RespiraWorks Systems Requirements

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Not Reviewed or Released

Section	identifier	title	Requirement
1_General_Product	RW-SYS-016	Reliability	The device must be able to work continuously (100% duty cycle) for a minimum of 48 hours and a target of 2 weeks without pause for maintenance, downtime, or repair.
1_General_Product	RW-SYS-057	Power Requirements AC	The system shall be compatible with 110V/60Hz and 220V/50HZ AC mains.
1_General_Product	RW-SYS-074	Power Requirements DC	The ventilator shall be capable of being run from a 12V power supply
1_General_Product	RW-SYS-024	Compatible with standard/portable O2 and air supply line.	The device shall be compatible with oxygen (DISS) and supply line interfaces standards
1_General_Product	RW-SYS-063	Hot water humidifier	The device shall be have the ability to integrate a hot water humidifier, the humidifiers tl meet ISO 80601-2-74:2017 are compatible with 22mm Respiratory Tubing per ISO 5356 standard. (Note that the fitting for standard breathing tubes and humidifiers is the same
1_General_Product	RW-SYS-076	Max 02 Line Pressure	The system shall be compatible with O2 pressure lines up to 440Kpa
1_General_Product	RW-SYS-136	Gas inlet markings	Gas inlet shall be clearly labelled with gas type, color, and specified pressure ranges alon with direction of flow
1_General_Product	RW-SYS-135	Shock and Vibration	The ventilator shall comply with shock and vibration tests as outlined in 80601-2-12
1_General_Product	RW-SYS-017	Display	The device parameters and alarms shall be readable and/or audible at a distance of 1m

1_General_Product	RW-SYS-069	Logging: Information Storage	The ventilator shall provide non-volatile data storage for at least 5000 events in an event log, including at least the following items: - Ventilation starts and stops - All confirmed Ventilation settings - All confirmed alarm settings - All occurrences and ends of alarms w all their related actions: Inhibitions, cancellations, resets, acknowledge button presses.Th ventilator shall provide a date and time stamp for all event log data. The event log shall note any change to the system's Real Time Clock by logging the Current Date/Time followed by the new Date/Time and a unique event code indicating the change.
1_General_Product	RW-SYS-054	Human Safe Components	The system components that come into contact with the patient airway circuit shall be compatible with the following standards ISO 18562-1 First Edition 2017-03: Biocompatibility Evaluation of Breathing Gas Pathway in Healthcare Applications - Part 1: Evaluation and Testing Within a Risk Management Process ISO 18562-2 First Edition 2017-03: Biocompatibility Evaluation of Breathing Gas Pathway in Healthcare Applications - Part 2: Tests for Emissions of Particulate Matter ISO 18562-3 First Edition 2017: Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 3: Tests for Emissions of Volatile Organic Compounds ISO 18562-4 First Edition 2017-03: Biocompatibility Evaluation of Breathing Gas Pathway in Healthcare Applications - Part 4: Tests for Leachables in Condensate
1_General_Product	RW-SYS-137	Altitude operation	Ventilator shall operate at altitudes below 10k ft
1_General_Product	RW-SYS-140	Cleaning	The ventilator construction shall continue to operate while being disinfected by standard cleaning agents (e.g. bleach)
1_General_Product	HW-024	Anti-Asphyxiation and Anti-Barotrauma	Patient needs to be protected against both asphyxiation and barotrauma in the event of power, mechanical, or computing failure.
2_Ventilator_modes	RW-SYS-131	Pretest Mode	The ventilator shall have a pre-test mode where the patient inhalation port and patient exhalation port are connected and the operation of the device is checked including the capability to produce the correct pressure and flow rate, the function of valves, and the function of tidal volume measurement.

