

# ***Siaretron 4000 - 15"***

***ICU Ventilator***

*Turbine-driven ventilation*

*Touch-Screen*

**User's Manual**



## GENERAL INFORMATION

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

The operation and maintenance of Siaretron 4000 15" lung ventilator must be entrusted to qualified technical personnel only. The responsibility of SIARE Engineering International Group s.r.l. concerning the Siaretron 4000 15" 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 Siaretron 4000 15" lung ventilator produced or updated after February 2019. It is possible that some information may not apply to previous versions. Contact SIARE Engineering International Group s.r.l. if you have any doubts.

*User's Manual, version DU3502101*

*Revision 1 - 10.02.2019*

## Observations

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

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

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



Directive 93/42 EEC

## Definitions

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



### **WARNING !!**

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



### **CAUTION**

This indicates the possibility of danger to the lung ventilator.



### **NOTE**

This indicates information worthy of note, making the operation of the Siaretron 4000 15" 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 Siaretron 4000 15" lung ventilator (*hereinafter called lung ventilator*) and the relative safety regulations.

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

- SIARE recommends establishing a maintenance and service contract with SIARE or the local authorised service dealer in order to guarantee the scheduled maintenance required to operate the lung ventilator in a safe and correct manner.
- To prevent the risk of fire, keep the lung ventilator and/or the oxygen tubes away from matches, lit cigarettes and inflammable material, such as anaesthetic gases and/or sources of heat.
- Do not connect the lung ventilator to the patient by flexible connectors, and antistatic or conductive tubes to prevent patient burnings during the use of high frequency surgical equipment, especially dangerous with antistatic tubes. The use of flexible connectors, antistatic or conductive tube is never permitted with lung ventilator.
- Do not use worn and consumed tubes or tubes contaminated by flammable substances like grease or oil to deliver oxygen; (fabrics, oil and other fuels can 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 lung ventilator should immediately be disconnected from the electrical power supply and from the battery (if fitted).
- When coming into contact with any component of the lung ventilator, the hospital procedures for the handling of infected material should always be respected.
- SIARE is aware that cleaning, sterilisation and disinfection procedures vary considerably from one health structure to another. SIARE cannot be held responsible for the efficacy of the cleaning and sterilisation procedures, nor for the other procedures carried out while the patient is being treated. As regards cleaning, sterilisation and disinfection of the product components, it is therefore recommended that the regulations currently in force in the country where the lung ventilator is installed be taken into consideration.
- The lung ventilator was not designed as a total monitoring device: some conditions of danger for the patients treated with vital support equipment will not trigger any alarm.
- Before using the lung ventilator or any connected component, carefully check that the lung ventilator is functioning correctly; when needed, the preliminary tests must be performed as described in the present manual.
- Do not use pointed instruments, such as pencils, screwdrivers or the like to make selections or settings as they could damage the surface of the LCD panel.
- Check the lung ventilator periodically as described in the relative "Maintenance" chapter and do not use it if it is faulty or malfunctioning. Replace any broken, missing, obviously worn, deformed or contaminated parts immediately, with spare parts supplied by SIARE.

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

**WARNING !!**

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

**WARNING !!**

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

**WARNING !!**

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

**WARNING !!**

Before connecting the lung 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 !!**

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

**WARNING !!**

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



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

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

## **Year of manufacture**

Check the identification data label of the Siaretron 4000 15" 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 Siaretron 4000 15" is 10 years.

## **Manufacturer**

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## Electromagnetic Compatibility

The Siaretron 4000 15" lung ventilator is designed to operate in the specified electromagnetic environment (see warning below).

The customer or the user of Siaretron 4000 15" lung ventilator should ensure that it is used in such an electromagnetic environment.



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



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



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

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# 1 INTRODUCTION

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

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

Even the maintenance procedures have been simplified and the parts subject to wear or deterioration have substantially decreased.

The new Siaretron 4000 lung ventilator is equipped with a turbine and with a 15” TFT display touch screen, is considerably different from all other previously manufactured versions of intensive care ventilators.

## 1.1 Presentation

The Siaretron 4000 15” (*hereinafter called lung ventilator*) is a lung ventilator equipped with an innovative pneumatic system based on a “double turbine” with the advantage to deliver neonatal volumes and to prevent the risks of fires for the high oxygen concentrations presence.

The Siaretron 4000 15” is a new generation equipment, designed for the treatment of acute and sub acute diseases and can be used on Adult, Paediatric and Neonatal (optional) patients. The lung ventilator provides new advanced features for operative modes management; it is equipped with different ventilation functions and thanks to its keyboard and decoder knob the user’s selection of most suitable settings are simplified.

For those who have a basic knowledge on how ventilators for resuscitation work, the use of this equipment is intuitive and a brief training course on regard would be enough.

The user’s interface (IGU) includes the keyboard, the decoder knob and the screen; the last one displays the lung ventilator settings and measured data, as well as various functions, allowing the user an immediate evaluation of the patient conditions; moreover, it is possible to select and display the temporal trends of the pressure, flow, volume, the loops of flow/volume, pressure/volume.

An immediate information management system, allows the User to set the alarms, collect data concerning the trend of the operating parameters (TREND) and the lung ventilator EVENTS log using the MENU.

The same system allows the user to set the patient type (adult, paediatric and neonatal), load or erase the PATIENT DATA and in case of needs, load automatically the DEFAULT PARAMETERS of the lung ventilator.

### 1.1.1 Main technical characteristics

The Siaretron 4000 15" lung ventilator is composed of two main blocks: the trolley and the ventilator block.

In turn, the lung ventilator block is divided in two parts: the upper part that includes a 15" TFT colour monitor touch screen, the board for the elaboration of all data and information (CPU) that supervises the operation and display of patient parameters.

The lower part of the lung ventilator block includes the pneumatic control and all the fittings or connections, both electrical and pneumatic, to the outside. In this area are also mounted the back-up batteries for use in case of power supply absence and the board for battery charge management.

The Siaretron 4000 15" foresees the possibility to upgrade the software for implementing advanced ventilation modalities and functionalities. The lung ventilator block can be used as a stand-alone part being separable from the trolley, by positioning it on a flat surface.

### 1.1.2 Foreseen use

The Siaretron 4000 system delivers controlled or spontaneous ventilations with a re-adjustable level of end expiration positive pressure (PEEP), of the trigger sensitivity and oxygen concentration.

Adult, paediatric and neonatal ventilation are available, thanks to an adjustable minimum Tidal Volume from 2 ml to 3000 ml.

After the switching-on of the lung ventilator it is possible to choose the patient type (adult, paediatric and neonatal) setting the relevant default parameters.

The lung ventilator is equipped with a flow and pressure trigger, also it includes the most modern ventilation modes: volume controlled ventilation modalities VC/VAC, VC/VAC-BABY, pressure controlled ventilation modalities APCV (BILEVEL ST), APCV-TV, SIMV by Volume and by Pressure, Pressure supported modalities PSV (BILEVEL S), PSV-TV, CPAP, SIGH, Non Invasive Ventilation (NIV APCV - NIV PSV), Drug Nebulizer and Manual Ventilation (MAN).

In spontaneous ventilation mode, it ensures inspiratory flow up to 190 l/min, both with control and support pressure.

The battery, in perfect conditions and fully charged, allows the lung ventilator to operate for at least 90 minutes (without humidifier), allowing to power the lung ventilator in case of transport within hospital facilities. It is possible to reach an autonomy of about 3 hours by the aid of an auxiliary external battery (or battery pack).



*The present manual explains how to use the Siaretron 4000 15" 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 lung ventilator or proceeding to maintenance.*



### **WARNING !!**

*Please read the recommendations and the instructions herein in order to ensure a correct and safe use of Siaretron 4000 15" both for the User and for the patient.*

*Siaretron 4000 15" must be used only for the purposes mentioned below and, in the manner, described herein, therefore the User must thoroughly follow these instructions for use.*

## **1.2 Correct operation**

For correct and complete operation, the lung ventilator must be:

- connected to the oxygen outlets of the medical gas distribution system or of the cylinders;
- correctly connected to the patient circuit;
- connected to a mains power supply with the same voltage as specified on the identification plate;
- correctly connected to all accessories and equipment necessary for the operation of the lung ventilator.



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

*The Siaretron 4000 15" lung ventilator doesn't require any high pressure air supply as it is equipped with an internal turbine.*

The lung ventilator incorporates a series of sensors for continuous patient monitoring, the most important of which are:

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



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



### **CAUTION**

*Before using the lung ventilator, the User 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 lung ventilator and all its parts.*



*For its employ the Siaretron 4000 15" lung ventilator 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.*

### 1.3 Norms and standards regulations

The Siaretron 4000 15" ICU lung ventilator (equipped with a turbine and with a 15" TFT display touch screen), is made in compliance with the following norms (and following updates) and it is manufactured according to UNI EN ISO 13485:2016 standards.

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

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

#### **EN 60601-1-2: 2015**

Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems.

#### **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 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

#### **IEC 601-2-12:2007**

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

#### **ISO 80601-2-12:2011**

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

#### **ISO 15223-1:2016**

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

#### **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)

#### **EN 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 (2007)**

Medical devices directive

*This page has been added to make front / back copy easier.*

## 2 DESCRIPTION

This chapter describes the Siaretron 4000 15" lung ventilator, equipped with a turbine and with a 15" TFT display touch screen; the main parts and modules of whose it is composed are specially considered.

*This chapter describes the following items.*

- 2.1 Overall view
- 2.2 Front view
- 2.3 Lung ventilator front view
  - 2.3.1 Electric connections side
  - 2.3.2 Gas supply side
- 2.4 15" LED display – Touch screen
  - 2.4.1 Touch screen
  - 2.4.2 Keyboard with soft key and encoder knob
  - 2.4.3 Operative mode
  - 2.4.4 Patient Data
  - 2.4.5 Physiological Respiratory Parameters (PRP)
  - 2.4.6 PRP list
  - 2.4.7 Monitoring of respiratory parameters
  - 2.4.8 Monitoring of Additional breathing parameters
  - 2.4.9 Alarm visualization
  - 2.4.10 Measures, charts and loops
  - 2.4.11 Loops area: lung status
  - 2.4.12 Graphic setting, operative functions and general informations
- 2.5 Rear view
- 2.6 Product identification - Labels

## 2.1 Overall view



Concerning the assembling, the interfacing and maintenance make reference to relevant chapters or contact the SIARE Service Centre.



### WARNING !!

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.



Siaretron 4000 15" lung ventilator, equipped with turbine and with a 15" TFT display touch screen; available models:

- code 960501 medical gas driven: Adults, Child and New Born patients
- **code 960502 turbine-driven:** Adults, Child and New Born patients



The picture is exclusively an example and shows a possible configuration of the Siaretron 4000 lung ventilator (hereinafter called lung ventilator).

## 2.2 Front view



**cfr. 2.4** 15" LED monitor - Touch screen

Support for patient circuit supporting arm

Support for humidifier

Wheels diameter 10 cm (2 wheels with brakes)

**cfr. 2.4.1** Keyboard with soft key and encoder knob

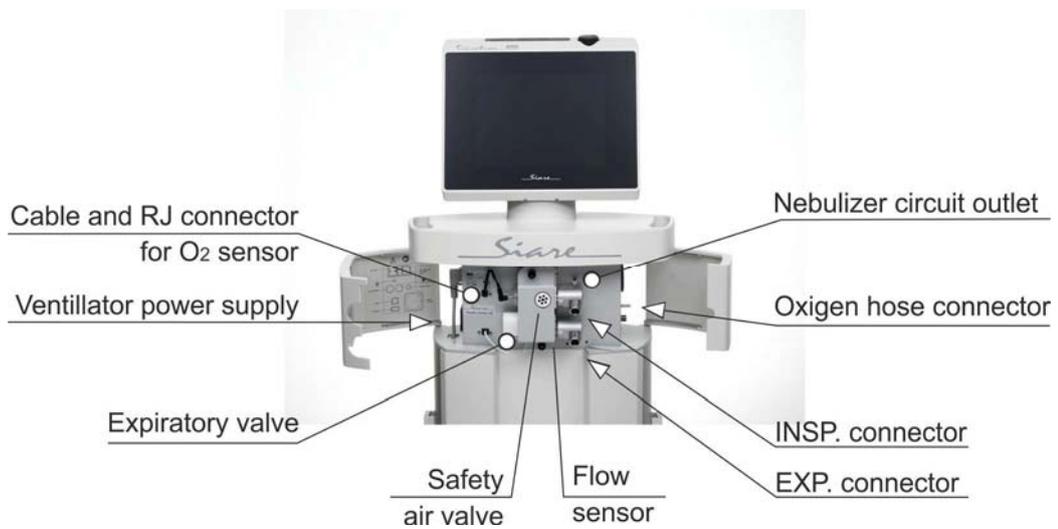
Transport handle

**cfr. 2.3** Attachments for patient circuit connection



For the description of above listed parts make reference to the paragraphs beside highlighted.

## 2.3 Lung ventilator front view



### Instruction label



Refer to instruction manual/booklet

**O<sub>2</sub> SENSOR** Oxygen cell (cfr. 3.2.1)

**O<sub>2</sub> SENSOR INLET** Cable end RJ connector for O<sub>2</sub> cell connection (cfr. 3.2.1)

**EXP. VALVE** Expiratory Valve

**EXP. FLOW SENSOR INLET** RJ connector for flow sensor connection

**NEBULIZER** Nebulizer circuit outlet (6 l/min) (cfr. 3.3.11)

**AIR SAFETY  
VALVE**

Safety air valve



Specific inlet allowing inspiration of ambient air by the patient when the volume of fresh gas and/or gas for inspiration is insufficient.

**INSP. TO  
PATIENT**

Inspiration connector for patient circuit (cfr. 3.3.7)

**EXP. FROM  
PATIENT**

Expiration connector for patient circuit (cfr. 3.3.7)

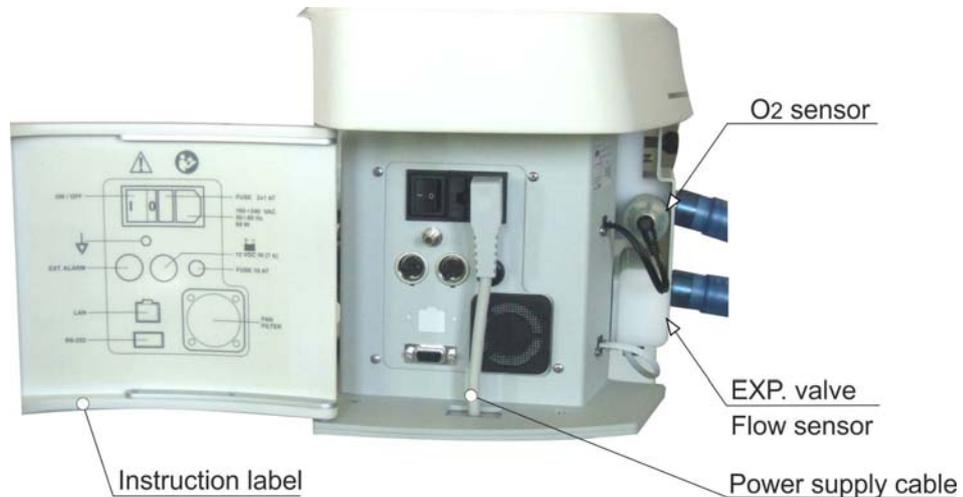
**EXP. FLOW  
SENSOR**

Expiratory flow sensor

**COVER UNIT**

Protection for flow sensor and oxygen cell

### 2.3.1 Electric connections side



#### Instruction label for connections



General warning sign



Instruction label: refer to instruction manual/booklet

**ON-OFF** I / O switch for ventilator powering

**FUSE 2x1 AT** Protection fuses for main power supply circuit at 220 Vac (2 x 1AT - 250V)

**100 - 240 VAC** Plug for main power supply connection at 100 - 240 VAC  
**(50 - 60 Hz / 60 VA)** Power consumption 60 VA.



Equipotential node



This is used for connection to the equipotential node of the electrical system.

**EXT. ALARM**

Connection for external remote alarm



**12 VDC IN (7 A)**

Connector for external power supply at 12 Vdc - 7 A.



The external supply voltage can be through a battery or a continuous energy source with above mentioned features.

**FUSE 10 AT**

Protection fuse for 12 Vdc power supply circuit

**LAN**

RJ 45 connector for network connection (optional)

**RS-232**

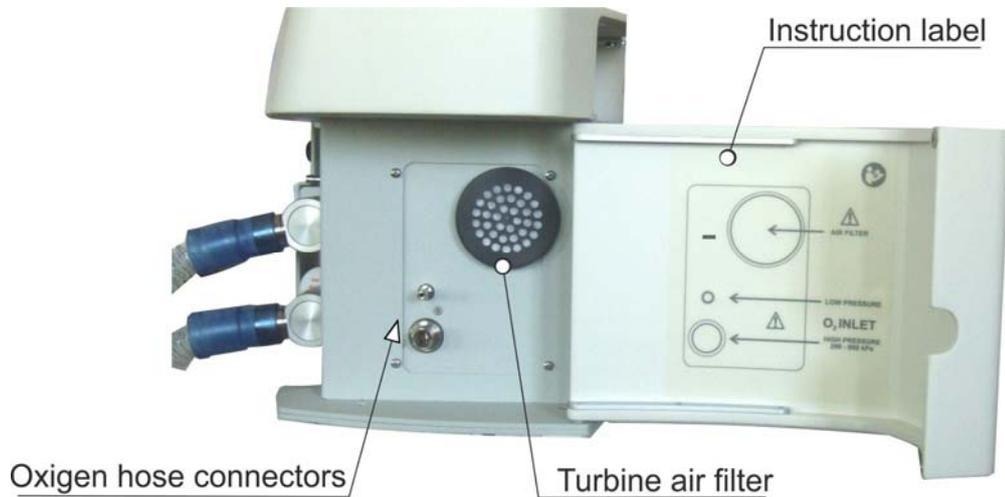
Optional connection for:

- sidestream or mainstream gas analyzer device
- data download

**FAN FILTER**

Cooling fan for lung ventilator

## 2.3.2 Gas supply side



### Instruction label for connections



Instruction label: refer to instruction manual/booklet.

#### O<sub>2</sub> INLET

Connector for O<sub>2</sub> hose connection from gas distribution system.



280 - 600 kPa



**LOW PRESSURE:** the medical O<sub>2</sub> low pressure source should have a maximum flow of 15 l/min.

**HIGH PRESSURE:** the medical O<sub>2</sub> high pressure source should be between 280 kPa and 600 kPa (2,8 - 6 bar / 40 - 86 psi).

## 2.4 15" LED display – Touch screen

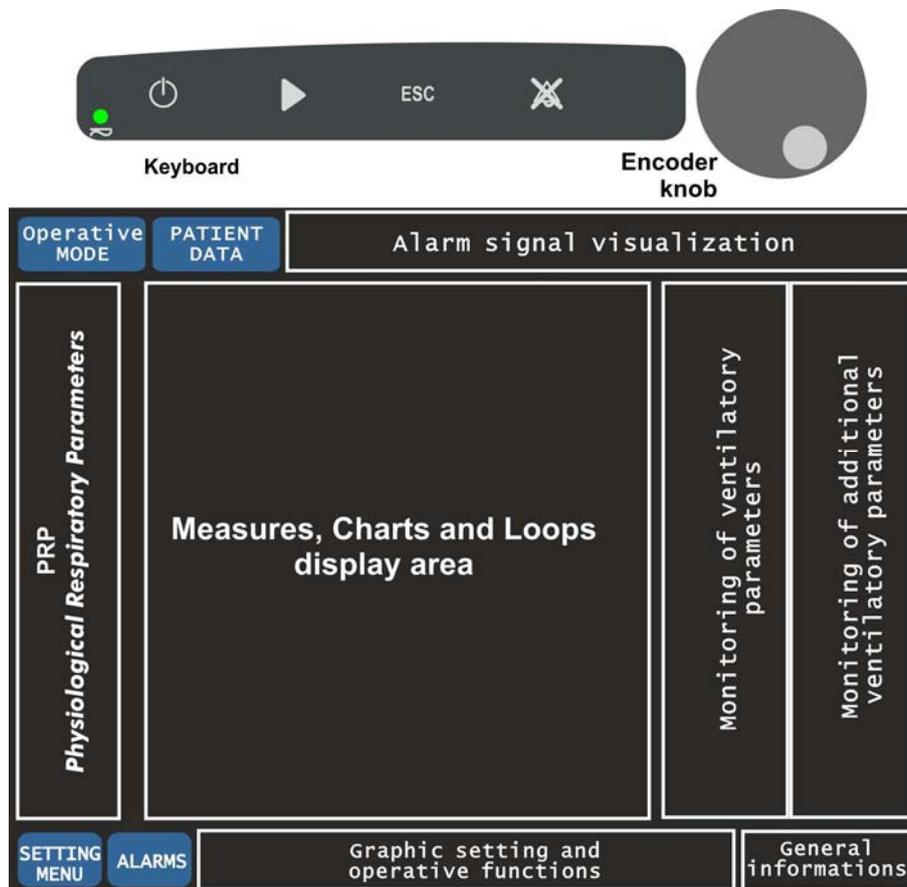
On the upper side of the ventilator is a 15" LED display that will show all information necessary for patient ventilation. Operating mode selection, respiratory parameters setup and display, visual and acoustic alarm warnings are the main featured information visualized.

By the use of the, touch screen system or the control keyboard and the encoder knob on the side of the ventilator to interact directly with the display: this system is defined as GUI (graphical user interface). The GUI is very easy to use by those who are already familiarised with lung ventilation: you can find in this paragraph all available functionalities.

The picture shows how the ventilator graphical interface is divided in different area:

- operative mode and patient data
- alarm visualization
- respiratory parameters
- measures, charts and loops display area
- monitoring of all respiratory parameters
- graphic setting and operative functions

This paragraph describes the functionalities available on graphical user interface.



## 2.4.1 Touch screen

In electronics a “ touch screen “ is a particular device resulting from the merge of a display/screen and a digital display, allowing user interaction with a graphic interface by fingers or particular objects.

Therefore, a touch screen is an inlet and outlet device at the same time.

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



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

### Operative command

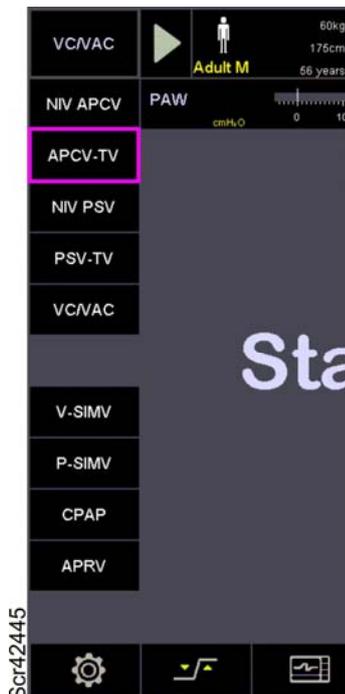


- Select icon to START ventilation in the selected operative mode.



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

### Operative mode



- Select the area indicating Operative Mode

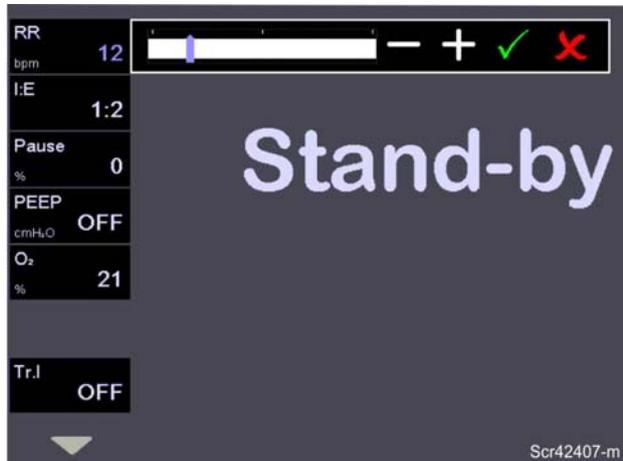


- All available operative modes are shown
- Select the new operative mode



- The new operative mode is available

## Respiratory parameters



- Select the area indicating the respiratory parameters to be modified



- The modification bar is displayed



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



- Confirm the selection



- Cancel



## Respiratory parameters visualization



- Select the area to display other respiratory parameters

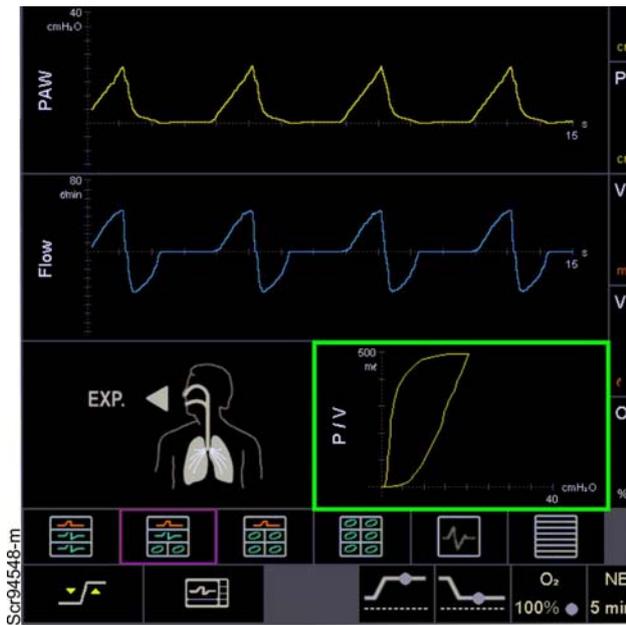


- Other respiratory parameters related to VC/VAC operative mode are displayed.
- To return to previous displaying, re-select

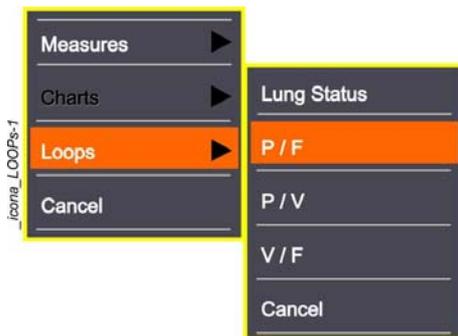


This displaying modality can be applied to patient's monitoring parameters.

## Graphic visualization



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



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



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



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

## 2.4.2 Keyboard with soft key and encoder knob

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



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

**ON/OFF** soft key.

Soft key to **START** ventilation.

**ESC** soft key for rapid escape from MENU - SETUP visualization.

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

Multifunction encoder knob.

### Control keyboard description



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

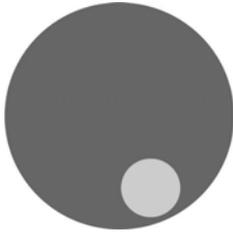
Whenever the condition that activated the alarm is no more present, by a second pressure of the key, it is possible to cancel the visual indication on the screen.



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

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

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



Use of encoder knob.

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



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



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



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

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



When the led is light on (green colour) it indicates that the ventilator is supplied by the main power supply.

### 2.4.3 Operative mode



You can select one of these ventilation modes using the touch screen (please see 2.4 .1 or 2.4.2).

APCV

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

APCV-TV

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

PSV

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

PSV-TV

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

VC/VAC

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



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

VC/VAC BABY

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



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

### V-SIMV

- Volume-targeted synchronised intermittent mandatory ventilation.



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

### P-SIMV

- Pressure-targeted synchronised intermittent mandatory ventilation.

### CPAP

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

### APRV

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



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



Alongside the Operative Mode acronym, the patient type set is specified (**Adult, Child, New Born**). In this way the default respiratory parameters are set automatically (breathing parameters and alarms levels).

Default Parameters: please refer to cfr. 4 Use of Lung Ventilator and cfr. 5 Alarm.



## 2.4.5 Physiological Respiratory Parameters (PRP)



VC/VAC operative mode selected.



- Select the icon for see all **PRP** parameters.



Selecting th **PRP** parameters icon (see *previous image*) the parameters related to the set Operative Mode are displayed



Modification of a **PRP** parameter.

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

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



Decreases the parameter value



Increases the parameter values



Confirms the set value



Cancels the setting bar

## 2.4.6 PRP list



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

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

**CPAP/PEEP**  
cmH<sub>2</sub>O **10**

### CPAP/PEEP (cmH<sub>2</sub>O)

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

**I:E**  
**1:2**

### I:E

Ratio between inspiration and expiration phases.

**O<sub>2</sub>**  
% **21**

### O<sub>2</sub>

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

**P.High**  
cmH<sub>2</sub>O **15**

### Pressure Low (cmH<sub>2</sub>O) - Pressure High (cmH<sub>2</sub>O)

Pressure levels to be set in APRV mode.

**P.Low**  
cmH<sub>2</sub>O **5**

**Pause**  
% **0**

### 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**  
cmH<sub>2</sub>O **OFF**

### PEEP (cmH<sub>2</sub>O)

Positive airway pressure value during expiratory phase.

**P<sub>insp</sub>**  
cmH<sub>2</sub>O **20**

### P<sub>insp</sub> (cmH<sub>2</sub>O)

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.

**P<sub>Max</sub>**  
cmH<sub>2</sub>O **17**

### P<sub>Max</sub> (cmH<sub>2</sub>O)

Maximum airway pressure limit.

**P<sub>min</sub>**  
cmH<sub>2</sub>O **6**

### P<sub>min</sub> (cmH<sub>2</sub>O)

Minimum airway pressure limit.

**PS**  
cmH<sub>2</sub>O 20

**PS (cmH<sub>2</sub>O)**

Positive airway support pressure value during inspiratory phase.

**RR**  
bpm 12

**RR (bpm)**

Lung ventilator respiratory rate.

**RRsimv**  
bpm 6

**RRsimv (bpm)**

Value of forced respiratory rate in SIMV mode.

**Sigh.Ampl.**  
% OFF

**Sigh. Ampl. (%)**

Sigh. Percentage increase of the set V<sub>ti</sub>.

**Sigh.Int.**  
b 100

**Sigh. Int. (b)**

Sigh. Activation frequency.

**Slope**  
4

**Slope**

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

**Ti**  
s 2.0

**Ti (s)**

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

**Ti Max**  
s 3.0

**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.

**T.Low**  
s 5

**Time Low (s) - Time High (s)**

**T.High**  
s 10

Duration of the two pressure levels set in APRV mode.

**Tr.E**  
% 25

**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 OFF

Tr. I (L/min) (cmH<sub>2</sub>O)

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

Vte ml 500

Vte (ml)

Expired tidal volume guaranteed for the patient.

Vti ml 500

Vti (ml)

Inspired tidal volume guaranteed for each breath.

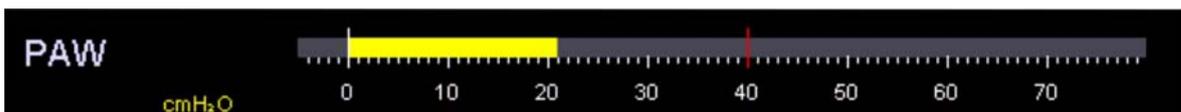
## 2.4.7 Monitoring of respiratory parameters



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



E.g. Here below the data in the images below refer to VC/VAC operating mode with standard PRP.



The light bar indicator (with scale from -0 to 80 cmH<sub>2</sub>O), displays the pressure inside the airways during the respiratory phase, in real time.

PAW 40  
21  
cmH<sub>2</sub>O 5

The value displayed is the maximum measured pressure inside the airways (cmH<sub>2</sub>O).

PEEP 15  
5  
cmH<sub>2</sub>O 0

The displayed value shows the positive pressure at the end of the expiration: the measurement unit is cmH<sub>2</sub>O. The User 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 (V<sub>te</sub>) x respiratory frequency (RF).



It shows the value of end expiration CO<sub>2</sub> (*end-tidal CO<sub>2</sub>*).

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

### Description



- V<sub>te</sub>: respiratory parameter
- ml : unit of measurement
- 503: value set by the User
- 1000 - 100: alarm limits

## 2.4.8 Monitoring of Additional breathing parameters



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



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

Cs  
ml/cmH<sub>2</sub>O ---

### Static compliance

It is one of the parameters of the lung mechanics: measured in ml/cmH<sub>2</sub>O, represents the lung compliance when the patient does not breathe.

You can use it to assess 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:

$C_s = \text{current inspired volume} / \text{pause pressure}$ .

Cd  
ml/cmH<sub>2</sub>O 18

### Dynamic compliance

It is one of the parameters of the lung mechanics: measured in ml/cmH<sub>2</sub>O, represents the lung compliance either during the inspiration or during the expiration.

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

$C_d = \text{current inspired volume} / \text{peak pressure}$

Fe  
l/min 29.89

### 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.

Fi  
l/min 23.09

### Inspiratory peak flow

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

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

Leak  
% ---

### Leak

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

The unit of measurement is %.

Map  
cmH<sub>2</sub>O 4.2

### Mean airways pressure

It shows the average calculated pressure for the airways: the unit of measurement is cmH<sub>2</sub>O.

O<sub>2</sub>  
l/min --.-

### 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% .

Plateau  
cmH<sub>2</sub>O --.-

### Pause pressure

It shows the pause pressure: the unit of measurement is cmH<sub>2</sub>O.

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

Ri  
cmH<sub>2</sub>O/l/s ---

### Inspiratory resistance

It is the parameter of the lung mechanics that describes the resistance to the opposite flow of the airways: measured in cmH<sub>2</sub>O/(l/s). The greater the patient resistance, the higher the airway pressure you need to apply to obtain the same volume.

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

$Ri = (\text{peak pressure} - \text{pause pressure}) / \text{inspired flow}.$

Te  
s 1.60

### 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.

Ti  
s 0.80

### 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.

Tpause  
s 0.00

### Inspiratory pause

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

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

## 2.4.9 Alarm visualization



- 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 User to the event as well as to inform him on the requested response speed.
- For more information, please see on chapter 5 Alarms.



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

- “Alarm bell” symbol indicating the alarm priority and status
- Text string referring to the active alarm



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

### ALARM SILENCING



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



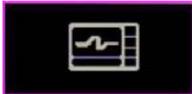
### WARNING !! Patient injury hazard

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

## 2.4.10 Measures, charts and loops

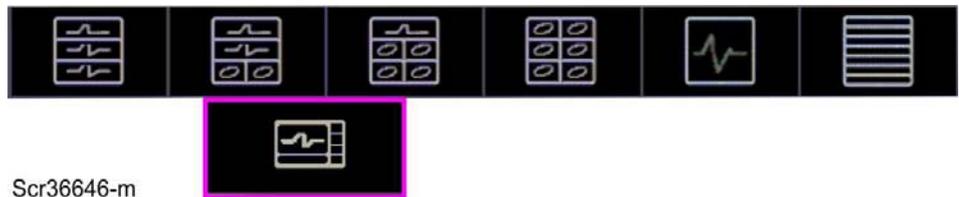


The lung ventilator is equipped with tools for charts and loops display so as to quickly and accurately notify the User on the patient's condition.

