**Introduction**

This assessment relates to requirements specified in the IEC 60601 (ISO 80601) series of standards for mains connected medical equipment.

The 60601 series of standards relate specifically to Medical Electrical Equipment (MEE), which in IEC 60601-1 section 3.6.3 is defined as equipment that is connected to the mains supply and used to treat or monitor a patient. Section 3.6.4 of the standard defines a Medical Electrical System (MES) is a combination of items of equipment, of which at least one is a MEE to be functionally inter-connected.

By virtue that the Emergency Ventilator operate at 12v supply and is not directly connected to mains power (it may in fact operate under its own battery power, disconnected from the mains), it does not fall under the definition of a MEE. It receives its 12v power from a combination power supply unit that is connected to the mains supply, which is separately qualified to the relevant conformity standards.

The Emergency Ventilator is however functionally inter-connected with this power supply unit, which makes the Emergency Ventilator an element of the MES. The ventilator must conform to all aspects of the IEC 60601 series of standard that apply to MES – but it is outside scope of conformity requirements that apply solely to MEE. By virtue of IEC 60601-2-12 section 10.2.2 the ventilator must conform to this standard, whether is has an internal or external power supply unit.

Functional safety and performance aspects for MES, such as those specified in IEC 60601-2-12, are all relevant to the Emergency Ventilator.

Contents

[IEC 60601-1 2](#_Toc37884622)

[IEC 60601-1-2 8](#_Toc37884623)

[IEC 60601-1-6 8](#_Toc37884624)

[IEC 60601-1-8 9](#_Toc37884625)

[IEC 60601-2-12 10](#_Toc37884626)

# IEC 60601-1

on Medical electrical equipment, Part 1 General requirements for safety and essential performance.

