ENGINEERING
INTERNATIONAL GROUP s.r.l.

Falco 202 Evo - 10.4”

Lung Ventilator

Turbine-driven ventilation

Touch Screen

User’s Manual

GENERAL INFORMATION

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It is however recommended that you make sure you have the most recent version of the manual. In the event of doubt, contact SIARE Engineering International Group s.r.l. (see the address on page IX). The information contained in the present User's Manual can be considered correct, but do not exclude professional knowledge by the user.

The operation and maintenance of Falco 202 Evo (10.4") lung ventilator must be entrusted to qualified technical personnel only. The responsibility of SIARE Engineering International Group s.r.l. concerning the Falco 202 Evo (10.4") lung ventilator and its use is limited to what is indicated in the guarantee supplied.

The contents of this manual do not in any way limit the right of SIARE Engineering International Group s.r.l. to revise, change or modify without prior notice the equipment (including the relative software) described herein.

Unless otherwise specifically agreed in writing, SIARE Engineering International Group s.r.l. is not obliged to supply such revisions, changes or modifications to the owner or user of the equipment (including the relative software) described herein.

The information contained in this manual refers to the versions of Falco 202 Evo (10.4") lung ventilator produced or updated after February 2019. It is possible that some information may not apply to previous versions. Contact SIARE Engineering International Group s.r.l. if you have any doubts.

User's Manual, version DU3104101

Revision 1 - 01.02.2019

Observations

SIARE Engineering International Group s.r.l. wishes to thank you for purchasing one of its products.

Any comment on the accuracy and usefulness of this User's Manual would be very helpful in allowing us to guarantee current and future users of the high-quality level of our manuals. We would be grateful if you would send us your comments (see address at page IX).

The SIARE trademark is used throughout this manual as an abbreviation for the manufacturer: SIARE Engineering International Group s.r.l.

CE 0476

Directive 93/42 EEC

Definitions

Three symbols are used in this User's Manual to indicate particularly important information.

WARNING !!

This indicates a condition of danger for the patient or for the User.

CAUTION

This indicates the possibility of danger to the lung ventilator.

NOTE

This indicates information worthy of note, making the operation of the Falco 202 Evo lung ventilator more efficient or practical.

Warnings, cautions and notes

You are advised to carefully read the information given alongside the three symbols shown on the previous page, since it contains considerations on the safety, the special requirements for the use Falco 202 Evo (10.4”) lung ventilator (*hereinafter called lung ventilator*) and the relative safety regulations.

- In order to understand how the lung ventilator works and how to use it correctly to ensure patient and user safety, the recommendations and instructions contained in this manual must be read with care and understood.
- In order to grant maximum reliability and to ensure the patient and User’s safety, the lung ventilator was designed and manufactured following warranty standards of quality of the product and its components. Any part of circuit must therefore only be replaced with original spare parts supplied or checked by SIARE.
- The lung ventilator must only be used for the purposes specified herein and the safety of the lung ventilator is therefore only guaranteed if it is used in accordance with the instructions given in this manual.
- The lung ventilator must only be used by qualified personnel and only in equipped and dedicated rooms, according to the regulations in force in the country where the lung ventilator is installed. Furthermore, during all the operation of lung ventilator, it is required the presence of qualified personnel.
- Regarding the general safety and to ensure correct technical assistance and avoid possible physical damage to the patient, the maintenance schedule foreseen in this manual must be respected; qualified personnel must only carry out maintenance of the lung ventilator or authorised modifications to the lung ventilator. The user of this product is solely responsible for any operating defect caused by improper use or interventions carried out by third parties other than specialised SIARE personnel.
- The maintenance and the replacement of any part have to be performed by authorized service personnel and only original SIARE spare parts or components checked by SIARE should be used.
- Regarding the general safety of the electro-medical equipment, it is important to follow all rules about the interaction between the machine and the patient, the User and the nearby environment.
- For any repairs to lung ventilator (due to malfunctioning, defects or failures), the user must contact SIARE or the authorised local Technical Service Centre; it is advisable to specify the data on the identification label (model, serial number, ……) when requesting intervention.
- SIARE recommends establishing a maintenance and service contract with SIARE or the local authorised service dealer in order to guarantee the scheduled maintenance required to operate the lung ventilator in a safe and correct manner.

- To prevent the risk of fire, keep the lung ventilator and/or the oxygen tubes away from matches, lit cigarettes and inflammable material, such as anaesthetic gases and/or sources of heat.
- Do not connect the lung ventilator to the patient by flexible connectors, and antistatic or conductive tubes to prevent patient burnings during the use of high frequency surgical equipment, especially dangerous with antistatic tubes. The use of flexible connectors, antistatic or conductive tube is never permitted with lung ventilator.
- Do not use worn and consumed tubes or tubes contaminated by flammable substances like grease or oil to deliver oxygen; (fabrics, oil and other fuels can easily ignite and they intensively burn in air with high concentration of oxygen.
- In the event of fire or an unpleasant smell (e.g. a smell of burning), the lung ventilator should immediately be disconnected from the electrical power supply and from the battery (if fitted).
- When coming into contact with any component of the lung ventilator, the hospital procedures for the handling of infected material should always be respected.
- SIARE is aware that cleaning, sterilisation and disinfection procedures vary considerably from one health structure to another. SIARE cannot be held responsible for the efficacy of the cleaning and sterilisation procedures, nor for the other procedures carried out while the patient is being treated. As regards cleaning, sterilisation and disinfection of the product components, it is therefore recommended that the regulations currently in force in the country where the lung ventilator is installed be taken into consideration.
- The lung ventilator was not designed as a total monitoring device: some conditions of danger for the patients treated with vital support equipment will not trigger any alarm.
- Before using the lung ventilator or any connected component, carefully check that the lung ventilator is functioning correctly; when needed, the preliminary tests must be performed as described in the present manual.
- Do not use pointed instruments, such as pencils, screwdrivers or the like to make selections or settings as they could damage the surface of the LCD panel.
- Check the lung ventilator periodically as described in the relative “Maintenance” chapter and do not use it if it is faulty or malfunctioning. Replace any broken, missing, obviously worn, deformed or contaminated parts immediately, with spare parts supplied by SIARE.
- Do not connect external devices NOT manufactured or NOT authorized by SIARE to the lung ventilator (example: scavenging systems, patient simulators, etc…..), and not described in the present user’s manual: in case of need contact SIARE.

- The correct functioning of the lung ventilator can be impaired if original SIARE spare parts and accessories are not used; the use of other accessories is however allowed only if formally authorised by SIARE in accordance with current safety regulations.
- SIARE assumes all foreseen legal liability if the lung ventilator is used and periodically maintained according to the instructions contained in this manual: the Technical Assistance Report, drawn up and signed by the authorised SIARE technician, is proof of the completion of the scheduled maintenance.
- Notwithstanding the lung ventilator is equipped with a safety valve which allows to the patient to breathe spontaneously the ambient air even in case of gas supply failure, the auxiliary ventilation system must be always promptly available; such a component is part of SIARE Engineering International Group s.r.l. products range.

WARNING !!

- The lung ventilator is not approved for operation in places where there is any risk of explosion.
- Do not use the lung ventilator in the presence of flammable gases.
- The lung ventilator cannot be used in the presence of explosive gases.

WARNING !!

- The lung ventilator shall not be used in a hyperbaric chamber.
- The lung ventilator shall not be used with nitric oxide.
- The lung ventilator shall not be used with helium or mixtures with helium.

WARNING !!

- Before starting the lung ventilator use, you have to carry out the preliminary checks.
- Before connecting the lung ventilator to other electrical equipment not described in this manual, a request for authorisation should be sent to Siare.
- Qualified staff must make the regulation of ventilation parameters.

WARNING !!

Do not block the gas intake port or emergency intake port, thereby interfering with PATIENT ventilation.

WARNING !!

An auxiliary ventilation system is suggested for the patients for which the lung ventilator represents a life support.

WARNING !!

Means for independent ventilation shall be available (i.e. manual resuscitation bag with mask) whenever the lung ventilator is in use.

SIARE declines all civil and penal responsibility in the following cases.

- If the lung ventilator is used in conditions and for purposes not stated or described in this manual.
- If the lung ventilator is used by non-qualified personnel.
- If periodic maintenance as foreseen by this manual has not been carried out correctly or has been skipped.
- If personnel not officially authorised by SIARE have performed maintenance.
- If non-original SIARE spare parts or components not checked by SIARE have been used.
- If the lung ventilator has been connected to equipment not complying with the safety norms for the intended use.
- Direct or indirect damage to persons or things caused by unauthorised technical intervention or by improper use of the lung ventilator not in accordance with the instructions contained in the users and maintenance manual.

Year of manufacture

Check the identification data label of the Falco 202 Evo l(10.4”) lung ventilator in the relative chapter.

Shelf life of medical device

The Directive 93/42EEC on medical devices foresees that the manufacturer defines the shelf life of the device according to the intended purpose. The shelf life foreseen by SIARE for the lung ventilator model Falco 202 Evo is 10 years.

Manufacturer

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Electromagnetic Compatibility

The Falco 202 Evo (10.4”) lung ventilator is designed to operate in the specified electromagnetic environment (see warning below).

The customer or the user of Falco 202 Evo lung ventilator should ensure that it is used in such an electromagnetic environment.

The lung ventilator complies with the EN 60601-1-2 regulations on Electromagnetic Compatibility of electro-medical equipment. It is in any case highly recommended not to use the lung ventilator adjacent to high-powered equipment or to units, which emit strong electro-magnetic fields. Mobile phones, cordless phones or other radio transmitters used in the vicinity of the lung ventilator could influence its operation. Whenever the lung ventilator should be necessarily used nearby to such equipment, it will be required to supervise its normal operation.

In general, as regards the regulations regarding “electromagnetic emissions”, “electromagnetic immunity” and “recommended separation distances between portable and mobile RF equipment and the device”, always refer to what is described in the lung ventilator manual.

Requirements applicable to cables, transducers and other accessories that could affect compliance with the requirements of 6.1 and 6.2

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1 INTRODUCTION

SIARE Engineering International Group s.r.l. is glad to introduce this new product, result of 40 years of experience and investment in technological innovation that we are implementing in recent years.

SIARE Engineering International Group s.r.l. has focused heavily on innovation of materials, ergonomics and ease of use of its equipment. All routine operations have been simplified and the operational procedures are “foolproof”, in this way there is no margin for the user to make incorrect or inadequate manoeuvres.

The new Falco 202 Evo (10.4”) lung ventilator is very different from all the previous versions and it has been conceived for the using in Intensive Care, Emergency and Transport. Even the maintenance procedures have been simplified and the parts subject to wear or deterioration have substantially decreased.

1.1 Intended use

The Falco 202 Evo (10.4”) is a lung ventilator equipped with an innovative pneumatic system including a turbine with differential cooler which grant a longer duration and a higher precision in the delivery of gas mixture.

The Falco 202 Evo can be used on Adult, Paediatric and Neonatal patients; it has been conceived for the using in emergency, transport, intensive care and for hospital patients affected by chronic respiratory failure (CRF). Thanks to its versatility and a lot of new functions, the Falco 202 Evo can be used on patients since the first hospital recovery and for the eventual sharpening of the pathology up to join a stable condition of the patient itself.

The Falco 202 Evo includes new advanced functionalities that help you manage the operating modes and the various patient ventilation functions; the keyboard and the encoder knob simplify the settings and the operations significantly.

The present manual explains how to use the Falco 202 Evo (10.4”) lung ventilator system and how performing some simple maintenance procedures.

SIARE recommends to read carefully the present manual and its relevant instructions before using the ventilator or proceeding to maintenance.

WARNING !!

Please read the recommendations and the instructions herein in order to ensure a correct and safe use of Falco 202 Evo both for the clinician and for the patient.

The Falco 202 Evo must be used only for the purposes mentioned below and, in the manner, described herein, therefore the clinician must thoroughly follow these instructions for use.

1.2 Main innovations

The new 2nd generation of Falco 202 Evo (10.4”) combines aesthetic and reliability in an ergonomic structure which permit to the device to be easy to use and easy to understand.

1.2.1 Automatic compensation of all ventilation parameters

- Automatic compensation of all measured and supplied ventilation parameters, with no need of User intervention.
- The new design is based on a dedicated microprocessor only for flow compensation: that guarantees an outstanding precision and response time, breath by breath.

1.2.2 Falco 202 Evo: high performance intensive care ventilator

- The same functions necessary in IGU, now available in a portable ventilator.
- It includes both pressure and flow trigger.
- It includes the most modern ventilation modes: volume-controlled ventilation modalities VC/VAC, VC/VAC-BABY, pressure-controlled ventilation modalities APCV (BILEVEL ST), APCV-TV, SIMV by Volume and by Pressure, Pressure supported modalities PSV (BILEVEL S), PSV-TV, CPAP, APRV, SIGH, Non Invasive Ventilation (NIV APCV – NIV PSV), Drug Nebulizer and Manual Ventilation (MAN).
- Adult, paediatric and neonatal ventilation, thanks to an adjustable Tidal Volume from 2 ml to 3000 ml.
- After the device switching-on the device, it is possible to choose the patient type (adult, paediatric and neonatal) setting the relevant default parameters.
- In spontaneous ventilation mode, it ensures inspiratory flow up to 190 l/min, both with control and support pressure.

1.2.3 PEEP and leakages compensation

- PEEP up to 50 cmH_2O with high precision and stability.
- Flow-by with automatic leaks compensation up to 60 l/min.
- NIV (Non Invasive Ventilation) by means of facial mask or helmet.

1.2.4 10.4” LED display touch screen and graphic interface

- New high resolution display with easy and user friendly graphical interface.
- Graphs, loops, measures, displayed simultaneously.
- Leaks percentage visualization (Leak: %).
- Visualization of the value of the O_2 consumption (L/min)

1.2.5 Small and powerful

- Dimensions, 290 x 245 x 215 mm (W x H x D) and light weight 5.5 Kg.
- These special features permit to the Falco 202 Evo to be handy and easy to use in small spaces even during transport.

1.2.6 Battery

- Thanks to Ni-Mh 12Vdc / 4.2Ah internal battery it has been possible to have a battery autonomy of about 4 hours.
- The battery can be recharged by 12Vdc power supply or by 100-240Vac / 50-60Hz mains.
- The battery is easily removable for service operations.

1.2.7 Turbine advantages

- The air is generated by the internal turbine, so no external air sources are requested to power the ventilator.
- It's practice in environments with limited infrastructures or with the need of frequent movements and transports.
- The Falco 202 Evo include one high pressure O_2 inlet and one low pressure O_2 inlet and gives the possibility to set the FiO_2 from 21% to 100%.

1.3 Main technical characteristics

1.3.1 Graphic user interface (GUI)

The graphic user interface (**GUI**) includes: a led 10.4" touch-screen display, a membrane keyboard and one encoder. The display shows the measured ventilation parameters, pressure, flow, volume curves, loops and trends; moreover, it shows the ventilation parameters and the leak percentage value (leak: %).

The user has the possibility to set all the functions available on the GUI using the keyboard and the encoder present on the front panel of the device.

The graphic interface includes a screen divided in areas where it shows:

- operative modes
- alarm messages and signals
- the monitoring of physiological breathing parameters
- the visualization of additional graphs, the breathing parameters, the leak (%) and oxygen consumption (L/min)
- function MENU for setting operation parameters
- special functions
- the visualization of clock, date, time functions and software version.

1.3.2 Electronics and driving

The electronic of the lung ventilator is developed on a single main board; this board handles all the information received by the connected devices (the graphic interface settings, sensors, turbine and monitor interface) and consequently set the ventilation.

The lung ventilator is equipped with a battery charger board which handle the charging of the internal Ni-Mh battery and with an internal power supply module (feeder) which takes care of the alarms relevant to the main power supply absence and/or discharged battery.

1.3.3 Pneumatics

The pneumatic part of the lung ventilator consists of various internal pneumatic circuits as well as actuators designed to control the flow and the pressure of the medical gases. The lung ventilator does not need to be connected to any medical gas distribution sources or to devices that supply compressed air since this is done independently by an internal turbine.

The lung ventilator is able to deliver Air/Oxygen mixtures as it could be connected to an external Oxygen source (*please, refer to chapter n. 2*).

1.4 Correct operation

For correct and complete operation, the Falco 202 Evo (10.4”) must be:

- correctly connected to the patient circuit;
- connected to a mains power supply with the same voltage as specified on the identification plate (or supplied by internal battery);
- properly connected to all accessories and equipment necessary for the operation of the lung ventilator;
- if requested, connected to the O_2 outlets of the medical gas distribution system.

The connections with main power supply, as well as connections with medical gas distribution system must be affected according to the indications contained in the present user’s manual (see on chapter 2).

The Falco 202 Evo incorporates a series of sensors for continuous patient monitoring, the most important of which are:

- the flow sensors on the expiratory (external) / inspiratory lines (internal), are used to measure the expiratory / inspiratory volumes of the patient;
- the pressure sensors (internal), used to control the pressure of the airways or of the medical gases;
- the oxygen sensor (external), used to measure the concentration of oxygen in the gas inspired by the patient.

The output signals (from the, pressure, flow and oxygen sensors) are filtered by an R-C circuit from the input circuits. This particular electronic filtering is used to eliminate disturbances before the signals themselves are processed by the microprocessor.

Before using the lung ventilator, the clinician should check the operation of all these sensors in order to avoid any incorrect assessments of patient's condition.

WARNING !!

Before using the lung ventilator on a patient, it is necessary to perform a series of preliminary checking to verify the correct operation of the equipment.

The preliminary checking has the aim to verify the correct connections and functionalities of the ventilator and all its parts.

For its employ the Falco 202 Evo has been designed and made to guarantee the full quality of the product and its components, in order to ensure the maximum reliability of the lung ventilator for the patient and user safety

To ensure the best performance of the lung ventilator periodic maintenance of the unit by qualified technical personnel is recommended. For further information, contact SIARE Engineering International Group s.r.l.

SIARE Engineering International Group s.r.l. recommends careful reading of this manual and the relative labels before operating the lung ventilator or carrying out any maintenance.

1.4.1 Use

The use of Falco 202 Evo (10.4”) lung ventilator is simple and intuitive for the persons skilled on resuscitation ventilators, a short training course is in enough to learn how to use it. A basic user interface: keyboard, encoder knob and a 10.4” touch screen display simplifying the selection of the most suitable settings. The 10.4” touch screen display, ventilator settings and the measured data, as well as several functions, allowing the clinician to asses patient's condition immediately; you can also select and view the trend of the pressure, flow, volume, flow/volume loops, pressure/volume, pressure/flow, over time.

An immediate information management system allows the clinician to set the alarms, collect data concerning the trend of the operating parameters (**TREND**) and the ventilator **EVENTS** log using the MENU. The same system allows the User to set the patient type (neonates, children, adults), load or erase the **PATIENT DATA** and in case of need, to load automatically the **DEFAULT PARAMETERS** of the lung ventilator.

1.5 Norms and standards regulations

The Falco 202 Evo (10.4”) lung ventilator is made in compliance with the following norms (and following updates) and it is manufactured according to UNI EN ISO 13485:2016 standards.

EN 60601-1 :2006/A1 :2011/A1 :2013
Medical electrical equipment. General requirements for basic safety and essential performance.

EN 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

IEC 601-1-6:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.

IEC 601-1-8:2012 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.

EN 601-2-12:2007 Medical Electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators.

ISO 80601-2-12:2011 Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators.

EN 62304:2006/AC:2008 Medical device software - Software life cycle processes.

ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

IEC 62353:2014 Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment

ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

2011/65/CE RoHS Directive (On the restriction of the use of certain hazardous substances in electrical and electronic equipment).

D.Lgs 49/2014 RAEE Directive (Implementation of the 2012/19/UE Directive on waste electrical and electronic equipment).

ISO 14971:2012 Medical devices. Application of risk management to medical devices.

UNI EN ISO 4135:2001 Anaesthetic and respiratory equipment - Vocabulary.

93/42/EEC (2007) European Medical Devices Directive.

2 DESCRIPTION

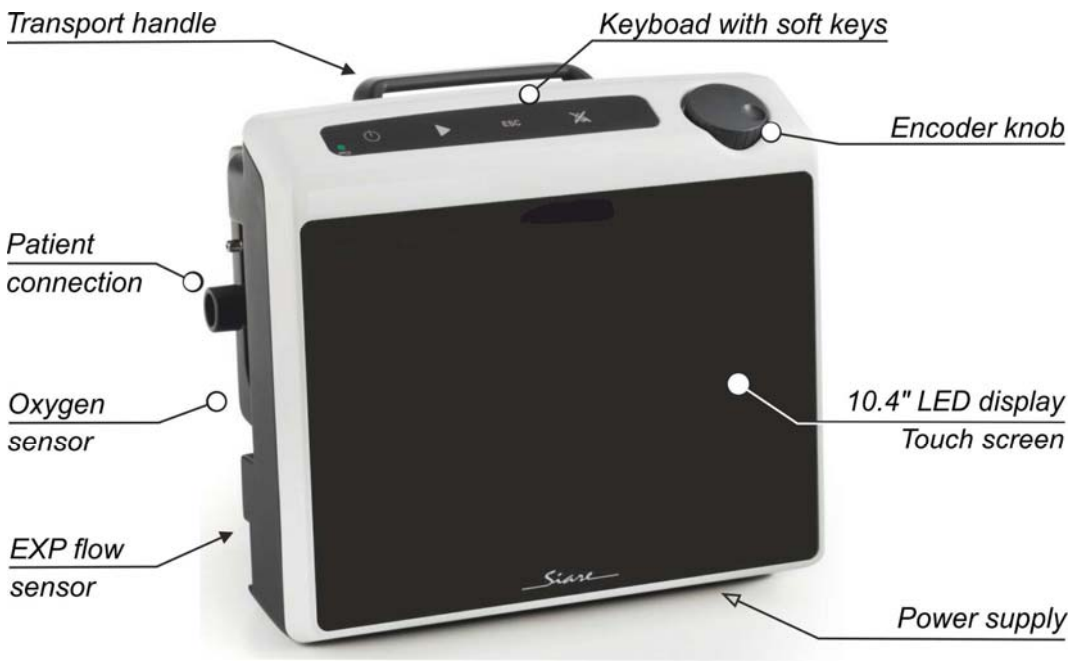
This section of the user manual features the main parts and components of Falco 202 Evo (10.4”) lung ventilator (*hereinafter called lung ventilator*) and some of its most used functionalities.

2.1 Overall view

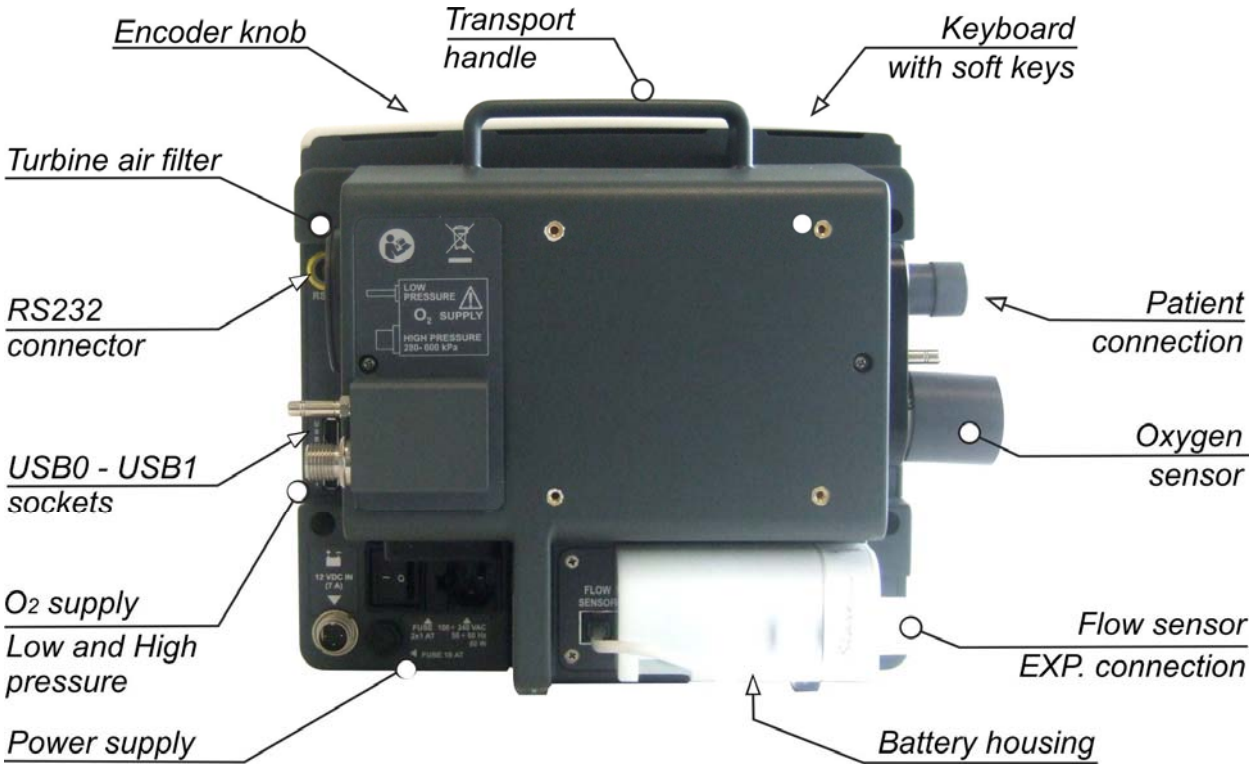
With regard to the assembly, the interface and the servicing operations, please refer to the relative chapter or contact Siare technical support service.

All the pictures and the examples shown in the present chapter have the sole purpose of being an example and they do not make any reference to real clinical cases.

Front view: Falco 202 Evo (10.4”)



Rear view : Falco 202 Evo (10.4”)



see 2.1 *Overall view (front, side and rear view)*

see 2.1.1 *Power supply area*

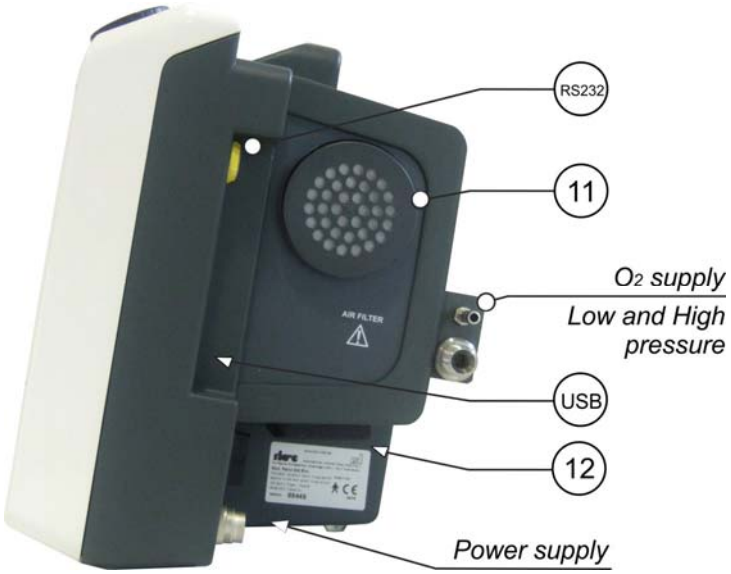
see 2.1.2 *Pneumatic area (Oxygen)*

see 2.1.3 *Patient connections*

see 2.2 *Touch screen / Keyboard and encoder knob*

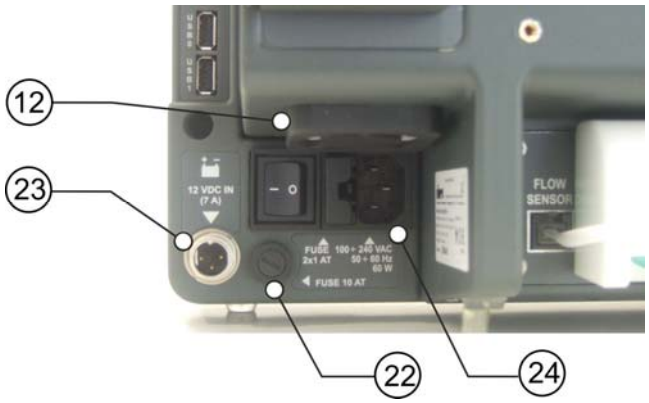
see 2.3 *Lung ventilator description*

Side view: Falco 202 Evo (10.4”)



11	**AIR FILTER**: turbine air filter
	O_2 connection *(see following chapter)*
12	**Air intake**
RS232	**RS-232** *(ODU connector)* for CO_2 sensor connection
USB	**USB connectors**: CPU programming or Trend and Events downloading
	Power supply (please, refer to following paragraph)

2.1.1 Power supply area



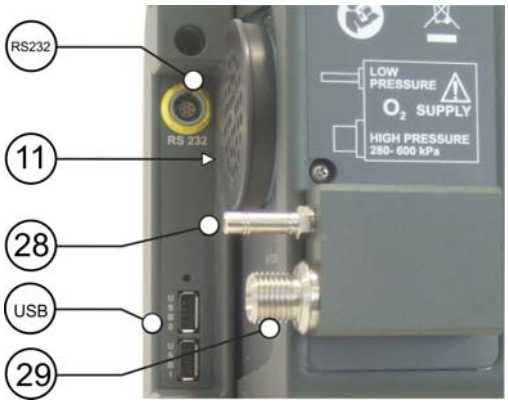
22	**FUSE 10 AT**: safety fuse for battery power circuit (1 x 10 AT)
23	**12 VDC IN (7 A)**: connector for external 12 Vdc 7A power supply

The external supply voltage can be provided trough a battery or a supply source having the characteristics above specified.

An external battery used as power source for the functioning of the Falco 202 Evo become integral part of this medical system.

24	**I / O**: lung ventilator supply switch **FUSE 2 x 1AT**: safety fuses for 220 Vac power supply circuits **100-240VAC 50-60Hz 60VA**: plug for mains power supply connection
12	**Air intake**

2.1.2 O_2 pneumatic area



USB	**USB sockets** for programming. One USB socket for CPU programming (near the reset button) and one USB socket for Screen Shoot (*for more instructions see on Service Manual*).
11	**AIR FILTER**: turbine air filter
28	**LOW PRESSURE**: connection for low pressure medical oxygen from a low pressure source
29	**HIGH PRESSURE**: connection for high pressure oxygen source

WARNING !!

LOW PRESSURE: the medical O_2 low pressure source should have a maximum flow of 15 l/min.

HIGH PRESSURE: the medical O_2 pressure should range from 280 kPa to 600 kPa (2.8 - 6 bar / 40 - 86 psi).

2.1.3 Patient connections

31	**FLOW SENSOR**: flow sensor placed on expiratory patient line
32	**O2 SENSOR:** mechanical guard for O2 sensor electrical connection
33	**V.EXP** (option): unused fitting
34	**NEBULIZER**: outlet fitting for nebulizer circuit (6 l/min)
35	**INSP. TO PATIENT**: inhalation fitting for patient circuit
36	Transport handle

2.2 Touch screen and Keyboard

2.2.1 Touch screen

In electronics a “ touch screen “ is a particular device obtained from the merge of a display/screen and a digital display, allowing user interaction with a graphic interface by fingers or particular objects. Therefore, a touch screen is an inlet and outlet device at the same time.

The touch screen, thanks to its features, can replace the functions of the keyboard with soft key and encoder knob, and can have, contemporarily, a larger display in the same space and a direct interactivity between user and device.

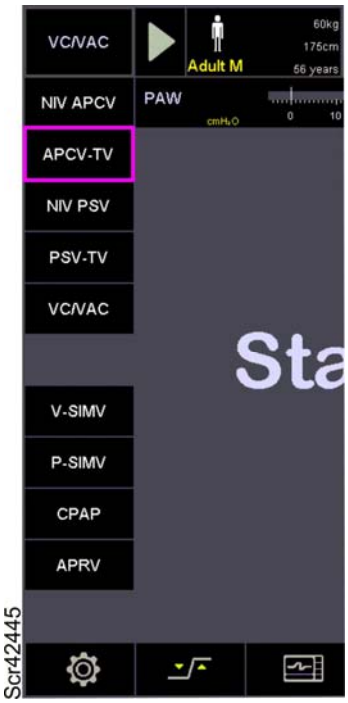
Here below some examples on how to use the “touch screen“.

Operative command

- Select icon to START ventilation in the selected operative mode.

- Select icon to STOP ventilation; lung ventilator goes to Stand-by mode.

Operative mode

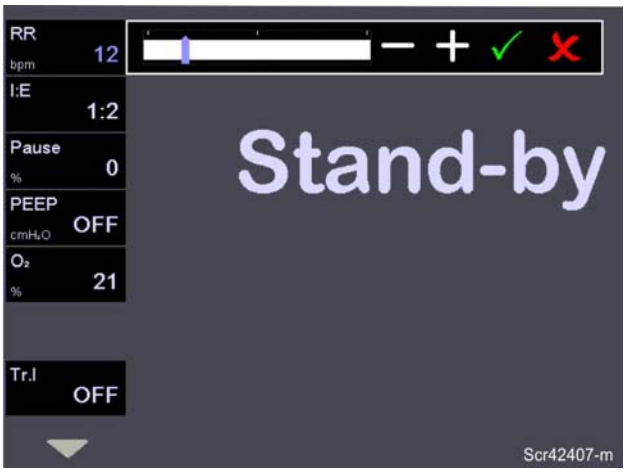


- Select the area indicating Operative Mode

- All available operative modes are shown
- Select the new operative mode

- Confirm the selection

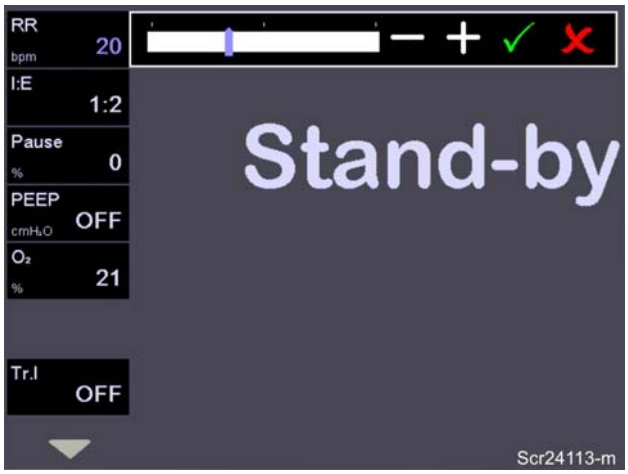
Respiratory parameters set



- Select the area indicating the respiratory parameters to be modified.

- The modification bar is displayed.

- Select the new parameter's value on the bar:
  - Drag the cursor
  - Select the icon + or -



- Confirm the selection

- Cancel

Respiratory parameters visualization

Scr24124-m

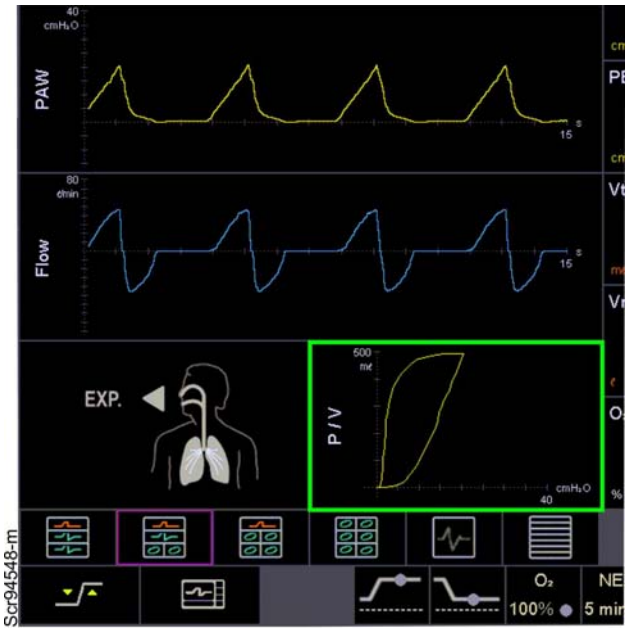
- Select the area to display other respiratory parameters.

Scr24129-m

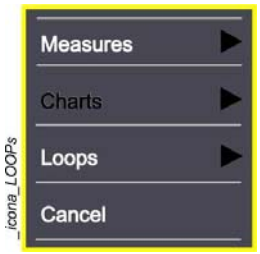
- Other respiratory parameters related to VC/VAC operative mode are displayed.
- To return to previous displaying, re-select.

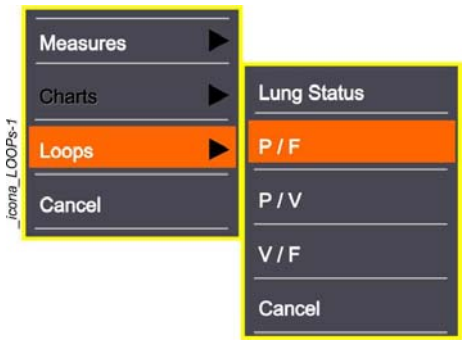
This displaying modality can be applied to patient's monitoring parameters.

Graphic visualization

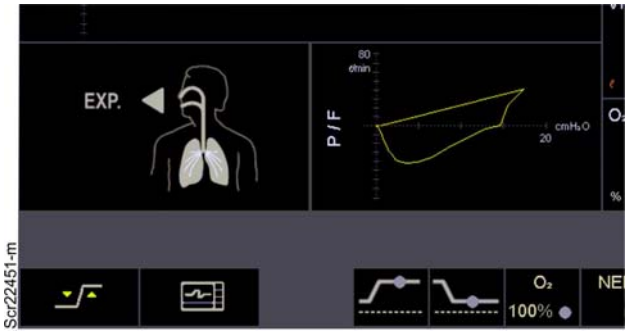


- The User can display different types of detections: Loops / Charts / Measures.
- Select the area indicating for example the graphic to be modified for a few seconds.
- The selected area (purple marked box) becomes green.
- Release and the drop-down menu and the list with available options appears.





- Select Loops: the drop-down menu and the list with available options appears.



- Select P / F.
- The PAW / FLOW Loop appears in place of PAW / Tidal Volume Loop.

The procedure described is applicable in all Loops / Charts / Measures areas and hence in the different available visualisations.

2.2.2 Keyboard - soft key and encoder knob

- A control keyboard and an encoder knob are available on the upper side of the lung ventilator.
- These components allow a rapid interaction between the User and the lung ventilator.

Main power supply indication by presence **led**.

ON/OFF soft key.

Soft key to **START** ventilation.

ESC soft key for rapid escape from MENÙ - SETUP visualization.

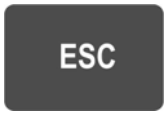
Soft key to silence an active alarm (**ALARM RESET**).

Multifunction encoder knob.

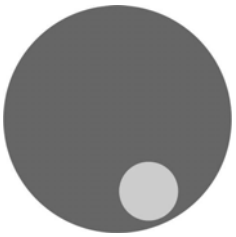
Control keyboard description

When an alarm condition is active, the activated acoustic alarm can be silenced by pressing the **ALARM RESET soft key**.

Whenever the condition that activated the alarm is no more present, by a second pressure of the key, it is possible to cancel the visual indication on the screen.



By pressing **ESC soft key,** it is possible to escape from “current” screen to return to “previous” one.



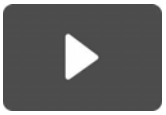
The multifunction encoder knob is used to select, modify and confirm all the functions shown on display.

The encoder knob is used to access the **MENU function** and then to function modes, parameters, alarms, parameters' values and all is concerned to the normal operation of lung ventilator.

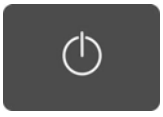
Use of encoder knob.

- Press the encoder to access the modification (enabling) of the parameter (function); turn clockwise or counter-clockwise to select the box.
- Turn clockwise (counter-clockwise) to increase (decrease); press the knob to confirm.

If the encoder knob is not pressed within 10 seconds to confirm a value after modifying it, the lung ventilator will restore the value prior to the modification.



By pressing **START soft key** it is possible to start ventilation in the selected operative mode and with parameters set by operator.



The functional switch ON or OFF of lung ventilator is possible by the **ON/OFF key**. To switch on the lung ventilator, press the ON/OFF key. After a few seconds a series of messages appears on the screen, indicating that the system is entered in the SELF TEST phase; this phase takes some minutes.

At the end of this procedure the equipment is ready to ventilate the patient. Keep pressed the **ON/OFF soft key** for a few seconds to switch off the lung ventilator (this function has been introduced to avoid accidental shutdowns of the same).

When the **Led is on** (green colour) it indicates that the lung ventilator is supplied by the main power supply.

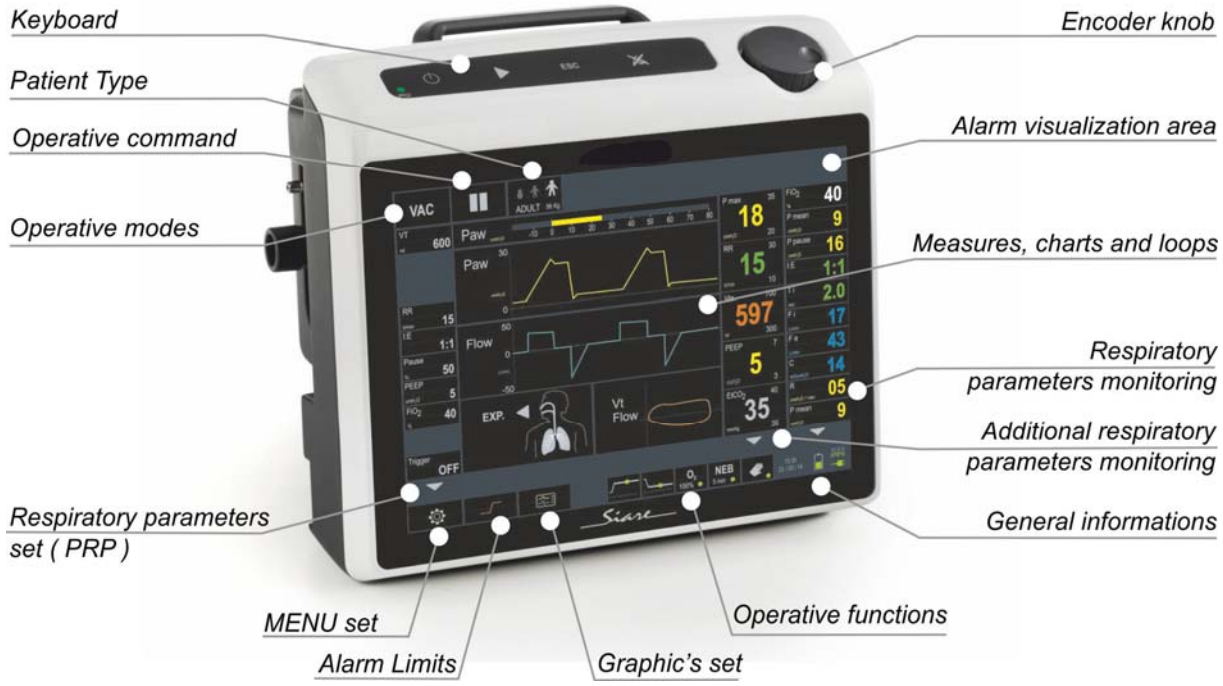
2.3 10.4’’ LED display touch screen

On the front side of Falco 202 Evo lung ventilator (*hereinafter called lung ventilator*) there is a 10.4” LED display (touch-screen) that visualizes all the information useful for patient ventilation.

