ENGINEERING
INTERNATIONAL GROUP s.r.l.

Morpheus ND

Anaesthesia Unit

User's Manual

GENERAL INFORMATION

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The operation and maintenance must be entrusted to qualified technical personnel only. The responsibility of SIARE ENGINEERING INTERNATIONAL GROUP s.r.l. as regards the anaesthesia unit and its use is limited to what is indicated in the guarantee supplied with the equipment.

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The information contained in this manual refers to the versions of MORPHEUS anaesthesia unit (_***ND***) produced or updated after January 2018. 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 DU33ND101

Revision - 13.05.2019.

Observations

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

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

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

CE 0476

Directive 93/42 EEC

Definitions

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

WARNING!!

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

CAUTION

This indicates the possibility of danger to the anaesthesia unit.

NOTE

This indicates information worthy of note, making the operation of the anaesthesia unit 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 of anaesthesia unit and the relative safety regulations.

- In order to understand how the anaesthesia unit 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 anaesthesia unit 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 anaesthesia unit must only be used for the purposes specified herein and the safety of the anaesthesia unit is therefore only guaranteed if it is used in accordance with the instructions given in this manual.
- The anaesthesia unit 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 anaesthesia unit is installed. Furthermore, during all the operation of anaesthesia unit, 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 anaesthesia unit or authorised modifications to the anaesthesia unit. 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 anaesthesia unit (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 anaesthesia unit in a safe and correct manner.
- To prevent the risk of fire, keep the anaesthesia unit 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 anaesthesia unit 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 anaesthesia unit.
- 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 anaesthesia unit should immediately be disconnected from the electrical power supply and from the battery (if fitted).
- When coming into contact with any component of the anaesthesia unit, 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 anaesthesia unit is installed be taken into consideration.
- The anaesthesia unit 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 anaesthesia unit or any connected component, carefully check that the anaesthesia unit 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 anaesthesia unit 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 anaesthesia unit (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 anaesthesia unit 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 anaesthesia unit 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 anaesthesia unit 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 anaesthesia unit is not approved for operation in places where there is any risk of explosion.
- The anaesthesia unit cannot be used in the presence of explosive gases.
- Do not use the anaesthesia unit in the presence of flammable gases.

WARNING !!

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

WARNING !!

- Before starting the anesthesia unit use, you have to carry out the preliminary checks.
- Qualified staff must make the regulation of ventilation parameters.
- Do not block the gas intake port or emergency intake port (valves group), thereby interfering with PATIENT ventilation.

WARNING !!

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

WARNING !!

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

WARNING !!

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

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

- If the anaesthesia unit is used in conditions and for purposes not stated or described in this manual.
- If the anaesthesia unit 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 anaesthesia unit 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 anaesthesia unit not in accordance with the instructions contained in the User's manual.

Year of manufacture

Check the identification data label of the MORPHEUS anaesthesia unit in the relative chapter.

Shelf life of medical device

The Directive 93/42/EEC 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 MORPHEUS anaesthesia unit is 10 years.

Manufacturer

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Electromagnetic Compatibility

The MORPHEUS anaesthesia unit is designed to operate in the specified electromagnetic environment (see warning below).

The customer or the user of MORPHEUS anaesthesia unit should ensure that it is used in such an electromagnetic environment.

The MORPHEUS anaesthesia unit 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 Anaesthesia unit 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 equipment could influence its operation. Whenever the anaesthesia unit 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 MORPHEUS anaesthesia unit user’s 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 PRESENTATION

SIARE ENGINEERING INTERNATIONAL GROUP s.r.l. is glad to introduce this new product, as the result of 40 years of experience and investment in technological innovation that we are implementing in recent years. Siare has heavily focused on the innovation of materials, ergonomics and ease of use.

The outcome of this work is a new anaesthesia unit which incorporates all advanced modalities required in modern gaseous anaesthesia, to meet all the expectations of end users.

The new anaesthesia unit, “MORPHEUS_ND HYBRID “, is considerably different from all the former ones manufactured versions: in fact, it can be configurable in different ways to respond to the numerous market demands and requirements.

The “MORPHEUS_ND HYBRID “, marks an epochal step, having solved all the critical points of an anaesthesia machine. SIARE has always been an innovative company in anaesthesia and intensive care, offering safe products realized with the suggestions and experience of the most exigent anaesthetists and resuscitation therapy doctors.

1.1 Intended Use

The Morpheus anaesthesia unit equipped with a 15” colour Touch Screen display, is an equipment of new generation, projected to be used in anaesthesia wards.

The lung ventilation module provides new advanced features for operative modes management; it is equipped with different ventilation functions and thanks to its keyboard and encoder knob the user’s selection of most suitable settings are simplified. Varying the breathing parameters, adjustable by user’s interface, the Morpheus_ND HYBRID anaesthesia unit can be used on Adults, Children, Neonatal patients.

The Morpheus_ND HYBRID anaesthesia unit is suitable for the administration of: Oxygen - Air - Nitrous Oxide / Xenon - Halothane - Enfluorane - Isoflurane - Sevoflurane - Desflurane mixtures. The fraction of inspired oxygen can vary from 21% to 99%.

For a correct comprehension of Morpheus_ND HYBRID anaesthesia unit operation and for a correct and safe use both for the Patient and User, the knowledge of recommendations and instructions indicated in the present User’s Manual is required.

For anyone who already has basic knowledge of anaesthesia unit functioning and of ventilation in general, the use of the “graphics user interface“ is intuitive and it will be sufficient to consult this user’s manual in order to use the anaesthesia unit correctly.

WARNING !!

The Morpheus_ND HYBRID anaesthesia unit 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.

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

1.2 Main innovations

The Morpheus_ND HYBRID anaesthesia unit represents a true new revolution, engineered with the help of anaesthetists of proven experience aiming to realize a safe device both for the doctor and for the patient.

The anaesthesia unit is equipped by a Turbine (hence the name “Morpheus HYBRID”) and provides a double functionality: the traditional gas supply system (Air and Oxygen) and the turbine functioning (in this case it is not necessary a pneumatic Air supply for the movement of the breathing system bellows). The system, during the switching on and the ‘Self-Test’ phase, detects the turbine functionality and prepare the anaesthesia unit for the correct functionality. In case of turbine operation, it is however and always necessary to foreseen an oxygen supply source, useful for operation of internal pneumatic system of Morpheus anaesthesia unit.

This double functionality presents important advantages and among them. Use of the equipment in environments where there is a lacking of medical air (this way, a considerable quantity of oxygen necessary for the pneumatic system, can be saved); moreover, this double functionality, in case of fault of one of the two systems the other is always available: it’s like to have an emergency ventilation always at your disposal.

1.2.1 Strengths of the new Morpheus_ND HYBRID

- Extremely small dimensions and weight (25 Kg without accessories): it can be positioned in any environment and situation, on a trolley, on a wall unit, on a shelf, etc.
- Can be equipped with a trolley (on request).
- It can be positioned both left and right of the patient thanks to the rotatable connections.
- Technologically advanced it is designed for a long life; requires low maintenance with low management costs.
- Turbine drive: external compressed air sources are not required; ideal in environments characterized by limited infrastructure or with the need for frequent travel and transport
- 15 "touch screen display. High resolution with easy and intuitive graphic interface; visualization of the ventilation graphs, loops, respiratory parameters, of the percentage value of the losses (Leak: %) and of the value in Liters / minute of the oxygen consumption (L / min).
- Reduced, simple and ergonomic controls.
- Intelligent graphic interface: the doctor has all the parameters under control and can choose the visual configuration he prefers.
- Double controls: in the event of a malfunction of the touch screen system it is possible to continue with the manual controls: encoder knob and keys (or vice versa).
- Dedicated ventilation for: Adults, Children and Infants (up to 2 ml to 1500 ml); when switched on it allows you to choose the type of patient (newborn, child, adult) by automatically setting the relative default respiratory parameters.
- The lung ventilator can work even in the absence of compressed gas and mains voltage. A special ultra-low noise compressor (29dB) guarantees the functionality of the fan even on battery power. Furthermore, the patented HYBRID system allows operation with compressed gases in the event of compressor failure. It is therefore also suitable for use in difficult and uncomfortable situations such as field hospitals etc.
- The patient circuit is quickly disassembled without additional pipe connections

- Standard auxiliary fresh gas outlet
- The fresh gas dosing system guarantees maximum safety thanks to the redundant system with double valve and double control. In this way, the supply of oxygen or overdoses of nitrous oxide in the event of a failure will never be interrupted.
- Emergency back-lit oxygen flowmeter that can be used even when the machine is off.
- The incorporated PROTOLOCK system identifies any wrong connection of the incoming gases during the initial test phase: this device avoids potentially deadly situations for the patient, as already happened with traditional systems.

1.3 Main characteristics: anaethesia unit structure

The mechanic structure of the anaesthesia unit is made of light aluminium alloy and plastic moulds: this ensures an excellent impact resistance thanks to its flexibility and excellent abrasion resistance.

The mechanic structure also includes:

- the housing for the valves group,
- the manual ventilation controls, a mechanical flow meter and three pressure gauges
- on the back side are provided the medical gas intakes, which are positioned in a rational and easily visible way,
- two horizontal guide for vaporizer supports (a vaporizer in use and one in parking)

The dimensions and weight of the anaesthesia unit are very reduced and allow its installation also in small rooms or small working areas or combined with pendant lifting systems. Two handles on the lateral perimeter allow to easily grasp and move the anaesthesia unit.

On the rear side, a full-height steel rod is available to fix the patient monitoring.

1.3.1 Valves group - Breathing System

- Completely renewed and performing, it presents the following definite advantages.
- Extraction from above and perfect integration with the work shelf.
- Automatic connections with double seal gaskets against accidental leaks.
- Mono-bloc, fully stérilisable in autoclave.
- Calibration of flow and O_2 sensors can be performed in automatic mode by the User; The access to flow sensor and O_2 sensor is simple and immediate.
- The CO_2 absorber canister is located in the upper side and it easy to disconnect by apposite unlock lever. With canister inserted the system makes automatic configuration in rebreathing modality; with taken off canister, the system makes automatic configuration in non rebreathing modality (real open circuit). It is possible to put and take off the canister during intervention.
- The canister is available in version for reuse and disposable version including soda lime granules.
- Low periodic and extraordinary maintenance operations; easy training of technical personnel thanks to the extreme rationality of the system and to the drastic reduction of accidental leaks.

1.3.2 Lung ventilation module

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

- The lung ventilation module equipped with a 15” colour Touch Screen display, delivers controlled or spontaneous ventilations with a re-adjustable level of end expiration positive pressure (PEEP), of the trigger sensitivity and oxygen concentration.
- It is characterized by a very simple and powerful user’s interface, with large graphic display of respiratory parameters, allows to choose the curves to be shown simultaneously and an easy interaction in the selection of MENUS. After the switching-on it is possible to choose the PATIENT TYPE (Adult, Paediatric and Neonatal) and setting automatically the relevant default parameters.
- The lung ventilation module 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, PSV, SIGH, non-invasive ventilation NIV (NIV APCV – NIV PSV) and Manual Ventilation (MAN).
- Adjustable Tidal Volume from 2 ml to 1500 ml. In spontaneous ventilation mode, it ensures inspiratory flow up to 190 l/min, both with control and support pressure.
- The graphics user’s interface includes the keyboard, the decoder knob and the touch screen; the last one displays, the lung ventilation module 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.
- Through the selection of special and dedicated icons (MENU-SETUP, PATIENT, GRAPHIC DATA, ALARMS) placed on the front of the monitor, the user can interact immediately with all the operating parameters of the anesthesia unit. (*see on chapter 3*).
- In the same way 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 anaesthesia unit and also set the alarms, collect data concerning the trend of the operating parameters (TREND) and the anaesthesia unit EVENTS.

1.3.3 Flowmeter

The flowmeter is electronic, completely integrated in the monitor, it presents all those advantages in use, previously illustrated in the pulmonary ventilation module. In fact the user does not act on the classic knobs, but selects the fresh gas flows and / or the oxygen concentration by exerting a slight pressure on the screen of the pulmonary ventilation module (see on chapter 3).

To complete the flow meter there are: a back-lit mechanical flow meter for total flow control and three pressure gauges for checking the inlet pressures of medical gases (O2, ARIA and N2O / XENO this last optional gas).

1.3.4 Trolley (optional)

The mechanical structure of the trolley is made with light aluminum alloy uprights and a steel base structure. The base of the base is made of shock-proof ABS with a polyester coating; this guarantees an excellent impact resistance thanks to the flexibility and excellent resistance to abrasion.

The dimensions and weight are very limited and allow installation even in small rooms or with restricted work areas. The chest of drawers is made with a monobloc drawer molded in PUR, roomy, sturdy and easy to clean. The drawer is mounted on highly smooth telescopic guides that allow complete extraction.

The worktop is monobloc, illuminated and very large, made in a single pur mold.

1.4 Proper operation

The connections with main power supply, as well as connections with medical gas distribution system must be affected according to the indications contained in the User manual (see on chapter 4).

For correct and complete functioning, the anaesthesia unit must be:

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

The anaesthesia unit incorporate a series of sensors for continuous patient monitoring; the most important of which are:

- the flow sensors on the expiratory/inspiratory lines, used to measure the expiratory/inspiratory volumes of the patient
- the pressure sensors, used to control the pressure of the airways and of the medical gases
- the oxygen sensor, used to measure the concentration of oxygen in the gas inspired by the patient.

CAUTION

Before using the anaesthesia unit, 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 anaesthesia unit on a patient, it is necessary to perform a series of preliminary checking to verify the correct operation of the equipment (see on chapter 4.6).

The preliminary checking has the aim to verify the correct connections and

functionalities of the anaesthesia unit and all its parts.

For its employ the anaesthesia unit has been designed and made to guarantee full quality of the product and its components, in order to ensure the maximum reliability of the medical device for the patient and user safety.

To ensure the best performance of the anaesthesia unit periodic maintenance of the unit by qualified technical personnel is recommended (see on chapter 7). 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 anaesthesia unit or carrying out any maintenance.

1.5 Norms and standards regulations

The **MORPHEUS_ND** anaesthesia unit is made in accordance with the following norms and it is manufactured according to UNI EN ISO 13485:2004 standards.

EN 60601-1 :2006/A1 :2011/A1 :2013	Medical electrical equipment - Part 1: General requirements for safety.
EN 60601-1-2:2007/EC:10; EN61000-6-1:07; EN 61000-6-3:07/A1:11	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems.
EN 80601-2-13:2011	Medical electrical equipment - Part 2-13: Particular requirements for the safety and essential performance of an anaesthetic workstation.
IEC 601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
IEC 601-1-8:2007	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	Medical device software - Software life cycle processes.
EN ISO 5356-1:2015	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets.
EN ISO 4135:2001	Anaesthetic and respiratory equipment - Vocabulary.
DIR. 93/42/EEC	Medical devices directive.
DIR. 2011/65/CE	RoHS Directive (on the restriction of the use of certain hazardous substances in electrical and electronic equipment).
D.Lgs 49/2014	RAEE Directive (Implementation of the 2012/19/UE Directive on waste electrical and electronic equipment).

2 MORPHEUS_ND - DESCRIPTION

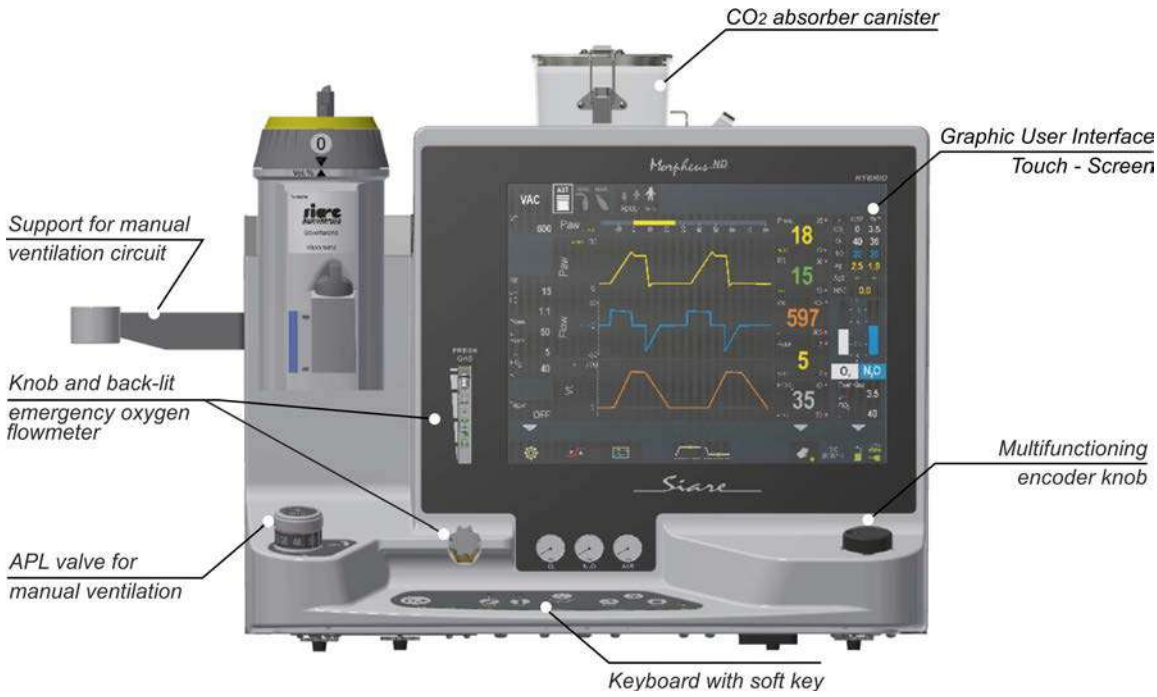
This chapter describes the structure and the main components / modules that make up the Morpheus_ND HYBRID anesthesia unit.

CAUTION

All the pictures and 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.

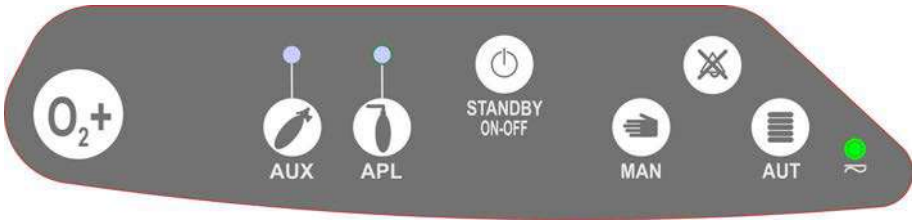
With regard to the assembly, the interface and the servicing operations, please refer to the relative chapter or contact Siare technical support service.

2.1 Front view



- CO_2 absorber canister releasable with unlock lever (*see on chapter 2.x and 4.2*)
- Graphic User Interface and Touch - Screen 15” (*see on chapter 3*)
- Multifunction encoder knob and keyboard (*see on chapter 2 and 3.1*)
- APL valve used in Manual ventilation (*see on chapter 2 and 5.8*)
- O_2 knob and back-lit emergency oxygen flowmeter

2.1.1 Keyboard for manual ventilation



Electronic type O2 BY-PASS control. Pressing the button puts oxygen in the anaesthesia circuit with a flow of about 35 l/min

Fresh gas selection control: enabling output connector (back of the anesthesia unit) at fresh gas exit (AUX)

Fresh gas exit selection control: enabling output connector BAG on valves group.

In MANUAL operative mode it is possible to select the correct mode to ventilate the patient:

- *by external auxiliary system, for example a manual ventilation system like MAPLESON C type or similar (AUX)*
- *or through the valves group (BAG)).*

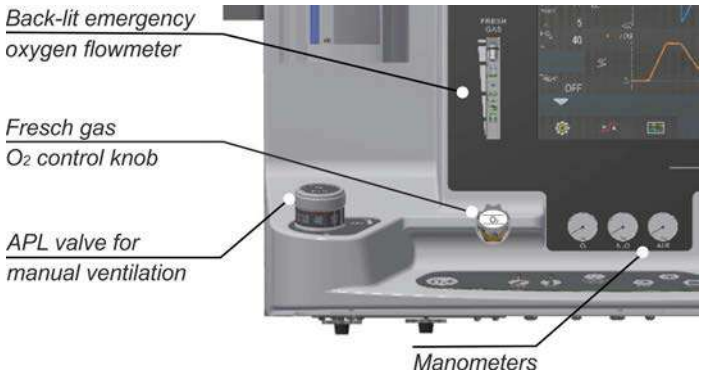
These commands are synchronized with the ventilatory manual operative mode so to avoid accidental or incoherent drives.

ALARM RESET

AUT - Soft key for enabling the automatic ventilation.

Indication of mains power supply presence.

2.1.2 Other commands



Back-lit flowmeter

Fresch gas control knob

The flowmeter and the knob are to be used mainly in an emergency. In fact, in the event of an emergency, with the anesthesia unit switched off (malfunctioning), the User can deliver a flow of fresh gas (oxygen) adjustable through the AUX outlet (located on the back of the DM) for manual ventilation of a patient.

APL valve (manual ventilation)

APL valve must be used for adjustment of airways maximum pressure during manual ventilation

- *The pressure value increases by turning clockwise the valve knob and it decreases by turning it counter-clockwise*
- *The adjustment range is around from 0 to 50 cmH_2O*

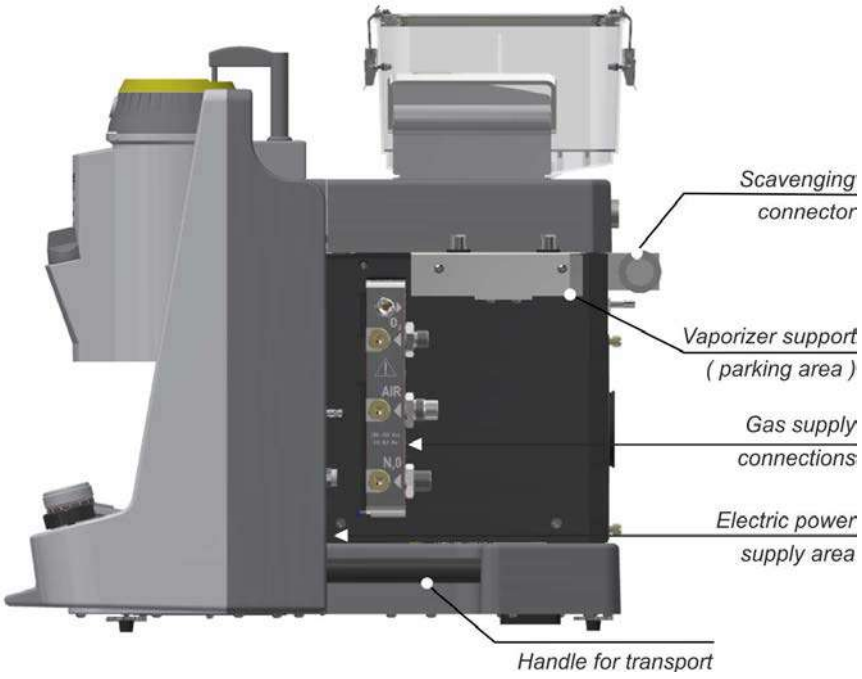
Manometers

The three manometers tell the User the medical gases feeding pressure.

CAUTION - In case of emergency.

*In case of emergency a knob delivering a monitored oxygen flow (**O_2**) from a back-lit mechanical flowmeter (safely calibrated) and indicating the oxygen delivered is foreseen (**FRESH GAS**)*

2.2 Side view – power supply connections



- Scavenging connector (*see on chapter 2.x and 4*)
- Vaporizer support – parking only (*see on chapter 2)*
- Gas supply connection (*see on chapter 2 and 4.3)*
- Electric power supply (*see on chapter 2.x and 4.5*)

On the front side of the anaesthesia unit there is a horizontal mono-bloc for rapid fixing of one vaporizer.
On the side of the anaesthesia unit there is an additional monobloc used as a parking lot for a possible additional vaporizer.

The device for coupling and uncoupling of the two vaporizers is a SIARETEX rapid type, Selectatec compatible.

2.2.1 Gas supply connection

- *Connections for O2 exit*
- *Connections for O2 entry*
- *Connections for Air entry*
- *Connections for N2O entry*

WARNING !! Risk of equipment failure

- *In order that the anaesthesia unit operates as specified, the inlet pressures of medical gases must be between 280 kPa and 600 kPa (2.8 - 6 bar): before use ensure that this requirement is met.*
- *The medical gas source shouldn't contain water: if you suspect the presence of water, connect a water trap to avoid damages on the unit and its components.*

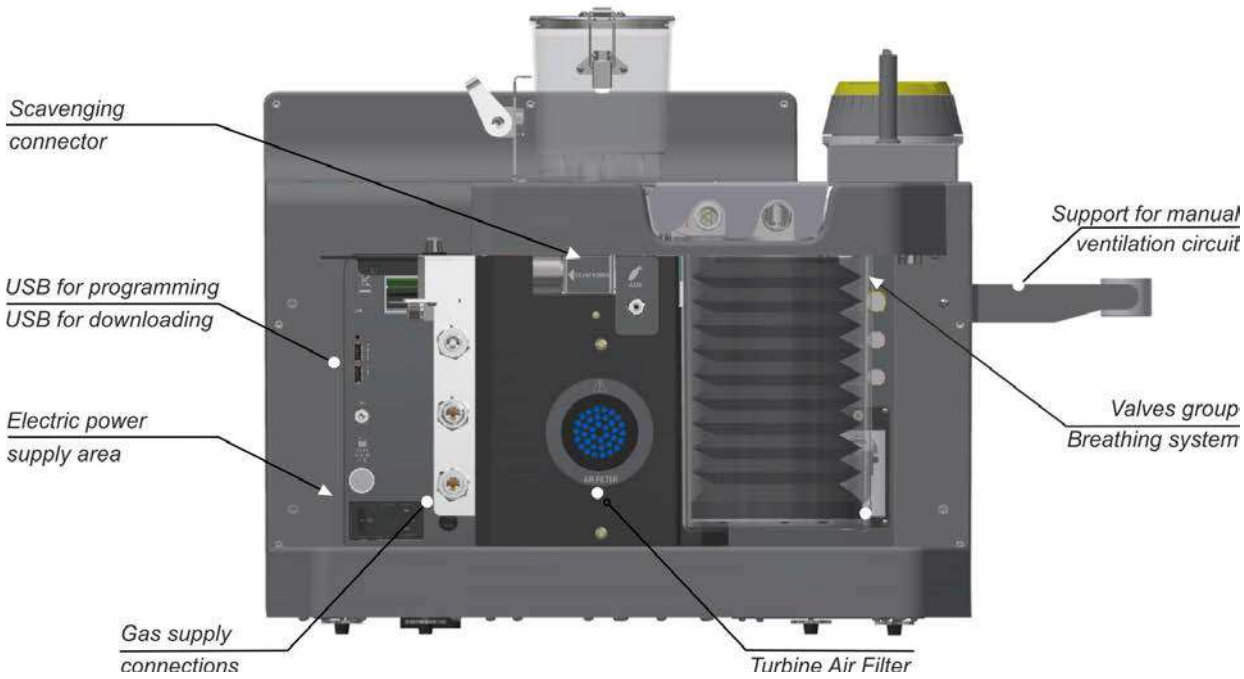
WARNING !! Fire danger

- *Do not connect to the connector for O2 exit devices which are not clearly guaranteed to operate with pure oxygen.*
- *Do not execute connections to the medical gas distribution system or to cylinders before having consulted the relevant chapter (see on chapter 4.3).*

CAUTION

- *With the anaesthesia unit operating by TURBINE, it is anyhow necessary the presence of an oxygen supply, useful for the operating of the internal pneumatic system.*
- *The gas used must be of medical type, therefore oil free and filtered.*

2.3 Back view



- Support for manual ventilation circuit (*see on chapter 5.8)*
- Valves group - Breathing system (*see on chapter 2.x*)
- Turbine Air Filters (*see on chapter 7 or on Service Manual)*
- Gas supply connection (*see on chapter 4.3*)
- Electric power supply area (*see on chapter 2.x and 4.5*)
- USB sockets (*see on chapter 3.8 and 5.3.14*)
- Scavenging connector (*see on chapter 2.x and 4*)

2.3.1 Electric power supply area

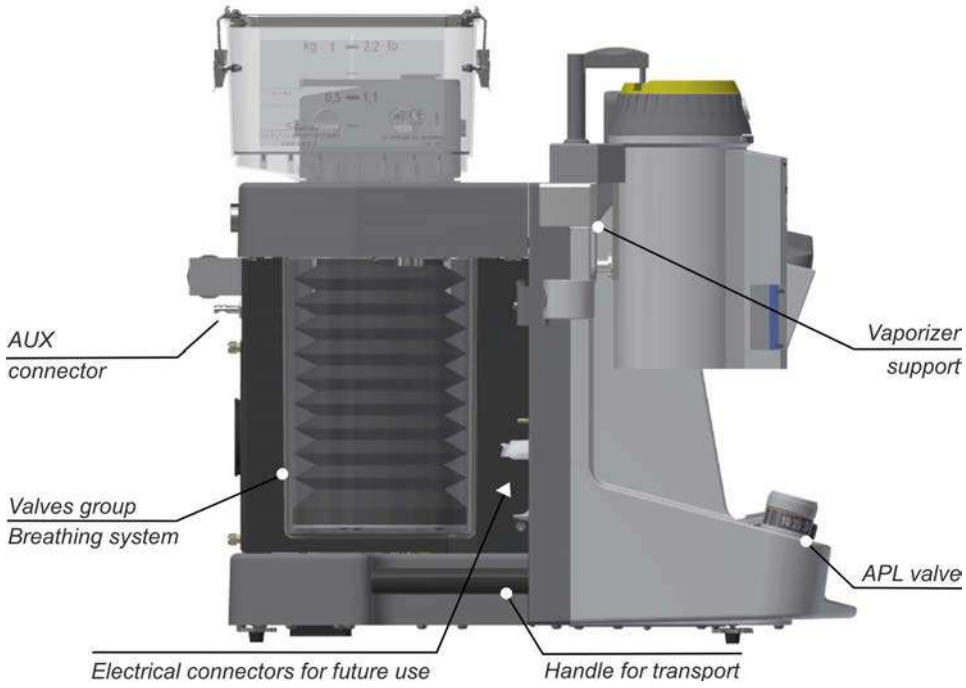
- ***USB0*** *: socket for CPU programming*
- ***USB1*** *: socket for Screen Shoot and for Patient data download (Trends and Events)*
- ***Equipotential node***

- ***12-14 VDC IN (7 A)*** *: connector for external 12 Vdc 7A power supply*
- ***Power supply group*** *: main switch, protection fuses (5x20 250V 2x10 AT), socket for connection of main supply power cable.*
- ***FUSE 10 AT*** *: safety fuse for battery power circuit (1 x 10 AT)*

WARNING !! Risk of equipment failure

Use and connect electric devices authorized by Siare, only.

2.4 Side view

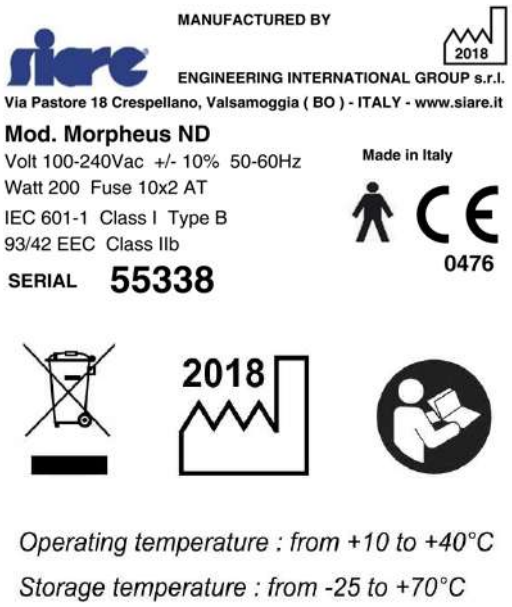


- Vaporizer support (*see on chapter 2*)
- APL valve for manual ventilation (*see on chapter 5.8*)
- Electrical connector : future uses *(optional)*
- Valves group - Breathing system (*see on chapter 2.6*)
- AUX connector (*see on chapter 5.8*)

2.5 Product identification label

The product identification label mentions the following information.

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



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

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

0476

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.

2.6 Valves group - Breathing system

The valves group (or also the breathing system) is the device that conveys the fresh gases (coming from anaesthesia module) to the patient; collects the exhaust gases and conveys them to the CO_2 absorber canister, and then toward the bellow of valves group to be delivered to the patient

When the CO_2 absorber canister is inserted, the system is automatically configured in rebreathing modality. When the CO_2 absorber canister is removed, the system is automatically configured in non-rebreathing modality (real open circuit). It is possible to insert and remove the canister during intervention.

When using the valves group in non-rebreathing, a greater amount of fresh gases must be delivered with respect to the Minute Volume value set on the anaesthesia unit.

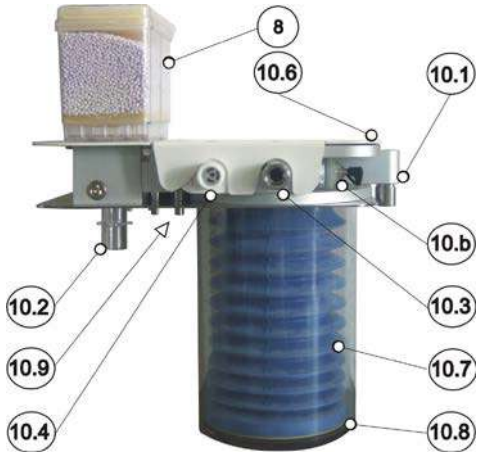
In any case, the anaesthesia unit ensures that the patient receives the Minute Volume by aspirating the missing amount from ambient air, through the apposite safety valve, but, in this case, patient anaesthesia is not guaranteed as the N_2O and anaesthetic agents supply will be present in an insufficient percentage in the gas mixture.

The manual ventilation is possible directly from the valves group (AUX connector) or with the TO and FRO external system.

Main features.

- Perfect integration with the work-shelf, upper extraction by apposite handle; completely autoclavable.
- Automatic connections with double tightness gaskets to prevent accidental leakages.
- It allows to ventilate in modalities: real open circuit, semi-closed circuit, closed circuit at low flows.
- It allows the spontaneous and manual ventilation also in case of anaesthesia unit failure or machine off.
- The gas recycling system is of selective type; therefore, the soda lime consumption of fresh gases is optimized.
- It's heated to reduce the accumulation of condensate and to heat the fresh gases.
- The passage to a ventilation modality to another is completely controlled by the anaesthesia unit without any user's action on valves group.
- The flow and oxygen sensor calibration are completely automatic and it does not require particular manual operations.
- Thanks to the extreme rationality of the system and to the drastic reduction of accidental leakages, the preventive and extraordinary maintenance operations are reduced to a minimum.

2.6.1 Patient circuit view



8 CO_2 absorber canister with lock lever

10.1 Connector for manual ventilation circuit

10.2 Connector for gas scavenging circuit

10.3 Connector for inspiratory line

10.4 Connector for expiratory line flow sensor

10.6 Valves group cover

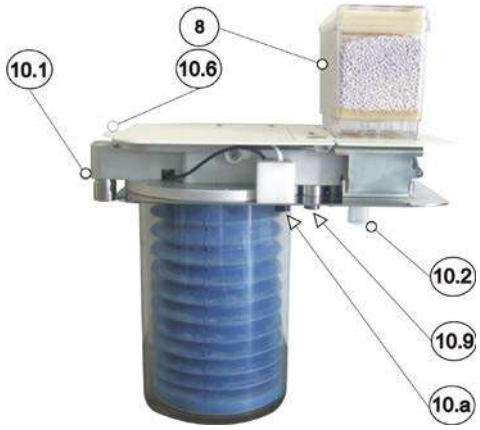
10.7 Bellows with weight

10.8 Bellows jar

10.9 Automatic gas connections to anaesthesia units

10.b Oxygen sensor and connection cable

2.6.2 Electric connexion view



8 CO_2 absorber canister with lock lever

10.1 Connector for manual ventilation circuit

10.2 Connector for gas scavenging circuit

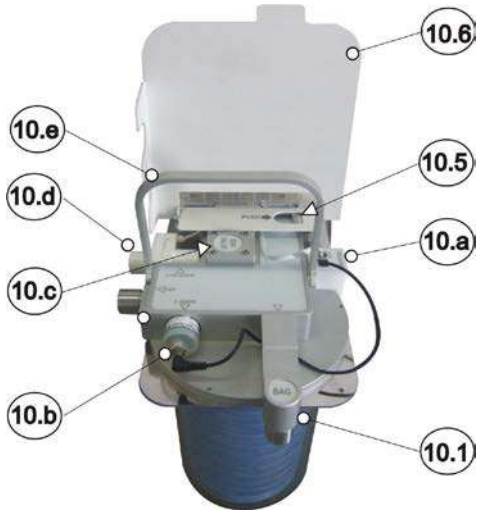
10.6 Valves group cover

10.9 Automatic gas connections

10.a Plastic support for:

- flow sensor RJ connector
- oxygen sensor RJ connector

2.6.3 Upper view



10.1 Connector for manual ventilation circuit

10.5 Unlock lever for CO_2 absorber canister release

10.6 Valves group cover

10.a Plastic support for:

- flow sensor RJ connector
- oxygen sensor RJ connector

10.b Oxygen sensor and connection cable

10.c Expiratory valve (EXP)

10.d Flow sensor and connection cable

2.7 Breathing system use

CAUTION

- *When the CO_2 absorber canister is inserted, the system is automatically configured in rebreathing modality.*
- *When the CO_2 absorber canister is removed, the system is automatically configured in non-rebreathing modality.*

2.7.1 CO_2 soda lime absorber canister

The CO_2 absorber canister is positioned in the upper side of valves group; it can be easily disconnected by apposite lock lever, this functionality makes it replaceable also during surgical interventions.

- When the CO_2 absorber canister is inserted, the system is automatically configured in rebreathing modality.
- When the canister is removed, the system is automatically configured in non-rebreathing modality (real open circuit).
- It is possible to insert and remove the canister during interventions. The canister is available in reusable or pre-loaded disposable versions.

About assembling and disassembling of absorber canister see on next chapter.

2.7.2 Assembling and disassembling of absorber canister (e.g. disposable model)

- To unpack carefully the CO_2 absorber canister.
- Shake the absorber canister (disposable model) in order to separate the soda lime granules.
- Remove the seal from absorber canister (disposable model).
- Insert the absorber canister in the apposite groove (opposite side of the “PUSH” lever).

- Press the apposite lock “PUSH” lever (unlock).
- Press down and release the apposite lock lever (unlock).
- Push (lever side) down the absorber canister.
- Release the lock “PUSH” lever (unlock).

- To take off the absorber jar, press the “PUSH” lever.
- Pull up (lever side) the CO2 absorber canister.
- Extract from the apposite groove (opposite to “PUSH” lever side).

2.7.3 Dismount of the valves group

- Dismount the eventual circuits or bags connected to the valves group connectors.
- Pull up the valves group cover.
- Pull up the handle.
- Extract the valves group, pulling it up vertically.
- The pneumatic connections are automatic with double tightness gaskets to prevent accidental leakages.

WARNING !! Risk of malfunctioning

All the interventions of maintenance on valves group, must be affected exclusively by personnel highly qualified and specifically trained and formally authorized by SIARE. Pay much ATTENTION during this operation.

- Lift and remove completely the valves group and position it on a flat surface.
- Continue with the Maintenance (see on chapter 7).

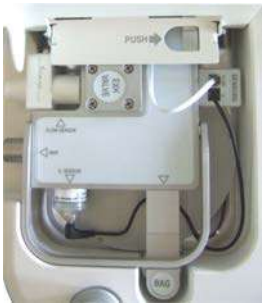
2.8 Breathing system accessories

2.8.1 O2 sensor

WARNING !! Risk of injury for the user

To avoid risks of electric shocks and/or break of components, during interventions, verify that the anaesthesia unit has been disconnected from power supply.

- Unpack carefully the O_2 cell.
- Pull up the valves group cover.
- Insert and screw the cell: in the space marked with the script “O_2 SENSOR”.



- Verify that the electric cable of cell connection is positioned into dedicated space.
- Connect the pin on the O_2 sensor.
- Connect the RJ connector on the dedicated outlet within the valves group.

2.8.2 Patient circuit

- *Connect the patient circuit to the apposite INS. and EXP. connectors on the valves group.*
- *Position the patient circuit on the patient circuit supporting arm.*

For more details about anaesthesia unit installation, please see on chapter 4.

CAUTION

Use a patient circuit suitable for the patient to ventilate.

Tidal Volume	Set of hoses
< 50 mL	*Neonatal*
from 50 to 200 mL	*Paediatrics*
> 210 mL	*Adults*

2.8.3 Manual ventilation kit

- *Connect the manual ventilation kit to the "BAG" connector on the valves group.*
- *Position the bag of the kit on the patient circuit supporting arm.*

For more details about manual ventilation, please see on chapter 5.8.9.

CAUTION

With the "APL" control is activated, the manual ventilation is performed by the valves group.

WARNING !! Risk of injury for the patient

During manual ventilation phase, the airways pressure can overcome the limit set on anaesthesia unit.

The max. pressure limit depends on APL valve regulation.

2.8.4 MAPLESON C Adult patient circuit

- *Connect the patient circuit to the "AUX" connector on the valves group (anaesthesia unit back side).*
- *Position the patient circuit on the patient circuit supporting arm.*

For more details about manual ventilation, please see on chapter 5.8.9.

CAUTION

With the "APL" control is activated, the manual ventilation is performed by the valves group.

WARNING !! Risk of injury for the patient

During manual ventilation phase, the airways pressure can overcome the limit set on anaesthesia unit.

The max. pressure limit depends on APL valve regulation.

3 USER INTERFACE MODULE

The interface module can be considered as the brain of the anesthesia unit model Morpheus_ND. The touch screen 15” display, as described in the following pages, allows the user to set the respiratory parameters needed by the patient but, at the same time, it allows to verify patient’s clinical trend, monitoring both from a graphical and numeric point of view the several ventilatory parameters

A further advantage of the user’s interface is the possibility to work with graphics on the delivery of the fresh gases through the electrical flowmeters, the possibility to set and display through a graphic the lows to be delivered to the patient as well as different functionalities correlated to it are some among the positive foreseen particulars.

For a better approach and comprehension of the user’s interface module features, we will split it into three different groups: the keyboard and the encoder knob, the ventilatory respiratory parameters (graphical user interface), electrical flowmeter.

At the end, the 15” touch screen graphical interface, will be easy to understand for those having a sufficiend acquired experience on lung ventilation and on SIARE’s devices. The User will find in this chapter all the information needed for using the anaesthesia unit the proper way.

WARNING !! Risk for Patient / User injury

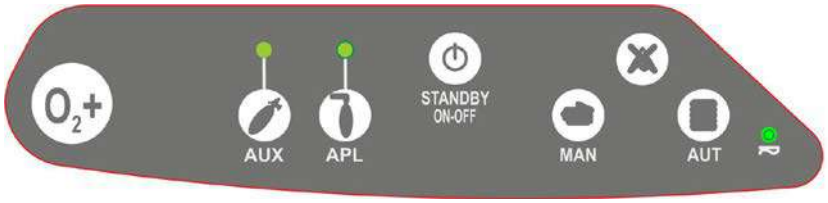
All the pictures and examples shown in the present chapter have the mere purpose of being an example and they do not make any reference to real clinical cases.

3.1 Keyboard with soft key and encoder knob

Well shaped from an ergonomic point of view, on the front of the anaesthesia unit, we have the keybor and a multifunctioning knob encoder

They keyboard includes either the controls for the working in auto mode, ot the controls for the patient's manual ventilation.

The multifunctioning encoder knob, in certain conditions, can be a valid support during the use of the touch screen.



As an alternative to the touch screen, the multifunctioning encoder knob is used to select, modify and confirm all the functions displayed on the monitor. The encoder knob is used to access the MENU function and then to function modes, parameters, alarms, parameters' values and everything pertaining to the normal operation of anaesthesia unit.

Use of the **multifunction encoder knob**.

- Press the encoder to access the modification (enabling) of the parameter (function); turn clockwise or counter-clockwise to select the parameter (function).
- 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 sistem will restore the value prior to the modification.

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

AUT - Soft key for enabling the automatic ventilation.

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

ALARM RESET - Soft key to silence an active alarm.

- When an alarm condition is enabled, the activated acoustic alarm can be silenced by pressing the ALARM RESET soft key.
- Whenever the condition that enabled the alarm is no more present, pressing again the key, it is possible to cancel the visual indication on the monitor.

MAN - Soft key for activation of manual ventilation.

- By pressing **MAN** soft key it is possible to start ventilation in the manual operative mode.

STAND-BY ON/OFF - Soft key for switch on and off the anaesthesia unit.

The functional switch ON or OFF of anaesthesia unit is possible by the **STAND-BY ON/OFF** soft key. To switch ON the anaesthesia unit, press this soft key. After a few seconds a series of messages are displayed in the monitor, indicating that the system is entered in the Self Test phase; this phase takes some minutes. At the end of this procedure (Self Test phase) the equipment is ready to ventilate the patient.

During patient's ventilation, pressing the **STAND-BY ON/OFF** soft key, the User will be requested to confirm the switch from patient's ventilation to the anaesthesia unit in Stand-by mode.

Keep pressed the **STAND-BY ON/OFF** soft key for a few seconds to switch OFF the anaesthesia unit: the system will require to confirm the switch off (this function has been introduced to avoid accidental shutdowns of the same).

APL - Soft key for enabling the connection and use the BAG.

By the anaesthesia unit in **MAN** operative mode, pressing this button (by using the valves group), the possibility to ventilate the patient using a manual ventilation circuit (hose + bag) is enabled.

When the **led** is light on (green colour) it indicates operation enabled.

CAUTION

With the manual ventilation, the **APL** regulator, located aside the control keybord, shall be used to determine the max value of the airways pressure in the patient.

Using this manualventilation mode (**APL** enabled), the system displays the monitoring of the patient's parameters.

AUX - Soft key for attivazione raccordo uscita gas freschi (**AUX**).

Working with the anaesthesia unit in **MAN operative mode**, pressing this button, the possibility to ventilate the patient by a manual ventilation circuit as the Mapleson C (to and fro) is enabled.

When the **led** is light on (green colour) it indicates the operation is enabled.

WARNING !! Risk for Patient injury

With this manual ventilation (**AUX** enabled), the system DOES NOT display the monitoring of the patient's parameters.

O2 + - Soft key for oxygen exit enabling.

Pressing the button, pure oxygen is introduced in the anaesthesia circuit with a flow of almost 35 l/min.

3.2 Anaesthesia unit switching ON

Before switching on the Morpheus_ND anesthesia unit, all the devices and accessories necessary for the operation of the anesthesia unit must be present and correctly connected: electric power and gas supplies connected, patient circuit, lung simulator, etcc...

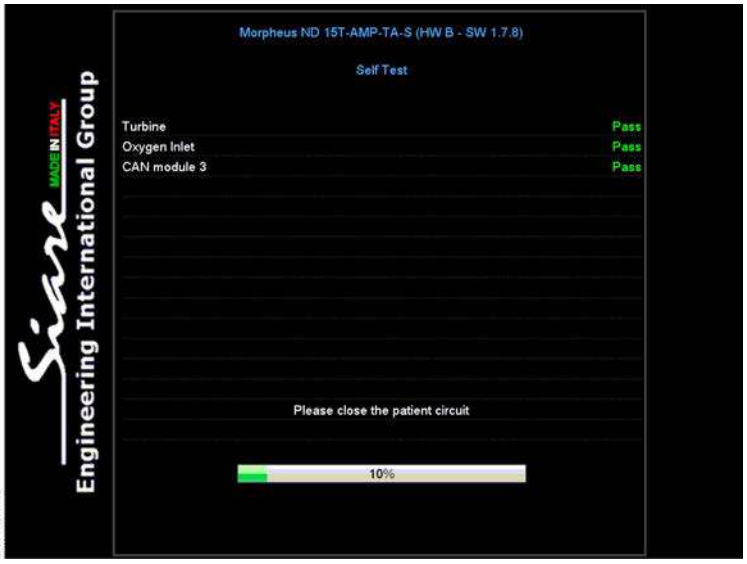
- Insert the plug of the power supply cable to the wall socket.
- Connect the power supply cable to the anaesthesia unit.
- Set the main switch (placed on the back side of the anaesthesia unit) to " **I** ".

- Make sure that on the unit keyboard, the green led is lit: that indicates the presence of mains power supply (ON).
- Hold the STANDBY ON-OFF key for few seconds.