|  |  |  |  |
| --- | --- | --- | --- |
| 4 | General requirements   * Conditions for application. * Risk management process. * Essential performance. * Expected service life. * Equivalent safety. * Parts that are in contact with the patient. * Single fault condition. * Components used within their ratings. * Use components of high integrity. * Power supply. * Compatibility with mains supply. * Power input. | YES | * The risk assessment considers both normal use and foreseeable misuse. * The risk analysis conforms to ISO 14971. * Essential performance is assessed to conform to IEC 60601-2-12. * Expected service life is defined in the device General Description. * The final residual risks are assessed to be acceptable (see risk analysis). * The parts in contact with the patient are non-conductive and CE-marked. * Single fault safety meets IEC 60601-2-12 requirements. * Functional specification describes technical ratings, which the design meets. * Critical components have predicate use in comparable medical devices. Relevant standards for components are identified and conformity is verified (see functional specification). Non-standard components are system tested. * External power supply is CE-marked. * External power supply is CE-marked. * External power supply is CE-marked. |
| 5 | General requirements for testing   * Type test * Number of samples. * Ambient temperature, humidity, atmospheric pressure. * Other conditions. * Supply voltages, type of current, nature of supply, frequency. * Repair and modification. * Humidity preconditioning treatment. * Sequence of tests. * Applied parts. * Accessible parts (test finger touching mains power). * Test hook. * Actuating mechanisms. | YES,  except section 5.7 | * Tests are performed in accordance with clause 4 and the risk management process in particular. Risk analysis shows conditions are adequately evaluated. * The emergency situation has priorities time to market over multiple sampling. Demands from the emergency situation justified a small sampling size. * The (limited) test are performed in the intended operating environment, in an Intensive Care Unit, within the expected influences. ICUs are controlled environments. * The device development and performance validation has occurred in an environment substantially different to the intended operating environment. Pre-clinical validation data meets performance specification. * External power supply is CE-marked. * Components ratings are specified in the Functional Specification. Testing is specified in the Production Test Specification. * Not applicable. * Tests are planned to be independent. System testing verifies non-interactions. * Device does not have any applied (electrical) parts. * Not applicable. Not MEE, operates at 12v. External PSU CE-marked. * Not applicable. Not MEE, operates at 12v. External PSU CE-marked. * Not applicable. Not MEE, operates at 12v. External PSU CE-marked. |
| 6 | Classification   * Protection against electrical shock. * Protection against harmful ingress of water or particles. * Method of sterilisation. * Mode of operation. | NO | * Not applicable. Not MEE, operates at 12v. External PSU CE-marked. * Not applicable. Not MEE, operates at 12v. External PSU CE-marked. Conformity assess to IEC 60601-2-12 for water test. * Not applicable. * Not applicable. Not MEE, operates at 12v. External PSU CE-marked. |
| 7 | Identification, marking and documents   * Usability of identification and markings and documents. * Legibility of markings. * Durability of markings. * Marking on MEE and MEE parts. * Identification. * Consult accompanying documents. * Accessories. * No error risk power socket. * Connection to mains supply. * Electrical input power from the supply mains. * Electrical output connectors. * IP classification. * Applied parts. * Mode of operation. * Fuses. * Physiological effects (safety signs and warning statements). * High voltage terminal device. * Cooling conditions. * Mechanical stability. * Protective packaging. * External pressure source. * Functional earth terminals. * Removable protective means. * Internal markings. * Power switch has on/off marking. * Control marking * Units of measure * Safety signs * Symbols * Protective earth colours, conductor and connector. * Colour codes of indicator light. * Colour codes of controls. * Accompanying documents and user instructions. | YES,  in part | * Assessed by clinicians. Usability evaluation is recorded in pre-clinical evaluation. * Marking are visible in positions of normal use, at angle up to 30 deg. and 1m distance. * Markings durable and resistant to usual cleaning agents. They are removable only by tools. Rubbing test recorded in pre-clinical evaluation. * Not applicable (not a MEE). * Device identified as a whole (no detachable parts). Software revision shown on power-up. * Not applicable. Symbol ISO 7000-1641 is not used. * Not applicable. Has no accessories. Uses generic combination circuit. * Single power socket. No potential for error. * Not applicable. Not MEE, operates at 12v. External PSU CE-marked * Not applicable. Not MEE, operates at 12v. External PSU CE-marked * Not applicable. Not MEE, operates at 12v. External PSU CE-marked * Not applicable. Not MEE, operates at 12v. External PSU CE-marked * Not applicable. No electrically conductive applied parts. * Not applicable. Not MEE, operates at 12v. External PSU CE-marked * Not applicable. Not MEE, operates at 12v. External PSU CE-marked * Not applicable. No unobvious effects unknown to qualified user of device. * Not applicable. * Not applicable. Cooling not required. * Not applicable. * Packaging evaluated for storage and transport. See pre-clinical evaluation. * Maximum supply pressure is marked. * Not applicable. Not a MEE. * Not applicable. Not a MEEE. No removable protections. * Battery labelled according to EC requirements. No heating elements, lamps, fuses, thermal switches, earth terminal, supply terminals, temperatures or high voltage. * Power switch is labelled ON/OFF. Combination power unit is switched on the wall. Battery backup. Power down require confirmation, by pushing button of front panel * Controls are clearly displayed on LCD. Change require confirmation action, by button pushes in 2 different locations on the device interface. * Uses EU harmonised standard ‘bar’, ‘mbar’ and ‘seconds’. * No operator warning signs. Pressure limit on reverse conforms units of measure. * Symbols are explained in the user instruction. Controls do not use symbols. * Not applicable. Not MEE, operates at 12v. External PSU CE-marked * Conforms to IEC 60601-1-8. * Not applicable. Controls are not colour coded. * User instructions include model, manufacturer, warnings, safety notices of residual risks and user specification/responsibilities. Specifies that the combination power supply is a Medical Equipment System. Specifies to care for backup battery and how to check. Describes the equipment, its installation/setup, how it functions, its performance characteristics, how it is started up and operated, its messages, its shutdown procedure, cleaning, maintenance, accessories, disposal (environmental), references to technical description. |
| 8 | Protection against electrical hazards from MEE | NO | * Not applicable. Not MEE, operates at 12v. External PSU CE-marked. The AAMI/FDA expert panel on Design Guidance for Emergency Use Ventilators has concluded that plastic breathing tubes provide adequate floating electrical isolation for patient leakage current. In accordance with IEC 60601 (ISO 80801) on mains powered medical devices, Electrical Shock Hazards are not applicable when the patient not being electrically connected to the ventilator. <https://www.aami.org/news-resources/covid-19-updates/covid_cr> |