2_Ventilator_modes	RW-SYS-132	Pressure Assist Mode	The system shall support Pressure Assist Mode. In this mode a breath cycle is defined by the control parameters below. The patient can exceed the respiratory rate by initiating additional breaths, but the breath parameters do not change.Control parameters:PIP. Pe Inspiratory Pressure.PEEP. Positive End-Exhalatory Pressure.FiO2. Fraction of Inspired Oxygen.I-time. Inspiratory (rise + dwell) time.Inspiratory sensitivity.RR. Respiratory Rate.Display parameters: PIP/PEEP/RR/FiO2/I-time.Relevant Alarms: * Low tidal volume * High tidal volume * High RR
2_Ventilator_modes	RW-SYS-133	Pressure Support Mode	The system shall support Pressure Support Mode. In this mode the breath cycle shall be defined by the control parameters below. The breath cycle shall be triggered exclusively the patient.Control parameters:SIP: Support Inspiratory Pressure. Like PIP, but specified a support pressure, not a target pressure.PEEP. Positive End-Exhalatory Pressure.FiO2. Fraction of Inspired Oxygen.I-time. Inspiratory (rise + dwell) time.Inspiratory sensitivityDisplay parameters: PIP/PEEP/RR/FiO2/I-time.Relevant Alarms: * Low tidal volume * High tidal volume * Low RR (apnea) *
2_Ventilator_modes	RW-SYS-134	Pressure Control Mode	The system shall support Pressure Control Mode. This mode shall not be featured. It is effectively a subset of Pressure Assist with zero patient inspiratory effort.
2_Ventilator_modes	RW-SYS-077	CPAP Pressure Support mode	The system shall support a HFNC operational mode. In this mode there are no breath cycles. The operator defines the following control parameters:* constant patient pressur (2-20 cmH2O, 2cm increments)constant pressure (2-20 cmH2O)constant flow rate (up to maximum possible L/min)constant FiO2 (21-100%).Needs a child requirement: Shall interface with nasal cannulas or pillows through a standard ET tube adapter interface.
3_Control_Parameters	RW-SYS-005	Positive End-Expiratory Pressure (PEEP) control	The device shall allow the user to establish a PEEP from 0 - 20 cm H2O with increments c cm H20.
3_Control_Parameters	RW-SYS-020	Respiratory Rate control	The device shall be able to provide a Respiratory Rate between 5 - 30 BPM with increme of 1BPM. This is available in Pressure Assist Mode (RW-SYS-132)
3_Control_Parameters	RW-SYS-021	I/E ratio control	The device shall be able to adjust the time ratio of inspiration and expiration from 1:1 to (Inhale to exhale). Increments of 1: .1
3_Control_Parameters	RW-SYS-032	Tidal Volume (TV) control	The device shall be able to support tidal volumes ranging from 200-800ml with incremen of 10mL
3_Control_Parameters	RW-SYS-072	Fraction of Infused Oxygen (FI02) control	The device shall be able to adjust the fraction of inspired O2 (FiO2) in supplied air from 0.21 to as close to 1 as possible with a minimum of 0.9, adjustable in increments of 0.05.

3_Control_Parameters	RW-SYS-078	Minimum Respiratory Rate	The system shall allow the operator to set the minimum respiratory rate of the patient. T device shall initiate a breath If respiration falls below this rate. This control is available in A/C modes.
3_Control_Parameters	RW-SYS-079	High Tidal Volume Level Alarm Trigger	This parameter will enable the operator to set a maximum inspiration tidal volume threshold between the bounds of 80 to 3000 ml in increments of 10ml
3_Control_Parameters	RW-SYS-080	High Pip Alarm Trigger	This parameter will enable the operator to set a PIP maximum threshold. A High priority alarm will occur if the PIP level is above the HIGH PIP level for three consecutive breaths. For pressure assisted modes the high PIP shall be automatically set to PIP +5 cmH20
3_Control_Parameters	RW-SYS-081	High Leak Level Alarm Trigger	This parameter will enable the operator to set a maximum leak threshold between the bounds of 5 to 150 lpm.
3_Control_Parameters	RW-SYS-127	Low Tidal Volume Alarm Trigger	This parameter will allow the operator to set a minimum inspiration tidal volume thresh between the bounds of
3_Control_Parameters	RW-SYS-128	High Respiratory Rate Alarm Trigger	This parameter will allow the operator to set a maximum respiratory rate between the bounds of 5-30 in increments of 1 BPM
3_Control_Parameters	RW-SYS-130	Apnea Alarm Trigger	This parameter will allow the operator to set an apnea alarm trigger between the range 1-30s with 1s incremements.
3_Control_Parameters	RW-SYS-003	Peak Inspiratory Pressure (PIP)	The device must be capable of supplying an inspiratory pressure from 5-55 cmH2O with increments of 1 cm H2O.
3_Control_Parameters	RW-SYS-129		This parameter will allow the operator to set a minimum respiratory rate between the bounds of 2-30 in increments of 1 BPM
4_Performance_Requirements	RW-SYS-083	Patient Pressure measurement	The ventilator shall display the current patient pressure measured at the gas outlet port. The system shall display this information as a graph with duration of 30 seconds updatec at a rate > 25 Hz
4_Performance_Requirements	RW-SYS-084	Tidal Volume measurement	The system shall display the inspiratory tidal volume in range of 0mL to 3000mL with resolution of 1mL
4_Performance_Requirements	RW-SYS-085	I:E ratio measurement	The system shall display the ratio of the inspiration time to the expiration time in the ran of 10:1 to 1:200 with display resolution of 0.1 for values under 10 and 1 for values over 1
4_Performance_Requirements	RW-SYS-086	PEEP measurement	The system shall measure and display the PEEP in increments of 1 cmH2O

