siare® ENGINEERING INTERNATIONAL GROUP s.r.l.

Morpheus

Anaesthesia Unit

Morpheus M

User's Manual

GENERAL INFORMATION

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It is however recommended that you make sure you have the most recent version of the manual. In the event of doubt, contact SIARE ENGINEERING INTERNATIONAL GROUP s.r.l. (see the address on page IX). The information contained herein can be considered correct, but do not exclude professional knowledge by the user of the equipment.

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.

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

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

The information contained in this manual refers to the versions of MORPHEUS anaesthesia unit produced or updated after May 2019. It is possible that some information may not apply to previous versions. Contact SIARE ENGINEERING INTERNATIONAL GROUP s.r.l. if you have any doubts.

User's Manual, version DU3300105

Revision 5 - 02.05.2019.

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 operator.

CAUTION

This indicates the possibility of danger to the equipment.

NOTE

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

- In order to understand how the MORPHEUS 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.
- The anaesthesia unit must only be used for the purposes specified herein and the safety of the equipment is therefore only guaranteed if it is used in accordance with the instructions given in this User's Manual.
- The materials used were carefully selected during the design stage after specific checks, tests and comparative trials: these materials are also constantly inspected during the production cycle to achieve the best results in terms of reliability and safety for the patient and the operator. 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 by qualified personnel and only in equipped and dedicated rooms, according to the regulations in force in the country where the equipment is installed.
- 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 equipment. 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.
- 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 of the equipment 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, specially dangerous with antistatic tubes. The use of flexible connectors, antistatic or conductive tube is never permitted with MORPHEUS 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 equipment is installed be taken into consideration.
- The MORPHEUS 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 equipment is functioning correctly; when needed, the auto-diagnostic test must be performed as described in the present User's 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 equipment (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 MORPHEUS 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 MORPHEUS is not approved for operation in places where there is any risk of explosion.
- Do not use the MORPHEUS in the presence of flammable gases.
- The MORPHEUS cannot be used in the presence of explosive gases.

WARNING !!

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

WARNING !!

- Before starting the MORPHEUS 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 MORPHEUS 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 !!

Independent ventilation tools should be available (i.e. manual resuscitator bag equipped with face mask) each time the ANESTHESIA 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 users and maintenance 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 93/42EEC on medical devices foresees that the manufacturer defines the shelf life of the device according to the intended purpose. The shelf life foreseen by SIARE for the MORPHEUS anaesthesia unit is 10 years.

Manufacturer

SIARE Engineering International Group s.r.l.

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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, result of 40 years of experience and investment in technological innovation that we are implementing in recent years.

Siare has focused heavily on innovation of materials, ergonomics and ease of use.

All routine operations have been simplified and the operational procedures are “foolproof”, in this way there is no margin for the user to make incorrect or inadequate manoeuvres.

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

Siare invested much on this project because we firmly believe that it will be a winning product.

The new anaesthesia unit is considerably different from all previously manufactured versions: in fact, it can be configurable in different models to respond to the numerous market demands and requirements.

It starts from a basic anaesthesia unit to arrive at a device that incorporates all advanced modalities required in modern gaseous anaesthesia, to meet all the expectations of final users.

1.1 Foreseen use

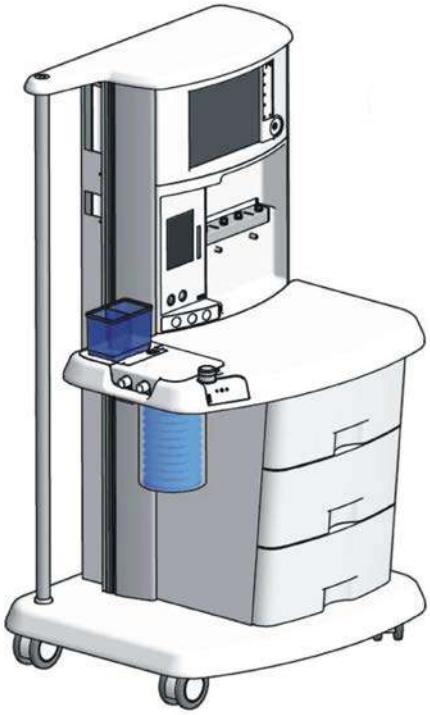
The MORPHEUS anaesthesia unit is an equipment of new generation, projected for use in anaesthesia department.

Varying the breathing parameters, adjustable by lung ventilator user’s interface, the MORPHEUS anaesthesia unit can be used on adults, children, neonatal patients.

The MORPHEUS anaesthesia unit is suitable for the administration of: Oxygen - Air - Nitrous Oxide - Halothane - Enfluorane - Isoflurane - Sevoflurane - Desflurane mixtures.

The fraction of inspired oxygen can vary from 21% to 99%.

1.2 Versions



MORPHEUS anaesthesia unit is equipped with a unique trolley configurable in three different models to respond to the numerous market demands and requirements.

The trolley is composed of the following parts:

- mechanic structure of the trolley
- work-shelf and chest
- valves group
- part of electric power supply

The three different models differ for:

- typology of lung ventilator:
- ventilator with basic DISPLAY
- ventilator with advanced 12” TFT display

Flowmeter box typology:

- flowmeter box at 3 GAS 3 ROTAMETERS
- flowmeter box at 3 GAS 5 ROTAMETERS
- ELECTRONIC flowmeter box

1.3 Main technical characteristics

1.3.1 Trolley

The mechanic structure of the trolley is made of light aluminium alloy columns with a steel base. The pedestal base is made of a shockproof ABS and polyester coated. This ensures an excellent impact resistance thanks to its flexibility and excellent abrasion resistance.

Its dimensions and weight are very reduced and allow its installation also in small rooms or small working areas or combined with pendant lifting systems. The chest is made of mono-bloc drawers mould in PUR, which are very capacious, rugged and easy to clean. The drawers are mounted on highly smoothing telescopic guides allowing a full extension of the drawers.

The work-shelf is mono-bloc, made of a unit PUR mould. The shelf also includes the housing for the valves group and the manual ventilation controls. The shelf is very wide and the large handle below the perimeter allows to hold and easily move the unit.

On the left side a steel rod at full height is provided for fixing the patient monitor and other accessories like for example the supporting arm for patient circuit, infusion pumps, etc.

The lateral uprights are provided with a vertical guide for fixing the accessories or lateral devices, e.g. the pendant lifting system, lateral lectern or PC support for medical record writing.

On the back side are the medical gas intakes, which are positioned in a rational and easily visible way. The intake for main supply system and pressure reducer-cylinder are also provided, with a non return valve and automatic change. In case of main gas failure just open the cylinder and the gas will be immediately available for use without additional manoeuvres.

1.3.2 Valves group

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 sterilizable in autoclave.
- Calibration of flow and O_2 sensors can be performed in automatic mode by the operator.
- 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.

1.3.3 Flowmeter box

The FLOWMETER BOX, is available 3 versions, 2 mechanical (at three or five flowmeters) and 1 electronic version which foresees the Xenon option.

The mechanical versions are characterized by the complete absence of mechanical controls; replaced by a small control panel located on the left side of the work-shelf to manage all manual ventilation operations. This solution allows the presence of audible and visual alarms of strong impact and without duration limits.

The electronic version is equipped with a wide 5,7" TFT colour monitor which allows an optimal view and wealth of information. The operator acts with knobs, so that to facilitate the use also to staff experienced with the traditional mechanical models. Wide possibility of parameters displaying among: gas supply pressure, delivered gas flow, delivered O_2 concentration, fresh gas total flow, consumption data.

Furthermore the following features are foreseen: a mechanical flowmeter for total flow control, also backlit; a push-button for selecting the gas to be combined to the oxygen (N_2O, AIR or XENON, this last one is optional).

1.3.4 Lung ventilator - basic DISPLAY

This type of lung ventilator is used on the LT version.

1.3.5 Lung ventilator - ventilator with advanced 12" TFT display

The lung ventilator, through the user's interface, allows to set and display a wide range of respiratory parameters useful for the operator for use of MORPHEUS anaesthesia unit. The lung ventilator version with advanced 12" TFT display foresees the following standard operative modes: APCV, APCV-TV, PSV, APNEA BACK-UP, VC-VAC, VC-VAC BABY, SIMV+PS (volumetric) - SPONT, MANUAL.

This lung ventilator type is characterized by a very simple and powerful user's interface, with large graphic display of respiratory parameters, the possibility to choose the curves to be shown simultaneously and an easy interaction in the selection of menus.

The valves group is automatically configured for the selected modality without manual procedures, avoiding errors or inadequate manoeuvres. The lung ventilator version with advanced 12" TFT display foresees the possibility to ad just the end expiration positive pressure (PEEP), the trigger sensitivity and it is equipped with FiO_2 monitoring with automatic calibration and leak test.

1.3.6 Various on lung ventilator

For the controlled ventilation of newborn patients, make reference to the chapter 7.4, about use with premature patients.

For a correct comprehension of MORPHEUS 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 lung ventilation in general, the use of the user interface is intuitive and it will be sufficient to consult this user's manual in order to use the MORPHEUS anaesthesia unit correctly.

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

- the flow sensor on the expiratory line, used to measure the expiratory volumes of the patient;
- the pressure sensors, used to control the pressure of the airways or of the medical gases;
- the oxygen sensor, used to measure the concentration of oxygen in the gas inspired by the patient.

In order to avoid mistakes in the evaluation of the patient's conditions, the operator shall verify the sensors are correctly working before using the anaesthesia machine.

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

1.4 Correct operation

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

- connected to the air and oxygen outlets of the medical gas distribution system or of the cylinders; the compressed air can also be supplied by a medical air compressor (optional);
- correctly connected to the patient circuit;
- connected to a mains power supply with the same voltage as specified on the identification plate;
- correctly connected to all accessories and equipment necessary for the operation of the MORPHUES anaesthesia unit.

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

For its employ the MORPHEUS 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 unit for the patient and user safety.

This user's manual explains how to use the MORPHEUS anaesthesia unit and how to carry out simple maintenance.

To ensure the best performance of the MORPHEUS anaesthesia unit periodic maintenance of the lung ventilator by qualified technical personnel is recommended. For further information, contact SIARE ENGINEERING INTERNATIONAL GROUP s.r.l.

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

1.5 Applicable norms

The MORPHEUS anaesthesia unit is made in accordance with the following norms and it is manufactured according to UNI EN ISO 13485:2016 standards.

EN 60601-1 :2006/A1 :2011/A1 :2013	Medical electrical equipment. General requirements for basic safety and essential performance.
EN 60601-1-2:2015	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic disturbances. Requirements and tests.
EN 60601-2-13:2006	Medical electrical equipment. Particular requirements for the safety and essential performance of anaesthetic systems
IEC 60601-1-6:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
IEC 601-1-8:2012	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
EN 62304:2006/AC:2008	Medical device software - Software life cycle processes.
ISO 4135:2001	Anaesthetic and respiratory equipment - Vocabulary.
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).
93/42/EEC (2007)	European Medical Devices Directive.
ISO 14971:2012	Medical devices. Application of risk management to medical devices.
ISO 10993-1:2009	Biological evaluation of medical devices – Part1: Evaluation and testing within a risk management process.

IEC 62353:2014	Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment
ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part1: General requirements

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2 DESCRIPTION

In this chapter are illustrated and mostly considered the main parts and modules which compose the MORPHEUS anaesthesia unit.

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

2.1 Introduction

WARNING!

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

To respond to the numerous market requests and requirements, the MORPHEUS anaesthesia foresees an single trolley which is configurable in thee different models.

- MORPHEUS LT
- **MORPHEUS M**
- **MORPHEUS E**

This three different models are different for type and ventilator section:

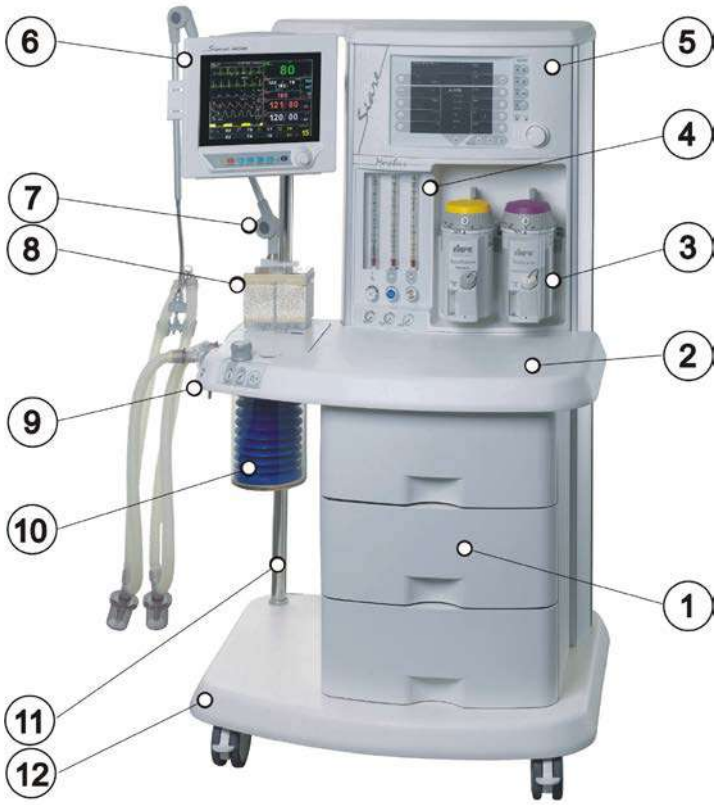
- Ventilator with basic DISPLAY (LT)
- **Ventilator with 12” TFT advanced display (VM.S)**

and per flowmeter box type:

- Flowmeter box at 3 GAS and 3 ROTAMETERS
- **Flowmeter box at 3 GAS and 5 ROTAMETERS**
- **ELECTRONIC flowmeter box**

2.2 Versions

2.2.1 MORPHEUS LT



1. Accessories chest

2. Work-shelf

3. Vaporizers for anaesthetic gas (rapid Siaretex connection type, compatible with vaporizers equipped with Interlock system).

4. Anaesthesia Module **(mechanical flowmeter box with three rotameters).**

5. Ventilator module **(LT).**

6. Vital signs monitor (on demand).

7. Patient circuit supporting arm (on demand).

8. CO_2 absorber canister releasable with unlock lever.

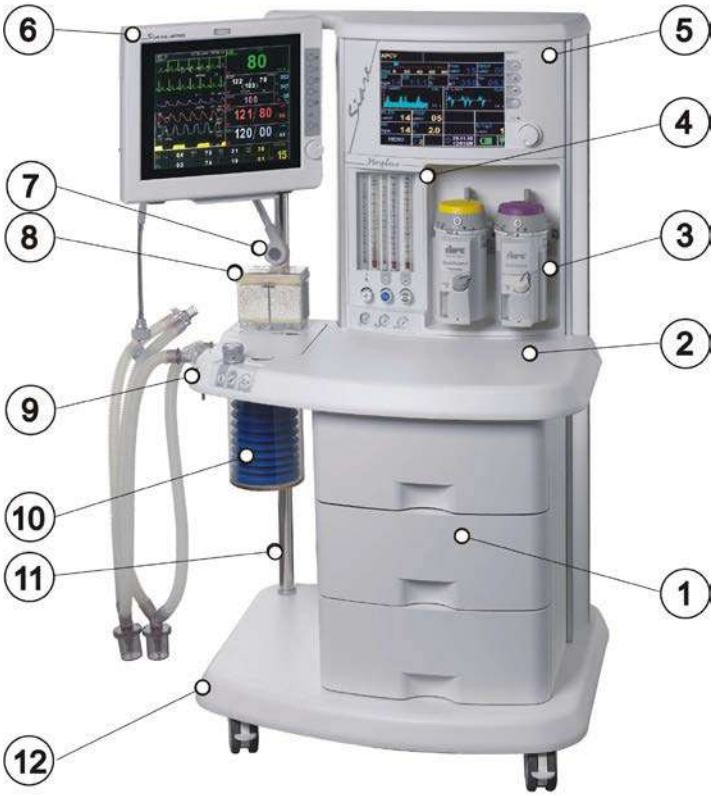
9. Control panel for the management of manual ventilation procedures.

10. Valves group (breathing system).

11. Steel vertical rod for accessories support

12. Trolley made with vertical uprights in light aluminium alloy and steel, cover made of impact-resistant ABS polyester coated.

2.2.2 MORPHEUS M



1. Storage drawers.

2. Work-shelf.

3. Vaporizers for anaesthetic gas (rapid Siaretex connection type, compatible with vaporizers equipped with Interlock system).

4. Anaesthesia module **(mechanical flowmeter box with five rotameters).**

5. Ventilator module **(VM.S).**

6. Vital signs monitor (on demand).

7. Patient circuit supporting arm (on demand).

8. CO2 absorber canister releasable with unlock lever.

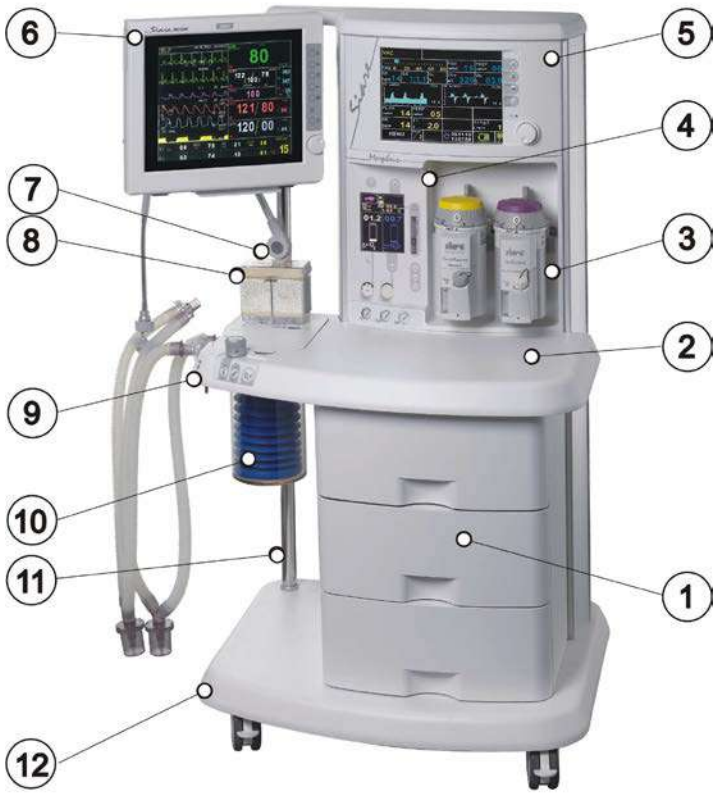
9. Control panel for the management of manual ventilation procedures.

10. Valves group (breathing system).

11. Steel vertical rod for accessories support

12. Trolley made with vertical uprights in light aluminium alloy and steel, cover made of impact-resistant ABS polyester coated.

2.2.3 MORPHEUS E



1. Storage drawers

2. Work-shelf.

3. Vaporizers for anaesthetic gas (rapid Siaretex connection type, compatible with vaporizers equipped with Interlock system).

4. Anaesthesia module **(electronic flowmeter box).**

5. Ventilator module **(VM.S).**

6. Vital signs monitor (on demand).

7. Patient circuit supporting arm (on demand).

8. CO2 absorber canister releasable with unlock lever.

9. Control panel for the management of manual ventilation procedures.

10. Valves group (breathing system).

11. Steel vertical rod for accessories support

12. Trolley made with vertical uprights in light aluminium alloy and steel, cover made of impact-resistant ABS polyester coated.

2.3 Trolley

The Morpheus trolley is composted by a mechanical structure with light aluminium alloy uprights and a steel base; it is foreseen also a steel vertical rod for fixing all patient monitoring and other accessories useful for anaesthesia unit operation.

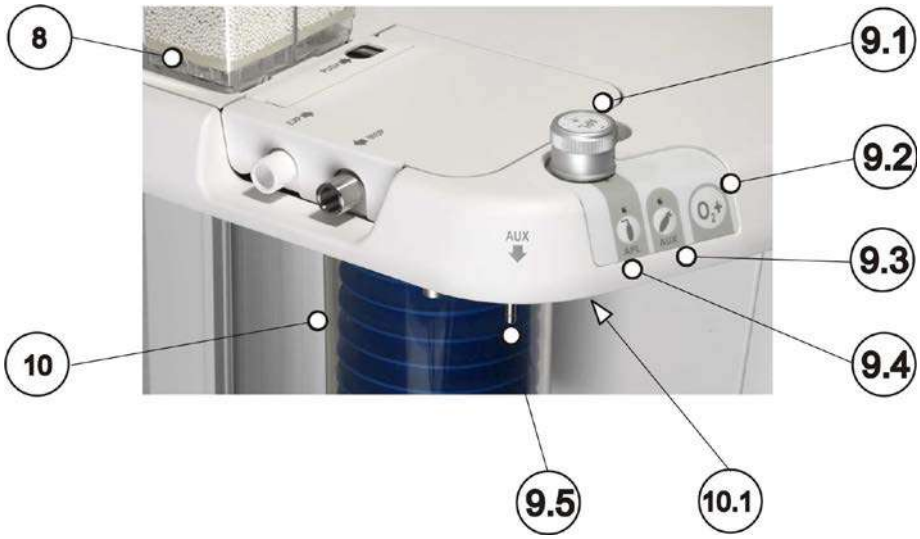
- The pedestal base is realised in shock-proof ABS and polyester coated.
- The chest is composed of three mono-bloc drawers mould in PUR, mounted on highly smoothing telescopic guides allowing a full extension of the drawers.
- The work-shelf is mono-bloc, and includes: the housing for the valves group and the manual ventilation controls and a large handle below the perimeter allows to hold and easily move the unit.
- On the back left side are the medical gas intakes and the electric power supply part.

2.3.1 Support for vaporizers

On the front side of the anaesthesia unit there is an horizontal mono-bloc for rapid fixing of two vaporizers.

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

2.3.2 Control panel for manual ventilation (9)



8 CO_2 absorber canister releasable by unlock lever.

9 Control panel for management of manual ventilation procedures.

9.1 APL valve for adjustment of airways maximum pressure during manual ventilation.

The pressure 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.

9.2 Electronic type O_2 BY-PASS control. Pressing the button puts oxygen in the anaesthesia circuit with a flow of about 35 l/min.

9.3 Fresh gas selection control: enabling output connector at fresh gas exit (AUX).

9.4 Fresh gas exit selection control: enabling valves group (APL).

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 (APL).