| 9 | Protection against mechanical hazards | YES | * Risk assessed against the hazards identified in Table 19: Crushing, shearing, cutting or severing, entanglement, trapping, stabbing or puncturing, friction or abrasion, expelled parts, high pressure fluid ejection, falling, instability, kinetic impact, moving and positioning of patient, vibration and noise. All are mitigated to tolerable levels. |
| 10 | Protection against unwanted and excessive radiation hazards | NO | * Not applicable. Equipment is not intended to produce radiation. |
| 11 | Protection against excessive temperatures and other hazards   * Maximum temperature during normal use * Temperature of applied parts. * Fire prevention in oxygen rich environment. * Fire prevention with flammable anaesthetics. * Ingress of water or cleaning fluids. * Compatibility with substances. * Biocompatibility. * Interruption of power supply. | YES,  in part | * Not applicable. Equipment is not intended to produce heat during normal use. * Not applicable. Applied parts are not intended to produce heat. * Environment is intended to be ambient. No component part is intended to reach 300 deg.C temperature or spark. Components are not combustible. * Not applicable. Not intended for flammable anaesthetics. * Passed the compliance test. * Gas path component parts are rated for oxygen compatibility. * Gas path components have a long history of safe use in currently marketed medical devices. Materials are selected for being reasonably pure and simple in nature. The gas pathway does not include any adhesives, Polyvinyl chloride (PVC) and care is given to ensure that gas pathways are free of foreign material (e.g. oil, particles, volatile organic compounds, mould release agents) or toxic compounds (e.g., formaldehyde), and do not release noxious gases (e.g., ozone, carbon monoxide) and fumes. This is included in the production specification. * Equipment has backup battery for 45min operation. |
| 12 | Accuracy of controls   * Control and instrument accuracy. * Usability to IEC 60601-1-6. * Alarm system to IEC 60601-1-8. * Protection against hazardous outputs. * Indication of parameters relevant to safety. * Radiation and acoustic pressure. | YES,  in part | * Controls set in steps that are conventional (1 BPM, 1 mbar) * Quick test of device and user instructions with qualified clinicians. Much simplified device. Risk is tolerated. * Plays IEC 60601-1-8 ‘melody’ but compromises on the tone. Risk is tolerated. * Duality (both controller and monitor) in the monitoring of peak pressure. Dual shutdown if reaches 40mbar. Solenoid valves default to closed position on total power failure. Breathing circuit vents through exhalation valve on shut down. * Risk management process has not identified any required indications (above normal). * Not applicable. No diagnostic or therapeutic radiation or acoustics. |
| 13 | Hazardous situations and fault conditions   * Excess emissions, deformations, temperature, leakage current/voltage or mechanical hazards shall not occur under single fault conditions. * On single fault in electrical, actuating, thermal or limiting devices, the normal condition shall be applied – also in the least favourable conditions. | YES | * All mitigated (several do not apply). See risk analysis. * Conformity assessment to IEC 60601-2-12 for ventilators. |
| 14 | Programmable electrical medical systems   * Application of ISO 14971 demonstrates acceptable risk. * Records and documents relating to ISO 14971 are maintained in the risk management file. * Risk management plan includes reference to PEMS validation plan. * Documented system for problem resolution in software life-cycle is maintained. Process for obtaining bug reports, assessing risks, decision to act or close, record of actions. * Network and data coupling hazards are identified. * Appropriate risk reduction shall be demonstrated. * PEMS architecture shall satisfy the requirement specification. * Design and implementation decomposed into sub-systems, as appropriate. * Verification of risk controls shall be performed. * PEMS validation plan include validation of basic safety and essential performance. * Where PEMS is a modification of earlier validated design, the control the PEMS under change control. * Technical descriptions of network/data coupling in intended use. | YES | * Demonstrated in risk analysis, conforming to ISO 14971. The AAMI/FDA expert panel on Design Guidance for Emergency Use Ventilators has concluded that due to the urgent development of design it is recommended to include a warning in the User Instructions that says “Due to the rapid development cycle for this emergency use device, all efforts were made to verify the software, but defects may still exist. The consequences of these defects are unknown and may pose a risk to the patient”. <https://www.aami.org/news-resources/covid-19-updates/covid_cr> * Met. See risk management file in the design dossier. * Risk management includes the reference. * System is documented in the design authority’s management system (this should require a bugs and resolutions database/table that can follow the design hand-over). * Not applicable. Equipment is standalone. * Met. See risk analysis. * Met. See Functional Specification and record of code walkthrough. * Controller and Monitor developed independently and supervise each other. * See record of code walkthrough. * See record of code walkthrough. * Not applicable. No earlier validated design. * Not applicable. Equipment is a standalone device. |
| 15 | Construction of MEE | NO | * Not applicable. Not MEE, operates at 12v. External PSU CE-marked. Equipment is separately conformity assessed to IEC 60601-2-12. |
| 16 | ME Systems   * Installation and modification shall not result in unacceptable risks. * Accompanying documentation contains needed system information, including intended and incompatible combinations, and warnings. Assembly and cleaning instructions. * Information is sufficient to ensure external power supply comply with IEC 60601-1. * Enclosure parts that can be removed without tools do not expose hazardous voltage contacts. * Separation devices. * Touch currents between parts does not exceed 100uA when connected and 500uA during interruption. * Earth leakage current of multiple socket outlet is <5mA. * Patient leakage current meets IEC 60601-1 Table 3 and 4. * Measurement (in multiple socket outlets). * Mechanical hazards to conform to section 9 above. * Interruption and restoring of power supply shall not result in hazardous situation. * Connectors (electric and gas) are such that incorrect connection or removal is prevented. * Mains power parts, components and layout. | YES | * Risk analysis demonstrated tolerable risks. User Instructions describes residual risks and incompatible modifications/combination devices (e.g. MRI). * User Instructions demonstrates this. * PSU requirement is labelled at power inlet socket on reverse on ventilated and is described in the User Instruction. * Met. Enclosure removal require tools, and opens to 12v circuitry only. * Not applicable. The equipment does not require or use any separation device. * Validated by design walk though by experienced design professionals. The AAMI/FDA expert panel on Design Guidance for Emergency Use Ventilators has concluded that plastic breathing tubes provide adequate floating electrical isolation for patient leakage current. <https://www.aami.org/news-resources/covid-19-updates/covid_cr> * Not applicable. MSE uses single socket. * Device is separated from patient by 1.6M non-conductive plastic tubing. Operating the equipment does not necessitate the operator being in the patient environment (i.e. not touching the patient). * Not applicable. MSE uses single socket. * See section 9 above. * Met. The interruption and restoration of power is seamless. * Met. See Functional Specification and Risk Analysis. * Not applicable. Not MEE, operates at 12v. External PSU CE-marked |
| 17 | Electromagnetic Compatibility conforming to IEC 60601-1-2 | YES | * See assessment to IEC 60601-1-2 below. |

