Second Edition
11-04-2020

Pakistan Engineering Council (PEC)

Fast Track Acceptance Test Procedure for Locally Manufactured Mechanical Ventilators for ICU

Acceptance Test Procedure (ATP)

Note: Always refer to latest version of this document published on PEC website.
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Office of Prime Interest:	**Pakistan Engineering Council, Ministry of Science & Technology, Government of Pakistan**

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COMPOSITION OF TECHNICAL AND EXPERT COMMITTEES

Technical and Expert Committees for Acceptance Test Procedure of Locally Manufactured ICU Ventilators

Team of Medical and Critical Care Experts:

1. **Maj. Gen. Aslam Khan (R): Prof. of Pulmonology and Critical Care, Bahria International Hospital, Rawalpindi.**
2. **Maj. Gen Shahab Naqvi (R): Prof. of Anesthesia and Critical Care, Rawal Institute of Health Sciences, Islamabad.**
3. **Maj. Gen. Dr. Ali Shan Rao: Prof. of Anesthesia and Critical Care, HOD Anesthesia CMH, Rawalpindi.**
4. **Dr. Arshad Taqi: Anesthetist and Critical Care specialist, Hameed Latif Hospital, Lahore.**
5. **Dr. Rana Imran Sikandar: Prof. of Anesthesia and Critical Care, PIMS Islamabad.**
6. **Dr. Saeeda Haider: Prof. of Anesthesia and Critical Care Indus Hospital Karachi.**
7. **Dr. Mushtaq Ahmad : Prof. of Cardiology, Bacha Khan Institute of Cardiology, Mardan.**
8. **Dr. Madiha Hashmi : Prof. of Anesthesia and Critical Care , Ziauddin Hospital Karachi.**
9. **Col Dr. Ahmad Burki: Prof. of Anesthesia and Critical Care, CMH, Rawalpindi.**
10. **Dr. Abdur Rashid: Pharmacist, Director and Chairman Clinical Study Committee-DRAP Islamabad.**
11. **Dr. A Q Javed Iqbal: Ex- Director Quality Assurance and Lab Testing- DRAP.**

Team of Biomedical and Professional Engineering Experts:

1. **Engr. Brig Tariq Javed (R): Advisor on Innovation (PEC), Former Commandant NUST College of EME, Project Management Professional (PMP).**
2. **Engr. Shafqat Iqbal: Former Dir/CEO Certification Services Pakistan, Former Head of Biomedical Engg at a Federal Hospital. B.E. Electrical, MBA Proj Mgt, Post Grad Trainings in Medical Equipment, 30+ Certifications in ISO standards at Accreditation and Certification level. 35 + years of experience in Biomedical, Accreditation and Certifications.**
3. **Air Vice Marshal Asad Ikram : Member PEC Innovation & Entrepreneurship Committee and Consultant NRTC. Fellow Royal Aeronautical Society. Former DG Aviation Research Innovation & Development and Commandant College of Aeronautical Engineering, NUST.**
4. **Engr. Dr. Asim Waris: Assistant Professor in the Department of Biomedical Engineering, School of Mechanical and Manufacturing Engineering (SMME), NUST, Islamabad, Member (IEEE).**
5. **Engr. Gp. Capt. Riasat Ali Changezi (R): Worked as standards and certification specialist International civil aviation (ICAO) master trainer and Airworthiness expert of state safety programme and Safety management system. Worked as Director Engineering development for indigenization and reverse engineering of value-added parts. Presently administrator of CAE Professionals group.**
6. **Engr. Dr Muhammad Shafique: Head of Biomedical Engineering Department, Riphah International University (RIU), Islamabad.**

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FOREWORD

This guidance document outlines a systematic approach for the testing and acceptance of locally developed mechanical ventilators.

The procedures stated in the document are for testing of ventilators to be evaluated by technical/expert committee designated by Pakistan Engineering Council (PEC) and Ministry of National Health Services, Regulation and Coordination (NHSRC) for regulatory approval. These testing procedures have been deliberated and are based on the consensus by specialists like Anesthetists, Pulmonologists Intensivists, Regulatory Experts and Biomedical Engineers.

It is also proposed that these procedures shall be reviewed and revised within six months period for improvement.

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DISCLAIMER AND LIMITATIONS

These ventilators would be for ventilatory support in ICUs and other healthcare facilities.

In the absence of any established standard on the subject, Pakistan Engineering Council took an initiative to formulate an Acceptance Test Procedure to facilitate indigenous development of Mechanical Ventilator System and their regulatory approvals.