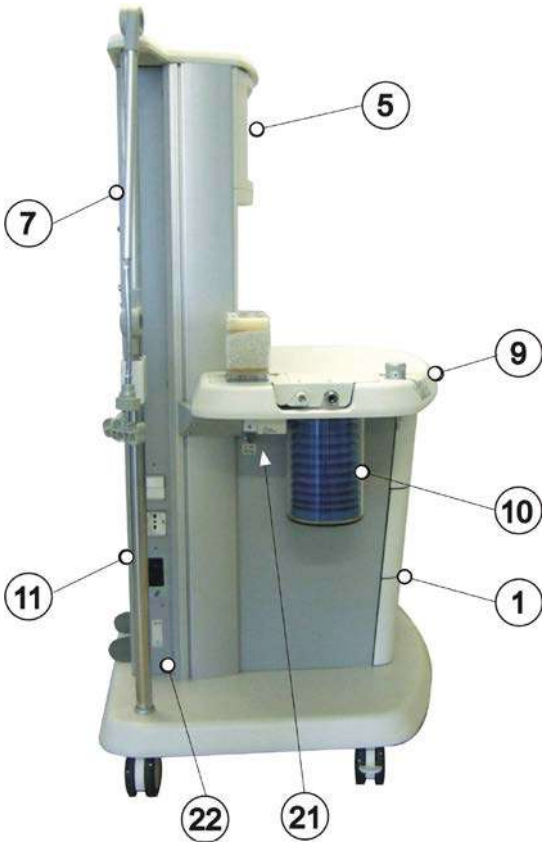
These buttons are synchronized with the ventilator manual operative mode so to avoid accidental or incoherent drives.

9.5 Fresh gas exit connector

10 Valves group

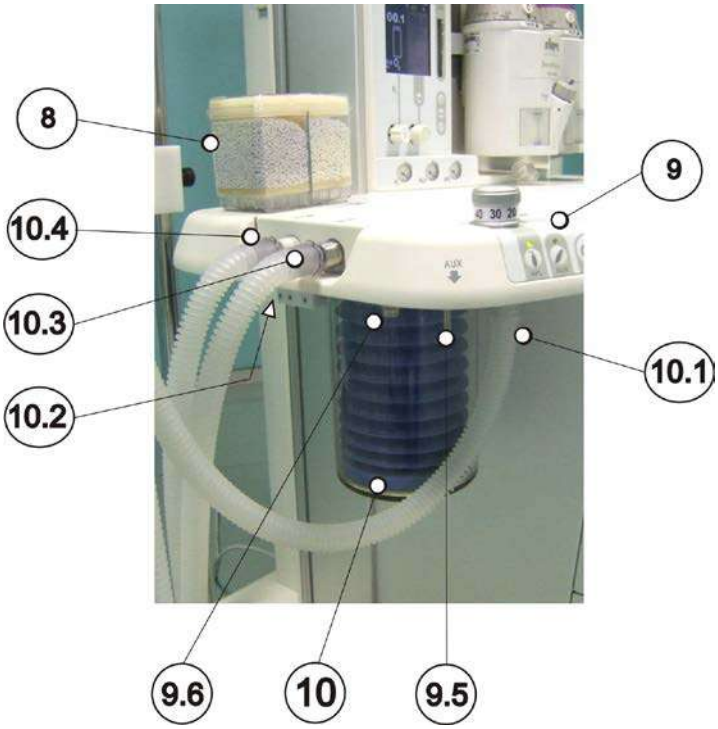
10.1 Connector for supplied manual ventilation kit

2.4 Side view



1	Accessories chest	**10**	Valves group
5	Ventilator module	**11**	Steel vertical rod for accessories support
7	Patient circuit supporting arm (on demand) and support.	**21**	Connections for scavenger
9	Control panel for management of manual ventilation procedures.	**22**	Electric power supply group

2.4.1 Valves group (10)



8 CO_2 absorber canister with lock lever.

9 Control panel for management of manual ventilation procedures.

9.5 Connector for fresh gas exit.

9.6 Not used.

10 Valves group (cfr. 3). (In the picture, version without cover).

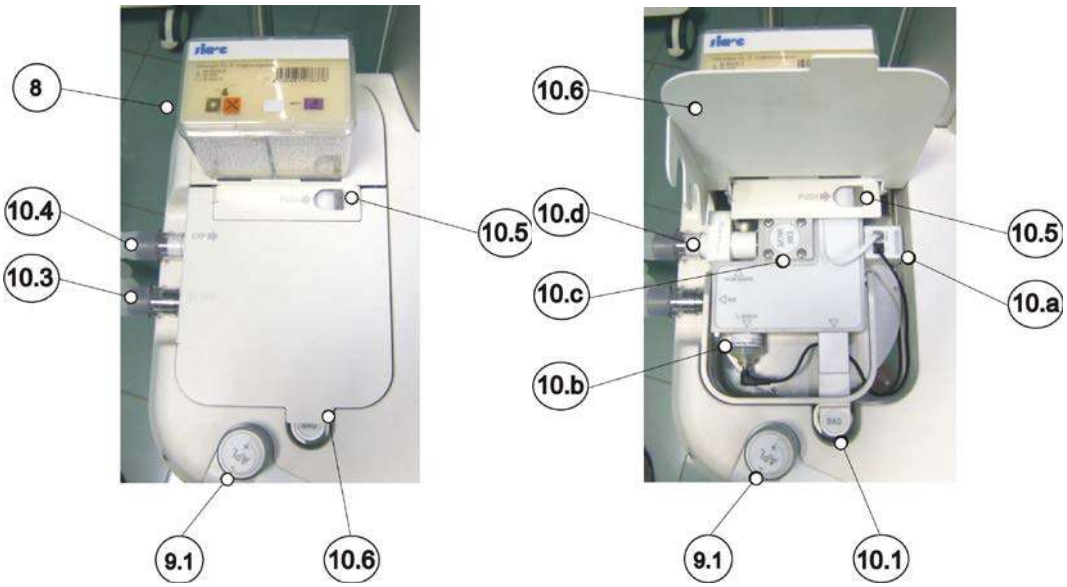
10.1 Connector for supplied manual ventilation kit.

10.2 Connector for gas scavenging circuit

10.3 Connector for inspiratory line.

10.4 Connector for expiratory line flow sensor.

Valves group – external and inside view



8 CO_2 absorber canister with lock lever.

10.1 Connector for supplied manual ventilation kit.

10.3 Connector for expiratory line flow sensor.

10.4 Connector for inspiratory line.

10.5 Unlock lever for CO_2 absorber canister release.

10.6 Valves group cover to gain access for accessories

10.a Support for connection:

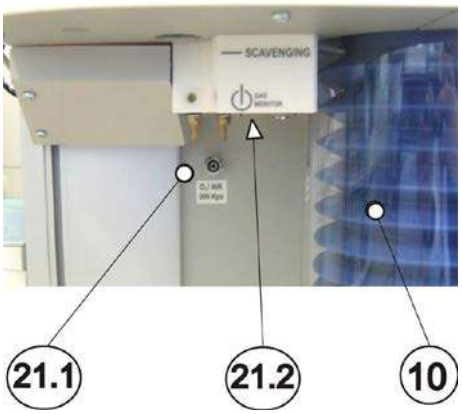
- flow sensor RJ connector
- oxygen sensor RJ connector

10.b Oxygen sensor and connection cable

10.c Expiratory valve (EXP)

10.d Flow sensor and connection cable

2.4.2 Connections for scavenger (21)

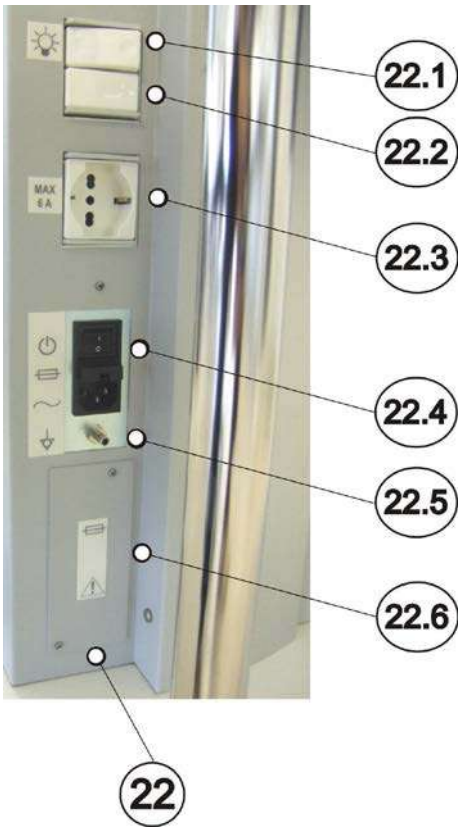


10 Valves group.

21.1 Gas supply connection for active gas scavenger

21.2 Gas scavenging connector.

2.4.3 Electric power supply group (22)



22.1 Switch for front panel light

22.2 Future uses

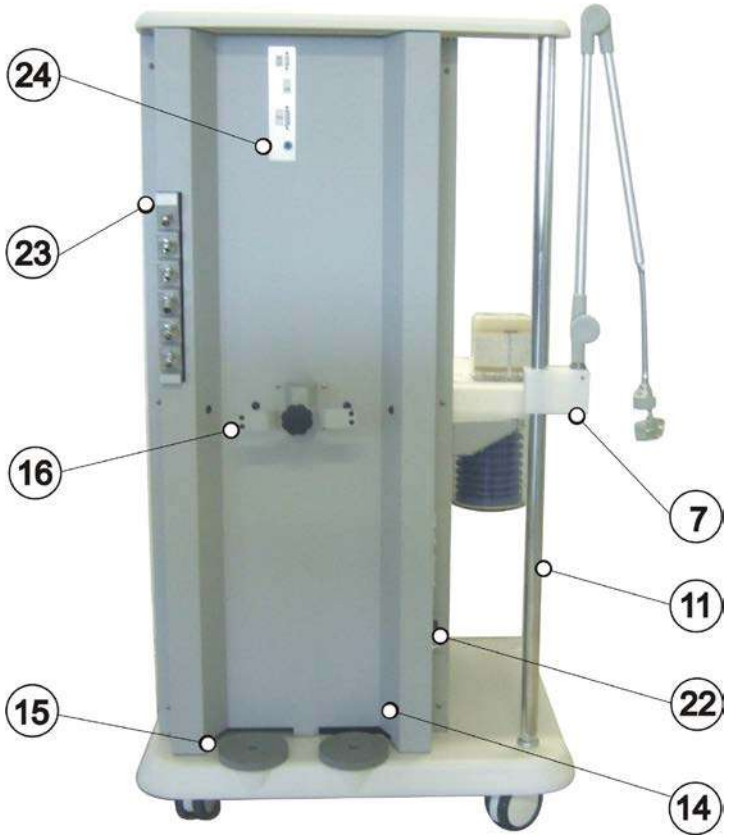
22.3 Socket for auxiliary devices (220Vac 6A)

22.4 Power supply group: main switch, protection fuses (5x20 250V 2x10 AT), socket for connection of main supply power cable.

22.5 Equipotential node

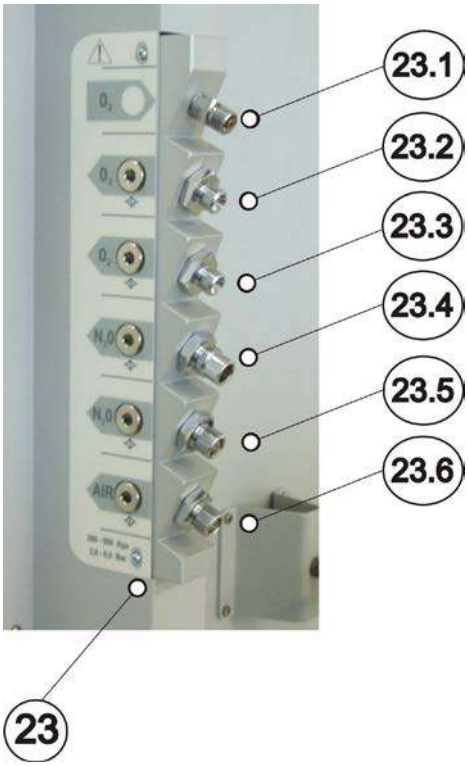
22.6 Fuses area

2.5 Back view



7	Patient circuit supporting arm (on demand) and support.	**16**	Fixing stirrup for cylinders
11	Steel vertical rod for accessories support.	**22**	Electric power supply group
14	Identification label	**23**	Gas supply group
15	Grey round rubber pads for cylinder support (max. two cylinders of 10 lt. capacity)	**24**	Connectors for services

2.5.1 Gas supply group (23)



23.1 Connections for **O_2** exit

23.2 Connections for **O_2** entry

23.3 Connections for **O_2** entry

23.4 Connections for **AIR** entry

23.5 Connections for **N_2O** entry

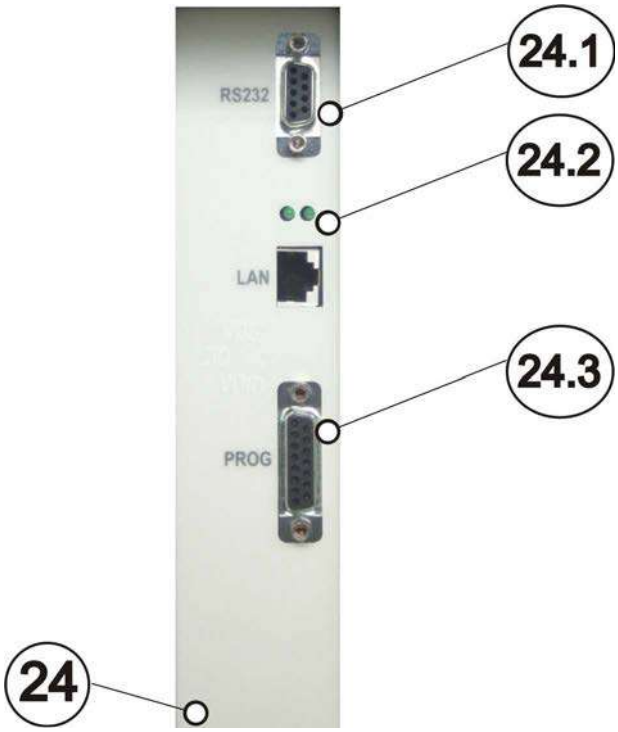
23.6 Connections for **N_2O** entry

Warning. Fire danger

Do not connect to the connector for O_2 exit (23.1) 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 (cfr. 6).

2.5.2 Connectors for services (24)



Morpheus E - Morpheus M

24.1 **RS232** : connection for data download or for gas analyser

24.2 **LAN** : network connection

24.3 **PROG** : connector for CPU board programming

WARNING! Risk of equipment failure.

Use and connect devices authorized by Siare, only.

2.6 Product identification label

The equipment identification label contains some very important data like the model and the serial number, which should be always signalled to the technical service and in every spare parts request. The serial number allows to identify unequivocally the equipment and the composition of the same at the moment of supply.

The manufacturer, the model, the tension and operating frequency, the engaged electric power, the fuses characteristics, the type and class are indicated (in accordance with IEC 601-1), class of the machine (in accordance with the Dir. 93/42 CEE), the serial number.

The product identification label mentions the following information.

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

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.

For a deeper description of MORPHEUS, see on:

- **Cfr. 3** Breathing system module
- **Cfr. 4** Flowmeter box model
- **Cfr. 5** Ventilator module

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3 VALVES GROUP MODULE

In this chapter is illustrated the valves group of MORPHEUS anaesthesia unit, taking into consideration its main parts and modules.

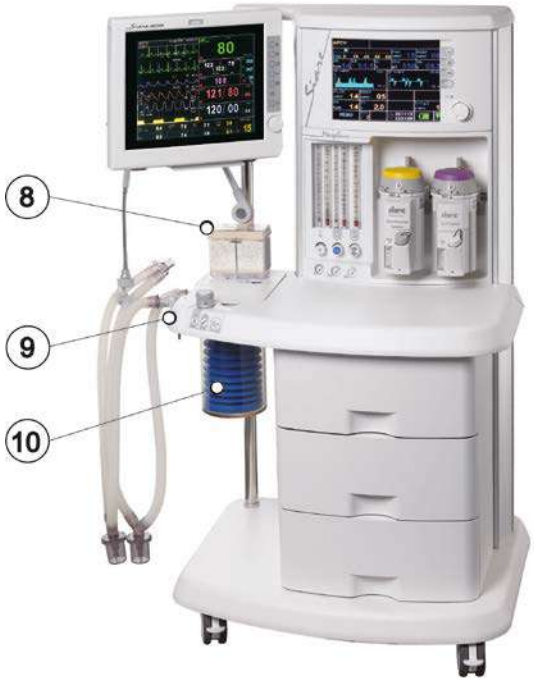
As regards assembling, interfacing and maintenance, refer to this manual or contact Siare's technical assistance service.

3.1 Introduction

WARNING!

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

Valves group (inside view)



Morpheus M

3.2 Valves group

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 ventilator. In any case, the ventilator 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.

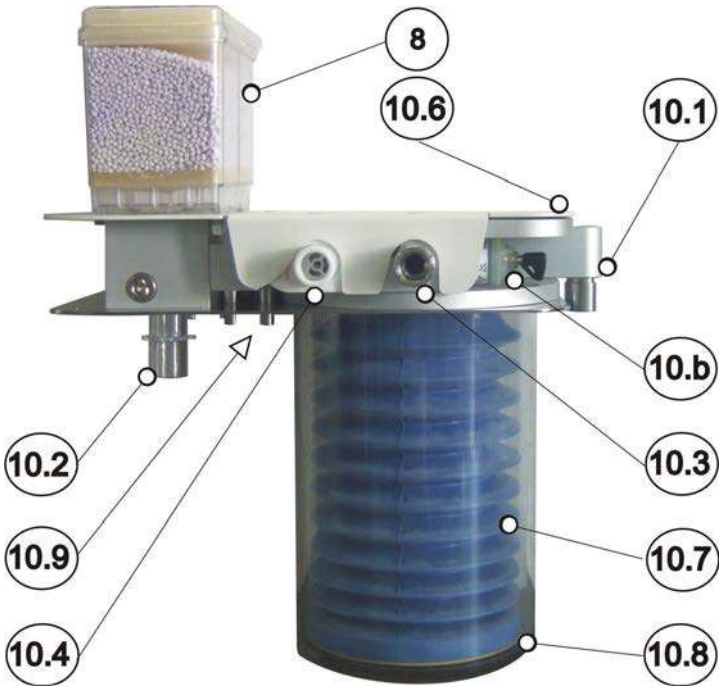
The manual ventilation is possible directly from the valves group or with the TO and FRO external system.

3.2.1 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 ventilator without any user's action on valves group.
- The flow and oxygen sensor calibration is 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.

3.3 Description

3.3.1 Patient circuit view



8 CO_2 absorber canister with lock lever

10.1 Connector for supplied manual ventilation kit

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 to gain access to the accessories; opening side

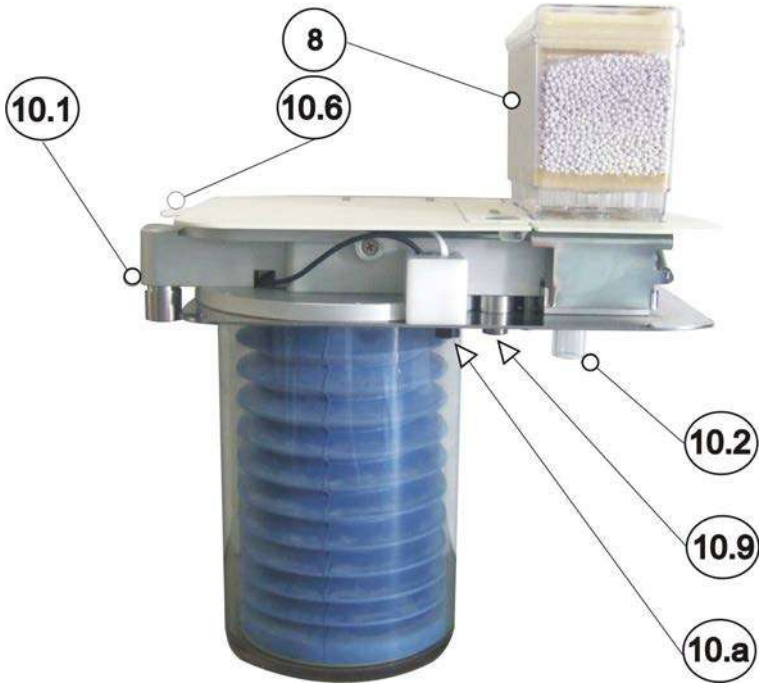
10.7 Bellows with weight

10.8 Bellows jar

10.9 Automatic gas connections to anaesthesia units

10.b Oxygen sensor and connection cable

3.3.2 Electric connection view



8 CO_2 absorber canister with lock lever

10.1 Connector for supplied manual ventilation kit

10.2 Connector for gas scavenging circuit

10.6 Valves group cover to gain access to the accessories; opening side

10.9 Automatic gas connections

10.a Support for connection:

- flow sensor RJ connector
- oxygen sensor RJ connector

3.3.3 Upper view

10.1 Connector for supplied manual ventilation kit

10.5 Unlock lever for CO_2 absorber canister release

10.6 Valves group cover to gain access for accessories

10.a Support for connection:

- 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

3.4 Use

	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.

3.4.1 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 make 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.

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

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

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

- To take off the absorber jar, press the “PUSH” lever.
- Pull up (lever side) the CO_2 absorber canister
- Extract from the apposite groove (opposite to “PUSH” lever side).

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 injury for the user/patient

All the interventions must be effected exclusively by personnel highly qualified and specifically trained and formally authorized by SIARE.

WARNING. Risk of malfunctioning

To be effected only in case of maintenance on valves group. Pay much ATTENTION during this operation.

- Lift and remove completely the valves group and position it on a flat surface.
- Continue with the maintenance (cfr. 10).

3.4.2 Connections to valves group

O_2 cell

WARNING. Risk of injury for the user

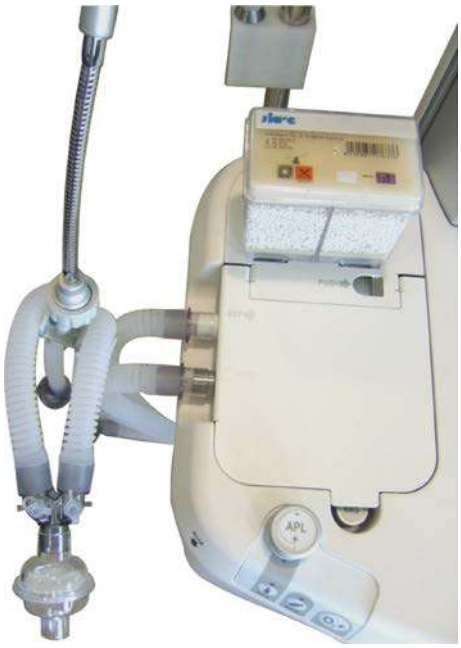
To avoid risks of electric shocks and/or break of components, during interventions, verify that the anaesthesia unit has been disconnected from power supply.