Operative mode selection, respiratory parameters setup and monitoring, visual and acoustic alarm warnings, loops and curves, are the main featured information visualized.

By the use of the touch screen system and/or the control keyboard and the encoder knob on the upper side of the lung ventilator to interact directly with the display: this system is defined as GUI (*graphical user interface*).

The GUI is very easy to use by those who are already familiarised with lung ventilation: you can find in this paragraph all available functionalities.



- In the following paragraphs an overview on the potential of the system is available as well as the information that can be displayed and on how to interact with the same.
- For further and more detailed information on the use of lung ventilator Falco 202 Evo, please refer to cap. 3, 4 and 5.

2.3.1 Selectable Operative Modes

- The Falco 202 Evo includes the most modern ventilation modes: volume controlled ventilation, pressure controlled ventilation, pressure supported, non invasive ventilation and manual ventilation.
- The User can select one of these ventilation modes using the touch screen or/and the keyboard (*please see cap. 2.2*).

APCV — Assisted pressure controlled ventilation, synchronised with patient's breathing with leak compensation.

APCV-TV — (Volume Targeted) Assisted pressure controlled ventilation, synchronised with patient's breathing and with assured current volume.

PSV — Assisted pressure support ventilation with assured respiratory rate set by the User (Apnea Back Up) with leak compensation.

PSV-TV — (Volume Targeted) Pressure support ventilation with assured current volume and assured safety respiratory rate set by the User (Apnea Back Up).

Volume targeted controlled ventilation synchronised with the patient if the inspiratory trigger is activated.

The VC/VAC Operative Mode is not active when the PATIENT TYPE selected is: **New Born**.

Volume targeted controlled ventilation synchronised with the patient if the inspiratory trigger for paediatric and neonatal patients is activated.

The VC/VAC-BABY Operative Mode is not active when the PATIENT TYPE selected is: **Adult**.

Volume-targeted synchronised intermittent mandatory ventilation.

The V-SIMV Operative Mode is not active when the PATIENT TYPE selected is: **New Born.**

Pressure-targeted synchronised intermittent mandatory ventilation.

Continuous Positive Airway Pressure applied on the airways with granted respiratory rate set by the User (Apnea Back Up) with leak compensation.

Airway pressure release ventilation: this type of ventilation features two positive pressure levels.

After selecting the most suitable operative mode for patient ventilation, the system will automatically display the physiological respiratory parameters (PRP) for the new setup.

2.3.2 Operative command: Start / Stop

Two controls next to the operative mode's selection is available and useful for the lung ventilator operations. The two controls are comparable with the ones located on the keyboard.

Select the icon to **Start** ventilation in the selected operative mode.

Select the icon to **Stop** ventilation; lung ventilator goes to Stand-by mode.

- The system will ask if you want the lung ventilator in **Stand-by** mode.

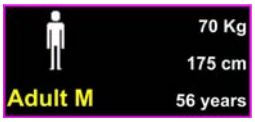
  Press YES: lung ventilator goes to **Stand-by** mode.

  Press NO: cancel the **Stop** command (the lung ventilator goes back to the selected operative mode).

2.3.3 Patient Data

Alongside the Operative Command, the **Patient Type** set is specified (**Adult, Child, New Born**). In this way the default respiratory parameters are set automatically (breathing parameters and alarms levels).

- Select the icon for see PATIENT DATA parameters.



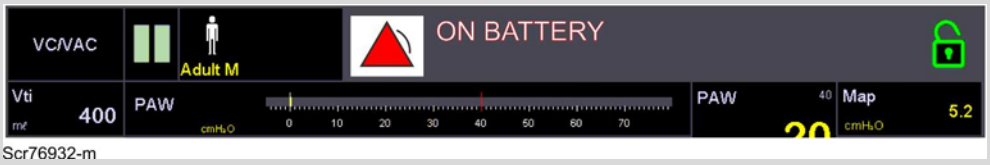
PATIENT DATA displaying allows setting / modification of these data.

- *Patient type*
- *Male / Female*
- *Name / Surname*
- *Physical date*
- *Birthday*
- *Note*

For further information about PATIENT DATA set, please see cap. 4.5.

2.3.4 Alarm visualization area

- The lung ventilator features automatic means for detecting and identifying any conditions that might put the patient at risk (based on the level of urgency and seriousness), using acoustic or visual alarm signals.
- The role of the alarm signal is to draw the attention of the User to the event as well as to inform him on the requested response speed.



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In case of alarm, the system displays the information below.

- An “alarm bell symbol” which indicates the priority and the alarm state.
- A string of text relevant to the type of active alarm.

A ‘lock icon’ to be used to inhibit the screen from possible accidental contacts “

The User can display the alarm set limits, selecting the dedicated Alarms icon. After editing the alarm settings, the relative signal will remain active and the status icon will blink for a pre-set time.

ALARM SILENCING

- Select the bell icon (or press the RESET key) to interrupt the acoustic signal for a pre-set period of time.
- During the silencing period, the text of the alarm will still be displayed.

- Select the bell icon (or press the RESET key) once again to delete the alarm text, only if the alarm activation condition is no longer present.
- If during the silencing period, a new alarm (of high priority) occurs, the alarms silencing command is automatically cancelled and the acoustic and visual signals are reactivated.

WARNING!! Patient injury hazard

The User should not interrupt patient control during alarms silencing period.

For more information, please see on chapter 5 Alarms.

2.3.5 Physiological Respiratory Parameters (PRP)

- Select VC/VAC operative mode.

- Selecting the PRP parameters icon.

- The parameters related to the set Operative Mode are displayed.

Modification of a **PRP** parameter.

Select a parameter (**e.g. RR** : Respiratory Rate)

- Select the RR icon.
- The bar for parameters setting is displayed.

	Decreases the parameter value
	Increases the parameter values
	Confirms the set value
	Cancels the setting bar

2.3.6 PRP list

The parameters marked with **BK** are referred to the **BACK-UP operative mode**.

RR BK (bpm): **Back-up respiratory rate**, used when an Apnoea condition arises to enable a controlled ventilation mode.

CPAP/PEEP (cmH_2O)

Continuous positive airway pressure during respiration phase in CPAP operative mode.

I:E

Ratio between inspiration and expiration phases.

O2

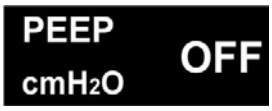
Concentration percentage delivered to the patient can be set from 21% to 100%.

Pressure Low (cmH2O) - Pressure High (cmH2O)

Pressure levels to be set in APRV mode.

Pause (%)

Inspiratory pause time. The “inspiratory pause time” is displayed on the screen in % (% of the inspiratory time). It is also used to calculate the lung mechanics parameters (resistance and static compliance).



PEEP (cmH2O)

Positive airway pressure value during expiratory phase.

Pinsp (cmH2O)

Maximum airway pressure limit value. The parameter is used in pressure controlled modes to fix an operating limit for the airway pressure that shall not be exceeded.

PMax (cmH2O)

Maximum airway pressure limit.

Pmin (cmH2O)

Minimum airway pressure limit.

PS (cmH2O)

Positive airway support pressure value during inspiratory phase.

RR (bpm)

Lung ventilator respiratory rate.

RRsimv (bpm)

Value of forced respiratory rate in SIMV mode.

Sigh. Ampl. (%)

Sigh. Percentage increase of the set Vti.

Sigh. Int. (b)

Sigh. Activation frequency.

Slope

This value shows the inspiration flow speed. It is possible to set the slope of the acceleration curve of the turbine: the setting is from 1 to 4. The value of 4 corresponds to the maximum turbine acceleration (depending also by the mechanical inertia).

Ti (s)

Time that **defines the lung ventilator inspiration duration. The values can be set based on the set RR.**

Ti max (s)

Time that defines the maximum duration of an inspiration. If the duration of the inspiratory phase is lower than the set value, the patient will be forced to exhale.

Time Low (s) - Time High (s)

Duration of the two pressure levels set in APRV mode.

Tr. E (%)

Percentage of the inhaled flow with regard to the maximum peak where the inspiratory phase ends and the expiratory phase begins.

Tr. I (L/min) (cmH2O)

Flow level (pressure) for detecting the patient spontaneous breathing.

Vte (ml)

Expired tidal volume guaranteed for the patient.

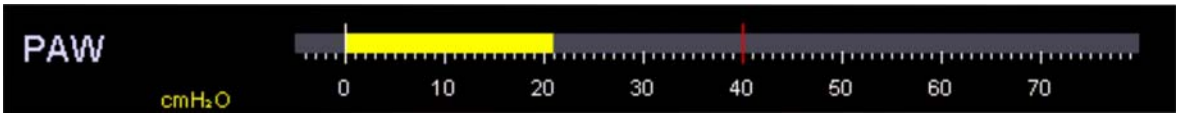
Vti (ml)

Inspired tidal volume guaranteed for each breath.

2.3.7 Monitoring of respiratory parameters

- Based on the lung ventilator parameters set by the User and on the patient's characteristics, the lung ventilator is able to monitor and measure a series of values necessary for the patient's clinical evaluation.
- At the top of the screen, there is a led indicator that displays the pressure inside the airways in real time. The measured and monitored values (right side of the screen) are updated after each breath of the patient.

E.g. Here below the data in the images below refer to VC/VAC operative mode.



The light bar indicator (with scale from -0 to 80 cmH2O), displays the pressure inside the airways during the respiratory phase, in real time.

The value displayed is the maximum measured pressure inside the airways (cmH2O).

The displayed value shows the positive pressure at the end of the expiration: the measurement unit is cmH2O.

The User can control if the lung ventilator is able to reach and keep the PEEP pressure level set, using this value.

The displayed value shows the real respiratory rate (number of breaths per time unit) taking into consideration for the calculation any spontaneous activity.

It shows the ratio between the inspiration time and the expiration time.

It shows the oxygen concentration value (as percentage) inhaled by the patient.

The inhaled oxygen concentration value is read by the system by means of the oxygen cell installed on the inspiratory line.

It shows the current volume value during patient's expiratory phase: the unit of measurement is ml.

The value is detected by the flow sensor installed on the expiratory line.

It shows the volume value expired by the patient per minute : the unit of measurement is L/min.

You can also calculate this value using the formula: current volume (Vte) x respiratory frequency (RF).

It shows the value of end expiration CO_2 (end-tidal CO_2).

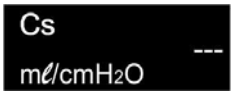
The value is detected by the gas sensor analyzer installed on the expiratory line.

Description	
	**Vte** : respiratory parameter **ml** : unit of measurement **503** : value set by the User **1000 - 100** : alarm limits

2.3.8 Monitoring of Additional breathing parameters

- Based on the lung ventilator parameters set by the User and on the patient's characteristics, the lung ventilator is able to monitor and measure a series of values necessary for the patient's clinical evaluation.
- The measured and monitored values (right side of the screen) are updated after each breath of the patient.

E.g. Here below the data in the images below refer to VC/VAC operative mode.



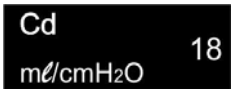
Static compliance

It is one of the parameters of the lung mechanics: measured in ml/cmH_2O, represents the lung compliance when the patient does not breathe.

You can use it to asses the lung elasticity: the higher the compliance, the more elastic the “lung”; the lower the compliance, the more “rigid” the lung.

The static compliance can be calculated using the formula below:

Cs = current inspired volume / pause pressure.



Dynamic compliance

It is one of the parameters of the lung mechanics: measured in ml/cmH_2O, represents the lung compliance either during the inspiration or during the expiration.

You can use it to asses the lung elasticity: the higher the compliance, the more elastic the “lung”; the lower the compliance, the more “rigid” the lung. The dynamic compliance can be calculated using the formula below:

Cd = current inspired volume / peak pressure

Expiratory peak flow

Use the flow sensor installed on the expiratory line to measure the exhaled flow peak. At the beginning of the expiration, a flow peak arises in correspondence with the expiratory valve opening and it depends on the lung resistance and compliance

This measure, just like the previous one, is not related to specific alarms thresholds, it only provides information on the ventilation status.

Inspiratory peak flow

Use the flow sensors installed on the inspiratory line to measure that maximum inhaled flow value (measured in l/min) and to view it on the screen.

For this value there are no alarm limits but it can be used to gather information on the ventilation status.

Leak

Shows the ‘Leak’ value measured that must be adequated to the ventilation mode enabled (volumetric or pressometric) and within the range in compliance with the local regulations.

The unit of measurement is %.

Mean airways pressure

It shows the average calculated pressure for the airways: the unit of measurement is cmH_2O.

Oxygen consumption calculation

The oxygen consumption value in L/min is displayed after one minute and in case of oxygen set value higher than 21%.

Pause pressure

It shows the pause pressure: the unit of measurement is cmH_2O.

When the inspiratory pause enables, the lung ventilator maintains the airway pressure constant (it maintains a pause pressure) for a certain amount of time of the inspiratory time, defined by the User (INSP PAUSE %). The static conditions allow the lung ventilator to calculate the breathing mechanics parameters.

Inspiratory resistance

It is the parameter of the lung mechanics that describes the resistance to the opposite flow of the airways: measured in $cmH_2O/(l/s)$. The greater the patient resistance, the higher the airway pressure you need to apply to obtain the same volume.

The formula used by the ventilator to calculate the inspiratory resistance is as follows:

Ri = (peak pressure – pause pressure) / inspired flow.

Expiratory time

It shows the duration of the patient's expiratory phase: the unit of measurement is the second. This parameter defines the expiration duration. This value depends on the respiratory rate and I:E ratio parameters.

Example: if RATE = 15 and I:E=1:1 you will have an expiratory phase of 2 seconds.

Inspiratory time

It shows the duration of the patient's inspiratory phase: the unit of measurement is the second. This value represents the total inspiratory time, and also includes the inspiratory pause period. This value depends on the respiratory rate and I:E ratio parameters.

For example: if RATE = 15 and I:E=1:1 you will have an inspiratory phase of 2 seconds.

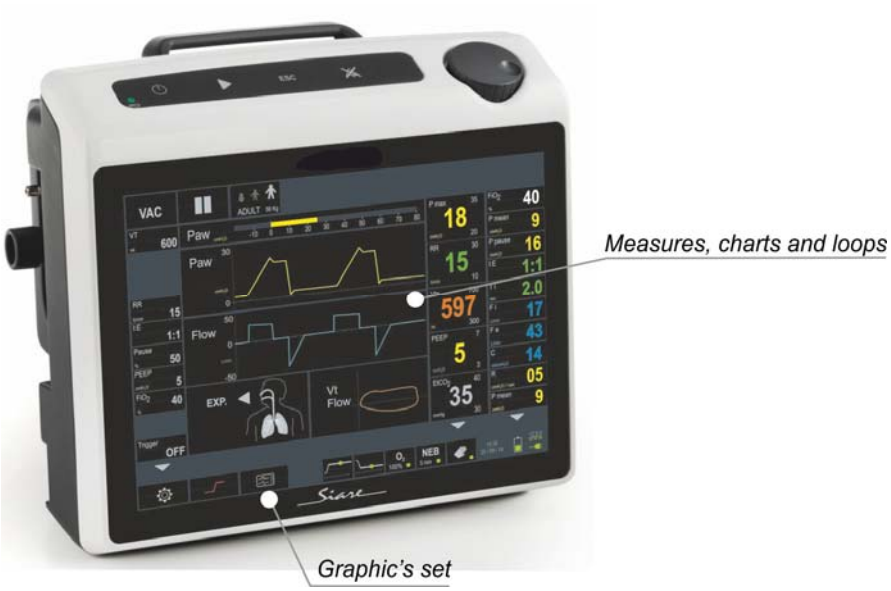
Inspiratory pause

It shows the duration of the patient's inspiratory standby phase: the unit of measurement is the second. This parameter represents the inspiratory time during which the lung ventilator keeps the airway pressure constant.

Example: if RATE=15, I:E=1:1, Ppause=50% you will have an inspiratory pause period of 1 second.

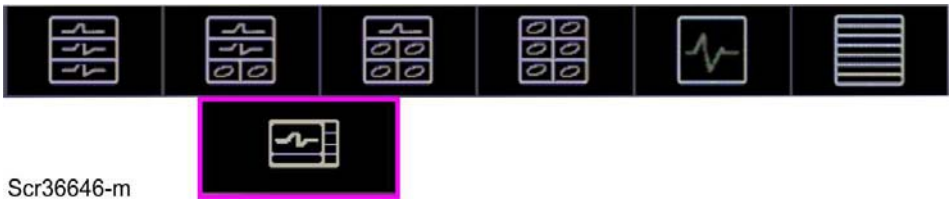
2.3.9 Measures, charts and loops

The lung ventilator is equipped with tools for charts and loops display so as to quickly and accurately notify the User on the patient's condition.



The User selecting the icon (**GRAPHIC's set**) can choose "which" and "how" to display in time the following detections:

- **Charts** : PAW , Flow , Tidal Volume, O_2, CO_2
- **Loops** : Tidal Volume / Flow , PAW / Tidal Volume , PAW / Flow
- **Measures** : respiratory parameters
- **Lung status icon**
- **Trends**
- **Event**



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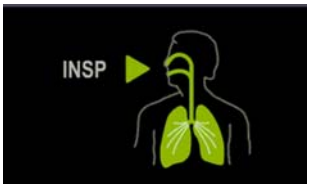
- To change the combination of curves displayed, the lung ventilator must be started.
- Select "**GRAPHICs**" icon to quit the function.

For more information, please see on cap. 4.10.

2.3.10 Loops area: lung status

- The lung status icon simulates the patient's lungs, graphically displaying the respiratory cycle by alternatively switching the lungs color.
- In fact in case of patient's spontaneous activity (Trigger), the lung status icon turns to yellow and if the “Low Pressure” alarm value set has not been exceeded the icon turns red.



During inspiration the lungs icon turns green.

The lungs turn green during inspiration only if the PAW exceeds the “Low Pressure” alarm value set.

During expiration the lungs icon turns light grey.

At trigger activation the lungs icon is yellow.

If the airways pressure does not reach the value of “Low Pressure” alarm parameter. the lungs icon turns red.

WARNING!! Patient injury hazard

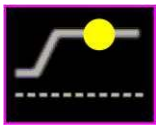
If the airways pressure does not reach the value of “Low Pressure” alarm parameter, the lungs icon turns red and after about 15 seconds, the system activates the Low Pressure alarm.

For more information, please see on cap. 4.10.

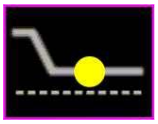
2.3.11 Operative functions and general informations

In the lower side of GUI there are a series of controls and functions that are useful for the Falco 202 Evo utilization.

Leds: if Led is lit. indicate that the relevant function is enabled (or if it has been enabled); if the led is off or in case it does not switch on, it means the relevant function is not enabled



INSP HOLD function



EXP HOLD function

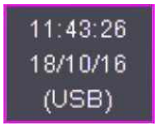
100% oxygen concentration function

NEBULIZER function

The “NEB” function is active only when the lung ventilator is supplied by oxygen (connection: HIGH PRESSURE).

MAN operative mode (lit green led: MAN function has been enabled)

*About “ **MAN** operative mode “, please see on cap. 4.7.12.*



- **Date & Time visualization**
- **(USB):** Indication of flash drive (USB) inserted on USB socket (see on cfr. 2.5) for downloading Screen Shoot.

General information

- Battery level (if the symbol is steadily lit and green, the battery is full).
- Presence of mains power supply, (the “green plug” symbol means that the device is powered from mains).

*About “ **General information** ”, please see on cap. 5.2.4.*

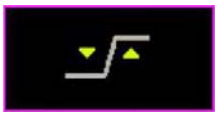
2.3.12 Menu, Alarms and Graphics' set

In the lower side of GUI there are a series of functions that are fundamental for the Falco 202 Evo utilization.

- Select the icon to access the **SETTING MENU**.
- Select the icon to " **Turn OFF** " the lung ventilator.
- Select the icon to improve the **Supplementary Tests**.

When the lung ventilator is in Stand-by mode, selecting this icon it is possible to enter the PATIENT DATA setting *(for more information, please see on cap. 4.3).*

The choice of the Patient Data (**Adult, Child, New Born**) set automatically the default physiologic respiratory parameters (PRP) of the lung ventilator (breathing parameters and alarms levels).



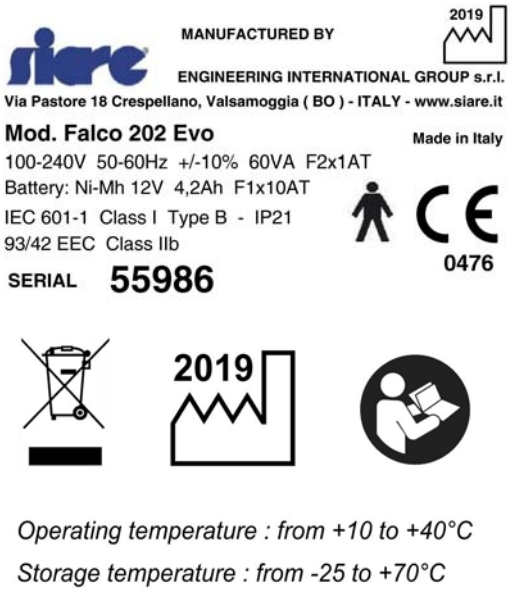
- Select the icon to access the lung ventilator's **ALARM LIMITS** page.

Select the icon to access the lung ventilator's GRAPHIC's set page.

2.4 Product identification label

The product identification label mentions the following information.

- Manufacturer
- Model name
- Main power supply
- Battery's features
- Fuses features
- Regulation (CE mark)
- Serial number
- Symbols (see description)



The mark identifies the protection level against electric shock (category of protection type B).

0476

CE mark, complying with European Regulation 93/42/CEE pertaining to medical devices.

RAEE marc, indicates the waste of electronic or electric equipments.

The number indicates the year of production of the equipment.

The symbol indicates 'refer to the instructions for use' of the equipment.

Hazard of: instability from horizontal forces.

The symbol stands for " **it is forbidden not to lean or push** " the equipment.

This precaution must be taken into consideration in order to maintain sufficient stability of the equipment.

3 PREPARATION FOR USE

In the first section of this chapter explains the main installation phases of Falco 202 Evo (10.4”) lung ventilator. In the second section highlights the preliminary checks to be carried out before using Falco 202 Evo (*hereinafter called lung ventilator*).

CAUTION

If this is the first time you install the Falco 202 Evo, please read this User manual carefully.

Please clean the lung ventilator and sterilise its components before use; use the maintenance instructions herein and follow the applicable norms in the country where the device is used.

UNPACKING

- Unpack the device properly.

Please keep the original packaging, in order to avoid any damage to the ventilator in case it shall be returned to the manufacturer.

TRANSPORT – Changing the lung ventilator's location

Move the lung ventilator using the suitable handle. Place the lung ventilator on a flat surface or on any hardware provided. Make sure that the lung ventilator cannot move accidentally during operation.

WARNING !! Personal injury - physical hazard

- If handled incorrectly, the lung ventilator might tip over causing physical personal injuries to patients and/or Users.
- Place the lung ventilator on a flat surface. If the lung ventilator is not suitably placed, it might move accidentally during operation.

WARNING !! Patient / clinician injury hazard

- The device and all its accessories should be mounted and connected by highly qualified technical staff, suitably trained and authorised by SIARE.
- Do not connect or disconnect parts or components of the lung ventilator when it is on or powered.
- Before using lung ventilator, carry out all necessary preliminary checks.

3.1 Before use

3.1.1 Mounting the O_2 sensor

WARNING !! User injury hazard

To avoid electric shock risk and/or components parts breakage during interventions, please make sure that the lung ventilator's power supply is cut off.

- Thoroughly unpack the O_2 cell.

- Insert and screw the cell in the space bearing the label “O_2 SENSOR”.

- Connect the pin to the O_2 sensor.
- Make sure that the RJ connector is correctly inserted in the lung ventilator's dedicated socket [connector FiO_2].

WARNING !! Patient injury hazard

When the lung ventilator is on, the system carries out a series of checks, such as including the O2 sensor *connection (“SELF TEST” phase see cap. 3.5).*

3.1.2 Battery recharge

The lung ventilator is provided with a battery (NiMh 12Vdc / 4,2Ah) that ensures its operation for at least 4 hours (if in perfect condition; 3 hours, depending on the ventilation parameters), in case the mains power supply is cut off.

In case of mains power failure the lung ventilator automatically switches on battery operation: an alarm will be displayed on the lung ventilator's screen, along with the message "**ON BATTERY**".

The battery can be recharged connecting the lung ventilator to the mains (100 - 240 Vac or 12 Vdc supply).

BATTERY RECHARGE

If this is the first time you use the lung ventilator, charge up the battery for at least 24 hours (the lung ventilator must not necessarily be on).

In order to ensure maximum operation autonomy, make sure that the recharge time is enough: to bring the charging level from 0 to 90% you need at least 10 hours of recharge with mains supply enabled.

The BATTERY LIFE time varies as follows.

- Old battery or not fully efficient.
- Unusual lung ventilator parameters.

- Insert the power supply cable plug (100 - 240 Vac) supplied with the device to the plug placed on the back of the lung ventilator.
- Insert the power supply cable plug (100 - 240 Vac) supplied into the mains socket.
- Set the main switch (placed on the back of the lung ventilator) to "I".

The mains voltage should match the one indicated on the identification plate placed on the back of the lung ventilator.

- Make sure that on the keyboard the green led (that indicates the presence of mains power supply) is on.

3.2 Preparation for use

3.2.1 Connection to power supply

The electrical connections are a very important part in the installation of the emergency lung ventilator. Incorrect connections or connections to unsuitable electrical systems can compromise the safety of the patient and the User.

Mains power supply must comply with the prescriptions in CEI 64-8/7 standards concerning the locations intended for type A medical use.

There are three types of power supplies available on the lung ventilator:

- **mains power supply** (100-240Vac / 50-60Hz)
- **low voltage power supply** (12Vdc / 7A)
- **battery supply** (NiMh 12Vdc - 4,2Ah battery: max. autonomy 4 hours).

Mains power supply

The mains power supply must match the one indicated on the identification plate, placed on the back of the lung ventilator: 100-240Vac / 50-60Hz.

WARNING !! Patient / clinician injury hazard

SIARE specialized personnel or qualified technical personnel formerly authorized by SIARE, shall always verify the following during the installation:

- the presence of the ground cable in the electric plug used to connect the lung ventilator.
- the electric plug used should be equipped with a lock in order to prevent erroneous placements in wrong plugs without ground.

- Insert the power supply cable plug (100-240 Vac) supplied with the device to the plug placed on the back of the lung ventilator.
- Insert the power supply cable plug (100-240 Vac) supplied into the mains socket.
- Set the main switch (placed on the back of the lung ventilator) to “I”.

- Make sure that on the lung ventilator keyboard (commands area) the green led (that indicates the presence of mains power supply) is on.

- The lung ventilator complies with the requirements for electro-medical devices detailed on cap. 1.5 (Norms and standards regulations).
- To ensure proper operation of the lung ventilator, please connect to it only additional devices that comply with the standards specified above.
- The User should be always sure that the power supply electric plug is accessible during the normal using and functioning of the device.

WARNING !! Personal injury - physical hazard

In order to avoid any electric shock hazard, make sure that the supply cable is connected to an electrical socket with the grounding cable connected.

Low voltage power supply

- A proper connector for low voltage power supply line (12Vdc / 7A) is placed on the lung ventilator rear side.
- Insert the 12Vdc power supply cable plug to the plug placed on the back of the lung ventilator.

Battery power supply

WARNING !! Risk of failure

- There should always be a battery installed inside the lung ventilator.
- If there is no battery, the lung ventilator is not protected against voltage drops or mains power supply cut off.
- The lung ventilator should not be used without a charged battery.
- The use with battery should be limited to short periods of time and should not be considered an alternative to mains power supply.
- Do not open the lung ventilator to replace the batteries or to carry out maintenance operations on the same battery charger.

BATTERY LIFE

The average life of the battery depends on the type of use and the storage conditions of the device.

- Old battery or not fully efficient,
- Unusual lung ventilator parameters.

Replace the battery each two years (*please refer to cap. 6 Maintenance*).

BATTERY ACOUSTIC ALARM

To silence the acoustic alarm, press the "**ALARM RESET**" soft key.

BATTERY RECHARGE. *Please refer to cap. 3.2.2*

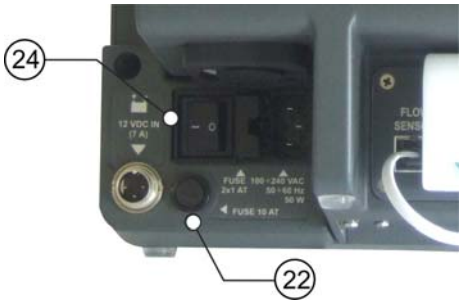
POWER SUPPLY

When the green led placed on the front of the lung ventilator is on, it shows that the lung ventilator is properly supplied (mains power supply ON).

3.2.2 Protection fuses

There are protection fuses installed on the following circuits.

- 220 VAC power supply: protection fuses of the circuit (2 x 1AT).
- Battery supply: protection fuse of the battery circuit (1 x 10AT).



Fuse replacing

WARNING !! Patient / clinician injury hazard

The operations described below must be carried out only by highly qualified staff, specifically trained and authorised by SIARE.

If a protection fuse breaks, please proceed as follows.

- Cut OFF mains power supply.
- Remove the fault or the cause that caused the fuse breakage.
- Replace the fuse with another one that has the same value and the same technical characteristics.

WARNING !! Patient / clinician injury hazard

Using fuses of incorrect value or with incorrect technical features might affect the lung ventilator's integrity and safety.

3.2.3 Medical gas connection

The fast connections mounting, suitable for the medical gas distribution system, as well as all pneumatic supply hoses maintenance and/or replacement operations should be carried out only by qualified staff, so as to prevent any gas inversions that might be fatal for the patient.

- Screw the pneumatic O_2 supply hose on the lung ventilator connector.
- Connect the pneumatic O_2 supply hose on the relevant connector on the gas system.
- Be sure that the pneumatic hose is well fixed and that the medical gas system is clean and without lubricants.

PNEUMATIC SUPPLY

The lung ventilator is supplied with a pneumatic hose including a DISS (Diameter Index Safety System). The installation technician taking care of the hose connection to the outlet must ensure that they are compatible with the hospital medical gas pipeline system.

WARNING !! Unit failure risk

- In order that the lung ventilator operates as specified, the input medical gas pressure should be between 280 kPa and 600 kPa (2.8 - 6 bar / 40 - 86 psi).
- Before using the lung ventilator, make sure that this requirement is met.
- After connecting the medical gas supply hose, make sure that the system works properly.

The lung ventilator can work even without an oxygen supply using the internal turbine only; in this case the FiO_2 could be set only to 21%.

WARNING !! Patient injury hazard

- The oxygen should be of medical type, without oil and filtered.
- The medical gas source shouldn't contain water: if you suspect the presence of water, connect a water trap to avoid damages on the lung ventilator and its components.

3.2.4 Bi-tube patient circuit connection

- Connect the patient circuit to INSP. TO PATIENT connector and to flow sensor (patient expiratory line).

Use a patient circuit suitable for the patient you want to treat.

Current volume	Hose
< 50 mL	Neonatal
from 50 to 200 mL	Paediatric
> 210 mL	Adults

3.2.5 Nebulizer

- Connect the supplied nebulizer circuit to the suitable coupling [NEBULIZER] on the lung ventilator.

Use the command (NEB function) available on the graphical user interface (GUI) to activate the Nebulizer function.

3.2.6 Use of antibacterial filters

Apply the antibacterial filters to the patient circuit.

For more information, please see documentation attached to the product.

• Moisture loss	6.7 mg H_2O/l
• Calculated moisture return	31.6mg H_20/l
• Resistance at 30L/min	0.2 cm H_20
• Resistance at 60L/min	0.8 cm H_20
• Compressible volume	59 ml
• Weight	31 g
• Connectors	22F/15M - 22M/15F

WARNING !! Patient injury hazard

To protect the patient from any dust and particles, you must install a filter between the inspiratory tube of the respiratory circuit and the patient.

WARNING !! Patient injury hazard

Replace the antibacterial filters as indicated in the maintenance instructions (*please, see on cap. 6*).

WARNING !! Patient injury hazard

- Please perform the “SELF TEST” phase every time you replace the patient circuit.
- The system will check the patient circuit every time you turn on the lung ventilator.

WARNING !! Strangulation hazard

- Pay utmost attention when connecting the patient to the lung ventilator.
- If not carefully placed, the tubes, cables, the patient circuit and other similar components installed on the lung ventilator might put the patient at risk.

WARNING !! Burns hazard

Do not use conductive masks or respiratory tubes during surgery with electrosurgical unit: they might cause burns.

3.2.7 Connection of GAS ANALYZER (Gas Sensor)

For more details and information about the CO_2 analyzer (Sidestream or Mainstream model) please refer to the user manual supplied with the GAS ANALYZER.

- Switch OFF the electric power supply
  - lung ventilator OFF -
- Connect the interface cable to the RS-232 connector (ODU connector).

- Connect the GAS ANALYZER to the interface device.

- Mainstream GAS ANALYZER
- Connect the sensor to the patient circuit.

- Sidestream GAS ANALYZER
- Connect the sampling line to the GAS ANALYZER.
- Connect the sampling line to the patient circuit.

- Verify the functioning of the **Mainstream GAS ANALYZER**
- Switch ON the electric power supply.
- A green LED (on the gas analyzer) indicates that the IRMA analyzer is ready for use.

- Verify the functioning of the **Sidestream GAS ANALYZER**
- Switch ON the electric power supply.
- A green LED (on the gas analyzer - sampling line) indicates that the ISA analyzer is ready for use.

GAS ANALYZER: Zeroing

Mainstream IRMA sensor: after around one minute from the device is turned on, it is necessary to perform the manual procedure of Zero Calibration *(please see on chapter 4: SETUP MENU).*

With sidestream ISA sensor: the zeroing of gas sensor measurement is activated in automatic mode; anyway, it is possible to perform the Zeroing calibration procedure when needed *(the green led blinks when the GAS ANALYZER turn-on).*

3.2.8 Data Connection (Trend and Events downloading)

- Connect a USB flash drive to the USB1 socket used for CPU programming and data download (*USB socket near the reset button*).
- For more information see chapter 4.2.2 (*SETUP - Other: Save to USB*).
- Request the guide with the relative instructions for data interpretation (*Procedure for downloading data*).

3.2.9 Connection of other devices

Connection of Siare devices

In order to connect to the lung ventilator other devices manufactured by Siare, please refer to the connection instructions attached to this manual.

WARNING !! Patient / clinician injury hazard

Do not connect to the lung ventilator any external devices NOT manufactured or NOT authorised by SIARE (example: discharge systems, patient simulators, etc…..), and that are not described in this user manual.

If necessary, please contact SIARE or the authorised Technical Support Service available in your area.

WARNING !! Patient injury hazard

When using additional components in the respiratory systems or configurations unsuitable for the equipment provided with the lung ventilator, the inspiratory and expiratory resistance might increase, exceeding the standard requirements.

If you are using this type of configurations, pay utmost attention to the values measured.

WARNING !! Electrical shock risk

In case of grounding cable malfunction, hooking-up other electrical devices to the additional lung ventilator outputs might cause an increase in the dispersion current beyond the allowed values.

The entire system must comply with the requirements for electro-medical devices, listed on cap. 1.5 (Norms and standards regulations).

WARNING !! Risk of injury for the patient

A **Nebulisation** or **Humidification** system can increase the resistance of breathing system filters and that the user needs to monitor the breathing system filter frequently for increased resistance and blockage.

Please see relevant note on chapter Index.

3.3 Use

To obtain better performances, leave the lung ventilator working for at least 15 minutes, before patient connection or before executing preliminary checks.

This operation will allow the system to reach the correct temperature for the spirometry.

3.3.1 Preliminary tests

Before using the lung ventilator on a patient, it is necessary to perform some of preliminary tests in order to check that the equipment is properly operating.

The preliminary checks have the aim to verify the correct connection and functionality of the lung ventilator and all its components.

The list of preliminary tests is available at the end of the present chapter or in APPENDIX chapter.

The preliminary tests should be performed:

- each time the lung ventilator is turned ON and used
- or whenever a connection is made or an important component is replaced (patient circuit, oxygen probe, flow sensor, etc…)

Before starting preliminary tests, the Falco 202 Evo lung ventilator must be:

- prepared for use (cfr. Maintenance, Cleaning, Disinfection and Sterilisation)
- correctly positioned
- all accessories and devices for correct operation must be predisposed
- electric power and gas supplies must be connected
- it is used a patient simulator fixed to the terminal of supplied patient circuit.

The patient simulator suggested for tests and checking's is SIARE code LS.AB.001 which is equipped with variable compliance and resistance.

WARNING !! Risk of explosion and/or fire

Do not use the lung ventilator if you detect any suspect oxygen leaks from the lung ventilator or any other unit next to it.

Close all oxygen supply sources and contact the nearest Siare Support Centre or any other support centres authorised by Siare.

Risk of accidental movement

If the lung ventilator is not blocked in the proper way, it could accidentally move during operation.

EMERGENCY CONDITIONS

- In emergency conditions, the preliminary checks can be skipped.
- You should carry out the preliminary checks once the emergency condition stops, and at least once a week.

Preventive MAINTENANCE

The preliminary checks do not remove the necessity for periodical preventive maintenance operations carried out by SIARE authorised staff, aimed at replacing the worn parts and checking the overall lung ventilator condition (*please refer to Maintenance chapter*).

For the periodical maintenance that you should carry out, please refer to Maintenance chapter.

WARNING !! Patient/User injury hazard

All maintenance and/or repair interventions require full knowledge of the lung ventilator, and therefore such operations must be carried out only by highly qualified staff, specifically trained and authorised by SIARE.

WARNING !! Serious patient injuries

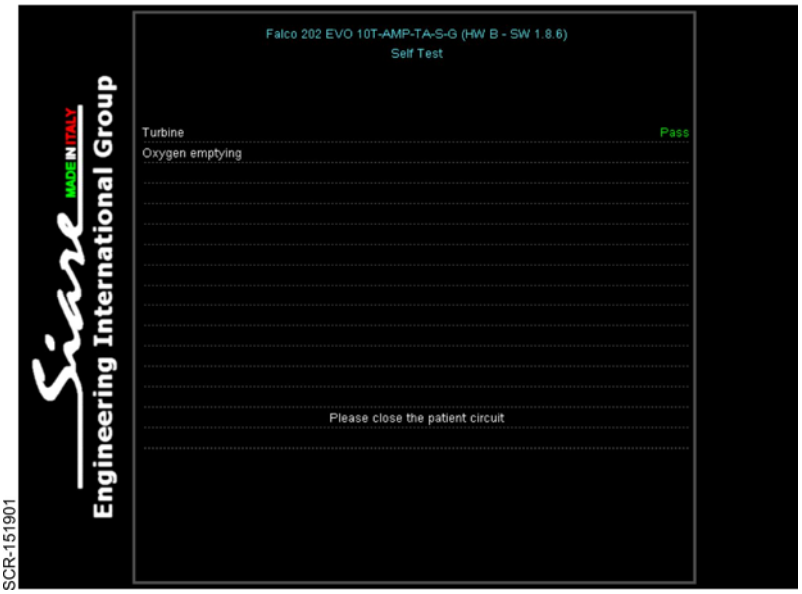
All figures and examples featured in this chapter are purely informative and do not refer to real clinical cases.

3.3.2 Ventilator switch ON / Self Test phase

- Set the main switch (placed on the back of the ventilator) to "**I**".
- Make sure that on the lung ventilator keyboard (commands area) the green led (that indicates the presence of mains power supply) is on.

- Hold the **ON-OFF** key for few seconds; the lung ventilator switches ON and the automatic Self Test phase starts.

During Self Test phase, the lung ventilator software carries out the self-diagnostic tests and checks a series of devices necessary for safe operation of the lung ventilator /patient.



SCR-151901

Self Test phase. Please close the patient circuit.

- **Turbine**: *turbine functioning check and status.*
- **Oxygen emptying**: *during this test the system provide to 21% calibration of the oxygen sensor.*

SCR-151908

- **Insp. Flow Sensor**: *check the operation of the Inspiratory Flow sensor.*
- **Exp. Flow Sensor**: *check the operation of the Expiratory Flow sensor.*
- **Pressure Sensor**: *check the operation of the Pressure sensor.*
- **Electrovalve:** *check the operation of the EV1/EV2 electrovalves.*

SCR-151901

SCR-151913

Self Test phase in progress.

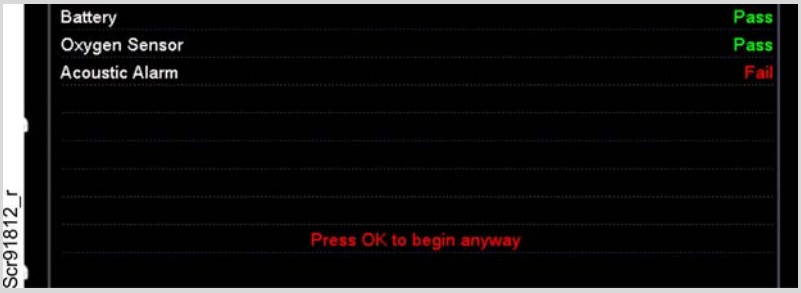
- **Patient Circuit**: *check the patient circuit connection and the presence of pressure in the circuit.*
- **Battery**: *check of the battery voltage value.*
- **Oxygen sensor**: *check of the electric connection and the calibration of O_2 sensor.*
- **Acoustic Alarm**: *check if the system generates the acoustic alarm signal.*

Note ! " **If the acoustic alarm is audible, please push the reset key** ".

Acoustic Alarm: Pass

Note ! *For a more correct and detailed analysis of the issues arising during Self Test phase, please consult the chap. 5.4 or consult the Service Manual.*

CAUTION. Acoustic Alarm: Fail.



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If you do not hear any acoustic alarm signal and/or you did not press the Alarm Reset key, the red message " **Press OK to begin anyway** " will appear on the screen.

SCR-151913

Self Test phase completed successfully.

Note !

" ***Press OK to begin*** ".

" ***Press Cancel for other tests*** ".

OK

Select OK: the system will display the PATIENT DATA page and later on, it will switch to Stand-by mode.

Cancel

Select Cancel: the system will display the Supplementary Tests page.

SCR-151952

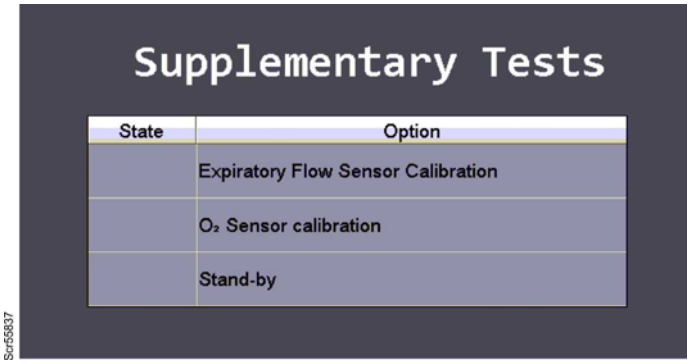
The Self Test phase **DID NOT** complete successfully.

- However, the system allows you to proceed. " ***Press START to begin anyway*** ".

WARNING !! Patient/User injury hazard

The Self Test phase did not complete successfully. Please see chap. 5.3 or contact the nearest Siare Support Centre or any other support centres authorised by Siare.