It is also proposed that these Acceptance Test Procedures (ATP) shall be reviewed and amended within six months period if required.

This whole procedure is being fast tracked to meet the emergency requirement of COVID-19 pandemic.

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Fast Track Acceptance Test Procedure for Locally Manufactured Mechanical Ventilators for ICU

1. Scope

This document is primarily intended for the independent technical testing committee comprising of Anesthetists, Pulmonologists, Intensivists, Biomedical Engineers, Professional Engineers and Regulatory Experts constituted by the Pakistan Engineering Council (PEC) and Ministry of National Health Services, Regulation and Coordination (NHSRC). This committee will use this document as a guideline for testing and regulatory approval of Pakistan Manufactured Ventilator System (PMVS).

2. Normative References:

2.1. Specifications set by the Pakistan Engineering Council (PEC), Ministry of Science and Technology, Government of Pakistan for the locally manufactured Ventilators, reference document PEC-EM-PMVS 001:2020 version 1.1, published on 11th April 2020 (www.pec.org.pk) and reviewed by Experts Committee (Ventilators) on 11th April 2020.

2.2. Specifications set by the Department of Health and Social Care, Government of U.K for Rapidly Manufactured Ventilator System, reference document RMVS001 3.1 published on 26th March 2020 (www.gov.uk).

3. Terms and Definitions

3.1. NHSRC National Health Services, Regulation & Coordination

3.2. PEC Pakistan Engineering Council

3.3. DRAP Drug Regulatory Authority of Pakistan

3.4. Experts Committee: Constitutes Medical, Regulatory, Biomedical and Professional Engineering Experts as cited on page 2 of this document.

3.5. PMVS Pakistan Manufactured Ventilator System

3.6. ATP Acceptance Test Procedure

3.7. Ventilation - Exchange of air between the lungs and the air (ambient or delivered by a ventilator), in other words, it is the process of moving air in and out of the lungs.

3.8. Oxygenation is the process of ensuring adequate oxygen supply to the cells of the human body.

3.9. ARDS – Acute Respiratory Distress Syndrome: a life-threatening form of respiratory failure where the lungs become severely inflamed due to an infection or injury and can't provide the body's vital organs with enough oxygen.

3.10. IPPV – Intermittent Positive Pressure Ventilation: a mandatory invasive ventilation mode used to replace a patient's breathing when they cannot for themselves. Can be either volume controlled, or pressure controlled. It does not synchronize any patient breathing efforts.

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3.11. CMV – Continuous Mandatory Ventilation
3.12. PCV – Pressure Controlled Ventilation
3.13. VCV – Volume Controlled Ventilation
3.14. SIMV-**PC** – Synchronized Intermittent Mandatory Ventilation – Pressure Controlled.
3.15. SIMV-VC- Synchronized Intermittent Mandatory Ventilation - Volume controlled.
3.16. CPAP- Continuous positive airway pressure.
3.17. BiPAP - Bi-level positive airway pressure.
3.17.1. IPAP- Inspiratory positive Airway Pressure.
3.17.2. EPAP - Expiratory Positive Airway Pressure
3.18. PEEP - Positive End Expiratory Pressure
3.19. I:E - Inspiratory to Expiratory ratio
3.20. RR - Respiratory Rate.
3.21. V_t -Tidal Volume is the volume of gas flowing into the lungs during one inspiratory cycle.
3.22. FiO_2 is the fraction of inspired oxygen in every breath.
3.23. HMEF – Heat and Moisture Exchange Filter.
3.24. RF – Radio Frequency for medical devices.
3.25. EM – Electro Magnetic Emissions: Many medical devices are sensitive to EM interference.
3.26. EGSS – Expired gas scavenging system.
3.27. EMC - Electro Magnetic Compatibility
3.28. Flow – Movement of respiratory gases in liters per minute at which the ventilator delivers breaths.
3.29. Compliance - Change in volume of air per unit change in pressure in the lungs.
3.30. OEM - Original Equipment Manufacturer
3.31. STPD Standard Temperature and Pressure Device
3.32. BTPS British Thermal and Pressure Standards

4. Pre-Requisites by OEM

This section covers all the pre-requisites that all OEMs will have to provide before initiating device evaluation process.

4.1. An Undertaking by the OEM's:

Signed Consent Form should be provided by the OEM's Owner or authorized Representative. This document should provide information about the condition of the equipment (working, partially working or damaged), safety and usefulness with regard to the intended purpose and indicate clearly that it will not risk / harm patient and users.

4.2. Compliance & Certifications:

List of ISO & other Standards (Product & Management Systems) for which regulatory compliance and certifications are claimed. Include Report or Certificate(s).