# IEC 60601-1-2

on Medical electrical equipment, Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

|  |  |  |  |
| --- | --- | --- | --- |
| All | EMC performance criteria and testing methods. | YES | The equipment electrical and electronic circuit is designed in accordance with best EMC practices, by qualified electronics engineers with extensive experiences in high-speed data communications. The data and actuator lines are copied form a design (of a third party manufacturer) that has obtained testing certificate of conformity to IEC 60601-1-2. Risk analysis demonstrates the associated EMC risks are tolerated, under the emergency circumstances.  The AAMI/FDA expert panel on Design Guidance for Emergency Use Ventilators has concluded that EMC testing is recommended but not required. Disclosure that these tests have not been performed and that other equipment must be kept at a distance should be considered sufficient. Such a disclosure is included in the User Instructions and labelled as a ‘warning’. <https://www.aami.org/news-resources/covid-19-updates/covid_cr> |

# IEC 60601-1-6

on Medical electrical equipment for basic safety and essential performance – Collateral standard: Usability.

|  |  |  |  |
| --- | --- | --- | --- |
| All | * Equipment shall provide adequate usability such that risks resulting from normal use and use errors are acceptable. * Usability is included in the risk analysis. * Equipment operating principles shall be explained in the user instructions. * User instructions shall be available electronically. * Usability in engineering processes. * Operator-equipment interface shall be verified. | YES | * One fundamental principles of the design is complexity reduction, to match the skills in the emergency ward. * Met. See Risk Analysis. * Met. See User Instructions. * Met. User Instructions are available in PDF file. * Assessed in design review and pre-clinical evaluation, involving qualified, experienced clinicians. Usability evaluation is recorded in pre-clinical evaluation. |

# IEC 60601-1-8

on Medical electrical equipment for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in electrical equipment and medical electrical systems.