- The unit switch ON and the automatic Self Test phase starts.
- *Please close the patient circuit.*

3.2.1 Self Test phase

During Self Test phase, the software carries out the self-diagnostic tests and checks a series of devices necessary for safe operation of the Unit /patient (*for further details ABOUT self test,please see on chapter see on 4.7.1*).



Scr15476

- The anaesthesia unit turns ON and the automatic Self Test phase starts.
- *Please close the patient circuit.*

Scr16388

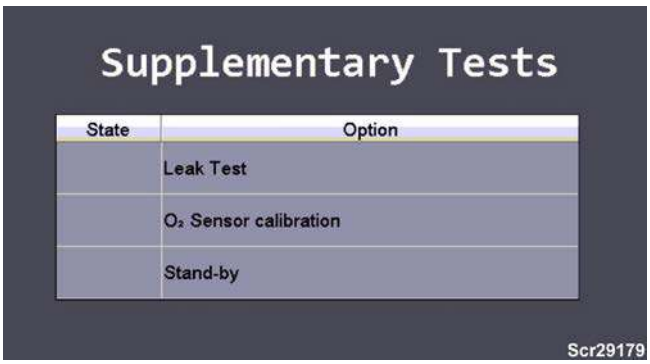
- **Acoustic Alarm test** : **“** *If the acoustic alarm is audible, please push the RESET key* ”.

The Self Test phase completed successfully.

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

Cancel

Press **Cancel** : the system will display the **Supplementary Tests** page.



Through of this page it is possible to perform the **Supplementary Test** (*for further details see on chapter 4.x*).

OK

Press **OK** : the system will display the **PATIENT DATA** page.

The **PATIENT DATA** displaying allows to set the patient data and characteristics.

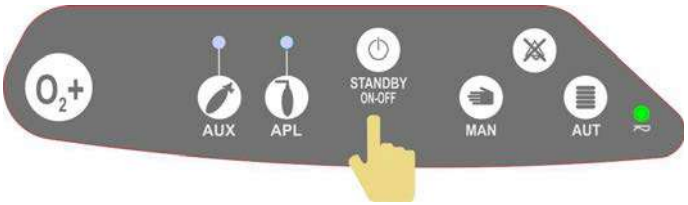
- In this phase select indifferently **Cancel** or **OK** to access Stand-by displaying.
- In case of variations on **PATIENT DATA** values press **OK** to confirm updatings.

Stand-by mode.

The software does not switch directly to Stand-by operative mode, but it previously displays a page which allows the adjustment of the anaesthesia unit setup.

3.2.2 Anaesthesia unit switching OFF

Anaesthesia unit in Stand-by **operative mode.**



- Hold the **STANDBY / ON-OFF** soft key for few seconds to switch-OFF the anaesthesia unit.

- The system requires to user if **Turn-Off** the Anaesthesia unit.

YES	**The Anaesthesia unit will be switched OFF.**
NO	The " Turn Off " command will be deleted ; the Anaesthesia unit goes back to the Stand-by mode.

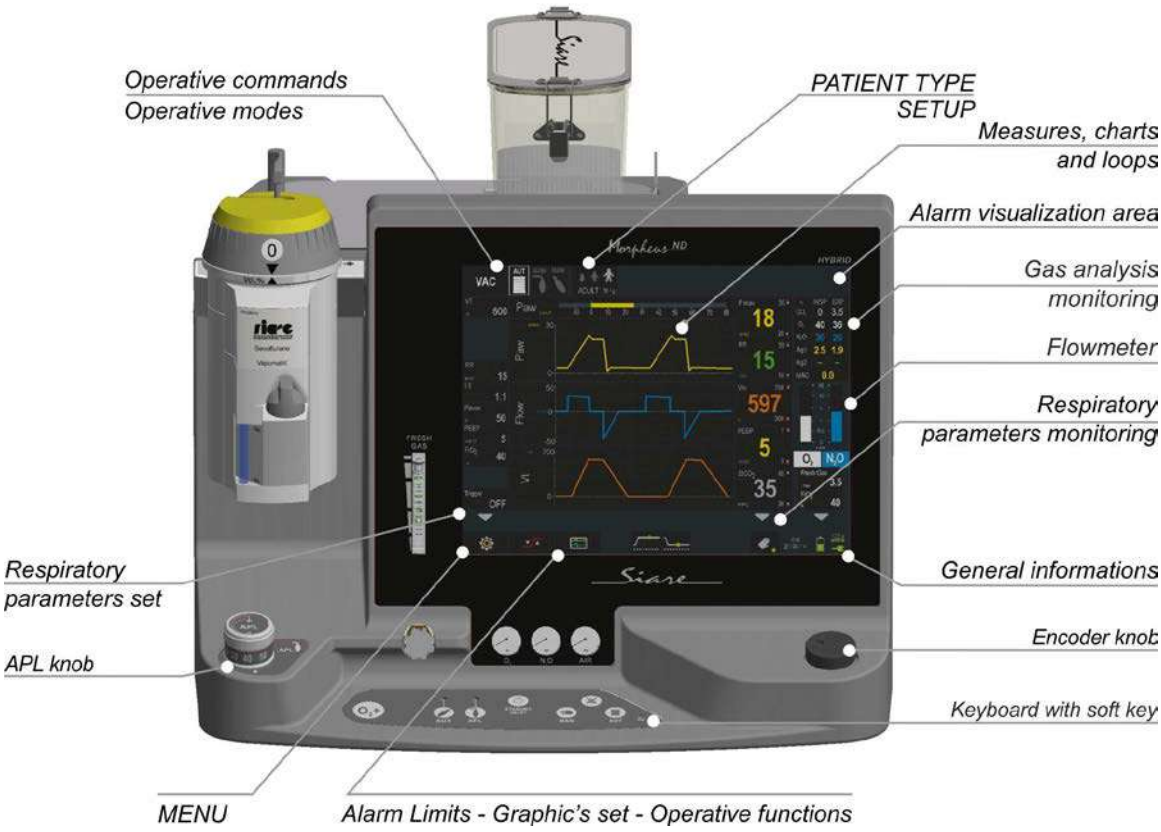
3.3 15” touch screen monitor

On the front of the anaesthesia unit, a 15” touch screen monitor, displays all the information needed for patient’s ventilation. Operatin mode selection, setting and displaying of respiratory parameters, graphics, alarms signals and electronic flowmeter (see on cfr. 4.3) are the main available and active functions.

By the use of the touch screen system along with the control keyboard / encoder knob the User can interact directly with the monitor: this system is defined as GUI (*graphical user interface*).

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

The picture shows how the GUI is divided in different area and funtions.



In the following paragraphs an overview on the potential of the system is available as well as the information that can be displayed and on how to interact with the same.

For more information about anaesthesia unit use, please refer to chapter 5.

3.3.1 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 a 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.

The different touch screen operation modes are highlighted in the following paragraphs.

3.3.2 Operative modes

The ***Morpheus_ND*** anaesthesia unit includes the most modern ventilation modes: volume controlled ventilation, pressure controlled ventilation, pressure supported, non invasive ventilation and manual ventilation.

WARNING !! Risk for Patient injury

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

When the anaesthesia unit is turned ON, the system restores the operative mode and the relevant parameter values set before the last shut-down.

CAUTION

An operative mode can be selected in two different operating conditions.

- Anaesthesia unit in **Stand-by** mode.
- During the **normal operation** of the anaesthesia unit.

Anaesthesia unit in Stand-by mode.

Select the area indicating Operative Mode (icon: VC/VAC)

All the operative modes foreseen are displayed

Select a new operative mode

Anaesthesia unit: Stand-by mode.

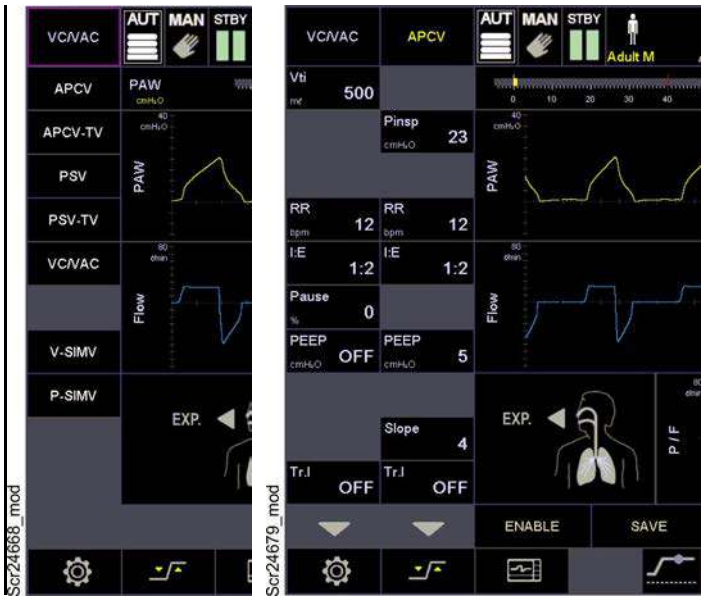
Operative mode selected: APCV

PRP parameters referred to the APCV operative mode can be displayed

Anaesthesia unit in Stand-by, ready to be used in APCV operative mode.

Anaesthesia unit in normal operation: operative mode VC/VAC.

- Select the area indicating Operative Mode (icon: VC/VAC)



All the operative modes foreseen can be displayed.

- Select a new operative mode.

- A second column with the PRP parameters referred to the APCV operative mode can be displayed.
- The system proposes to the User three potential choices to enable or not enable a new operative mode.

YES : The system switch to the new operative mode: APCV

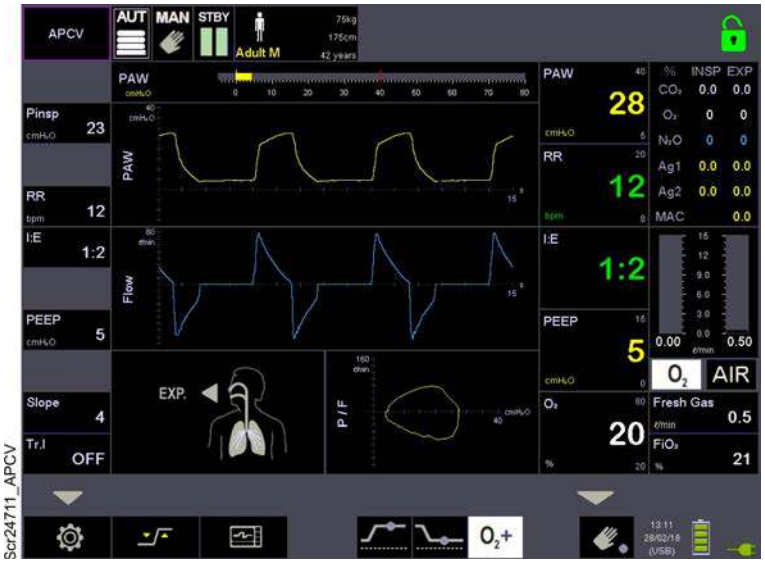
NO : to exit

YES : The system remains in VC/VAC; the PRP parameters of the selected operative mode are saved.

NO : to exit

YES : it goes back to VC/VAC operative mode.

NO : to exit



Scr24711_APCV

ENABLE

YES : The Anaesthesia unit directly switches to the new selected operative mode APCV.

Scr24621_VAC

SAVE

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

The anaesthesia unit continues to ventilate in VC/VAC operative mode.

Scr24621_VAC

CANC

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

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

Operative modes list

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

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

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

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

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

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

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

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

Volume-targeted synchronised intermittent mandatory ventilation.

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

P-SIMV

Pressure-targeted synchronised intermittent mandatory ventilation.

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

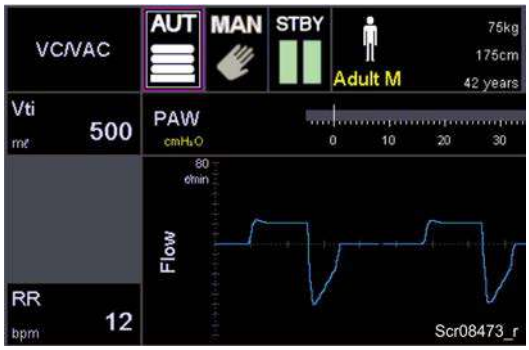
Alongside the operative command icon, the patient type set is specified (Adult, Child, New Born). In this way the default respiratory parameters are set automatically (breathing parameters and alarms levels).

Default Parameters: please refer to cfr. 7 Use of User interface module and cfr. 6 Alarm.

3.3.3 Operative commands

Three controls next to the operative modes selection are available and useful for the anaesthesia unit operations. The controls are comparable with the ones located on the keyboard.

Operative command : AUT / MAN / STAND-BY



Three control keys useful for anaesthesia unit operation are foreseen next to operative modes selection.

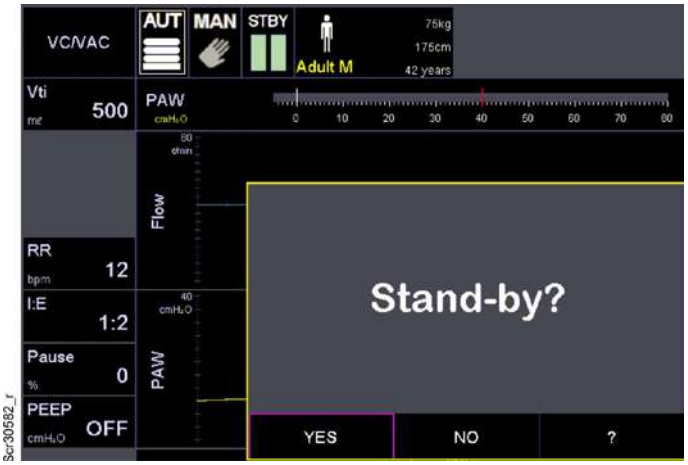
The three control keys here below are similar to those present on the keyboard with soft key.

By touch **AUT** it is possible to start ventilation in the selected ventilatory mode and with parameters set by User.

By touch **MAN** it is possible to start ventilation in the manual mode.

By touch **STBY** it is possible to switch from a normal operative mode to a Stand-By phase of anaesthesia unit.

When the User wants to stop the ventilation (both manual or automatic) and to switch a Stand-by status, the system always displays a request to confirm this action.



- The system will ask if you want the anaesthesia unit in **Stand-by** mode.

  Press YES: anaesthesia unit goes to **Stand-by** mode.

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

3.3.4 PATIENT DATA

Alongside the operative command icons, the **PATIENT TYPE** set is specified (**Adult, Child, New Born**).

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

CAUTION - Anaesthesia unit switched ON.

At the end of Self-Test phase, the system does not switch directly to Stand-by operative mode, but it previously displays a page which allows the adjustment of the following type of **PATIENT informations** and anaesthesia unit SETUP.

- **PATIENT DATA**
- SETUP parameters (please see on 3.2.5)

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

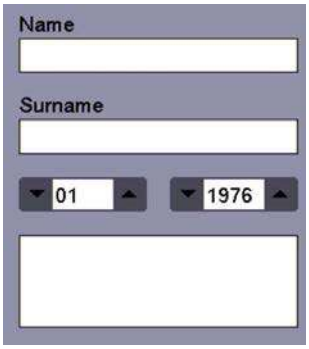
- *Patient type*
- *Male / Female*
- *Name / Surname*
- *Physical data of the patient*
- *Birthday*
- *Note*

CAUTION

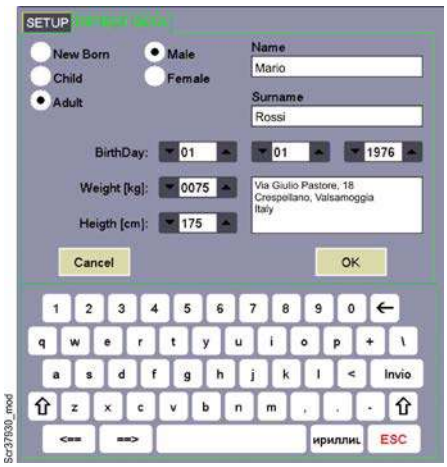
During the normal operation of the anaesthesia unit, the User can modify the PATIENT DATA selecting the icon:

- SETTING MENU / PATIENT DATA
- or by touching the relative icon (PATIENT DATA)

- The choice of the patient typology, set automatically the default functioning parameters of the anaesthesia unit (breathing parameters and alarms levels).



- An apposite keyboard appears on the display when the space to fill-in is selected.



- Once completed the entering of PATIENT DATA, **Save** or **Cancel** what is indicated in the page.

Scr38785

- Select **Cancel**

Yes : the PATIENT DATA settings will NOT be saved.

Scr38780

- Select **OK**

Yes : the PATIENT DATA setting will be saved.

Scr37929_mod

The system will display the PATIENT DATA screen.

3.3.5 SETUP

Alongside the operative command icon, the **PATIENT TYPE** set is specified (**Adult, Child, New Born**).

CAUTION - Anaesthesia unit switched ON.

At the end of Self-Test phase, the system does not switch directly to Stand-by operative mode, but it previously displays a page which allows the adjustment of the following type of PATIENT informations and anaesthesia unit **SETUP parameters**.

- PATIENT DATA (please see on 3.2.4)
- **SETUP parameters**

Anaesthesia unit in visualizzazione PATIENT TYPE.

- Select **SETUP** *(see on next page).*

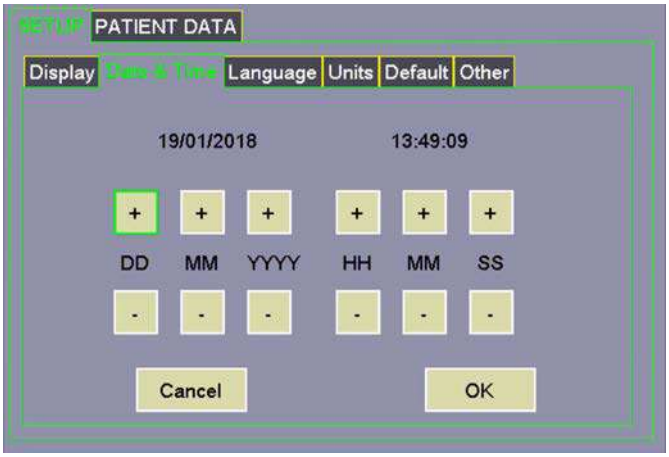
CAUTION

During the normal operation of the anaesthesia unit, the User can modify the SETUP parameters selecting the icon **MENU** .

A series of pages (displaying) are available to determine the operation **SETUP** of anaesthesia unit.

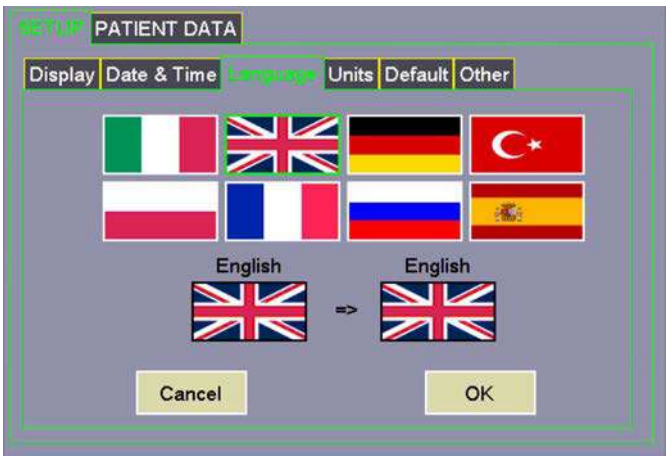
Display

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



Date & Time

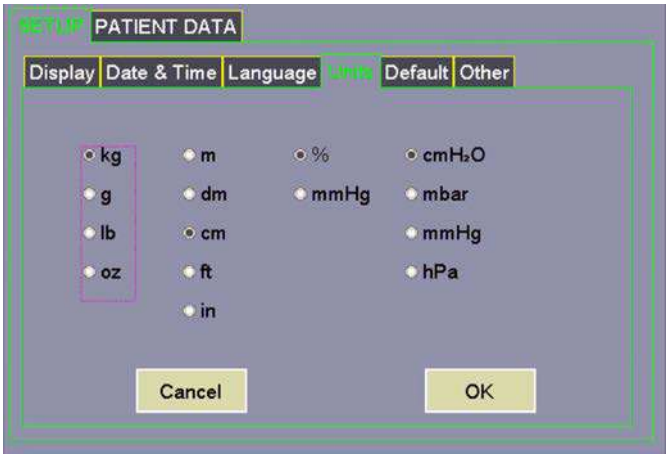
- *Date*
- *Time*



Language

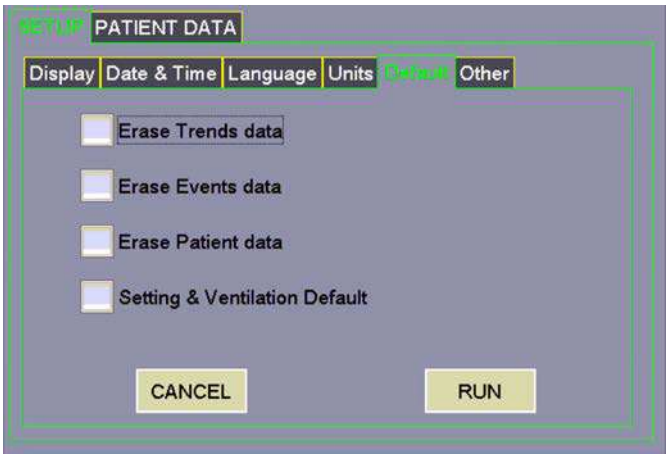
- *Italian*
- *English*
- *German*
- *Turkey*
- *Polish*
- *French*
- *Russian*

Spanish



Units

- *Weight (referred to the patient)*
- *Height (referred to the patient)*
- *CO_2 (unit of measurement)*
- *Pressure (unit of measurement)*



Default

- *Erase Trends data*
- *Erase Events data*
- *Erase Patient data*
- *Setting & Ventilation Default*

Other

- *NIV Enable*
- *Power Failure*
- *APNEA TIME*
- *N_2O / Xe*
- *CHANGE PASSWORD*

Save to USB

Scr41936

- 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.

Scr41933

- Select OK

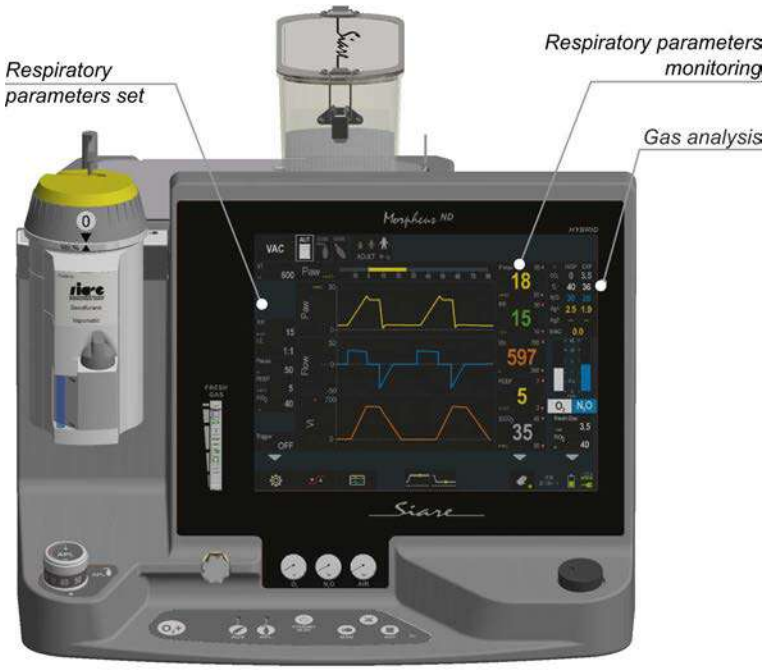
  YES : the set values will be saved.

  NO : it remains in SETUP page.

Scr51314_Stand-by

The system will display the **Stand-by** screen.

3.4 Physiological respiratory parameters



In this paragraph the User will find a description of available physiological respiratory parameters (referred to from now on as PRP) selectable on user interface module.

3.4.1 Respiratory parameters display

Just for our examples we refer to the Operative Modes available with ADULT Patient Data (VC/VAC).

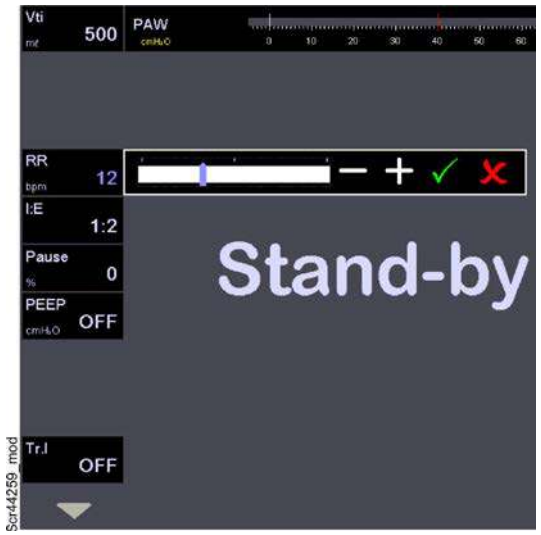
Select the icon for see the PRP parameters.

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

Other respiratory parameters related to VC/VAC operative mode are displayed

To return to previous displaying, re-select

3.4.2 Respiratory parameter modification (Respiratory Rate)



Select the area indicating the respiratory parameters to be modified.

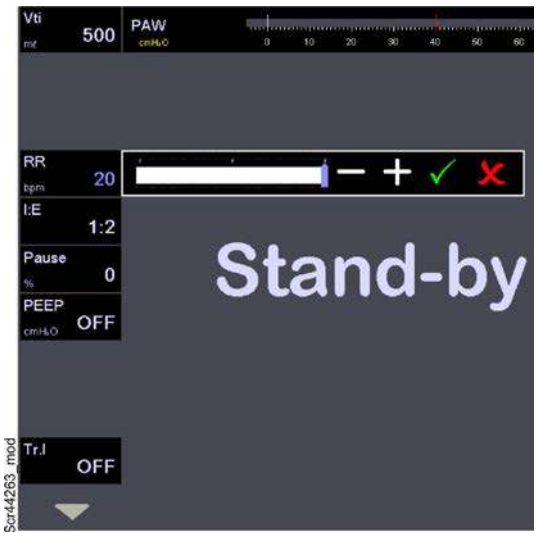
The modification bar is displayed.

To **decrease** the parameter value

To **increase** the parameter value

To **confirm** set value

The system **goes back** to Stand-by page without modification.



- The value of Respiratory Rate has been modified.
- Select **Confirm** to close modification bar

3.4.3 List of available respiratory parameter

WARNING !! Risk for Patient injury

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** must be set by the User in Stand-by mode before activating the necessary operative mode.

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

Selecting the PRP parameters icon the parameters relevant to the set Operative Mode are displayed.

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.

I:E

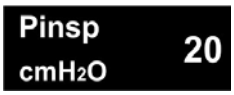
Ratio between inspiration and expiration phases.

Pause (%)

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

PEEP (cmH2O)

Positive airway pressure value during expiratory phase.

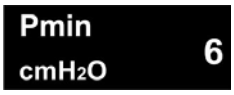


Pinsp (cmH2O)

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

PMax (cmH2O)

Maximum airway pressure limit.



Pmin (cmH2O)

Minimum airway pressure limit.

PS (cmH2O)

Positive airway support pressure value during inspiratory phase.

RR (bpm)

Anaesthesia unit respiratory rate.

RRsimv (bpm)

Value of forced respiratory rate in SIMV mode.

Sigh. Ampl. (%)

Sigh. Percentage increase of the set Vti.

Sigh. Int. (b)

Sigh. Activation frequency.

Slope

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

Ti (s)

Time that defines the anaesthesia unit inspiration duration. The values can be set based on the set RR.

Ti max (s)

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

Tr. E (%)

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

Tr. I (L/min) (cmH2O)

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

Vte (ml)

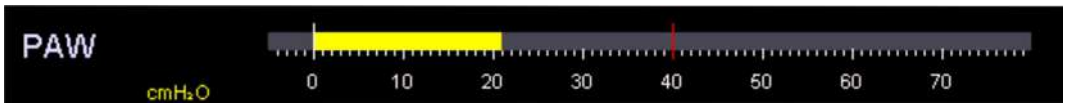
Expired tidal volume guaranteed for the patient.

Vti (ml)

Inspired tidal volume guaranteed for each breath.

3.4.4 Monitoring of respiratory parameter

Based on the ventilatory parameters set by the User and on the patient's characteristics, the system is able to monitor and measure a series of values necessary for the patient's clinical evaluation.



At the top of the monitor, there is a light bar indicator (with scale from 0 to 80 cmH_2O), that displays the pressure inside the airways during the respiratory phase, in real time. The measured and monitored values (right side of the monitor) are updated after each breath of the patient.

Press the icon under the respiratory parameters column repeatedly to see (in sequence) the all available **respiratory parameters.**

Meaning of the values reported in the cell

Vte : respiratory parameter

ml : unit of measurement

503 : value set by the User

1000 - 100 : alarm limits

PAW

The value displayed is the maximum measured pressure inside the airways (cmH_2O).

RR

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

I:E

The displayed value shows the ratio between the inspiration time and the expiration time.

PEEP

The displayed value shows the positive pressure at the end of the expiration: the measurement unit is cmH2O. The User can control if the anaesthesia unit is able to reach and keep the PEEP pressure level set, using this value.

O2

The displayed value 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.

Vte

The displayed value 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.

Vti

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

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

FiCO2

The displayed value shows the value of CO_2 maximum concentration in the CO2 inspiratory phase (insp-fraction CO_2).

The value is detected by the gas sensor analyzer installed on the patient circuit.

EiCO2

The displayed value shows the value of CO_2 maximum concentration at CO2 end expiration (end-tidal CO_2).

The value is detected by the gas sensor analyzer installed on the patient circuit.

Monitoring of " additional breathing parameters "

Mean airways pressure

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

Pause pressure

It shows the pause pressure: the unit of measurement is cmH2O. When the inspiratory pause enables, the anaesthesia unit 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 anaesthesia unit to calculate the breathing mechanics parameters.

Inspiratory peak flow

Use the flow sensors installed on the inspiratory line to measure that maximum inhaled flow value (measured in l/min) and to view it on the monitor. For this value there are no alarm limits but it can be used to gather information on the ventilation status.

Inspiratory time

It shows the duration of the patient's inspiratory phase: the unit of measurement is the second. This value represents the total inspiratory time, and also includes the inspiratory pause period.

This value depends on the respiratory rate and I:E ratio parameters. For example: if RATE = 15 and I:E=1:1 you will have an inspiratory phase of 2 seconds.

Inspiratory pause

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

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

Expiratory time

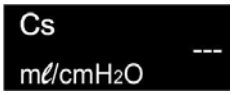
It shows the duration of the patient's expiratory phase: the unit of measurement is the second. This parameter defines the expiration duration. This value depends on the respiratory rate and I:E ratio parameters.

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

Inspiratory resistance

It is the parameter of the lung mechanics that describes the resistance to the opposite flow of the airways: measured in cmH2O/(l/s). The greater the patient resistance, the higher the airway pressure you need to apply to obtain the same volume.

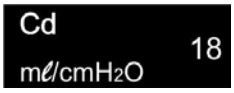
The formula used by the anaesthesia unit to calculate the inspiratory resistance is as follows: Ri = (peak pressure – pause pressure) / inspired flow.



Static compliance

It is one of the parameters of the lung mechanics: measured in ml/cmH2O, represents the lung compliance when the patient does not breathe. You can use it to asses the lung elasticity: the higher the compliance, the more elastic the “lung”; the lower the compliance, the more “rigid” the lung.

The static compliance can be calculated using the formula below: Cs = current inspired volume / pause pressure.



Dynamic compliance

It is one of the parameters of the lung mechanics: measured in ml/cmH2O, represents the lung compliance either during the inspiration or during the expiration.

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

The dynamic compliance can be calculated using the formula below: Cd = current inspired volume / peak pressure

Expiratory peak flow

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

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

Leak

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

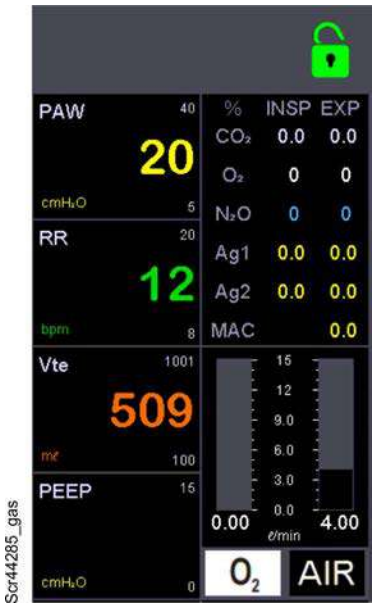
The unit of measurement is %.

O2 [Calculation of oxygen consumption]

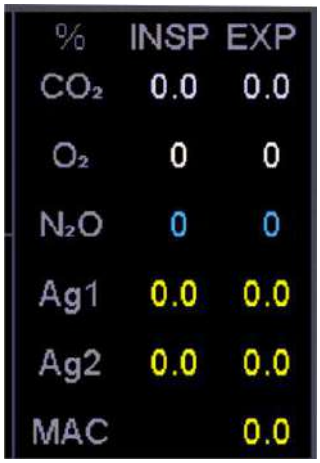
It shows the value of oxygen consumption in L/min ; it is displayed after one minute and for oxygen values set over 21%.

3.4.5 Monitoring of " gas analysis parameters "

The values monitored are measured through a Sidestream or Mainstream GAS analyzer connected to the Anaesthesia unit.



The measuring ranges of the considered gas are available on the technical data sheet relevant to the type of sensor used.



INSP : in the relevant line are shown the percentages of values measured in inspiratory phase.

EXP : in the relevant line are shown the percentages of values measured in expiratory phase.

CO2 : Percentages of CO2 measured in INSP and EXP phases.

O2 : Percentages of O2 measured in INSP and EXP phases.

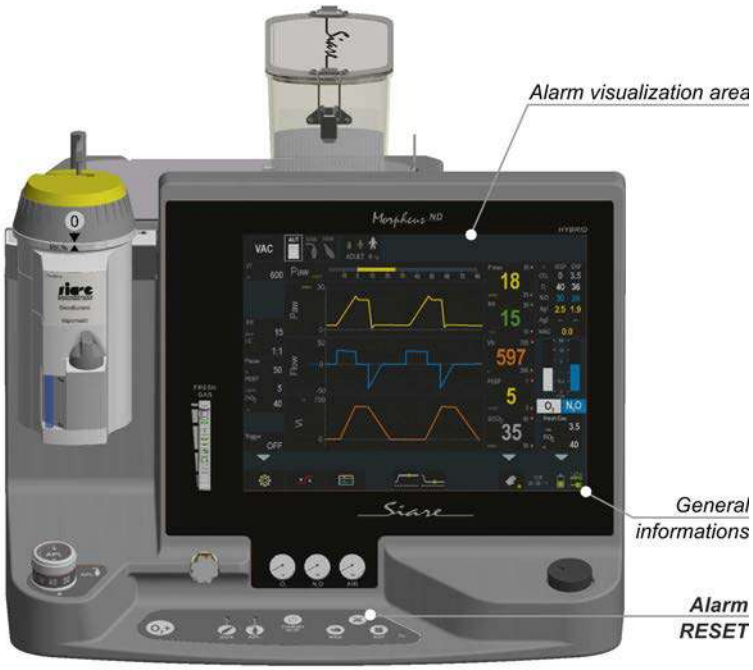
N2O : Percentages of N2O measured in INSP and EXP phases.

Ag1 : Percentages of anaesthetic gas Ag1 measured in INSP and EXP phases.

Ag2 : Percentages of anaesthetic gas Ag2 measured in INSP and EXP phases.

MAC : Minimum alveolar concentration MAC measured in Exp phase (see relevant User's Manual).

3.5 Alarms areas



The anaesthesia unit 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 about **Alarms parameters and Limits setup**, please see on **chapter 6**.

Scr53047_r

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.

ALARM SILENCING

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

WARNING !! Risk for Patient / user injury.

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

Setting up the Alarms limits (Respiratory Parameter)

Anaesthesia unit in Stand-by mode.

Just for our examples we refer to the Operative Modes available with ADULT Patient Data (VC/VAC).

Select the icon for see the Alarms parameters.

ALARM Limits page is displayed.

- **Select** Cancel

  YES: the system quits ALARMS page and DO NOT save modifications.

  NO: the system goes back to ALARMS page.

- **Select** OK

  YES: The system quits ALARMS page and save modifications.

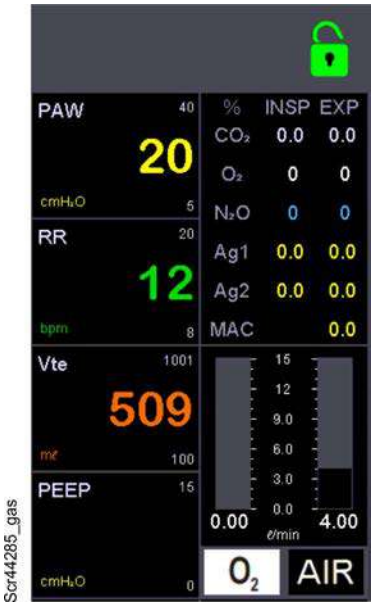
  NO: The system goes back to ALARMS page.

WARNING !! Risk for Patient / user injury.

- The anaesthesia unit 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.

Alarms limits visualization

It's possible to display the ALARM Limits page (**Respiratory Parameter**) even selecting any respiratory parameter monitored.



ALARM Limits page (GAS Sensor).

Select the alogenated gas area.

The **Alarm Limits screen** (gas sensor) appears.

- **Select** Cancel

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

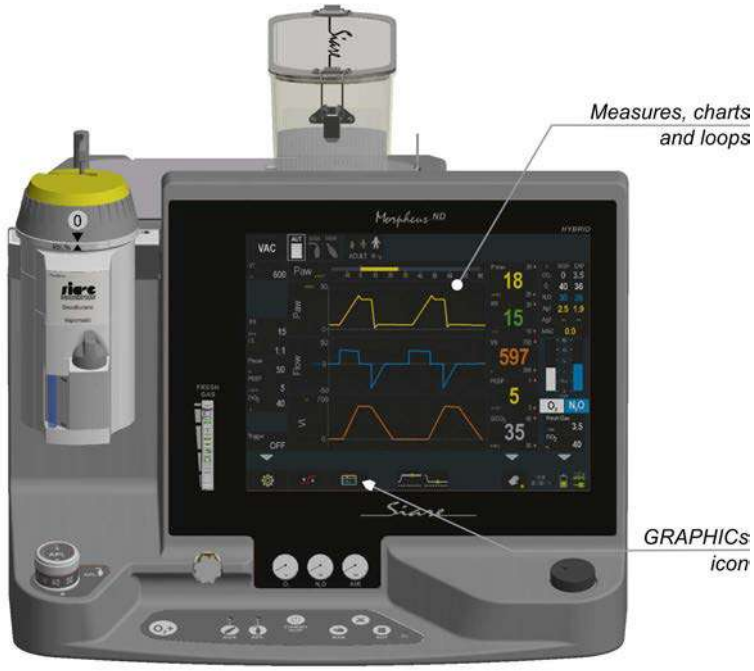
  NO: it remains in Alarm page.

- **Select** OK

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

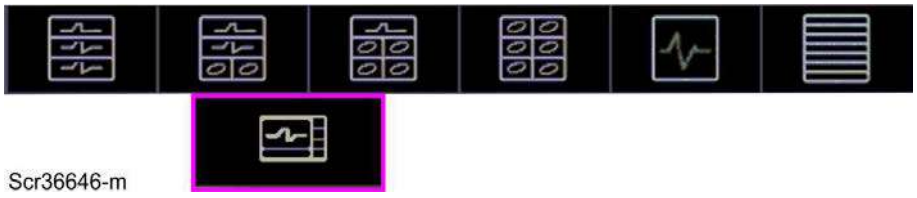
  NO: it remains in Alarm page.

3.6 Measures, charts and loops



The anaesthesia unit is equipped with a feature called **GRAPHICs** that allows the user to combine on display the Loops, the Charts and the Measured patient respiratory parameters in different ways.

Moreover, it allows to display the Trends and Events.



Select this icon (**GRAPHICs**) to choose “which“ and “how” to display the following detections.

Charts : PAW , Flow , Tidal Volume, Gas

Loops : Tidal Volume / Flow , PAW / Tidal Volume , PAW / Flow , Lung status icon

Measures : Breathing respiratory parameters, Gas

Trends and Events

Reselect the icon (**GRAPHICs)** to quit the function.

3.6.1 Available graphics combinations

WARNING !! Risk for Patient / user injury.

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

Scr92208-1

1st combination

3 charts

Scr92258-2

2nd combination

2 charts

2 loops or 1 loop and 1 lung status icon

Scr92270-3

3rd combination

1 chart

3 loops or 2 loops and 1 lung status icon

1 measured respiratory parameter

Scr98363-4

4th combination

2 loops or 1 loop and 1 lung status icon

4 measured respiratory parameters or different combinations

Scr98371-5

5th combination

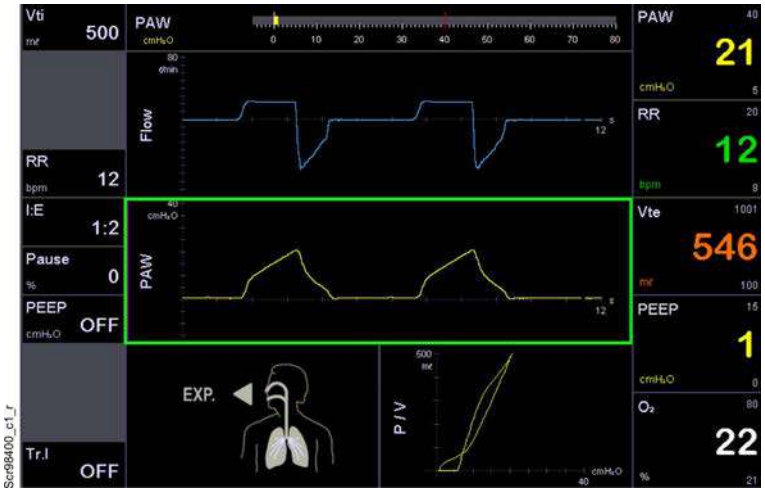
Trends

Scr98376-6

6th combination

Events

3.6.2 How to edit a new Charts

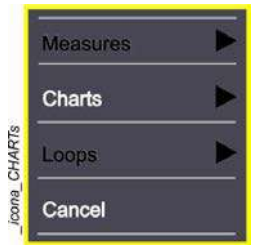


To change the combination of Charts detections, the anaesthesia unit must be started-up.

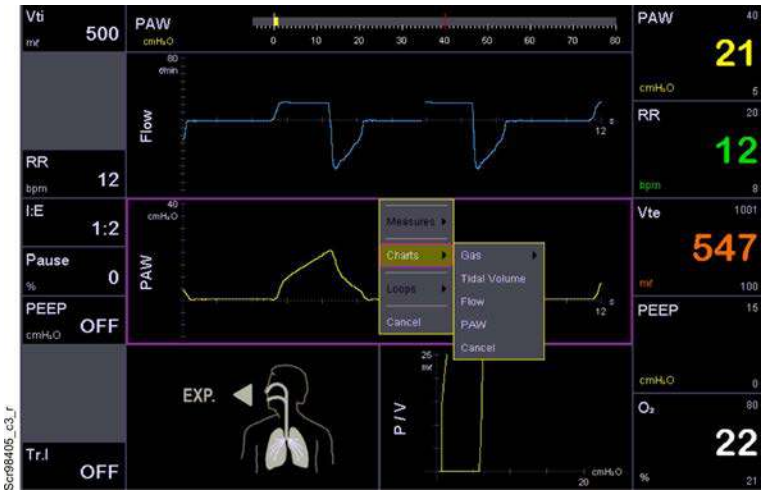
The selection of the box of one of the **Charts** displayed, enable the visualization of a drop-down menu with the list of the options available.

Keep selected the area of the **FLOW** graphic some seconds; the perimeter of the selected area by violet becomes green.

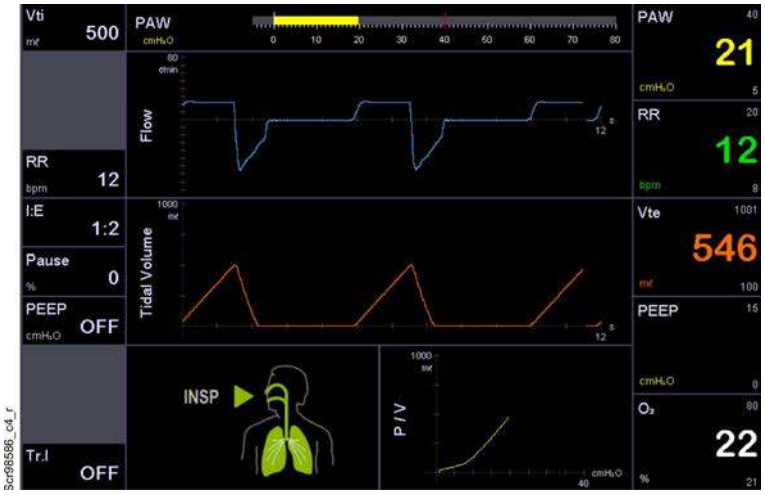
Release. The drop-down menu with the list of the available options appears.



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



Available Charts*: Gas, Tidal Volume, Flow , PAW.*



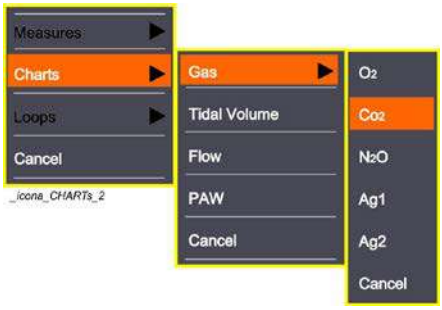
Tidal Volume chart is selected.

The **Tidal Volume** chart is displayed and it replaces the Flow graphic.

Gas charts is selected.

The drop-down menu with the list of the available Gas type appears.

Select the Gas to be monitored through a graphic.



Available Gas charts*: O_2, CO_2, N_2O, Ag1, Ag2 .*

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

3.6.3 How to edit a new Loop

Scr00547_L1_r

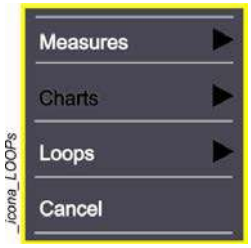
To change the combination of Loops detections, the anaesthesia unit must be started-up.

The selection of the box of one of the **Loops** displayed, enable the visualization of a drop-down menu with the list of the options available.

Keep selected the area of the loop some seconds (**PAW / Volume**); the perimeter of the selected area by violet becomes green.

Scr00559_L2_r

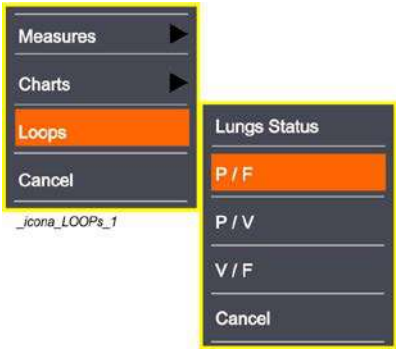
Release. The drop-down menu with the list of the available options appears.



_icona_LOOPs

Scr00581_L3_r

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



_icona_LOOPs_1

Available Loops: Tidal Volume / Flow , PAW / Tidal Volume , PAW / Flow , Lung status icon

The PAW / Flow loop is selected.

- The **P / F** loop is displayed and it replaces the previous loop.

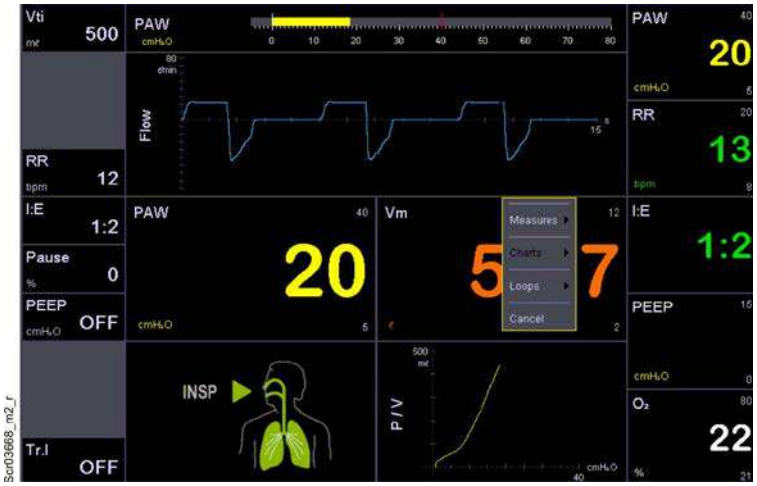
The procedure described is applicable to all the loops areas and in the different visualizations available.