1. Unpack carefully the O_2 cell
2. Pull up the valves group cover.
3. Insert and screw the cell: in the space marked with the script "O_2 SENSOR".

4. 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.

Double hose patient circuit

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

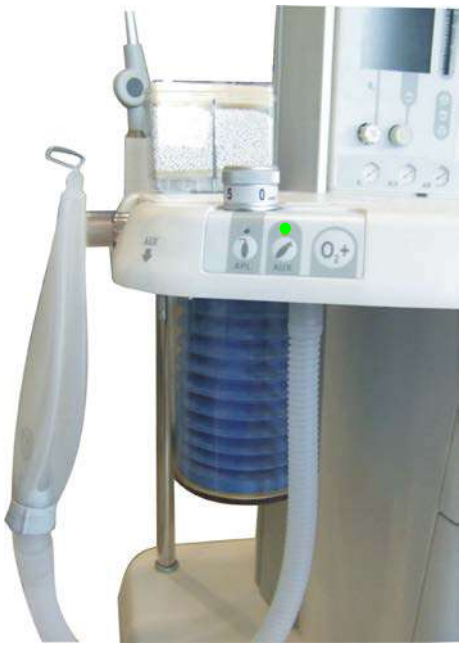


Use a patient circuit suitable for the patient to ventilate.

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

Kit for manual ventilation

- Connect the hose of supplied manual ventilation to the “Bag” connector on the valves group.
- Position the bag of the kit on the patient circuit supporting arm.



MAN (MANUAL) operative mode:

- select the MAN operative mode on the ventilator membrane key board;
- on front panel, on front panel, the “APL” membrane control is activated (the green led lights on);
- manage the quantity of fresh gases for manual ventilation through the gas flowmeter box;
- set the APL valve at the desired maximum pressure.

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, the airways pressure can overcome the limit set on lung ventilator.

The pressure limit depends on APL valve regulation.

MAPLESON C adult patient circuit

- Connect the hose of supplied patient circuit to the “AUX” connector on front panel.
- Position the patient circuit on patient circuit supporting arm.

MAN (MANUAL) operative mode:

- select the MAN operative mode on the ventilator membrane key board;
- on front panel, press the “AUX” membrane key (the green led lights on);
- manage the quantity of fresh gases for manual ventilation of the patient through the gas flowmeter box.

Control panel for manual ventilation

On the left side of work-shelf it is positioned a small control panel to manage all the operations of manual ventilation with the valves group.

This panel includes the following functions.

- The APL valve for the adjustment of airways maximum pressure during manual ventilation.

  The pressure increases by turning clockwise the valve knob and it decreases by turning counter-clockwise.

  The range of regulation is around from 0 to 50 cm H_2O.

- Electronic O_2 BY-PASS button. By pressing this button pure OXYGEN is released into the anaesthesia circuit with a flow of approximately 35 l/min.

Thanks to this type of control it will be possible to enable the REMOTE option, a remote control that could be positioned by the doctor near the patient with the aim to facilitate the operativity of induction and awakening manoeuvres.

Fresh gases exit selection control: enabling of fresh gases exit connector (AUX).

Fresh gases exit selection control: enabling of valves group (APL).

4 DESCRIPTION

In this chapter is illustrated the anaesthesia module of the MOPRHEUS anaesthesia unit, and more precisely model S5 (flowmeter at 3 gas with 5 rotameters).

As regards assembly, interfacing and maintenance, refer to this manual or contact Siare's technical assistance service.

4.1 Introduction

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.

Morpheus M

Anaesthesia module **S5** (mechanical flowmeter box with five rotameters).

4.2 Anaesthesia module with mechanical flowmeters box

The anaesthesia module with mechanical flowmeters box, has the function to adjust the flow and concentration of gas mixture (Air, O_2, and N_2O) as well as to deliver it to the anaesthetic gas vaporizer. It allows selecting the mixture to be delivered Air - O_2, or N_2O - O_2 and the O_2 enrichment to the delivered mixture in emergency situations.

The anaesthesia module includes a device, which guarantees a minimum concentration of 25% oxygen in all medical gas erogating conditions (MIX - LIFE device).

Through the three pressure gauges on the front panel the anaesthesia module allows the continuous control of medical gas feeding pressure coming from the gas pipelines system (accuracy ±10%).

The flowmeters allow to measure the capacity of the relevant gases with an accuracy of ±10% of the displayed value or ±1% of end scale value choosing the highest one between the two limits.

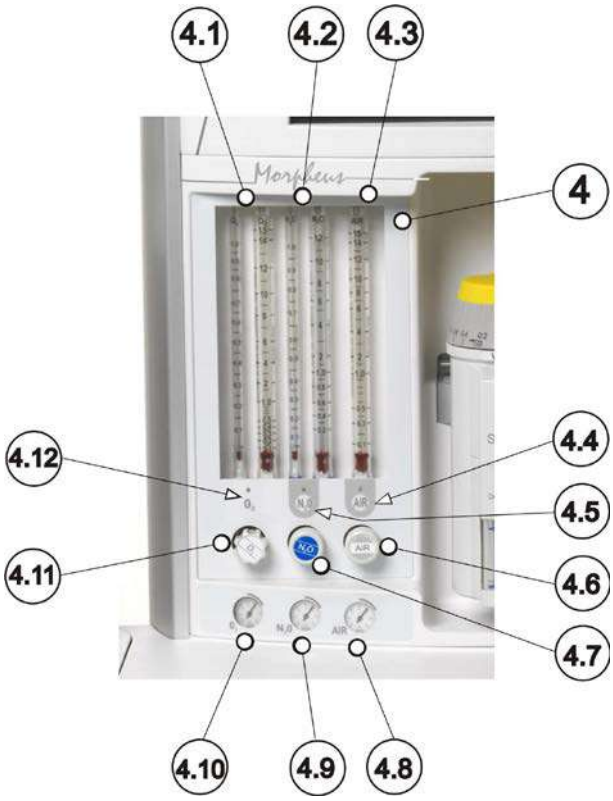
4.2.1 Main features

Oxygen rotameter	• Scale: 0.1 - 15 l/min. • Resolution: 0.1 l/min up to 1 l/min and 1 l/min up to 15 l/min • Accuracy: ± 10% of read value or: ± 1% of end scale whichever is the worse case.
Nitrous oxide rotameter	• Scale : 0.2 - 12 l/min. • Resolution: 0.1 l/min up to 1 l/min and 0.5 l/min up to 12 l/min • Accuracy: ± 10% of read value or: ± 1% of end scale whichever is the worse case.
Air rotameter	• Scale: 0.1 - 15 l/min. • Resolution: 0.1 l/min up to 1 l/min and 1 l/min up to 15 l/min • Accuracy: ± 10% of read value or: ± 1% of end scale whichever is the worse case.

Low flows oxygen rotameter	Scale 0.1 - 1 l/min. Resolution: 0.05 l/min Accuracy: ± 10% of read value or: ± 1% of end scale whichever is the worst case.
Low flow nitrous oxide rotameter	Scale: 0.1 - 1 l/min. Resolution: 0.05 l/min Accuracy: ± 10% of read value or: ± 1% of end scale whichever is the worst case.
Medical gas supply	OXYGEN • Pressure included between 280 kPa and 600 kPa (2,8 - 6 bar) • Max. required flow 90 l/min. NITROUS OXIDE • Pressure included between 280 kPa and 600 kPa (2,8 - 6 bar) • Max. required flow 15 l/min. MEDICAL COMPRESSED AIR • Pressure included between 280 kPa and 600 kPa (2,8 - 6 bar) • Max. required flow 90 l/min.
Gauges	No. 3 on front panel (O_2 - N_2O - AIR), scale 0 - 6 bar
Alarms	Lack or low oxygen pressure with consequent cut-off of Nitrous Oxide delivery.

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 LACK OR LOW OXYGEN PRESSURE • CUT-OFF: audible alarm with immediate cut-off of Nitrous Oxide delivery. AGAINST FRESH GAS HIGH PRESSURE IN SUPPLY • Safety valve calibrated at 0.8 bar for the protection of the glass rotameters. 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 N_2O • Selection by membrane key on the flowmeter front panel.
Control for activation of exit of fresh gas for manual ventilations	Setting of manual modality (MAN) on ventilator keyboard with automatic deviation of fresh gas or deviation 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 push button, max flow 35 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)
OUT gas sockets on gas supply group	• No. 1 sockets for O_2 • No. 1 sockets O_2 - AIR for active scavenger feeding • 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)

4.3 Description of S5 version



4 Anaesthesia module (in the example shown above, the mechanical flowmeter box with five flowmeters).

4.1 Oxygen flowmeter (max. flow 15 l/min).
Oxygen flowmeter with 1 liter end-scale for low flows.

4.2 Nitrous Oxide flowmeter (max. flow 12 l/min).
Nitrous Oxide flowmeter with 1 liter end-scale for low flows.

4.3 AIR flowmeter (max. flow 15 l/min).

4.4 Membrane key for Air delivery selection.

- Green led: air delivery is possible.

4.5 Membrane key for Nitrous Oxide delivery selection.

- Green led: nitrous oxide delivery is possible

WARNING! Risk of injury for the patient.

This operation and selection system prevents the administration at the same time of air and nitrous oxide.

Only the gas selected by key button (green led on) will be available on flowmeters.

4.6 Air flow regulator for fresh gas (it opens in counter-clockwise).

4.7 Nitrous Oxide flow regulator for fresh gas (it opens in counter-clockwise).

The opening of this regulator automatically supplies a flow of oxygen of about 25% of the total mixture.

The flow of oxygen is visible on flowmeter, through the red indicator turning. This safety device (MIX LIFE) avoids the incorrect administration of hypoxic mixtures.

4.8 Manometer for Air supplies pressure control.

4.9 Manometer for Nitrous Oxide supply pressure control.

4.10 Manometer for Oxygen supplies pressure control.

4.11 Oxygen flow regulator for fresh gas (it opens in counter-clockwise).

4.12 Membrane key to select oxygen delivery.

Red led. **ALARM.** Oxygen supply pressure lower than 2,8 bar

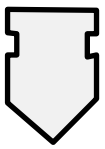
4.3.1 Notes

WARNING! Risk of break of anaesthesia module.

In order to not compromise the correct working or damage the gas flowmeters, it is necessary to avoid closing of the regulators too tightly.

The indicated flow value must be read at the upper level of the rim of the flowmeter indicator when it rotates.

If there is not rotation, call the Siare technical assistance.

Reading point of flowmeter 

WARNING! Risk of injury for the patient.

CUT-OFF ALARM. If the anaesthesia module sounds a whistle, it means that the pressure of the oxygen is too low; immediately taking action to reset the oxygen pressure.

If the pressure of the main system is not available, use the oxygen gas cylinder for emergency cases.

Before using the anaesthesia unit on a patient it is necessary to per form a series of preliminary checks to verify the correct equipment operation.

Among the preliminary checks to be performed, it is also include the flowmeter box.

5 LUNG VENTILATOR MODULE

This charter illustrates the lung ventilator module, and the graphics of display are mainly taken into consideration. All information to use and display parameters and functions of ventilator module are reported in a simple way.

WARNING! Risk of injury for the user / patient

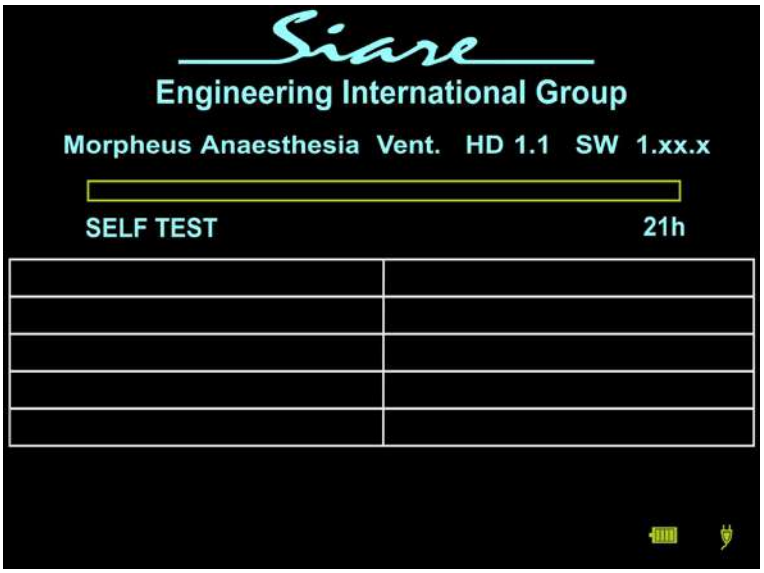
- All the pictures and the examples shown in the present chapter have the mere purpose of being an example and they do not make any reference to real clinical cases.
- For the use of the Morpheus anaesthesia unit, please refer to Chapter 6 and 7 related to this subject.

5.1 Ventilator switching on

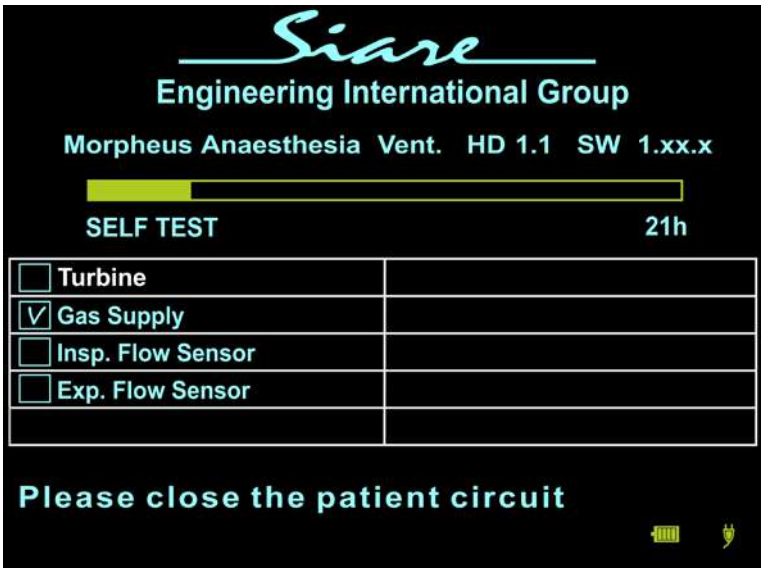
- Place the main power switch in position I (ON) ; anaesthesia unit power on.
- On the ventilator front panel, verify the electric power supply led; green led on.

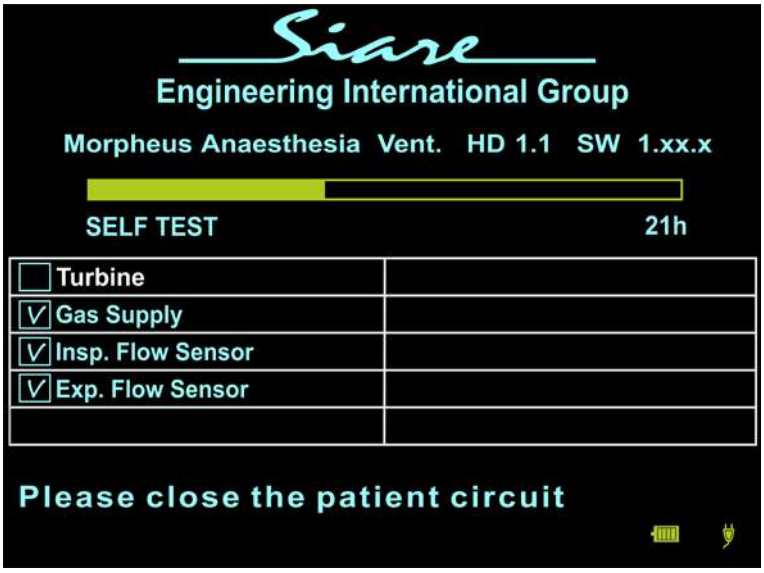
- Keep **STAND BY / ON-OFF** Soft key pressed for a few seconds to turn the ventilator module on.

The automatic " SELF TEST " phase begins.



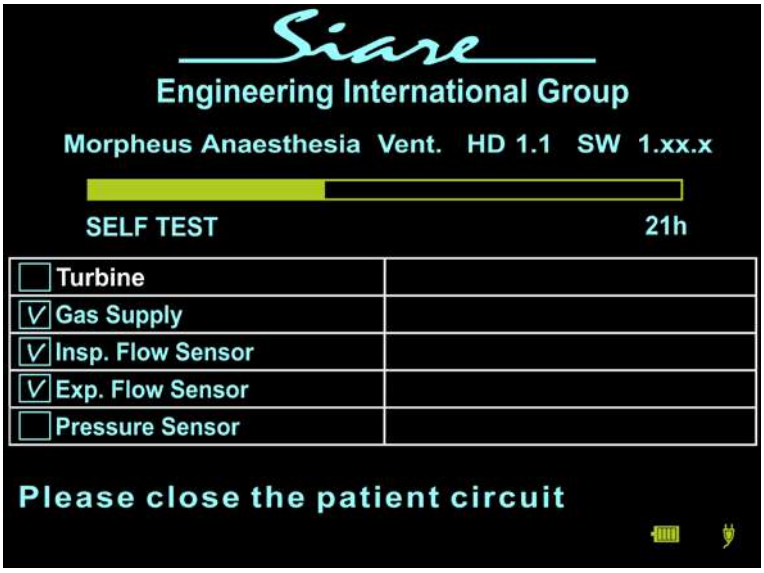
Checking of Morpheus operation.





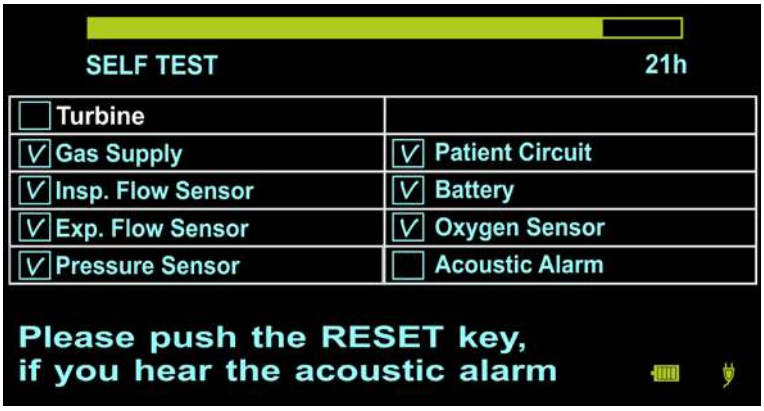
Follow the instructions for the checking of pressure and flow sensor

- In order to carry out the " SELF TEST " correctly, close or plug the Y-shaped coupling of the patient circuit, as requested on the display screen.



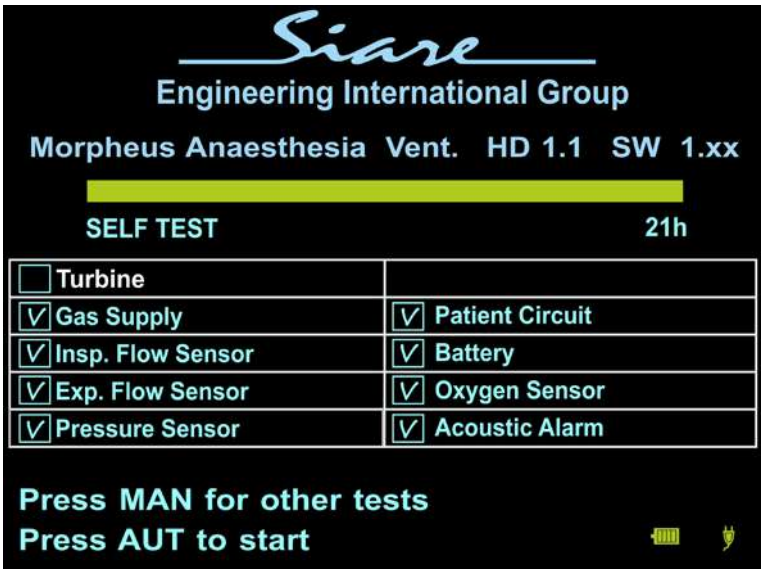
The 'SELF TEST' phase continues

Displaying at the end of the first phase of ‘SELF TEST’



Checking of the acoustic alarm operation

- **IN PRESENCE** of the acoustic alarm, press Alarm Reset (see picture here below).
- **IN ABSENCE** of acoustic alarm, do not press Alarm Reset (on the display an error message ‘Press AUT to start’ appears, see the picture below)



“ SELF TEST “ completed

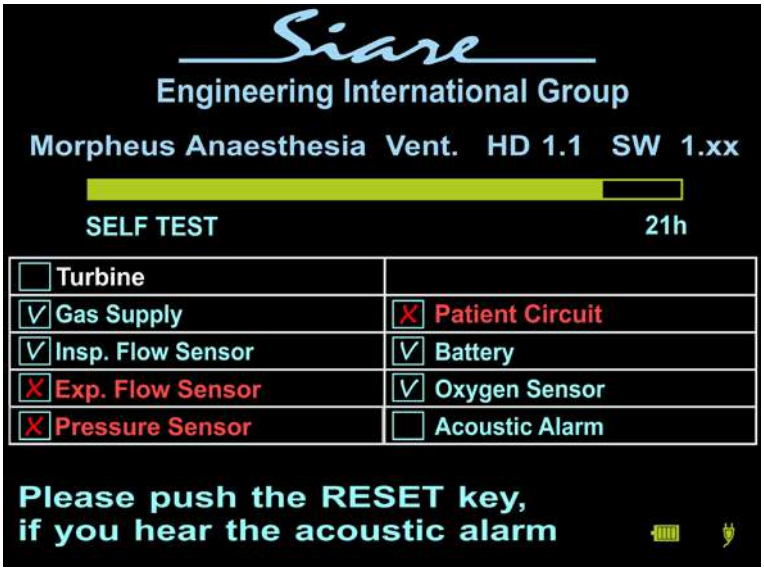
- Press the **MAN** key to enter in TEST ON DEMAND (see cfr. 6)
- Press the **AUT** key to enter the ventilator display in STAND-BY mode.