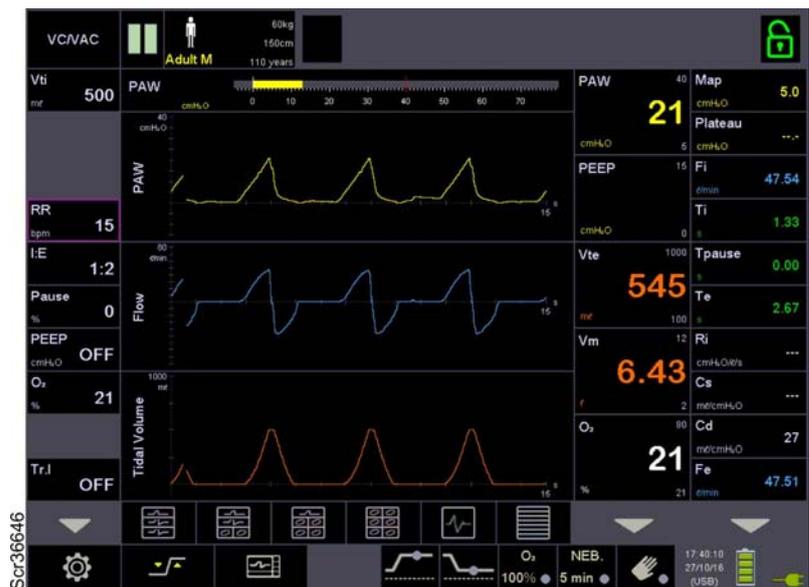


The User selecting the icon (**GRAPHICS**) can choose “which“ and “how” to display in time the following detections:

- **Charts:** PAW , Flow , Tidal Volume, O<sub>2</sub>, CO<sub>2</sub>
- **Loops:** Tidal Volume / Flow , PAW / Tidal Volume , PAW / Flow
- **Measures:** respiratory parameters
- **Lung status icon**



Scr36646-m



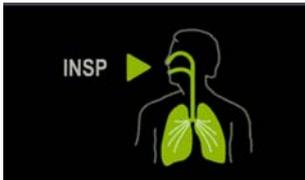
- To change the combination of curves displayed, the lung ventilator must be started.
- Select “**GRAPHICS**” icon to quit the function.
- For more information, please see on chapter 4.10.

## 2.4.11 Loops area: lung status



The lung status icon simulates the patient's lungs, graphically displaying the respiratory cycle by alternatively switching the lungs color.

In fact, in case of patient's spontaneous activity (Trigger), the lung status icon turns to yellow and if the “**Low Pressure of Airways**” alarm value set has not been exceeded the icon turns red.



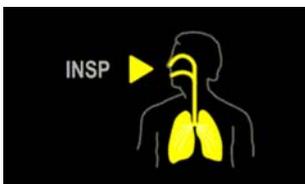
During inspiration the lungs icon **turns green**.



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



During expiration the lungs icon turns **light grey**.



At trigger activation the lungs icon is **yellow**.



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



### **WARNING !! Patient injury hazard**

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



For more information, please see on chapter 4.10.

## 2.4.12 Graphic setting, operative functions and general informations

In the lower side of GUI there are a series of controls and functions that are fundamental for use of Siaretron 4000 lung ventilator.



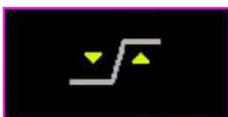
Select the icon to access the lung ventilator's **SETTING MENU**.

- Select the icon to **Turn OFF** the lung ventilator.
- Select the icon to improve the lung ventilator **Supplementary Tests**.

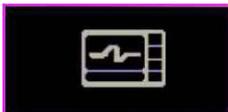


When the lung ventilator is in Stand-by mode, selecting this icon it is possible to enter the **PATIENT DATA** setting (*for more information, please see on chapter 4.3.1.*).

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



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



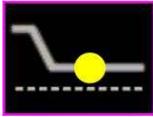
Select the icon to access the lung ventilator's **GRAPHICS** set.



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



**INSP HOLD** function



**EXP HOLD** function



**100% oxygen** concentration function



**NEBULIZER** function



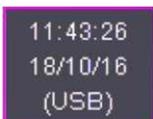
The “**NEB**” function is active only when the lung ventilator is supplied by oxygen (connection: **HIGH PRESSURE**).



**MAN** operative mode



About “**MAN** operative mode “, please see on chapter 4.8.11.



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

#### **General information**

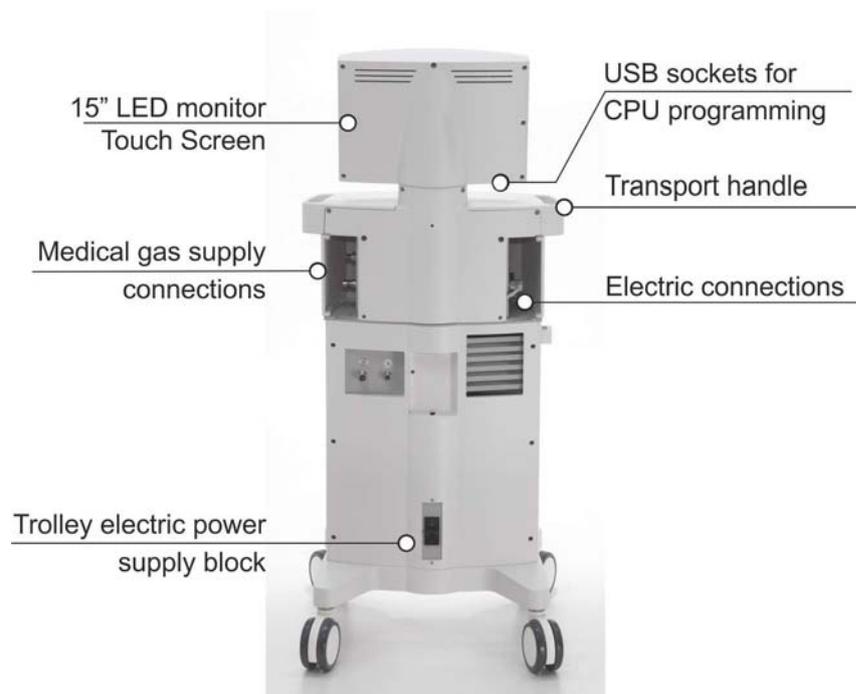


- Battery level (if the symbol is steadily lit and green, the battery is full).
- Presence of mains power supply, (the “green plug” symbol means that the device is powered from mains).



- About “General information”, please see on chapter 5.2.4.
- For more information about “Graphic setting, operative functions”, please see on chapter 4.10.

## 2.5 Rear view



### cfr. 2.4 15" LED monitor - Touch screen

#### **Note! USB sockets for programming**

One USB socket for CPU programming (near the reset button) and one USB socket for Screen Shoot (for more instructions see on Service Manual).



### cfr. 3.3 Gas supply connection (O<sub>2</sub>)

Electric power supply block

**ON-OFF** I / O switch for ventilator power supply

**FUSE** Protection fuses for 220 Vac power supply circuit (2 x 3,15 AT - 250V without air compressor)

**100 - 240 VAC** Connection of main power supply cable 100 - 240 VAC.

**100 - 240 VAC** Plug for "Electronic Heated Humidifier" power supply

## 2.6 Product identification - Labels

The product identification label mentions the following information.

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


**MANUFACTURED BY**   
**ENGINEERING INTERNATIONAL GROUP s.r.l.**  
 Via Pastore 18 Crespellano, Valsamoggia (BO) - ITALY - www.siare.it  
**Mod. Siaretron 4000**  
 100-240Vac 50-60Hz +/-10% **Made in Italy**  
 60VA Fuse 2x1AT Weight 26Kg   
 IEC 601-1 Class I Type B   
 93/42 EEC Class IIb **0476**  
**SERIAL 57213**



*Operating temperature : from +10 to +40°C*

*Storage temperature : from -25 to +70°C*



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



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



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



The number indicates the year of production of the equipment.



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



**Hazard of: instability from horizontal forces.**

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

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

*This page has been added to make front / back copy easier.*

## 3 PREPARATION TO USE

This chapter explains the main installation phases of Siaretron 4000. In the first section is illustrated how to install the device. In the second section it is illustrated how to perform the preliminary tests before using the Siaretron 4000 (*hereinafter called lung ventilator*).

*This chapter describes the following items.*

- 3.1 *Notes*
- 3.2 *Before the use*
  - 3.2.1 *Assembling of O<sub>2</sub> cell*
  - 3.2.2 *Battery recharge*
- 3.3 *Preparation to use*
  - 3.3.1 *Medical gas connection (O<sub>2</sub>)*
  - 3.3.2 *Connection of medical gas supply from cylinder*
  - 3.3.3 *Mains power supply*
  - 3.3.4 *External 12Vdc power supply*
  - 3.3.5 *Protection fuses*
  - 3.3.6 *Patient circuit supporting arm*
  - 3.3.7 *Patient circuit connections*
  - 3.3.8 *Antibacterial filter (HME)*
  - 3.3.9 *Gas analyzer connection (Gas Sensor)*
  - 3.3.10 *Data Connection (Trend and Events downloading)*
  - 3.3.11 *Nebulizer connection*
  - 3.3.12 *Humidifier connection*
  - 3.3.13 *Connection of other equipments*
- 3.4 *List of predisposition sequence for use*
- 3.5 *Use*
  - 3.5.1 *Preliminary tests*
  - 3.5.2 *Ventilator switch-on / SELF TEST phase*
  - 3.5.3 *Turn the lung ventilator OFF*
- 3.6 *Preliminary checks - Introduction*
- 3.7 *Preliminary checks - SUPPLEMENTARY TEST*
  - 3.7.1 *Expiratory Flow Sensors Calibration*
  - 3.7.2 *O<sub>2</sub> Sensor calibration*
  - 3.7.3 *Exit from SUPPLEMENTARY TESTS*
- 3.8 *Preliminary checks - LUNG VENTILATOR*
  - 3.8.1 *PRP setup*
  - 3.8.2 *Preliminary checks - PARAMETERS MONITORING*
  - 3.8.3 *Preliminary checks - ALARMS*
  - 3.8.4 *Alarm limits check*
  - 3.8.5 *Conclusions*
- 3.9 *Preliminary checks sequence list*

## 3.1 Notes



### UNPACK THE EQUIPMENT

- Unpack carefully.
- It is suggested to keep the original package, to avoid damages to the equipment in case of it should be returned to the factory.



### TRANSPORT – equipment moving

- Move the trolley/lung ventilator using the handles positioned laterally to the work shelf which allow to grab and move easily the unit.

The Siaretron 4000 lung ventilator must be moved possibly by two persons in good physical condition; this condition facilitates the manoeuvrability of the unit.

- During this transport phase, be careful not to bump or hit the unit with foreign bodies (e.g., tables, doors, elevator, etc....).
- Do not try to drag the unit over obstacles in general (hoses, cables or other obstacles on the floor).



### WARNING !! Risk of personal-physical injuries

If handled incorrectly, the unit may tip over causing personal-physical injuries to the patients and/or users.

- Remove the eventual devices positioned on the shelves or fixed laterally.
- Ensure that the front panels are closed.
- Pay much warning to eventual obstacles in the path during moving and positioning phases.



### WARNING !! Collision danger

Pay much warning during moving, positioning and use phases.

The devices or accessories applied can collide with other objects or persons present in the path and/or in the operating room.

**WARNING !! Accidental moving danger**

If the unit is not correctly positioned, it could accidentally move during operation.

- Position correctly the trolley/lung ventilator on a flat surface.
- Apply the unit brakes to ensure that it could not accidentally move during operation.

**WARNING !! Risk of injury for the user / patient**

- The assembly and connection of all the accessories must be carried out by highly qualified technical personnel, trained and formally authorised by SIARE.
- This type of lung ventilator not suitable for and therefore cannot be used in a hyperbaric chamber.
- To avoid an increase in the concentration of oxygen in the surrounding air, the lung ventilator should only be used in appropriately ventilated rooms.
- Do not connect or disconnect parts or components when the lung ventilator is on or connected to the mains power supply.
- Before using the lung ventilator, carry out all the necessary preliminary tests.



- If this is the first time you install the lung ventilator, it is suggested to consult thoroughly this user manual.
- Before using the unit, clean the external surfaces and sterilize the components.
- Use the maintenance instructions provided in this user manual and respecting the regulations in force in the country where the unit is sold.

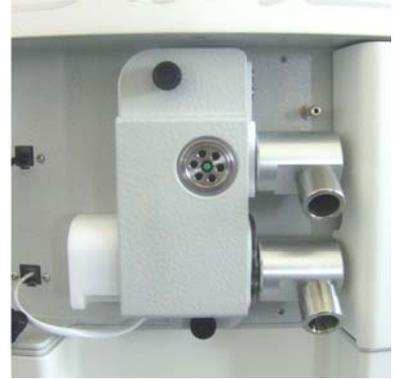
**WARNING !! Risk of injury for the patient**

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.

## 3.2 Before the use

### 3.2.1 Assembling of O<sub>2</sub> cell

- Open the left front panel of the trolley.
- Disassemble the cover of valves group.
- Screw the O<sub>2</sub> sensor inside its location taking care not to damage the thread.
- Insert the spin in the apposite O<sub>2</sub> sensor connector.



#### **WARNING !! Risk of injury for the patient.**

Verify to have correctly inserted the spin and the RJ connector on the apposite outlet inside the lung ventilator.

- Mount the cover of valves group.
- Close the left front panel of the trolley.



#### **WARNING !! Risk of injury for the patient**

- Check of electric connection of O<sub>2</sub> sensor.
- At lung ventilator start-up, the system checks the presence of the electric connection to the O<sub>2</sub> cell ("SELF TEST" phase).

### **3.2.2 Battery recharge**

The lung ventilator is provided with a battery (2 batteries Pb 12 Vdc - 1,3 Ah) that guarantees (if perfectly efficient) at least 90 minutes operation (with default physiological respiratory parameters), in case the mains power supply is cut off.

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

The lung ventilator battery can be recharged by connecting the equipment to main power supply (using power cable supplied with the unit) and placing the main switch in " I " position.



#### **BATTERY RECHARGE**

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

In order to ensure maximum operation autonomy, make sure that the recharge time is enough: to bring the charging level from 0 to 90% you need at least 8 hours of recharge with mains supply enabled.



#### **The BATTERY LIFE time varies as follows**

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

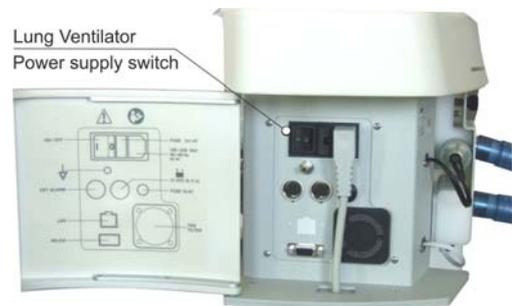
**Follow the instructions.**

- Connect the outlet of the power cable to the plug on the unit.
- Insert the plug of the power cable in the mains supply wall socket.

The electric main power supply must correspond to that indicated in the identification label of the lung ventilator.



- Place the main switch (located in the back side of the trolley) in position "I".
- Place the power supply switch of the lung ventilator (located in the left side of the trolley) in position "I".



- Verify on lung ventilator top side (user's control area) if the green led is light on (it indicates the main power supply).



To ensure maximum autonomy of operation, it is necessary to guarantee sufficient recharging time.

To bring the charge level from 0 to 90% takes approximately 8 hours recharging through the mains power supply.



It is not necessary to start-up the lung ventilator.

### 3.3 Preparation to use

#### 3.3.1 Medical gas connection (O<sub>2</sub>)

- Screw the pneumatic O<sub>2</sub> supply hose on the lung ventilator connector.
- Connect the pneumatic O<sub>2</sub> supply hose on the relevant connector on the gas system.
- Be sure that the pneumatic hose is well fixed and that the medical gas system is clean and without lubricants.



The O<sub>2</sub> hose is already supplied with screw connection DISS type (Diameter Index Safety System) for connection to the unit connector.

The installation technician taking care of the hose connection to the outlet must ensure that they are compatible with the hospital medical gas pipeline system.



To prevent inversions of gases that can be FATAL for the patient, assembly of the connectors compatible with the hospital distribution system and all the maintenance and/or replacement operations of the medical gas supply hoses must be carried out by highly qualified technical personnel only.



The lung ventilator can work even without an oxygen supply using the internal turbine only; in this case the FiO<sub>2</sub> could be set only to 21%.



#### **WARNING !! Lung ventilator failure risk**

- In order that the lung ventilator operates as specified, the input medical gas pressure must be between 280 kPa and 600 kPa (2,8 - 6 bar / 40 - 86 psi).
- Before using the lung ventilator, make sure that this requirement is met.
- After connecting the medical gas supply tube, make sure that the system works properly.

**WARNING !! Risk of gas failure**

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

**WARNING !! Risk of gas failure**

- If the gas supply hoses are not correctly connected, the unit will not be available in case of gas supply failure.
- Ensure that supply hoses are connected according with the indication engraved on the gas inlet bloc and the illustrations in the side of the equipment.

### 3.3.2 Connection of medical gas supply from cylinder

- Screw the pneumatic O<sub>2</sub> supply hose on the lung ventilator connector.
- Connect the pneumatic O<sub>2</sub> supply hose on the relevant connector of the cylinder pressure reducer (O<sub>2</sub>).
- Ensure that the gas supply hoses are connected and work correctly.



We suggest you to install on reducers the same inlets used on the distribution system so as to make switching from one system to the other safe and quick (at least for oxygen).

**WARNING !! Risk of explosion**

- If the pressure reducers for O<sub>2</sub> are touched with fingers/hands soiled with oil or grease, there is the risk of explosion.
- Do not apply oil or grease on the O<sub>2</sub> cylinders pressure reducers and never touch with fingers soiled with oil or grease.

### 3.3.3 Mains power supply

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

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

The power supplies foreseen on lung ventilator unit are of three types:

- by main power supply (100 - 240Vac / 50 - 60Hz)
- by internal battery (2 batteries Pb / 12Vdc - 1.3Ah)
- by external power supply (12Vdc / 7A).

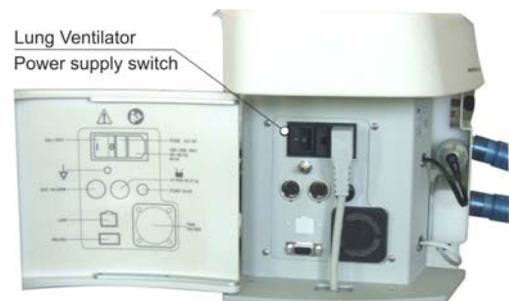
#### Connection to the mains power supply

The main electric power supply must correspond to that indicated on the identification label (electric power supply, frequency and power consumption) located on the unit: 100 - 240Vac / 50 - 60Hz / 60 VA.

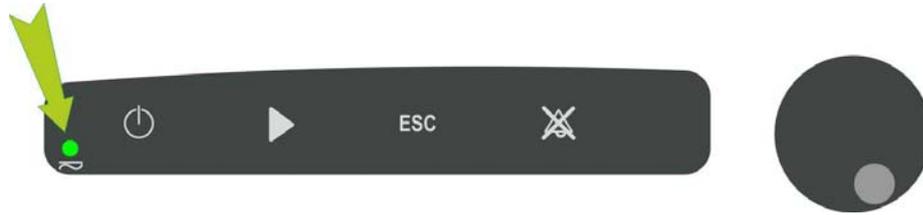
- Connect the power cable outlet to the plug on the unit.
- Insert the plug of the power cable in the main power supply outlet.
- Position the main switch (located in the back side of the trolley) in position "I".



- Place the power supply switch of the lung ventilator (located in the left side of the lung ventilator) in position "I".



- Verify on lung ventilator top side (user's control area) if the green led is on (it indicates the presence of main power supply).



### **WARNING !! Risk of personal-physical injuries**

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 Siaretron 4000 lung ventilator complies with the requirements for electro-medical devices detailed on chapter 1.3 (Norms and standards regulations).
- To ensure proper operation of the Siaretron 4000 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 Siaretron 4000 lung ventilator.

## Battery power supply



### WARNING !! Risk of failure

- The batteries, inside the lung ventilator, must always be installed.
- If the batteries are not fitted, the lung ventilator is not protected against fluctuations or failures of the power supply.
- The lung ventilator must not be used without batteries charged and in perfect conditions.
- The use of the battery must be limited to short periods and is not foreseen as an alternative to the mains power supply.
- Do not open the lung ventilator to replace the battery or to carry out maintenance operations on the battery charger.

When the led on the top side is on it indicates that the lung ventilator is correctly supplied.



To silence the acoustic alarm, push the “ **ALARM RESET** “ soft key; located on the lung ventilator top side.



### BATTERY LIFE

The battery life time varies as follows:

- old battery or not perfectly efficient;
- not standard ventilatory parameters.

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

## Battery recharge



The lung ventilator battery can be recharged by leaving the unit connected to the main power supply (using power cable supplied with the unit) it is not necessary that the unit is on.



For battery recharging follow what specified in technical data sheet (*Battery re-charging time*).



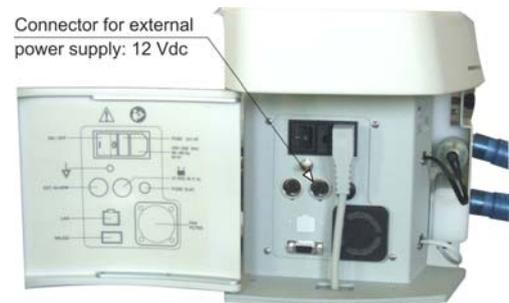
### **WARNING !! Risk of failure**

In case of power supply failure, the optional devices connected to the supplementary electric socket are not supplied by the battery.

Pay much warning to all power supply indicators of connected devices.

### 3.3.4 External 12Vdc power supply

The Siaretron 4000 lung ventilator can be supplied by an apposite cable to an external 12Vdc power supply (7 A Max.).



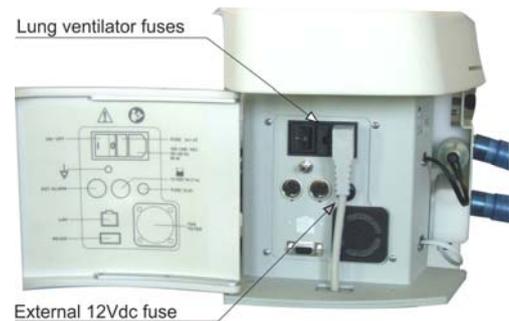
### **WARNING to the polarities!!**

The red cable must be connected to the positive pole (+) of the battery.

### 3.3.5 Protection fuses

Protection fuses are foreseen in the following circuit:

- Main power supply (protection fuses without compressor: 2 x 3,15 AT).
- Lung ventilator power supply fuses (2x1 AT).
- External 12Vdc power supply fuse (10 AT).



#### **WARNING !! Risk of injury for the user / patient**

The operations described here below must be carried out by highly qualified technical personnel, trained and formally authorised by SIARE only.

#### **In case of break of protection fuse:**

- interrupt the main power supply;
- eliminate the malfunctioning or the cause which caused the fuse break,
- replace the protection fuse with one with the same value and technical characteristics.



#### **WARNING !! Risk of injury for the user / patient**

Fuses with wrong values and technical characteristics can compromise equipment integrity and lung ventilator safety.

### 3.3.6 Patient circuit supporting arm

- Insert the patient circuit supporting arm in the opposite bracket
- Place the patient circuit supporting arm
- Lock the pivot with the hex screw and the knob to avoid the patient circuit supporting arm turns.



### 3.3.7 Patient circuit connections



Use a patient circuit suitable for the patient to ventilate.

Tidal Volume	Set of hoses
< 50 mL	Neonatal
From 50 to 200 mL	Paediatric
> 210 mL	Adult

- Connect the supplied patient circuit to the opposite INS and EXP connectors on the lung ventilator.
- Position the patient circuit on the patient circuit supporting arm.



### 3.3.8 Antibacterial filter (HME)

Apply the antibacterial filters to the patient circuit.

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



• Moisture loss	6.7 mg H <sub>2</sub> O/l
• Calculated moisture return	31.6mg H <sub>2</sub> O/l
• Resistance at 30L/min	0.2 cm H <sub>2</sub> O
• Resistance at 60L/min	0.8 cm H <sub>2</sub> O
• Compressible volume	59 ml
• Weight	31 g
• Connectors	22F/15M - 22M/15F



#### **WARNING !! Risk of injury for the patient**

To protect the patient from particles and dust, it is necessary to use a filter between the inspiratory hose and the patient, i.e., the filter on the Y connector or the filter on inspiratory hose.



#### **WARNING !! Risk of injury for the patient**

Replace the antibacterial filters as indicated in the maintenance instructions.



#### **WARNING !! Risk of injury for the patient**

- Please perform the "SELF TEST" phase (lung ventilator - switch ON) every time you replace the patient circuit.
- The system will check the patient circuit every time you switch ON the lung ventilator.



#### **WARNING !! Risk of strangling**

- Pay special warning when connecting the patient circuit to the lung ventilator.
- If not carefully positioned, the hoses, the cables, the patient circuit and other similar components to the lung ventilator, these can be dangerous for the patient.



#### **WARNING !! Risk of burns**

Do not use conductive masks or conductive breathing hoses during surgery with electrosurgical units because they can cause burns.

### 3.3.9 Gas analyzer connection (Gas Sensor)



For more details and information about the CO<sub>2</sub> analyzer (Sidestream or Mainstream model) please refer to the user manual supplied with the GAS ANALYZER.

- Extract the **gas analyzer** and the **cable + interface module**, from package.
- Switch OFF the lung ventilator power supply - *lung ventilator OFF* -
- Connect the interface cable between the RS-232 connector (positioned on the side of the lung ventilator) and the interface module.
- Connect the *GAS ANALYZER* to the *interface* module.



#### Mainstream GAS ANALYZER

- Apply the gas sensor to the patient circuit.



#### Sidestream GAS ANALYZER

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





Verify the functioning of the **Mainstream** GAS ANALYZER

- Switch ON the electric power supply.
- A green LED (on the gas analyzer) indicates that the IRMA analyzer is ready for use.



Verify the functioning of the **Sidestream** GAS ANALYZER

- Switch ON the electric power supply.
- A green LED (on the gas analyzer - sampling line) indicates that the ISA analyzer is ready for use.



#### **GAS ANALYZER : Zeroing**

- **Mainstream IRMA sensor:** after around one minute from the device is turned on, it is necessary to perform the manual procedure of Zero Calibration (please see 3.5 TESTS ON DEMAND).
- **With sidestream ISA sensor:** the zeroing of gas sensor measurement is activated in automatic mode; anyway, it is possible to perform the Zeroing calibration procedure when needed (the green led blinks when your turn-on the *GAS ANALYZER*).

### **3.3.10 Data Connection (Trend and Events downloading)**



- Connect a USB flash drive to the USB1 socket used for CPU programming and data download (*USB socket near the reset button*).
- For more information see chapter 4.3.2 (**SETUP - Other: Save to USB**).
- Request the guide with the relative instructions for data interpretation (*Procedure for downloading data*).

### 3.3.11 Nebulizer connection

- To connect the Nebulizer it is necessary to use the apposite connector provided on the front side of lung ventilator.



Use the control provided on the Graphical Users Interface (GUI) NEB function to enable the Nebulizer functionality (cfr 4.2.4).



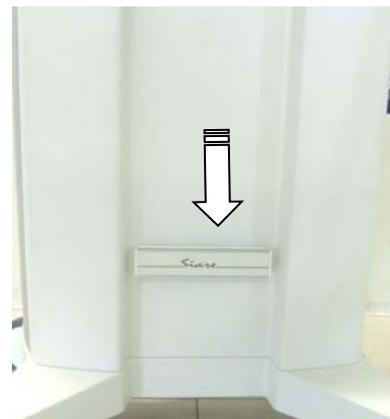
#### **WARNING !! Risk of injury for the patient**

The lung ventilator accuracy can be affected by the gas added by the use of a nebulizer.

### 3.3.12 Humidifier connection

A support for Vapour 2 humidifier mounting is provided on the front side of the trolley.

The Vapour2 must be inserted on the **INSP** line of patient circuit, using the hose provided with humidifier (code A2000 or P2000).



For further doubts on which types of humidifiers should be used on Siaretron 4000 lung ventilator, contact Siare.

- Connect the provided hose (code A2000 or P2000), from **INSP** connector of lung ventilator to the **external connector** of Monopack column.
- Connect the patient circuit to the **EXP** connector of lung ventilator and the **central connector** of the Monopack column.
- Connect the temperature probe to the **TEMP PROBE** connector of Vapour2 and intrRS-232ce it in the **hole for probe of the straight connector** provided to be mounted on patient circuit.
- Connect the plug of the Vapour2 supply cable to the electric outlet in the rear side of the trolley.



**WARNING !! Trouble risk**

The Vapour 2 humidifier must be installed by qualified technical personnel, trained and formally authorized by SIARE; for additional information, consult the provided user's manual.



**WARNING !! Risk of injury for the patient**

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

Please see relevant note on chapter Index.

### 3.3.13 Connection of other equipments



#### Connection to Siare equipment

If the equipment to be connected is a SIARE unit, all the instructions necessary for the connection to lung ventilator can be found in the documentation supplied.



#### **WARNING !! Risk of injury for the user / patient**

Do not connect external devices NOT manufactured or NOT authorized by SIARE to the lung ventilator (e.g., scavenging systems, patient simulators), and not described in the present user's manual.

In case contact SIARE or the Authorized Local Service



#### **WARNING !! Risk of injuries for the patient**

When using additional components in the respiratory systems or configurations not conform to those supplied with the lung ventilator, the inspiratory and expiratory resistance can increase until overcome the standard requirements.

When using configurations of this type, it is necessary to pay particular WARNING to the measuring values.



#### **WARNING !! Risk of electric shock**

In case of malfunctioning of ground conductor, the connection of other electric equipment to the supplementary outlet of the lung ventilator could cause an increase in leakage current over the values allowed by the law.

In case of connection of other devices to the supplementary outlet, it is necessary to verify the total leakage current.

In case of overcoming of the values allowed for total leakage current, do not connect other devices to the supplementary outlet of lung ventilator; connect other devices to a separate electric outlet.

All the system must satisfy the requirements for electromedical equipment stated by the IEC/EN 60601-1-1 and IEC/EN 60601-1-2. directives.

### **3.4 List of predisposition sequence for use**

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3.3.13	<i>Connection of other equipments</i>	3-20
3.4	<i>List of predisposition sequence for use</i>	3-21

## 3.5 Use



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

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

### 3.5.1 Preliminary tests

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

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



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



The preliminary tests should be performed:

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

#### Before starting preliminary tests, the Siaretron 4000 lung ventilator must be:

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



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

**WARNING !! Risk of explosion and/or fire**

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

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

**Risk of accidental movement.**

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

Apply the unit brakes to prevent accidentally movements (front side of the trolley/lung ventilator).

**Emergency conditions**

In emergency conditions, the preliminary checks can be skipped.

You should carry out the preliminary checks once the emergency condition stops, and at least once a week.

**Preventive MAINTENANCE**

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

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

**WARNING !! Patient/User injury hazard**

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

**WARNING !! Serious patient injuries**

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

### 3.5.2 Ventilator switch-on / SELF TEST phase

- Set the main switch (placed on the back of the lung ventilator) to “I”.
- Make sure that on the lung ventilator keyboard (commands area) the green led (that indicates the presence of mains power supply) is on.
- Hold the **ON-OFF** key for few seconds; the lung ventilator switches ON and the automatic **Self Test** phase starts.



**Self Test phase.** Please close the patient circuit.



The lung ventilator turns on and the automatic **Self Test** phase begins.

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



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



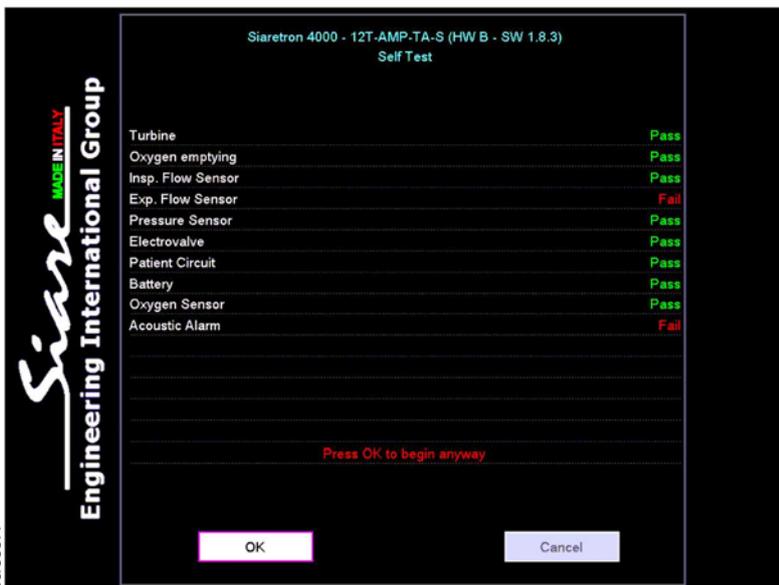
For a more correct and detailed analysis of the issues arising during Self Test phase, please consult **chapter 5.5** or the Service Manual.