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4.3. Documents of Technical Specifications

4.3.1. General: Information about type of ventilation invasive or non-invasive ventilation, for Adult and pediatric patients etc. **Clinical Environments**: Hospitals, Institutions, Transport and Home care. **Alarm Volume**: Range in Decibels. **Battery Power**: Timings for continuous use. **Power Sources**: AC (wall plugin) DC (external batteries), battery backup (at least 1 hour upto 3 hours): timings. **External Power Requirements:** AC power, DC power. **Physical Dimensions**: Weight, Height, Depth. **User Interface**: Display size, type (touch or buttons). **Operating Environment**: Temperature, humidity, Pressure. **Electromagnetic Compatibility and Protection**: Standards implemented, Electro Static Discharge (ESD) levels etc.

4.3.2. Controls: Breath Rate, PEEP, FiO2, Flow Cycle, IPAP, Tidal Volume, Time Cycle, etc. Modes of ventilation: PCV, VCV, SIMV-PC, SIMV-VC, AC – PC, AC-VC, Pressure support (5-30 cm of H_20), CPAP and BIPAP (Optional).

4.3.3. Alarms: Battery alarm, Circuit Integrity alarm, Fail Alarm, Device alarms, High Breath Rate alarm, High FiO2 alarm, High PEEP, Low Breath Rate, Low FiO2, Low Inspiratory Pressure, Low PEEP, Oxygen failure alarm, tidal volume, minute volume alarm, disconnection alarm or any other alarm as required.

4.3.4. User Manual

The user manual at minimum must contain the following information in an easy to understand language like General Information, Device Description, Safety, Installation, Operation, Maintenance, Replacement Parts, Additional Attachments (Warranty, etc.) and all of the above mentioned specifications.

4.3.5. Service Manual

Revision History (if any), Notices, Safety Information, Equipment Symbols, Introduction, Theory of Operation, Disassembly and Assembly, Software Download Procedure, Calibration Procedure, Operational Verification Procedure, Troubleshooting, Frequently Asked Questions, Maintenance and Cleaning, Specifications, Appendix, Index, Addition attachments (schematics, control diagram etc)

4.4. Medical Device Accessories: The ventilator should include test lung and all other accessories at the time of evaluation.

4.5. QA/QC report: By OEM

4.6. Material Test Reports: By OEM

4.7. Functional Test Reports: If any performed by OEM

4.8. Performance Test Reports: (Clinical Study / trials) performed by OEM.

4.9. Calibration Certificate along with List of equipment used for calibration: By OEM

4.10. Adverse Effects Feedback Form: By OEM

4.11. Complaint Form: By OEM

4.12. Certificate(s): If Device is approved by any Regulatory Body or CE Marked by EU Notified Body etc.

5. Technical Specification Requirements

5.1. Modes of Ventilation:

5.1.1. Controlled Modes: PCV, VCV (must include both)

5.1.2. Assist Modes: SIMV-PC, SIMV-VC / AC – PC, AC-VC

5.1.3. Spontaneous mode: Pressure support (5-40 cm H_20), CPAP and BiPAP (Optional).

5.2. Set Parameters: PEEP (upto 20 cm of H_2O), FiO_2 (0.21-1), Tidal Volume (200-700 ml, optional 800 ml), I: E Ratio (1:1 to 1:3), Triggering (Flow triggering-0.5 to 5 liters per minute), Respiratory rate (8-35 per minute), pressure control (0-40 cm H_2O), pressure support (0-40 cm H_2O).

5.3. Measured Parameters: Exhaled Tidal Volume, Respiratory rate, Plateau Pressure, Peak airway pressure, FiO_2.

5.4. Cycling: Flow, Pressure, Volume and/or time cycling.

5.5. Alarms: Battery alarm, Circuit Integrity alarm, High and Low Breath Rate alarm, Peak Inspiratory Pressure alarm, FiO_2 alarm, Oxygen failure alarm, tidal volume alarm, minute volume alarm and disconnection alarm.

5.6. Built-in Compressor is mandatory; if it is not possible in initial design then the OEM will mention in the statement and will render a certificate to ensure that it will be incorporated in 2nd design.

5.7. Non- invasive Ventilation (NIV): Optional and preferable.

5.8. Electrical Connections: Equipment to provide standard electrical connections.

5.9. Peak Inspiratory Flow Rate –Ventilator should be able to manage peak inspiratory flow rates up to 100 lpm

5.10. Safety Valve: At least one safety valve must be incorporated in patients circuitry to avoid sudden unexpected increase in pressure.