|  |  |  |  |
| --- | --- | --- | --- |
| 6 | Alarm system   * Alarms are grouped by PHYSIOLOGICAL, TECHNICAL or OTHER * Alarm priority is defined based on severity and onset potential * Disclosure of intelligent alarm system. * Visible alarm signals. * Audible alarm signals. * Audible alarm volume shall make it distinguishable and disclosed in the User Instructions. * Characteristics of verbal alarm signals. * Disclosure of delays. * Alarm presets. * Alarm presets levels are disclosed in User Instructions. * When power is lost for 30 seconds or less, the pre-existing alarm setting must be maintained. * Adjustable alarm limits. * Alarm system security – means of restricting access. * Alarm system inactivation. * Reminder signals. * Alarm reset may be marked with symbol. * Latching and non-latching alarms. * Distributed alarm systems. * Alarms should be logged. | YES | * Met. User Instructions defines these. * Met. IEC 60601-1-8 Table 1 used to assign priority. * Not applicable. Equipment does not include the definition for intelligent alarms. * Partially met. Compromise on colour combinations, for purpose of faster development time and implementation by lower technology that is more readily available in all world regions in need of emergency ventilators. See Functional Specification. Risk assessed to be tolerable. * Met. See User Instructions. * Not applicable. Verbal alarm signals not used. * Met. See User Instructions. * Met. User Instruction contains a warning that hazard can exist when equipment with similarly sounding alarms are used in the same area. * Met. See User Instructions. * Met. Equipment uses fixed default levels only. * Not applicable. Limits are not adjustable. * Not applicable. Only ‘Mute’ button exists and is described in User Instructions. * Met. Alarm is deactivated for 120s when the alarm ‘Mute’ is pressed. Generation of new alarm continue to happen in the background, to prevent masking by ‘Mute’. * Not applicable. Permanent disablement of alarms is not included. The 120s ‘Mute’ occurs only while the operator is in attendance. * Not applicable. Alarms reset automatically with ‘Mute’ is pressed. * Met. See latching descriptions in User Instructions. * Not applicable. Equipment does not have a distributed alarm system. * Equipment logs the last 10 alarm events. |

# IEC 60601-2-12

on Medical electrical equipment – Particular requirements for the safety of lung ventilators – Critical care ventilators.

