ENGINEERING
INTERNATIONAL GROUP s.r.l.

Falco 202

Lung ventilator

turbine-driven ventilation

User manual

GENERAL INFORMATION

The information contained in this manual are the exclusive property of SIARE Engineering International Group s.r.l. and may not be reproduced in any way without authorisation. SIARE Engineering International Group s.r.l. reserves the right to modify or replace this manual at any time without prior notice.

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 lung ventilator must be entrusted to qualified technical personnel only. The responsibility of SIARE Engineering International Group s.r.l. concerning the Falco 202 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 lung ventilator produced or updated after April 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 DU3222102

Revision 2- 18.04.2019

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 operator.

CAUTION

This indicates the possibility of danger to the ventilator.

NOTE

This indicates information worthy of note, making the operation of the Falco 202 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 lung ventilator (*hereinafter called ventilator*) and the relative safety regulations.

- In order to understand how the 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 operator's safety, the 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 ventilator must only be used for the purposes specified herein and the safety of the ventilator is therefore only guaranteed if it is used in accordance with the instructions given in this manual.
- The 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 ventilator is installed. Furthermore, during all the operation of 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 ventilator or authorised modifications to the 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 operator and the nearby environment.
- For any repairs to 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 ventilator in a safe and correct manner.
- To prevent the risk of fire, keep the 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 ventilator to the patient by flexible connectors, and antistatic or conductive tubes to prevent patient burnings during the use of high frequency surgical equipment, specially dangerous with antistatic tubes. The use of flexible connectors, antistatic or conductive tube is never permitted with 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 easy 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 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 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 ventilator is installed be taken into consideration.
- The 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 ventilator or any connected component, carefully check that the 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 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 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 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 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 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 ventilator is not approved for operation in places where there is any risk of explosion.
- Do not use the ventilator in the presence of flammable gases.

WARNING !!

The ventilator cannot be used in the presence of explosive gases.

WARNING !!

Before starting the ventilator use, you have to carry out the preliminary checks.

WARNING !!

Before connecting the ventilator to other electrical equipment not described in this manual, a request for authorisation should be sent to Siare.

WARNING !!

Qualified staff must make the regulation of ventilation parameters.

WARNING !!

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

WARNING !!

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

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

- If the ventilator is used in conditions and for purposes not stated or described in this manual.
- If the 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 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 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 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 is 10 years.

Manufacturer

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Electromagnetic Compatibility

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

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

The 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 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 ventilator could influence its operation. Whenever the 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 ventilator manual.

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

Table of contents

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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 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 Foreseen use

The Falco 202 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 can be used on Adult, Paediatric; it has been conceived for home care and transport use.

The Falco 202 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 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 both for the clinician and for the patient.

The Falco 202 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 lung ventilators Falco 202 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 operator 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: high performance home 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: APCV, APCV-TV, PSV, PSV-TV (Auto Weaning), VC/VAC, V-SIMV+PS, P-SIMV+PS, CPAP, SIGH, Apnea BACK-UP, NIV PSV, NIV PSV-TV, CPAP, Manual Ventilation (MAN).
- Adult, paediatric ventilation, thanks to an adjustable Tidal Volume from 50 ml to 3000 ml.
- After the device switching-on the device, it is possible to choice the patient type (adult, paediatric) setting the relevant default parameters.
- In spontaneous ventilation mode, it ensures inspiratory flow up to 170 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 9” LED display and graphic interface

- New high resolution display with easy and user friendly graphical interface.
- Five graphs displayed simultaneously.
    - P-t; V-t; F-t
    - One loop (up to three available loops: P-V; P-F; F-V)
    - Additional breathing parameters
    - CO_2 graphic (gas analyzer optional)
- Leaks percentage visualization (Leak: %).
- Display 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 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.

1.3 Main technical characteristics

1.3.1 Graphic user interface (GUI)

The graphic user interface (**GUI**) includes: a led 9" 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:

- the operatives mode
- the 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)
- the function MENU for setting operation parameters
- the 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 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);
- correctly connected to all accessories and equipment necessary for the operation of the lung ventilator;
- if requested, connected O_2 inlet at low pressure.

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

The Falco 202 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-optional), used to measure the concentration of oxygen in the gas inspired by the patient.

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 has been designed and made to guarantee 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 of Falco 202

The use of Falco 202 lung ventilator is simple and intuitive for the persons familiarised with resuscitation ventilators, a short training course is in enough to learn how to use it.

A basic user interface: keyboard, encoder knob and a 9” display that simplifies the selection of the most suitable settings.

The 9” screen displays the 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 operator to set the patient type (neonates, children, adults), load or erase the PATIENT DATA and in case of needs, load automatically the DEFAULT PARAMETERS of the lung ventilator.

1.5 Norms and standards regulations

The Falco 202 lung ventilator is made in accordance with the following norms (and following updates) and it is manufactured according to UNI EN ISO 13485:2004 standards.

EN 60601-1:2006/ A1:2011/ A1:2013

Medical electrical equipment - Part 1: General requirements for safety.

EN 60601-1-2:2015	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. 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 60601-1-11:2015	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
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 14971:2012	Medical devices. Application of risk management to medical devices
EN ISO 4135:2001	Anaesthetic and respiratory equipment - Vocabulary.
DIR. 93/42/EEC	Medical devices directive.
DIR. 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).

2 DESCRIPTION

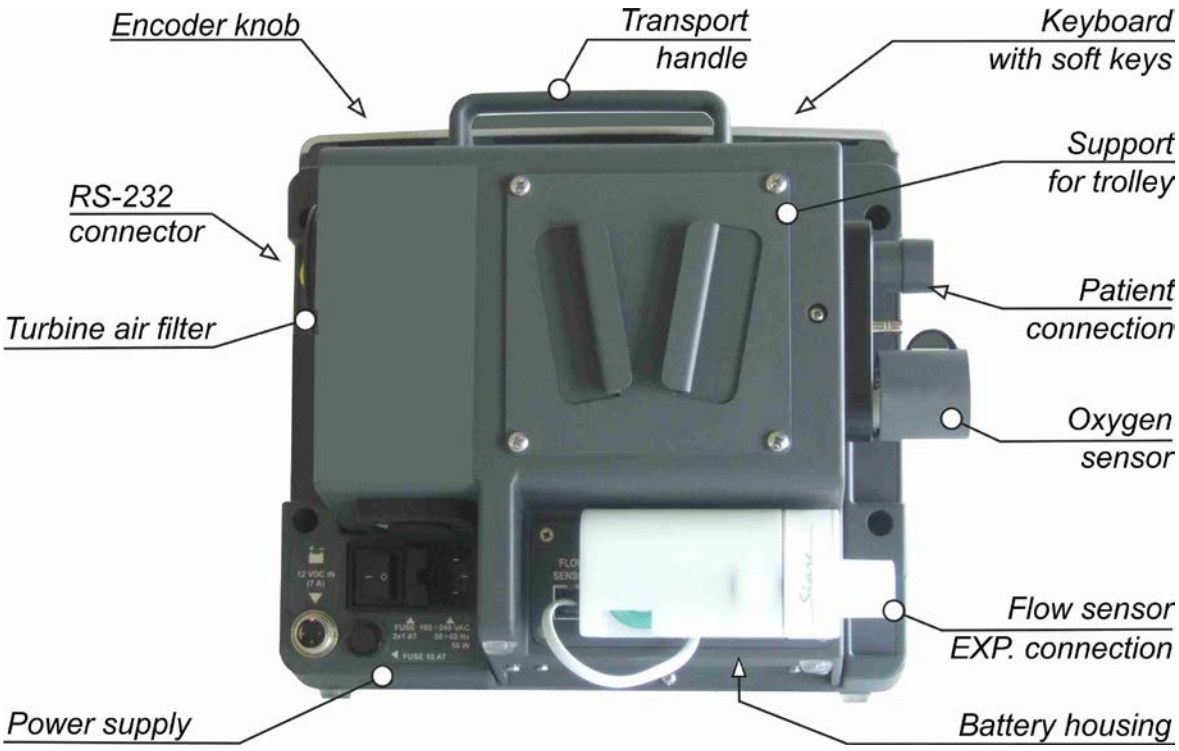
This section of the user manual features the main parts and components of the Falco 202 lung ventilator for Intensive Care, Emergency and Transport (hereinafter called ventilator) and some of its most used functionalities.

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

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

Falco 202: front view (code 980222)

Falco 202 - rear view



see 2.1 Side view

see 2.2 Power supply area

see 2.3 Pneumatic area (low O_2 pressure)

see 2.4 Patient connections

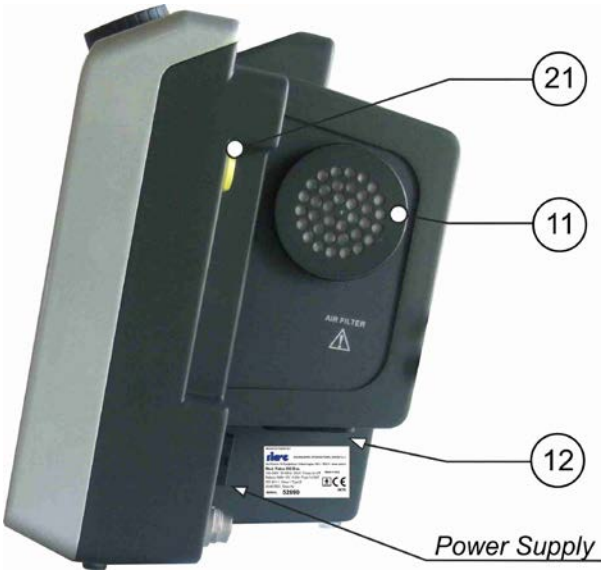
see 2.5 Keyboard with soft keys and encoder knob

see 2.6 9” LED display

see 2.7 Main Menu

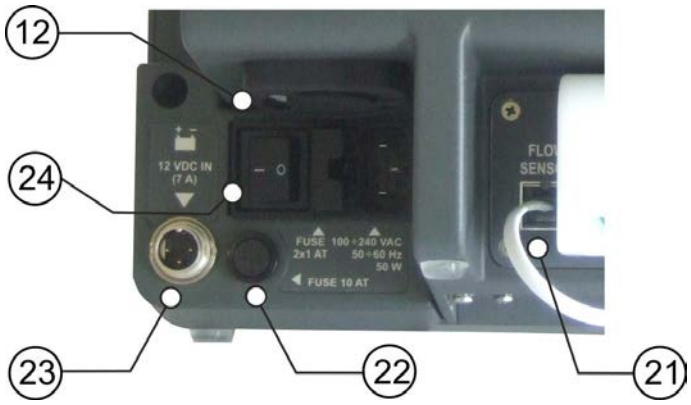
For more information please refer to the paragraphs highlighted on the side.

2.1 Side view



11	**AIR FILTER** : turbine air filter
	O_2 connection (see next chapter)
12	Air intake
21	**RS-232 connector** (ODU connector) : CO_2 sensor connection or Trend and Events downloading
	Electric power supply (please, refer to next paragraph)

2.2 Power supply area



21 **FLOW SENSOR** : RJ connector for flow sensor connection

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 specified above.

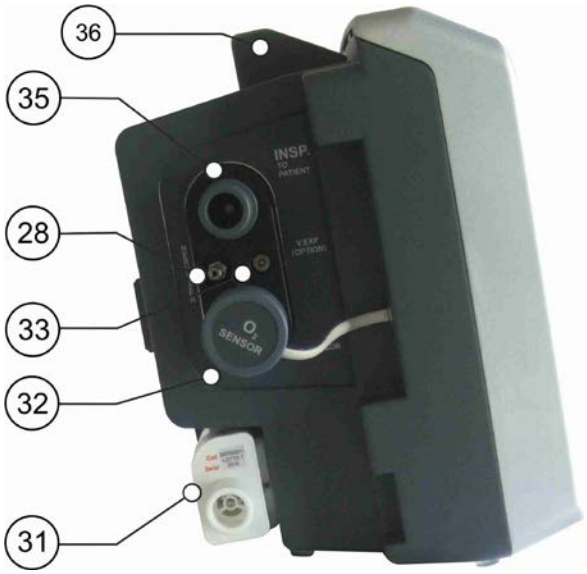
An external battery used as power source for the functioning of the Falco 202 become integral part of this medical system.

24

- **I / O** : 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

2.3 Patient connections



31 **FLOW SENSOR** : flow sensor placed on expiratory patient line

32 **O2 SENSOR** : mechanical guard for O2 sensor electrical connection (optional)

33 **V.EXP** (option) : unused fitting

28 **O2 (LOW PRESSURE)** : medical oxygen connection from a low pressure source

WARNING !!

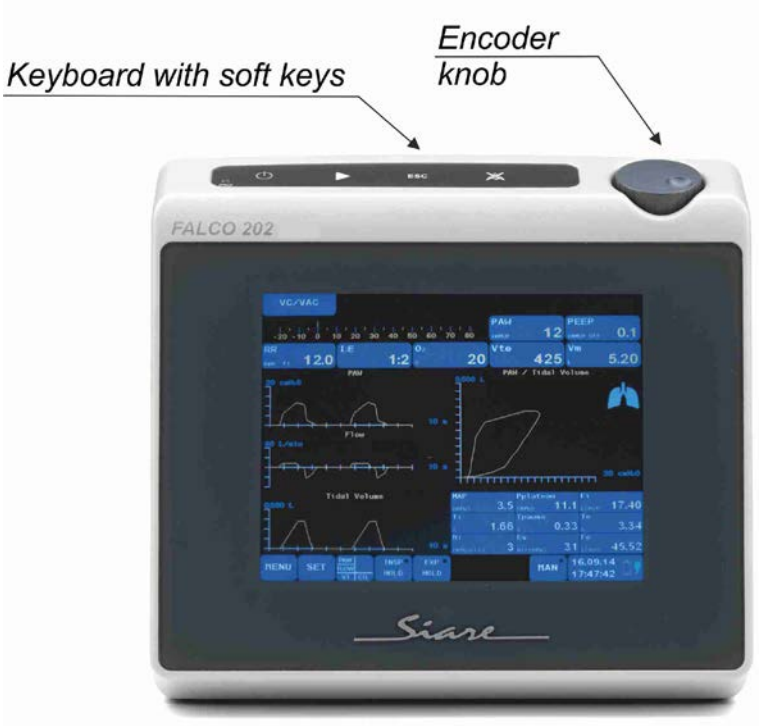
LOW PRESSURE : low O2 pressure source, max flow 15 l/min.

35 **INSP. TO PATIENT** : inhalation fitting for patient circuit

36 Transport handle

2.4 Keyboard with soft keys and encoder knob

A control keyboard and an encoder knob are available on the upper side of the ventilator. These components allow quick and easy use of the Falco 202 lung ventilator (referred to from now on as ventilator).



2.4.1 Encoder knob : use

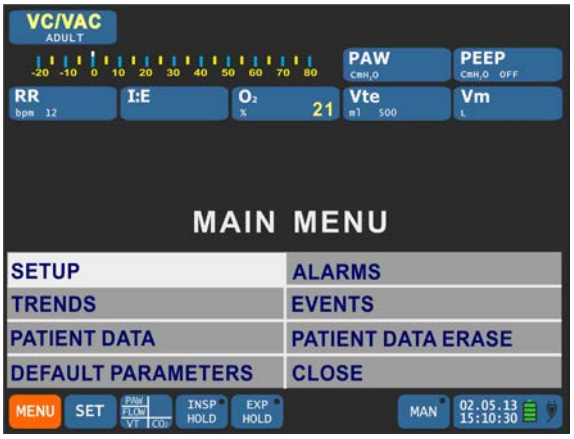
ENCODER KNOB

The encoder knob is a multifunctional tool: it is used for selecting and editing all ventilator functions.

Ventilator in **STAND-BY**: press the encoder knob to activate the SET function (it changes color).

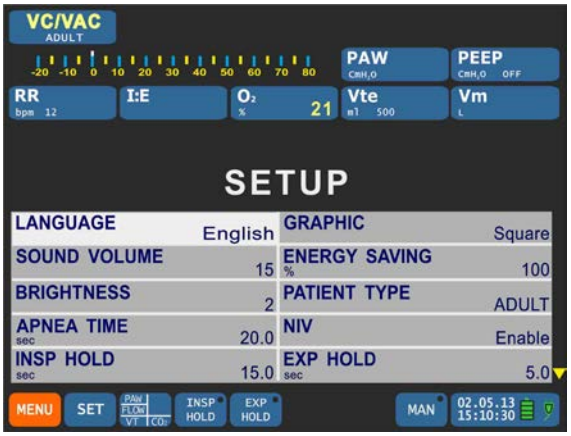
Turn clockwise or anti-clockwise to select the desired box (item) : e.g. **MENU** (changes color).

Press the knob to confirm (the box **MENU** changes color); you will see the **MAIN MENU** page at SETUP option.



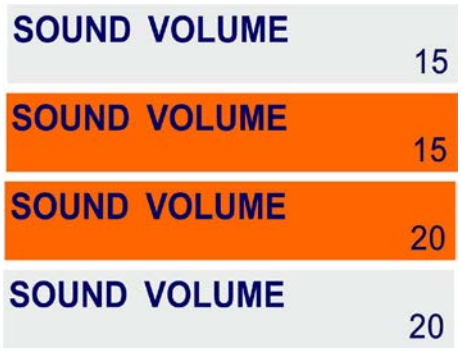
- SETUP function activated (box in different color).

- Press the knob; you will see the SETUP parameters page at the **LANGUAGE** item.



- LANGUAGE function activated (box in different color).

- Turn clockwise or anti-clockwise to select the desired box (item) : e.g. **SOUND VOLUME** (the box changes color).



- **SOUND VOLUME** function activated: used to change the level of the VOLUME parameter (from 15 to 20); press the knob (the box changes color).
- Turn it clockwise (anticlockwise) to increase (decrease) the parameter value (from 15 to 20).
- Press the knob to confirm the changes made to the **SOUND VOLUME** parameter (20); the box changes color.

If you do not press the encoder knob within 60 sec. after selecting the parameter (or the value you want to change), the ventilator will restore the parameter value (value that you want to change), as it was before selecting it.

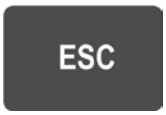
- In order to edit other parameters: turn the encoder knob clockwise (anticlockwise).
- Press the ESC soft keys to go back to STAND-BY display.
- The system automatically returns to STAND-BY or ventilator operation display.

2.4.2 Soft keys: use

ALARM RESET

Press this key to silence the acoustic warning of an active alarm.

After removing the alarm cause, press this key once again to cancel the visual warning displayed on the screen.



ESC

Press this key to exit the “current” screen and return to the “previous” one.

START - ENTER

Press this key to start the ventilation in the pre-set mode, using the physiological respiratory parameters set by the clinician.

ON/OFF

Press the ON/OFF key to start and stop the ventilator. To access the ventilator, press the ON/OFF key. After a few seconds, on the screen will appear a series of messages indicating that the system entered the “SELF-TEST” mode ; this phase will take a few minutes.

At the end of this procedure, push START to begin, the system goes to STAND-BY mode, ready to ventilate the patient. To turn the ventilator off, hold the ON/OFF key for few seconds and then confirm the action.

The system features a turn off delay that helps you prevent any accidental ventilator deactivation during operation.

Mains voltage presence indicator

If the led is on (green color), it means that the lung ventilator is powered from the mains.

2.5 9” LED display

On the front side of Falco 202 lung ventilator for Intensive Care, Emergency and Transport (referred to from now on as ventilator) is a 9” LED display that will show all information necessary for patient ventilation.

The main featured information are: operating mode selection, respiratory parameters setup and display, visual and acoustic alarm warnings.

Use the control keyboard and the encoder knob on the top of the ventilator to interact directly with the display: this system is defined as GUI (graphical user interface).

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

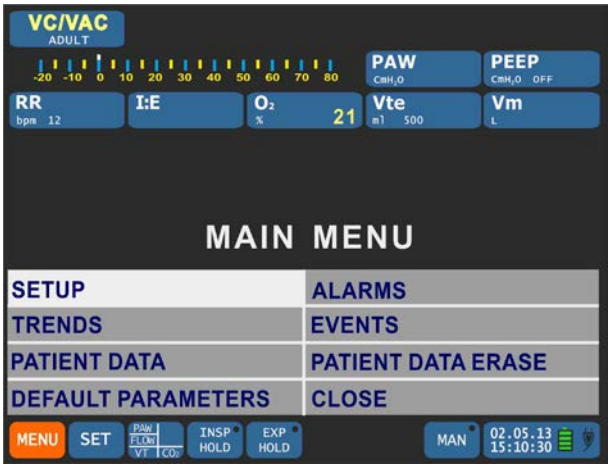
You can see in the figure below how the GUI is divided into monitoring areas, parameters setup areas and alarm display areas.

2.5.1 Operative functions and graphic setting

The basic commands and functions of the ventilator are displayed and can be selected from the bottom of the screen (GUI), using the encoder knob (please see 2.5.1).

MENU

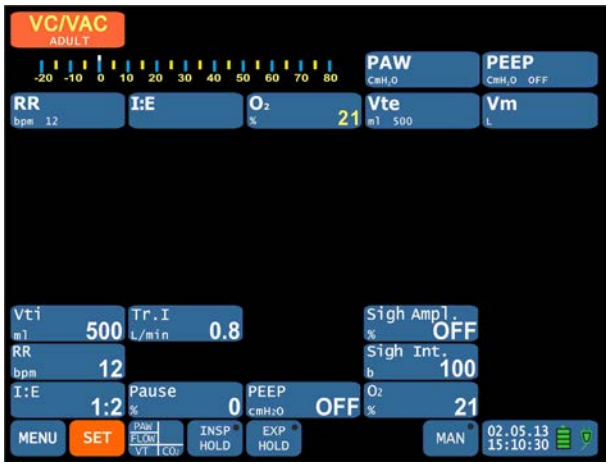
Select the **MENU** function to view the **MAIN MENU** (please see 2.7).



SET

Select the **SET** function to view/edit the operating mode and all the relative physiological respiratory parameters (**PRP**).

*(**SET** function: please refer to the note on the following page).*



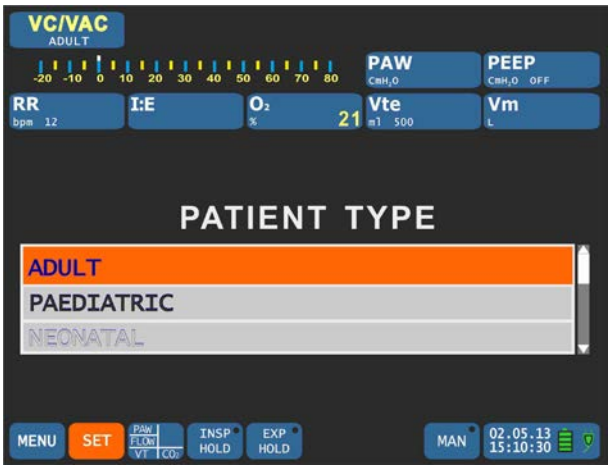
When the ventilator is switched-on, selecting **SET** function it is possible to choice the PATIENT TYPE (ADULT, PAEDIATRIC).

The choice of the patient type set automatically the default functioning parameters of the lung ventilator (breathing parameters and alarms levels).

SET

Function **SET : first selection**

The **SET** function permits to show/modify the patient type choice (ADULT, PAEDIATRIC).



NOTE : SET function

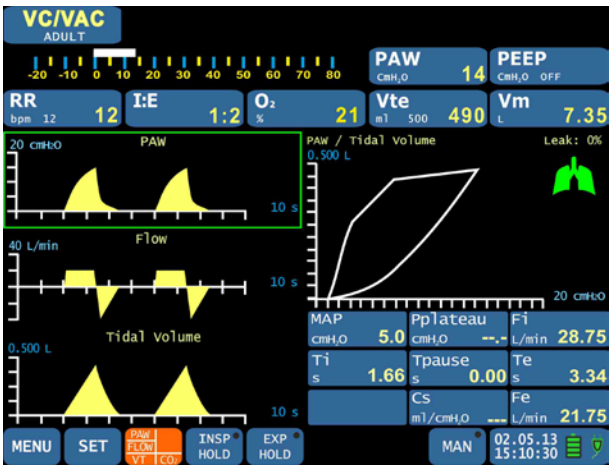
The choice of the patient type permits then to show/modify the breathing physiological parameters (**PRP**) referred to the current Operative Mode.

SET function : for more informations please refer to cfr 4.

PAW FLOW VT CO2

Use the **GRAPHIC** function to select and edit the curves, the loops, additional respiratory parameters position and which loops and curves should be showed on the screen (please see 2.6.5 or 4.10).

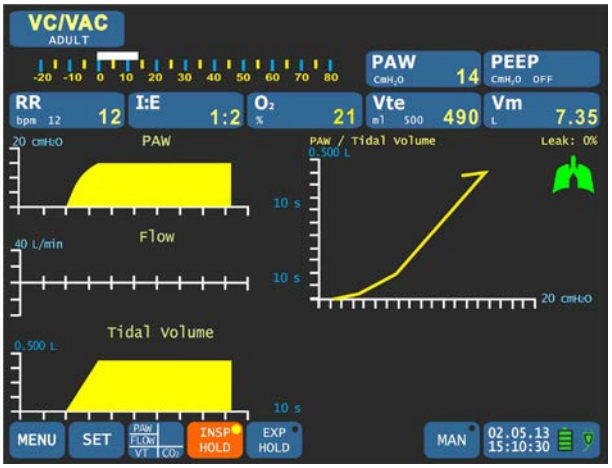
By enabling this function you can also see the additional respiratory parameters (if necessary).



This function is available only when the ventilation is active; please see 4.10.

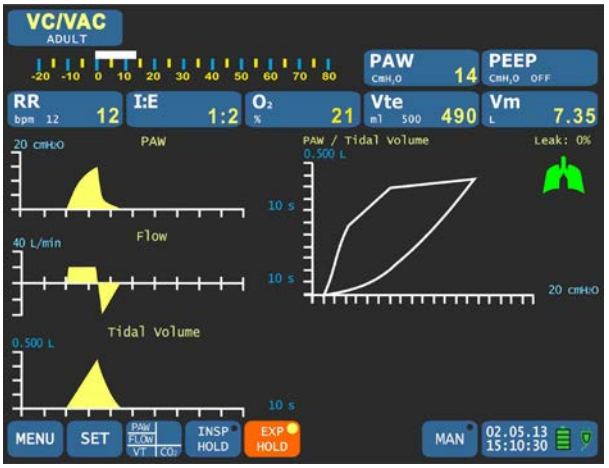
“**Forced inspiration hold**” function.

By activating this function, the system will extend the inspiration time, from 5 up to 15 seconds.



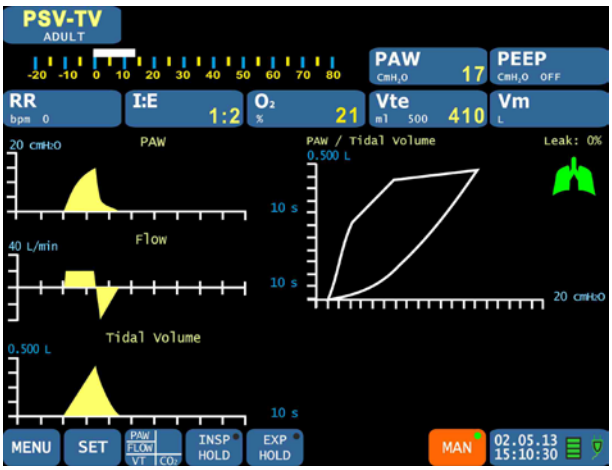
“**Forced expiration hold**” function.

By activating this function, the system will extend the expiration time from 5 up to 10 seconds.



“**Manual**” breathing function.

By activating this function, the clinician can force manually a breathing act to the patient.



- Date (dd/mm/yy).
- Time.
- 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).

General information

General information: please see 5.1.4.

2.5.2 Respiratory parameters monitoring

- Based on the ventilator parameters set by the clinician 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 are updated after each breath of the patient.

The data in the images below refer to VC/VAC operating mode with standard PRP, and they are only informative, they do not refer to real clinical cases.

The light bar indicator (with scale from -20 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.

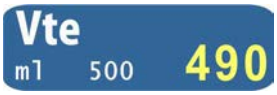
The clinician can control if the ventilator is able to reach and keep the PEEP pressure level set, using this value.

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.

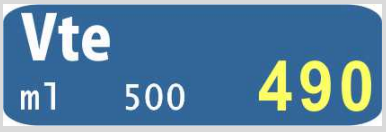


It shows the current volume value during patient's expiratory phase: the unit of measurement is ml. The value is detected by the flow sensor installed on the expiratory line.

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 rate (RR).

Key



Vte : respiratory parameter

ml : unit of measurement

500 : value set by the clinician

490 : measured value

The lung icon simulates the patient's lungs, graphically displaying the respiratory cycle by alternatively switching the lungs color (please see 2.6.6).

2.5.3 Operative mode

The ventilator includes the most modern ventilation modes: volume controlled ventilation, pressure controlled ventilation, pressure supported, non invasive ventilation and manual ventilation.

You can select one of these ventilation modes using the **SET** function (please see cfr. 2.5.1 or cfr. 2.7).

NIV 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.

NIV PSV Assisted pressure support ventilation with assured respiratory rate set by the clinician (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 clinician (Apnea Back-Up).

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

Volume-targeted synchronised intermittent mandatory ventilation.

Pressure-targeted synchronised intermittent mandatory ventilation.

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

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

The displayed parameters can also be set based on the patient conditions, by simply activating the function **SET**.

Below the Operative Mode acronym, the PATIENT TYPE set is specified (**ADULT, PAEDIATRIC**).

In this way the default respiratory parameters are set automatically (breathing parameters and alarms levels).

Default Parameters: please refer to cfr. 4.12.2 and cfr. 5.2.4.

Assisted pressure controlled ventilation, synchronised with **ADULT** patient's breathing and with assured current volume.

Assisted pressure controlled ventilation, synchronised with **PAEDIATRIC** patient's breathing and with assured current volume.

2.5.4 Alarm signals area

The 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 clinician to the event as well as to inform him on the requested response speed.

For more details and information on alarms operation, please see chapter 5 Alarms.

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

- text string referring to the active alarm
- “alarm bell” symbol indicating the alarm priority and status.

You can edit the alarm settings (**SET - MENU - ALARMS**) even when they are active.

After editing the alarm settings, the relative signal will remain active and the status icon will blink for a pre-set time.

ALARM SILENCING

- Press the ALARM 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.
- Press the ALARM 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

Alarms silencing. The clinician should not interrupt patient control during alarms silencing period.

2.5.5 Graphic area

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

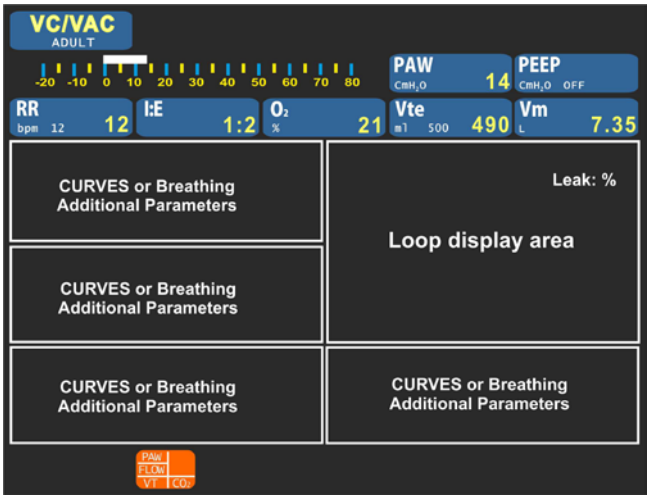
The graphics function allows you to view the patient's data in real time, by means of:

- PAW (Pressure) / Time curve - Flow / Time curve - Volume / Time curve
- PAW (Pressure) / Current Volume Loop - Current Volume / Flow Loop - PAW (Pressure) / Flow Loop
- Leak: %
- Oxygen consumption calculation (L/min)

The User can **choose 4 different areas** available on the display to place:

- CURVES (Pressure - Flow - Volume - CO_2)
- Breathing Additional Parameters

While only one area is available for the LOOPS.



To change the combination of curves displayed, the ventilation must be started.

ESC

Press **ESC** to exit from "**Graphic**" function.

Leak: %

The measured Leak value should be adequate to the active ventilation type (volumetric or pressometric) and within the tolerances of the local norms.

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% .

2.5.6 Graphic view : lungs icon

The lung ventilator is equipped with tools for detecting and monitoring the breathing phases. A suitable lung icon simulates the patient's lungs, graphically displaying the respiratory cycle by alternatively switching the lungs color.

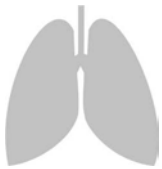
The lung icon is particularly meaningful for quick patient breathing monitoring.

In fact in case of patient's spontaneous activity (Trigger), the lung 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 “Low Pressure” limit value is not exceeded, the lungs icon turns red.

WARNING! Patient injury hazard

If the “Low Pressure” alarm value set is not exceeded, the lungs icon turns red and after about 15 seconds, the system activates the low pressure alarm.

2.5.7 Additional respiratory parameters

Based on the ventilator parameters set by the clinician 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 clinician can use the “Graphic” function (please see 2.6.5) to define a display area for a series of additional respiratory parameters.

The data in the images below refer to VC/VAC operating mode with standard PRP, and they are only informative, they do not refer to real clinical cases (please see 4.8.15).

It shows the average calculated pressure for the airways: the unit of measurement is cmH2O.

It shows the plateau pressure: the unit of measurement is cmH2O.

The flow sensor installed on the inspiratory line measures the maximum inhaled flow value (measured in L/min) and the value is displayed on the screen.

It shows the duration of the patient's inspiratory phase: the unit of measurement is second.