4_Performance_Requirements	RW-SYS-087	Instantaneous Volume Measurement	The system shall display the flow rate provided to the patient as a graph with duration of 30 seconds updated at a rate >25Hz and units of liters / minute.
4_Performance_Requirements	RW-SYS-042	Assist Control Mode Delay	During patient assist control modes, the device shall provide patient pressure within 100 ms after onset of respiratory effort (Ppat < PEEP) Pressure assist mode/ Pressure support and others
4_Performance_Requirements	RW-SYS-045	Tidal Volume per minute	The device shall be cable of delivering a minute volume of 30 liters / minute.
4_Performance_Requirements	RW-SYS-088	General Performance Requirements	Commanded parameters not specified in the requirements shall be within 10% of the commanded value
4_Performance_Requirements	RW-SYS-089	Inspiration Trigger Performance	Inspiration cycle shall be triggered when XX (FLOW VS PRESSURE TRIGGER)
4_Performance_Requirements	RW-SYS-092	Peak Inspiratory Flow Rate	The device shall be capable of a peak inspiratory flow rate of at least 80L/min (best case 120 L/min)
4_Performance_Requirements	RW-SYS-093	Breath Rate	The output breath rate shall be within +-1 breath of the commanded value
4_Performance_Requirements	RW-SYS-094	PEEP Pressure during the exhalation Pressure Fall	The pressure overshoot during the pressure fall phase shall not exceed 0.8*PEEP-1 cmH2
4_Performance_Requirements	RW-SYS-095	PEEP Pressure during the Exhalation Steady Phase	Actual PEEP shall be within PEEP setting +-1 cm H2O + 10%.
4_Performance_Requirements	RW-SYS-096	Measured Respiratory Rate	The system shall measure the respiratory rate with an accuracy of +- 1 BPM
4_Performance_Requirements	RW-SYS-082	Respiration Rate measurement	The ventilator shall compute and display the breath rate in increments of 1 breath/min.

4_Performance_Requirements	RW-SYS-050		The device shall be capable of 4 hours (1.5 hours) [WHICH IS IT?] of battery powered operation at nominal settings.
4_Performance_Requirements	RW-SYS-138	FiO2 measurement and display	Ventilator shall display FiO2 as measured prior to patient inhale limb.
5_Alarms	RW-SYS-097	Alarm Backup	There shall be a redundant alarm audible at 60-80 dBa at 1 meter.
			The system shall have multiple priority alarms indicating the severity of the condition. These modes shall be: High - Likely to cause PATIENT injury or death within seconds to several minutes if uncorrected Medium - Do not cause PATIENT injury or death until at least several to many minutes have elapsed Low - May cause PATIENT injury only after many minutes to hours have passed
5_Alarms	RW-SYS-098	Alarm Severities	
5_Alarms	RW-SYS-099	Alarm Priorrities	Alarms shall be shown according to their severity. The highest severity alarm shall be displayed to the user
5_Alarms	RW-SYS-100	Alarm Visual Indicator Distance	Alarm visual indication shall be capable of being read by the user from a distance of 1m
5_Alarms	RW-SYS-101	Alarm Visual Indication for High Severity	High severity alarms shall be indicated with a red color and a flashing frequency of 2Hz with a 50% duty cycle
5_Alarms	RW-SYS-102	Alarm Visual Indication for Low Severity	Low severity alarms shall be indicated with a yellow color which shall be constantly on.
5_Alarms	RW-SYS-103	Alarm Visual Indication for Medium Severity	Medium severity alarms shall be indicated with a yellow color, and a flashing frequency o 0.5Hz with a 50% duty cycle
5_Alarms	RW-SYS-104	Alarm Auditory Signal - High Severity	High severity alarms shall have an auditory signal consisting of 4/10 pulses with each pul lasting 200ms with a pulse frequency of 500Hz.
5_Alarms	RW-SYS-106	Alarm Inactivation	A press on the AUDIO PAUSE / ALARM PAUSE key shall initiate an auditory alarm signal pause of all active alarms during 60 seconds (Assuming that all the active alarms can be inhibited). The alarm activation symbol shall be displayed during the inactivation state w the symbol IEC 60417-5576
5_Alarms	RW-SYS-107	Alarm Dismissal	The system shall have a means to dismiss alarms which states have been previously set.