### CAUTION. Acoustic Alarm: Fail.



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



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

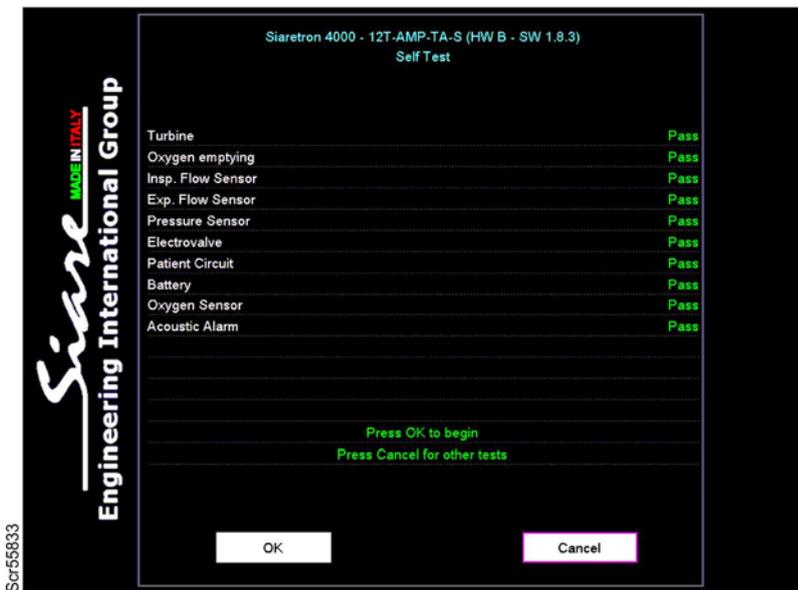
If the **Self Test** phase has **NOT** been completed successfully, the system allows the operator to proceed and display the following message.

**Note!** “Press OK to begin anyway”



### WARNING !! Patient/User 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.



The **Self Test** phase completed successfully.

If the **Self Test** phase has been completed successfully, the system displays the following message.

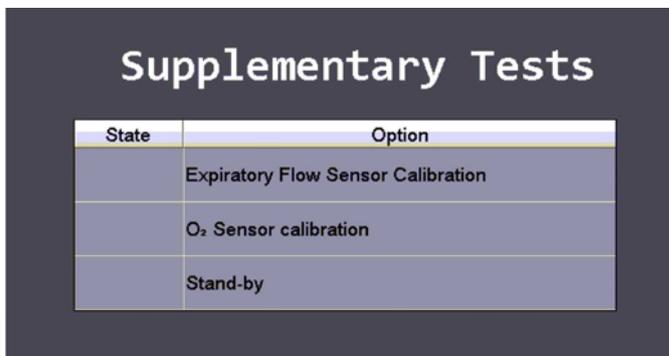
“ Press **OK** to begin “

“ Press **Cancel** for other tests “

Scr55833

Cancel

The system will display the **Supplementary Tests** page.



Scr55837

By means of this page it is possible to perform:

- *the Expiratory Flow Sensor Calibration*
- *the O<sub>2</sub> Sensor calibration*
- *or switch to the Stand-by visualization*



For a correct and more detailed analysis of Supplementary Tests, see chapter 3.7.

OK

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



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

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



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



### Operative Mode Stand-by

In Stand-by mode, the User can set and / or modify:

- the operating mode
- the lung ventilator parameters
- the alarm limits related to the operating mode that will be used on the patient to be treated.

Scr34638

### 3.5.3 Turn the lung ventilator OFF

Stand-by operating mode.

- Hold the **ON-OFF** key for few seconds to turn the lung ventilator off.



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

- **Press NO:** cancel the command (the lung ventilator returns to Stand-by mode).
- **Press YES:** the lung ventilator will be switched **OFF**.



#### Lung ventilator OFF - Oxygen emptying

During the switching off the lung 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 FiO<sub>2</sub> 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 4 phases.

- **SUPPLEMENTARY TEST**
  - Exp. Flow Sensor calibration (*see note at the beginning of chap. 3.7.1*)
  - O<sub>2</sub> Sensor calibration
- **LUNG VENTILATOR**
  - Respiratory parameters
  - Spirometry
- **LUNG VENTILATOR ALARMS**
- **OPTIONAL**



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

Running or cancelling the preliminary checks might result in a malfunction during ventilatory operation: pay utmost attention.

Always carry out all preliminary checks, unless there is an emergency situation.

You should carry out the preliminary checks once the emergency condition stops, and at least once a week.



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<sub>2</sub>) and the patient circuit.
- Insert and connect the oxygen sensor.
- Connect a patient simulator to the patient circuit terminal.
- Lung ventilator ON: Stand-by mode.

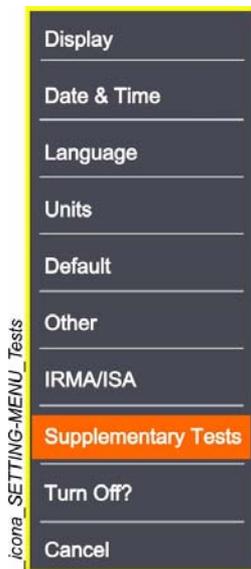
### 3.7 Preliminary checks - SUPPLEMENTARY TEST



To carry out the Supplementary Test you must know the keyboard operating mode and the options available in the lung ventilator Setting MENU (please see chapter 2.4).



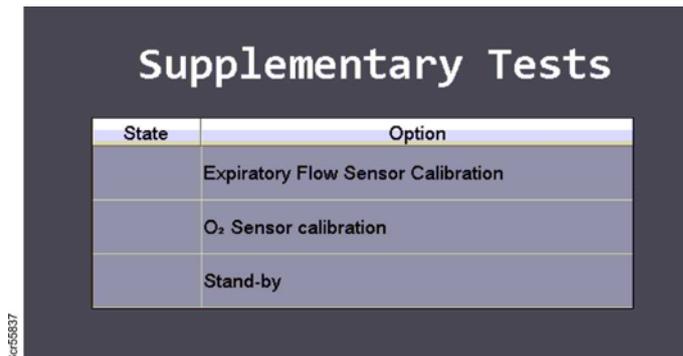
Select the icon to access the lung ventilator's **SETTING MENU**.



The **Supplementary Tests** screen appears.



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



### 3.7.1 Expiratory Flow Sensors Calibration



#### WARNING !! Ventilator malfunctions risk

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

- Noted differences are more than 15% (over 100ml) between the set Volume value (  $V_{Ti}$  -  $V_{Te}$  ) and the expired Tidal Volume reading (  $V_{Te}$  ).
- In the case of maintenance intervention or replacement of components

- **Select** Expiratory Flow Sensors Calibration.

Supplementary Tests	
State	Option
	Expiratory Flow Sensor Calibration
	O <sub>2</sub> Sensor Calibration
	Stand-by

Scr00600

- The system will activate the Flow Sensors Calibration.

Siaretron 4000 - 12T-AMP-TA-S (HW B - SW 1.8.3)  
Expiratory Flow Sensor Calibration

Total operating hours 98h 49m 42s  
Partial operating hours 2h 55m 47s

Inlet Oxygen Pressure (bar)  
Inspiratory Flow (l/min) 1028mV 205 ( 0.0)  
Expiratory Flow (l/min) 156 -> 87  
Pressure (cmH<sub>2</sub>O) ( 0.2) 202  
Battery voltage 13.4  
O<sub>2</sub> sensor reading 0mV 0  
Turbine temperature (29°C) 244  
Turbine Current 0mA  
Turbine PWM (%)  
Turbine speed  
FiComp (%) 000

0%

OK Verify Cancel

Scr63852



#### CAUTION

Not being a useful procedure for the purpose of "Preliminary Checks", see chapter 4.17 for a more detailed description of the same.

### 3.7.2 O2 Sensor calibration



#### WARNING !! Ventilator malfunctions risk

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

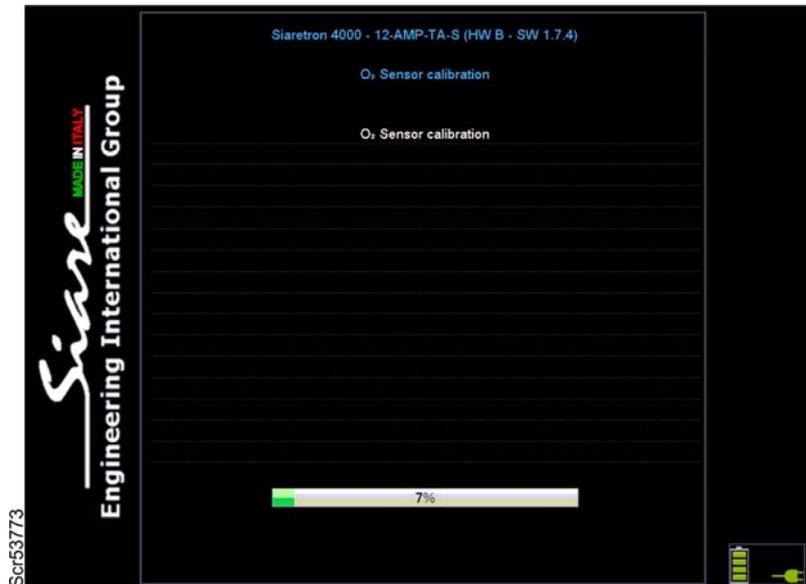
To avoid any patient injury risks, carry out this procedure monthly.

- Select: **O2 Sensor calibration.**

Supplementary Tests	
State	Option
	Expiratory Flow Sensor Calibration
	<b>O2 Sensor Calibration</b>
	Stand-by

Scr00600

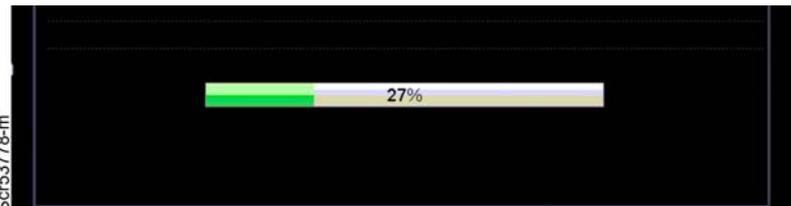
- The **O2 Sensor calibration** screen appears.
- The system will activate the sensor calibration.



Scr53773

#### O2 sensor calibration in progress.

**Note!** To check if the O2 sensor works properly, the software reads the electrical value (mV) generated by the cell when è in presence of a flow with a 21% O2 concentration (air).



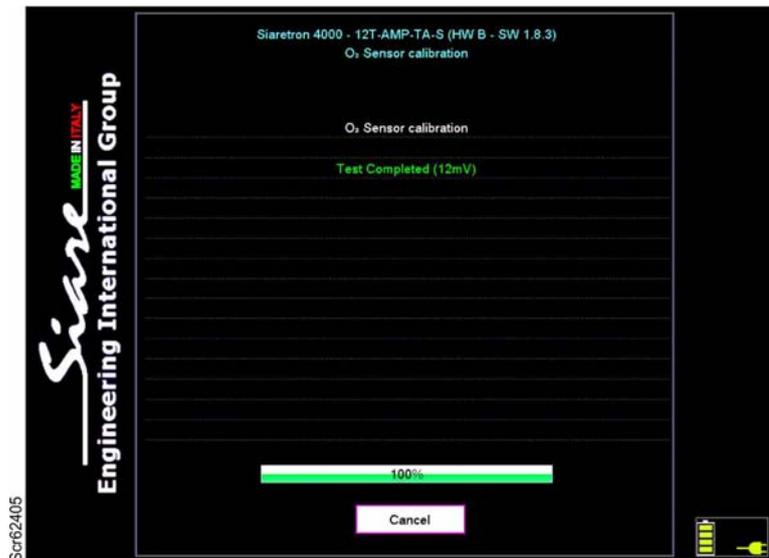
Scr53778-m



At the end of the O<sub>2</sub> sensor calibration a message is showed (if the O<sub>2</sub> sensor is new and in perfect conditions): **Test Completed ( XXmV )** which show the value in Volts measured by the sensor with 21% Oxygen ( *Optimal value = 13mV* ).

The **Calibration procedure** has been successfully completed.

- The oxygen sensor calibration procedure was completed successfully: the measured voltage value is 12mV.
- At the end of the procedure the "Supplementary Tests" page is automatically displayed.



### 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 "Maintenance ".

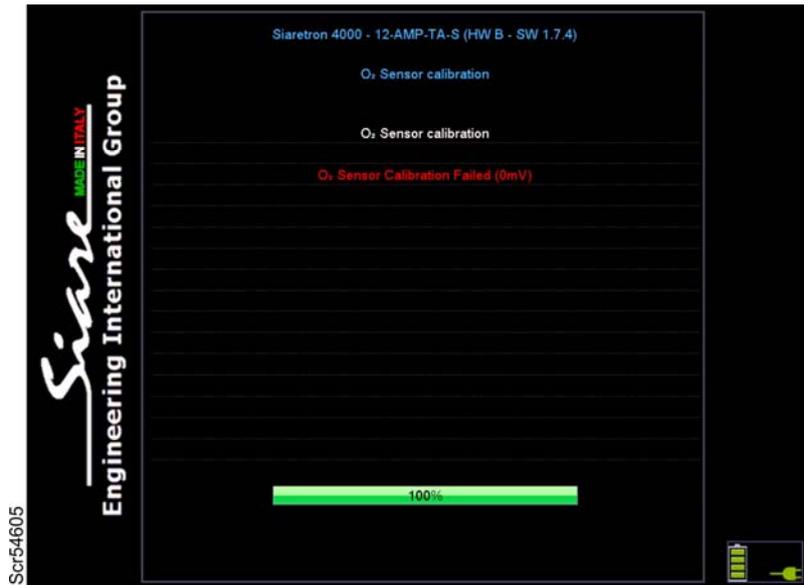
### **Conditions to be met for proper calibration:**



- the O<sub>2</sub> sensor must be placed in its seat
- the O<sub>2</sub> 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.

- The oxygen sensor calibration procedure was not completed successfully.
- O2 Sensor Calibration Failed.



### WARNING !! Ventilator malfunctions risk



If the TEST result is negative check:

- if the O2 sensor is installed and electrically connected to the ventilator;
- if the O2 sensor is worn out (the oxygen detection cell is worn out; replace the O2 sensor).



### TESTS 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.

### 3.7.3 Exit from SUPPLEMENTARY TESTS

- The system automatically quits O2 sensor calibration after a few seconds.
- Select **Stand-by**: the system will leave the **Supplementary Tests**.

Supplementary Tests	
State	Option
	Expiratory Flow Sensor Calibration
	O2 Sensor Calibration
	Stand-by

Scr00600



### CAUTION - Supplementary Tests

The tests to be performed before starting the lung ventilator have been illustrated: it is suggested to perform these tests within the foreseen times and defined by the present Manual and / or by the local regulations in force.

## 3.8 Preliminary checks - LUNG VENTILATOR

### 3.8.1 PRP setup



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



#### Preliminary checks to be carried out on the lung ventilator.

- Respiratory parameters setup.
- Spirometry proper operation check.

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



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



#### Modification of the PRP

- Select the parameter you want to change.
- For more information about PRP set, please see on chapter 2.4.1



3. Set the physiological respiratory parameters (PRP)

- Vti 500
- RR 15
- I:E 1:2
- Tr. I -1 cmH<sub>2</sub>O  
1 L/min
- Pause 0
- PEEP OFF, 5, 10 cmH<sub>2</sub>O
- O<sub>2</sub> 21%



4. Select / Press **START**: the lung 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.

### 3.8.2 Preliminary checks - PARAMETERS MONITORING



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



- Check the compliance between the parameters set and those monitored.
  - In the middle of the screen the system displays the operating curves.
  - On the right side of the screen you can see the monitored parameters.



- Change the PRP values.
  - PEEP: 5, 10 cmH<sub>2</sub>O
  - Tr. I: -2 cmH<sub>2</sub>O, 3 L/min
  - O<sub>2</sub>: 60%
- Check the correspondence between the monitored parameters and the displayed curves.
- Select the key to display all the parameters.





### 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<sub>2</sub> %) corresponds.
- Make sure that the lung ventilator responds properly at parameters variation.
- Make sure that that the trigger works properly.
- Make sure that the values set for respiratory frequency and volume are properly displayed and the pressure, volume and flow curves match the monitored parameters.
- Make sure that the alarms intervene properly.



### CAUTION

- If the oxygen measured value differs from the set value by more than +/- 10%, please repeat the “**O<sub>2</sub> Sensor Calibration**” procedure: Supplementary Test.
- If the V<sub>te</sub> measured value differs from the set value by more than +/- 20% (Adult parameters), please go to the “**CALIBRATION PROGRAMS**” visualization to perform the calibration of the expiratory flow sensor (see chapter 4.16).

### 3.8.3 Preliminary checks – ALARMS



To carry out the preliminary checks relative to lung ventilator's alarms, you need to know how the system and the alarms work: please see chapter 2.4.



9. Select the icon to access the lung ventilator's ALARMS.
  - The Alarm Limits screen appears.



- Check the Alarms Limits and if necessary, change the values set, based on the test you want to carry out.
- Select the Alarm parameter you want to change. For more information about use of touch screen or key board, please see on chapter 2.4.

#### Exit the Alarm Limits screen

Select **Cancel**

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

Select **OK**

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



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

### 3.8.4 Alarm limits check



#### WARNING !! Severe patient injuries

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

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



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



10. Select VC/VAC operative mode.

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

#### High Pressure

- Set the high pressure alarm limit to a value higher than the PAW ventilation pressure by 5 cmH<sub>2</sub>O.
- Block the patient simulator (using your hands) during ventilation.
- The system activates the airways HIGH PRESSURE alarm: silence the alarm.
- Unlock the patient simulator.

#### PAW

#### Low Pressure

- Set the low pressure alarm limit to 5 cmH<sub>2</sub>O.
- 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**

- During ventilation please set PEEP = 10 cmH<sub>2</sub>O
- Set the high pressure limit to 5 cmH<sub>2</sub>O.
- The system activates the HIGH PEEP alarm: silence the alarm.
- Restore the default alarm value.

**PEEP**

**Low**

- During ventilation please set PEEP = 3 cmH<sub>2</sub>O
- Set the low pressure limit to 8 cmH<sub>2</sub>O.
- The system activates the LOW PEEP alarm: silence the alarm.
- Restore the default alarm value.

**High EXP Vt**

- During ventilation, set V<sub>ti</sub> to 500 ml.
- Set the high expired V<sub>te</sub> alarm limit to 400 ml.
- The system activates the high expired V<sub>te</sub> alarm: silence the alarm.
- Restore the default alarm value.

**Vte**

**Low EXP Vt**

- During ventilation, set V<sub>ti</sub> to 200 ml.
- Set the low expired V<sub>te</sub> alarm limit to 250 ml.
- The system activates the low expired V<sub>te</sub> alarm: silence the alarm.
- Restore the default alarm value.

**High**

- Set the high expired V<sub>m</sub> alarm limit to 8 l.
- During ventilation, set V<sub>ti</sub> to 800 ml / 15 bpm.
- The system activates the high expired V<sub>m</sub> alarm: silence the alarm.
- Restore the default alarm value.

**Vm**

**Low**

- Set the low expired V<sub>m</sub> alarm limit to 5 l.
- During ventilation, set V<sub>ti</sub> to 175 ml / 20 bpm.
- The system activates the low expired V<sub>m</sub> alarm: silence the alarm.
- Restore the default alarm value.

**High oxygen concentration**

- Set a O2 concentration to 50% on the lung ventilator.
- Set the high O2 concentration alarm limit to 30%.
- The system activates the high O2 alarm: silence the alarm.
- Restore the default alarm value.

**O2**

**Low oxygen concentration**

- Set a O2 concentration to 30% on the lung ventilator.
- Set the low O2 concentration alarm limit to 50%.
- The system activates the low O2 alarm: silence the alarm.
- Restore the default alarm value.



**High / Low FiO2**

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

**High respiratory rate**

- During ventilation please set RR = 20 bpm.
- Set the high respiratory rate alarm limit to 15 bpm.
- The system activates the high RR alarm: silence the alarm.
- Restore the default alarm value.

**RR**

**Low respiratory rate**

- During ventilation please set RR = 10 bpm.
- Set the low respiratory rate alarm limit to 15 bpm.
- The system activates the low RR alarm: silence the alarm.
- Restore the default alarm value.

- During ventilation, set the main power supply switch to OFF ( 0 ).
- The system activates the main power failure alarm: silence the alarm.
- Restore the main switch and set it to ON ( 1 ).

- Close the medical gas supply during lung ventilator operation.
- The system activates the gas supply failure alarm: silence the alarm.
- Restore the medical gas supply.

### 3.8.5 Conclusions

Carry out all preliminary checks and make sure that they were completed successfully before connecting the patient to the Siaretron 4000 lung ventilator.



#### **Preliminary checks phase failed.**

- Please see Alarms chapter and/or Trouble Shooting chapter.
- Please contact the nearest Siare Support Centre or any other support centres authorised by Siare.



#### **WARNING !! Patient injury hazard**

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



#### **WARNING !! User and patient injury hazard**

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

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

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

### **3.9 Preliminary checks sequence list**

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## 4 LUNG VENTILATOR USE

This chapter shows you how to use the Siaretron 4000 15" lung ventilator for intensive care, (*referred to from now on as lung 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 Operator must choose the Operative modes and the alarm limits that best match patient's physiological state and pathologies.

*This chapter describes the following items.*

- 4.1 Notes
- 4.2 Stand-by mode
  - 4.2.1 Self Test phase
- 4.3 PATIENT DATA / SETUP parameters
  - 4.3.1 PATIENT DATA
  - 4.3.2 MENU ( SETUP parameters )
- 4.4 Setting up the UGI language
- 4.5 Setting the PATIENT DATA
  - 4.5.1 Erasing the PATIENT DATA
- 4.6 Setting up the ALARMS
- 4.7 Operative modes
  - 4.7.1 Operative Modes selection procedure
  - 4.7.2 APCV ( NIV APCV )
  - 4.7.3 APCV-TV
  - 4.7.4 PSV ( NIV PSV )
  - 4.7.5 PSV-TV
  - 4.7.6 VC-VAC
  - 4.7.7 VC-VAC BABY
  - 4.7.8 V-SIMV
  - 4.7.9 P-SIMV
  - 4.7.10 CPAP
  - 4.7.11 APRV (Airway Pressure Release Ventilation)
  - 4.7.12 MAN operative mode
  - 4.7.13 APNEA BACK-UP
- 4.8 Physiological respiratory parameters ( PRP )
  - 4.8.1 PRP parameters setting procedure
  - 4.8.2 Monitoring of respiratory parameters

- 4.9 *Ventilation phase*
  - 4.9.1 *Ventilation interruption*
- 4.10 *Operative functions and Graphic settings*
- 4.11 *GRAPHICs visualization*
  - 4.11.1 *Combinations of the graphics displayed*
  - 4.11.2 *Modification Charts combination*
  - 4.11.3 *Loops combination modification*
  - 4.11.4 *TRENDS visualization*
  - 4.11.5 *EVENTS visualization*
- 4.12 *DEFAULT PARAMETERS*
- 4.13 *Alarms SETUP*
- 4.14 *Patient data SETUP*
- 4.15 *List of functions*
- 4.16 *List of default parameters*
- 4.17 *CALIBRATRION PROGRAMS*
  - 4.17.1 *Preliminary*
  - 4.17.2 *Calibration Programs displaying*
  - 4.17.3 *Turbine characterization*
  - 4.17.4 *Expiratory flow sensors calibration*
  - 4.17.5 *High Altitude usage ( On - Off )*
  - 4.17.6 *VTEc ( On - Off )*
  - 4.17.7 *Nebulizer Enable ( On – Off )*
  - 4.17.8 *ScreenShot Enable ( On – Off )*
  - 4.17.9 *Self Test*
- 4.18 *Power Off*
- 4.19 *Other functions*
  - 4.19.1 *Reset to ZERO the “Partial operating hours“*
  - 4.19.2 *Data Connection (Trend and Events downloading)*
  - 4.19.3 *Default parameters set*
  - 4.19.4 *Touch Screen set*

## 4.1 Notes



### **WARNING !! Patient/Operator injury hazard**

Before starting the lung ventilator, you have to:

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



### **CAUTION**

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

- set the airway pressure limit alarm to a value that does not exceed 20 cmH<sub>2</sub>O; this way you will prevent any problems that might arise due to incorrect respiratory volume or frequency setup (you can increase the pressure if the patient's pathology and conditions require such modification).
- check the set oxygen concentration (FiO<sub>2</sub>) as high concentrations might affect the patient's health.
- please consult this User Manual.



### **WARNING !! Patient injury hazard**

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

## 4.2 Stand-by mode

### 4.2.1 Self Test phase

- Set the main switch (placed on the back of lung ventilator) in position “I” (ON).
- Make sure that on the lung ventilator keyboard (commands area), the green led (that indicates the presence of mains power supply) is on.
- Hold the **ON-OFF** key for few seconds to start the lung ventilator and the automatic **Self Test** phase begins.



#### Self Test phase starts.

- Please close the patient circuit.

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

For more information on the **Self Test** please refer to the chap. 3.5.2.



#### Self Test phase completed successfully.

- Press **Cancel** to go to **Supplementary Tests**.
- Press **OK** to go to **Stand-by mode**.

Cancel

The system will display the **Supplementary Tests** page.

## Supplementary Tests

State	Option
	Expiratory Flow Sensor Calibration
	O <sub>2</sub> Sensor calibration
	Stand-by

Scr5937

By means of this page it is possible to perform the **Supplementary Tests** (for more information, please refer to the chap. 3.5.2).

OK

The system will display the **PATIENT DATA** page.

VC/VAC 70kg 175cm 56 years Adult M

Vt 500 PAW 40 Map 0.0

RR 12 I:E 1:2 Pause 0 PEEP OFF O<sub>2</sub> 21 Tr.I OFF

SETUP PATIENT DATA

New Born  Male Name   
 Child  Female Surname   
 Adult BirthDay: 01 / 01 / 1961  
Weight [kg]: 0070   
Height [cm]: 175

Cancel OK

Scr14329

Through this page it is possible to set the following **PATIENT DATA** (for more information, please refer to the chap. 4.3).

VC/VAC Adult M

Vt 500 PAW 40 Leak % ---

RR 12 I:E 1:2 Pause 0 PEEP OFF O<sub>2</sub> 21 Tr.I OFF

Stand-by

Scr22642

### Modo operativo Stand-by

In Stand-by mode, the User can set and / or modify:

- the operating mode
- the lung ventilator parameters
- the alarm limits related to the operating mode that will be used on the patient to be treated.

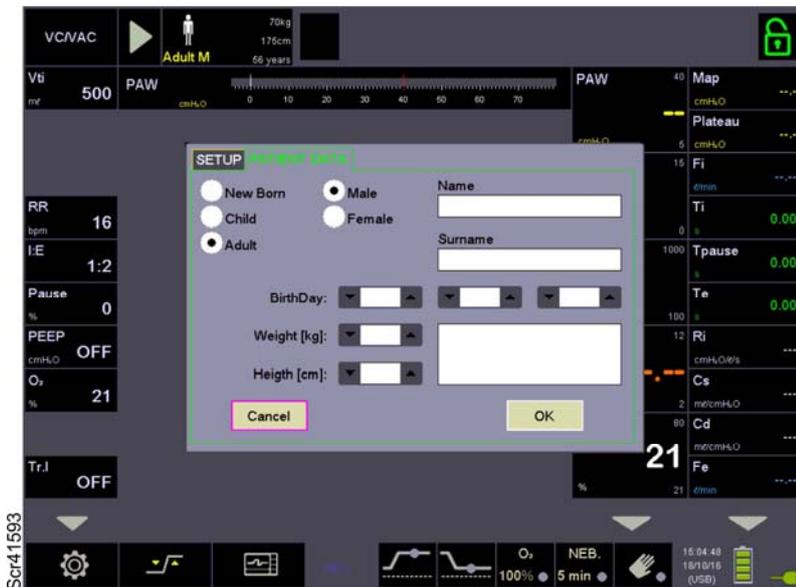
## 4.3 PATIENT DATA / SETUP parameters



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

- *PATIENT DATA* (see chap. 4.3.1)
- *SETUP parameters* (see chap. 4.3.2)

### 4.3.1 PATIENT DATA



The PATIENT DATA displaying allows to set the following data.

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



The system displays the "**Stand-by**" page without saving the data stored in the **PATIENT DATA** page.

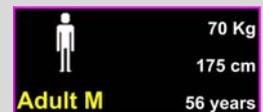


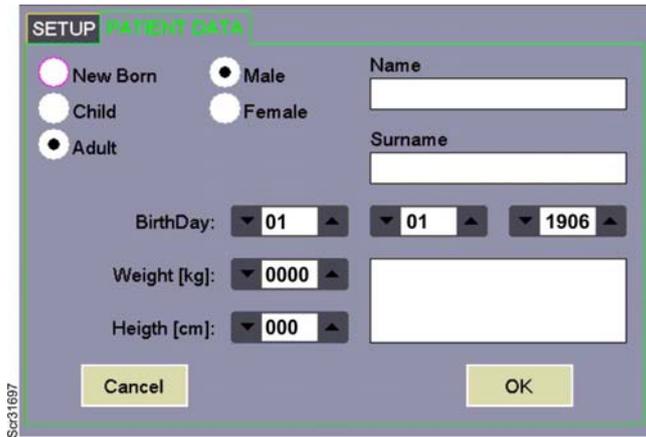
The system displays the "**Stand-by**" page, saving the data stored in the **PATIENT DATA** page.



#### CAUTION

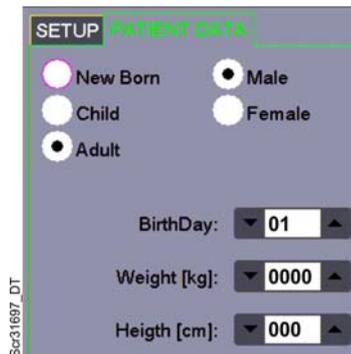
During the normal operation of the lung ventilator, the User can modify the PATIENT DATA selecting the function: *MENU - SETUP / PATIENT DATA* (cfr. 2.4) or by touching the relative icon (*PATIENT DATA*).



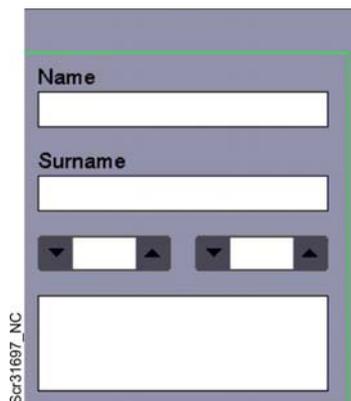


**PATIENT DATA page view.**

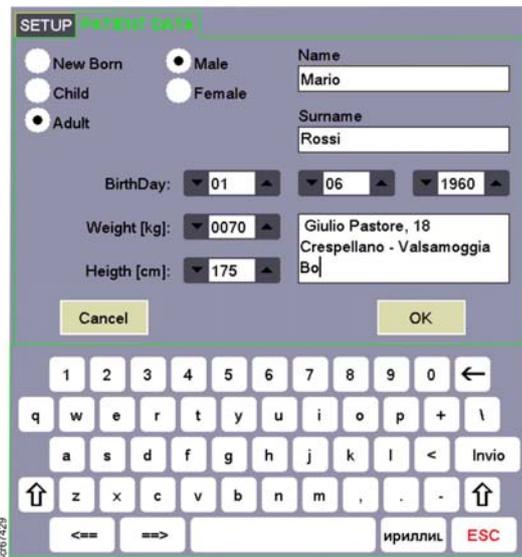
- The choice of the **Patient Type** (Adult, Child, New Born), set automatically the default functioning parameters of the lung ventilator (*breathing parameters and alarms levels*).



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



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



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

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



Scr12246

- Select 

The PATIENT DATA setting will NOT be saved.



Scr12242

- Select 

The PATIENT DATA setting will be saved.



Scr22642

- The system will display the Stand-by screen (in the figure on the side the PATIENT DATA have been saved).

### 4.3.2 MENU (SETUP parameters)



#### CAUTION

The User can modify and set the lung ventilator parameters selecting the function: *MENU - SETUP*.



- Select MENU - SETUP



#### Display

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



Scr08487

### Date & Time

- *Date*
- *Time*



Scr65989

### Language

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



Scr08492

### Units

- *Weight (referred to the patient)*
- *Height (referred to the patient)*
- *CO<sub>2</sub> (unit of measurement)*
- *Pressure (unit of measurement)*



Scr21146

### Default

- Trends data Default
- Patient data Default
- Setting & Ventilation trends data Default



Scr08499

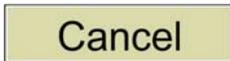
### Other

- NIV Enable
- Power Failure
- APNEA TIME
- CHANGE PASSWORD
- Save to Usb



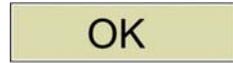
Scr70170

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

- Select  **Cancel**  
**YES:** to quit SETUP page without saving.  
**NO:** it remains in SETUP page.



- Select



**YES:** the set values will be saved.

**NO:** it remains in SETUP page.



- The system will display the Stand-by screen.



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

## 4.4 Setting up the UGI language

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

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

**Mode 2:** during normal operation of lung ventilator.

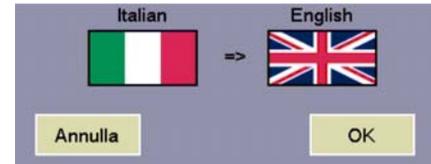
### Mode 1





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

- Select the flag.



- Confirm the choice.



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



The UGI ( User Graphic Interface ) language is ENGLISH.

## Mode 2



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

- Select: **MENU - SETUP**



- Select: **Language**

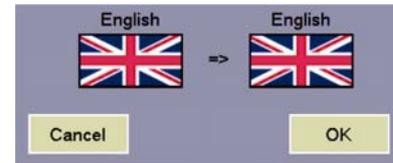


At Language page the **SETUP / PATIENT DATA** screen is displayed.



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

- Select the flag.



- Confirm the choice.



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



The UGI ( User Graphic Interface ) language is ENGLISH.