It shows the duration of the patient's inspiratory standby phase: the unit of measurement is second

It shows the duration of the patient's expiratory phase: the unit of measurement is second.

It is one of the two parameters of the lung mechanics: measured in ml/cmH2O.

The flow sensor installed on the expiratory line measures the exhaled flow peak (measured in L/min) and the value is displayed on the screen.

2.5.8 General informations

This area mainly displays two types of information:

- the battery level and the mains power supply status (present / missing)
- date (*dd.mm.yy*) and time .

- Indication of set hour (dd.mm.yy)
- Indication of set date (hh.mm.ss)
- Battery level indication
- Mains power supply status indication (please see cfr. 5)

The date and time can be set using the encoder knob.

For the keyboard with soft keys and encoder knob methodology of use, please see chapter 2.5.

2.6 MAIN MENU

The **MENU function** is one of the most important GUI functions: in fact it allows the clinician to access the **MAIN MENU** area to set the basic functions for proper ventilator operation.

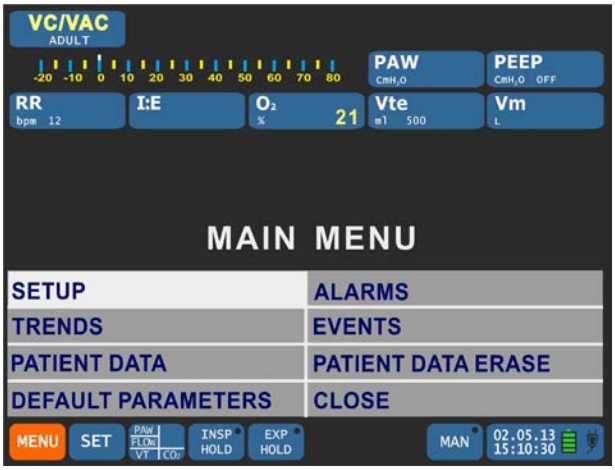
Before using the Falco 202 lung ventilator for Intensive Care, Emergency and Transport, please use the **MENU function** to set all necessary items for proper ventilator operation.

Use the encoder knob to select the **MENU** function and view the **MAIN MENU**.

- Ventilator in STAND-BY: press the encoder knob to activate the SET function (it changes color).

- Turn clockwise or anti-clockwise to select the desired box (item) : e.g. **MENU** (changes color).

- Press the knob to confirm (the box **MENU** changes color); you will see the **MAIN MENU** page at SETUP option.



- **SETUP** function activated (box in different color).

SETUP

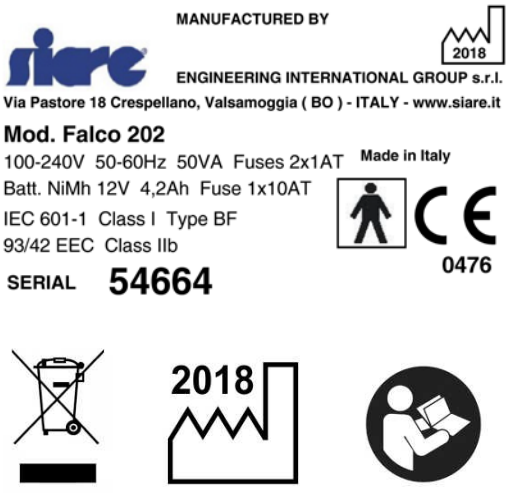
For more information on the **MAIN MENU** and on the available parameters (**SETUP**), please see cfr. 4 Ventilator Use.

SETUP	▪ LANGUAGE ▪ GRAPHIC ▪ SOUND VOLUME ▪ ENERGY SAVING ▪ BRIGHTNESS ▪ PATIENT TYPE ▪ APNEA TIME ▪ NIV ▪ INSP HOLD ▪ EXP HOLD ▪ GAS SENSOR CO2 UNITS (inactive parameter) ▪ PASSWORD (inactive parameter) ▪ TCP SETTING (inactive parameter) ▪ TECHNICAL CONTACT ▪ COLORS ▪ TESTS ON DEMAND ▪ GAS SENSOR (inactive parameter) ▪ CLOSE
ALARMS	Please see ALARMS chapter (please see 5).
TRENDS	The clinician can check the medium, long-term trend of the most important respiratory parameters: Vte - FR - PAW - PEEP - Vm (please see cfr. 4.11.3).
EVENTS	The clinician can check the ventilator's operation in terms of time; the system displays information on the system operation and the alarms activated during patient ventilation (please see cfr. 4.11.4).
PATIENT DATA	The clinician can set the patient data at the beginning of the ventilation (please see cfr. 4.5).
PATIENT DATA ERASE	The clinician can delete the previous data before a new ventilation (please see cfr. 4.6).
DEFAULT PARAMETERS	The clinician can restore the default parameters: factory set (please see cfr. 4.11.7).
CLOSE	Back to MAIN MENU.

2.7 Product identification label

The product identification label mentions the following information.

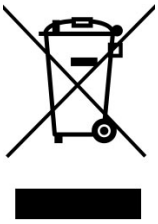
- Manufacturer
- Model name
- Main power supply
- Battery's features
- Fuses features
- Regulation (CE mark)
- Serial number
- Symbols (see description)



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

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.

3 PREPARATION FOR USE

The first section of this chapter describes the installation procedures for the Falco 202 lung ventilator for Intensive Care, Emergency and Transport (hereinafter called ventilator); the second section highlights the preliminary checks to be carried out before using Falco 202.

If this is the first time you install the ventilator, please read this user manual carefully.

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

3.1 General warnings

UNPACKING

Properly unpack the device.

Please keep the original packaging as to avoid damaging the ventilator if you have to introduce it once again in the production plant.

TRANSPORT – Changing the ventilator's location

Move the ventilator using the suitable handle.

- Place the ventilator on a flat surface or on the fastening screws delivered along with the device: make sure that the ventilator cannot move accidentally during operation.

WARNING !! Personal injury - physical hazard

If handled incorrectly, the ventilator might tip over causing physical personal injuries to patients and/or operators.

WARNING !! Accidental moving hazard

If the ventilator is not suitably placed, it might move accidentally during operation.

Place the ventilator on a flat surface.

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 ventilator when it is on or powered.

WARNING !! Patient/clinician injury hazard

Before using it, carry out all necessary preliminary checks relative to the lung ventilator.

WARNING !! Patient injury hazard

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

3.2 Before use

3.2.1 Mounting the O2 sensor (optional)

WARNING !! Operator injury hazard.

To avoid electric shock risk and/or components parts breakage during interventions, please make sure that the 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 ventilator's dedicated socket [connector FiO_2].

WARNING !! Patient injury hazard

When the ventilator is on, the system carries out a series of checks, such as including the O_2 sensor connection (“SELF TEST” phase see cfr. 4.2.1).

3.2.2 Battery recharge

- The 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 ventilator automatically switches on battery operation: an alarm will be displayed on the ventilator's screen, along with the message " POWER SUPPLY FAULT ".
- The battery can be recharged connecting the ventilator to the mains (100 - 240 Vac or 12Vdc supply).

BATTERY RECHARGE

If this is the first time you use the ventilator, charge up the battery for at least 24 hours (the 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.

BATTERY LIFE

The battery operation time varies as follows:

- old battery or not fully efficient
- unusual ventilator parameters.

- Insert the power supply cable plug (100 - 240 Vac) supplied with the device to the plug placed on the back of the 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 ventilator) to "**I**".

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

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

3.3 Preparation for use

3.3.1 Connection to power supply

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

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

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 device.
- the electric plug used should be equipped with a lock in order to prevent erroneous placements in wrong plugs without ground.

There are three types of power supplies available on the 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 .

- Insert the power supply cable plug (100 - 240 Vac) supplied with the device to the plug placed on the back of the 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 ventilator) to "**I**".

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

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.

- The lung ventilator complies with the requirements for electro-medical devices detailed on chapter 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.

Low voltage power supply

A proper connector for low voltage power supply line (12Vdc / 7A) is placed on the ventilator rear side.

- Insert the 12Vdc power supply cable plug to the plug placed on the back of the ventilator.

Battery power supply

- There should always be a battery installed inside the ventilator.
- If there is no battery, the ventilator is not protected against voltage drops or mains power supply cut off.
- The 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 ventilator to replace the batteries or to carry out maintenance operations on the same battery charger.

BATTERY LIFE

The battery operation time varies as follows: old battery or not fully efficient, unusual 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 “ key placed on the front side of the ventilator.

BATTERY RECHARGE. Please refer to chapter 3.2.2

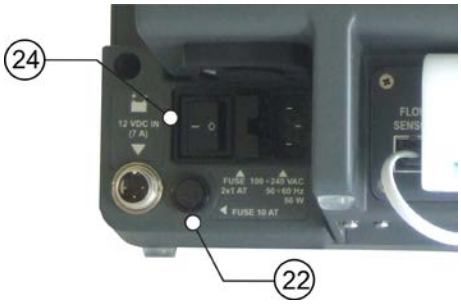
POWER SUPPLY

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

3.3.2 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 ventilator's integrity and safety.

3.3.3 Patient circuit connection

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

	Current volume	*Tubes set*
Use a patient circuit suitable for the patient you want to treat.	*from 50 to 200 mL*	*paediatric*
	> 210 mL	*adults*

3.3.4 Use of antibacterial filters

Use antibacterial filters on patient circuit.

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.

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 ventilator.

WARNING !! Strangulation hazard.

Pay utmost attention when connecting the patient to the ventilator.

If not carefully placed, the tubes, cables, the patient circuit and other similar components installed on the 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.

3.3.5 Data Connection (Trend and Events downloading)

Connect the interface cable to the ODU connector (RS-232) and to a PC serial port.

A dedicated software permits the download and the analysis of the data stored in the lung ventilator.

3.3.6 Five wheels support

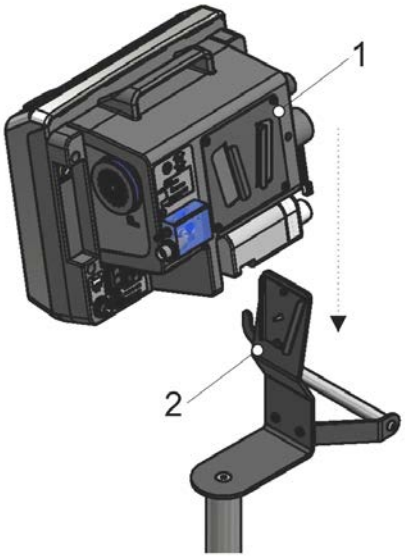
Assembly the trolley using the instructions supplied with the trolley.

CAUTION

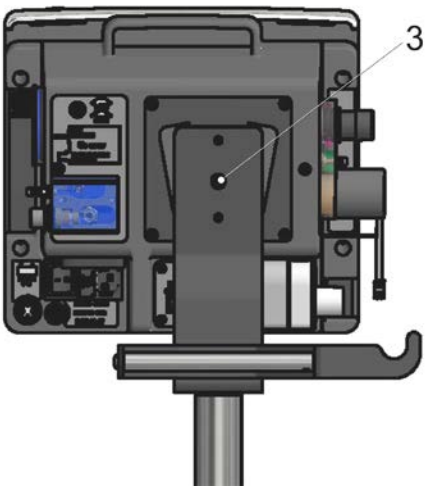
Before positioning the ventilator, be sure that the trolley has been properly mounted, that the screws and bolts are well tighten and that the wheels move properly.

- Put the brakes on the trolley.
- Raise and position the ventilator on the female guide of the trolley.

Note: *the support plate on the ventilator (* 1 *) should slide inside the female guide of the trolley up to the end.*



- Well tight the knob (3) to lock the ventilator support plate to the female guide of the trolley.



3.3.7 Connection of other devices

Connection of Siare devices

In order to connect to the 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 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 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 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 chapter 1.5 (Norms and standards regulations).

3.4 Lung ventilator use

In order to get the best performance, leave the ventilator ON for at least 15 minutes before carrying out the preliminary checks.

This operation will allow the system to reach optimal spirometry conditions.

3.4.1 Highlights

Before using the ventilator on a patient, you have to carry out a series of preliminary checks to make sure that it works properly.

The purpose of the preliminary checks is to make sure that the ventilator and all its components are properly connected and operative.

You can find the list and description of the preliminary checks at the end of this chapter, or the list in **Appendix chapter**.

The preliminary checks should be carried out:

- every time you start and use the ventilator
- every time you replace or connect an important component (patient circuit, oxygen sensor, flow sensor, etc….)

Before proceeding with the preliminary checks, the ventilator must be:

- ready for use: please refer to Maintenance chapter (cleaning, disinfection and sterilisation)
- properly placed
- equipped with all accessories and devices necessary for its operation
- connected to the medical gas (O_2, if necessary) and electrical power supply
- connected to a patient simulator at the provided patient circuit terminal.

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

WARNING !! Explosion and/or fire hazard

Do not use the ventilator if you detect any suspect oxygen leaks from the 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.

Accidental moving hazard.

If the ventilator is not suitably placed, it might move accidentally 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 ventilator condition (please see Maintenance).

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

WARNING !! Patient/clinician injury hazard

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

WARNING !! Serious patient injuries

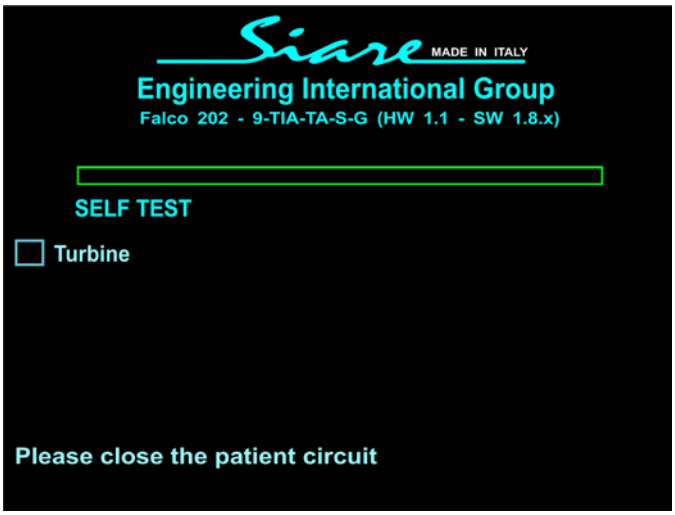
All figures and examples featured in this chapter are purely informative and do not refer to real clinical cases.

3.4.2 Ventilator switch-on / “ SELF TEST “ phase

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

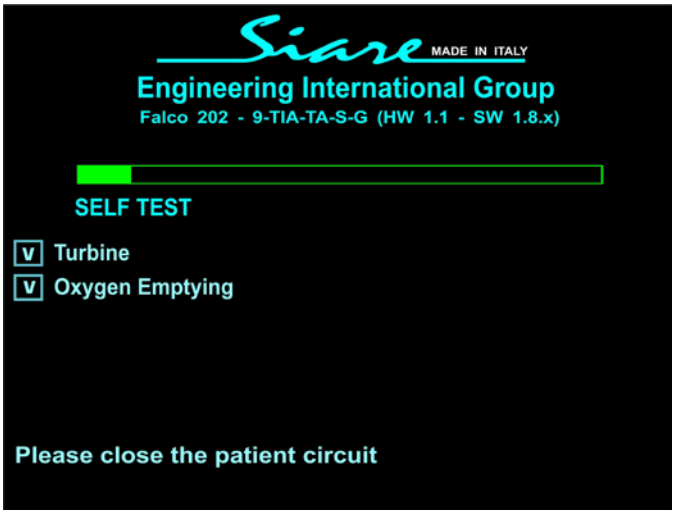
- Hold the ON-OFF key for few seconds to start the ventilator.

“ **SELF TEST** “ phase. Close the patient circuit.



The ventilator turns on and the automatic “ SELF TEST “ phase begins.

- Turbine functioning check and status.



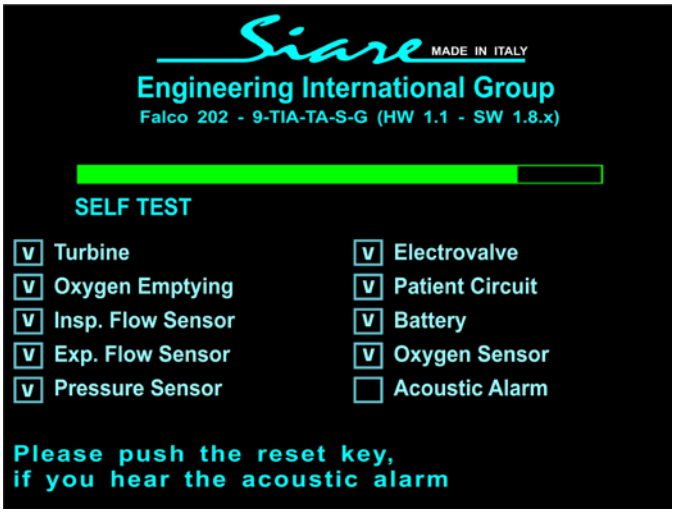
- The system pull out the O_2 in excess in the device in order to calibrate the 21% O_2 concentration in a proper way.

During **“ SELF TEST “ phase**, the ventilator software carries out the self-diagnostic tests and checks a series of devices necessary for safe ventilator operation.

“ SELF TEST “ : self-diagnostic tests list

• Turbine functioning check and status.	**Turbine**
• During this test phase the system provide to 21% calibration of the oxygen sensor.	**Oxygen Emptying**
• Check the operation of the Inspiratory Flow sensor.	**Insp. Flow Sensor**
• Check the operation of the Expiratory Flow sensor.	**Exp. Flow Sensor**
• Check the operation of the pressure sensor by checking PAW reading.	**Pressure Sensor**
• Expiratory electro-valve functioning check.	**Electrovalve**
• This test verify the patient circuit connection checking the presence of pressure in the circuit opening and closing the expiratory valve.	**Patient Circuit**
• Check the battery voltage value.	**Battery**
• Check the electric connection and the calibration of the O_2 sensor (voltage delivered by the O_2 sensor at 21%: value between 9 to 14ml).	**Oxygen sensor**
• The clinician should check if the system generates the acoustic signal, he can confirm the test by silencing the alarm.	**Acoustic Alarm**

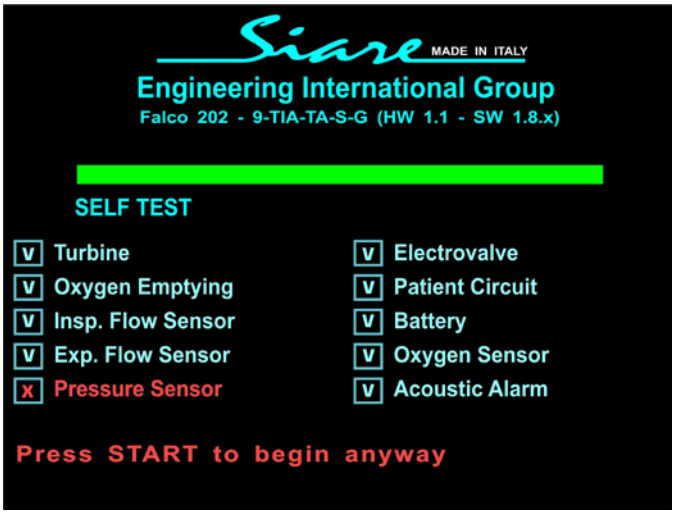
For a more correct and detailed analysis of the issues arising during “ SELF TEST “ phase, please consult the Service Manual.



- The “ SELF TEST “ phase completed successfully.

Acoustic alarm operation check.

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

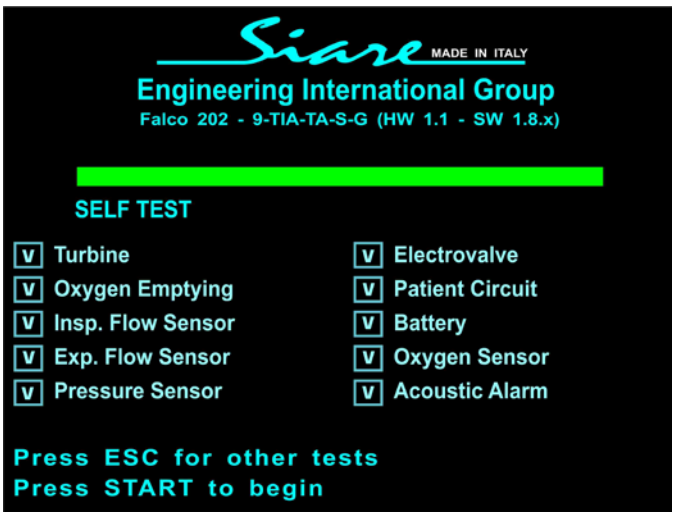


- The “ SELF TEST “ phase did not complete successfully.

WARNING !! Patient/clinician injury hazard

The “ SELF TEST “ phase did not complete successfully. Please see chapter 5 and contact the nearest Siare Support Centre or any other support centres authorised by Siare.

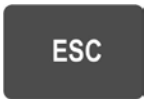
However, the system allows you to proceed. Press START.

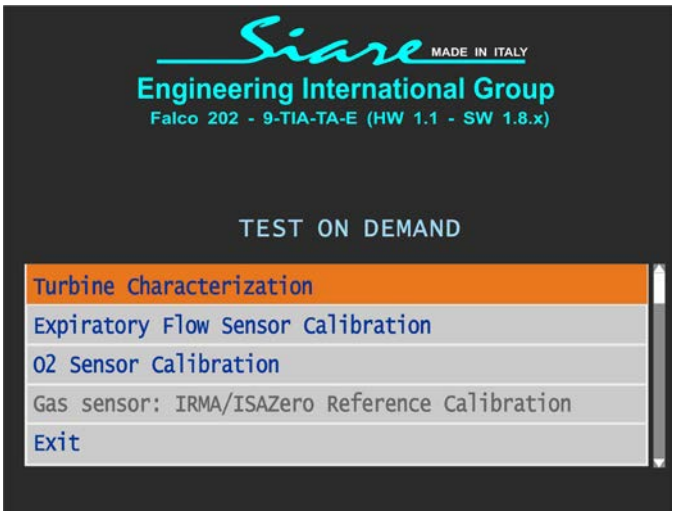


The " **SELF TEST** " phase completed successfully.

- Go to TESTS ON DEMAND by pressing **ESC**.
- Go to STAND-BY operating mode, by pressing **START.**

- After completing the " SELF TEST " phase, press ESC to go to TESTS ON DEMAND.



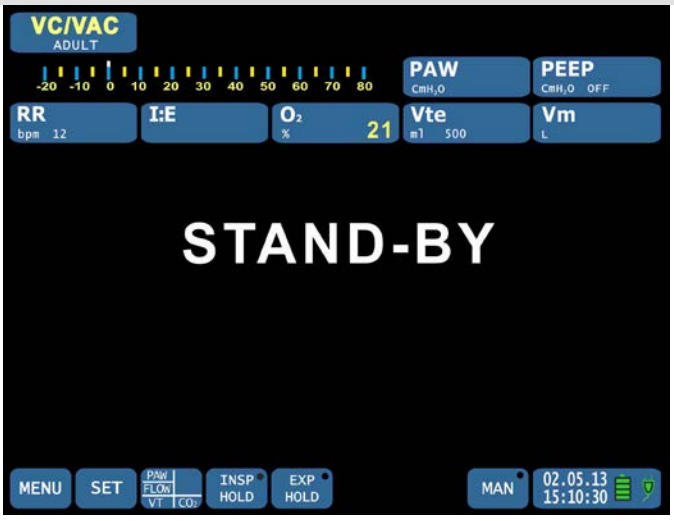


TESTS ON DEMAND

By means of this function it is possible:

- calibrate the turbine
- calibrate the expiratory flow sensor
- calibrate the O_2 Sensor

- After completing the " SELF TEST " phase, press **START** to go to STAND-BY mode.



STAND-BY mode

- After carrying out the SELF TEST or before turning the ventilator off, it automatically switches to this mode.
- In this mode you can set and/or edit all ventilator parameters and alarms limit relative to the operating mode that you will use on the patient that you want to treat.

3.5 Turn the lung ventilator OFF

- STAND-BY operating mode.
- Hold the ON-OFF key for few seconds to turn the ventilator OFF.

- Turn the lung ventilator OFF.

- Press NO: the ventilator goes back to STAND-BY operating mode.

- Press YES: the lung ventilator turns OFF.

CAUTION

Lung ventilator OFF - Oxygen emptying

During the switching OFF the ventilator 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.

This procedure grants: a longer oxygen 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.

3.6 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 3 phases.

- **TESTS ON DEMAND**
  - O_2 Sensor calibration
- **Ventilator**
  - Respiratory parameters
  - Spirometry
- **Lung Ventilator alarms**

WARNING !! Lung ventilator failure risk.

Running or cancelling the preliminary checks might result in a malfunction during ventilator 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.

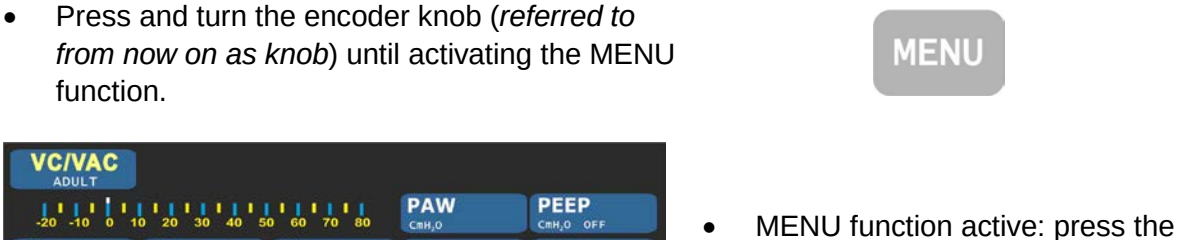
The lung ventilator must be ready for use in order for you to proceed with the preliminary checks.

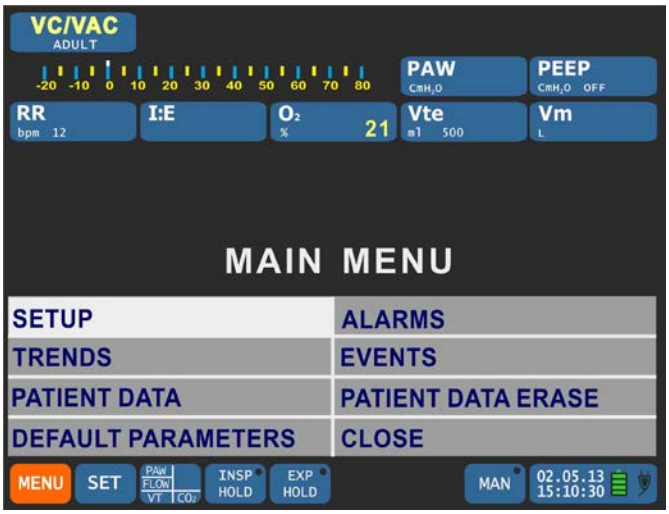
- Connect the power supply, the medical gas (O_2) and the patient circuit.
- Insert and connect the oxygen sensor.
- Connect a patient simulator to the patient circuit terminal.
- Ventilator ON : STAND-BY operating mode.

3.6.1 Preliminary checks - TESTS ON DEMAND

To carry out the TESTS ON DEMAND you must know the keyboard operating mode and the options available in the ventilator MENU (please see chapter 2).

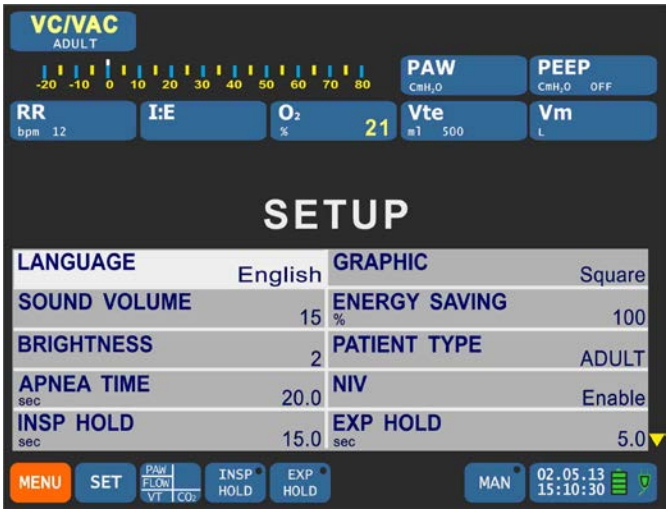
- Press and turn the encoder knob (*referred to from now on as knob*) until activating the MENU function.



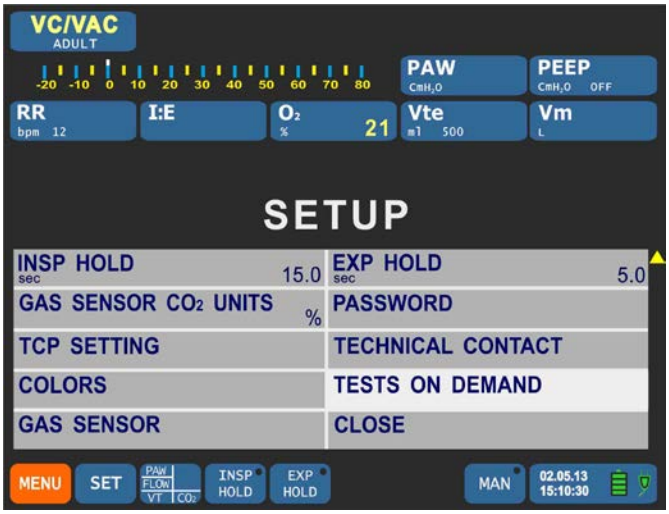


- MENU function active: press the knob.

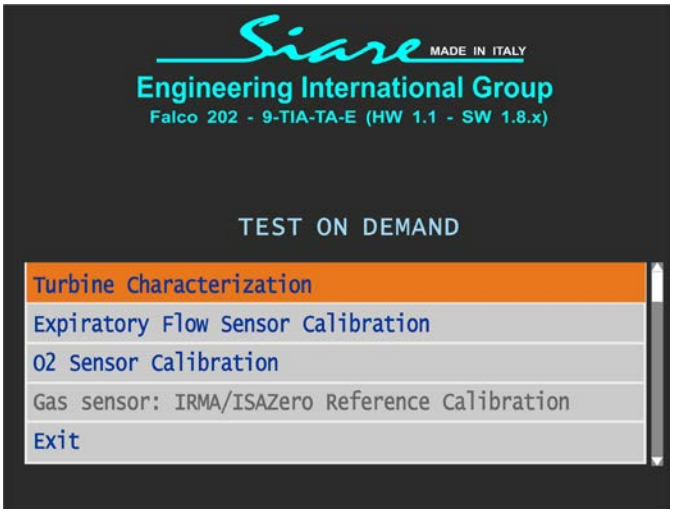
- The system will display the MAIN MENU screen, SETUP parameters.



- SETUP function active: press the knob.
- The system will display the page containing the parameters you want to set.



- Turn the knob to activate the parameters:



- Press the knob selecting, TESTS ON DEMAND.
- The TESTS ON DEMAND screen appears.

CAUTION - TESTS ON DEMAND

The TESTS ON DEMAND **screen shows various tests**.

- *Turbine Characterization*
- *Expiratory Flow Sensors Calibration*
- **O_2 Sensor Calibration**

On this TEST ON DEMAND phase you should consider the O_2 Sensor calibration while for the other tests please refer to chapter 3.8.

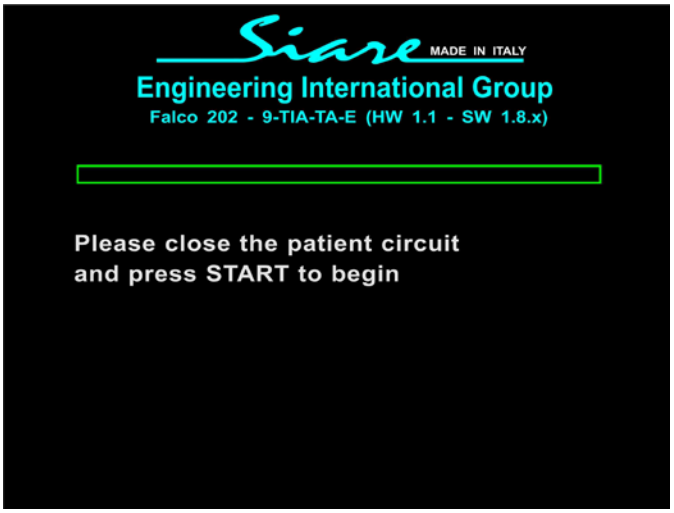
3.6.2 O_2 Sensor calibration

WARNING !! Ventilator malfunctions risk

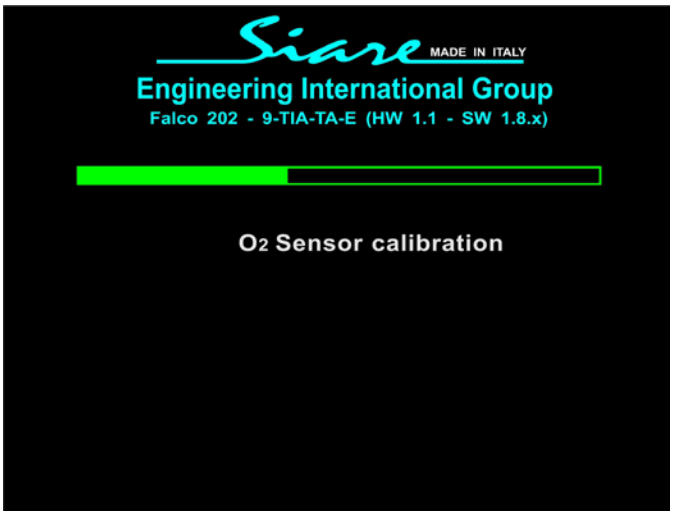
This procedure should be carried out to check the proper operation of the O_2 sensor.

