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2. Design specifications

2.0.1. Features

SPEC-31 Ventilation mode

Device has a Pressure Controlled Ventilation (PCV) mode

SPEC-46 Usability user-interface

The user-interface is intuitive, simple, and straightforward to use

SPEC-34 Visualized measurements

Volume [mL], pressure [cm H2O] and flow [L/min] must be visualized on the device's screen in graphs or as numbers

SPEC-150 Instructions For Use

Instructions For Use (IFU) are supplied with every device and are available for download online

SPEC-42 Compatibility with standard hospital equipment

The device is compatible with standard hospital equipment according to NEN-EN-ISO 5359:2014/A1:2017 and ISO 5361:2016

SPEC-141 Inspiratory hold

The device can perform an inspiratory hold to determine Plateau Pressure.
When the button is pressed, respiration stops at the peak of the inspiration, while measuring the pressure in the system. When the user lets go of the button, respiration instantly starts again

SPEC-156 Expiratory Hold

The device can perform an expiratory hold to determine PEEP.
When the button is pressed, respiration stops at the end of the expiration, while measuring the pressure in the system. When the user lets go of the button, respiration instantly starts again

SPEC-73 Interruption of power supply

Device is equipped with a UPS to continue ventilation in case of power failure

SPEC-60 Breaks

The device has breaks that shall be used when the device doesn't need to be moved

SPEC-27 Flow Sensor

Device must be equipped with a flow sensor

SPEC-153 HEPA filter

Device can be equipped with a HEPA filter

SPEC-25 HME-filter

Device must be equippable with an ISO 9360-1:2000 certified HME-filter and should be equipped with such a HME filter. These HME filters are disposable and must be changed with every patient.

SPEC-166 Ventilator

The device has a ventilator to mix potential leaking oxygen with surrounding air

2.0.1.1. Ventilation Parameters

SPEC-155 Ppeak setting

The pressure above PEEP can be set by the user in the range 5 to 40 cm H2O, in intervals of 1 cm H2O

SPEC-35 PEEP setting

The positive end-expiratory pressure (PEEP) must be adjustable between 5 and 30 cm H2O, and the PEEP can be adjusted per 1 cm H2O

SPEC-20 Breathing rate setting

The breathing rate can be set by the user between 5/min and 40/min

SPEC-38 I:E ratio setting

Inspiratory:expiratory ratio must be adjustable between 2:1 and 1:3

SPEC-37 FiO2 setting

The FiO2 must be adjustable per 5%

2.0.1.2. Alarms

SPEC-6 Alarm for Inspiratory O2 concentration (FiO2)

An alarm for a too high or too low fractional inspiratory oxygen level.

SPEC-9 Alarm for positive end-expiratory pressure (PEEP)

SPEC-8 Alarm for Tidal volume (Tv)

Provide an alarm when the tidal volume is outside the accepted range set by the user.

SPEC-89 Alarm for Peak Pressure (Ppeak)

SPEC-87 Alarm for Apnea or disconnect

Alarm when inspiratory or expiratory airflow circuit is blocked or disconnected

SPEC-84 Alarm for empty battery

Device issues a warning when battery is almost empty.

SPEC-19 Clear explanation per alarm on GUI

When an alarm or warning is issued, the device must clearly indicate what alarm is issued

2.0.2. Performance

SPEC-95 Error margins: Tidal Volume

Maximum error between internally and externally measured Tidal Volume is 5%

SPEC-94 Error margins: I:E ratio

Maximum error between set and measured I:E ratio is 0.05

SPEC-93 Error margins: FiO2

Maximum error margin between measured and set FiO2 is 5%

SPEC-92 Error margins: breating rate

Maximum error between measured and set breating rates is 1/min

SPEC-90 Error margins: Lung/airway pressure

Maximum pressure loss between device and patient lungs is 10 cm H2O

SPEC-36 FiO2 range

Device is able to provide a FiO2 between 21% and 100% at 5% accuracy.

SPEC-26 Tidal Volume

Device is able to provide tidal volumes between 300 and 700 mL

SPEC-40 Inspiratory Flow

The inspiratory flow that the device delivers to the patient has a peak value of at least 1.5 L/s

SPEC-118 Reliability

Under the same settings the device should give the same output.

SPEC-128 14 day reliability

Device must be able to operate continuously for at least 14 days, preferably more. Specify expected durability in documentation.