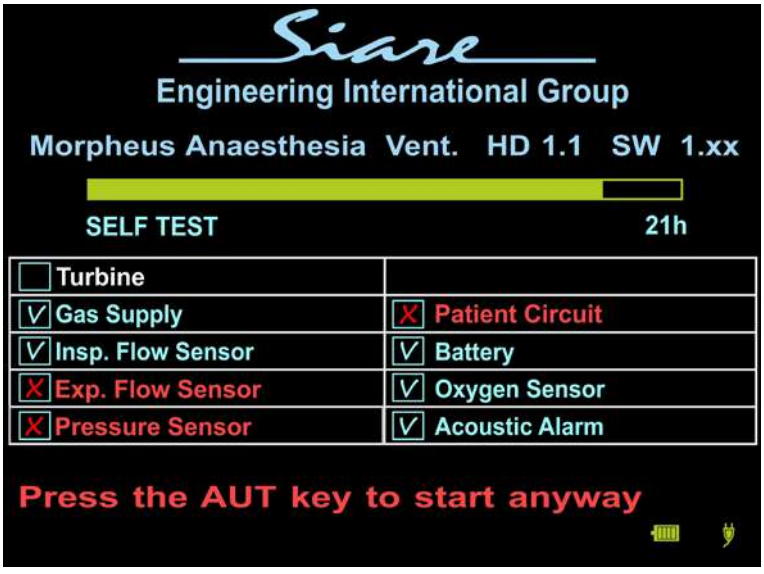
During “ SELF TEST “ phase, the ventilator software carries out the self-diagnostic tests and checks a series of devices necessary for the safety of Morpheus Anaesthesia unit.

5.1.1 “ SELF TEST” not passed

WARNING! Patient/clinician injury hazard.

The malfunctioning and some phases of the ‘SELF TEST’ did not pass, is highlighted by the system.





WARNING! Risk of injury for the patient.

Press the **AUT** soft key to enter the ventilator module display in **STAND-BY**.

Consult the chapters 8 and 9 to solve the problem.

If the malfunctioning is not solved, contact the nearest Siare Service Centre or authorized by Siare.

5.1.2 STAND-BY displaying at the end of " SELF TEST " phase

STAND-BY : Mode in which the ventilator is placed before the start-up or the switching off

STAND-BY : The operative mode can be selected, the ventilation parameter related to the operative mode of interest can be configured or modified.

Rotate and/or press the encoder knob to select the box of the operative mode or of the ventilation parameter to be set and/or modified.

Press the **AUT** soft key to start ventilating a patient using an automatic operative mode.

For further information on operating logic and how setting the operating parameters of Operative Modes, make reference to the chapter, cfr. 5.3 and 5.5.

5.2 Ventilator switching off

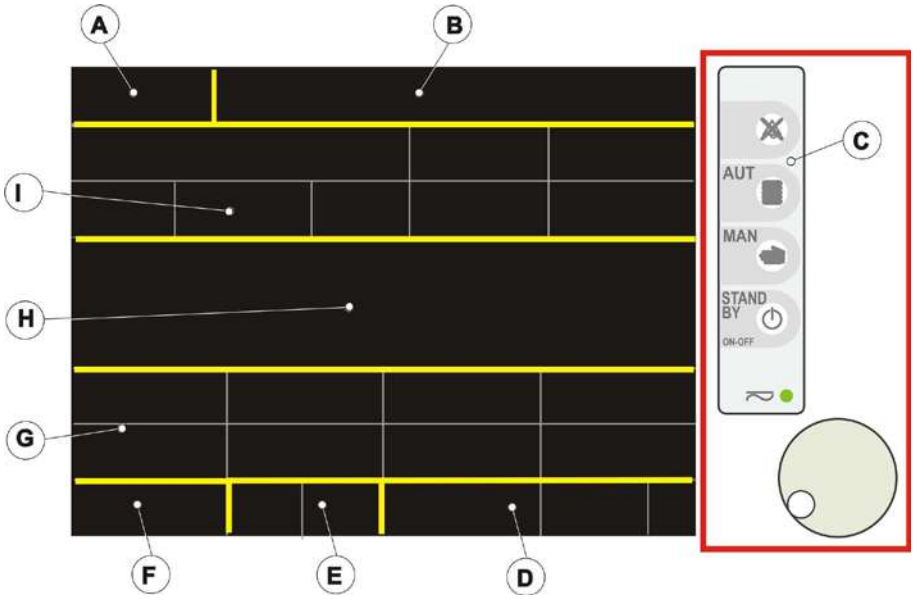
- Anaesthesia unit and working of lung ventilator
- Press the **STAND BY / ON-OFF** soft key to stop the ventilator

- Anaesthesia unit and lung ventilator in **STAND-BY**
- Keep pressed the **STAND BY / ON-OFF** soft key for a few seconds to turn the ventilator module OFF

Press the **STAND BY / ON-OFF** soft key : the ventilator return in the state of STAND-BY operative mode

Press the **AUT** soft key : the ventilator turns OFF

5.3 Monitoring areas and parameters configuration



A. Operative mode

B. Alarms

C. User's controls area

D. General information

E. Graphics setting area

F. Mai menu

G. Ventilation parameters setting area

H. Graphics displaying and gas monitoring

I. Ventilation parameters monitoring area

Use of encoder knob

Through the encoder it is possible to select the ventilation parameter window to be set and/or modified.

- Rotate clockwise and counter-clockwise to select the parameter of interest; press the encoder to access the parameter modification.
- Rotate clockwise (counter-clockwise) to increase (decrease) the parameter value; press the encoder to confirm the value.

5.4 Operative mode area (A)

Automatic Ventilation

- Turn the encoder knob to select the required operative mode ; press **AUT** button to activate the ventilation.
- Press the STAND BY soft key to interrupt the ventilation.

APCV	Assisted pressure controlled ventilation, synchronised with patient's breathing.
APCV - TV	(Volume Targeted) Assisted pressure controlled ventilation, synchronised with patient's breathing and with assured current volume.
PSV	Assisted pressure support ventilation with assured respiratory rate set by the clinician (Apnoea Back Up).
VC/VAC	Volume controlled ventilation synchronised with the patient if the inspiratory trigger is activated.
VC/VAC BABY	Volume controlled ventilation synchronised with the patient if the inspiratory trigger for neonates and premature births is activated.
SIMV	Synchronized Intermittent Mandatory Ventilation.
MAN	Manual ventilation

Manual Ventilation

- Press the **MAN** soft key to activate the manual ventilation.
- Press the **STAND BY** soft key to interrupt the ventilation.

For further information on operating logic and how setting the operating parameters of Operative Modes, make reference to the chapter, cfr. 7.

5.5 Alarms area (B)

The alarm area provides two indications:

- an information list relevant to the activated alarm type;
- the displaying of the “alarm bell” symbol.

Typology of alarm present on ventilator.

- Configurable alarms
- System alarms

For further information on the operating logic and how setting the Alarms operating parameters, make reference to the relevant chapter, cfr. 8.

Meaning of “alarm bell” symbol

The “alarm bell” symbol changes colour depending on the priorities and state of activated alarm.

Medium priority : yellow

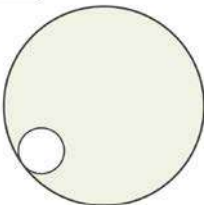
Suspended alarm : yellow and strikethrough

High priority : red

5.6 User's controls area (C)

On the right side of front panel a control board and an encoder knob are provided.

These components allow a rapid interaction between the user and the ventilator.



Soft key for audible alarm silencing. **ALARM RESET**

Soft key for activation of automatic ventilation. **AUT**

Soft key for activation of manual ventilation. **MAN**

Button for lung ventilator switch on (switch-off) / stop ventilation / STAND-BY condition / ESC function. **STAND BY ON/OFF**

The green led on indicates the presence of main power supply.

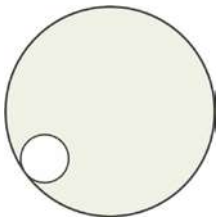
Multifunctional encoder knob.

5.6.1 Operator controls description

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

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

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



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

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

Use of encoder knob.

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

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

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

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

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

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

When the led is light on (orange colour) it indicates that the ventilator is supplied by the auxiliary battery.

5.7 General information area (D)

Indication of set hour and date.

Indication of operation time of anaesthesia unit.

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

- with fix symbol the battery is completely charged;
- with flashing symbol the battery is under charging.

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

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

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

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

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

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

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

The colour of the last flashing “notch” is red (high priority alarm): this extremely serious alarm condition indicates that the battery is almost completely low.

Red colour indication, flashing: power failure indication.

Red colour indication, crossed, flashing: indication of power failure alarm “inhibition”.

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

5.8 Graphics setting area (E)

Use this function to set the type and number of graphics (1 or 2 or no graphics), displayed during the anaesthesia unit operation.

The selected graphics are shown on the L or R side of graphics displaying and gas monitoring area (H).

How to SET a type of graphic

- Press and rotate the encoder to select the desired graphic setting area.

- Press the encoder to activate the graphic setting area.

- Rotate the encoder to select the type of graphic to be displayed.

- Press the encoder to confirm the type of graphic to be displayed

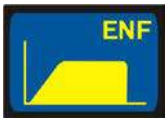
- The PAW graphic is displayed during the anaesthesia unit operation.

GRAPHICS displayed

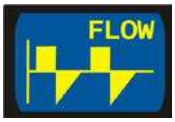
- No displaying enabled

- HAL

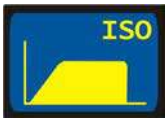
- PAW



- ENF

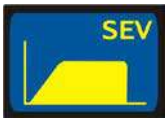


- FLOW



- ISO

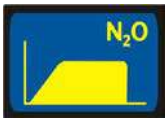
- Vte



- SEV

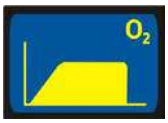
- CO_2

- DEV

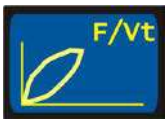


- N_2O

- Vt / PAW (*)



- O_2



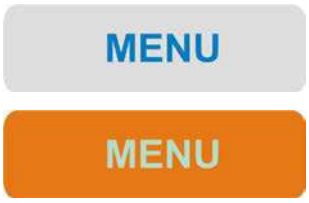
- F / Vt (*)

- RP1 (*)

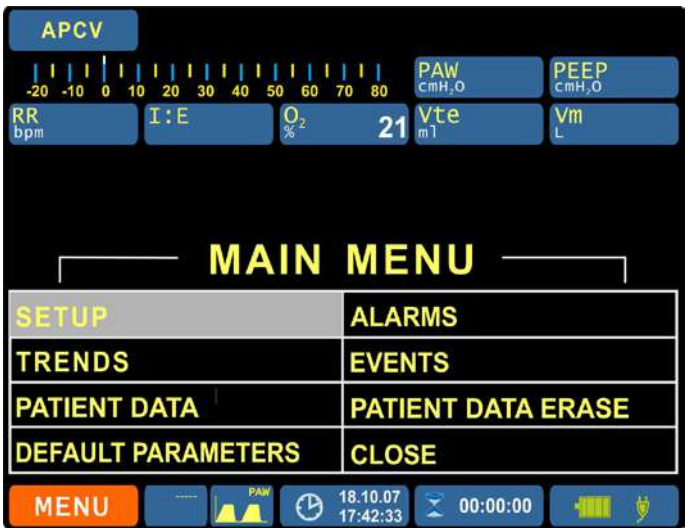
At the paragraph “Graphics displaying area” (cfr. 5.11) are shown the functions to enable the characteristics of graphics displayed.

(*) These graphics cannot be displayed by activating the function ***MENU - SETUP - GRAPHICS VISUALIZ - Single Charts***

5.9 Main Menu area (F)



- Press the encoder knob to select the MENU area.
- Press the encoder knob to display the “MAIN MENU” page.



- Rotate the encoder to select the desired item of MAIN MENU area [e.g. **SETUP**].
- Press the encoder to display the page of desired item of MAIN MENU [e.g. **SETUP**].

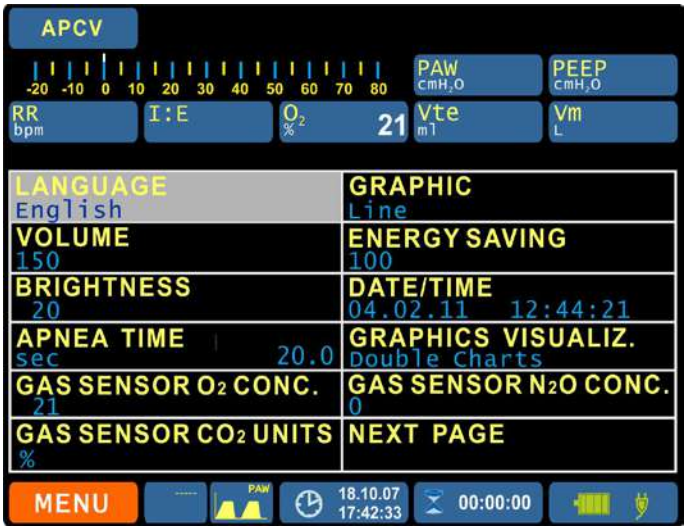
To return to the initial page, **STAND-BY** mode:

- select the item **CLOSE** and press the encoder

- or, press directly the **STAND BY / ON-OFF** soft key

5.9.1 Main Menu – SETUP

Use the MENU - SETUP function to set the items necessary for the correct operation of the unit.



Area Main Menu items - SETUP

LANGUAGE	It is possible to set the language among the following: • *English* • *French* • *Spanish* • *Italian* • *German*
GRAPHIC	It is possible to select the type of graph: area or line. ***Line:*** the graphs line is traced without filling, as shown in the picture. ***Area:*** the graphs line is full as in alongside picture
VOLUME	It is possible to choose the acoustic intensity of the alarm signal. ***100 - 255***

ENERGY SAVING	It is possible to set the percentage value of the energy consumption of the machine. The energy saving condition is active after 30 minutes calculated from the moment the keys are not pressed, either the soft keys or the encoder. If the value 0% is set the screen, when the energy saving function is activated, will be black.
	0 - 100
BRIGHTNESS	It is possible to set the brightness of the screen
	1 - 30
DATE/TIME	It is possible to set the data and hour field. Pressing the encoder it will be possible to select single fields and, by turning the knob, it will be possible to set and /or modify the desired date and hour. Press the STAND-BY soft key to return to **SETUP- MAIN MENU** view.

APNOEA TIME	Selecting the **"Apnoea Time"** it is possible to set the time after which the apnoea back-up function to support patient ventilation, will be activated. The duration of the apnoea time can be set within 5 and 60 seconds.
	Da 5 a 60 s.

It is recommended to pay much attention to such parameter setting because an incorrect adjustments could lead to serious consequences for the patient: in particular we suggest to set a value around 20 seconds.

GRAPHICS VISUALIZZATION	It is possible to select the graphs displaying modality:
	Single Charts in the graphs displaying area, it is displayed a sole graph. ***Double Charts*** in the graphs displaying area, two graphs are displayed.

O_2 CONCENTRATION	Compensation parameter for **O_2** measurement

The 3 values are referred to the concentration of O_2

- **21%**
- **50 %**
- **85 %**

N_2O CONCENTRATION	Compensation parameter for **NO_2** measurement

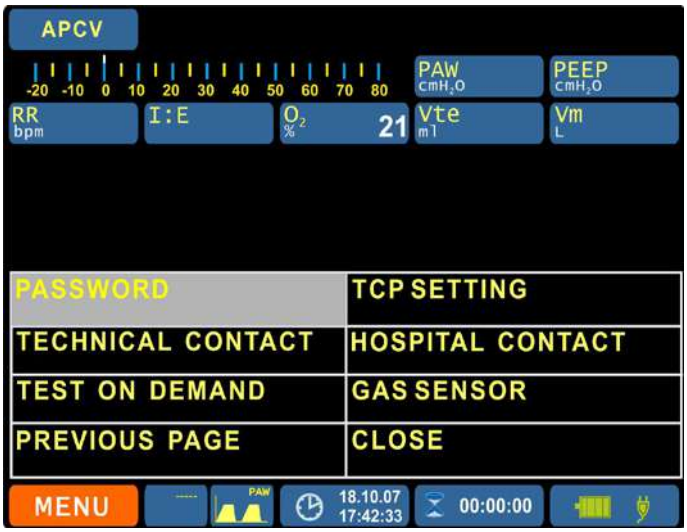
The 2 values are referred to the concentration of N_2O

- **0 %**
- **50 %**

CO_2 MEASUREMENT UNIT	It is possible to select the measurement unit of **CO_2**

- **%**
- **mmHg**

NEST PAGE	It allows to switch to the second view of SETUP.



PASSWORD	***Function NOT enabled: future uses***

TCP SETTING	***Optional function: it is not available in the current HW version***

TECHNICAL CONTACT

Selecting the "**Technical Contact** " it is possible to access to a screen where setting the data relevant to the service contact developed in 6 lines of text.

Pressing the encoder it is possible to select the single fields and, the values could be set and /or modified by turning the knob.

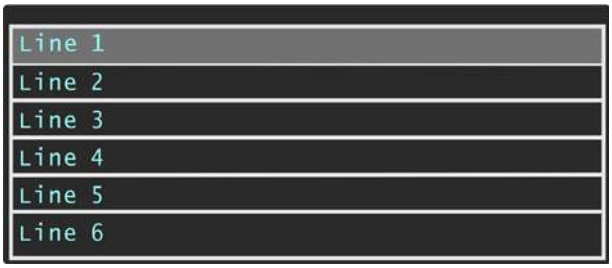
Press the STAND BY soft key to return to the **SETUP - MAIN MENU** view**.**

HOSPITAL CONTACT

Selecting the "**Hospital Contact**" it is possible to access to a screen where setting the data relevant to the hospital contact developed in 6 lines of text.

Pressing the encoder it is possible to select the single fields and, the values could be set and /or modified by turning the knob.

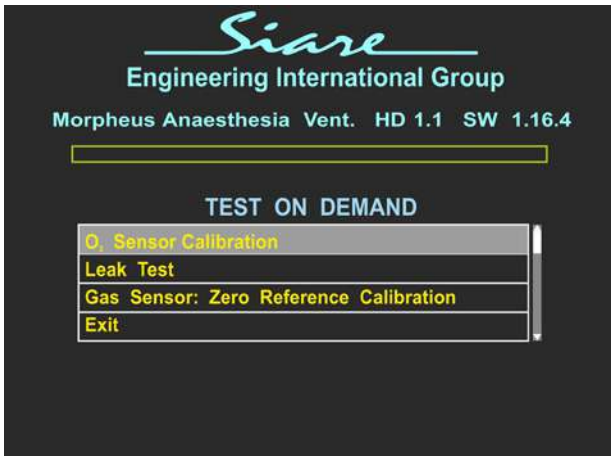
Press the STAND BY soft key to return to the **SETUP - MAIN MENU** view**.**



TESTS ON DEMAND

Selecting the "**TESTS ON DEMAND**" it is possible to access to a screen where activating the functional tests.

*See at paragraph "**Preliminary controls – TESTS ON DEMAND**" (cfr. 6.5) the instructions for parameter modification.*



GAS SENSOR	To access screens where it is possible to display the state of gas analyzer in use, select the **"Gas Sensor** " box.

- ***Sensor Configuration Register 0***
- ***Sensor Configuration Register 1***
- ***Sensor Service Status Register***
- ***Sensor Error Register***
- ***Data Valid Register***
- ***Adapter Status Register***
- ***Gas Sensor: Zero Reference Calibration***

The information available and displayed are purely indicative of the connected gas analyzer state and operation; and the same description is already mostly exhaustive and it does not need further explanation.

Besides, the information relevant to this parameter are dedicated to highly qualified personnel, specifically trained and formally authorized by SIARE.

For further information on the GAS SENSOR operation, please refer to the relevant chapter.

PREVIOUS PAGE	Return to the first **SETUP** view.

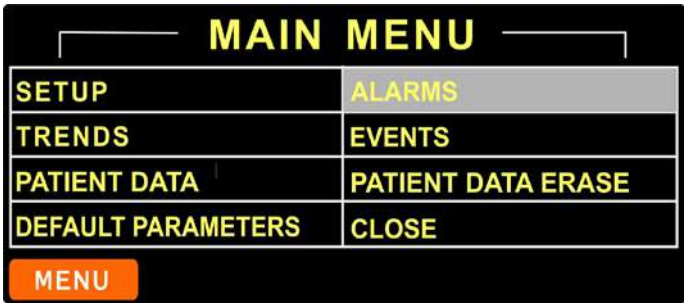
CLOSE	Return to **MAIN MENU** view.

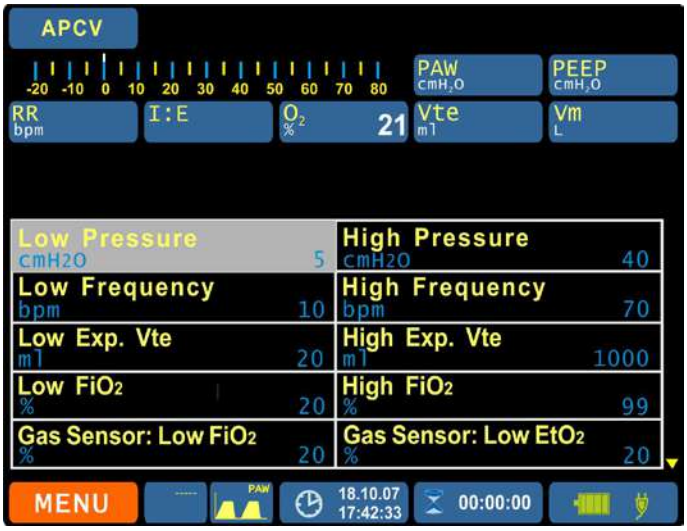
To return to the initial page, **STAND-BY** mode:

- select the item **CLOSE** and press the encoder knob
- or, press directly the **STAND BY / ON-OFF** soft key
- the system returns automatically after around 30 seconds to the STAND-BY view.

5.9.2 Main Menu – ALARMS

- Rotate the encoder to select the desired item of MAIN MENU area [e.g. **ALARMS**].
- Press the encoder to display the page of desired item of MAIN MENU [e.g. **ALARMS**].





- Rotate the encoder knob to see all the alarms configurable (the yellow arrows appearing sideway, highlight the presence of further alarms).