- To avoid any patient injury risks, carry out this procedure monthly.

- TESTS ON DEMAND. O_2 sensor calibration screen.



- Press the knob; the system will activate the O_2 sensor calibration.
- Close the patient circuit (close manually the patient connector).
- Press START to start the procedure.



- Oxygen sensor calibration procedure in progress.

NOTE. *To check if the O_2 sensor works properly, 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).*

- A flow having a 21% O_2 concentration *(air)* is automatically generated by the ventilator during the test.
- The oxygen sensor calibration procedure was completed successfully: the measured voltage value is 13mV.

NOTE. *Optimal value = 13mV.*

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.

Conditions to be met for proper calibration:

- the O_2 sensor must be placed in its seat
- the O_2 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.

REPLACING THE OXYGEN CELL

The oxygen cell must be replaced when, at the end of the calibration phase, appears a detected voltage value lower than 8mV and/or if the system displays the relevant alarm message.

To order the replace sensor and to dispose of the worn one, please see chapter 6 " Maintenance ".

- The oxygen sensor calibration procedure was not completed successfully.

WARNING !! Ventilator malfunctions risk

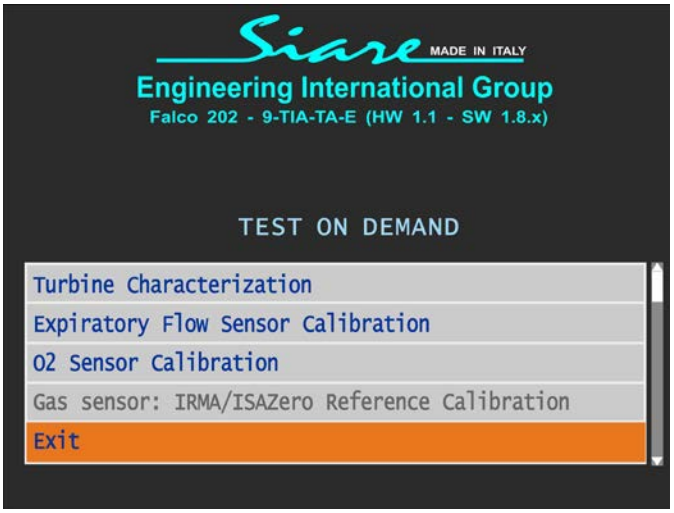
If the TEST result is negative check:

- if the O_2 sensor is installed and electrically connected to the ventilator
- if the O_2 sensor is worn out (the oxygen detection cell is worn out; replace the O_2 sensor).

TESTS ON DEMAND FAILED

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

3.6.3 Exit from TESTS ON DEMAND



- Turn the knob to select the option: Exit.

Exit TESTS ON DEMAND

- Press the encoder knob to exit from the TESTS ON DEMAND screen.
- Press the ESC soft key: the system will leave the TESTS ON DEMAND screen.

CAUTION - TESTS ON DEMAND

For additional informations on the " **TESTS ON DEMAND** " not listed in this paragraph please refer to 3.8.

3.6.4 Preliminary checks - Lung Ventilator

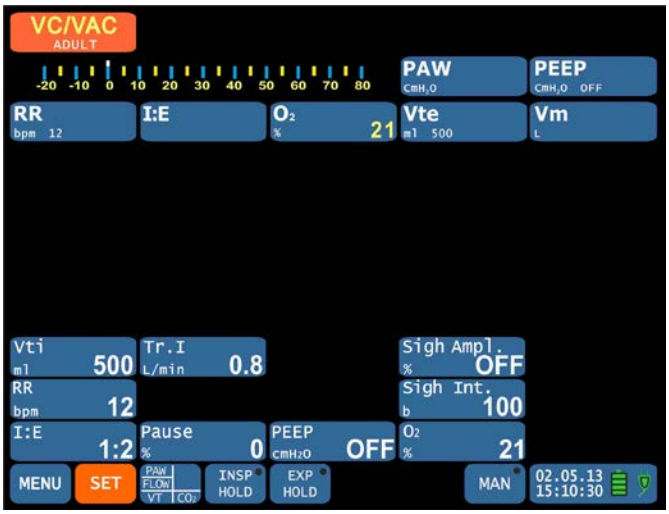
To carry out the preliminary checks you need to know how the encoder keyboard and the Physiological Respiratory Parameters (referred to from now on as PRP) work.

Preliminary checks to be carried out on the ventilator.

- Respiratory parameters setup.
- Spirometry proper operation check.

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

1) Ventilator in STAND-BY.



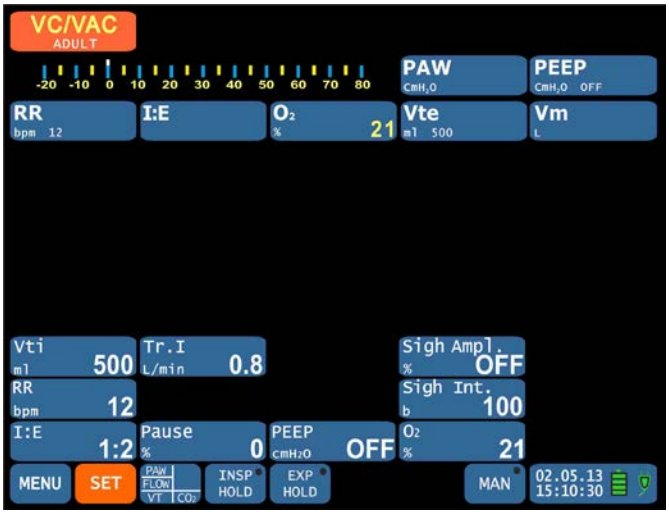
2) Select and operating mode (VC-VAC).

- Press the knob: the system will activate the SET function.

- Press the knob once again: the system will display the respiratory parameters.

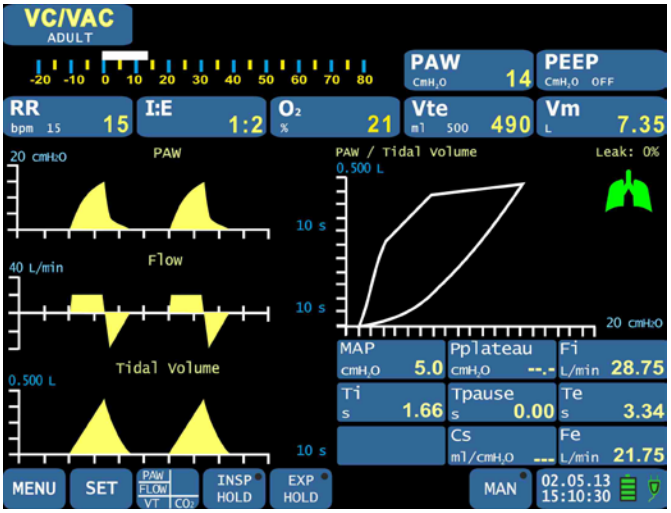
Modification of the PRP

- Turn the knob, select the parameter you want to change, press the knob to activate the value editing function.
- Turn the knob clockwise to increase (anticlockwise to decrease) the value of the selected parameter.
- Press the knob to confirm the modification.



3) Set the physiological respiratory parameters (PRP)

Vti	**500**
RR	**15**
I:E	**1:2**
Tr. I	**-1 cmH2O**
	1 L/min
Pause	**0**
PEEP	**OFF, 5, 10 cmH2O**
O2	**21%**

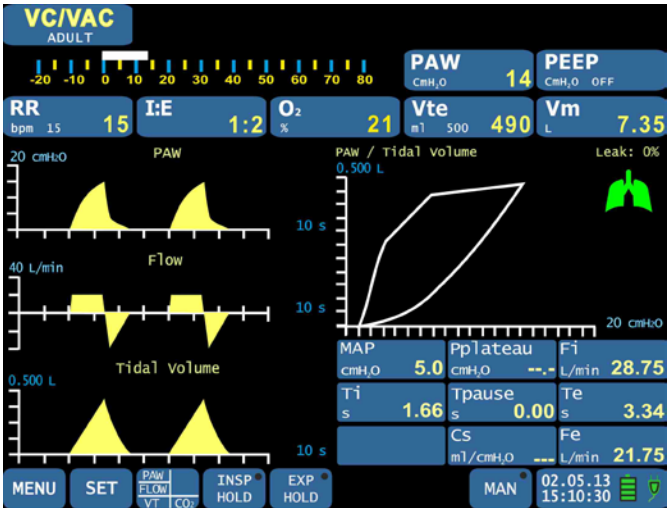


4) Press the START button: the ventilator begins its cycle.

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

3.6.5 Preliminary checks - Parameters monitoring

- Based on the PRP set by the clinician 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 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 top of the screen you can see the monitored parameters.

6) Change the PRP values.

- PEEP : 5, 10 cmH_2O
- Tr. I : -1 cmH_2O, 1 L/min
- O_2 : 60%

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

Note: Oxygen consumption calculation

The oxygen consumption value is showed in L/min for oxygen settings of more than 21%.

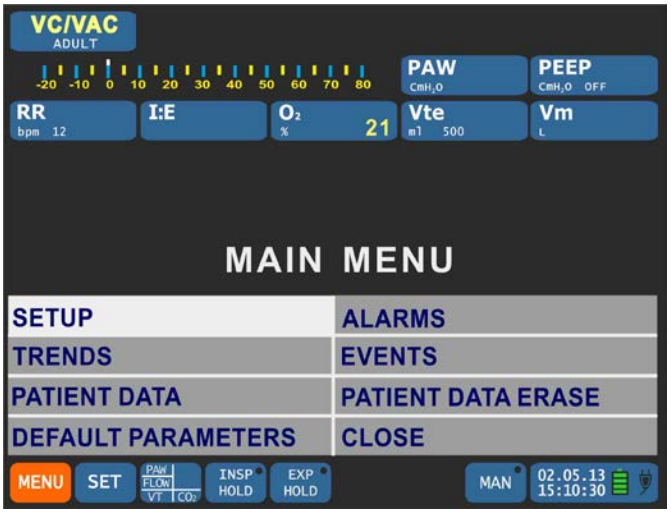
Ventilator operation check

- 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 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.

- If the O_2 measured value differs from the set value by more than +/- 10%, please repeat the "O_2 Sensor Calibration" procedure: TEST ON DEMAND.
- If the Vte measured value differs from the set value by more than +/- 20% (ADULTS parameters), please go to the "CALIBRATION PROGRAMS" visualization to perform the calibration of the expiratory flow sensor (see chapter 3.8 and/or 4.13).

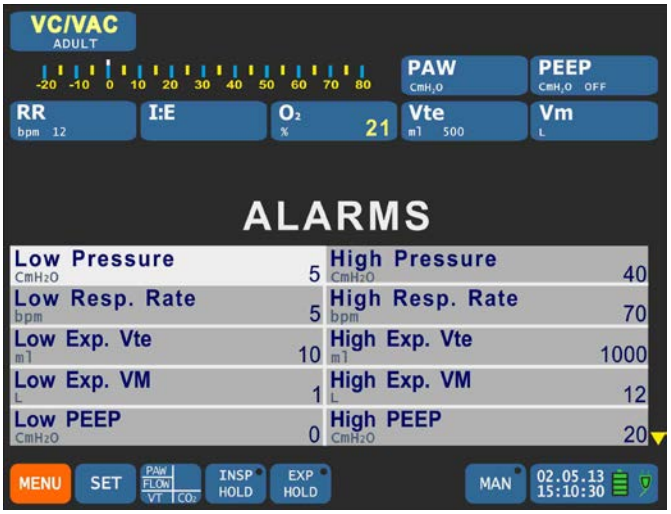
3.6.6 Preliminary checks – Alarms

To carry out the preliminary checks relative to ventilator's alarms, you need to know how the keyboard and the alarms work: please refer to the relative chapters.



- Press and turn the knob: the system will activate the MENU function.

- Press the knob once again; the system will display the MAIN MENU screen, SETUP option.



- Turn the knob: the system will activate the ALARMS option.

- Press the knob: the system will activate the ALARMS page.

Check the alarms setup and if necessary change the values set, based on the test you want to carry out.

- Turn the knob, select the alarm you want to change, press the knob to activate the value editing function.
- Turn the knob clockwise to increase (anticlockwise to decrease) the value of the selected alarm.
- Press the knob to confirm the modification of the alarm value.

Exit the ALARMS screen

- Press the ESC soft key; the system will leave the ALARMS screen.
- After about 60 seconds the system automatically returns to STAND-BY or ventilator operation display.

3.6.7 Alarms check

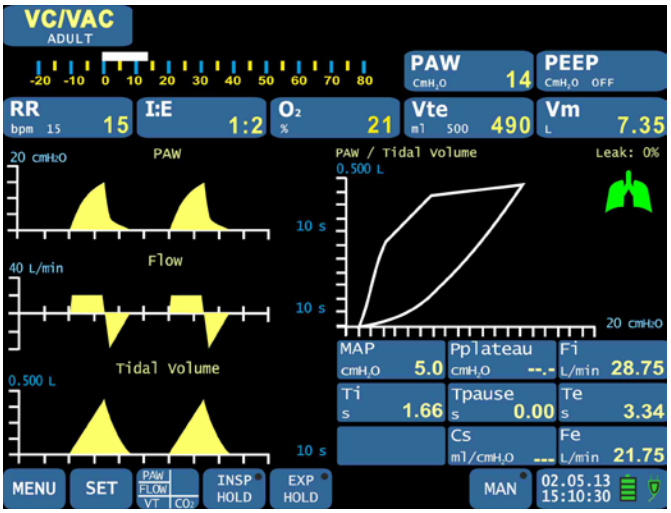
WARNING !! Severe patient injuries

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 checking:

- check the alarms setup, and change the set values whenever necessary *(please see previous paragraph)*
- select VC/VAC operative mode



- Press the START button: the ventilator begins its cycle.

LOW PRESSURE

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

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.

• Set the low respiratory rate (high respiratory rate) alarm limit to 15 bpm (15 bpm). • During ventilation please set RR = 10 bpm (RR = 20 bpm). • The system activates the low (high) respiratory rate alarm: silence the alarm. • Restore the default alarm value.	**LOW RESP. RATE (HIGH RESP. RATE)**
• Set the low expired Vte alarm limit to 250 ml. • During ventilation, set Vti to 100 ml. • The system activates the low expired Vte alarm: silence the alarm. • Restore the default alarm value.	**LOW EXP. VOLUME**
• Set the high expired Vte alarm limit to 500 ml. • During ventilation, set Vti to 750 ml. • The system activates the high expired Vte alarm: silence the alarm. • Restore the default alarm value.	**HIGH EXP. VOLUME**
• Set the low FiO_2 concentration alarm limit to 50%. • Set a FiO_2 concentration to 30% on the ventilator. • The system activates the low FiO_2 alarm: silence the alarm. • Restore the default alarm value.	**LOW O_2 CONCENTRATION**
• Set the high low FiO_2 concentration alarm limit to 30%. • Set a FiO_2 concentration to 50% on the ventilator. • The system activates the high FiO_2 alarm: silence the alarm. • Restore the default alarm value.	**HIGH O_2 CONCENTRATION**
• During ventilation, set the main power supply switch to OFF (0). • The system activates the mains power failure alarm: silence the alarm. • Restore the main switch and set it to ON (I).	**POWER SUPPLY FAULT**

- Close the medical gas supply during ventilator operation.
- The system activates the gas supply failure alarm: silence the alarm. **LOW O_2 SUPPLY**
- Restore the medical gas supply.

High / Low FiO_2

If the ventilator is in STAND-BY the alarms are not active.

3.6.8 Conclusions

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

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 alarms set values before connecting a patient to the ventilator.
- Change the alarms setup based on the clinical situation.

WARNING !! Operator and patient injury hazard

The intensive care 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 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.

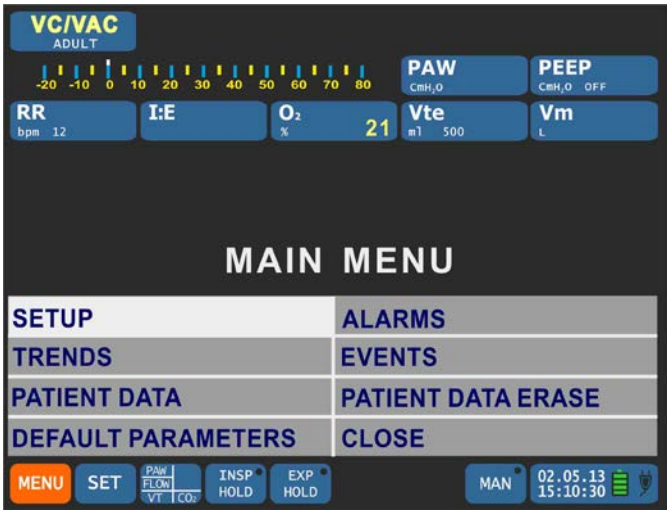
3.7 List of preliminary checks

3.8 “ TESTS ON DEMAND “

WARNING !! Patient / operator injury hazard

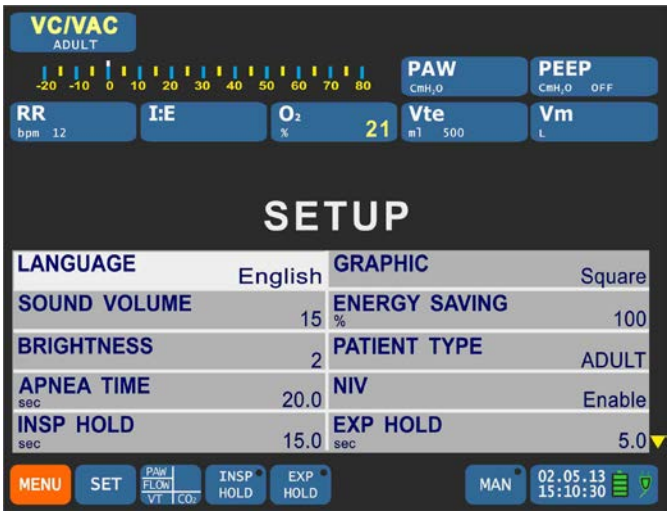
The procedures described are critical operations and must be carried out only by authorised staff as they might affect the lung ventilator safety and proper operation.

To display the TEST ON DEMAND screen, press and turn the encoder knob (*referred to from now on as knob*) until activating the MENU function.

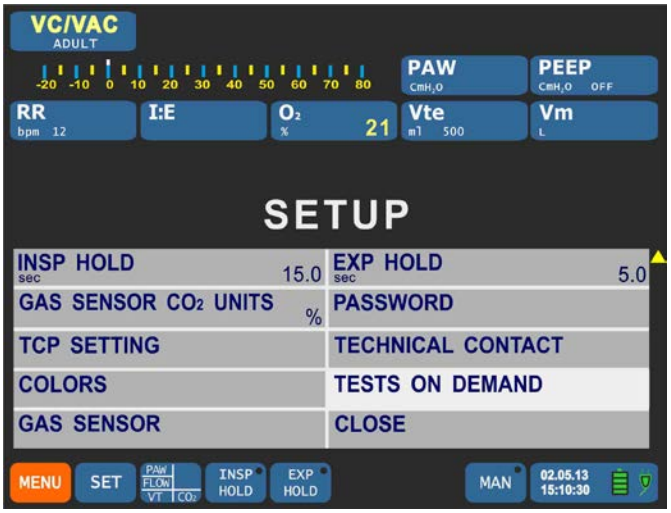


- **MENU** function active: press the knob.

- The system will display the MAIN MENU screen, **SETUP** parameters.

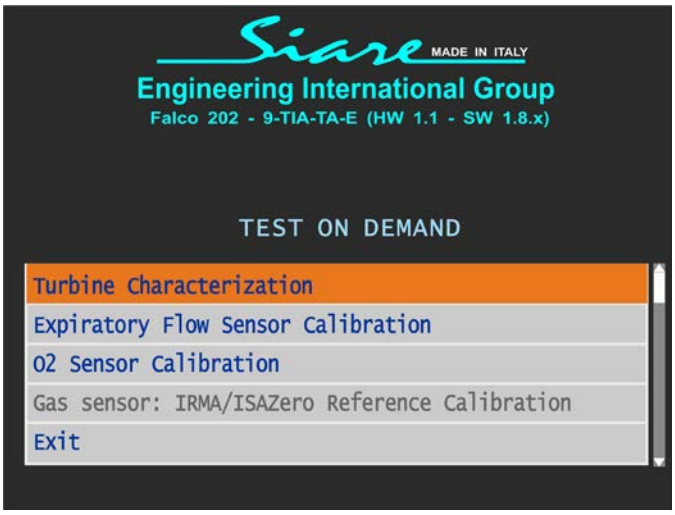


- **SETUP** function active: press the knob.
- The system will display the page containing the parameters you want to set.



- Turn the knob to activate the parameters:

TESTS ON DEMAND



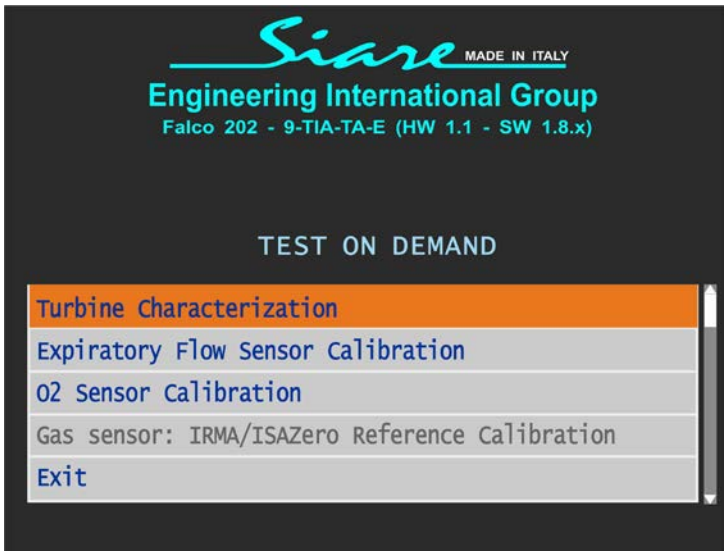
- Press the knob selecting, **TESTS ON DEMAND**.
- The **TESTS ON DEMAND** screen appears.

3.8.1 Turbine Characterization

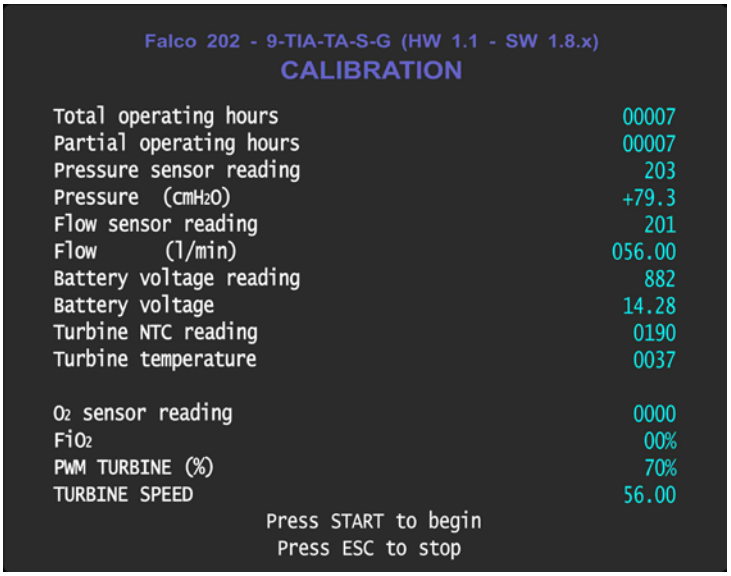
In order to start the **Turbine characterization (calibration) program** is necessary the intervention of qualified SIARE personnel or qualified technical personnel authorized by SIARE.

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

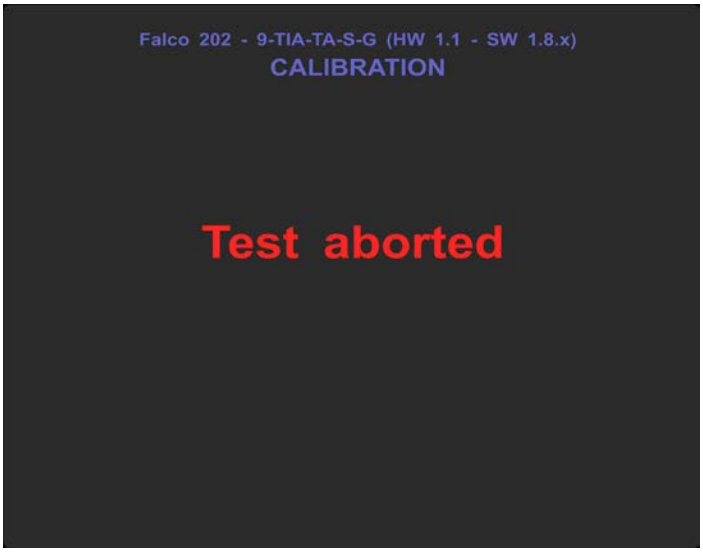
- when you note differences out of tolerance (more than 2% of the end of the scale + 8% of the measured value) on the airways pressure values between the set and measured values
- software update or first turning-on after an important repairing (for ex. turbine replacement or inspiratory flow sensor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



- Turn the encoder knob to select the parameter to be calibrated: the activated message is highlighted.



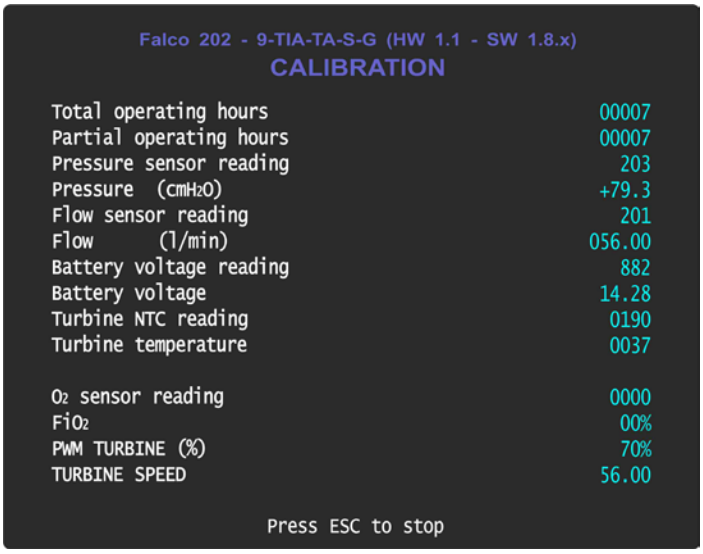
- Press the encoder knob: the **Turbine characterization program** is showed.



Press ESC to stop

- **Press ESC** to not perform the **Turbine characterization and exit from the relevant screen**.

The system will show the " **Test Aborted** " message and after some seconds will show again the **MAIN MENÚ**.



Press START to begin

- **" CALIBRATION " phase. Close the patient circuit**.
- Press **START**: the turbine characterization calibration will start.

Note. *Press ESC: the calibration stops.*

If the calibration is performed regularly the system shows the **" Test Completed "** message.

The system and after some seconds will show again the **MAIN MENÚ**.

.

If the calibration gives a negative result, the system shows the **"Test Failed "** message.

TEST FAILED

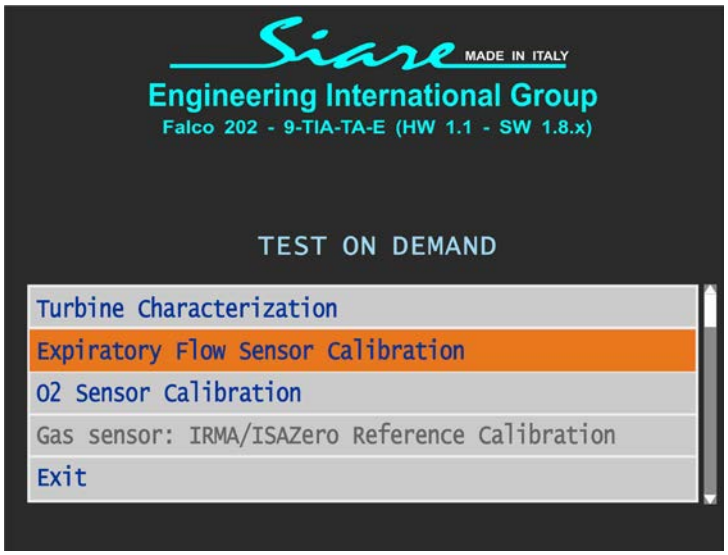
If the system fails the test, please see chapter Alarms - Trouble Shooting or contact the nearest Siare Support Centre or any other support centres authorised by Siare.

3.8.2 Expiratory flow sensors calibration

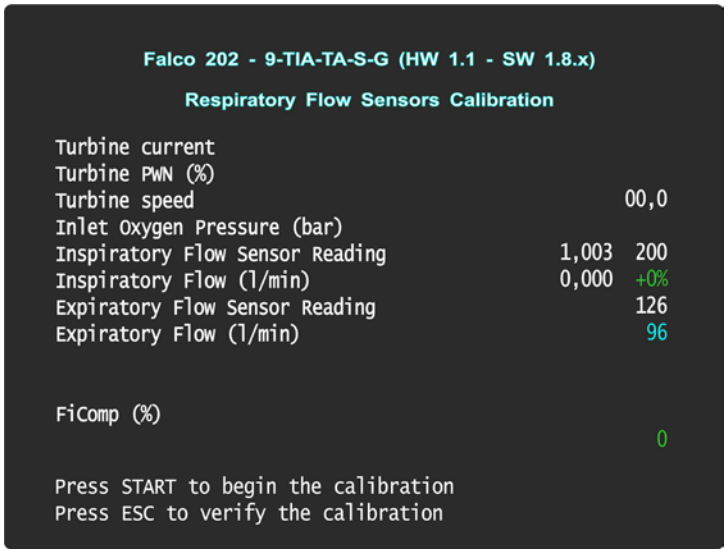
In order to start the **Expiratory Flow Sensors Calibration program** is necessary the intervention of qualified SIARE personnel or qualified technical personnel authorized by SIARE.

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

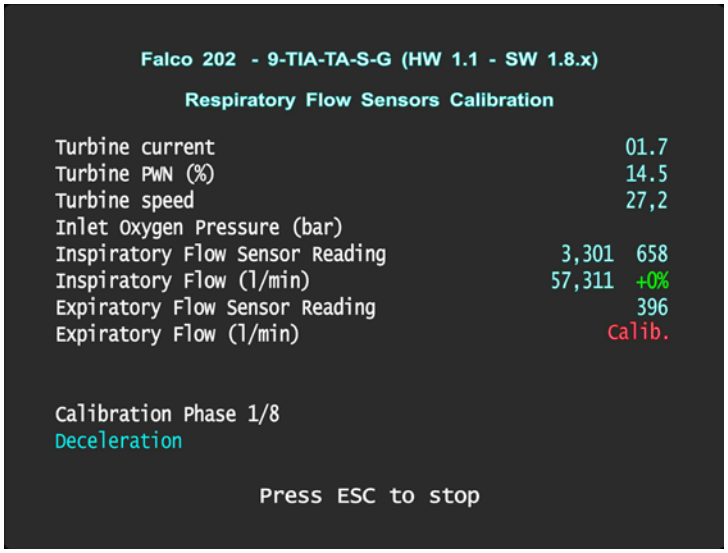
- noted differences are more than 15% (over 100ml) between the set Volume value (VTi - Vte) and the expired Tidal Volume reading (Vte).
- in case of first calibration of ventilator or replacement of flow sensors (INSP inside the unit or EXP outside the unit), it is suggested to perform this Calibration.



- Turn the encoder knob to select the parameter to be calibrated: the activated message is highlighted.

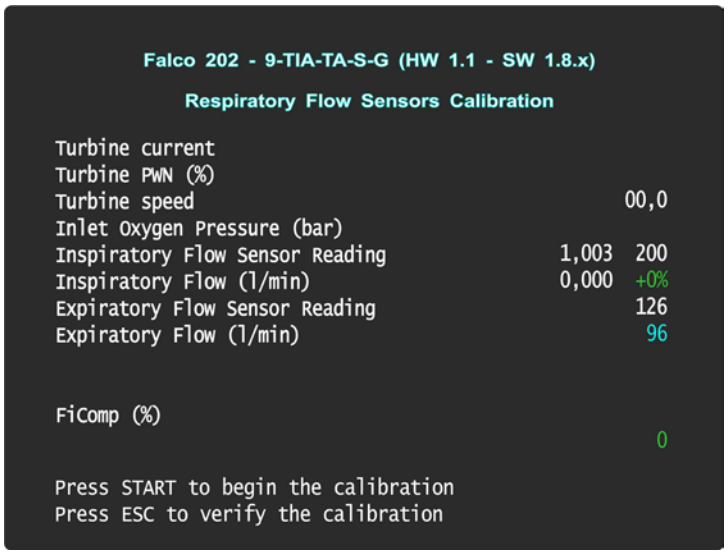


- Press the encoder knob: the **Expiratory Flow Sensors Calibration program** is showed.



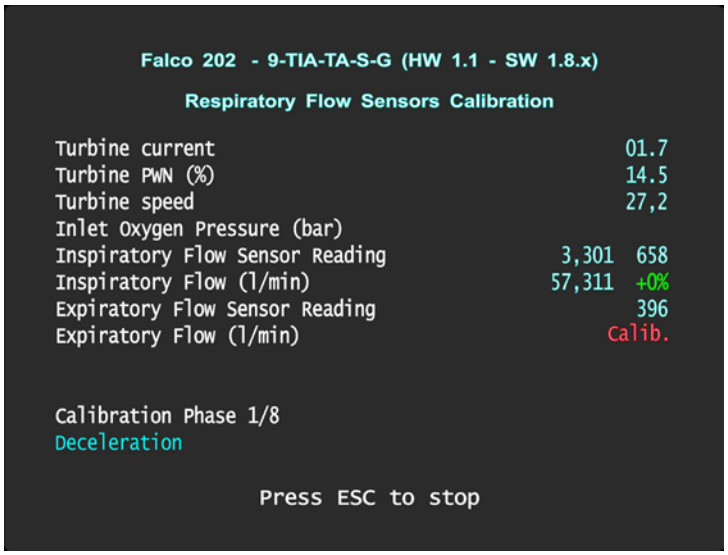
Press ESC to verify the calibration.