2.0.3. Safety

SPEC-29 Peak pressure

Device must keep the peak pressure always below 70 cm H2O

SPEC-146 Flow sensor shielding

Flow sensor is electrically shielded, all components near the flow sensor are non-conductive or sufficiently grounded

SPEC-144 Airflow materials

All components through which inspiratory air can flow are

- biocompatible
- oxygen compatible
- clean
- non-porous
- have a high auto-ignition temperature

SPEC-129 Robustness

The device is able to withstand continous use and transport

SPEC-126 Cleaning and disinfection

The device and its materials are able to withstand regular cleaning and disinfection

SPEC-120 Alarms are easy to understand and intuitive

The alarms are made according to ISO 60601-1-8

SPEC-113 Impairment of cooling

The medical device must remain safe during the failure of cooling systems, f.e. when ventilation openings are covered.

SPEC-103 No air leakage

The device may not leak air or oxygen

SPEC-100 External exhaust outlets

External exhaust outlets are placed in the bottomplate of the device, where they cannot be blocked by walls or other objects

SPEC-99 Temperature of inspirated air

Temperature of the inspirated air and the tubes through which the air flows must be below 30 degrees celcius

SPEC-85 High Voltage circuit outside casing

The high voltage circuitry shall be separated from the high O2 network

SPEC-83 Testing of the fail-safe valve during production

The correct functioning of fail-safe valves shall be tested during production

SPEC-80 Housing impact test

The housing must withstand an impact of a solid smooth steel ball, approximately 50 mm in diameter and with a mass of 500 g ± 25 g, falling freely from 1,3 m height once onto each relevant part of the test sample or swinging like a pendulum, that drops through a vertical distance of 1,3 m, against vertical surfaces. The test is not applied to flat panel displays.

SPEC-79 Housing mechanical resistance

The housing must be able to withstand forces of 250 N without breaking

SPEC-72 Leakage current testing

Since the protective earthing is accessible, leakage current is considered touch current, and the acceptance level for leakage current is <100 uA.

SPEC-71 Patient leakage current

The values for patient leakage must not exceed 50 uA

SPEC-70 Touch current

Touch current from or between parts of the medical device within the patient environment must not exceed 100 µA. Leakage current from accessible outer surfaces of the equipment is also considered to be touch current.

SPEC-67 Acoustic Energy

The acoustic energy emitted by the device shall not exceed 80 dB during worst case normal use

SPEC-65 Sharp edges

The device shall have no sharp edges that could lead to tearing of protective gloves or the skin

SPEC-63 Instability unintended force

The device must be able to withstand unintended forces without tipping over.

SPEC-62 Instability incline surface

Device must not overbalance when placed on an inclined surface at 10 degrees from the horizontal

SPEC-143 Visibility User Interface

The user interface can be easily used and is clearly visible when wearing protective eyewear

SPEC-145 Watchdog program

A watchdog program checks every second if every part of the software does what it is supposed to do. When a part of the software malfunctions, the watchdog will instruct a different part to reboot the malfunctioning part.

SPEC-53 Power Supply

The device shall use a IEC 60601-1 certified mains supply adapter for connection to a 230V AC supply mains.

SPEC-32 Expirated air

The expirated air must always be separated from inpiratory air

SPEC-44 Non-conductive exterior casing

The exterior casing of the device must be made of a non-conductive material or the material must be grounded

SPEC-45 Protective equipment

The device can be used by users wearing personal protective equipment such as gloves and protective glasses

SPEC-23 Protected off switch

The off switch is protected for accidental pressing

SPEC-22 The O2 and air input connectors

The O2 and air input connectors comply with ISO 18082:2014 and are non-interchangeable

SPEC-18 Battery use warning

When power supply fails and the device starts running on battery power, an alarm is issued

SPEC-5 Pressure relief valve

The device has a mechanical pressure relief valve that opens at 70 cm H2O

SPEC-4 Calibrate sensors during assembly

All pressure sensors and the flow sensor must be calibrated during assembly

SPEC-2 Robustness internal components

All internal components are tightly secured to the bottomplate

SPEC-1 Ingress of water

The exterior casing is spraying water proof (comparable with IP-22)

SPEC-162 Installation Verification

Installation Verification is performed after assembly:

- Serial numbers of components have to be registered
- The power supply has to be inspected
- The device has to be inspected visually
- Pressure sensors have to be inspected
- The device has to be turned on and off and power down has to be inspected
- Electrical safety has to be inspected
- Sensors, valves and output have to be tested
- Gas system integrity has to be tested.