3.6.4 How to edit a new Measures

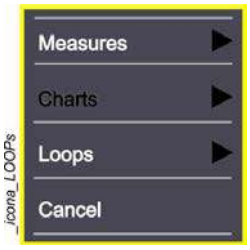
To change the combination of Measures detections, the anaesthesia unit must be started-up.

The selection of the box of one of the **Measures** displayed, enable the visualization of a drop-down menu with the list of the options available.

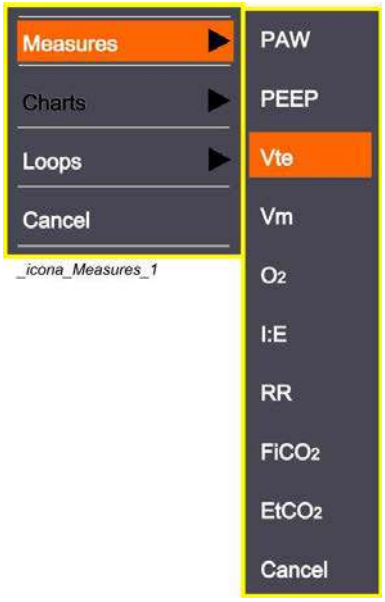
Keep selected the area of the measure some seconds (**Vm**); the perimeter of the selected area by violet becomes green.



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



Select a Measure. The drop-down menu with the list of the available measured parameters appears.



_icona_Measures_1

Available Measures: PAW , PEEP , Vte , Vm , O_2 , I:E , RR , $FiCO_2$, $EtCO_2$, ...

The Vte is selected.

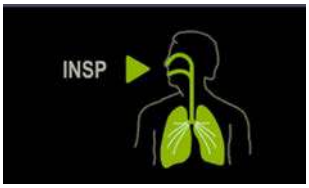
The **Vte** measures is displayed and it replaces the previous measured parameter.

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

3.6.5 Meaning of lung status icon

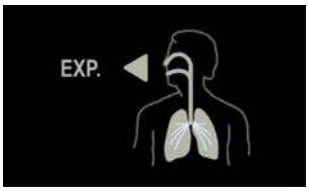
The lung status icon simulates the patient's lungs, graphically displaying the respiratory cycle by alternatively switching the lungs color.

In fact in case of patient's spontaneous activity (Trigger), the lung status icon turns to yellow and if the " LOW PRESSURE" alarm value set has not been exceeded the icon turns red.

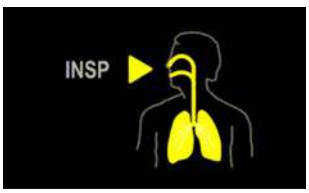


During inspiration the lungs icon turns green.

The lungs turn green during inspiration only if the PAW exceeds the " LOW PRESSURE" alarm value set.



During expiration the lungs icon turns light grey.



At trigger activation the lungs icon is yellow.

If the airways pressure does not reach the value of " LOW PRESSURE " alarm parameter. the lungs icon turns red.

WARNING!! Risk for Patient injury.

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

3.6.6 TRENDs

Scr98371-5

Selecting TRENDs function, to visualize the most significant respiratory parameters on medium - long term.

Select the **GRAPHICs** icon.

Select the **TRENDs** icon

Scr98371-5_r

Monitored respiratory parameters:

- **Rate**
- **PAW**
- **PEEP**
- **Vm**
- **Vte**

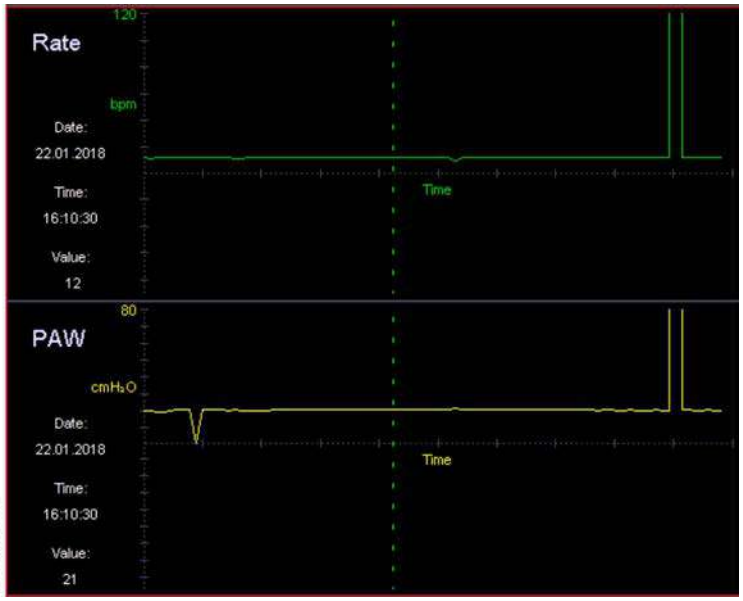
The storage capacity for each parameter is 72 hours with sampling at every 4 minutes.

The vertical scrollbar allows to select the respiratory parameters.

The horizontal scrollbar allows to check the parameters values in the time.

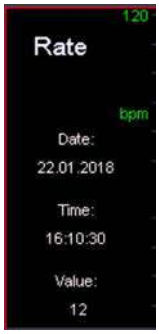
The vertical dashed bar (green) indicates the movement of the values measured in the time.

The vertical dashed bar can be moved and can be put in a specific position in the graphic selecting the option required (numeric value reading referred to a specific parameter in a specific moment)



Scr98371-5_r

On the left side of the TRENDs graphic the following data are reported: the monitored respiratory parameter, the date and the hour (it varies depending on the position of the vertical dashed bar) in which the parameter value has been measured.



CAUTION

To erase the values of the TRENDs stored, select MENU / DEFAULT / Erase Trends data

Erase TRENDs data

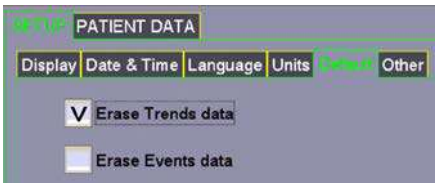
Scr42967_MENU

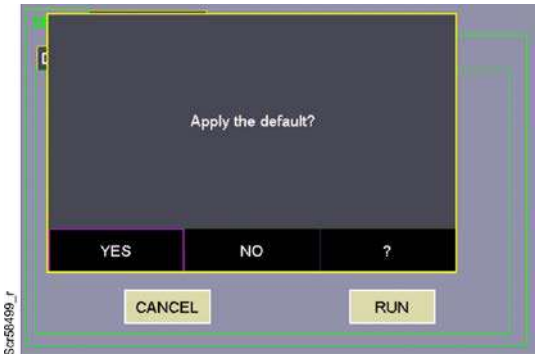
- Select **MENU**

- Select **Default**

Icona_SETTING-MENU

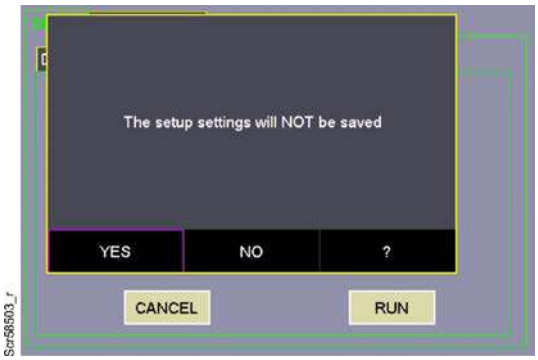
- Select**: Erase TRENDs data**





- Cancel the choice: **select**

Cancel



- Confirm the choice: **select**

RUN

All the former values TRENDs have been deleted; the system is ready for a new data storage.

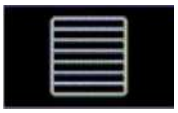
3.6.7 EVENTs

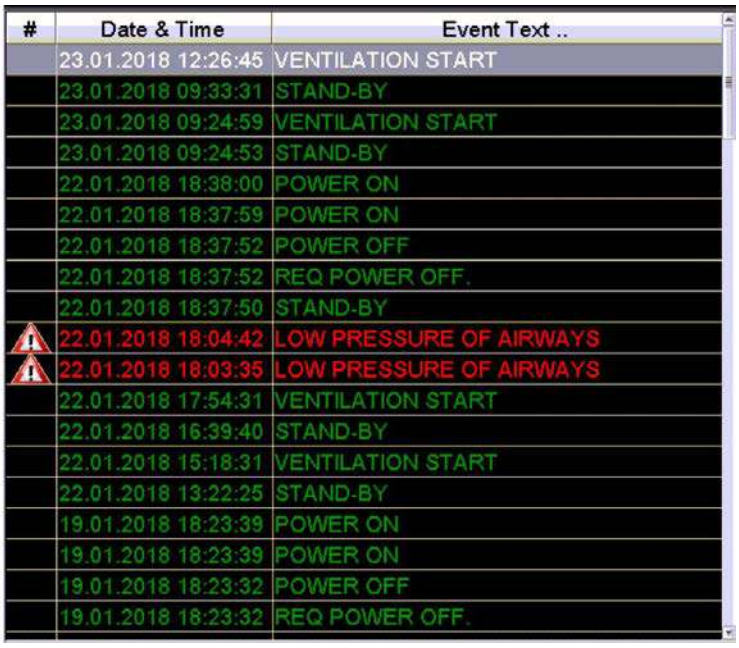
Scr98376-6

Selecting EVENTs function, to visualize the most significant information on the anaesthesia unit operation over time.

- Select the **GRAPHICs** icon.

- Select the **EVENTs** icon





#	Date & Time	Event Text ..
	23.01.2018 12:26:45	VENTILATION START
	23.01.2018 09:33:31	STAND-BY
	23.01.2018 09:24:59	VENTILATION START
	23.01.2018 09:24:53	STAND-BY
	22.01.2018 18:38:00	POWER ON
	22.01.2018 18:37:59	POWER ON
	22.01.2018 18:37:52	POWER OFF
	22.01.2018 18:37:52	REQ POWER OFF.
	22.01.2018 18:37:50	STAND-BY
⚠	22.01.2018 18:04:42	LOW PRESSURE OF AIRWAYS
⚠	22.01.2018 18:03:35	LOW PRESSURE OF AIRWAYS
	22.01.2018 17:54:31	VENTILATION START
	22.01.2018 16:39:40	STAND-BY
	22.01.2018 15:18:31	VENTILATION START
	22.01.2018 13:22:25	STAND-BY
	19.01.2018 18:23:39	POWER ON
	19.01.2018 18:23:39	POWER ON
	19.01.2018 18:23:32	POWER OFF
	19.01.2018 18:23:32	REQ POWER OFF.

Scr98376-6_r

The monitored EVENT refer mainly to the alarms (active alarms) and the various operating conditions of the anaesthesia unit (POWER ON, POWER OFF, STAND-BY, VENTILATION START, etcc…..).

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

The vertical scrollbar allows to display all the events.

The table of the Events provides the following indications:

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

CAUTION

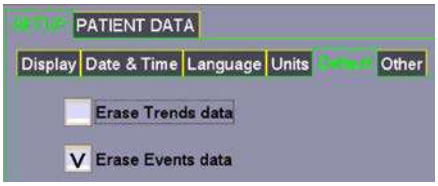
To erase the EVENTs data stores, select MENU / DEFAULT / Erase Events data.

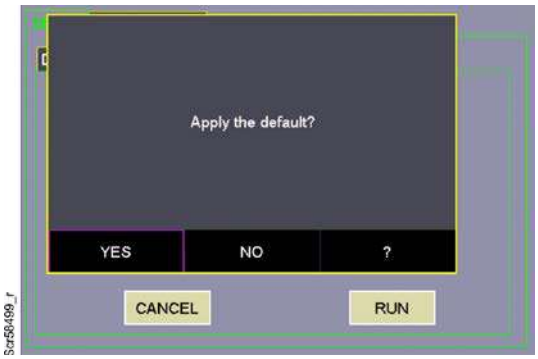
Erase EVENTs data

- Select **MENU**

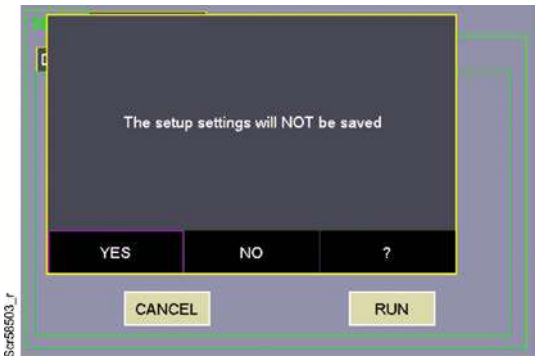
- Select **Default**

- Select**: Erase EVENTs data**





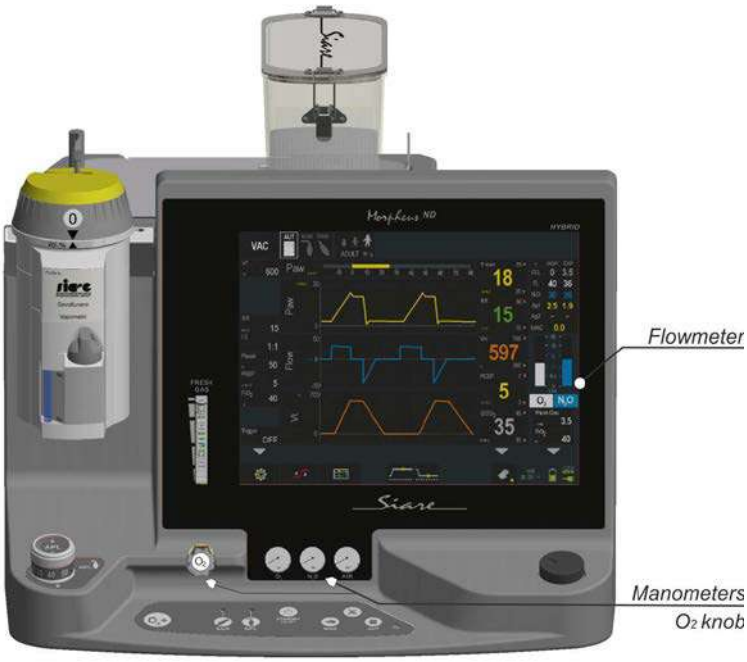
- Cancel the choice: **select**



- Confirm the choice: **select**

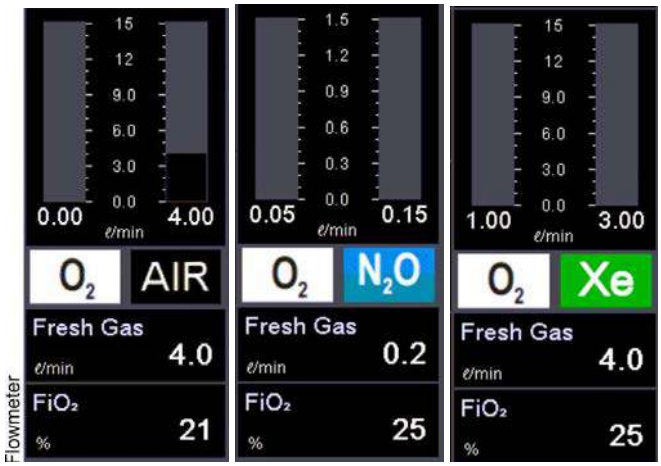
All the former EVENTs data have been erased; the system is ready for a new data storage.

3.7 Flowmeter



A great innovation is the flowmeter integrated on the front of the anaesthesia unit or better to say, included in the user's interface.

In this condition, the User will have a unique touch screen and the possibility to modify from a graphical point of view the fresh gases values delivered, the possibility to set and display from a graphical point of view the flows delivered to the patient and will have further functions available related to the flowmeter.

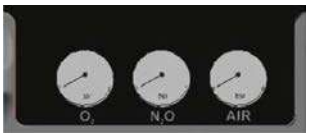


The flowmeter allows to:

To adjust both the flow and the concentration of the gas mix (Air, O2, N_2O, Xe) displaying it on the monitor.

To select the the mix to be delivered (Ait - O_2, N_2O - O_2 , Xe - O_2) and to enrich the mix deliverd by oxygen in case of emergency;

Through the control MIX-LIFE it grants a minimum concentrationof 25% of oxygen (FiO_2) in case N_2O is used (N*itrous oxide*) o Xe (*Xenon*).



To verify continuously the medical gases feeding pressure.

CAUTION

In case of emergency a knob delivering a monitored oxygen flow (**O_2**) from a mechanical flowmeter (safely calibrated) and indicating the oxygen delivered is foreseen (**FRESH GAS**)

Gas flow adjustment

CAUTION

The procedure described is applicable to all the gases foreseen (Air, Oxygen, Nitrous Oxide and Xenon).

Flowmeter

In case we want to increase the AIR flow in the fresh gases circuit:

- Verify the gases set on the flowmeter (**O2 e AIR**).
- Select **Fresh Gas** (set **4 l/min**)

Scr75338-Air

- The modification bar is displayed.

To **decrease** the AIR flow

To **increase** the AIR flow

To **confirm** the value of the AIR flow set

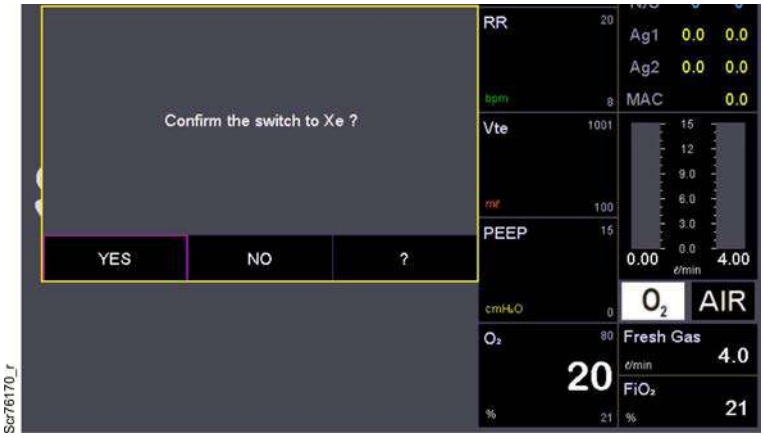
The system **goes back** to Stand-by page without modification.

The AIR flow in the FRESH GAS circuits has been increased from **4 l/min to 8 l/min**.

Gas type selection

In case we want to modify the gas used in the fresh gases circuit:

- Select **AIR**



The system requires a confirmation for the modification and in this case, it requires the User to confirm he wants to use the Xenon:

- Confirm to switch to **Xe**

The flowmeter will automatically set on **Xe** enabling the funtion MIX LIFE with FiO2 **at 25%**

NO : **AIR** set will remain unchanged

CAUTION

The procedure to go back to the use of **AIR** (so from Xe or N2O to **AIR**) is the same; the system requires to confirm the modification.

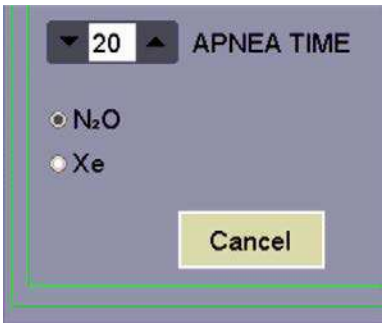
It's anyway necessary to point out that the User can decide to choose both the Nitrous Oxide and **the** Xenon instead of **AIR**

- Select **MENU**

- Select **Other**

This Page (**MENU / SETUP)** allows to set some parameters (see on cfr. 3.2.5) among which the type of gas to be used.

- **N2O or Xe**



- **Select**

YES : to quit **SETUP/ Other** page without saving.

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

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

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

- **Select**

3.8 MENU, Operative functions and general informations

In the lower side of user interface module there are a series of controls and functions that are fundamental for use of anaesthesia unit.

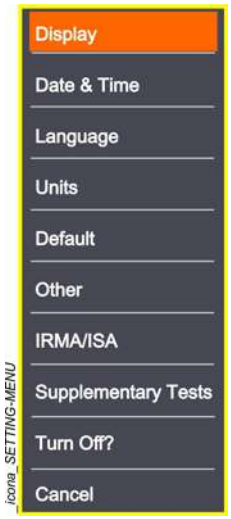
Some of these functions (icons) have already been described in the previous paragraphs.

Scr51314_mod

MENU

Scr42967_MENU

- Selecting this icon, a drop-down MENU allowing the user to enter directly different options is displayed on the monitor



The **drop-down MENU** allows to enter the following options:

- *Anaesthesia unit's SETUP / PATIENT DATA (see on cfr 3.2.4 and 3.2.5).*

Setting of the gas IRMA/ISA sensor (see on cfr 4.x).

- *Supplementary Tests (see on cfr 4.x).*
- *Anaesthesia unit: " Turn OFF " (the system always requires a confirmation for the switch off of the device).*
- *Cancel : for going back to the former Stand-by visualization*

In Stand-by mode, selecting the MENU icon it is possible to enter to the PATIENT DATA setting (*for further informations*, *see on cfr 3.2.4 and 3.2.5).*

The choice of the PATIENT DATA (Adult, Child, New Born) set automatically the default physiologic respiratory parameters (PRP) of the anaesthesia unit (breathing parameters and alarms levels).

Alarm Limits

Select this icon to access anaesthesia unit **ALARM LIMITS** (*for further informations*, *see on cfr 3.4 or chapter 6).*

GRAPHICs

Select this icon to access anaesthesia unit **GRAPHICs** (*for further informations*, *see on cfr 3.5).*

INSP HOLD

Select the INSP HOLD mode: the system will extend the inspiration time **to 20 seconds**. The function activation is displayed by the monitor and signalled by the yellow LED inside the box, that turns on.

Scr44056_INSP

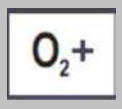
EXP HOLD

Select the EXP HOLD mode: the system will extend the expiration time **to 20 seconds**. The function activation is displayed by the monitor and signalled by the yellow LED inside the box, that turns on.

Scr44337_EXP

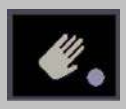
CAUTION

INSP HOLD and EXP HOLD modes can be disabled selecting the relevant icon; automatically (20 seconds); pressing the encoder knob.



BY-PASS O2 Control

Selecting the icon, pure oxygen is introduced in the anaesthesia circuit with a flow of approx 35 l/min



MANUAL MANUAL fucntion enabling

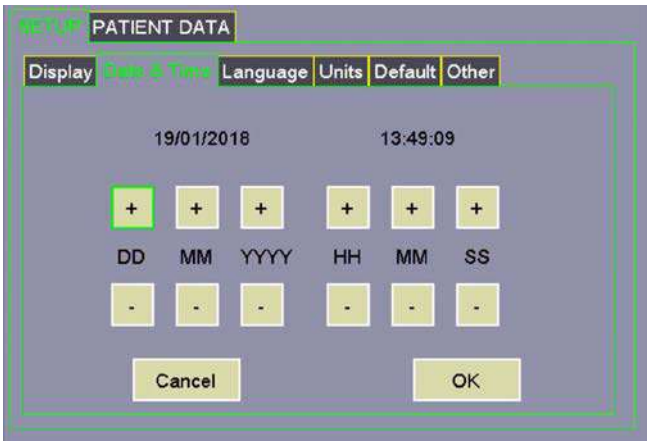
- Select the icon to activate the manual ventilation to the patient: by selecting the MAN mode the system provides the patient with a breath.
- The breath ventilation parameters depend on the operative mode set: the function activation is monitored by the monitor and signaled by the green LED inside the box, that turns on.
- This mode is active while the anaesthesia unit is running.

For more details about Manual function, see on chapter 5.x (Anaesthesia unit use)

The selection of this icon, allows directly to update Time and Date set (*see on cfr. 3.2.5).*

To modify select **+** or **-** ; select **OK** to confirm.

To quit **SETUP / Date & Time** , select **Cancel**.



CAUTION

The message **(USB)** that appears inside the icon (Time / Date) indicates that a key enabled for the download of patients data or for the download of the ScreenShots has been connected to the **USB1** output (see on cfr. 5.13.4).

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).

For more details about this icon, see on chapter 6 (Alarms)

3.9 List of default parameters

Parameters	Adult	Paediatric	Neonatal
Mode	VC/VAC	APCV-TV	APCV
VT (ml)	500	200	-
RR (bpm)	14	25	40
I:E	1:2	1:2	1:2
Inspiratory Pause (%)	10%	-	-
Trigger (cmH_2O)	-2	-1	-1
PEEP (cmH_2O)	5	4	3
FiO2 (%)	21%	21%	21%
Pinsp (cmH_2O)	-	-	20
Pmin (cmH_2O)	-	5	-
Pmax (cmH_2O)	-	30	-
Slope	-	3	3

4 PREPARATION TO USE

- In the first part of this chapter it is illustrated how to install the Morpheus_ND anaesthesia unit.
- In the second part it is illustrated how to perform the preliminary tests before using the Morpheus_ND anaesthesia unit (*hereinafter called anaesthesia unit*).

4.1 General warnings

CAUTION - UNPACK THE EQUIPMENT

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

TRANSPORT - Equipment moving

- Move the trolley/anaesthesia unit by the wide handle under the work-shelf perimeter which allows to grab and easily move the unit.

The anaesthesia unit must be moved possibly by two persons in good physical condition; this condition facilitates the maneuverability of the unit.

- During the 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 anaesthesia unit over obstacles in general (hoses, cables or other obstacles on the floor).

WARNING !! Risk of personal-physical injuries

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

- Remove the eventual devices positioned on the unit or fixed laterally.
- Dismount any additional device on the arms or on the upper side of the anaesthesia unit.
- Ensure that the drawers are closed (trolley).
- Pay much warning to eventual obstacles in the path during moving and positioning phases.

WARNING !! Accidental moving danger

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

- Position correctly the anaesthesia unit on a flat surface.
- Apply the trolley/anaesthesia 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 anaesthesia unit is 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 anaesthesia unit should only be used in appropriately ventilated rooms.
- Do not connect or disconnect parts or components when the anaesthesia unit is on or connected to the mains power supply.
- Before using the anaesthesia unit, carry out all the necessary preliminary tests.

CAUTION

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

WARNING !! Serious patient injuries

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.

4.2 Before the use

4.2.1 O_2 cell assembling

- Insert and screw the cell: in the space marked with the script " **O2 CELL** ".
- Connect the electric cable of the cell passing it into dedicated space.
  - The O_2 cell connector
  - The RJ connector on the specific socket within the valves group.

WARNING !! Risk for Patient injury

- Visual check of electric connection of oxygen cell.

At each anaesthesia unit start-up, the system checks the presence of the electric connection to the O_2 cell (Self Test phase, see on chapter 5.2 or chapter 4.7)

4.2.2 Assembling of absorber canister

On the anaesthesia unit it is possible to use a multipurpose rechargeable absorber canister or a disposable pre-loaded absorber canister.

It is recommended to use only original SIARE spare parts or spare parts checked and approved by SIARE.

The absorber canister is positioned in the upper side of valves group. The specific lock (unlock) lever makes very easy to hook (unhook) the canister.

Mount the CO_2 absorber canister on the anaesthesia unit as shown in the picture.

- To unpack carefully the CO_2 absorber canister.
- Shake the absorber canister (disposable model) in order to separate the soda lime granules.
- Remove the seal from absorber canister (disposable model).
- Insert the absorber canister in the apposite groove (opposite side of the "PUSH" lever).

- Press the specific lock “PUSH” lever (unlock).
- Press down and release the specific lock lever (unlock).
- Ensure the correct assembly

When the CO_2 absorber canister is inserted, the system is automatically configured in rebreathing modality.

When the canister is removed, the system is automatically configured in non rebreathing modality (real open circuit).

It is possible to insert and remove the canister during interventions. The canister is available in reusable or pre-loaded disposable versions.

WARNING !! Risk of personal injuries

Handle the absorber canister with care.

The absorber (soda lime) is corrosive and highly irritanting for the skin, the eyes, and, if inhaled, for respiratory airways.

For the “Self Test” (Leak Test and O_2 Calibration) phases, it is NOT necessary that the CO_2 absorber canister is mounted on the valves group.

WARNING !! Risk for Patient injury

The soda lime loses humidity: if the humidity falls below the minimum set value, undesired reactions could occur regardless of the type of employed soda lime and anesthetic gas.

- CO_2 reduced absorption
- Increased heat generation in the soda lime and then increased temperature of inhalation gases
- CO formation
- Anesthetic gas for inhalation absorption and/or decomposition

These reactions could be dangerous for the patient. In case of use of dry gas and only if necessary, just briefly rinse the anaesthesia system.

4.2.3 Battery charger

The anaesthesia unit is equipped with an internal battery that guarantees (if perfectly efficient) at least 120 minutes operation (90 minutes, according to ventilatory parameters), in case of power failure. The switching to battery operation is made automatically: on the unit screen appears the relevant message “ POWER SUPPLY FAULT ”.

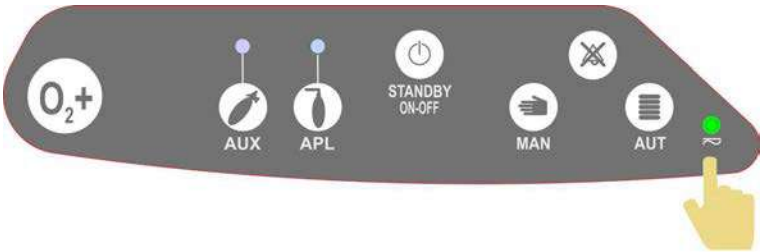
The anaesthesia unit battery can be recharged by connecting the equipment to main power supply and placing the main switch in " **I** " position.

Carry a battery charge at least 10 hours, before using the the anaesthesia unit the first time.

The operating time of anaesthesia unit guaranteed by the battery, can vary in the following cases: old battery or not perfectly efficient, not standard ventilatory parameters, presence of electronic flowmeter box.

- Insert the plug of the power supply cable to the wall socket.
- Connect the power supply cable to the anaesthesia unit.
- The electric main power supply must correspond to the one indicated in the identification label on the back side of the unit.
- Set the main switch (placed on the back side of the anaesthesia unit) to “ **I** “.

- Verify on the front module of unit (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 10 hours recharging through the mains power supply.
- It is not necessary to start-up the anaesthesia unit.

4.3 Preparation to use

4.3.1 Medical gas connection

- With the unit operating by TURBINE, it is anyhow necessary the presence of an oxygen supply, useful for the operating of the internal pneumatic system.
- The equipment can also work with oxygen supply only, but in this case the FiO_2 will be adjustable at 99% only.
- The gas used must be of medical type, therefore oil free and filtered.

- Screw the gas supply hoses to relevant connectors of the gas supply group.
- Screw the gas supply hoses to the relevant connectors of the hospital distribution system.
- Ensure that all the supply hoses are connected and are correctly working.

The hoses are already supplied with screw connections DISS type (Diameter Index Safety System) for connection to the anaesthesia unit connectors. The installation technician taking care of the hoses connection to the outlets 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.

WARNING !! Risk of equipment failure

In order that the anaesthesia unit operates as specified, the inlet pressures of medical gases must be between 280 kPa and 600 kPa (2.8 - 6 bar). Before use ensure that this requirement is met.

The medical gas source shouldn't contain water: if you suspect the presence of water, connect a water trap to avoid damages on the unit and its components.

WARNING !! Risk of power failure

- If all the gas supply hoses are not correctly connected, the anaesthesia unit will not be available in case of gas supply failure.
- Ensure that all supply hoses are connected according with the indication engraved on the gas inlet bloc and the relative illustrations.
- After the hoses connections, verify that the anaesthesia unit is correctly working.

4.3.2 Connection of medical gas supply to cylinders (optional)

- Screw the gas supply hoses to the connectors of the cylinders pressure reducers.
- Ensure that all the gas supply hoses are connected and work correctly: the cylinders hoses are supplied with the screw connector DISS type.

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 gas power failure

In case of failure of the hospital's medical gas distribution system, the cylinders will supply a reserve gas supply.To avoid a complete gas power failure, the cylinders must always remain near the anaesthesia unit, with the pressure reducers closed.

WARNING !! Risk of explosion

- If the pressure reducers for O_2 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_2 cylinders pressure reducers and never touch with fingers soiled with oil or grease.

WARNING !! Risk of gas power failure

- Connection on the same connector of the gas supply anesthesia unit from the cylinder and the hospital gas plant.
- If the cylinder pressure reducer is open during operation with the medical gas distribution system of the hospital, there is the danger of undesired erogation of medical gas from reservoir cylinders.
- Close the cylinder pressure reducer in case the hospital medical gas distribution system is sufficient.

4.3.3 Medical gas connection checks

WARNING !! Risk of gas power failure

This check is strictly necessary and has to be performed whenever a hose from hospital gas distribution system (or cylinder supply) is mounted on the unit (first connection or first replacement of hoses or connectors for maintenance reasons).

CAUTION

Only highly qualified personnel can fit the anaesthesia unit with connectors compatible with the hospital medical gas distribution system and perform all maintenance and replacement of medical gas supply hoses so as to avoid inversion of gas that can be FATAL for the patient.

Follow these instructions.

1. Connect to the main gas system only the AIR hose (***if supplied***), select AIR on the anaesthesia module and open the three regulators of the anaesthesia module. Only the AIR flowmeter should raise and its relevant pressure gauge should indicate a pressure included between 280 kPa and 600 kPa (2,8-6 bar).

2. Connect to the hospital gas system only the Oxygen hose and open the three regulators of the anaesthesia module. Only the oxygen flowmeter should raise and its relevant pressure gauge should indicate a pressure included between 280 kPa and 600 kPa (2,8-6 bar).

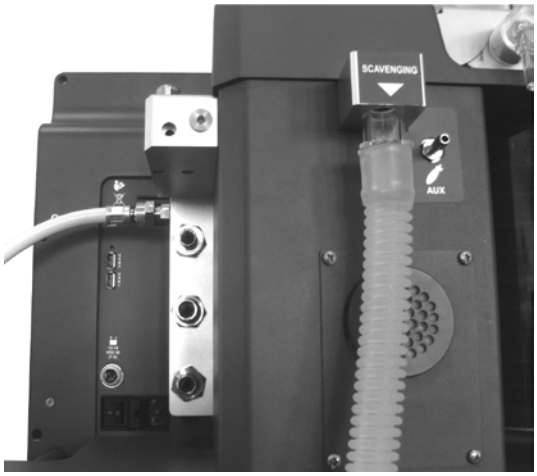
3. Connect to the hospital gas system only the Nitrous Oxide hose, select N2O on the anaesthesia module and open the three regulators of the anaesthesia module. Only the oxygen and nitrous oxide flowmeters should raise and the relevant pressure gauge should indicate a pressure included between 280 kPa and 600 kPa (2,8-6 bar).

4. With open N2O pressure reducer, disconnect the Oxygen hose and verify that the oxygen goes down, that the delivery of Nitrous Oxide stops and that the CUT-OFF alarm whistle is audible.

4.3.4 Connection of anaesthetic gases scavenging system

For more details about scavenging system manufactured by SIARE, please refer to relative User and Service manual.

- **SCAVENGINGS** : gas scavenging connector.
- **O2** : gas supply connection for active gas scavenger.



WARNING !! Risk for Patient injury.

- If the scavenging collector of the anaesthesia unit is blocked, in the breathing system and in patient lungs could create a negative pressure.
- Always ensure that the collector is not obstructed and/or blocked.

4.3.5 Use of antibacterial filter

Apply the antibacterial filters to the patient circuit.

WARNING !! Risk of injury for the patient

To protect the patient from particles and dust, generated for example by the soda lime, it is necessary to use a filter between the inpiratory 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 (please, see on chapter 7).

4.3.6 Patient circuit connections

Insert the patient circuit supporting arm in the specific bracket, fixed to the full-height steel rod used for accessories mounting.

CAUTION

Use a suitable patient circuit for the patient ventilation.

Tidal Volume	Set of hoses
< 50 mL	Neonatal
from 50 to 200 mL	Paediatrics
> 210 mL	Adults

- Connect the patient circuit to the specific INS. and EXP. connectors on the valves group.
- Position the patient circuit on the patient circuit supporting arm.

WARNING !! Risk for Patient injury.

- Whenever the circuit is changed or replaced, it is necessary to perform the Leak Test to verify eventual leaks and the compliance of patient circuit (please see chapter. 4.8).
- The system checks the patient circuit at every start-up of the unit: Self Test phase, see on chapter 5.2 or chapter 4.7)

WARNING !! Risk of strangling

Pay special warning when connecting the patient circuit to the anaesthesia unit. If not carefully positioned, the hoses, the cables, the patient circuit and other similar components to the anaesthesia unit, 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.

4.3.7 Gas analyzer connection

For further information on operating logic and on gas sensor malfunctioning, make reference to the gas analyzer manual supplied with the device.

- Extract the gas analyzer and the cable + interface module, from package.
- Switch OFF the anaethesia unit power supply - OFF
- Connect the interface cable between the RS-232 connector (positioned on the side of anaethesia unit) 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.

CAUTION

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.
- **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 you turn-on the GAS ANALYZER*).

4.3.8 Data Connection (Trend and Events downloading)

- Connect a USB drive to a **USB0** socket for CPU programming *(USB near the reset button).*
- Connect a USB drive to a **USB1** socket for Trend and Events data downloading *(see picture).*

Trend and Events downloading

A dedicated software permits the download and the analysis of the data stored in the Morpheus_ND anaesthesia unit (*for more details, please see on chapter 5.13.4*).

4.4 MAN ventilation

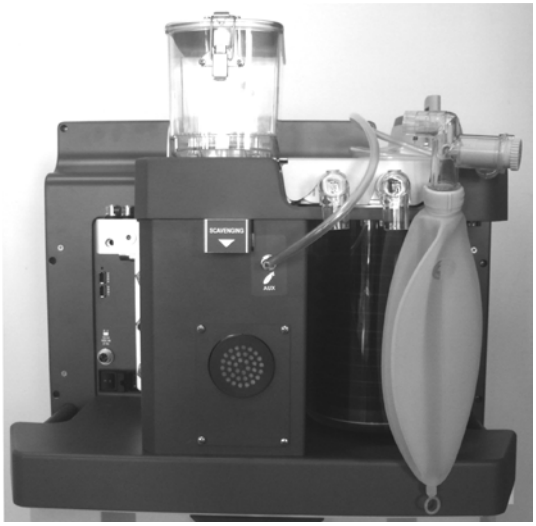
4.4.1 Fresh gases exit - TO and FRO patient circuit

WARNING !! Risk for Patient injury

Do not connect the patient directly to the fresh gases exit without an adequate ventilation circuit with pressure relief system.

If the patient is connected to the fresh gases exit without an adequate ventilation circuit with pressure relief system, there will be an high pressure dangerous for the patient.

- Apply to the TO and FRO patient circuit to the anaesthesia unit (AUX connector) as shown in the picture.

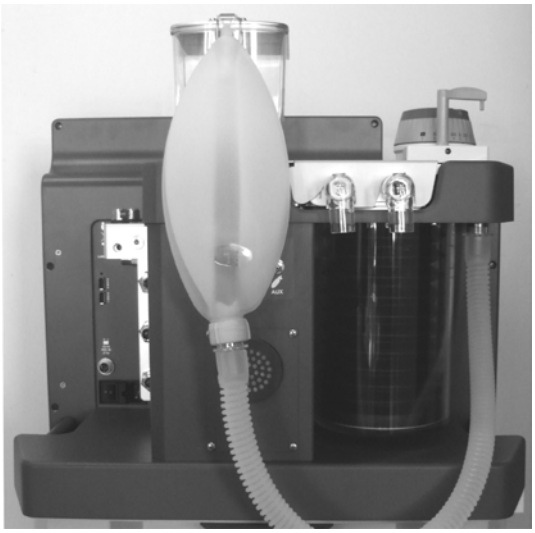


Select MAN operative mode.

To activate the TO and FRO patient circuit act on the fresh gases exit selection control: enabling exit connector (AUX).

4.4.2 Connection of circuit for manual ventilation

- Apply to the manual ventilation patient circuit to the anaesthesia unit (BAG connector) as shown in the picture.



Select MAN operative mode.

To activate the manual ventilation patient circuit act on the fresh gases exit selection control: enabling of valves group BAG connector (APL).

4.5 Connection to power supply

The electrical connections are a very important part in the installation of the anaesthesia unit. Incorrect connections or connections to unsuitable electrical systems can compromise the safety of the patient and the User. The mains power supply must comply with the CEI 64-8/7 regulations concerning type A premises for medical use.

The power supplies foreseen on MORPHEUS_ND anaesthesia unit are of three types:

- by main power supply (100 - 240Vac / 50 - 60Hz)
- by low voltage power supply (12Vdc / 7A)
- by internal battery (NiMh 4,5 Ah 12Vcc : max. autonomy 2 hours).

4.5.1 Main power supply

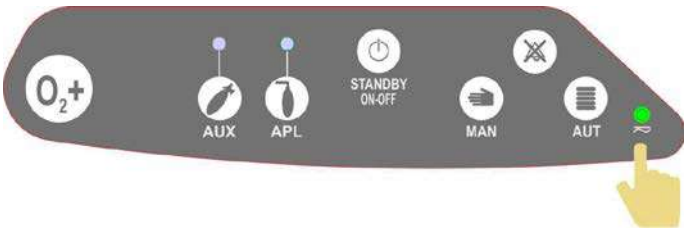
The main electric power supply must correspond to that indicated on the identification label (electric power supply, frequency and power consumption) located on the back side of anaesthesia unit: 100 - 240Vac / 50 - 60Hz / 120 VA.

WARNING !! Patient / User injury hazard

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

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

- Connect the power cable outlet to the plug on the anaesthesia 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 anaesthesia unit) in position “I”.
- Verify on ventilator module front side if the green led is lit (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.

CAUTION

- The Morpheus_ND complies with the requirements for electro-medical devices detailed on chapter 1.3 (Norms and standards regulations).
- To ensure proper operation of the Morpheus_ND, 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 Morpheus_ND.

4.5.2 Low voltage power supply

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

WARNING !! Risk of wrong feeding polarity

- Connect to the **12-14 VDC IN** connector the apposite cable supplied with the anaesthesia unit.
- The brown cable must be connected to the positive polarity.

4.5.3 Battery power supply

- The operation time of the anaesthesia unit guaranteed by the battery can vary in the following cases: old battery or not fully efficient, unusual ventilatory parameters, presence of electronic flowmeter box.
- Replace the battery each two years (*please refer to chapter 7 Maintenance*).

WARNING !! Risk of personal-physical injuries

- The battery, inside the anaesthesia unit, must always be installed.
- If the battery is not fitted, the anaesthesia unit is not protected against fluctuations or failures of the power supply.
- The anaesthesia unit must not be used without a mains power supply.
- 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 mains power supply module to replace the battery or to carry out maintenance operations on the battery charger.

- To silence the acoustic alarm, push the key " **ALARM RESET** ".

- When the led on the front panel is on it indicates that the anaesthesia unit is correctly supplied.

Battery charger

The anaesthesia unit battery can be recharged by leaving the anaesthesia 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 at chapter 4.2.3.

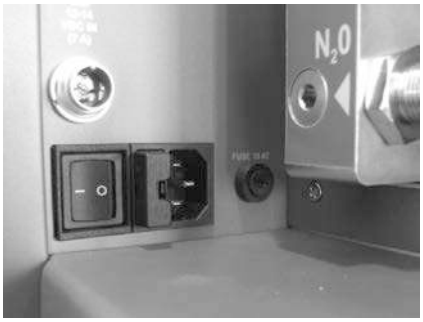
WARNING !! Risk of failure

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

4.5.4 Protection fuses

There are protection fuses installed on the following circuits.

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



WARNING !! Risk for Patient / User injury

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, please proceed as follows.

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

WARNING !! Risk for Patient / User injury

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

4.6 Connection to other equipments

Connection to Siare equipment

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

WARNING !! Risk for Patient / User injury

Do not connect external devices NOT manufactured or NOT authorized by SIARE to the anaesthesia unit (e.g., scavenging systems, patient simulators), and not described in the present user's manual. In case of need contact SIARE.

WARNING !! Risk of injuries for th patient

When using additional components in the respiratory systems or configurations not conform to those supplied with the anaesthesia unit, the inspiratory and expiratory resistence 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 outlets of the anaesthesia unit could cause an increase in leakage current over the values allowed by the law.
- In case of connection of other devices to the supplementary outlets, it is necessary to verify the total leakage current.
- In case of overcoming of the values allowed for total leakage current, do not connnect the devices to the supplementary outlets of anaesthesia unit, but to separate electric outlets.
- All the system must comply with the requirements for electromedical equipment stated by the IEC/EN 60601-1-1 and IEC/EN 60601-1-2 directives.

4.7 Use - Preliminary tests

To obtain better performances, leave the anaesthesia unit 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.

4.7.1 Introduction to preliminary tests

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

The preliminary aim to verify the correct connection and functionality of the anaesthesia unit and all its components.

The list of preliminary tests is available at the end of this chapter or at chapter 8 APPENDIX .

CAUTION

The preliminary tests should be performed:

each time the anaesthesia unit 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 Morpheus_ND anaesthesia unit must be:

- prepared for the 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 checks 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 anaesthesia unit if you detect any suspect oxygen leaks from the anaesthesia unit 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 anaesthesia unit 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 anaesthesia unit).

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 anaesthesia unit condition.

For the periodical checks that you should carry out, please refer to chapter 7 Maintenance.

WARNING !! Risk for Patient / User injury

All maintenance and/or repair interventions require full knowledge of the anaesthesia unit, 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.

4.8 Power-ON / Self Test phase

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

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

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

Scr15476

The anaesthesia unit turns ON and the automatic **Self Test phase** begins.

" Please close the patient circuit "

Scr16349

Self Test phase in progress.

Scr16385

Self Test phase in progress.

" If the acoustic alarm is audible, please push the RESET key "

- Acoustic Alarm test.

Acoustic Alarm test

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

Scr16388

Self Test phase completed successfully.

" Press OK to begin "

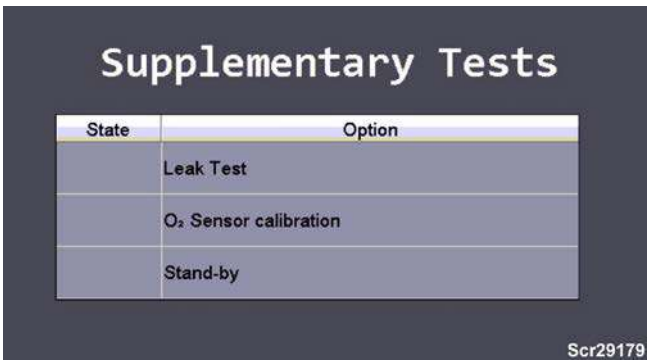
" Press Cancel for other tests "

OK — *Go to **Stand-by** operating mode, by pressing **OK** or **AUT** soft key.*

Cancel — *Go to " **other tests** " , by pressing Cancel.*

Cancel

Press **Cancel** : the system will display the **Supplementary Tests** page.



Supplementary Tests

Through this page it is possible to perform the Supplementary Test (*for further details see chapter 4.8*).

- Leak test
- O2 Sensor calibration

Before connecting the anaesthesia, unit and ventilate a patient it is always necessary to perform a series of preliminary checks to verify the correct operation.

OK

Press **OK** : the system will display the **PATIENT DATA** page.

PATIENT DATA

The **PATIENT DATA** displaying allows to set the patient data and characteristics.

- *PATIENT DATA*
- *SETUP*

The software does not switch directly to Stand-by mode, but it first displays a PAGE which allows the adjustment of the PATIENT DATA (if necessary or required).

The PATIENT DATA displaying allows to set the patient data and characteristics.

- PATIENT DATA *(see on chapter 5.3.1).*
- SETUP anaesthesia unit parameters *(see on chapter 5.3.2).*

Scr51314_Stand-by

Stand-by mode

In this phase press indifferently one of the two keys (**Cancel or OK**) to access Stand-by visualization.

In case of variations of **PATIENT DATA** values, press **OK** to confirm the updating.

Stand-by mode

After carrying out the Self Test or before turning the anaesthesia unit OFF, it automatically switches to this operative mode.

In this operative mode you can set and/or edit all anaesthesia unit parameters (PRP) and/or alarms, etc… relative to the operative mode that you will use on the patient that you want to treat.

In Stand-by you can select the operative mode and set and/or edit all anaesthesia unit parameters (PRP) that belong to the operative mode in question.

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

For methodology of the use of touch screen and/ or control keyboard and encoder knob, see chapter 3.1 and chapter 3.3.

4.8.1 Self Test phase : Fail

The Self Test phase did not complete successfully

During the Self Test phase, the software carries out self-diagnostic tests: during this phase one or more devices essential for safe and correct operation of the anesthesia unit / patient ***does not exceed the test*** *(see image:* ***Fail****).*

Scr17763

The Self Test phase was not completed successfully.