## 4.5 Setting the PATIENT DATA

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

**Mode 1:** at ventilator start-up at the end of Self Test phase (see on 4.3).

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

### Mode 2

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



- Select: **MENU - SETUP**

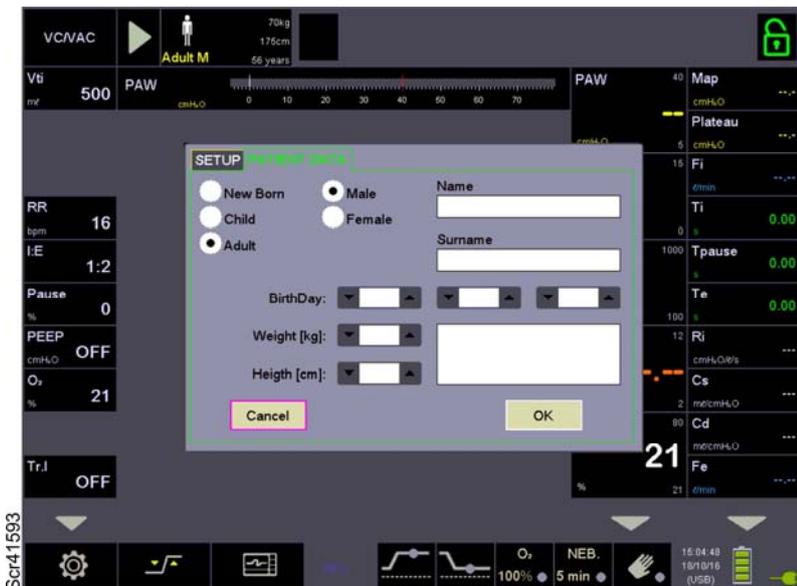


- Select: **Display**





Select: **PATIENT DATA**



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

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



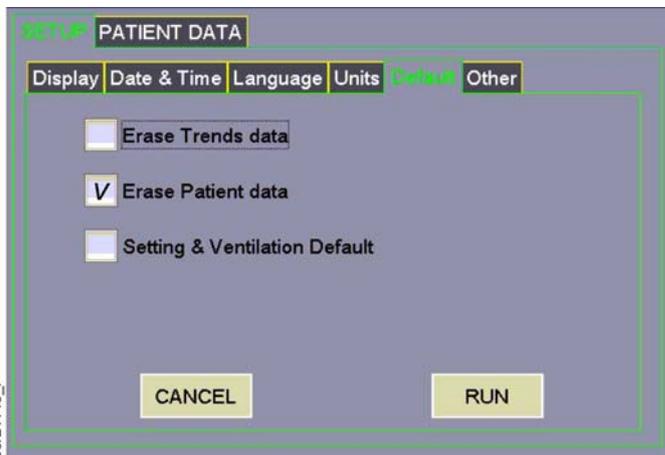
To set/modify the PATIENT DATA see on 4.3.1.

## 4.5.1 Erasing the PATIENT DATA

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



- Select: **MENU – SETUP**
- Select: **Default**



Select: **Erase Patient data.**

- **Cancel the choice:** select

Cancel

- **Confirm the choice:** select

RUN



Scr31671

**RUN**

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



Scr21146

- Select: **PATIENT DATA**

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



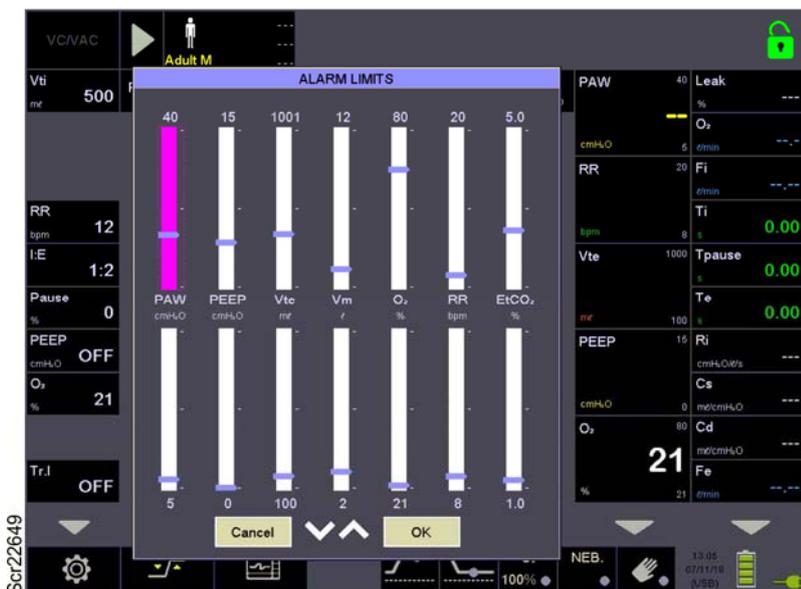
To enter the PATIENT DATA see on 4.3.1.

## 4.6 Setting up the ALARMS

Lung ventilator in Stand-by operative mode.



- Select: **ALARMS**



- Select 

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

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



For ALARMS parameters and limits setup, please see on 5.3 ALARMS setup.

## 4.7 Operative modes



### WARNING !! Patient injury hazard

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

### 4.7.1 Operative Modes selection procedure



#### CAUTION

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



#### CAUTION

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

- Lung ventilator in Stand-by
- During the normal operation of the lung ventilator

#### 1. Stand-by (operative mode selection)



- Select the icon, VC/VAC.

VC/VAC



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



- Operative mode selected: APCV-TV.



### CAUTION

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



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



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

## 2. Lung Ventilator in operation Stand-by (operative mode selection)

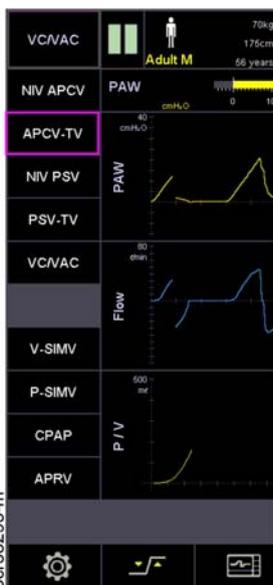


- Operative mode: VC/VAC.

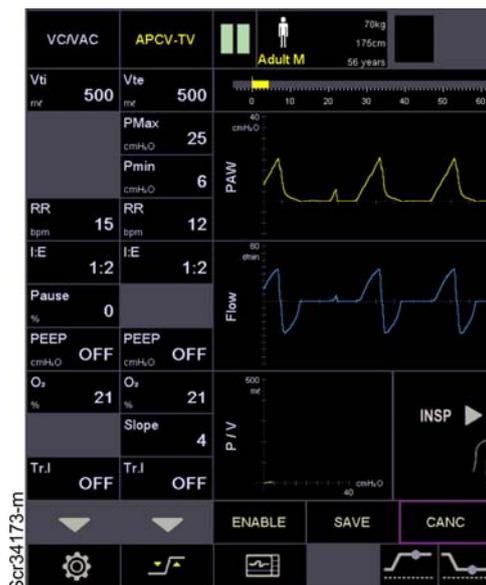
VC/VAC

- All the operative modes foreseen can be displayed.

Scr34160



Scr38295-m



Scr34173-m

- Select a new operative mode.

APCV-TV

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

### CAUTION



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

ENABLE

SAVE

CANC



Scr41327

**YES:** The Lung ventilator directly switches to the new selected operative mode **APCV-TV**.

**NO:** Exit.



Scr34160

**YES:** Possible PRP parameters of the APCV-TV Operative Mode modified, are stored by the system: the system is fitted for a future APCV-TV ventilation mode

The lung ventilator continues to ventilate in VC/VAC operative mode.

**NO:** Exit.



Scr34173

**NO:** The system remains in the condition where the PRM of the two operative modes selected are displayed.

**YES:** The system goes back to the VC/VAC

## Operative mode list

### 4.7.2 APCV ( NIV APCV )

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

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

APCV

NIV APCV



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

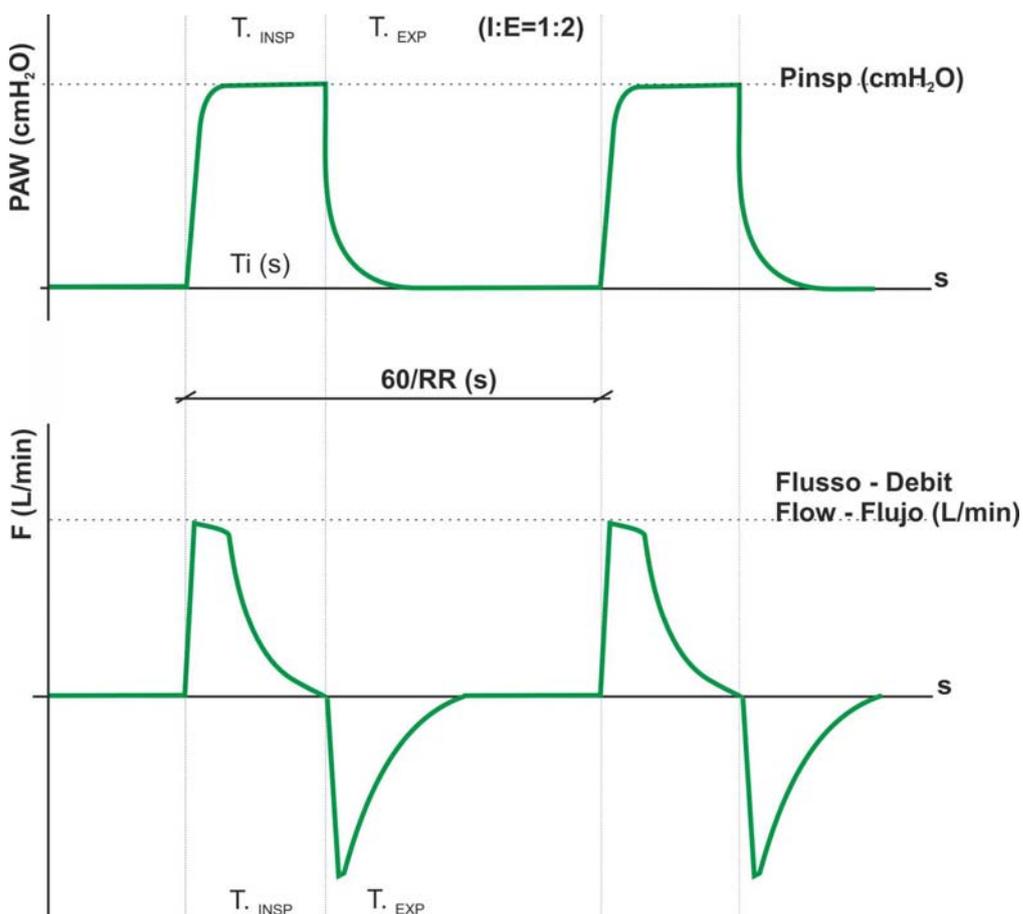
In APCV the current volume depends on the inspiratory pressure (Pinsp) and on the patient's lungs characteristics (compliance, lung capacity) therefore the tidal volume will vary depending on changes in lung mechanics.

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

Use the settable parameters to define an inspiratory trigger (Tr. I) used to set a flow expressed in litres per minute (or a pressure in cmH<sub>2</sub>O) 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.

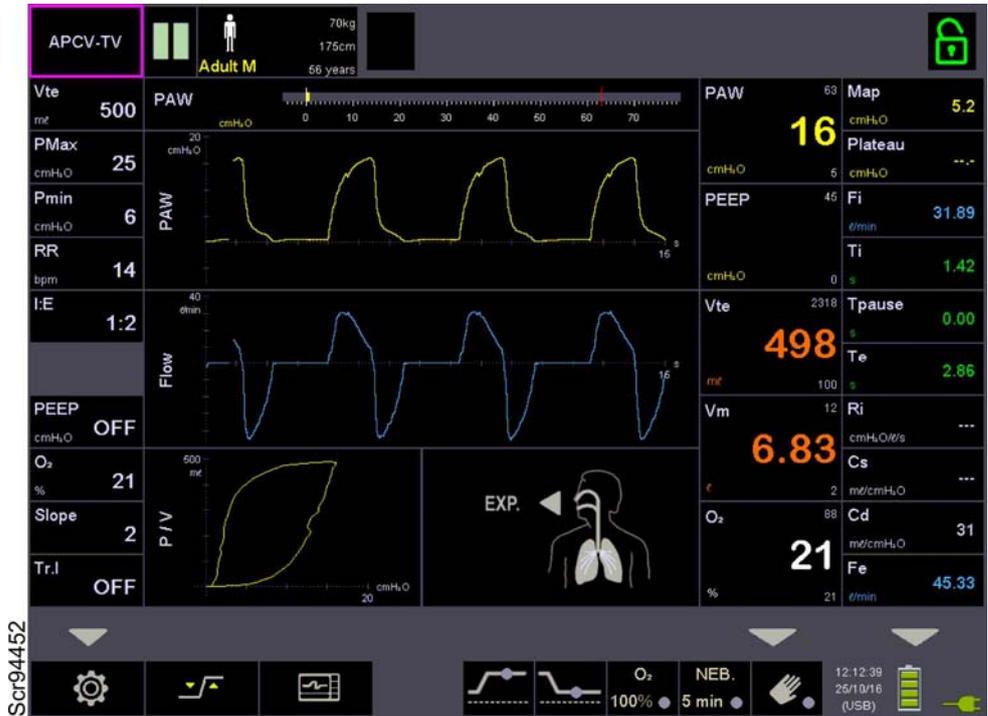


### 4.7.3 APCV-TV

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



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

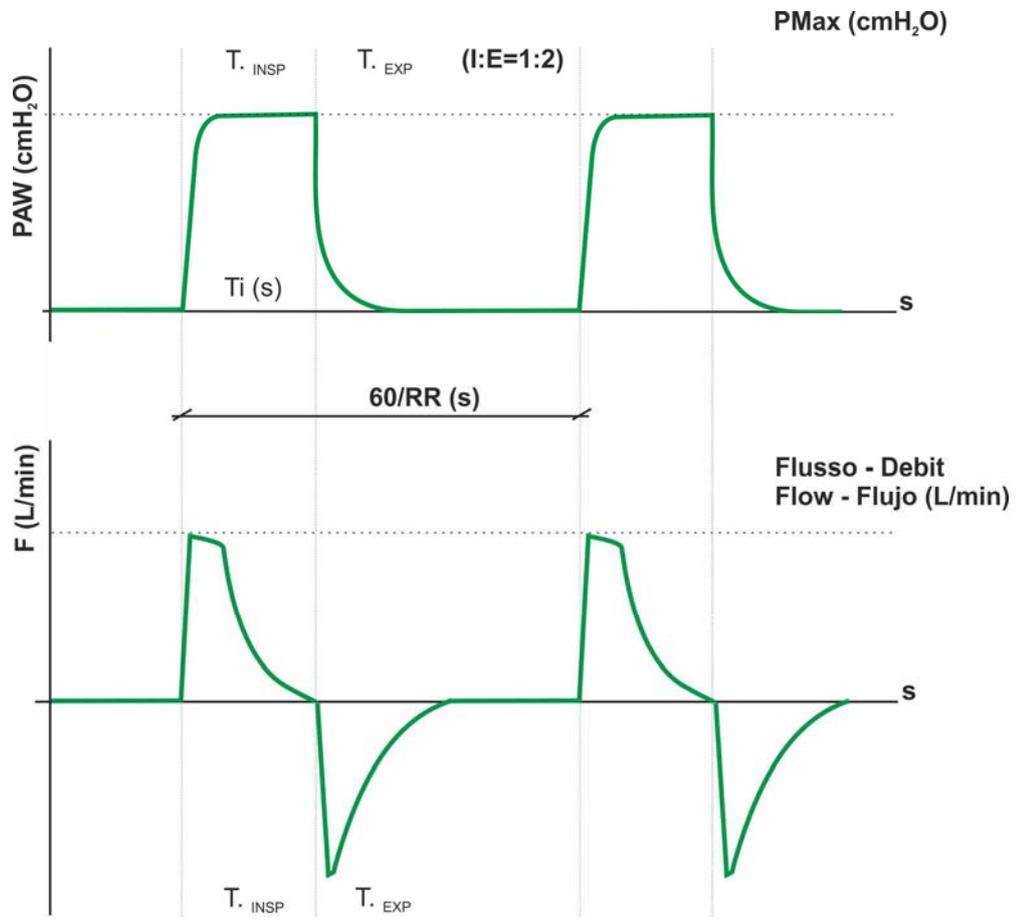


The system generates a ventilation at automatic inspiration pressure (automatic P<sub>insp</sub>), in order for the expired volume to equal the volume set (V<sub>te</sub>).

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

Use the settable parameters to define an inspiratory trigger (Tr. I) used to set a flow expressed in litres per minute (or a pressure in cmH<sub>2</sub>O) that represents the limit for detecting the patient's spontaneous breathing attempt.

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



#### 4.7.4 PSV ( NIV PSV )

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

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



PSV is an assisted type of ventilation with pre-set pressure support (PS) with guaranteed safety respiratory rate set by the Operator 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 operative mode to ventilate a patient who is sedated or paralysed.

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

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

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

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

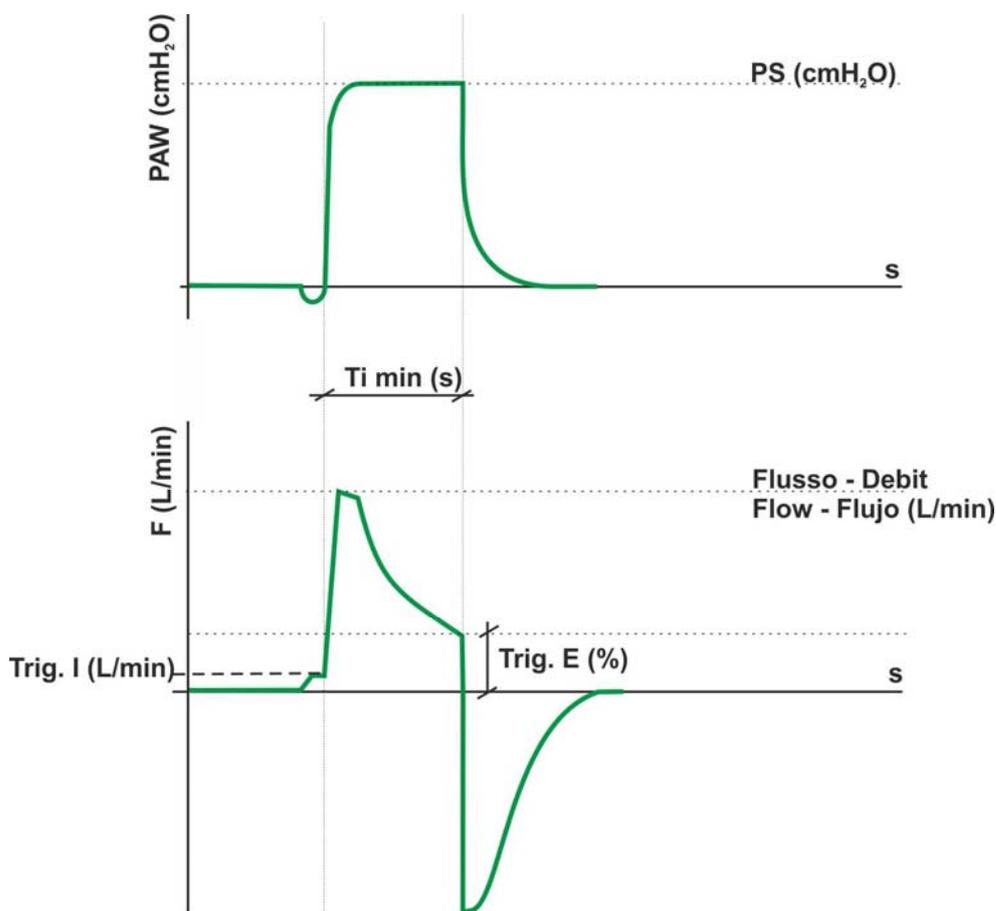
With optimal PSV, the breathing pattern can be standardised (by increasing the  $V_{te}$  and reducing the respiratory rate) and the work of breathing can be reduced, improving the respiratory exchange ratios.

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



If the patient does not trigger (spontaneous breathing during the Apnea time (*set in **SETUP - Other***), the system enables 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).



## 4.7.5 PSV-TV

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

PSV-TV

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



PSV-TV is an assisted pressure support ventilation with guaranteed current volume and guaranteed safety respiratory rate set by the Operator 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 operative mode to ventilate a patient who is sedated or paralysed.

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

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

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

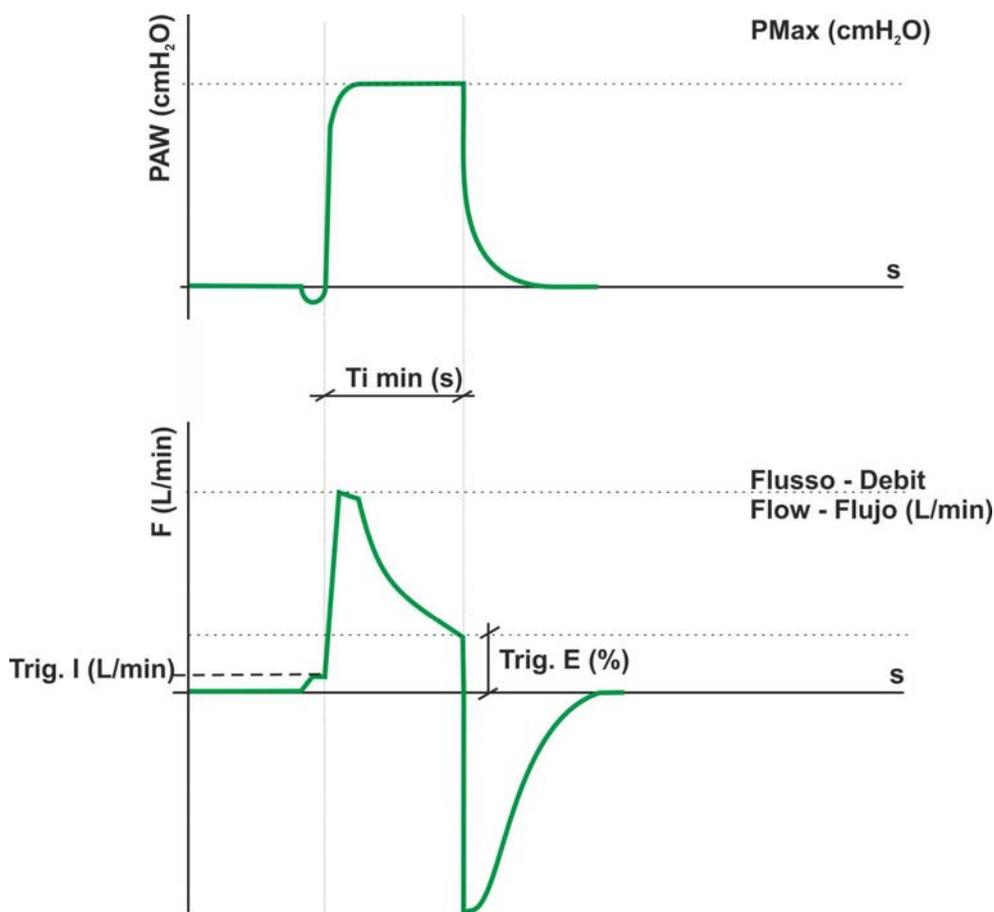
This technique saves the patient from the work of breathing, as he only has to reach the small quota necessary to enable the lung ventilator trigger (Tr. I). This way, the respiratory rate depends on patient spontaneous activity and the PAW depends on set parameter values and patient patophysiological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

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



If the patient does not trigger (spontaneous breathing during the Apnea time (*set in **SETUP - Other***), the system enables 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).



## 4.7.6 VC-VAC

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

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

VC/VAC



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

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

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

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

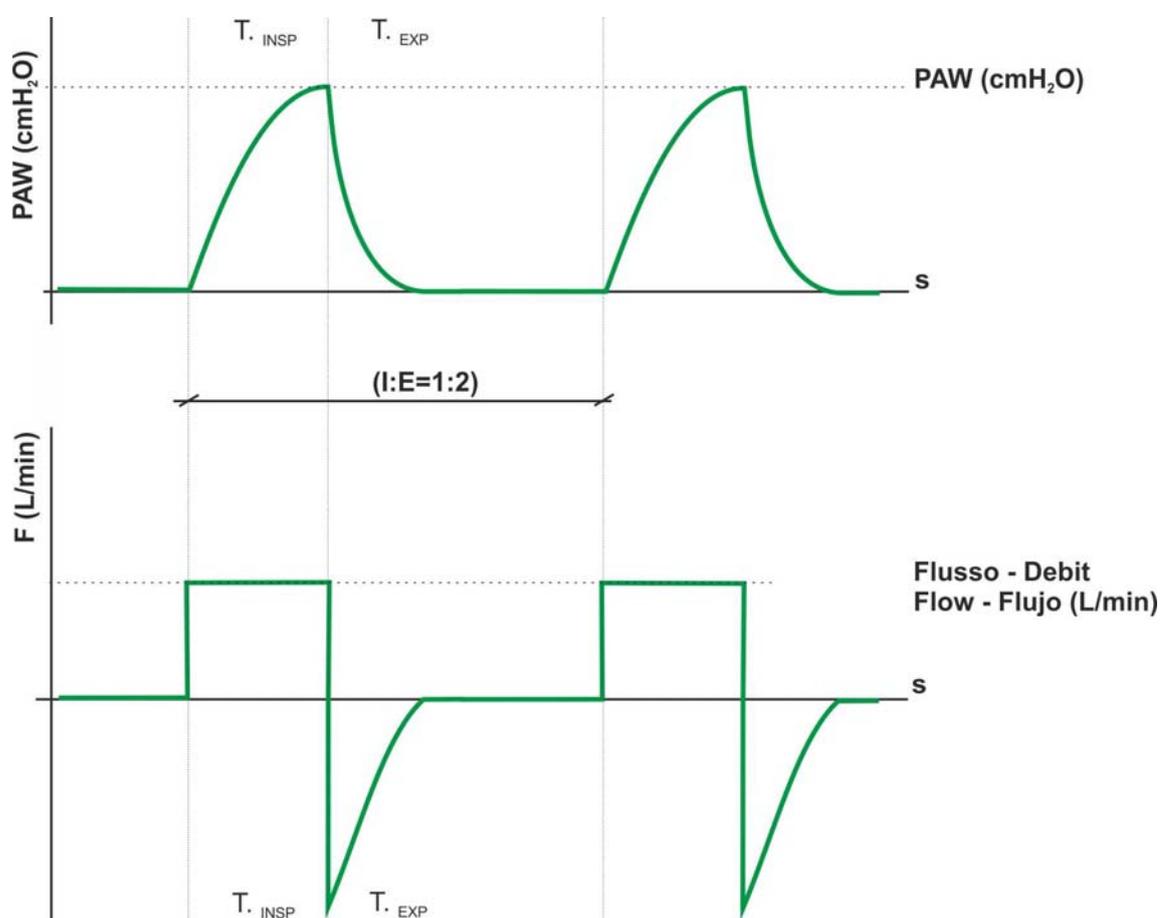
The patient's breathing attempt is detected by the system (Tr. I) and it automatically sends inside the airway a gas flow at a pre-set volume (Vti).

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

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

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

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



#### 4.7.7 VC-VAC BABY

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



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



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

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



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

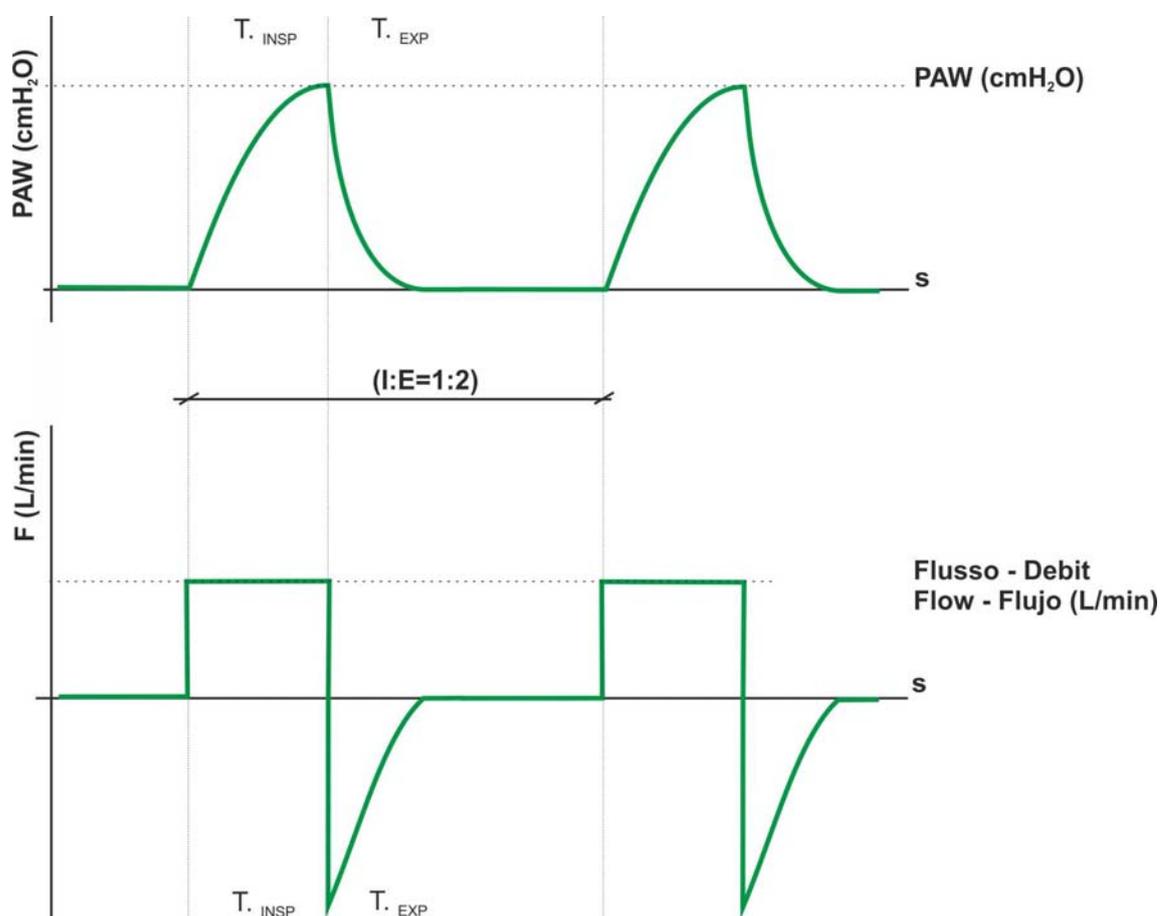
In this type of ventilation, the work of breathing is fully assumed by the lung ventilator, and therefore it is used when the patient is unable to breath on his own, or in order to assure an efficient pre-set current volume and therefore the mechanical ventilation must fully replace the spontaneous breathing.

The volume ( $V_{te}$ ) 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 ( $V_{te}$ ).

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

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



## 4.7.8 V-SIMV

Volume-targeted synchronised intermittent mandatory ventilation.

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

V-SIMV



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

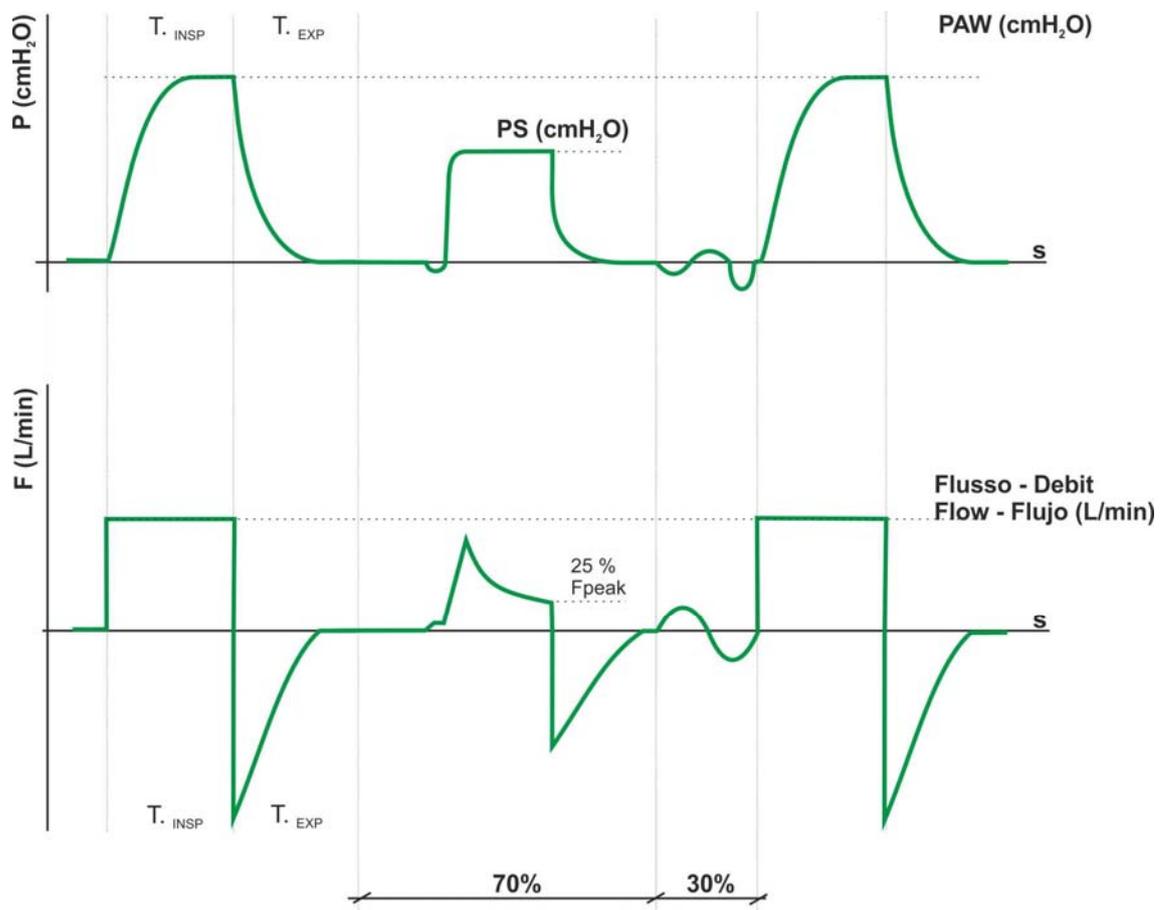
**The Operative Mode V-SIMV is active only with patients: ADULT and PAEDIATRIC.**

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

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

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

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



The graphic shows how the SIMV operative mode works.

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

## 4.7.9 P-SIMV

Pressure-targeted synchronised intermittent mandatory ventilation.