If the calibration verify ends correctly the system shows the **"Test Completed "** message.



Press START to begin the calibration.

- **" CALIBRATION " phase.** Close the patient circuit.
- Press **START**: the expiratory flow sensors calibration starts



- The expiratory flow sensors calibration is in progress.

Note. *Press ESC: the calibration stops and the system shows the* ***" Test Aborted "*** *message*

If the calibration ends properly the system shows the **“ Test Completed “** message.

The system shows the MAIN MENÚ after some seconds.

If the calibration fails the system shows the **“Test Failed “** message

TEST ABORTED

If the system fails the test, please see chapter Alarms - Trouble Shooting or contact the nearest Siare Support Centre or any other support centres authorised by Siare.

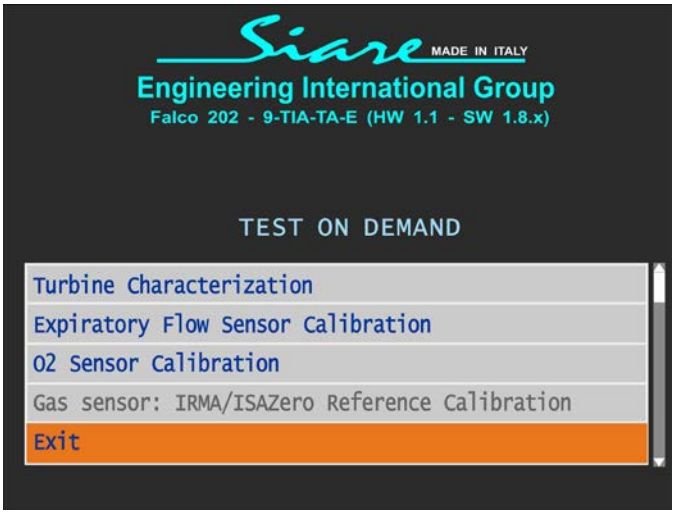
- At the end of the **Expiratory flow sensors calibration** the system come back to the MAIN MENU**.**
- In case of first calibration of ventilator, we suggest to execute this procedure after having checked the PEEP calibration and after performing a **Turbine characterization.**
- For more information please refer to the SERVICE manual.

3.8.3 O_2 Sensor calibration

CAUTION

For additional informations on the “ TEST ON DEMAND ” not mentioned in this chapter, please refer to 3.6.2.

3.8.4 Exit from TESTS ON DEMAND



- Turn the knob to select the option: **Exit**.

Exit TESTS ON DEMAND

- Press the **encoder knob** to exit from the TESTS ON DEMAND screen.
- Press the **ESC** soft key: the system will leave the TESTS ON DEMAND screen.

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4 LUNG VENTILATOR USE

This chapter shows you how to use the Falco 202 lung ventilator for intensive care, emergency and transport (*referred to from now on as ventilator*).

Thoroughly read this chapter and the entire manual to make sure respiratory parameters and alarm limits are set correctly and choose the most suitable ventilation mode.

The clinician must choose the operating modes and the alarm limits that best match patient's physiological state and pathologies.

4.1 General warnings

WARNING !! Patient/clinician injury hazard

Before starting the ventilator you have to:

- carry out the preliminary checks (please see the previous chapter)
- set the language and the patient data (please see 4.5)
- set and check the alarms limits (please see 4.7)
- set the physiological respiratory parameters and the operating mode that match the patient's clinical situation best (please see 4.8).

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

- set the airway pressure limit alarm to a value that does not exceed 20 cmH2O; 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 (FiO2) as high concentrations might affect the patient's health
- please consult this Operator Manual.

WARNING !! Patient injury hazard

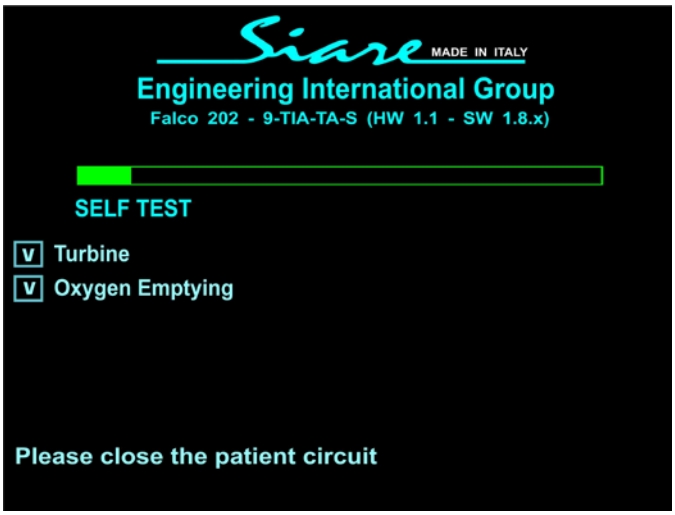
All figures and examples featured in this chapter are purely informative and do not refer to real clinical cases.

4.2 STAND-BY mode

4.2.1 “ SELF TEST “ phase

- Set Cap4-1_Use_980222_UE_rev1 the main switch (placed on the back of the ventilator) to “**I**”.
- Make sure that on the 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 to start the ventilator.

“ **SELF TEST** “ phase. Close the patient circuit.



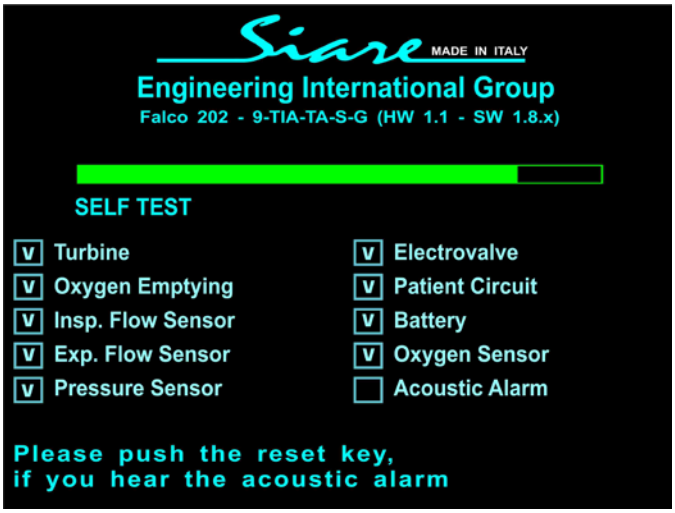
The ventilator turns on and the automatic “ SELF TEST “ phase begins.

- Turbine functioning check and status.
- The system pull out the O_2 in excess in the device in order to calibrate the 21% O_2 concentration in a proper way.

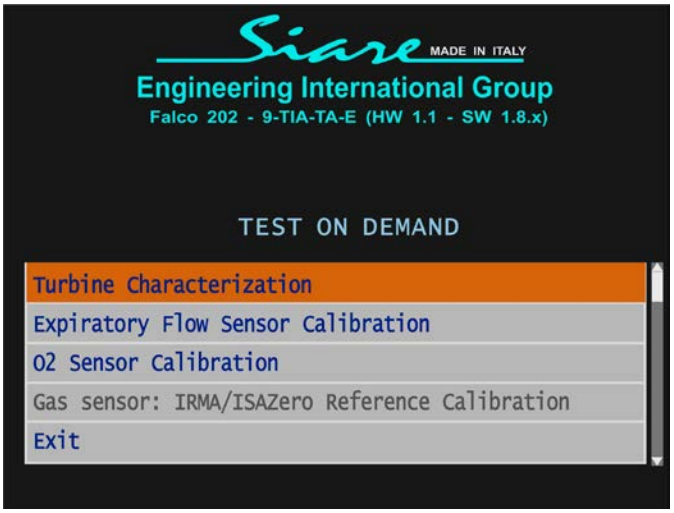
“SELF TEST” phase.

During “ SELF TEST “ phase, the ventilator software carries out the self-diagnostic tests and checks a series of devices necessary for safe operation of the ventilator.

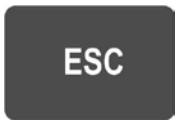
For more information on the “SELF TEST” please refer to the chapter 3.4.2.



- The " SELF TEST " phase completed successfully.



After the " SELF TEST " phase is completed, press **ESC** to go to TESTS ON DEMAND.



After the " SELF TEST " phase is completed, press **START** to go to STAND-BY mode.

STAND-BY operating mode.

TESTS ON DEMAND

By means of this function it is possible to:

- calibrate the turbine
- calibrate the expiratory flow sensor
- calibrate the O_2 Sensor
- perform the zeroing of Gas Analyzer (optional device)

STAND-BY

- After carrying out the SELF TEST or before turning the ventilator off, it automatically switches to this operating mode.
- In this operating mode you can set and/or edit all ventilator parameters (SETUP, ALARMS, etc…) relative to the operating mode that you will use on the patient that you want to treat.

In STAND-BY (SET function) you can select the operating mode and set and/or edit all ventilator parameters (PRP) that belong to the operating mode in question.

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

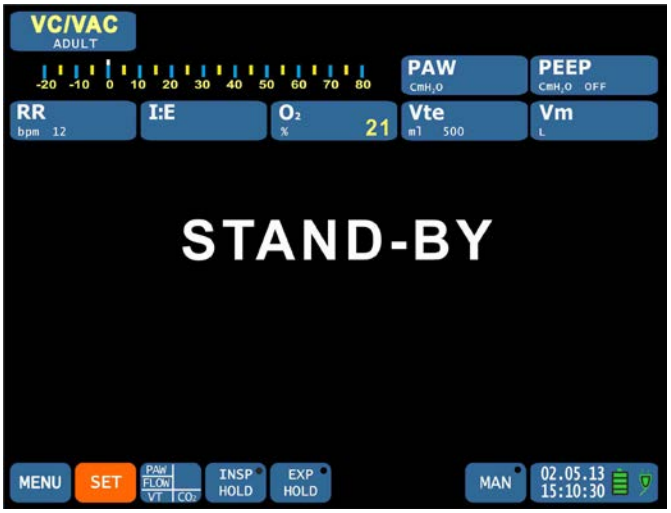
4.2.2 Keyboard with soft key and encoder knob use

For the keyboard with soft key and encoder knob methodology of use, please see chapter 2.4.

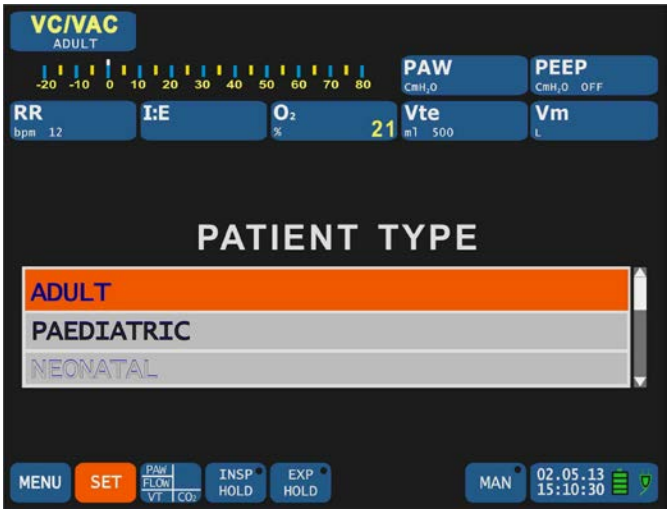
4.3 Choice of the patient type

When the lung ventilator is switched ON (STAND-BY operative mode), selecting SET function it is possible to choice the Patient Type (ADULT, PAEDIATRIC, NEONATAL).

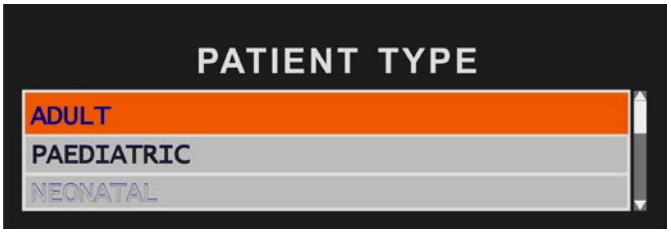
The choice of the Patient Type, set automatically the default functioning parameters of the lung ventilator (breathing parameters and alarms levels).



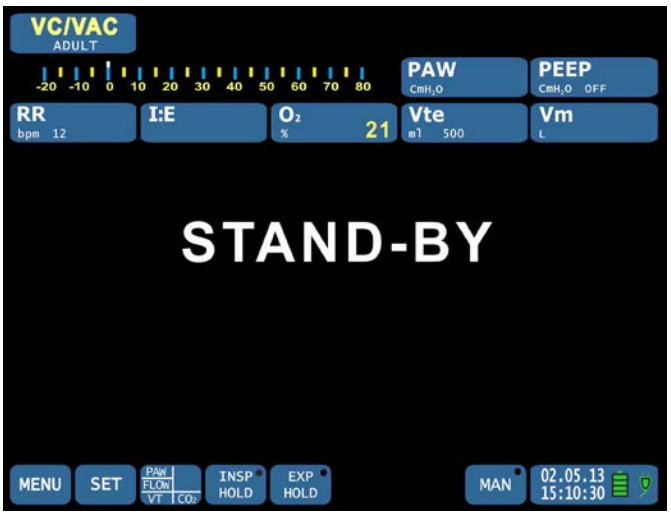
- Lung ventilator power ON and in STAND-BY operating mode.
- Press the encoder knob; the system will select the SET function.



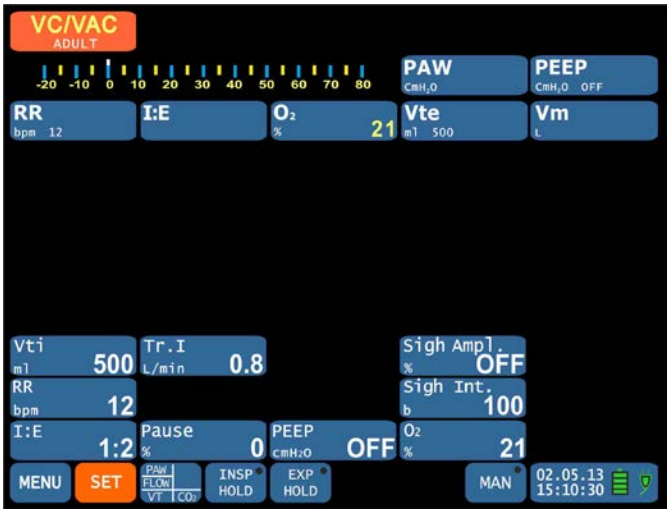
- Press the encoder knob to confirm your choice.
- The system will display the PATIENT TYPE screen choice (ADULT, PAEDIATRIC, NEONATAL).
-



- Turn and press the encoder knob to select the PATIENT TYPE.



- Below the Operative Mode acronym, the PATIENT TYPE set is specified: ADULT.
- When setting the PATIENT TYPE, the relevant default respiratory parameters and alarms limits are also automatically set.



- Press the encoder knob to confirm your choice.
- Use the SET function to view/edit the operating mode and all the relative physiological respiratory parameters (PRP).

After the PATIENT TYPE choice, the SET function permits to show/modify the operative mode and the physiological respiratory parameters (PRP).

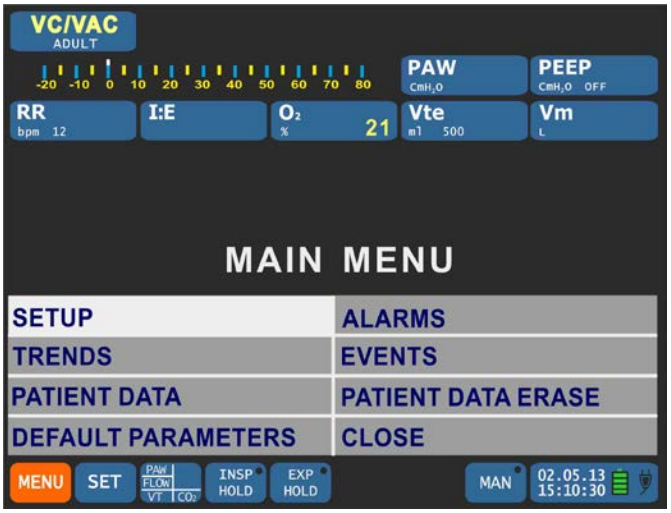
CAUTION

During the normal functioning of the lung ventilator, the PATIENT TYPE choice (ADULT, PAEDIATRIC, NEONATAL) can be effected selecting the function MENU - SETUP - PATIENT TYPE.

4.4 Setting up the MENU language

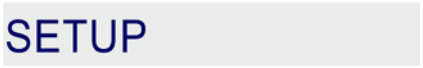
Ventilator in **STAND-BY** operating mode.

- Press the encoder knob: the system will activate the SET function.
- Turn and select the MENU function.



- Press the knob to confirm your choice.
- The system will display the MAIN MENU screen, SETUP parameters.

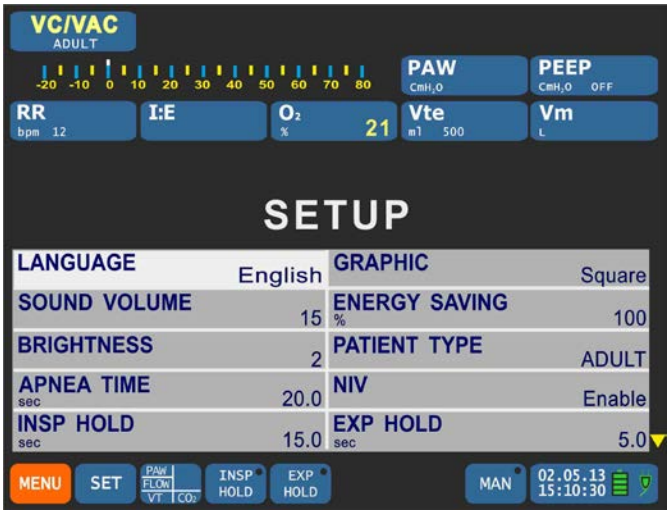
- Press the knob to confirm your choice.



- The system will display the SETUP screen, LANGUAGE - Italian option.

To change the MENU language proceed as described herein (see cfr. 2.4):

- press the encoder to apply the Language change
- turn clockwise (anticlockwise) to select the desired language
- press the knob to confirm.



- The system will display the SETUP screen, **LANGUAGE - English** option

4.4.1 SETUP screen parameters editing procedure

To change other parameters proceed as described herein (see cfr. 2.4):

- turn the encoder knob clockwise (anticlockwise) to select another option from the SETUP screen
- press the encoder to apply the change
- turn clockwise (anticlockwise) to select the new value
- press the knob to confirm.

ESC

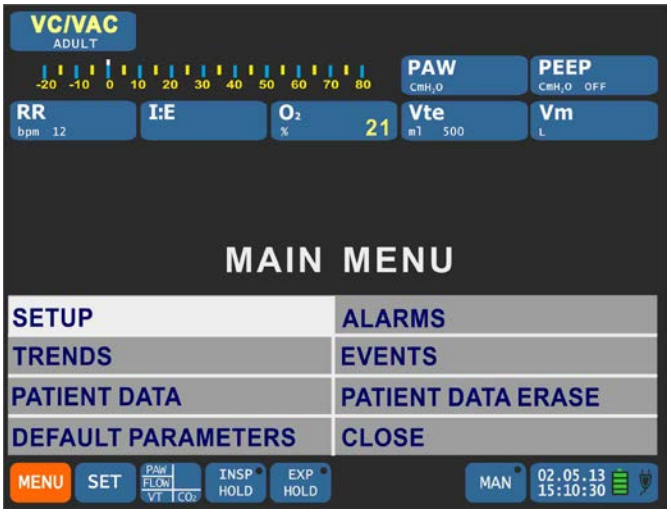
Press **ESC** to exit the SETUP screen and go back to STAND-BY mode.

Wait for the system to return to STAND-BY screen automatically.

4.5 Setting the PATIENT DATA

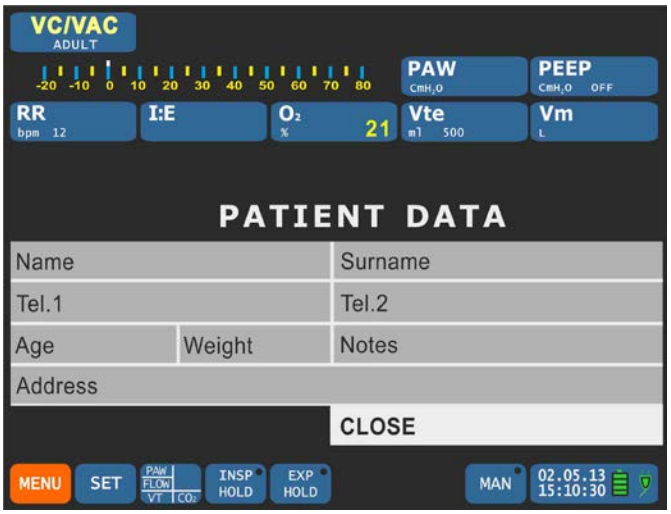
Ventilator in **STAND-BY** operating mode.

- Press the encoder knob: the system will activate the SET function.
- Turn and select the MENU function.



- Press the knob to confirm your choice.
- The system will display the **MAIN MENU** screen, SETUP parameters.

- Turn the knob to select the **PATIENT DATA** option.



- Press the knob to confirm your choice.
- The system will display the **PATIENT DATA** page.

To exit **PATIENT DATA** screen.

- Press the **ESC** soft key.
- Select **CLOSE** option and press the encoder.
- Wait for the system to return to STAND-BY mode automatically.

4.5.1 Procedure for setting the PATIENT DATA

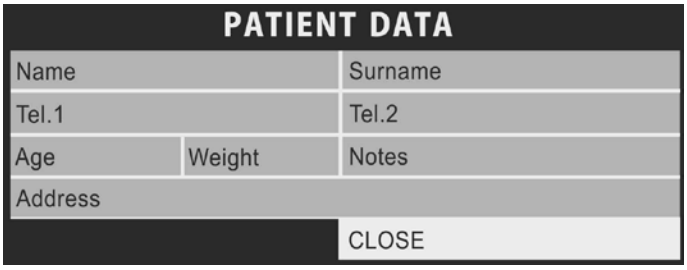
You can see below how to enter the patient name (this is shown only as an example).

Use the encoder knob to enter the patient's identification data.

The fields for entering the name and surname have a limit of 14 characters.

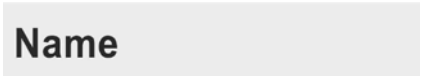
The lower-case letters are placed after the upper-case letters.

To save the data inserted in each parameter (**e.g. Name**), you have to scroll through all 14 available character spaces.



Ventilator displaying the **PATIENT DATA** screen.

- Turn the encoder knob to select the first parameter you want to set, **Name**.



- Press the knob to activate the text insertion inside **Name** box (the first character space appears).

- Turn the knob to enter “the first letter” of the patient name (first the upper-case letters, then the lower-case letters).

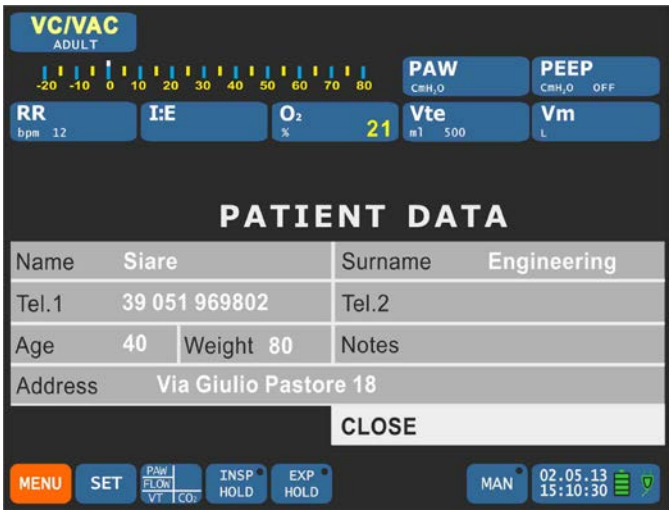
- Press the knob to confirm the letter entered in the first highlighted text box (the second character space appears),

- Turn the knob to enter “the second letter” of the patient name (first the upper-case letters, then the lower-case letters).

- Press the knob to confirm and turn it again to proceed with entering the rest of the patient's **Name**.

To save the first parameter, **Name** (and the others) you have to scroll through all characters spaces available for each parameter.

After setting the Patient's Name the clinician can proceed in the same manner to fill in the entire **PATIENT DATA** sheet.



- After entering all patient identification data, select the **CLOSE** box and press the encoder.

CLOSE

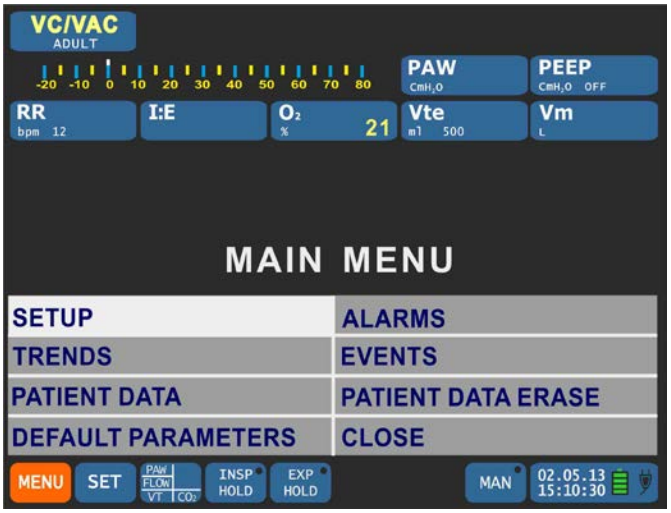
PATIENT DATA

- The entered identification data can be edited in the same manner.
- Press the **ESC** soft key to exit a patient identification data field, without scrolling through all available character spaces.
- Press the **PATIENT DATA ERASE** function to delete the patient identification data saved in the system.

4.6 Erasing the PATIENT DATA

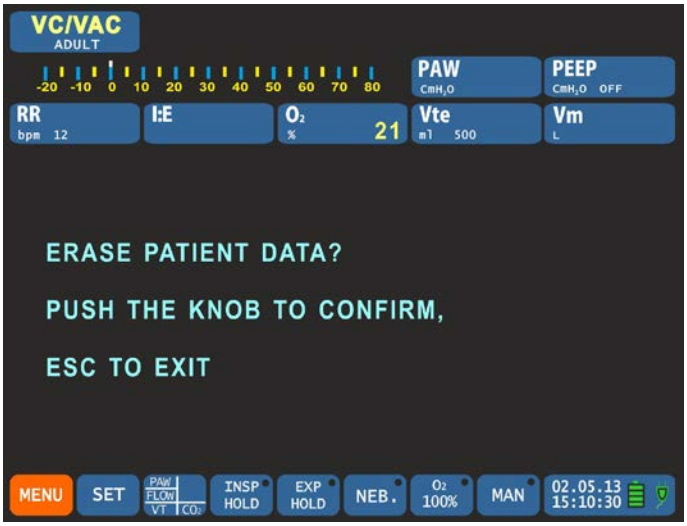
Ventilator in **STAND-BY** operating mode.

- Press the encoder knob: the system will activate the **SET** function.
- Turn and select the **MENU** function.



- Press the knob to confirm your choice.
- The system will display the MAIN MENU screen, **SETUP** parameters.

- Turn the knob to select the option **PATIENT DATA ERASE**



- Press the knob to confirm your choice.
- The system will display the **PATIENT DATA ERASE** page.

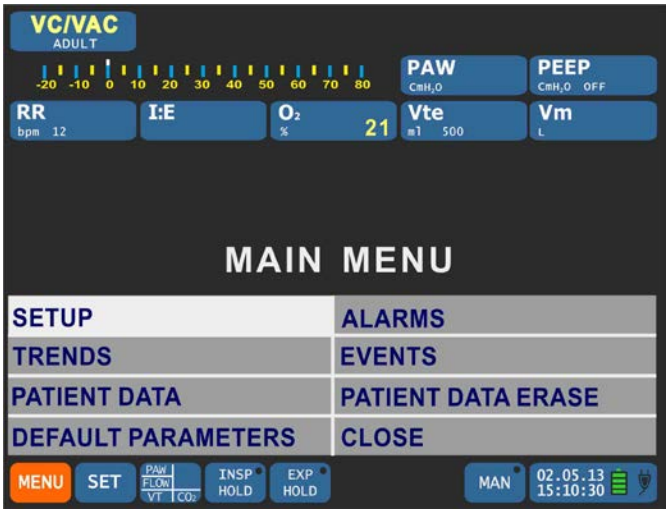
To exit the **PATIENT DATA ERASE** screen.

- Press the **ESC** soft key.
- Wait for the system to return to **STAND-BY** screen automatically.

4.7 Setting up the ALARMS

Ventilator in **STAND-BY** operating mode.

- Press the encoder knob: the system will activate the **SET** function.
- Turn and select the **MENU** function.

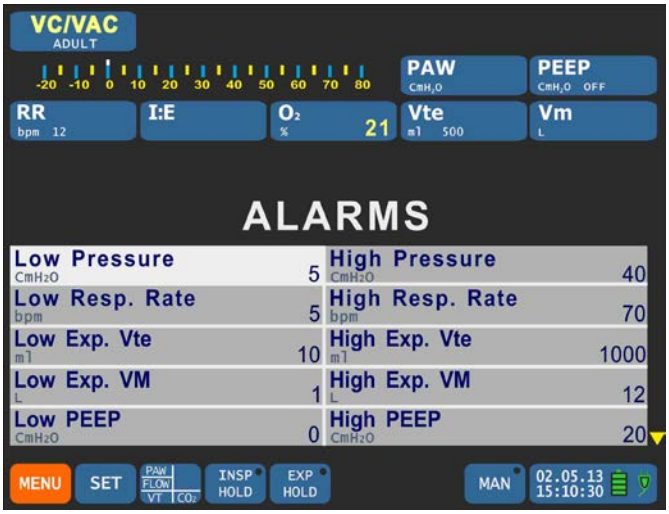


MENU

- Press the knob to confirm your choice.
- The system will display the MAIN MENU screen, **SETUP** parameters.

- Turn the knob to select the option **ALARMS**.

ALARMS



- Press the knob to confirm your choice.
- The system will display the **ALARMS** page.

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

4.8 Operating modes and PRP parameters

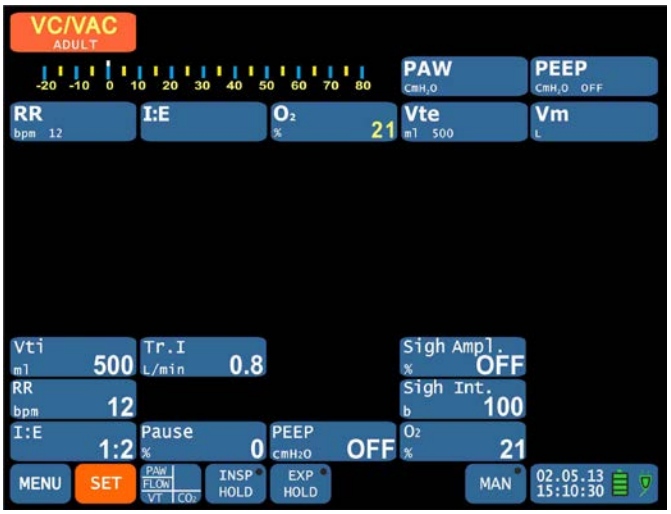
In the following chapter you will find a description of available physiological respiratory parameters (referred to from now on as PRP) and the operating modes selectable on Falco 202 lung ventilator.

WARNING !! Patient injury hazard

Thoroughly read this chapter and the entire user's manual to make sure you set the **PRP** correctly and choose the most suitable ventilation mode.

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

4.8.1 Operating mode and PRP parameters editing procedure



- Ventilator in STAND-BY mode

- Press the encoder knob two times; the system will activate the SET function (changes colour).

- The system will display all PRP relative to the set operating mode (VC/VAC).

When the 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 PATIENT TYPE : ADULT.

The procedure for setting a new operating mode or for editing the **PRP** values, implies using the encoder knob and the control keyboard as described on cfr. 2.4.

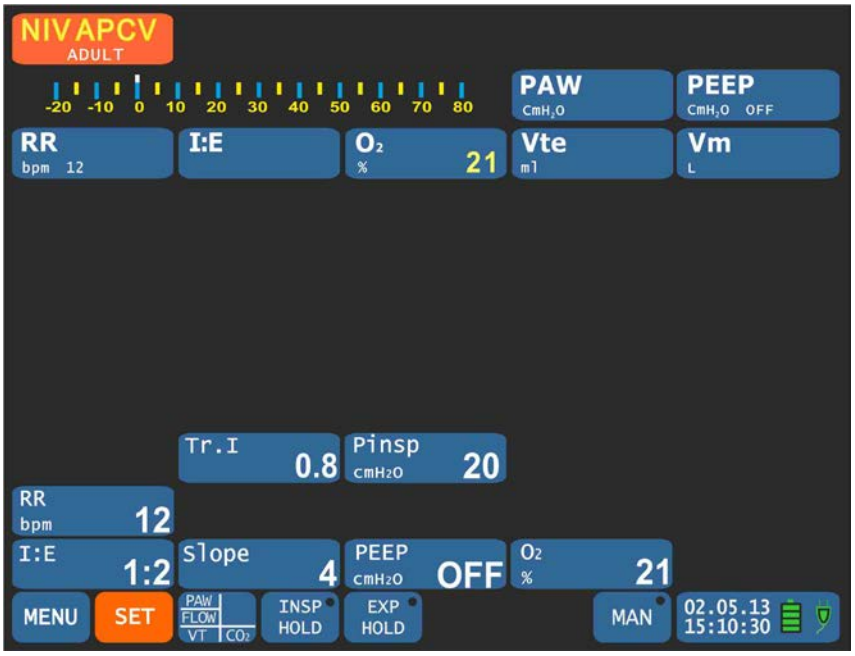
To exit SET screen:

- press the **ESC** soft key
- wait for the system to return to **STAND-BY** mode automatically.