5_Alarms	RW-SYS-108	Alarms - Apnea	If no breath is triggered within the specified apnea time interval, the ventilator shall respond with a medium priority alarm with the display text "APNEA ALARM"
5_Alarms	RW-SYS-109	Alarms - Breath Rate	When the breath rate has exceeded the breath rate setting, the device shall trigger a medium level alarm with the display text "HIGH BREATH RATE"
5_Alarms	RW-SYS-110	Alarms - Pressure Low	The system shall trigger a low pressure alarm with a high priority in the event of a low inspiratory pressure. The text shall be displayed as "LOW INSP P". This alarm shall be automatically reset upon the first breath with inspiration pressure above the threshold
5_Alarms	RW-SYS-111	Alarms - Pressure High	The system shall trigger a high pressure alarm with high priority in the event the pressur level goes above the high inspiratory pressure threshold for at least three consecutive breath cycles. The audible indication shall be stopped upon the first inspiratory breath th goes below the threshold, but the display shall remain active until the alarm is cancelled.
5_Alarms	RW-SYS-112	Alarms - End Tidal Volume (VTE)	The system shall initiate a medium priority HIGH VTE alarm when the VTE measured valu is above the HIGH VTE for all ventilation modes except CPAP mode The system shall initiate a medium priority Low VTE alarm when the VTE measured value is above the Low VTE for all ventilation modes except CPAP mode
5_Alarms	RW-SYS-113	Alarms - Inspiratory Tidal Volume (VTI)	The system shall initiate a medium priority HIGH VTI alarm when the VTI measured value is above the HIGH VTI for all ventilation modes The system shall initiate a medium priority Low VTE alarm when the VTE measured value is above the Low VTE for all ventilation modes
5_Alarms	RW-SYS-114	Alarms proximal tube disconnection	The ventilator shall initiate a medium priority alarm when the proximal tube is not connected for all ventilation modes.
5_Alarms	RW-SYS-115	Alarm Obstruction	The ventilator shall initiate a high priority alarm if no significant volume can be delivered the patient while the target pressure is reached
5_Alarms	RW-SYS-116	Alarms - High Leakage	A high priority alarm shall be triggered when excessive leakage is observed in the patient circuit
5_Alarms	RW-SYS-117	Alarms - Involuntary Shutdown	The ventilator shall initiate continuous tone alarm when shut down occurs while ventilating. The alarm shall last at least 2 min.
5_Alarms	RW-SYS-118	Alarms - Loss of AC Mains	The ventilator shall provide a medium priority alarm if an AC power source (previously available) is lost or disconnected
5_Alarms	RW-SYS-119	Alarms - Low Battery	A ventilator operating on AC shall provide a low priority alarm when the estimated remaining operating time is 30 minutes or below.
5_Alarms	RW-SYS-120	Alarms - Critically Low Battery	A ventilator operating on battery shall provide a high priority alarm when the estimated remaining operating time is 10 minutes or below.

5_Alarms	RW-SYS-121	Alarms - Battery Failure	The ventilator shall provide a high priority alarm if the battery is absent or not available, if the battery is unchargeable.
5_Alarms	RW-SYS-122	Alarms - Overtemperature	Abnormal temperatures concerning blower (motor temperature) power management system (ambiance close to main heat sinker) and battery (cells temperature) shall be monitored and shall fall under alarm condition and safety actions if they go out of bound
5_Alarms	RW-SYS-068	Multiple Alarms	The device shall be allow the user to view all alarms if multiple alarms are simultaneousl present.
5_Alarms	RW-SYS-139	O2 disconnect alarm	The ventilator shall issue a high priority alarm in the event of O2 disconnection
6_Safety	RW-SYS-010	Pressure: Inherent Protection	The device must, through inherently safe features, prevent patient pressures from exceeding 40/80(depends on SRD) cmH2O in any operating cases or failure modes.Cover SR-20:P_plateau must not exceed 30-35 cmH2OP_peak must not exceed P_plateau + 2 cmH2OOverpressure valve opens at 60 cmH2O
6_Safety	RW-SYS-012	Filter Exhaust/Inlet	The device shall be capable of filtering intake and exhaust to below 0.3 um (HEPA) or fin in order to limit the spread of virus from contaminated patients and to prevent the contamination of the device from patients.
6_Safety	RW-SYS-123	Audible Acoustical limit	The ventilator shall comply with the audible acoustic pressure limites as specified in 806 2-12
6_Safety	RW-SYS-124	Ingress Protection	Ventilator shall have ingress protection level of IP21.IP2x = No penetration into ventilato by solid objects > 12.5mm (e.g. fingers)IPx1 = Dripping water (vertically falling drops) shall have no harmful effect.Ref: www.dsmt.com/resources/ip-rating-chart/
6_Safety	RW-SYS-125	Temperature Sensing	System shall be capable of sensing the temperature of heating elements (blower motor, battery cell during operation)
6_Safety	RW-SYS-009	Asphyxiation Prevention	The device shall prevent pressure from dropping below -4 cm H20 and limit the resistanc to 3 cmH20/l/s.
6_Safety	RW-SYS-141	Patient antiviral filters	The ventilator design shall include antiviral filters on the patient inhale and exhale limbs.