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

P-SIMV

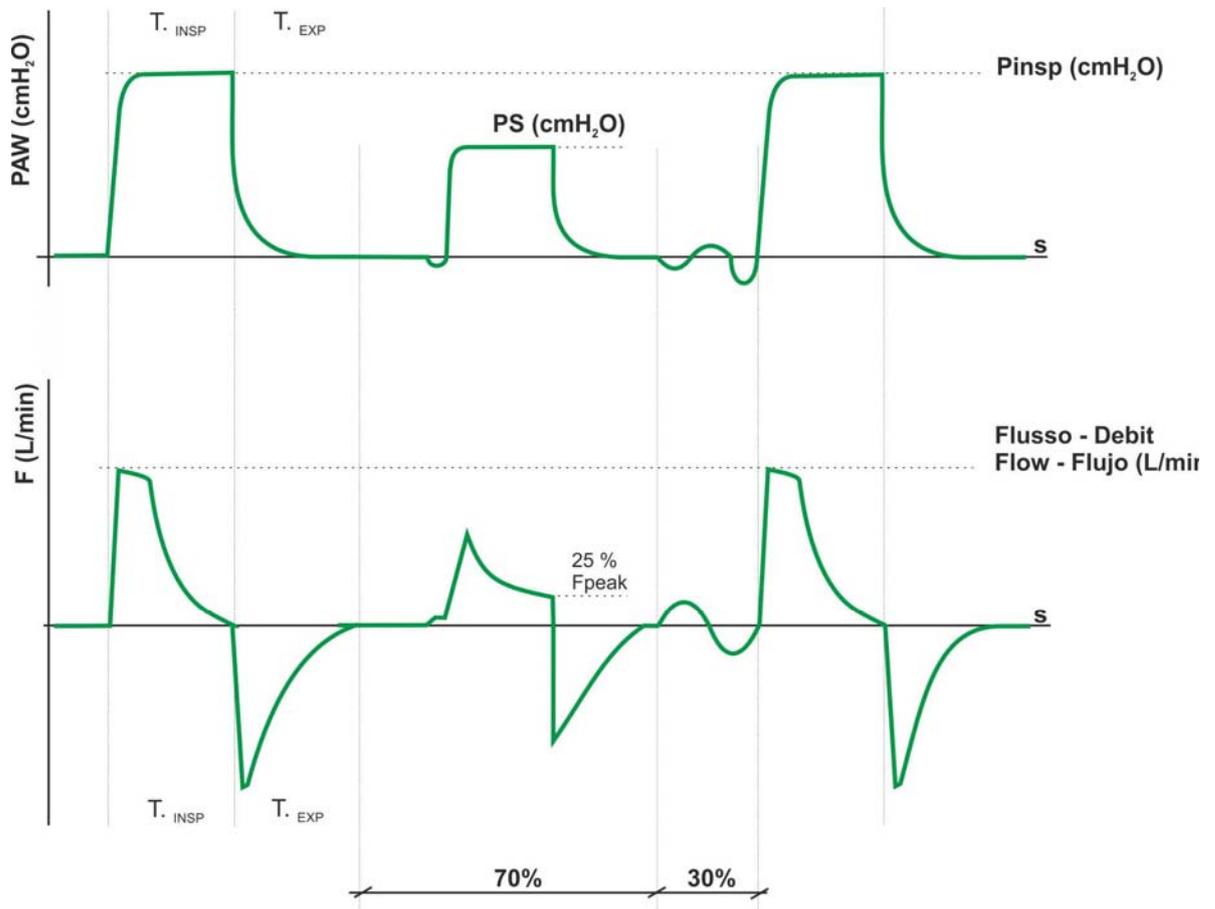


P-SIMV is a synchronised intermittent mandatory ventilation, during which the lung ventilator generates a certain number of breaths per minute (RR<sub>simv</sub>) at a pre-set inspiratory pressure (P<sub>insp</sub>) providing pressure support (PS) during the spontaneous phase.

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

The spontaneous phase is characterised by the set inspiration time (T<sub>i</sub>) that once the pressure support value (PS) set by the Operator is reached, leaves its place to the expiration phase (Tr. E).

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



The graphic shows how the SIMV operative mode works.

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

## 4.7.10 CPAP

Positive continuous pressure applied on the airway.

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

CPAP



CPAP is a spontaneous positive pressure ventilation at continuous flow.

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

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



### WARNING !! Patient injury hazard

If the patient does not trigger (spontaneous breathing during the Apnea time (*set in SETUP - Other*), the system enables 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).

## 4.7.11 APRV (Airway Pressure Release Ventilation)

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

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



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

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

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

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



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



### WARNING !! Patient injury hazard

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

#### 4.7.12 MAN operative mode

**MANUAL** ventilation available in all operative modes.



- By selecting the MAN mode (at the bottom of the display) the system provides the patient with a breath.
- The breath ventilation parameters depend on the set operative mode.
- The function activation is monitored by the screen and signalled by the green LED inside the box, that turns on.
- This mode is active while the lung ventilator is running.

#### 4.7.13 APNEA BACK-UP

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

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



##### **WARNING !! Patient injury hazard**

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

## 4.8 Physiological respiratory parameters ( PRP )

In the following chapter you will find a description of available physiological respiratory parameters (referred to from now on as PRP) selectable on Siaretron 4000 lung ventilator.



### WARNING !! Patient injury hazard

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

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

### 4.8.1 PRP parameters setting procedure



### CAUTION

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



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



- Select the icon for see all PRP parameters.



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

**VC/VAC operative mode: available PRP parameters.**



- Select the icon for see the PRP parameters.



- Reselect the icon for see all PRP parameters.



**Modifying a PRP parameter**

(e.g. RR: Respiratory Rate).

- Select the RR icon.

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



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



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



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



### WARNING !! Patient injury hazard



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

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



For more information about PRP respiratory parameters, please see on chapter 2.4.6.

## 4.8.2 Monitoring of respiratory parameters



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



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



For more information about monitoring of respiratory parameters, please see chapter 2.4.7 and chapter 2.4.8.

## 4.9 Ventilation phase

### Before starting the ventilation, you have to:

- carry out all lung ventilator connections (medical gases, power supply, patient circuit, .....)
- carry out the preliminary checks (please see chapter 3.7)
- set and check the patient data, language and alarm limits
- set the Physiological Respiratory Parameters and the operative mode that match the patient's clinical situation best.



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



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



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

### 4.9.1 Ventilation interruption



- Press ON/OFF, to return in **Stand-by** mode.
- The system will ask you if you want to stop the ventilation (switch to **Stand-by** mode).  
**YES**: stop ventilation.  
**NO**: cancel the command.

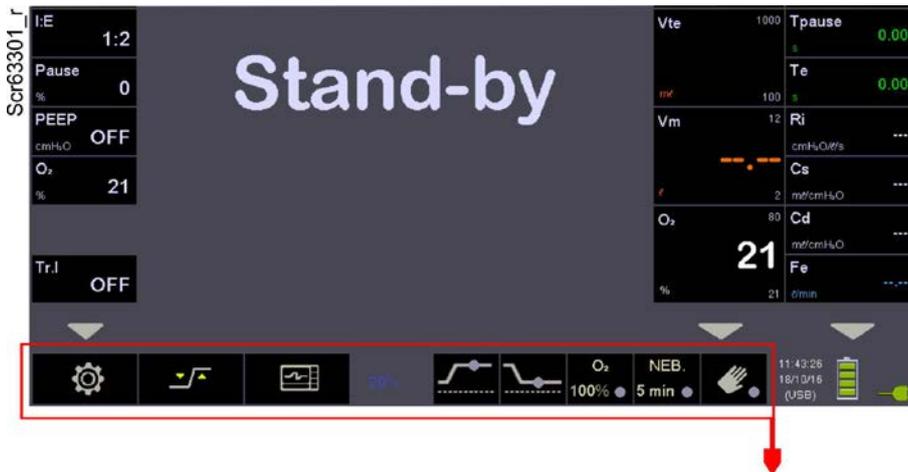


- Lung ventilator in **Stand-by** mode.



- Press ON/OFF, to **Turn-off** the lung ventilator.  
The system will ask you if you want to **Turn-off** the lung ventilator (switched off).  
**YES**: lung ventilator will be switched off.  
**NO**: cancel the command (the lung ventilator returns to Stand-by mode).

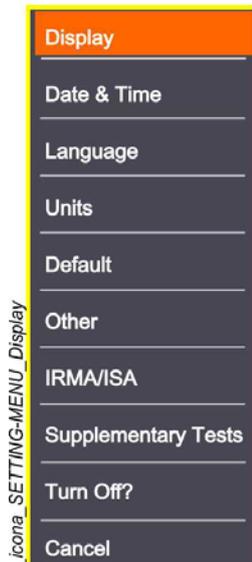
## 4.10 Operative functions and Graphic settings



During the patient ventilation, the User can intervene using the graphical user interface, by selecting the “**operative functions**” in the lower side on the screen.



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



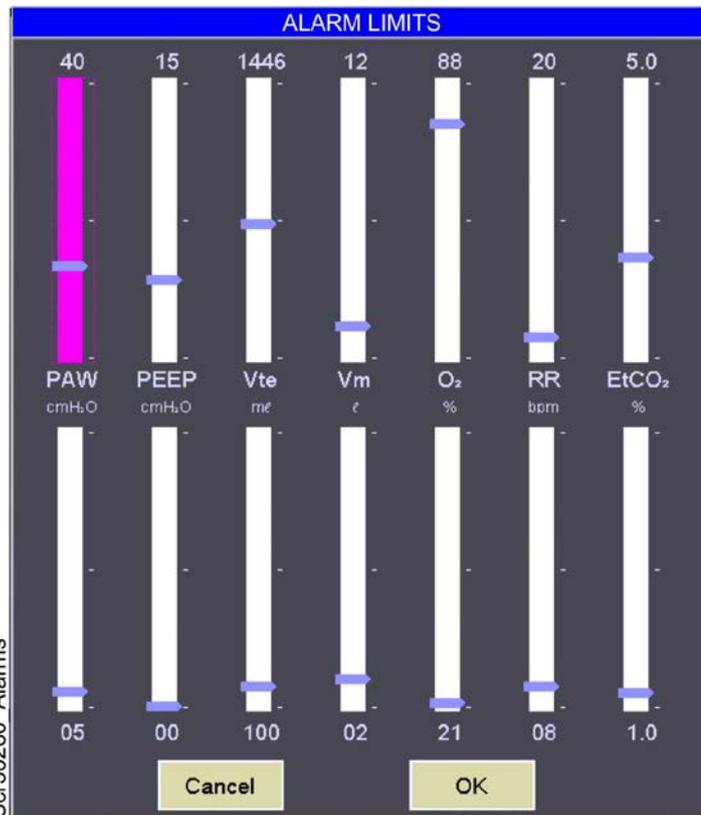
To go back to the **Stand-by** display, select **Cancel**.



The functions that can be activated from the **SETTING MENU** are shown in Chapter 4.11.



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

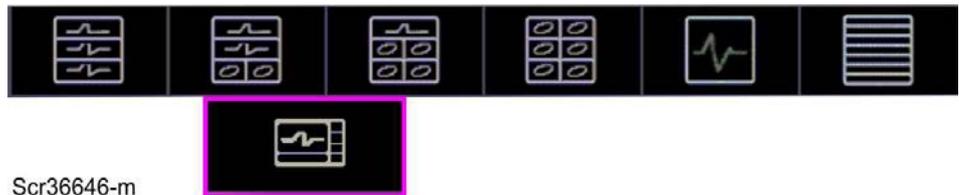


- For **ALARM LIMITS**, please see on chapter 5 (Alarms).
- To go back to the **Stand-by** display, select **Cancel** or **OK** (follow the instructions displayed).



The selection of **GRAPHICS** icon allows how to display in real time patient's respiratory parameters through the following detections:

1. **Charts:** PAW, Flow, Tidal Volume, O<sub>2</sub>, CO<sub>2</sub>
2. **Loops:** Tidal Volume / Flow, PAW / Tidal Volume, PAW / Flow
3. **Lung status icon**
4. **Measures:** respiratory parameters



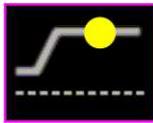
Scr36646-m

The user has got 6 icons available and he can select among 6 different kind of visualization.

4 combinations of graphic displaying, Trends, Events.



- For **GRAPHICS** setting, please see chapter 4.11.
- To quit the function, select again the icon **GRAPHICS**.



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

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



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

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



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



**INSP HOLD and EXP HOLD modes:**

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



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

### O<sub>2</sub> 100% mode

Select the function **O<sub>2</sub> 100%**, the system will provide 100% oxygen concentration for 5 minutes (pre-set time).

After the pre-set time the systems automatically restores the previously set O<sub>2</sub> concentration value.

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



The **O<sub>2</sub> 100%** mode is deactivated:

- automatically after 5 minutes
- or by select the icon O<sub>2</sub> 100%



### **WARNING!! Patient injury hazard**

The O<sub>2</sub> 100% mode is not available if the oxygen pressure supply is lower than 1,5 bar.



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

### NEB. operative mode

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

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



### **WARNING!! Risk for the patient**

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



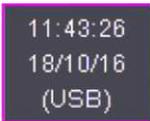
Select the icon to activate the manual ventilation to the patient.

### MAN operative mode

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

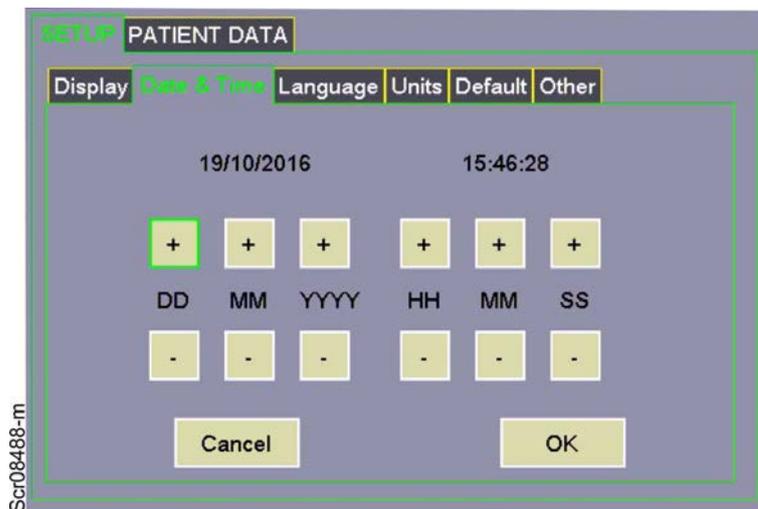
The breath ventilation parameters depend on the set operative mode. The function activation is monitored by the screen and signalled by the green LED inside the box, that turns on.

This mode is active while the lung ventilator is running.



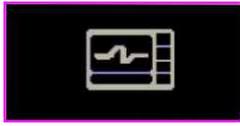
The selection of the **Time** icon, allows to update time and date set.

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



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

## 4.11 GRAPHICs visualization



The function GRAPHICs allows the user to combine the **Loops**, the **Charts** and the **Measured** patient respiratory parameters in different ways

Moreover, it allows to display the Trends and Events.

### 4.11.1 Combinations of the graphics displayed



#### **WARNING !! Patient injury hazard**

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

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



2. **Charts:** PAW, Flow  
**Loop:** PAW / Tidal Volume  
**Lung status icon**



- Charts: PAW**  
**Loop: Tidal Volume / Flow, PAW / Tidal Volume**  
 3. **Lung status icon**  
**Measures: Vte**



- Loop: PAW / Flow, PAW / Tidal Volume**  
 4. **Lung status icon**  
**Measures: Vt<sub>i</sub>, Vt<sub>e</sub>, PAW**



5. **Trends**



## 6. Events



### 4.11.2 Modification Charts combination

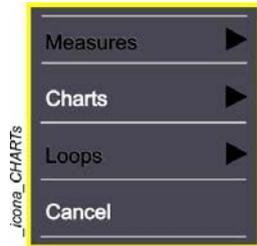


- The user can display different kind of **Charts** detections.
- The selection of the box of one of the **Charts** displayed, enable the visualization of a screen of a drop-down menu with the list of the options available.
- Available charts: PAW, Flow, Tidal Volume, O<sub>2</sub>, CO<sub>2</sub>.

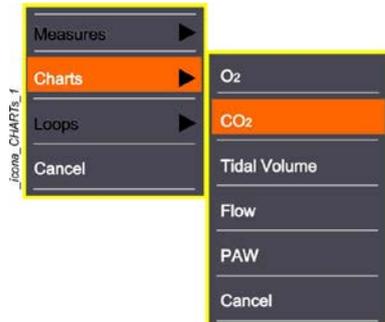
**Keep selected** the area of the graphic some seconds; the selected area (the violet frame) becomes green.



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



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



**Select CO2.**

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



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

### 4.11.3 Loops combination modification

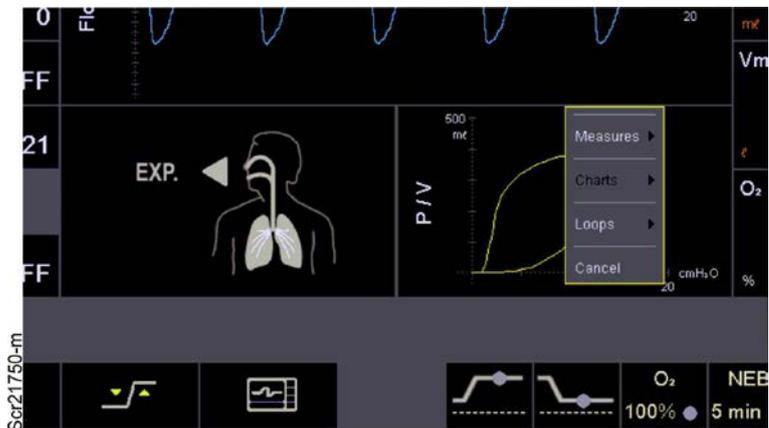
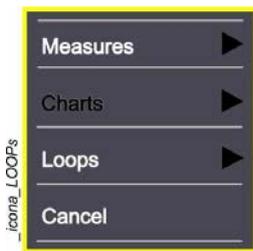


- The user can display different kinds of **Loops** detections.
- The selection of the frame of one of the Loops displayed, enable the visualization of a drop-down menu with the list of the options available.
- Available **Loops**: Tidal Volume / Flow, PAW / Tidal Volume, PAW / Flow.

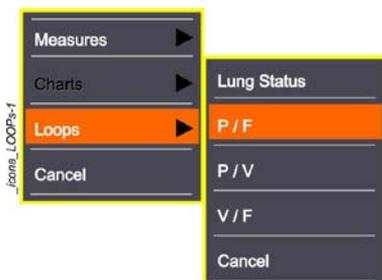
**Keep selected** the area of the graphic some seconds; the selected area (the violet frame) becomes green.



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



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



**Select P / F.**

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



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

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



**Select Vti.**

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



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

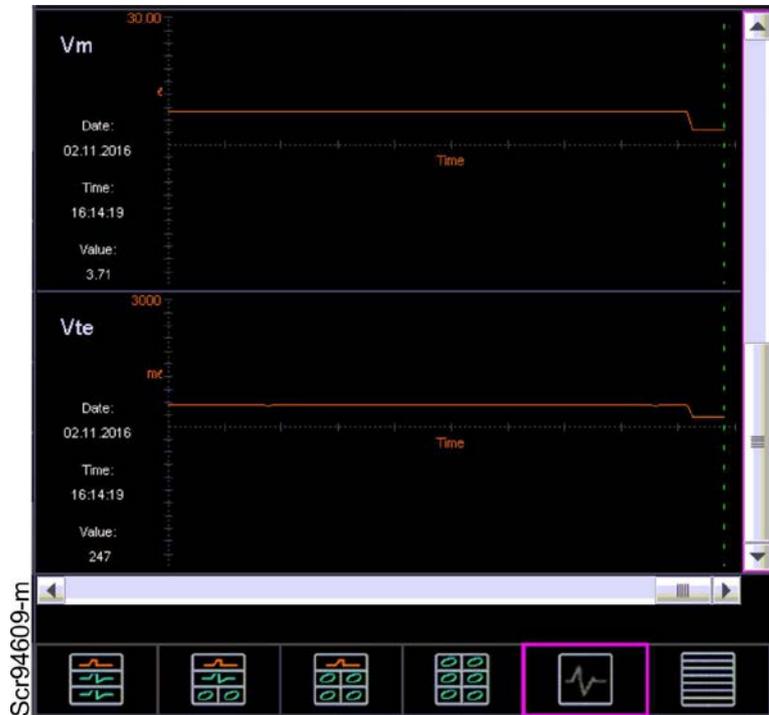
#### 4.11.4 TRENDS visualization

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

Monitored Respiratory parameters:

- Rate
- P Insp
- PEEP
- Vm
- Vte

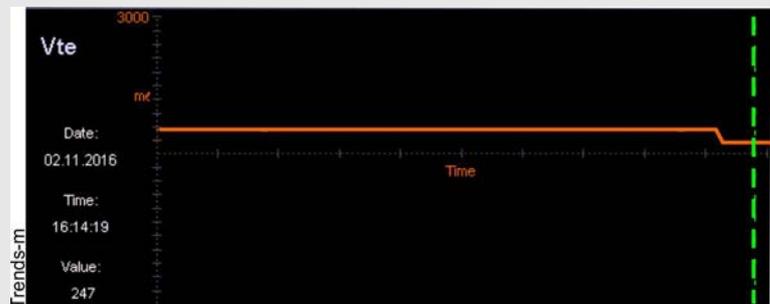
The storage capacity for each parameter is 72 hours with sampling at every 4 minutes.



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



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



#### 4.11.5 EVENTS visualization

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

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

#	Date & Time	Event Text ..
	04.11.2016 16:55:18	POWER ON
	04.11.2016 16:54:34	VENTILATION START
	04.11.2016 16:54:31	STAND-BY
	04.11.2016 16:33:49	POWER SUPPLY FAULT
	04.11.2016 16:27:40	VENTILATION START
	04.11.2016 16:27:30	POWER ON
	04.11.2016 16:27:39	Date/Time Change
	04.11.2016 16:27:08	STAND-BY
	04.11.2016 12:43:50	VENTILATION START
	04.11.2016 12:42:10	STAND-BY
	03.11.2016 18:44:51	POWER ON
	03.11.2016 18:44:51	POWER ON
	03.11.2016 18:44:47	POWER OFF
	03.11.2016 18:44:47	REQ POWER OFF.
	03.11.2016 09:20:08	STAND-BY
	02.11.2016 18:13:35	VENTILATION START
	02.11.2016 18:03:51	STAND-BY
	02.11.2016 18:03:48	HIGH RESPIRATORY RATE
	02.11.2016 18:03:43	HIGH RESPIRATORY RATE



The vertical scrollbar allows to display all the events.



The Table of the Events provides the following indications:

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

#	Date & Time	Event Text ..
	04.11.2016 16:55:18	POWER ON
	04.11.2016 16:54:34	VENTILATION START
	04.11.2016 16:54:31	STAND-BY
	04.11.2016 16:33:49	POWER SUPPLY FAULT
	04.11.2016 16:27:40	VENTILATION START
	04.11.2016 16:27:30	POWER ON

## 4.12 DEFAULT PARAMETERS

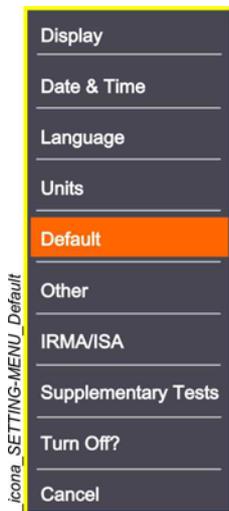
Select the **DEFAULT PARAMETERS** function to restore the lung ventilator **DEFAULT PARAMETERS**: ( Factory - set ).



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

Lung Ventilator: **Stand-by**

Select: **SETTING MENU / Default**



Enable: **Setting & Ventilation Default**

Select: **RUN**

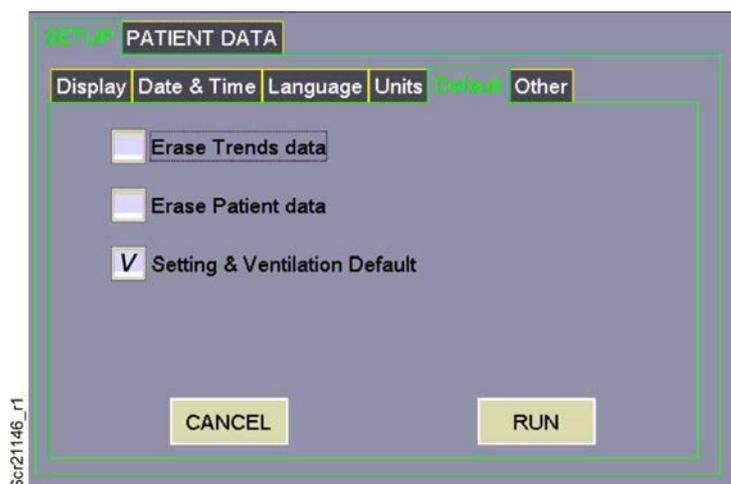
**YES:** the default parameter values will be improved.

**NO:** the system cancel the RUN command

Select: **Cancel**

**YES:** exit without saving default parameter values

**NO:** the system remains in **Default** page.



### 4.13 Alarms SETUP



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

### 4.14 PATIENT DATA setup

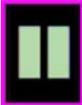
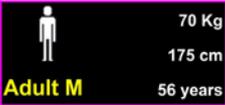


For **Patient Data** parameters and setup please see 4.2 PATIENT DATA.

### 4.15 List of functions



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

	<b>Operative mode</b>	<ul style="list-style-type: none"><li>• See on chapter 4.7</li></ul>
	<b>Ventilation status</b>	<ul style="list-style-type: none"><li>• See on chapter 2.4</li></ul>
	<b>Patient data</b>	<ul style="list-style-type: none"><li>• See on chapter 4.3</li></ul>
	<b>Password</b>	<ul style="list-style-type: none"><li>• See on chapter 5.2</li></ul>



<b>Display</b>	<ul style="list-style-type: none"> <li>• <i>Brightness</i></li> <li>• <i>Energy saving</i></li> <li>• <i>Sound volume</i></li> <li>• <i>Touch audio</i></li> </ul>
<b>Date &amp; Time</b>	<ul style="list-style-type: none"> <li>• <i>Date</i></li> <li>• <i>Time</i></li> </ul>
<b>Language</b>	<ul style="list-style-type: none"> <li>• <i>Italian, English, German, Turkey, Polish, French, Russian, Spanish</i></li> </ul>
<b>Units</b>	<ul style="list-style-type: none"> <li>• <i>Weight (referred to the patient)</i></li> <li>• <i>Height (referred to the patient)</i></li> <li>• <i>CO2 (unit of measurement)</i></li> <li>• <i>Pressure (unit of measurement)</i></li> </ul>
<b>Default</b>	<ul style="list-style-type: none"> <li>• <i>Trends data Default</i></li> <li>• <i>Patient data Default</i></li> <li>• <i>Setting &amp; Ventilation Default</i></li> </ul>
<b>Other</b>	<ul style="list-style-type: none"> <li>• <i>NIV Enable</i></li> <li>• <i>Power Failure</i></li> <li>• <i>APNEA TIME</i></li> <li>• <i>CHANGE PASSWORD</i></li> <li>• <i>Save to USB</i></li> </ul>
<b>IRMA/ISA</b>	<ul style="list-style-type: none"> <li>• <i>Gas Sensor ( IRMA or ISA type )</i></li> </ul>
<b>Supplementary Tests</b>	<p><i>Enabling the Supplementary Tests function.</i></p> <p><i>The system shows the test available on the lung ventilator.</i></p> <p><i>Before using the lung ventilator on a patient, you have to carry out a series of preliminary checks to make sure that it works properly.</i></p>
<b>Turn Off</b>	<ul style="list-style-type: none"> <li>• <i>See on chapter 4.9.1</i></li> </ul>
<b>Cancel</b>	<ul style="list-style-type: none"> <li>• <i>See on chapter 4.3.2</i></li> </ul>



### Alarms Limits

- See on chapter 5 Alarms



### GRAPHICs visualization

- Charts
- Loops
- Lung status icon
- Measures
- Trends
- Events



### INSP Hold

- See on chapter 4.10



### EXP Hold

- See on chapter 4.10



### 100% Oxygen

- See on chapter 4.10



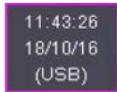
### Nebulizer function

- See on chapter 4.10



### Operative mode: MAN

- See on chapter 4.10 – 4.7.12



### Time / Data

- See on chapter 4.10



### Battery / Power supply

- See on chapter 5 Alarms

#### 4.16 List of default parameters

Parameters	Adult	Paediatric	Neonatal
Mode	VC/VAC	APCV-TV	NIV APCV
VT (ml)	500	200	-
RR (bpm)	12	25	30
I:E	1:2	1:2	1:1
Inspiratory Pause (%)	0%	-	-
Trigger (cmH <sub>2</sub> O)	OFF	OFF	OFF
PEEP (cmH <sub>2</sub> O)	OFF	OFF	OFF
FiO <sub>2</sub> (%)	21%	21%	21%
Pinsp (cmH <sub>2</sub> O)	-	-	20
Pmin (cmH <sub>2</sub> O)	-	5	-
Pmax (cmH <sub>2</sub> O)	-	25	-
Slope	-	2	2

## 4.17 CALIBRATION PROGRAMS

### 4.17.1 Preliminary



#### **WARNING !! Patient / operator injury hazard.**

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



#### **WARNING !! Patient / operator injury hazard.**

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



- 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.



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

### 4.17.2 Calibration Programs displaying

- Set the main switch (placed on the back of the trolley/lung ventilator) in position “I” (ON).



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



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

Calibration Programs	
State	Option
	Self Test
	Turbine Characterization
	Expiratory Flow Sensor Calibration
Off	Usage at High Altitude
Off	VTEc
Off	Nebulizer Enable
Off	ScreenShoot Enable
	Power Off

Scr35670

- The lung ventilator switches ON and the **Calibration Programs** page is displayed.



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

### 4.17.3 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.
- For more information, please refer to the SERVICE manual.

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

Calibration Programs	
State	Option
	Self Test
	<b>Turbine Characterization</b>
	Expiratory Flow Sensor Calibration
Off	Usage at High Altitude
Off	VTEc
Off	Nebulizer Enable
Off	ScreenShoot Enable
	Power Off

Scr35672



Scr41553



OK

The **turbine characterization** program starts.

Cancel

Selecting '**Cancel**' you quit from the Turbine Characterization Program and you go back to the '**Calibration Programs**' page.

#### 4.17.4 Expiratory flow sensors calibration

The **expiratory flow sensors calibration** is necessary in the following cases.

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

Calibration Programs	
State	Option
	Self Test
	Turbine Characterization
	Expiratory Flow Sensor Calibration
Off	Usage at High Altitude
Off	VTEc
Off	Nebulizer Enable
Off	ScreenShoot Enable
	Power Off



OK

Cancel

Verify

The **expiratory flow sensors calibration** program starts.

Selecting '**Cancel**', you quit the expiratory flow sensors calibration and you go back to the 'Calibration Programs' visualization.

Selecting '**Verify**' you can check the correct expiratory flow sensors calibration through the displaying of the flow parameters (l/min) Exp-Insp.

OK

- To start the expiratory flow sensors calibration.

**Note!** The system administers 8 constant flows at pre-set intervals and acquires the values of the flow sensor signal, constructing its characteristic.



ESC

Select **ESC** to stop the respiratory flow sensors calibration.

Cancel

Select **Cancel** to stop the respiratory flow sensors calibration.



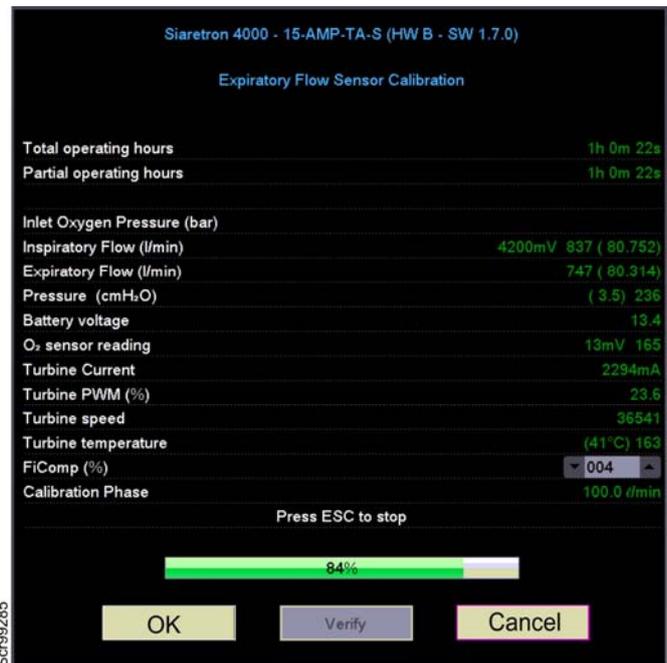
- At the end of the **Expiratory flow sensors calibration** the system come back to the “Calibration Programs “ menu.
- In case of first calibration of lung ventilator, we suggest to execute this procedure after having checked the PEEP calibration and after performing a **Turbine characterization** (see 4.16.3).
- For more information please refer to the SERVICE manual.

Verify

- To start the check on the expiratory flow sensors calibration.

**Note!** *The purpose of this procedure is to visualize and check the values of inspiratory flow and expiratory flow (in l / min) stored during the calibration phase of the expiratory flow sensor.*

*The two values measured and displayed (inspiratory flow and expiratory flow) must have a numerical value very similar to each other.*



ESC

Select **ESC** to stop the respiratory flow sensors calibration.

Cancel

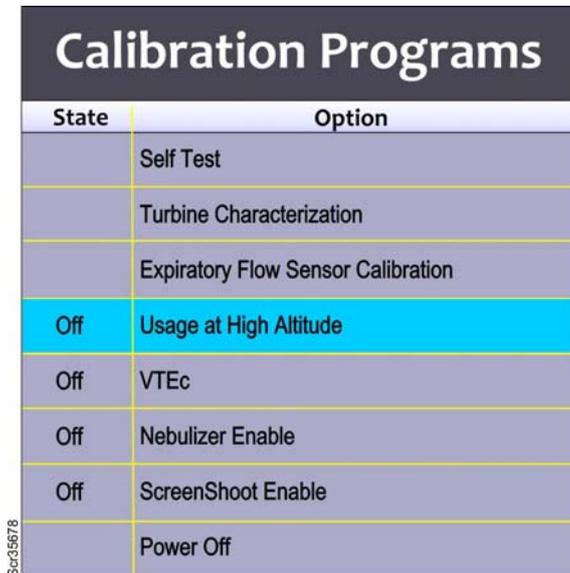
Select **Cancel** to stop the respiratory flow sensors calibration.



- At the end of the check on the expiratory flow sensors calibration the system goes back to the “Calibration Programs “ menu.
- For further information please refer to the SERVICE manual.