6. Device Evaluation Methodology

OEM is required to provide all information as per clause 4.0 and demonstrate the device as per specification requirements given in clause 5.0 above. After successful demonstration physical and operational qualification will be undertaken as given in clause 6.0 below. After successful qualification of physical and operational requirements a recommendation will be made to proceed for Performance Qualification (Clinical Study). Note: A separate guideline will be issued containing details of Testing Modalities.

6.1. Physical & Operational Qualification: At an independent testing lab under the supervision of Technical Testing Team constituted by PEC and reps of OEM. An undertaking of Impartiality and Confidentiality to be given by the Testing Team.

6.1.1. Pre-Check Records:

6.1.1.1. Test ID: PEC–POQ-xxx-yy-zzzz, Date, Location, Testing Team, OEM Rep Name, Contact Details of all, Reference ATP Version

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Key: xxx = ISB, RWP, LHR or KHI, yy= Version of ATP, zzzz= Ser No.

6.1.1.2. Device Related Info: OEM & Contact Detail, Device Name, Origin, Device ID, Serial No., Physical Condition, Details of Accessories incl.

6.1.2. Test Setup

6.1.2.1. Test Equipment:

Gas Flow Analyzer(s) like Fluke VT 305 Gas Flow Analyzer, IMT PF 300, IMT CITREX H5, EMC Tester, Digital Multi-meter, Air & Oxygen Supply (Wall outlets or Cylinder), Test Lung etc. or equivalent available test equipment or comparative analysis.

6.1.2.2. Ventilator test conditions

6.1.2.2.1. Connected to gas supplies as specified for normal use.

6.1.2.2.2. Industrial grade oxygen and air may be substituted for the equivalent medical gas, as appropriate, unless otherwise stated.

6.1.2.2.3. When using substitute gases, care should be taken to ensure that the test gases are oil free and appropriately dry.

6.1.2.2.4. If air can be used instead of oxygen without affecting performance this should be done to conserve medical oxygen supplies.

6.1.2.2.5. Gas flowrate, volume and leakage are expressed as STPD apart from the breathing system which are expressed as BTPS.

6.1.2.3. Test lay out

6.1.2.3.1. Attach the ventilator via the intended breathing system to an adult test lung with variable compliance and resistance with an electronic ventilator tester.

6.1.2.3.2. Attach pressure sensor at the connection of the breathing system and the test lung with a 10-90% rise time of ≤ 10 ms.

6.1.2.3.3. Attach pressure sensor to the test lung after the adjustable flow resistor with a 10-90% rise time of ≤ 10 ms. (to measure PEEP)

6.1.2.3.4. Attach a flow sensor between the breathing system and the test lung with a 10-90% rise time of ≤ 10 ms.

6.1.2.3.5. Place an oxygen sensor (0-100 % ± 1%) in the inspiratory limb of the breathing system. (Optional) Place a temperature sensor between the breathing system and the test lung (0-50 °C ±0.5 °C)

6.1.2.3.6. Data acquisition from sensors to be ≥ 200 samples s^{-1}.

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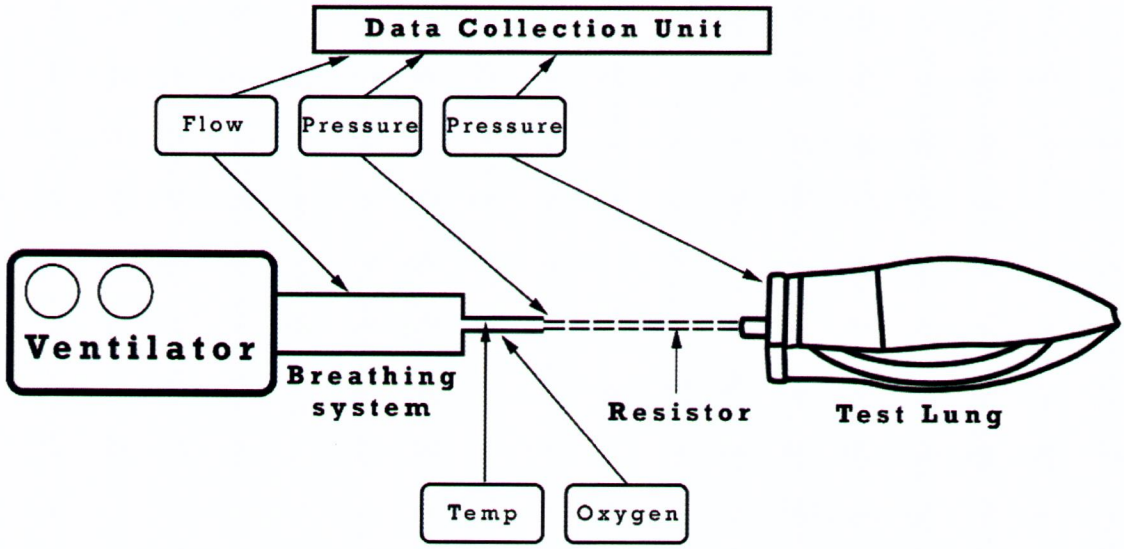