Despite this phase of Self Test has not been overcome, the system allows to proceed.

" Press Ok to begin anyway "

OK

WARNING !! Risk for Patient / user injury

- *Individuate the typology of problem detected during the Self Test (see on next chapter).*
- *Please see on chapter 6: Alarms and Troubleshooting.*
- *Turn OFF the Anasthesia Unit and repeat the Self Test.*
- *If the problem persists, contact the nearest Siare Technical Centre or any other Technical Centre authorised by Siare.*

For further information on ventilation module, and in particular on how to set the language used on graphic interface (see chapter 4.7.2).

4.8.2 Self Test : list of self-diagnostic tests

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

Device	Test Description
Turbine	Turbine functioning check.
Oxygen Inlet	Verification of the presence of O_2 supply pressure.
CAN module 3	Check of communication (CAN BUS) between Inspiratory Valves board and Main Board. Check of communication (CAN BUS) between the PEEP valves board and Main Board.
INSP. Flow sensor	Check of the operation of the Inspiratory Flow sensor (the system generates a flow of 20 l/min and wait for a reading of INSP sensor of 15 l/min at least)
EXP. Flow sensor	Check of the operation of the Expiratory Flow sensor (the system generates a flow of 20 l/min and wait for a reading of EXP sensor of 15 l/min at least).
Electrovalve	Check of the operation of the Electrovalve (on the flow and pressure pneumatic circuit).
Patient Circuit	This test verifies the patient circuit connection checking the presence of pressure in the circuit opening and closing the expiratory valve.
Battery	Check of the battery voltage value (to pass the test, the battery must have an residual autonomy higher than 50%).
Oxygen Sensor	Check of the electric connection of the O_2 sensor (to pass the test, the voltage delivered by the O_2 sensor at 21% must be higher than 8 mv).
Protolock O_2	Check of the correct connection of Oxygen gas.
Protolock Air	Check of the correct connection of Air gas.
Acoustic Alarm	The User should check if the system generates the acoustic signal, and can confirm the test by press the Alarm RESET key.

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

If the " Self Test " phase is not overcome consult the chapters 8 (Alarms and Troubleshooting) or contact the nearest Siare Technical Centre or a Technical Centre authorized by Siare.

4.9 Preliminary checks

4.9.1 Introductions

The preliminary checks are divided in 4 sections

SUPPLEMENTARY TEST

- O_2 Sensor Calibration
- Leak Test

FLOWMETER

VENTILATION MODULE

- Physiological respiratory parameters
- Parameters monitoring
- Anaesthesia unit alarms

OPTIONAL

WARNING !! Risk of unit 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.

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

CAUTION

The anaesthesia unit must be ready for use in order for you to start with the preliminary checks. Proceed with the following operations / verifications.

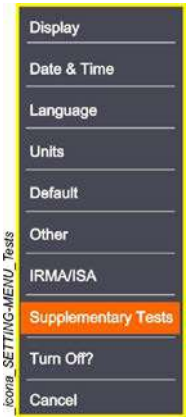
- *Connect, electric power supply, medical gas and patient circuit.*
- *Insert and connect, oxygen sensor.*
- *Insert, CO_2 canister and Manual ventilation KIT*
- *Connect a patient simulator to the patient circuit terminal.*
- *Anaesthesia unit ON : Stand-by mode.*

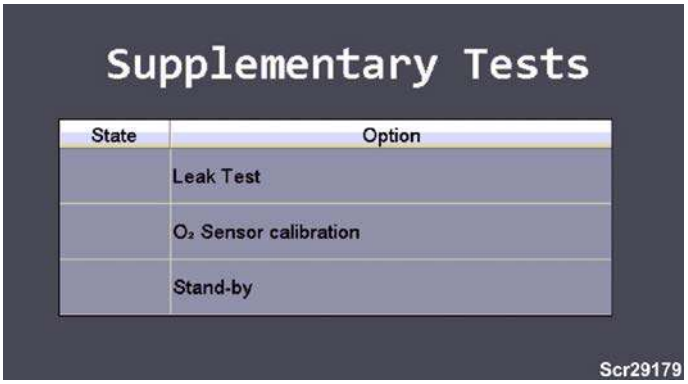
4.9.2 Supplementary Test

Before connecting anaesthesia unit to the patient it is always necessary to perform a **Preliminary Test** to verify the correct operation of Morpheus_ND.

- Select **MENU**

- Select **Supplementary Tests**





The **Supplementary Tests** screen appears.

4.9.3 Leak Test

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

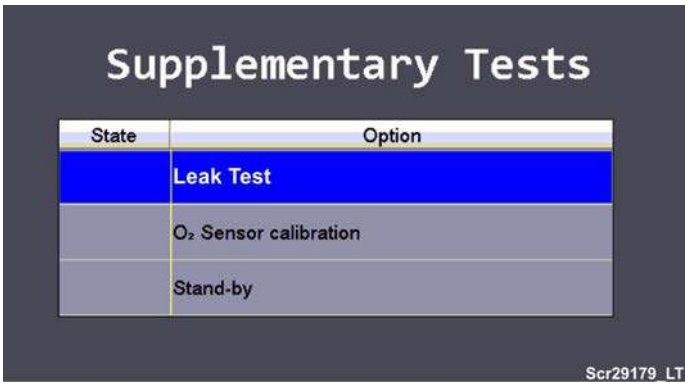
The **Leak Test** verifies that there are no leaks higher than 100 ml in the anaesthesia unit pneumatic circuits.

Perform the **Leak Test weekly**.

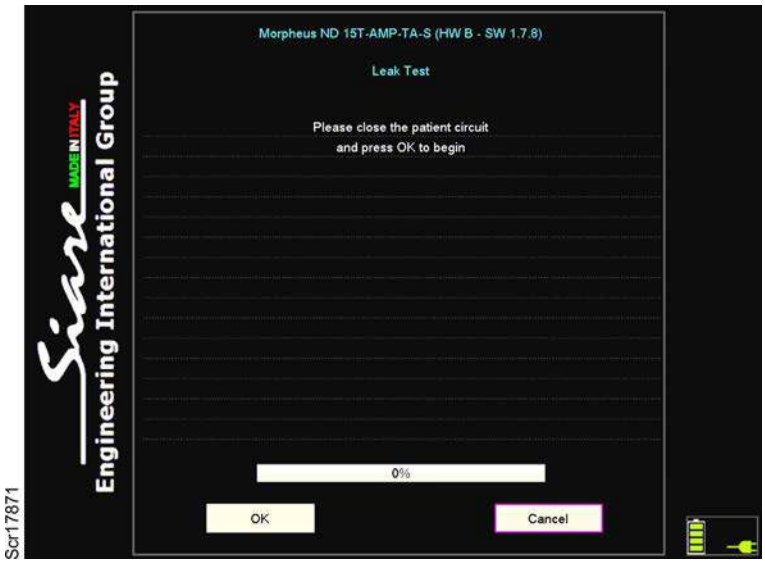
CAUTION

Before performing the **Leak Test**, ensure that:

- the gas fresh regulators on ventilation module are closed (0.00)
- the CO_2 absorber canister is not mounted on valves group
- the supplied manual ventilation kit is not fixed to the valves group connector
- the patient circuit is closed (Y of patient circuit is correctly closed / plugged).



- Select **Leak Test**.



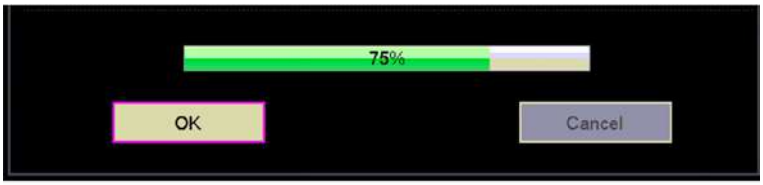
The **Leak Tests** page appears.

After having verified what described in the previous “caution points” perform the instructions as required on the display.

“ Please close the patient circuit and press OK to begin “

OK	Selecting **OK** the Leak Test begins.
Cancel	Selecting **Cancel** the system quits Leak Test and goes back to the “ **Supplementary Tests** ” screen.

Scr29188_r



Scr86616_r

The **Leak Test** procedure is in progress.

Scr04943_mod

Leak Test procedure has been successfully completed: the measured value is 9 ml/min.

If the procedure of **Leak Test** has been correctly performed the message " **Test Completed** " is displayed.

In case the test has not passed, one of the following messages is displayed.

" Test Aborted "

" Test Failed "

LEAK TEST

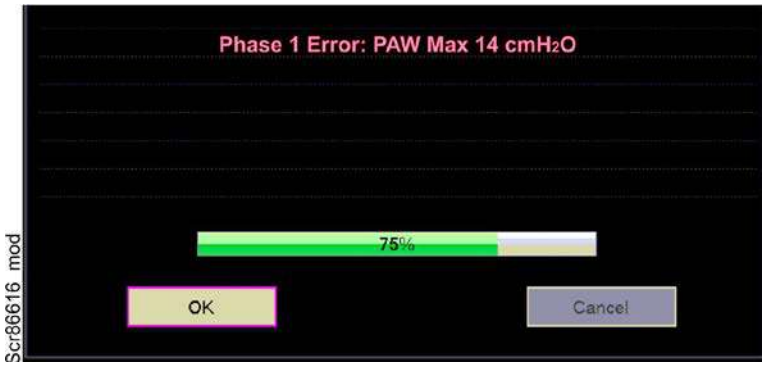
Based on known and calculated data (flow, pressure and time), the software calculates the parameters displayed at the end of test. The value of the compliance obtained during the Leak Test is used for the "compensation of dead space" function (e.g. 0,3 x cmH2O measured).

Range of values accepted by the Leak Test	Min.	Max.
Patient Circuit Compliance	0,2	4
Leak (ml/min)	0	100

4.9.4 Leak Test not overcome

WARNING !! Risk of anaesthesia unit failure

The Leak Test is not overcome when the pressure inside the pneumatic circuit does not reach al least 27 cmH2O.



Scr86616 mod

Leak Test procedure has not been successfully completed: the measured pressure value is 14 cmH2O.

CAUTION - Leak Test ERROR

Verify that :

- the anaesthesia unit is in STAND-BY
- the patient circuit is correctly connected to the flow sensor and to the INSP connector (on breathing system)
- Y of patient circuit is correctly closed / plugged
- the anaesthesia unit delivers a flow (check the breathing system).

Repeat the Leak test.

Leak Test ERROR

Please see chapter 6 : Alarms and Troubleshooting.

If the problem persists, contact the Siare Technical Centre or a Technical Centre authorized by Siare.

4.9.5 O_2 Sensor calibration

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

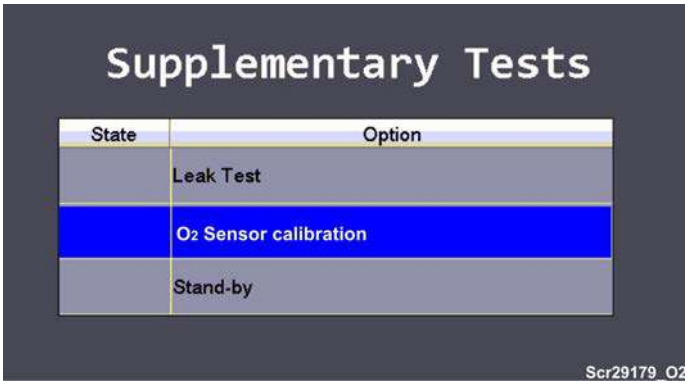
The **O_2 sensor calibration** should be carried out to check the proper operation of the oxygen sensor.

Perform the **O_2 sensor calibration monthly.**

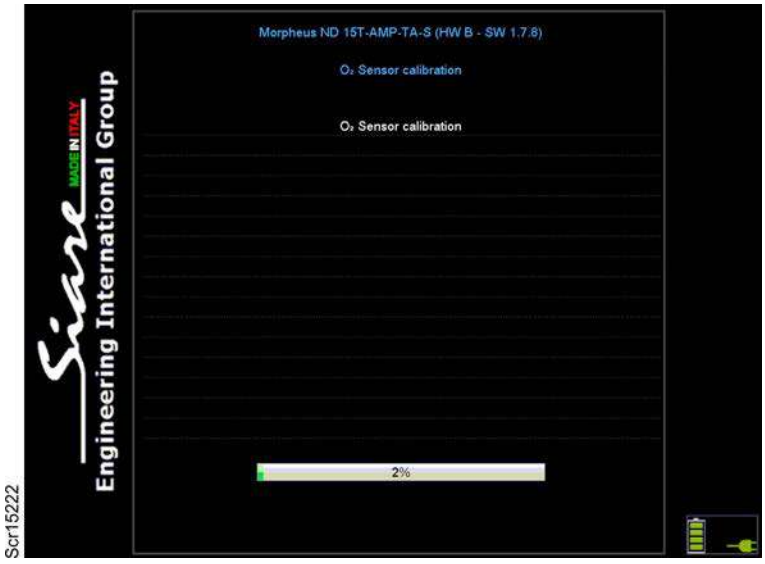
CAUTION

Before performing the **O2 sensor calibration**, ensure that:

- the gas fresh regulators on ventilation module are closed (0.00)
- the O_2 sensor must be placed in its seat
- the O_2 must be electrically connected through the suitable cable
- the medical gases must be properly connected.
- If any of these conditions is not met, the calibration cannot be successful.



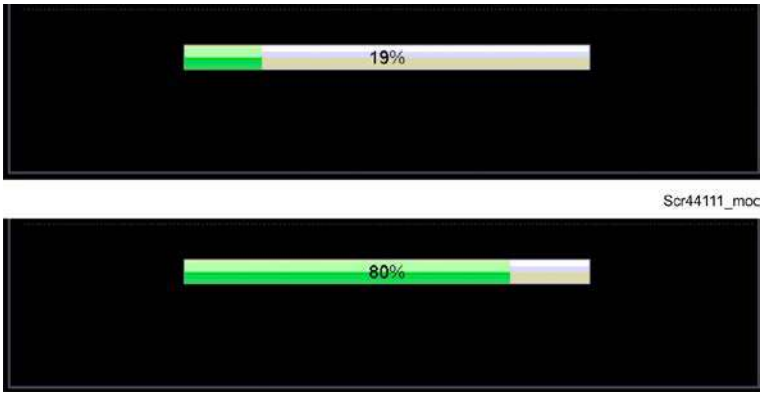
- Select **O_2 Sensor calibration**.



The **O_2 Sensor calibration** page appears.

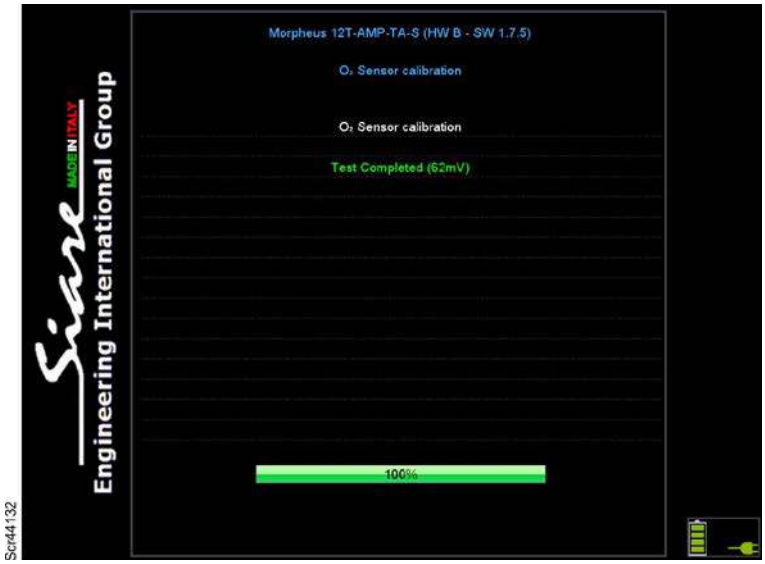
The system automatically activates the **O_2 sensor calibration.**

The software reads the electrical value (mV) generated by the oxygen sensor when immersed in a pure oxygen flow provided during the calibration by the anaesthesia unit in order to check if the O2 sensor works properly.



The **O2 sensor calibration** is in progress.

A flow having a **100% O2** concentration is automatically generated during the calibration.



O2 sensor calibration has been successfully completed : the measured value is 62 mV.

If the procedure of **O2 sensor calibration** has been correctly performed the message " **Test Completed** " is displayed.

In case the test has not passed, the following message can be displayed.

" Test Aborted "

" Test Failed "

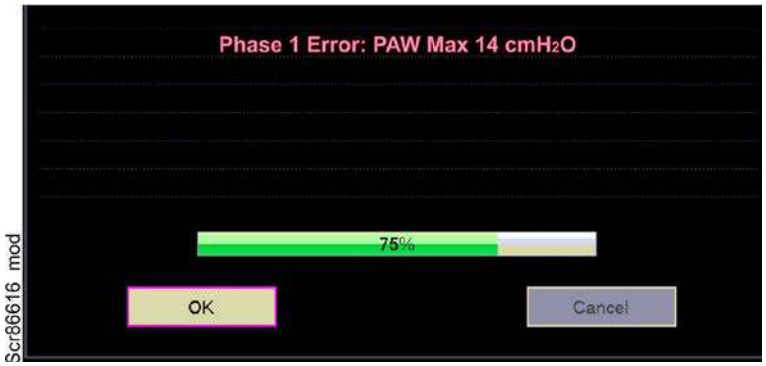
CAUTION

At the end of the O2 sensor calibration a message is displayed (if the O2 sensor is new and in perfect conditions): **Test Completed (XXmV)** showing the value in Volts measured by the sensor with 100% Oxygen.

4.9.6 O_2 Sensor calibration not overcome

WARNING !! Risk of DM failure

The **oxygen sensor calibration** is not overcome when the detected voltage value is not included between 43 mV and 67 mV.



The **oxygen sensor calibration** procedure has not been successfully completed.

O_2 Sensor calibration failed.

WARNING !! Malfunctions risk - calibration failed

- Check if the oxygen sensor is installed and electrically connected to the anaesthesia unit.
- Check if the oxygen sensor is worn out (the oxygen detection cell is worn out); replace the oxygen sensor.
- Repeat the oxygen sensor calibration.

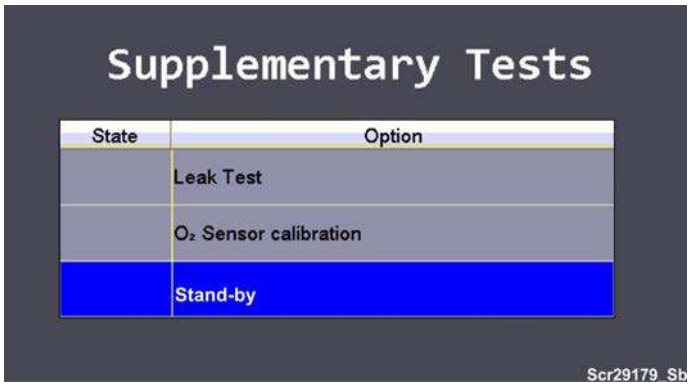
CAUTION - Replacing the oxygen cell

The oxygen cell must be replaced when, at the end of the calibration phase, appears a detected voltage value **not included between 43 mV and 67 mV 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 7 : Maintenance.

O_2 Sensor calibration failed: please see chapter 6 : Alarms and Troubleshooting.

4.9.7 Exit from SUPPLEMENTARY TESTS



- Select Stand-by to go to Stand-by mode.

The system leaves the Supplementary Tests and displays the Stand-by page.

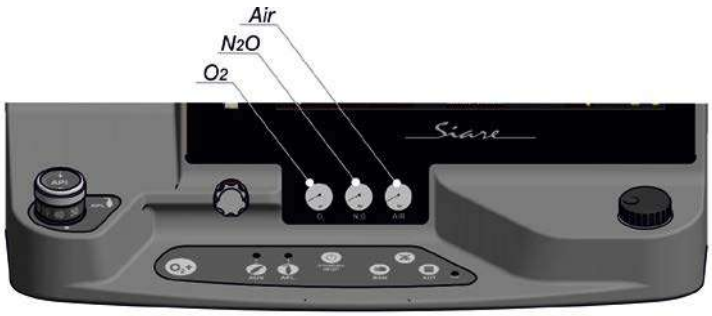
CAUTION - Supplementary Tests

In previous paragraphs the Tests to be performed before start up the Morpheus_ND anaesthesia unit have been illustrated.

These tests are suggested to be performed within timing set and defined in the present User's Manual and/or by local regulations in force.

4.10 Flowmeter module

For more informations on use, controls meaning and parameters of flowmeter, consult the chapter 3.7: Flowmeter.



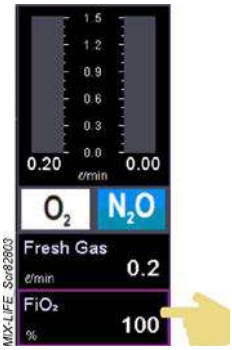
Manometers

Verify that the pressures of medical gases displayed in the manometers are from 280 kPa to 600 kPa (2,8 - 6 bar).

MIX-LIFE: device used to avoid the administration of hypoxic mixtures

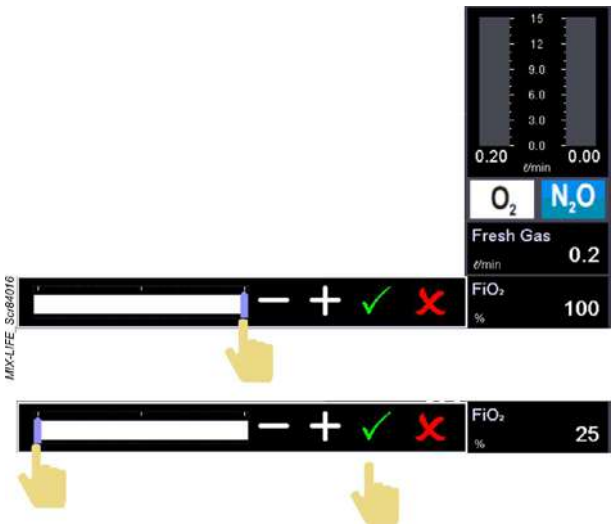
- **Select AIR icon** to enable the Nitrous (N_2O) on the flowmeter.

Yes: confirm the switch to N_2O



- The Nitrous icon (N_2O) is displayed: default values
  - **Fresh Gas: 0.2 l/min**
  - **FiO_2: 100 %**
- **Select FiO_2 100 % icon**

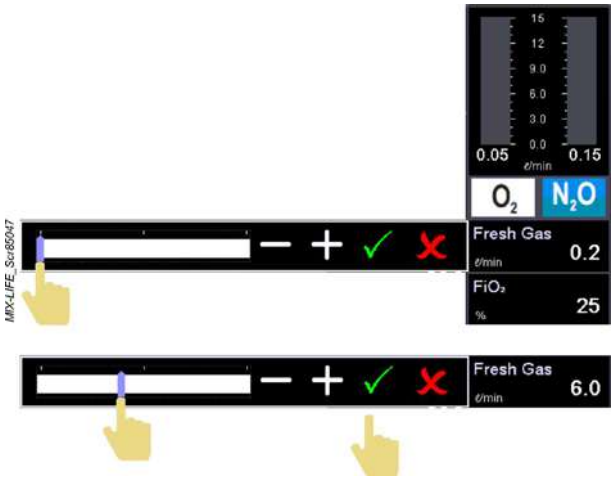
MIX-LIFE: device used to avoid the administration of hypoxic mixtures



The modification bar is displayed

• Use the cursor or encoder knob to change the FiO2 value from 100% to 25%

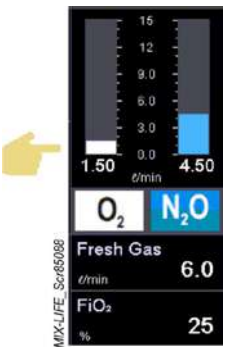
- **Select Confirm**
  - **FiO2: 25 %**

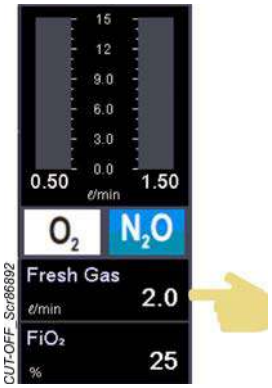


- **Select Fresh Gas 0.2 l/min icon**
- The modification bar is displayed
- Use the cursor or encoder knob to change the value from 0.2 l / min to 6 l / min
- **Select Confirm**
  - **Fresh Gas 6 l/min**

- Select **MAN** operative mode icon or press **MAN** soft key

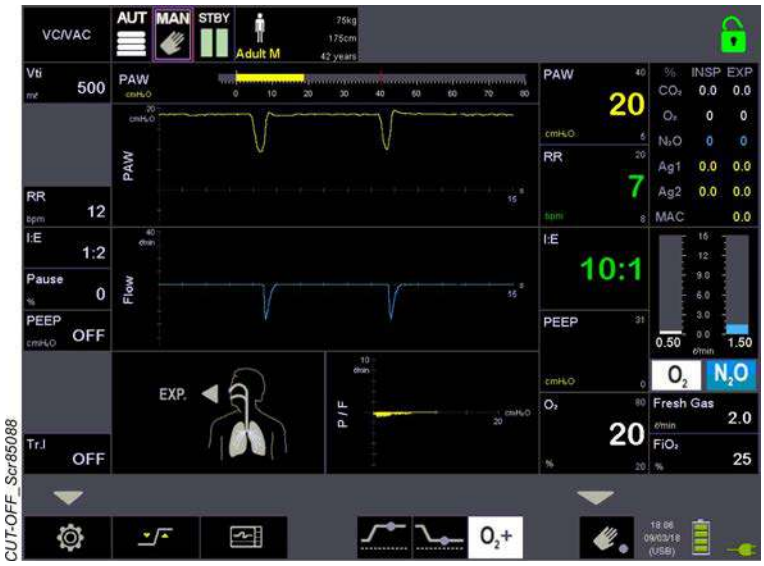
Verify that you read on O2 flowmeter a passage of gas included between 1.5 and 3 l/min (25% of 6 l/min).





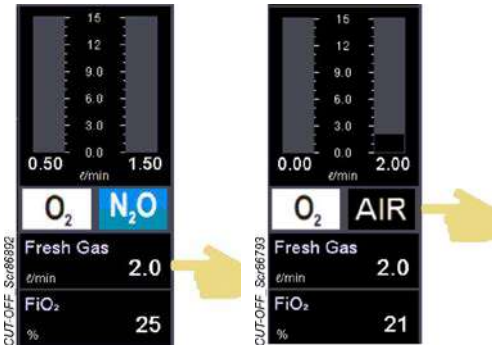
CUT-OFF: alarm activated in case of leak of O2 pressure or low O2 pressure

- **Select Fresh Gas icon**
- The modification bar is displayed
- Use the cursor or encoder knob to change the value to approximately 2 l / min.



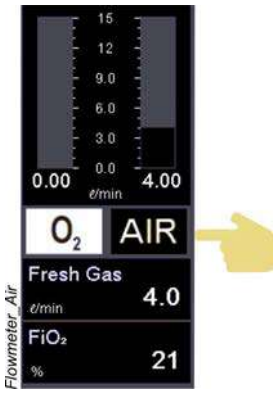
- Select **MAN** operative mode icon or press **MAN** soft key.

- Close the O2 supply from distribution system.



- After few seconds the O2 pressure on O2 manometer must fall to zero.
- The flowmeter automatically switches from N2O to Air (see figure on the left side).

- The relative visual and acoustic alarms are activated.
- At the end of the test, **restore the O2 supply** from distribution system.



Against the simultaneous delivery of Air and N2O.

To avoid simultaneous delivery of Air and N2O, a single icon is provided in the area of the flow meter

Air Supply Check

- Connect to the 'BAG' connection the kit for the manual ventilation.
- Select **MAN** operative mode.
- Press **APL** soft key (green led light on).
- Check of the pneumatic circuit: the manual KIT bag inflates; the pressure increases in the patient simulator.
- Close the Air supply from distribution system.

Verify that:

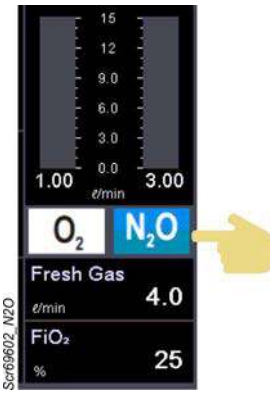
- the **Air** pressure on **Air** manometer must fall to zero.
- the **Air** pressure on the pneumatic circuit (bag – patient simulator) goes to zero.
- the visual and acoustic alarms are enabled again.

At the end of the test, press **STANDBY** soft key (**OK**).

Against the simultaneous delivery of Air and N2O.

N2O Supply Check

- KIT for the manual ventilation connected.
- Select **MAN** operative mode.
- Press **APL** soft key (green led light on).
- Check of the pneumatic circuit: the manual KIT bag inflates; the pressure increases in the patient simulator.
- Close the **N2O** supply from distribution system.



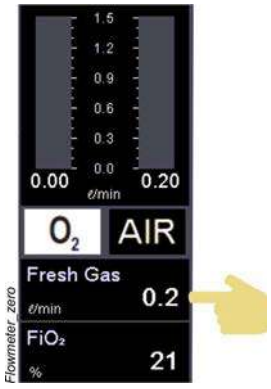
Verify that:

- the **N2O** pressure on **N2O** manometer must fall to zero.
- the **N2O** pressure on the pneumatic circuit (bag – patient simulator) goes to zero.
- the relevant visual and acoustic alarms are enabled.

At the end of the test, press **STANDBY** soft key (**OK**).

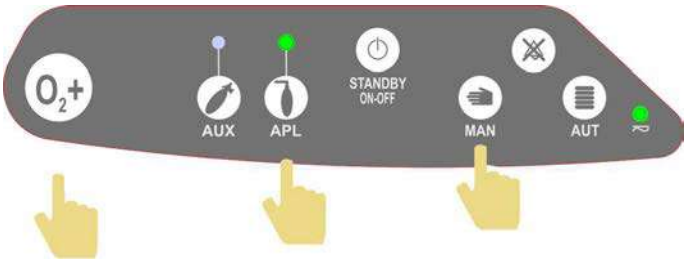
From the medical gas distribution system, restore the Air and Nitrous supply and correct operating conditions of the anaesthesia unit.

BY-PASS push button.



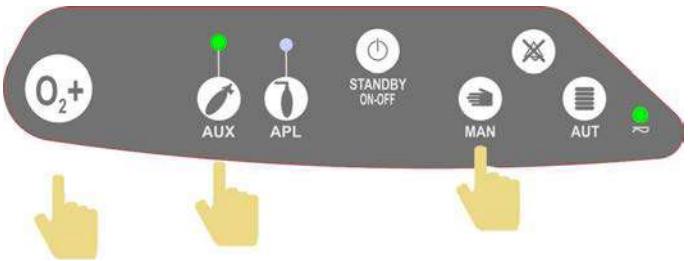
- Select **Fresh Gas** icon
- The modification bar is displayed
- Use the cursor or the encoder knob to set the value at zero (0,2 l/min).

Verify APL soft key.



- Select **MAN** operative mode.
- Press **APL** soft key (green led light on).
- Press BY-PASS button(**O2+**)
- • Check that the oxygen flow reaches the manual KIT bag: the bag inflates.
- At the end of the test, press **STANDBY** soft key (**OK**).

Verify AUX soft key.



- Select **MAN** operative mode.
- Press **AUX** soft key (green led light on).
- Press BY-PASS button(**O2+**)
- Verify that the oxygen flow reaches the AUX connector located on the back of the anaesthesia unit (used for the TO and FRO circuit connection).
- At the end of the test, press **STANDBY** soft key (**OK**).

For next checking verify that:

- the patient circuit is connected to valves group; INSP. and EXP. connectors
- the patient circuit is connected the patient simulator (SIARE type)
- the circuit for manual ventilation is connected to the “ BAG “ connector

VC/VAC ventilation

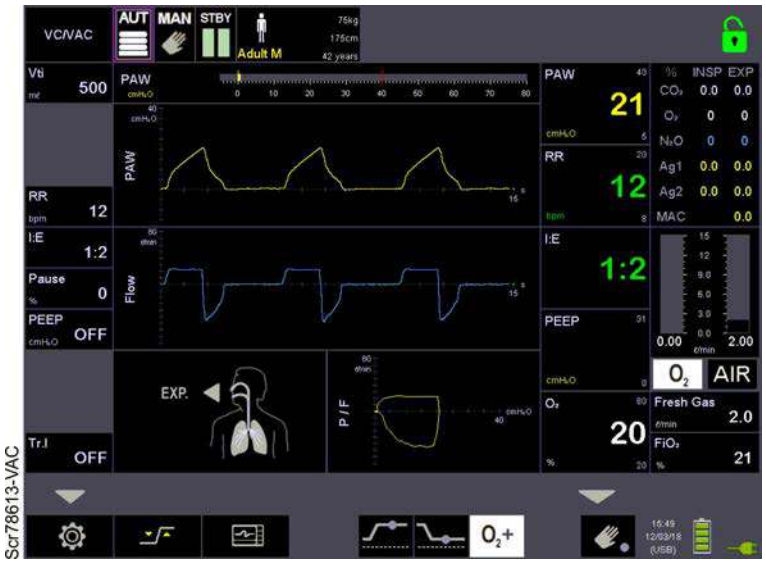
- **Select Fresh Gas icon**

The modification bar is displayed

- Set the value at approx 2 l/min.

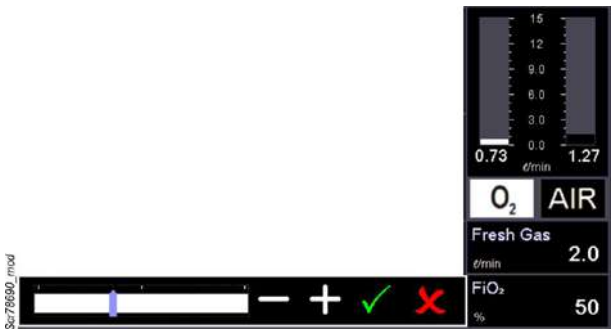
Anaesthesia unit in **Stand-by** operative mode.

- **Select / Press AUT**: the anaesthesia unit begins its ventilation cycle.



- The anaesthesia unit starts the inspiratory (expiratory) phase by determining a variation of the measured parameters in the ventilation monitoring area.
- Check the proper functioning of the anaesthesia unit.

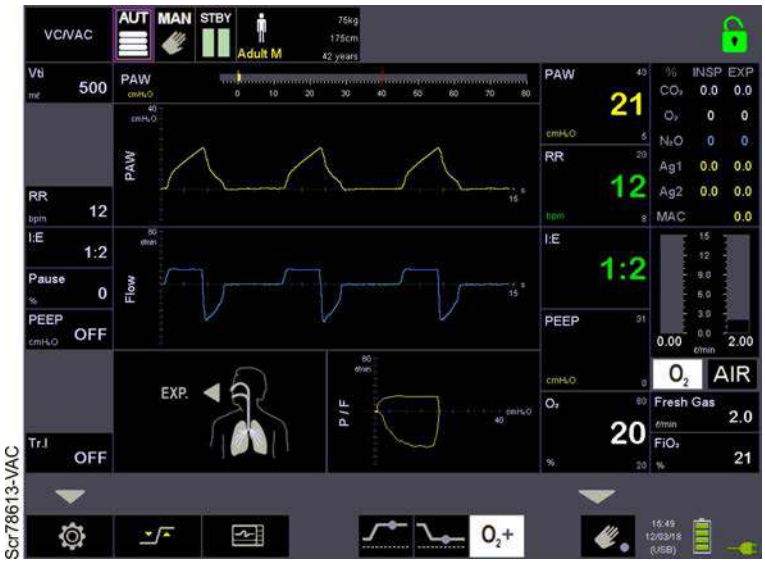
For the setting of the physiological respiratory parameters (following PRF) useful for the preliminary controls on the anaesthesia unit, see chapter below.



O2 concentration

- **Select FiO2 icon**
- The modification bar is displayed
- Set the value to 50% (the values of the flows on the flow meter symbols vary).

- Check that the value of O2 (see parameter monitoring area), is adjusted to the set value of FiO2 of the flowmeter: approximately 50%.



- **At the end of the test, FiO2 icon and** bring the value back to 21%.
- Check that the value of O2 adjusts to the new set value of FiO2 of the flowmeter: approximately 21%.

CAUTION

Verify the presence of CO2 soda lime absorber canister and that the soda lime in the canister is not exhausted.

4.11 Ventilation module

Preliminary checks to be carried out on the ventilation module.

- Physiological respiratory parameters (PRP)
- Parameters monitoring
- Anaesthesia unit alarms

For information on use, controls meaning and breathing parameters of ventilation module, consult chapter 3 : User Interface Module.

Physiological respiratory parameters (PRP)

Scr78595-STBY

Set standard physiological respiratory parameters (PRP).

Operative mode : VC-VAC

Vti : 500

RR : 12

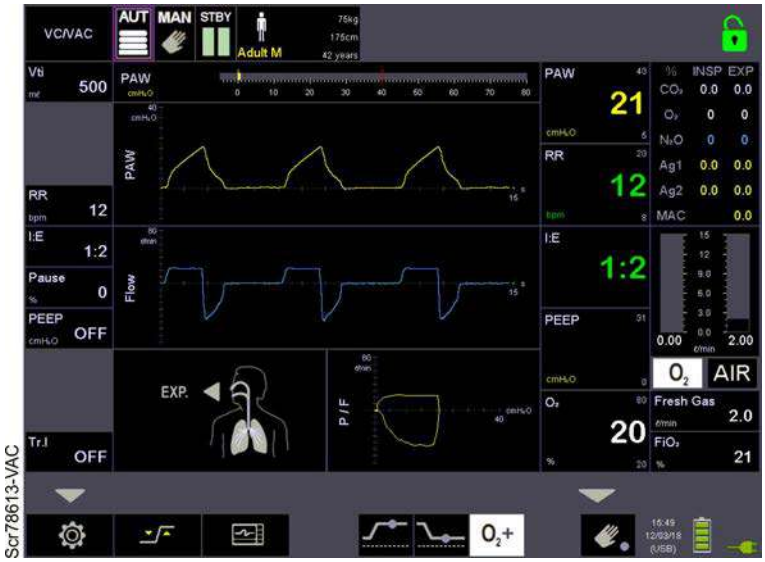
I:E : 1:2

Pause : 0

PEEP : OFF (5, 10 cmH2O)

Tr.I : OFF (-1 cmH2O / 1 L/min)

FiO2 : 21 %

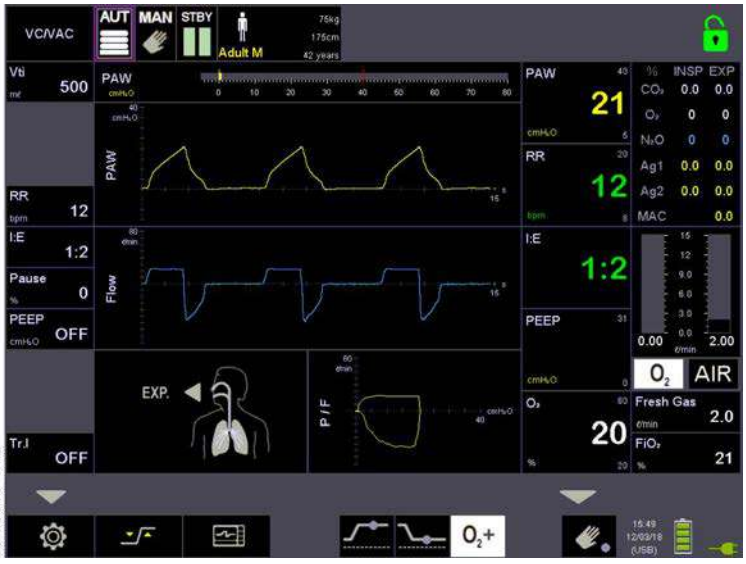


Scr78613-VAC

- **Select / Press AUT** : the unit begins its ventilation cycle.

Based on the PRP set by the User and on the patient's [patient simulator] characteristics, the User Interface Module 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 User Interface Module on for at least 15 minutes. This way the system will be able to reach its operating condition.



Scr78613-VAC

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.

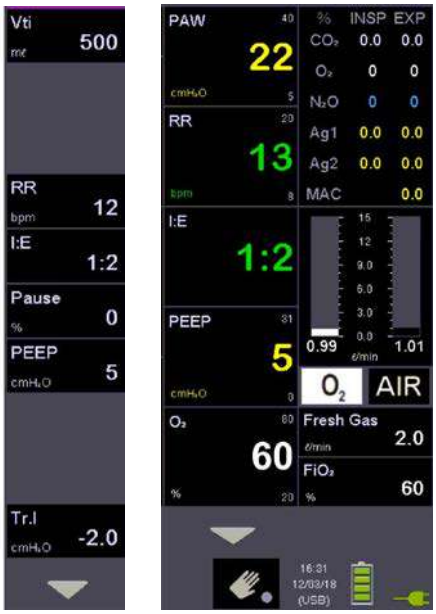
Scr80081

Change the set physiological respiratory parameters (PRP).

PEEP : 5, 10 cmH2O

Tr. I : -2 cmH2O, 3 L/min

O2 : 60%



- Check the correspondence between the monitored parameters and the displayed curves.
- Select the key to display all the parameters.

CAUTION - Unit operation check

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

CAUTION

- If the O_2 measured value differs from the set value by more than +/- 10%, please repeat the “O_2 Sensor Calibration” procedure: Supplementary Test *(see on chapter 5.8.5).*
- If the Vte measured value differs from the set value by more than +/- 20% (Adult parameters), please go to the “Calibration Programs” visualization to perform the calibration of the expiratory flow sensor *(see on chapter 5.12).*

Alarm limits check

Select the icon to access the anaesthesia unit'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. For additional information on Alarms Limits and on relevant settings, see chapter 6 (Alarms).

Exit the Alarm Limits screen

OK

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

NO: it remains in Alarm page.

Cancel

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

NO: it remains in Alarm page.

WARNING !! Severe patient injuries

Before starting the ventilation, check the alarms setup, change the set values whenever necessary.

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

Check the proper activation of the visual and acoustic signals.

	High Pressure	Set the high pressure alarm limit to a value higher than the PAW ventilation pressure by 5 cmH_2O. Block the patient simulator (using your hands) during ventilation. The system activates the airways HIGH PRESSURE alarm: silence the alarm. Unlock the patient simulator.
PAW		
	Low Pressure	Set the low pressure alarm limit to 5 cmH_2O. Disconnect the patient simulator from the patient circuit during ventilation. After about 20 seconds the system activates the airways LOW PRESSURE alarm: silence the alarm. Reconnect the patient simulator.
	High	During ventilation please set PEEP = 10 cmH_2O Set the high pressure limit to 5 cmH_2O The system activates the HIGH PEEP alarm: silence the alarm. Restore the default alarm value.
PEEP		
	Low	During ventilation please set PEEP = 3 cmH_2O Set the low pressure limit to 8 cmH_2O. The system activates the LOW PEEP alarm: silence the alarm. Restore the default alarm value.
	High EXP Vt	During ventilation, set Vti to 500 ml. Set the high expired Vte alarm limit to 400 ml. The system activates the high expired Vte alarm: silence the alarm. Restore the default alarm value.
Vte		
	Low EXP Vt	During ventilation, set Vti to 200 ml. Set the low expired Vte alarm limit to 250 ml. The system activates the low expired Vte alarm: silence the alarm. Restore the default alarm value.

	High	Set the high expired Vm alarm limit to 8 l. During ventilation, set Vti to 800 ml / 15 bpm. The system activates the high expired Vm alarm: silence the alarm. Restore the default alarm value.
Vm		
	Low	Set the low expired Vm alarm limit to 5 l. During ventilation, set Vti to 175 ml / 20 bpm. The system activates the low expired Vm alarm: silence the alarm. Restore the default alarm value.
	High oxygen concentration	Set a O_2 concentration to 50% on the unit. Set the high O_2 concentration alarm limit to 30%. The system activates the high O2 alarm: silence the alarm. Restore the default alarm value.
O_2		
	Low oxygen concentration	Set a O_2 concentration to 30% on the unit. Set the low O_2 concentration alarm limit to 50%. The system activates the low O_2 alarm: silence the alarm. Restore the default alarm value.

High / Low FiO2

If the anaesthesia unit is in Stand-by mode 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).
Power supply fault	The system activates the main power failure alarm: silence the alarm.
	Restore the main switch and set it to ON (I).
	Close the medical gas supply during anaesthesia unit operation.
Low O_2 gas supply	The system activates the gas supply failure alarm: silence the alarm.
	Restore the medical gas supply.

4.12 Conclusions

Carry out all preliminary checks and make sure that they were completed successfully before connecting the patient to the Morpheus_ND Anaesthesia Unit.

Preliminary checks phase failed.

Please see Alarms chapter and/or Troubleshooting chapter.

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

WARNING !! Risk for Patient injury.

Check the alarm limits setup values before connecting a patient to the anaesthesia unit. Change the alarm limits setup based on the clinical situation.

WARNING !! Risk for Patient / user injury.

The intensive care anaesthesia unit 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 anaesthesia unit, 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.

5 MORPHEUS_ND USE

This chapter shows you how to use the **Morpheus_ND** anaesthesia unit. 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 User must choose the Operative modes and the alarm limits that best match patient's physiological state and pathologies.

The correct setting of respiratory parameters and alarms limits, as well as the selection of most suitable ventilation modality are not described in the manual.

CAUTION

The choice of the operation modalities and alarm limits most suitable for the physiological conditions and pathologies of the patient under anaesthesia, it will be up to the User.

WARNING !! Risk for Patient / User injury

For the safety of users and patients, before making operative the Unit, the User should have performed a series of checks and inspections.

- *Carry out the preliminary checks (please see chapter 6)*
- *Prepare the flowmeter for operation*
- *Set the language and the Patient Data*
- *Check and set the Alarms Limits (please see chapter 5)*
- *Set the physiological respiratory parameters and the operative mode that best matches the patient's clinical situation.*

CAUTION

Before subjecting the patient to a ventilation treatment, please:

- *set the airway pressure limit alarm to a value that does not exceed 30 cmH_2O; this way you will prevent any problems that might arise due to incorrect respiratory volume or frequency setup (you can increase the pressure if the patient's pathology and conditions require such modification)*
- *check the set oxygen concentration (FiO_2) as high concentrations might affect the patient's health*
- *please consult this User Manual.*

The breathing parameters and the alarms must be always set even when the use of a spontaneous ventilations is required; in case of patient's apnoea, the anaesthesia unit will be immediately available for correct ventilation.

5.1 Flowmeter

5.1.1 Dosing and administration of fresh gas

The term " fresh gas " means the gas mixture that is dosed in the anaesthesia module and in the anaesthetic vaporizer.

The fresh gas is continuously delivered to the valves group to be administered to the patient.

The excess of gas that may be present in the patient circuit is automatically eliminated through the scavenger connection. The quantity (in l/min) of fresh gas can be greater, equal to or lower than the Minute Volume:

- if it is higher or equal it is an high flow open circuit (without soda lime canister)
- if it is lower it is a semi-closed circuit
- if the flow is lower than 1 l/min it is a low flow semi-closed circuit

WARNING !! Risk for patient / user injury

Administration of fresh gas in the breathing system

In order to deliver the fresh gas flow into the valves group (breathing system) press the APL key on the work shelf.

Otherwise, pressing the AUX key the fresh gas will go onto the TO and FRO.

Low flows semi-closed circuit (REBREATHING)

- The " fresh gas " flow in the patient circuit is a little higher than the basal consumption of the patient; therefore, the used gas concentration can be very different than the ones of the fresh gas.
- There is a high consumption of soda lime.
- There is a low consumption of fresh gas.
- The temperature and humidity of the fresh gas are optimal.

***Required supervision**: pay attention to the gas concentration monitoring (O_2, N_2O, CO_2 and halogenated gas).*

High flows open circuit (NON REBREATHING)

To perform this type of ventilation it is necessary to take off the soda lime canister from valves group.

- The breathing gas concentration is similar to the fresh gas ones.
- There is a high consumption of fresh gas.
- The temperature and humidity of breathing gas are low. The high flow ventilation is recommended only for pre-anaesthesia and awakening or for brief surgeries.
- There is not CO_2 accumulation in the patient circuit.

Required supervision: normal

Semi-closed circuit (REBREATHING)

- The fresh gas flow in the patient circuit is lower than the ones breathed by the patient; therefore the fresh gas concentration of the breathed gas is different than the ones of the fresh gas, related to the BREATHED GAS / FRESH GAS ratio.
- There is a medium consumption of soda lime.
- There is a medium consumption of fresh gas.
- The temperature and humidity of the fresh gas are acceptable for a long surgery situation.

