and neonates from 400gm-25kgs 2.3 The device can be operated on: > a trolley			
3	**Human interface**			
	3.1 High resolution 17'' colour fully touch screen without hard key 3.2 Screen with day/night switch and automatic switch-over at configured time 3.3 Display of curves, trends, loops, lung display and measured values 3.4 Display of curves, trends, loops and measured values can be strategically configure according to user preference			

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	3.5 Screen configuration can be transferred to another device via USB 3.6 Simultaneous display of pressure, flow, volume waves and loops 3.7 Ventilation curves are filled out and not displayed as lines 3.8 Simultaneous display of 4 ventilation curves and 4 short trends possible 3.9 Possibility to display the following loops: 3.10 Paw-V, Flow-Paw, V-Flow, Ptrach-V, Flow-Ptrach 3.11 Integrated help texts and online short IFU for important ventilation functionalities (e.g. ventilation modes) via screen texts 3.12 Display can be connected directly to an external projector (analogue or digital) for training purposes 3.13 Display can be print sceen via export sceen shoot for teaching purposes/ presentation attachment			
4	**Ventilation modes**			
	4.1 ***Volume targeted ventilation:*** - Volume-targeted ventilation based on pressure controlled ventilation and expiratory tidal Volume 4.2 ***Pressure controlled ventilation:*** - mandatory ventilation/CMV, assisted controlled ventilation/AC - SIMV, SIMV with pressure support			

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	- PC-ventilation with a minimum amount of mandatory minute volume - Pressure controlled ventilation with free spontaneous patient breathing during the inspiratory and expiratory phase 4.3 ***Spontaneous breathing:*** - CPAP with and without pressure - CPAP with volume support 4.4 ***High frequency oscillation (HFO)*** - Pressure controlled HFO with frequencies up to 20 Hz - Pressure controlled HFO with intermittent sigh breaths - Pressure controlled HFO with a volume guarantee 4.5 APRV mode			
5	**Additional ventilation functionalities**			
	5.1 Non-invasive ventilation that can operate in CPAP and controlled ventilation for neonates			
	- Alarm management adapted to mask or prong nasal CPAP/ controlled ventilation - Automatic continuous adjustment of the inspiratory trigger and termination criteria according to leak 5.2 Mandatory ventilation with inversed inspiratory – expiratory time ratio 5.3 Automatic tube compensation with adjustable compensation rate - Compensation rate is adjustable from 0 to 100%			

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	- Tube compensation can be used with any conventional ventilation mode - Tube compensation for in- and expiration and inspiration only - Tube compensation available for mandatory and spontaneous phase 5.4 Adjustable apnea ventilation with pressure regulated (to maintain consistent) tidal volume function and set minimum minute ventilation 5.5 Sigh function with adjustable intermittent PEEP and adjustable duration of the sigh phases 5.6 Manual inspiration hold functionality 5.7 Integrated pneumatic nebulizer with synchronized gas delivery to inspiratory flow 5.8 O_2 suction procedure with a pre oxygenation (max. 180 s), a post oxygenation (max.120 s) and a suction phase (max. 120 s) 5.9 Integrated continuous high flow oxygen application within the device 5.10 RFID functionality for: - Automatic recognition of accessories - Automatic recognition of breathing hose system and recognition and alerting of hose misconnection			
6	**Monitoring**			
	6.1 Calibration of pressure and flow sensor possible any time during ventilation 6.2 ***Pressure monitoring*** Measurement of:			

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	- peak pressure - mean airway pressure - plateau pressure - positive end-expiratory pressure - minimum pressure - end-expiratory pressure for mandatory breaths			
	6.3 ***Flow and volume monitoring*** Measurement of: - tidal volume - inspiratory tidal volume during spontaneous breaths - inspiratory and expiratory tidal volume during mandatory breaths - expiratory minute volume - inspiratory minute volume - leakage corrected minute volume - peak flow - spontaneously breathed minute ventilation - leakage minute volume in % and/or L/min			

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	6.5 ***O_2 monitoring*** Paramagnectic / Consumption free electrochemical measurement of: - inspiratory O_2 concentration FiO_2 - do not required replacement within 5 years 6.6 ***Monitoring of breathing rate, compliance, resistance and I:E ratio*** Measurement of: - total respiratory rate - spontaneous respiratory rate - mandatory respiratory rate - compliance - resistance - inspiration to expiration time ratio - inspiration to expiration time ratio for spontaneous breathing 6.7 ***Diagnostic monitoring*** Measurement of: - rapid shallow breathing index RSB - tidal volume during pressure support			