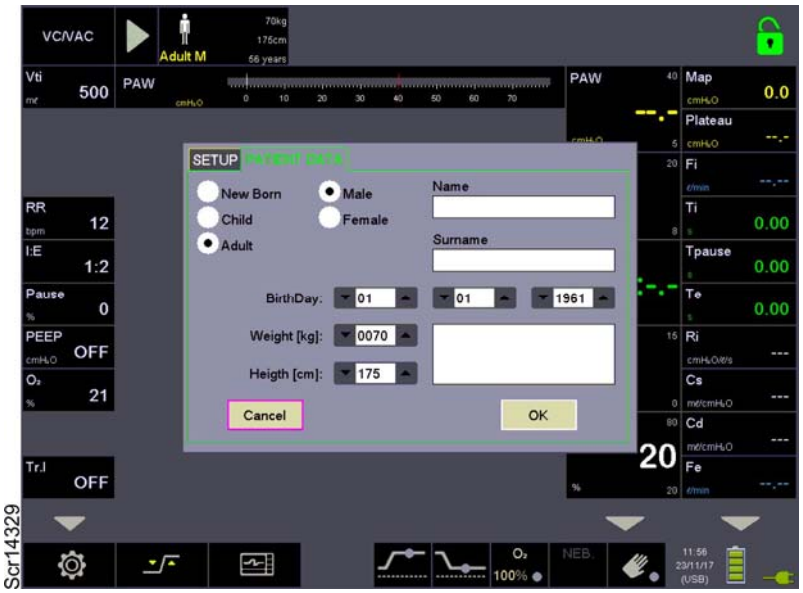
Cancel	The system will display the Supplementary Tests page.



By means of this page it is possible to perform:

- *Exp. Flow Sensor Calibration*
- *O2 Sensor calibration*
- *Switch to the Stand-by visualization*

OK	The system will display the PATIENT DATA page and later on it will switch to the Stand-by visualization.



Through this page it is possible to set the following **PATIENT DATA**:

- *Patient type*
- *Male / Female*
- *Name / Surname*
- *Physical date*
- *Birthday*
- *Note*

- PATIENT DATA set *(see on chapter 4.3.1)*.
- Select **Cancel or OK** for going ahead and display Stand-by page.

Stand-by mode

- In Stand-by mode the User can set and/or edit all lung ventilator parameters and alarms limit relative to the operating mode that you will use on the patient that you want to treat.

3.3.3 Turn the lung ventilator OFF

- **Stand-by mode**. Hold the ON-OFF key a few seconds to turn the lung ventilator OFF.

- The system will ask you if you want to **Turn-Off** the lung ventilator (switched off).

  Press NO: cancel the command (the lung ventilator returns to Stand-by mode).

  Press YES: the lung ventilator will be switched OFF.

During the switching OFF the system performs a clean of the oxygen inside the lung ventilator which grants a 21% concentration on the inspiratory line.

This procedure grants a longer O_2 sensor life and a quicker " Self Test " phase when the device is turned-on. The duration of this procedure depends by the FiO2 present in the inspiratory line and can be of 60 seconds max.

3.4 Preliminary checks - Introduction

WARNING !! Patient injury hazard

All figures and examples featured in this chapter are purely informative and do not refer to real clinical cases.

The preliminary checks are divided in 4 phases.

- SUPPLEMENTARY TESTS

- Exp. Flow Sensor calibration *(see note at the beginning of chap. 3.4.2)*
- O_2 Sensor calibration

- LUNG VENTILATOR

- Respiratory parameters
- Spirometry

- LUNG VENTILATOR ALARMS

- OPTIONAL

WARNING !! Risk of ventilator failure and/or injuries for the patient

- Running or cancelling the preliminary checks might result in a malfunction during ventilatory operation: pay utmost attention.
- Always carry out all preliminary checks, unless there is an emergency situation.
- You should carry out the preliminary checks once the emergency condition stops, and at least once a week.

CAUTION

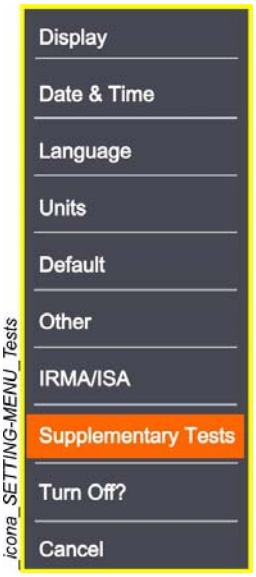
The lung ventilator must be ready for use in order for you to proceed with the preliminary checks.

- Connect the power supply, the medical gases and the patient circuit.
- Insert and connect the oxygen sensor.
- Connect a patient simulator to the patient circuit terminal.
- Lung ventilator ON: Stand-by mode.

3.4.1 Supplementary Tests

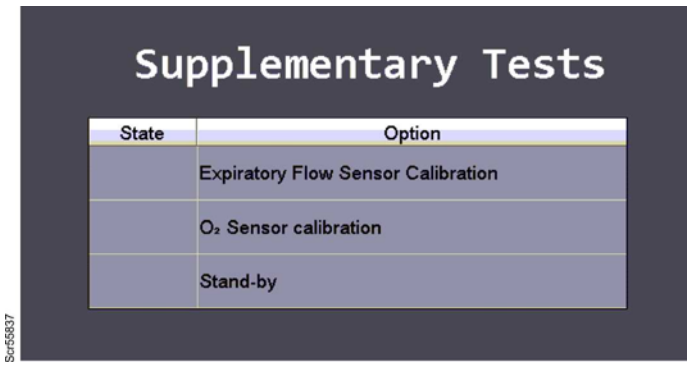
To carry out the Supplementary Tests you must know the keyboard operating mode and the options available in the lung ventilator SETTING MENU (*please see chapter 4*).

- Select the icon to access the lung ventilator's SETTING MENU.



- Select **Supplementary Tests**.
- To go back to Stand-by displaying, select Cancel.

- The Supplementary Tests screen appears.



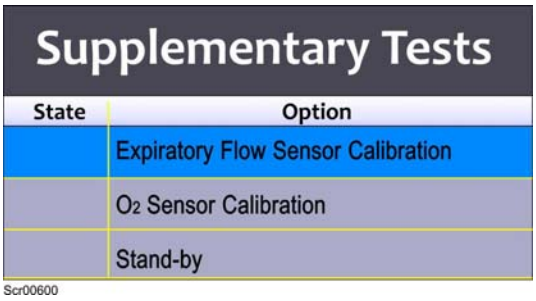
3.4.2 Expiratory Flow Sensors Calibration

WARNING !! Ventilator malfunctions risk

The activation of this procedure is only necessary in the following cases.

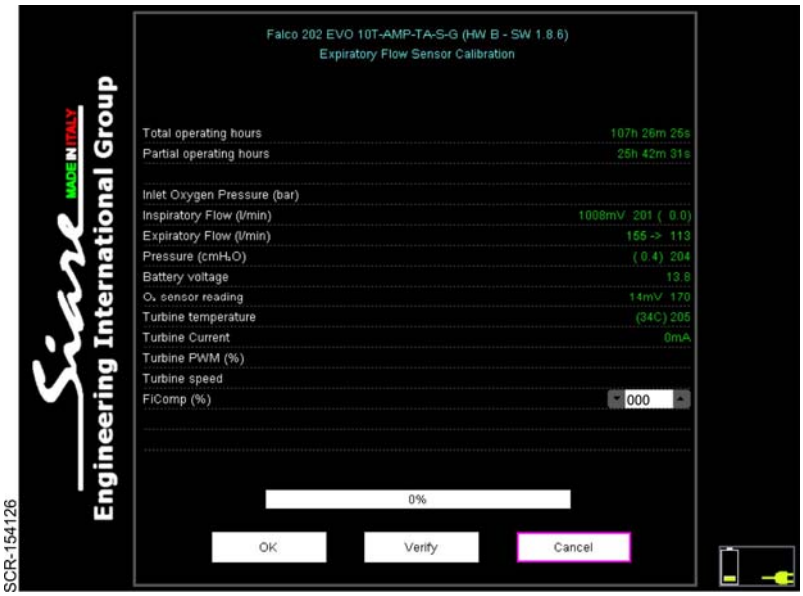
- Noted differences are more than 15% (over 100ml) between the set Volume value (VTi - Vte) and the expired Tidal Volume reading (Vte).
- In the case of maintenance intervention or replacement of components

- **Select** Expiratory Flow Sensors Calibration.



Scr00600

- The system will visualize the Expiratory Flow Sensors Calibration page.



SCR-154126

CAUTION

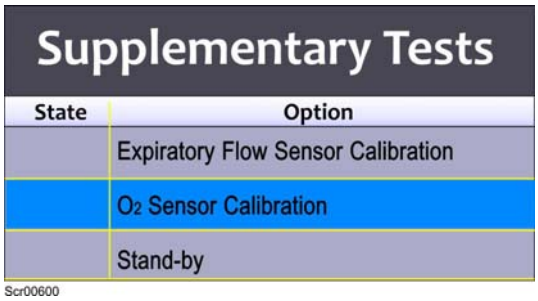
Not being a useful procedure for the purpose of "Preliminary Checks", see chapter 4.16 for a more detailed description of the same.

3.4.3 O_2 sensor calibration

WARNING !! Risk of M.D. failure and/or injuries for the patient

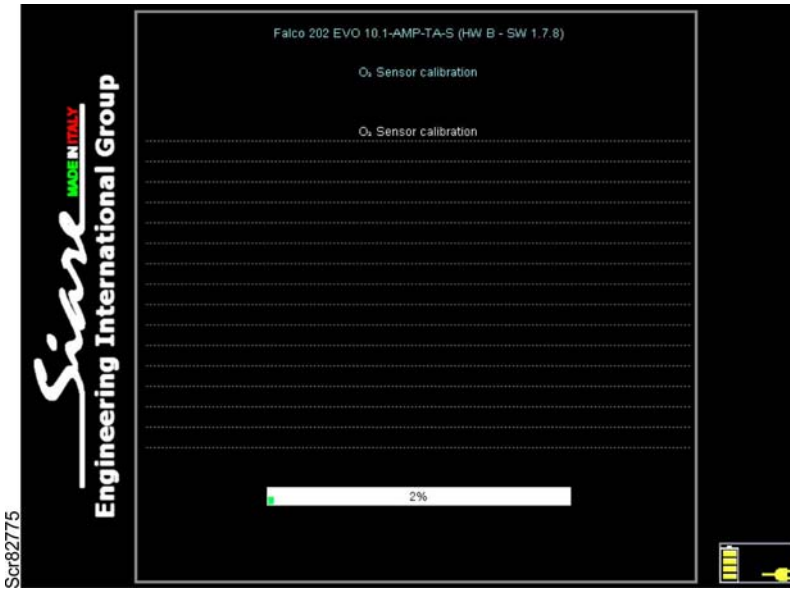
- This procedure should be carried out to check the proper operation of the oxygen sensor.
- Perform this procedure monthly.

- Select O_2 Sensor calibration.



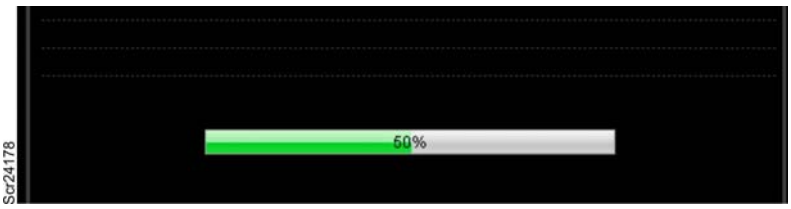
Scr00600

- The system automatically will enable the O_2 sensor calibration.
- To determine the correct operation of the O_2 sensor, the software reads the electrical value (mV) generated by the cell when è in presence of a flow with a 21% O_2 concentration (Air) .



Scr82775

- The O_2 sensor calibration in progress.



Scr24178

At the end of the O_2 sensor calibration a message is showed (if the O_2 sensor is new and in perfect conditions): Test Completed (XXmV) which show the value in Volts measured by the sensor with 21% Oxygen.

- The oxygen sensor calibration procedure was completed successfully: the measured voltage value is 14mV.

- At the end of the procedure, the system automatically goes back to the Supplementary Tests

SCR-154353

Conditions to be met for proper calibration

- The O_2 sensor must be placed in its seat.
- The O_2 sensor must be electrically connected through the suitable cable.
- The medical gases must be properly connected.

If any of these conditions is not met, the calibration cannot be successful.

CAUTION - REPLACING THE OXYGEN CELL

- The oxygen cell must be replaced when, at the end of the calibration phase, appears a detected voltage value that is not between 9 mV to 14 mV and/or if the system displays the relevant alarm message.
- To order the replace sensor and/or to dispose of the worn one, please see chapter 6 “**Maintenance**“.

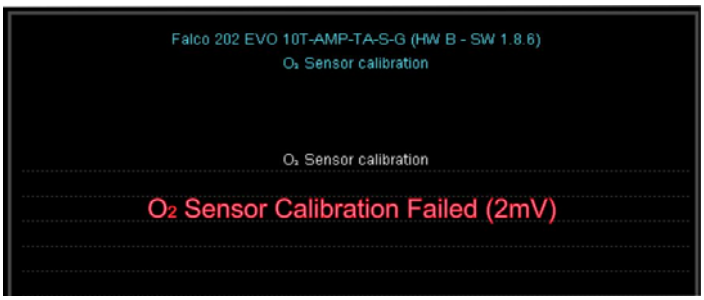
CALIBRATION procedure Failed

If the system does not exceed the preliminary checks phase, please see chapter 5 Alarms - Trouble Shooting or contact the nearest Siare Support Centre or any other support centres authorised by Siare.

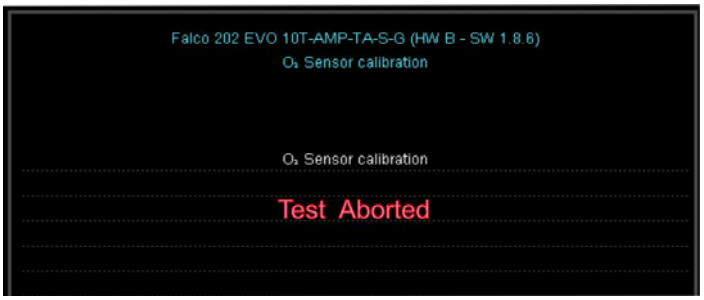
O_2 Sensor calibration not overcome

The oxygen sensor calibration procedure was not completed successfully.

- O_2 Sensor Calibration **Failed**.



- O_2 Sensor Calibration **Aborted**.

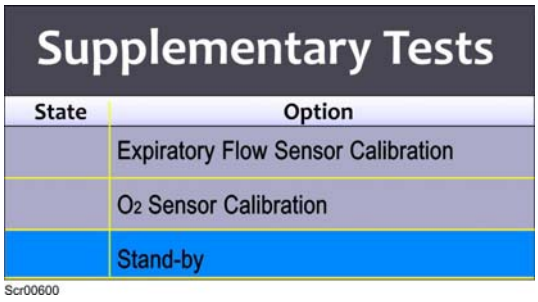


WARNING !! The TEST result is negative

- Check if the oxygen sensor is installed and electrically connected.
- Check if the O_2 sensor is worn out (the oxygen detection cell is worn out; replace the O22 sensor).
- Repeat O_2 Sensor Calibration.

3.4.4 Exit from Supplementary Tests

- The system automatically quits O_2 sensor calibration after a few seconds.
- Select Stand-by: the system will leave the Supplementary Tests.



Scr00600

CAUTION - Supplementary Tests

- In the previous paragraphs the tests to be performed before using the lung ventilator have been shown.
- It's recommended to perform the tests on schedule defined by this manual or by the local norms in force.

3.5 Preliminary checks - Lung Ventilator

To carry out the preliminary checks you need to know how the system and the Physiological Respiratory Parameters (**PRP**) work.

Preliminary checks to be carried out on the Lung Ventilator.

- Respiratory parameters setup.
- Spirometry proper operation check.

In order to carry out the preliminary checks, proceed as follows.

1. Lung Ventilator in STAND-BY.
2. Select VC-VAC operative mode.

Modification of the PRP

- Select the parameter you want to change.
- For more information about PRP set, please see on chap. 2.3.5.

For tests and checks, please use the patient simulator **SIARE cod. LS.AB.001** that is equipped with variable resistance and compliance.

3. Set the physiological respiratory parameters (PRP)

Vti 500

RR 15

I:E 1:2

Pause 0

PEEP OFF, 5, 10 cmH2O

O2 21%

Tr. I -2 cmH2O

1 L/min

4. Select / Press **START**: the lung ventilator begins its cycle.

3.5.1 Preliminary checks – MONITORING PARAMETERS

- Based on the PRP set by the User and on the patient's [patient simulator] characteristics, the lung ventilator is able to monitor and measure a series of values necessary for the patient's clinical evaluation.
- Before checking the value of the set parameters, leave the lung ventilator on for at least 15 minutes. This way the system will be able to reach its operating condition.

5. Check the compliance between the parameters set and those monitored.

- In the middle of the screen the system displays the operating curves.
- On the right side of the screen you can see the monitored parameters.

6. Change the PRP values.

- PEEP: 5, 10 cmH2O
- Tr. I: -2 cmH2O, 3 L/min
- O2: 60%

7. Check the correspondence between the monitored parameters and the displayed curves.

8. Select the key to display all the parameters.

CAUTION. Lung Ventilator operation check

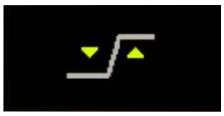
- Make sure that the airways pressure increases during the inspiratory phase.
- Make sure that the airways limit pressure intervenes (pressometric operating mode).
- Make sure that the variation in the set oxygen concentration value (O_2 %) corresponds.
- Make sure that the lung ventilator responds properly at parameters variation.
- Make sure that that the trigger works properly.
- Make sure that the values set for respiratory frequency and volume are properly displayed and the pressure, volume and flow curves match the monitored parameters.
- Make sure that the alarms intervene properly.

CAUTION

- If the O_2 measured value differs from the set value by more than +/- 10%, please repeat the “O2 Sensor Calibration” procedure: Supplementary Test.
- If the Vte measured value differs from the set value by more than +/- 20% (Adult parameters), please go to the “CALIBRATION PROGRAMS” visualization to perform the calibration of the expiratory flow sensor (see chap. 4.16).

3.5.2 Preliminary checks – ALARMS

To carry out the preliminary checks relative to lung ventilator's alarms, you need to know how the system and the alarms work: please see chap. 2.3.



9. Select the icon to access the lung ventilator's ALARMS.

- The Alarm Limits screen appears.

- Check the Alarms Limits and if necessary change the values set, based on the test you want to carry out.
- Select the Alarm parameter you want to change. For more information about use of touch screen or key board, please see on chap. 2.2.

Exit the Alarm Limits screen

Select Cancel

- YES: to quit Alarm page; the alarm set will NOT be saved.
- NO: it remains in Alarm page.

Select OK

- YES: to quit Alarm page; the alarm set will be saved.
- NO: it remains in Alarm page

To set or modify the Alarm Limits make reference to chapter 5 (Alarms).

3.5.3 Alarm limits check

WARNING !! Severe patient injuries

The alarms must trigger at the proper time and in the correct manner.

- Check the proper activation of the visual and acoustic signals.

Before starting the alarm limits, check the alarms setup, and change the set values whenever necessary (please see previous paragraph).

10. Select **VC/VAC** operative mode.

11. Press **START**: the lung ventilator begins its ventilation cycle.

PAW

High Pressure

- Set the high pressure alarm limit to a value higher than the PAW ventilation pressure by 5 cmH_2O.
- Block the patient simulator (using your hands) during ventilation.
- The system activates the airways HIGH PRESSURE alarm: silence the alarm.
- Unlock the patient simulator.

Low Pressure

- Set the low pressure alarm limit to 5 cmH_2O.
- Disconnect the patient circuit during ventilation.
- After about 20 seconds the system activates the airways LOW PRESSURE alarm: silence the alarm.
- Reconnect the patient simulator.

PEEP	**High**	• During ventilation please set PEEP = 10 cmH_2O • Set the high pressure limit to 5 cmH_2O. • The system activates the HIGH PEEP alarm: silence the alarm. • Restore the default alarm value.
	Low	• During ventilation please set PEEP = 3 cmH_2O • Set the low pressure limit to 8 cmH_2O. • The system activates the LOW PEEP alarm: silence the alarm. • Restore the default alarm value.
Vte	**High EXP Vt**	• During ventilation, set Vti to 500 ml. • Set the high expired Vte alarm limit to 400 ml. • The system activates the high expired Vte alarm: silence the alarm. • Restore the default alarm value.
	Low EXP Vt	• During ventilation, set Vti to 200 ml. • Set the low expired Vte alarm limit to 250 ml. • The system activates the low expired Vte alarm: silence the alarm. • Restore the default alarm value.
Vm	**High**	• Set the high expired Vm alarm limit to 8 l. • During ventilation, set Vti to 800 ml / 15 bpm. • The system activates the high expired Vm alarm: silence the alarm. • Restore the default alarm value.
	Low	• Set the low expired Vm alarm limit to 5 l. • During ventilation, set Vti to 175 ml / 20 bpm. • The system activates the low expired Vm alarm: silence the alarm. • Restore the default alarm value.

O_2	**High oxygen concentration**	• Set a O_2 concentration to 50% on the lung ventilator. • Set the high O_2 concentration alarm limit to 30%. • The system activates the high O_2 alarm: silence the alarm. • Restore the default alarm value.
	Low oxygen concentration	• Set a O_2 concentration to 30% on the lung ventilator. • Set the low O_2 concentration alarm limit to 50%. • The system activates the low O_2 alarm: silence the alarm. • Restore the default alarm value.

High / Low FiO_2

If the lung ventilator is in Stand-by the alarms are not active.

RR	**High respiratory rate**	• During ventilation please set RR = 20 bpm. • Set the high respiratory rate alarm limit to 15 bpm. • The system activates the high RR alarm: silence the alarm. • Restore the default alarm value.
	Low respiratory rate	• During ventilation please set RR = 10 bpm. • Set the low respiratory rate alarm limit to 15 bpm. • The system activates the low RR alarm: silence the alarm. • Restore the default alarm value.

Power Supply Fault	• During ventilation, set the main power supply switch to OFF (0). • The system activates the main power failure alarm: silence the alarm. • Restore the main switch and set it to ON (I).
Low O_2 Gas Supply	• Close the medical gas supply during lung ventilator operation. • The system activates the gas supply failure alarm: silence the alarm. • Restore the medical gas supply.

3.5.4 Conclusions

Carry out all preliminary checks and make sure that they were completed successfully before connecting the patient to the Falco 202 Evo lung ventilator.

CAUTION - Preliminary checks phase failed.

Please see Alarms chapter and/or Trouble Shooting chapter.

Please contact the nearest Siare Support Centre or any other support centres authorised by Siare.

WARNING !! Patient injury hazard

- Check the alarm limits setup values before connecting a patient to the lung ventilator.
- Change the alarm limits setup based on the clinical situation.

WARNING !! User and patient injury hazard

The intensive care lung ventilator must be inspected and serviced once it reaches 1000 hours of operation or, in case of limited use, at least once every 6 months.

All maintenance and/or repair interventions require full knowledge of the lung ventilator, and therefore such operations must be carried out only by highly qualified staff, specifically trained and authorised by SIARE.

Any improper intervention or unauthorised modification may affect the device's safety, putting the patient at risk.

3.6 Preliminary checks sequence list

4 LUNG VENTILATOR USE

This chapter shows you how to use the Falco 202 Evo (10.4”) lung ventilator for intensive care, (*hereinafter called lung ventilator*).

Thoroughly read this chapter and the whole manual to make sure respiratory parameters and alarm limits are set correctly and choose the most suitable ventilation mode. The User must choose the Operative modes and the alarm limits best matching patient's physiological state and pathologies.

WARNING !! Patient/User injury hazard

Before starting the lung ventilator, you have to:

- carry out the preliminary checks *(please see the previous chapter).*
- set the language and the PATIENT DATA *(please see chap. 4.3 and chap. 4.2).*
- set and check the Alarms limits *(please see chap. 4.5).*
- set the physiological respiratory parameters and the operative mode that match the patient's clinical situation best *(please see chap. 4.7).*

CAUTION

Before subjecting the patient to a lung ventilation treatment, please:

- set the airway pressure limit alarm to a value that does not exceed 20 cmH_2O; this way you will prevent any problems that might arise due to incorrect respiratory volume or frequency setup (you can increase the pressure if the patient's pathology and conditions require such modification).
- check the set oxygen concentration (FiO_2) as high concentrations might affect the patient's health.
- please consult this User Manual.

WARNING !! Patient injury hazard

All figures and examples featured in this chapter are purely informative and do not refer to real clinical cases.

Graphics interface and control keyboard use

For methodology of the use of touch screen and/ or control keyboard and encoder knob, see chap. 2.2.

4.1 Ventilator switch ON / Self Test phase

- Set the main switch (placed on the back of the ventilator) to "**I**".
- Make sure that on the lung ventilator keyboard (commands area) the green led (that indicates the presence of mains power supply) is on.

- Hold the **ON-OFF** key for few seconds; the lung ventilator switches ON and the automatic Self Test phase starts.

During Self Test phase, the lung ventilator software carries out the self-diagnostic tests and checks a series of devices necessary for safe operation of the lung ventilator /patient.

SCR-151901

Self Test phase. Please close the patient circuit

The Self Test phase in progress.

- For more information on the **Self Test please** refer to chap. 3.3.2.

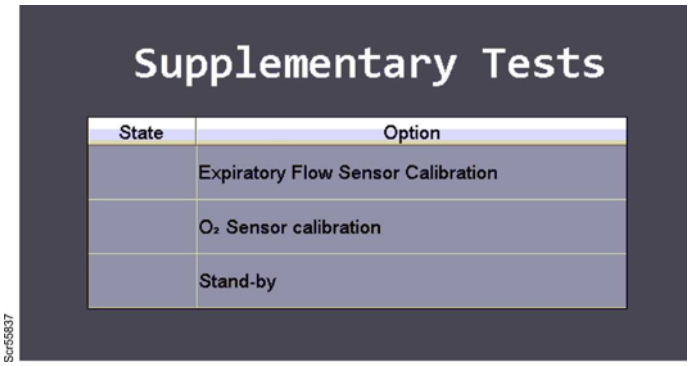
SCR-151913

The Self Test phase completed successfully.

- Press **OK** to begin
- Press **Cancel** for other tests

Cancel

The system will display the Supplementary Tests page.



Through of this page it is possible to perform the Supplementary Test (*for further details see on 3.4*).

OK

The system will display the PATIENT DATA page.

PATIENT DATA

By means of this page it is possible set the PATIENT DATA (*for further details see on par 4.2*).

- Select **Cancel** or **OK** for procedures and to display the Stand-by page.

Stand-by mode

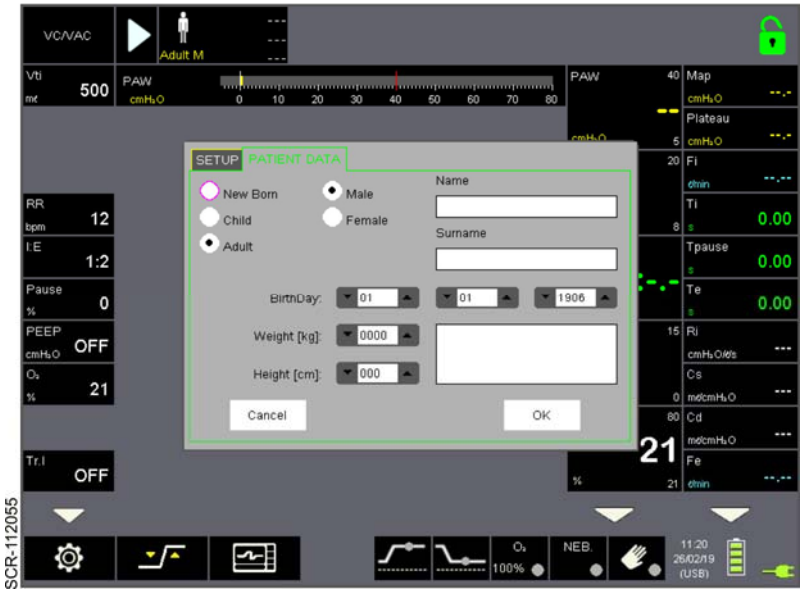
- In Stand-by mode the User can set and/or edit all lung ventilator parameters and alarms limit relative to the operating mode that you will use on the patient that you want to treat.

4.2 PATIENT DATA / SETUP parameters

Actually, the lung ventilator software does not switch directly from Self Test phase to Stand-by operative mode, but it previously displays a page which allows the adjustment of the following types of information and machine setup.

- PATIENT DATA *(see on 4.2.1)*
- SETUP parameters (*see on 4.2.2*)

4.2.1 PATIENT DATA



PATIENT DATA displaying allows to set the following data.

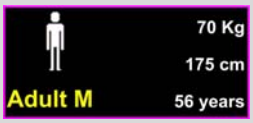
- *Patient type*
- *Male / Female*
- *Name / Surname*
- *Physical date*
- *Birthday*
- *Note*

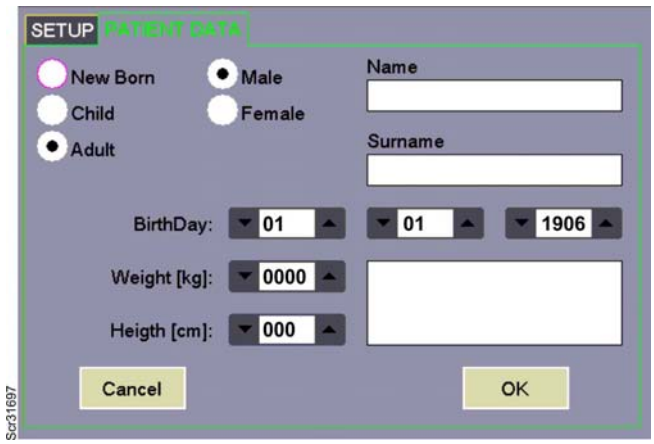
CAUTION

When the lung ventilator is switched ON (at the end of Self Test phase), selecting PATIENT DATA function it is possible to choose the patient typology (Adult, Child, New Born / Male, Female).

CAUTION

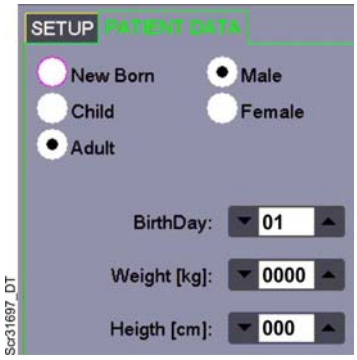
During the normal operation of the lung ventilator, the User can modify the PATIENT DATA selecting the function: SETTING MENU / PATIENT DATA or by touching the relative icon (PATIENT DATA).



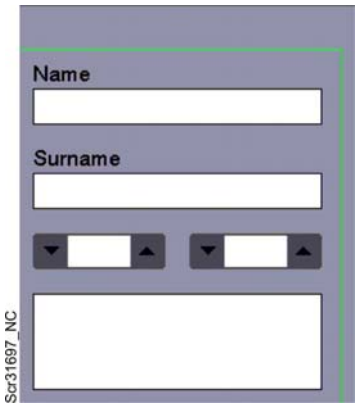


PATIENT DATA page view.

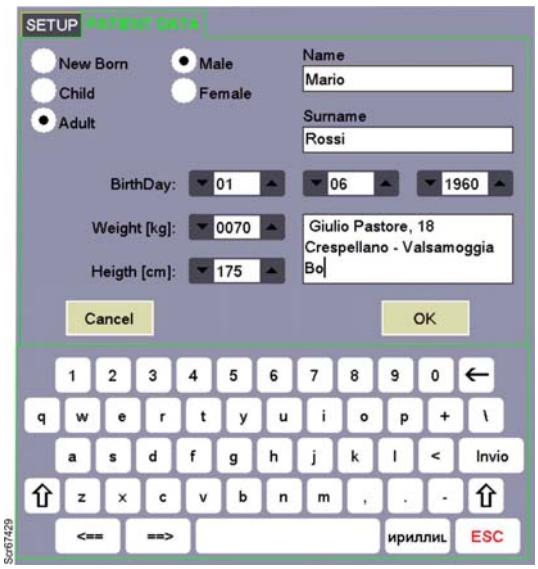
- The choice of the Patient Type, set automatically the default functioning parameters of the lung ventilator (*breathing parameters and alarms levels*).



- Select and set the patient type and the related physical data.



- Select the desired data area: the system displays a keyboard for entering the Patient Data.



Once completed the entering of patient data, save or cancel what is typed in the page.

- *Select **OK** :*
- *Select **Cancel** :*

Once completed the entering of patient data, save or cancel what is indicated in the page.

- **Select** Cancel

  PATIENT DATA setting will NOT be saved.

- **Select** OK

  PATIENT DATA setting will be saved.

- The system will display the Stand-by screen.

4.2.2 SETUP parameters

CAUTION

During the normal operation of the lung ventilator, the User can modify the parameters SETUP selecting the function: SETUP MENU.

SCR-111949_Menu

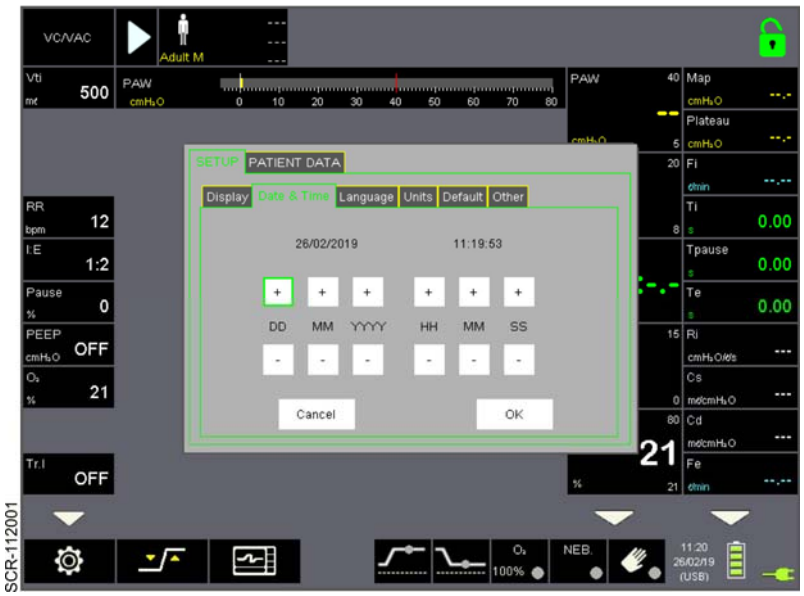
The SETUP displaying allows to determine the operation settings of lung ventilator.

- *Select SETUP MENU*

SCR-111955

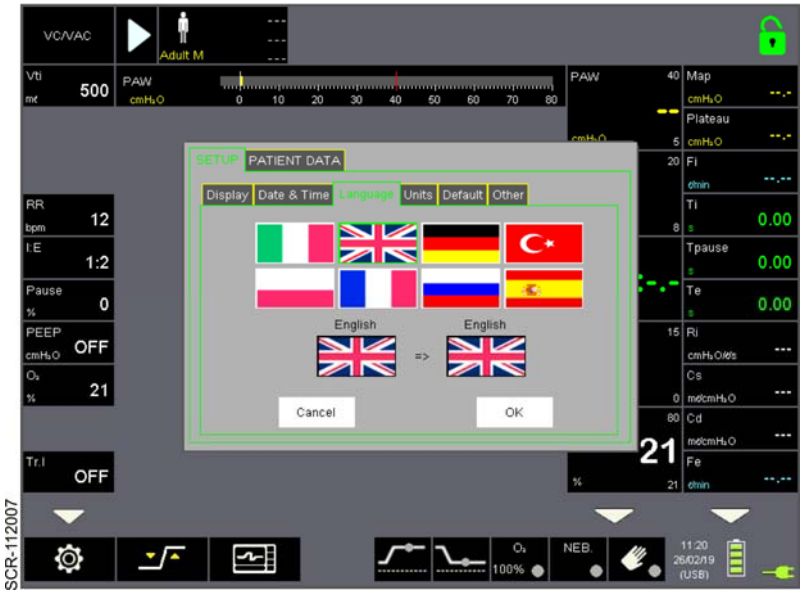
Display

- *BRIGHTNESS*
- *ENERGY SAVING*
- *SOUND VOLUME*
- *TOUCH AUDIO*



Date & Time

- *Date*
- *Time*

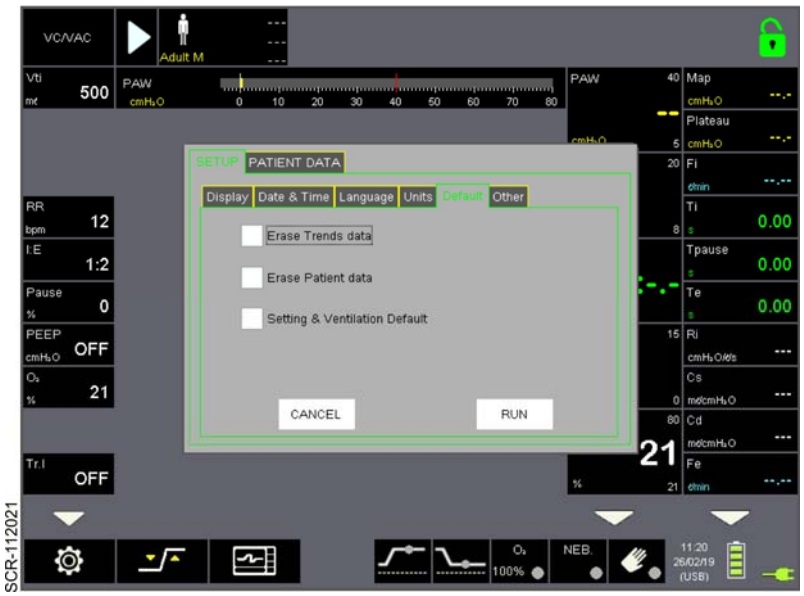


Language

- *Italian*
- *English*
- *German*
- *Turkey*
- *Polish*
- *French*
- *Russian*
- *Spanish*

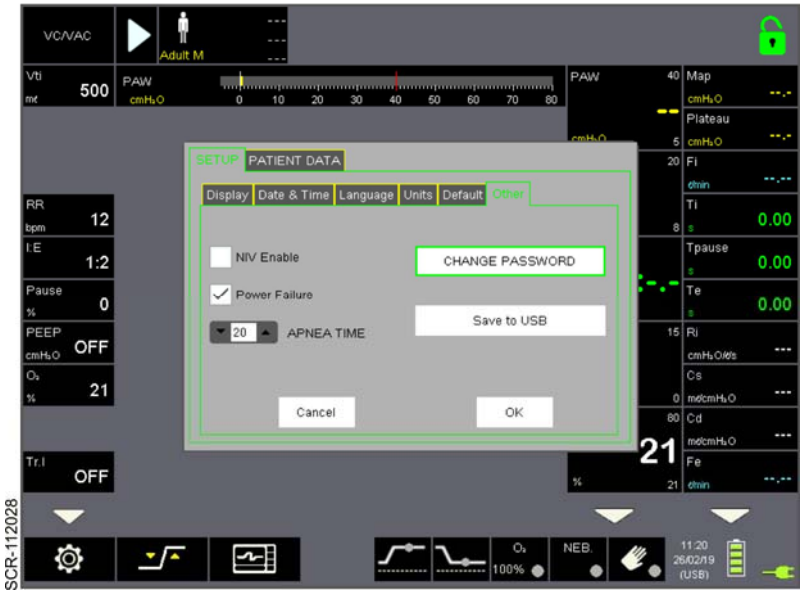
Units

- *Weight (referred to the patient)*
- *Height (referred to the patient)*
- *CO2 (unit of measurement)*
- *Pressure (unit of measurement)*



Default

- *Trends data Default*
- *Patient data Default*
- *Setting & Ventilation rends data Default*



Other

- *NIV Enable*
- *Power Failure*
- *APNOEA TIME*
- *CHANGE PASSWORD*
- *Save to USB*

At the end, save or cancel what is set in SETUP pages.

- **Select** Cancel

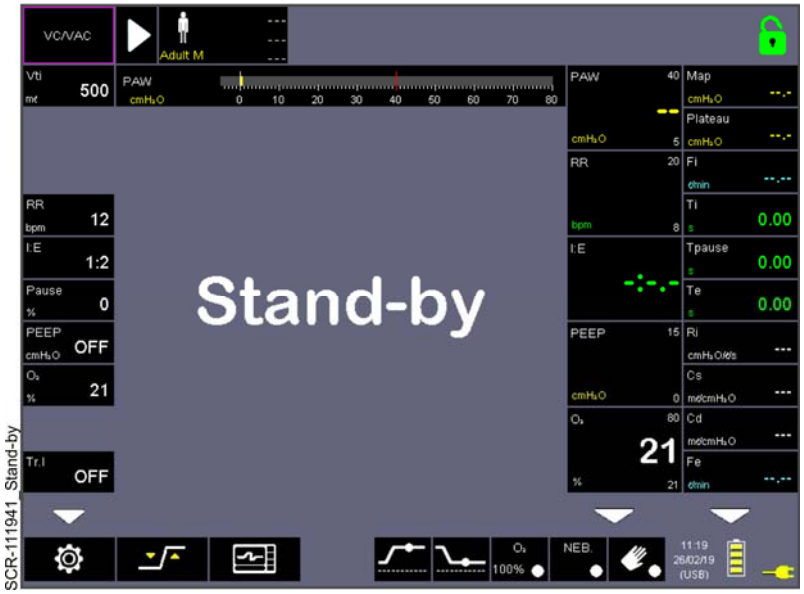
YES: to quit SETUP page without saving.

NO: it remains in SETUP page.

- **Select** OK

YES: the set values will be saved.

NO: it remains in SETUP page.



- The system will display the Stand-by screen.

It is suggested to set the parameters: see the following chapters.

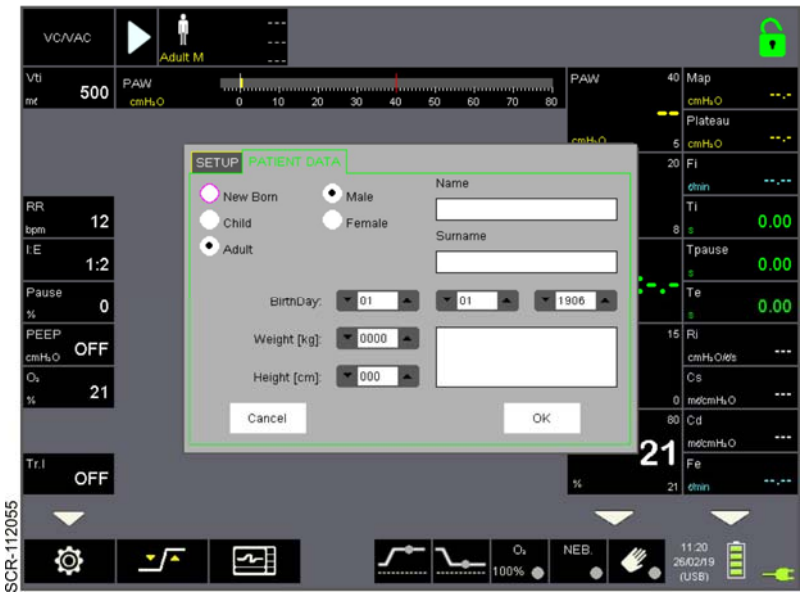
4.3 Setting up the UGI language

Two ways are available to set/modify the UGI (User Graphic Interface) language.