6.1.3. Demonstration of functions and parameters by OEM:

6.1.3.1. Self-test: Automatic test(s) performed by a device upon itself when switched on, to detect any malfunction, a missing component, or a change in its configuration.

6.1.3.2. Panel Labels:

A clearly visible permanent label. The size and font of the text on the labels should be appropriate to the size of the device.

Must include clear labelling of all critical functions and controls using standard terms, pictograms and colors that will be readily recognized by Pakistani healthcare staff.

Must include clear marks or labels to indicate the default settings of 90-100% oxygen, 500mls tidal volume, 5 cmH_2O PEEP and rate 16 breaths per min.

6.1.3.3. Functions & Parameter Setting: OEM must demonstrate ventilator with parameters and specifications mentioned in clause 5.0 above.

6.1.4. Volume Controlled Ventilation Test (Compliance) (Appendix A)

6.1.5. Volume Controlled Ventilation Test (Resistance)(Appendix B)

6.1.6. Volume Controlled Ventilation Test (Tidal Volume) (Appendix C)

6.1.7. Pressure Controlled Ventilation Test (15 cmH_2O) (Appendix D)

6.1.8. Pressure Controlled Ventilation Test (30 cmH_2O) (Appendix E)

6.1.9. Acceptable Performance Parameters:

6.1.9.1. Under steady-state conditions, the indicated airway pressure shall be accurate to within ± (2 +(4 % of the actual reading)) cmH_2O.

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6.1.9.2. The accuracy of measurement of expired volumes greater than 50 ml shall be within ± (4,0 +(15 % of the actual volume expired through the patient-connection port)) ml.

6.1.9.3. Oxygen concentrations will be ± 5 % of the set value.

6.1.9.4. Disconnect alarm will sound within 3 seconds of disconnection.

6.1.10. Pressure Relief Tests

6.1.10.1. Set ventilator to 250 – 300 mls tidal volume or 30 cmH_2O Inspiratory pressure with 10 cmH_2O PEEP at a rate of 10 per min.

6.1.10.2. Set maximum pressure level and alarm to 35 cmH_20.

6.1.10.3. Compress test lung until pressure alarms and ventilator stops inflating and alarms

6.1.10.4. Record maximum pressure reached.

6.1.10.5. Set pressure to maximum value or 70 cmH_20, whichever is lower.

6.1.10.6. Detach test lung and occlude patient end of breathing system.

6.1.10.7. Confirm that pressure in system does not exceed 80 cmH_2O and that alarm is activated.

6.1.11. Closed Suctioning Test

6.1.11.1. Set ventilator to 250 – 300 mls tidal volume or 30 cmH_2O Inspiratory pressure with 10 cmH_2O PEEP at a rate of 10 min^{-1}.

6.1.11.2. Attach intended breathing system to ventilator.

6.1.11.3. Set maximum vacuum to -200 cmH_20 when inlet occluded.

6.1.11.4. Open suction flow control to a free suction flow of 30 lpm.

6.1.11.5. Attach a closed suction system with a 14 Fr catheter fully retracted (important in some systems to produce a gas tight seal).

6.1.11.6. Attach a test lung with a compliance of 10ml / cmH_2O (+/- 10%) to the patient connection port of the closed suction system.

6.1.11.7. Advance suction catheter into test lung.

6.1.11.8. Operate suction control on closed suction system for 3 seconds whilst withdrawing.

6.1.11.9. Confirm PEEP does not drop below 5 cmH_2O.

6.1.11.10. Retract suction catheter fully. Repeat 5 times.

6.1.11.11. Repeat but increase suction time to 30 seconds, (PEEP will be lost, and alarms may sound).

6.1.11.12. Confirm ventilator returns to default settings when suction is stopped.

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6.1.12. Monitoring & Alarms:

6.1.12.1. Must Alarm at: gas or electricity supply failure, machine switched off while in mandatory ventilation mode, inspiratory airway pressure exceeded, inspiratory pressure not achieved, tidal volume not achieved or exceeded.