4.8.2 NIV APCV (APCV)

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

The system displays all PRP relative to the set operating 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).

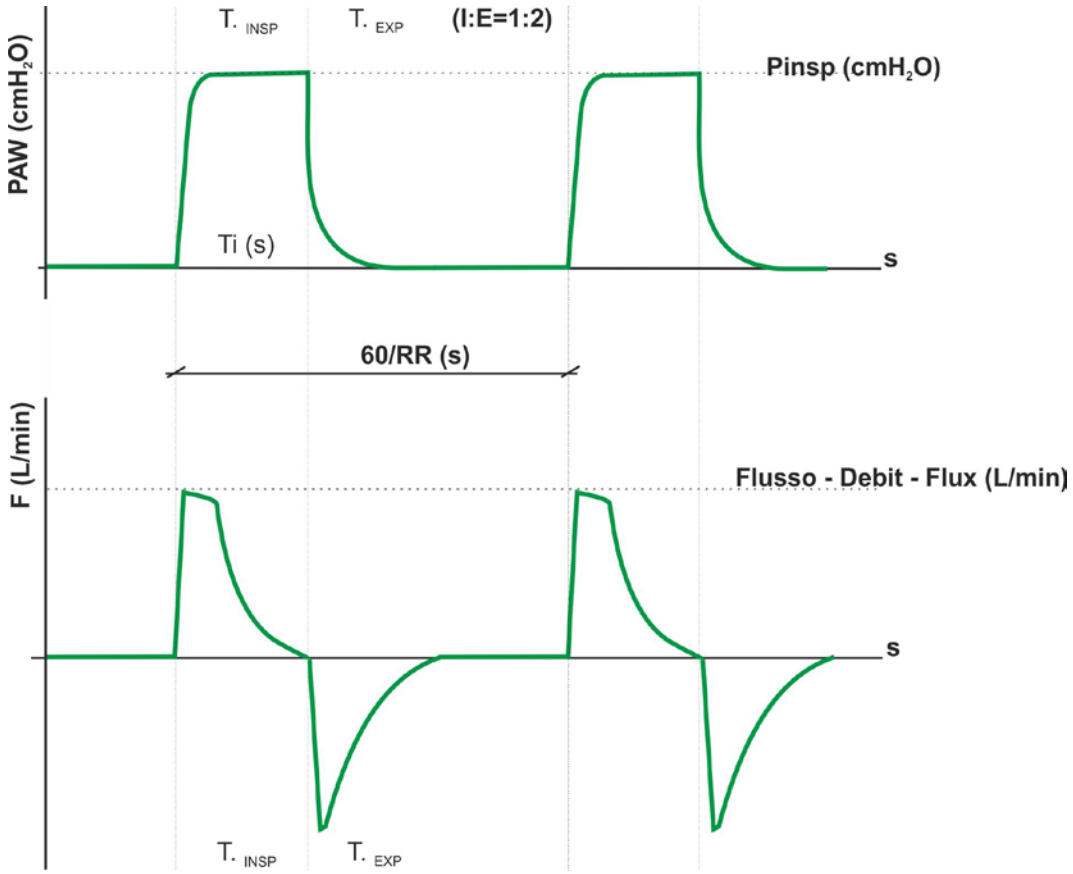
In APCV the current volume depends on the inspiratory pressure (Pinsp) and on the patient's lungs characteristics (compliance, lung capacity) therefore the tidal volume will vary depending on changes in lung mechanics.

During the inspiratory phase, the ventilator generates a settable flow (Slope). When the airway pressure reaches the control value (Pinsp), this pressure level is kept constant by the 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.

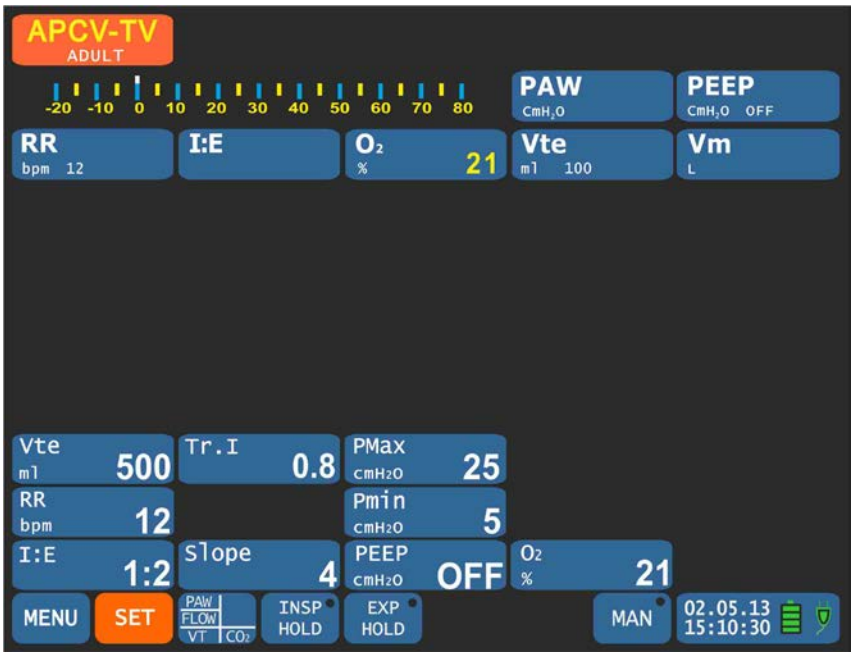
If the pressure set is not reached, make sure that the patient circuit is perfectly sealed and that the PRP parameters are properly set.



4.8.3 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 operating mode.



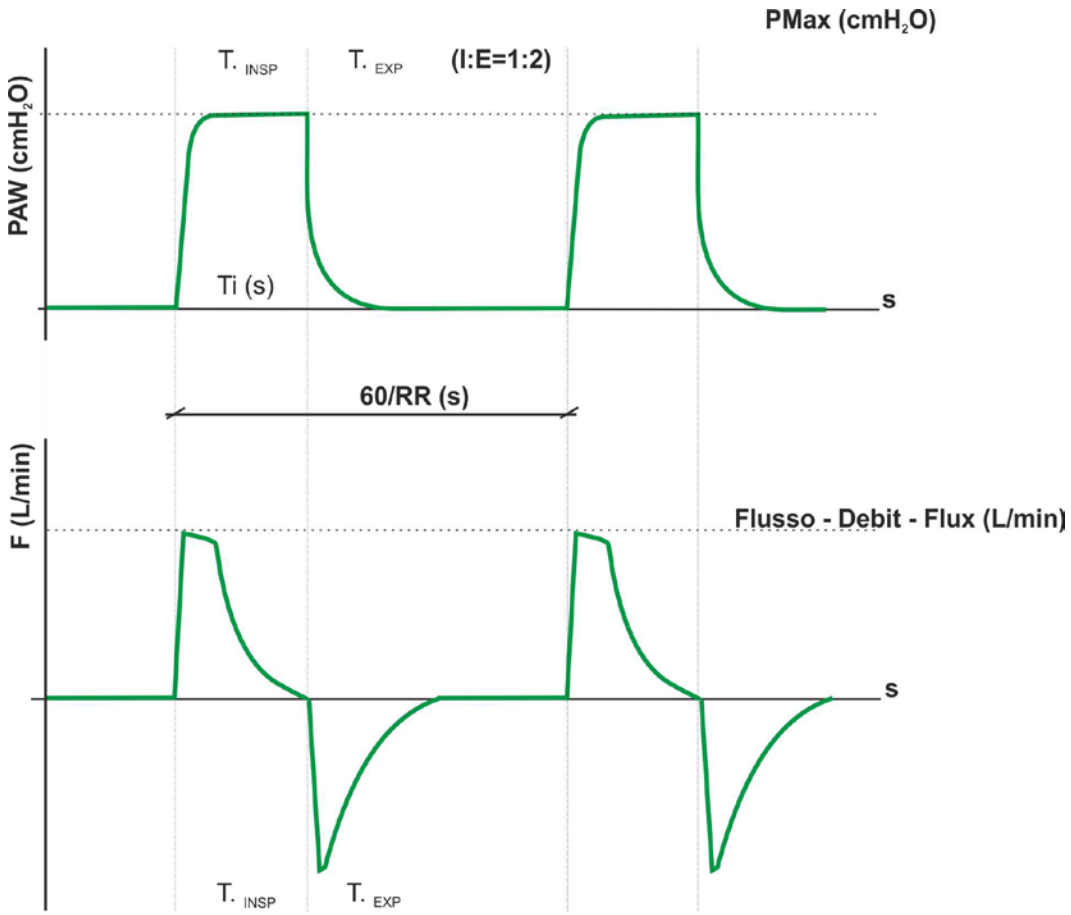
APCV-TV is a pressure controlled ventilation, synchronised with the patient's breathing (automatic Pinsp) with guaranteed current volume (Vte).

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 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 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.

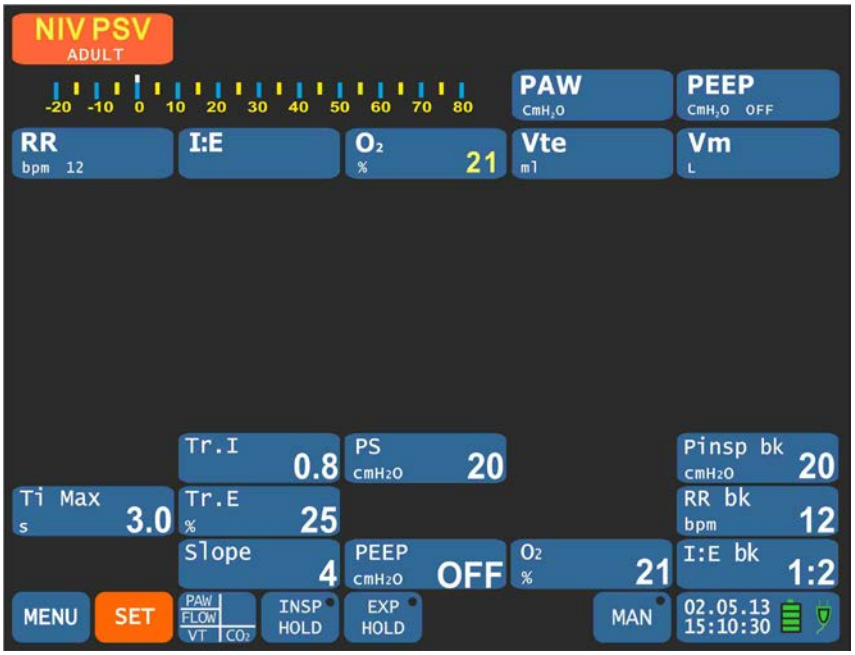
The greater the value, the greater the patient's effort to breath.



4.8.4 NIV PSV (PSV)

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

The system displays all PRP relative to the set operating mode.



PSV is an assisted type of ventilation with pre-set pressure support (PS) with guaranteed safety respiratory rate set by the clinician in case of patient apnea (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 operating 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 ventilator provides a constant positive support pressure (PS) pre-set by the clinician 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 ventilator trigger (Tr. I).

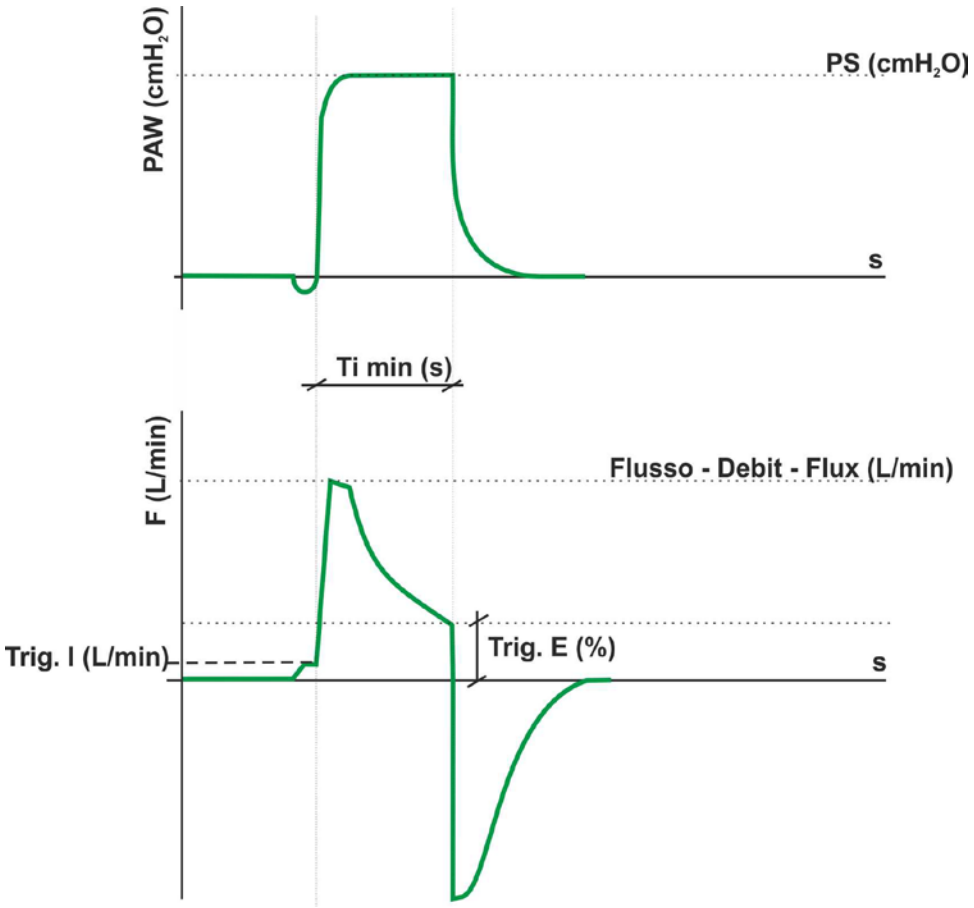
This way, the respiratory rate depends on patient spontaneous activity and the current volume depends on set parameter values and patient patophysiological conditions.

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 ventilator. Each breath initiated by the patient (Tr. I activated) is supported by the 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 apnea time set in MAIN MENU - SETUP), the system activates the APNEA 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).

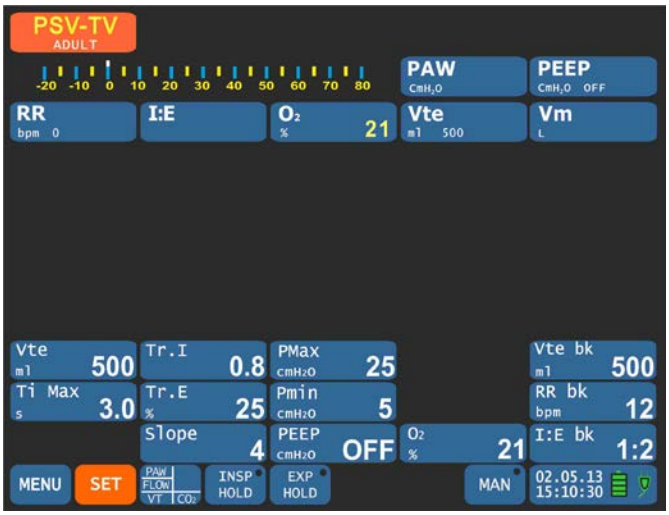


4.8.5 PSV-TV

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

PSV-TV

The system displays all PRP relative to the set operating mode.



PSV-TV is an assisted pressure support ventilation with guaranteed current volume and guaranteed safety respiratory rate set by the clinician in case of patient apnea (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 operating 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 ventilator provides support at an guaranteed volume (Vte) pre-set by the clinician.

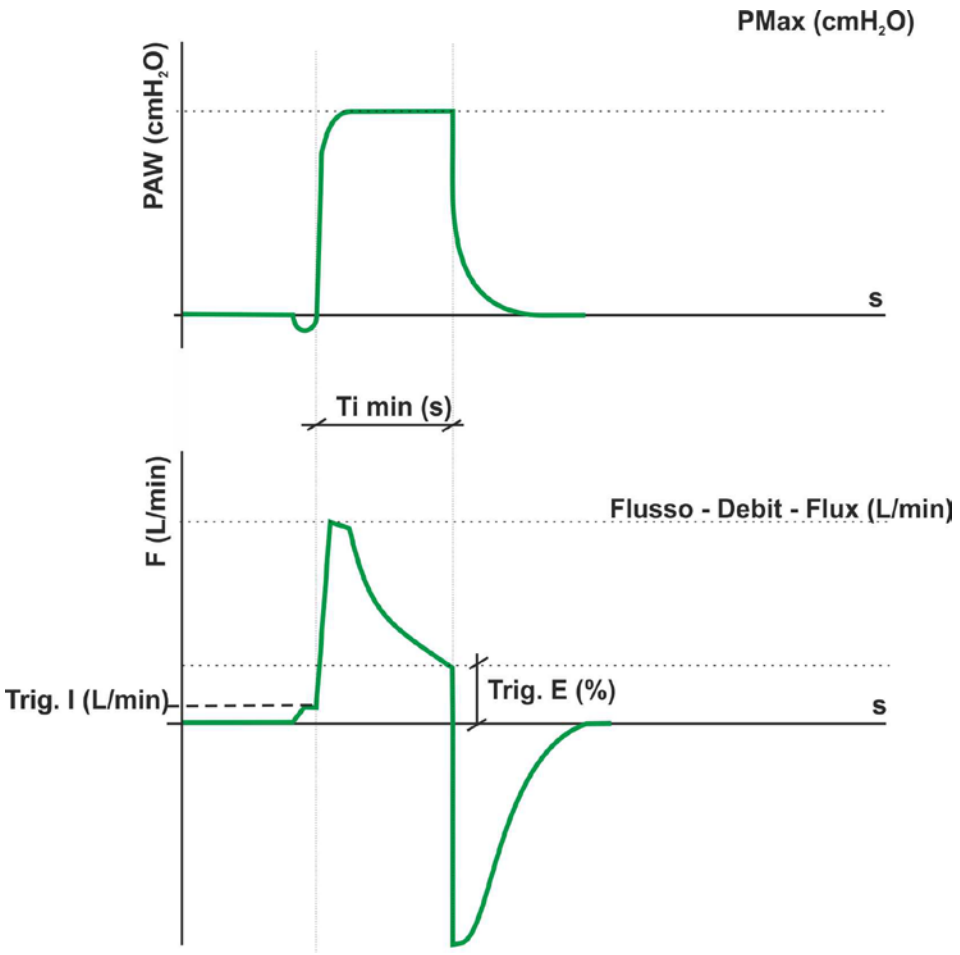
When the Vte pre-set value is reached, the expiration takes the place of the inspiration (according to Tr. E - percentage of the inspiratory flow peak beyond which the expiration can begin).

This technique saves the patient from the work of breathing, as he only has to reach the small quota necessary to enable the 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 ventilator. Each breath initiated by the patient (Tr. I activated) is supported by the ventilator, that sends inside the airway an guaranteed tidal volume, pre-set by the clinician.

If the patient does not trigger (spontaneous breathing during the apnea time set in MAIN MENU - SETUP), the system activates the APNEA acoustic and visual alarm.

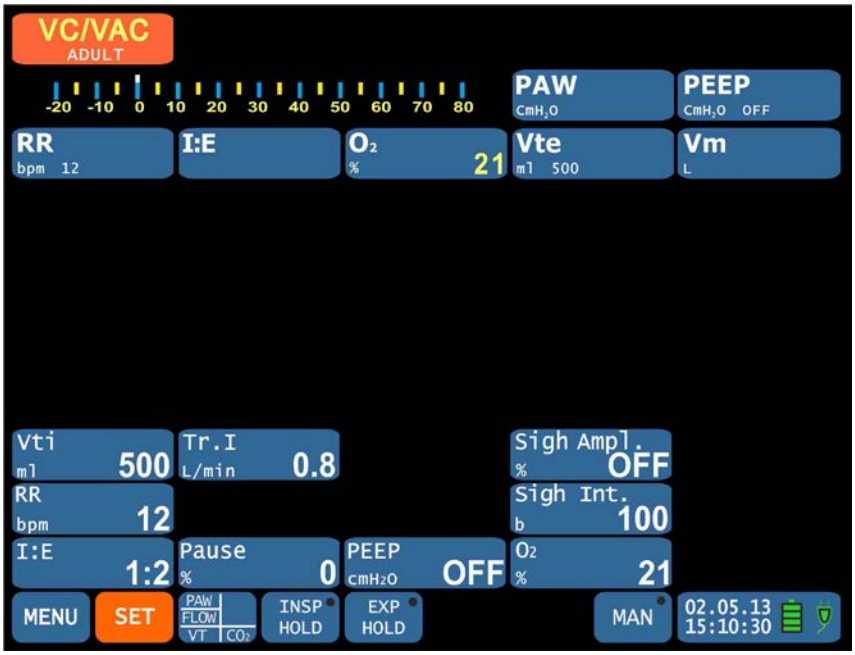
The system will automatically provide an APCV-TV ventilation with set safety respiratory rate (RR bk) and I:E ratio (I:E bk).



4.8.6 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 operating 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 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.

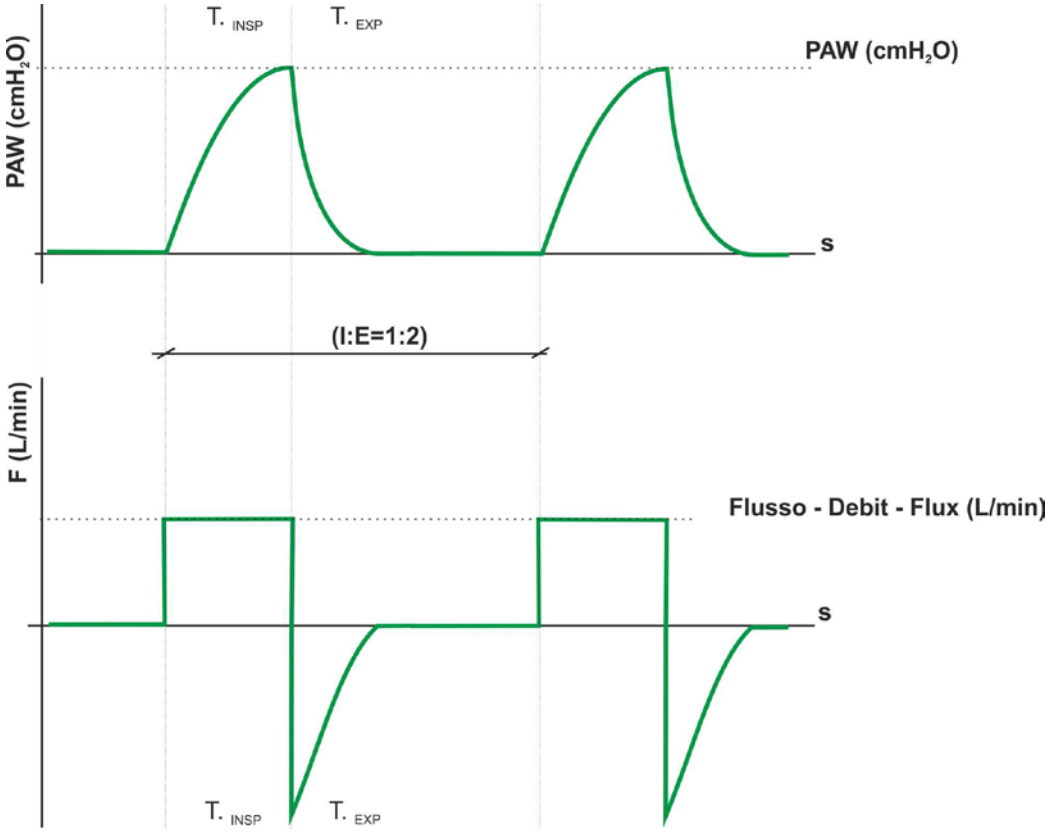
The patient's breathing attempt is detected by the system (Tr. I) and it automatically sends inside the airway a gas flow at a pre-set volume (Vti).

To combine the assisted mode with the control mode, the clinician 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 activates the trigger, the 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 ventilator screen.

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

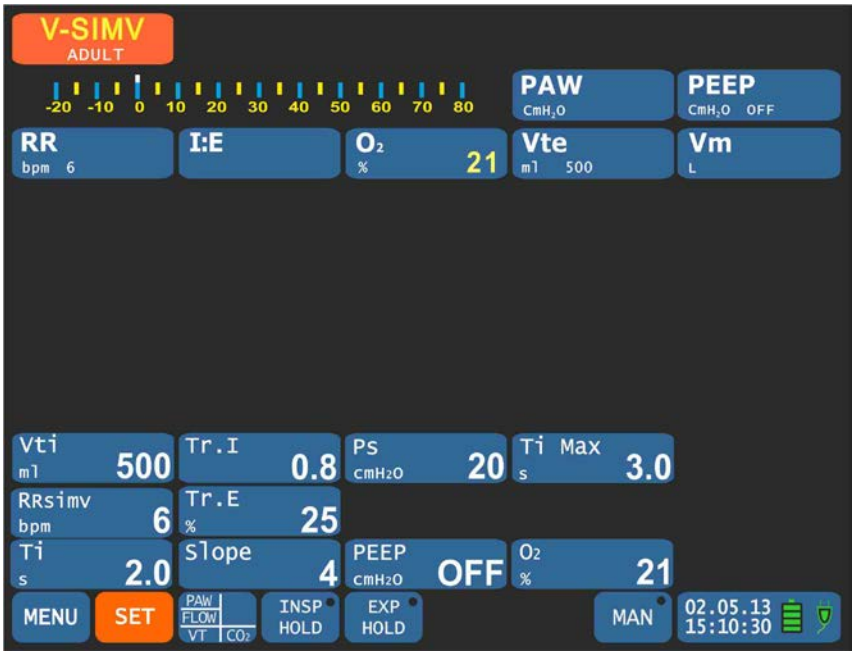
If the patient's spontaneous breathing respiratory rate is greater (than the respiratory rate set on the ventilator) the machine will increase the number of breaths per minute (with regard to the number set in the control panel) and displays the value on the integrated monitor.



4.8.7 V-SIMV

Volume-targeted synchronised intermittent mandatory ventilation.

The system displays all PRP relative to the set operating mode.



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

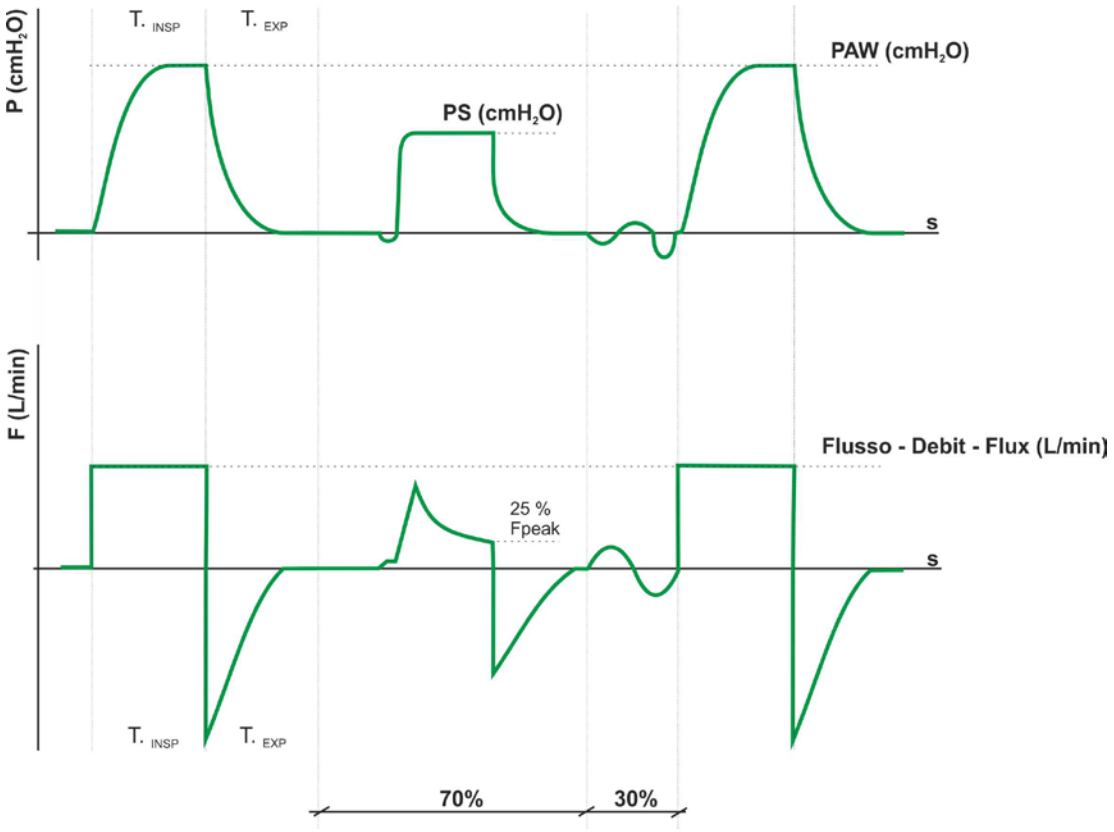
The Operative Mode V-SIMV is active only with patients: ADULT and PAEDIATRIC.

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 activate 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 clinician is reached, leaves its place to the expiration phase (Tr. E).

Therefore, in SIMV mode, the 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 ventilator) to an assisted ventilation mode.



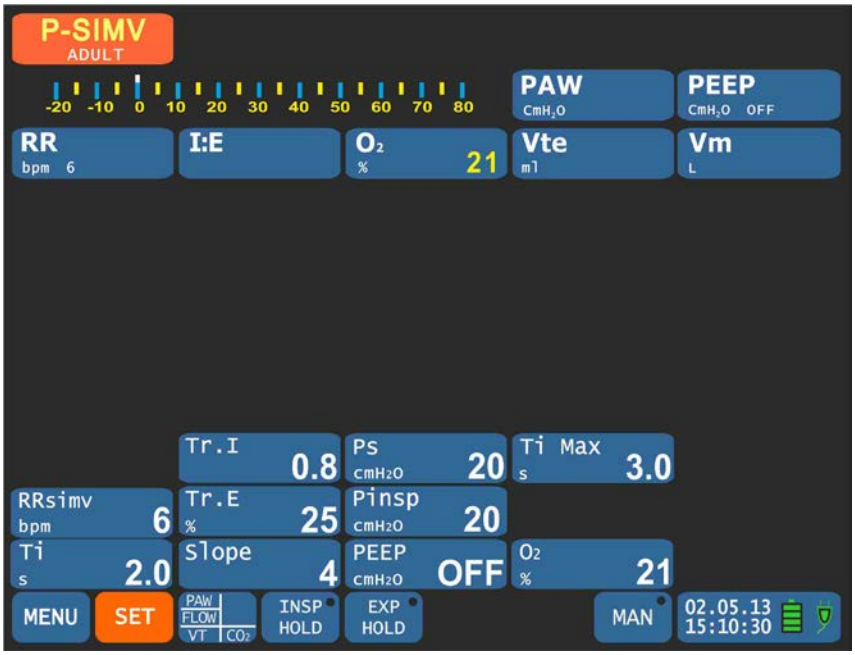
The graphic shows how the SIMV operating mode works.

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.

4.8.8 P-SIMV

Pressure-targeted synchronised intermittent mandatory ventilation.

The system displays all PRP relative to the set operating mode.

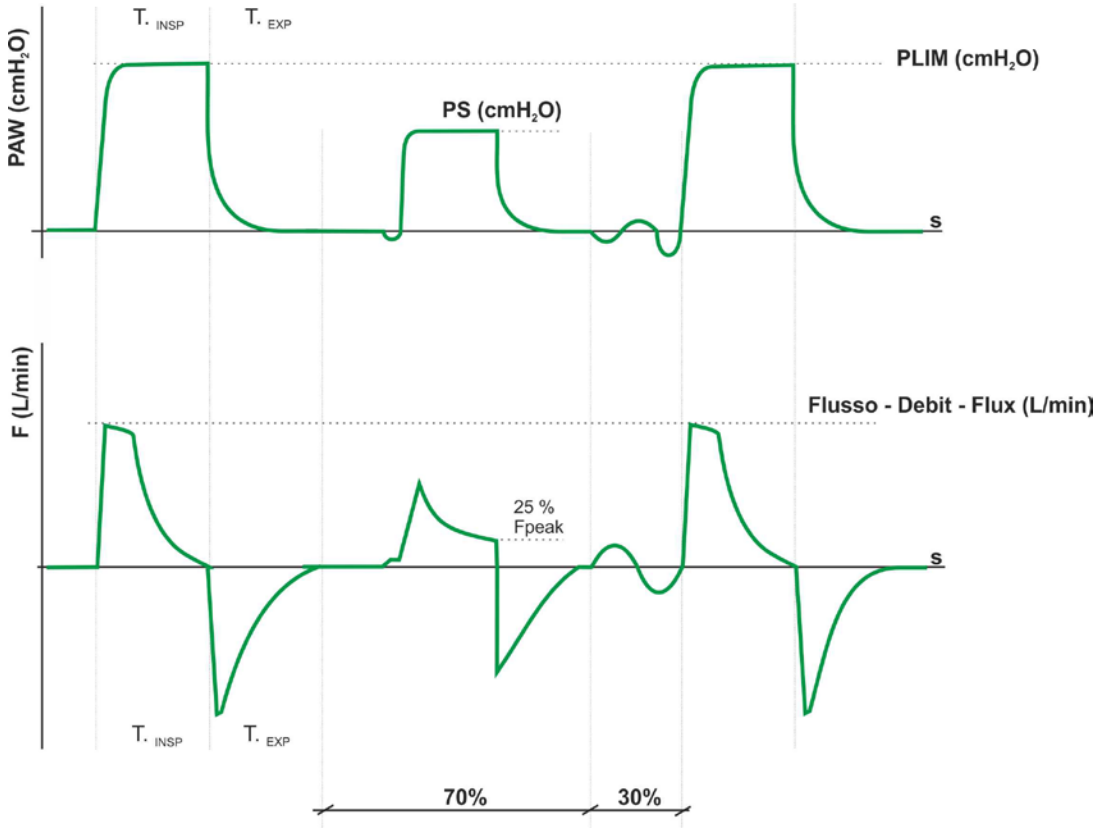


P-SIMV is a synchronised intermittent mandatory ventilation, during which the ventilator generates a certain number of breaths per minute (RRsimv) at a pre-set inspiratory pressure (Pinsp) providing pressure support (PS) during the spontaneous phase.