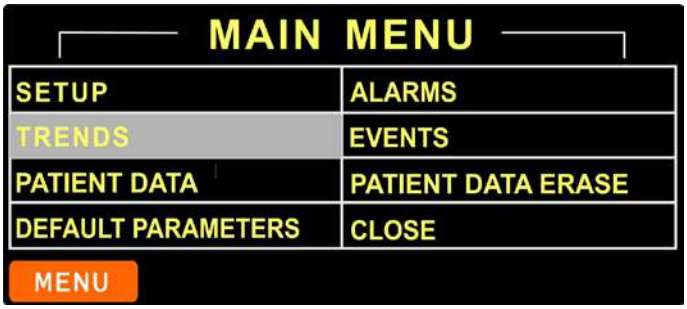
The ventilator module is equipped with automatic means for detection and identification of serious and sudden events through alarm signals or information signals.

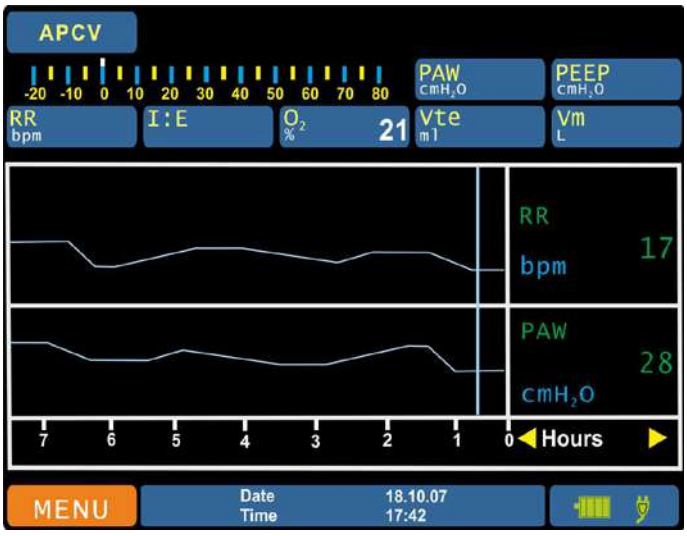
The aim of the alarm signal is to draw the attention of the user on the event.

For further information, please refer to the Chapter ‘Alarms’ (cfr 8).

5.9.3 Main Menu – TRENDS

- Rotate the encoder to select the desired item of MAIN MENU area [e.g. **TRENDS**].
- Press the encoder to display the page of desired item of MAIN MENU [e.g. **TRENDS**].





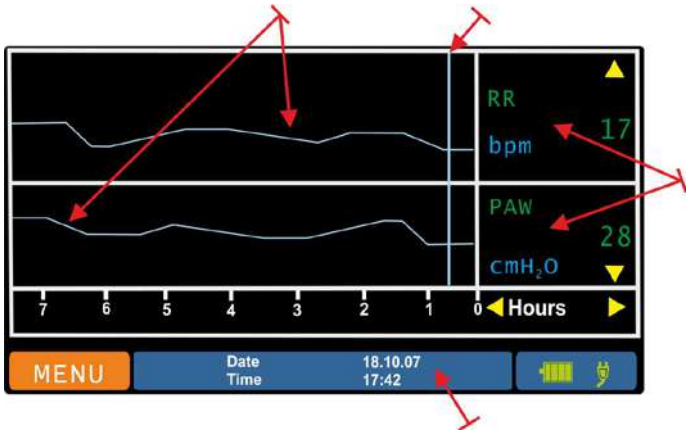
The system through the **TRENDS** modality, enable the user to monitor the most significant breathing parameters on medium – long period of a patient. The examined PRF, monitored and displayed in sequences and in pairs are:

- the respiratory rate or breaths of the patient - **RR** (bpm)
- the airways pressure - **PAW** (cmH2O)
- the end expiration positive pressure - **PEEP** (cmH2O)
- the minute volume expired by the patient - **VM** (L)
- the expired tidal volume - **Vte** (ml)

The capacity to store each parameter is of 72 hours with data sampling at 4 minutes.

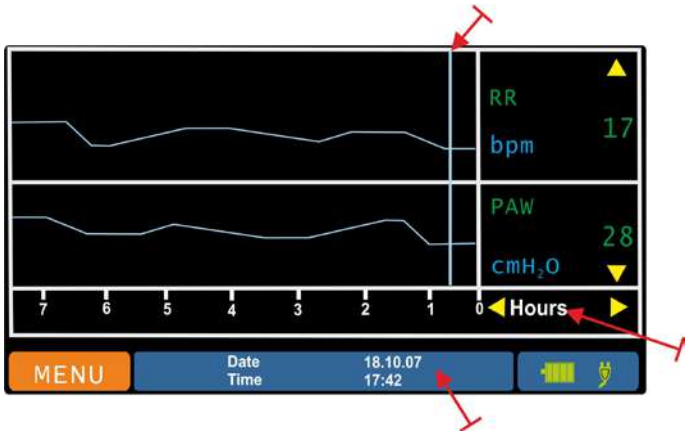
TRENDS displaying includes:

- indication by trait or vertical bar which indicates on displayed graph the time shift
- the graphs, displayed in pairs
- the parameters, selectable in pairs by the encoder
- the temporal references on 72 hours with sampling/displaying every 4 minutes



To display the TRENDS parameters

Rotate the encoder knob clockwise (counter clockwise); the signalling tract/vertical bar on the two graphic trends displayed.



Rotate the encoder, the coloured vertical bar moves towards the left of the screen and at the same time the data relevant to sampling **Date** and **Time** are updated.

At 4 minutes steps (sampling period) it is possible to display the time trend of selected parameters.

Rotate the encoder clockwise (counter-clockwise) to move the trait/vertical bar indication on the two displayed trend graphs and consequently, the following data change:

- **the numerical value of the two enabled parameters**
- **the time and the date of detection**

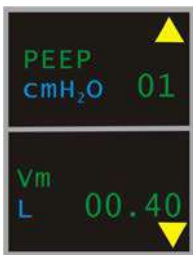
How to display further TRENDS parameters

Press the encoder, this way further available parameters can be displayed.

The possibility to display other available parameters is evidenced by the yellow arrows appearing alongside the parameters value.

Rotate the encoder clockwise (counter-clockwise): changing a parameter at a time in sequence.

Press the encoder to go back to display time TRENDS.

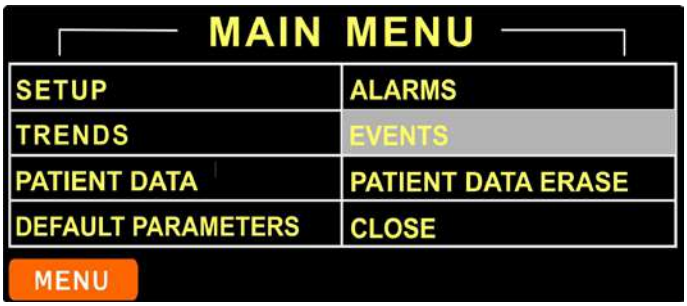


Rotate and/or press the encoder to pass from display time TRENDS to the selection of parameters to be displayed.

To escape and return back to initial view, press the **STAND BY / ON-OFF** key.

5.9.4 Main Menu – EVENTS

- Rotate the encoder to select the desired item of MAIN MENU area [e.g. **EVENTS**].
- Press the encoder to display the page of desired item of MAIN MENU [e.g. **EVENTS**].



The system through the **EVENTS** modality allows to the user to monitor the history on the operation of ventilator also including the alarm conditions activated during the patient ventilation. The EVENT indication is divided into:

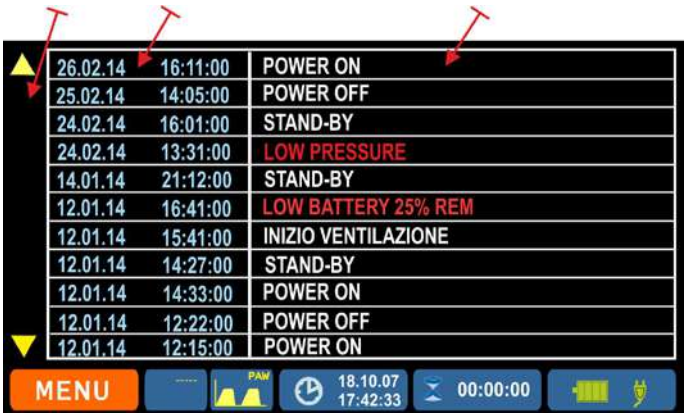
- **Time area** : date [26.02.14] and hour [16.11.00]
- **Description area** :
  - **Event text in WHITE**: information on ventilator operating state
  - **Event text in RED** : information of activated alarm

The capacity of events storage is of 72 hours.

The EVENTS displaying includes:

The main parts featuring the events overview are:

- an arrow indicates the time movement
- a column indicating event date and hour
- a column indicating the event description (white - red)



Displaying the EVENTS

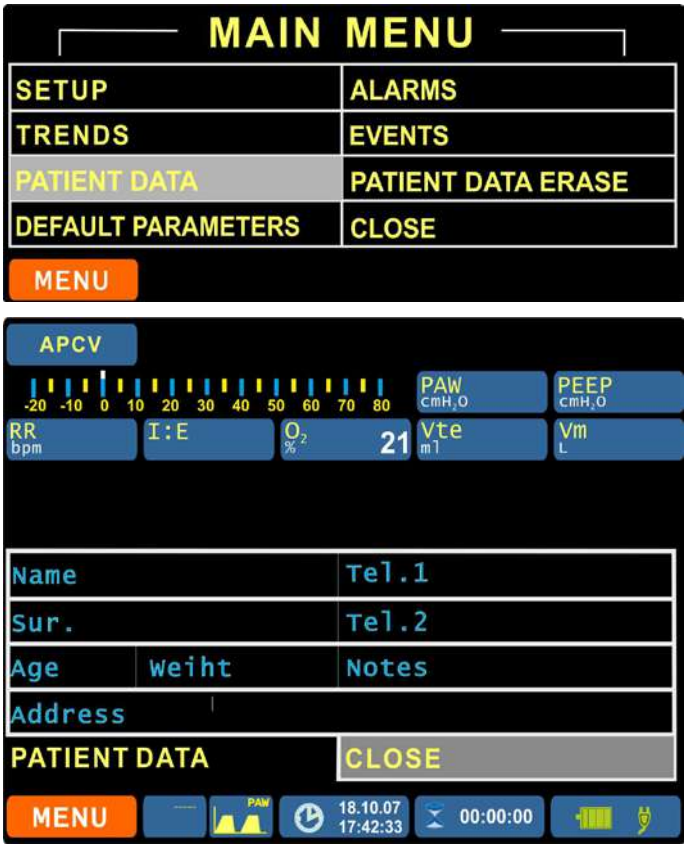
Turn the encoder clockwise (counter-clockwise): the temporary displaying of the EVENTS can be modified

The possibility to display the other available parameters is evidenced by yellow arrows appearing alongside the parameters value.

To escape and return back to initial view, press the **STAND BY / ON-OFF** key.

5.9.5 Main Menu – PATIENT DATA

- Rotate the encoder to select the desired item of MAIN MENU area [e.g. **PATIENT DATA**].
- Press the encoder to display the page of desired item of MAIN MENU [e.g. **PATIENT DATA**].



For **NOT** loading patient data and go back to the first page:

- press the **STAND BY / ON-OFF** soft key
- or, select **QUIT** and press the encoder.

How to load the PATIENT DATA (e.g. Name)

Name

Rotate the encoder to activate the **Name** box to fill in.

Name

Press the encoder to activate the script in the **Name** box to fill in.

Name S

Rotate to select the first letter of the name to be written.

Name S

Press to confirm and continue to complete the name insertion.

- In the logic of characters to be displayed, small letters come after capital letters.
- Proceed as previously described in the page for the filling of all **PATIENT DATA**.

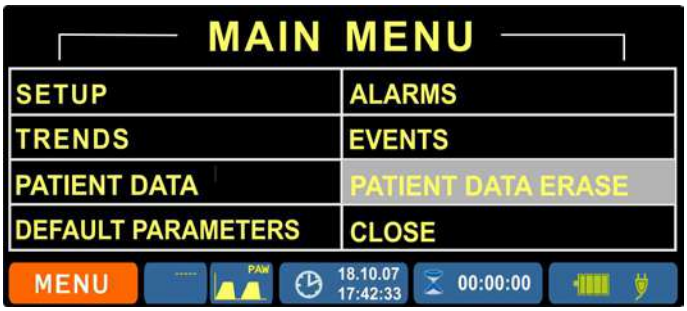
In case of mistake in the digits of patient data, press the STAND BY soft key and then the encoder knob.

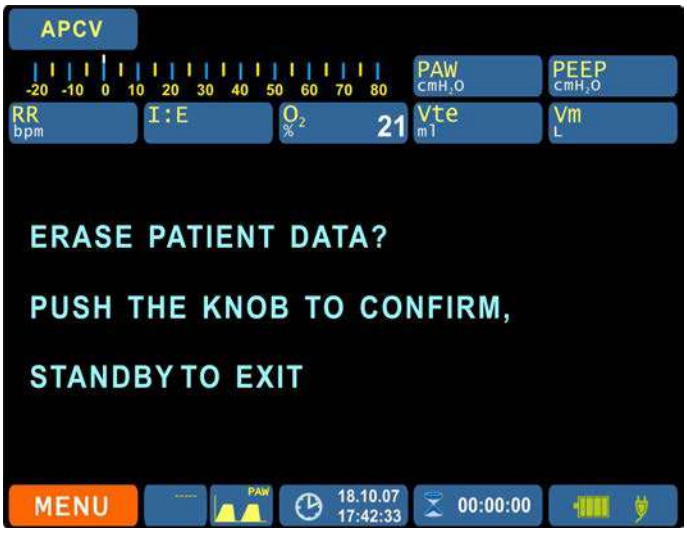
Name Siare

Press STAND BY to proceed to fill in the next box.

5.9.6 Main Menu – PATIENT DATA ERASE

- Rotate the encoder to select the desired item of MAIN MENU area [e.g. **PATIENT DATA ERASE**].
- Press the encoder to display the page of desired item of MAIN MENU [e.g. **PATIENT DATA ERASE**].





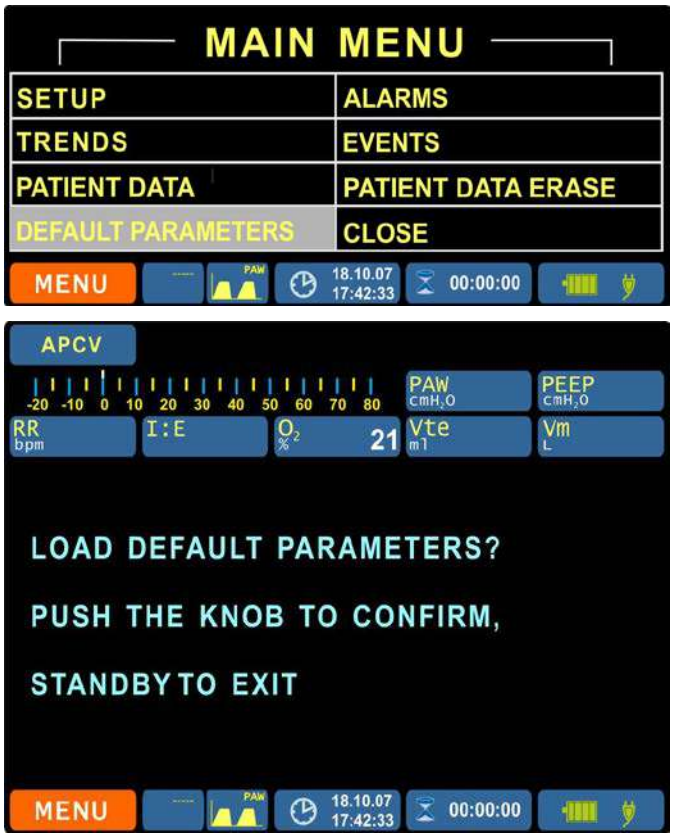
Follow the instructions on the display of the lung ventilator

Press the encoder to confirm the **ERASE PATIENT DATA, the MAIN MENU** is displayed

Press directly the **STAND BY / ON-OFF** soft key to exit and **NOT** CANC. PATIENT DATA.

5.9.7 Main Menu – DEFAULT PARAMETERS

- Rotate the encoder to select the desired item of MAIN MENU area [e.g. **DEFAULT PARAMETERS**].
- Press the encoder to display the page of desired item of MAIN MENU [e.g. **DEFAULT PARAMETERS**].



Follow the instructions on the display of the lung ventilator

Press the encoder to **LOAD DEFAULT PARAMETERS, the MAIN MENU** is displayed

Press directly the **STAND BY / ON-OFF** soft key to exit and **NOT** load the **DEFAULT PARAMETERS**.

WARNING! Risk of injury for the patient.

The load of the DEFAULT PARAMETERS **does not enable** the MORPHEUS TURBINE driven.

5.10 Ventilation parameters setting area (G)

WARNING! Risk of injury for the patient.

- According to the preferred mode of ventilation, the same respiratory physiological parameter (**PRF**) can be a dependent variable (i.e. variable as a result of changing other parameters) or independent (i.e. quantity whose change is to change values of other parameters).
- The **PRF** can be adjusted also during lung ventilator operation, adapting them to the patient clinical conditions.

The respiratory physiological parameters can be set **manually in STAND-BY** before activating any operative mode.

The system allows to set the default respiratory physiological parameters in (MAIN MENU – DEFAULT PARAMETERS) suitable for the ventilation of an adult patient.

In the picture the displayed parameters are referred to the APCV-TV operative mode and have the mere purpose of being an example and they do not make any reference to real clinical cases.

APCV-TV Operative Mode

- Press and rotate the encoder to select the parameter to be modified [e.g. **Vte**].

- Press the encoder to modify the parameter [**Vte**].
- Rotate clockwise (counter-clockwise) to increase (decrease) the parameter value [**Vte**].

- Press the encoder to confirm the value.

- Press and rotate the encoder to select the parameter to be modified.

- Press the **STAND BY / ON-OFF** soft key to exit from the parameters setting area.

5.10.1 Operative modes and relevant ventilation parameters

APCV

Set the max limit value of airways pressure. The parameter it is used in the pressure control modalities and it is to fix an operative limit on airways pressure which should not be overcome.

Set the airways positive pressure value in expiratory phase.

Set the ventilator respiratory rate.

Set the relation between inspiratory and expiratory phases.

Set the flow value during the inspiratory phase.

Set the flow level (pressure) to recognize the patient spontaneous activity. (L/min) - (cmH_2O).

APCV - TV

Set the desired value of tidal volume to be guaranteed to the patient.

Maximum limit of airways pressure, beyond which the PLIM parameter cannot go.

Set the airways positive pressure value in expiratory phase.

Set the ventilator respiratory rate.

Set the relation between inspiratory and expiratory phases.

Set the flow level (pressure) to recognize the patient spontaneous activity. (L/min) - (cmH2O).

PSV

Set the airways positive pressures support value in inspiratory phase.

Set the airways positive pressure value in expiratory phase.

Set the time establishing the minimum duration of inspiratory period. Therefore, in case the inspiratory phase has a duration lower than such set value, the patient will be forced to remain in inspiratory phase for such time.

Set the back-up respiratory rate used when the apnoea condition occurs to activate a ventilation mode controlled by the unit.

Set the flow level (pressure) to recognize the patient spontaneous activity. (L/min) - (cmH2O).

Set the expiratory flow percentage respect to the max peak of the inspirited flow when the inspiration stops.

Set the flow value during the inspiratory phase.

Set the time establishing the duration of the inspiratory period of the ventilator. It is possible to set values in function of RR parameter set.

VC/VAC

Set the value of guaranteed tidal volume at each breathing act.

Set the ventilator respiratory rate.

Set the relation between inspiratory and expiratory phases.

Set the flow level (pressure) to recognize the patient spontaneous activity. (L/min) - (cmH2O).

Set the airways positive pressure value in expiratory phase.

Set the duration of the inspiratory pause. The duration is shown on display in % (% of inspiratory time). Furthermore, it s used for calculation of parameters of pulmonary mechanic (resistance and static compliance).

Set the desired value of tidal volume to be guaranteed to the patient.

Maximum limit of airways pressure, beyond which the PLIM parameter cannot go.

Set the airways positive pressure value in expiratory phase.

Set the ventilator respiratory rate.

Set the relation between inspiratory and expiratory phases.

Set the flow level (pressure) to recognize the patient spontaneous activity. (L/min) - (cmH_2O).

SIMV

Set the value of guaranteed tidal volume at each breathing act.

Set the value of forced respiratory rate in SIMV mode.

Set the time establishing the duration of the inspiratory period of ventilator.

Set the flow level (pressure) to recognize the patient spontaneous activity. (L/min) - (cmH_2O).

Set the expiratory flow percentage respect to the max peak of the inspirited flow when the inspiration stops.

Set the airways positive pressures support value in inspiratory phase.

Set the flow value during the inspiratory phase.

Set the airways positive pressure value in expiratory phase.

MAN

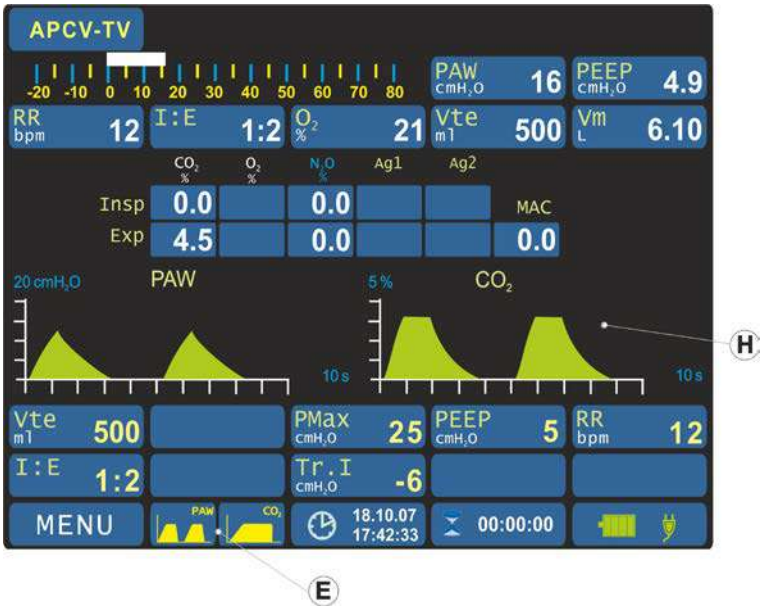
For further information on the logic and how setting the ventilation parameters, make reference to the relevant paragraph.