Mode 1: at ventilator start-up at the end of Self Test phase.

Mode 2: during normal operation of lung ventilator.

4.3.1 Mode 1



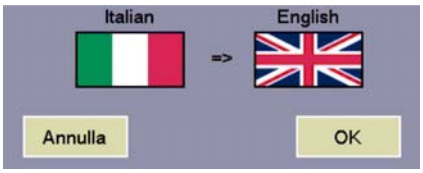
At the end of Self Test phase, the system displays the page: **PATIENT DATA**.

- Select: **SETUP**

- Select: **Language**

A series of MENU languages are available and identified by an icon.

- Select **the flag**.



- Confirm the choice.

OK

- **Press YES**: the setting will be saved.
- **Press NO**: it remains to language setting.

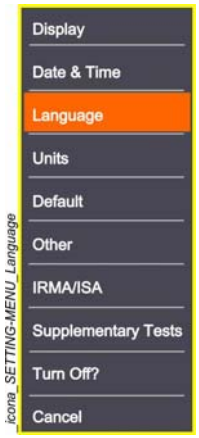
The UGI (User Graphic Interface) language is **ENGLISH**.

4.3.2 Mode 2

Lung ventilator in Stand-by operative mode.

- Select: **SETTING MENU**

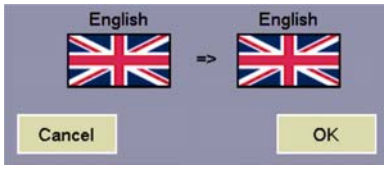
- Select: **Language**



At Language page the SETUP / PATIENT DATA screen is displayed.

A series of MENU languages are available and identified by an icon.

- Select the flag



- Confirm the choice

- **Press YES**: the setting will be saved.
- **Press NO**: it remains to Language setting.

The UGI (User Graphic Interface) language is ENGLISH.

4.4 PATIENT DATA Setting

Two ways are available to set/modify **PATIENT DATA**.

Mode 1: at ventilator start-up at the end of Self Test phase (*see on 4.2.1*).

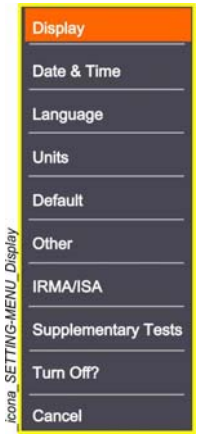
Mode 2: during normal operation of lung ventilator (*see on 4.6.1*).

4.4.1 Mode 2

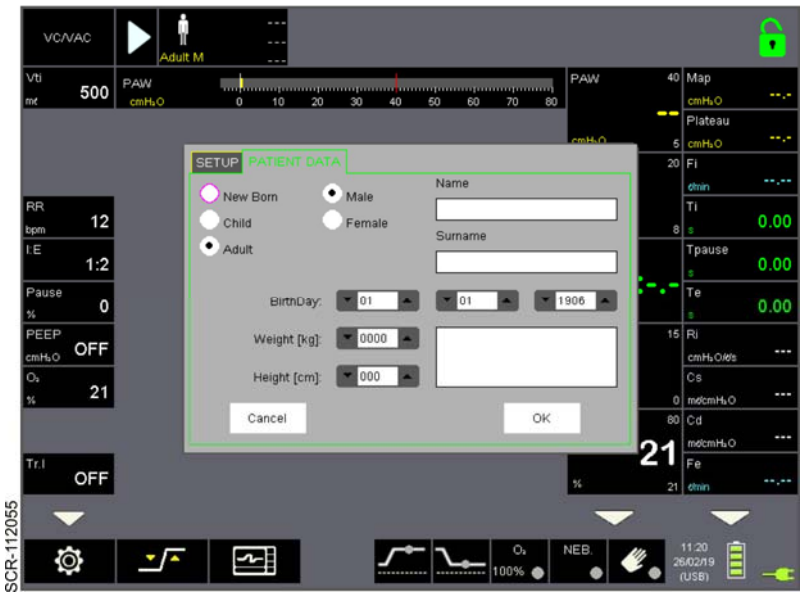
Lung ventilator in Stand-by operative mode.

- Select: **SETTING MENU**

- Select: **Display**



- Select: **PATIENT DATA**



The displaying of PATIENT DATA allows to set / modify the following data.

- *Patient type*
- *Male / Female*
- *Name / Surname*
- *Physical date*
- *Birthday*
- *Note*

To set/modify the **PATIENT DATA**; see on 4.3.1.

4.4.2 Erasing the PATIENT DATA

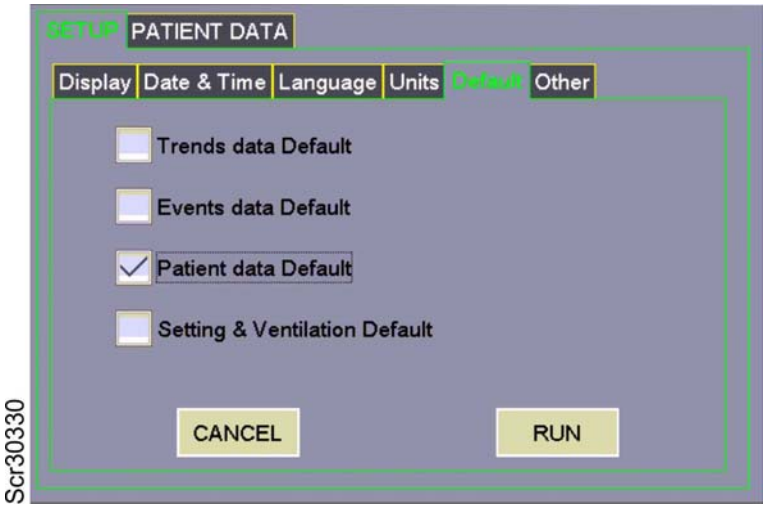
Lung ventilator in Stand-by operative mode.

SCR-111949_Menu

- Select: **SETTING MENU**

- Select: **Default**

icona_SETTING-MENU



Scr30330

- Select: **Patient data Default**

Confirm the choice: **select**

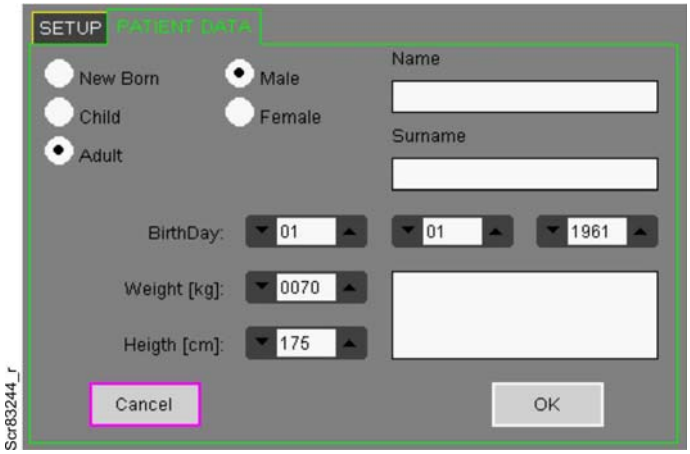
RUN

Cancel the choice: **select**

Cancel

RUN

- **Press YES**: to **RUN** the selected DEFAULT.
- **Press NO**: to **cancel** the command.

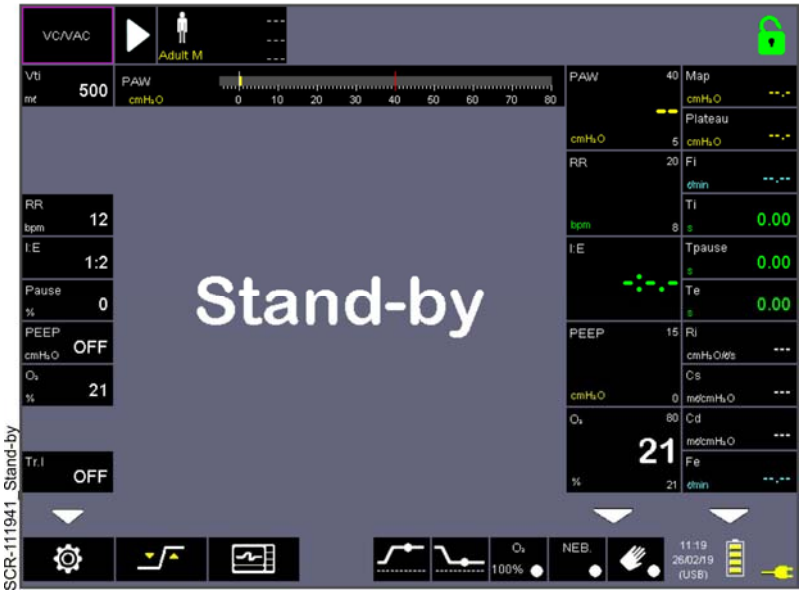


- Select: **SETTING MENU**
- Select: **Display**
- Select: **PATIENT DATA**

The page of **PATIENT DATA** is displayed in Default configuration.

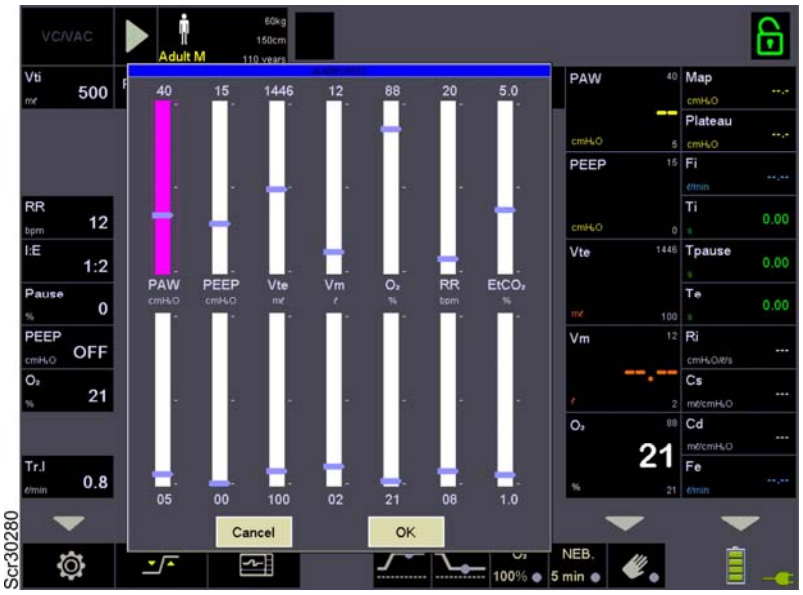
To enter the **PATIENT DATA**; *see chap. 4.2.1.*

4.5 Setting up the ALARMS



Lung ventilator in Stand-by operative mode.

- Select: **ALARMS**



- Select Cancel

  YES: to quit Alarm page; the alarm set will NOT be saved.

  NO: it remains in Alarm page.

- Select OK

  YES: to quit Alarm page; the alarm set will be saved.

  NO: it remains in Alarm page.

For ALARMS parameters and limits setup, please see on 5.2.

4.6 Operative modes

In the following chapter you will find a description of available Operative Modes selectable on Falco 202 Evo lung ventilator.

WARNING !! Patient injury hazard

The User must choose the Operative modes that match the patient's physiological features and pathologies best.

4.6.1 Operative Modes setting procedure

CAUTION

- When the lung ventilator is turned ON, the system restores the operative mode and the relevant parameter values set before the last shut-down.
- Just for our examples we refer to the Operative Modes available with ADULT Patient Data (VC/VAC).

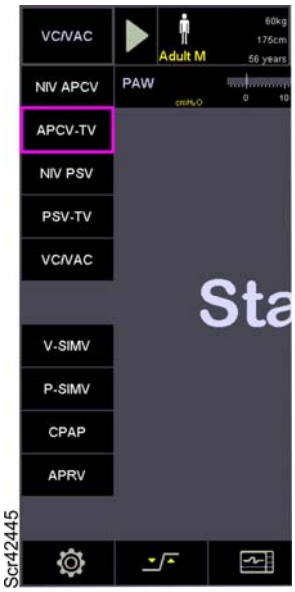
CAUTION

A new operative mode can be selected in two different operating conditions.

1. **Lung ventilator in Stand-by mode.**
2. **During the normal operation of the lung ventilator.**

1. Lung ventilator in Stand-by mode

- Select the icon, VC/VAC.



- All the operative modes foreseen are displayed.
- Select a new operative mode.

- Operative mode selected: APCV-TV.

CAUTION

If the lung ventilator is in Stand-by mode, the system does not require any confirmation or enabling for setting a new operative mode.

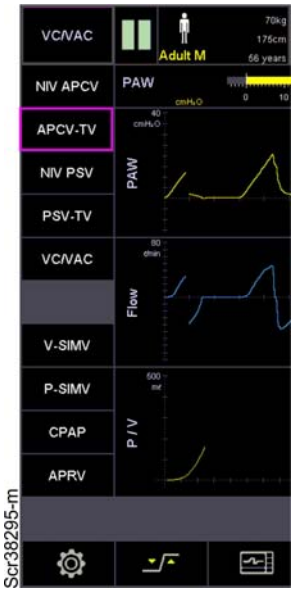
- PRP parameters referred to the APCV-TV operative mode can be displayed.
- Select the icon for see all PRP parameters.

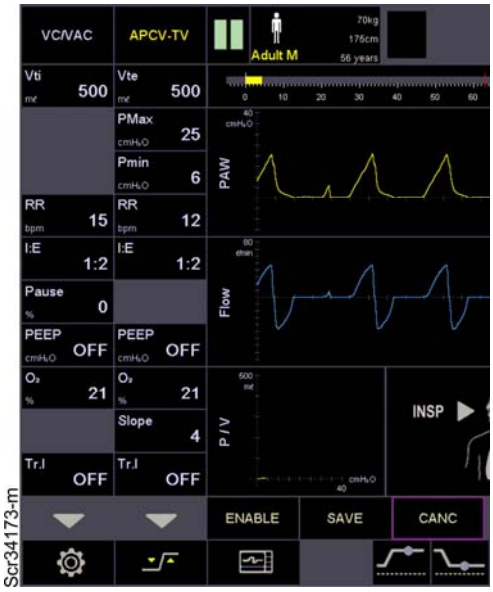
Lung ventilator in Stand-by, ready to be used in **APCV-TV** operative mode.

2. Lung ventilator in normal operation

- Operative mode: VC/VAC.

- All the operative modes foreseen can be displayed.





- Select a new operative mode.

- APCV-TV operative mode selected.
- A second column with the PRP parameters referred to the APCV-TV operative mode can be displayed.

CAUTION

When the lung ventilator is working, the system requires a confirmation by the user for the modification of the operative mode.

Scr41327

ENABLE

- **YES**: The Lung ventilator directly switches to the new selected operative mode **APCV-TV**
- **NO**: to exit.

Scr34160

SAVE

- **YES:** The PRP parameters of the APCV-TV operative mode modified, are stored by the system; the system is fitted for a future APCV-TV ventilation mode.
  The lung ventilator continues to ventilate in VC/VAC operative mode.
- **NO**: to exit.

Scr34173

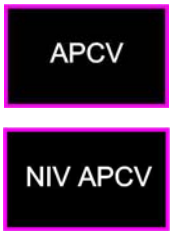
CANC

- **NO**: The system remains in the condition where the PRM of the two operative modes selected are displayed.
- **YES**: The system goes back to the **VC/VAC**.

4.6.2 APCV (NIV APCV)

Assisted pressure controlled ventilation, synchronised with patient's breathing with leak compensation.

- The system displays all PRP relative to the set operative mode.



APCV is a pressure controlled ventilation, synchronised with the patient's breathing with leak compensation.

With this parameters configuration, APCV is a pressure controlled ventilation, synchronised with the patient's breathing, during which the system generates a patient ventilation at a pre-set inspiratory pressure (Pinsp), a pre-set flow (Flow), a calculated I:E ratio and a settable respiratory rate (RR).

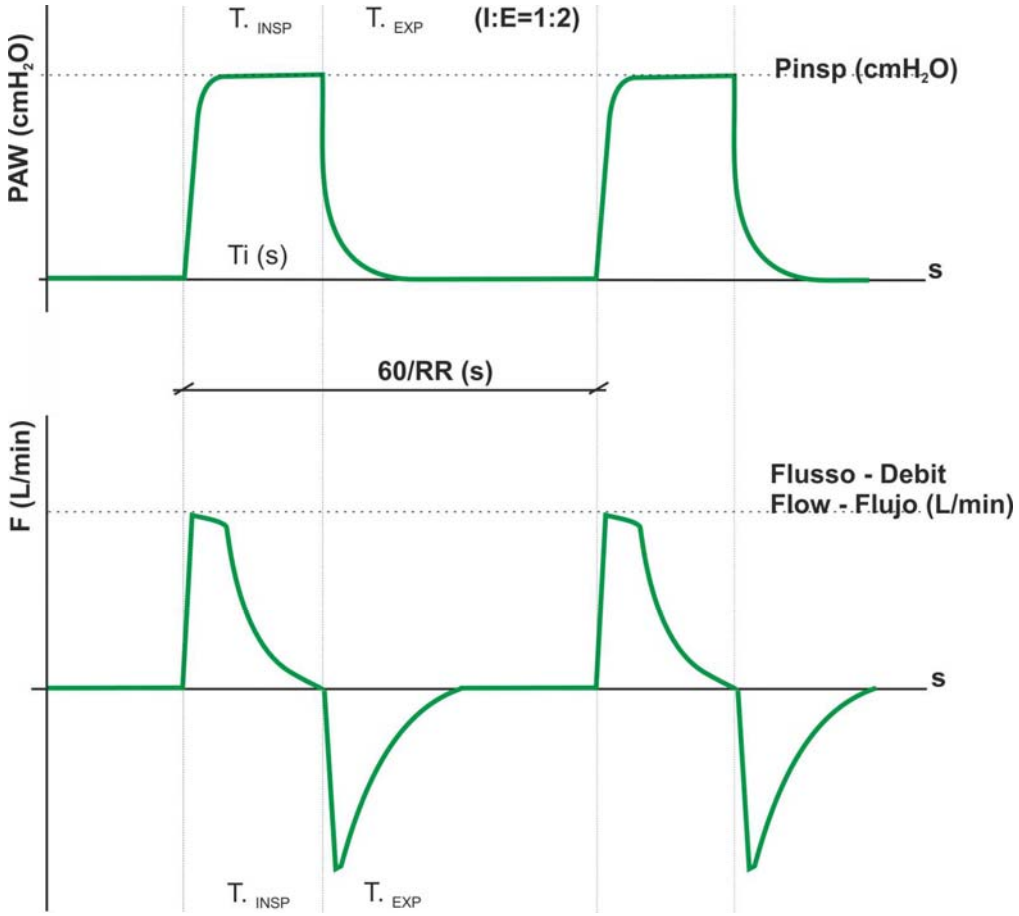
In APCV the current volume depends on the inspiratory pressure (Pinsp) and on the patient's lungs characteristics (compliance, lung capacity) therefore the tidal volume will vary depending on changes in lung mechanics.

During the inspiratory phase, the lung ventilator generates a settable flow (Slope). When the airway pressure reaches the control value (Pinsp), this pressure level is kept constant by the lung ventilator until the end of the inspiration that you can set using (RR).

Use the settable parameters to define an inspiratory trigger (Tr. I) used to set a flow expressed in litres per minute (or a pressure in cmH2O) that represents the limit for detecting the patient's spontaneous breathing attempt.

The greater the value, the greater the patient's effort to breath.

If the pressure set is not reached, make sure that the patient circuit is perfectly sealed and that the PRP parameters are properly set.



4.6.3 APCV-TV

(Volume Targeted) Pressure controlled ventilation, synchronised with patient's breathing and with guaranteed current volume.

- The system displays all PRP relative to the set operative mode.

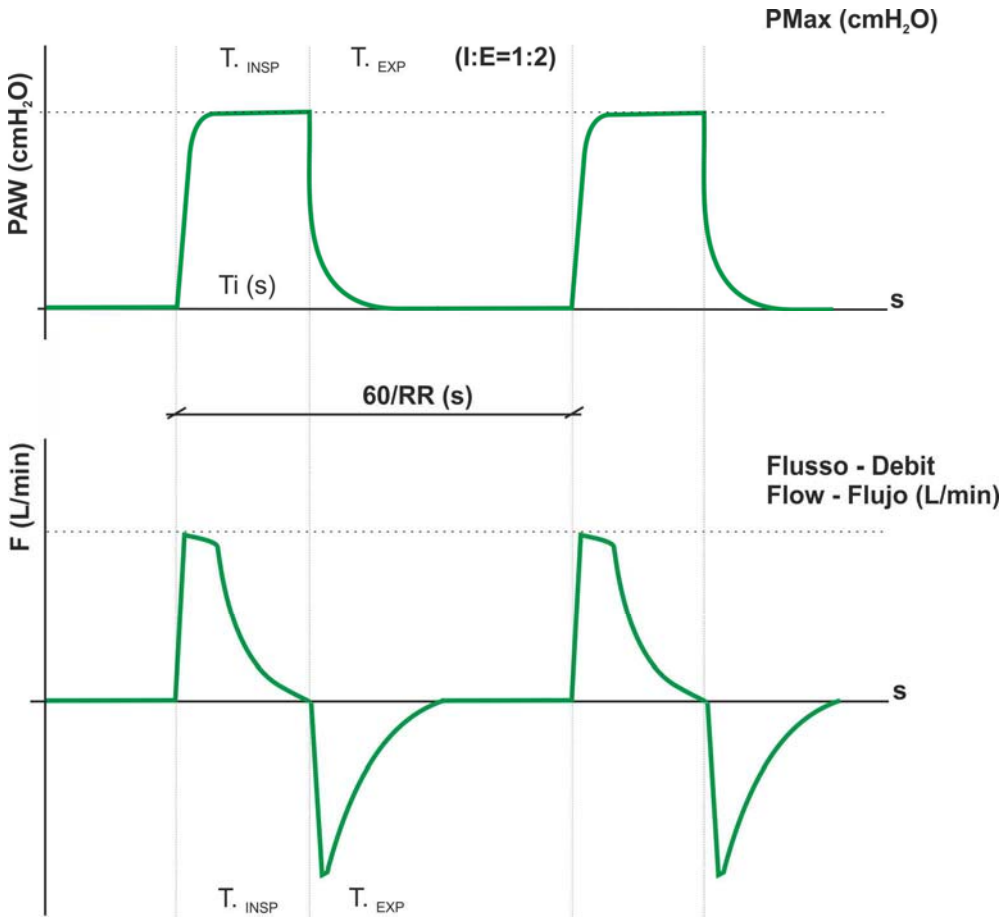
APCV-TV is a pressure controlled ventilation, synchronised with the patient's breathing (automatic Pinsp) with guaranteed current volume (Vte).

The system generates a ventilation at automatic inspiration pressure (automatic Pinsp), in order for the expired volume to equal the volume set (Vte).

During the inspiratory phase, the lung ventilator generates an automatic flow. When the pressure reaches the control value inside the airway (automatic Pinsp, at maximum PMax), this pressure level is kept constant by the lung ventilator until the end of the inspiration that you can set using the (RR) and the I:E ratio.

Use the settable parameters to define an inspiratory trigger (Tr. I) used to set a flow expressed in litres per minute (or a pressure in cmH2O) that represents the limit for detecting the patient's spontaneous breathing attempt.

The greater the value, the greater the patient's effort to breath.


PMax (cmH2O)
T. INSP
T. EXP
(I:E=1:2)
PAW (cmH2O)
Ti (s)
s
60/RR (s)
Flusso - Debit
Flow - Flujo (L/min)
F (L/min)
s
T. INSP
T. EXP

4.6.4 PSV (NIV PSV)

Assisted pressure support ventilation with guaranteed safety respiratory rate, set by the User (Apnoea Back Up) with leak compensation.

- The system displays all PRP relative to the set operative mode.

PSV is an assisted type of ventilation with pre-set pressure support (PS) with guaranteed safety respiratory rate set by the User in case of patient apnoea (RR bk) and with leak compensation.

PSV can be used to sustain spontaneous ventilation for patients with stabilised ventilation needs or who are in weaning phase.

Therefore, keep in mind that, in order to have the ventilator's support, when using PSV mode, the patient must be able to inhale and so you can't use this operative mode to ventilate a patient who is sedated or paralysed.

Therefore, **the Tr. I parameter can't be set to OFF**.

PSV is a ventilation technique during which, at the beginning of the patient's spontaneous inspiratory effort, the lung ventilator provides a constant positive support pressure (PS) pre-set by the User with high-speed flow supply, until the pressure inside the airway reaches the desired support value.

When the set support pressure is reached, the expiration takes the place of the inspiration (according to Tr. E - percentage of the inspiratory flow peak beyond which the expiration can begin). This technique saves the patient from the work of breathing, as he only has to reach the small quota necessary to enable the lung ventilator trigger (Tr. I).

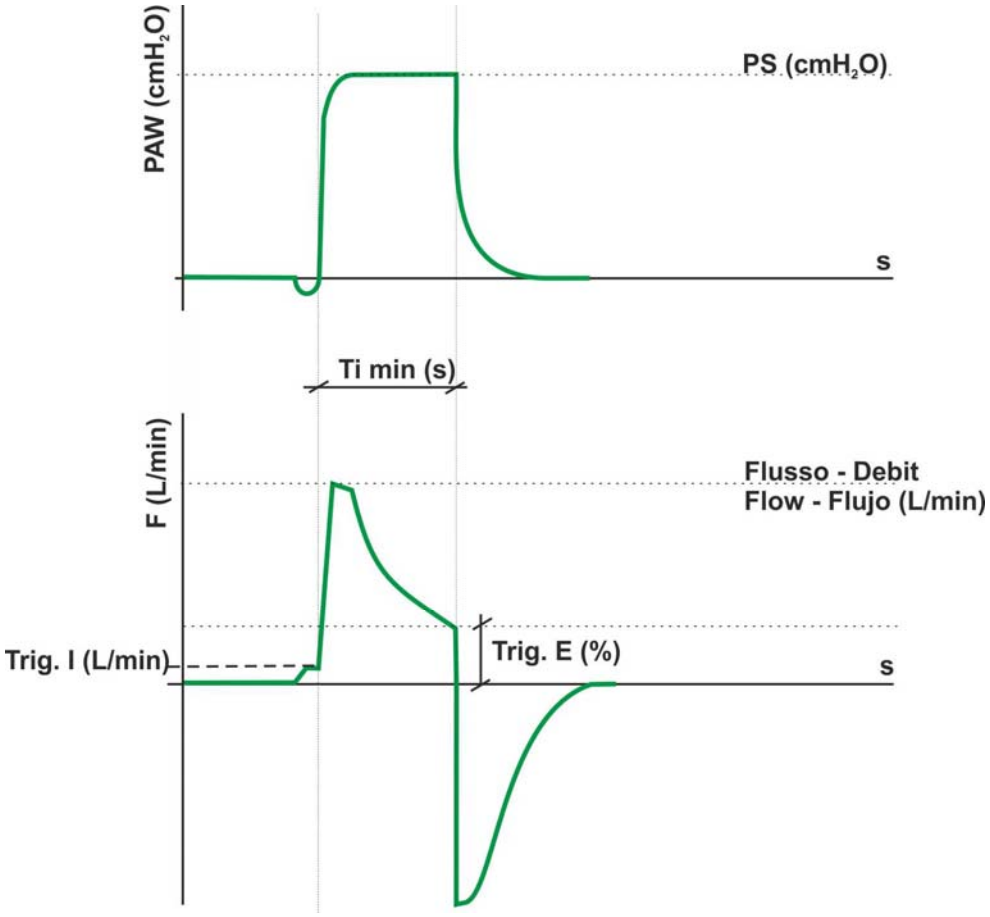
This way, the respiratory rate depends on patient spontaneous activity and the current volume depends on set parameter values and patient patophysiological conditions.

With optimal PSV, the breathing pattern can be standardised (by increasing the Vte and reducing the respiratory rate) and the work of breathing can be reduced, improving the respiratory exchange ratios.

In this mode the patient's work of breathing is assumed by the lung ventilator. Each breath initiated by the patient (Tr. I enabled) is supported by the lung ventilator, that sends a gas flow inside the airway, at a certain pre-set pressure, called support pressure (PS).

If the patient does not trigger (spontaneous breathing during the apnoea time set in *SETUP - Other*), the system enables the APNOEA acoustic and visual alarm.

The system will automatically provide an APCV ventilation with set safety respiratory rate (RR bk) and I:E ratio (I:E bk).



4.6.5 PSV-TV

(Volume Targeted) Pressure support ventilation with guaranteed current volume and guaranteed safety respiratory rate set by the User (Apnoea Back Up).

PSV-TV

- The system displays all PRP relative to the set operative mode.

PSV-TV Scr25687

PSV-TV is an assisted pressure support ventilation with guaranteed current volume and guaranteed safety respiratory rate set by the User in case of patient apnoea (RR bk).

PSV-TV can be used to sustain spontaneous ventilation for patients with stabilised ventilation needs or who are in weaning phase.

Therefore, keep in mind that, in order to have the ventilator's support, when using PSV-TV mode, the patient must be able to inhale and so you can't use this operative mode to ventilate a patient who is sedated or paralysed.

Therefore, the Tr. I parameter **can't be set to OFF**.

PSV-TV is a ventilation technique during which, at the beginning of the patient's spontaneous inspiratory effort, the lung ventilator provides support at an guaranteed volume (Vte) pre-set by the User.

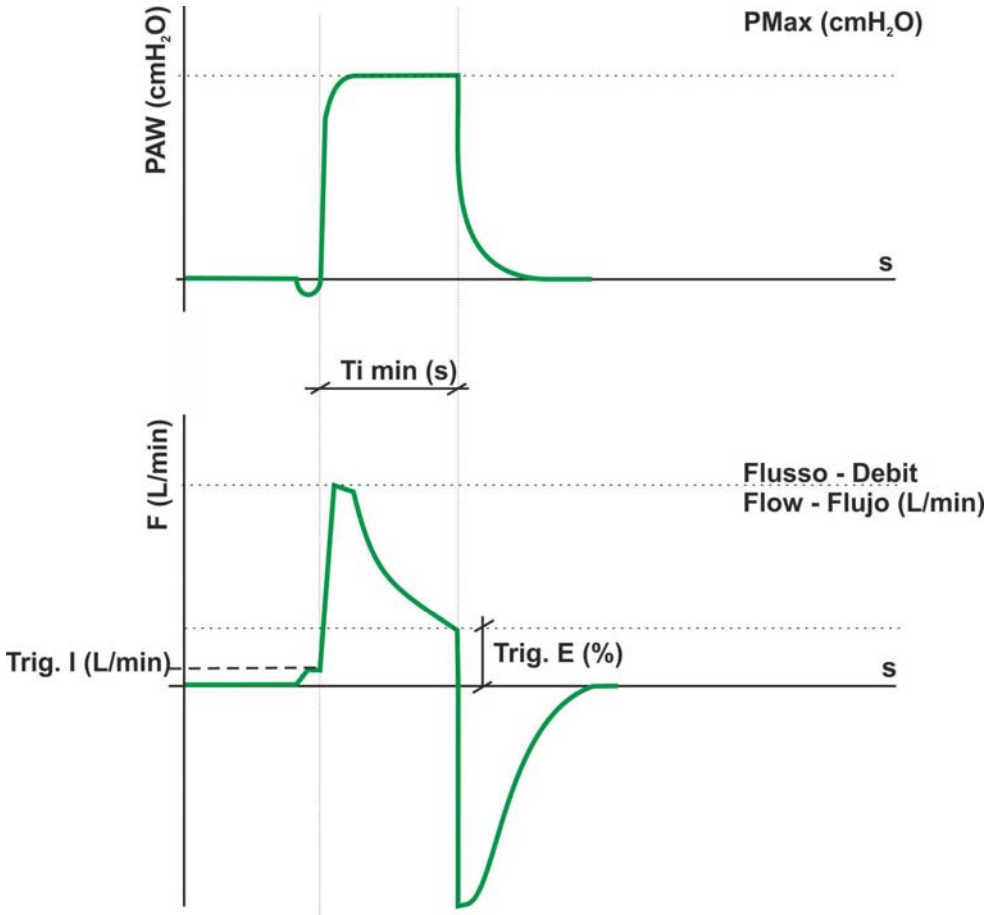
When the Vte pre-set value is reached, the expiration takes the place of the inspiration (according to Tr. E - percentage of the inspiratory flow peak beyond which the expiration can begin).

This technique saves the patient from the work of breathing, as he only has to reach the small quota necessary to enable the lung ventilator trigger (Tr. I). This way, the respiratory rate depends on patient spontaneous activity and the PAW depends on set parameter values and patient patophysiological conditions.

In this mode the patient's work of breathing is assumed by the lung ventilator. Each breath initiated by the patient (Tr. I enabled) is supported by the lung ventilator, that sends inside the airway an guaranteed tidal volume, pre-set by the User.

If the patient does not trigger (*spontaneous breathing during the apnoea time set in SETUP - Other*), the system enables the APNOEA acoustic and visual alarm.

The system will automatically provide an APCV-TV ventilation with set safety respiratory rate (RR bk) and I:E ratio (I:E bk).



4.6.6 VC-VAC

Volume targeted controlled ventilation synchronised with the patient if the inspiratory trigger is active.

- The system displays all PRP relative to the set operative mode.

VC/VAC is a volume-targeted controlled ventilation (Vti), synchronised with the patient's breaths if the inspiratory trigger (Tr. I) is active.

The Operative Mode VC/VAC is active only with patients: ADULT and PAEDIATRIC.

In this type of ventilation, the work of breathing is fully assumed by the lung ventilator, and therefore it is used when the patient is unable to breath on his own, or in order to assure an efficient pre-set current volume and therefore the mechanical ventilation must fully replace the spontaneous breathing.

The inspired volume (Vti) is pre-set and generated in a pre-set time (RR and I:E) and determines the characteristics and the pressure range necessary to reach the pre-set amount of gas mixture that must be provided.

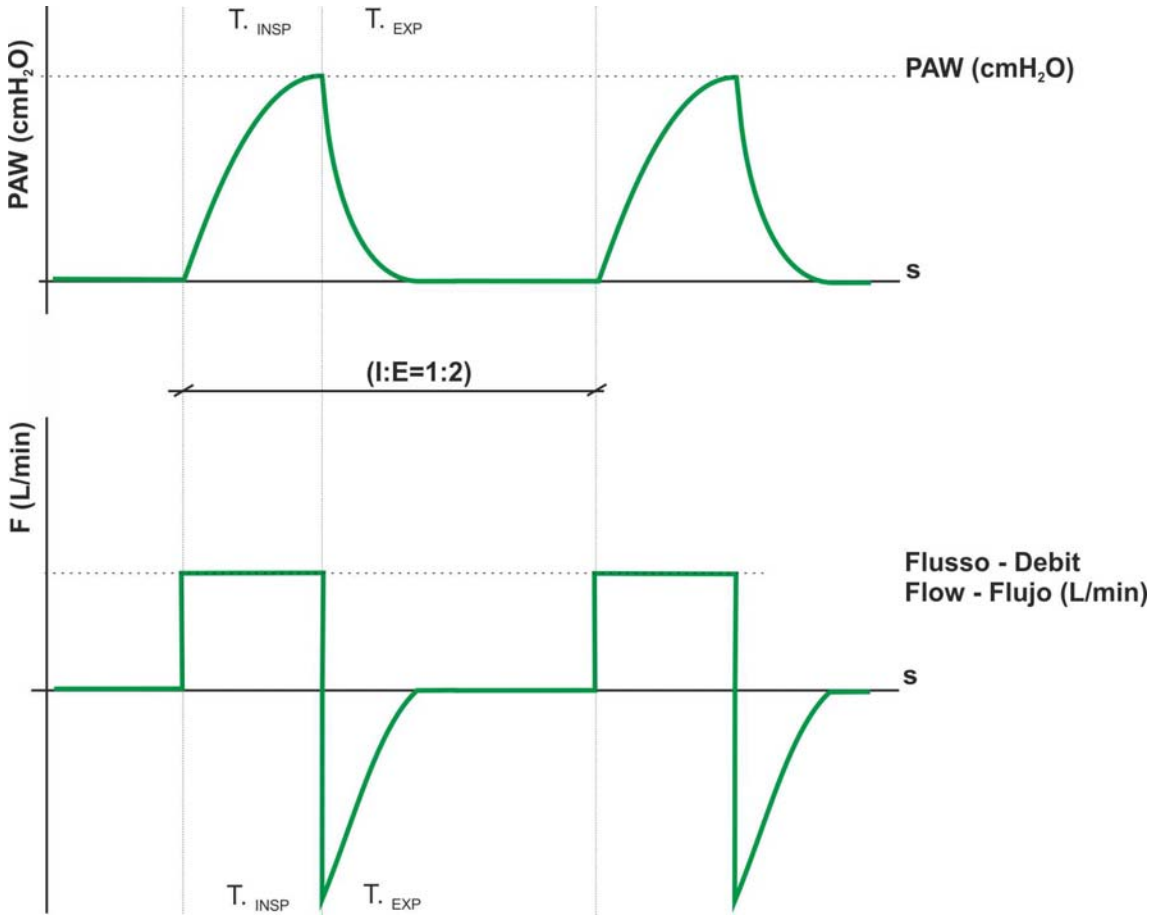
The patient's breathing attempt is detected by the system (Tr. I) and it automatically sends inside the airway a gas flow at a pre-set volume (Vti).

To combine the assisted mode with the control mode, the User must adjust the trigger sensitivity (Tr. I) at a value that suits the patient.

If during the expiratory phase, the patient generates a spontaneous breath that enables the trigger, the lung ventilator will synchronise its activity to the patient's spontaneous breath, recalculating the I:E cycle times starting from that event and displaying them on the lung ventilator screen.

This way the lung ventilator provides a minimum number of breaths as indicated on the RATE display of the integrated screen.

If the patient's spontaneous breathing respiratory rate is greater (than the respiratory rate set on the lung ventilator) the machine will increase the number of breaths per minute (with regard to the number set in the control panel) and displays the value.



4.6.7 VC-VAC BABY

Volume targeted controlled ventilation synchronised with the patient if the inspiratory trigger for paediatric and neonatal patients is active.

- The system displays all PRP relative to the set operative mode.

VC/VAC BABY is a volume-targeted controlled ventilation (Vte), synchronised with the patient's breaths if the inspiratory trigger (Tr. I) is enabled.

The Operative Mode VC/VAC BABY is active only with patients: PAEDIATRIC and NEONATAL.

The VC/VAC BABY operative mode also includes two additional parameters identifying the maximum and the minimum pressure limit (PMax. - Pmin) that can be reached during ventilation.

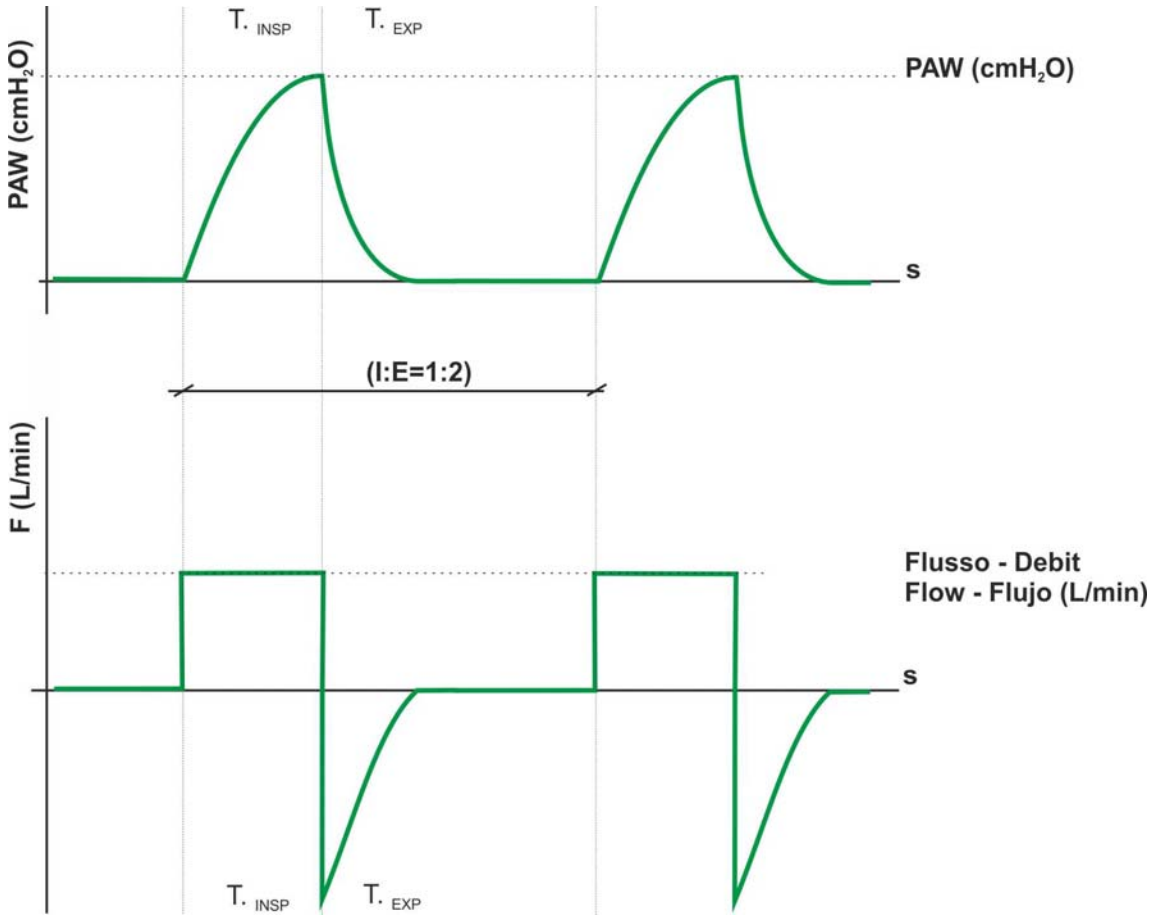
In this type of ventilation, the work of breathing is fully assumed by the lung ventilator, and therefore it is used when the patient is unable to breath on his own, or in order to assure an efficient pre-set current volume and therefore the mechanical ventilation must fully replace the spontaneous breathing.

The volume (Vte) is pre-set and generated in a pre-set time (RR and I:E) and determines the characteristics and the pressure range necessary to reach the pre-set amount of gas mixture that must be provided.

The patient's breathing attempt is detected by the system (Tr. I) and it automatically sends inside the airway a gas flow at a pre-set volume (Vte).

To combine the assisted mode with the control mode, the User must adjust the trigger sensitivity (Tr. I) at a value that suits the patient.

If during the expiratory phase, the patient generates a spontaneous breath that enables the trigger, the lung ventilator will synchronise its activity to the patient's spontaneous breath, recalculating the I:E cycle times starting from that event and displaying them on the lung ventilator screen.



4.6.8 V-SIMV

Volume-targeted synchronised intermittent mandatory ventilation.

- The system displays all PRP relative to the set operative mode.

V-SIMV is a synchronised intermittent mandatory ventilation, during which the lung ventilator generates a certain number of breaths per minute (RRsimv) at a pre-set volume (Vti).