#### 4.17.5 High Altitude usage ( On - Off )

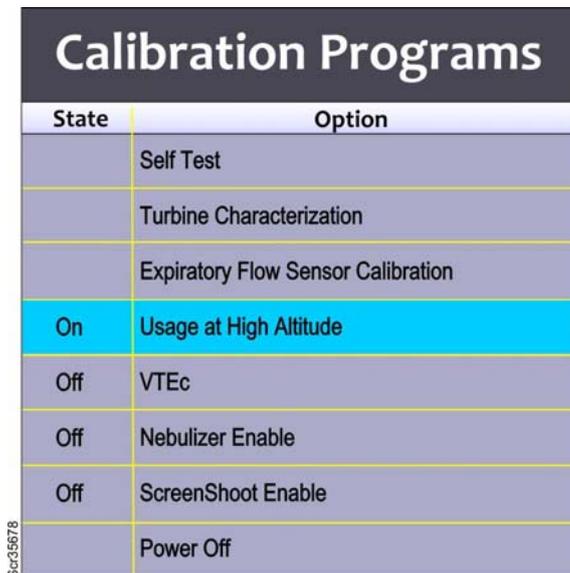
The activation of the Usage at High Altitude (High Altitude: **On**) function, is useful to optimize the calculation of oxygen concentration (FiO<sub>2</sub>) at heights higher than 2000 mt on the sea level.



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Calibration Programs	
State	Option
	Self Test
	Turbine Characterization
	Expiratory Flow Sensor Calibration
Off	Usage at High Altitude
Off	VTEc
Off	Nebulizer Enable
Off	ScreenShoot Enable
	Power Off

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



Scr35678

Calibration Programs	
State	Option
	Self Test
	Turbine Characterization
	Expiratory Flow Sensor Calibration
On	Usage at High Altitude
Off	VTEc
Off	Nebulizer Enable
Off	ScreenShoot Enable
	Power Off

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

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



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

#### 4.17.6 VTEc ( On - Off )

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

Calibration Programs	
State	Option
	Self Test
	Turbine Characterization
	Expiratory Flow Sensor Calibration
Off	Usage at High Altitude
Off	VTEc
Off	Nebulizer Enable
Off	ScreenShoot Enable
	Power Off

Scr35674

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

Calibration Programs	
State	Option
	Self Test
	Turbine Characterization
	Expiratory Flow Sensor Calibration
Off	Usage at High Altitude
On	VTEc
Off	Nebulizer Enable
Off	ScreenShoot Enable
	Power Off

Scr35674

- The **VTEc** function is enabled (**On**).

**Nota.** Select or press the encoder knob again; the **VTEc** function is disabled (**Off**).



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

#### 4.17.7 Nebulizer Enable ( On – Off )

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

Calibration Programs	
State	Option
	Self Test
	Turbine Characterization
	Expiratory Flow Sensor Calibration
Off	Usage at High Altitude
Off	VTEc
Off	Nebulizer Enable
Off	ScreenShoot Enable
	Power Off

Scr35675

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

Calibration Programs	
State	Option
	Self Test
	Turbine Characterization
	Expiratory Flow Sensor Calibration
Off	Usage at High Altitude
Off	VTEc
On	Nebulizer Enable
Off	ScreenShoot Enable
	Power Off

Scr35675

- The **Nebulizer** function is enabled (**On**).

**Nota.** Select or press the encoder knob again; the **Nebulizer** function is disabled (**Off**).



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

#### 4.17.8 ScreenShot Enable ( On – Off )

This option, if enabled, allows the operator to store on an USB key an instant image (*image saved in bmp format*) during the operation of the lung ventilator.

Calibration Programs	
State	Option
	Self Test
	Turbine Characterization
	Expiratory Flow Sensor Calibration
Off	Usage at High Altitude
Off	VTEc
Off	Nebulizer Enable
Off	ScreenShot Enable
	Power Off

Sec35676

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

Calibration Programs	
State	Option
	Self Test
	Turbine Characterization
	Expiratory Flow Sensor Calibration
Off	Usage at High Altitude
Off	VTEc
Off	Nebulizer Enable
On	ScreenShot Enable
	Power Off

Sec35676

- The **ScreenShot** function is enabled (**On**).

**Nota.** *Select or press the encoder knob again; the **ScreenShot** function is disabled (**Off**).*



For further details, see chapter 2 or see on Service Manual.



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

### 4.17.9 Self Test

Once the lung ventilator is switched on the system (sw) carries out the self-diagnostic tests (**Self Test**) and checks a series of devices necessary for safe lung ventilator operation.

- Select the function (or select and press by the encoder knob).
- Self Test phase starts.

Calibration Programs	
State	Option
	Self Test
	Turbine Characterization
	Expiratory Flow Sensor Calibration
Off	Usage at High Altitude
Off	VTEc
Off	Nebulizer Enable
Off	ScreenShoot Enable
	Power Off

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OK

Go to **Stand-By** operating mode, selecting **OK** (START).

Cancel

Go to **Supplementary Tests** selecting **CANCEL** (ESC).

## 4.18 Power Off

- Select **Power Off** to switch OFF the lung ventilator.

Calibration Programs	
State	Option
	Self Test
	Turbine Characterization
	Expiratory Flow Sensor Calibration
Off	Usage at High Altitude
Off	VTEc
Off	Nebulizer Enable
Off	ScreenShoot Enable
	Power Off

Ser35677

## 4.19 Other functions

### 4.19.1 Reset to ZERO the “Partial operating hours “



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

	Turbine Characterization
	<b>Expiratory Flow Sensor Calibration</b>
Off	VTEc

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



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



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

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

#### 4.19.2 Data Connection (Trend and Events downloading)



#### Lung Ventilator: OFF.

The system software permits the download of the data stored in the Siaretron 4000 15" memory.

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

- Connect a USB drive to a USB1 socket.

Calibration Programs	
State	Option
	Self Test
	Turbine Characterization
	Expiratory Flow Sensor Calibration
Off	Usage at High Altitude
Off	VTEc
Off	Nebulizer Enable
On	ScreenShoot Enable
	Power Off

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

- **ScreenShoot Enable - On**

ScreenShoot enable:

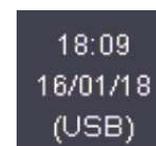
- **select Self Test**

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

#### Lung Ventilator: Stand-by.



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



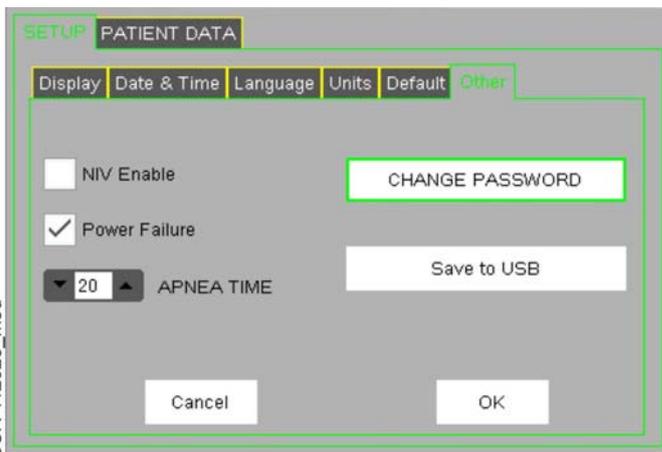


- Select **SETUP**



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

- Select **Other**



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

- Select **Save to USB**



- Switching OFF the lung ventilator.



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

### 4.19.3 Default parameters set

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

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



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

### 4.19.4 Touch Screen set

The Siaretron 4000 lung ventilator is equipped with a 15" colour Touch Screen display.

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



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

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

# 5 ALARMS

This chapter illustrates the part of the system relevant to the alarms operation of the Siaretron 4000 15" lung ventilator (*hereinafter called lung ventilator*); also the operating logic and issues for alarms action are taken into consideration.

*This chapter describes the following items.*

- 5.1 *Introduction*
- 5.2 *Displaying and used symbols*
  - 5.2.1 *A1 - Alarm area*
  - 5.2.2 *A2 - ALARMS parameter*
  - 5.2.3 *A3 - General information area*
  - 5.2.4 *A4 - Acoustic alarm silencing*
- 5.3 *Alarms setting*
  - 5.3.1 *Setting of ALARMS limits values*
  - 5.3.2 *Setting of ALARMS volume*
  - 5.3.3 *Setting of DEFAULT parameters*
  - 5.3.4 *Alarms DEFAULT parameters values*
- 5.4 *Summary table of alarm characteristics*
  - 5.4.1 *Alarms configurable by user*
  - 5.4.2 *System alarms*
  - 5.4.3 *Gas Sensor Alarms*
- 5.5 *Troubleshooting*
  - 5.5.1 *Troubleshooting list*

## 5.1 Introduction



### **WARNING !! Risk of injury for the user / patient**

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

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

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

### **Level of 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**

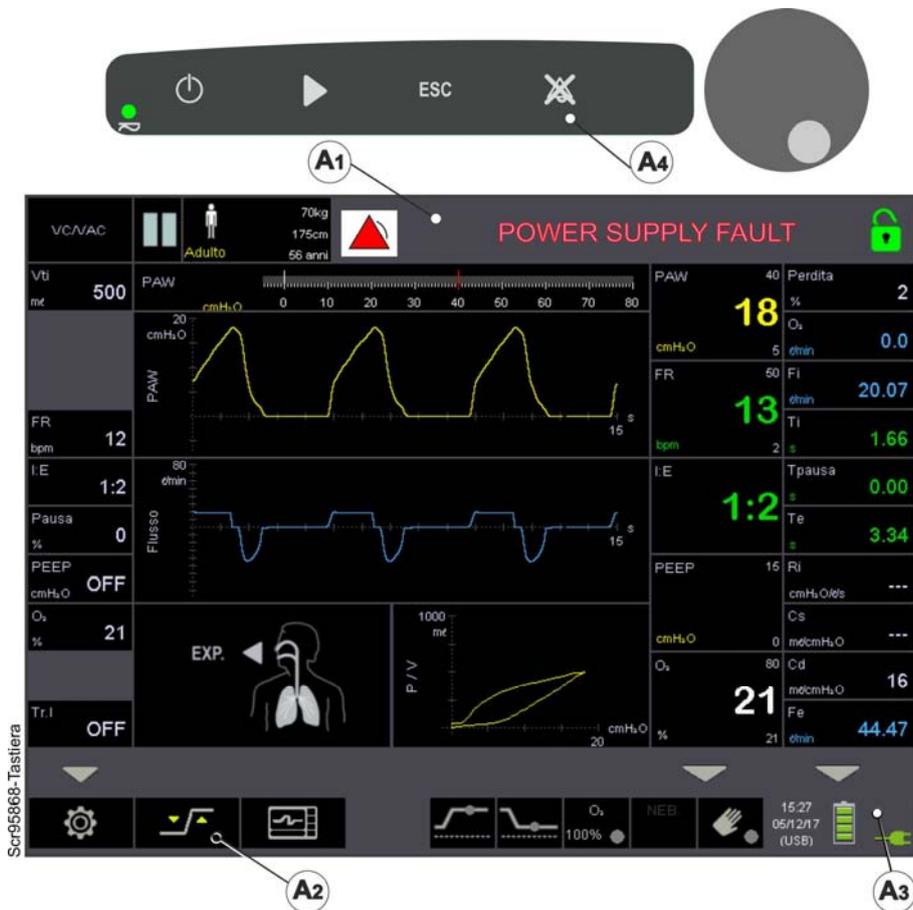
- Severe, i.e. leading to irreversible damage.
- Moderate, i.e. leading to reversible damage.
- Minor, i.e. involving a distress or leading to a minor damage.



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.

## 5.2 Displaying and used symbols



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

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

**A2 - ALARMS parameter**

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

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

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

**A4 - Soft key for acoustic alarm silencing**

## 5.2.1 A1 - Alarm area

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



### CAUTION

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

#### Alarms configurable by User

- Low / High Pressure of Airways
- Low / High Respiratory Rate
- Low / High Expiratory Volume
- Low / High Volume Minute
- Low / High PEEP
- Low / High O<sub>2</sub> Concentration
- Gas Sensor: Low / High EtCO<sub>2</sub>
- On Battery (*Power Failure - MENU SETUP - Other*)
- Apnoea (*MENU SETUP- Other*)

#### System alarms

- Low Battery: 50% Remaining
- Low Battery: 25% Remaining
- Low Battery
- Battery Disconnected
- Battery Charger Disconnected
- Battery Overtemperature
- (Patient) Circuit Disconnected
- Low O<sub>2</sub> Supply
- Turbine Failure
- Turbine Overtemperature
- Turbine Overcurrent
- MAINTENANCE 1000 hours (\* a symbol replace the alarm bell image).



### WARNING !! ( \* ) MAINTENANCE 1000 HOURS

Once reached 1000 hours operation this symbol appears.

Contact the Siare Service Centre or a Centre authorized by Siare for preventive maintenance.



## Gas Sensor alarms

- Sampling Line Clogged
- No Sampling Line
- Replace Adapter
- No Adapter
- Unspecified Accuracy (.....)
- Error (.....)
- No Breaths
- Low EtCO<sub>2</sub>
- High EtCO<sub>2</sub>
- Check the Flow Sensor (.....)



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

### Priority / alarm status: “ alarm bell symbol “:

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

#### Media priority

- Yellow bell



#### Suspended alarm

- Yellow bell crossed through



#### High priority

- Red bell



#### Suspended alarm

- Red bell crossed through



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



Lock icon (open) green color: **touch screen enabled.**



Lock icon (closed) red color: **touch screen disabled.**

## 5.2.2 A2 - ALARMS parameter

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



- Select: **ALARMS** icon



The **Alarm Limits** screen appears.

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



### **WARNING !! Risk of injury for the user / patient**

- The lung ventilator used in the same health environments can have **different 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.
- The alarms setting to the range limit could make the alarm not properly working.

### 5.2.3 A3 - General information area

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



**Green “BATTERY” symbol:** battery completely charge:

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

**Green “PLUG” symbol:** lung ventilator connected to the main power supply.



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

- Active alarm: **On Battery.**



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



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



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

**The alarm remains always actives to indicate the occurred malfunctioning.**

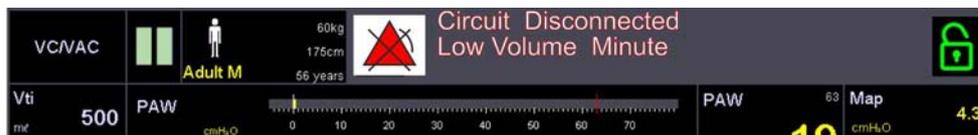
## 5.2.4 A4 - Acoustic alarm silencing



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

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

- By pressing the Alarm Reset soft key.
- By selecting the bell evidencing the active state of the alarm.



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### **WARNING !! Risk of injury for the user / patient**

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

### **NOTE**

- The ALARM RESET is active and will stop the acoustic alarm for a defined time.
- During the alarm silencing the alarm text is showed on the panel.
- A new ALARM RESET 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.



## 5.3 Alarms setting

### 5.3.1 Setting of ALARMS limits values



#### WARNING !! Risk of injury for the patient

Using in the same area more than one medical device having different alarm limits setting, the User could have a potential false misinterpretation.



- Before using the lung ventilator, it is suggested to adjust the parameters necessary for the correct operation of the lung ventilator.
- During operation it is possible to adapt the ALARM limits values setting in function of the patient clinical situation.



The User can modify and display the Alarm Limits values in two different ways; through the ALARMS selection icon or selecting a respiratory parameter.

- Select: ALARMS icon



The Alarm Limits screen appears.

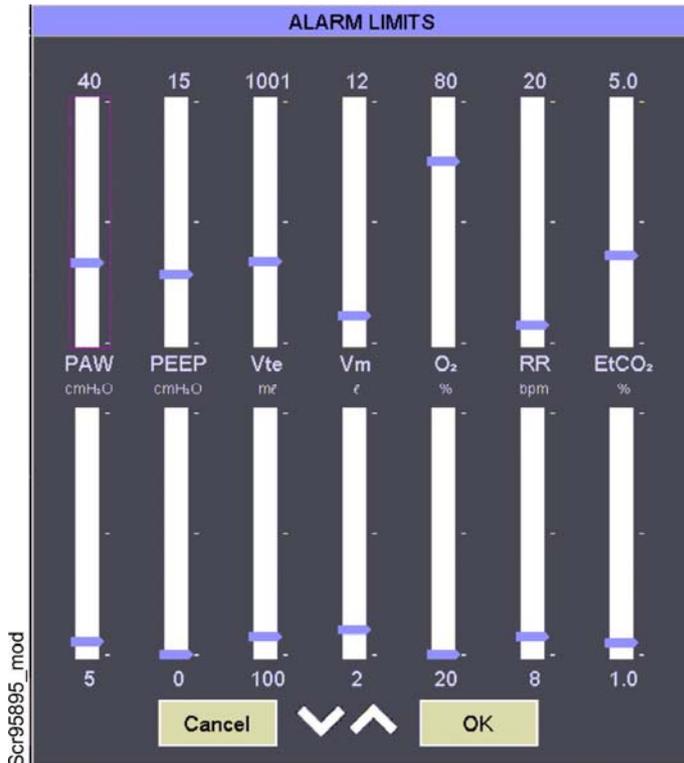
- Select **Cancel**

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

**NO:** it remains in Alarm page.
- Select **OK**

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

**NO:** it remains in Alarm page.



- Select the Alarm Limits to be modified.

Available **Alarm Limits**.

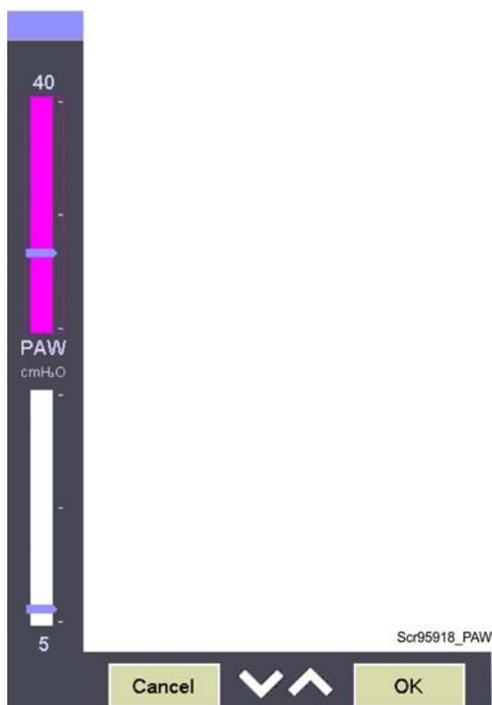
- PAW
- PEEP
- Vte
- Vm
- O<sub>2</sub>
- RR
- EtCO<sub>2</sub>



The values set by the scrolling cursor are displayed in the parameter monitoring box ( e.g. PAW ).



- Select the **Alarm Limits** to be modified.
- The parameter bar is highlighted and the monitoring parameter box on display is activated ( e.g. PAW ).



- **40:** High Alarm Limits value set (it is displayed in the PAW parameter box)
- **Coloured bar:** the bar is active to be modified
- **Scrolling cursor:** to be used for setting the parameter value
- **PAW:** PAW parameters
- **cmH<sub>2</sub>O:** unit of measurement
- **White bar:** the bar **IS NOT** active to be modified
- **Scrolling cursor:** to be used for setting the parameter value
- **5:** Low Alarm Limits value set (it is displayed in the PAW parameter box)
- **Arrows:** it increases or decrease a factor equal to 1 the value of the selected alarm.



The selection of both the bar or the cursor of the alarm can be done by using the encoder knob or the touch screen.

After modification of Alarm limit (**PAW**) values:

- **Select** 

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

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

### 5.3.2 Setting of ALARMS volume



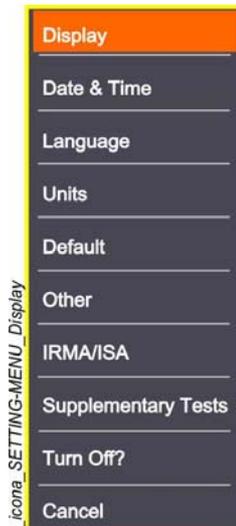
The SOUND VOLUME parameter allows the adjustment of the volume of acoustic alarms signals at any priority level.

Acoustic intensity value at 1 mt distance

- Minimum level Acoustic Volume setting at 1 = **54dBA**
- Maximum level Acoustic Volume setting at 20 = **70dBA**



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



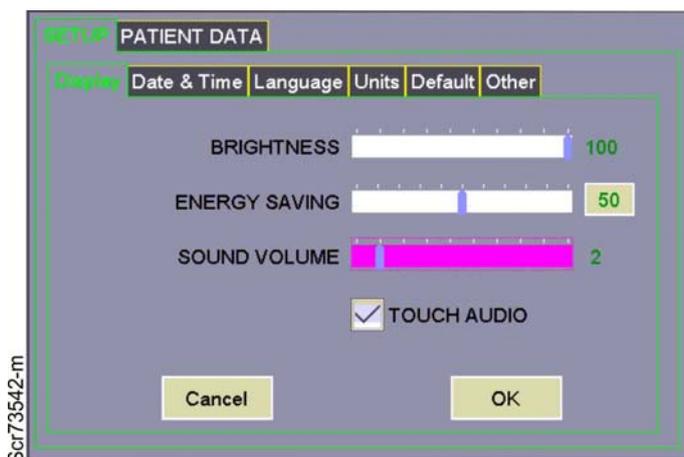
- Select **Display**
- To go back to the **Stand-by** displaying, select **Cancel**

The **Display** page allows to set:

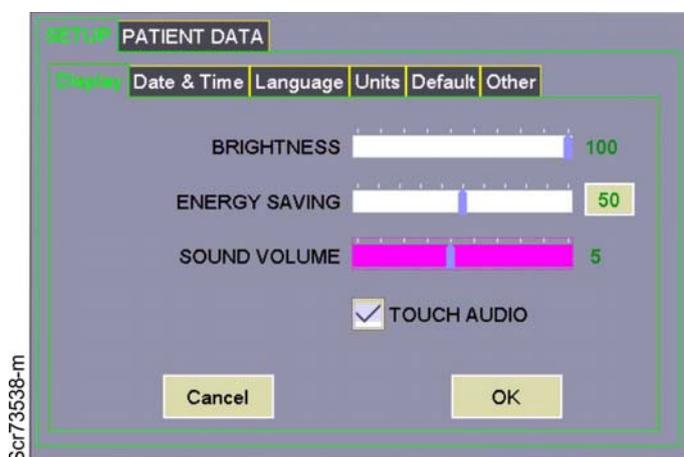
- **BRIGHTNESS**
- **ENERGY SAVING**
- **SOUND VOLUME**
- **TOUCH AUDIO**



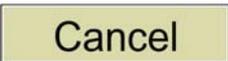
- Select the **SOUND VOLUME** scrolling cursor



- Set the **SOUND VOLUME**



After modification of **SOUND VOLUME** value.

- Select 

**YES:** to quit from Display page; the set will NOT be saved.

**NO:** it remains in Display page.
- Select 

**YES:** to quit Display page; the set will be saved.

**NO:** it remains in Display page.



**WARNING !! Risk of injury for the patient**

When the alarm Sound Volume is set to the minimum value (Setting = 1), its intelligibility can be lost.

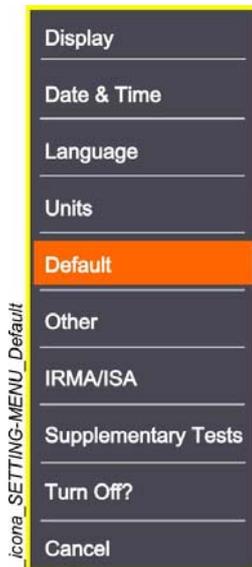
### 5.3.3 Setting of DEFAULT parameters



The DEFAULT page allows setting the standard factory parameters.



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



icona\_SETTING-MENU\_Default



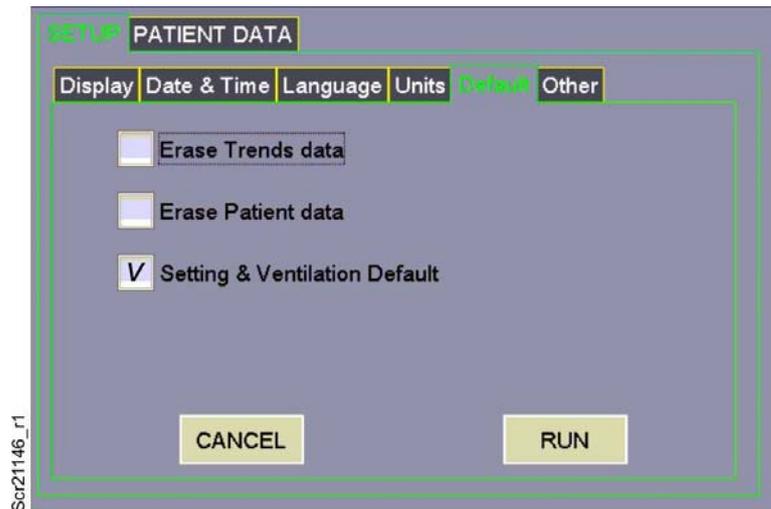
- Select **Default**
- To go back to **Stand-by** page, select Cancel

The **Default** page allows to set:

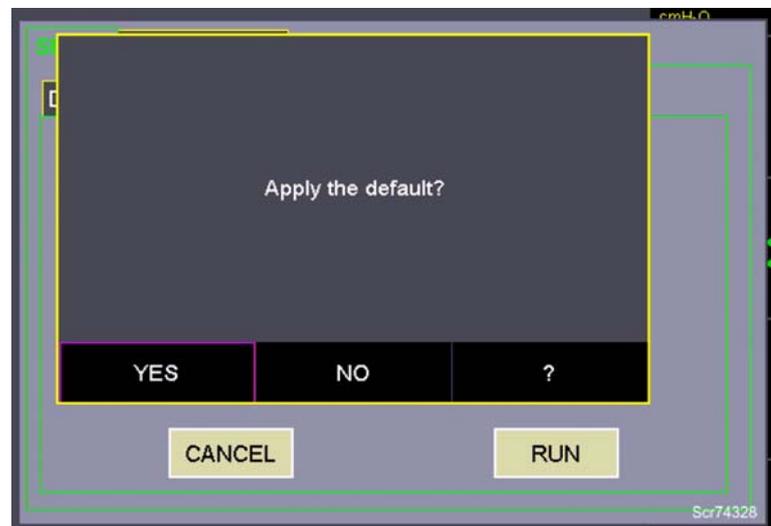
- *Trends data Default*
- *Patient data Default*
- **Setting & Ventilation Default**



- Select **Setting & Ventilation Default**
- Select **RUN**



- The system requires to confirm the application of default parameters.



Possible User's options.

- Select **RUN**  
**YES:** to quit Default page; the Default Parameters will be saved.  
**NO:** it remains in Default page.
- Select **Cancel**  
**YES:** to quit Default page; the Default Parameters will NOT be saved.  
**NO:** it remains in Default page.

### 5.3.4 Alarms DEFAULT parameters values

Alarm Settings	Adult	Paediatric	Neonatal
Pressure (cmH <sub>2</sub> O)	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 <sub>2</sub> O)	0 - 15		
FiO <sub>2</sub> (%)	21 - 80		
Gas sensor	1.0 - 5.0		
On Battery <i>(configurable in: MENU SETUP – Other - Power Failure)</i>	Enable		
Apnea Time <i>(configurable in: MENU SETUP – Other – Apnoea Time)</i>	20 sec.		

## 5.4 Summary table of alarm characteristics

### 5.4.1 Alarms configurable by user

Alarms	Priority	Delay Time (s)	Suspendable	Suspendable for (s)	Inhibition
Low Pressure of Airways	<i>HIGH</i>	15	YES	15	NO
High Pressure of Airways	<i>HIGH</i>	0	NO	-	NO
Low Respiratory Rate	<i>HIGH</i>	3 patient breaths	YES	30	NO
High Respiratory Rate	<i>HIGH</i>	3 patient breaths	YES	30	NO
Low Expiratory Volume	<i>HIGH</i>	15	YES	30	NO
High Expiratory Volume	<i>HIGH</i>	0	YES	30	NO
Low Volume Minute	<i>HIGH</i>	60	YES	30	NO
High Volume Minute	<i>HIGH</i>	60	YES	30	NO
Low PEEP	<i>HIGH</i>	0	YES	30	NO
High PEEP	<i>HIGH</i>	0	YES	30	NO
Low O <sub>2</sub> Concentration	<i>HIGH</i>	30	YES	30	NO
High O <sub>2</sub> Concentration	<i>HIGH</i>	30	YES	30	NO
Low EtCO <sub>2</sub>	<i>HIGH</i>	30	YES	30	NO
High EtCO <sub>2</sub>	<i>HIGH</i>	30	YES	30	NO
Apnoea	<i>HIGH</i>	5 - 60	YES	30	NO
On Battery	<i>HIGH</i>	15	YES	120	YES

## 5.4.2 System alarms

Alarms	Priority	Delay Time (s)	Suspendable	Suspendable for (s)	Inhibition
Low O <sub>2</sub> Supply	HIGH	0	YES	30	if FiO <sub>2</sub> =21%
Low Battery 50% Rem.	HIGH	0	YES	-	YES
Low Battery 25% Rem.	HIGH	0	YES	-	YES
Low Battery 10 Min. Rem.	HIGH	0	NO	-	NO
Battery Disconnected	HIGH	0	NO	-	NO
Battery Overtemperature	HIGH	0	NO	-	NO
(Patient) Circuit Disconnected	HIGH	0	NO	-	NO
Turbine Failure	HIGH	0	NO	-	NO
Turbine Overtemperature	HIGH	0	NO	-	NO
Turbine Overcurrent	HIGH	0	NO	-	NO
<i>CAN-BUS Failure</i>	<i>HIGH</i>	<i>0</i>	<i>NO</i>	<i>-</i>	<i>NO</i>
Maintenance 1000 hours	HIGH	0	YES	-	NO

### 5.4.3 Gas Sensor Alarms

Alarms	Priority	Delay Time (s)	Suspendable	Suspendable for (s)	Inhibition
Sampling Line Clogged	<i>HIGH</i>	<i>0</i>	<i>YES</i>	<i>30</i>	<i>NO</i>
No Sampling Line	<i>HIGH</i>	<i>0</i>	<i>YES</i>	<i>30</i>	<i>NO</i>
Replace Adapter	<i>HIGH</i>	<i>0</i>	<i>YES</i>	<i>30</i>	<i>NO</i>
No Adapter	<i>HIGH</i>	<i>0</i>	<i>YES</i>	<i>30</i>	<i>NO</i>
Unspecified Accuracy	<i>HIGH</i>	<i>0</i>	<i>YES</i>	<i>30</i>	<i>NO</i>
Error	<i>HIGH</i>	<i>0</i>	<i>YES</i>	<i>30</i>	<i>NO</i>
No Breaths	<i>HIGH</i>	<i>0</i>	<i>YES</i>	<i>30</i>	<i>NO</i>
Low EtCO <sub>2</sub>	<i>HIGH</i>	<i>0</i>	<i>YES</i>	<i>30</i>	<i>NO</i>
High EtCO <sub>2</sub>	<i>HIGH</i>	<i>0</i>	<i>YES</i>	<i>30</i>	<i>NO</i>
Check the Flow Sensor					

## 5.5 Troubleshooting

This chapter is an indicative but not exhaustive guide for the user and the service engineer, providing indications for eliminating, as quickly as possible, most of the problems that may have caused malfunctioning or alarm signals.

This chapter describes the possible causes of problems, indicated by alarms that are activated during normal functioning.



### **WARNING !!**

If the problem persists, carry out a complete check of the lung ventilator to identify any irregularities.

If the problem cannot be resolved, contact the Siare Service Centre or a Centre authorized by Siare.

### 5.5.1 Troubleshooting list

**Switch ON failure** The lung ventilator does not switch on.

- Check that it is connected to the main power supply.
- Check that the main switch is turned to the I position (ON).
- Check the main fuses.
- Check the display connection cable.
- Contact the Siare Service Centre or a Centre authorized by Siare.

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

- Check if the LED power indicator is ON.
- Check that it is connected to the main power supply.
- Check that the main switch is turned to the I position (ON).
- Check the correct connections of the plug, the fuses and the connector, and the condition of the cable (if necessary, restore the connections and replace the cable if it is damaged).
- Check that power is present at the relative socket by plugging in another electrical device. If there is no power, use another socket or check the overload switch on the electrical panel of the room.
- Check the 12V voltage is properly supplied to the main board.

**Initialization phase** The initialization phase is not completed.  
**- SELF TEST**

Verify and intervene in function on the error messages and indications evidenced during the “**SELF TEST**” phase.

- **Turbine:** if this step is not passed means that the turbine is not running so check if the turbine cable is properly connected and if the turbine is properly powered. If so, the turbine is broken so it must be changed.
- **Oxygen emptying:** during this test phase the system performs a clean of the oxygen inside the circuits and the device which grants a 21% concentration on the inspiratory line of the lung ventilator.
- **Insp. flow sensor:** if this step is not passed means that the inspiratory flow is not measured correctly by the sensor (the turbine starts delivering the flow suitable with PWM = 45%, the insp. flow sensor test is passed if the flow measured by the insp. flow sensor is > 50 l/min). So, check if the inspiratory flow sensor cable is properly connected and if the 10V supply voltage of the flow sensor is properly supplied from the main board. If so, the inspiratory flow sensor is broken and must be replaced.
- **Exp. flow sensor:** if this step is not passed this means the expiratory flow is not measured correctly by the sensor (the exp. flow sensor test is passed if the flow measured by the exp. flow sensor is > 30 l/min). So, check if the expiratory flow sensor cable is properly connected. if the problem is not solved, please perform the expiratory flow sensor calibration. If the calibration doesn't solve the problem, this means the expiratory flow sensor is broken and must be replaced.
- **Pressure sensor:** if this step is not passed, it means that the airway pressure is not measured correctly by the sensor so check if the inspiratory flow is generated by the ventilator; check if there are leakages in the inspiratory and expiratory line of the ventilator or in the patient circuit; check the pressure measured on the ventilator.
- **Electrovalve:** if this step is not passed means that the electrovalves EV1/EV2 are not able to close the expiratory valve so check if the inspiratory flow is generated by the ventilator; check if there are leakages in the inspiratory and expiratory line of the ventilator or in the patient circuit; check if the 12Vdc reach the expiratory electrovalve, if the voltage is correct replace the electrovalve.
- **Patient circuit:** if this step is not passed means that the measured airway pressure is very low so check if there are leakages in the inspiratory and expiratory line of the ventilator or in the patient circuit.

- **Battery:** if this step is not passed means that the battery voltage is less than 11Vdc so connect the ventilator to the main power supply for 10 hours with the main switch on the I position (ON) and check again.

Check if the 12V voltage is properly supplied from the main board and the battery charger board. If the problem is not solved, replace the battery.