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 activate 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 clinician is reached, leaves its place to the expiration phase (Tr. E).

Therefore, in SIMV mode, the 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 ventilator) to an assisted ventilation mode.



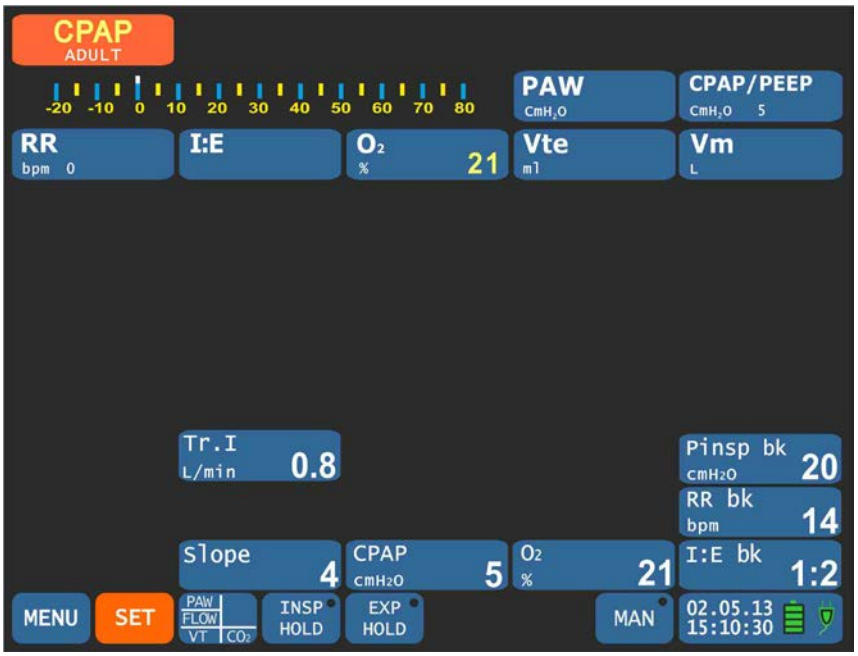
The graphic shows how the SIMV operating mode works.

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.

4.8.9 CPAP

Positive continuous pressure applied on the airway.

The system displays all PRP relative to the set operating mode.



CPAP is a spontaneous positive pressure ventilation at continuous flow.

In this operating 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 apnea time set in MAIN MENU - SETUP), the system activates the APNEA acoustic and visual alarm.

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

During the Apnea Back-up activation (in APCV ventilation), if you push the ALARM RESET button only the acoustic alarm is silenced. Then, the system will come back to CPAP ventilation only when the patient will be able to breath spontaneously.

4.8.10 MAN operating mode

MANUAL ventilation available in all operating modes.

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

The breath ventilation parameters depend on the set operating 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.

4.8.11 APNEA BACK-UP

Apnea BACK-UP is a safety function available in three of the operating modes: PSV, PSV-TV and CPAP.

The apnea BACK-UP function activates if the patient, ventilated in one of the modes above, stops breathing.

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

WARNING !! Patient injury hazard

When the ventilator switches to this safety mode automatically, the clinician CANNOT edit the ventilation parameters.

The ventilator continues its activity and the clinician acknowledges the emergency condition.

When the apnea BACK-UP function activates, the ventilation parameters used are those set based on the selected operating mode.

WARNING !! Patient injury hazard

To return to the initial ventilation conditions (operating modes, PSV, PSV-TV and CPAP press the alarm silencing soft key.

4.8.12 Physiological respiratory parameters (PRP)

The physiological respiratory parameters must be set by the clinician in STAND-BY mode before activating the necessary operating mode.

The system allows you to set default PRP (**MAIN MENU - DEFAULT PARAMETERS)** suited for ventilating an adult patient.

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 ventilator runs, adapting them to the patient's clinical situation.

The parameters marked with BK are referred to the **Back-Up** operating mode.

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

CPAP (cmH2O)

Continuous positive airway pressure during respiration phase.

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).

I:E

Ratio between inspiration and expiration phases.

RR (bpm)

Ventilator respiratory rate.

RRsimv (bpm)

Value of forced respiratory rate in SIMV mode.

O2

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

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.

Pressure Low (cmH2O) - Pressure High (cmH2O)

Pressure levels to be set in APRV mode.

PS (cmH2O)

Positive airway support pressure value during inspiratory phase.

Sigh. Ampl. (%)

Sigh. Percentage increase of the set Vti.

Sigh. Int. (b)

Sigh. Activation frequency.

Ti (s)

Time that defines the 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)

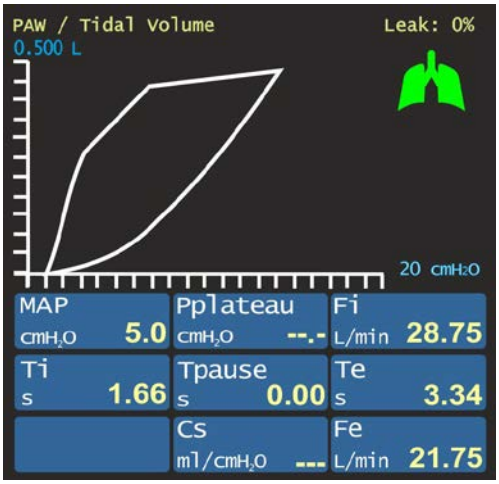
Expired tidal volume guaranteed for the patient.

Vti (ml)

Inspired tidal volume guaranteed for each breath.

4.8.13 Additional respiratory parameters

By selecting the GRAPHIC setup function using the encoder knob, the clinician can select and edit the curves, loops and additional parameters position.



Mean airways pressure

It shows the average calculated pressure for the airways: the unit of measurement is cmH2O.

Pause pressure

It shows the pause pressure: the unit of measurement is cmH2O.

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

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.

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 ventilator keeps the airway pressure constant.

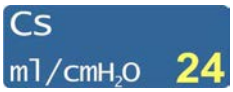
Example: if RATE=15, I:E=1:1, Ppause=50% you will have an inspiratory pause period of 1 second.

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

Static compliance



It is one of the two parameters of the lung mechanics: measured in ml/cmH_2O. 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

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.

For additional ventilation parameters monitoring, please see 4.10.

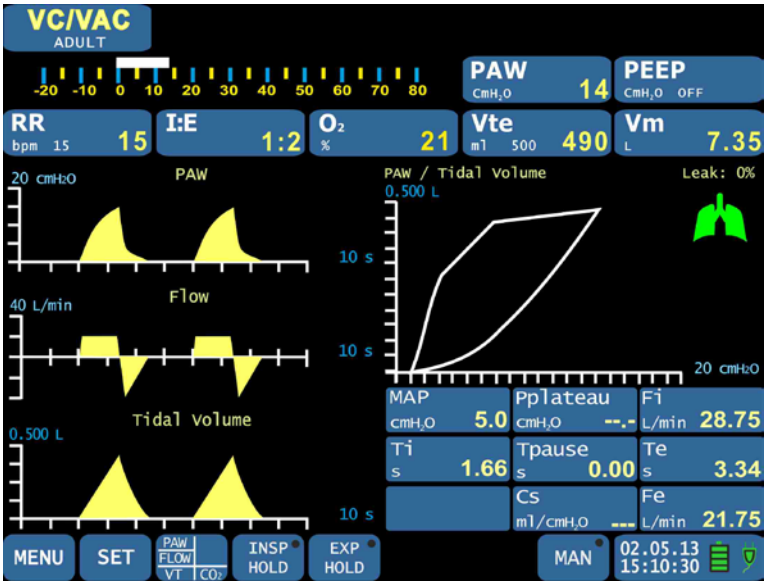
4.9 Ventilation phase

Before starting the ventilation you have to:

- carry out all ventilator hardware connections (medical gases, power supply, patient circuit, ……..)
- carry out the preliminary checks (please see chapter 3.6)
- set the language and the patient data
- set and check the alarms limits
- set the Physiological Respiratory Parameters and the operating mode that match the patient's clinical situation best.

Based on the **PRP** set by the clinician 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.

- Press **START** soft key to begin the ventilation in the selected mode with the most suitable **PRP** for the clinical situation of the patient.
- To returns in **STAND-BY** mode, please see 4.9.1.



- In the upper section of the display you can find some values that will help you asses the patient's clinical condition.
- In the main section you can see the curves that show the trend of the respiratory parameters.
- On the right side of the screen there is a suitable lung icon that simulates the patient's lungs, graphically displaying the respiratory cycle by alternatively switching the lungs color.

4.9.1 Ventilation interruption

Ventilator running

- To interrupt the ventilation, hold the **ON-OFF** key for several seconds.

- The system will ask you if you want to stop the ventilation (switch to STAND-BY mode).

- Press **ENTER** to switch to STAND-BY mode.

- Wait for a few seconds or press the **ON/OFF** key : the ventilator switches back to the previous condition, in the set ventilation mode.

Ventilator in STAND-BY mode

- To stop the ventilator, hold the **ON-OFF** key for several seconds.

- The system will ask whether to remain in STAND-BY or to shut down.

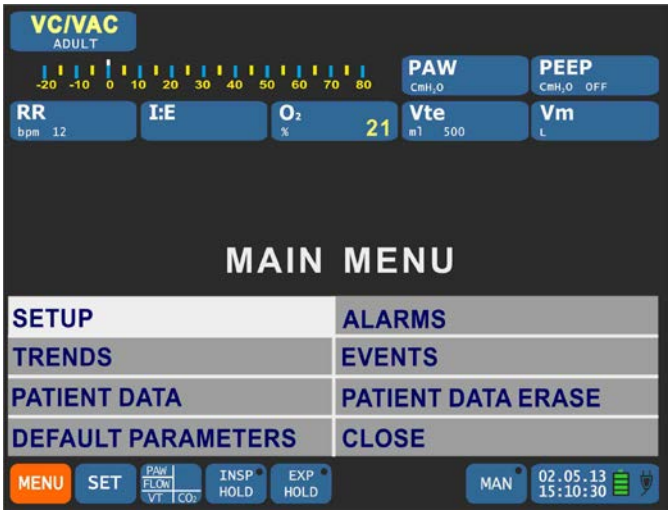
- Press the **ENTER** key to turn the ventilator off.

- Press the **ON/OFF** key : the ventilator returns to STAND-BY.

4.10 Graphical settings and operating functions

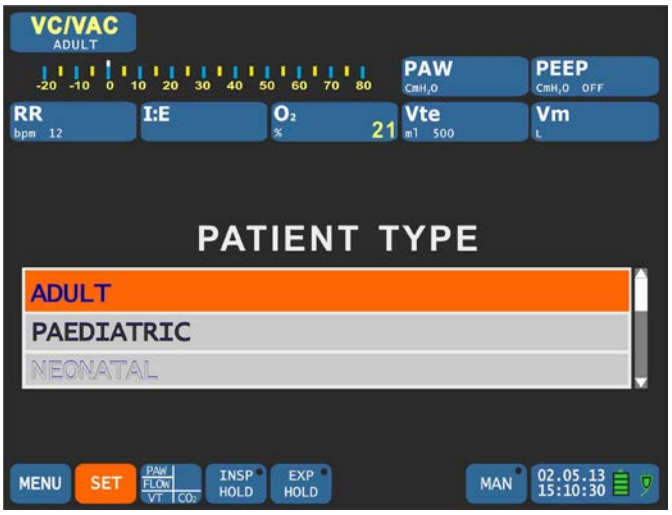
During the ventilation, the clinician can intervene using the graphical user interface, by selecting the options in the lower side on the screen.

Select the **MENU** function using the encoder knob to access the ventilator's **MAIN MENU** (please see 4.11) where you can find all the functions displayed in the figure.



Function **SET** : first selection

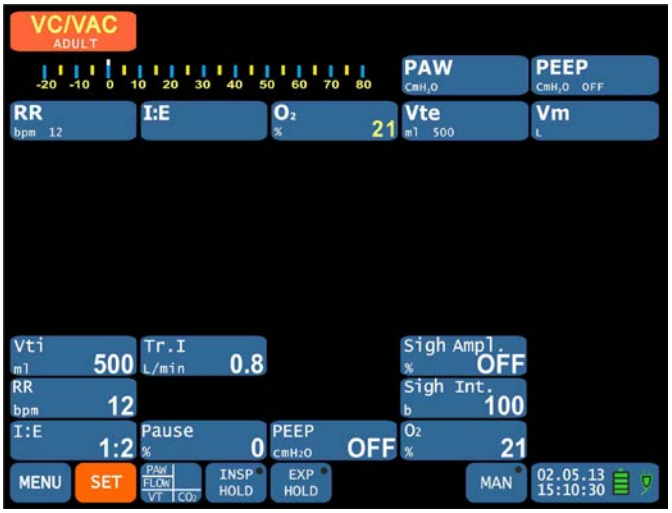
The SET function permits to show/modify the patient type choice (ADULT, PAEDIATRIC, NEONATAL).



When the ventilator is switched on and the **SET** function is selected it is possible to choice the patient type (ADULT, PAEDIATRIC, NEONATAL).

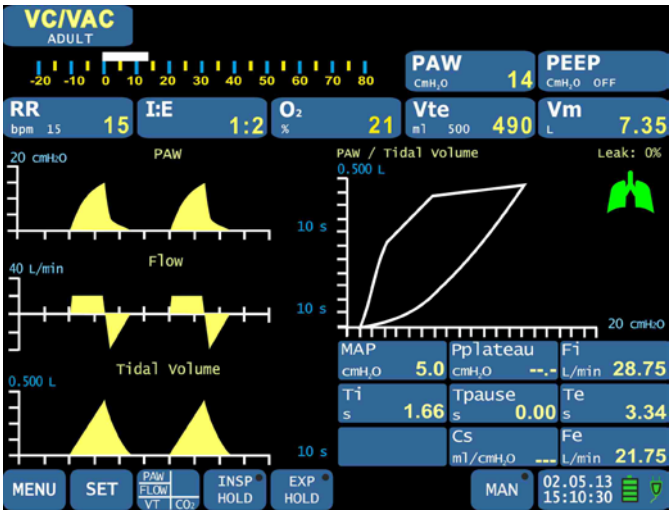
The choice of the patient type permits to set automatically the default of the lung ventilator (patient breathing parameters and alarms setting).

Select the **SET** function using the encoder knob to access the ventilator operating mode setup and **PRP** configuration as you can see in the figure (please see 4.8).



Select the **GRAPHIC** function using the encoder knob, to view the patient's data in real time, by means of:

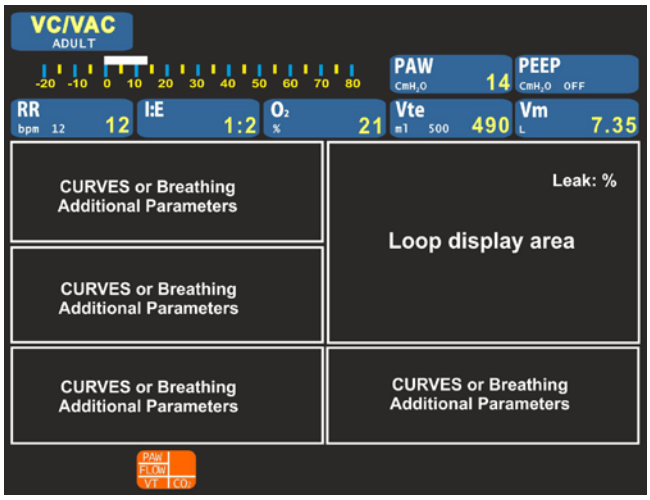
- Curves: PAW / Time , Flow / Time , Volume / Time , CO2
- **Loops**: PAW / Current Volume , Current Volume / Flow , PAW / Flow
- **Additional parameters table**.



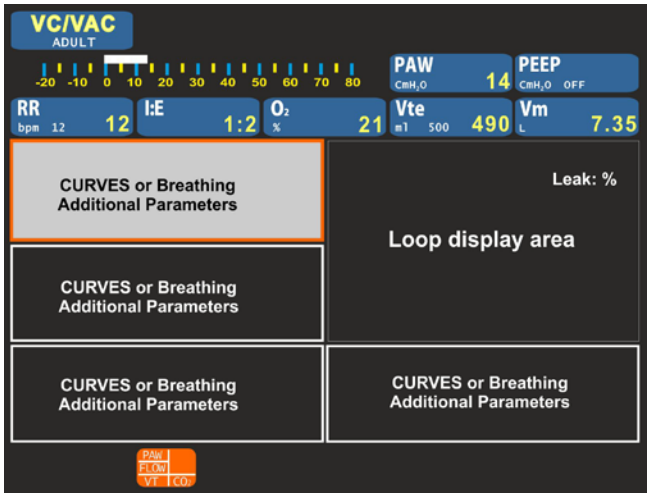
To change the combination of **GRAPHIC** displayed on the screen, the ventilator must be on.

Areas available on the display :

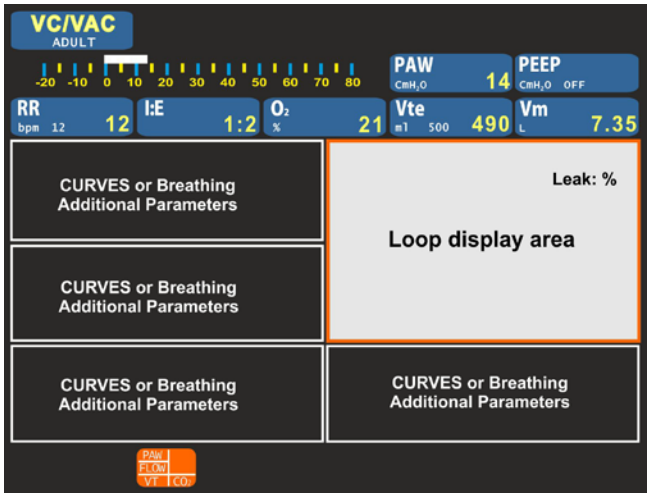
- 4 areas (frames) for the additional parameters and curves;
- 1 area (frame) for loops positioning.



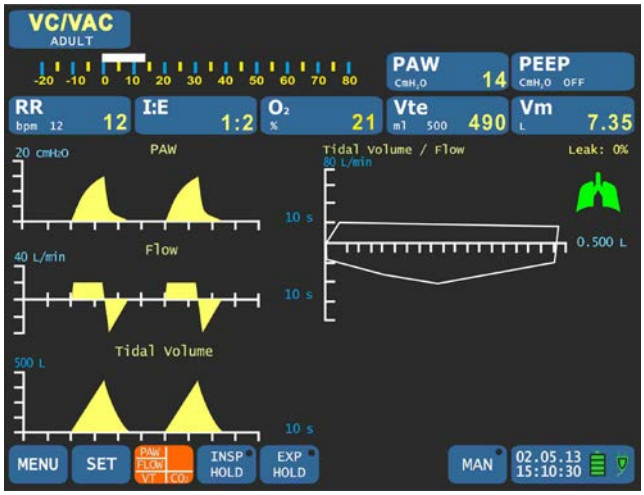
- Press the knob to highlight the first frame.



- Turn the knob: the frames will be highlighted in sequence.
- Press the knob to confirm the frame modification.

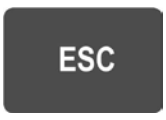


- Turn the knob, the various types of curves will be displayed in sequence.
- Press the knob to confirm your choice.



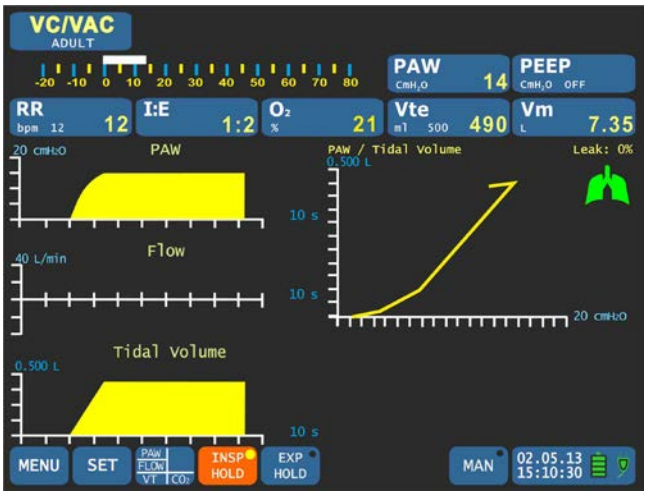
To return to ventilation view:

- press the ESC soft key;
- wait for the system to return to ventilation screen automatically.



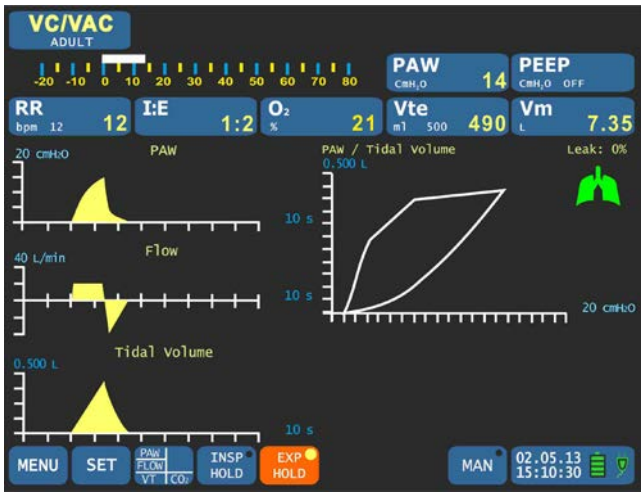
Select the INSP HOLD mode and press the encoder knob: the system will extend the inspiration time from 5 up to 15 seconds.

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 and press the encoder knob: the system will extend the expiration time from 5 up to 10 seconds.

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



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

INSP HOLD and EXP HOLD modes:

- are deactivated automatically
- or by pressing the encoder knob.

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

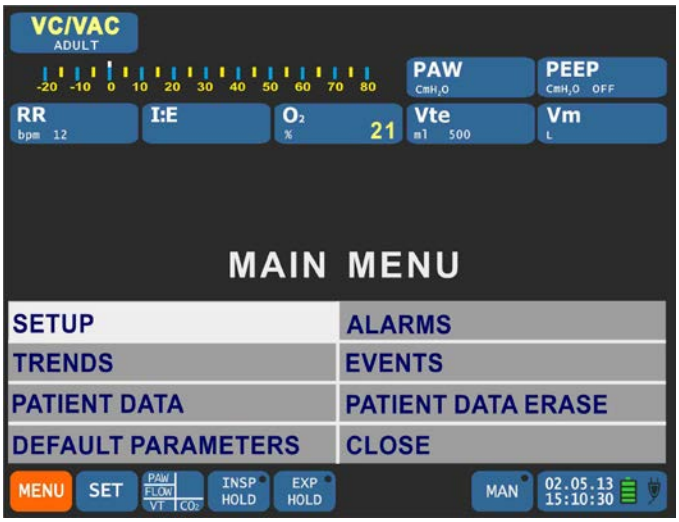
The breath ventilation parameters depend on the set operating mode. The function activation is monitored by the screen and signalled by the green LED inside the box, that turns on.

This mode is active while the lung ventilator is running.

4.11 MAIN MENU

By selecting the MENU function you can view the MAIN MENU page and set the functions necessary for proper ventilator operation.

Before using the Falco 202 lung ventilator for intensive care, emergency and transport, please use the **MENU function** to set all necessary items for proper ventilator operation.



- Use the encoder knob to select the **MENU** box (the **MENU** box changes color)
- Press the knob, on the display will appear the **MAIN MENU**.
- **SETUP** function activated (box in different color).

SETUP

The procedure for selecting an option from the MAIN MENU, implies using the encoder knob and the control keyboard as described on chapter 2.4.

4.11.1 MAIN MENU – SETUP

To set the parameters in the SETUP option please see 4.12 **MENU - SETUP**.

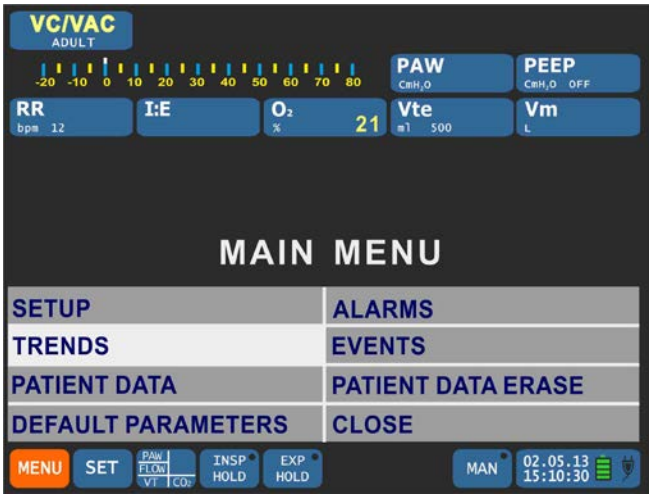
4.11.2 MAIN MENU – ALARMS

For ALARMS parameters and limits setup please see 5.2.4 **ALARMS** setup.

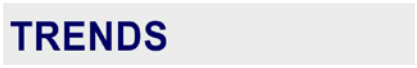
4.11.3 MAIN MENU – TRENDS

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

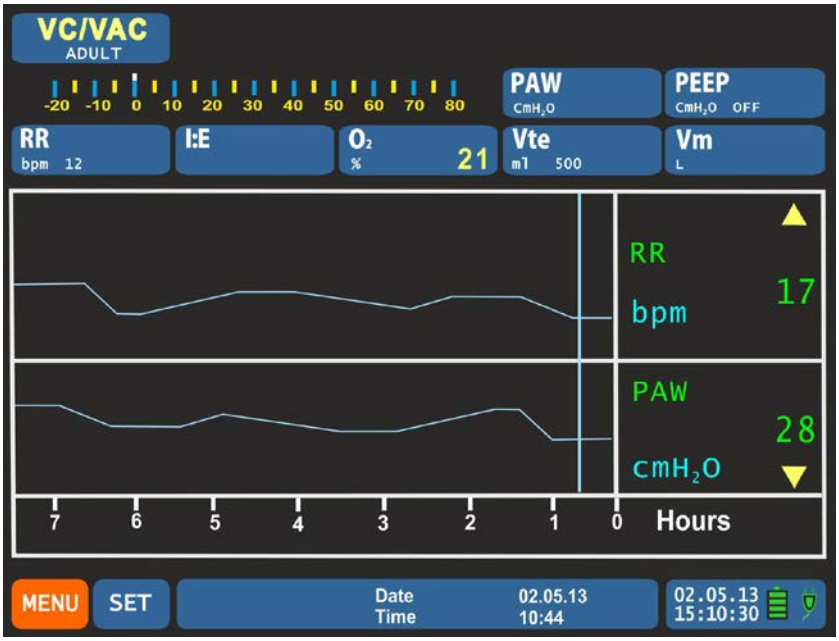
The storage capacity for each parameter is 72 hours with sampling at every 4 minutes.



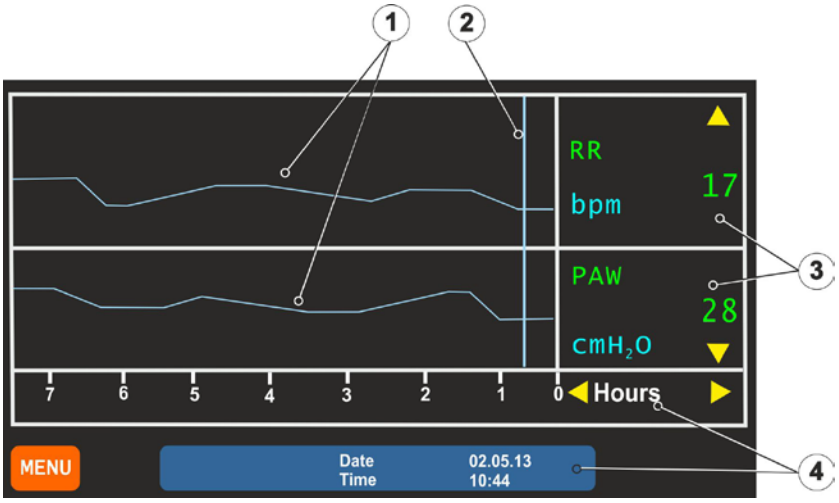
- Use the encoder knob to select the **TRENDS** box (the **TRENDS** box changes color).



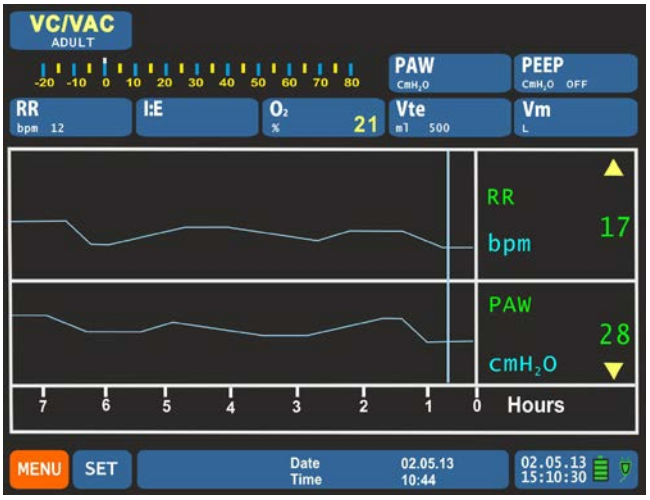
- Press the knob, on the display will appear the page **TRENDS.**
- The yellow arrow show the active work area.



1. PRP curves (graphic), viewed in pairs.
2. Vertical bar that shows the references movement in time.
3. PRP, selectable in pairs.
4. References over time on 72 hours with sampling at every 4 minutes.



TRENDS view



Press the knob:

- the parameters screen activates (turn the knob to choose the pair of parameters to monitor).

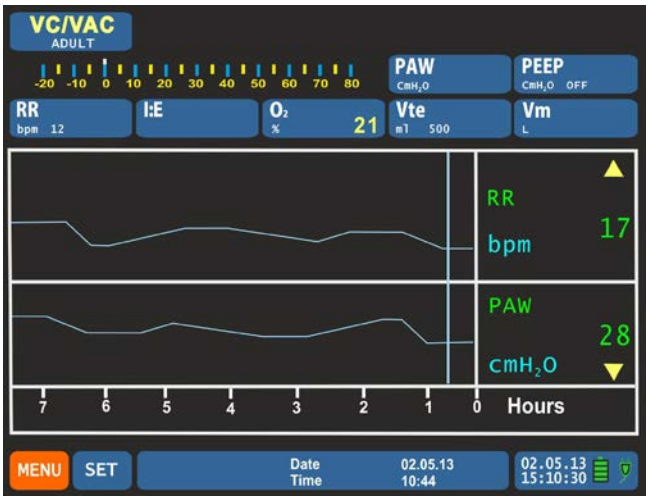
Press the knob:

- the vertical bar scrolling activates (turn the knob to move the bar in time).

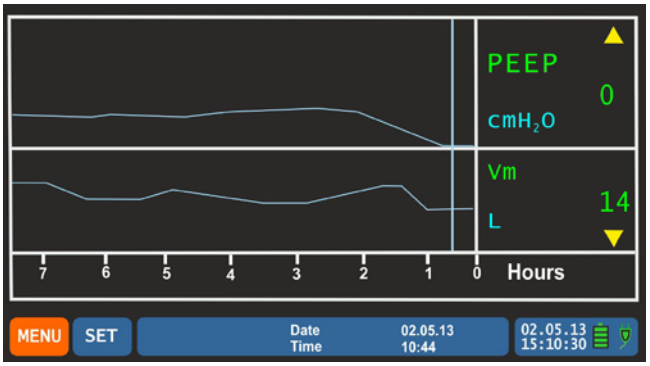
The parameters, that you can select in pairs using the encoder knob are:

- the respiratory frequency or breaths - RR (bpm)
- the airway pressure - PAW (cmH2O)
- the positive expiration-end pressure - PEEP (cmH2O)
- the expired minute volume - VM (L)
- the expired current volume - Vte (ml).

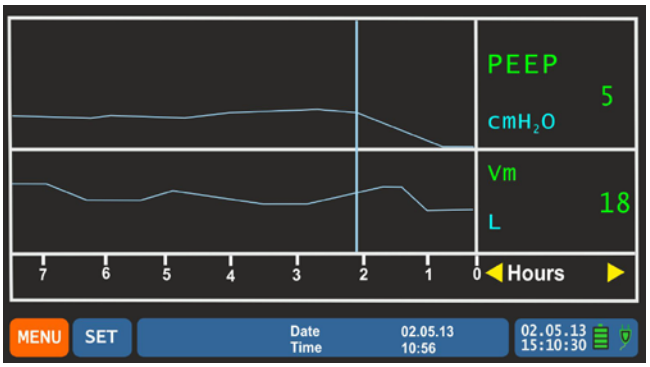
Editing TRENDS view.