5.11 Graphics displaying area (H - E)

The system allows displaying and selecting:

- the type and the number (max. 2) of graphics available **(Graphics setting area**)
- the type of graphic (**SETUP** - **GRAPHIC: Line / Square**)
- the number and consequently the relevant dimension (**GRAPHICS VISUALIZATION: Single / Double**)

- Press and rotate the encoder knob to select the **Graphic displaying Area (E)**
- Press and rotate the encoder knob to select the graphic to be displayed.



The graphics displayed are defined by the **Graphic Setting Area (E)** used to set the type and no of graphics (1 or 2 or none)

The selected graphics are shown respectively on the L or R side in the graphics displaying area and gas monitoring (H).

At the paragraph “Graphics setting area” (cfr. 5.8) there are listed the types of graphics/parameters available and how to display them.

- No displaying enable, PAW, FLOW, Vte, CO_2, N_2O, O_2, HAL, ENF, ISO, SEV, DEV, Vt / PAW, F / Vt, RP1
- Further available parameters.

GRAPHIC displaying: Line / Square (H)

The **MENU - SETUP - GRAPHIC** function allows to the user to select the type of graphic.

Line: the line of graphics is traced without filling

Square: the line of graphics is solid

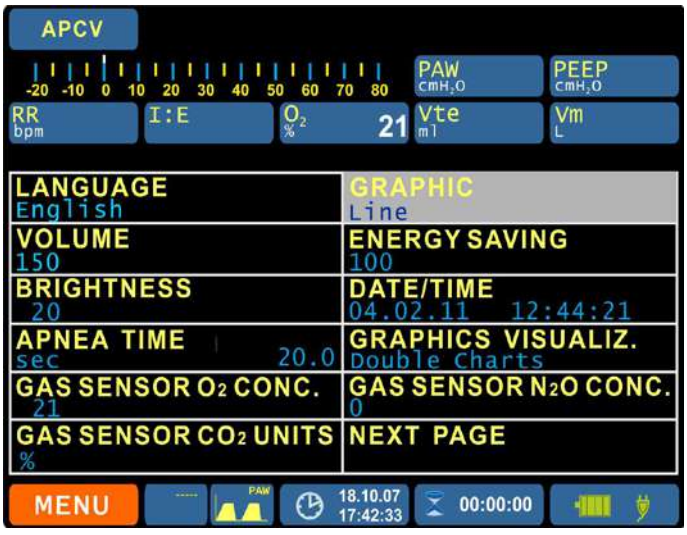
Press the encoder “twice” to display the “**MAIN MENU**” page.

Press the encoder to display the “SETUP” page.

Rotate the encoder to select the desired item of SETUP Square [**e.g. GRAPHIC**].

Press the encoder to modify the parameter value.

Rotate clockwise (counter-clockwise) to modify the parameter value; press the encoder to confirm the value.



GRAPHICS VISUALIZATION : Single / Double

The **MENU - SETUP - GRAPHIC VISUALIZ.** function allows the operator displaying, two graphics in spite of one, a larger type of graphic: Single or Double graphics.

Single Charts: it is displayed a unique graphic, larger dimensions.

Double Charts: two graphics are displayed.

Press the encoder “twice” to display the “**MAIN MENU**” page.

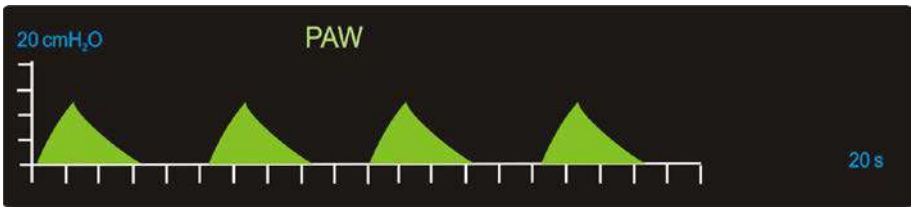
Press the encoder to display the “**SETUP**” page.

Rotate the encoder to select the desired item of SETUP Square [**e.g. GRAPHICS VISUALIZ.**].

Press the encoder to modify the parameter value.

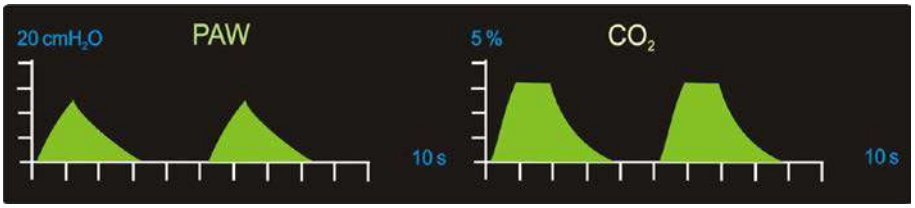
Rotate clockwise (counter-clockwise) to modify the parameter value; press the encoder to confirm the value.

Single charts visualization

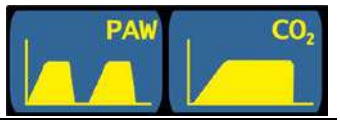


"Graphics displaying area" **E** allows the operator to select and displaying one graphic only.

Double charts visualization



"Graphics displaying area" **E** allows the operator to select and displaying two graphics.



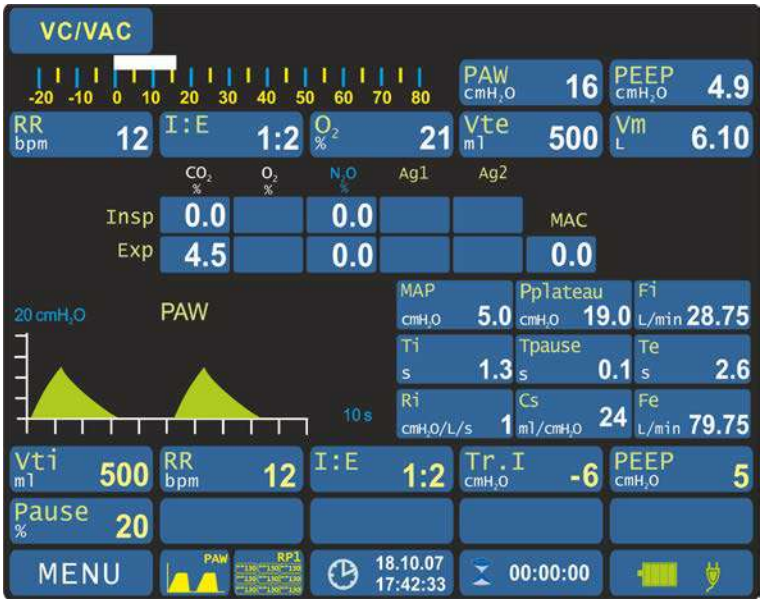
At the paragraph 'Graphics setting area' (5.8) the graphics than can be displayed are shown.

To return to the initial page :

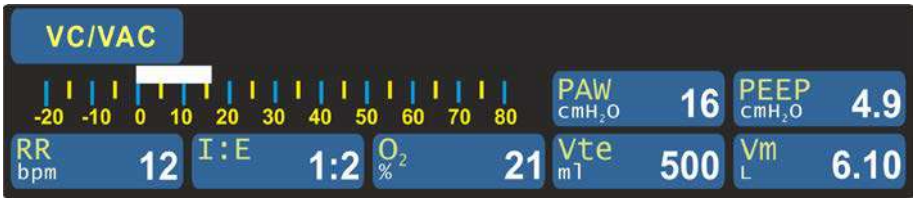
- select the item **NEXT PAGE - CLOSE** and press the encoder

- or, press directly the **STAND BY / ON-OFF** soft key

5.12 Ventilation parameters monitoring area



5.12.1 Respiratory parameters monitoring



	*Airways pressure*	The led bar indicator (with scale from -20 to + 80 cmH_2O) displayed in real-time the airways pressure.
	*Positive expiratory airways pressure*	Indicates the end expiration positive pressure value.
	*Respiratory rate*	It indicates the real respiratory rate value considering, in the calculation, also the eventual spontaneous activity.
	*Inspiratory : Expiratory ratio*	It indicates the relation between inspiratory and expiratory time.

FiO2

It indicates the value of O_2 concentration inspired by the patient.

Tidal expired volume

It indicates the value of tidal volume during the patient inspiratory phase.

Minute volume

It indicates the value of minute volume expired by the patient.

5.12.2 GAS parameters monitoring

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

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.

CO_2 Percentages of **CO_2** measured in Insp and Exp phases.

O_2 Percentages of **O_2** measured in Insp and Exp phases.

N_2O Percentages of **N_2O** 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.

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

See relevant User's Manual.

5.12.3 ADDITIONAL parameters monitoring

This graphic configuration is active in **H** area and it is used to monitor additional respiratory parameters (concerning the displaying procedure please refer to the previous paragraph).

Mean airways pressure

It indicates the mean airways pressure: the measurement unit is cmH_2O.

Pause pressure

It indicates the pause pressure: the measurement unit is cmH_2O.

When the inspiratory pause is enabled, the ventilator maintains a constant airways pressure (i.e. it maintains a pause pressure) for a fraction of the inspiratory time defined by the user (INSP PAUSE %).

The stationary conditions allow the ventilator to calculate the parameters of the respiratory mechanics.

Inspiratory time

It indicates the duration of the patient's inspiratory time: the measurement unit is seconds.

This value represents the total inspiratory time and also includes the inspiratory pause time if enabled.

The value depends on the breathing rate parameters and the I:E ratio (except in the SIMV operative mode).

Example: setting **RATE = 15 and I:E=1:1** gives an **inspiratory time of 2** seconds.

Inspiratory pause

It indicates the duration of the patient's inspiratory pause: the measurement unit is seconds.

This measurement represents the inspiratory time during which the ventilator maintains a constant airways pressure.

Example: setting **RATE=15, I:E=1:1, Ppause=50%** gives an **inspiratory pause time of 1** second.

Expiratory time

It indicates the duration of the patient's expiratory time: the measurement unit is seconds.

This parameter defines expiratory time duration. The value depends on the breathing rate parameters and the I:E ratio.

Example: setting **RATE = 15 and I:E=1:1** gives an **expiratory time of 2** seconds.

Inspiratory peak flow

The flow sensors on the inspiratory line can also measure the maximum value of the inspiratory flow (measured in l/min) and display it on the screen.

There are no alarm limits for this value but it can be used to obtain information on ventilation status.

Expiratory peak flow

The flow sensor on the expiratory line can also measure the expiratory peak flow.

When the expiratory valve opens at the start of expiration, there is a peak in the flow which depends on lung resistance and compliance.

Like the previous measurement, this is not linked to particular alarm thresholds but provides information on ventilation status.

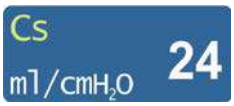
Inspiratory resistance

This is the parameter of lung mechanics that describes the resistance to the flow opposed by the airways: it is measured in $cmH_2O/(l/s)$.

The higher the patient's resistance, the higher the pressure that must be applied to the airways to achieve the same volume.

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

Ri = (peak pressure - pause pressure) / inspiratory flow.



Static compliance

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

It allows an estimation of lung elasticity: the higher the compliance, the greater the "elasticity" of the lungs; the lower the compliance, the greater the "rigidity" of the lungs.

Static compliance is measured with the following algorithm:

CS = Inspired tidal volume / pause pressure

For further information on the logic and how monitoring the ventilation parameters, make reference to the chapter 7.

WARNING! Risk of injury for the patient.

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

5.13 Calibration programs (service area)

WARNING! Risk of injury for the patient / operator.

- This chapter is specifically intended for specialist SIARE personnel or qualified technical personnel, formally authorised by SIARE to work on MORPHEUS series equipment.
- SIARE disclaims all liability with regard to technical interventions carried out on equipment without formal authorisation from SIARE.
- The procedures described are critical operations and must be performed by authorised personnel only as they may affect the safety and correct operation of the unit.

The specialist SIARE personnel or qualified technical personnel, formally authorised by SIARE, must be aware of the full contents of this manual before carrying out the operations described below.

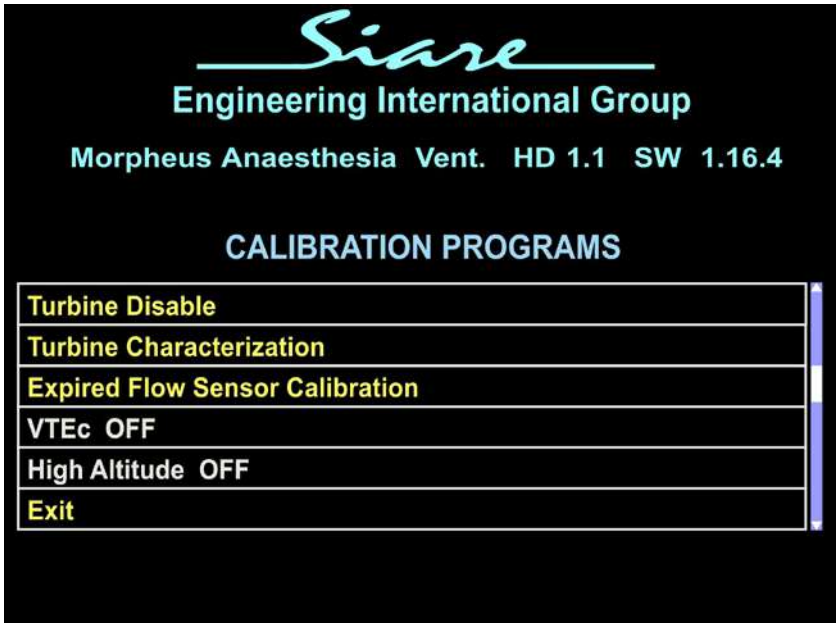
Authorised SIARE technicians have the appropriate tools and spare parts and are trained to operate while ensuring product safety.

WARNING! Risk of injury for the patient.

- All the pictures and the examples shown in the present chapter have the mere purpose of being an example and they do not make any reference to real clinical cases.
- To make the anaesthesia unit Morpheus work, refer to Chapters 6 and 7 for the relevant use.

5.13.1 Introduction

The lung ventilator (from SW version 1.16.4) foresees an area where some programs useful for the calibration of the equipment are available.



WARNING! Risk of injury for the patient / operator

The different colour of the string identifying the program indicates if the same is ENABLED or NOT (e.g. VTEc OFF).

5.13.2 Encoder knob

The encoder knob is the tool for enabling or disabling the calibration programs.

.

- Turn the encoder knob to select the string of the program to be enabled (disabled(); the enabled string is highlighted.
- Press the encoder knob to enable (disable) the program desired.
- Once the program has been enabled (or disabled), follow the instructions appearing on the display.

If the operator or the service engineer authorized does not enable or disable any calibration program, after few seconds, the system automatically turns into the ‘SELF TEST’ phase (see cfr. 5.1)

5.13.3 Disable/ Enable turbine (not available)

With such a configuration, the Anaesthesia unit Morpheus works turbine driven.

The activation (desactivation) of the function **Disable Turbine** determines the type of functioning foreseen on the anaesthesia unit.

With such a configuration, the Anaesthesia unit Morpheus is activated by medical gas (both functions Turbine and Turbine characterization are disabled)

In case the DEFAULT PARAMETERS have been re-configured in SETUP, the enabling of the TURBINE function could be necessary.

In this specific case, the system foresees as a DEFAULT configuration the operating by medical gases.

5.13.4 Turbine characterization (not available)

For the activation of the **Turbine Characterization** programs, it's recommended this operation to be performed by qualified personnel formally authorized by SIARE to intervene on the MORPHEUS line equipments.

5.13.5 Expired flow sensor calibration

The activation of the **Expiratory Flow Sensor Calibration** is needed when differences higher than 15% (over 100 ml) between the configured Volume (VTi – Vte) and expired Tidal volume (Vte) are detected.

In case it's the first calibration of the ventilator, it's recommended to effect this calibration after having checked both the calibration of the PEEP and of the APL and the verification of possible leaks (TEST ON DEMAND).

5.13.6 VTEc OFF

The activation of the function **VTEc (VTEc ON**) is useful to optimize the Vte calculation displayed during the functioning of the anaesthesia machine.

5.13.7 High Altitude

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

5.13.8 Exit

The selection of the string '**Exit**' allows the operator to quit the CALIBRATION PROGRAMS.

If the operator or the engineer authorized does not activate or disable any calibration program, after few seconds, the system automatically turns into the 'SELF TEST' phase (see cfr 5.1)

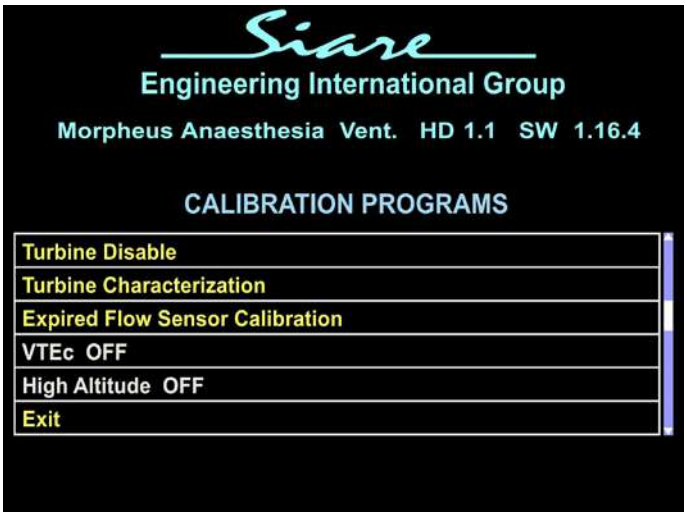
5.13.9 CALIBRATION PROGRAMS activation

To enable the CALIBRATION PROGRAM displaying the anaesthesia unit Morpheus must be correctly connected and work.

- Prepared for the use (cfr.: Maintenance, Cleaning and Disinfection and Sterilization).
- Correctly positioned.
- All the accessories and devices for the functioning to be prepared.
- Power supply and gases properly connected.
- A patient simulator shall be connected to the patient circuit equipped with the machine.

Anaesthesia unit Morpheus powered (ventilator switched off).

- Press at the same time the buttons : STAND BY and ALARM RESET.
- After few seconds, the anaesthesia unit Morpheus switches on and displays an area where the programs needed for the calibration are available.



See Service Manual for further details and instructions on the use of CALIBRATION PROGRAMS.

6 PREPARATION TO USE

In the first part of this chapter it is illustrated how to install the MORPHEUS anaesthesia unit.

In the second part it is illustrated how to perform the preliminary tests before using the MORPHEUS anaesthesia unit.

WARNING! Risk of injury for the user / patient

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

6.1 General warnings

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 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 shelves 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.
- Pay much warning to eventual obstacles in the path during moving and positioning phases.

WARNING! Accidental moving danger

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

- Position correctly the anaesthesia unit on a flat surface.
- Apply the 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.

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.

6.2 Before the use

6.2.1 Assembling of O2 cell

- Insert and screw the cell: in the space marked with the script "O_2 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 of injury for the patient

Check of electric connection of O_2 cell.

At each anaesthesia unit start-up, the system checks the presence of the electric connection to the O_2 cell ("SELF TEST" phase: cfr. 6.4.1 or cfr. 7).

6.2.2 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 CO2 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 CO2 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) phase it is NOT necessary that the CO_2 absorber canister is mounted on the valves group.

WARNING. Risk of injury for the patient

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:

- Reduced absorption of CO_2,
- Increased heat generation in the soda lime and then increased temperature of inhalation gases,
- Formation of CO,
- Absorption and/or decomposition of anesthetic gas for inhalation.

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.

6.2.3 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 ventilation parameters), in case of power failure.
- The switching to battery operation is made automatically: on the ventilator screen appears the relevant message “Power failure”.
- The anaesthesia unit battery can be recharged by connecting the equipment to main power supply (using power cable supplied with the unit) and placing the main switch in " **I** " position.

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.

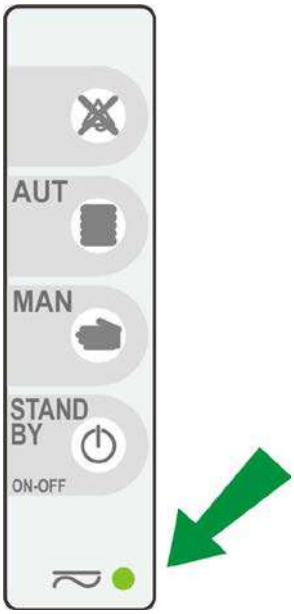
Follow the instructions.

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

The electric main power supply must correspond to the one indicated in the identification label on the back side of the machine.

- Turn the main switch (located on the back side of the unit) in position “I”.

- Verify on the front module of ventilator (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.

6.3 Preparation to use

6.3.1 Medical gas connection

- The compressed air must be of medical type, therefore oil free and filtered.
- The equipment can also work with oxygen supply only, but in this case the FiO_2 will be adjustable at 99% only.

Screw the gas supply hoses (O_2, AIR, N_2O) to relevant connectors of the gas supply group.

Screw the gas supply hoses (O_2, AIR, N_2O) to the relevant connectors of the hospital distribution system (O_2, AIR, N_2O).

Ensure that all the supply hoses are connected and are correctly working.

The O_2, N_2O, AIR 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 (O_2, N_2O, AIR) 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 anesthesia machine 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.

WARNING! Risk of power failure.

If all the gas supply hoses (from main system and cylinder)are not correctly connected, the system 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 illustrations in the back side of the equipment.

After having connected the supply hoses, verify that the system is correctly working.

6.3.2 Connection of medical gas supply from cylinders

Screw the gas supply hoses (O_2, N_2O) to the relevant connectors of the gas supply group. Screw the gas supply hoses (O_2, N_2O) to the relevant connectors of the cylinders pressure reducers (O_2, N_2O).

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 medical gas distribution system of the hospital, the gas cylinders of the anaesthesia unit will provide a reserve gas supply.

To avoid a complete gas power failure, the cylinders must always remain on the anaesthesia unit, with the pressure reducers closed (even if the anesthesia unit is connected to the medical gas distribution system of the hospital).

WARNING! Risk of gas power failure.

If all the pressure reducers are 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 cylinders pressure reducers in case the hospital medical gas distribution system is sufficient.

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.

6.3.3 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 machine (first connection or first replacement of hoses or connectors for maintenance reasons).

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, 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 N_2O 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 N_2O 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.