6.1.12.2. Monitoring Continuous Display: Current settings of tidal volume, PEEP, FiO_2, ventilation mode; Current airway pressure; Exhaled tidal volume and Breathing rate.

6.1.13. Electrical & EMC :

Voltage, Backup Battery, Leakage Current, EMC/EMI (to be verified in hospital environment).

6.1.14. Sound Levels: To be assessed physically

6.1.15. Infection Control:

6.1.15.1. All external surfaces cleanable, compatible with bacterial-viral filter(s). Refer to ISO 17664:2017

6.1.16. Biological Safety: Refers to ISO 18562-1:2017

6.1.17. Robustness:

6.1.17.1. Portable with stable floor standing.

6.1.17.2. All electrical and electronic components as per industrial grade.

6.1.17.3. 100% duty cycle for 14 days (for Final Product).

6.1.18. Software Safety:

Following will exhibit that software has been developed under satisfactory control and is safe and effective before use:

6.1.18.1. Refer to standards given in ISO Standards for Electro medical Devices.

6.1.18.2. Software Development Plan, System & Software requirements specifications, appropriate software architecture and software design documents, a risk management plan and report, software verification validation plans and reports, a software release note.

6.1.19. Calibration Checks: Calibration performance by OEM.

6.1.20. Test Report: Signed by Testing Team and OEM's Rep

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7. Performance Qualification: (for Clinical Trial and Validation)

A clinical trial and validation should be conducted under the supervision of expert team comprising of Anesthetists, Pulmonologists, Intensivists, and Biomedical Engineers, Professional Engineers and Regulatory Experts constituted by the Pakistan Engineering Council (PEC) and Ministry of National Health Services, Regulation and Coordination (NHSRC), along with hospital and OEM reps.

7.1. Installation Qualification: (a part of clinical trial and validation)

Device setup in hospital environment.

7.1.1. Training to clinical trial and validation team: by OEM

7.1.1.1. OEM must demonstrate ventilator with parameters and specifications mentioned in clause 5 above.

7.1.2. Operational & Preventive Maintenance: OEM to provide

7.2. Clinical trials and validation structure: Clinical trials and validation report should be structured while observing standard guidelines given by Expert Committee (Ventilators).

7.2.1. Minimum Number of Hours on Human Subjects: 96 hours continuous operation (more than 1 human subject may be used).

7.2.2. Clinical trial and validation report: Signed by Clinical test/trials team and OEM's rep.

7.3. User Feedback & Acceptance: Form under development.

7.4. Recommendations for Regulatory Acceptance

7.4.1. Test Report of Physical & Functional Qualification with recommendations.

7.4.2. Clinical trials and validation report with recommendations.

7.4.3. User feedback and recommendations.

8. Annexes – Forms, Sample Test, Clinical trials and validation report format etc to be provided for clinical test/trials team separately.

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Appendix A

Volume Controlled Ventilation Test (Compliance)

Test No	Test Lung Compliance ml/cmH_2O ± 10%	Test Lung Resistance cmH_2O/l/s ± 10%	Tidal Volume mls	Rate Min $^{-1}$	I:E	O_2 %	PEEP
1	50	5	500	20	1:2	50-60	5
2	50	5	500	20	1:2	90-100	5
3	50	5	500	12	1:2	50-60	5
4	50	5	500	12	1:2	90-100	5
5	50	5	500	20	1:2	50-60	10
6	50	5	500	20	1:2	90-100	10
7	50	5	500	12	1:2	50-60	10
8	50	5	500	12	1:2	90-100	10
9	50	5	500	20	1:2	50-60	15
10	50	5	500	20	1:2	90-100	15
11	50	5	500	12	1:2	50-60	15
12	50	5	500	12	1:2	90-100	15
13	20	5	500	20	1:2	50-60	5
14	20	5	500	20	1:2	90-100	5
15	20	5	500	12	1:2	50-60	5
16	20	5	500	12	1:2	90-100	5
17	20	5	500	20	1:2	50-60	10
18	20	5	500	20	1:2	90-100	10
19	20	5	500	12	1:2	50-60	10
20	20	5	500	20	1:2	50-60	10
21	20	5	500	20	1:2	50-60	15
22	20	5	500	20	1:2	90-100	15
23	20	5	500	12	1:2	50-60	15
24	20	5	500	20	1:2	50-60	15
25	10	5	500	20	1:2	50-60	5
26	10	5	500	20	1:2	90-100	5
27	10	5	500	12	1:2	50-60	5
28	10	5	500	12	1:2	90-100	5
29	10	5	500	20	1:2	50-60	10
30	10	5	500	20	1:2	90-100	10
31	10	5	500	12	1:2	50-60	10
32	10	5	500	20	1:2	50-60	10
33	10	5	500	20	1:2	50-60	15
34	10	5	500	20	1:2	90-100	15
35	10	5	500	12	1:2	50-60	15
36	10	5	500	20	1:2	50-60	15