Required supervision*: pay attention to the gas concentration monitoring (O_2, N_2O, CO_2 and halogenated gas).*

5.1.2 Administration of fresh gas in the "TO and FRO" system

In order to deliver the fresh gas flow to the TO and FRO system it is necessary to perform the following operations:

- Anaesthesia unit in Stand-by mode.
- TO and FRO patient circuit connected to the AUX connector (if the connector is positioned on the back side of the anaesthesia unit).
- Check if the flowmeter is correctly set.
- Press the MAN key to enabling MANUAL operative mode.

- Press the AUX key to enabling of fresh gas outlet connector (AUX).

WARNING !! Risk for Patient injury

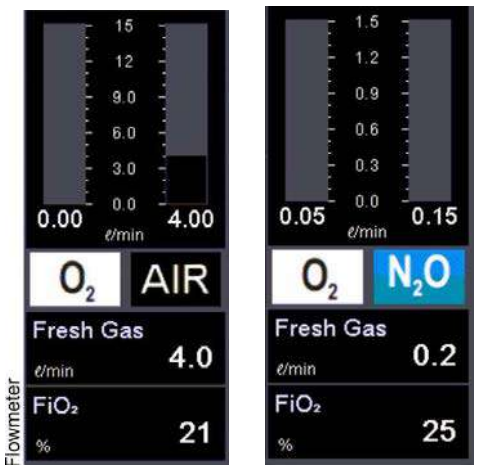
In order to deliver the fresh gas flow into the valves group (breathing system) press the APL key on the work shelf.

Otherwise, pressing the AUX key the fresh gas will go onto the TO and FRO.

5.1.3 Flowmeter pre-setting

After calculation of Minute Volume needed by the patient basing physiologic and pathologic conditions (*obtained from the product of Tidal Volume x Respiratory Rate (Vti x RR)) ;* determinate the total flow of fresh gas to be introduced in the patient circuit basing on chosen dosage.

For more informations about Flowmeter use, see on chapter 3.7 .



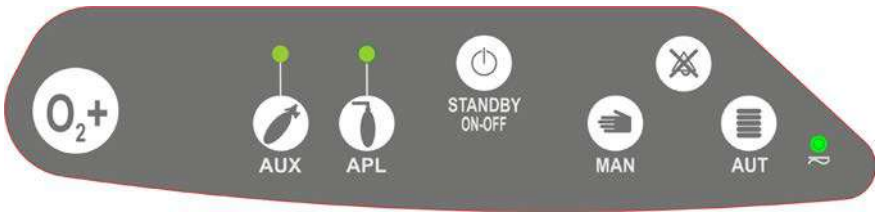
- Select the anaesthetic gas to be combined with the oxygen (**Air or N_2O**).
- Adjust the flow checking the value displayed in the box **Fresh Gas**.

WARNING !! Risk for Patient injury

The two gas (***Air and N_2O or Xe***) *cannot be used at the same time.*

The use of N_2O (or Xe) gas, determines the automatic use of oxygen in the measure of 25% (MIX-LIFE).

- Adjust the **O_2** flow by **FiO_2**.
- Verify that the sum of the flows read on electronic flowmeters corresponds to the foreseen value of Fresh Gases.
- Adjust the concentration of anaesthetic agent onto the vaporiser.



Select the type of desired breathing circuit on the keyboard,

- **AUX**: enabling of fresh gas outlet connector.
- **APL** : enabling of valves group.

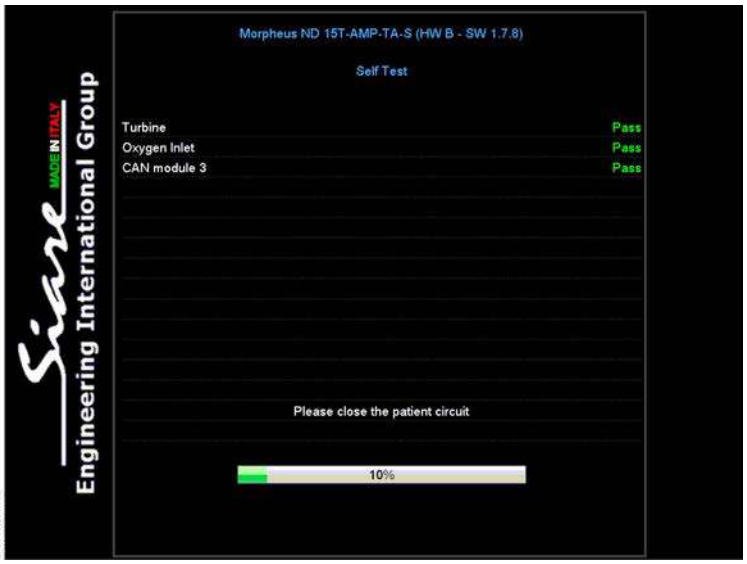
The anaesthesia unit is ready to start the phase of patient ventilation according with the modalities described in the following paragraphs.

CAUTION - Electric control

The activation of this key, allows to enrich the mixture of gas delivered to the patient, conveying pure oxygen (flow of around 35 l/min.) in the valves group or in the TO and FRO patient circuit with the aim of cleaning the circuit in case of emergency, early awakening, etc.

5.2 Anaesthesia Unit switching ON - Self Test phase

- Set the main switch (placed on the back side of the anaesthesia unit) to " I ".
- Make sure that on the unit keyboard (commands area) the green led (indicating the presence of mains power supply) is ON.
- Hold the STANDBY ON-OFF key for few seconds; the unit switches ON and the automatic Self Test phase starts.



Scr15476

- The anaesthesia unit turns ON and the automatic Self Test phase starts.
- *Please close the patient circuit.*

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

Scr16349

- Self Test phase in progress.

Scr16388

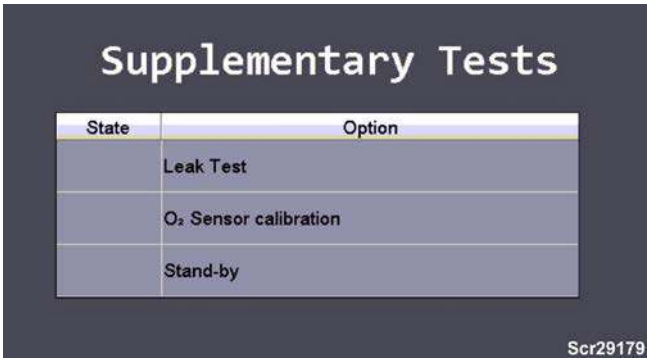
- **Acoustic Alarm test** : " *If the acoustic alarm is audible, please press the RESET key* ".

The Self Test phase has been successfully completed.

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

Cancel

Press Cancel : the system will display the **Supplementary Tests** page.



Scr29179

Supplementary Tests

Through of this page it is possible to perform the Supplementary Test (*for further details see on chapter 6.8.2*).

OK

Press **OK** : the system will display the **PATIENT DATA** page.

PATIENT DATA

The software does not switch directly to Stand-by operative mode, but it previously displays a page which allows the adjustment of the anaesthesia unit setup.

The **PATIENT DATA** displaying allows to set the patient data and characteristics.

- *PATIENT DATA (see 5.3.1)*
- *SETUP parameters (see 5.3.2)*

Scr51314_Stand-by

Stand-by mode

- In this phase select indifferently **Cancel** or **OK** to access Stand-by displaying.

- In case of variations on **PATIENT DATA** values press **OK** to confirm updatings.

CAUTION : Stand-by

After carrying out the Self Test or before turning the anaesthesia unit OFF, it automatically switches to this operative mode.

In Stand-by mode the User can set and/or edit all the anaesthesia unit parameters (PRP) and/or alarms, etc… related to the operative mode to be used on the patient to treat.

- In Stand-by the User can select the operative mode and set and/or edit all anaesthesia unit parameters (PRP) brlonging to the operative mode
- The PRP can also be adjusted while the anaesthesia unit runs, adapting them to the patient's clinical situation.
- For methodology of the use of touch screen and/ or control keyboard and encoder knob, see chapter 3.1. and 3.2.1.

5.3 PATIENT DATA / SETUP parameters

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

- **PATIENT DATA *(see on 5.3.1)***
- SETUP parameters (see on 5.3.2)

5.3.1 PATIENT DATA

Scr16391

PATIENT DATA displaying allows to set the following data.

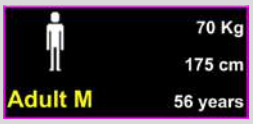
- *Patient type*
- *Male / Female*
- *Name / Surname*
- *Physical date*
- *Birthday*
- *Note*

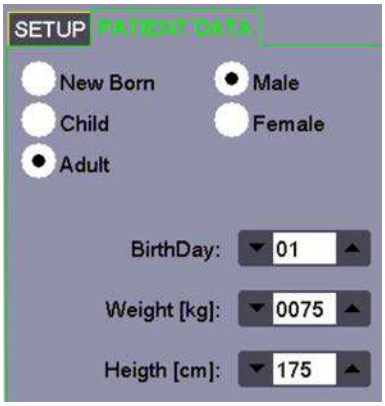
CAUTION

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

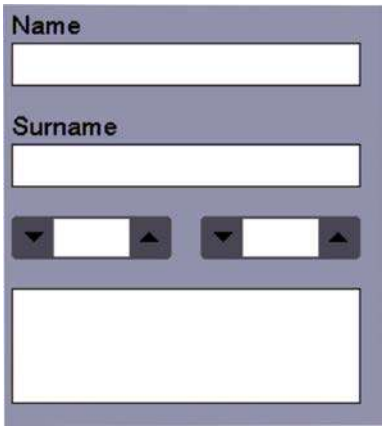
CAUTION

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

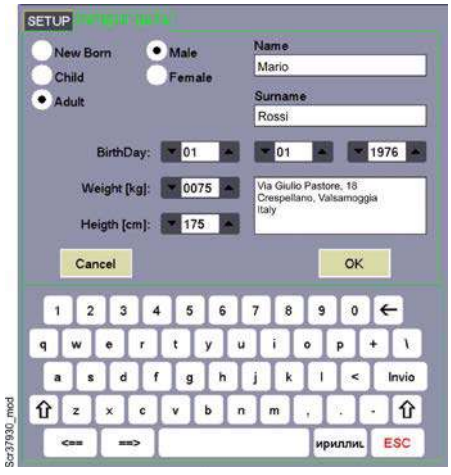




- The choice of the patient type, automatically sets the default function parameters of the unit (breathing parameters and alarms levels).



- A designated keyboard appears on the display when the space to fill-in is selected.



Scr37949

Once completed the entering of PATIENT DATA, save or cancel what is indicated in the page.

- Select Cancel

PATIENT DATA setting will NOT be saved.

Scr38780

- Select OK

PATIENT DATA setting will be saved.

Scr51314_Stand-by

- The system will display the Stand-by screen.

5.3.2 SETUP parameters

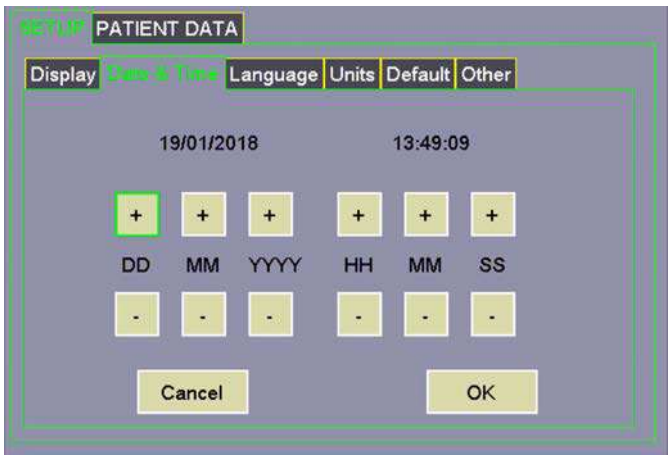
CAUTION

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

The **SETUP** displaying allows to determine the operation settings of anaesthesia unit.

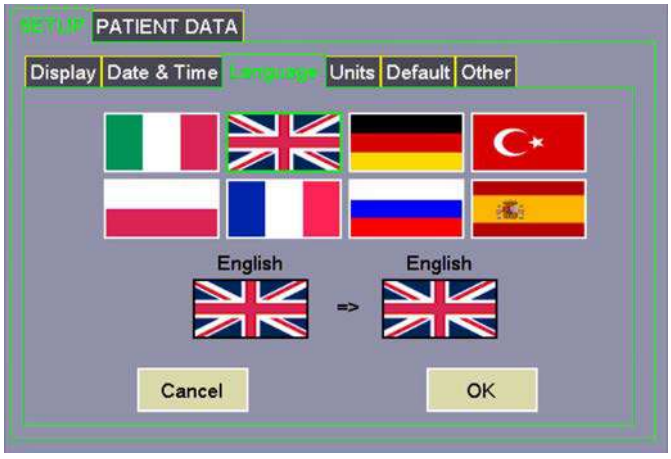
Display

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



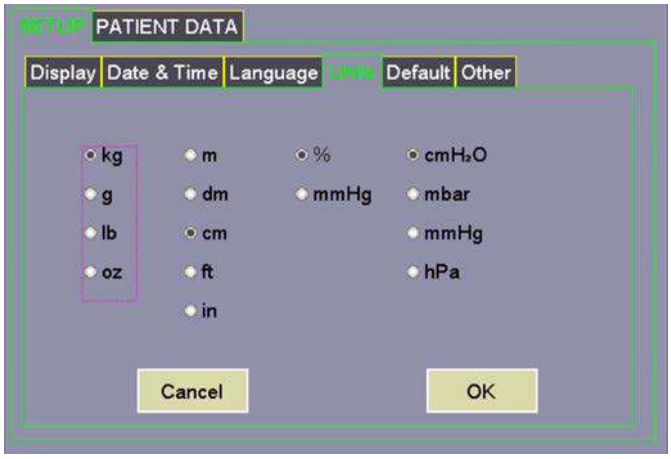
Date & Time

- *Date*
- *Time*



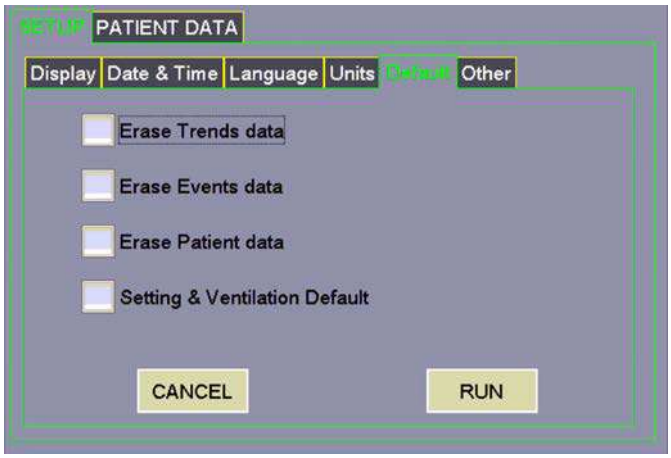
Language

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



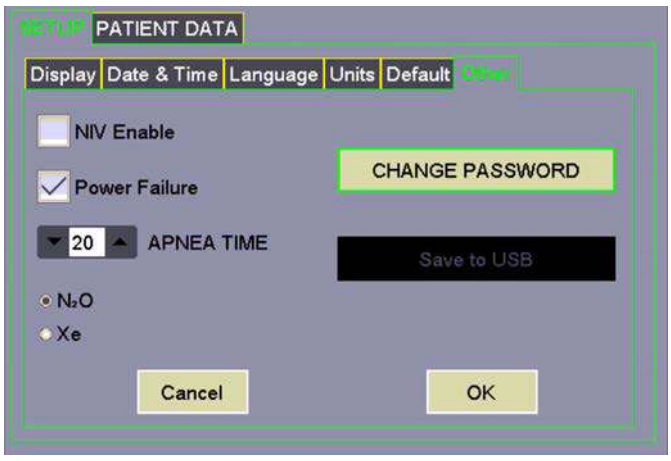
Units

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



Default

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



Other

- *NIV Enable*
- *Power Failure*
- *APNEA TIME*
- *N2O / Xe*
- *CHANGE PASSWORD*
- *Save to USB*

Scr41936

Scr41933

Scr51314_Stand-by

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

- Select Cancel

YES: to quit SETUP page without saving.

NO: it remains in SETUP page.

- Select OK

YES: the set values will be saved.

NO: it remains in SETUP page.

- The system will display the Stand-by screen.
- In the following chapter how to set/modify the SETUP Parameters.

5.4 Setting up the UGI language

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

- **Mode 1** : at unit start-up at the end of Self Test phase.
- **Mode 2** : during normal operation of unit.

5.4.1 Mode 1

Scr37929_mod

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

- Select: **SETUP**

Scr41874

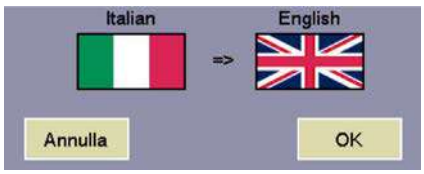
Si visualizza la pagina **Display** .

- Select: **Language**

Scr60134

A series of languages are available and identified by a flag icon (*in the picture: Italian*).

- Select the flag which identifies the desired language to be set (e.g. English).



Scr60411

- Confirm the choice.

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

Now, the UGI (User Graphic Interface) language set is **English.**

5.4.2 Mode 2

Scr51314_Stand-by

Unit in **Stand-by** operative mode.

- Select: **SETTING MENU**

Scr42967_MENU

- Select: **Language**

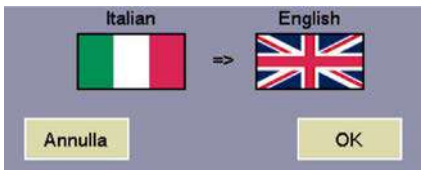
Icona_SETTING-MENU_Language

The **SETUP / Language** page is displayed.

Scr60134

A series of languages are available and identified by a flag icon (*in the picture: Italian*).

- Select the flag which identifies the desired language to be set (e.g. English).



Scr60411

- Confirm the choice

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

Now, the UGI (User Graphic Interface) language set is **ENGLISH**.

5.5 PATIENT DATA Setting

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

- **Mode 1** : at unit start-up at the end of Self Test phase (*see on chapter 5.3.1*).
- **Mode 2** : during normal operation of unit.

5.5.1 Mode 2

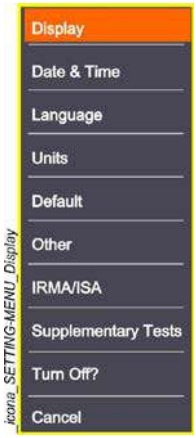
Scr51314_Stand-by

Unit in **Stand-by** operative mode.

- Select: **SETTING MENU**

Scr42967_MENU

- Select: **Display**



icona_SETTING-MENU_Display

Scr41874

- Select: **PATIENT DATA**

Scr37929_mod

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

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

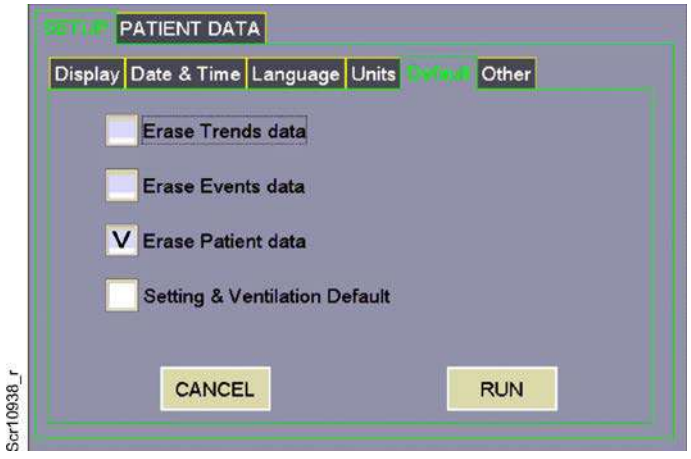
To set/modify the **PATIENT DATA** , *see on chapter 5.3.1*.

5.5.2 Erasing the PATIENT DATA

Unit in **Stand-by** operative mode.

- Select: **SETTING MENU**
- Select: **Default**

- Select: Erase Patient data

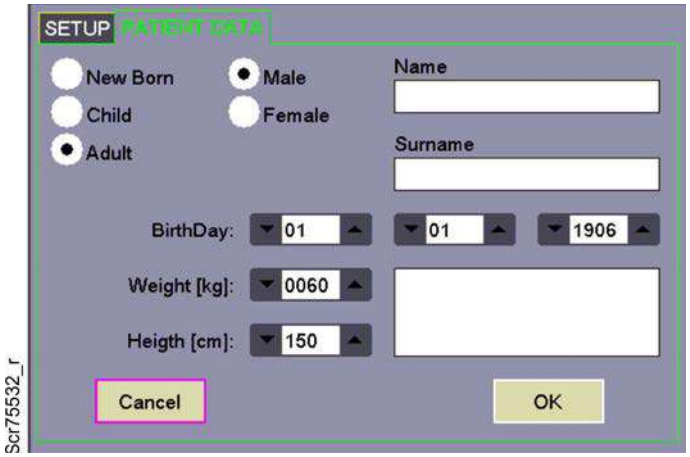


- **Confirm the choice**: select

- **Cancel the choice**: select

RUN

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



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

The PATIENT DATA page, shows an example of Default configuration .

To set/modify the **PATIENT DATA** , *see chapter 5.3.1*.

5.6 Setting up the ALARMS

Two ways are available to set/modify **Alarm Limits** values

- **Mode 1** : with unit in **Stand-by** operative mode.
- **Mode 2** : during normal operation of Unit (*see on chapter 6.2.1*).

5.6.1 Mode 2

Unit in Stand-by operative mode.

- Select**: ALARMS** icon

- Select Cancel

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

  NO : it remains in Alarm page.

- Select OK

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

  NO : it remains in Alarm page.

For ALARMS parameters and ALARMS limits setup, please see on chapter 6.2.

5.7 Operative modes

In the following chapter you will find a description of available Operative Modes selectable on Morpheus Unit.

WARNING !! Patient injury hazard

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

5.7.1 Operative Modes setting procedure

CAUTION

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

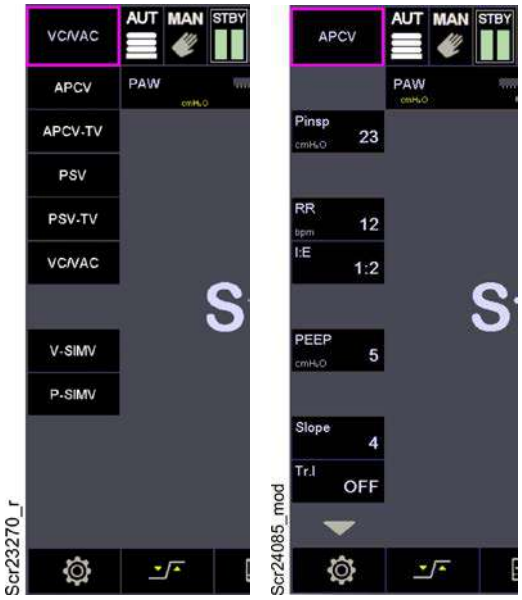
CAUTION

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

1. Anaethesia unit in **Stand-by** mode.
2. During the **Normal Operation** of the anaethesia unit.

1. Anaesthesia Unit in Stand-by mode

- Select the icon



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

- Operative mode selected: **APCV.**

CAUTION

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

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

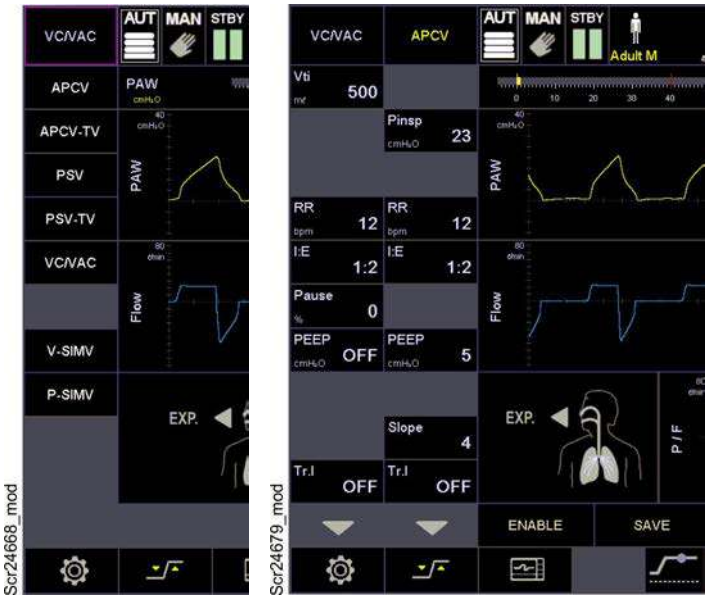
Unit in Stand-by, ready to be used in APCV operative mode.

2. Anaesthesia Unit in normal operation

Scr24621_VAC

- Operative mode: **VC/VAC**.

- All the operative modes foreseen can be displayed.



Scr24668_mod
Scr24679_mod

- Select a new operative mode.

- APCV operative mode selected.

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

CAUTION

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

Scr24711_APCV

ENABLE

- **YES** : The unit directly switches to the new selected operative mode **APCV**
- **NO** : to exit

Scr24621_VAC

SAVE

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

Scr24621_VAC

CANC

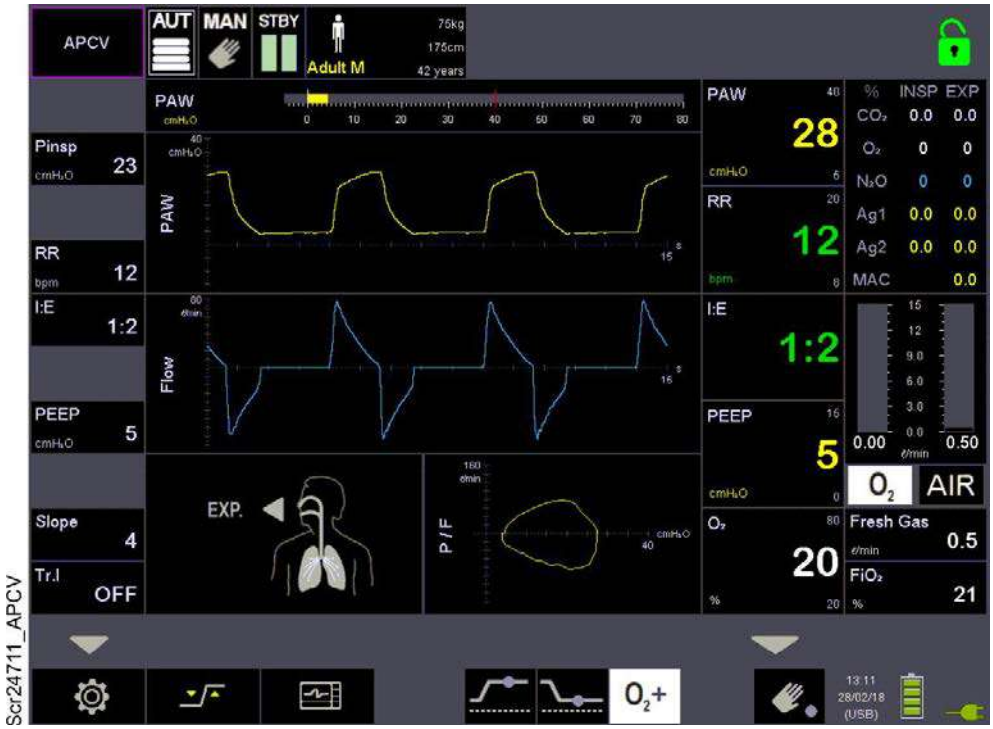
- **NO** : The system remains in the condition where the PRM of the two operative modes selected are displayed.
- **YES** : The system goes back to the **VC/VAC** .

5.8 Operative modes list

5.8.1 APCV (NIV APCV)

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

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



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

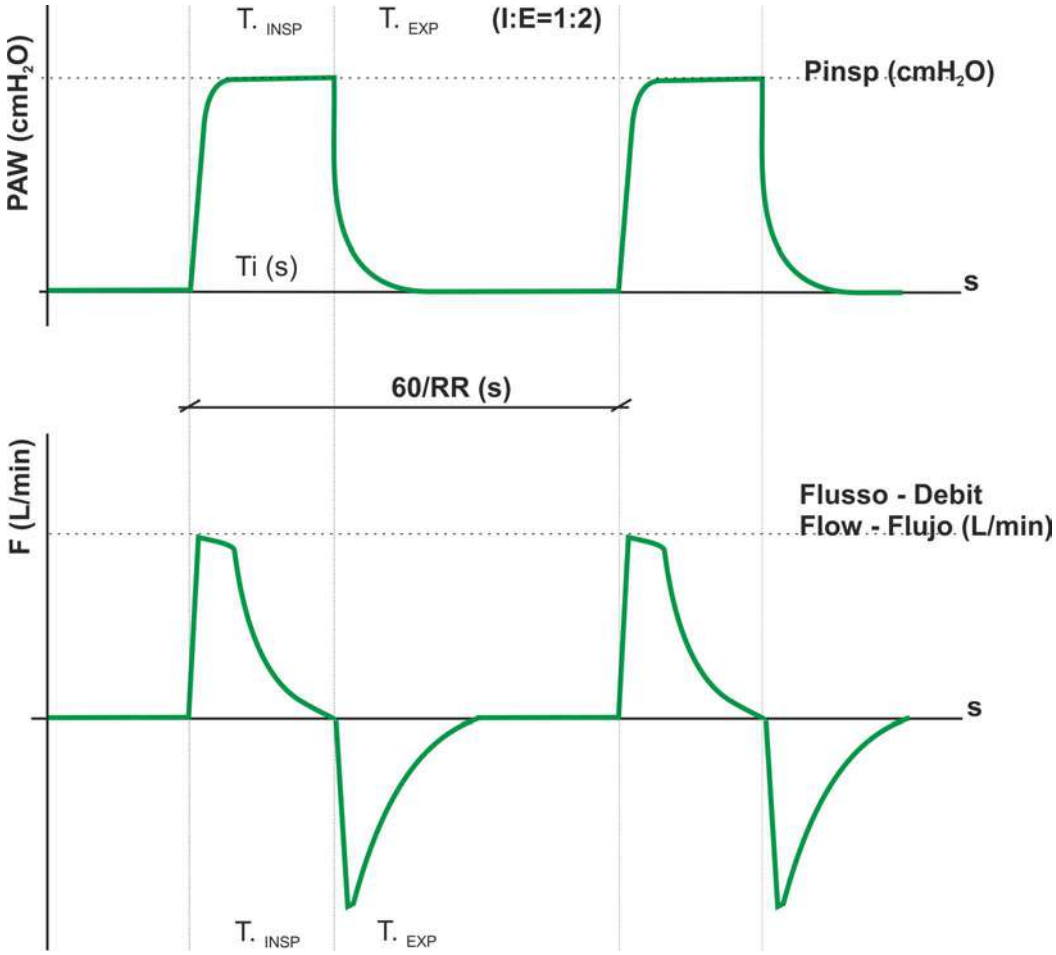
With this parameters configuration, APCV is a pressure controlled ventilation, synchronised with the patient's breathing, during which the system generates a patient ventilation at a pre-set inspiratory pressure (Pinsp), a pre-set flow (Slope), a calculated I:E ratio and a settable respiratory rate (RR).

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 Unit generates a settable flow (Slope). When the airway pressure reaches the control value (Pinsp), this pressure level is kept constant by the Unit 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_2O) that represents the limit for detecting the patient's spontaneous breathing attempt.

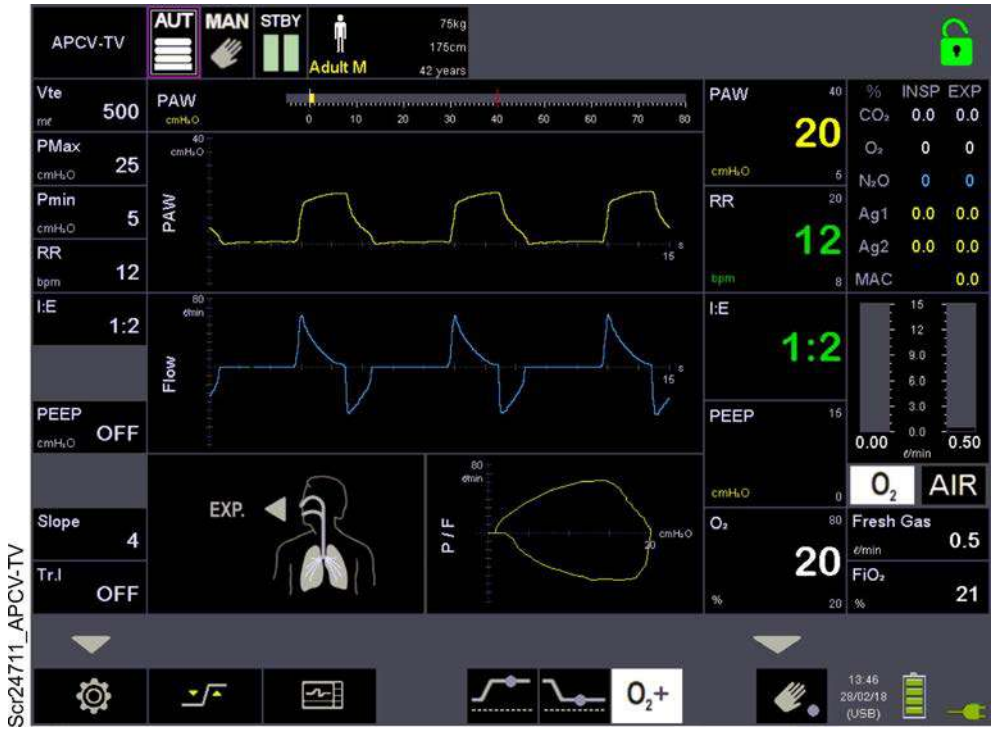
The greater the value, the greater the patient's effort to breath. If the pressure set is not reached, make sure that the patient circuit is perfectly sealed and that the PRP parameters are properly set.



5.8.2 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 operative mode set.



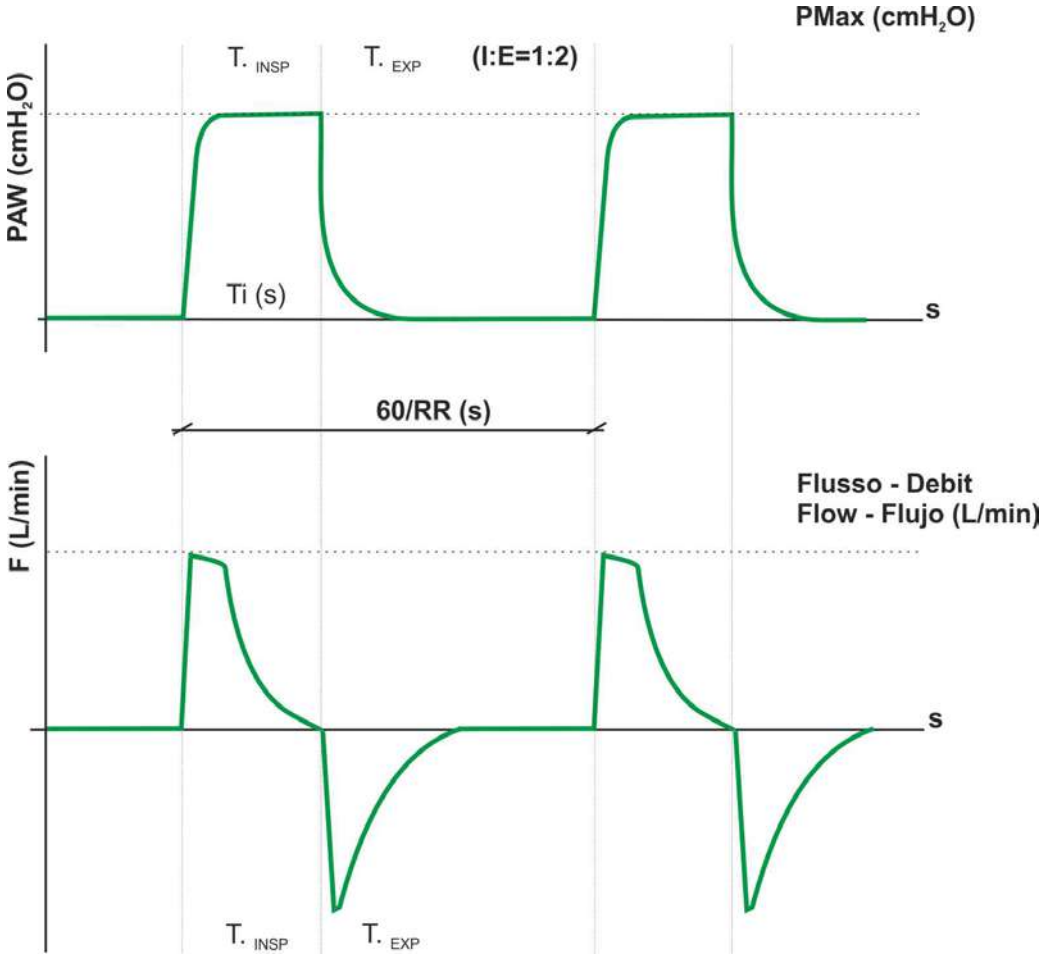
APCV-TV is a pressure controlled ventilation, synchronised with the patient's breathing (automatic Pinsp) with guaranteed current volume (Vte).

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

During the inspiratory phase, the Unit generates an automatic flow (Slope). When the pressure reaches the control value inside the airway (automatic Pinsp, at maximum PMax), this pressure level is kept constant by the Unit 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_2O) that represents the limit for detecting the patient's spontaneous breathing attempt.

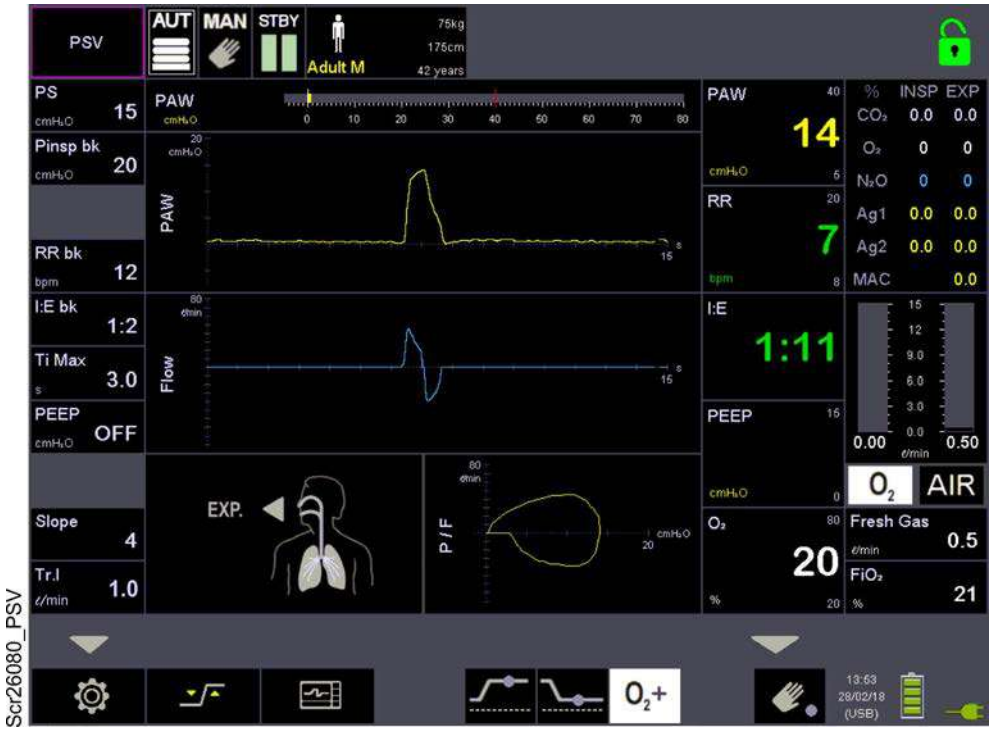
The higher is the value, the bigger is the patient's effort to breath.



5.8.3 PSV (NIV PSV)

Assisted pressure support ventilation with guaranteed safety respiratory rate, set by the User (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 User 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 unit'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 Unit provides a constant positive support pressure (PS) pre-set by the User with high-speed flow supply, until the pressure inside the airway reaches the desired support value.

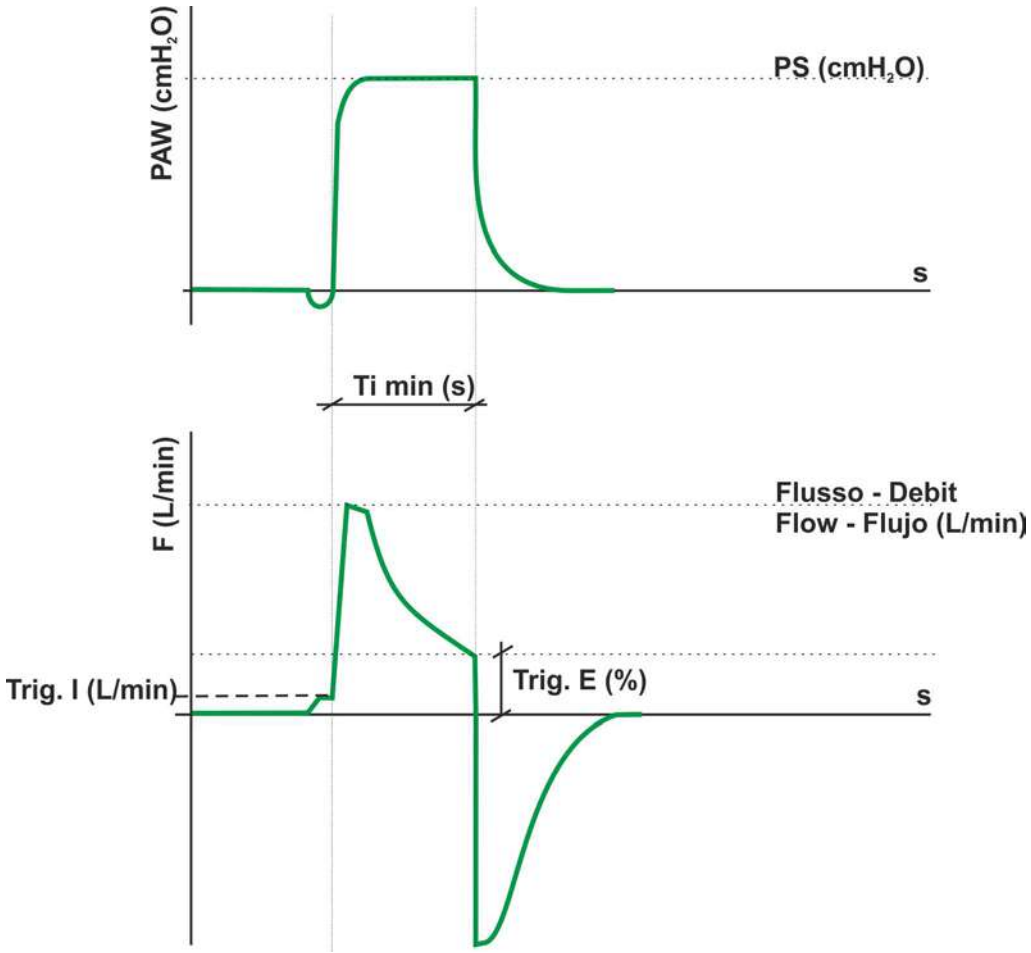
When the set support pressure is reached, the expiration takes the place of the inspiration (according to Tr. E - percentage of the inspiratory flow peak beyond which the expiration can begin). This technique saves the patient from the work of breathing, as he only has to reach the small quota necessary to enable the Unit trigger (Tr. I). This way, the respiratory rate depends on patient spontaneous activity and the current volume depends on set parameter values and patient patophysiological conditions.

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

In this mode the patient's work of breathing is assumed by the Unit. Each breath initiated by the patient (Tr. I enabled) is supported by the Unit, 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.

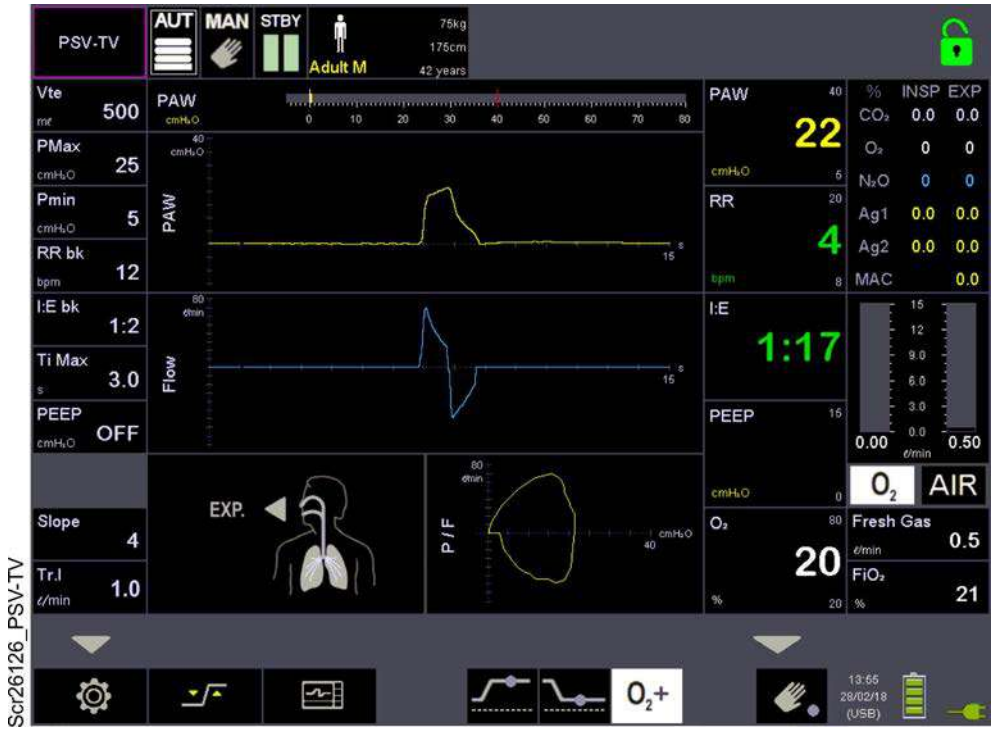
The system will automatically provide an **APCV** ventilation with set safety respiratory rate (RR bk) and I:E ratio (I:E bk).



5.8.4 PSV-TV

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

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



Scr26126_PSV-TV

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

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

Therefore, keep in mind that, in order to have the unit'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 unit provides support at a guaranteed volume (Vte) pre-set by the User.

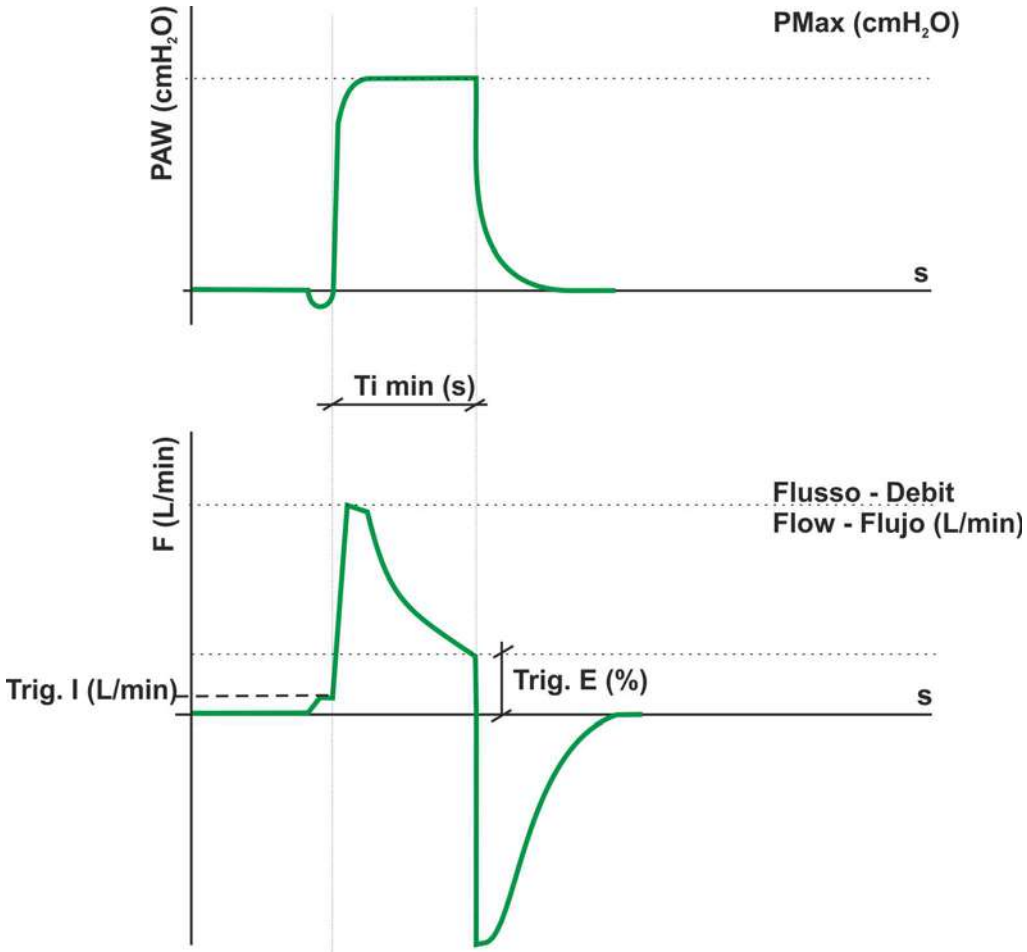
When the Vte pre-set value is reached, the expiration takes the place of the inspiration (according to Tr. E - percentage of the inspiratory flow peak beyond which the expiration can begin).