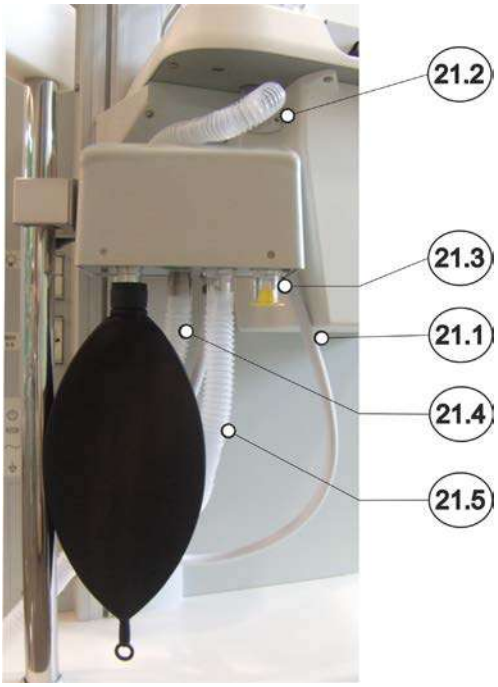
6.3.4 Connection of anesthetic gases scavenging system

Refer on the manual, relative to the scavenger manufactured by SIARE.

WARNING! Risk of injury for the patient.

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.



21.1 Gas supply connection for active gas scavenger

21.2 Morpheus / MRI : gas scavenging connector

21.3 Connection evacuation gas inlet from To and Fro circuit

Note. *In case the connection is not used, plug the connection*

21.4 Gas scavenging connector outlet to the pipeline system

21.5 Gas scavenging connector inlet from Morpheus/MRI

6.3.5 Patient circuit connections

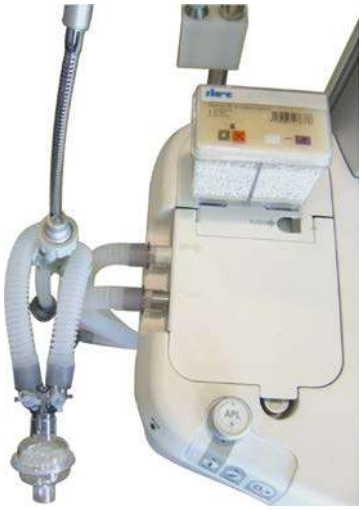
Insert the patient circuit supporting arm in the specific bracket, fixed to the full-height steel rod used for accessories mounting.

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*

Connect the supplied 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 of injury for the patient.

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 (Preliminary tests cfr. 6.4).

The system checks the patient circuit at every start-up of the unit: “SELF TEST” phase (Preliminary tests : cfr. 6.4 or cfr. 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.

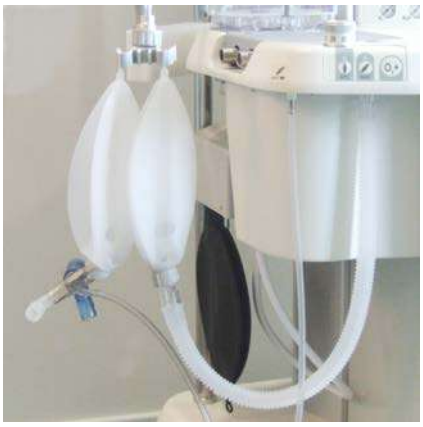
6.3.6 Fresh gases exit – TO and FRO patient circuit

WARNING! Risk of injury for the patient.

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 as shown in the picture.



MAN operative mode

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

6.3.7 Connection of circuit for manual ventilation

Apply to the anaesthesia unit the circuit for manual ventilation as shown in the picture.

MAN operative mode

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

6.3.8 Use of antibacterial filter

Apply the antibacterial filters to the patient circuit.

WARNING! Risk of injury for the patient.

Replace the antibacterial filters as per maintenance instructions (cfr. 10).

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.

6.3.9 Gas analyzer connection

Apply to the patient circuit the gas analysis modules at the connector for services (**24**) as shown in the picture.

- Extract the gas analyzer module, provided of the special cable, from package.
- By the supplied “interface cable”, connect the gas analyzer connector to the 9 poles connector positioned on the rear side of the anaesthesia unit.
- **IRMA:** apply the gas analyzer module, on the patient circuit Y connector.
- **ISA:** apply the sampling line on the patient circuit Y connector.

For futher information on operating logic of GAS SENSOR function,make reference to the relevant paragraph.

6.3.10 Mains 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 operator.

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 anaesthesia unit are of two types:

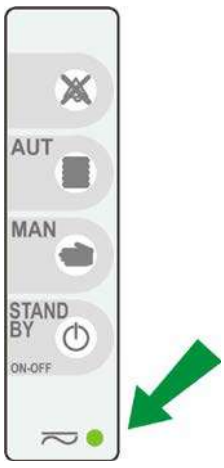
- by main power supply;
- by internal battery.

Connection to the mains power supply

The main electric power supply must correspond to that indicated on the identification label (electric power supply, frequency and power consumption) located on the back side of anaesthesia unit:

- 100 ÷ 240Vac / 47 ÷ 63Hz / 200W

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

WARNING! Risk of personal-physical injuries

To prevent the risk of electric shock, connect the power cable of the lung ventilator to an earthed socket.

The MORPHEUS anaesthesia unit complies with the requirements on electromedical equipment stated in the IEC/EN 60601-1-1 and IEC/EN 60601-1-2 directive.

To ensure correct functioning of the MORPHEUS anaesthesia unit, it is advisable that any equipment to which it is connected also complies with the regulations mentioned above.

Battery power supply

- The battery, inside the MORPHEUS 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 "; located on the ventilator front panel.

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

The operation time of the 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.

Battery charger (cfr. 6.2.3)

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 par. 6.2.3.

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.

6.3.11 Protection fuses

Protection fuses are foreseen in the following circuit:

- Main power supply
- Socket for auxiliary devices (max. 6 A)
- 12Vdc light led power supply
- 5Vdc power supply for valves group heating
- 12Vdc flowmeter box power supply
- 12Vdc ventilator power supply
- 12Vdc battery

WARNING! Risk of injury for the user / patient

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

In case of break of protection fuse:

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

WARNING! Risk of injury for the user / patient

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

6.3.12 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 of injury for the user / patient

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

6.3.13 Table of predisposition sequence for use

6.4 Preliminary tests – Introduction

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

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

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

The preliminary test's 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 (valves group, patient circuit, oxygen probe, etc…)

Before starting with anaesthesia unit MORPHEUS verify that:

- it has been prepared for use (cfr. Maintenance - Cleaning, disinfection and sterilisation).
- it has been correctly positioned.
- all accessories and deviced for correct operation have been predisposed.
- electric power and gas supplies have been connected.
- it is used a patient simulator fixed to the terminal of supplied patient circuit.

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

WARNING! Risk of explosion and/or fire

In case of suspected oxygen loss from anaesthesia unit or from other neareby, do not start using the unit.

Close all the oxygen supplies and contact the nearest Siare Service Center.

Risk of accidental movement.

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

Apply the anaesthesia unit brakes to prevent accidentally movements (front side of equipment).

WARNING! Risk of injury for the user / patient.

Other setting functionalities are activated through user's controls, but only for default parameters in service procedures.

All maintenance and/or repair operations require perfect knowledge of the equipment and must therefore be carried out by highly qualified personnel, specifically trained and formally authorised by SIARE only.

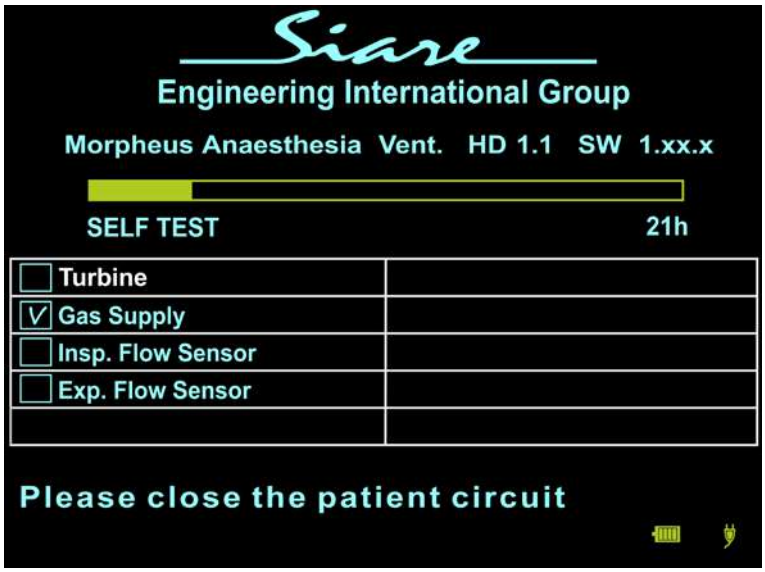
6.4.1 Verification activity - " SELF TEST "

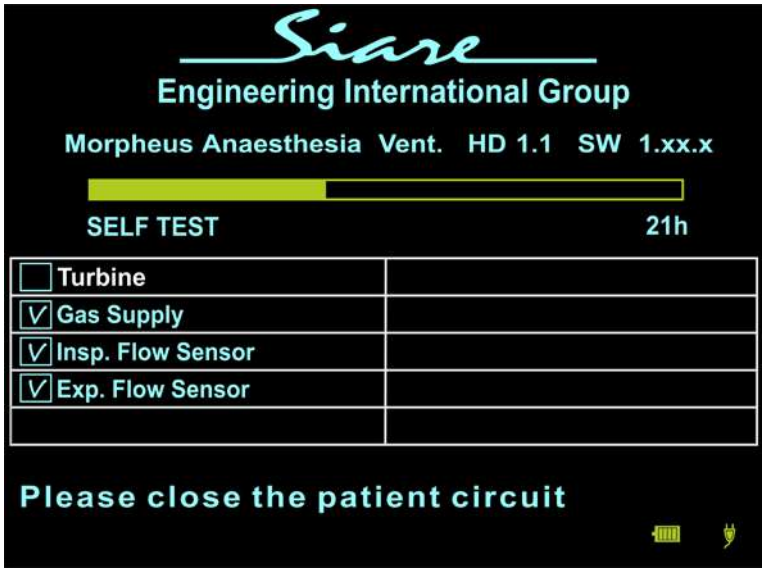
- Place the main power switch in position I (ON) ; anaesthesia unit power on.
- On the ventilator front panel, verify the electric power supply led; green led on.

- Keep **STANDBY / ON-OFF** Soft key pressed for a few seconds to turn the ventilator module on.

The automatic " SELF TEST " phase begins.

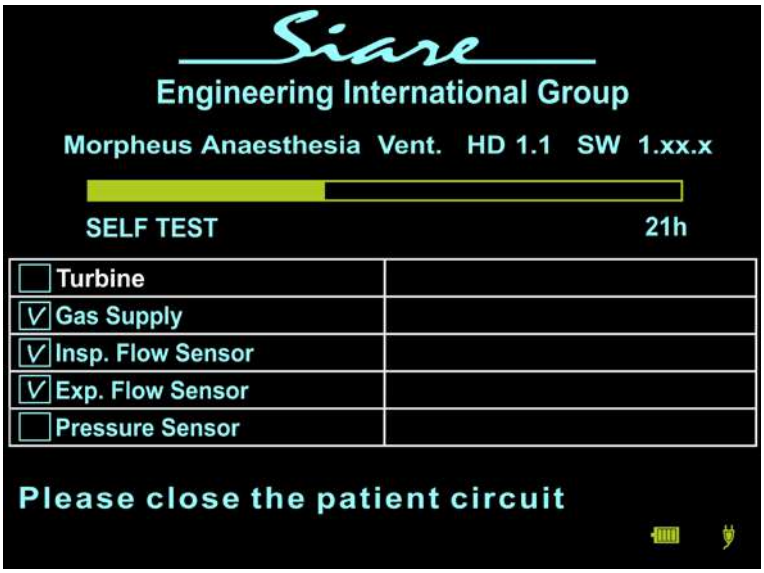
Checking of Morpheus operation.





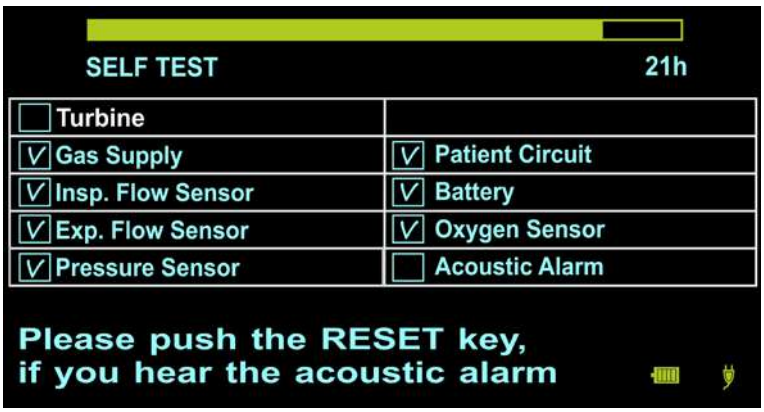
Follow the instructions for the checking of flow sensors and pressure

- In order to carry out the " SELF TEST " correctly, close or plug the Y-shaped coupling of the patient circuit, as requested on the display screen.



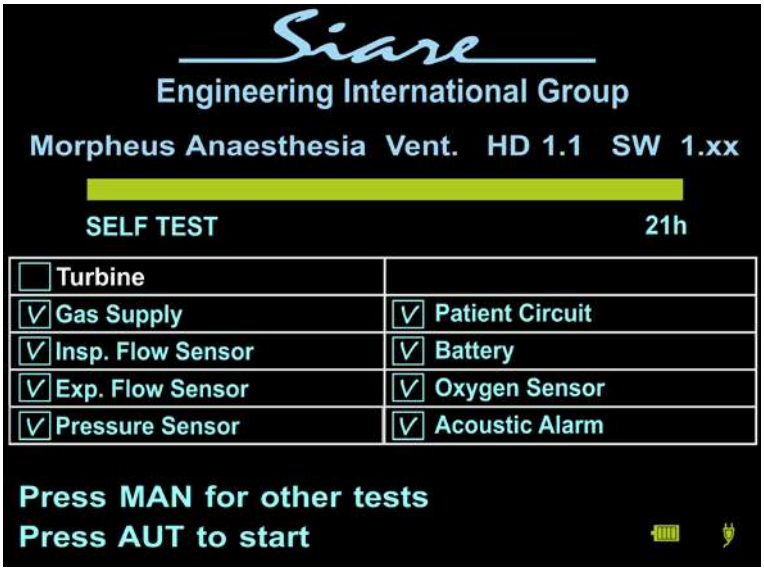
The 'SELF TEST' phase continues

Displaying at the end of the first ‘SELF TEST’ phase.



Checking of the Acoustic alarm functioning

- In **PRESENCE** of acoustic alarm, press Alarm Reset (see the picture below)
- In **ABSENCE** of acoustic alarm, do not press Alarm Reset (on the display an error message appears ‘Press AUT for starting’ (see picture at the following page)



“ SELF TEST “ completed.

- Press the **MAN** key to enter in TEST ON DEMAND (see cfr. 6)
- Press the **AUT** key to enter the ventilator display in STAND-BY mode.

Press the **MAN** key to enter in TEST ON DEMAND

Pressing the button **MAN,** allows the access to a screen where it's possible to enable some supplementary tests.

See paragraph **Preliminary tests - TEST ON DEMAND**" (cfr. 6.5) for the instructions on the test procedure.

Press the **AUT** key to enter the ventilator display in STAND-BY mode

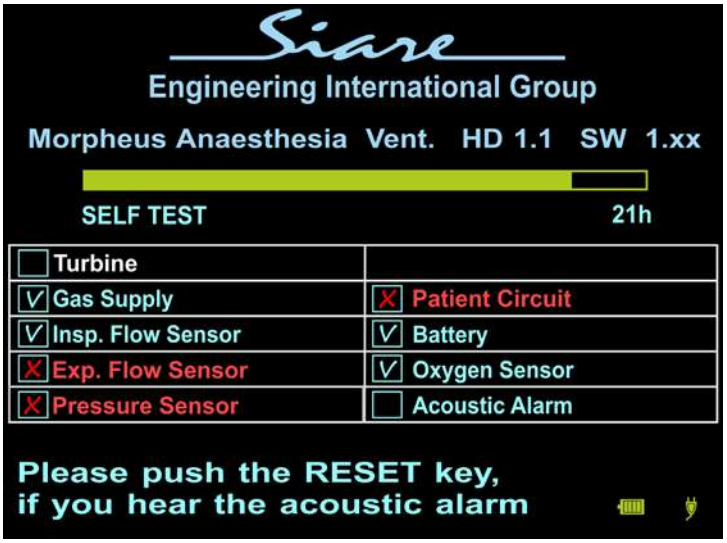
STAND-BY is the state condition of the lung ventilator at start-up of patient ventilation, or before turning off.

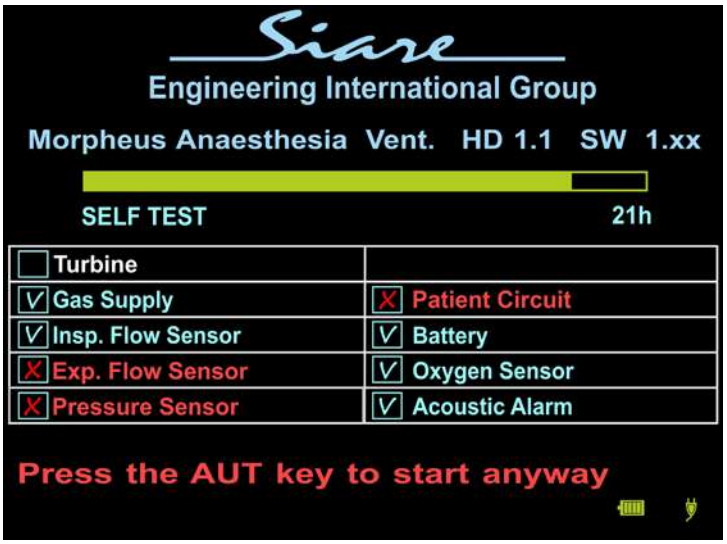
For further information, see cfr. 7.4 '**Operative modes'**

6.4.2 “ SELF TEST “ not overcome

WARNING! Patient/clinician injury hazard.

The malfunctioning and the failure in some SELF TEST phases is highlighted by the system.





WARNING! Risk of injury for the patient.

Press the **AUT** soft key to enter the ventilator module display in **STAND-BY** mode.

Consult the chapters 8 and 9 to solve the problem.

If the malfunctioning is not solved, contact the nearest Siare Service Centre or authorized by Siare.

6.4.3 “ SELF TEST “ Verifications

During the ‘SELF TEST’ phase, the ventilator software performs the auto-diagnosis test and checks some devices necessary to the safe functioning of the Morpheus anaesthesia unit.

Turbine	Verification of SETUP – Turbine parameter (Enabled or Disabled).
Gas Supply	Verification of the presence of Air and O_2 supply pressure.
Insp. Flow Sensor	Verification of INSP flow sensor operation (with turbine option only).
Exp. Flow Sensor	Verification of EXP flow sensor operation.
Pressure Sensor	Verification of pressure sensor operation through control of PAW reading.
Patient Circuit	Verification of patient circuit connection through checking of pressure presence.
Battery	Checking on battery power.
Oxygen Sensor	Verification of O_2 cells connection in the valves group.
Acoustic Alarm	Verification by the user of acustic signal emission, the confirmation of the test is made by silencing of that alarm.

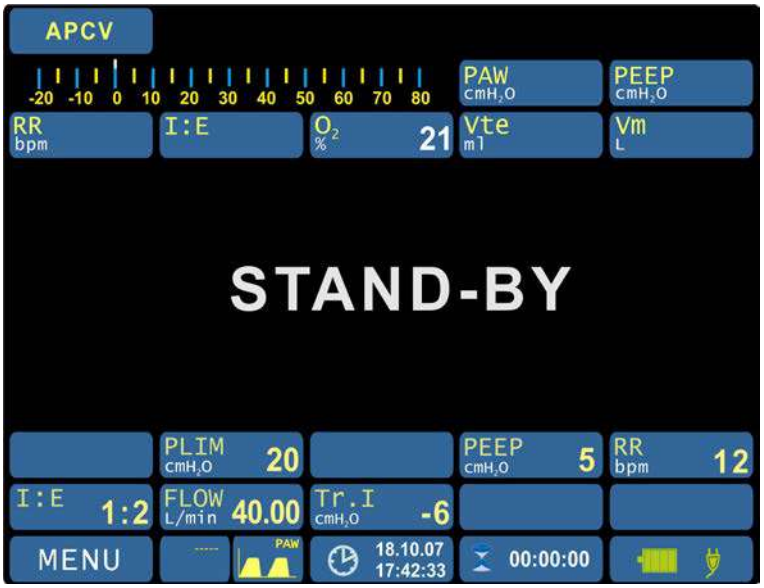
For a correct and deeper analysis of the problems arising from the “SELF TEST “ phase, consult the service manual.

If the “ SELF TEST “ phase is not overcome consult the chapters 8 (Alarms) and 9 (Troubleshooting) or contact the nearest Siare Service Centre or a center authorized by Siare.

6.4.4 STAND-BY displaying

STAND-BY : is the state condition of the lung ventilator at start-up of patient ventilation, or before turning off.

STAND-BY : Is possible to select the operative mode and/or modify all the ventilatory parameters relevant to the interested operative modality.



Rotate and /or press the encoder knob to select the operative mode box or ventilation parameter to be set and or/modify

Press the button AUT to start to ventilate a patient with an automatic operative mode.

Ventilator shitching off

For further information, see cfr. 5.2 '**Ventilator Switching off'**

6.5 Preliminary tests – Operating phase

The anaesthesia unit must be **ON**, in **STAND-BY** operative mode, once overcome the preliminary tests.

The preliminary tests aer divided in four categories:

1. **TEST ON DEMAND**
   - *O_2 Sensor Calibration*
   - *Leak Test*
   - *Gas Sensor: Zero Reference Calibration*
2. **Flowmeter module**
3. **Ventilator module**
   - Respiratory parameters
   - Spirometry
4. **Alarms**

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

A performance or cancellation of preliminary tests could determine a malfunctioning during the unit operation: pay much warning.

Unless in case of emergency situation, always follow all preliminary tests.

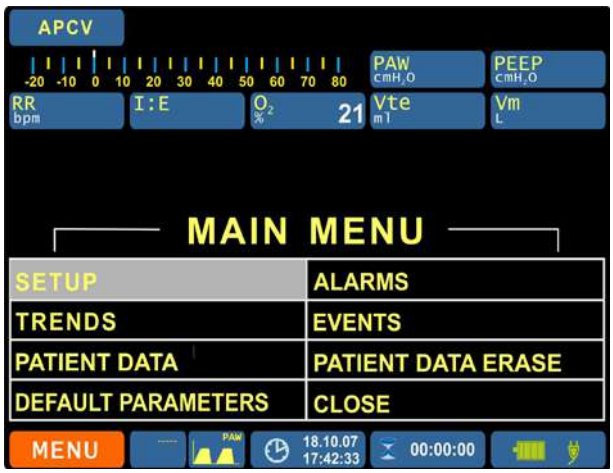
If the preliminary tests are not performed due to an emergency situation, they could be performed in the more complete way as soon as possible.