- **Oxygen sensor:** if this step is not passed means that the 21% of oxygen is not measured correctly by the sensor so check the oxygen sensor cable if it is properly connected; perform the oxygen calibration in the test on demand MENU and check the oxygen output if the voltage is under 9mV the oxygen sensor is exhausted and so it must be changed.
- **Acoustic alarm:** at the end of the self test the activate the alarm sound. If the sound is heard by the operator the alarm reset button must be pressed, if it is not heard check if the speaker cable is well connected and the voltage on the main board connector otherwise the speaker is defective and must be replaced.

- Turn off and on the lung ventilator and repeat "SELF TEST" phase.
- If the problem persists, contact the Siare Service Centre or a Centre authorized by Siare.

#### Soft keys and encoder knob

This condition occurs when the control keyboard or the Encoder are not working.

- Switch the lung ventilator OFF and then switch back ON.
- Continuity test of the keyboard and encoder cable.
- If the problem persists, contact the Siare Service Centre or a Centre authorized by Siare.

**(Patient) Circuit disconnected**

This alarm conditions occurs in case of disconnection of the patient circuit (missed Vte detection for three times).

- Vte volume limit for circuit disconnected condition: 50ml for ADULT, 20 ml for PAEDIATRIC, 0 ml for NEONATAL patient).
- Check that the mask, endotrachéal tube and patient circuit are not in some way split, disconnected or connected wrongly. If this is the case, eliminate the problem or replace them.
- Check the correct settings of the patient's respiratory parameters (according to the operative mode selected: Volume/Flow, Rate, I/E, Trigger).
- Check that the patient circuit is connected correctly to the lung ventilator and to the patient.
- Contact the Siare Service Centre or a Centre authorized by Siare.

**Low O<sub>2</sub> gas pressure**

This alarm is activated when the pressure is insufficient (< 2.7 bar) for the lung ventilator to operate correctly.

- Check that the medical gases are correctly connected to the lung ventilator. Restore the connections or replace the tubes if damaged.
- Check that there is sufficient pressure in the supply system or in the cylinders. Adjust or repair the supply system (or replace the cylinders) if the pressure is insufficient.
- Contact the Siare Service Centre or a Centre authorised by Siare.

**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 **BATTERY LEVEL 50% and 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).

<b>Low battery</b>	<p>This alarm condition is present when the charge battery level is such to be guaranteed a residual autonomy of about 10 minutes.</p> <ul style="list-style-type: none"> <li>▪ Verify the power supply connection; recharge the battery.</li> <li>▪ 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.</li> </ul>
<b>Battery disconnection</b>	<p>This alarm condition is present when the battery is not properly connected to the device.</p> <ul style="list-style-type: none"> <li>▪ Check the battery connection.</li> <li>▪ If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.</li> </ul>
<b>Battery charger disconnected</b>	<p>The alarm condition is present when the battery does not charge properly.</p> <ul style="list-style-type: none"> <li>▪ Check the correct connection of the battery.</li> <li>▪ Check the output voltage from the charging card to the battery (12Vdc)</li> <li>▪ If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.</li> </ul>
<b>Battery overtemperature</b>	<p>This alarm condition is present when the battery pack internal temperature pass the 75°C.</p> <ul style="list-style-type: none"> <li>▪ If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.</li> </ul>
<b>Exhausted O<sub>2</sub> sensor</b>	<p>The oxygen sensor is exhausted.</p> <ul style="list-style-type: none"> <li>▪ See information on FiO<sub>2</sub> % low alarm.</li> <li>▪ Replace the oxygen sensor with a new one.</li> <li>▪ If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.</li> </ul>
<b>Disconnected O<sub>2</sub> cell</b>	<p>This alarm indicates the connection status of the oxygen sensor.</p> <ul style="list-style-type: none"> <li>▪ Check that the oxygen cell is correctly connected.</li> <li>▪ Check the condition of the cable and the connector (if necessary, restore the connection and replace the cable if damaged).</li> <li>▪ Replace the oxygen sensor with a new one.</li> <li>▪ If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.</li> </ul>

**1000 working hours**

This alarm condition occurs at overcoming of 1000 working hours from the last reset.

- When this alarm occurs, it is recommended to perform the preventive maintenance procedure, check the ventilator operation and finally reset the working hours.
- Contact the Siare Service Centre or a Centre authorised by Siare to execute the periodic scheduled maintenance.

**FiO<sub>2</sub> % 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.

**FiO<sub>2</sub> % low**

This alarm is activated when the measured concentration of oxygen is below the set limit.

- Check that the oxygen cell is fitted correctly in its housing.
- Check that the corresponding alarm limits are set correctly.
- Calibrate the oxygen cell: if the problem occurs again after a short time, replace the oxygen cell.
- Check that the feeding pressure of the medical gases is correct: if it is not, check the pressure of the distribution system and the correct connection to the supply.
- Contact the Siare Service Centre or a Centre authorised by Siare.

**Min. Vte / VM**

This alarm condition occurs in case the Vte is lower than set value.

- Check that the corresponding alarm limits are set correctly.
- Check that the mask, endotracheal tube and patient circuit are not in some way split, disconnected or connected wrongly. If this is the case, eliminate the problem or replace them.
- Check that the mask, endotracheal tube and patient circuit are not in some way clogged, bent or crushed. If this is the case, eliminate the problem or replace them.
- Check the correct settings of the patient's respiratory parameters (according to the operative mode selected: Volume/Flow, Rate, I/E, Trigger).
- Check that the patient circuit is connected correctly to the lung ventilator and to the patient.

- Check if the lung ventilator works properly verifying the airways pressure. If the lung ventilator works properly perform the expiratory flow sensor calibration.
- Contact the Siare Service Centre or a Centre authorised by Siare.

#### **Max. Vte / VM**

This alarm condition occurs in case the Vte is higher than set value.

- Check that the corresponding alarm limits are set correctly.
- Check the correct settings of the patient's respiratory parameters (according to the operative mode selected: Volume/Flow, Rate, I/E, Trigger).
- Check if the lung ventilator works properly verifying the airways pressure. If the lung ventilator works properly perform the expiratory flow sensor.
- Contact the Siare Service Centre or a Centre authorised by Siare.

#### **Low (High) PEEP**

This alarm condition occurs if the measured PEEP value is lower (higher) than the value set.

- Check that the corresponding alarm limits are set correctly.
- Check if the mask / endotracheal tube / patient circuit / expiratory valve (membrane), are not damaged, if holes are present or if they are connected in a bad way. If it's the case, replace them or solve the trouble.
- Check if the lung ventilator works properly verifying the airways pressure.
- In case of differences higher than 2 cmH<sub>2</sub>O (10%) between the value set and the value read, a turbine calibration shall be performed.
- Check the EV1/EV2 electrovalves.
- Contact the Siare Service Centre or a Centre authorised by Siare.

**PAW high**

In this condition, the patient circuit + patient system presents a higher resistance than expected or a lower compliance. This causes an increase in airways pressure that exceeds the set limit.

- Check that the corresponding alarm limits are set correctly.
- Check that the mask, endotrachéal tube and patient circuit are not in some way clogged, bent or crushed. If this is the case, eliminate the problem or replace them.
- Check the correct settings of the patient's respiratory parameters (according to the operative mode selected: Volume/Flow, Rate, I/E, Trigger).
- Check that the luminous PAW bar on lung ventilator (the airways pressure curve) correctly follows the inspiration / expiration cycle.
- Check that nothing is limiting the patient's respiratory capacity.
- Contact the Siare Service Centre or a Centre authorised by Siare.

**PAW low**

In this condition, the patient circuit + patient system presents a lower resistance than expected or a higher compliance. This causes insufficient ventilation pressure.

- Check that the corresponding alarm limits are set correctly.
- Check that the mask, endotrachéal tube and patient circuit are not in some way split, disconnected or connected wrongly. If this is the case, eliminate the problem or replace them.
- Check the correct settings of the patient's respiratory parameters (according to the operative mode selected: Volume/Flow, Rate, I/E, Trigger).
- Check that the luminous PAW bar on lung ventilator (the airways pressure curve) correctly follows the inspiration / expiration cycle.
- Check that the patient circuit is connected correctly to the lung ventilator and to the patient.
- Check that the low pressure level is higher than the PEEP level set. If not, increase it above the PEEP level.
- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

**RR high**

This alarm is enabled when the respiratory rate value is higher than the set value.

- Check that the corresponding alarm limits are set correctly.
- Check that the patient's respiratory parameters are set correctly.
- Check that the sensitivity of the Trigger is appropriate to the patient's physiological conditions.
- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

**RR low**

This alarm is activated when the respiratory rate value is lower than the set value.

- Check that the corresponding alarm limits are set correctly.
- Check that the patient's respiratory parameters are set correctly.
- Check that the lung ventilator operates correctly, checking the airways pressure trend. If the lung ventilator operates correctly, check the flow sensor and the correct connection of its cable.
- Check that the mask, endotrachéal tube and patient circuit are not in some way split, disconnected or connected wrongly. If this is the case, eliminate the problem or replace them.
- Check that the sensitivity of the Trigger is appropriate to the patient's physiological conditions.
  
- Check that the patient circuit is connected correctly to the lung ventilator and to the patient.
- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

**Apnea**

In this condition, no spontaneous respiratory activities is detected (RR = 0).

- Check that the patient's respiratory parameters are set correctly.
- Check that the sensitivity of the Trigger is appropriate to the patient's physiological conditions.
- Check that the mask, endotrachéal tube and patient circuit are not in some way split, disconnected or connected wrongly. If this is the case, eliminate the problem or replace them.
- Check that the lung ventilator operates correctly, checking the airways pressure trend. If the lung ventilator operates correctly, check the flow sensor and the correct connection of its cable.

- Check that the patient circuit is connected correctly to the lung ventilator and to the patient.
- Contact the Siare Service Centre or a Centre authorised by Siare.

**Expiratory flow sensor calibration failed**

The user can note indirectly, by monitoring the flow graph, the value of the expired volume and the peak value of expired flow, if the self-calibration of the flow sensor has been successful or not.

- Check the proper mounting of the sensor (patient circuit) and the relevant connections to the lung ventilator and to the patient.
- Check if the patient circuit is properly closed during the calibration.
- Replace the sensor and repeat the expiratory flow sensor calibration.
- Perform the turbine calibration and repeat the expiratory flow sensor calibration.
- Contact the Siare Service Centre or a Centre authorised by Siare.

**Turbine over-temperature (over-current)**

The maximum safety level for the temperature (current) of the turbine is passed (80 - 85 °C).

- The lung ventilator automatically stop the ventilation to avoid dangers to the patient safety.
- Check if the turbine air filter is clean or clogged.
- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

**Turbine failure**

The turbine doesn't work properly (failure).

- The lung ventilator automatically stop the ventilation to avoid dangers to the patient safety.
- Check if the turbine air filter is clean or clogged.
- Perform the turbine calibration.
- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

**Turbine calibration failed** The turbine doesn't work properly (failure).

- Check if the patient circuit is properly closed during the calibration.
- During the calibration check the inspiratory flow sensor reading. If the reading is over 10 l/min, means that there is a leakage in the patient circuit. Eliminate the leakage and perform again the turbine calibration.
- Replace the turbine and perform again the turbine calibration.
- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

**CO2 Analyzer** Malfunctioning.

- Check that the patient's respiratory parameters are set correctly.
- Check the proper mounting of the sensor (patient circuit) and the relevant connections to the lung ventilator and to the patient.
- Check the IRMA/ISA is enabled in the **CALIBRATION PROGRAM**.
- Check the state indicator on the CO2 analyzer, is a fixed green LED.
- Check the errors shown in the GAS SENSOR area.
- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.



For further information on operating logic and on gas sensor malfunctioning, make reference to the GAS ANALYZER manual supplied with the device.

## 6 MAINTENANCE

To guarantee the regular ventilator operation of the Siaretron 4000 15" lung ventilator for intensive care (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.

*This chapter describes the following operation.*

- 6.1 Notes
- 6.2 Cleaning, disinfection and sterilization
- 6.3 General indications
  - 6.3.1 Cleaning
  - 6.3.2 Disinfection and sterilization
  - 6.3.3 Disinfection by immersion (chemical)
- 6.4 Cleaning, disinfection and sterilization table
  - 6.4.1 Sterilization of EXP V. Monoblock ( exhalation block with flow sensor )
  - 6.4.2 Disposable bacteria filter
- 6.5 Periodic maintenance
  - 6.5.1 Maintenance operations
    - 6.5.2 Cleaning, disinfection and sterilization before use with another patient
- 6.6 Repairs and spare parts
  - 6.6.1 Spare parts kit for lung ventilator
- 6.7 Miscellaneous
  - 6.7.1 Storage
  - 6.7.2 Repackaging and shipment
  - 6.7.3 Disposal

## 6.1 Notes



- To guarantee the regular ventilator operation of the lung ventilator for intensive care (*hereinafter called lung ventilator*), perform the following maintenance interventions with the recommended frequency.
- All interventions must comply with to the practice and protocols in force in each facility.
- The instructions for carrying out more detailed tests, for trouble-hooting and for other interventional procedures, information intended for qualified technical personnel, are contained in the relative chapter.



On completion of the maintenance operations, all removed components should be disposed of according to current waste disposal regulations: components that cannot be destroyed should be sterilized before disposal.

Follow current regulations for the disposal or recycling of all removed components.



### **WARNING !! Risk of injury for the user / patient**

To ensure the safety of the patient and the User, the lung ventilator must be inspected and checked when the limit of **1000 working hours has been reached or, in the event of limited use of the machine, at least every 6 months.**

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

Inappropriate intervention or unauthorised modifications can compromise safety and cause danger to the patient.



To avoid the danger of electric shock during maintenance and/or repair operations, make sure that all power supplies have been disconnected, disconnect the power supply source (positioning the special danger signs) and disable the protection switch of the lung ventilator.



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

## 6.2 Cleaning, disinfection and sterilization

The User is responsible for carrying out the ordinary maintenance as foreseen in this chapter.

Cleaning, disinfecting, sterilizing and replacement of parts must be carried out as indicated in this manual in order to avoid damage to the lung ventilator which could also endanger patient and User safety.



### **WARNING !! Risk of personal injury**

- Do not attempt to dismantle, clean or rinse parts or components, such as the screen or knobs, with liquids or compressed air.
- To avoid exposing the patient to sterilizing substances, these parts must be sterilized as described below. Remember that exposure to sterilizing substances can reduce the working life of some components.
- Always use filters to protect circuits and lung ventilator: if foreseen, handle the filters with care to reduce the risks of bacterial contamination or material damage to a minimum.
- Always respect the hospital procedures regarding the control of infections.
- The lung ventilator does not require particular maintenance and preventive operations other than those indicated in this manual or in order to respect standards applied in the specific country where the lung ventilator is sold.



- Siare is aware that working procedures can differ considerably from one health care facility therefore it is impossible to indicate specific procedures suitable for every requirement.
- SIARE cannot be held responsible for the effectiveness of the cleaning, disinfection and sterilization procedures, nor for the other procedures carried out while the patient is being treated.
- This manual can provide only general instructions for cleaning, disinfection and sterilization. Nevertheless it is User's responsibility to ensure the validity and effectiveness of the methods used.

## 6.3 General indications

### 6.3.1 Cleaning

Use a disposable cloth moistened with neutral detergent, a chemical substance or the equivalent; use water to remove any traces of chemical residuals.

- Do not clean or re-use disposable products.
- Do not use hard brushes to clean the components, or other instruments that could damage their surface.
- Wash the components with hot water and a neutral detergent solution.
- Rinse the parts well with clean hot water (tap water can be used) and leave to dry.
- Siare recommends that the components are checked every time they are cleaned and any damaged part should be replaced.
- Whenever a part or component is changed, check the functioning of the lung ventilator.



#### CAUTION

Follow manufacturer's instructions for the detergent substances used: the use of detergents that are too strong could compromise the working life of the components.

Deposits of cleansing substances can cause damage or micro cracks, especially on parts exposed to high temperatures during sterilization.

### 6.3.2 Disinfection and sterilization

To disinfect the components, dismantle them and place them in a steam disinfection chamber at 93°C for 10 minutes.

After this first operation and before placing the components in an autoclave, wrap them in muslin or in a similar material.

Effective sterilization is achieved in an autoclave at 121°C for approx. 15 minutes.



#### WARNING !! Risk of injury for the patient

Always refer to the instructions provided by the autoclave manufacturer regarding temperature and time.



- Do not disinfect, sterilize or re-use disposable products.
- Disinfect and sterilize every time an infected patient is ventilated.
- In normal conditions, disinfect and sterilize depending on the frequency of the lung ventilator's use and in any case at least once a month.



- That the components should be checked every time they are sterilized and any damaged parts should be replaced.
- Carrying out a functioning test of the machine whenever parts or components are replaced.

### 6.3.3 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.

## 6.4 Cleaning, disinfection and sterilization table

Component	Procedure	Notes
Outer casing	<p>Use a moistened disposable cloth with neutral detergent or a chemical substance or the like. Use water to remove any remaining traces of chemical.</p> <p>The User may use disinfectants (e.g. Buraton 10 F, diluted according to the manufacturer's instructions or VPRO 60C°) to clean the components.</p> <p>Disinfectants based on the following substances can cause damage:</p> <ul style="list-style-type: none"> <li>▪ halogen-releasing compounds;</li> <li>▪ strong organic acids;</li> <li>▪ oxygen-releasing compounds.</li> </ul> <p>Remove any dust from the surfaces or in openings using a vacuum cleaner or a soft cloth.</p>	<p>Make sure that no sprays or liquids penetrate inside the equipment and the connectors.</p>
Screen	See above.	Do not use cloths or sponges that could scratch the surface.



To avoid damaging the labels and outer surfaces of the lung ventilator, use only the chemical substances listed.

Patient circuit (silicone tubes)	<p>Dismantle and clean: sterilize in an autoclave, disinfect with steam or chemically.</p> <p>Check that there are no splits in the tubes and replace them if they are damaged.</p>	<p>121°C rubber cycle.</p> <p>Before using again, eliminate any humidity inside the tubes by means of compressed air.</p>
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The patient circuit can be sterilized by means of steam but this can lead to early wear of the tubes.

Yellowing and reduced flexibility are side effects caused by sterilization using steam.



**WARNING !! Risk of injury for the patient**

It is necessary to have at least one spare patient circuit in stock for routine use and /or accidental breaks.

Couplings and connectors	Dismantle and clean: sterilize in an autoclave, disinfect with steam or chemically.  Check that there are no splits and replace them if they are damaged.	Before using again, eliminate any humidity inside the components by means of compressed air.
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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.
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- Do not clean or re-use disposable circuit tubes.

Components that cannot be destroyed should be sterilized and disinfected according to local standards.

Mask	<ul style="list-style-type: none"><li>▪ Perform daily cleaning of the mask following the instructions of the responsible doctors or recommended by the Manufacturer.</li><li>▪ Hang up the clean mask to provide that it is completely dry before use.</li><li>▪ Always clean the mask and the hoses or use a new mask in case the lung ventilator must be used with a different patient.</li><li>▪ 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.</li></ul>	See Manufacturer's instructions.
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Water trap filter	If reusable: clean, then sterilize in autoclave or chemically disinfect.	Check the presence of fissures and replace in case of damages.
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Other accessories	Carefully follow the manufacturer's instructions.	Refer to the accompanying documentation.
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Electrical connections	On the aim to guarantee patient and User safety it is necessary to keep the power supply cable in perfect conditions.	Perform daily checking's of cable condition; any damage, also a minimum damage, must be promptly eliminated.  Eventually replacing the whole cable.
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### 6.4.1 Sterilization of EXP V. Monoblock (Exhalation block with flow sensor)

EXP V. Monoblock	Disinfect with steam ( 93° - 10 minutes ) or chemically.	<p>It is possible to sterilize the component with gamma rays or ethylene oxide (ETO).</p> <p>When disinfection is complete, rinse with running, preferably decalcified, water; shake and drain off any remaining water.</p> <p>Leave the components to dry completely.</p>
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#### CAUTION



- The EXP V. monoblock includes the expiratory valve and the flow sensor.
- Do not attempt to dismantle or clean with compressed air.
- The EXP. V. monoblock can be washed and disinfected by immersing it in a bowl with 3 centimetres of liquid (chemical), keeping the connector for the electrical connections facing upwards, following the manufacturer's instructions (*see following note about recommended chemical agents*).



#### The following are chemical agents recommended for cold sterilization of flow sensor.

- 5.25% - 6.15% Sodium Hypochlorite solution
- Protex wipes ( Didecyl Dimethyl Ammonium Chloride )



#### WARNING !! Risk of device failure

##### EXP valve and EXP flow sensor disinfection.

- Do not use formaldehyde or phenol-based disinfectants as they can cause cracking and reticulation of plastic parts.
- Do not use too strong disinfectants as they can compromise the working life of the immersed parts.
- Rinsing and carefully drying the components since marks and other damage can occur when the components are exposed to high temperatures.

## 6.4.2 Disposable bacteria filter



### CAUTION

It is important to use a disposable bacteria filter at the expiratory port of lung ventilator between the patient circuit's expiratory limb and the expiratory flow sensor.

Disposable bacteria filter	Do not clean or re-use if the filters are the disposable type.	Components that cannot be destroyed should be sterilized and disinfected according to local standards.
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### WARNING !! Risk of device failure

#### Disposable bacteria filter.

- Do not attempt to sterilize and reuse a disposable bacterial /HEPA filter. It is meant for single use.
- Do not use filters that aren't in sealed pack.
- Do not try to dry the filter and reuse in the same patient in case of increased resistance.
- Do not use it longer than the time-period recommended by manufacturer.
- Do not use filters that had exceeded the expiry date.



#### Disposable bacteria filter.

- Replace the bacterial filter as per manufacturer's advice (24 - 72 hours).
- If used with humidifier, change the filter more frequently (as and when the resistance increases or patient's "work of breathing" increases).
- Immediately replace the filter if it is stained with blood, secretions or other human fluid
- Check the expiry date before using on patient.
- Change the filter early if nebulisation is done frequently.

## 6.5 Periodic maintenance



### CAUTION

The lung ventilator does not require particular maintenance and preventive operations other than those indicated in this manual or in order to respect standards applied in the specific country where the lung ventilator is sold.

- Inspections and periodic maintenance are ensured by taking out a maintenance contract with SIARE or an authorised dealer.
- Contact SIARE for information regarding authorised Service Centres in your area.
- When you require service, please indicate the serial number of the unit and the problem to SIARE or to your authorised technicians.
- SIARE assumes responsibility for all provisions foreseen by the law, if the equipment is used and maintained as per the instructions in this manual and the technical manual
- The Technical Assistance Report, signed by the authorised SIARE technician, is proof of the completion of the scheduled maintenance.

### 6.5.1 Maintenance operations



### WARNING !! Risk of injury for the patient

Always refer to the instructions contained in the previous section: cleaning, disinfection and sterilization of the components.

The table summarizes the preventive maintenance frequency and procedures to be carried out on the lung ventilator.

Frequency	Component	Procedure / Action
Several times a day / according to local practice and standards	Patient circuit	Check for any water collection, drain and clean the tubes when necessary.
	Disposable bacteria filter	Replace.
	Condensation trap filter	Check for any water collection, drain and clean when necessary.

Frequency	Component	Procedure / Action
Every day / when necessary	Oxygen sensor	Calibrate according to the procedures described in this manual.
	Condensation trap filter	Check for any water collection, drain and clean when necessary.
	Lung ventilator	General cleaning and checks.
	Turbine air filter	
	EXP. V. Monoblock	Sterilize / disinfect according to the procedure described in this manual and according to local standards.
Every 2 weeks (at least)	Turbine air filter	Replace.
		Components that cannot be destroyed should be sterilized before disposal.
Every 6 months or 1000 working hours ( * )	Lung ventilator	The lung ventilator must be inspected and checked in general and any worn parts must be replaced.  Use the appropriate preventive maintenance kit.
	Oxygen sensor	Replace.  The working life of the cell depends on the working environment. If the temperature or the O <sub>2</sub> % is high, the working life of the sensor will be lower.
	O <sub>2</sub> and Turbine air filter	Replace.
	Patient circuit (silicone tubes)	Sterilize according to the procedure described in this manual and according to local standards.
	Washers / O-Rings	Components that cannot be destroyed should be sterilized before disposal.
Every year ( * )	Lung ventilator	Check the lung ventilator performance.  This includes an electrical safety test and inspection of the lung ventilator for mechanical damage and legibility of the labels.  The lung ventilator must also be inspected and checked in general and worn parts must be replaced, using the appropriate preventive maintenance kit.  Use the appropriate preventive maintenance kit.

Frequency	Component	Procedure / Action
Every two years / when necessary	Internal battery	<p>Replace.</p> <p>This operation must only be carried out by qualified technical personnel, according to the instructions contained in the relative service and maintenance manual.</p> <p>The working life of the battery depends on the working conditions and environment.</p>



**WARNING !! Risk of injury for the patient ( \* )**

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

Inappropriate intervention or unauthorised modifications can compromise safety and cause danger to the patient.



**CAUTION**

To avoid damage to components due to excessive wear, carry out preventive maintenance and replace parts following the recommended frequency.



**Turbine : estimated working life**

The working life of the turbine depends on the working environment conditions, and on the regular maintenance effected on the device.

**6.5.2 Cleaning, disinfection and sterilization before use with another patient**

We recommend the use of procedures for sterilization and disinfection referred to in the preceding paragraphs when a new patient must use the lung ventilator.



**WARNING !! Risk of injury for the patient**

It is recommended to sterilize / disinfect the lung ventilator every time is used with another patient.

## 6.6 Repairs and spare parts



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

### 6.6.1 Spare parts kit for lung ventilator



**Code: R502000A1**

Spare parts kit for annual maintenance to be used with the Siaretron 4000 15", code 960502.

## 6.7 Miscellaneous

### 6.7.1 Storage



If for any reason the lung ventilator is not used, we suggest leaving it in its original packaging and storing it in a safe and dry place.



If it is believed that the lung ventilator will be left unused for at least 6 months, Siare recommends disconnecting the battery or recharging it every 3/6 months, depending on the storage temperature.

See the technical sheet in the Appendix A.

### 6.7.2 Repackaging and shipment



If it is necessary to return the equipment to SIARE for any reason, we suggest using the original packaging to prevent damage to the equipment during shipment.

If this is no longer available, order a repackaging kit.

### 6.7.3 Disposal

Batteries, accumulators, oxygen cells and electronic parts in general:

- do not put them in the fire, explosion risk
- do not open them, corrosion danger
- do not recharge batteries
- do not throw them away with normal waste.



The batteries and the accumulators are special waste materials and they must be disposed of in appropriate containers in accordance with local regulations for the disposal of such waste materials.



The components of the electronic boards can contain compounds, such as arsenic, lead, cadmium, mutagenic and cancerogenous agents, that are a health hazard if dispersed in the environment in an uncontrolled way.

For further information contact the relevant authorities for environmental and public health monitoring.

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# A APPENDIX

This chapter includes all the information and data necessary to provide full knowledge and interpretation of the Siaretron 4000 15" lung ventilator (*hereinafter called lung ventilator*) manual.

*This chapter describes the following operation.*

- A.1 *Technical sheet*
  - A.1.1 *Ventilator for Intensive Care - code 960502*
- A.2 *Preliminary checks*
- A.3 *Table for Identification of medical gas hose colours*
- A.4 *IP classification*
  - A.4.1 *First digit: solid particle protection*
  - A.4.2 *Second digit: liquid ingress protection*
  - A.4.3 *Additional letters*
- A.5 *Pneumatic diagram*
  - A.5.1 *Pneumatic diagram legend*
- A.6 *Glossary*
- A.7 *Electromagnetic compatibility tables*
  - A.7.1 *Annex A: Table 1*
  - A.7.2 *Annex B: Table 2*
  - A.7.3 *Annex C: Table 3*
  - A.7.4 *Annex E: Table 5*

## A.1 Technical sheet

### A.1.1 Ventilator for Intensive Care - code 960502

#### GENERAL DATA

Siaretron 4000 15" electronic lung ventilator is equipped with turbine and with a TFT 15" colour monitor touch screen displaying the curves of pressure, flow, volume, the loops of breathing parameters, the trends and the ventilation parameters.

Siaretron 4000 15" lung ventilator is suitable for ventilation of adult, paediatric and neonatal patients. Siaretron 4000 15" lung ventilator is equipped with a flow generation system by turbine with separate cooling system granting higher quality and safety standards in patient ventilation.

Siaretron 4000 15" is equipped with a flow and pressure trigger, it provides the most advanced volume controlled ventilation modalities VC/VAC, VC/VAC-BABY, pressure controlled ventilation modalities APCV (BILEVEL ST), APCV-TV, SIMV by Volume and by Pressure, Pressure supported modalities PSV (BILEVEL S), PSV-TV, CPAP, APRV, SIGH, Non Invasive Ventilation (NIV APCV - NIV PSV), Drug Nebulizer and Manual Ventilation (MAN).

Siaretron 4000 15" is supplied with back up long lasting batteries and its software can be updated for new modes and last generation ventilation strategies.

#### NORMS



The lung ventilator complies with the essential requirements and it is realized according to the references of the Annex II of 93/42/EEC Medical Devices Directive.

Class and type according to IEC 601-1

Class I Type B

Class according to 93/42 EEC Directive

Class IIb

Electromagnetic compatibility (EMC)

Conform to the requirements of the EN 60601-1-2:2015 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 60601-2-12:2007; ISO 80601-2-12:2011; ISO 15223-1:2016; DIR. 2011/65/CE; D.Lgs 49/2014; ISO 14971:2012; EN ISO 4135:2001

## ENVIRONMENTAL CONDITIONS

<b>Operating</b>	<ul style="list-style-type: none"><li>▪ Relative humidity: 30 - 95% non-condensing</li><li>▪ Temperature: from +10 to +40°C</li></ul>
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<b>Storage</b>	<ul style="list-style-type: none"><li>▪ Relative humidity: &lt; 95%</li><li>▪ Temperature: from -25 to +70°C</li></ul>
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## TECHNICAL DATA

<b>Dimensions (W x H x D)</b>	Ventilator unit and trolley 530 x 1400 x 460 mm
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<b>Weight</b>	26 Kg
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<b>Electric power supply</b>	100 - 240Vac / 50 - 60Hz
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<i>Power</i>	Max 60 VA
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<i>External power supply (low tension)</i>	12 Vdc / 7 A
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<i>Internal battery</i>	2 batteries (Pb 12 Vdc - 1,3 Ah)
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<i>Internal battery operation</i>	90 minutes max.
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<i>Battery re-charging time</i>	About 8 hours
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<b>External electric connections</b>	<ul style="list-style-type: none"><li>▪ RJ connector for O2 cell connection</li><li>▪ RJ connector for Flow sensor connection</li></ul>
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<i>Electric external connections (optional)</i>	<ul style="list-style-type: none"><li>▪ RS232 for CO2 module</li><li>▪ USB 1 (connector for CPU programming)</li><li>▪ USB 2 (connector for transfer patient data, events, trends)</li></ul>
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<b>Patient connections</b>	Male conic connectors 22 mm / Female of 15 mm (according to EN ISO 5356-1:2015 norm)
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<b>Supply pressure (O<sub>2</sub>)</b>	<ul style="list-style-type: none"><li>▪ Low pressure (max 15 l/min)</li><li>▪ High pressure 280 kPa - 600 kPa / 2.8 - 6 bar / 40 - 86 psi</li></ul>
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<i>Max flow requested (O<sub>2</sub>)</i>	80 l/min
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<b>IP degree of protection</b>	IP21
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## LUNG VENTILATOR FUNCTIONAL FEATURES

Use destination	Ventilator for Intensive Care Therapy; it is suitable for ventilation of Adult, Paediatric and Neonatal patients.
Operation principle	<ul style="list-style-type: none"> <li>• Time cycled at constant volume</li> <li>• Pressure cycled</li> <li>• Microprocessor controlled flow</li> <li>• Spontaneous breath with integrated valve</li> </ul>
Pressure automatic compensation	Automatic compensation of atmospheric pressure on measured pressure: present (max. 5000 mt)
Dead space compensation	Automatic compensation of mechanical and patient circuit dead space
Automatic leaks compensation	Max 60 l/min (NIV APCV , NIV PSV)
Leak % visualization	Present
Visualization of the oxygen consumption calculation	Present
Altitude compensation for oxygen sensor	Present
Respiratory parameters default setting	Present (Neonatal, Paediatric, Adult)
Ventilation modalities	<ul style="list-style-type: none"> <li>• APCV (BILEVEL ST), APCV-TV, PSV (BILEVEL S), PSV-TV (Auto Weaning), VC/VAC, VC/VAC BABY, V-SIMV+PS, P-SIMV+PS, CPAP, APRV</li> <li>• SIGH, NEB (Nebulizer), Apnea BACK-UP (PSV, PSV-TV, CPAP), MANUAL</li> </ul>
Breathing rate VC/VAC	From 4 to 150 bpm
Inspiratory Time / Expiratory Time (maximum, minimum)	<ul style="list-style-type: none"> <li>• Ti min = 0.036sec (minimum inspiratory time)</li> <li>• Ti max = 9.6sec (maximum inspiratory time)</li> <li>• Te min = 0.08sec (minimum expiratory time)</li> <li>• Te max = 10.9sec (maximum expiratory time)</li> </ul>
Breathing rate V-SIMV e P-SIMV	From 1 to 60 bpm
SIMV Inspiratory time	From 0.2 to 5.0 sec.