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

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).



5.8.5 VC-VAC

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

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

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 unit, and therefore it is used when the patient is unable to breath on his own, or in order to assure an efficient pre-set current volume and therefore the mechanical ventilation must fully replace the spontaneous breathing.

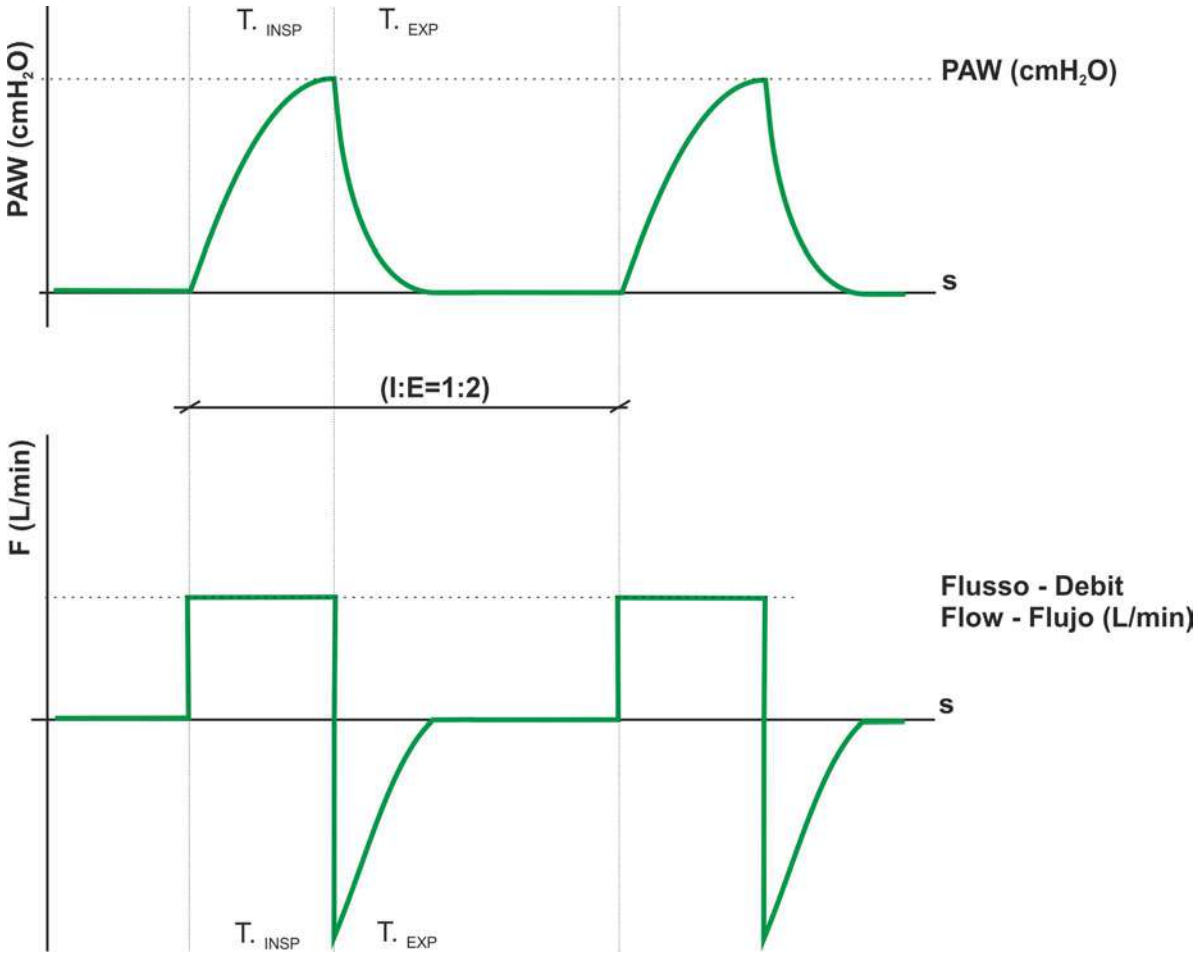
The inspired volume (Vti) is pre-set and generated in a pre-set time (RR and I:E) and determines the characteristics and the pressure range necessary to reach the pre-set amount of gas mixture that must be provided.

The patient's breathing attempt is detected by the system (Tr. I) and it automatically sends inside the airway a gas flow at a pre-set volume (Vti). To combine the assisted mode with the control mode, the User must adjust the trigger sensitivity (Tr. I) at a value that suits the patient.

If during the expiratory phase, the patient generates a spontaneous breath that enables the trigger, the Unit 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 unit screen.

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

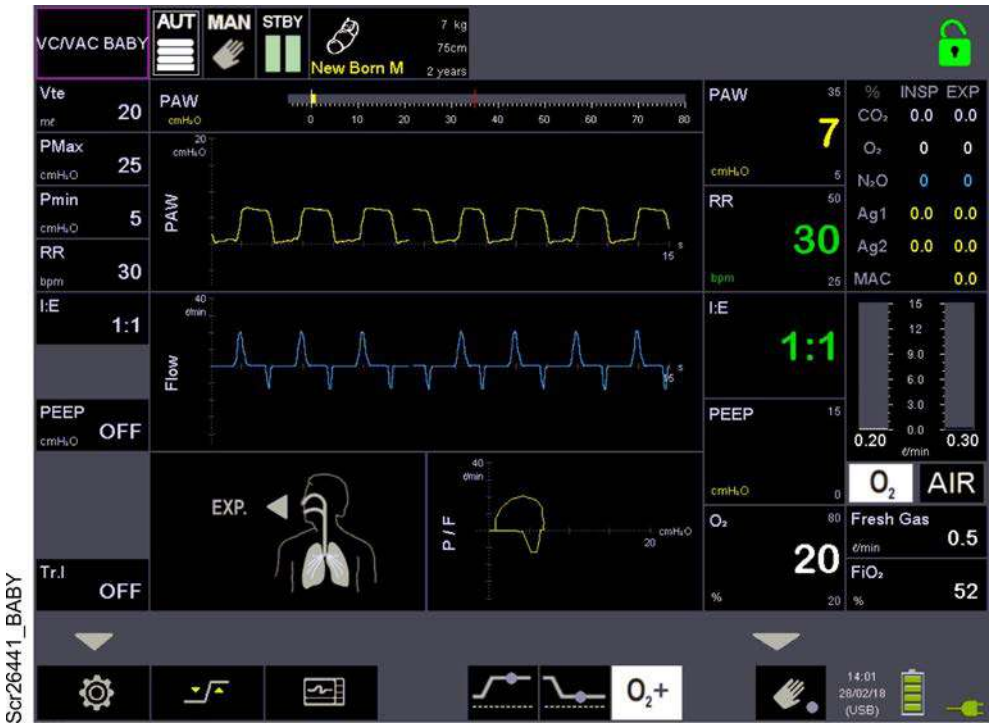
If the patient's spontaneous breathing respiratory rate is higher (than the respiratory rate set on the Unit) the machine will increase the number of breaths per minute (with regard to the number set in the control panel) and displays the value.



5.8.6 VC-VAC BABY

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

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



Scr26441_BABY

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.

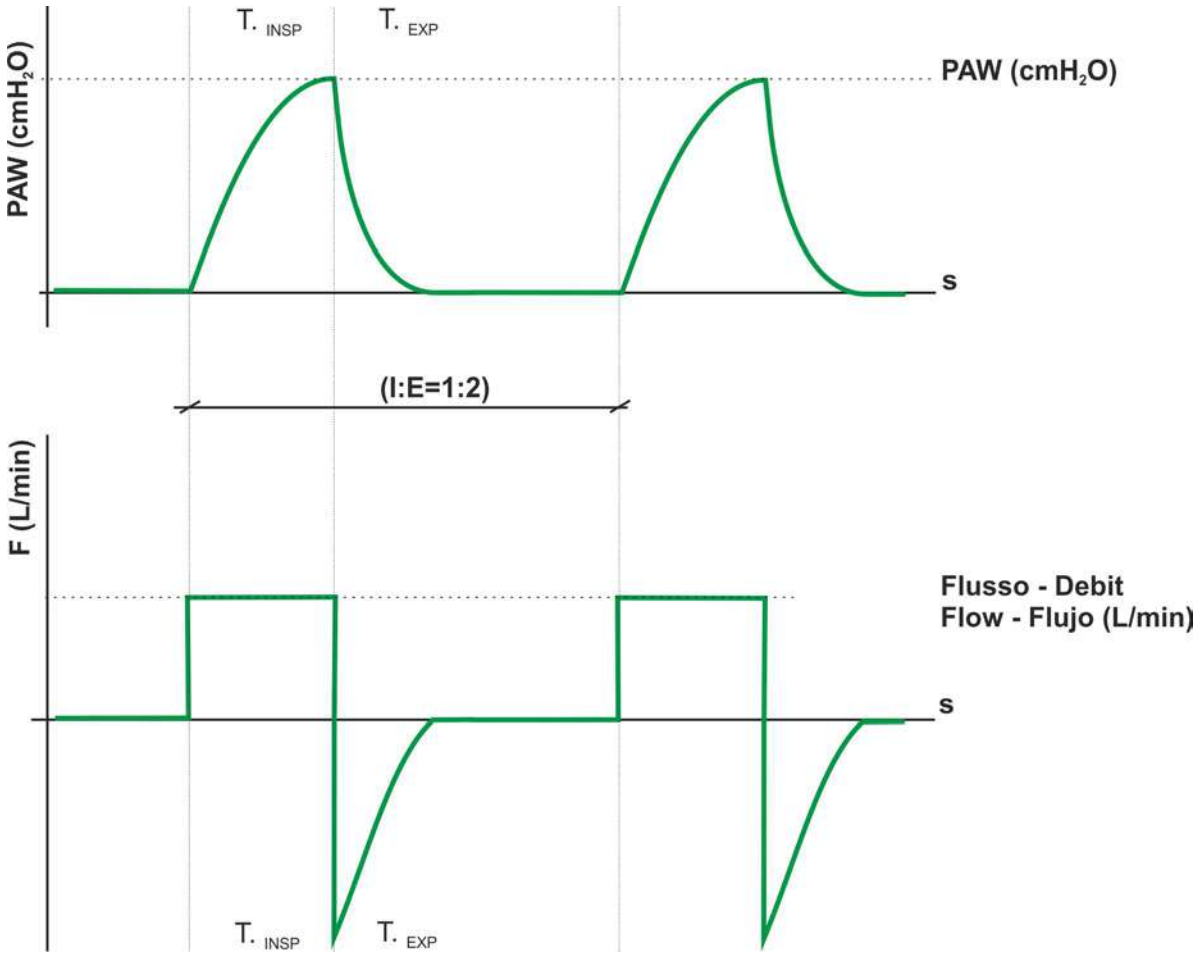
In this type of ventilation the work of breathing is fully assumed by the unit, and therefore it is used when the patient is unable to breath autonomously, or in order to assure an efficient pre-set current volume and therefore the mechanical ventilation must fully replace the spontaneous breathing.

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

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

The User must adjust the trigger sensitivity (Tr. I) at a value suitable for the the patient to combine the assisted mode with the control mode,

If during the expiratory phase, the patient generates a spontaneous breath enabling the trigger, the Unit 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 screen.



5.8.7 V-SIMV

Volume-targeted synchronised intermittent mandatory ventilation.

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

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

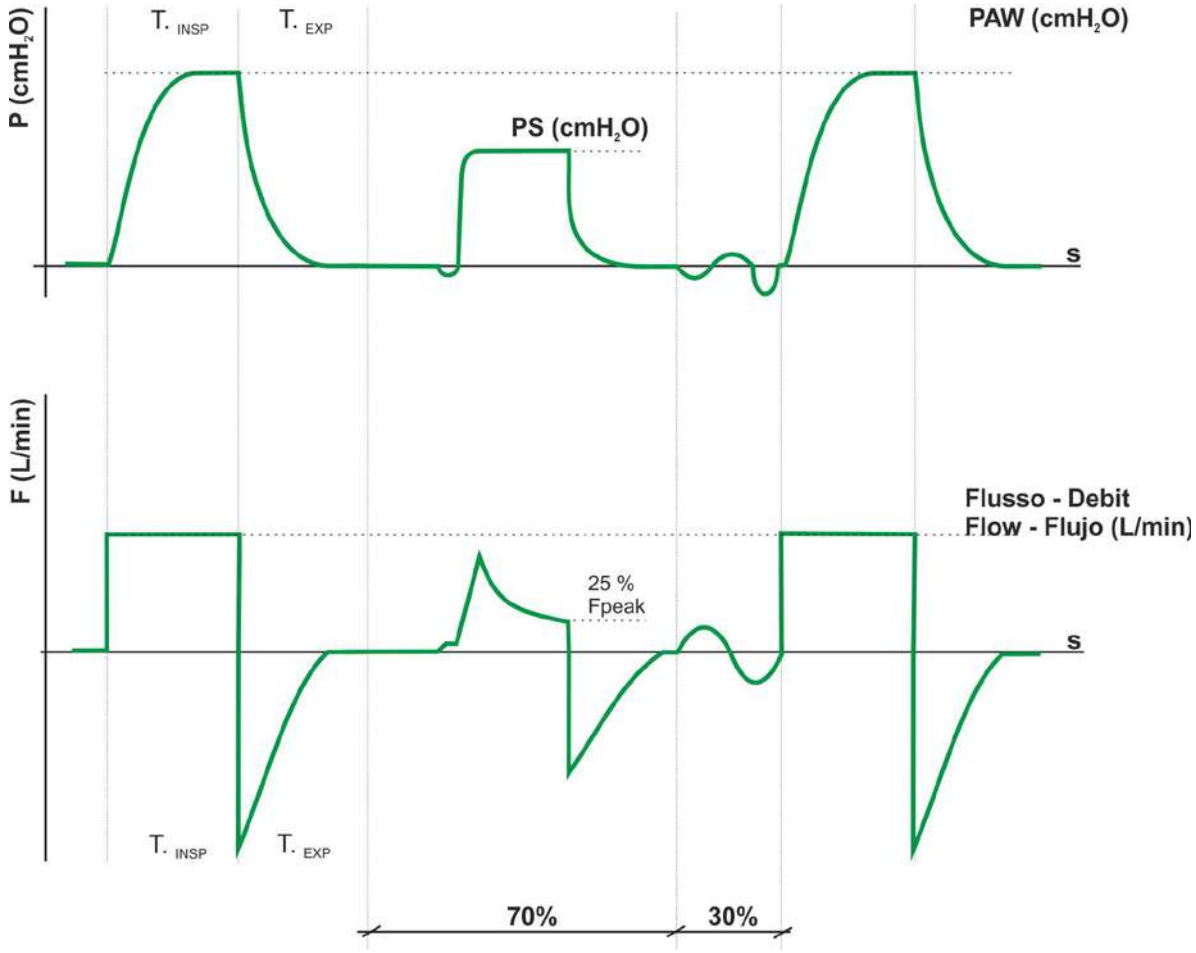
The Operative Mode V-SIMV is active only with patients: ADULT and PAEDIATRIC.

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

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



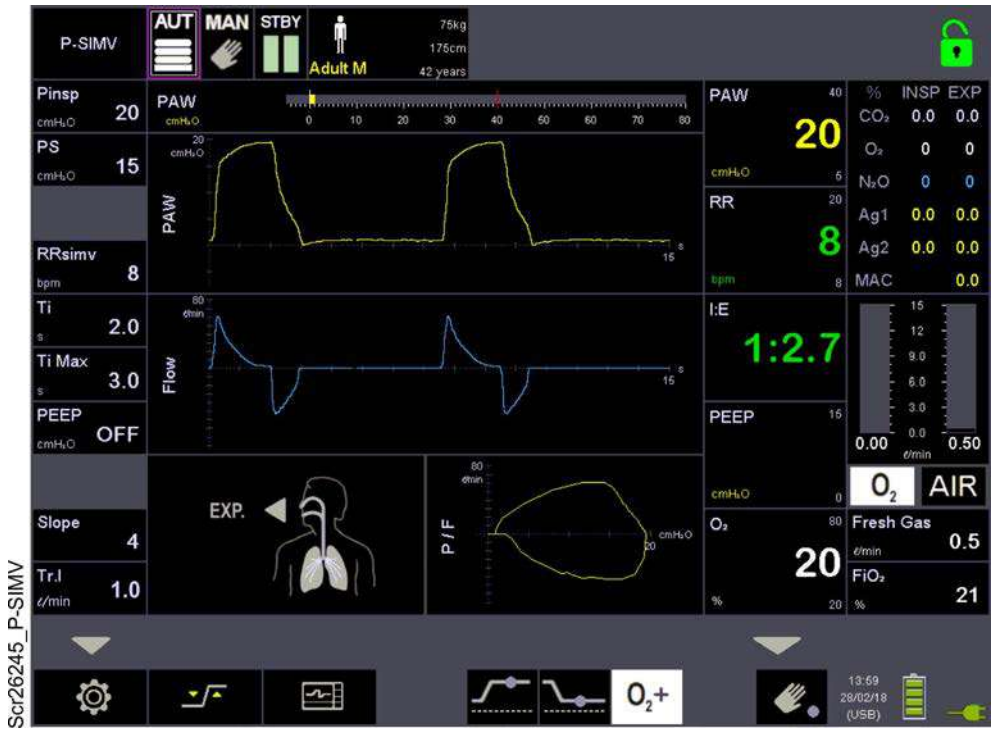
The graphic shows how the SIMV operative mode works.

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.

5.8.8 P-SIMV

Pressure-targeted synchronised intermittent mandatory ventilation.

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

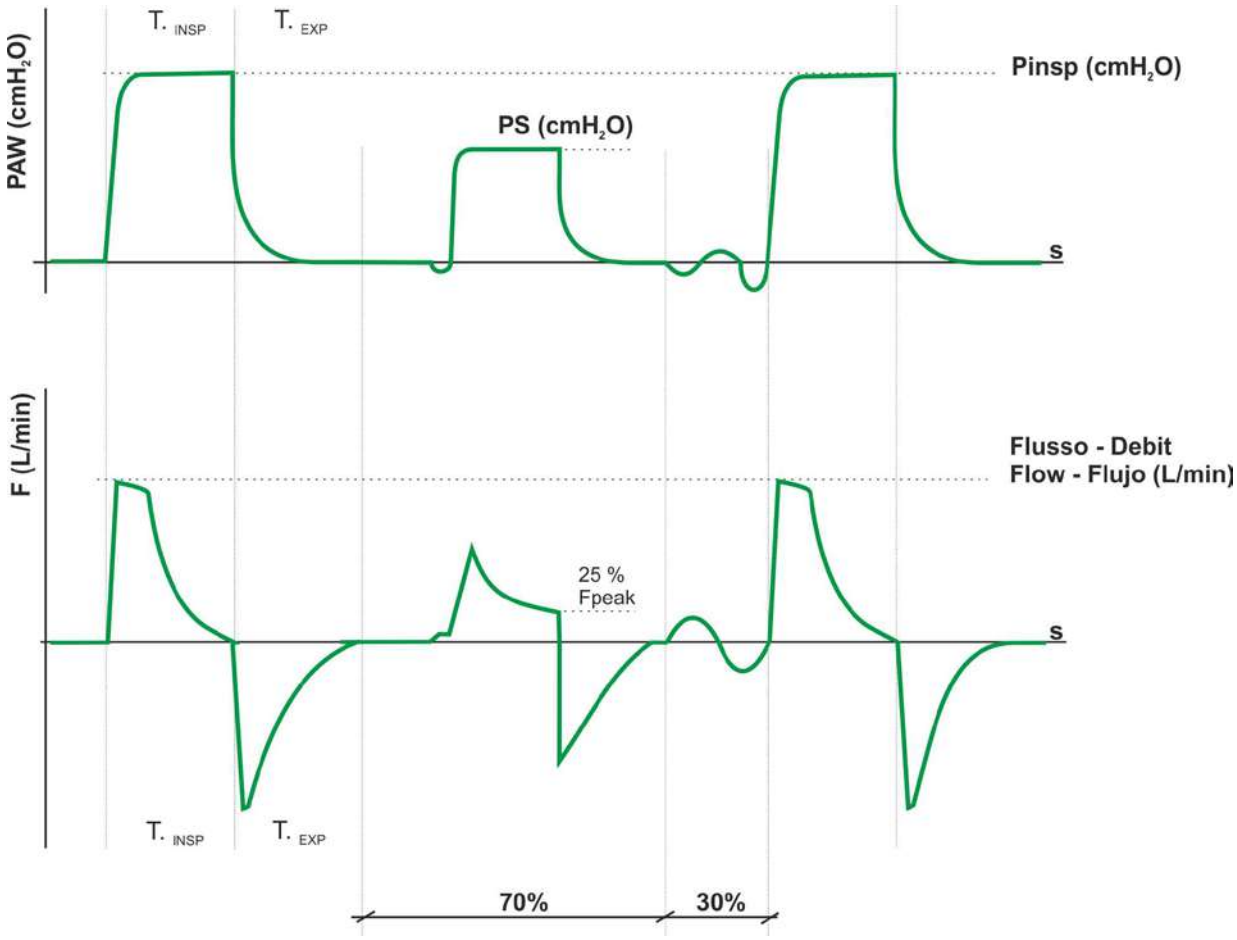


P-SIMV is a synchronised intermittent mandatory ventilation, during which the Unit generates a certain number of breaths per minute (RRsimv) at a pre-set inspiratory pressure (Pinsp) providing pressure support (PS) during the spontaneous phase.

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

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

Therefore, in SIMV mode, the Unit 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 unit) 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.

5.8.9 MAN operative mode

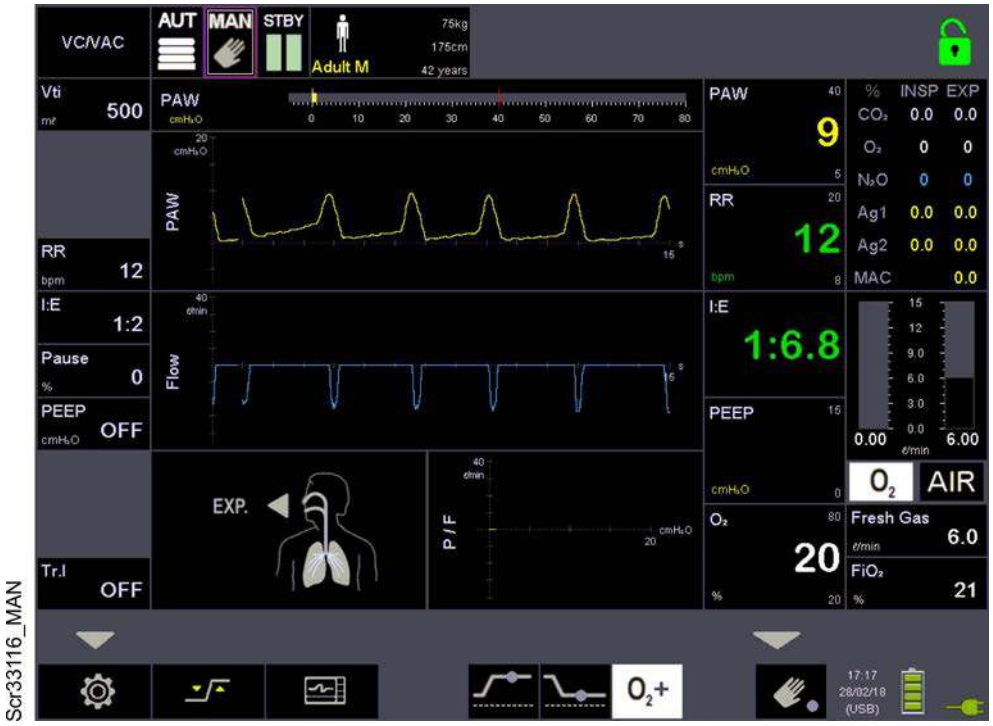
Tha Manual ventilation can be performed in two different modes.

- Through the supplied manual circuit acting on bag connected to “BAG” connector placed on valves group.
- Otherwise, with an auxiliary ventilation system, Mapleson C (To and Fro) type, connected to “AUX” connector placed on valves group.

To activate the MAN operative mode it is necessary:

- select MAN on display

- or pres MAN key on the keyboard



Scr33116_MAN

WARNING !! Patient injury hazard

Place the APL regulator (Airways pressure limit regulator) at a value suitable for the type of patient to be ventilated. In the manual ventilation the APL regulator is used to determine the maximum value of such pressure in the airways.

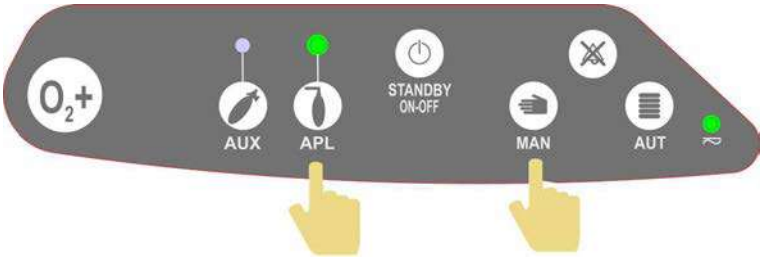
Set on Flowmeter box enough fresh gases for the correct ventilation of the pazient.

- The CO_2 absorber canister must be inserted, because the system is automatically configured in rebreathing modality.

1. MAN operative mode : manual circuit

- The manual ventilation can be effected by the bag connected to the “BAG” connector positioned on the breathing system through the supplied manual circuit (*see picture on the right*).

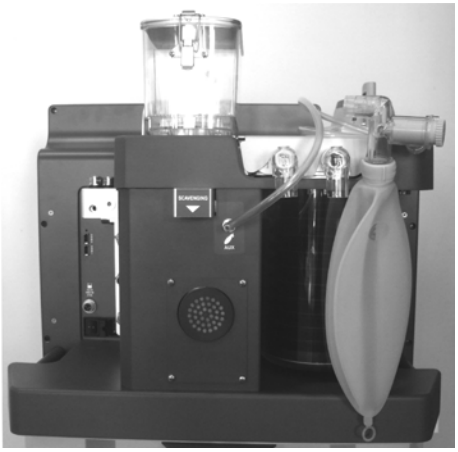
- Select **MAN.**
- On the work-shelf keyboard must be selected the **APL** key (green led on).
- The anaethesia unit is ready for manual ventilation.



During manual ventilation (with MAN operative mode activated), it is possible to detect on the display the pressure curve and the various parameters monitoring.

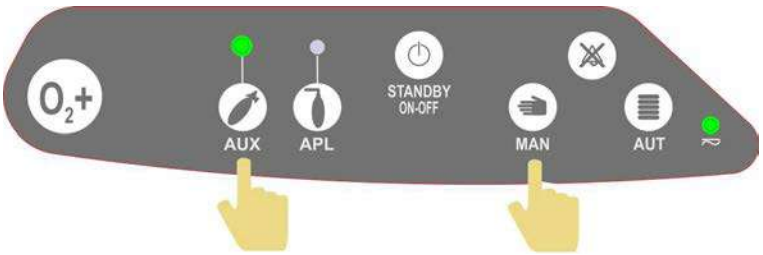
Tthe anaesthesia unit displays the graphic of both the Pressure and the Vte value of the Minute Volume.

2. MAN operative mode : Mapleson C (To and Fro) manual circuit



- A manual ventilation can be performed also with an auxiliary ventilation system, Mapleson C type (To and Fro), connected to the “AUX” connector placed on the valves group (*see picture on the right*).

- Select **MAN.**
- On the work-shelf keyboard must be selected the **AUX** key (green led on).
- The anaethesia unit is ready for manual ventilation.



During manual ventilation (with MAN operative mode activated), it is possible to detect on the display the monitored pressure curve and the various parameters (the anaesthesia unit displays the graphic of both Pressure and Vte values).

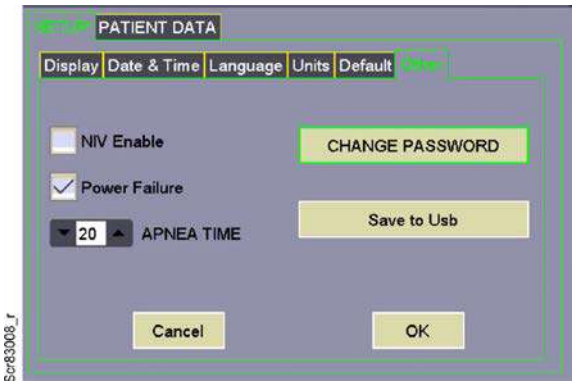
With this type of manual ventilation (AUX key activated), the system (even if the MAN operative mode is selected) does NOT display the monitored parameters.

- In MAN operative mode press (select) on soft keyboard (display) the STAND BY / ON-OFF (STBY) key to return to Stand-by operative mode.
- In MAN operative mode press (select) on soft keyboard (display) the AUT (AUT) key to return to next functioning operative mode used.

5.8.10 APNEA BACK-UP

- Apnea BACK-UP is a safety function available in two operative modes : PSV and PSV-TV.
- Apnea BACK-UP function enables if the patient, ventilated in one of the above mentioned modes (PSV and PSV-TV), stops breathing.

- Select: **SETTING MENU**
- Select: **Other**



- After a pre-set time (***SETUP - Other : APNEA TIME*** : see photo on the left), will appear the relevant alarms and the system automatically starts the patient ventilation using the pre-set bk paramameters.

WARNING !! Patient injury hazard

The anaesthesia unit continues its activity and the User acknowledges the emergency condition. When the Apnea BACK-UP function enables, the back-up ventilation parameters used are those set based on the selected operative mode.

The User takes note of existing emergency status and can :

- Continue ventilating the patient in back-up condition and eventually adjust the ventilation parameters
- Switch to a ventilation by volume or pressure more suitable to patient conditions; in this case the Apnea-Back-up alarm condition will terminate.

5.9 Physiological Respiratory Parameters (PRP)

In the chapter 3.3 the User will find a description of available Physiological Respiratory Parameters selectable on anaesthesia unit.

- Chapter 3.3.1 Respiratory parameters display
- Chapter 3.3.2 Respiratory parameter modification (Respiratory Rate)
- Chapter 3.3.3 List of available respiratory parameter
- Chapter 3.3.4 Monitoring of respiratory parameter
- Chapter 3.3.5 Monitoring of " gas analysis parameters "

WARNING !! Patient injury hazard

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

5.10 Ventilation phase

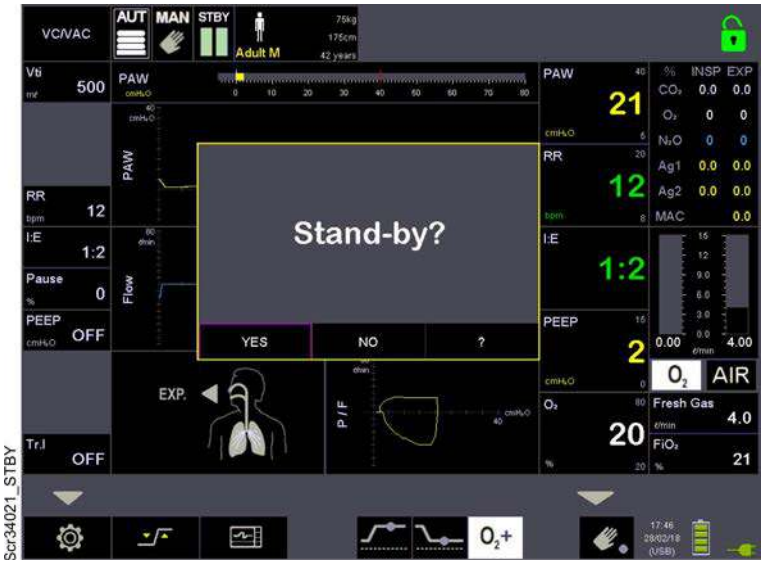
- Based on the ventilation parameters set by the User and on the patient's characteristics, the anaesthesia unit is able to monitor and measure a series of values necessary for the patient's clinical evaluation.
- On the top of the screen, there is a led indicator that displays the pressure inside the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

Scr24621_VAC

- Operative mode selected: **VC-VAC**.
- Select **AUT** (or MAN) 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** showing the trend of the respiratory parameters.
- On the right side of the display you can find **monitored values** that will help you evaluate the patient's clinical condition.
- In the upper part the Operative Mode is displayed as well as both **AUT, MAN and Stand-BY (STBY)** 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.

5.10.1 Ventilation interruption



- Select **STBY**, 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.

Anaesthesia unit in **Stand-by mode**.

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

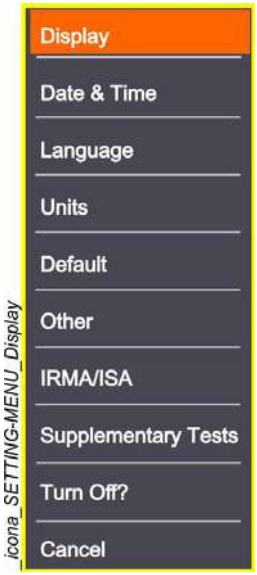
  YES: anaesthesia unit will be switched off.

  NO: cancel the command (the anaesthesia unit returns to Stand-by mode).

5.10.2 SETUP MENU

During the patient ventilation, the User can intervene using the graphical user interface, by selecting the “Operative functions” at the bottom of the screen.

- Select the icon to access the anaesthesia unit's SETTING MENU.



icona_SETTING-MENU_Display

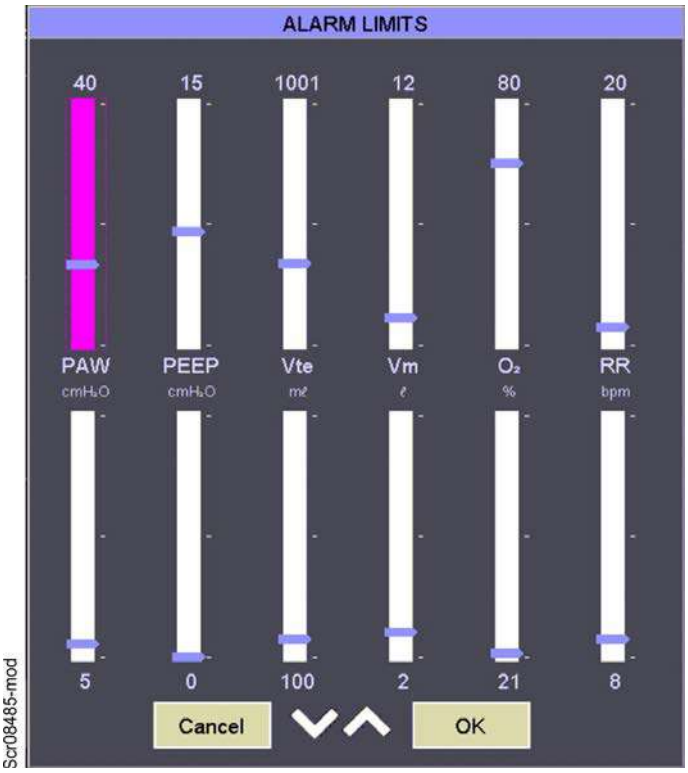
Scr42967_MENU

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

The **SETTING MENU** functions are shown in chapter 3.7.

5.10.3 Alarm limits

- Select the icon to access the anaesthesia unit's ALARM LIMITS.



- To go back to the Stand-by display, select **Cancel** or **OK** (follow the instructions displayed).
- For **ALARM LIMITS**, please see chapter 6 (Alarms).

5.10.4 GRAPHICs visualization

The anaesthesia unit is equipped with a feature called GRAPHICs that allows the user to combine on display the **Loops**, the **Charts** and the **Measured** patient respiratory parameters in different ways.

Moreover, it allows to display the Trends and Events.

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

- Charts: PAW, Flow , Tidal Volume, Gas
- Loops: Tidal Volume / Flow, PAW / Tidal Volume , PAW / Flow , Lung status icon
- Measures: Breathing respiratory parameters, Gas
- Trends and Events

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

- To quit the function, select again the icon **GRAPHICs**.
- For GRAPHICs setting, please see chapter 3.5.

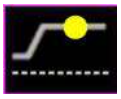
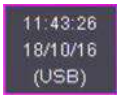
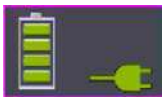
5.10.5 INSP – EXP hold and Manual breath

The functions that can be activated from the IGU are shown in chapter 3.7.

5.11 Functions list

	Operative mode — *See chapter 3.2.2 and 5.8*
	Operative commands — *See chapter 3.11*
	Patient data — *See chapter 3.2.4*
	
	Alarms faults — *See chapter 6*
	Password — *See chapter 6.1.1*
	Physiological respiratory parameters — *See chapter 3.3.1*
	Monitoring of respiratory parameter — *See chapter 3.3.4 and 3.3.5*
	Calibration programs — *See chapter 5.12*

SETUP parameters	*See chapter 3.7*
Display	• *Brightness* • *Energy saving* • *Sound volume* • *Touch audio*
Date & Time	• *Date* • *Time*
Language	• *Italian, English, German, Turkey, Polish, French, Russian, Spanish*
Units	• *Weight (referred to the patient)* • *Height (referred to the patient)* • *CO_2 (unit of measurement)* • *Pressure (unit of measurement)*
Default	• *Erase Trends data* • *Erase Events data* • *Erase Patient data* • *Setting & Ventilation Default*
Other	• *NIV Enable* • *Power Failure* • *APNEA TIME* • *N_2O / Xe* • *CHANGE PASSWORD* • *Save to USB*
IRMA/ISA	*See chapter 3.8*
Supplementary Tests	*See chapter 4.8*
Turn Off	*See chapter 5.10.1*
Cancel	*See on chapter 5.10.1*

	Alarms Limits	*See chapter 6*
	GRAPHICs visualization	*See chapter 3.5*
	INSP Hold	*See chapter 3.7*
	EXP Hold	*See chapter 3.7*
	MAN function	*See chapter 3.7*
	Time / Data	*See chapter 3.2.5 and 3.7*
	Battery / Power supply	*See chapter 6*

5.12 Calibration programs

WARNING !! Risk for Patient / User injury

The informations herein are exclusively intended to be used by SIARE specialised staff or qualified technical staff, formally authorised by SIARE for the use of the Morpheus anaesthesia unit.

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 !! Risk for Patient / User injury

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

CAUTION

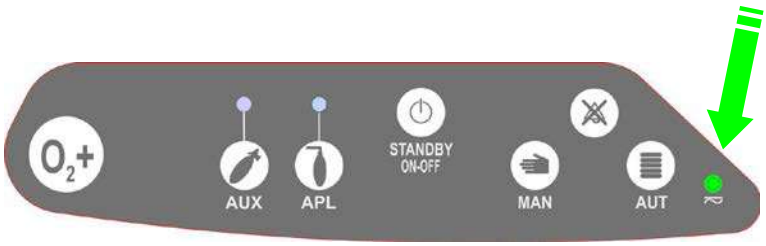
- SIARE staff or qualified technical staff, formally authorized by SIARE, must know the full content of this manual (and of the Service manual), before carrying out the operations described below.
- SIARE authorized technician has got the suitable tools and spare parts and he is trained to work in compliance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

CAUTION

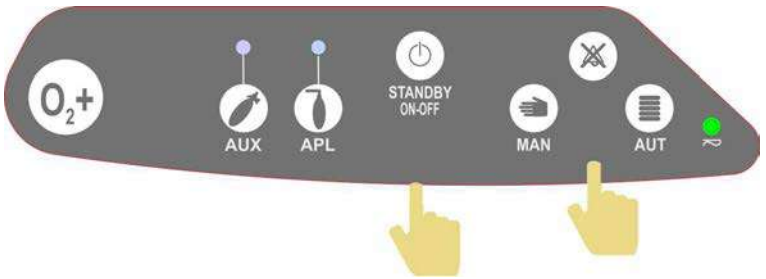
- To enable the “Calibration Programs” display the MND should be operating and correctly connected.
- For tests and checks, please use the **patient simulator SIARE code LS.AB.001** that is equipped with variable resistance and compliance.
- For a more correct and detailed analysis of the “Calibration Programs”, please consult the SERVICE manual.

For methodology of touch screen and/or control keyboard use, see chapter 3.1 .

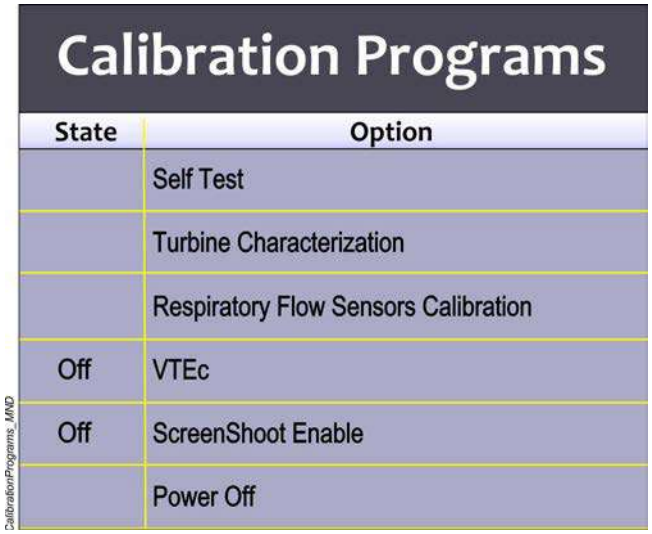
5.12.1 Calibration Programs displaying



- Set the main switch (placed on the side back of anaesthesia unit) in position " **I** " (ON).
- Make sure that on the keyboard (user commands area) the green led (indicating the presence of mains power supply) is ON.



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



The list of the procedures available is displayed in the 'Calibration Programs page'

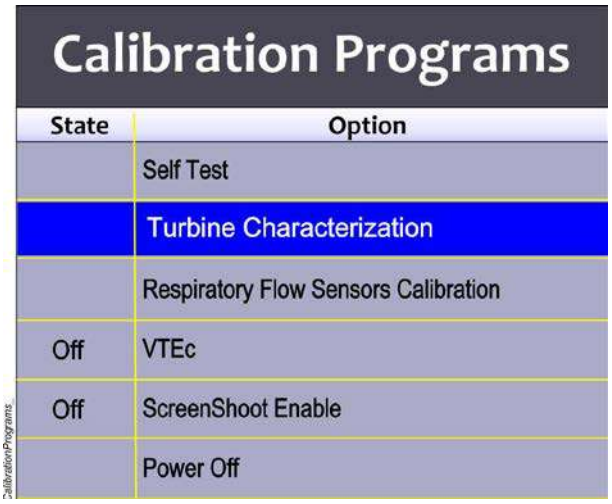
Select :

- **Self Test**, to switch to the normal operation of the anaesthesia unit.
- **Power Off,** to switch OFF the anaesthesia unit.

5.12.2 Turbine Characterization

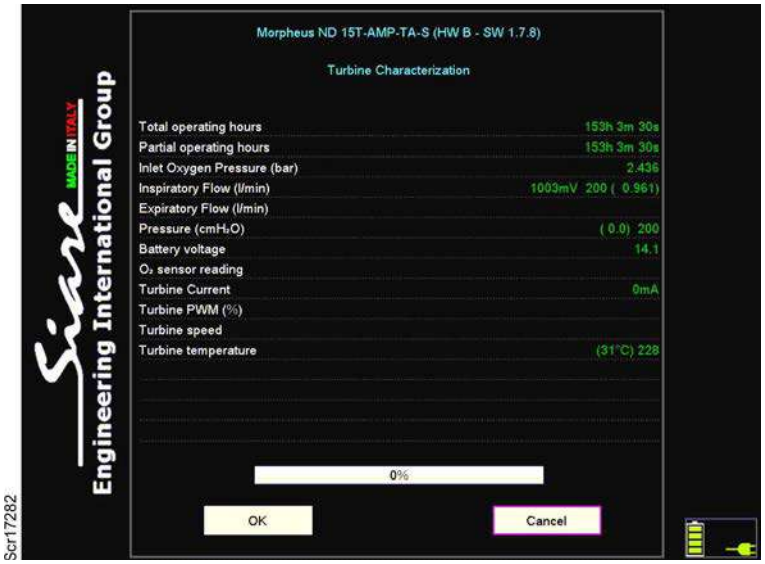
The **Turbine Characterization** (calibration program) is necessary in the following cases.

- When the User notes some 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 **Turbine Characterization**

In order to start the Turbine Characterization is necessary the intervention of qualified SIARE personnel or qualified technical personnel authorized by SIARE. For further information on the procedure please refer to the SERVICE manual.

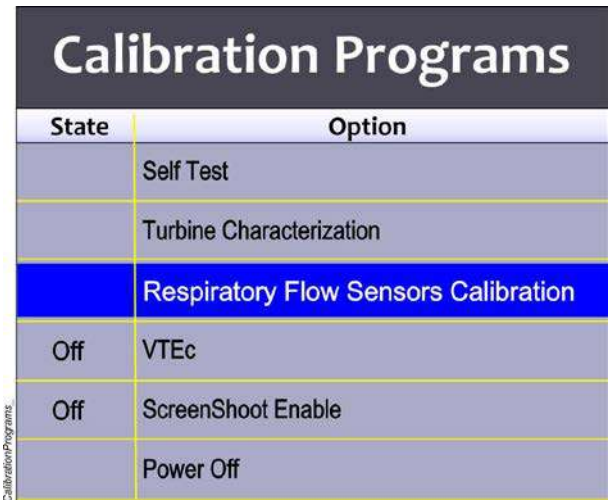


- The page to perform **Turbine Characterization** is displayed.
- **Select** OK
  The turbine characterization program starts.
- **Select** Cancel
  The system quits Turbine Characterization program and goes back to the " **Calibration Programs "** screen.

5.12.3 Respiratory Flow Sensors Calibration

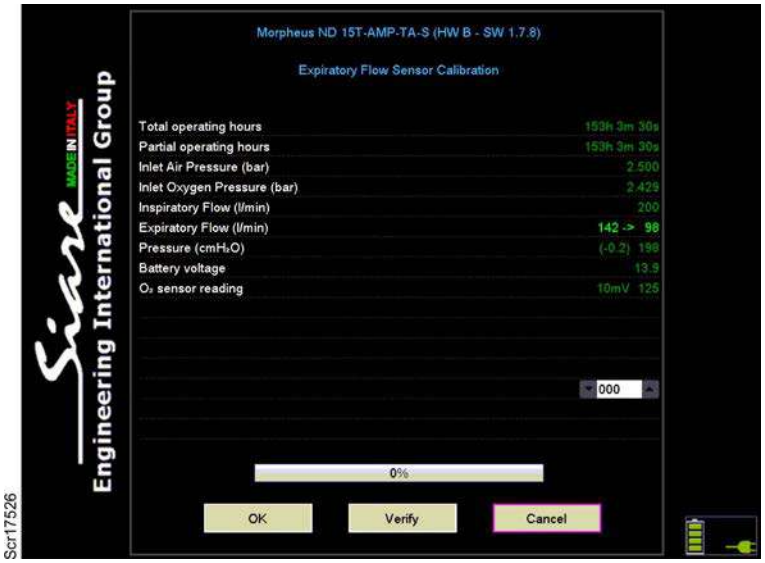
The **Respiratory Flow Sensors Calibration** is necessary in the following cases.

- When the User note 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 ventilation module or replacement of flow sensors (INSP inside the unit or EXP outside the unit), it is suggested to perform this calibration.