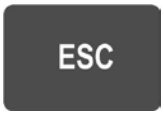
- The two yellow arrows show that the **PRP** area is active.



- Press and turn the encoder knob: select the two parameters you want to monitor (e.g. Vm - PEEP).
- Press the encoder knob: the two yellow arrows show that the Hours area is active (the vertical bar movement activates).



- Turn the encoder knob, the vertical moves to the left of the screen.
- At the same time the system updates the Date and Time (sampling every 4 minutes).
- At the same time the system updates the values of the selected parameters (e.g. Vm - PEEP): the system displays the trend of the parameters values.



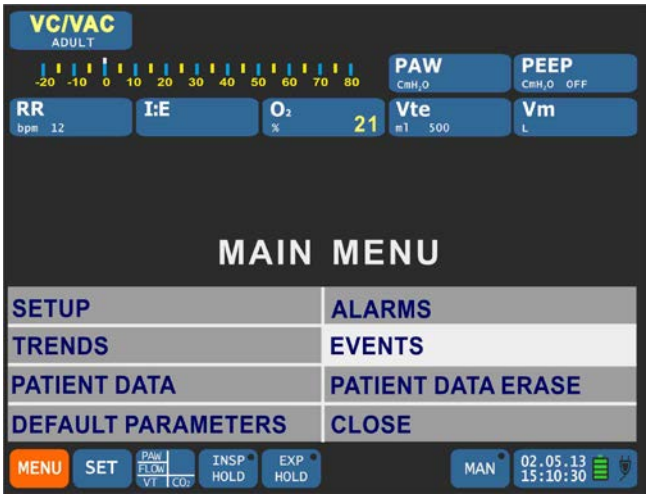
- Press **ESC** to exit the TRENDS screen and go back to STAND-BY screen.
- Wait for the system to return to **STAND-BY** screen automatically.

4.11.4 MAIN MENU – EVENTS

Select the EVENTS function to monitor the information on the 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).

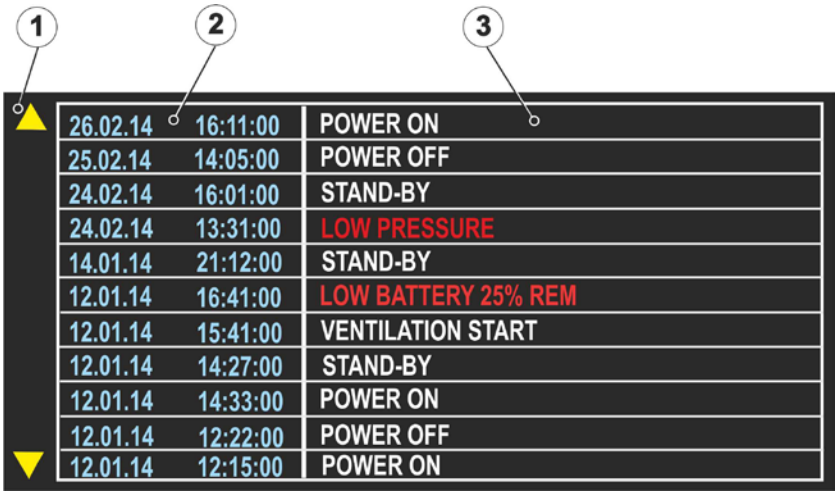
The system can register up to 100 events, including the alarms.



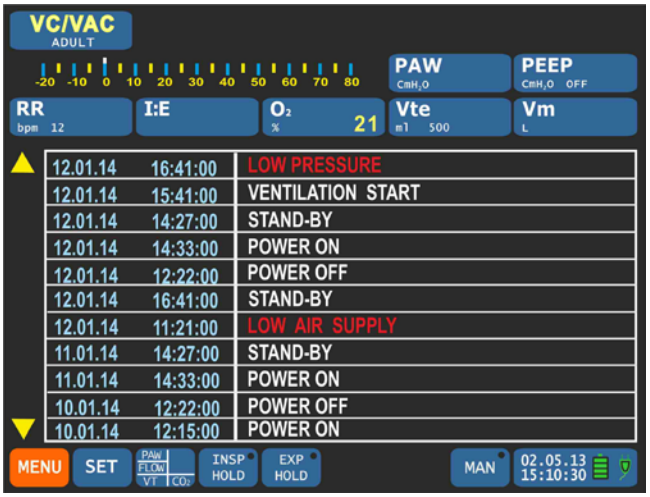
- Use the encoder knob to select the **EVENTS** box (the **EVENTS** box changes color).

- Press the knob, on the display will appear the page **EVENTS**.

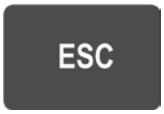
1. Events time change indicator.
2. Event date [26.02.14] and time [16.11.00] indicator.
3. Event description (white - red).
    - WHITE text : information on the ventilator operating status.
    - RED text : information on event's alarms .



EVENTS view



- Turn the knob clockwise (anticlockwise) to view the EVENTS saved in the table.



- Press **ESC** to exit the EVENTS screen and go back to STAND-BY.
- Wait for the system to return to **STAND-BY** screen automatically.

4.11.5 MAIN MENU - PATIENT DATA

To set the parameters in the patient data option please see 4.5 **PATIENT DATA.**

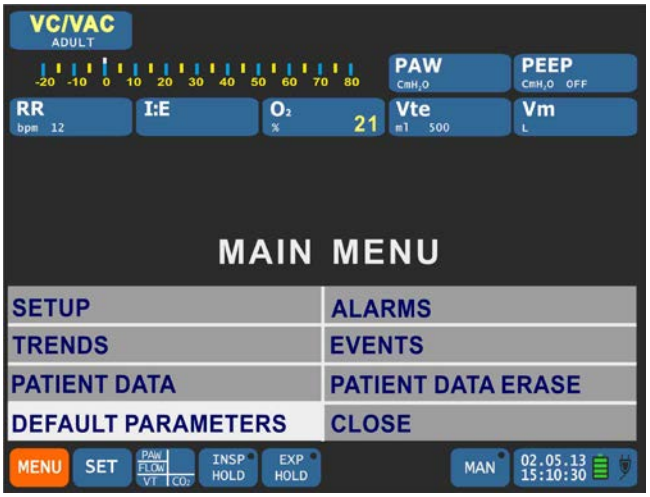
4.11.6 MAIN MENU - PATIENT DATA ERASE

To delete the patient data, please see 4.6 **PATIENT DATA ERASE**.

4.11.7 MAIN MENU - DEFAULT PARAMETERS

Select the **DEFAULT PARAMETERS** function to restore the lung ventilator DEFAULT PARAMETERS : (Factory - SET).

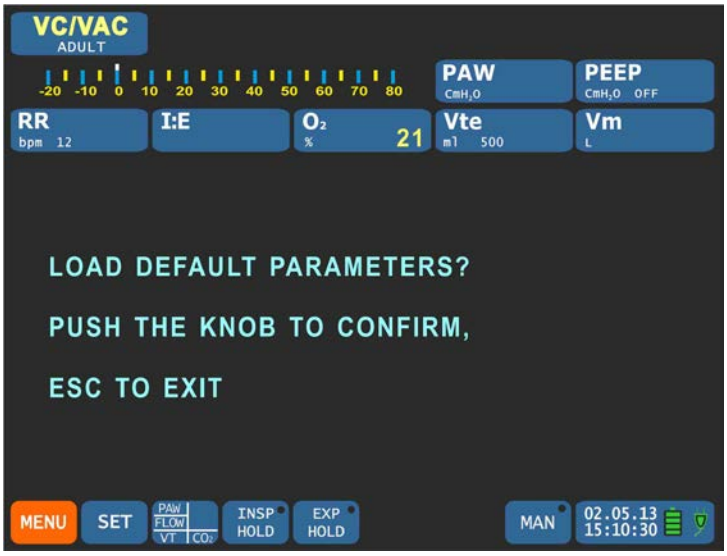
By factory parameters we refer to all operation settings (MENU, SETUP, ALARMS limits, IGU colours).



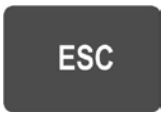
- Use the encoder knob to select the **DEFAULT PARAMETERS** box (the DEFAULT PARAMETERS box changes color).

DEFAULT PARAMETERS

- Press the knob, on the display will appear the page **DEFAULT PARAMETERS**.

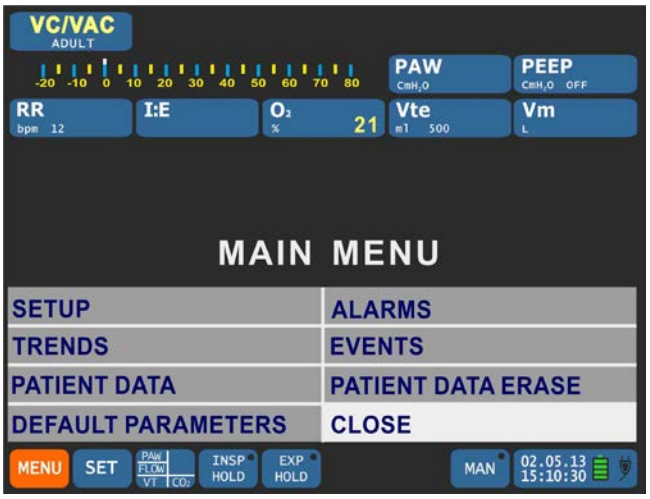


Press the knob to restore the **DEFAULT PARAMETERS**.



- Press **ESC** to exit from DEFAULT PARAMETERS screen and go back to MAIN MENU.
- Wait for the system to return to **STAND-BY** screen automatically.

4.11.8 MAIN MENU – CLOSE

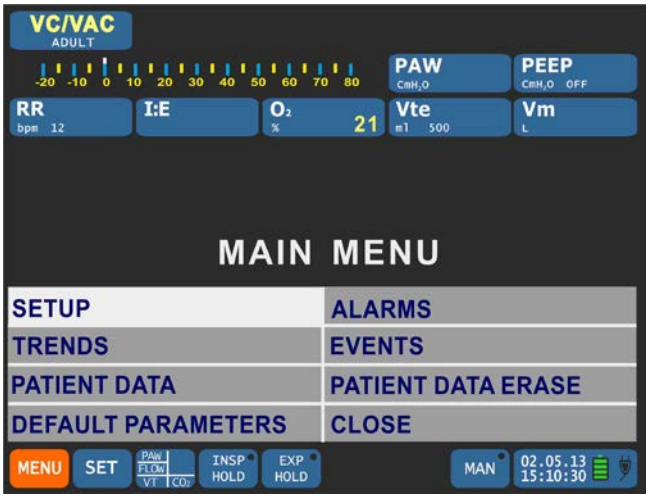


- Select the **CLOSE** box to exit the MAIN MENU and go back to **STAND-BY** view or to patient ventilation view.

If the clinician does not select any function in the MAIN MENU the system returns automatically to the previous display.

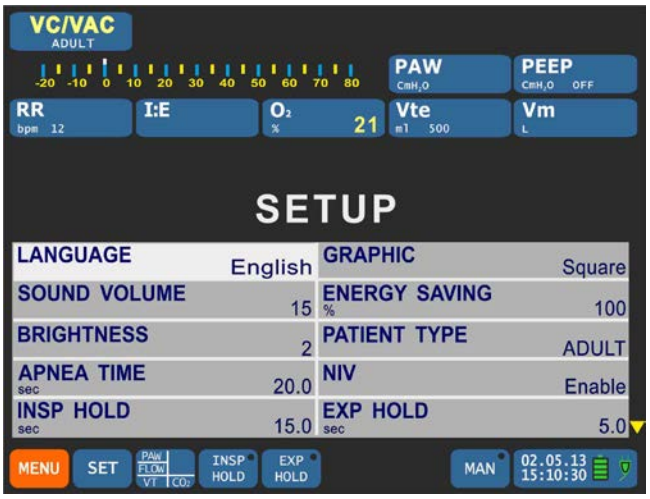
4.12 MAIN MENU – SETUP

Select the **MENU** function to access the **MAIN MENU** screen and a series of functions such as **SETUP**, essential for setting up the ventilator operation.



- Use the encoder knob to select the **MENU** box (the MENU box changes color).
- Press the knob, on the display will appear the **MAIN MENU** at the option SETUP.

SETUP function activated (box in different color).



- Press the knob, on the display will appear the **SETUP** screen at the option **Language**.

- The yellow arrow shows that you can view other options by turning the knob.

The procedure for selecting an option from MAIN MENU – SETUP, implies using the encoder knob and the control keyboard as described herein (please see 2.4).

4.12.1 SETUP options in MAIN MENU

LANGUAGE English	Selection of the lung ventilator display language.
English, French, Spanish, Italian, German, etcc….	
GRAPHIC Square	Selection of the type of graphic displayed during respiratory phase: Area or Line.
Line: The graphics line is traced without filling *Area: the graphics line is filled*	
SOUND VOLUME 15	Regulation of the alarm signal acoustic intensity: 1 - 20
ENERGY SAVING % 100	Regulation of the machine power consumption percentage: 0 - 100.
Power saving mode that activates after 30 minutes, if no command is selected and the keyboard and encoder knob are not used	If set to 0, when activating this function, the display will show a black screen.
BRIGHTNESS 2	Regulation of the display brightness: 1 - 30
PATIENT TYPE ADULT	Setting of the patient type connected to the ventilator.
ADULT, PAEDIATRIC	The PATIENT TYPE selection activates the default physiological breathing parameters (PRF) and alarms (pre-set at factory) according to the Operative Mode selected (see on cfr. 4.3).

The **PATIENT TYPE** choice is showed on the display of the ventilator together with the selected Operative Mode.

APNEA TIME sec 20.0

Setting the time delay after which the APNEA BACK-UP support function activates.

The time can be set from 5 to 60 sec.

WARNING !! Patient injury hazard

Pay utmost attention when setting this parameter as its incorrect regulation might seriously affect the patient: we recommend you to set this value at about 20 seconds.

NIV Enable

Enable the visualization of the acronym NIV in the following ventilation modes.

APCV - NIV APCV

PSV - NIV PSV

INSP HOLD sec 15.0

Setting of the activation time of the function INSP HOLD : 5 - 15 secs.

EXP HOLD sec 5.0

Setting of the activation time of the function EXP HOLD : 5 - 10 secs..

GAS SENSOR CO_2 UNITS %

Function not available.

PASSWORD

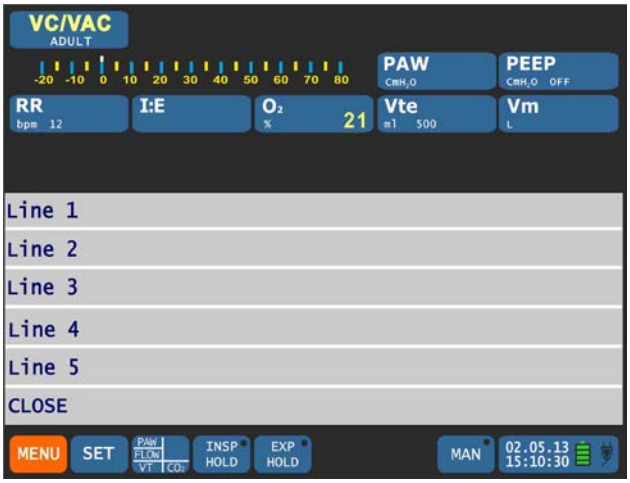
Function not available.

TCP SETTING

Function not available.

TECHNICAL CONTACT

Setting the data relative to contacts for technical leave, available on 6 different contact lines.



The methodology for the compilation of the text lines is similar to the description in section 4.5 **PATIENT DATA** setup.

COLORS

There are some parameters that allow the clinician to change the display colours of parameters and box.

- *Color of Parameters Values*
- *Color of Parameters Names*
- *Color of Parameters U.o.M.*
- *Color of Parameters Box Border*
- *Color of Parameters Box Background*
- *Color of Small R.T. Box Border*
- *Color of Small R.T. Box Background*
- *Color of Big R.T. Box Border*
- *Color of Big R.T. Box Background*
- *Color of Big R.T. Value*
- *Color of Small R.T. Value*
- *Text of Status Bar*
- *CLOSE*

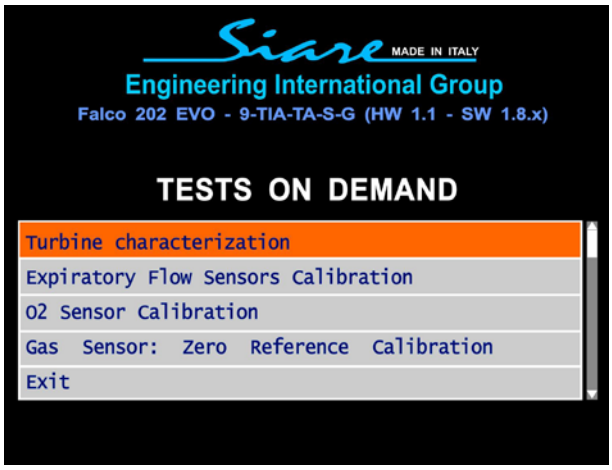
To restore the display pre-set colours, please see 4.11.7 **MAIN MENU** - DEFAULT PARAMETERS.

TESTS ON DEMAND

Enabling the TEST ON DEMAND function.

The system shows the test available on the lung ventilator.

Before using the ventilator on a patient, you have to carry out a series of preliminary checks to make sure that it works properly.



Please see 3.8 for instructions regarding the TEST ON DEMAND function and how to use it.

GAS SENSOR	Not available.
CLOSE	If you select the **CLOSE** option, the system will switch to **MAIN MENU**.

4.12.2

List of default parameters

Parameters	Adult	Paediatric	Neonatal
Mode	VC/VAC	APCV-TV	NIV APCV
VT (ml)	500	200	-
RR (bpm)	14	25	40
I:E	1:2	1:2	1:2
Inspiratory Pause (%)	10%	-	-
Trigger (cmH2O)	-2	-1	-1
PEEP (cmH2O)	5	4	3
FiO2 (%)	21%	21%	21%
Pinsp (cmH2O)	-	-	20
Pmin (cmH2O)	-	5	-
Pmax (cmH2O)	-	30	-
Slope	-	3	3

4.13 CALIBRATRION PROGRAMS

4.13.1 Preliminary

WARNING!! Patient / operator injury hazard

- The informations herein are exclusively intended for use by SIARE specialised staff or qualified technical staff, formally authorised by SIARE to use Falco 202 lung ventilator.
- 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 / operator injury hazard.

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

CAUTION

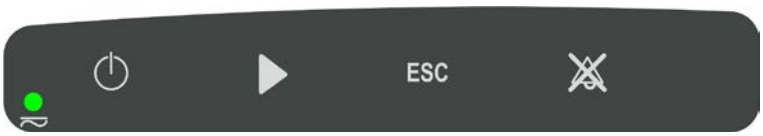
- The specialist SIARE staff or qualified technical staff, formally authorized by SIARE, must know the full content of this manual (and of the Service manual), before carrying out the operations described below.
- The SIARE authorized technician avails of suitable tools and spare parts and is trained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

CAUTION

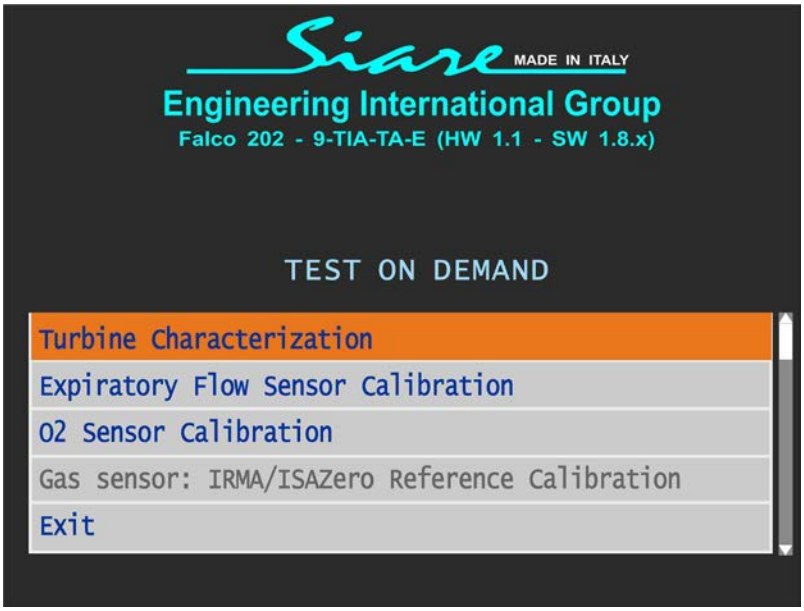
- To activate the calibration programs display the Falco 202 series ventilator should be operating and correctly connected.
- For tests and checks, please use the patient simulator SIARE cod. LS.AB.001 that is equipped with variable resistance and compliance.
- For a more correct and detailed analysis of the “CALIBRATRION PROGRAMS”, please consult the SERVICE manual.

4.13.2 “ CALIBRATRION PROGRAMS “ displaying

- Set the main switch (placed on the back of the ventilator) to “I”.
- Make sure that on the ventilator keyboard (operator 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 start up the ventilator.
- The “ CALIBRATION PROGRAMS “ is displayed



WARNING!! Patient / operator injury hazard

The different colour of the message **VTEc ON** (yellow) - **VTEc OFF** (white) indicates if the function is ENABLE (black) or DISABLED (white).

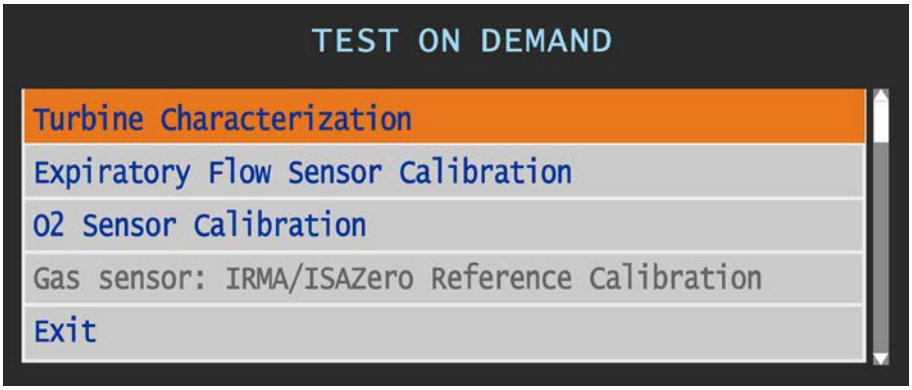
If the user or the authorized technician does not activate or disable any **CALIBRATION PROGRAMS**, after a few seconds, the system switches automatically to “ **SELF TEST** “ phase.

4.13.3 Turbine characterization

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

- When you note 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)

Turn the encoder knob to select the parameter to be calibrated: the activated message is highlighted.



CAUTION

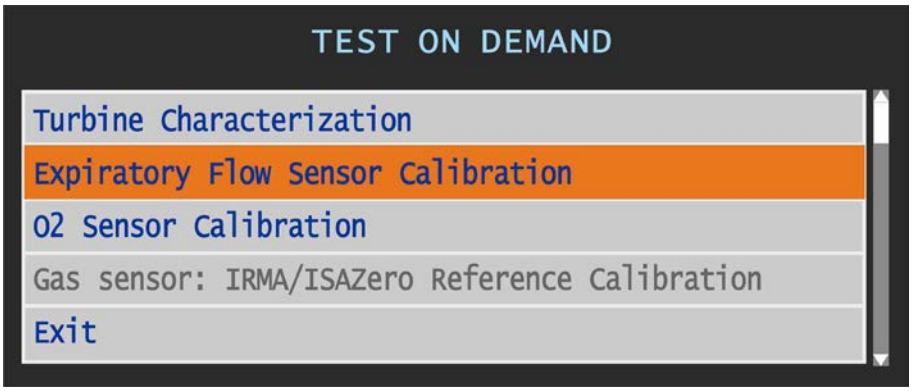
- In order to start the **Turbine characterization calibration program** is necessary the intervention of qualified SIARE personnel or qualified technical personnel authorized by SIARE.
- For more information on the procedure please refer to the cfr. 3.8.1 and/or SERVICE manual.

4.13.4 Expiratory flow sensors calibration

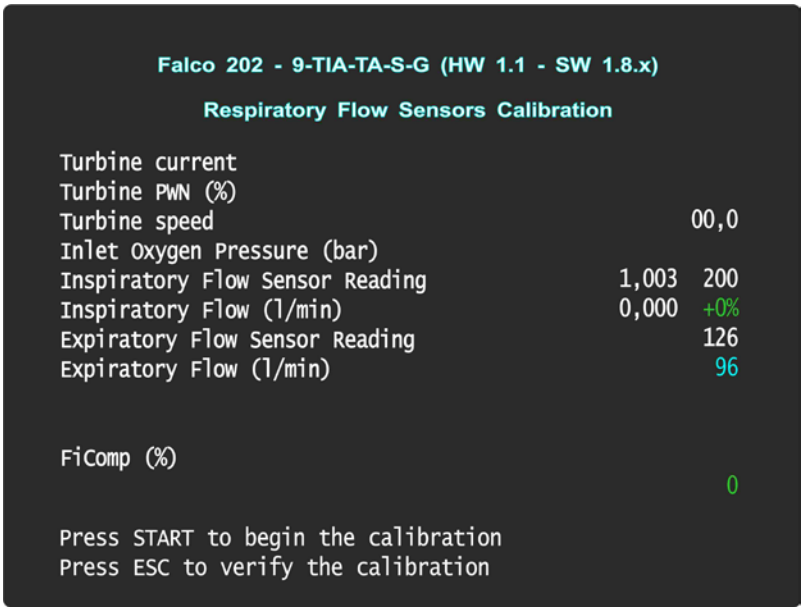
The Expiratory flow sensors calibration is necessary in the following cases.

- 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 ventilator or replacement of flow sensors (INSP inside the unit or EXP outside the unit), it is suggested to perform this Calibration.

Turn the encoder knob to select the parameter to be calibrated: the activated message is highlighted.

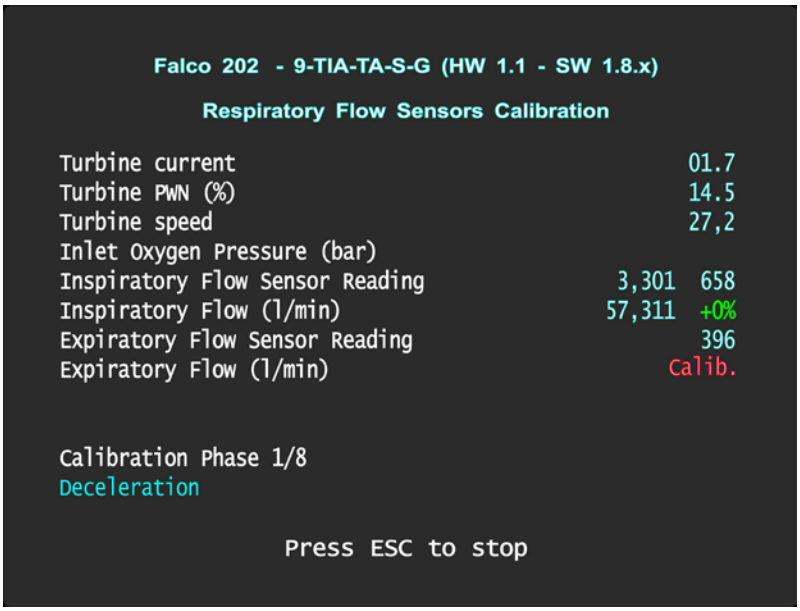


- Press the encoder knob: the **Expiratory flow sensors calibration program** is showed



- Press **START** to begin the expiratory flow sensors calibration.
- Press **ESC** to verify the expiratory flow sensors calibration.

- Press **START** to begin the expiratory flow sensors calibration.

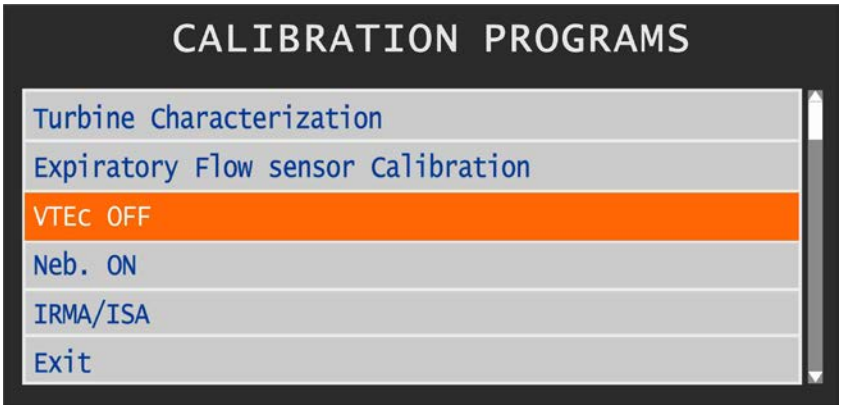


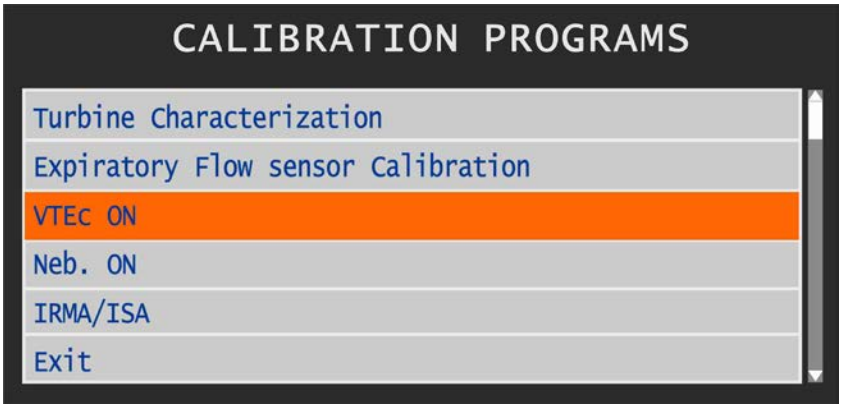
- Press **ESC** to stop the expiratory flow sensors calibration.

- At the end of **the Expiratory flow sensors calibration** the system come back to the " **CALIBRATRION PROGRAMS** " menu.
- In case of first calibration of ventilator, we suggest to execute this procedure after having checked the PEEP calibration and after performing a **Turbine characterization** (see 4.13.3).
- For more information please refer to the SERVICE manual.

4.13.5 VTEc (ON – OFF)

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





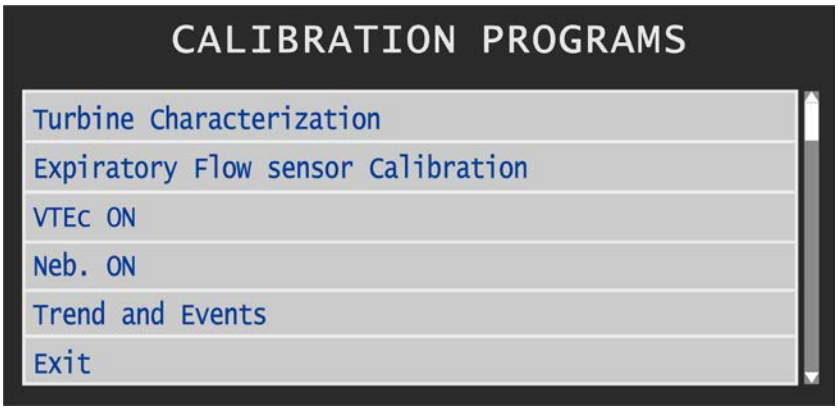
Select **Exit** to go to the " SELF TEST " phase and escape from " **CALIBRATION PROGRAMS**" window.

4.13.6 Trend and Events

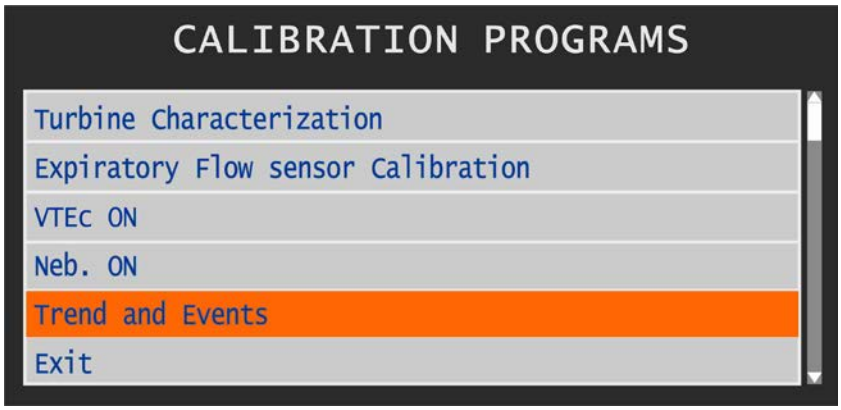
From software version **sw 1.6.6** it is available a string for:

- IRMA / ISA $EtCO_2$ Sensor
- Trends and Events

In order to be able to use these functions it is necessary an interface cable for the connection of the RS 232 port to the IRAM/ISA sensors or for the connections to a PC serial port to download the data.