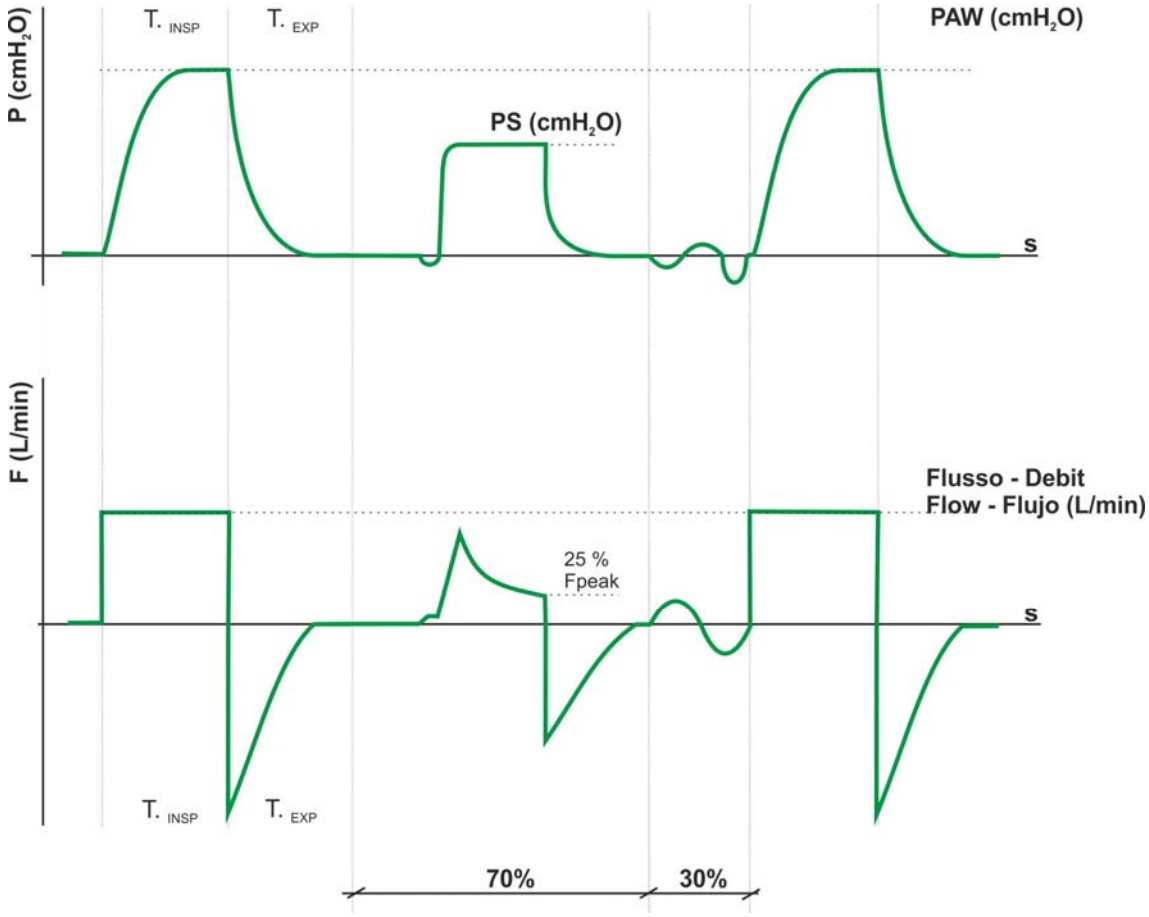
The Operative Mode V-SIMV is active only with patients: ADULT and PAEDIATRIC.

SIMV allows the patient to breath spontaneously, between the forced breaths, with a pre-set positive pressure support (PS) if the patient's breath is strong enough to enables the flow trigger (Tr. I - this parameter can’t be set to OFF).

The spontaneous phase is characterised by the set inspiration time (Ti) that once the pressure support value (PS) set by the User is reached, leaves its place to the expiration phase (Tr. E).

Therefore, in SIMV mode, the lung ventilator can provide a combination of spontaneous and controlled breathing.

SIMV mode is frequently used as a weaning ventilation mode from a fully controlled ventilation (completely depending on the lung ventilator) to an assisted ventilation mode.



The graphic shows how the SIMV operative mode works.

The spontaneous activity between one synchronised breath and the other is 70% managed in pressometric mode (PS) while the remaining 30% represents the window for the activation of the forced synchronised breathing.

4.6.9 P-SIMV

Pressure-targeted synchronised intermittent mandatory ventilation.

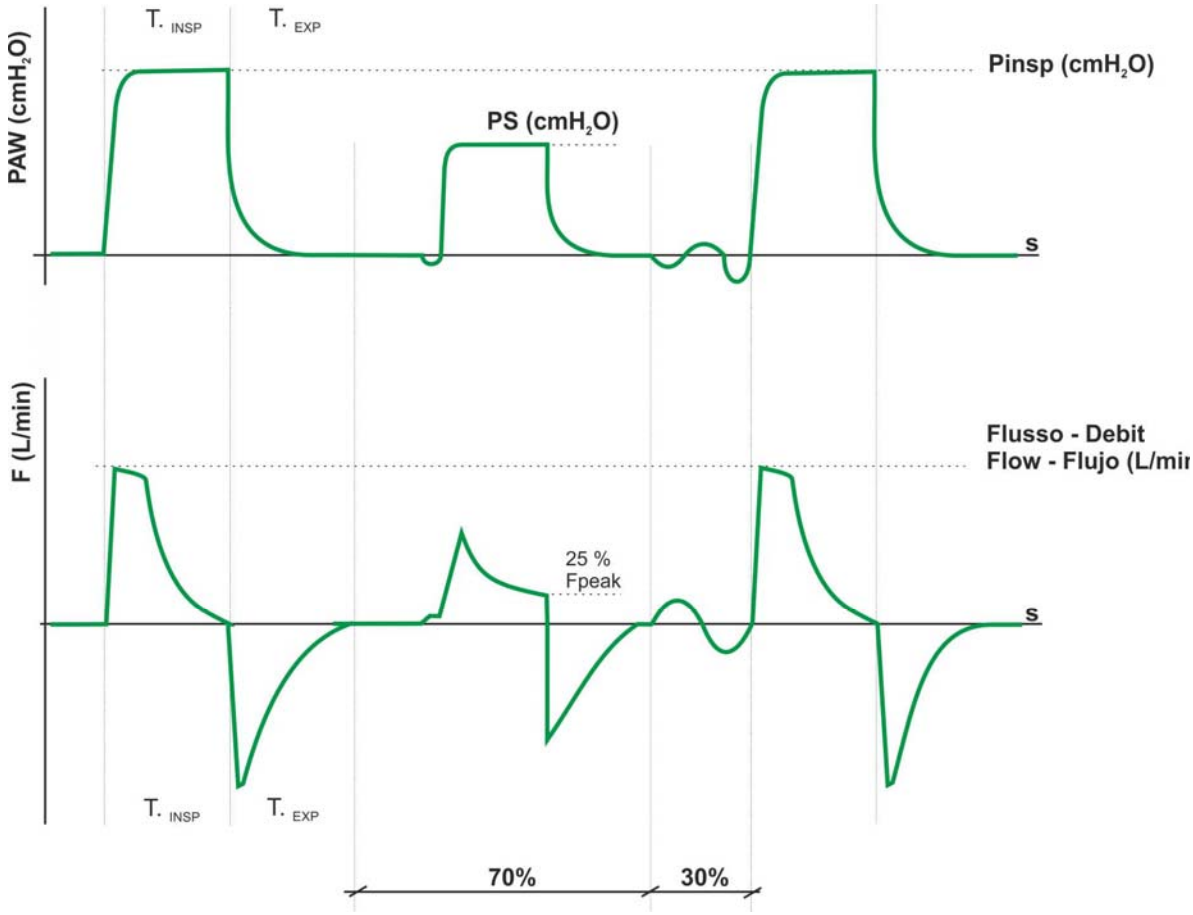
- The system displays all PRP relative to the set operative mode.

P-SIMV is a synchronised intermittent mandatory ventilation, during which the lung ventilator generates a certain number of breaths per minute (RRsimv) at a pre-set inspiratory pressure (Pinsp) providing pressure support (PS) during the spontaneous phase.

SIMV allows the patient to breath spontaneously, between the forced breaths, with a pre-set positive pressure support (PS) if the patient's breath is strong enough to enable the flow trigger (Tr. I - this parameter can’t be set to OFF).

The spontaneous phase is characterised by the set inspiration time (Ti) that once the pressure support value (PS) set by the User is reached, leaves its place to the expiration phase (Tr. E).

Therefore, in SIMV mode, the lung ventilator can provide a combination of spontaneous and controlled breathing. SIMV mode is frequently used as a weaning ventilation mode from a fully controlled ventilation (completely depending on the lung ventilator) to an assisted ventilation mode.



The graphic shows how the SIMV operative mode works.

The spontaneous activity between one synchronised breath and the other is 70% managed in pressometric mode (PS) while the remaining 30% represents the window for the activation of the forced synchronised breathing.

4.6.10 CPAP

Positive continuous pressure applied on the airway.

- The system displays all PRP relative to the set operative mode.

CPAP is a spontaneous positive pressure ventilation at continuous flow.

In this operative mode the patient is free to breath spontaneously inside the circuit but at a pressure greater than the atmospheric one, with increased residual functional capacity.

During spontaneous breathing the pressure value varies around the set value, it tends to drop when the patient inhales and to rise when the patient exhales.

WARNING !! Patient injury hazard

If the patient does not trigger (spontaneous breathing during the apnoea time set in *SETUP - Other*), the system enables the APNOEA acoustic and visual alarm.

The system will automatically provide an APCV ventilation with set safety respiratory rate (RR bk) and I:E ratio (I:E bk).

4.6.11 APRV (Airway Pressure Release Ventilation)

Airway ventilation and pressure release: this type of ventilation features two positive pressure levels.

- The system displays all PRP relative to the set operative mode.

APRV is a spontaneous ventilation mode with constant positive pressure on 2 different levels, during which the lung ventilator keeps the two pressure levels set constant.

In this operative mode the patient is free to breath spontaneously inside the circuit but at a pressure greater than the atmospheric one, with increased residual functional capacity. The User can set on the lung ventilator the pressure of the two levels and the relative times.

- LOW LEVEL pressure - LOW level TIME
- HIGH LEVEL pressure - HIGH level TIME

During spontaneous breathing the pressure value varies around the set value, it tends to drop when the patient inhales and to rise when the patient exhales. If during spontaneous breathing the patient does not reach the airway low pressure limit (LOW PAW), after 20 seconds the system enables the relative alarm.

In APRV the patient breaths on two positive pressure levels not synchronised with the patient's spontaneous breathing.

WARNING !! Patient injury hazard

If the patient stops breathing, after 20 seconds the system enables the low PAW acoustic and visual alarm (low airway low pressure).

4.6.12 MAN operative mode

MANUAL ventilation available in all operative modes.

By selecting the MAN mode (at the bottom of the display) the system provides the patient with a breath.

The breath ventilation parameters depend on the set operative mode. The function activation is monitored by the screen and signalled by the green LED inside the box, that turns on. This mode is active while the lung ventilator is running.

4.6.13 APNOEA BACK-UP

Apnoea BACK-UP is a safety function available in two of the Operative modes: PSV, PSV-TV and CPAP. **Apnoea BACK-UP** function enables if the patient, ventilated in one of the modes above, stops breathing.

After a pre-set time (Apnoea Time) in the *SETUP - Other*, will appear the relative alarms and the system automatically starts ventilating the patient.

WARNING !! Patient injury hazard

- When the lung ventilator switches to this safety mode automatically, the User CANNOT edit the ventilation parameters.
- The lung ventilator continues its activity and the User acknowledges the emergency condition.
- When the apnoea BACK-UP function enables, the ventilation parameters used are those set based on the selected operative mode.

4.7 PRP parameters

In the following chapter you will find a description of available physiological respiratory parameters (*referred to from now on as PRP*) selectable on Falco 202 Evo lung ventilator.

WARNING !! Patient injury hazard

Thoroughly read this chapter and the entire manual to make sure you set the PRP correctly.

The User must choose the Operative modes that match the patient's physiological features and pathologies best.

4.7.1 PRP parameters setting procedure

CAUTION

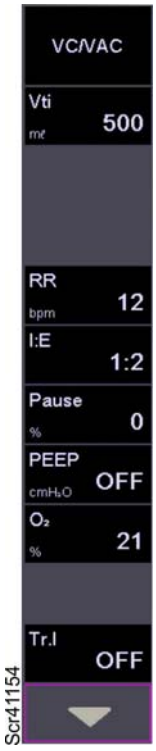
- When the lung ventilator is turned ON, the system restores the operative mode and the relevant parameter values set before the last shut-down.
- Just for our examples we refer to the Operative Modes available with ADULT Patient Data (VC/VAC).

- Select: **VC/VAC** operative mode.

- Select the icon for see all PRP parameters.

Selecting the PRP parameters icon (*see the image on the next page*) the parameters relevant to the set Operative Mode are displayed.

VC/VAC operative mode: available PRP parameters.



- Select the icon for see the PRP parameters.

- Reselect the icon for see all PRP parameters.

Modifying a PRP parameter

(*e.g. RR: Respiratory Rate*).

- Select the RR icon.

Note. *The bar for RR parameter is displayed.*

	To decrease the parameter value
	To increase the parameter value
	To confirm set value
	The system goes back to Stand-by page.

- The physiological respiratory parameters (PRP) must be set by the User in Stand-by mode before activating the necessary operative mode.
- The system allows you to set Default PRP (**SETUP - Default**) suited for ventilating an Adult patient.

- During the ventilation of the patient, use the dedicated icon (PRP parameters) to display the parameters referred to the Operative Mode set.

WARNING !! Patient injury hazard

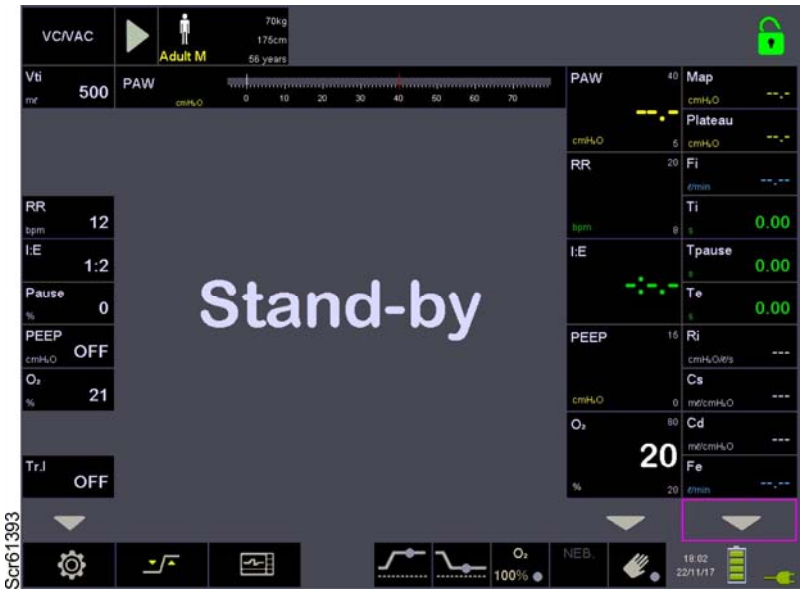
Depending on the chosen ventilation mode, the same PRP can be a dependent variable (that varies depending on other parameters modification) or an independent variable (a value that if modified, affects the values of other parameters).

The PRP can also be adjusted while the lung ventilator runs, adapting them to the patient's clinical situation.

For more information about PRP respiratory parameters, *please see on chap. 2.3.5.*

4.7.2 Monitoring of respiratory parameters

- Based on the ventilator parameters set by the User and on the patient's characteristics, the lung ventilator is able to monitor and measure a series of an “parameters” values necessary for the patient's clinical evaluation.
- The data in the images below refer to VC/VAC operative mode with standard PRP, and they are only informative, they do not refer to real clinical cases.



- Selecting PRP icon parameters (*see the image above*) the respiratory parameters and/or the additional respiratory parameters are displayed.

For more information about monitoring of respiratory parameters, *please see chap. 2.3.7 and chap. 2.3.8.*

4.8 Ventilation phase

Before starting the ventilation, you have to:

- carry out all lung ventilator connections (medical gases, power supply, patient circuit, ……..)
- carry out the preliminary checks *(please see chap. 3.4)*
- set and check the patient data, language and alarm limits
- set the Physiological Respiratory Parameters and the operative mode that match the patient's clinical situation best.

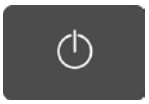
Based on the PRP set by the User according to the patient's characteristics, the lung ventilator is able to display and measure a series of values necessary for the patient's clinical evaluation.

VAC_Scr26077

- Press **START** to begin the ventilation in the selected mode with the most suitable PRP for the clinical situation of the patient.

- On the left side of the display you can find **PRP parameters**.
- In the main section you can see the **Charts** that show the trend of the respiratory parameters.
- On the right side of the display you can find values that will help you asses the **patient's clinical condition**.
- In the upper part the Operative Mode is displayed as well as both **Start** and **Stop** controls for the ventilation and the message for active alarms.
- At the bottom, the **Functions to be activated** by the user as well as time and status of the power supply are available.

4.8.1 Ventilation interruption

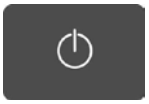


- Press **ON/OFF**, to return in Stand-by mode.
- The system will ask you if you want to stop the ventilation (switch to Stand-by mode).

  YES: stop ventilation.

  NO: cancel the command.

Lung ventilator in **Stand-by mode**.



- **Press ON/OFF**, to Turn-off the lung ventilator.
- The system will ask you if you want to Turn-off the lung ventilator (**switched off**).

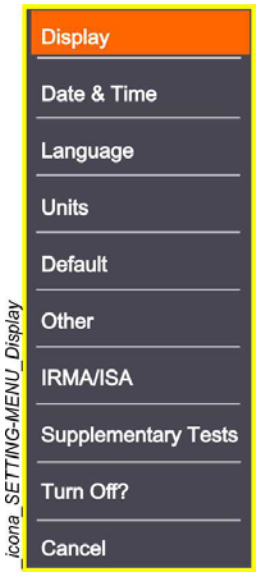
  YES: lung ventilator will be switched off.

  NO: cancel the command (the lung ventilator returns to Stand-by mode).

4.9 Operative functions and Graphic settings

During the patient ventilation, the User can intervene using the graphical user interface, by selecting the " **Operative Functions** " in the lower side on the screen.

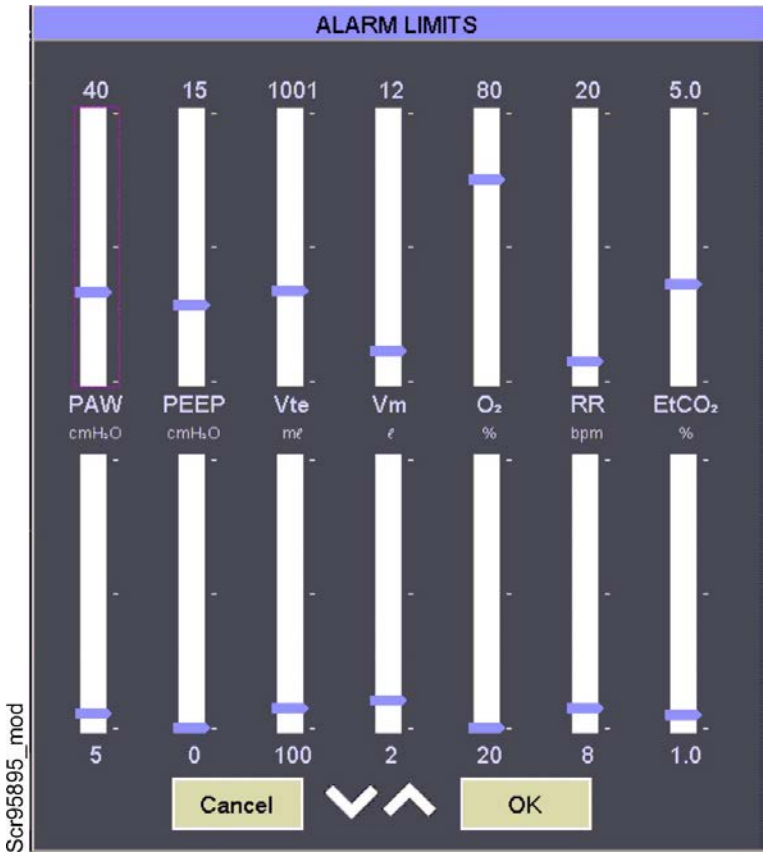
- Select the icon to access the lung ventilator's **SETTING MENU.**



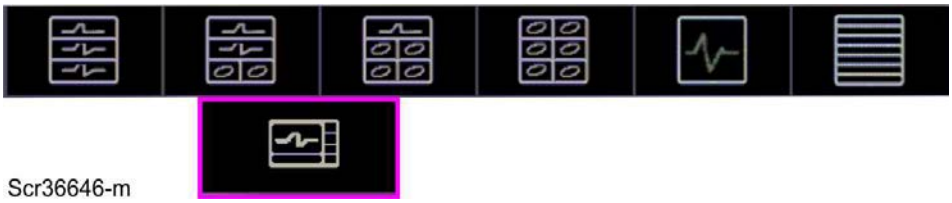
- Select Cancel, to go back to the Stand-by display.

NOTE ! *The functions that can be enabled from the SETTING MENU are shown in chap. 4.14.*

- Select the icon to access the lung ventilator's **ALARM LIMITS.**



- For **ALARM LIMITS**, please see on chapter 5 (Alarms).
- To go back to the Stand-by display, select Cancel or OK (follow the instructions displayed).



Scr36646-m

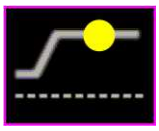
- Select the **GRAPHICs** icon: six icons representing 6 types of graphic visualizations are displayed are displayed (*see the above picture*)

  The User can display four different graphic types (*see list below*) and the visualization of Trends and Events.

1. **Charts**: PAW , Flow , Tidal Volume, O_2, CO_2
2. **Loops:** Tidal Volume / Flow , PAW / Tidal Volume , PAW / Flow
3. **Lung status icon**
4. **Measures**: respiratory parameters.

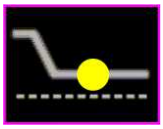
Scr60289

- For **GRAPHICs setting**, *please see on chap. 4.10.*
- To quit the function, select again the icon GRAPHICs.



Select the INSP HOLD mode: the system will extend the inspiration time to 20 seconds.

The function activation is displayed by the screen and signalled by the yellow LED inside the box, that turns on.



Select the EXP HOLD mode: the system will extend the expiration time to 20 seconds.

The function activation is displayed by the screen and signalled by the yellow LED inside the box, that turns on.

The User can enable both modes in sequence; the lung ventilator will carry out both modes, giving priority to the mode that was activated first.

INSP HOLD and EXP HOLD modes:

- are deactivated automatically (after 20. sec.)
- or by pressing the encoder knob.

Select the icon to supply an oxygen concentration of 100% to the patient.

O2 100% mode

- Select the function O2 100%, the system will provide 100% oxygen concentration for 5 minutes (pre-set time).
- After the pre-set time the systems automatically restores the previously set O2 concentration value.
- The function activation is monitored by the screen and signalled by the yellow LED inside the box, that turns on.

The O2 100% mode is deactivated:

- automatically after 5 minutes
- or by select the icon O2 100%

WARNING !! Patient injury hazard

The O2 100% mode is not available if the oxygen pressure supply is lower than 1,5 bars.

Select the icon to supply to the patient a flow of 6 litres/min.

NEB. operative mode

Select the NEB mode to enable the nebulizer use. The lung ventilator provides a flow of 6 litres/min through the relative connector for a period of time equal to the inspiratory time.

The function activation is signalled by the green LED inside the box, that turns on.

WARNING !! Patient injury hazard

The Nebulizer activation can increase the oxygen concentration delivered to the patient.

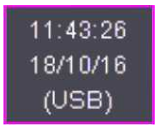
Select the icon to activate the manual ventilation to the patient.

MAN operative mode

By selecting the MAN mode, the system provides the patient with a breath.

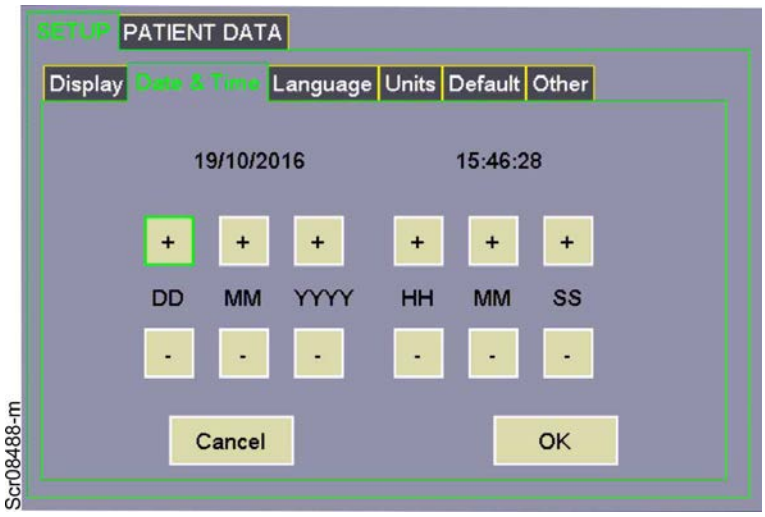
The breath ventilation parameters depend on the set operative mode. The function activation is monitored by the screen and signalled by the green LED inside the box, that turns on.

This mode is active while the lung ventilator is running.



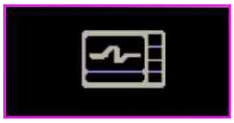
The selection of the Time icon, allows to update time and date set.

Page: **SETUP / Date & Time** is displayed.



- For **Date & Time** setting, please see chap. 4.3.1.
- To modify select **+ or -** ; select **OK** to confirm.
- To quit SETUP / Date & Time , **select Cancel**.

4.10 GRAPHICs visualization



The icon GRAPHICs allows the User to combine the **Loops, Charts and Measured** (patient respiratory parameters) in different display ways.

Moreover, it allows to display the **Trends and Events**.

4.10.1 Combinations of the graphics displayed

WARNING !! Patient injury hazard

All figures and examples featured in this chapter are purely informative.

1. **Charts:** PAW , Flow , Tidal Volume

2. **Charts:** PAW , Flow

Loop: PAW / Tidal Volume

Lung status icon

Charts: PAW

Loop: Tidal Volume / Flow , PAW / Tidal Volume

3. **Lung status icon**

Measures: Vte

Loop: PAW / Flow , PAW / Tidal Volume

4. **Lung status icon**

Measures: Vti, Vte, PAW

5. **Trends**

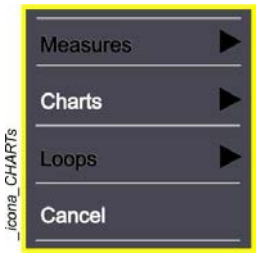
6. Events

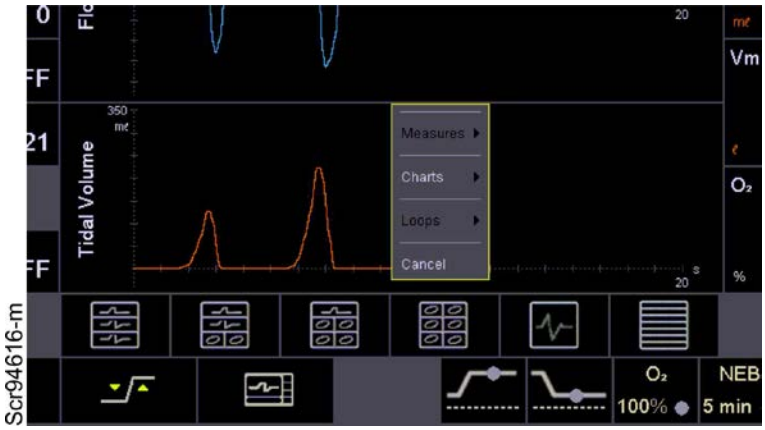
4.10.2 Modification Charts combination

- The user can display different kind of Charts detections.
- The selection of the box of one of the Charts displayed, enable the visualization of a screen of a drop-down menu with the list of the options available.
- Available charts: PAW , Flow , Tidal Volume, O_2, CO_2 .

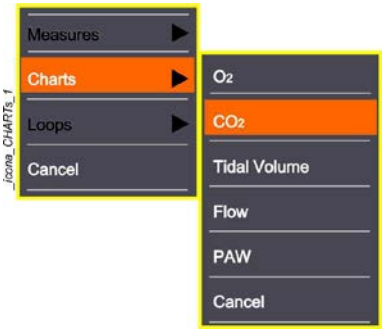
- **Keep selected the area** of the graphic some seconds; the selected area (the violet frame) becomes green.

- **Release**; the drop-down menu with the list of the options available appears.





- **Select Charts:** the drop-down menu with the list of the options available appears.



- **Select CO_2**.

  The CO2 graphic is displayed and it replaces the Tidal Volume graphic.

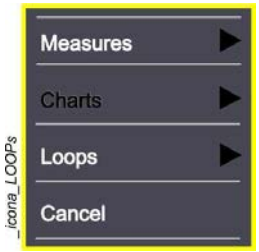
The procedure described is applicable to all the Charts areas and in the different visualizations available.

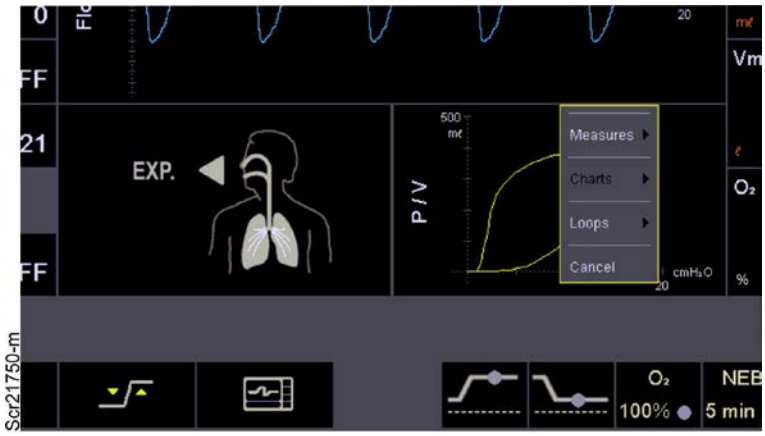
4.10.3 Loops combination modification

- The user can display different kinds of Loops detections.
- The selection of the frame of one of the Loops displayed, enable the visualization of a drop-down menu with the list of the options available.
- Available Loops: Tidal Volume / Flow , PAW / Tidal Volume , PAW / Flow.

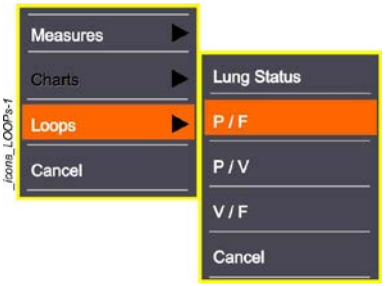
- **Keep selected the area** of the graphic some seconds; the selected area (the violet frame) becomes green.

- **Release**; the drop-down menu with the list of the options available appears.





- **Select Loops:** the drop-down menu with the list of the options available appears.

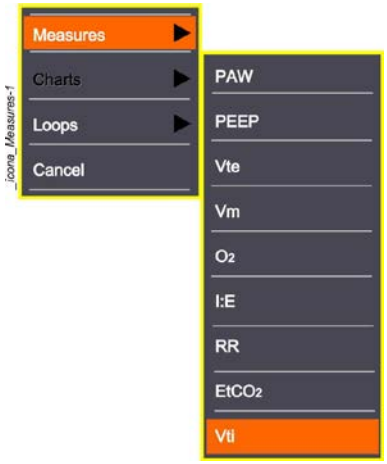


- **Select P / F.**

  The PAW / FLOW Loop is displayed and it replaces the PAW / Tidal Volume Loop.

The procedure described is applicable to all the LOOPs areas and in all the different visualizations available.

- **Select Measures**: a drop-down menu with a list of the respiratory parameters available appears.



- **Select Vti.**

  The respiratory parameter Vti is displayed and it replaces the PAW / Tidal Volume Loop.

The procedure described is applicable to all the MEASURES areas and in all the different visualizations available.

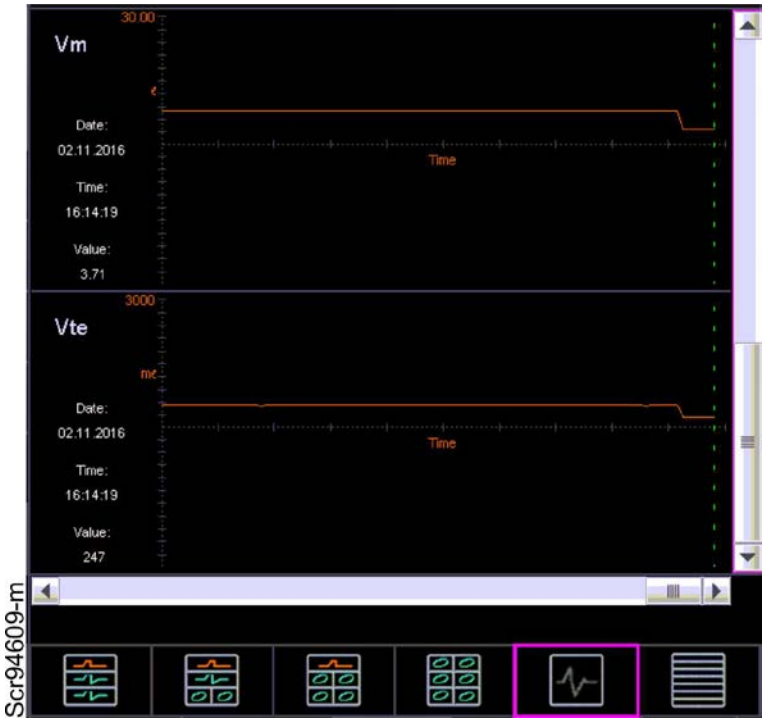
4.10.4 TRENDS visualization

Select the TRENDS visualization to monitor the most significant respiratory parameters on medium - long term.

Monitored Respiratory parameters:

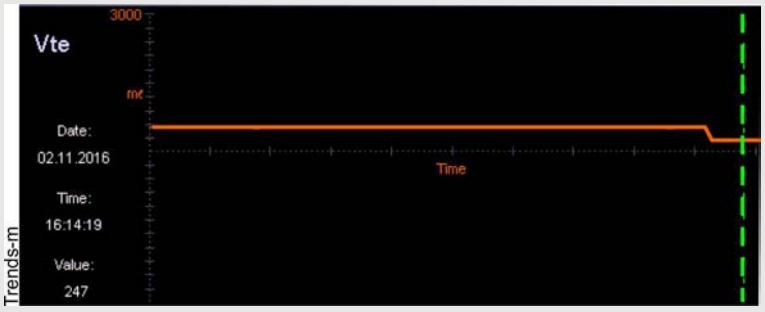
- Rate
- P Insp
- PEEP
- Vm
- Vte

The storage capacity for each parameter is 72 hours with sampling at every 4 minutes.



- The vertical scrollbar allows to display the respiratory parameters monitored.
- The horizontal scrollbar allows to check the parameters in the timeframe.
- The vertical dashed bar (in the graphic) indicates on the graphic the movement of the values measured in the timeframe.

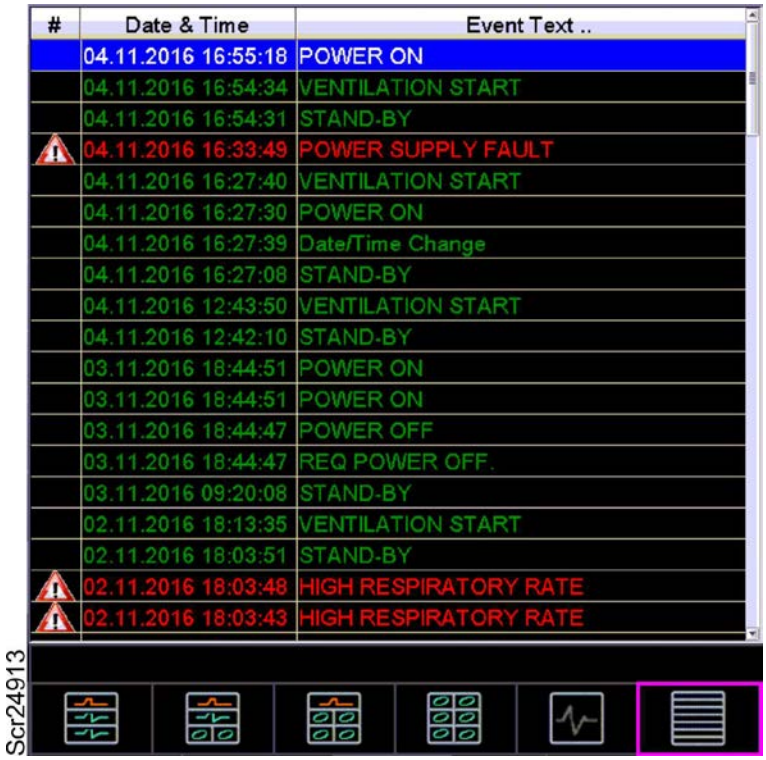
- On the left side of the Trends graphic are mentioned the data measured and related to the parameter displayed and to the vertical dashed bar.



4.10.5 EVENTS visualization

Select the EVENTS function to monitor the information on the lung ventilator operation over time. The monitored EVENT refer mainly to the alarms (active alarms) and the various operating conditions of the lung ventilator (POWER ON, POWER OFF, STAND-BY, VENTILATION START).

The system can register up to 100 events, including the alarms.



The vertical scrollbar allows to display all the events.

The Table of the Events provides the following indications:

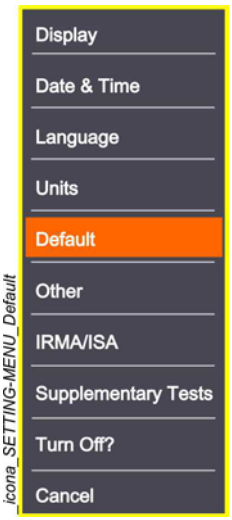
- Alarm icon
- Event date and time indication
- Event description: green (lung ventilator operating conditions), red (information on event's alarms)

4.11 Default parameters

The screen **PATIENT DATA / Default** allows the User to restore the Default parameters (***Factory set***).

Restoring "***Factory set*** " means to set once again the Default parameters of the lung ventilator (MENU, SETUP, PRP, ALARMS limits).

Select: **SETTING MENU / Default**



Lung ventilator in Stand-by mode.

Select: RUN

YES: the default data will be improved.

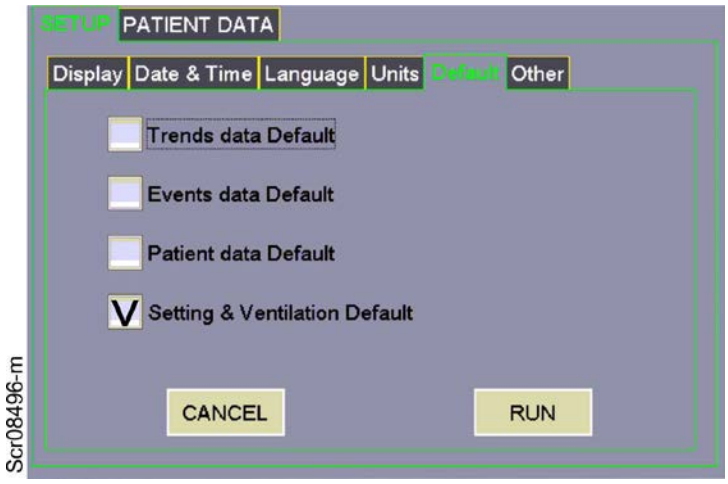
NO: the system cancels the RUN command.

Select: Cancel

YES: exit without perform any other operation.

NO: the system remains in Default page.

Enable: Setting & Ventilation Default



4.12 Alarms SETUP

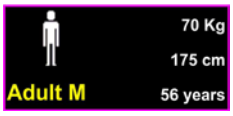
For ALARMS parameters and limits setup ***please see chap. 5.2*** ALARMS setup.

4.13 Patient Data SETUP

For Patient Data parameters and setup ***please see chap 4.2*** PATIENT DATA.

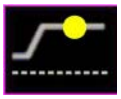
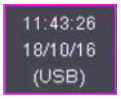
4.14 List of functions

Here below the list of the available functions and positioning inside the Graphic User Interface.



Operative mode	• *See on chap. 4.6*
Ventilation status	• *See on chap. 2.3.2*
Patient data	• *See on chap. 4.2*
Password	• *See on chap. 5.1.2*

Display	• *Brightness* • *Energy saving* • *Sound volume* • *Touch audio*
Date & Time	• *Date* • *Time*
Language	• *Italian, English, German, Turkey, Polish, French, Russian, Spanish*
Units	• *Weight (referred to the patient)* • *Height (referred to the patient)* • *CO2 (unit of measurement)* • *Pressure (unit of measurement)*
Default	• *Trends data Default* • *Patient data Default* • *Setting & Ventilation Default*
Other	• *NIV Enable* • *Power Failure* • *APNEA TIME* • *CHANGE PASSWORD* • *Save to USB*
IRMA/ISA	• *Gas Sensor (IRMA or ISA type)*
Supplementary Tests	• *Enabling the Supplementary Tests function.* • *The system shows the test available on the lung ventilator.* • *Before using the lung ventilator on a patient, you have to carry out a series of preliminary checks to make sure that it works properly.*
Turn Off	• *See on chap. 4.9.1*
Cancel	• *See on chap. 4.3.2*

 **Alarms Limits**	• *See* on chapter 5 Alarms
 **GRAPHICs visualization**	• Charts • *Loops* • *Lung status icon* • *Measures* • *Trends* • *Events*
 **INSP Hold**	• *See on chap. 4.9*
 **EXP Hold**	• *See on chap. 4.9*
 **100% Oxygen**	• *See on chap. 4.9*
 **Nebulizer function**	• *See on chap. 4.9*
 **Operative mode: MAN**	• *See on chap. 4.6.12 and chap. 4.9*
 **Time / Data**	• *See on chap. 4.2.2*
 **Battery / Power supply**	• *See on chapter 5 Alarms*

4.15 List of default parameters

Parameters	Adult	Child	New Born
Mode	VC/VAC	APCV-TV	APCV
VT (ml)	500	400	-
RR (bpm)	12	12	12
I:E	1:2	1:2	1:2
Inspiratory Pause (%)	10%	-	-
Trigger (cmH_2O)	OFF	OFF	OFF
PEEP (cmH_2O)	OFF	OFF	OFF
FiO_2 (%)	21%	21%	21%
Pinsp (cmH_2O)	-	-	20
Pmin (cmH_2O)	-	5	-
Pmax (cmH_2O)	-	25	-
Slope	-	3	3

4.16 Calibration Programs

4.16.1 Preliminary

WARNING !! Patient / User injury hazard

- The information's herein are exclusively intended for use by SIARE specialised or qualified technical staff, formally authorised by SIARE.
- In order to start the **Calibration Program** is necessary the intervention of SIARE personnel or qualified technical personnel authorized by SIARE.
- The procedures described are critical operations and must be carried out only by authorised staff as they might affect the equipment's safety and proper operation.

WARNING !! Patient / User injury hazard

All figures and examples featured in this chapter are purely informative and do not refer to real clinical cases.