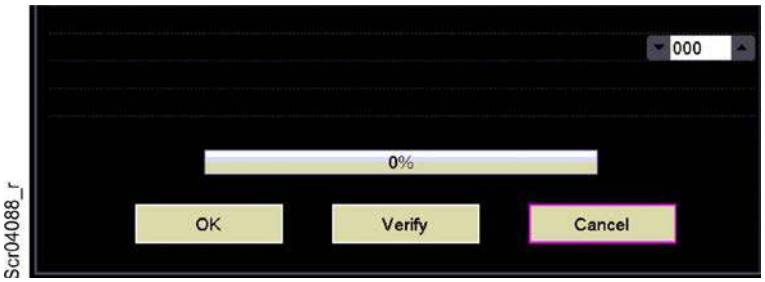
- Select **Respiratory Flow Sensors Calibration.**

In order to start the Flow Sensors Calibration is necessary the intervention of qualified SIARE personnel or qualified technical personnel authorized by SIARE. For more information on the procedure please refer to the SERVICE manual.



The page to perform **Expiratory Flow Sensors Calibration** is displayed.

- **Select** OK
  The Expiratory Flow Sensors Calibration program is performed.
- **Select** Cancel
  The Expiratory Flow Sensors Calibration phase may be aborted.
- **Select** Verify
  The User can check the correct calibration through the displaying of the flow parameters (l/min) Inspiratory and Expiratory Flow.

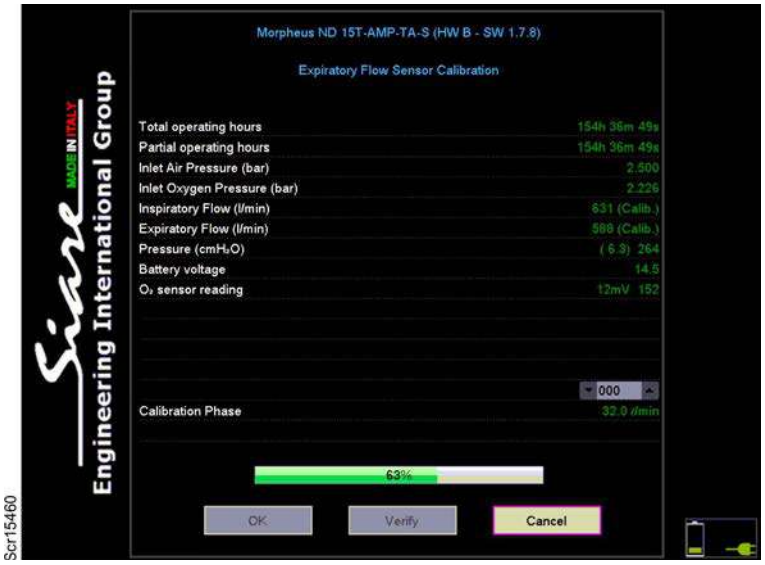


Scr04088_r

- Compensation percentage factor for fine-tuning the inspired flow sensor reading.
- This is a default parameter, set during MND testing phase.

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

This value is properly adjusted during the factory test after having assembled the unit and it can be modified only by authorized personnel. A wrong factor could affect and compromise the safety and the correct working of the anaesthesia unit.

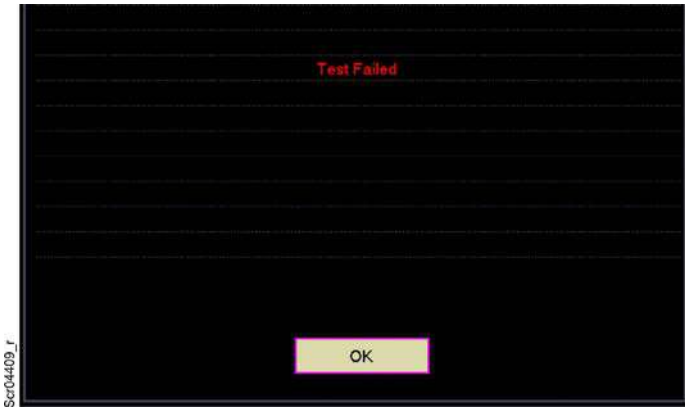


Scr15460

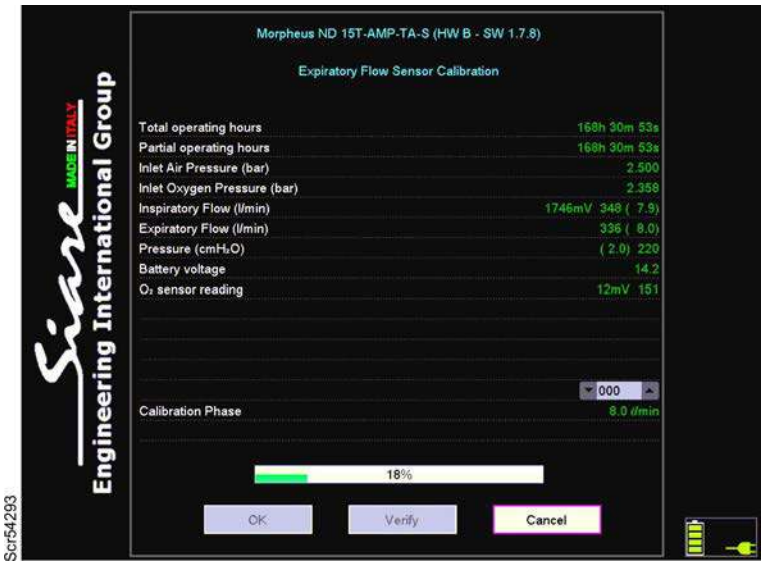
- **Select** OK
- The Expiratory Flow Sensors Calibration program is performed and proceeding correctly.
- *Calibration phases: 0, 4, 8, 12, 16, 20, 24, 32, 40, 48, 60.*

- If the calibration phase is performed correctly the system shows the message: " **Test Completed** "; after some seconds the system will switch automatically to "Calibration **Programs**" visualization.
- In case of first calibration of MND, we suggest to perform this procedure after having checked the **PEEP calibration** and after performing a **Turbine Characterization** (*see previous chapter*).
- For further information please refer to the SERVICE manual.

- Successfully completed Expiratory Flow Sensors Calibration.
- *Calibration phase:* ***Test Completed.***



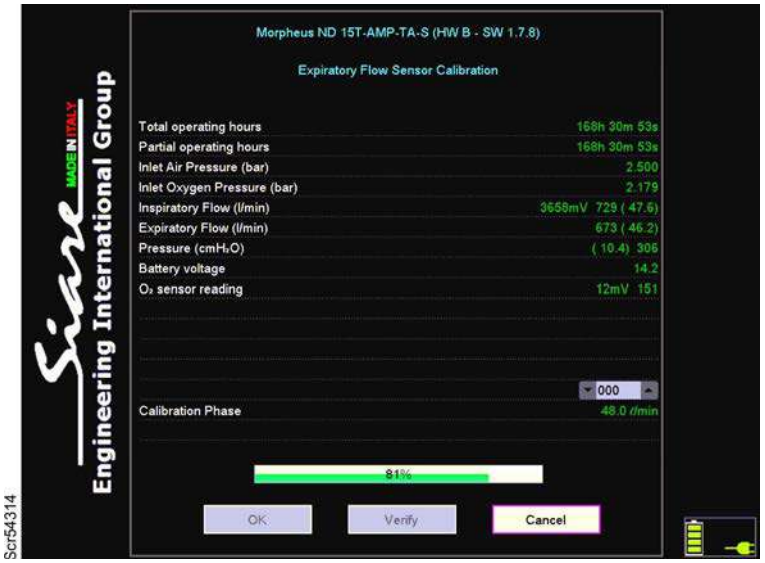
- Not successfully completed Expiratory Flow Sensors Calibration.
- *Calibration phase:* ***Test Aborted.***
- *Calibration phase:* ***Test Failed.***



- **Select** Verify
- The Flow Sensors verification program is performed and proceeding correctly.
- *Verification phases: 0, 4, 8, 12, 16, 20, 24, 32, 40, 48, 60.*

The aim of this procedure is to compare and verify the **Inspiratory Flow and Expiratory Flow** (measured values in l/min) stored during the Expiratory Flow Sensors Calibration phase. The two measured and displayed values should have a numerical value very similar to each other.

- The image highlights the two parameters during the verification phase **Inspiratory Flow and Expiratory Flow** (measured values in l/min)



- The verification program is performed and proceeding correctly.

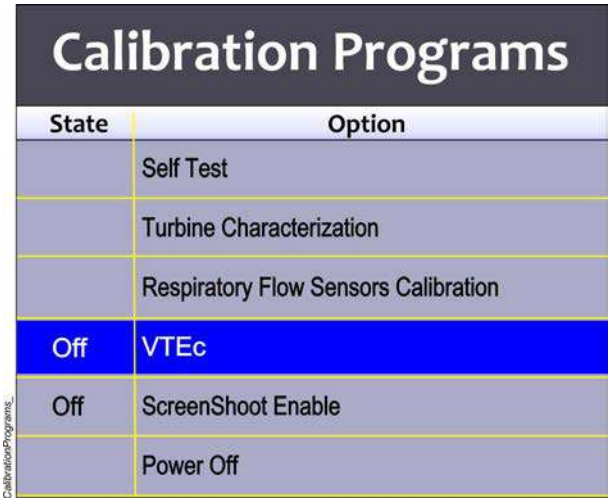
CAUTION

- If the **verification phase** is performed correctly the system shows the message: " **Test Completed** "; after some seconds the system will switch automatically to " **Calibration Programs** " visualization.
- If the verification gives a negative result, the system shows the message: "**Test Failed** " or " **Test Aborted** ".
- For further information please refer to the SERVICE manual.

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

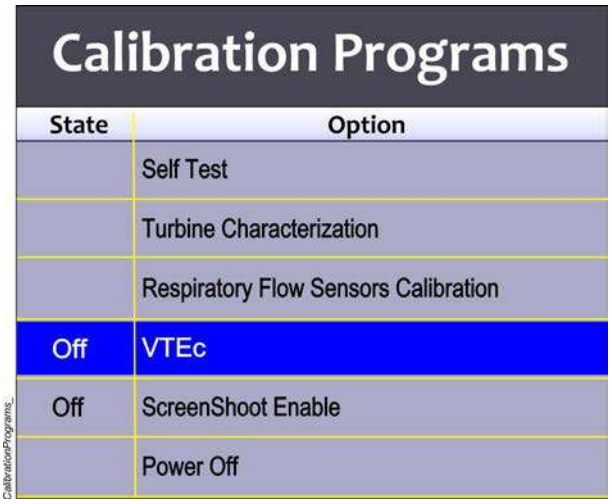
If Expiratory Flow Sensors Calibration and/or relevant verification are not positive, consult the SERVICE manual or contact Siare or a Technical Centre authorized by Siare.

5.12.4 VTEc (On - Off)



- **VTEc - Off**

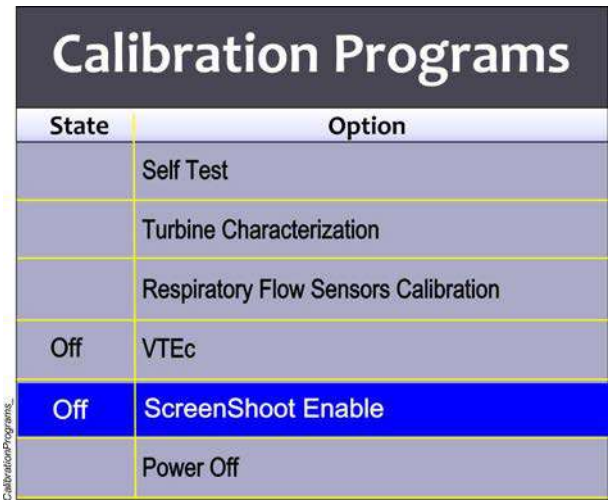
- Selecting the line the VTEc is enabled (On) and vice versa.



- **VTEc - On**

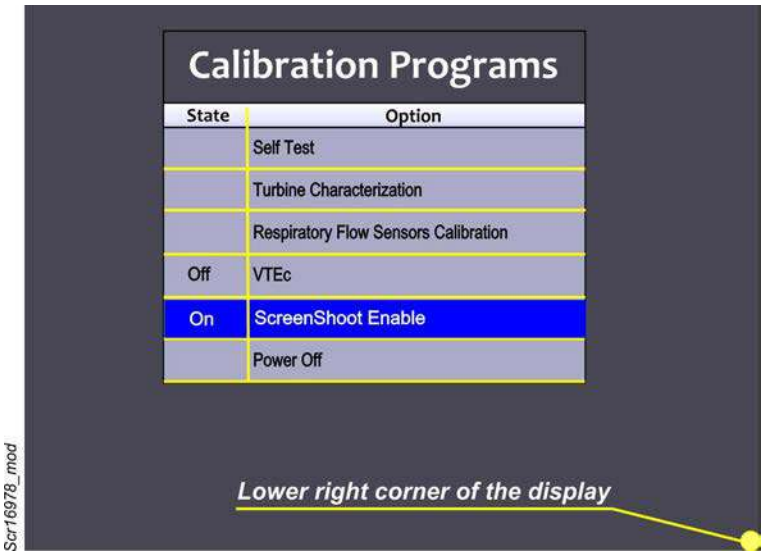
The activation of VTEc (VTEc On) function is necessary to optimize the displaying of calculation of the Vte parameter displayed during ventilation operation.

5.12.5 ScreenShot Enable (Off - On)



- **ScreenShoot Enable – Off**

- Selecting the VTEc, the line is enabled (On) and vice versa.



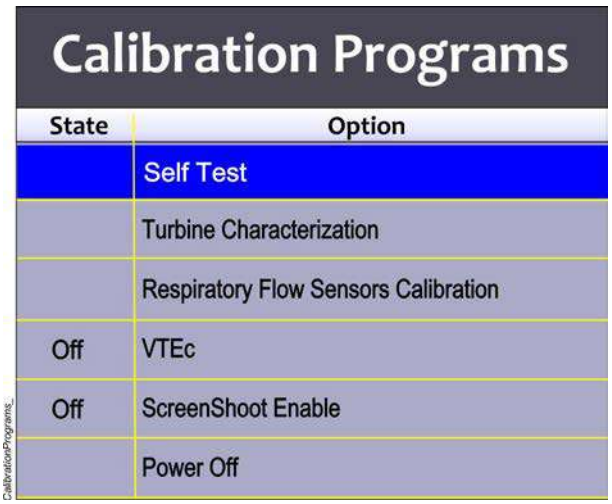
- **ScreenShoot Enable – On**

Allows the User's to store on an USB key an instant image (*image saved in bmp format*) during the operation of the anaesthesia unit (*for further details, please see on chapter 2*).

To save instant images on MND operation.

- Insert USB key (an empty USD key is suggested) into the connector on rear side of MND (*please see on chapter 2*).
- Enable the ScreenShoot Enable On function
- Press on the lower right corner of the display; on USB key an image (bmp format) will be saved anytime this display area will be pressed.

5.12.6 Self Test



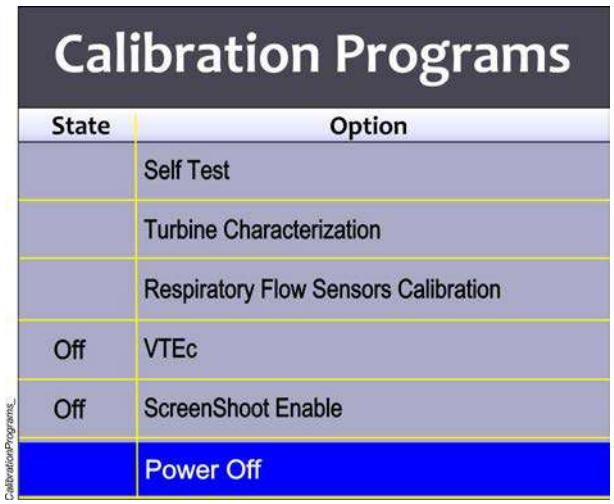
- Select **Self Test** to switch to the normal operation of the anaesthesia unit

- The automatic **Self Test** phase begins.
- *Please close the patient circuit.*

Self Test

During the Self Test phase, the software carries out the self-diagnostic tests and checks a series of devices necessary for safe operation of the anaesthesia unit /patient *(for further details, please see on 5.2).*

5.12.7 Power Off



- Select **Power Off** to switch off the anaesthesia unit.

5.13 Other functions

5.13.1 Default parameters set

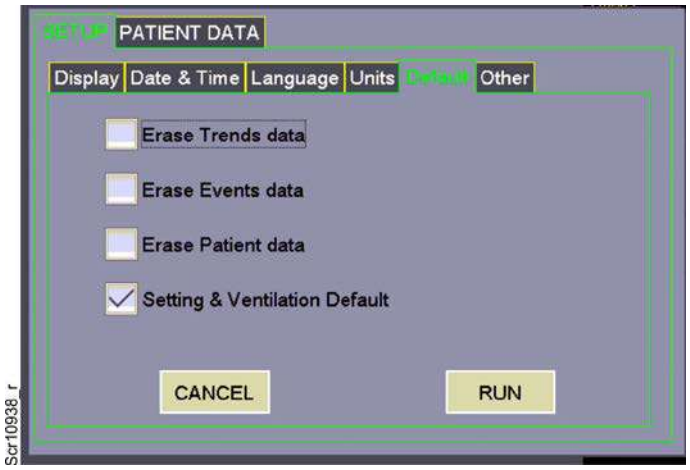
CAUTION

By “Default **Parameters**” we refer to settings : MENU, SETUP, ALARMS limits, ecc…). Default parameters setup allows the User to restore the Morpheus anaesthesia unit factory settings.

Unit in **Stand-by** operative mode.

- Select: **SETTING MENU / Default**

- The **Default** page appears.



- 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.

CAUTION

Through the same procedure, the User can cancel also all data previously stored related to:

- **Trends data (Erase)**
- **Events data (Erase)**
- **Patient data (Erase)** *see on chapter 5.5.2*

5.13.2 Touch screen set

- The Morpheus anaesthesia unit 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).

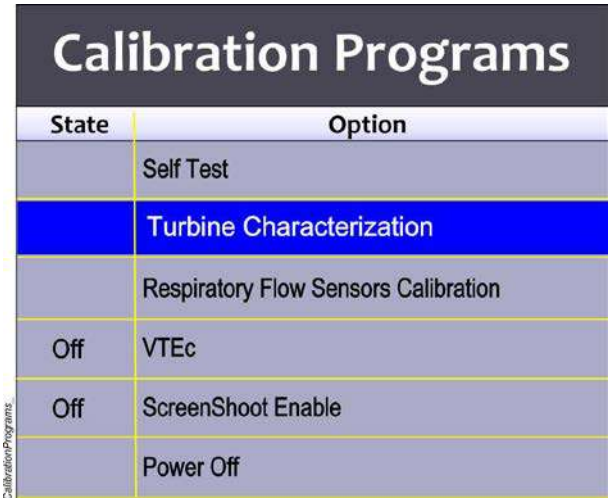
WARNING !! Risk of DM failure and/or injuries for the patient

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

5.13.3 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 Respiratory Flow Sensors Calibration page.

As an example, the Turbine Characterization displaying is used.

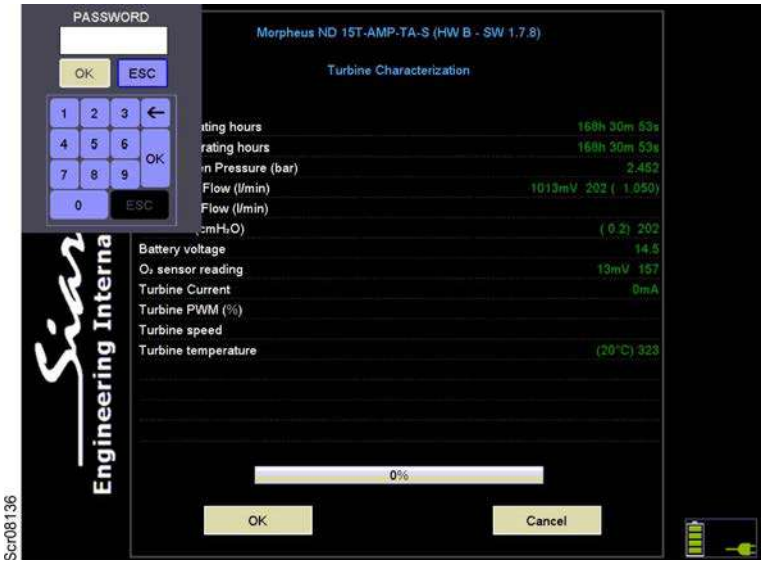


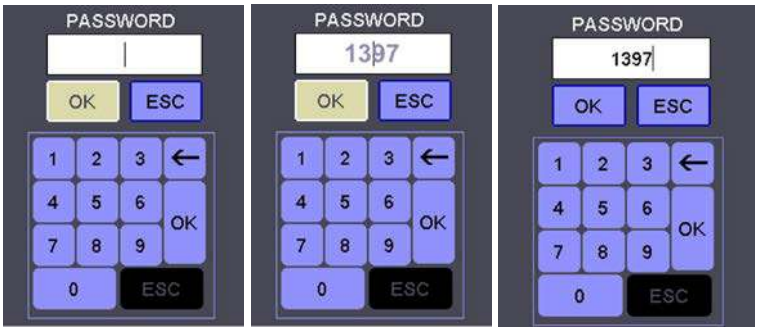
- Select **Turbine Characterization**
- The page to perform **Turbine Characterization** will be displayed.

Reset to ZERO

- Press **Alarm RESET** (hold the soft key for few seconds).

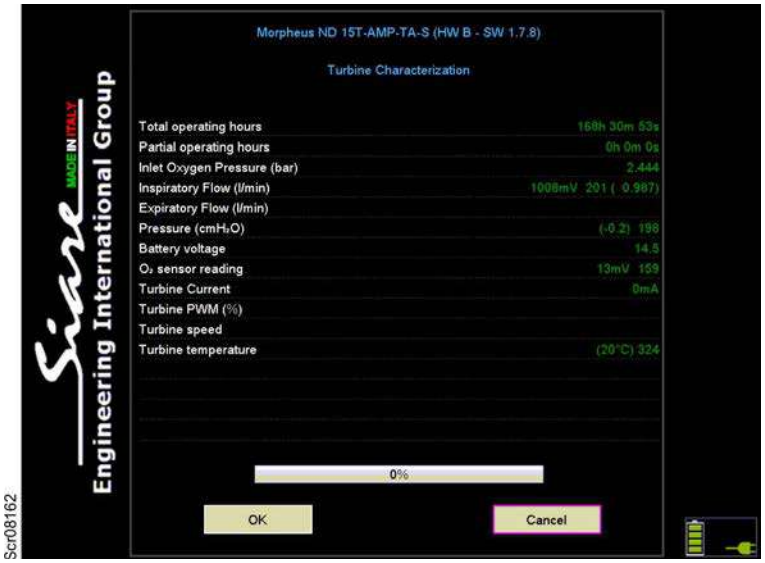
- An area for PASSWORD dialling is displayed.





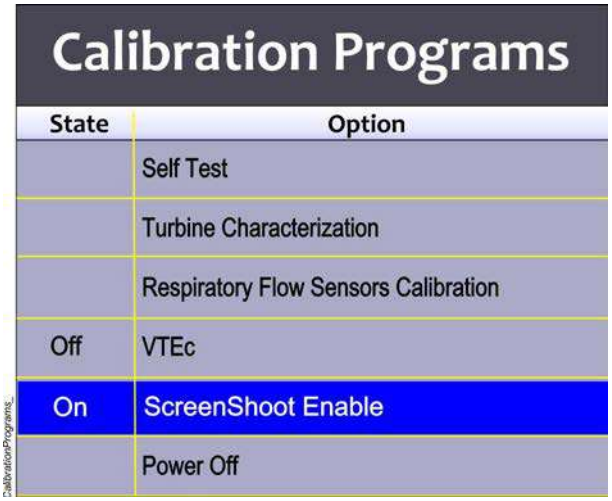
- Select the white area (a key board appear).
- Digit the following code: **1397**.
- Press OK (the partial operating hours are reset).

Partial operating hours = 0h 0m 0s



- **Select** Cancel to quit Turbine Characterization program.
- **Select** OK to perform the Turbine Characterization program.

5.13.4 Data Connection (Trend and Events downloading)



Anaesthesia unit OFF.

The system software permits the download of the data stored in the Morpheus_ND anaesthesia unit.

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

- Connect a USB drive to a USB1 socket.

To perform the data download it is necessary to switch on the anesthesia unit 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 5.2*)

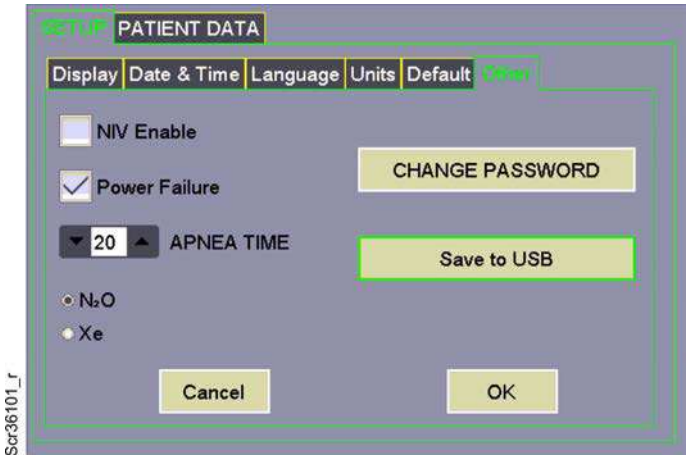
Anaesthesia unit in Stand-by.

- **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 anaesthesia unit.

- **Select Other**



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

- Select Save to USB

- Switching OFF the anaesthesia unit.

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

6 ALARMS

The first section of the paragraph illustrates the part of the system relevant to the alarms operation of the **Morpheus_ND** anaesthesia unit; also, the operating logic and issues for alarms action are taken into consideration.

The second section of the chapter is an indicative but not exhaustive User's guide useful also for the engineer to detect in a short delay the causes or the reasons of a malfunctioning or an alarm signal.

WARNING !! Risk for Patient / User injury

Before using the anaesthesia unit, it is recommended to check the values of the alarm limits (Min. and Max) that have been set.

The **Morpheus_ND** anaesthesia unit is equipped with automatic means for detection and identification of serious and sudden events through alarm signals or information signals.

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

Level or urgency

- Immediate, the event is potentially able to develop in a period of time which is generally not enough to undertake a corrective manual action.
- Briefly, 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.

6.1 Displaying and symbols used

Alarms display area

A1 - ALARM signalization area (see on 6.2.1)

A2 - ALARMS Limits configurable by User : respiratory parameters (see on 6.2.2)

A3 - ALARMS Limits configurable by User : gas sensor (see on 6.2.3)

A3 - General information signal area : battery charge level and main power presence (see on 6.2.4)

A4 - Soft key for acoustic alarm silencing : alarm reset (see on 6.2.5)

6.1.1 A1 - List of active alarms messages

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 “.

Priority / alarm status: “ alarm bell symbol “ icon

The icon takes on a colour based on the priority and status of the enabled alarm.

Medium priority

- Yellow bell

Suspended alarm

- Yellow bell crossed through

High priority

- Red bell

Suspended alarm

- Red bell crossed through

Alarms configurable by User

- LOW PRESSURE OF AIRWAYS
- HIGH PRESSURE OF AIRWAYS
- LOW PEEP
- HIGH PEEP
- LOW EXP. VOLUME
- HIGH EXP. VOLUME
- LOW VOLUME MINUTE
- HIGH VOLUME MINUTE
- LOW O_2 CONCENTRATION
- HIGH O_2 CONCENTRATION
- LOW RESPIRATORY RATE
- HIGH RESPIRATORY RATE
- POWER SUPPLY FAULT (***Power Failure : Setting MENU – Other***)
- APNEA (***APNEA TIME : Setting MENU – Other***)

System alarms

- LOW BATTERY 50% REM.
- LOW BATTERY 25% REM.
- LOW BATTERY 10 MIN. REM.
- BATTERY DISCONNECTED
- BATTERY OVERTEMPERATURE
- TURBINE FAILURE
- TURBINE OVERTEMPERATURE
- TURBINE OVERCURRENT
- CIRCUIT DISCONNECTED (patient circuit)
- LOW O_2 SUPPLY
- LOW AIR SUPPLY
- CAN-BUS FAILURE
- BATTERY CHARGER DISCONNECTED
- CHECK FLOW SENSOR (*not used*)
- LOW INSP. VOLUME (*not available*)
- MAINTENANCE 1000 hours (* a symbol replace the alarm bell image; see following note).

WARNING !! (*) MAINTENANCE 1000 HOURS

Once the anaesthesia unit reached **1000 hours** operation this symbol appears. Contact Siare Technical Centre or a Technical Centre authorized by Siare for preventive maintenance.

Gas Sensor alarms

- Gas Sensor: Sampling Line Clogged
- Gas Sensor: No Sampling Line
- Gas Sensor: Replace Adapter
- Gas Sensor: No Adapter
- Gas Sensor: O_2 Port Failure
- Gas Sensor: O_2 Sensor Error
- Gas Sensor: Unspecified Accuracy (……)

Gas Sensor alarms

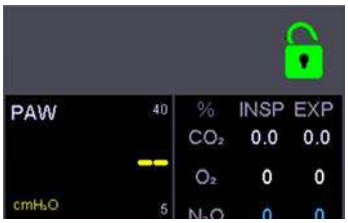
- Gas Sensor: Error (……)
- Gas Sensor: No Breaths
- Gas Sensor: Replace O_2 Sensor
- Gas Sensor: O_2 Calibration Required
- Gas Sensor: Low FiO_2
- Gas Sensor: Low EtO_2
- Gas Sensor: Low $EtCO_2$
- Gas Sensor: High $EtCO_2$
- Gas Sensor: Low $FiCO_2$
- Gas Sensor: High $FiCO_2$
- Gas Sensor: Low FiN_2O
- Gas Sensor: High FiN_2O
- Gas Sensor: Low EtN_2O
- Gas Sensor: High EtN_2O
- Gas Sensor: Low FiAg1
- Gas Sensor: High FiAg1
- Gas Sensor: Low EtAg1
- Gas Sensor: High EtAg1
- Gas Sensor: Low FiAg2
- Gas Sensor: High FiAg2
- Gas Sensor: Low EtAg2
- Gas Sensor: High EtAg2
- Gas Sensor: Mixed Agents MAC < 3
- Gas Sensor: Mixed Agents MAC >= 3

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

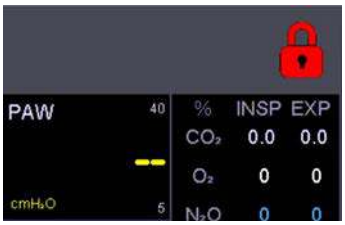
Lock icon

Lock icon (open) green color : touch screen enabled.

Lock icon (closed) red color : touch screen disabled.



- Select the **lock icon** (open) green color.



- The red icon is displayed (closed)
- .The touch screen monitor is disabled.

If the User touches the touch screen of the monitor a window proposing the two following options appears

- **OK** for disabling the Screen Lock.
- **ESC** to leave the Screen Lock enabled.

6.1.2 A2 - ALARMS Limits : respiratory parameters

Touching this icon, a window showing the Alarm limits is displayed: the User can possibly set the Min and Max values of each single alarm.

- Select: **ALARMS icon**

***Nota**. The alarm limits can be modified also while the equipment works.*

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.

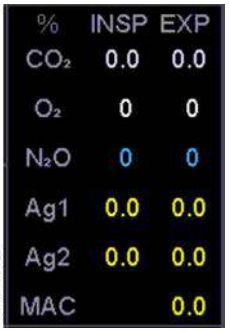
WARNING !! Risk for Patient / User injury

- *The anaesthesia unit 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.*

6.1.3 A3 - ALARMS limits : gas sensor

Touching this icon, a window showing the available Alarm limits appears and the User can possibly set the Min and Max values of each single alarm

- Select: **gas sensor area**



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 for Patient / User injury

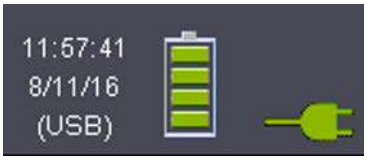
- *The anaesthesia unit used in the same health environments can have different preset configurations of alarm limits.*
- *Verify that the preset alarm limits are appropriate for the new patient and adjust the alarm limits on values suitable to the new condition of use.*
- *The alarms limits setting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

6.1.4 A4 - General information area

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

Green “**BATTERY**” symbol: battery completely charge:

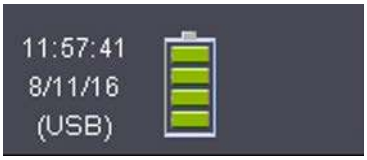
- with fix symbol the battery is complete charge;
- with flashing symbol the battery is in charging phase.



Green “PLUG” symbol: anaesthesia unit connected to the main power supply.

The absence of Green “**PLUG**” symbol indicates that the anaesthesia unit is not connected to the main power supply.

- Active alarm : POWER SUPPLY FAULT.



The battery charge level is highlighted 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% Rem).
- 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% Rem).

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 10 Min. Rem.)

The alarm remains always actives to indicate the occurred malfunctioning.

6.1.5 A5 - Acoustic alarm silencing

During the normal operating phase of anaesthesia unit, 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.

WARNING !! Risk for Patient / User injury

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

- The acoustic alarm silencing is active and will stop the acoustic alarm for a defined time.
- During the alarm silencing the alarm text is showed on the panel.
- A new alarm silencing will cancel the alarm text only if the alarm conditions is disappeared.
- If during the alarm silencing a new high priority alarm occur, the alarm silencing is cancelled and the acoustic signal and the visual texts are activated again.

CAUTION

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

6.2 Alarms setting

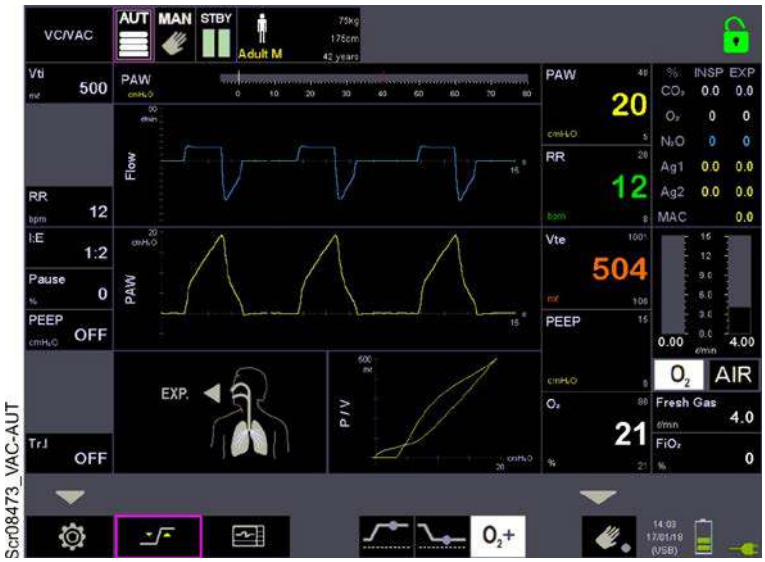
6.2.1 Setting of ALARMS limits values

The User can modify and display the Alarm Limits values in two different ways; through the ALARMS selection icon or selecting a Respiratory Parameter icon.

WARNING !! Risk for Patient injury

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 anaesthesia unit it is suggested to adjust the parameters necessary for the correct operation of the anaesthesia unit.
- During operation it is possible to adapt the ALARM limits values setting in function of the patient clinical situation.



Scr08473_VAC-AUT

- Select: ALARMS icon

Scr08485

The **Alarm Limits** screen appears.

- Select 

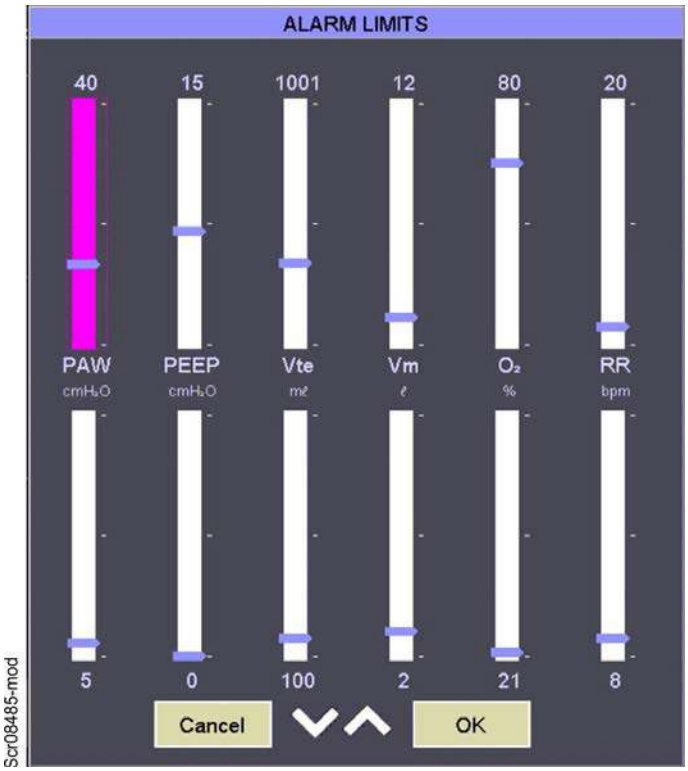
YES: to quit Alarm page; the alarm set will NOT be saved.

NO: it remains in Alarm page.

- Select 

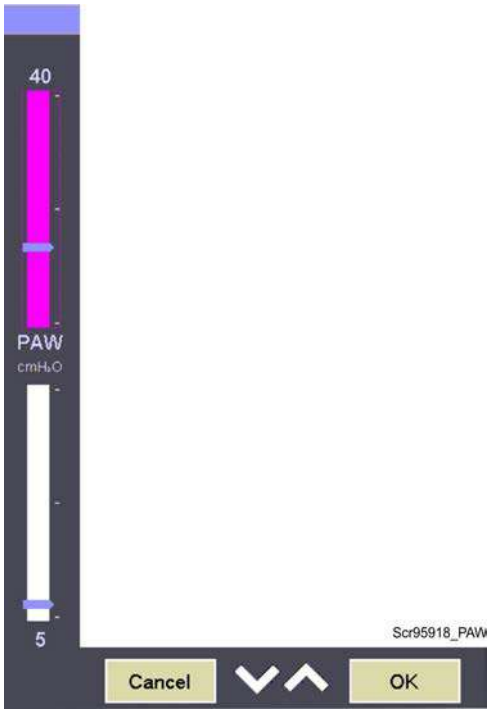
YES: to quit Alarm page; the alarm set will be saved.

NO: it remains in Alarm page.



- Select the Alarm Limits to be modified (e.g. PAW).
- The parameter bar is highlighted and the monitoring parameter box on display is activated (e.g. PAW : 40 cmH2O).

The values set by the scrolling cursor are displayed in the parameter monitoring box
(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 value
- **PAW**: respiratory parameters
- **cmH2O**: unit of measurement

- **White bar**: the bar IS NOT active to be modified
- **Scrolling cursor**: to be used for setting the 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.

- Select the **Alarm Limits** to be modified.
- Increase (decrease) the value to be modified (***e.g. PAW : 50 cmH2O***).

The selection of both the bar and the cursor of the alarm can be done using the encoder knob or the touch screen.

After modification of Alarm limit (PAW) values :

- Select Cancel

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

NO: it remains in Alarm page.

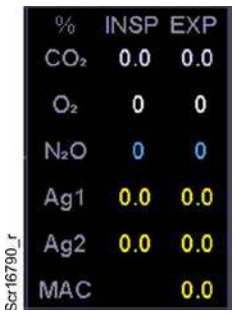
- Select OK

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

NO: it remains in Alarm page.

The procedure described for respiratory parameter alarms limits setting is also applied in the same way for gas sensor alarm limits setting.

Select area highlighted in the picture aside to enable the relevant page (*see chapter. 6.1.3*).



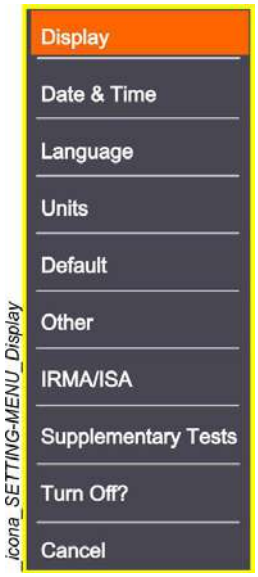
6.2.2 Setting of ALARMS volume

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

Acoustic intensity value at 1 mt distance

- Minimum level Acoustic Volume setting at 1 = 54dBA
- Maximum level Acoustic Volume setting at 20 = 84dBA

- Select the icon to access the anaesthesia unit's SETTING MENU.



icona_SETTING-MENU_Display

Scr11347

- Select **Display**

- To go back to the Stand-by displaying, select Cancel

The Display page allows to set:

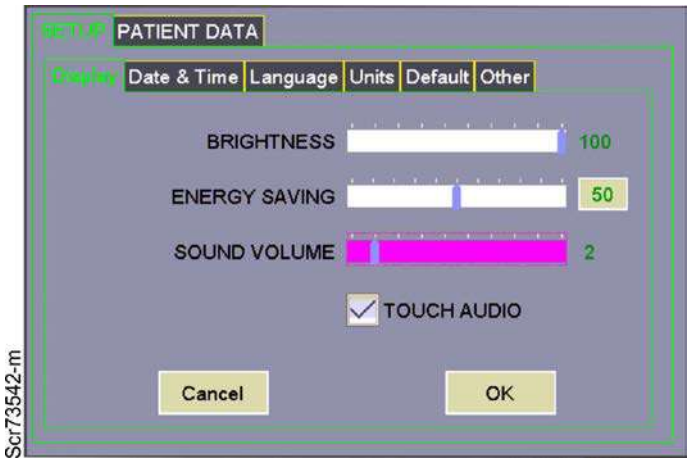
- *BRIGHTNESS*
- *ENERGY SAVING*
- *SOUND VOLUME*
- *TOUCH AUDIO*

Scr11383

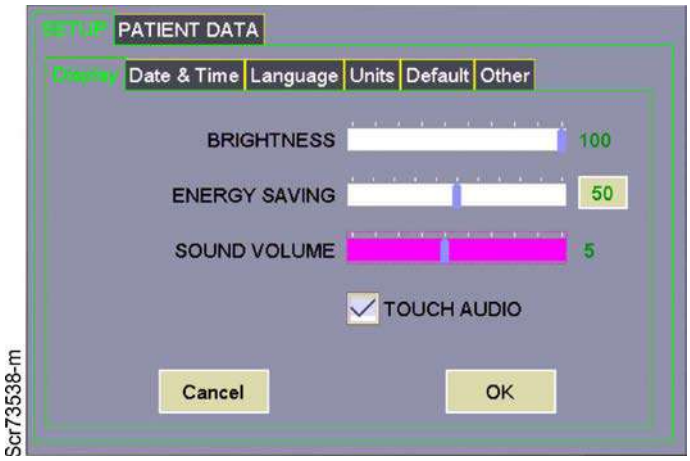
WARNING !! Risk for Patient injury

Using in the same area more than one medical device having different alarm limits setting, the User could have a potential false misinterpretation.

- Select the **SOUND VOLUME** scrolling cursor



- Set the **SOUND VOLUME**



After modification of SOUND VOLUME value.

- Select Cancel

YES: to quit from Display page; the set will NOT be saved.

NO: it remains in Display page.

- Select OK

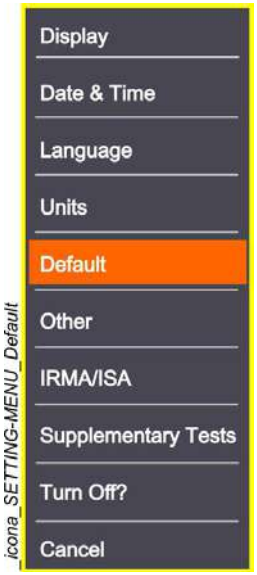
YES: to quit Display page; the set will be saved.

NO: it remains in Display page.

6.2.3 Setting of DEFAULT parameters

The DEFAULT page allows setting the standard factory parameters.

- Select the icon to access the anaesthesia unit's SETTING MENU.



icona_SETTING-MENU_Default

Scr11347

- Select **Default**

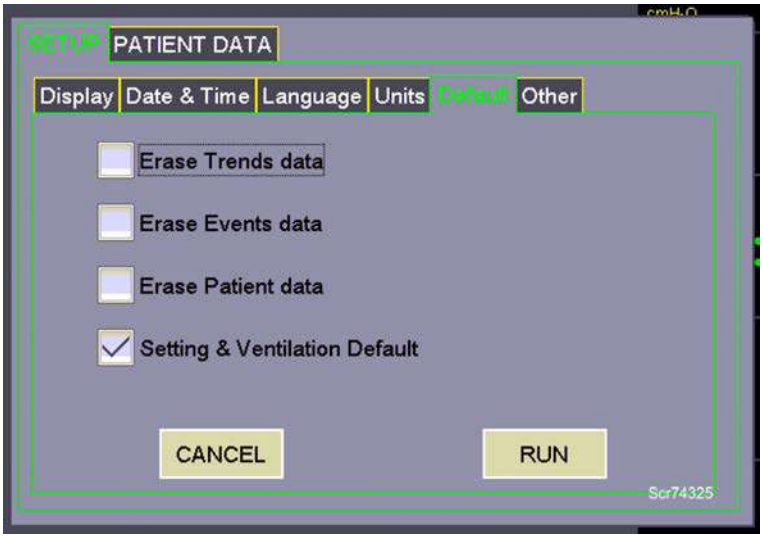
- To go back to Stand-by page, select Cancel

The Default page allows to set:

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

Scr11395

- 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.

6.2.4 Alarms DEFAULT parameters values

Alarm Settings	*Adult*	*Paediatric*	*Neonatal*
PAW : Pressure (cmH_2O)	*5 - 40*	*5 - 35*	*5 - 35*
PEEP (cmH_2O)	*0 - 15*		
Vte : Tidal Volume (ml)	*100 - 1000*	*50 - 300*	*10 - 50*
Vm : Minute Volume (L)	*2 - 12*	*1 - 8*	*0 - 3*
O_2 (%) : Oxygen	*21 - 80*		
RR : Respiratory Rate (bpm)	*8 - 20*	*12 - 30*	*25 - 50*
Power Failure	*Enable*		
Apnea Time (configurable in SETUP - Other area)	*20 sec.*		

6.3 Tables of alarm characteristics

6.3.1 Alarms configurable by User

Alarm type	Priority	Activation delay (sec.)	Suspendable	Suspension delay (sec.)	Inhibition
LOW PRESSURE OF AIRWAYS	*HIGH*	*15*	*YES*	*15*	*NO*
HIGH PRESSURE OF AIRWAYS	*HIGH*	*0*	*NO*	*-*	*NO*
LOW RESPIRATORY RATE	*HIGH*	*3 patient breaths*	*YES*	*30*	*NO*
HIGH RESPIRATORY RATE	*HIGH*	*3 patient breaths*	*YES*	*30*	*NO*
LOW EXP. VOLUME	*HIGH*	*15*	*YES*	*30*	*NO*
HIGH EXP. VOLUME	*HIGH*	*0*	*YES*	*30*	*NO*
LOW VOLUME MINUTE	*HIGH*	*60*	*YES*	*30*	*NO*
HIGH VOLUME MINUTE	*HIGH*	*60*	*YES*	*30*	*NO*
LOW PEEP	*HIGH*	*0*	*YES*	*30*	*NO*
HIGH PEEP	*HIGH*	*0*	*YES*	*30*	*NO*
LOW FiO_2	*HIGH*	*30*	*YES*	*30*	*NO*
HIGH FiO_2	*HIGH*	*30*	*YES*	*30*	*NO*
LOW $EtCO_2$	*HIGH*	*30*	*YES*	*30*	*NO*
HIGH $EtCO_2$	*HIGH*	*30*	*YES*	*30*	*NO*
Apnea	*HIGH*	*5 - 60*	*YES*	*30*	*NO*
POWER SUPPLY FAULT	*HIGH*	*15*	*YES*	*120*	*YES*

6.3.2 System alarms

Alarm type	Priority	Activation delay (sec.)	Suspendable	Suspension delay (sec.)	Inhibition
LOW O_2 SUPPLY	HIGH	0	YES	30	*if FiO2=21%*
LOW AIR SUPPLY					
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
BATTERY CHARGER DISCONNECTED					
CIRCUIT DISCONNECTED (patient circuit)	HIGH	0	NO	-	NO
TURBINE FAILURE	HIGH	0	NO	-	NO
TURBINE OVERTEMPERATURE	HIGH	0	NO	-	NO
TURBINE OVERCURRENT	HIGH	0	NO	-	NO
CAN-BUS FAILURE	HIGH	0	NO	-	NO
MAINTENANCE 1000 Hours	HIGH	0	YES	-	NO
CHECK FLOW SENSOR	(*not used*)				
LOW INSP. VOLUME	(*not available*)				

6.3.3 Gas Sensor alarms

Alarm type	Priority	Activation delay (sec.)	Suspendable	Suspension delay (sec.)	Inhibition
Sampling Line Clogged	*HIGH*	*0*	*YES*	*30*	*NO*
No Sampling Line	*HIGH*	*0*	*YES*	*30*	*NO*
Replace Adapter	*HIGH*	*0*	*YES*	*30*	*NO*
No Adapter	*HIGH*	*0*	*YES*	*30*	*NO*
O2 Port Failure					
O2 Sensor Error					
Unspecified Accuracy (……)	*HIGH*	*0*	*YES*	*30*	*NO*
Error (…….)	*HIGH*	*0*	*YES*	*30*	*NO*
No Breaths	*HIGH*	*0*	*YES*	*30*	*NO*
Replace O2 Sensor					
O2 Calibration Required					
Low (……)	*HIGH*	*0*	*YES*	*30*	*NO*
High (……)	*HIGH*	*0*	*YES*	*30*	*NO*
Mixed Agents MAC < 3					
Mixed Agents MAC >= 3					

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

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6.4 Troubleshooting

This paragraph describes the possible causes of problems, indicated by alarms that are during normal functioning.