2.0.4. Information provided to the user

2.0.4.1. IFU

SPEC-152 IFU: regulatory requirements

The medical device must be accompanied by an IFU with referral address of the manufacturer. These documents can be shared electronically or in printing. Additionally the following must be included:

- a list of all items that are part of the medical device,
- instructions for installation, assemblation and modification,
- instructions for cleaning, desinfection, sterilization of each item or the entire device,
- the safety measures that should be applied during installation,
- which parts are suited for the patient environment,
- Measures that must be applied during preventive maintenance,
- the permissible environmental conditions of use of the ME SYSTEM including conditions for transport and storage,
- advice to the RESPONSIBLE ORGANIZATION: – to carry out all adjustment cleaning, sterilization and disinfection PROCEDURES specified therein;
- advice to the RESPONSIBLE ORGANIZATION: – that the assembly of ME SYSTEMS and modifications during the actual service life require evaluation to the requirements of this standard.
- the name of the device;
- the manufacturer of the device;
- the adress of the manufacturer;
- Indications and contra-indications,
- intended use and intended user;
- the clinical benefit for the patient;
- the performance characteristics;
- the degree of accuracy for the parameters of the device;
- how to verify if the right accessories are used;
- undesirable side-effects;

- preperation of the device before use;
- that users must receive a training before using the device;
- information on maintenance and cleaning of the device and accessories;
- information on cleaning and disinfection between the use on different patients;
- all the warnings that will lead to malfunction of the device and/or changes in the working of the device that will lead to risks to the patient. This will include enviromental changes, like diagnostic or therapeutic procedures;
- how the device can safely be disposed;
- publication or printing date with version number;
- that SAE's must be meantioned to the manufacturer;
- how to safely use the software on the device.

SPEC-47 IFU: intended use

IFU contains an explanation of the intended use of the device

SPEC-13 IFU: Device not for use during transport

Warning in IFU that the device may not be used during patient transport

SPEC-14 IFU: Check device before use

Warning in IFU that device functionality must be checked before use

SPEC-98 IFU: Do not use when damaged

Instructions For Use mention that the device must be inplugged when damaged, for example after a fall or when other parts are visibly damaged.

SPEC-117 IFU: turn off device before unplugging

Warning in the IFU that the device has to be turned off on the user interface before cutting the power

SPEC-134 IFU: ventilator settings

The IFU mentions the upper and lower limits of the ventilation settings

SPEC-135 IFU: Explanation of the alarms

The alarms, their causes, and how to deal with them should be clearly explained in the IFU.

SPEC-137 IFU: HEPA filter

The IFU contains instructions about the use of the HEPA-filter

SPEC-51 IFU: Instructions for correct and safe maintanance

The instructions for use shall state instructions for correct and safe maintenance

SPEC-138 IFU: alarm boundaries

The IFU explains how to set the upper and lower alarm boundaries and mentions the alarm limits

SPEC-17 Training and clear IFU for the users

IFU and training materials are developed and validated in collaboration with medical doctors and nurses. IFU warns that the device can only be used by trained users.

SPEC-49 IFU: checked by experts

The Instructions for use shall be reviewed by both internal quality control and external experts

2.0.4.2. Label

SPEC-151 Label: regulatory requirements

The label on the device will contain:

- the device name;
- a serial number;
- the manufacturer with address;
- the manufacturing date, as part of the serial number or seperatly;
- immediate warnings with icons.

All will be written in text or official icons.

SPEC-64 Emergency use sticker

The device has a clear warning sticker with the text that it is a device which is meant for use ONLY in emergencies on COVID-19 patients.

SPEC-115 Emergency number on label

A telephone number is shown on the label that can be called when assistance is required

SPEC-133 HEPA filter warning sticker

Sticker above the expiratory air connector of the device with the text that the HEPA filter must be placed before use

SPEC-61 Do not push warning

The label has a warning to not push (ISO 7010 P017).

SPEC-154 Fire warning sticker

The label contains a warning to keep device away from open fire

SPEC-148 Device label

The label is placed on the device and must be visible from the point of use by the user.

SPEC-130 Intuitive for use - training

Must not require more than 30minutes training for a doctor with some experience of ventilator use.

SPEC-48 Vocabulary and Semantics

Always use the standard nomenclature as defined in BS ISO 19223:2019 regarding lung ventilators and related equipment: Vocabulary and semantics.

SPEC-167 Open Source

All documentation of the AIRone is online available for free. When documentation goes missing or is unreadable, the user can refer to the online database.