CAUTION

- The specialist SIARE staff or qualified technical staff, formally authorized by SIARE, must know the full content of this manual (and of the Service manual), before carrying out the operations described below.
- The SIARE authorized technician avails of suitable tools and spare parts and is trained to work in compliance with product safety.
- SIARE declines all liability for technical interventions carried out on the equipment without formal authorisation from SIARE.

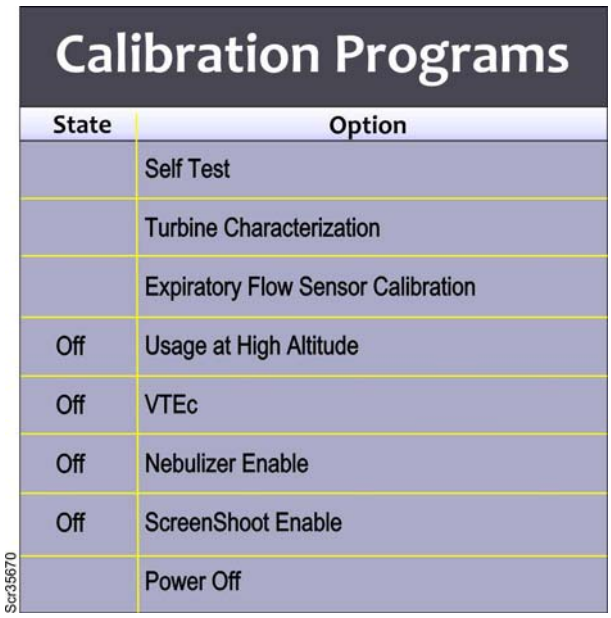
- In order to start the **Calibration Program,** display the lung ventilator should be operating and correctly connected.
- For tests and checks, please use the patient simulator SIARE cod. **LS.AB.001** that is equipped with variable resistance and compliance.
- For a more correct and detailed analysis of the **Calibration Programs**, please consult the SERVICE manual.

4.16.2 " Calibration Programs " displaying

- Set the main switch (placed on the back of the ventilator) to " **I** ".

- Make sure that on the lung ventilator keyboard (User commands area) the green led (that indicates the presence of mains power supply) is ON.

- In sequence, keep pressed for a few seconds the **ALARM RESET** and **ON-OFF** soft keys to switch-up the lung ventilator.



- The **Calibration Programs** page is displayed.

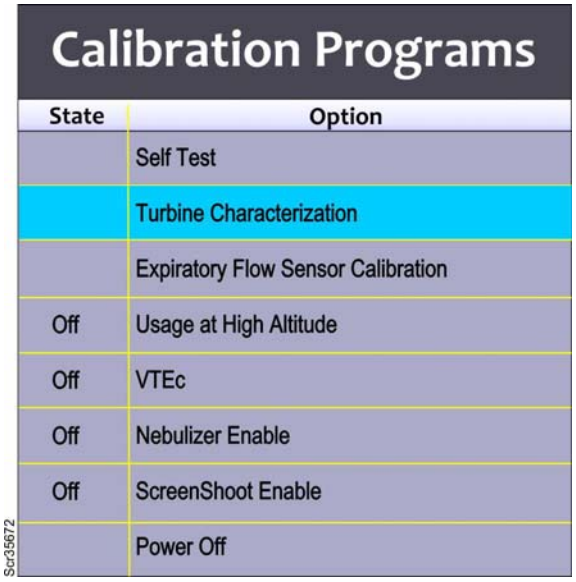
- Select **Self Test** to switch to the normal operation of the lung ventilator *(see chap 4.2).*
- Select **Power Off** to switch-OFF the lung ventilator.

4.16.3 Turbine characterization

The **turbine characterization** calibration is necessary in the following cases.

- When you notice differences out of tolerance (more than 2% of the end of the scale + 8% of the measured value) on the airways pressure values between the set and measured values.
- Software update or first turning-on after an important repairing (for ex. turbine replacement or inspiratory flow sensor replacement).

- Select the function (*or select and press by the encoder knob*).
- The Turbine Calibration page is displayed.



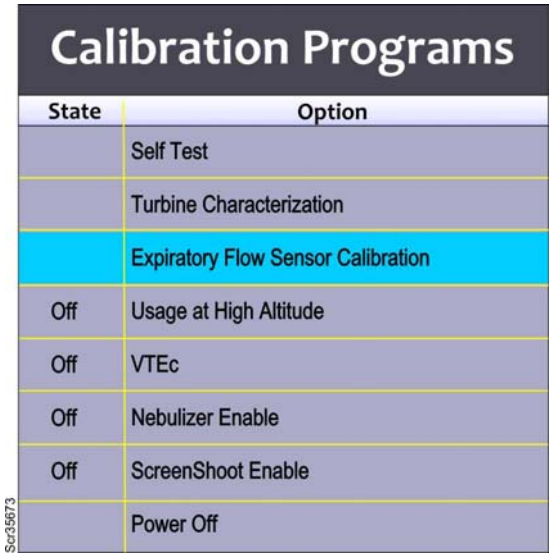
OK	The turbine characterization program starts.
Cancel	Selecting ‘Cancel’ you quit the Turbine. Characterization Program and the system goes back to the ‘Calibration Programs’ visualization.

In order to start the **turbine characterization calibration program** is necessary the intervention of qualified SIARE personnel or qualified technical personnel authorized by SIARE.

4.16.4 Expiratory Flow Sensors Calibration

The **Expiratory Flow Sensors Calibration** is necessary in the following cases.

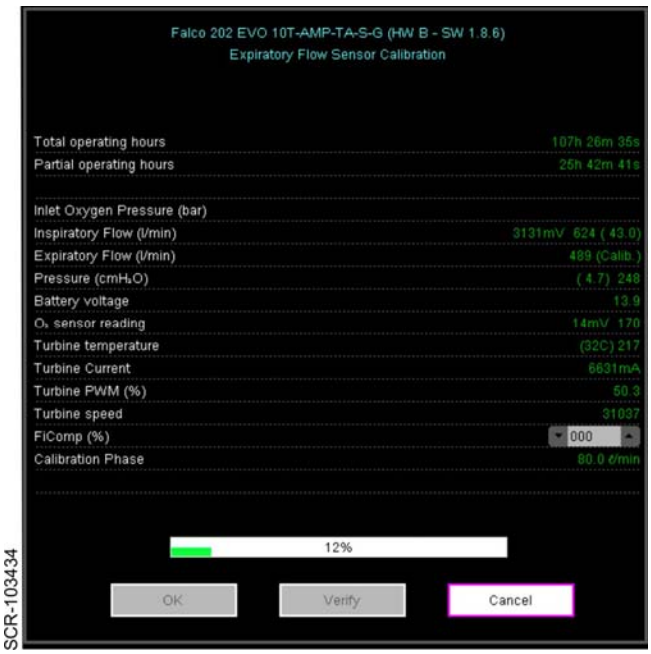
- Noted differences are more than 15% (over 100ml) between the set Volume value (VTi - Vte) and the expired Tidal Volume reading (Vte).
- In case of first calibration of lung ventilator or replacement of flow sensors (INSP inside the unit or EXP outside the unit), it is suggested to perform this calibration.



- Select the function (*or select and press by the encoder knob*).

- The **Expiratory Flow Sensors Calibration** page is displayed.

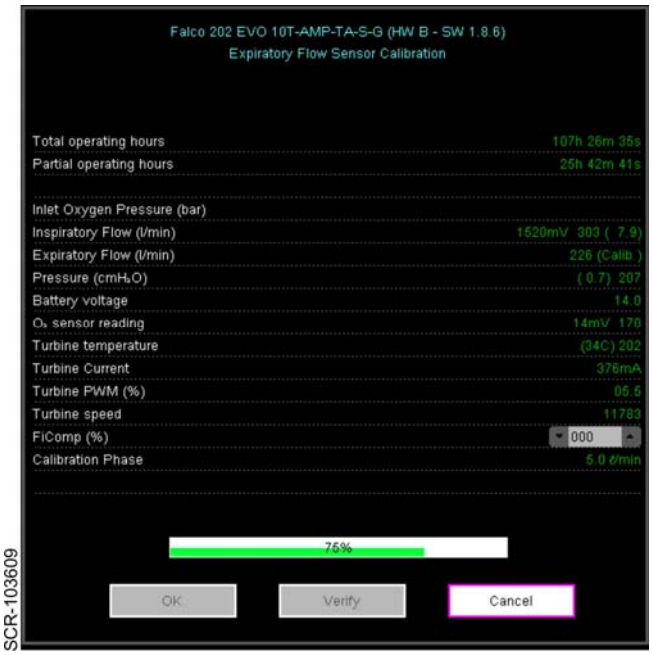
OK	The Expiratory Flow Sensors Calibration program starts.
Cancel	The User **quit** the Expiratory Flow Sensors Calibration and the system goes back to the **Calibration Programs** visualization.
Verify	The User can **check** the correct Expiratory Flow Sensors Calibration through the displaying of the Exp - Insp flow parameters.



SCR-103434

- Select OK

The Expiratory Flow Sensors **calibration phase** starts.



SCR-103609

- The system delivers constant flows at pre-set intervals (*calibration steps: 80, 65, 50, 25, 10, 5, 2.5, 0 liters / minutes*) and acquires the values of the flow sensors signal, constructing the characteristic.

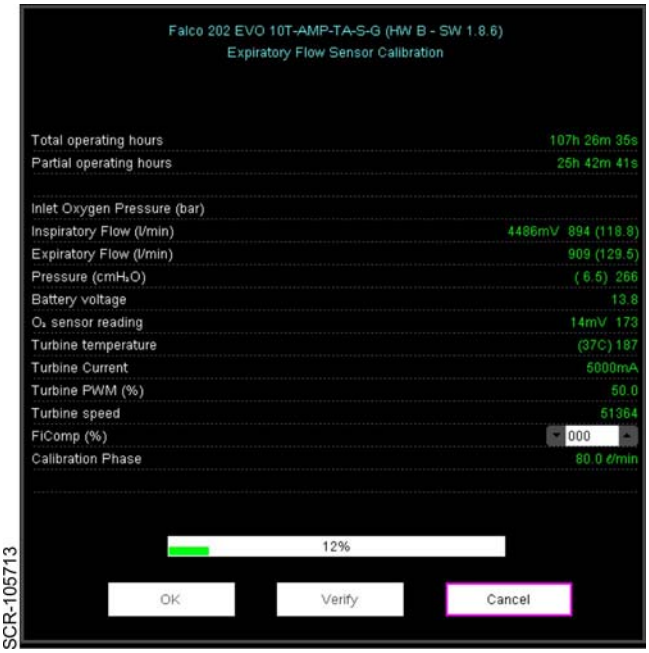
ESC

Select **ESC** to stop the Expiratory Flow Sensors Calibration phase.

Cancel

Select **Cancel** to stop the Expiratory Flow Sensors Calibration.

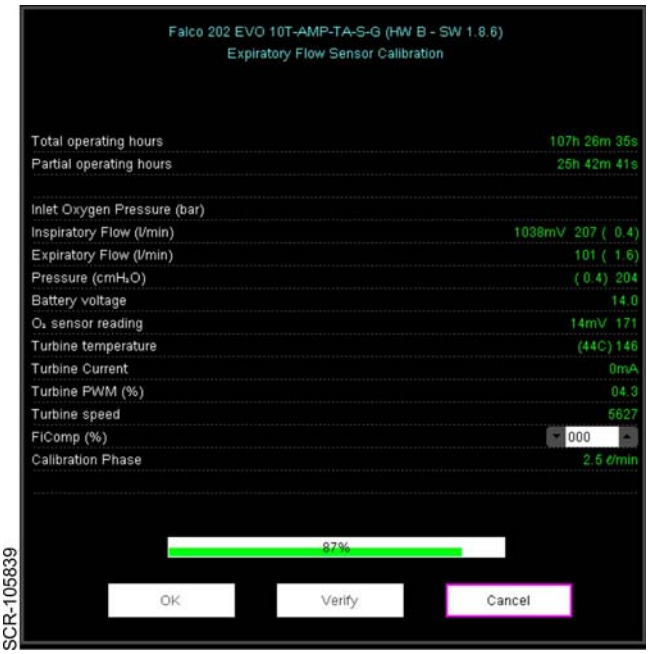
- At the end of the **Expiratory Flow Sensors Calibration** phase the system goes back to the Calibration Programs menu.
- In case of first calibration, it is suggested to perform this operation after checking the calibration of PEEP and Turbine (*see on service manual*).



SCR-105713

- Select Verify

The Expiratory Flow Sensors Calibration **check phase** starts.



SCR-105839

- The aim of this procedure is to display and check the Inspiration Flow and Expiration Flow measured values (in l/min) stored during the Expiratory Flow Sensors Calibration phase.

The two measured and displayed values should have a numerical value very similar to each other.

ESC

Cancel

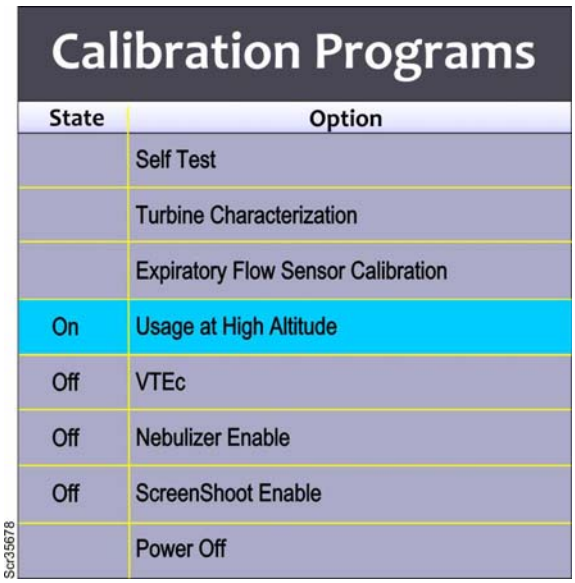
Select **ESC** to stop the Expiratory Flow Sensors Calibration phase check.

Select **Cancel** to stop the Expiratory Flow Sensors Calibration check.

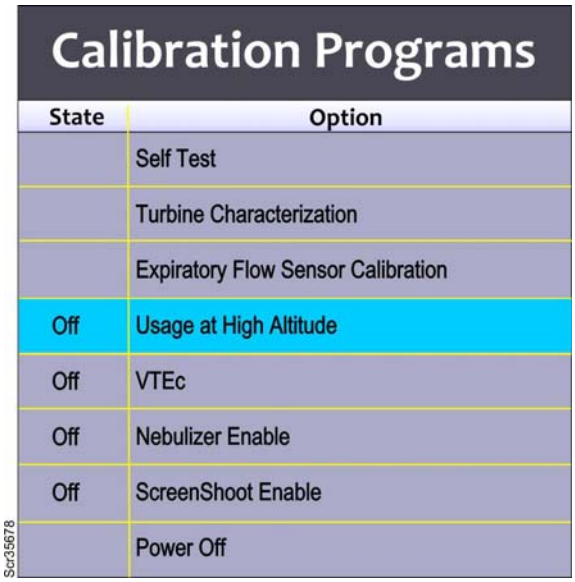
At **the end of** the Expiratory Flow Sensors Calibration check the system goes back to the **Calibration Programs** menu.

4.16.5 High Altitude usage (On - Off)

The activation of the Usage at High Altitude (High Altitude: **On**) function, is useful to optimize the calculation of oxygen concentration (FiO_2) at heights higher than 2000 mt on the sea level.



- Select the function (*or select and press by the encoder knob*).



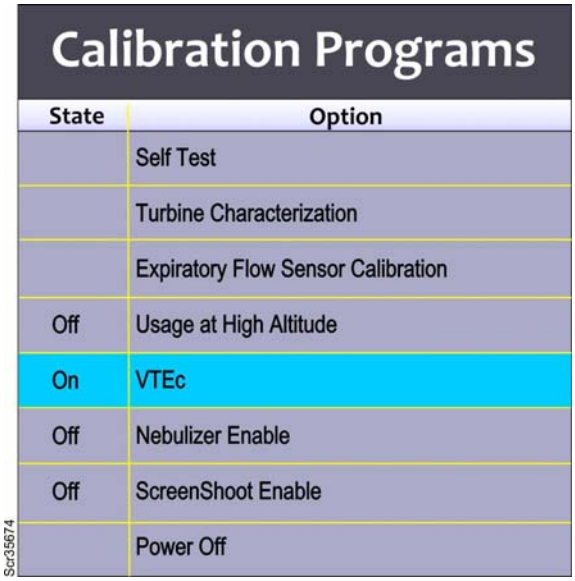
- The Usage at High Altitude function is enabled (**On**).

Nota. *Select or press the encoder knob again; the Usage at High Altitude function is disabled (**Off**).*

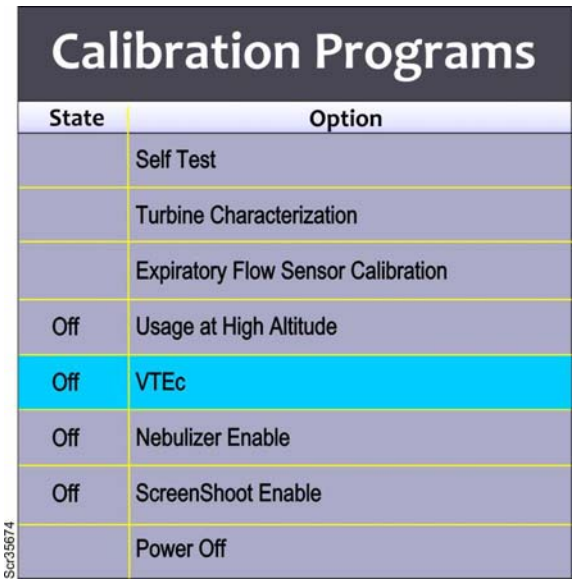
Select **Self Test** to go to the SELF TEST phase and escape from Calibration Programs window.

4.16.6 VTEc (On - Off)

The activation of **VTEc** (VTEc On) function is necessary to optimize the displaying of calculation of the Vte parameter displayed during lung ventilator operation.



- Select the function (*or select and press by the encoder knob*).

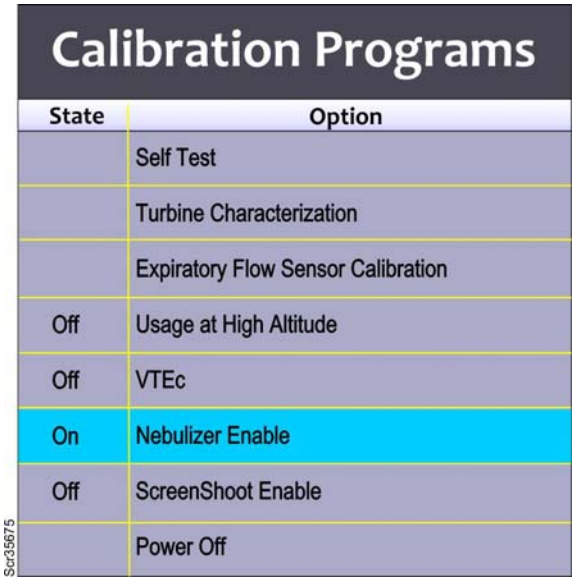


- VTEc function (**On**) is enabled.
- Press again the encoder knob; VTEc function is disabled (**Off**)

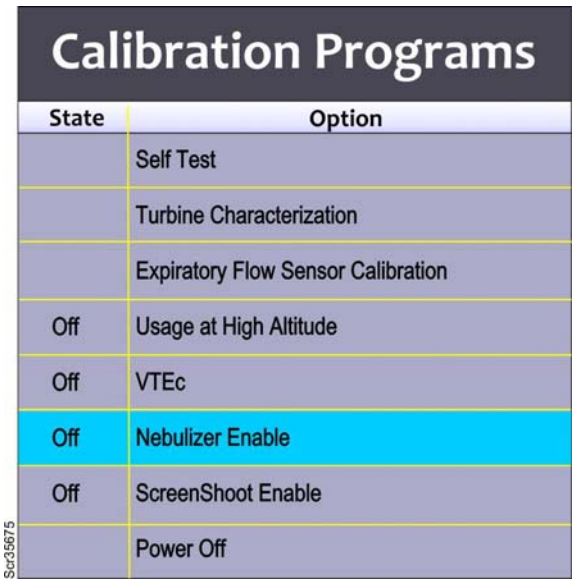
Select **Self Test** to go to the SELF TEST phase and escape from Calibration Programs window.

4.16.7 Nebulizer Enable (On - Off)

The activation of this function to enable (disable) the Nebulizer function (Nebulizer On - Nebulizer Off).



- Select the function (*or select and press by the encoder knob*).

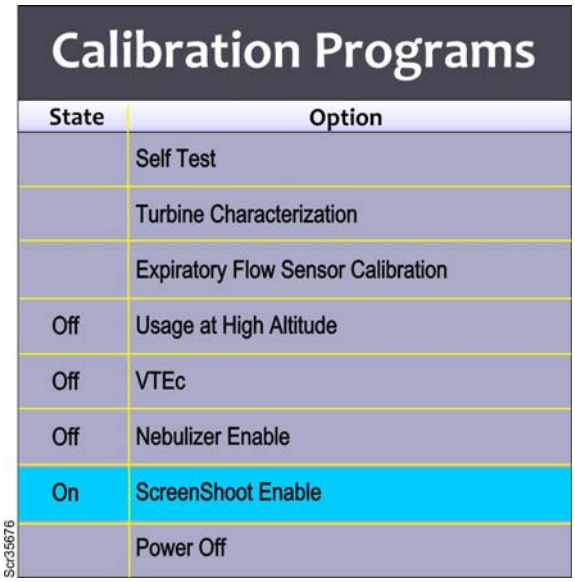


- NEB function (**On**) is enabled.
- Press again the encoder knob; NEB function is disabled (**Off**)

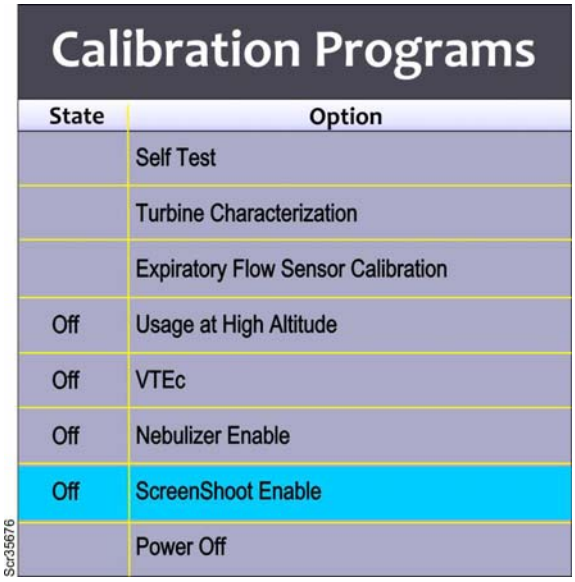
Select **Self Test** to go to the SELF TEST phase and escape from Calibration Programs window.

4.16.8 ScreenShoot Enable (On - Off)

This option, if enabled, allows the User to store on an USB key an instant image (image saved in bmp format) during the operation of the lung ventilator, (*for further details, see on chapter 2*).



- Select the function (*or select and press by the encoder knob*).

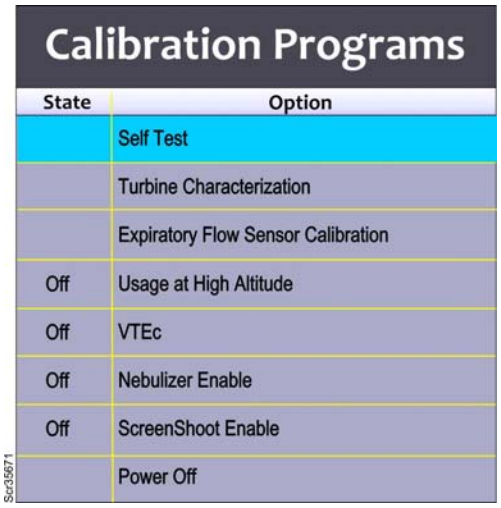


- ScreenShoot function is enabled (**On**).
- Press again the encoder knob; ScreenShoot function is disabled (**Off**)

Select **Self Test** to go to the SELF TEST phase and escape from Calibration Programs window.

4.16.9 Self Test

Once the Falco 202 Evo lung ventilator is switched ON, the system (SW) carries out the self-diagnostic tests (Scf Test) and checks a series of devices necessary for safe lung ventilator operation.



- Select the function (*or select and press by the encoder knob*).

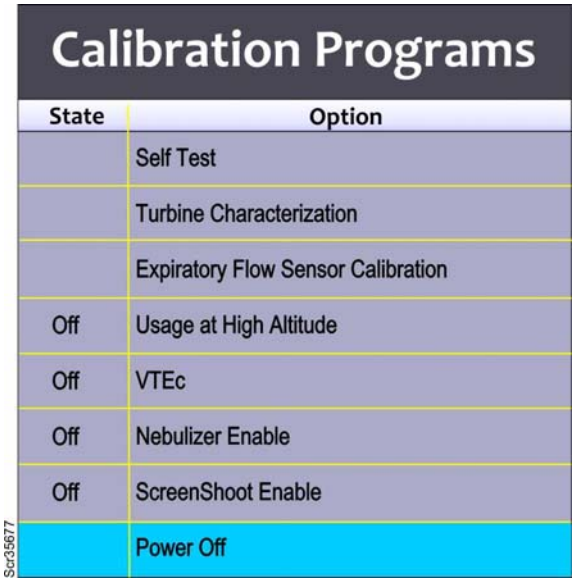
The Self Test phase starts.

For further details, about the **Self Test** phase, *see on chap. 3.3.2.*

The Self Test phase completed successfully.

OK	Select **OK** for displaying the Stand-by screen.
Cancel	Select **Cancel** for displaying the Supplementary tests screen.

4.17 Power Off

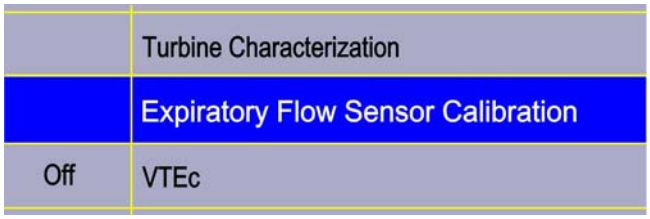


- Select the function (*or select and press by the encoder knob*).
- The lung ventilator is switched OFF

4.18 Other functions

4.18.1 Reset to ZERO the “Partial operating hours “

The zeroing of the partial operating hours *can be performed both in the page of turbine characterization, and in the expiratory flow sensors calibration page. As an example, the Expiratory Flow Sensors Calibration displaying is used.*



- Select the function (*or select and press by the encoder knob*).

- The **Expiratory Flow Sensors Calibration** page is displayed.
- To continue, see the note (ATTENTION) below.

WARNING !! Risk of DM failure and/or injuries for the patient

- Refer directly to SERVICE Manual.
- Contact SIARE or a Centre authorized by SIARE.

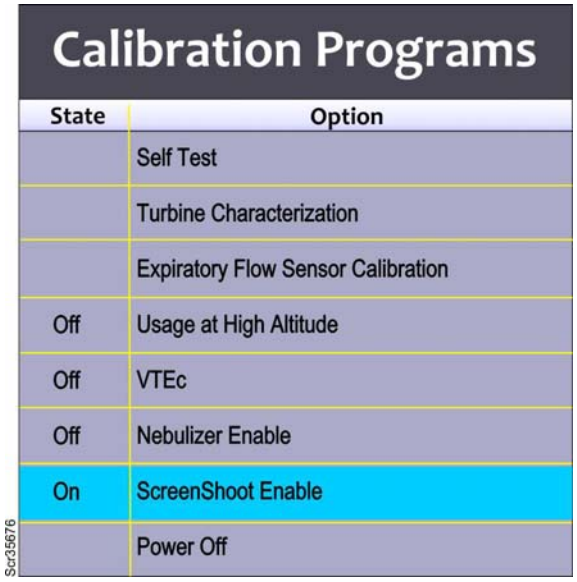
4.18.2 Data Connection (Trend and Events downloading)

Lung Ventilator: OFF.

The system software permits the download of the data stored in the Falco 202 Evo 10.4".

Note! *Ask Siare for the dedicated program to transform the stored and downloaded data (see procedure below) into a file that can be read and interpreted by the User.*

- Connect a USB drive to a USB1 socket.



To perform the data download it is necessary to switch ON the lung ventilator to enter the "Calibration Programs" and enable:

- **ScreenShoot Enable - On**

ScreenShoot enable:

- **select Self Test**

and follow the procedures indicated during the power up phase of the unit (*see on chapter 3.3*)

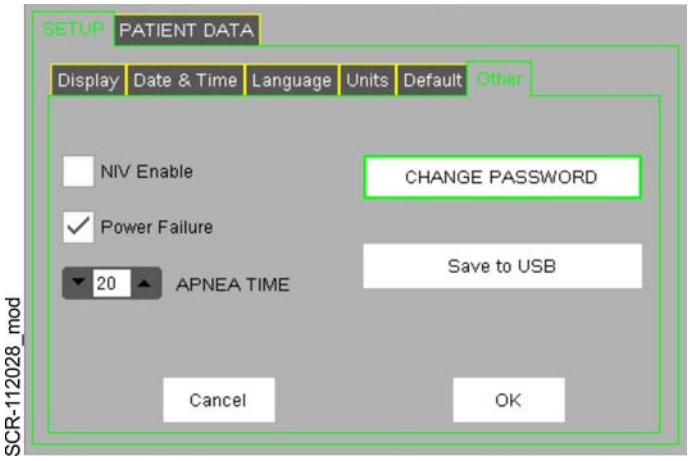
Lung Ventilator: Stand-by.

- **Check that the USB drive is connected and active:** see image below (USB).

- **Select SETUP**

A series of pages (displaying) are available to determine the operation SETUP of lung ventilator.

- Select **Other**



The system displays a page where the command is enabled that enables the saving on USB drive of: Trend and Events.

- Select **Save to USB**

- Switching OFF the lung ventilator.

- The Trend and Events data are saved on the USB drive in TXT format.
- Ask Siare for the dedicated program to transform the TXT file into a readable and interpretable file of the User.

4.18.3 Default parameters set

By selecting the function: ***MENU SETUP / DEFAULT***, the operator has the possibility to restore the original factory parameters (default parameters).

With the term "Default Parameters" we refer to all the DM settings (MENU, SETUP, ALARMS Limits, etc ...).

For more information on the default parameters setup, see chapter 4.11.

4.18.4 Touch Screen set

The Falco 202 Evo lung ventilator is equipped with a 15” colour Touch Screen display.

In case of Touch Screen system malfunctioning, it is possible to perform calibration of the same system (see on Service Manual).

WARNING !! Risk of DM failure and/or injuries for the patient

- Refer directly to SERVICE Manual.
- If the problem persists, contact the Siare Service Centre or a Centre authorized by Siare.

5 ALARMS

This chapter illustrates the part of the system relevant to the alarms operation of the Falco 202 Evo (10.4") lung ventilator (*hereinafter called lung ventilator*); also, the operating logic and issues for alarms action are taken into consideration.

WARNING !! Risk of injury for the user / patient

- All the pictures and the examples shown in the present chapter have the mere purpose of being an example and they do not make any reference to real clinical cases.
- Before using the lung ventilator, it is recommended to set the parameters referred to the alarms.

The lung ventilator is equipped with automatic means for detection and identification of serious and sudden events through alarm signals or information signals.

The aim of the alarm signal is to draw the attention of the user on the event, as well as to indicate the required response speed.

Level or urgency

- Immediate, the event is potentially able to develop in a period of time which generally is not enough to undertake a corrective manual action.
- Brief, the event is potentially able to develop in a period of time which generally is enough to undertake a corrective manual action.
- Delayed, i.e. that the event is potentially able to develop in a not specified period of time.

Level of severity

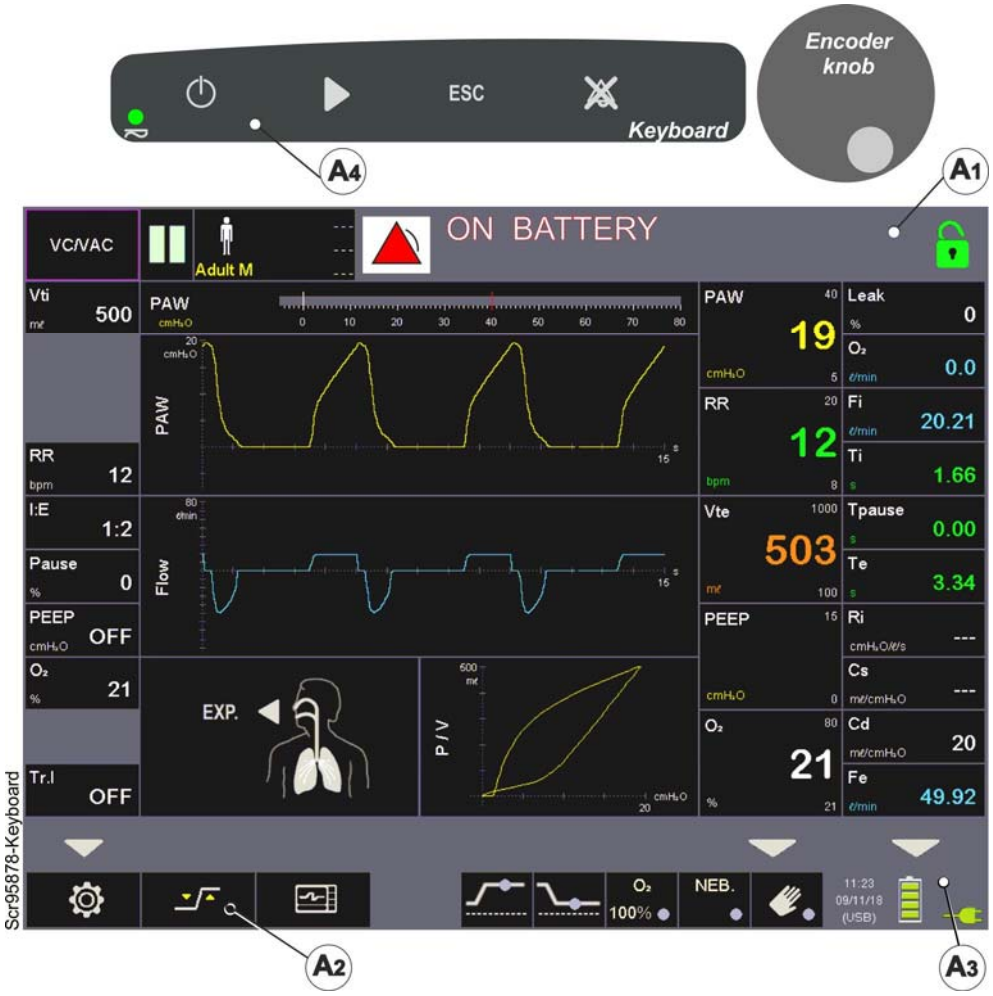
- Severe, i.e. leading to irreversible damage.
- Moderate, i.e. leading to reversible damage.
- Minor, i.e. involving a distress or leading to a minor damage.

The combination of urgency level and severity level of the listed factors, determines the assignment of priority condition of an alarm situation.

The parameters and characteristics (activation time, presence or lack of an acoustic and/or luminous indicator) and the possible user's actions respect to the alarm signals (silencing, suspend, inhibit) are described here below.

5.1 Displaying and used symbols

5.1.1 Alarms display area



A1 - Alarm area: this area of the monitor provides the following indications.

- A text string related to the type of active alarm.
- An "**alarm bell symbol**" indicating the priority and the alarm status.
- A "**lock icon**" to be used to inhibit the screen from possible accidental contacts.

A2 - ALARMS parameter

- Touching the icon, it is possible to entry in the ALARMS area and to access the Min and Max. alarms value setting.

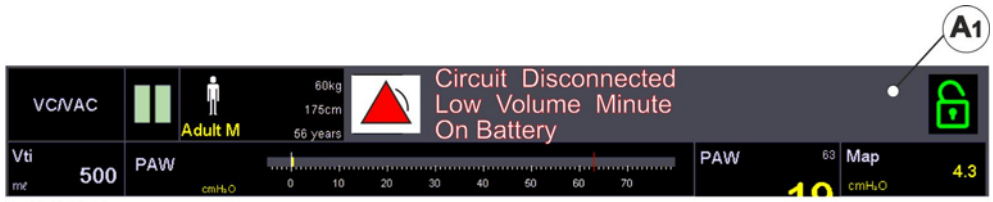
A3 - General information signal area: this area of the monitor provides the following indications.

- Battery charge level and main power presence (failure).

A4 - Soft key for acoustic alarm silencing

5.1.2 A1 - Alarm area

This area shows the text of the enabling alarm/s and the priority / status of the same and a lock icon indicating whether the touch screen is enabled.



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CAUTION

Three different alarms can be displayed at most and simultaneously; any further alarm signals will be displayed in sequence at intervals of 3/5 seconds.

Alarms configurable by User

- Low / High Pressure of Airways
- Low / High Respiratory Rate
- Low / High Expiratory Volume
- Low / High Volume Minute
- Low / High PEEP
- Low / High O_2 Concentration
- Gas Sensor: Low / High $EtCO_2$
- On Battery (*Power Failure - MENU SETUP - Other*)
- Apnoea (*MENU SETUP- Other*)

System alarms

- Low Battery: 50% Remaining
- Low Battery: 25% Remaining
- Low Battery
- Battery Disconnected
- Battery Charger Disconnected
- Battery Overtemperature
- (Patient) Circuit Disconnected
- Low O_2 Supply
- Turbine Failure
- Turbine Overtemperature
- Turbine Overcurrent
- MAINTENANCE 1000 hours (* *a symbol replace the alarm bell image*).

WARNING !! (*) MAINTENANCE 1000 HOURS

When this 1000-hour operation is reached, this symbol appears. Contact the Siare Service Center or authorized Siare for preventive maintenance.

Gas Sensor alarms

- Sampling Line Clogged
- No Sampling Line
- Replace Adapter
- No Adapter
- Unspecified Accuracy (……)
- Error (.....)
- No Breaths
- Low $EtCO_2$
- High $EtCO_2$
- Check the Flow Sensor (……)

Characters sequence (…..) has to be considered as an indicator to which the equipment inserts a value in function.

Priority / alarm status: "alarm bell symbol**"**

The "alarm bell" symbol, assumes a colour based on the priority and status of the activated alarm.

Media priority

- Yellow bell

Suspended alarm

- Yellow bell crossed through

High priority

- Red bell

Suspended alarm

- Red bell crossed through

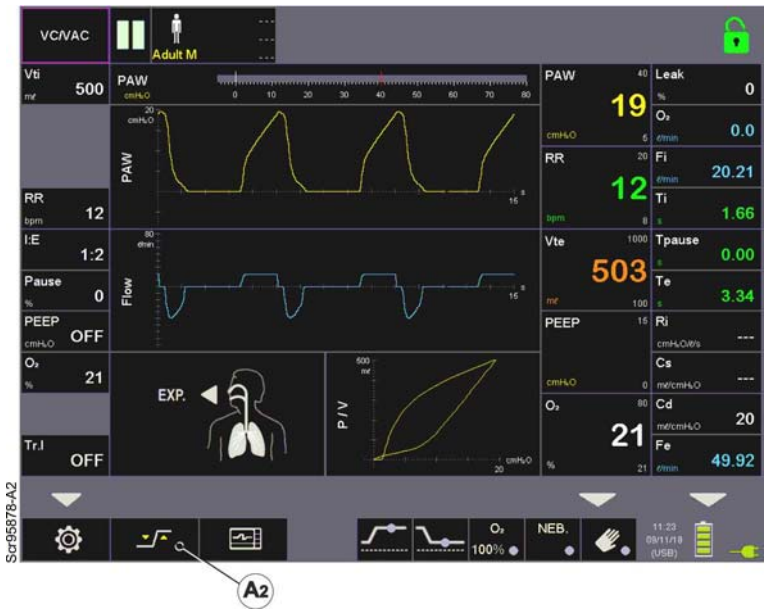
"Padlock" icon used to inhibit the screen from accidental contacts

"Padlock" icon (open) green color: **touch screen enabled**

"Padlock" icon (closed) red color: **touch screen disabled**

5.1.3 A2 - ALARMS parameter

This monitor area, allows to display and set the Min and Max. alarms limit values.



- Select: **ALARMS icon**

The **Alarm Limits** screen appears.

- **Select** Cancel

  YES: to quit Alarm page; the alarm set will NOT be saved.

  NO: it remains in Alarm page.

- **Select** OK

  YES: to quit Alarm page; the alarm set will be saved.

  NO: it remains in Alarm page.

WARNING !! Risk of injury for the user / patient

- The lung ventilator used in the same health environments can have **different pre-set configurations** of alarm limits.
- Verify that the **pre-set alarm limits** are appropriate for the new patient and adjust the alarm limits on values suitable to the new condition of use.
- The alarms setting to the range limit could make the alarm not properly working.

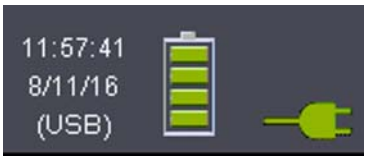
5.1.4 A3 - General information area

This area shows the battery charge level and the power supply status (present/absent).

Scr95868-A3

Green "BATTERY" symbol: battery completely charge:

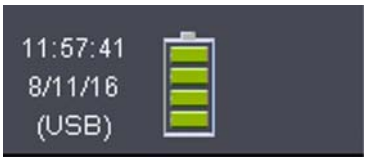
- with fix symbol the battery is complete charge;
- with flashing symbol, the battery is in charging phase.



Green "PLUG" symbol: lung ventilator connected to the main power supply.

The absence of Green "PLUG" symbol indicates that the lung ventilator is not connected to the main power supply.

- Active alarm: ***On Battery***.



The battery charge level is evidenced by the presence of coloured "notches" within the symbol, where each notch represents the 25% charging level.

- **ORANGE** flashing symbol, 2 notches: it indicates that the charge level of the battery is at 50%.
  - The relevant alarm is active **(*Low Battery: 50% Remaining*).**
- **ORANGE** flashing symbol, 1 notch: it indicates that the charge level of the battery is at 25%.
  - The relevant alarm is active **(*Low Battery: 25% Remaining*).**

The colour of the last flashing "notch" is red (High priority alarm): this extremely serious alarm condition indicates that the battery is almost completely low **(*Low Battery*)**

The alarm remains always actives to indicate the occurred malfunctioning.

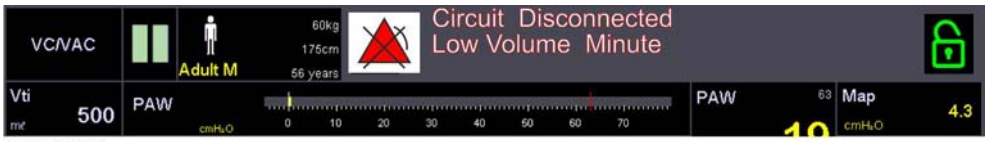
5.1.5 A4 - Acoustic alarm silencing

- It’s possible to change the alarm settings even when the alarms are activated.
- After changing an alarm setting, the relevant sign is lighted and the status icon will flash for a defined time.

During the normal operating phase of lung ventilator, it is possible to silence the active acoustic alarm.

- By pressing the **Alarm Reset** soft key.

- By selecting the bell evidencing the active state of the alarm.



Scr95878-A1

WARNING !! Risk of injury for the user / patient

The User should never stop checking the patient conditions during the alarm silencing.