|  |  |  |  |
| --- | --- | --- | --- |
| Note: Clauses of the General Standard IEC 60601-1 are repeated in IEC 60601-2-12, where the latter states that the former applies. Such repeats are not documented in this assessment (they are assessed above). Only the assessment of requirements that are particular to IEC 60601-2-12 are recorded here. | | | |
| 6 | Identification and markings   * Indication of origin on the outside of equipment. * Auxiliary sockets marking. * Gas supply input power marked to ISO 5359, including supply range and nominal flow requirements. * Operator accessible ports are marked ‘Gas Output’, Gas Return’ and ‘Patient Pressure’. * Pressure may be displayed in cmH2O. * Identification of gas cylinder and connectors. * Instructions for Use defined first cleaning and maximum reuses and reusable patient parts. * Technical description of computed values, breath trigger and breathing system specification. * Disclose of pneumatic diagram and any restrictions on the sequence of components within the breathing system. * Description of the maximun limited pressure (Pmax). | YES | See above under IEC 60601-1, plus   * Outside of equipment includes the manufacturer name and address. Note, the device is not CE-marked and will not have an Authorised Representative for such purpose. * Not appliable. No auxiliary sockets. * Met. See label specification. * Met. See label specification. * Not applicable. ‘mbar’ is chosen unit. May be converted to regional preferences by simply changing the label to say ‘cmH2O’. The 2 units are within 2.7% range and are practically interchangeable (within measurement tolerance). * Not applicable. * Not applicable. The device has no reusable parts. * Met. See User Instructions. * Met. See User Instructions. * Met. See User Instructions. |
| 7 | Power input | NO | See above under IEC 60601-1. |
| 8 | Basic safety | YES | See above under IEC 60601-1. |
| 9 | Removable protective means | NO | See above under IEC 60601-1. |
| 10 | Environmental conditions   * This standard applies to both internally and externally powered equipment. * Pneumatic power supplies. | YES | See above under IEC 60601-1, plus   * Met. Full assessment to IEC 60601-2-12 is performed (this assessment). * Not applicable. Equipment is not pneumatically powered. |
| 11 to 12 | Not used | NO | Not used. |
| 13 | General – protection against electrical shock | NO | See above under IEC 60601-1. |
| 14 | Requirements relating to classification | NO | See above under IEC 60601-1. |
| 15 | Limitation of voltages and/or energy | YES | See above under IEC 60601-1. |
| 16 | Enclosure and protective covers | YES | See above under IEC 60601-1. |
| 17 | Separation | YES | See above under IEC 60601-1. |
| 18 | Protective earthing, functional earthing and potential equalization | YES | See above under IEC 60601-1. |
| 19 | Continuous leakage currents and patient leakage currents   * Patient leakage current shall be measures from all parts that are defined a Applied Parts | YES | See above under IEC 60601-1, plus   * Equipment does not have any electrical Applied Parts |
| 20 | Dielectric strength | NO | See above under IEC 60601-1. |
| 21 | Mechanical strength | YES | See above under IEC 60601-1. |
| 22 | Moving parts | NO | See above under IEC 60601-1. |
| 23 | Surfaces, corners and edges | YES | See above under IEC 60601-1. |
| 24 | Stability in normal use | YES | See above under IEC 60601-1. |
| 25 | Expelled parts | NO | See above under IEC 60601-1. |
| 26 | Vibration and noise | YES | See above under IEC 60601-1. |
| 27 | Pneumatic and hydraulic power | YES | See above under IEC 60601-1. |
| 28 | Suspended masses | YES | See above under IEC 60601-1. |
| 29 to 35 | Protection from unwanted X-radiation; Alpha, beta, gamma, neutron radiation and other; Microwave radiation; Light radiation (including lasers); Infra-red radiation; Ultra-violet radiation; Acoustic energy | NO | See above under IEC 60601-1. |
| 36 | Electromagnetic Compatibility (EMC) | YES | See above under IEC 60601-1 and IEC 60601-1-2. |
| 37 to 41 | Protection against ignition of flammable anaesthetic mixtures. | NO | See above under IEC 60601-1. |
| 42 to 43 | Protection against excessive temperatures and ignition of oxidants, shall be effective under a single fault condition | YES | Met. Environment is intended to be ambient, without elevated oxygen concentration. Single component fault resulting in over-heating (>300 deg.C) will not ignite ambient. Single fault resulting in an oxygen leak will not be met by high heat (non-faulty) components. The enclosure bottom venting holes to evacuate any oxygen leak failure. |
| 44 | Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility. | YES | See above under IEC 60601-1, plus   * Enclosure with stand top down spillages. * No part is required for detached and reattached for cleaning or disinfection. * Risk analysis demonstrated acceptable toxicity and leaching profiles. * Components in the patient gas flow path are resistant to high oxygen concentrations. |
| 45 | Pressure vessels and part subject to pressure (IEC 60601-1 does not apply to breathing systems). | YES | See above under IEC 60601-1, plus   * No pressure vessel. * Critical parts rating exceeds operating pressure by clear safety margin. See Functional Specification and its critical parts identification. |
| 46 | Human error | YES | See above under IEC 60601-1. |
| 47 | Electrostatic charges | YES | See above under IEC 60601-1. |
| 48 | Biocompatibility. | YES | See above under IEC 60601-1. |
| 49 | Interruption of power supply   * On total power failure (mains and battery), the alarm must signal high priority for at least 120s (2 min). * There must be a prior alarm of impending battery power fail. * Ventilator must enable spontaneous breathing under total power or gas supply failure. Breathing resistance values shall be disclosed. | YES | See above under IEC 60601-1, plus   * The alarm sound for 3min after total power failure. * Low battery failure is signalled at least 10 minutes prior to total failure. * Equipment incorporates a pair of low resistance directional valves to enable spontaneous breathing, without rebreathing. |