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	All measures with trend display and cursor for analysis 6.8 ***Graphical representation of the current lung status*** - ability to provide lung and tracheal visual illustrating current resistance and compliance during ventilation - graphical representation of current compliance and resistance in anatomical analogy to the lung 6.8 ***Smart Pulmonary View - Graphical representation to display current lung status*** - Ability to provide lung and tracheal visual illustrating current resistance and compliance during ventilation - Graphical representation of current compliance in anatomical analogy to the lung - Graphical representation of current resistance in anatomical analogy to the airways - Representation of lung resistance excluding ET tube resistance - Graphical illustration providing clear representation of spontaneous and mandatory ventilation pattern - Ability to provide visual illustration representing current spontaneous breathing activity in combination with current resistance and compliance activity - Graphical (including symbol) representation of trigger activity - Ability to perform a “calibration” measurement of current lung status as reference for ventilation management			

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7	**Basic settings**			
	7.1 Respiratory rate: 0.5 – 150/min 7.2 Inspiration time: 0.1 – 3 s 7.3 Tidal volume (for pressure support): 0.002 – 0.3 L 7.4 Inspiratory flow: 2 – 30 L/min 7.5 Inspiratory pressure: 1 – 80 mbar 7.6 Pressure limit: 2 – 100 mbar 7.7 PEEP and intermittent PEEP: 0 – 35 mbar 7.8 Pressure support: 0 – 80 mbar 7.9 Trigger sensitivity: 0.2 – 5 L/min 7.10 Rise time for pressure support: 0 – 2 s 7.11 O2 concentration: 21 – 100 Vol%			
8	**Alarms**			
	8.1 Alarm messages by priority (Note / Caution / Warning) 8.2 360 degree alarm light 8.3 Automatic alarm volume change for day and night mode configurable 8.4 A fault – cause – remedy function with clear text display is integrated in the device for all alarms			

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	8.5 The following alarm limits are adjustable: - MV high/low - f high - P_{AW} high - $etCO_2$ high/low - apnea alarm delay time (5 – 60 s) - disconnection time in NIV (0 – 60 s)			
9	**Accessories**			
	9.1 Reusable breathing circuits for HFOV (Hytrel set) x2 9.2 Reusable silicon breathing circuit X2 9.3 Water trap x2 9.4 Flow sensor ISO x1 9.5 Flow sensor with Y piece x4 9.6 Flow sensor insert (box of 5 pcs) x2 9.7 Expiratory valve x2 9.8 Oxygen sensor paramagnectic x1 (installed in unit) 9.9 Trolley with 4 castors wheel x1			

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	9.10 Infinity hinge arm x1 9.11 Humidifier Fisher and Paykel x1 AND accessories 9.12 Fisher Paykel humidifier accessories, chamber and tubing X 2 pack (10 pieces per pack) 9.13 Heater wyre and hose adaptor x1 set 9.14 O2 hose and air hose at least 3 meter x1 set 9.15 232 serial port x3 9.16 CPAP baby flow prong , mask and caps varies sizes from extreme premature to term.Starter pack X2 9.17 External Backup battery for 6 hours 9.18 Pulse oximeter masimo technology complete with cable, reusable sensor x1 9.19 Disposable Neonate SpO2 Probe (20/bx)			
10	**Service and Training**			
	10.1 The application training provided by factory trained personnel with clinical background only 10.2 The technical service provided by factory trained engineer with with more than 10 years experience only 10.3 Service manual and instruction for use available 10.4 Online simulator or CD trainer should be available 10.5 User manual in both hard copy and soft copy should be provided			

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	10.6 1 year comprehensive service warranty with 6 monthly PPM			
11	Warranty Two Year against Manufacturing Defect from Date Commissioning. Parts availability for at 10 years from date of testing and commissioning. Breakdown respond time should be within 48 hours within warranty period Vendor to specified the warranty period for the parts and accessories			
12	Service Free Preventive Maintenance Service 1 X 6 Monthly During Warranty Period. Supplies have to provide at least two (2) copies of the Operation Manuals in both soft and hard copy during testing and commissioning. Supplies has to provide at least two (2) copies of Instructions for use Manuals with trouble Shoot Guide, Article Numbers Catalogue and ordering Information.			
13	Training On Site Training By Application Specialist And Factory Trained Personnel On Operation Clinical Applications Running Self-Test And Basic Trouble Shooting			
	** SUPPLIER MUST HAVE AND IS REQUIRED TO ATTACH MEDICAL DEVICES ACT LICENSE.			