NOTE

- The acoustic alarm silencing is active and will stop the acoustic alarm for a defined time.
- During the alarm silencing the alarm text is showed on the panel.
- A new alarm silencing will cancel the alarm text only if the alarm conditions is disappeared.
- If during the alarm silencing a new high priority alarm occur, the alarm silencing is cancelled and the acoustic signal and the visual texts are activated again.

5.2 Alarms setting

5.2.1 Setting of ALARMS limits values

WARNING !! Risk of injury for the patient

Using in the same area more than one medical device having different alarm limits setting, the User could have a potential false misinterpretation.

CAUTION

Before using the lung ventilator, it is suggested to adjust the parameters necessary for the correct operation of the lung ventilator. During operation it is possible to adapt the ALARM limits values setting in function of the patient clinical situation.

- **Select**: ALARMS icon

The **Alarm Limits** screen appears.

- **Select** Cancel

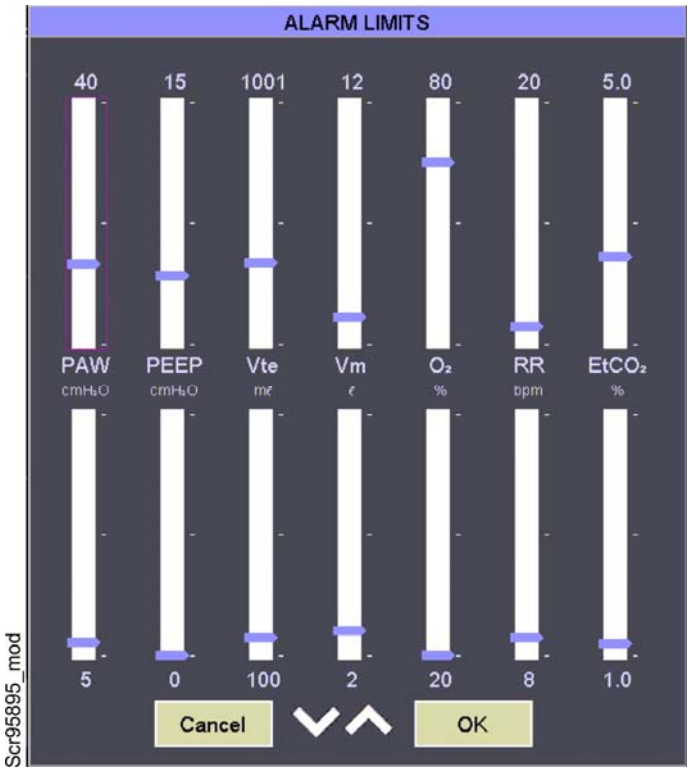
  YES: to quit Alarm page; the alarm set will NOT be saved.

  NO: it remains in Alarm page.

- **Select** OK

  YES: to quit Alarm page; the alarm set will be saved.

  NO: it remains in Alarm page.



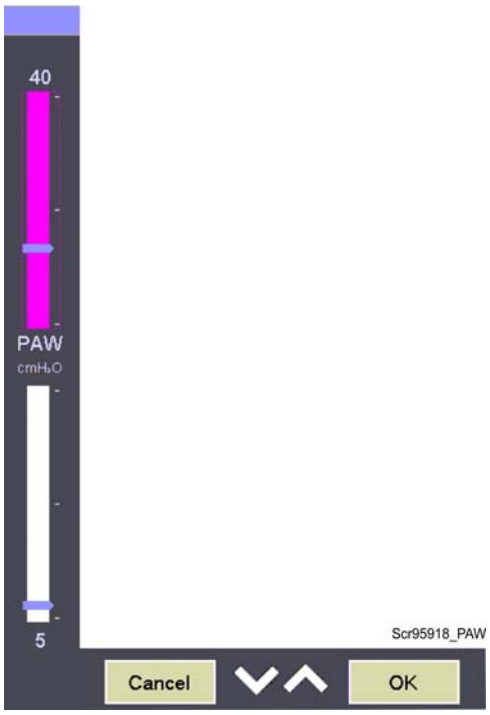
- Select the Alarm Limits to be modified.

  Available **Alarm Limits**.

  - PAW
  - PEEP
  - Vte
  - Vm
  - O2
  - RR
  - EtCO2

The values set by the scrolling cursor are displayed in the parameter monitoring box **(e.g. PAW**).

- Select the **Alarm Limits** to be modified.
- The parameter bar is highlighted and the monitoring parameter box on display is activated (**e.g. PAW**).



- **40**: High Alarm Limits value set (it is displayed in the PAW parameter box)
- **Coloured bar**: the bar is active to be modified
- **Scrolling cursor**: to be used for setting the parameter value
- **PAW**: PAW parameters
- **cmH2O**: unit of measurement
- **White bar**: the bar **IS NOT** active to be modified
- **Scrolling cursor**: to be used for setting the parameter value
- **5**: Low Alarm Limits value set (it is displayed in the PAW parameter box)
- **Arrows**: it increases or decrease a factor equal to 1 the value of the selected alarm.

The selection of both the bar or the cursor of the alarm can be done by using the encoder knob or the touch screen.

After modification of Alarm limit (**e.g. PAW**) values :

- **Select** Cancel

  YES: to quit Alarm page; the alarm set will NOT be saved.

  NO: it remains in Alarm page.

- **Select** OK

  YES: to quit Alarm page; the alarm set will be saved.

  NO: it remains in Alarm page.

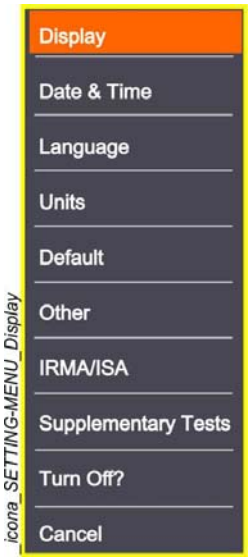
5.2.2 Setting of ALARMS volume

The **SOUND VOLUME** parameter allows the adjustment of the volume of acoustic alarms signals at any priority level.

Acoustic intensity value at 1 mt distance

- Minimum level Acoustic Volume setting at 1 = 54dBA
- Maximum level Acoustic Volume setting at 20 = 84dBA

- Select the icon to access the lung ventilator's SETTING **MENU**.

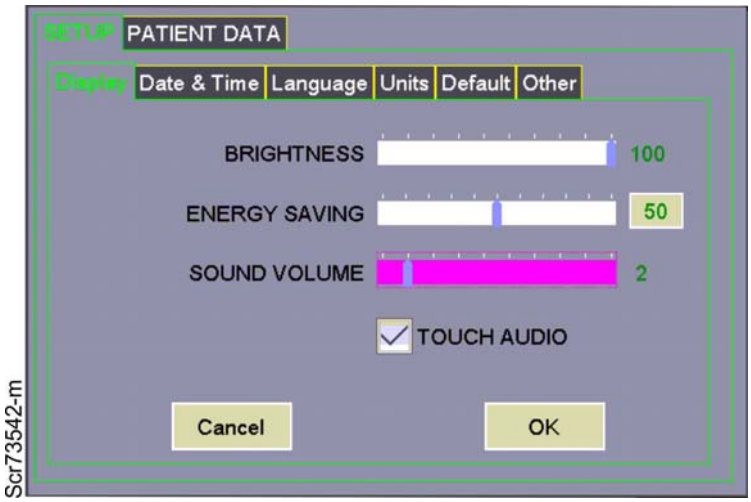


- Select **Display**
- To go back to the **Stand-by** displaying, select Cancel

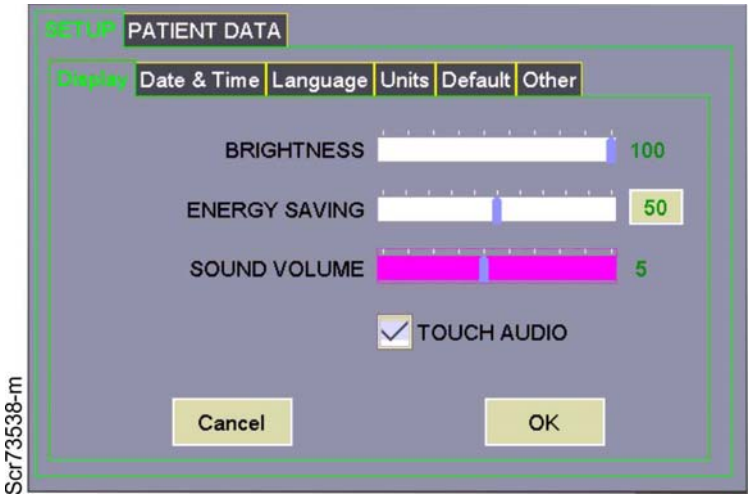
The **Display** page allows to set:

- *BRIGHTNESS*
- *ENERGY SAVING*
- ***SOUND VOLUME***
- *TOUCH AUDIO*

- Select the **SOUND VOLUME** scrolling cursor



- Set the **SOUND VOLUME**



After modification of **SOUND VOLUME** value.

- **Select** Cancel

  YES: to quit from Display page; the set will NOT be saved.

  NO: it remains in Display page.

- **Select** OK

  YES: to quit Display page; the set will be saved.

  NO: it remains in Display page.

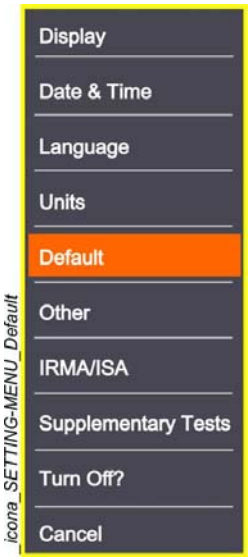
WARNING !! Risk of injury for the patient

When the alarm Sound Volume is set to the minimum value (Setting = 1), its intelligibility can be lost.

5.2.3 Setting of DEFAULT parameters

The DEFAULT page allows setting the standard factory parameters.

- Select the icon to access the lung ventilator's SETTING **MENU**.



icona_SETTING-MENU_Default

SCR-111949_Menu

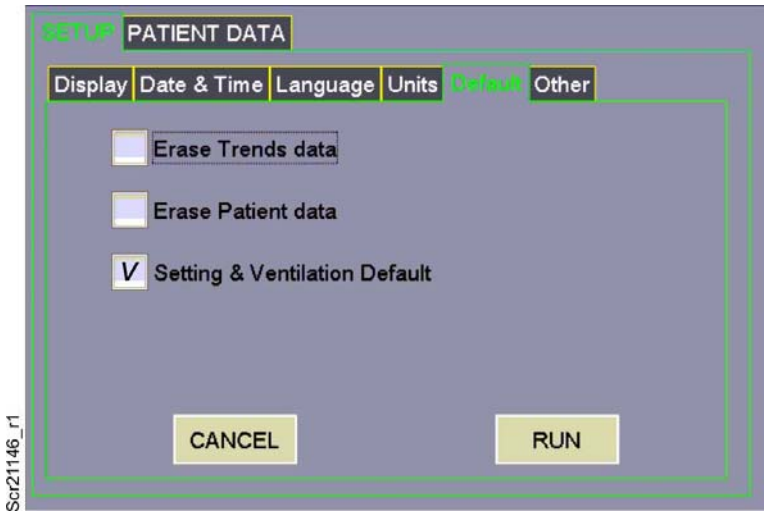
- Select **Default**
- To go back to **Stand-by** page, select Cancel

The **Default** page allows to set:

- *Trends data Default*
- *Patient data Default*
- ***Setting & Ventilation Default***

SCR-112021

- Select **Setting & Ventilation Default**
- Select **RUN**



- The system requires to confirm the application of default parameters.

Possible User's options.

- **Select** RUN

  YES: to quit Default page; the Default Parameters will be saved.

  NO: it remains in Default page.

- **Select** Cancel

  YES: to quit Default page; the Default Parameters will NOT be saved.

  NO: it remains in Default page.

5.2.4 Alarms DEFAULT parameters values

Alarm Settings	Adult	Paediatric	Neonatal
Pressure (cmH_2O)	**5 - 40**	**5 - 35**	**5 - 35**
Respiratory Rate (bpm)	**8 - 20**	**12 - 30**	**25 - 50**
Tidal Volume (ml)	**100 - 1000**	**50 - 300**	**10 - 30**
Minute Volume (L)	**2 - 12**	**1 - 8**	**0 - 3**
PEEP (cmH_2O)	**0 - 15**		
FiO_2 (%)	**21 - 80**		
Gas sensor	**1.0 - 5.0**		
On Battery (*configurable in: MENU SETUP – Other - Power Failure*)	**Enable**		
Apnea Time (*configurable in: MENU SETUP – Other – Apnoea Time*)	**20 sec.**		

5.3 Summary table of alarm characteristics

5.3.1 Alarms configurable by user

Alarms	Priority	Delay Time (s)	Suspendable	Suspendable for (s)	Inhibition
Low Pressure of Airways	*HIGH*	*15*	*YES*	*15*	*NO*
High Pressure of Airways	*HIGH*	*0*	*NO*	*-*	*NO*
Low Respiratory Rate	*HIGH*	*3 patient breaths*	*YES*	*30*	*NO*
High Respiratory Rate	*HIGH*	*3 patient breaths*	*YES*	*30*	*NO*
Low Expiratory Volume	*HIGH*	*15*	*YES*	*30*	*NO*
High Expiratory Volume	*HIGH*	*0*	*YES*	*30*	*NO*
Low Volume Minute	*HIGH*	*60*	*YES*	*30*	*NO*
High Volume Minute	*HIGH*	*60*	*YES*	*30*	*NO*
Low PEEP	*HIGH*	*0*	*YES*	*30*	*NO*
High PEEP	*HIGH*	*0*	*YES*	*30*	*NO*
Low O_2 Concentration	*HIGH*	*30*	*YES*	*30*	*NO*
High O_2 Concentration	*HIGH*	*30*	*YES*	*30*	*NO*
Low $EtCO_2$	*HIGH*	*30*	*YES*	*30*	*NO*
High $EtCO_2$	*HIGH*	*30*	*YES*	*30*	*NO*
Apnoea	*HIGH*	*5 - 60*	*YES*	*30*	*NO*
On Battery	*HIGH*	*15*	*YES*	*120*	*YES*

5.3.2 System alarms

Alarms	Priority	Delay Time (s)	Suspendable	Suspendable for (s)	Inhibition
Low Battery: 50% Remaining	HIGH	0	YES	-	YES
Low Battery: 25% Remaining	HIGH	0	YES	-	YES
Low Battery	HIGH	0	NO	-	NO
Battery Disconnected	HIGH	0	NO	-	NO
Battery Overtemperature	HIGH	0	NO	-	NO
Battery Charger Disconnected	HIGH	0	NO	-	NO
(Patient) Circuit Disconnected	HIGH	0	NO	-	NO
Low O_2 Supply	HIGH	0	YES	30	if FiO_2=21%
Turbine Failure	HIGH	0	NO	-	NO
Turbine Overtemperature	HIGH	0	NO	-	NO
Turbine Overcurrent	HIGH	0	NO	-	NO
Maintenance 1000 hours	HIGH	0	YES	-	NO

5.3.3 Gas Sensor Alarms

Alarms	Priority	Delay Time (s)	Suspendable	Suspendable for (s)	Inhibition
Sampling Line Clogged	*HIGH*	*0*	*YES*	*30*	*NO*
No Sampling Line	*HIGH*	*0*	*YES*	*30*	*NO*
Replace Adapter	*HIGH*	*0*	*YES*	*30*	*NO*
No Adapter	*HIGH*	*0*	*YES*	*30*	*NO*
Unspecified Accuracy	*HIGH*	*0*	*YES*	*30*	*NO*
Error	*HIGH*	*0*	*YES*	*30*	*NO*
No Breaths	*HIGH*	*0*	*YES*	*30*	*NO*
Low $EtCO_2$	*HIGH*	*0*	*YES*	*30*	*NO*
High $EtCO_2$	*HIGH*	*0*	*YES*	*30*	*NO*
Check the Flow Sensor	*HIGH*	*0*	*YES*	*30*	*NO*

5.4 Troubleshooting

This chapter is an indicative but not exhaustive guide for the user and the service engineer, providing indications for eliminating, as quickly as possible, most of the problems that may have caused malfunctioning or alarm signals.

This chapter describes the possible causes of problems, indicated by alarms that are activated during normal functioning.

WARNING !!

If the problem persists, carry out a complete check of the lung ventilator to identify any irregularities.

If the problem cannot be resolved, contact the Siare Service Centre or a Centre authorized by Siare.

5.4.1 Troubleshooting list

Switch ON failure	The lung ventilator does not switch on.

- Check that it is connected to the main power supply.
- Check that the main switch is turned to the I position (ON).
- Check the main fuses.
- Check the display connection cable.
- Contact the Siare Service Centre or a Centre authorized by Siare.

Power Failure	There is a power supply fault and the lung ventilator are operating on the battery.

- Check if the LED power indicator is ON.
- Check that it is connected to the main power supply.
- Check that the main switch is turned to the I position (ON).
- Check the correct connections of the plug, the fuses and the connector, and the condition of the cable (if necessary, restore the connections and replace the cable if it is damaged).
- Check that power is present at the relative socket by plugging in another electrical device. If there is no power, use another socket or check the overload switch on the electrical panel of the room.
- Check the 12V voltage is properly supplied to the main board - CPU.

Initialization phase - SELF TEST	The initialization phase is not completed.

Verify and intervene in function on the error messages and indications evidenced during the "**SELF TEST**" phase.

- **Turbine**: if this step is not passed means that the turbine is not running so check if the turbine cable is properly connected and if the turbine is properly powered. If so, the turbine is broken so it must be changed.
- **Oxygen emptying**: during this test phase the system performs a clean of the oxygen inside the circuits and the device which grants a 21% concentration on the inspiratory line of the lung ventilator.
- **Insp. flow sensor**: if this step is not passed means that the inspiratory flow is not measured correctly by the sensor (the turbine starts delivering the flow suitable with PWM = 45%, the insp. flow sensor test is passed if the flow measured by the insp. flow sensor is > 50 l/min). So check if the inspiratory flow sensor cable is properly connected and if the 10V supply voltage of the flow sensor is properly supplied from the main board. If so, the inspiratory flow sensor is broken and must be replaced.
- **Exp. flow sensor**: if this step is not passed this means the expiratory flow is not measured correctly by the sensor (the exp. flow sensor test is passed if the flow measured by the exp. flow sensor is > 30 l/min). So check if the expiratory flow sensor cable is properly connected. if the problem is not solved, please perform the expiratory flow sensor calibration. If the calibration doesn't solve the problem, this means the expiratory flow sensor is broken and must be replaced.
- **Pressure sensor**: if this step is not passed, it means that the airway pressure is not measured correctly by the sensor so check if the inspiratory flow is generated by the ventilator; check if there are leakages in the inspiratory and expiratory line of the ventilator or in the patient circuit; check the pressure measured on the ventilator.
- **Electrovalve**: if this step is not passed means that the electrovalves EV1/EV2 are not able to close the expiratory valve so check if the inspiratory flow is generated by the ventilator; check if there are leakages in the inspiratory and expiratory line of the ventilator or in the patient circuit; check if the 12Vdc reach the expiratory electrovalve, if the voltage is correct replace the electrovalve.
- **Patient circuit**: if this step is not passed means that the measured airway pressure is very low so check if there are leakages in the inspiratory and expiratory line of the ventilator or in the patient circuit.

- **Battery**: if this step is not passed means that the battery voltage is less than 11Vdc so connect the ventilator to the main power supply for 10 hours with the main switch on the I position (ON) and check again.

  Check if the 12V voltage is properly supplied from the main board and the battery charger board. If the problem is not solved, replace the battery.
- **Oxygen sensor**: if this step is not passed means that the 21% of oxygen is not measured correctly by the sensor so check the oxygen sensor cable if it is properly connected; perform the oxygen calibration in the test on demand MENU and check the oxygen output if the voltage is under 9mV the oxygen sensor is exhausted and so it must be changed.
- **Acoustic alarm**: at the end of the self test the activate the alarm sound. If the sound is heard by the operator the alarm reset button must be pressed, if it is not heard check if the speaker cable is well connected and the voltage on the main board connector otherwise the speaker is defective and must be replaced.

Turn off and on the lung ventilator and repeat “SELF TEST” phase.

If the problem persists, contact the Siare Service Centre or a Centre authorized by Siare.

Soft keys and encoder knob	This condition occurs when the control keyboard or the Encoder are not working.

- Switch the lung ventilator OFF and then switch back ON.
- Continuity test of the keyboard and encoder cable.
- If the problem persists, contact the Siare Service Centre or a Centre authorized by Siare.

(Patient) Circuit disconnected	This alarm conditions occurs in case of disconnection of the patient circuit (missed Vte detection for three times). Vte volume limit for circuit disconnected condition: 50ml for ADULT, 20 ml for PAEDIATRIC, 0 ml for NEONATAL patient). ▪ Check that the mask, endotrachéal tube and patient circuit are not in some way split, disconnected or connected wrongly. If this is the case, eliminate the problem or replace them. ▪ Check the correct settings of the patient's respiratory parameters (according to the operative mode selected: Volume/Flow, Rate, I/E, Trigger). ▪ Check that the patient circuit is connected correctly to the lung ventilator and to the patient. ▪ Contact the Siare Service Centre or a Centre authorized by Siare.
Low O_2 gas pressure	This alarm is activated when the pressure is insufficient (< 2.7 bar) for the lung ventilator to operate correctly. ▪ Check that the medical gases are correctly connected to the lung ventilator. Restore the connections or replace the tubes if damaged. ▪ Check that there is sufficient pressure in the supply system or in the cylinders. Adjust or repair the supply system (or replace the cylinders) if the pressure is insufficient. ▪ Contact the Siare Service Centre or a Centre authorised by Siare.
Low Battery: 50% (25%) Remaining	This alarm is activated when the charge level of the battery is at 25% (50%) of the fully charged level. ▪ Check that it is connected to the main power supply. ▪ Recharge the battery. ▪ If the alarm is activated when the battery has not provided the time autonomy indicated on the technical sheet, request the intervention of a Service Centre.

It is possible to silence the **LOW BATTERY LEVEL 50% e LOW BATTERY LEVEL 25%** alarms pressing the ALARM RESET button on the control keyboard.

- The **LOW BATTERY LEVEL 50%** alarm will sound again when the battery level will join the following battery alarm level: LOW BATTERY LEVEL 25%.
- The **LOW BATTERY LEVEL 25%** alarm will sound again when the battery level will join the following battery alarm level: **LOW BATTERY** (10 mins).

Low battery (10 minutes)	This alarm condition is present when the charge battery level is such to be guaranteed a residual autonomy of about 10 minutes.
	▪ Verify the power supply connection; recharge the battery. ▪ If the alarm is activated when the battery has not provided the time autonomy indicated on the technical sheet, request the intervention of a Service Centre.
Battery disconnection	This alarm condition is present when the battery is not properly connected to the device.
	▪ Check the battery connection. ▪ If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.
Battery charger disconnected	The alarm condition is present when the battery does not charge properly.
	▪ Check the correct connection of the battery. ▪ Check the output voltage from the charging card to the battery (12Vdc) ▪ If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.
Battery overtemperature	This alarm condition is present when the battery pack internal temperature pass the 75°C.
	▪ If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.
O_2 sensor	The oxygen sensor is exhausted.
	▪ See information on FiO_2 % low alarm. ▪ Replace the oxygen sensor with a new one. ▪ If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.
O_2 sensor	This alarm indicates the connection status of the oxygen sensor.
	▪ Check that the oxygen cell is correctly connected. ▪ Check the condition of the cable and the connector (if necessary, restore the connection and replace the cable if damaged). ▪ Replace the oxygen sensor with a new one. ▪ If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

1000 working hours	This alarm condition occurs at overcoming of 1000 working hours from the last reset.
	▪ When this alarm occurs, it is recommended to perform the preventive maintenance procedure, check the ventilator operation and finally reset the working hours. ▪ Contact the Siare Service Centre or a Centre authorised by Siare to execute the periodic scheduled maintenance.
FiO2 % high	This alarm is activated when the measured concentration of oxygen exceeds the set limit.
	▪ Check that the corresponding alarm limits are set correctly. ▪ Calibrate the oxygen cell: if the problem occurs again after a short time, replace the oxygen cell. ▪ Contact the Siare Service Centre or a Centre authorised by Siare.
FiO2 % low	This alarm is activated when the measured concentration of oxygen is below the set limit.
	▪ Check that the oxygen cell is fitted correctly in its housing. ▪ Check that the corresponding alarm limits are set correctly. ▪ Calibrate the oxygen cell: if the problem occurs again after a short time, replace the oxygen cell. ▪ Check that the feeding pressure of the medical gases is correct: if it is not, check the pressure of the distribution system and the correct connection to the supply. ▪ Contact the Siare Service Centre or a Centre authorised by Siare.
Min. Vte / VM	This alarm condition occurs in case the Vte is lower than set value.
	▪ Check that the corresponding alarm limits are set correctly. ▪ Check that the mask, endotracheal tube and patient circuit are not in some way split, disconnected or connected wrongly. If this is the case, eliminate the problem or replace them. ▪ Check that the mask, endotracheal tube and patient circuit are not in some way clogged, bent or crushed. If this is the case, eliminate the problem or replace them. ▪ Check the correct settings of the patient's respiratory parameters (according to the operative mode selected: Volume/Flow, Rate, I/E, Trigger).

- Check that the patient circuit is connected correctly to the lung ventilator and to the patient.
- Check if the lung ventilator works properly verifying the airways pressure. If the lung ventilator works properly perform the expiratory flow sensor calibration.
- Contact the Siare Service Centre or a Centre authorised by Siare.

Max. Vte / VM	This alarm condition occurs in case the Vte is higher than set value.

- Check that the corresponding alarm limits are set correctly.
- Check the correct settings of the patient's respiratory parameters (according to the operative mode selected: Volume/Flow, Rate, I/E, Trigger).
- Check if the lung ventilator works properly verifying the airways pressure. If the lung ventilator works properly perform the expiratory flow sensor.
- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

Low (High) PEEP	This alarm condition occurs if the measured PEEP value is lower (higher) than the value set.

- Check that the corresponding alarm limits are set correctly.
- Check if the mask / endotracheal tube / patient circuit / expiratory valve (membrane), are not damaged, if holes are present or if they are connected in a bad way. If it’s the case, replace them or solve the trouble.
- Check if the lung ventilator works properly verifying the airways pressure.
- In case of differences higher than 2 cmH_2O (10%) between the value set and the value read, a turbine calibration shall be performed.
- Check the EV1/EV2 electrovalves.
- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

PAW high	In this condition, the patient circuit + patient system presents a higher resistance than expected or a lower compliance. This causes an increase in airways pressure that exceeds the set limit.

- Check that the corresponding alarm limits are set correctly.
- Check that the mask, endotrachéal tube and patient circuit are not in some way clogged, bent or crushed. If this is the case, eliminate the problem or replace them.
- Check the correct settings of the patient's respiratory parameters (according to the operative mode selected: Volume/Flow, Rate, I/E, Trigger).
- Check that the luminous PAW bar on lung ventilator (the airways pressure curve) correctly follows the inspiration / expiration cycle.
- Check that nothing is limiting the patient's respiratory capacity.
- Contact the Siare Service Centre or a Centre authorised by Siare.

PAW low	In this condition, the patient circuit + patient system presents a lower resistance than expected or a higher compliance. This causes insufficient ventilation pressure.

- Check that the corresponding alarm limits are set correctly.
- Check that the mask, endotrachéal tube and patient circuit are not in some way split, disconnected or connected wrongly. If this is the case, eliminate the problem or replace them.
- Check the correct settings of the patient's respiratory parameters (according to the operative mode selected: Volume/Flow, Rate, I/E, Trigger).
- Check that the luminous PAW bar on lung ventilator (the airways pressure curve) correctly follows the inspiration / expiration cycle.
- Check that the patient circuit is connected correctly to the lung ventilator and to the patient.
- Check that the low pressure level is higher than the PEEP level set. If not, increase it above the PEEP level.
- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

RR high	This alarm is enabled when the respiratory rate value is higher than the set value.

- Check that the corresponding alarm limits are set correctly.
- Check that the patient's respiratory parameters are set correctly.
- Check that the sensitivity of the Trigger is appropriate to the patient's physiological conditions.
- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

RR low	This alarm is activated when the respiratory rate value is lower than the set value.

- Check that the corresponding alarm limits are set correctly.
- Check that the patient's respiratory parameters are set correctly.
- Check that the lung ventilator operates correctly, checking the airways pressure trend. If the lung ventilator operates correctly, check the flow sensor and the correct connection of its cable.
- Check that the mask, endotrachéal tube and patient circuit are not in some way split, disconnected or connected wrongly. If this is the case, eliminate the problem or replace them.
- Check that the sensitivity of the Trigger is appropriate to the patient's physiological conditions.
- Check that the patient circuit is connected correctly to the lung ventilator and to the patient.
- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

Apnea	In this condition, no spontaneous respiratory activities is detected (RR = 0).

- Check that the patient's respiratory parameters are set correctly.
- Check that the sensitivity of the Trigger is appropriate to the patient's physiological conditions.
- Check that the mask, endotrachéal tube and patient circuit are not in some way split, disconnected or connected wrongly. If this is the case, eliminate the problem or replace them.
- Check that the lung ventilator operates correctly, checking the airways pressure trend. If the lung ventilator operates correctly, check the flow sensor and the correct connection of its cable.

- Check that the patient circuit is connected correctly to the lung ventilator and to the patient.
- Contact the Siare Service Centre or a Centre authorised by Siare.

Expiratory flow sensor calibration failed	The user can note indirectly, by monitoring the flow graph, the value of the expired volume and the peak value of expired flow, if the self-calibration of the flow sensor has been successful or not.

- Check the proper mounting of the sensor (patient circuit) and the relevant connections to the lung ventilator and to the patient.
- Check if the patient circuit is properly closed during the calibration.
- Replace the sensor and repeat the expiratory flow sensor calibration.
- Perform the turbine calibration and repeat the expiratory flow sensor calibration.
- Contact the Siare Service Centre or a Centre authorised by Siare.

Turbine over-temperature (over-current)	The maximum safety level for the temperature (current) of the turbine is passed (80 - 85 °C).

- The lung ventilator automatically stop the ventilation to avoid dangers to the patient safety.
- Check if the turbine air filter is clean or clogged.
- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

Turbine failure	The turbine doesn’t work properly (failure).

- The lung ventilator automatically stops the ventilation to avoid dangers to the patient safety.
- Check if the turbine air filter is clean or clogged.
- Perform the turbine calibration.
- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

Turbine calibration failed	The turbine doesn't work properly (failure in calibration phase).

- Check if the patient circuit is properly closed during the calibration.
- During the calibration check the inspiratory flow sensor reading (parameter on display). If the reading is over 10 l/min, means that there is a leakage in the patient circuit. Eliminate the leakage and perform again the turbine calibration.
- Replace the turbine and perform again the turbine calibration.
- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

CO_2 Analyzer	Malfunctioning.

- Check that the patient's respiratory parameters are set correctly.
- Check the proper mounting of the sensor (patient circuit) and the relevant connections to the lung ventilator and to the patient.
- Check the IRMA/ISA is enabled in the **CALIBRATION PROGRAM.**
- Check the state indicator on the CO_2 analyzer, is a fixed green LED.
- Check the errors shown in the **GAS SENSOR** area.
- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

For further information on operating logic and on gas sensor malfunctioning, make reference to the GAS ANALYZER manual supplied with the device.

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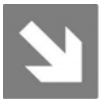
6 MAINTENANCE

- To guarantee the regular ventilation operation of the Falco 202 Evo (10.4”) lung ventilator for intensive care, emergency and transport (*hereinafter called lung ventilator*), perform the following maintenance interventions with the recommended frequency.
- All interventions must comply with to the practice and protocols in force in each facility.
- The instructions for carrying out more detailed tests, for trouble-hooting and for other interventional procedures, information intended for qualified technical personnel, are contained in the relative chapter.



On completion of the maintenance operations, all removed components should be disposed of according to current waste disposal regulations: components that cannot be destroyed should be sterilized before disposal.

Follow current regulations for the disposal or recycling of all removed components.

WARNING !! Risk of injury for the user / patient

To ensure the safety of the patient and the User, the lung ventilator must be inspected and checked when the limit of **1000 working hours has been reached or, in the event of limited use of the machine, at least every 6 months.**

All maintenance and/or repair operations require perfect knowledge of the lung ventilator and must therefore only be carried out by highly qualified personnel, specifically trained and formally authorised by SIARE.

Inappropriate intervention or unauthorised modifications can compromise safety and cause danger to the patient.

To avoid the danger of electric shock during maintenance and/or repair operations, make sure that all power supplies have been disconnected, disconnect the power supply source (positioning the special danger signs) and disable the protection switch of the lung ventilator.

Before performing the maintenance or repairing works, also in case of returning the lung ventilator for repairing to manufacturer, it is required to clean and disinfect the lung ventilator.

6.1 Cleaning, disinfection and sterilization

The User is responsible for carrying out the ordinary maintenance as foreseen in this chapter.

Cleaning, disinfecting, sterilizing and replacement of parts must be carried out as indicated in this manual in order to avoid damage to the lung ventilator which could also endanger patient and User safety.

WARNING !! Risk of personal injury

- Do not attempt to dismantle, clean or rinse parts or components, such as the screen or knobs, with liquids or compressed air.
- To avoid exposing the patient to sterilizing substances, these parts must be sterilized as described below. Remember that exposure to sterilizing substances can reduce the working life of some components.
- Always use filters to protect circuits and lung ventilator: if foreseen, handle the filters with care to reduce the risks of bacterial contamination or material damage to a minimum.
- Always respect the hospital procedures regarding the control of infections.
- The lung ventilator does not require particular maintenance and preventive operations other than those indicated in this manual or in order to respect standards applied in the specific country where the lung ventilator is sold.

- Siare is aware that working procedures can differ considerably from one health care facility therefore it is impossible to indicate specific procedures suitable for every requirement.
- SIARE cannot be held responsible for the effectiveness of the cleaning, disinfection and sterilization procedures, nor for the other procedures carried out while the patient is being treated.
- This manual can provide only general instructions for cleaning, disinfection and sterilization. Nevertheless, it is User's responsibility to ensure the validity and effectiveness of the methods used.

6.2 General indications

6.2.1 Cleaning

Use a disposable cloth moistened with neutral detergent, a chemical substance or the equivalent; use water to remove any traces of chemical residuals.

- Do not clean or re-use disposable products.
- Do not use hard brushes to clean the components, or other instruments that could damage their surface.
- Wash the components with hot water and a neutral detergent solution.
- Rinse the parts well with clean hot water (tap water can be used) and leave to dry.
- Siare recommends that the components are checked every time they are cleaned and any damaged part should be replaced.
- Whenever a part or component is changed, check the functioning of the lung ventilator.

Follow manufacturer's instructions for the detergent substances used: the use of detergents that are too strong could compromise the working life of the components.

Deposits of cleansing substances can cause damage or micro cracks, especially on parts exposed to high temperatures during sterilization.

6.2.2 Disinfection and sterilization

To disinfect the components, dismantle them and place them in a steam disinfection chamber at 93°C for 10 minutes.

After this first operation and before placing the components in an autoclave, wrap them in muslin or in a similar material.

Effective sterilization is achieved in an autoclave at 121°C for approx. 15 minutes.

WARNING !! Risk of injury for the patient

Always refer to the instructions provided by the autoclave manufacturer regarding temperature and time.

- Do not disinfect, sterilize or re-use disposable products.
- Disinfect and sterilize every time an infected patient is ventilated.
- In normal conditions, disinfect and sterilize depending on the frequency of the lung ventilator's use and in any case at least once a month.

- That the components should be checked every time they are sterilized and any damaged parts should be replaced.
- Carrying out a functioning test of the machine whenever parts or components are replaced.

6.2.3 Disinfection by immersion (chemical)

If a steam disinfection chamber is not available, the dismantled parts can be chemically disinfected by means of immersion.

Immerse the dismantled components in the solution with the disinfectant, following the manufacturer's instructions.

- Not using formaldehyde or phenol-based disinfectants as they can cause cracking and reticulation of plastic parts;
- Not using too strong disinfectants as they can compromise the working life of the immersed parts;
- Rinsing and carefully drying the components since marks and other damage can occur when the components are exposed to high temperatures.

When disinfection is complete, rinse with running, preferably decalcified, water; shake and drain off any remaining water. Leave the components to dry completely.

After this first operation and before placing the components in an autoclave, wrap them in muslin or in a similar material.

Effective sterilization is achieved in an autoclave at 121°C for approx. 15 minutes.

Always refer to the instructions provided by the autoclave manufacturer regarding temperature and time.

6.3 Cleaning, disinfection and sterilization table

Component	Procedure	Notes
Outer casing	Use a moistened disposable cloth with neutral detergent or a chemical substance or the like. Use water to remove any remaining traces of chemical. The User may use disinfectants (e.g. Buraton 10 F, diluted according to the manufacturer's instructions or VPRO 60C°) to clean the components. Disinfectants based on the following substances can cause damage: ▪ halogen-releasing compounds; ▪ strong organic acids; ▪ oxygen-releasing compounds. Remove any dust from the surfaces or in openings using a vacuum cleaner or a soft cloth.	Make sure that no sprays or liquids penetrate inside the equipment and the connectors.
Screen	See above.	Do not use cloths or sponges that could scratch the surface.

To avoid damaging the labels and outer surfaces of the lung ventilator, use only the chemical substances listed.

Patient circuit (silicone tubes)	Dismantle and clean: sterilize in an autoclave, disinfect with steam or chemically. Check that there are no splits in the tubes and replace them if they are damaged.	121°C rubber cycle. Before using again, eliminate any humidity inside the tubes by means of compressed air.

The patient circuit can be sterilized by means of steam but this can lead to early wear of the tubes.

Yellowing and reduced flexibility are side effects caused by sterilization using steam.

WARNING !! Risk of injury for the patient

It is necessary to have at least one spare patient circuit in stock for routine use and /or accidental breaks.

Couplings and connectors	Dismantle and clean: sterilize in an autoclave, disinfect with steam or chemically. Check that there are no splits and replace them if they are damaged.	Before using again, eliminate any humidity inside the components by means of compressed air.

Turbine air filter	Dismantle and clean with hot water and a neutral detergent solution. Check that there are no splits and replace them if they are damaged.	Before mounting the filter again, eliminate any humidity inside the components by means of compressed air.

- Do not clean or re-use disposable circuit tubes.

Components that cannot be destroyed should be sterilized and disinfected according to local standards.

Mask	▪ Perform daily cleaning of the mask following the instructions of the responsible doctors or recommended by the Manufacturer. ▪ Hang up the clean mask to provide that it is completely dry before use. ▪ Always clean the mask and the hoses or use a new mask in case the lung ventilator must be used with a different patient. ▪ If the lung ventilator is used with more than one patient in the clinic, insert an antibacterial filter between the patient outlet and the hose.	See Manufacturer's instructions.

Water trap filter	If reusable: clean, then sterilize in autoclave or chemically disinfect.	Check the presence of fissures and replace in case of damages.

Other accessories	Carefully follow the manufacturer’s instructions.	Refer to the accompanying documentation.

Electrical connections	On the aim to guarantee patient and User safety it is necessary to keep the power supply cable in perfect conditions.	Perform daily checking’s of cable condition; any damage, also a minimum damage, must be promptly eliminated. Eventually replacing the whole cable.

6.3.1 Sterilization of EXP V. Monoblock (exhalation block with flow sensor)

EXP V. Monoblock	Disinfect with steam (93° - 10 minutes) or chemically.	It is possible to sterilize the component with gamma rays or ethylene oxide (ETO). When disinfection is complete, rinse with running, preferably decalcified, water; shake and drain off any remaining water. Leave the components to dry completely.

CAUTION

- The EXP V. monoblock includes the expiratory valve and the flow sensor.
- Do not attempt to dismantle or clean with compressed air.
- The EXP. V. monoblock can be washed and disinfected by immersing it in a bowl with 3 centimetres of liquid (chemical), keeping the connector for the electrical connections facing upwards, following the manufacturer's instructions *(see following note about recommended chemical agents).*

The following are chemical agents recommended for cold sterilization of flow sensor.

- 5.25% - 6.15% Sodium Hypochlorite solution
- Protex wipes (Didecyl Dimethyl Ammonium Chloride)

WARNING !! Risk of device failure

EXP valve and EXP flow sensor disinfection.

- Do not use formaldehyde or phenol-based disinfectants as they can cause cracking and reticulation of plastic parts.
- Do not use too strong disinfectants as they can compromise the working life of the immersed parts.
- Rinsing and carefully drying the components since marks and other damage can occur when the components are exposed to high temperatures.

6.3.2 Disposable bacteria filter

CAUTION

It is important to use a disposable bacteria filter at the expiratory port of lung ventilator between the patient circuit's expiratory limb and the expiratory flow sensor.

Disposable bacteria filter	Do not clean or re-use if the filters are the disposable type.	Components that cannot be destroyed should be sterilized and disinfected according to local standards.

WARNING !! Risk of device failure

Disposable bacteria filter.

- Do not attempt to sterilize and reuse a disposable bacterial /HEPA filter. It is meant for single use.
- Do not use filters that aren't in sealed pack.
- Do not try to dry the filter and reuse in the same patient in case of increased resistance.
- Do not use it longer than the time-period recommended by manufacturer.
- Do not use filters that had exceeded the expiry date.

Disposable bacteria filter.

- Replace the bacterial filter as per manufacturer's advice (24 - 72 hours).
- If used with humidifier, change the filter more frequently (as and when the resistance increases or patient's "work of breathing" increases).
- Immediately replace the filter if it is stained with blood, secretions or other human fluid
- Check the expiry date before using on patient.
- Change the filter early if nebulisation is done frequently.

6.4 Periodic maintenance

CAUTION

The lung ventilator does not require particular maintenance and preventive operations other than those indicated in this manual or in order to respect standards applied in the specific country where the lung ventilator is sold.

- Inspections and periodic maintenance are ensured by taking out a maintenance contract with SIARE or an authorised dealer.
- Contact SIARE for information regarding authorised Service Centres in your area.
- When you require service, please indicate the serial number of the unit and the problem to SIARE or to your authorised technicians.
- SIARE assumes responsibility for all provisions foreseen by the law, if the equipment is used and maintained as per the instructions in this manual and the technical manual
- The Technical Assistance Report, signed by the authorised SIARE technician, is proof of the completion of the scheduled maintenance.

6.4.1 Maintenance operations

WARNING !! Risk of injury for the patient

Always refer to the instructions contained in the previous section: cleaning, disinfection and sterilization of the components.

The table summarizes the preventive maintenance frequency and procedures to be carried out on the lung ventilator.

Frequency	Component	Procedure / Action
Several times a day / according to local practice and standards	Patient circuit	Check for any water collection, drain and clean the tubes when necessary.
	Disposable bacteria filter	Replace.
	Condensation trap filter	Check for any water collection, drain and clean when necessary.