| 50 | Accuracy of operating data   * If alarm is inhibited, then there must be visual indication that it is inhibited. * Alarms should not be inhibited or suspended for more than 120s. * When audible alarm is muted, the visual alarm message must remain displayed. * Remote alarm signal capability (if provides). | YES | See above under IEC 60601-1, plus   * When ‘Alarm Mute’ is active, the alarm indicate light will flash, to indicate the inhibition. * The ‘Alarm Mute’ time is 120s. * Alarm message is displayed during ‘Mute’. * Not appliable. Not provided. |
| 51 | Protection against hazardous outputs   * Failure in one supply gas (air, oxygen) should automatically switch to the other gas. Accompanied by at least a low priority alarm. * Protection against inadvertent adjustments. * Means to prevent pressure at patient connection reaching 125mbar under normal use and single fault condition. * Patient press shall be indicated and accurate to within 2% of full scale reading and 4% of actual reading. * Adjustable pressure limitations. * High pressure alarm limit may be independently adjustable. * Measurement of volume alarms (if intended). * The maximum delay before announcing a high pressure alarm is 17 seconds. | YES | See above under IEC 60601-1, plus   * Met. Ventilators accepts one pre-blended gas. * Adjustment require 3 steps on at least 2 push buttons: Selection/commitment, adjustment, confirmation. Buttons are separated by more than 2 finger widths and have different functional spaces. * Both controller and monitor measures pressure and controls a shutdown vale independently. This duality shouts down gas supply at >40mbar, to relieve the circuit through the exhalation valve. * Met. See Pre-clinical validation data. * Not applicable. Pressure Control ventilation. Does not interact with any volume setting and limitations are therefore not required or implemented. * Not applicable. Default high pressure alarm is 3mbar about set. * Not applicable. Not intended to measure volume. * The high pressure alarm is delayed by maximum 4 seconds. |
| 52 | Abnormal operation under fault conditions   * Single fault condition shall not cause the monitoring or alarm system and the corresponding ventilation control function to fail in such a way that the monitoring function becomes simultaneously ineffective, and thus fail to detect the loss of the monitored ventilator function. | YES | See above under IEC 60601-1, plus   * Monitor and controller are implemented independent and isolated electrically, with each their alarm sounding and alarm display functionality. This duality meets the requirement. |
| 53 | Environmental tests | YES | See above under IEC 60601-1. |
| 54 to 56 | Construction requirements   * Limit reverse gas flow from gas input to supply port to 100ml/min under normal use. * Cross-flow between supply gasses shall not excess 100ml/h under normal or single fault conditions. Unless a cross-flow alarm is maintained, in which case it is max 100ml/min. * Gas supply connector shall be NIST of male quick connect to ISO 5359. * Patient circuit conical connectors comply with ISO 5356. * Manual ventilation port is 22mm to ISO 5356. * Directional, emergency air intake port must accept connector and it cannot be fitted in a way that causes hazard to patient. * Accessory port (if provides) is to ISO 5356. * Any monitoring probe port must not be compatible with ISO 5356. Different means to secure the probe must be provided. * If 30mm exhaust gas port is used, then it must be compatible with ISO 5356 for anaesthesia scavenging systems. * Visual displays must be clearly visible. * Reservoir bags shall comply with ISO 5362. * Humidifier or HME comply with ISO 8155 or ISO 9360 respectively. * Pulse oximeters and capnometers shall comply with ISO 9919 or ISO 9918 respectively. * Oxygen monitor shall comply with ISO 7767. * Monitoring devices integrated into the ventilator shall conform to their respective standards. * Leakage from breathing circuit shall not exceed 200ml/min at 50mbar. | YES | See above under IEC 60601-1, plus   * Only one supply line. No risk of supply line mixing. The chosen pressure regulator does not flow in reverse. Diaphragm would close. * Not applicable. The equipment receives a single (pre=blended) gas input. * Met. See Functional Specification. * Met. See Functional Specification. * Not applicable. No manual ventilation port. * Intake is protected from being covered, underneath the enclosure standing on feet. * Not applicable. Not provided. * Pressure monitoring port uses a non-standard push on barbed spigot, for receiving a 6mm OD PCV tube. * Not applicable. 30mm port is not used. * See Usability in the Pre-clinical Evaluation. * Not applicable. Bags not used. * Not applicable. Humidifier and HME are generic combination devices, with their own separate conformity assessments. * Not applicable. Pulse oximetry and capnometers are generic combination devices, with their own separate conformity assessments. * Not applicable. Does not incorporate an oxygen monitor. Ventilator receives pre-blended gas that is monitored in the combination gas supply system. * Not applicable. No monitoring device is integrated. * Not applicable. The breathing circuit is a generic combination device, with its own separate conformity assessment. |
| 57 | Mains parts   * Power cord shall be non-detachable by a pull of 30N. | NO  YES | See above under IEC 60601-1, plus   * Power cord is anchored to the back of ventilator by a P-clip. |
| 58 | Protective earthing – terminals and connections | NO | See above under IEC 60601-1. |
| 59 | Construction and layout | YES | See above under IEC 60601-1. |