WARNING !! Risk for Patient / User injury

- If the problem persists, carry out a complete check of the anaesthesia unit to identify any irregularities.
- If the problem cannot be resolved, contact the Siare Service Centre or a Centre authorized by Siare.

6.4.1 Troubleshooting list

Switch ON failure The anaesthesia unit does not switch on.

- Check that it is connected to the main power supply.
- Check that the main switch (side back) 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 anaesthesia unit 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 - SELF TEST The initialization phase is not completed.

Verify and intervene in function on the error messages and indications evidenced during the "**SELF TEST**" phase.

- **Turbine**: if this step is not passed means that the turbine is not running so check if the turbine cable is properly connected and if the turbine is properly powered. If so, the turbine is broken so it must be changed.
- **Oxygen Inlet:** if this step is not passed, it means that the oxygen gas is not correctly connected to the anaesthesia unit. Restore the connection or replace the hose 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.
- **CAN module 3:** if this step has not passed, it means that the communication system (defined as CAN bus) between the CPU and the peripheral cards does not work properly. Open the anesthesia unit and check the electrical (CAN bus) and mechanical (correctly inserted connector) connection between the CPU board and the Inspiratory valves board and PEEP board.
- **Insp. Flow Sensor**: if this step has not passed, it 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 has not passed, it 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.
- **Electrovalve**: if this step has not passed means that the electrovalves are not able to close the expiratory valve so check if the inspiratory flow is generated by the medical device; check if there are leakages in the inspiratory and expiratory line of the anaesthesia unit or in the patient circuit; check if the 12Vdc reach the expiratory electrovalve board, if the voltage is correct replace the electrovalve/board.
- **Patient circuit**: if this step is not passed, it means that the measured airway pressure is very low so check if there are leakages in the inspiratory and expiratory line of the anaesthesia unit or in the patient circuit.
- **Battery**: if this step is not passed, it means that the battery voltage is less than 11Vdc so connect the anaesthesia unit 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, it 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.

- **Protolock O2**: if this step has not passed, it means that the anesthetic unit has not been correctly connected to an oxygen source. Check the correct connection of the gas supply circuit.
- **Protolock Aria**: if this step has not passed, it means that the anesthetic unit has not been correctly connected to a medical air source. Check the correct connection of the gas supply circuit.
- **Acoustic alarm**: at the end of the self test the activate the alarm sound. If the sound is heard by the User 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 anaesthesia unit 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 anaesthesia unit 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.

CAN-BUS failure	This alarm condition occurs in case of system failure (electronic boards).

- Check if the CAN-BUS cable between the main board and the O2 EV board is properly connected.
- Check if the voltage supplied by the power supply board is > 10.5V. If not, the problem could be caused by the power supply board and it should be replaced.
- If the anaesthesia unit is battery powered, the problem could be caused by the low output voltage of the battery.
- 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 anaesthesia unit and to the patient.
- Contact the Siare Service Centre or a Centre authorized by Siare.

Low O_2 gas pressure	This alarm is activated when the pressure is insufficient (< 2.7 bar) for the anaesthesia unit to operate correctly.

- Check that the medical gases are correctly connected to the anaesthesia unit. Restore the connections or replace the tubes if damaged.
- Check that there is sufficient pressure in the supply system or in the cylinders. Adjust or repair the supply system (or replace the cylinders) if the pressure is insufficient.
- Contact the Siare Service Centre or a Centre authorised by Siare.

Low Air gas pressure	This alarm is activated when the pressure is insufficient (< 2.7 bar) for the anaesthesia unit to operate correctly.

- Check that the medical gases are correctly connected to the anaesthesia unit. 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, if the pressure is insufficient.
- Contact the Siare Service Centre or a Centre authorised by Siare.

Low battery level 25% (50%)	This alarm is activated when the charge level of the battery is at 25% (50%) of the fully charged level.

- Check that it is connected to the main power supply.
- Recharge the battery.
- If the alarm is activated when the battery has not provided the time autonomy indicated on the technical sheet, request the intervention of a Service Centre.

It is possible to silence the **LOW BATTERY LEVEL 50% e LOW BATTERY LEVEL 25%** alarms pressing the ALARM RESET button on the control keyboard.

- The **LOW BATTERY LEVEL 50%** alarm will sound again when the battery level will join the following battery alarm level: LOW BATTERY LEVEL 25%.
- The **LOW BATTERY LEVEL 25%** alarm will sound again when the battery level will join the following battery alarm level: **LOW BATTERY** (10 mins).

Low battery (10 minutes)	This alarm condition is present when the charge battery level is such to be guaranteed a residual autonomy of about 10 minutes.

- Verify the power supply connection; recharge the battery.
- If the alarm is activated when the battery has not provided the time autonomy indicated on the technical sheet, request the intervention of a Service Centre.

Battery disconnected	This alarm condition is present when the battery is not properly connected to the device.

- Check the battery connection.
- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

Battery overtemperature	This alarm condition is present when the battery pack internal temperature pass the 75°C.

- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

Battery charger disconnected	This alarm condition is present when the system detects a malfunction in the circuit / recharge card

- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

Exhausted O_2 sensor	The oxygen sensor is exhausted.

- See information on FiO_2 % low alarm.
- Replace the oxygen sensor with a new one.
- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

Disconnected O_2 cell	This alarm indicates the connection status of the oxygen sensor.

- Check that the oxygen cell is correctly connected.
- Check the condition of the cable and the connector (if necessary, restore the connection and replace the cable if damaged).
- Replace the oxygen sensor with a new one.
- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

1000 working hours	This alarm condition occurs at overcoming of 1000 working hours from the last reset.

- When this alarm occurs, it is recommended to perform the preventive maintenance procedure, check the anaesthesia unit 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_2 % high	This alarm is activated when the measured concentration of oxygen exceeds the set limit.

- Check that the corresponding alarm limits are set correctly.
- Calibrate the oxygen cell: if the problem occurs again after a short time, replace the oxygen cell.
- Contact the Siare Service Centre or a Centre authorised by Siare.

FiO_2 % 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 anaesthesia unit and to the patient.
- Check if the anaesthesia unit works properly verifying the airways pressure. If the anaesthesia unit 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 anaesthesia unit works properly verifying the airways pressure. If the anaesthesia unit 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 anaesthesia unit works properly verifying the airways pressure.
- In case of differences higher than 2 cmH_2O (10%) between the value set and the value read, a turbine calibration shall be performed. Check the PEEP 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 anaesthesia unit (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 anaesthesia unit (the airways pressure curve) correctly follows the inspiration / expiration cycle.
- Check that the patient circuit is connected correctly to the anaesthesia unit 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 anaesthesia unit operates correctly, checking the airways pressure trend. If the anaesthesia unit 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 anaesthesia unit 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 anaesthesia unit operates correctly, checking the airways pressure trend. If the anaesthesia unit operates correctly, check the flow sensor and the correct connection of its cable.
- Check that the patient circuit is connected correctly to the anaesthesia unit 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 anaesthesia unit 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 of the turbine has passed (80 - 85 °C).

- The anaesthesia unit 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 anaesthesia unit automatically stops the ventilation to avoid dangers to the patient safety.
- Check if the turbine air filter is clean or clogged.
- Perform the turbine calibration.
- If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.

Turbine calibration failed	The turbine doesn't work properly (failure).

- 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.

Multigas 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 anaesthesia unit and to the patient.
- Check the IRMA/ISA is enabled in the CALIBRATION PROGRAM.
- Check the state indicator on the multigas 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.

7 MAINTENANCE

- *To guarantee the regular operation of the **Morpheus_ND** anaesthesia unit, perform the following maintenance interventions with the recommended frequency.*
- *All interventions must comply with the practice and protocols in force in each facility.*
- *The instructions for carrying out further detailed tests, for trouble-shooting and for additional interventional procedures, information intended for qualified technical personnel, are contained in the dedicated chapter.*

- *On completion of the maintenance operations, all removed components should be disposed according to current waste disposal regulations.*
- *Components that cannot be destroyed should be sterilised 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 anaesthesia unit 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 equipment and therefore must be carried out only 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 all the protection switches of the equipment.

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

7.1 Cleaning, disinfection and sterilisation

The User is responsible for carrying out the ordinary maintenance as foreseen in this chapter.

Cleaning, disinfecting, sterilising and replacement of parts must be carried out as indicated in this manual in order to avoid damage to the equipment 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 equipment: 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 anaesthesia unit 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 anaesthesia unit is sold.*

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

7.2 General instructions

7.2.1 Cleaning

Use a disposable cloth moistened with neutral detergent, a chemical substance or the equivalent; use water to remove any traces of chemical.

- Do not clean or re-use disposable products.
- Do not use hard brushes to clean the components, or other instruments that could damage their surface.
- Wash the components with hot water and a neutral detergent solution.
- Rinse the parts well with clean hot water (tap water can be used) and leave to dry.
- Siare recommends that the components should be checked every time they are cleaned and any damaged parts should be replaced.
- Whenever a part or component is changed, check the functioning of the equipment.

Follow the manufacturer's instructions for the detergent substances used: the use of detergents that are too strong could compromise the working life of the components.

Deposits of detergent substances can cause damage or micro cracks, especially on parts exposed to high temperatures during sterilisation.

7.2.2 Disinfection and sterilisation

To disinfect the components, dismantle them and place them in a steam disinfection chamber at 93°C for 10 minutes.

After this first operation and before placing the components in an autoclave, wrap them in muslin or in a similar material.

Effective sterilization is achieved in an autoclave at 121°C for approx. 15 minutes.

WARNING !! Risk of injury for the patient

Always refer to the instructions provided by the autoclave manufacturer regarding temperature and time.

- *Do not disinfect, sterilize or re-use disposable products.*
- *Disinfect and sterilize every time an infected patient is ventilated.*
- *In normal conditions, disinfect and sterilize according to how often the anaesthesia unit is used and in any case at least once a month.*

That the components should be checked every time they are sterilized and any damaged parts should be replaced.

Carrying out a functioning test of the machine whenever parts or components are replaced.

7.2.3 Disinfection by immersion (chemical)

If a steam disinfection chamber is not available, the dismantled parts can be chemically disinfected by means of immersion.

Immerse the dismantled components in the solution with the disinfectant, following the manufacturer's instructions.

- *Not using formaldehyde or phenol-based disinfectants as they can cause cracking and reticulation of plastic parts;*
- *Not using too strong disinfectants as they can compromise the working life of the immersed parts;*
- *Rinsing and carefully drying the components since marks and other damage can occur when the components are exposed to high temperatures.*

When disinfection is complete, rinse with running, preferably decalcified, water; shake and drain off any remaining water. Leave the components to dry completely.

After this first operation and before placing the components in an autoclave, wrap them in muslin or in a similar material.

Effective sterilization is achieved in an autoclave at 121°C for approx. 15 minutes.

Always refer to the instructions provided by the autoclave manufacturer regarding temperature and time.

7.3 Cleaning, disinfection and sterilisation table

Component	Procedure	Notes
Outer casing	Use a moistened disposable cloth with neutral detergent or a chemical substance or the like. Use water to remove any remaining traces of chemical. The User may use disinfectants (e.g. Buraton 10 F, diluted according to the manufacturer's instructions or VPRO 60C°) to clean the components. Disinfectants based on the following substances can cause damage: ▪ halogen-releasing compounds; ▪ strong organic acids; ▪ oxygen-releasing compounds. Remove any dust from the surfaces or in openings using a vacuum cleaner or a soft cloth.	Make sure that no sprays or liquids penetrate inside the equipment and the connectors.
Screen	See above	Do not use cloths or sponges that could scratch the surface.

To avoid damaging the labels and outer surfaces of the anaesthesia unit, use only the chemical substances listed.

Patient circuit (silicone tubes)	Dismantle and clean: sterilize in an autoclave, disinfect with steam or chemically. Check that there are no splits in the tubes and replace them if they are damaged.	121°C rubber cycle. Before using again, eliminate any humidity inside the tubes by means of compressed air.

The patient circuit can be sterilized by means of steam but this can lead to early wear of the tubes.

Yellowing and reduced flexibility are side effects caused by sterilization using steam.

WARNING !! Risk of injury for the patient

It is necessary to have at least one spare patient circuit in stock for routine use and /or accidental breaks.

CAUTION

- *Do not clean or re-use disposable circuit tubes.*

Components that cannot be destroyed should be sterilized and disinfected according to local standards.

Couplings and connectors	Dismantle and wash the component with hot water or neutral detergent solution. Check that there are no splits and replace them if they are damaged.	Before using again, dry it and eliminate any humidity inside the components by means of compressed air.
Breathing system	Dismantle and clean: sterilize in an autoclave, disinfect with steam or chemically.	

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.

Mask	• Perform daily cleaning of the mask following the instructions of the responsible doctors or recommended by the Manufacturer. • Hang up the clean mask to provide that it is completely dry before use. • Always clean the mask and the hoses or use a new mask in case the anaesthesia unit must be used with a different patient. • If the anaesthesia unit is used with more than one patient in the clinic, insert an antibacterial filter between the patient outlet and the hose.	See Manufacturer's instructions

Water trap filter	If reusable: clean, then sterilize in autoclave or chemically disinfect.	Check the presence of fissures and replace in case of damages.

Other accessories	Carefully follow the manufacturer's instructions.	Refer to the accompanying documentation.

Electrical connections	On the aim to guarantee patient and User safety it is necessary to keep the power supply cable in perfect conditions.	Perform daily checking's of cable condition; any damage, also a minimum damage, must be promptly eliminated. Eventually replacing the whole cable.

7.3.1 Sterilization of " EXP flow sensor "

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

WARNING!! Risk of device failure

Do not attempt to dismantle or clean with compressed air.

The EXP flow sensor 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.

WARNING !! Risk of device failure

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.*

The following are generic agents recommended for cold sterilization of EXP flow sensor.

- *Cidex Plus*
- *Cidex OPA*
- *Denatured Ethyl Alcohol*
- *70% Iso-Propyl Alcohol*
- *5.25% - 6.15% Sodium Hypochlorite solution*
- *Sporox II (Hydrogen Peroxide)*
- *Protex wipes (Octyl decyl dimethyl ammonium chloride, Dioctyl dim ethyl ammonium chloride, Didecyl dimethyl ammonium chloride, Alkyl dimethyl benzyl ammonium chloride)*
- *Hexanios G+R*
- *Liquid alkaline cleaner*

7.3.2 Disposable bacteria filter

CAUTION

It is important to use a disposable bacteria filter at the expiratory port of anaesthesia unit between the patient circuit's expiratory limb and the expiratory flow sensor.

Disposable bacteria filter	Do not clean or re-use if the filters are the disposable type.	Components that cannot be destroyed should be sterilized and disinfected according to local standards.

WARNING!! Risk of device failure

Disposable bacteria filter.

- *Do not attempt to sterilize and reuse a disposable bacterial /HEPA filter. It is meant for single use.*
- *Do not use filters that aren't in sealed pack.*
- *Do not try to dry the filter and reuse in the same patient in case of increased resistance.*
- *Do not use it longer than the time-period recommended by manufacturer.*
- *Do not use filters that had exceeded the expiry date.*

Disposable bacteria filter.

- *Replace the bacterial filter as per manufacturer's advice (24 - 72 hours).*
- *If used with humidifier, change the filter more frequently (as and when the resistance increases or patient's "work of breathing" increases).*
- *Immediately replace the filter if it is stained with blood, secretions or other human fluid*
- *Check the expiry date before using on patient.*
- *Change the filter early if nebulisation is done frequently.*

7.4 Periodic maintenance

The anaesthesia unit 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 unit 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.

7.4.1 Maintenance operations table

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 following table summarizes the preventive maintenance frequency and procedures to be carried out on the anaesthesia unit.

Frequency	Component	Procedure / Action
Several times a day **Every day / when necessary** **According to local practice and standards**	Patient circuit	Check for any water collection, drain and clean the tubes when necessary.
	Condensation trap filter	
	Disposable bacteria filter	Replace
	Oxygen sensor	Calibrate according to the procedures described in this manual.
	EXP Flow sensor	Sterilize / disinfect according to the procedure described in this manual and according to local standards.
	Anaesthesia unit	General cleaning and checks.
	Turbine air filter	
	Breathing system	Dismount the components and clean, then sterilize in autoclave, disinfect by steam or chemically.
Every week / when necessary	Oxygen sensor	Calibrate according to the procedures described in this manual.
	Turbine air filter	Replace. Components that cannot be destroyed should be sterilized before disposal.
	Anaesthesia unit	General cleaning and checks.
	Breathing system	Dismount the components and clean, then sterilize in autoclave, disinfect by steam or chemically.
Every 6 months or 1000 working hours	Anaesthesia unit	The anaesthesia unit must be inspected and checked in general and any worn parts must be replaced. Use the appropriate preventive maintenance kit. This operation must only be carried out by qualified technical personnel, according to the instructions contained in the relative service and maintenance manual.

Frequency	Component	Procedure / Action
Every 6 months or 1000 working hours	Oxygen sensor	Replace. The working life of the cell depends on the working environment. If the temperature or the O2 % is high, the working life of the sensor will be lower.
	Gas filters and Turbine air filter	Replace. Sterilize according to the procedure described in this manual and according to local standards. Components that cannot be destroyed should be sterilised before disposal.
	Disposable bacteria filter	
	Patient circuit (silicone tubes)	
	Washers / O-Rings	
Every year (*)	Anaesthesia unit	Check the performance. This includes an electrical safety test and inspection of the anaesthesia unit for mechanical damage and legibility of the labels. The anaesthesia unit must also be inspected and checked in general and worn parts must be replaced, using the appropriate preventive maintenance kit. These operations must only be carried out by qualified technical personnel, according to the instructions contained in the relative service and maintenance manual.
Every two years / when necessary	Internal battery	Replace. This operation must only be carried out by qualified technical personnel, according to the instructions contained in the relative service and maintenance manual. The working life of the battery depends on the working conditions and environment.

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

All maintenance and/or repair operations require perfect knowledge of the anaesthesia unit 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 damage to components due to excessive wear, carry out preventive maintenance and replace parts following the recommended frequency.

7.4.2 Cleaning, disinfection and sterilization before use with another patient

We recommend the use of procedures for sterilization and disinfection referred to in the preceding paragraphs when a new patient must use the anaesthesia unit.

WARNING !! Risk of injury for the patient

It is recommended to sterilize / disinfect the unit every time is used with another patient.

7.4.3 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.

Turbine air filter : Replace (when necessary)

This operation must only be carried out by qualified technical personnel, according to the instructions contained in the relative service and maintenance manual.

The working life of the air filter depends on the working conditions and environment.

7.5 Repairs and spare parts

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

7.5.1 Annual kit for Morpheus_ND anaesthesia unit

Code: R064001A1

Spare parts kit for annual maintenance to be used with the Morpheus_ND anaesthesia unit.

7.6 Miscellaneous

7.6.1 Storage

If for any reason the anaesthesia unit 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 anaesthesia unit 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.

7.6.2 Repackaging and shipment

If it is necessary to return the equipment to SIARE for any reason, we suggest using the original packaging to prevent damage to the equipment during shipment.

If this is no longer available, order a repackaging kit.

7.6.3 Disposal

Batteries, accumulators, O_2 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.

8 APPENDIX

This chapter includes all the information and data necessary to provide full knowledge and interpretation of the manual for the **MORPHEUS_ND** anaesthesia unit equipped with turbine and colour display 15” touch screen.

8.1 Technical sheet: code MND.SE-T

INTENDED USE

The Morpheus ND HYBRID anaesthesia unit with lung ventilator, with 15” TFT colour Touch Screen display can be used on adult, children and newborn patients.

The operating principle we have called "HYBRID" is unique because two systems coexist simultaneously: the main system consists of a special new age silent technology turbine that allows operation without the need of gas and a second oxygen emergency system that intervenes in case of anomaly of the main system

The microprocessor automatically chooses which system to use, giving priority to the turbine as it permits to reduce the gas consumption (very important in places where the compressed air is not available). The user shouldn’t intervene as the system is completely automatic.

This new age technology turbine is extremely silent (<29dB) also during its operation, and thanks to the exclusive cooling system, it guarantees a life of more than 20,000 hours. In case of failure of one of the 2 systems, the other one is available. It's like having an emergency ventilator.

In addition, the Morpheus ND incorporates the Protolock safety device that allows to identify any error in the connection of gases that could be fatal for the patient.

The Morpheus ND HYBRID is suitable for administration of Oxygen - Air - Nitrous Oxide / Xenon - Halothane - Enflurane - Isoflurane - Sevoflurane - Desflurane mixtures.

GENERAL DESCRIPTION

The Morpheus_ND HYBRID anaesthesia unit is completed with:

- electronic gas mixing system (integrated in the Touch Screen)
- electronic lung ventilator with 15” TFT colour Touch Screen display
- valves group: open, semi-closed, closed, heated, with soda lime absorber of 1 Kg. capacity
- SIARETEX rapid connection device, Selectatec compatible for 2 vaporizers (park positioned)
- gas supply group
- gas analysis system (optional)
- trolley (optional)

STRUCTURE	
Lung ventilator	Light aluminium alloy and plastic moulds
Dimensions	55 x 51 x 42,5 (W x D x H) cm
Weight	25 kg (without accessories) -
Support for 2 vaporizers	On horizontal guide: SIARETEX rapid connection device, Selectatec compatible for 2 vaporizers (1 vaporizer in use and one park positioned)
Trolley (optional)	• Pivoting antistatic wheels, diameter 100 mm (2 with brakes) • No. 1 full extension drawers • Worktop: 60 x 34 cm (W x D) • No. 2 vertical cylinders supports, on the back side (for cylinders up to 5 litres capacity) and round rubber pads • Auxiliary power supply sockets: No. 1 220 Vac Schuko socket (max 6 A).
Dimensions (trolley)	75,5 x 73,5 x 92,5 (W x D x H) cm (w/o optional vital signs Patient Monitor)
Trolley weight	37 kg (without accessories)

TECHNICAL FEATURES	
Electric power supply	100 - 240Vac / 50 - 60Hz
Power	200 VA max.
Battery	NiMh 4,5 Ah 12Vcc
Battery operation	around 120 minutes operation
Battery re-charging time	About 10 hours
Electric external connections	• RS232 for serial connection of Gas Analyzer • USB 1 (connector for CPU programming) • USB 2 (connector for transfer patient data, events, trends)
Shelf lighting	12Vdc by led
Illuminated auxiliary flow meter	12Vdc by led

ENVIRONMENTAL CONDITIONS	
Operating	• Relative humidity: 30 - 95% non-condensing • Temperature: from +10 to +40°C
Storage	• Relative humidity: < 95% • Temperature: from -25 to +70°C

NORMS

CE 0476	The anaesthesia unit is conforming to the essential requirements and it is realized according to the references of the Annex II of 93/42/EEC Medical Devices Directive.
Class and type according to IEC 601-1	Class I Type B
Class according to 93/42 EEC Directive	Class IIb
Electromagnetic compatibility (EMC)	Conform to the requirements of the EN 60601-1-2: 2007 and following
Norms	EN 60601-1:2006/A1:2011/A1:2013 ; EN 60601-1-2:2007/EC:10 ; EN61000-6-1:07 ; EN 61000-6-3:07/A1:11 ; EN 60601-2-13:2006 ; IEC 60601-1-6:2013 ; IEC 60601-1-8:2012 ; EN 62304:2006/AC:2008 ; EN ISO 4135:2001 ; DIR. 2011/65/CE ; D.Lgs 49/2014 ; ISO 14971:2012

ELECTRONIC GAS MIXING SYSTEM

	• It has the function to regulate the capacity and the concentration of gas mixture (Air, O_2, N_2O) by displaying them on the right side of the TFT monitor (15") colors monitor and deliver it to the anaesthetic gas vaporizer. • It allows to select the mixture to be delivered (Air - O_2, or N_2O - O_2) and the oxygen enrichment for delivered mixture in case of emergency. The anaesthesia module includes a device which guarantees a minimum concentration of 25% of oxygen with all mixtures set different from air / oxygen (MIX-LIFE device • PROTOLOCK system. The exclusive SIARE safety device that analyzes the coherence of the gases connected to the machine when the machine is switched on, warning the operator in case of incorrect connections, thus avoiding possible fatal accidents to the patient • Through the three pressure gauges on the front panel it allows the continuous control of medical gas feeding pressure coming from the gas pipelines system or from the cylinders. • The flowmeter is electronically controlled with double coupled valves to always guarantee correct delivery even in the event of a fault. An electronic flow meter continuously monitors the correct supply of gases • The electronic flowmeter box provides the option on demand to use an alternative anaesthetic gas in spite of N_2O: the Xenon (Xe).
AUTO TEST	When the electronic flow meter is switched on automatically, various control tests are performed.
Fresh gases flow	• From 0.2 to 15 L / min with oxygen and air. • 0.2 to 14 L / min with oxygen and nitrous oxide. • Resolution: 0.1 L / min.
Oxygen concentration	• From 25% to 100% with mixtures of nitrous oxide and oxygen • From 21% to 100% with mixtures of air and oxygen • Resolution: 1%

Medical gas supply	OXYGEN • Pressure included between 280 kPa and 600 kPa (2,8 – 6 bar) • Max. required flow 14 L/min. (with electric operation) • Max. required flow 68 L/min. (with HYBRID oxygen emergency operation)
	NITROUS OXIDE • Pressure included between 280 kPa and 600 kPa (2,8 – 6 bar) • Max. required flow 9 L/min.
	MEDICAL COMPRESSED AIR Pressure included between 280 kPa and 600 kPa (2,8 – 6 bar) Max. required flow 15 L/min.
Safety devices	• AGAINST THE ADMINISTRATION OF HYPOXIC MIXTURES MIX-LIFE: it always guarantees a minimum concentration of 25 % oxygen on mixtures which includes nitrous oxide. • IN CASE OF WRONG MEDICAL GASES CONNECTIONS Acoustic and visual alarm (Protolock) • IN CASE OF LACK OR LOW OXYGEN PRESSURE CUT-OFF: audible alarm with immediate cut-off of nitrous oxide delivery. • AGAINST OVERPRESSURE IN FLOWMETER BOX: pressure sensor for the protection of the flowmeter components • IN CASE OF LACK OR COMPRESSED AIR LOW PRESSURE: all the devices (gas feeding) supplied by compressed air are automatically supplied by oxygen. • AGAINST THE SIMULTANEOUS DELIVERY OF AIR AND N2O: • Selection by only one icon on the touch screen. • ALARM fan lock
Gauges	No. 3 on front panel (O_2 - N_2O - AIR), scale 0 - 6 bar
Control for activation of exit of fresh gas for manual ventilations.	• MANUAL mode setting (MAN) from Touch Screen and ventilator keyboard with automatic deviation of fresh gas to the manual system of anaesthesia unit valves group, or to a “TO and FRO” circuit with visual indicator. • AUTOMATIC deactivation of manual ventilation systems directly by ventilator control.
O_2 emergency by-pass	By apposite membrane key on the front shelf, and touch screen max flow 30 L/min.
IN gas sockets on gas supply group	• No. 3 sockets for distribution system (O_2 - N_2O - AIR) • No. 2 sockets for cylinder (O_2 - N_2O) - Optional
OUT gas sockets on gas supply group	• No. 1 sockets for O_2 • No. 1 sockets O_2 - AIR for active scavenger feeding (Optional) • No. 1 fresh gas connector for external use for ex. TO AND FRO (selectable by apposite membrane key on the front shelf - AUX).

Other	• Socket for recycle of exhaust monitor gas • Connection for anaesthetic gas scavenging (optional device: active type, or passive type)
Patient connections	Male conic connectors 22 mm / Female of 15 mm (according to EN ISO 5356-1:2015 norm)

BREATHING SYSTEM

- Compact system with automatic connections, easy dismountable and autoclavable.
- It allows the ventilation in modality: real open circuit, semi-closed circuit, closed circuit at low flows.
- The system also allows the spontaneous and manual ventilation in case of anaesthesia unit breakdown or machine off.
- Top special CO_2 absorber canister of 1 Kg with rapid connection: this allows canister replacement also during interventions (the canister is autoclavable and reusable).
- The recycling system is a selective type; hence the soda lime and fresh gas consumption are reduced to the minimum.
- The heated valves group reduces the condensation and heats the fresh gas.
- The transition from one ventilation modality to another is completely controlled by the ventilator without any user's action on valves group.

LUNG VENTILATOR

User's interface	15" TFT high resolution colour display with membrane keyboard and encoder
Operation principle	• Time cycled at constant volume • Pressure cycled • Microprocessor controlled flow • Spontaneous breath with integrated valve
Gas	• Medical compressed Air or Oxygen supply with pressure included between 280 kPa and 600 kPa (2,8 – 6 bar) • Low pressure compressor drive independent from the gas supply system (in this case it's necessary a pneumatic Oxygen supply only for the delivery of fresh gases max 14 l/min). • Oxygen (in case of compressor failure) with pressure included between 280 kPa and 600 kPa (2.8 - 6 bar).
Pressure automatic compensation	Automatic compensation of atmospheric pressure on measured pressure: present
Dead space compensation	Automatic compensation of mechanical and patient circuit dead space
Leak % visualization	Present
Visualization of the oxygen consumption calculation	Present

SELF TEST	• Primary test: at anaesthesia unit's start-up, a control test of low pressure compressor operation, medical gas supply presence, INSP. and EXP. flow sensors operation, patient circuit leakage check, pressure sensor back-up battery state, oxygen cell state, correct medical gases connections (Protolock), integrity of audible alarm is automatically performed. This test takes around 15 seconds • Tests on demand: the anaesthesia unit has a tests on demand which is activated by the user in the ventilator menu. This subtest permits to verify the dead space and losses or to perform the oxygen cell calibration.
Respiratory parameters default setting	Present (Neonatal, Paediatric, Adult)
Ventilation modalities	APCV, APCV-TV, PSV, PSV-TV, VC/VAC, VC/VAC BABY (integrated NEONATAL ventilation mode), V-SIMV (Volumetric +PS; SPONT) , P-SIMV (Pressometric +PS; SPONT). SIGH, Apnea BACK-UP (NIV PSV, NIV PSV-TV), MAN (Manual).
Breathing rate VC/VAC	From 4 to 150 bpm
Inspiratory Time / Expiratory Time (maximum, minimum)	• Ti min = 0.036sec (minimum inspiratory time) • Ti max = 9.6sec (maximum inspiratory time) • Te min = 0.08sec (minimum expiratory time) • Te max = 10.9sec (maximum expiratory time)
Breathing rate V-SIMV e P-SIMV	From 1 to 60 bpm
SIMV Inspiratory time	From 0.2 to 5.0 sec.
Tidal volume	• From 100 to 1500 ml (Adult) • From 50 to 400 ml (Paediatric) • From 2 to 100 ml (Neonatal)
I:E ratio	From 1:10 to 4:1
Inspiratory pause	From 0 to 60 % of the inspiratory time
Inspiratory pressure limit	Pinsp: from 2 to 80 cmH2O (in function of low and high pressure alarm set)
Inspiratory ramp Slope	1, 2, 3, 4 (acceleration slope) - (4 max. acceleration) (in operative modes by pressure only)
PEEP	From OFF, 2 to 30 cmH2O
PEEP adjustment	Microprocessor controlled valve
O2 concentration	Adjustable from 21 to 100% with electronic integrated mixer.
Trigger detective method	Through sensor (Pressure or Flow)
Pressure trigger (I)	Pressure adjustable from OFF; -1 to -20 cmH2O under PEEP level (step of 1 cmH2O)

Flow trigger (I)	Flow adjustable from OFF; 0.3 to 15 L/min • from 0.3 to 1 L/min (step of 0.1 L/min) • from 1 L/min to 2 L/min (step of 0.5 L/min) • from 2 L/min to 15 L/min (step of 1 L/min)
Trigger E	From 5 to 90 % of the inspiratory flow peak
Exp. Valve control	Electrovalve response time of Exp. valve : 4 msec.
Inspiratory flow (FLOW)	190 l/min
Flow-by	Automatic
PS (pressure support)	From 2 to 80 cmH2O (PSV, V-SIMV, P-SIMV)
SIGH in VC/VAC modality	• Interval: 40 ÷ 500 bpm (step 1 bpm) • Amplitude: OFF, 1 ÷ 100% of set Tidal Volume (step 10%)
Functions	• MENU function (SETUP – PATIENT DATA) • Alarms Limits • Graphics visualization (Auto-Range) • INSP Block - EXP Block (max 20 sec.) • MAN control (manual ventilation)
Expandability	Software upgradeable
USER INTERFACE	
Touch screen monitor	Module with TFT LED display with touch screen
Dimensions	15”
Displaying area	30,5 x 22,8 mm
Display keyboard	Touch screen controls + keyboard and encoder knob for rapid access to the operative functions • selection, set up and confirmation of physiological breathing parameters • selection and direct activation of function
Calibration Programs	• Self Test • Turbine Characterization • Expiratory Flow Sensor Calibration • VTEc • ScreenShoot Enable

Displaying and settings	• Operative Mode setting • AUT, MAN e Stand-by mode Setting • Display of signals and alarm messages, screen lock • Setting and monitoring of physiological breathing parameters • MENU function for setting operation parameters • Graph function for display of curves, LOOPS, respiratory parameters, gas parameters • Alarm Limits setting function • Enabling of particular operational functions • Display, clock, date and time, power, battery charger • Visualization of software version
MENU function - SETUP	• Display (Brightness, Energy Saving, Sound Volume, Touch Audio) • Date & Time • Language • Units • Default (Default parameters: Erase Trend data, Erase Events data, Erase Patient data, Setting & Ventilation Default) • Other (NIV Enable, Power Failure, Apnea Time N2O / Xe, PASSWORD change, Data saving on USB) • Gas Sensor (IRMA/ISA) • Supplementary Tests (Leak test, O2 Sensor Calibration)
MENU function - PATIENT DATA	The PATIENT DATA can be set or deleted
Alarm limits	PAW (cmH2O), PEEP (cmH2O), Vte (ml), VM (L/min), O2 (%), RR (bpm)
Displayed graphics	• CURVES: Pressure (PAW) - Flow - Volume (Vte) - Gas • LOOPS: Pressure/Volume - Flow/Volume - Pressure/Flow - Lung ventilation icon • MEASURES: Respiratory parameters, Gas • Events • Trends
Trends	Storage capacity (72 h) of all measured parameters Foreseen Trends: Rate, PAW, PEEP, Vm, Vte.
Events	Memory storage up to 100 machine events including the alarms.
Physiological breathing parameters setting	I:E, Pause (%), PEEP, Pinsp, PMax, Pmin (cmH2O), PS (cmH2O), FR, FRsimv (bpm), SIGH (Sigh. Amp. (%) - Sigh. Int. (b)), Slope, Ti, Ti Max (s), Tr. E (%), Tr. I (L/min - cmH2O), Vte, Vti (ml), BACK-UP parameters.

Range of measured parameters	• Respiratory rate (range: 0 ÷ 200 bpm) • I:E ratio (range 1:99 ÷ 99:1) • % of FiO2 - EiCO2 (range: 0% ÷ 100%) • Tidal Volume: Vte, Vti (range: 0 ÷ 3000 ml) • Minute Volume (range: 0 ÷ 40 l/min) • PAW: peak, mean, plateau, PEEP (range -20 ÷ 80 cmH2O) • Inspiratory Peak Flow : Fi (range: 1 ÷ 190 l/min) • Expiratory Peak Flow : Fe (range: 1 ÷ 150 l/min) • Tinsp., Texp, Tpause (range 0.036 ÷ 10.9 sec) • Static and Dynamic compliance (range: 10 ÷ 150 ml/cmH2O) • Resistance (range: 0 ÷ 400 cmH2O/l/s) • Leak (%)
Displayed parameters	PAW (cmH2O), FR (bpm), I:E, PEEP (cmH2O), O2 (% - l/min), Vte (ml), VM (L/min), FiCO2 (%), EiCO2 (%) MAP (cmH2O), Pplateau (cmH2O), Fi , Fe (L/min), Ti , Tpause, Te (sec.), Ri (cmH2O/l/s), Cs, Cd (ml/cmH2O), Leak (%), O2 (L/min)
Gas parameters displayed	CO2, O2, N2O, Ag1, Ag2, MAC
Flow sensor	Magnetic disturbance (patented), multi-usage type
Calibration	Automatic (started by the operator)
Maintenance	By steam or chemical disinfection
Oxymeter	Electronic (value displayed in breathing parameters)
Calibration	Automatic (started by the Operator)
Safety	• Electronic and mechanical limit of airways pressure • Self-diagnosis system

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
Alarms with limits set up by the operator	
Airways pressure	High – Low
PEEP	High – Low
Expired tidal volume	High – Low
Expired minute volume	High – Low
FiO2 concentration	High – Low
Respiratory rate	High – Low
Electric power supply	Alarm occurs in case of failure of external power supply
Apnea time	Low Rate (function of Apnea BACK-UP)
System alarms	
Level (charge)	Battery at 50%
Level (charge)	Battery at 25%
Battery level (low)	10 Minutes
Disconnected battery	Yes / No
Battery over temperature	Indication of exceeding the temperature limits inside the battery
Battery charger disconnected	Indication of failure in the battery charge
Turbine fault	Signals in case of a blower fault condition
Turbine over temperature	Indication of exceeding the temperature limits inside the turbine
Turbine over current	Indication of exceeding the current limits inside the turbine
Circuit disconnected	Indication of patient circuit disconnected
Gas feeding: O2	Low (< 2,7 bar)
Gas feeding: Air	Low (< 2,7 bar)
CAN BUS error	Electronic boards CAN connection wrong
Maintenance	1000 hours

Flowmeter alarms	• Lack or low O_2 pressure with consequent cut-off of N_2O delivery • Lack or low N_2O pressure • Lack or low Xe pressure • Lack or low AIR pressure • Fresh gas occlusion • Wrong fresh gases connection (PROTOLOCK)

Gas Analyzer

Gas Analyzer	Sampling line obstruction Sampling line absent Adaptor replacement Adaptor absent O_2 socket failure Error O_2 Sensor Accuracy not specified Error Sigh absence O_2 Sensor replacement O_2 Calibration required Low FiO2 , Low EtO2 , Low - High EtCO2 , Low - High FiCO2 , Low - High FiN2O , Low - High EtN2O , Low - FiAg1 , Low - EtAg1 , Low - High FiAg2 , Low - High EtAg2 , Mixed Agents MAC < 3 , Mixed Agents MAC >= 3

SELF-TEST alarms

Turbine	The correct functioning of the low pressure compressor is tested
Oxygen Inlet	Verification oxygen pressure
CAN module 3	Verification BUS CAN turbine operation
INSP. Flow sensor	Verification of flow sensor operation
EXP. Flow sensor	Verification of flow sensor operation
Electrovalve	The correct functioning of electro-valve is tested
Patient circuit	Verification of patient circuit

Battery	Checking on battery power
Oxygen sensor	Cell condition
Protolock O2	Verification and Oxygen presence
Protolock Air	Verification and Air presence
Acoustic alarm	Verification by the user of acoustic signal emission, the confirmation of the test is made by silencing of that alarm

Gas analysis (optional)

Gas analysis	Integrated software for analysis of CO2, O2, N2O, AG automatic identification, MAC.
Mainstream device	• IRMA AX+ (CO2, N2O, primary and secondary agents, HAL, ISO, ENF, SEV, DES). • IRMA CO2 (CO2)
Sidestream device	• ISA AX+ (CO2, N2O, Agents) • ISA CO2 (CO2) • ISA OR+ (CO2, N2O, Agents, O2)
Technical characteristics	Consult the relevant technical data sheets for mainstream and sidestream modules.

ACCESSORIES

Standard accessories	• User's Manual • O2 supply hose • N2O supply hose • Air supply hose • Top Special CO2 absorber canister of 1 kg (no. 1 / code 30910) • O2 cell • Disposable Patient circuit (adults) • Manual ventilation KIT • Electric power supply cable • Scavenging connector 22M-30M
Other optional accessories	See current export price list

8.2 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 apnoea and starts the corresponding ventilation when the interval between the two respiratory cycles exceeds the set apnoea time.
Automatic alarm resetting	This occurs when an alarm is disabled, i.e. when the alarm conditions are no longer present, without pressing the alarm reset key. ALARM RESET
Basic flow	Constant flow (depending on the sensitivity value set in the “trigger value” parameter) circulating in the patient circuit with respect to which the ventilator measures the Flow Trigger value.
CE	A certificate of origin issued by the European Economic Community indicating that the equipment conforms to the Medical Device Directive (MDD), 93/42/EEC.
Clinical alarm	An alarm that can indicate an abnormal physiological condition
cm	Centimetre (unit of length).
cmH_2O	Centimetres of water (unit of pressure = 0.98068 mbar = 1 hPa).
Compliance (Cs)	This term defines the variation in volume of the respiratory tract determined by a variation in pressure; it is measured in ml/cmH_2O. It provides an indication of the elastic properties of the respiratory system and its components (Inspiratory Tidal Volume / Pause Pressure).
Compressor	The Compressor (optional) provides the system with compressed air and can be used instead of the mains or cylinder supply of compressed air.
CPU	Central processing unit
DISS	Diameter Index Safety Standard: a standard for high pressure gas input connectors.
EMC	Electromagnetic Compatibility
EN	European norm referring to the European Economic Community
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_2	Parameter set by the User and monitored. The % setting of FiO_2 determines the percentage of oxygen in the gas delivered to the patient. The monitored data of the % of FiO_2 indicate the percentage of oxygen delivered to the patient, measured on the inspiratory line.
Flow Trigger	Method of recognition of the inspiratory effort of the patient, during which the ventilator controls the basic flow circulating in the patient circuit. An inspiratory attempt by the patient is translated into a decrease of the basic flow, which the ventilator recognizes as a spontaneous breath and delivers a synchronized breath.
GUI	Graphics user interface, the part of the ventilator which comprises the screen, the keys and the knob. The GUI is equipped with an independent CPU which monitors the data of the ventilator and the patient. The screen displays the monitored information, including the alarms, the monitored parameters, the graphs, the ventilator settings and the messages.
High priority alarm	As defined by the international standards organizations, this is an alarm which requires immediate intervention to ensure the safety of the patient. During a high priority alarm, the corresponding red signal flashes rapidly, a high priority acoustic alarm signal is emitted (a series of five tones repeated twice, followed by a pause, then repeated again) and an alarm message is displayed in the upper part of the screen.
hPa	Hectopascal (unit of pressure, approximately equal to 1 cmH_2O).
Hz	Hertz (unit of measurement of frequency, indicating cycles per second).
I:E ratio	The ratio between inspiratory time and expiratory time
IEC	International Electrotechnical 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 cmH_2O/(litres/sec) or hPa/(litres/sec).(peak pressure - pause pressure / inspiratory flow).

sec	Second (unit of time).
SIMV+PS	Synchronized Intermitted 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	Intermitted ventilation by assisted positive pressure: a ventilation mode which allows to deliver controlled ventilations only (started by the patient, by the ventilator or by User) basing on current settings.
Vdc	Direct current voltage
Ventilations per minute (bpm)	Respiratory rate unit (Resp/min).

8.3 Electromagnetic compatibility tables

8.3.1 Annex A: Table 1

<table>
<tr><th colspan="4">Guidance and manufacturer’s declaration – electromagnetic emissions</th></tr>
<tr><td colspan="4">The Morpheus is intended for use in the electromagnetic environment specified below. The customer or the user of the Morpheus should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Virdict</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>Compliance</td><td>The Morpheus 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td>Compliance</td><td rowspan="3">The Morpheus 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:

Warning: 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 Morpheus or shielding the location.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td><td>Class A, B, C, D, o NOT APPLICABLE</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Compliance</td><td>Compliance</td></tr>
</table>

8.3.2 ANNEX B: Table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
The Morpheus is intended for use in the electromagnetic environment specified below. The customer or the user of the Morpheus should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level / Virdict**	**Electromagnetic environment – guidance**
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) toline(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.

8.3.3 ANNEX C: Table 3

Guidance and manufacturer's declaration – electromagnetic immunity				
The Morpheus is intended for use in the electromagnetic environment specified below. The customer or the user of the Morpheus should assure that it is used in such an environment.				
IMMUNITY test	**IEC 60601 TEST LEVEL**	**Compliance level effective**	**Compliance level**	**Electromagnetic environment – guidance** **Recommended separation distances**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands	VRMS	3 Veff	SEE Annex E
	10 Vrms 150 kHz to 80 MHz in ISM bands	VRMS	10 Veff	SEE Annex E
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	V/m	10 V/m	80 ÷ 800 MHz SEE Annex E
				800 ÷ 2500 MHz SEE Annex E
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 				
Note: At 80 MHz and 800 MHz, the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				

8.3.4 ANNEX E: Table 5

Recommended separation distances between portable and mobile RF communications equipment and the Morpheus.

The Morpheus is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Morpheus can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Morpheus as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter m**			
	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

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.

Note :

At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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.

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.

Note: the values shown in the table refer to the standard levels of the norm, 3V for V1 and 10V for V2

8.4 Preliminary tests

In the following table:

List of preliminary tests - Morpheus ANAESTHESIA UNIT

8.4.1 List of preliminary tests - Morpheus anaesthesia unit

Make a copy of this checklist and fill-it in while following the preliminary test described in chapter 5.

The unit may be used only if all the tests have been passed with positive answers.

Hospital.....

Department.....

Serial number of unit .....

OPERATING CHECK - To be performed everyday when the machine is turned-on			
1 - is the medical gas air pressure correct?		YES	NO
2 - Does the flowmeter for the NITROUS OXIDE open correctly?		YES	NO
3 - Does the MIX-LIFE device work properly?		YES	NO
4 - Does the CUT-OFF device work properly?		YES	NO
5 - Does the OXYGEN flowmeter open correctly?		YES	NO
6 - Does the AIR flowmeter open correctly?		YES	NO
7 - Does the BY-PASS flow reach the reservoir balloon?		YES	NO
8 - Is there soda lime and is it not turned?		YES	NO
9 - Does the BY-PASS flow reach the TO AND FRO balloon?		YES	NO
10 - Does the airway pressure rise during the inspiratory cycle?		YES	NO
11 - Does the airway pressure limit work?		YES	NO
OXYMETER CALIBRATION To be performed weekly or when the probe is replaced			
Was it possible to regulate the oxygen concentration to 21%?		YES	NO
12 - Does the opening of the OXYGEN flowmeter increase the concentration on the oxymeter?		YES	NO
13 - Does the low airway pressure alarm work?		YES	NO
14 - Does the low oxygen concentration alarm work?		YES	NO
15 - Do the TIDAL VOLUME and RATE on the breathing monitor work correctly?	Monitor not present	YES	NO

LEAK TEST To be performed everyday when the machine is turned-on		
The leak test has been overcome?	YES	NO
SCHEDULED MAINTENANCE To be performed by the User.		
Has the periodic maintenance (that should be performed by the User) performed?	YES	NO
SCHEDULED MAINTENANCE To be performed by SIARE's Service Department		
Has the scheduled maintenance been performed?	YES	NO

Date..... Signature.....

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Morpheus ND

Anaesthesia Unit

User's Manual

User's Manual, DU33ND101

Revision 1 - 13.05.2019

SIARE ENGINEERING INTERNATIONAL GROUP s.r.l.

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