Frequency	Component	Procedure / Action
Every day / when necessary	Oxygen sensor	Calibrate according to the procedures described in this manual.
	Condensation trap filter	Check for any water collection, drain and clean when necessary.
	Lung ventilator	General cleaning and checks.
	Turbine air filter	
	EXP. V. Monoblock	Sterilize / disinfect according to the procedure described in this manual and according to local standards.
Every 2 weeks (at least)	Turbine air filter	Replace. Components that cannot be destroyed should be sterilized before disposal.
Every 6 months or 1000 working hours **(*)**	Lung ventilator	The lung ventilator must be inspected and checked in general and any worn parts must be replaced. Use the appropriate preventive maintenance kit.
	Oxygen sensor	Replace. The working life of the cell depends on the working environment. If the temperature or the O_2 % is high, the working life of the sensor will be lower.
	O_2 and Turbine air filter	Replace. Sterilize according to the procedure described in this manual and according to local standards. Components that cannot be destroyed should be sterilized before disposal.
	Patient circuit (silicone tubes)	
	Washers / O-Rings	
Every year **(*)**	Lung ventilator	Check the lung ventilator performance. This includes an electrical safety test and inspection of the lung ventilator for mechanical damage and legibility of the labels. The lung ventilator must also be inspected and checked in general and worn parts must be replaced, using the appropriate preventive maintenance kit. Use the appropriate preventive maintenance kit.

Frequency	Component	Procedure / Action
Every two years / when necessary	Internal battery	Replace. This operation must only be carried out by qualified technical personnel, according to the instructions contained in the relative service and maintenance manual. The working life of the battery depends on the working conditions and environment.

WARNING !! Risk of injury for the patient (*)

All maintenance and/or repair operations require perfect knowledge of the lung ventilator and must therefore only be carried out by highly qualified personnel, specifically trained and formally authorised by SIARE.

Inappropriate intervention or unauthorised modifications can compromise safety and cause danger to the patient.

CAUTION

To avoid damage to components due to excessive wear, carry out preventive maintenance and replace parts following the recommended frequency.

Turbine: estimated working life

The working life of the turbine depends on the working environment conditions, and on the regular maintenance effected on the device.

6.4.2 Cleaning, disinfection and sterilization before use with another patient

We recommend the use of procedures for sterilization and disinfection referred to in the preceding paragraphs when a new patient must use the lung ventilator.

WARNING !! Risk of injury for the patient

It is recommended to sterilize / disinfect the lung ventilator every time is used with another patient.

6.5 Repairs and spare parts

Use only original SIARE spare parts or spare parts checked and approved by SIARE.

6.5.1 Spare parts kit for lung ventilator

Code: R209000P1

Spare parts kit for annual maintenance to be used with the Falco 202 Evo (10.4”), **code 980104**.

Code: R209000CL

Battery kit to be used with the Falco 202 Evo (10.4”), **code 980104.**

6.6 Miscellaneous

6.6.1 Storage

If for any reason the lung ventilator is not used, we suggest leaving it in its original packaging and storing it in a safe and dry place.

If it is believed that the lung ventilator will be left unused for at least 6 months, Siare recommends disconnecting the battery or recharging it every 3/6 months, depending on the storage temperature.

See the technical sheet in the Appendix A.

6.6.2 Repackaging and shipment

If it is necessary to return the equipment to SIARE for any reason, we suggest using the original packaging to prevent damage to the equipment during shipment.

If this is no longer available, order a repackaging kit.

6.6.3 Disposal

Batteries, accumulators, oxygen cells and electronic parts in general:

- do not put them in the fire, explosion risk
- do not open them, corrosion danger
- do not recharge batteries
- do not throw them away with normal waste.

The batteries and the accumulators are special waste materials and they must be disposed of in appropriate containers in accordance with local regulations for the disposal of such waste materials.

The components of the electronic boards can contain compounds, such as arsenic, lead, cadmium, mutagenic and cancerogenous agents, that are a health hazard if dispersed in the environment in an uncontrolled way.

For further information contact the relevant authorities for environmental and public health monitoring.

A ANNEX

This chapter includes all the information and data necessary to provide full knowledge and interpretation of Falco 202 Evo (10.4”) lung ventilator.

A.1 Technical sheet

GENERAL DATA	
	FALCO 202 EVO 10” electronic lung ventilator is equipped with turbine and with a TFT 10,4” colour monitor touch screen displaying the curves of pressure, flow, volume, the loops of breathing parameters, the trends and the ventilation parameters. FALCO 202 EVO 10” lung ventilator is suitable for ventilation of adult, paediatric and neonatal patients. FALCO 202 EVO 10” lung ventilator is equipped with a flow generation system by turbine with separate cooling system granting higher quality and safety standards in patient ventilation. FALCO 202 EVO 10” is equipped with a flow and pressure trigger, it provides the most advanced volume-controlled ventilation modalities VC/VAC, VC/VAC-BABY, pressure-controlled ventilation modalities APCV (BILEVEL ST), APCV-TV, SIMV by Volume and by Pressure, Pressure supported modalities PSV (BILEVEL S), PSV-TV, CPAP, APRV, SIGH, Non-Invasive Ventilation (NIV APCV - NIV PSV), Drug Nebulizer and Manual Ventilation (MAN). FALCO 202 EVO 10” is supplied with back up long lasting batteries and its software can be updated for new modes and last generation ventilation strategies.
NORMS	
CE 0476	The lung ventilator is conform to the essential requirements and it is realized according to the references of the Annex II of 93/42/EEC Medical Devices Directive.
Class and type according to IEC 601-1	Class I Type B
Class according to 93/42 EEC Directive	Class IIb
Electromagnetic compatibility (EMC)	EN 60601-1-2: 2015 and following
Norms	DIR. 93/42/CEE (2007); EN 60601-1 :2006/A1 :2011/A1 :2013; EN 60601-1-2 :2015; IEC 601-1-6:2013; IEC 601-1-8:2012; EN 60601-2-12:2007; ISO 80601-2-12:2011; EN 62304:2006/AC:2008; ISO 10993-1:2009; IEC 62353:2014; ISO 15223-1:2016; DIR. 2011/65/CE; D.Lgs 49/2014; ISO 14971:2012; EN ISO 4135:2001

ENVIRONMENTAL CONDITIONS	
Operating	Relative humidity: 30 - 95% non-condensing Temperature: from +10 to +40°C
Storage	Relative humidity: < 95% Temperature: from -25 to +70°C

TECHNICAL DATA	
Dimensions (W x H x D)	290 x 245 x 215 mm
Weight	5,5 Kg
Electric power supply	100 - 240Vac / 50 - 60Hz
Power	Max 60 VA
External power supply (low tension)	12 Vdc / 7 A
Internal battery	Battery NiMh 12Vdc - 4.2 Ah
Internal battery operation	Max 4 hours
Battery re-charging time	About 10 hours
External electric connections	▪ RJ connector for O_2 cell connection ▪ RJ connector for Flow sensor connection
Electric external connections (optional)	▪ RS232 for CO_2 module ▪ USB 1 (connector for CPU programming) ▪ USB 2 (connector for transfer patient data, events, trends)
Patient connections	Male conic connectors 22 mm / Female of 15 mm (according to EN ISO 5356-1:2015 norm)
Supply pressure (O_2)	▪ Low pressure (max 15 l/min) ▪ High pressure 280 kPa - 600 kPa / 2.8 - 6 bar / 40 - 86 psi
Max flow requested (O_2)	80 l/min
IP degree of protection	IP21

LUNG VENTILATOR FUNCTIONAL FEATURES	
Use destination	FALCO 202 EVO is a lung ventilator for use in emergency rooms, transport, intensive care units and with patients affected by respiratory diseases and it is suitable for ventilation of adult, paediatric and neonatal patients.
Operation principle	• Time cycled at constant volume • Pressure cycled • Microprocessor controlled flow • Spontaneous breath with integrated valve
Pressure automatic compensation	Automatic compensation of atmospheric pressure on measured pressure: present (max. 5000 mt)
Dead space compensation	Automatic compensation of mechanical and patient circuit dead space
Automatic leaks compensation	Max 60 l/min (NIV APCV, NIV PSV)
Leak % visualization	Present
Visualization of the oxygen consumption calculation	Present
Altitude compensation for oxygen sensor	Present
Respiratory parameters default setting	Present (Neonatal, Paediatric, Adult)
Ventilation modalities	• APCV (BILEVEL ST), APCV-TV, PSV (BILEVEL S), PSV-TV (Auto Weaning), VC/VAC, VC/VAC BABY, V-SIMV+PS, P-SIMV+PS, CPAP, APRV • SIGH, NEB (Nebulizer), Apnea BACK-UP (PSV, PSV-TV, CPAP), MAN (Manual).
Breathing rate VC/VAC	From 4 to 150 bpm
Inspiratory Time / Expiratory Time (maximum, minimum)	• Ti min = 0.036sec (minimum inspiratory time) • Ti max = 9.6sec (maximum inspiratory time) • Te min = 0.08sec (minimum expiratory time) • Te max = 10.9sec (maximum expiratory time)
Breathing rate V-SIMV e P-SIMV	From 1 to 60 bpm

SIMV Inspiratory time	From 0.2 to 5.0 sec.
Tidal volume	• From 100 to 3000 ml (Adult) • From 50 to 400 ml (Paediatric) • From 2 to 100 ml (Neonatal)
I:E ratio	From 1:10 to 4:1
Inspiratory pause	From 0 to 60 % of the inspiratory time
Inspiratory pressure limit	Pinsp: from 2 to 80 cmH_2O (in function of low and high pressure alarm set)
Inspiratory ramp Slope	1, 2, 3, 4 (acceleration slope) - (4 max. acceleration) (in operative modes by pressure only)
PEEP	From OFF, 2 to 50 cmH_2O
PEEP adjustment	Microprocessor controlled valve
O_2 concentration	Adjustable from 21 to 100% with electronic integrated mixer.
Trigger detective method	Through sensor (Pressure or Flow)
Pressure trigger (I)	Pressure adjustable from OFF; -1 to -20 cmH_2O under PEEP level (step of 1 cmH_2O)
Flow trigger (I)	Flow adjustable from OFF; 0.3 to 15 L/min • from 0.3 to 1 L/min (step of 0.1 L/min) • from 1 L/min to 2 L/min (step of 0.5 L/min) • from 2 L/min to 15 L/min (step of 1 L/min)
Trigger E	From 5 to 90 % of the inspiratory flow peak
Inspiratory flow (FLOW)	190 l/min
Flow-by	Automatic
PS (pressure support)	From 2 to 80 cmH_2O (PSV, V-SIMV+PS, P-SIMV+PS)
SIGH in VC/VAC modality	• Interval: 40 ÷ 500 bpm (step 1 bpm) • Amplitude: OFF, 10 ÷ 100% of set Tidal Volume (step 10%)
CPAP	Pressure: from 3 to 50 cmH_2O
APRV	• Time High and Time Low: from 1 to 200 sec. • Pressure High and Pressure Low: from 3 to 50 cmH_2O.

Functions	• MENU function (SETUP – PATIENT DATA) • Alarms Limits • Graphics visualization (Auto-Range) • INSP Block - EXP Block (max 20 sec.) • O_2 100% control (O_2 to 100% max. 5 min.) • NEB control (6 l/min) • MAN control (manual ventilation)
NEB	Drug nebulizer: selectable to 6 l/min with automatic compensation on forced ventilation modes and dedicated output
Patient circuit	• Double hose 150 cm. Adult/Paediatric patient circuit (expiratory valve on the ventilator) • Double hose 150 cm. Neonatal patient circuit (expiratory valve on the ventilator)
Expandability	Software upgradeable
USER INTERFACE	
Touch screen monitor	Module with TFT LED display with touch screen
Dimensions	10,4”
Displaying area	262x163 mm
Display keyboard	Keyboard for rapid access of functions. Encoder knob for: • selection, set up and confirmation of physiological breathing parameters • selection and direct activation of function
Displaying and settings	• Operative Mode setting • Visualization of alarm messages and signals • Setting and monitoring of physiological breathing parameters • Visualization of additional graphs and breathing parameters • MENU function for setting operation parameters • Activation of special functions • Visualization of operative mode, clock, date and time functions • Visualization of software version

Calibration Programs	• Self Test • Turbine Characterization • Expiratory Flow Sensor Calibration • Usage at High Altitude • VTEc • Nebulizer Enable • ScreenShoot Enable
MENU function - SETUP	• Display *(Brightness, Energy Saving, Sound Volume, Touch Audio)* • Date & Time • Language • Units (Weight, Height, CO2, Pressure) • Default (Default parameters: Erase Trend data, Erase Patient data, Setting & Ventilation Default) • Other (NIV Enable, Power Failure, Apnea Time, Change Password, Save to USB) • IRMA/ISA (Gas Sensor) • Supplementary Tests (Expiratory Flow Sensor Calibration, O2 Sensor Calibration) • Turn Off?
MENU function - PATIENT DATA	The PATIENT DATA can be set or deleted
Alarm Limits	PAW (cmH_2O), PEEP (cmH_2O), Vte (ml), VM (L/min), O_2 (%), RR (bpm), $EtCO_2$ (%)
Displayed graphics	• CURVES: Pressure (PAW) - Flow - Volume (Vte) - O_2 (CO_2 optional) • LOOPS: Pressure / Volume - Flow / Volume - Pressure/Flow • Graphics: INSP-EXP cycle • Events • Trends
Events	Memory storage up to 100 machine events including the alarms.
Trends	Storage capacity (72 h) of all measured parameters.

Physiological breathing parameters setting	Vti (ml), RR (bpm), I:E, Pause (%), PEEP (cmH2O), O2 (%),Tr. I (L/min - cmH2O), SIGH (Sigh. Amp. (%), Sigh. Int. (b)), Vte (ml), PMax, Pmin, Pinsp (cmH2O), Slope, BACK-UP parameters, PS (cmH2O), RRsimv (bpm), Ti (s), Ti Max (s), Tr. E (%), CPAP (cmH2O), Pressure High - Low (cmH2O), Time High - Low (s).
Range of measured parameters	• Respiratory rate (range: 0 ÷ 200 bpm) • I:E ratio (range 1:99 ÷ 99:1) • % of O_2 (range: 0% ÷ 100%) • Tidal Volume: Vte, Vti (range: 0 ÷ 3000 ml) • Minute Volume (range: 0 ÷ 40 l/min) • *PAW: peak, mean, plateau, PEEP (range -20 ÷ 80 cmH2O)* • Inspiratory Peak Flow: Fi (range: 1 ÷ 190 l/min) • Expiratory Peak Flow: Fe (range: 1 ÷ 150 l/min) • Tinsp., Texp, Tpause (range 0.036 ÷ 10.9 sec) • Static and Dynamic compliance (range: 10 ÷ 150 ml/cmH_2O) • Resistance (range: 0 ÷ 400 cmH_2O/l/s) • EtCO_2: with optional CO_2 module (range: 0 ÷ 10%) • Leak (%) (range: 0 ÷ 100%) • O_2 consumption (range: 0 ÷ 100l/min)
Displayed parameters	PAW , PEEP, CPAP (cmH2O), RR (bpm), I:E, O2 (% - l/min), Vte (ml), VM (L/min), EtCO2 (%), MAP (cmH2O), Pplateau (cmH2O), Fi , Fe (L/min), Ti , Tpause, Te (sec.), Ri (cmH2O/l/s), Cs, Cd (ml/cmH2O), Leak (%)
Flow sensor	Magnetic disturbance (patented), multi-usage type
Calibration	Automatic (started by the operator)
Maintenance	By steam or chemical disinfection
Oxymeter	Electronic (value displayed in breathing parameters)
Calibration	Automatic (started by the Operator)
CO_2 analyzer	Optional function (Sidestream or Mainstream module available)

ALARMS	
Alarm types	• By MENU: with limits set by the operator • By DEFAULT: the operator cannot set them up
Alarm default setting	Present (Neonatal, Paediatric, Adult)
Alarm priority	High - Mean - Standby
Alarms visualization	Max 3 alarms simultaneously; additional alarms, scroll every 3-5 sec.

Alarms with limits set up by the operator	
Pressure of Airways	High – Low
Respiratory Rate	High – Low
Expiratory Volume	High – Low
Volume Minute	High – Low
PEEP	High – Low
O_2 Concentration	High – Low
$EtCO_2$	High – Low (with optional CO_2 gas analyser)
On Battery	Alarm occurs in case of failure of external power supply
Apnoea	Low Rate (function of Apnoea BACK-UP)

System alarms	
Low Battery: 50% Remaining	Battery at 50%
Low Battery: 25% Remaining	Battery at 25%
Low Battery	10 Minutes
Battery Disconnected	Yes / No
Battery Overtemperature	Indication of exceeding the temperature limits inside the battery
Circuit Disconnected	Indication of patient circuit disconnected
O_2 Supply	Low (< 2,7 bar)
Turbine Failure	Signals in case of a blower fault condition
Turbine Overtemperature	Indication of exceeding the temperature limits inside the turbine

Turbine Overcurrent	Indication of exceeding the current limits inside the turbine
Maintenance	1000 hours
CO_2 Analyzer	Sampling Line Clogged, No Sampling Line, Replace Adapter, No Adapter, Unspecified Accuracy, Error, No Breaths, Low/High EtCO_2.

SELF-TEST alarms

Turbine	The correct functioning of the turbine is tested
Oxygen emptying	It is performed a washing of the remaining oxygen present within the lung ventilator, order to measure the offset of the oxygen sensor
INSP.- EXP. Flow sensor	Verification of EXP flow sensor operation
Pressure sensor	Verification of pressure sensor operation through control of PAW reading
Electrovalve	The correct functioning of electro-valve is tested
Patient circuit	Verification of patient circuit
Battery	Checking on battery power
Oxygen sensor	Cell condition
Acoustic alarm	Verification by the user of acoustic signal emission, the confirmation of the test is made by silencing of that alarm

ACCESSORIES

Supplied Accessories

- User's Manual
- Double hose patient circuit
- Antibacterial filter for patient circuit
- Nebulizer set
- Power cable
- Vehicular cable for 12 Vdc
- O_2 supply hose
- O_2 cell

Optional Accessories *Refer to price list*

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A.2 Preliminary checks

See the table here below.

List of preliminary checks.

Ref.	Description	Measure	Result	Notes
1.	Lung Ventilator: ON/OFF switch		☐ Pos. ☐ Neg.	
2.	SELF TEST overcome		☐ Pos. ☐ Neg.	
3.	O2 sensor calibration (TEST)	_____ %	☐ Pos. ☐ Neg.	
4.	O2 - FiO2 alarm check		☐ Pos. ☐ Neg.	
5.			☐ Pos. ☐ Neg.	
OPERATIVE MODE : VC-VAC / Parameters MONITORING				
6.	Vti check: **500mv**		☐ Pos. ☐ Neg.	
7.	Rate check: **15**		☐ Pos. ☐ Neg.	
8.	I:E ratio check: **1:2**		☐ Pos. ☐ Neg.	
9.	PEEP check: (**5 – 10 cmH2O**)		☐ Pos. ☐ Neg.	
10.	PAUSE check: **50 %**		☐ Pos. ☐ Neg.	
11.	FiO2 check: **21%**		☐ Pos. ☐ Neg.	

	ALARM CHECKS			
12.	High / Low Pressure		☐ Pos. ☐ Neg.	
13.	High / Low Respiratory Rate		☐ Pos. ☐ Neg.	
14.	High / Low Expired Vte		☐ Pos. ☐ Neg.	
15.	High / Low Minute Volume		☐ Pos. ☐ Neg.	
16.	High / Low PEEP		☐ Pos. ☐ Neg.	
17.	High / Low FiO_2		☐ Pos. ☐ Neg.	
18.	Main power failure		☐ Pos. ☐ Neg.	
19.	Low O_2 Supply		☐ Pos. ☐ Neg.	
20.	Gas analyzer (option)		☐ Pos. ☐ Neg.	*(With optional CO_2 module)*
	RESPIRATORY PARAMETER CHECKS			
21.	Pmax		☐ Pos. ☐ Neg.	
22.	PEEP		☐ Pos. ☐ Neg.	
23.	RR (Respiratory Rate)		☐ Pos. ☐ Neg.	
24.	I:E		☐ Pos. ☐ Neg.	
25.	O_2 concentration		☐ Pos. ☐ Neg.	
26.	Vte (Expired Volume)		☐ Pos. ☐ Neg.	
27.	VM (Minute Volume)		☐ Pos. ☐ Neg.	
28.	Additional respiratory parameters		☐ Pos. ☐ Neg.	

A.3 IP classification

The IP Code, International Protection Marking, IEC standard 60529, sometimes interpreted as Ingress Protection Marking, classifies and rates the degree of protection provided against intrusion (body parts such as hands and fingers), dust, accidental contact, and water by mechanical casings and electrical enclosures. It is published by the International Electro technical Commission (IEC).

The equivalent European standard is EN 60529. This table shows what each digit or part of the IP code represents.

IP indication	First digit	Second digit	Third digit	Additional letter
	Solid particle protection	Liquid ingress protection	Mechanical impact resistance	Other protections
IP	Single numeral: 0 – 6	Single numeral: 0–9	Single numeral: 0 – 9	Single letter
Mandatory	Mandatory	Mandatory	No longer used	Optional

A.3.1 First digit: solid particle protection

The first digit indicates the level of protection that the enclosure provides against access to hazardous parts (e.g., electrical conductors, moving parts) and the ingress of solid foreign objects.

Level sized	Effective against	Description
0	—	No protection against contact and ingress of objects
1	>50 mm	Any large surface of the body, such as the back of a hand, but no protection against deliberate contact with a body part
2	>12.5 mm	Fingers or similar objects
3	>2.5 mm	Tools, thick wires, etc.
4	>1 mm	Most wires, slender screws, large ants etc.
5	Dust protected	Ingress of dust is not entirely prevented, but it must not enter in sufficient quantity to interfere with the satisfactory operation of the equipment.
6	Dust tight	No ingress of dust; complete protection against contact (dust tight). A vacuum must be applied. Test duration of up to 8 hours based on air flow.

A.3.2 Second digit: liquid ingress protection

The second digit indicates the level of protection that the enclosure provides against harmful ingress of water. The ratings for water ingress are not cumulative beyond IPX6.

A device which is compliant with IPX7, covering immersion in water, need not be compliant with IPX5 or IPX6, covering exposure to water jets.

A device which meets both tests is indicated by listing both tests separated by a slash, e.g. IPX5 / IPX7.

Level	Protection against	Effective against	Details
0	None	—	—
1	Dripping water	Dripping water (vertically falling drops) shall have no harmful effect on the specimen when mounted in an upright position onto a turntable and rotated at 1 RPM.	Test duration: 10 minutes. Water equivalent to 1 mm rainfall per minute.
2	Dripping water when tilted at 15°	Vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle of 15° from its normal position. A total of four positions are tested within two axes.	Test duration: 2.5 minutes for every direction of tilt (10 minutes total). Water equivalent to 3 mm rainfall per minute.
3	Spraying water	Water falling as a spray at any angle up to 60° from the vertical shall have no harmful effect, utilizing either: a) An oscillating fixture, or b) A spray nozzle with a counterbalanced shield. Test a) is conducted for 5 minutes, then repeated with the specimen rotated horizontally by 90° for the second 5-minute test. Test b) is conducted (with shield in place) for 5 minutes minimum.	For a spray nozzle: Test duration: 1 minute per square meter for at least 5 minutes Water volume: 10 litres per minute Pressure: 50–150 kPa For an oscillating tube: Test duration: 10 minutes Water Volume: 0.07 l/min per hole

Level	Protection against	Effective against	Details
4	Splashing of water	Water splashing against the enclosure from any direction shall have no harmful effect, utilizing either: a) An oscillating fixture, or b) A spray nozzle with no shield. Test a) is conducted for 10 minutes. Test b) is conducted (without shield) for 5 minutes minimum.	Oscillating tube: Test duration: 10 minutes, or spray nozzle (same as IPX3 spray nozzle with the shield removed).
5	Water jets	Water projected by a nozzle (6.3 mm) against enclosure from any direction shall have no harmful effects.	Test duration: 1 minute per square meter for at least 15 minutes Water volume: 12.5 litres per minute Pressure: 30 kPa at distance of 3 m
6	Powerful water jets	Water projected in powerful jets (12.5 mm nozzle) against the enclosure from any direction shall have no harmful effects.	Test duration: 1 minute per square meter for at least 3 minutes Water volume: 100 litres per minute Pressure: 100 kPa at distance of 3 m
6K	Powerful water jets with increased pressure	Water projected in powerful jets (6.3 mm nozzle) against the enclosure from any direction, under elevated pressure, shall have no harmful effects. Found in DIN 40050, and not IEC 60529.	Test duration: at least 3 minutes Water volume: 75 litres per minute Pressure: 1000 kPa at distance of 3 m
7	Immersion, up to 1 m depth	Ingress of water in harmful quantity shall not be possible when the enclosure is immersed in water under defined conditions of pressure and time (up to 1 m of submersion).	Test duration: 30 minutes - ref IEC 60529, table 8. Tested with the lowest point of the enclosure 1000 mm below the surface of the water, or the highest point 150 mm below the surface, whichever is deeper.

Level	Protection against	Effective against	Details
8	Immersion, 1 m or more depth	The equipment is suitable for continuous immersion in water under conditions which shall be specified by the manufacturer. However, with certain types of equipment, it can mean that water can enter but only in such a manner that it produces no harmful effects. The test depth and duration is expected to be greater than the requirements for IPx7, and other environmental effects may be added, such as temperature cycling before immersion.	Test duration: Agreement with Manufacturer. Depth specified by manufacturer, generally up to 3 m.
9K	Powerful high temperature water jets	Protected against close-range high pressure, high temperature spray downs. Smaller specimens rotate slowly on a turntable, from 4 specific angles. Larger specimens are mounted upright, no turntable required, and are tested freehand for at least 3 minutes at distance of 0.15–0.2 m. There are specific requirements for the nozzle used for the testing. This test is identified as IPx9 in IEC 60529.	Test duration: 30 seconds in each of 4 angles (2 minutes total) Water volume: 14–16 litres per minute Pressure: 8–10 MPa (80–100 bar) at distance of 0.10–0.15 m Water temperature: 80 °C

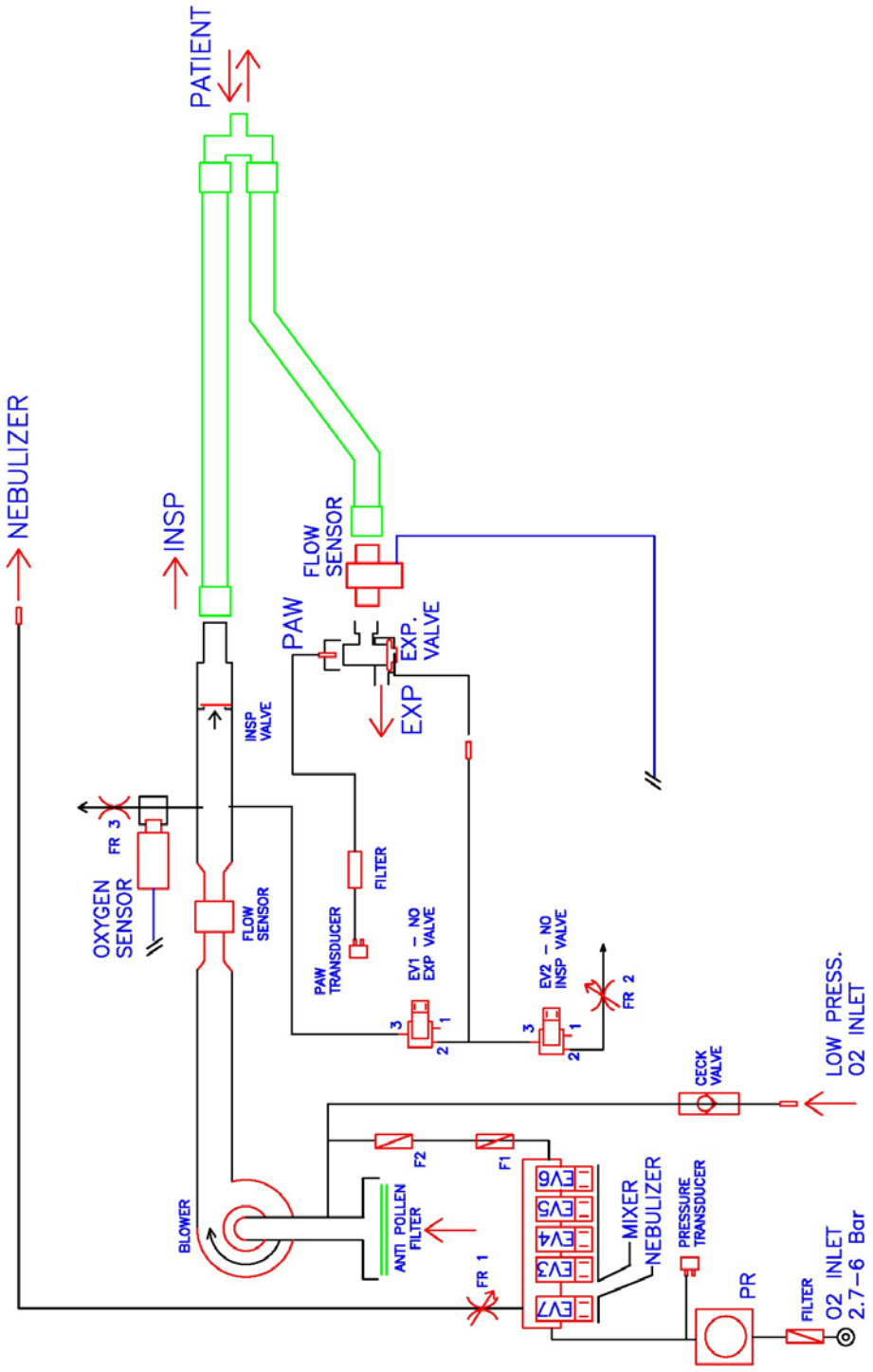
(All tests with the letter "K" are defined by ISO 20653 (replacing DIN 40050-9) and are not found in IEC 60529, except for IPx9 which is the same as the IP69K water test.)

A.3.3 Additional letters

Further letters can be appended to provide additional information related to the protection of the device.

Letter	Meaning
f	Oil resistant
H	High voltage device
M	Device moving during water test
S	Device standing still during water test
W	Weather conditions

A.4 Pneumatic diagram



A.4.1 Pneumatic diagram legend

O_2 (2,7 - 6 Bar)	Inlet for medical oxygen coming from an high pressure source (2,7 – 6 bar).
Filter	Medical gas infeed filter
PR	Pressure regulator. It reduces the infeed gas pressure at a stable value of 2.6 bar.
Pressure transducer	Medical gas supply pressure sensor. It signals when the gas pressure is missing or is insufficient.
MIXER	Group of 4 electro-valves, that opening and closing, allow the mixing of O_2 with Air at a frequency corresponding to the O_2 concentration set.
Blower	The turbine is driven by a brushless motor and it has the function to administrate the room air to the patient, once opportunely filtered by a dust and pollen filter at inlet. The turbine rotation speed is regulated by a microprocessor control.
Oxygen sensor	Polarographic oxygen transducer. It measures the real oxygen concentration administered to the patient.
Flow sensor	It has the function to measure the flows of Air and O_2 administered to the patient. The measuring range of such a sensor is from 0.1 to 200 l/min.
INSP valve	Unidirectional mechanical valve positioned on the inspiratory line. It has the function to allow the patient to breathe room air in case of emergency and to protect the turbine against backflows on inspiratory line.
PAW pressure transducer	Pressure sensor by semi-conductor. It has the function to continuously measure the inner pressure of breathing circuit.
EXP valve	Expiratory valve servo-controlled by the EV1-NA and EV2-NA electro-valves, it is closed during the inspiratory phase and it is open during the expiratory phase.
EV1-NA	12 V pilot electro-valve, normally open, controlled by microprocessor, it is closed when the PEEP value is set on 0 or in case the high pressure alarm limit is reached.
EV2-NA	12 V pilot electro-valve, normally open, controlled by microprocessor, it has the function to regulate the necessary flow to drive the expiratory valve.

A.5 Glossary

A	Ampere (current intensity measurement unit)
Alarm message	A message which appears together with an alarm indication; this consists of a basic message indicating the type of alarm.
Alarm silencing or suspension key	Key that stops the acoustic alarm signal for a software value preset by the last pressing of the key.
Apnea	End of ventilation. The ventilation system indicates apnea and starts the corresponding ventilation when the interval between the two respiratory cycles exceeds the set apnoea time.
Automatic alarm resetting	This occurs when an alarm is disabled, i.e. when the alarm conditions are no longer present, without pressing the alarm reset key. ALARM RESET
Basic flow	Constant flow (depending on the sensitivity value set in the “trigger value” parameter) circulating in the patient circuit with respect to which the ventilator measures the Flow Trigger value.
CE	A certificate of origin issued by the European Economic Community indicating that the equipment conforms to the Medical Device Directive (MDD), 93/42/EEC.
Clinical alarm	An alarm that can indicate an abnormal physiological condition
cm	Centimetre (unit of length).
cmH_2O	Centimetres of water (unit of pressure = 0.98068 mbar = 1 hPa).
Compliance (Cs)	This term defines the variation in volume of the respiratory tract determined by a variation in pressure; it is measured in ml/cmH_2O. It provides an indication of the elastic properties of the respiratory system and its components (Inspiratory Tidal Volume / Pause Pressure).
Compressor	The Compressor (optional) provides the system with compressed air and can be used instead of the mains or cylinder supply of compressed air.
CPU	Central processing unit
DISS	Diameter Index Safety Standard: a standard for high pressure gas input connectors.
EMC	Electromagnetic Compatibility

EN	European norm referring to the European Economic Community
Error	Category of conditions detected during functioning of the system implying an open safety status. A fan FAILURE means that the fan cannot be clinically used and must be repaired immediately.
EXP. PAUSE	Expiratory pause, a manoeuvre started by the User which closes the inspiratory and expiratory valves during the expiratory phase of a breath.
FiO_2	Parameter set by the User and monitored. The % setting of FiO_2 determines the percentage of oxygen in the gas delivered to the patient. The monitored data of the % of FiO_2 indicate the percentage of oxygen delivered to the patient, measured on the inspiratory line.
Flow Trigger	Method of recognition of the inspiratory effort of the patient, during which the ventilator controls the basic flow circulating in the patient circuit. An inspiratory attempt by the patient is translated into a decrease of the basic flow, which the ventilator recognizes as a spontaneous breath and delivers a synchronized breath.
GUI	Graphics user interface, the part of the ventilator which comprises the screen, the keys and the knob. The GUI is equipped with an independent CPU which monitors the data of the ventilator and the patient. The screen displays the monitored information, including the alarms, the monitored parameters, the graphs, the ventilator settings and the messages.
High priority alarm	As defined by the international standards organizations, this is an alarm which requires immediate intervention to ensure the safety of the patient. During a high priority alarm, the corresponding red signal flashes rapidly, a high priority acoustic alarm signal is emitted (a series of five tones repeated twice, followed by a pause, then repeated again) and an alarm message is displayed in the upper part of the screen.
hPa	Hectopascal (unit of pressure, approximately equal to 1 cmH_2O).
Hz	Hertz (unit of measurement of frequency, indicating cycles per second).
I:E ratio	The ratio between inspiratory time and expiratory time
IEC	International Electro-technical Commission: international organization for the definition of standards.

INSP. PAUSE	Inspiratory pause, a manoeuvre started by the User which closes the inspiratory and expiratory valves during the inspiratory phase of a breath. This manoeuvre can be used to determine the static compliance (C) and the resistance (R).
ISO	International Standards Organization
kg	Kilogramme (unit of weight).
L	Litre (unit of volume).
L/min	Litres per minute (unit of flow).
Loop	Parameter-based curve with respect to time
Low priority alarms	As defined by the international standards organizations, this is an alarm that indicates a change in the patient-ventilator system. During a low priority alarm, the corresponding yellow signal lights up and an alarm message is displayed in the upper part of the screen.
m	Meter (unit of length).
Maintenance	All the operations necessary to maintain the equipment in working order or to carry out cleaning, maintenance, repairs, modifications, revisions and performance checks.
MAN	If the MANUAL key is pressed in PSV mode, the system delivers pressure controlled ventilation to the patient.
MAP	Indication of the mean airways pressure
Medium priority alarm	As defined by the international standards organizations, this is an abnormal condition which requires immediate intervention to ensure the safety of the patient. During a medium priority alarm, the corresponding yellow signal flashes. A medium priority acoustic alarm signal is emitted (a repeated series of three tones) and an alarm message is displayed in the upper part of the screen.
min	Minute (unit of time).
Minute Volume	Expired tidal volume normalized to the unit of time (L/min). The system estimates the total minute volume on a 60 second basis or on previous ventilations, whichever is the shorter. The value displayed includes the compensation for compliance.

mL	Millilitre (unit of volume).
Mode	Ventilation mode; an algorithm which determines the type and sequence of ventilation: the system offers a series of possible choices, including assisted, spontaneous or synchronized ventilation.
ms	Millisecond (unit of time).
NIST	Non-interchangeable screw thread: standard for high pressure gas inlet connectors.
Patient circuit	All the inspiratory-expiratory conduits, including the tubes, the humidifier and the filters (when foreseen).
PAW	Measured airways pressure
PEEP	Positive end expiratory pressure: the minimum level of pressure maintained in the patient circuit during ventilation. Parameter set by the User and monitored.
Pressure Trigger	Method of recognition of the inspiratory effort of the patient, in which the ventilator controls the pressure in the patient circuit. The ventilator enables ventilation when the airways pressure decreases by an amount at least equal to the selected threshold value in a defined period of time.
RAM	Random access memory
Resistance (Ri)	The drop in pressure caused by a flow passing through a conduit: measured in cmH_2O/(litres/sec) or hPa/(litres/sec).(peak pressure - pause pressure / inspiratory flow).
sec	Second (unit of time).
STAND BY	Ventilation system in pause status: no ventilation is enabled when the ventilator is in this status.
System error	Definition used by the safety system of the ventilator. System errors include faults of the hardware inside the ventilator and which affect its performance, software errors which occur momentarily inside the ventilator and interfere with its normal functioning, an inadequate supply of alternate current or gas and the problems of integrity of the patient circuit (block or disconnection). In general system errors are not corrected automatically
T Exp	Expiratory time: duration of the expiratory interval of a breath.

T Insp	Inspiratory time: duration of the inspiratory interval of a breath.
T pause	Pause time: percentage of inspiratory time during which the ventilator maintains a constant airways pressure. Used for calculation of the respiratory mechanics parameters (compliance and resistance).
Tidal volume	Inspired and expired tidal volume during each breath. The value delivered by the system is a parameter set by the User which determines the volume delivered to the patient during controlled volume ventilation. Tidal volume includes the compensation for compliance and for pressure and body temperature.
TREND	Medium and long-term monitoring of the respiratory parameters.
VA	Volt -Ampere (unit of power).
Vac	Alternate current voltage
VC-VAC	Intermitted ventilation by assisted positive pressure: a ventilation mode which allows to deliver controlled ventilations only (started by the patient, by the ventilator or by User) basing on current settings.
Vdc	Direct current voltage
Ventilations per minute (bpm)	Respiratory rate unit (Resp/min).

A.6 EMC tables - Guidance and manufacturer’s declaration

A.6.1 Table 1

Emissions		
Emissions test	**Conformity**	**Electromagnetic environment – guidance**
RF Emissions Cispr 11	Group 1	The appliance uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions Cispr 11	Class B	The appliance is suitable for use in all establishments, included domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A Conforms	It is possible to use the device in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Conforms	

A.6.2 Table 2

Immunity aspects			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**Test level EN 60601-1-2**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) EN 61000-4-2	± 6 Kv contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Burst/Fast transient EN 61000-4-4	± 2 kV power supply lines	± 2 kV power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycles 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 seconds	<5 % UT (>95 % dip in UT) for 0,5 cycles 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field EN 61000-4-8	3 A/m	3 A/m	Magnetic power frequency fields should be that of a typical commercial or hospital environment.

A.6.3 Table 3

<table>
<tr><th colspan="4">Immunity aspects at R.F.</th></tr>
<tr><td colspan="4">The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>Test level
EN 60601-1-2</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF conducted
EN 61000-4-6</td><td>3 Veff from 150kHz to 80MHz</td><td>3 Veff from 150kHz to 80MHz</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
d = 1,2 ·√P from 150kHz to 80MHz
d = 1,2 √P from 80 MHz to 800 MHz
d = 2,3 √P from 800 MHz to 2,5 GHz
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m)</td></tr>
<tr><td>RF Radiated
IEC 61000-4-3</td><td>3 Veff from 80MHz to 2,5 GHz</td><td>3 Veff from 80MHz to 2,5 GHz</td></tr>
<tr><td colspan="4">Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
</table>

A.6.4 Table 4

Recommended separation distances between portable and mobile RF communications equipment and the device.

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	From 150kHz to 80MHz **$d = 1{,}2 \cdot \sqrt{P}$**	From 80MHz to 800MHz **$d = 1{,}2 \cdot \sqrt{P}$**	From 800MHz to 2GHz **$d = 2{,}3 \cdot \sqrt{P}$**
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes:

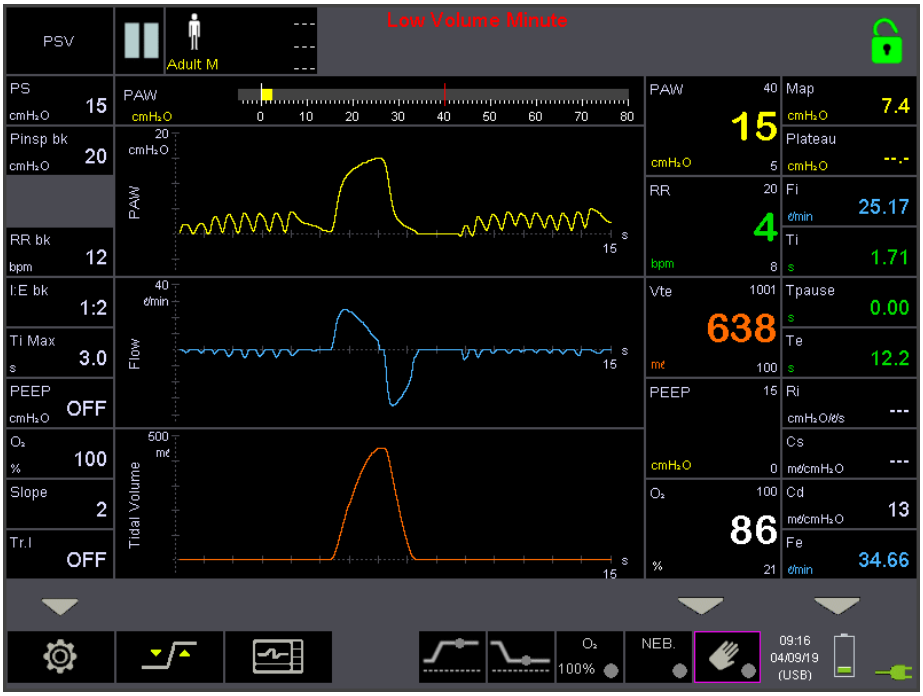
At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

B APENDIX

This chapter contains all the information and data to set the **CPR MODE** on the Falco 202 Evo 10.4

STEP	
1.	In the Setting Menu it brings the apnea alarm at least 40 sec.
2.	Select the PSV mode and adjust the following parameters • PS: **20** cmH2O or other preferred value • PEEP: **OFF** • FiO2: **100%** or other preferred value • Trigger: **OFF**
3.	Press the MAN key on the screen to obtain forced inflation after each cycle of chest compressions

EXAMPLE	
Example of ventilator screen during **CPR Mode**	

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Falco 202 Evo - 10.4”

Portable Lung Ventilator

Turbine-driven ventilation

Touch Screen

User’s Manual - 980104

version DU3104101

Revision - 01.02.2019

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