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Appendix B

Volume Controlled Ventilation Test (Resistance)

Test No	Test Lung Compliance ml/cmH_2O ± 10%	Test Lung Resistance cmH_2O/l/s ± 10%	Tidal Volume mls	Rate Min $^{-1}$	I:E	O_2 %	PEEP
1	50	5	500	20	1:2	50-60	5
2	50	5	500	20	1:2	90-100	5
3	50	5	500	12	1:2	50-60	5
4	50	5	500	12	1:2	90-100	5
5	50	5	500	20	1:2	50-60	10
6	50	5	500	20	1:2	90-100	10
7	50	5	500	12	1:2	50-60	10
8	50	5	500	12	1:2	90-100	10
9	50	5	500	20	1:2	50-60	15
10	50	5	500	20	1:2	90-100	15
11	50	5	500	12	1:2	50-60	15
12	50	5	500	12	1:2	90-100	15
13	20	20	500	20	1:2	50-60	5
14	20	20	500	20	1:2	90-100	5
15	20	20	500	12	1:2	50-60	5
16	20	20	500	12	1:2	90-100	5
17	20	20	500	20	1:2	50-60	10
18	20	20	500	20	1:2	90-100	10
19	20	20	500	12	1:2	50-60	10
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21	20	20	500	20	1:2	50-60	15
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25	10	50	500	20	1:2	50-60	5
26	10	50	500	20	1:2	90-100	5
27	10	50	500	12	1:2	50-60	5
28	10	50	500	12	1:2	90-100	5
29	10	50	500	20	1:2	50-60	10
30	10	50	500	20	1:2	90-100	10
31	10	50	500	12	1:2	50-60	10
32	10	50	500	20	1:2	50-60	10
33	10	50	500	20	1:2	50-60	15
34	10	50	500	20	1:2	90-100	15
35	10	50	500	12	1:2	50-60	15
36	10	50	500	20	1:2	50-60	15

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Appendix C

Volume Controlled Ventilation Test (Tidal Volume)

Test No	Test Lung Compliance ml/cmH_2O ± 10%	Test Lung Resistance cmH_2O/l/s ± 10%	Tidal Volume mls	Rate Min $^{-1}$	I:E	O_2 %	PEEP
1	50	5	300	20	1:2	50-60	5
2	50	5	300	20	1:2	90-100	5
3	50	5	300	12	1:2	50-60	5
4	50	5	300	12	1:2	90-100	5
5	50	5	300	20	1:2	50-60	10
6	50	5	300	20	1:2	90-100	10
7	50	5	300	12	1:2	50-60	10
8	50	5	300	12	1:2	90-100	10
9	50	5	300	20	1:2	50-60	15
10	50	5	300	20	1:2	90-100	15
11	50	5	300	12	1:2	50-60	15
12	50	5	300	12	1:2	90-100	15
13	20	20	300	20	1:2	50-60	5
14	20	20	300	20	1:2	90-100	5
15	20	20	300	12	1:2	50-60	5
16	20	20	300	12	1:2	90-100	5
17	20	20	300	20	1:2	50-60	10
18	20	20	300	20	1:2	90-100	10
19	20	20	300	12	1:2	50-60	10
20	20	20	300	20	1:2	50-60	10
21	20	20	300	20	1:2	50-60	15
22	20	20	300	20	1:2	90-100	15
23	20	20	300	12	1:2	50-60	15
24	20	20	300	20	1:2	50-60	15
25	10	50	300	20	1:2	50-60	5
26	10	50	300	20	1:2	90-100	5
27	10	50	300	12	1:2	50-60	5
28	10	50	300	12	1:2	90-100	5
29	10	50	300	20	1:2	50-60	10
30	10	50	300	20	1:2	90-100	10
31	10	50	300	12	1:2	50-60	10
32	10	50	300	20	1:2	50-60	10
33	10	50	300	20	1:2	50-60	15
34	10	50	300	20	1:2	90-100	15
35	10	50	300	12	1:2	50-60	15
36	10	50	300	20	1:2	50-60	15

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Appendix D

Pressure Controlled Ventilation Test (15 cmH_2O)