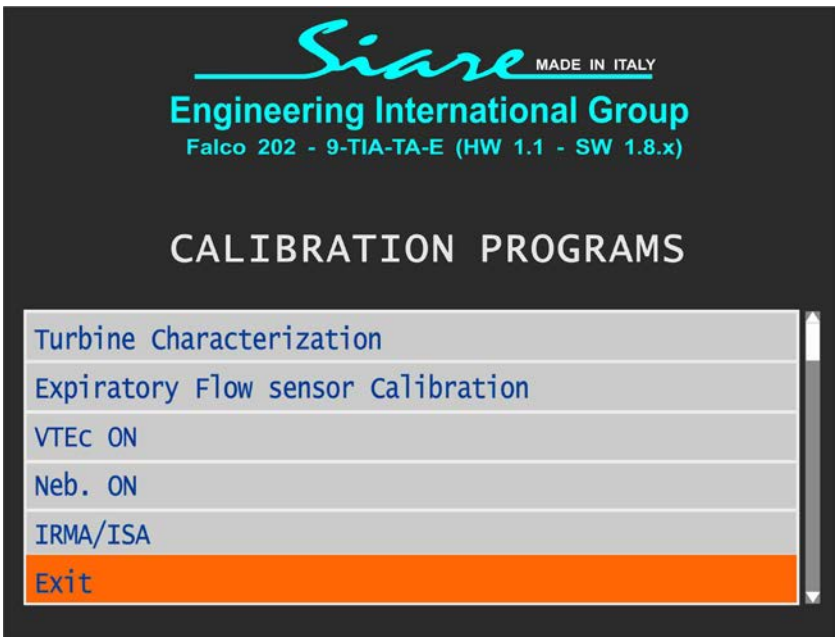
4.13.7 Setting IRMA / ISA the RS-232 port is able to detect the EtCO2 sensor.



Setting Trend and Events the RS-232 port is activated for the Falco 202 data downloading.

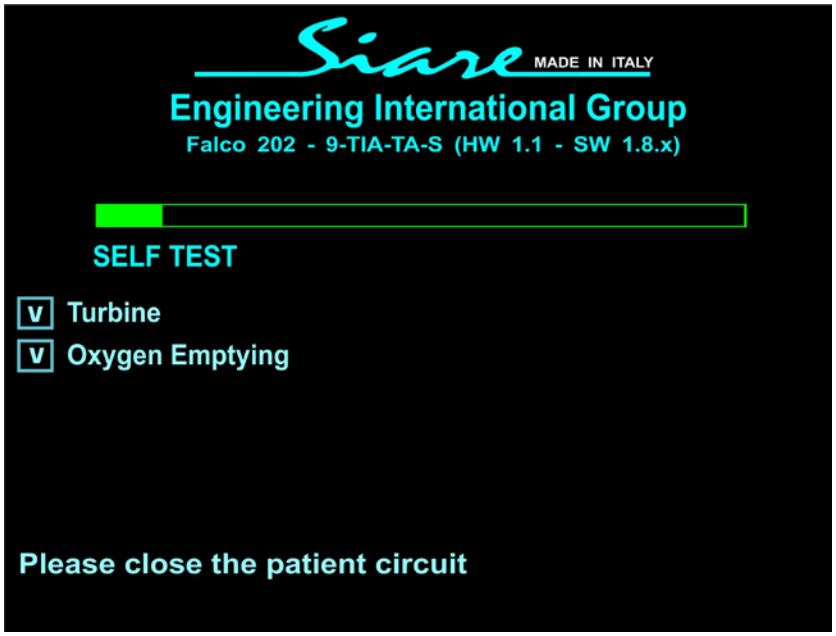
Select **Exit** to go to the " SELF TEST " phase and escape from " **CALIBRATION PROGRAMS** " window.

4.13.8 Exit



Select **Exit** to go to the " SELF TEST " phase and escape from " **CALIBRATION PROGRAMS** " window.

The " **SELF TEST** " phase starts.



5 ALARMS

This chapter illustrates the part of the system relevant to the alarms operation of the Falco 202 lung ventilator (*hereinafter called 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.

WARNING !! Risk of injury for the patient

Before using the ventilator, it is recommended to set the entries and the parameters referred to the alarms.

The 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

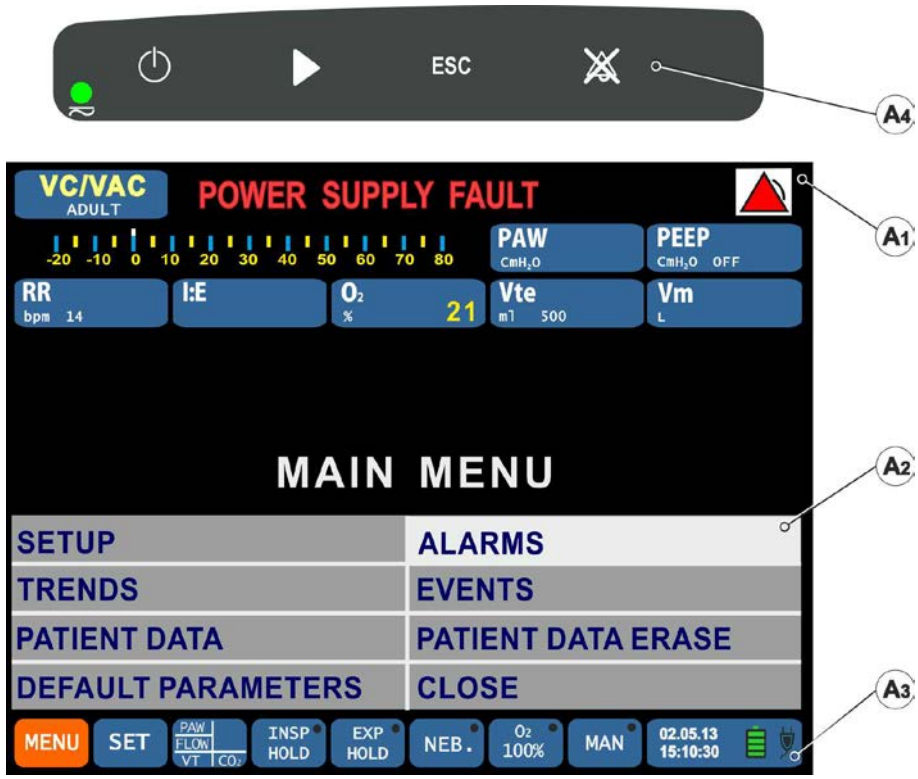
- Severe, i.e. leading to irreversible damage.
- Moderate, i.e. leading to reversible damage.
- Minor, i.e. involving a distress or leading to a minor damage.

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

A2 - MAIN MENU / ALARMS parameter.

- Through the encoder it is possible to select the entry of the MAIN MENU - ALARMS area 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.
- The main power presence (failure).

A4 - Soft key for acoustic alarm silencing.

5.1.2 A1 - Alarm area

This area shows the text of the active/s alarm/s and the priority / status of the same.

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

Active alarms text strings

Alarms configurable by User

- Low / High Pressure
- Low / High Resp. Rate
- Low / High Exp. Vte
- Low / High Exp. VM
- Low / High PEEP
- Low / High FiO2
- Gas Sensor: Low / High EtCO2
- Power Failure
- Apnea time (configurable in MAIN MENU - SETUP area)

System alarms

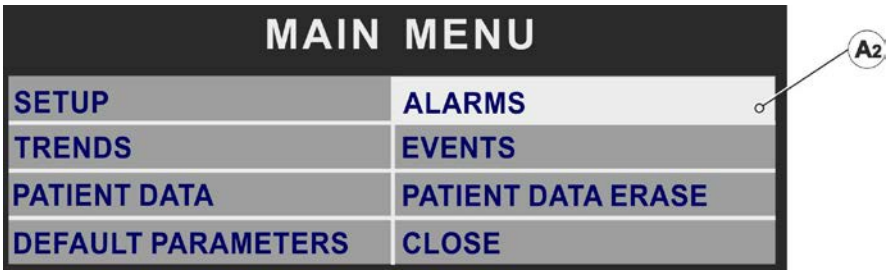
- Low Battery 50% Rem.
- Low Battery 25% Rem.
- Low Battery 10 Min. Rem.
- Battery Disconnected
- Battery Overtemperature
- (Patient) Circuit Disconnected
- Turbine Failure
- Turbine Over-Temperature
- Turbine Over-Current
- CAN-BUS Failure

System alarms

- Low Battery 50% Rem.
- Low Battery 25% Rem.
- Low Battery 10 Min. Rem.
- Battery Disconnected
- Battery Overtemperature
- (Patient) Circuit Disconnected
- Turbine Failure
- Turbine Over-Temperature
- Turbine Over

5.1.3 A2 - MAIN MENU / ALARMS parameters

This monitor area, through the encoder knob (MAIN MENU - ALARMS), allows to display and set the Min and Max. alarms values.



Low Pressure	*From 2 to 60 cmH2O*
High Pressure	*From 20 to 81 cmH2O*
Low Resp. Rate	*From 1 to 11 bpm*
High Resp. Rate	*From 13 to 150 bpm*
Low Exp. Vte	*From 0 to 1400 ml (10 ml steps)*
High Exp. Vte	*From 1 to 3000 ml (10 ml steps)*
Low Exp. VM	*From 0 to 20 L*
High Exp. VM	*From 1 to 100 L*
Low PEEP	*From 0 to 19 cmH2O*
High PEEP	*From 1 to 51 cmH2O*
Low FiO2	*From 20 to 98 %*
High FiO2	*From 21 to 100 %*
Gas Sensor : Low EtCO2	*From 0.4 to 12.9 %*
Gas Sensor : High EtCO2	*From 0.5 to 13.0 %*
Power Failure	*Enable / Disable*

WARNING !! Risk of injury for the user / patient

The ventilators used in the same health environments can have different preset configurations of alarm limits.

Verify that the preset alarm limits are appropriate for the new patient and adjust the alarm limits on values suitable to the new condition of use.

5.1.4 A3 - General information area

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

Green “BATTERY” symbol, indication of the battery charge level:

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

Green “PLUG” symbol, indication of the main power supply presence.

Red “PLUG” symbol, flashing: indication of power failure.

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

Green flashing symbol, 2 notches: it indicates that the charge level of the battery is at 50% - the relevant alarm is active.

Orange flashing symbol, 2 notches: it indicates that the battery charge level is at 50% - the relevant alarm is active.

Green flashing symbol, 1 notch: it indicates that the battery charge level is at 25% - the relevant alarm is active.

Red flashing symbol, 1 notch: it indicates that the battery charge level is at 25% - the relevant alarm is active.

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.

Red color signal, flashing: indication of main power failure.

The green “PLUG” symbol: indication of the presence of main power supply.

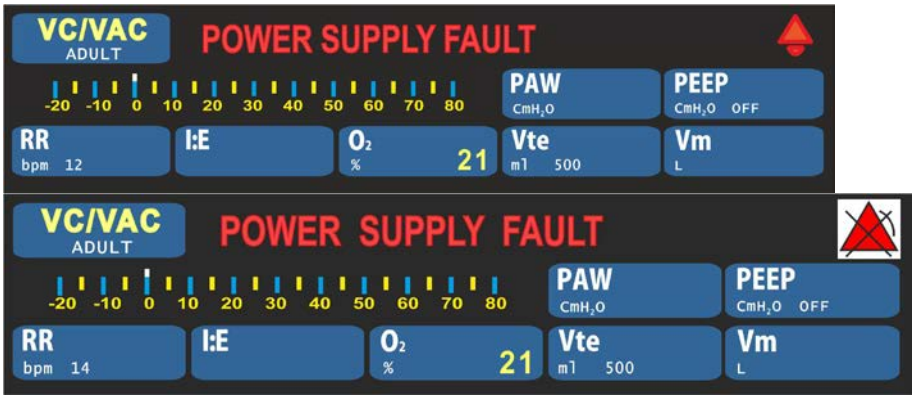
The power failure alarm is reported both by the visual signals of the corresponding message in the alarm area and the high priority red bell as well as by the flashing electrical power symbol.

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.

The soft key, during the normal operating phase of ventilator, allows the silencing of active acoustic alarm.



WARNING !! Risk of injury for the user / patient

The user should never stop checking the patient conditions during the alarm silencing.

- Pushing the RESET button will stop the acoustic alarm for a defined time.
- During the alarm silencing the alarm text is showed on the panel.
- Pushing further the RESET button 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

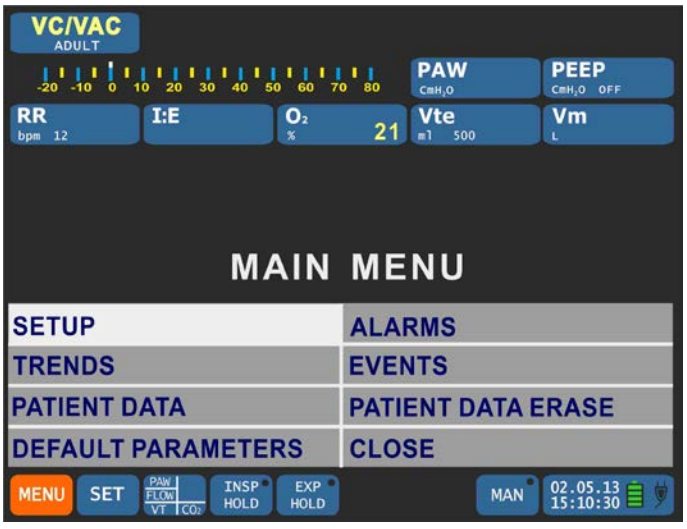
5.2.1 Setting of ALARMS limits values

Before using the ventilator it is suggested to use the MENU function to adjust the items necessary for the correct operation of the equipment.

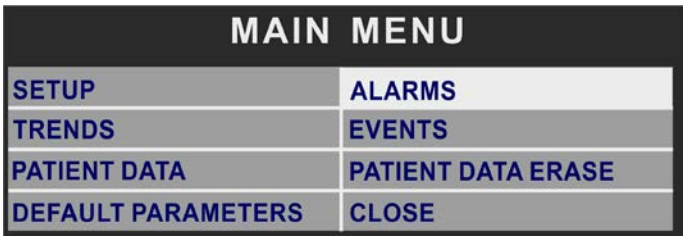
During operation it is possible to adapt the alarm setting in function of the patient clinical situation.

Press the encoder knob, the **SET** function is activated.

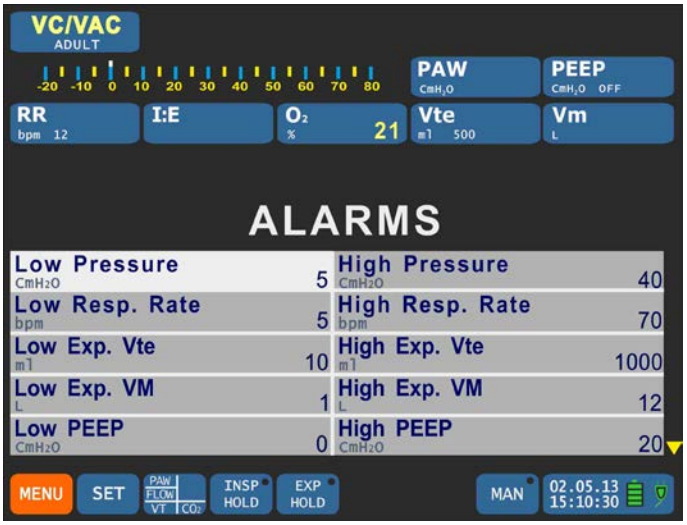
Turn the encoder knob, select "**MENU**" , press the knob to confirm.



- The "MAIN MENU" is displayed.



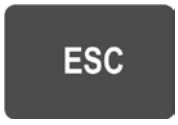
- Turn the encoder knob clockwise to select the ALARMS function.



- Press the encoder to access to the parameters of ALARMS box.

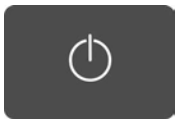
Use the encoder knob to select the alarms and modify the preset values.

- Turn clockwise (counter-clockwise) to select the alarm; press the encoder to access to the parameter modification.
- Turn clockwise (counter-clockwise) to increase (decrease) the value of the parameter; press the knob to confirm the set value.
- Turn clockwise (counter-clockwise) to select another alarm to be modified.



Press the **ESC** soft key to return to the MAIN MENU.

Wait for the system to return automatically to STAND-BY visualization.



Press the **ON-OFF** key to return to STAND-BY visualization.

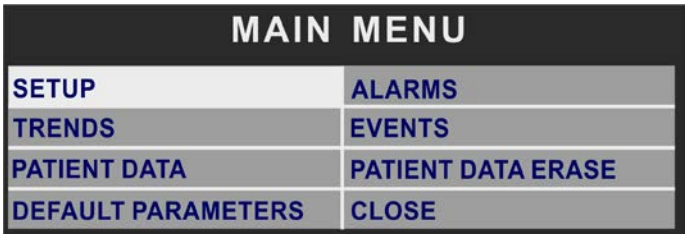
5.2.2 Setting of ALARMS volume

The Volume parameter allows the adjustment of the volume of acoustic alarms signals at any priority level.

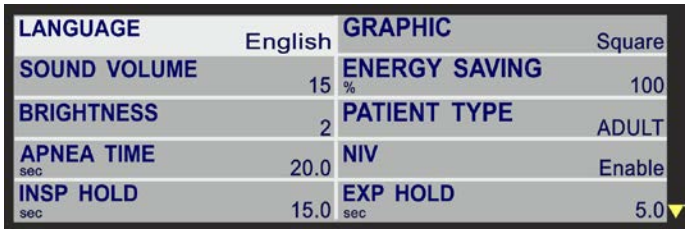
Press the encoder knob, the **SET** box is activated.

Turn the encoder knob, select “MENU”.

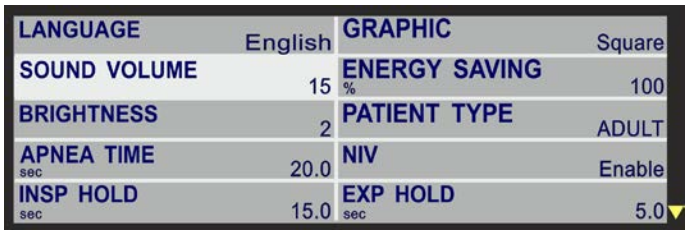
Press the knob to confirm; the “**MAIN MENU**” page is displayed.



- Press the encoder to access to the displaying of **SETUP** page contents.



- Turn the encoder knob clockwise to select the **SOUND VOLUME** box.



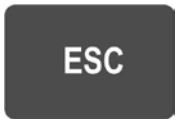
Press the encoder knob to enable the box modification.

Turn the encoder knob clockwise (counter-clockwise) to modify the value of VOLUME parameter.

Press the encoder knob to confirm the modification of the VOLUME parameter value.

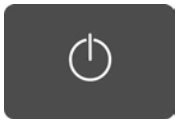
If it is necessary to modify the other parameters values, proceed as previously described.

- Turn the encoder knob clockwise (counter-clockwise) to select another box of SETUP display.
- Press the encoder to access to the modification.
- Turn clockwise (counter-clockwise) to increase (decrease).
- Press the knob to confirm.



Press the **ESC** soft key to return to the MAIN MENU.

Wait for the system to return automatically to the STAND-BY visualization.



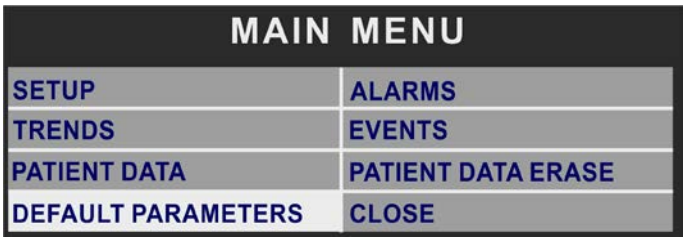
Press **ON-OFF** key to return to STAND-BY visualization.

5.2.3 Setting of DEFAULT values

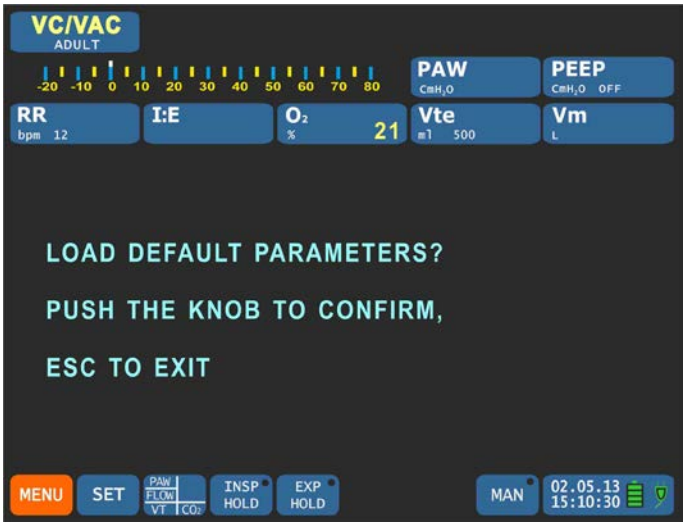
The DEFAULT PARAMETER allows setting the standard factory parameters.

Press the encoder knob, the **SET** function is activated

Turn the encoder knob, select “**MENU**” , press the knob to confirm.



- The “**MAIN MENU**” page is displayed.
- Turn clockwise the encoder knob to select the **DEFAULT PARAMETERS** function.



- Press the encoder to access to the DEFAULT PARAMETERS function.

To enter the standard **FACTORY PARAMETERS** press the encoder knob.

In order not to modify the stored parameters press the **ESC** soft key and return to **MAIN MENU** visualization.

Wait for a few seconds, the system automatically returns to STAND-BY display.

Press **ON-OFF** key to return to STAND-BY visualization.

5.2.4 Alarms DEFAULT 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 - 30**	**10 - 30**
Minute Volume (L)	**2 - 12**	**1 - 8**	**1 - 4**
PEEP (cmH_2O)	**0 - 15**		
FiO_2 (%)	**21 - 80**		
Power Failure	**Enable**		
Apnea Time *(configurable in MAIN MENU – SETUP area)*	**20 sec**		

5.3 Troubleshooting

This chapter is an indicative but not exhaustive guide for the user and the technician, 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.

5.3.1 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.
- Contact the Siare Service Centre or a Centre authorized by Siare.

Power Failure	There is a power supply fault and the lung ventilator is operating on the battery.

- 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.

Initialization phase - SELF TEST	The initialization phase is not completed and the system is blocked.

- Verify and intervene in function on the error messages and indications evidenced during the “SELF TEST” phase.
- 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. ▪ If the problem persists, contact the Siare Service Centre or a Centre authorized by Siare.
CAN-BUS failure	This alarm condition occurs in case of system failure (electronic boards).
	▪ 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).
	▪ 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 battery level 25% (50%)	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 overtemperature	This alarm condition is present when the battery pack internal temperature pass the 75°C. The ventilator go in STAND-BY mode.
	▪ If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.
Exhausted O_2 sensor	The oxygen sensor is exhausted.
	▪ See information on FiO2 % 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.
Disconnected O_2 cell	This alarm indicates the connection status of the oxygen sensor.
	▪ Check that the oxygen cell is correctly connected. ▪ Replace the oxygen sensor with a new one. ▪ Check the condition of the cable and the connector (if necessary, restore the connection and replace the cable if damaged). ▪ If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.
FiO_2 % 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.
- 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.
- 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 check the flow sensor calibration and its connection with the device.
- 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 check the flow sensor calibration and its connection with the device. ▪ 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. If the lung ventilator works properly check the flow sensor calibration and its connection with the device. ▪ In case of differences higher than 2 cmH_2O (10%) between the value set and the value read, a turbine calibration shall be performed. ▪ 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.
- If the problem persists, 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 activated when the respiratory rate value is higher than the set value.

- Check that the corresponding alarm limits are and the patient's respiratory parameters 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.
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.

- Replace the sensor and repeat the 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 (100 - 105 °C).

- The lung ventilator switch off automatically to avoid dangers to the patient safety.
- 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 switch off automatically to avoid dangers to the patient safety.
- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

6 MAINTENANCE

- To guarantee the regular ventilator operation of the Falco 202 lung ventilator for intensive care, emergency and transport (*hereinafter called ventilator*), perform the following maintenance interventions with the recommended frequency.
- All interventions must be conform 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 operator, the ventilator must be inspected and checked when the limit of 2**000 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 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 ventilator.

Before performing the maintenance or repairing works, also in case of returning the ventilator for repairing to manufacturer, it is required to clean and disinfect the ventilator.

6.1 Cleaning, disinfection and sterilization

The operator 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 ventilator which could also endanger patient and operator 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 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 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 ventilator is sold.

- Siare is aware that working procedures can differ considerably from one health structure to another: it is therefore impossible to indicate specific procedures that are suitable for all requirements.
- SIARE cannot be held responsible for the efficacy of the cleaning, disinfection and sterilization procedures, nor for the other procedures carried out while the patient is being treated.
- This manual can only provide general instructions for cleaning, disinfection and sterilization. It is nevertheless the operator's responsibility to ensure the validity and efficacy 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.

- 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 should be checked every time they are cleaned and any damaged parts should be replaced.
- Whenever a part or component is changed, check the functioning of the ventilator.

Follow the 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 detergent 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 according to how often the ventilator is used 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.

6.2.4 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 operator 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 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.

EXP V. Monoblock	Disinfect with steam or chemically.	It is possible to sterilize the component with gamma rays or ethylene oxide (ETO).

The EXP V. monoblock includes the expiratory valve and the flow sensor.

WARNING !! Risk of device failure.

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, keeping the connector for the electrical connections facing upwards.

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.
- 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.

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 operator 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.

6.2.5 Periodic maintenance

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 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.

6.2.6 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.
	Patients filter	Check for wear.
	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 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 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.

6.2.7 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.

6.3 Repairs and spare parts

Use only original SIARE spare parts or spare parts checked and approved by SIARE.

6.3.1 Spare parts kit for lung ventilator

Code : R20922000P1/GE

Spare parts kit for annual maintenance to be used with the Falco 202, code **980222**.

Code : R209000CL

Battery kit to be used with the Falco 202, code **980222**.

6.4 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.

6.5 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 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 lung ventilator.

A.1 Technical sheet

GENERAL DATA	
	Falco 202 is a lung ventilator conceived for use in home care and transport, with patients affected by respiratory diseases and it is suitable for ventilation of adult and paediatric patients. Falco 202 is equipped with a flow generation system by turbine with separate cooling system granting higher quality and safety standards in patient ventilation. The Falco 202 colour display shows the curves of pressure, flow, volume, the loops of breathing parameters, the trends and the ventilation parameters.
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 BF
Class according to 93/42 EEC Directive	Class IIb
Electromagnetic compatibility (EMC)	Conform to the requirements of the EN 60601-1-2: 2007 and following
Norms	EN 60601-1 :2006/A1 :2011/A1 :2013; EN 60601-1-2 :2015; IEC 601-1-6:2013; IEC 601-1-8:2012; EN 62304:2006/AC:2008; ISO 10993-1:2009; IEC 62353:2014; EN 60601-1-11:2015**;** 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 for O_2 cell connection
Electric external connections (optional)	RS232 for CO_2 module or for PC connection (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
Max flow requested (O_2)	≥ 15 l/min
IP degree of protection	IP21
Noise	< 30 dB

LUNG VENTILATOR FUNCTIONAL FEATURES	
Use destination	Falco 202 is a lung ventilator for use in home care and transport with patients affected by respiratory diseases and it is suitable for ventilation of adult and paediatric 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
Dead space compensation	Automatic compensation of mechanical and patient circuit dead space
Automatic leaks compensation	Max 60 l/min
Leak % visualization	Present
Respiratory parameters default setting	Present (Paediatric, Adult)
Ventilation modalities	• APCV, APCV-TV, PSV, PSV-TV (Auto Weaning), VC/VAC, V-SIMV+PS, P-SIMV+PS, CPAP/PSV • SIGH, Apnea BACK-UP (NIV PSV, NIV PSV-TV, CPAP/PSV) , MANUAL
Breathing rate VC/VAC	From 4 to 80 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)
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	O_2 - Air mixture enrichment by O_2 inlet at low pressure
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, P-SIMV)
SIGH in VC/VAC modality	Interval : 40 ÷ 500 bpm (step 1 bpm) Amplitude : OFF, 10 ÷ 100% of set Tidal Volume (step 10%)
CPAP/PSV	Pressure: from 3 to 50 cmH_2O
Other controls	• MENU function, SET function • Function to select Loops, Curves, Parameters' Map displaying • INSP Block (range 5.0 - 15.0 sec / step 0.1 sec.) • EXP Block (range 5.0 - 10.0 sec / step 0.1 sec.) • MAN control (manual ventilation)
Patient circuit	• Single hose 150 cm. Adult/Paediatric patient circuit with expiratory valve and proximal flow sensor • Double hose 150 cm. Adult/Paediatric patient circuit (expiratory valve on the ventilator)
Expandability	Software upgradeable

USER INTERFACE	
Monitor	Module with TFT LED display
Dimensions	9”
Displaying area	168x126 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
MENU function	• SETUP • Alarms • Trends • Events • Patient data • Patient data erase • Default parameters
SETUP parameters (setting)	• Language • Graphic • Sound Volume • Energy Saving • Brightness • Patient Type • Apnea Time • NIV • INSP Hold – EXP Hold • Technical Contact • Colours • Tests on Demand

Trends	Storage capacity (72 h) of all measured parameters.
Events	Memory storage up to 100 machine events including the alarms.
Patient data	The patient data can be set and cancelled
Default parameters	The default parameters can be restored
SETTING function (set of physiological breathing parameters)	CPAP (cmH_2O), Slope, I:E, RR(bpm), RRsimv (bpm), Pause (%), PEEP (cmH_2O), Pinsp (cmH_2O), PMax - Pmin - PS (cmH_2O), SIGH (% - bpm), Ti (s), Ti Max (s), Tr. E (%), Tr. I (L/min - cmH_2O), Vte - Vti (ml), BACK-UP parameters
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 cmH_2O) • 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 compliance (range: 10 ÷ 150 ml/cmH_2O)
Displayed parameters	RR (bpm), I:E, **(*)** FiO_2 (%), Vte (ml), VM (L/min), PAW , PEEP, CPAP (cmH_2O)
Additional displayed parameters	MAP (cmH_2O), Pplateau (cmH_2O), Fi (L/min), Fe (L/min), Ti (sec.), Te (sec.), Tpause (sec.), Cs (ml/cmH_2O)
Displayed graphics	• CURVES: Pressure - Flow - Volume • LOOPS : Pressure / Volume - Flow / Volume - Pressure/Flow • Auto range
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)

(*) *Optional : if FiO2 option is present*

ALARMS	
Alarm types	By MENU: with limits set by the operator
	By DEFAULT: the operator cannot set them up
Alarm default setting	Present (Paediatric, Adult)
Alarm priority	High - Mean - Standby
Alarms with limits set up by the operator	
Airways pressure	High – Low
Respiratory rate	High – Low
Expired tidal volume	High – Low
Expired minute volume	High – Low
PEEP	High – Low
FiO_2 concentration	High – Low
Electric power supply	Alarm occurs in case of failure of external power supply
Apnea	Low Rate (function of Apnea BACK-UP)
System alarms	
Level (charge)	Battery at 50%
Level (charge)	Battery at 25%
Battery level (low)	10 Minutes
Disconnected battery	Yes / No
Battery over temperature	Indication of exceeding the temperature limits inside the battery
Circuit disconnected	Indication of patient circuit disconnected
Turbine fault	Signals in case of a blower fault condition
Turbine over temperature	Indication of exceeding the temperature limits inside the turbine
Turbine over current	Indication of exceeding the current limits inside the turbine
CAN BUS error	Electronic boards CAN connection wrong
Maintenance	2000 hours

SELF-TEST alarms	
Turbine	The correct functioning of the turbine is tested
EXP.- INSP. Flow sensor	Verification of EXP flow sensor operation
Airways 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 150 cm. Adult/Paediatric patient circuit ▪ Antibacterial filter for patient circuit ▪ Power cable ▪ Vehicular cable for 12 Vdc ▪ Flow sensor (disposable)
Optional Accessories	▪ Sling transport bag ▪ Additional battery pack for 6 hours operation ▪ Kit for FIO2 monitoring (from 21% to 100%) ▪ Stand with 5 wheels with ventilator support ▪ Double hose adult/paediatric silicone patient circuit cm 120

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.	O_2 sensor calibration (TEST)	_____ %	☐ Pos. ☐ Neg.	
4.	O_2 - FiO_2 alarm check		☐ Pos. ☐ Neg.	
5.				
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 cmH_2O**)		☐ Pos. ☐ Neg.	
10.	PAUSE check: **50 %**		☐ Pos. ☐ Neg.	
11.	FiO_2 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.	**N.A.**
20.	Gas analyzer (option)		☐ Pos.	☐ Neg.	**N.A.**
RESPIRATORY PARAMETERS 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 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 operator which closes the inspiratory and expiratory valves during the expiratory phase of a breath.
FiO_2	Parameter set by the operator 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 operator 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 operator 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 operator 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 operator) basing on current settings.
Vdc	Direct current voltage
Ventilations per minute (bpm)	Respiratory rate unit (Resp/min).

A.4 EMC tables - Guidance and manufacturer's declaration

A.4.1 Table 1

<table>
<tr><th colspan="3">Emissions</th></tr>
<tr><th>Emissions test</th><th>Conformity</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF Emissions
Cispr 11</td><td>Group 1</td><td>The appliance use 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.</td></tr>
<tr><td>RF Emissions
Cispr 11</td><td>Class B</td><td>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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A

Conforms</td><td rowspan="2">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.</td></tr>
<tr><td>Voltage fluctuations/
flicker emissions
IEC 61000-3-3</td><td>Conforms</td></tr>
</table>

A.4.2 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 % U_T (>95 % dip in U_T) for 0,5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 seconds	<5 % U_T (>95 % dip in U_T) for 0,5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) 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.4.3 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.4.4 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:

1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Falco 202

Lung ventilator

turbine-driven ventilation

User's Manual

version DU3222102

980222

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