Tidal volume	<ul style="list-style-type: none"> <li>▪ From 100 to 3000 ml (Adult)</li> <li>▪ From 50 to 400 ml (Paediatric)</li> <li>▪ From 2 to 100 ml (Neonatal)</li> </ul>
I:E ratio	From 1:10 to 4:1
Inspiratory pause	From 0 to 60 % of the inspiratory time
Inspiratory pressure limit	P <sub>insp</sub> : from 2 to 80 cmH <sub>2</sub> O (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)
<b>PEEP</b>	From OFF, 2 to 50 cmH <sub>2</sub> O
<i>PEEP adjustment Microprocessor controlled valve</i>	
O <sub>2</sub> concentration	Adjustable from 21 to 100% with electronic integrated mixer.
Trigger detective method	Through sensor (Pressure or Flow)
<i>Pressure trigger ( I )</i>	
	Pressure adjustable from OFF; -1 to -20 cmH <sub>2</sub> O under PEEP level (step of 1 cmH <sub>2</sub> O)
<i>Flow trigger ( I )</i>	
	Flow adjustable from OFF; 0.3 to 15 L/min
	<ul style="list-style-type: none"> <li>• from 0.3 to 1 L/min (step of 0.1 L/min)</li> <li>• from 1 L/min to 2 L/min (step of 0.5 L/min)</li> <li>• from 2 L/min to 15 L/min (step of 1 L/min)</li> </ul>
<i>Trigger E</i>	
	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 <sub>2</sub> O (PSV, V-SIMV+PS, P-SIMV+PS)
SIGH in VC/VAC modality	<ul style="list-style-type: none"> <li>• Interval: 40 ÷ 500 bpm (step 1 bpm)</li> <li>• Amplitude: OFF, 10 ÷ 100% of set Tidal Volume (step 10%)</li> </ul>
CPAP/PSV	Pressure: from 3 to 50 cmH <sub>2</sub> O
APRV	<ul style="list-style-type: none"> <li>• Time High and Time Low: from 1 to 200 sec.</li> <li>• Pressure High and Pressure Low: from 3 to 50 cmH<sub>2</sub>O.</li> </ul>

<b>Functions</b>	<ul style="list-style-type: none"> <li>• MENU function (SETUP – PATIENT DATA)</li> <li>• Alarms Limits</li> <li>• Graphics visualization (Auto-Range)</li> <li>• INSP Block - EXP Block (max 20 sec.)</li> <li>• O2 100% control (O2 to 100% max. 5 min.)</li> <li>• NEB control (6 l/min)</li> <li>• MAN control (manual ventilation)</li> </ul>
Miscellaneous	Connector for “Remote Alarm”
NEB	Drug nebulizer: selectable to 6 l/min with automatic compensation on forced ventilation modes and dedicated output
Patient circuit	<ul style="list-style-type: none"> <li>• Double hose 150 cm. Adult/Paediatric patient circuit (expiratory valve on the ventilator)</li> <li>• Double hose 150 cm. Neonatal patient circuit (expiratory valve on the ventilator)</li> </ul>
Expandability	Software upgradeable
<b>USER INTERFACE</b>	
Touch screen monitor	Module with TFT LED display with touch screen
<i>Dimensions</i> 15”	
<i>Displaying area</i> 304 x 228 mm	
Display keyboard	<p>Keyboard for rapid access of functions. Encoder knob for:</p> <ul style="list-style-type: none"> <li>• selection, set up and confirmation of physiological breathing parameters</li> <li>• selection and direct activation of function</li> </ul>
Displaying and settings	<ul style="list-style-type: none"> <li>• Operative Mode setting</li> <li>• Visualization of alarm messages and signals</li> <li>• Setting and monitoring of physiological breathing parameters</li> <li>• Visualization of additional graphs and breathing parameters</li> <li>• MENU function for setting operation parameters</li> <li>• Activation of special functions</li> <li>• Visualization of operative mode, clock, date and time functions</li> <li>• Visualization of software version</li> </ul>

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| Calibration Programs | <ul style="list-style-type: none"> <li>• Self Test</li> <li>• Turbine Characterization</li> <li>• Expiratory Flow Sensor Calibration</li> <li>• Usage at High Altitude</li> <li>• VTEc</li> <li>• Nebulizer Enable</li> <li>• ScreenShoot Enable</li> </ul> |
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| <b>MENU function - SETUP</b> | <ul style="list-style-type: none"> <li>• Display (<i>Brightness, Energy Saving, Sound Volume, Touch Audio</i>)</li> <li>• Date &amp; Time</li> <li>• Language</li> <li>• Units (Weight, Height, CO2, Pressure)</li> <li>• Default (Default parameters: Erase Trend data, Erase Patient data, Setting &amp; Ventilation Default)</li> <li>• Other (NIV Enable, Power Failure, Apnea Time, Change Password, Save to USB)</li> <li>• Gas Sensor (IRMA/ISA)</li> <li>• Supplementary Tests (Expiratory Flow Sensor Calibration, O2 Sensor Calibration)</li> <li>• Turn Off?</li> </ul> |
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<b>MENU function - PATIENT DATA</b>	The PATIENT DATA can be set or deleted
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<b>Alarm Limits</b>	PAW (cmH2O), PEEP (cmH2O), Vte (ml), VM (L/min), O2 (%), RR (bpm), EtCO2 ( % )
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|---------------------------|--|
| <b>Displayed graphics</b> | <ul style="list-style-type: none"> <li>• CURVES: Pressure (PAW) - Flow - Volume (Vte) - O2 (CO2 optional)</li> <li>• LOOPS: Pressure / Volume - Flow / Volume - Pressure/Flow</li> <li>• Graphics: INSP-EXP cycle</li> <li>• Events</li> <li>• Trends</li> </ul> |
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*Events* Memory storage up to 100 machine events including the alarms.

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*Trends* Storage capacity (72 h) of all measured parameters.

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Physiological breathing parameters setting	Vti (ml), RR (bpm), I:E, Pause (%), PEEP (cmH2O), O2 (%), Tr. I (L/min - cmH2O), SIGH (Sigh. Amp. (%), Sigh. Int. (b)), Vte (ml), PMax, Pmin, Pinsp (cmH2O), Slope, BACK-UP parameters, PS (cmH2O), RRsimv (bpm), Ti (s), Ti Max (s), Tr. E (%), CPAP (cmH2O), Pressure High - Low (cmH2O), Time High - Low (s).
<i>Range of measured parameters</i>	<ul style="list-style-type: none"> <li>• Respiratory rate (range: 0 ÷ 200 bpm)</li> <li>• I:E ratio (range 1:99 ÷ 99:1)</li> <li>• % of O2 (range: 0% ÷ 100%)</li> <li>• Tidal Volume: Vte, Vti (range: 0 ÷ 3000 ml)</li> <li>• Minute Volume (range: 0 ÷ 40 l/min)</li> <li>• PAW: peak, mean, plateau, PEEP (range -20 ÷ 80 cmH2O)</li> <li>• Inspiratory Peak Flow: Fi (range: 1 ÷ 190 l/min)</li> <li>• Expiratory Peak Flow: Fe (range: 1 ÷ 150 l/min )</li> <li>• Tinsp., Texp, Tpause (range 0.036 ÷ 10.9 sec)</li> <li>• Static and Dynamic compliance (range: 10 ÷ 150 ml/cmH2O)</li> <li>• Resistance (range: 0 ÷ 400 cmH2O/l/s)</li> <li>• EtCO2: with optional CO2 module (range: 0 ÷ 10%)</li> <li>• Leak (%) (range: 0 ÷ 100%)</li> <li>• O2 consumption (range: 0 ÷ 100l/min)</li> </ul>
<i>Displayed parameters</i>	PAW, PEEP, CPAP (cmH2O), RR (bpm), I:E, O2 (% - l/min), Vte (ml), VM (L/min), EtCO2 ( % ), MAP (cmH2O), Pplateau (cmH2O), Fi , Fe (L/min),  Ti, Tpause, Te (sec.), Ri (cmH2O/l/s), Cs, Cd (ml/cmH2O), Leak ( % )
<b>Flow sensor</b>	Magnetic disturbance (patented), multi-usage type
<i>Calibration</i>	Automatic (started by the operator)
<i>Maintenance</i>	By steam or chemical disinfection
<b>Oxymeter</b>	Electronic (value displayed in breathing parameters)
<i>Calibration</i>	Automatic (started by the Operator)
<b>CO2 analyzer</b>	Optional function (Sidestream or Mainstream module available)

## ALARMS

Alarm types	By MENU: with limits set by the operator By DEFAULT: the operator cannot set them up
Alarm default setting	Present (Neonatal, Paediatric, Adult)
Alarm priority	High - Mean - Standby
Alarms visualization	Max 3 alarms simultaneously; additional alarms, scroll every 3-5 sec.

### *Alarms with limits set up by the operator*

Pressure of Airways	High – Low
Respiratory Rate	High – Low
Expiratory Volume	High – Low
Volume Minute	High – Low
PEEP	High – Low
O2 Concentration	High – Low
EtCO2	High – Low (with optional CO2 gas analyser)
On Battery	Alarm occurs in case of failure of external power supply
Apnoea	Low Rate (function of Apnoea BACK-UP)

### *System alarms*

Low Battery: 50% Remaining	Battery at 50%
Low Battery: 25% Remaining	Battery at 25%
Low Battery	10 Minutes
Battery Disconnected	Yes / No
Battery Overtemperature	Indication of exceeding the temperature limits inside the battery
Circuit Disconnected	Indication of patient circuit disconnected
O2 Supply	Low (< 2,7 bar)

Turbine Failure	Signals in case of a blower fault condition
Turbine Overtemperature	Indication of exceeding the temperature limits inside the turbine
Turbine Overcurrent	Indication of exceeding the current limits inside the turbine
Maintenance	1000 hours
CO2 Analyzer	Sampling Line Clogged, No Sampling Line, Replace Adapter, No Adapter, Unspecified Accuracy, Error, No Breaths, Low/High EtCO2.

### **SELF-TEST alarms**

Turbine	The correct functioning of the turbine is tested
Oxygen emptying	It is performed a washing of the remaining oxygen present within the lung ventilator, order to measure the offset of the oxygen sensor
INSP.- EXP. Flow sensor	Verification of EXP flow sensor operation
Pressure sensor	Verification of pressure sensor operation through control of PAW reading
Electrovalve	The correct functioning of electro-valve is tested
Patient circuit	Verification of patient circuit
Battery	Checking on battery power
Oxygen sensor	Cell condition
Acoustic alarm	Verification by the user of acoustic signal emission, the confirmation of the test is made by silencing of that alarm

### **ACCESSORIES**

- Supplied Accessories**
- User's Manual
  - Double hose patient circuit
  - Antibacterial filter for patient circuit
  - Nebulizer set
  - Power cable
  - O2 supply hose
  - O2 cell

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**Optional Accessories** Refer to price list.

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## A.2 Preliminary checks



See the table here below.

### List of preliminary checks

REF.	DESCRIPTION	MEASURE	RESULT	NOTES
1.	ON/OFF SWITCH		<input type="checkbox"/> Pos. <input type="checkbox"/> Neg.	
2.	SELF TEST overcome		<input type="checkbox"/> Pos. <input type="checkbox"/> Neg.	
3.	O <sub>2</sub> sensor calibration (TEST)	_____ %	<input type="checkbox"/> Pos. <input type="checkbox"/> Neg.	
4.	O <sub>2</sub> - FiO <sub>2</sub> alarm check		<input type="checkbox"/> Pos. <input type="checkbox"/> Neg.	
5.				
<b>OPERATIVE MODE : VC-VAC / PARAMETERS MONITORING</b>				
6.	Vti check: <b>500mv</b>		<input type="checkbox"/> Pos. <input type="checkbox"/> Neg.	
7.	Rate check: <b>15</b>		<input type="checkbox"/> Pos. <input type="checkbox"/> Neg.	
8.	I:E ratio check: <b>1:2</b>		<input type="checkbox"/> Pos. <input type="checkbox"/> Neg.	
9.	PEEP check: ( <b>5 – 10 cmH<sub>2</sub>O</b> )		<input type="checkbox"/> Pos. <input type="checkbox"/> Neg.	
10.	PAUSE check: <b>50 %</b>		<input type="checkbox"/> Pos. <input type="checkbox"/> Neg.	
11.	FiO <sub>2</sub> check: <b>21%</b>		<input type="checkbox"/> Pos. <input type="checkbox"/> Neg.	

<b>ALARM CHECKS</b>					
12.	High / Low Pressure		<input type="checkbox"/> Pos.	<input type="checkbox"/> Neg.	
13.	High / Low Frequency		<input type="checkbox"/> Pos.	<input type="checkbox"/> Neg.	
14.	High / Low Expired Vte		<input type="checkbox"/> Pos.	<input type="checkbox"/> Neg.	
15.	High / Low Volume Minuto		<input type="checkbox"/> Pos.	<input type="checkbox"/> Neg.	
16.	High / Low airways PEEP		<input type="checkbox"/> Pos.	<input type="checkbox"/> Neg.	
17.	High / Low oxygen concentration		<input type="checkbox"/> Pos.	<input type="checkbox"/> Neg.	
18.	Main power failure		<input type="checkbox"/> Pos.	<input type="checkbox"/> Neg.	
19.	Gas supply failure		<input type="checkbox"/> Pos.	<input type="checkbox"/> Neg.	
20.	High / Low EtCO <sub>2</sub>		<input type="checkbox"/> Pos.	<input type="checkbox"/> Neg.	(with optional CO <sub>2</sub> module)
<b>RESPIRATORY PARAMETERS CHECKS</b>					
21.	Pmax Check		<input type="checkbox"/> Pos.	<input type="checkbox"/> Neg.	
22.	Peep Check		<input type="checkbox"/> Pos.	<input type="checkbox"/> Neg.	
23.	Rate Check		<input type="checkbox"/> Pos.	<input type="checkbox"/> Neg.	
24.	I:E Check		<input type="checkbox"/> Pos.	<input type="checkbox"/> Neg.	
25.	O <sub>2</sub> Check		<input type="checkbox"/> Pos.	<input type="checkbox"/> Neg.	
26.	Vte Check		<input type="checkbox"/> Pos.	<input type="checkbox"/> Neg.	
27.	VM Check		<input type="checkbox"/> Pos.	<input type="checkbox"/> Neg.	

### A.3 Table for Identification of medical gas hose colours

<b>GAS</b>	<b>SYMBOL</b>	<b>ISO &amp; UK</b>	<b>USA</b>	<b>GERMANY</b>
OXYGEN	O <sub>2</sub>	White	Green	Blue
NITROUS OXIDE	N <sub>2</sub> O	Blue	Blue	Grey
CARBON DIOXIDE	CO <sub>2</sub>	Grey	Grey	-
CYCLOPROPANE	C <sub>3</sub> H <sub>6</sub>	Orange	Orange	-
MEDICAL AIR	AIR	White & Black	Yellow	Yellow
ENTONOX 50/50 N <sub>2</sub> O/O <sub>2</sub>	N <sub>2</sub> O + O <sub>2</sub>	Blue & White	-	-
EMPTY	-	Yellow	-	-

## A.4 IP classification

The IP Code, International Protection Marking, IEC standard 60529, sometimes interpreted as Ingress Protection Marking, classifies and rates the degree of protection provided against intrusion (body parts such as hands and fingers), dust, accidental contact, and water by mechanical casings and electrical enclosures. It is published by the International Electro technical Commission (IEC).

The equivalent European standard is EN 60529. This table shows what each digit or part of the IP code represents.

IP indication	First digit	Second digit	Third digit	Additional letter
	Solid particle protection	Liquid ingress protection	Mechanical impact resistance	Other protections
IP	Single numeral: 0 – 6	Single numeral: 0–9	Single numeral: 0 – 9	Single letter
Mandatory	Mandatory	Mandatory	No longer used	Optional

### A.4.1 First digit: solid particle protection

The first digit indicates the level of protection that the enclosure provides against access to hazardous parts (e.g., electrical conductors, moving parts) and the ingress of solid foreign objects.

Level sized	Effective against	Description
0	—	No protection against contact and ingress of objects
1	>50 mm	Any large surface of the body, such as the back of a hand, but no protection against deliberate contact with a body part
2	>12.5 mm	Fingers or similar objects
3	>2.5 mm	Tools, thick wires, etc.
4	>1 mm	Most wires, slender screws, large ants etc.
5	Dust protected	Ingress of dust is not entirely prevented, but it must not enter in sufficient quantity to interfere with the satisfactory operation of the equipment.
6	Dust tight	No ingress of dust; complete protection against contact (dust tight). A vacuum must be applied. Test duration of up to 8 hours based on air flow.

#### A.4.2 Second digit: liquid ingress protection

The second digit indicates the level of protection that the enclosure provides against harmful ingress of water. The ratings for water ingress are not cumulative beyond IPX6.

A device which is compliant with IPX7, covering immersion in water, need not be compliant with IPX5 or IPX6, covering exposure to water jets. A device which meets both tests is indicated by listing both tests separated by a slash, e.g. IPX5 / IPX7.

Level	Protection against	Effective against	Details
0	None	—	—
1	Dripping water	Dripping water (vertically falling drops) shall have no harmful effect on the specimen when mounted in an upright position onto a turntable and rotated at 1 RPM.	Test duration: 10 minutes. Water equivalent to 1 mm rainfall per minute.
2	Dripping water when tilted at 15°	Vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle of 15° from its normal position.  A total of four positions are tested within two axes.	Test duration: 2.5 minutes for every direction of tilt (10 minutes total).  Water equivalent to 3 mm rainfall per minute.
3	Spraying water	Water falling as a spray at any angle up to 60° from the vertical shall have no harmful effect, utilizing either: a) An oscillating fixture, or b) A spray nozzle with a counterbalanced shield.  Test a) is conducted for 5 minutes, then repeated with the specimen rotated horizontally by 90° for the second 5-minute test.  Test b) is conducted (with shield in place) for 5 minutes minimum.	For a spray nozzle:  Test duration: 1 minute per square meter for at least 5 minutes  Water volume: 10 litres per minute  Pressure: 50–150 kPa  For an oscillating tube:  Test duration: 10 minutes  Water Volume: 0.07 l/min per hole
4	Splashing of water	Water splashing against the enclosure from any direction shall have no harmful effect, utilizing either: a) An oscillating fixture, or b) A spray nozzle with no shield.  Test a) is conducted for 10 minutes.  Test b) is conducted (without shield) for 5 minutes minimum.	Oscillating tube:  Test duration: 10 minutes, or spray nozzle (same as IPX3 spray nozzle with the shield removed).

Level	Protection against	Effective against	Details
5	Water jets	Water projected by a nozzle (6.3 mm) against enclosure from any direction shall have no harmful effects.	Test duration: 1 minute per square meter for at least 15 minutes Water volume: 12.5 litres per minute Pressure: 30 kPa at distance of 3 m
6	Powerful water jets	Water projected in powerful jets (12.5 mm nozzle) against the enclosure from any direction shall have no harmful effects.	Test duration: 1 minute per square meter for at least 3 minutes Water volume: 100 litres per minute Pressure: 100 kPa at distance of 3 m
6K	Powerful water jets with increased pressure	Water projected in powerful jets (6.3 mm nozzle) against the enclosure from any direction, under elevated pressure, shall have no harmful effects. Found in DIN 40050, and not IEC 60529.	Test duration: at least 3 minutes Water volume: 75 litres per minute Pressure: 1000 kPa at distance of 3 m
7	Immersion, up to 1 m depth	Ingress of water in harmful quantity shall not be possible when the enclosure is immersed in water under defined conditions of pressure and time (up to 1 m of submersion).	Test duration: 30 minutes - ref IEC 60529, table 8. Tested with the lowest point of the enclosure 1000 mm below the surface of the water, or the highest point 150 mm below the surface, whichever is deeper.
8	Immersion, 1 m or more depth	The equipment is suitable for continuous immersion in water under conditions which shall be specified by the manufacturer. However, with certain types of equipment, it can mean that water can enter but only in such a manner that it produces no harmful effects. The test depth and duration is expected to be greater than the requirements for IPx7, and other environmental effects may be added, such as temperature cycling before immersion.	Test duration: Agreement with Manufacturer. Depth specified by manufacturer, generally up to 3 m .

Level	Protection against	Effective against	Details
<b>9K</b>	Powerful high temperature water jets	<p>Protected against close-range high pressure, high temperature spray downs.</p> <p>Smaller specimens rotate slowly on a turntable, from 4 specific angles. Larger specimens are mounted upright, no turntable required, and are tested freehand for at least 3 minutes at distance of 0.15–0.2 m.</p> <p>There are specific requirements for the nozzle used for the testing.</p> <p>This test is identified as IPx9 in IEC 60529.</p>	<p>Test duration: 30 seconds in each of 4 angles (2 minutes total)</p> <p>Water volume: 14–16 litres per minute</p> <p>Pressure: 8–10 MPa (80–100 bar) at distance of 0.10–0.15 m</p> <p>Water temperature: 80 °C</p>



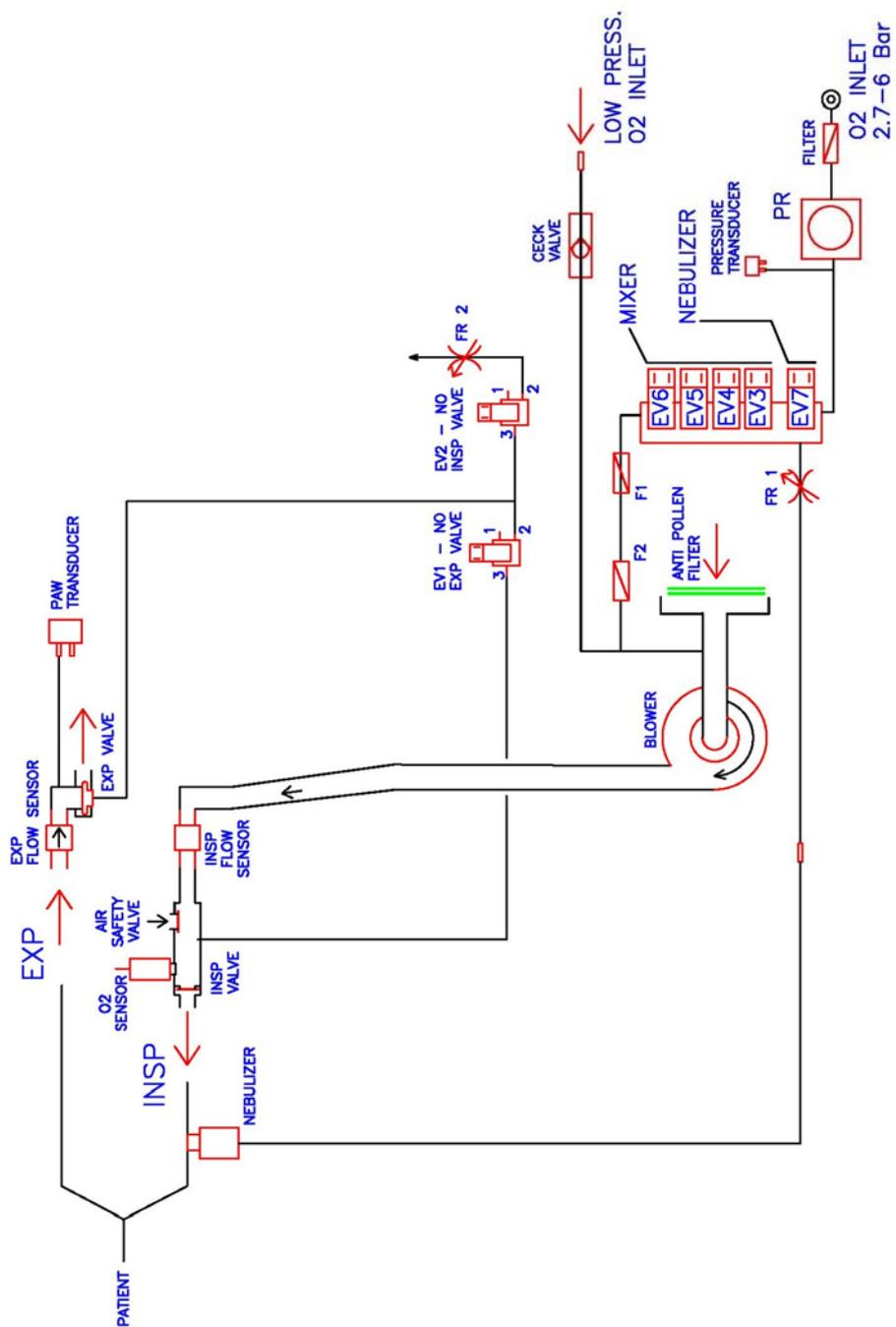
(All tests with the letter "K" are defined by ISO 20653 (replacing DIN 40050-9) and are not found in IEC 60529, except for IPx9 which is the same as the IP69K water test.)

#### A.4.3 Additional letters

Further letters can be appended to provide additional information related to the protection of the device.

Letter	Meaning
<b>f</b>	Oil resistant
<b>H</b>	High voltage device
<b>M</b>	Device moving during water test
<b>S</b>	Device standing still during water test
<b>W</b>	Weather conditions

## A.5 Pneumatic diagram



## A.5.1 Pneumatic diagram legend

<b>O<sub>2</sub> ( 2,7 - 6 Bar )</b>	Inlet for medical oxygen coming from a high pressure source (2,7 – 6 bar).
<b>Filter</b>	Medical gas infeed filter
<b>PR</b>	Pressure regulator. It reduces the infeed gas pressure at a stable value of 2.6 bar.
<b>Pressure transducer</b>	Medical gas supply pressure sensor. It signals when the gas pressure is missing or is insufficient.
<b>MIXER</b>	Group of 4 electro-valves, that opening and closing, allow the mixing of O <sub>2</sub> with Air at a frequency corresponding to the O <sub>2</sub> concentration set.
<b>Blower</b>	The turbine is driven by a brushless motor and it has the function to administrate the room air to the patient, once opportunely filtered by a dust and pollen filter at inlet. The turbine rotation speed is regulated by a microprocessor control.
<b>Oxygen sensor</b>	Polarographic oxygen transducer. It measures the real oxygen concentration administered to the patient.
<b>Flow sensor</b>	It has the function to measure the flows of Air and O <sub>2</sub> administered to the patient. The measuring range of such a sensor is from 0.1 to 200 l/min.
<b>INSP valve</b>	Unidirectional mechanical valve positioned on the inspiratory line. It has the function to allow the patient to breathe room air in case of emergency and to protect the turbine against backflows on inspiratory line.
<b>PAW pressure transducer</b>	Pressure sensor by semi-conductor. It has the function to continuously measure the inner pressure of breathing circuit.
<b>EXP valve</b>	Expiratory valve servo-controlled by the EV1-NA and EV2-NA electro-valves, it is closed during the inspiratory phase and it is open during the expiratory phase.
<b>EV1-NA</b>	12 V pilot electro-valve, normally open, controlled by microprocessor, it is closed when the PEEP value is set on 0 or in case the high pressure alarm limit is reached.
<b>EV2-NA</b>	12 V pilot electro-valve, normally open, controlled by microprocessor, it has the function to regulate the necessary flow to drive the expiratory valve.

## A.6 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.
APCV	Pressure controlled ventilation: type of controlled ventilation during which the ventilator delivers an inspiratory pressure set by the user for an inspiratory time also set by the user.
Apnoea	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 <sub>2</sub> O	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 <sub>2</sub> O. 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
EPU	Electric power supply unit: the battery powers the system with direct current if the alternate current supply is not available. On the basis of the ventilator settings, the battery can provide back-up power for at least 3 hours in rated and perfect working conditions.
Error	Category of conditions detected during functioning of the system implying an open safety status. A fan FAILURE means that the fan cannot be clinically used and must be repaired immediately.
EXP. PAUSE	Expiratory pause, a manoeuvre started by the user which closes the inspiratory and expiratory valves during the expiratory phase of a breath.
FiO <sub>2</sub>	Parameter set by the user and monitored. The % setting of FiO <sub>2</sub> determines the percentage of oxygen in the gas delivered to the patient. The monitored data of the % of FiO <sub>2</sub> 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 <sub>2</sub> O).
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 organisation for the definition of standards.

INSP. PAUSE	Inspiratory pause, a manoeuvre started by the user which closes the inspiratory and expiratory valves during the inspiratory phase of a breath. This manoeuvre can be used to determine the static compliance (C) and the resistance (R).
IPPV	Intermittent Positive Pressure Ventilation
IPPV - AST	Assisted Intermittent Positive Pressure Ventilation: a ventilation mode that makes it possible to deliver only controlled ventilation (started by the patient, the ventilator or the user) on the basis of the current settings.
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	Metre (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
PCV	Pressure controlled ventilation: a type of controlled ventilation during which the ventilator delivers an inspiratory pressure set by the user for an inspiratory time also set by the user.
PEEP	Positive end expiratory pressure: the minimum level of pressure maintained in the patient circuit during ventilation. Parameter set by the user and monitored.
Pressure Trigger	Method of recognition of the inspiratory effort of the patient, in which the ventilator controls the pressure in the patient circuit. The ventilator enables ventilation when the airways pressure decreases by an amount at least equal to the selected threshold value in a defined period of time.
PSV	Pressure support ventilation: a type of spontaneous ventilation in which the ventilator delivers pressure set by the user during the inspiratory phase.
RAM	Random access memory
Resistance (Ri)	The drop in pressure caused by a flow passing through a conduit: measured in $\text{cmH}_2\text{O}/(\text{litres}/\text{sec})$ or $\text{hPa}/(\text{litres}/\text{sec})$ . (peak pressure - pause pressure / inspiratory flow).
sec	Second (unit of time).
SIMV+PS	Synchronized Intermittent Mandatory Volumetric ventilation with spontaneous ventilation by pressure support.
SPONT	In SPONT mode, the patient activates all ventilations delivered by ventilator without any controlled respiratory rate set. The patient makes spontaneous breaths by pressure support.
STANDBY	Ventilation system in pause status: no ventilation is enabled when the ventilator is in this status.

System error	Definition used by the safety system of the ventilator. System errors include faults of the hardware inside the ventilator and which affect its performance, software errors which occur momentarily inside the ventilator and interfere with its normal functioning, an inadequate supply of alternate current or gas and the problems of integrity of the patient circuit (block or disconnection). In general system errors are not corrected automatically
T Exp	Expiratory time: duration of the expiratory interval of a breath.
T Insp	Inspiratory time: duration of the inspiratory interval of a breath.
T pause	Pause time: percentage of inspiratory time during which the ventilator maintains a constant airways pressure. Used for calculation of the respiratory mechanics parameters (compliance and resistance).
Tidal volume	Inspired and expired tidal volume during each breath. The value delivered by the system is a parameter set by the user which determines the volume delivered to the patient during controlled volume ventilation. Tidal volume includes the compensation for compliance and for pressure and body temperature.
TREND	Medium and long-term monitoring of the respiratory parameters.
VA	Volt - Ampere (unit of power).
Vac	Alternate current voltage
VC-VAC	Intermittent ventilation by assisted positive pressure: a ventilation mode which allows to deliver controlled ventilations only (started by the patient, by the ventilator or by user) basing on current settings.
Vdc	Direct current voltage
Ventilations per minute (bpm)	Respiratory rate unit (Resp/min).

## A.7 Electromagnetic compatibility tables

### A.7.1 Annex A: Table 1

Guidance and manufacturer's declaration – electromagnetic emissions			
The Siaretron 4000 is intended for use in the electromagnetic environment specified below. The customer or the user of the Siaretron 4000 should assure that it is used in such an environment.			
Emissions test	Compliance	Verdict	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	Compliance	The Siaretron 4000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	Compliance	The Siaretron 4000 is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:  <b>Warning:</b> This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Siaretron 4000 or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	Class A, B, C, D, or NOT APPLICABLE	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliance	Compliance	

## A.7.2 Annex B: Table 2

<b>Guidance and manufacturer's declaration – electromagnetic immunity</b>			
The Siaretron 4000 is intended for use in the electromagnetic environment specified below. The customer or the user of the Siaretron 4000 should assure that it is used in such an environment.			
<b>IMMUNITY test</b>	<b>IEC 60601 test level</b>	<b>Compliance level / Virdict</b>	<b>Electromagnetic environment – guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 Kv contact ± 8 kV air	± 6 kV contact ± 8 kV air	Residential – Hospital – Other
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Residential – Hospital – Other
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Residential – Hospital – Other
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle  40 % UT (60 % dip in UT) for 5 cycles  70 % UT (30 % dip in UT) for 25 cycles  <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0,5 cycle  40 % UT (60 % dip in UT) for 5 cycles  70 % UT (30 % dip in UT) for 25 cycles  <5 % UT (>95 % dip in UT) for 5 s	Residential - Hospital - Other
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Residential - Hospital - Other

**NOTE** UT is the a.c. mains voltage prior to application of the test level.

**A.7.3 Annex C: Table 3**

<b>Guidance and manufacturer’s declaration – electromagnetic immunity</b>				
The Siaretron 4000 is intended for use in the electromagnetic environment specified below. The customer or the user of the Siaretron 4000 should assure that it is used in such an environment.				
<b>IMMUNITY test</b>	<b>IEC 60601 TEST LEVEL</b>	<b>Compliance level effective</b>	<b>Compliance level</b>	<b>Electromagnetic environment – guidance Recommended separation distances</b>
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands	VRMS	[V1] VRMS	SEE ANNEX E
	10 Vrms 150 kHz to 80 MHz in ISM bands	VRMS	[V2] VRMS	SEE ANNEX E
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	V/m	[E1] V/m	80 ÷ 800 MHz SEE ANNEX E
				800 ÷ 2500 MHz SEE ANNEX E
<p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>				
<p><b>Note:</b></p> <ol style="list-style-type: none"> <li>At 80 MHz and 800 MHz, the higher frequency range applies.</li> <li>These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</li> </ol>				

**A.7.4 Annex E: Table 5**

<b>Recommended separation distances between portable and mobile RF communications equipment and the Siaretron 4000.</b>				
<p>The Siaretron 4000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Siaretron 4000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Siaretron 4000 as recommended below, according to the maximum output power of the communications equipment.</p>				
Rated maximum output power of transmitter  <b>W</b>	Separation distance according to frequency of transmitter m			
	150 kHz ÷ 80 MHz outside ISM bands  $d = \left[ \frac{3,5}{V_1} \right] \sqrt{P}$	150 kHz ÷ 80 MHz in ISM bands  $d = \left[ \frac{12}{V_2} \right] \sqrt{P}$	80 MHz ÷ 800 MHz  $d = \left[ \frac{12}{E_1} \right] \sqrt{P}$	800 MHz ÷ 2,5 GHz  $d = \left[ \frac{23}{E_1} \right] \sqrt{P}$
0,01	0,12	0,12	0,12	0,23
0,1	0,37	0,38	0,38	0,73
1	1,17	1,20	1,20	2,30
10	3,69	3,79	3,79	7,27
100	11,67	12,00	12,00	23,00
<p>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.</p> <p><b>Note :</b></p> <ol style="list-style-type: none"> <li>At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</li> <li>The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.</li> <li>An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.</li> </ol>				

**Note: the values shown in the table refer to the standard levels of the norm, 3V for V<sub>1</sub> and 10V for V<sub>2</sub>**



# **Siaretron 4000 - 15''**

## **ICU ventilator**

*Turbine-driven ventilation*

*Touch-Screen*

### **User's Manual - 960502**

*User's Manual, version DU3502101*

**Revision 1 - 10.02.2019**

#### **SIARE ENGINEERING INTERNATIONAL GROUP s.r.l.**

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