Test No	Test Lung Compliance ml/cmH_2O ± 10%	Test Lung Resistance cmH_2O/l/s ± 10%	Plateau Pressure cmH_2O	Rate Min $^{-1}$	I:E	O_2 %	PEEP
1	50	5	15	20	1:2	50-60	5
2	50	5	15	20	1:2	90-100	5
3	50	5	15	12	1:2	50-60	5
4	50	5	15	12	1:2	90-100	5
5	50	5	15	20	1:2	50-60	10
6	50	5	15	20	1:2	90-100	10
7	50	5	15	12	1:2	50-60	10
8	50	5	15	12	1:2	90-100	10
9	50	5	15	20	1:2	50-60	15
10	50	5	15	20	1:2	90-100	15
11	50	5	15	12	1:2	50-60	15
12	50	5	15	12	1:2	90-100	15
13	20	20	15	20	1:2	50-60	5
14	20	20	15	20	1:2	90-100	5
15	20	20	15	12	1:2	50-60	5
16	20	20	15	12	1:2	90-100	5
17	20	20	15	20	1:2	50-60	10
18	20	20	15	20	1:2	90-100	10
19	20	20	15	12	1:2	50-60	10
20	20	20	15	20	1:2	50-60	10
21	20	20	15	20	1:2	50-60	15
22	20	20	15	20	1:2	90-100	15
23	20	20	15	12	1:2	50-60	15
24	20	20	15	20	1:2	50-60	15
25	10	50	15	20	1:2	50-60	5
26	10	50	15	20	1:2	90-100	5
27	10	50	15	12	1:2	50-60	5
28	10	50	15	12	1:2	90-100	5
29	10	50	15	20	1:2	50-60	10
30	10	50	15	20	1:2	90-100	10
31	10	50	15	12	1:2	50-60	10
32	10	50	15	20	1:2	50-60	10
33	10	50	15	20	1:2	50-60	15
34	10	50	15	20	1:2	90-100	15
35	10	50	15	12	1:2	50-60	15
36	10	50	15	20	1:2	50-60	15

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Appendix E

Pressure Controlled Ventilation Test (30 cmH_2O)

Test No	Test Lung Compliance ml/cmH_2O ± 10%	Test Lung Resistance $cmH_2O/l/s$ ± 10%	Plateau Pressure cmH_2O	Rate Min^{-1}	I:E	O_2 %	PEEP
1	50	5	30	20	1:2	50-60	5
2	50	5	30	20	1:2	90-100	5
3	50	5	30	12	1:2	50-60	5
4	50	5	30	12	1:2	90-100	5
5	50	5	30	20	1:2	50-60	10
6	50	5	30	20	1:2	90-100	10
7	50	5	30	12	1:2	50-60	10
8	50	5	30	12	1:2	90-100	10
9	50	5	30	20	1:2	50-60	15
10	50	5	30	20	1:2	90-100	15
11	50	5	30	12	1:2	50-60	15
12	50	5	30	12	1:2	90-100	15
13	20	20	30	20	1:2	50-60	5
14	20	20	30	20	1:2	90-100	5
15	20	20	30	12	1:2	50-60	5
16	20	20	30	12	1:2	90-100	5
17	20	20	30	20	1:2	50-60	10
18	20	20	30	20	1:2	90-100	10
19	20	20	30	12	1:2	50-60	10
20	20	20	30	20	1:2	50-60	10
21	20	20	30	20	1:2	50-60	15
22	20	20	30	20	1:2	90-100	15
23	20	20	30	12	1:2	50-60	15
24	20	20	30	20	1:2	50-60	15
25	10	50	30	20	1:2	50-60	5
26	10	50	30	20	1:2	90-100	5
27	10	50	30	12	1:2	50-60	5
28	10	50	30	12	1:2	90-100	5
29	10	50	30	20	1:2	50-60	10
30	10	50	30	20	1:2	90-100	10
31	10	50	30	12	1:2	50-60	10
32	10	50	30	20	1:2	50-60	10
33	10	50	30	20	1:2	50-60	15
34	10	50	30	20	1:2	90-100	15
35	10	50	30	12	1:2	50-60	15
36	10	50	30	20	1:2	50-60	15

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9. Revisions

This document should be reviewed and revised as and when required by Expert Committee (ventilator) to meet the changing requirements.

Version	Date Issued	Description
1.0 First Edition	2nd April, 2020	Initial document
1.1 Second Edition	11th April 2020	Revision in specifications by Expert Committee, separate section of specification requirements, formatting and more clarity. Term RMVS is replaced by PMVS.

End of Document

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