6.5.1 Preliminary checks - TEST ON DEMAND

The choice of the entries necessari for TESTS ON DEMAND activation is made, or at the end of “SELF TEST” or through the selection of MENU – MAIN MENU box.

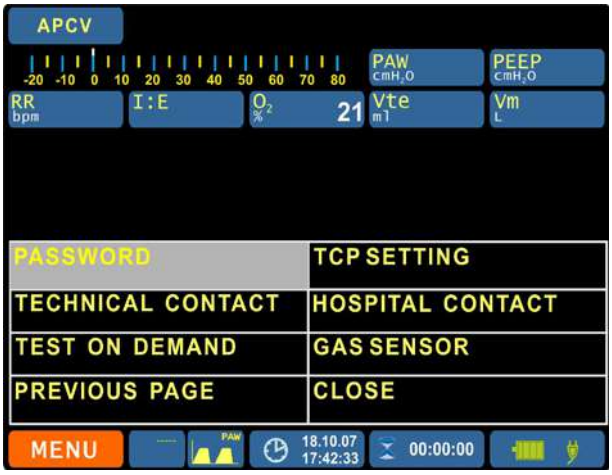
Press (turn) the encoder until activating the **MENU** box.

Press the encoder: the **MAIN MENU** view appears.



Turn (press) the encoder to select the **SETUP** entry: the first view appears.

Turn (press) the encoder to select the **NEXT PAGE** entry: the second view appears.



Turn (press) the encoder to select the entry: **TEST ON DEMAND.**

Selecting the “**TEST ON DEMAND**” box, you enter a view where it i possible to activate the functional tests.

O_2 SENSOR CALIBRATION

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

This test verifies the correct O_2 sensor operation.

WARNING! - Risk of injury to the patient.

Perform the O_2 sensor calibration test weekly.

- Select the **O_2 Sensor Calibration** entry.
- Press the encoder: the calibration of the oxygen cells mounted in the valves group is activated.

To determine the correct operation of O_2 cells, the system reads the electric value (mV) generated by the cell when immersed in a pure oxygen flow erogated during the test by the anaesthesia unit.

At the end of O_2 sensor calibration the display shows the message: **Test Completed (about 60mV)**

Test completed (60mV) indicates the correct value in tension of the O_2 sensor at 99% of oxygen.

For a correct calibration it is necessary that the O_2 sensor is:

- mounted on specific site;
- electrically connected by the specific cable;
- that the supply gas are correctly connected.

If one of these conditions have not been effected the calibration is not correct.

REPLACEMENT OF O2 SENSOR

The oxygen cell must be replaced when at the end of the calibration phase appears a reading power value other than **60mV** (indicatively - 20%) and/or in case of displayed alarm message.

For ordering the spare cells and for disposal of depleted ones consult the " Maintenance" chapter.

LEAK TEST

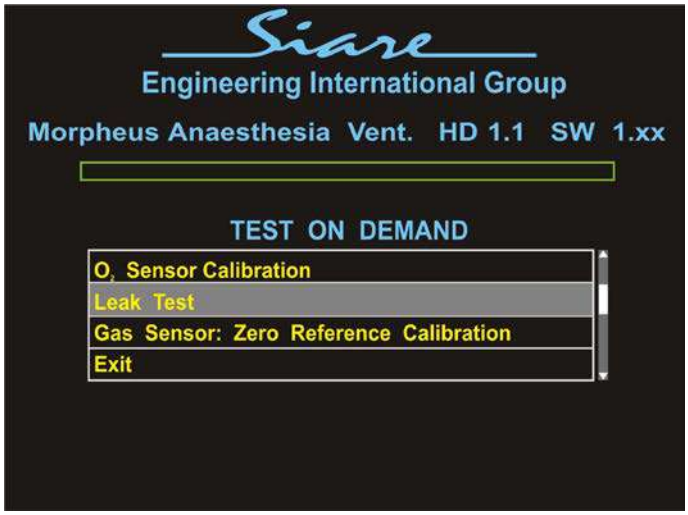
WARNING! - Risk of anaesthesia unit failure and/or injuries for the patient.

This test verifies that there are no leaks higher than 100 ml in the anaesthesia unit pneumatic circuits.

WARNING! - Risk of injury for the patient.

Perform the **Leak Test** weekly.

- Select the **Leak Test** entry.
- Press the encoder: the **Leak Test** is activated.

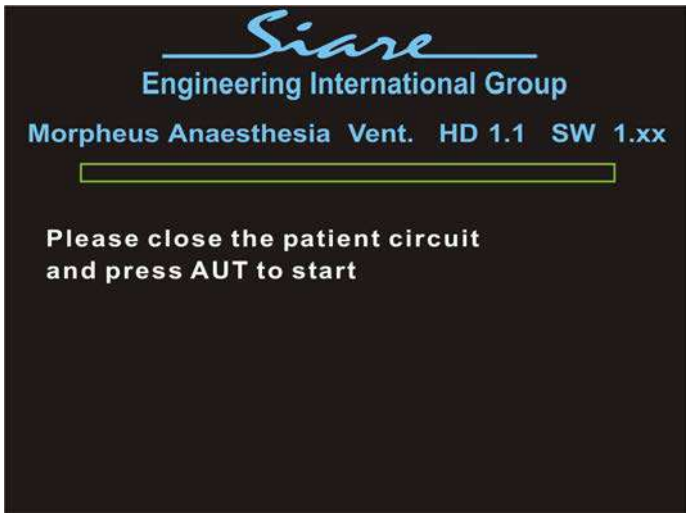


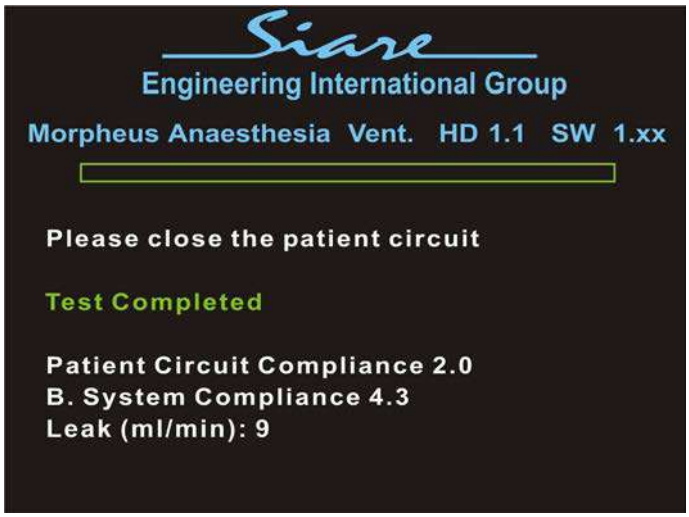
Before performing the Leak Test, ensure that:

- the gas flow regulators of flowmeter box are closed;
- the CO_2 absorber canister is not mounted on valves group;
- the supplied manual ventilation kit is not connected to the valves group connector.

Verified what listed in the previous note:

- close the patient circuit;
- press the AUT key located on the keypad of ventilator, as required on the display.





Basing on known and calculated data (flow, pressure and time), it is possible to find out the parameters shown on the display.

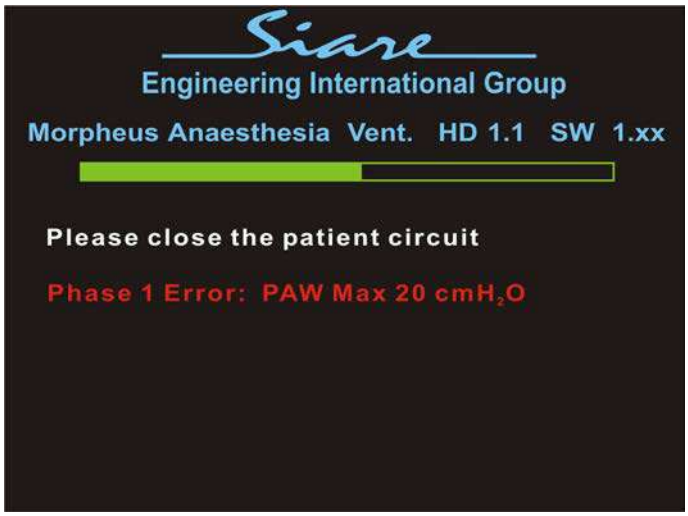
The values of the compliance obtained durino the LEAK TEST are displayed for the “compensation of dead space” function.

Range of values accepted by the LEAK TEST	**Min.**	**Max.**
Patient Circuit Compliance	*0,2*	*4*
B. System Compliance	*Standard value (4.3)*	
Leak (ml/min):	*0*	*100*

LEAK TEST not overcome

WARNING! - Risk of anaesthesia unit failure.

This test is not overcome when the pressure within the pneumatic circuit does not arrive to 30 cmH_2O.



If the " **TEST ON DEMAND** " phase is not overcome, consult the chapters 8 (Alarms) and 9 (Troubleshooting) or contact the nearest Siare Service Centre or authorized by Siare.

GAS SENSOR - ZERO CALIBRATION

WARNING – Risk of failure of anaesthesia unit and/or injury to the patient.

This **PROCEDURE,** to be used to perfom the zeroing of gas analyzer, **is ENABLED** only when a **GAS PROBE** is connected to the relevant connector positioned on the back side of the unit for anaesthesia.

It is possible to perform the Zero Calibration of the gas probes also by the controls: **MENU' – SETUP – FOLLOWING PAGE – GAS PROBE.**

Before performing the **Zero Calibration**, ensure that the electric connecting cable of the probe is correctly connected.

- **ISA sidestream probe :** before performing the **Zero Calibration**, consult instructions to relative User's Manual.
- **IRMA mainstream probe** : before performing the **Zero Calibration,** consult instructions to relative User's Manual.

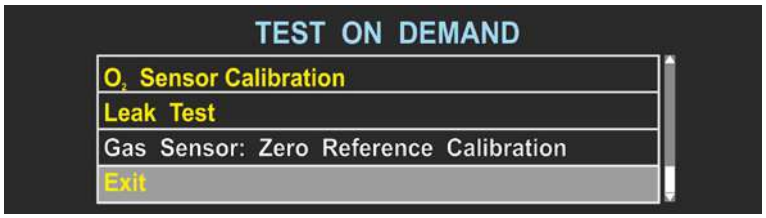
- Select the item, Gas Probe: Zero Calibration
- Press the encoder: the Gaz Probe zeroing procedure is activated.

The probe calibration procedure starts and takes a few seconds.

State indicator on the probe: the green flashing indicator signals that the probe zeroing is in progress.

If the calibration procedure cannot be activated (see picture here below) ensure that:

- the probe is correctly connected
- the state indicator on the probe, is a fix green light: the system is OK

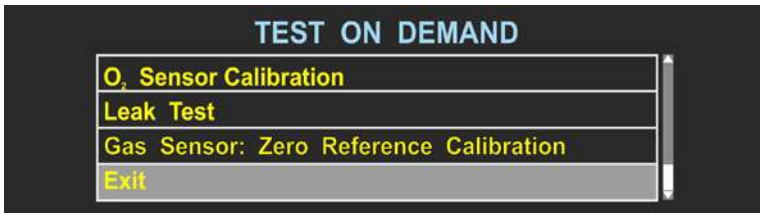


WARNING – Risk of failure to the anaesthesia unit and/or of patient injuries.

If the calibration procedure of gas probe is not overcome (Test Aborted): (Sidestream ISA gas probe) and cfr. 9 (Mainstream IRMA gas probe).

Exit to TEST ON DEMAND

Turn the encoder to select the entry:
EXIT.



Turn (press) the encoder until returning to the view of : **MAIN MENU / SETUP / STAND-BY.**

6.5.2 Preliminary checks – Flowmeter box

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

- Before using the anaesthesia unit on a patient it is necessary to perform a series of preliminary tests to verify the correct unit operation.
- The list of preliminary tests is available at the end of the present chapter.

The preliminary tests must be performed:

- every time that the anaesthesia unit is turned on and used
- every time that is effected a connection or an important component is replaced (e.g., valves group, patient circuit, oxygen cells)

- Supply the anaesthesia unit through the main switch (cfr. 6.3.10).
- Turn the ventilator on by the membrane key on front side of ventilator (cfr. 6.3.10).
- STAND-BY operative mode.

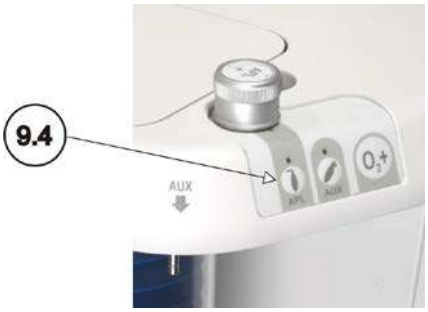
Flowmeter box

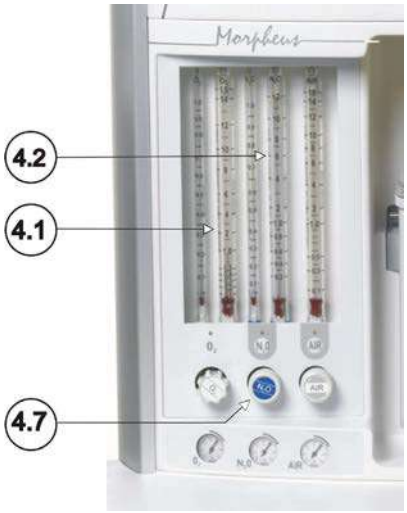
Manometers

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).

- Activate the enabling control (**9.4**) of valves group.

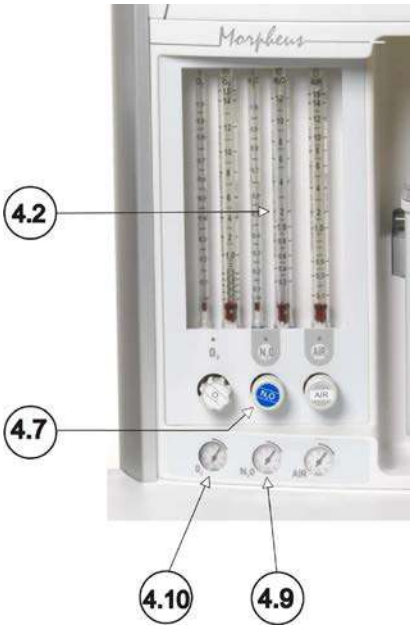




- Enable and open the N_2O (**4.7**) regulator at 6 l/min on the flowmeter (**4.2**).
- Verify that with O_2 reculator closet you read on flowmeter (**4.1**) a passage included between 1.5 and 3 l/min.

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

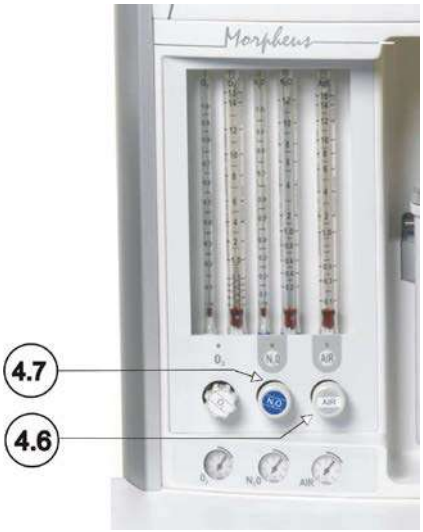
- Enable and open the N_2O regulator (**4.7**) at around 2 l/min on flowmeter (**4.2**).
- Close the O_2 supply from distribution system.
- The O_2 pressure on manometer (**4.10**) must fall to zero and after a few seconds iN_2O must automatically close and the pressure on the relevant manometer must fall (**4.9**).
- The acoustic alarm (whistle) of flowmeter box must sound.



Restore the O_2 supply from distribution system and close the N_2O regulator on flowmeter box.

Against the simultaneous delivery of Air and N_2O.

- Enable and open the N_2O regulator (**4.7**); verify that gas is passing through and close it.
- Enable and open the Air regulator (**4.6**); verify that gas is passing and close it.



BY-PASS push button.

- Close all three regulators of the flowmeter box.
- Enabled selection control for valves group enabling (**9.4**).
- Press the BY-PASS (**9.2**) push button.
- Verify that the O_2 flow reaches the valves group bag.

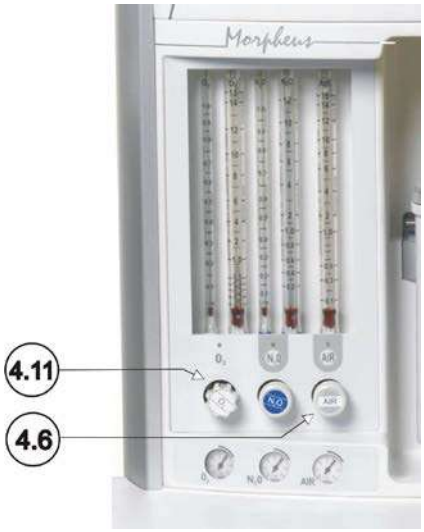
- Enabled fresh gas exit selection control (**9.3**)
- Press the BY-PASS (**9.2**) push button
- Verify that the O_2 flow reaches the TO and FRO circuit bag connected to the AUX connector (**9.5**).
- Restore the control enabling the selection of valves group (**9.4**).

This function is active also with anaesthesia unit OFF.

- Apply the patient circuit to valves group; INSP.and EXP. connectors
- Apply the patient simulator (SIARE type) to the patient circuit connector.

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

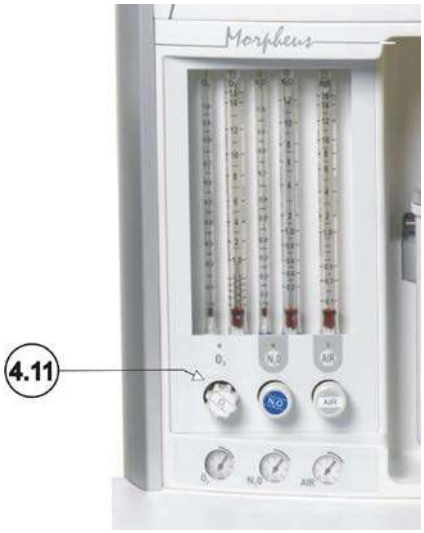
- Apen the O_2 (**4.11**) regulator or AIR (**4.6**) at 2 l/min.
- Press the AUT key to activate the VC/VAC ventilation (cfr. 6.5.3)
- The anaesthesia unit begins the inspiratory (expiratory) phase determining a variation of parametes measured in the monitoring area of ventilator.
- Check the regular operation of the anaethesia unit.



For setting the respiratory physiological parameters (hereinafter RPP) useful for preliminary tests on lung ventilator, consult the cfr. 6.5.3.

O_2 concentration

- Open the O_2 regulator (**4.11**) at 7 l/min.
- Verify that the oxygen concentration of parameters measured in the monitoring area of ventilator [O_2], increases.
- Close the O_2 regulator.



Verify the presence of soda lime in the jar and that it is not exhausted.

6.5.3 Preliminary tests - Lung ventilator

For physiological respiratory parameters checking, see cfr. 5.2 and/or 7.

The choice of the necessary entries to activate the preliminary tests on lung ventilator, is made by setting the parameters and selecting the boxes of the respiratory physiological parameters (hereafter RPP).

VC/VAC Operative mode

The VC/VAC is a volume controlled ventilation (Vti), synchronized with thel patient breaths if the inspiratory trigger is activated (Trig. I).

Set the following respiratory physiological parameters.

Vti	**500 ml**
RR	**12 bpm**
I/E	**1:2**
Trig. I	**-6**
PEEP	**5**
Pausa	**10**

For tests and checks the suggested patient simulator is **SIARE code LS.AB.001** which is equipped with variable compliance and resistance.

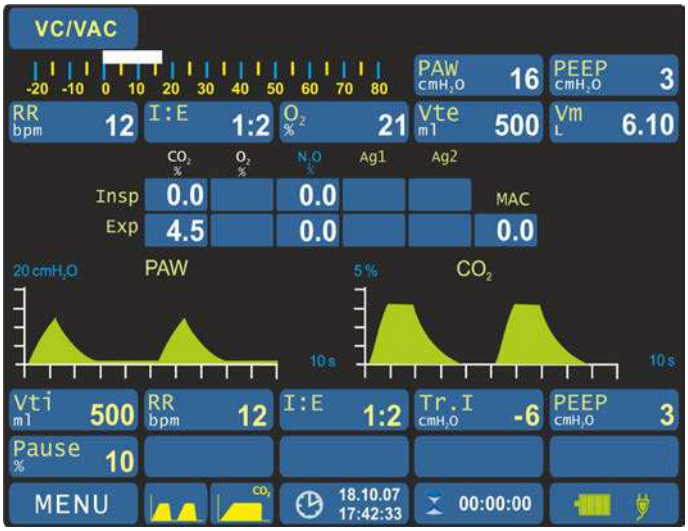
Parameters monitoring

Press the AUT key: the anaesthesia unit begins ventilating.

- Basing on set respiratory physiological parameters and on patient characteristics [patient simulator], the ventilator module can measure and monitor a series of significative magnitude for clinical evaluation.
- Check the correspondence of measured parameters in function of set ones.
- The measured values are updated at each breath.

Vary the set parameters values and verify their correspondence on measured parameters:

- **Vti - Vte**
- **RR**
- **I:E**
- **VM**
- **PEEP**
- **FiO2 (flowmeter box)**



Ensure of the correct operation, checking also that:

- the airways pressure increases during the inspiratory phase
- the airways pressure limit intervenes (pressometric operative mode)
- the opening of oxygen flowmeter determines the increasing of concentration on oximeter (O_2 %)
- at varying of ventilation parameters, the anaesthesia unit operation corresponds
- the trigger operation is efficacious
- the volume and respiratory rate set values are displayed correctly and the pressure, volume and flow curves are in accordance with monitored parameters.

In the upper side are displayed the measured parameters: accepted tolerance +/- 10% of set value.

In the lower side are displayed the set parameters.

Before checking the parameters, leave the anaesthesia unit in operation for at least 10 minutes.

This time allows to the anaesthesia unit to operate at full.

If they measured values differ from set value of more than 15-20%, repeat the flow sensor **"TEST ON DEMAND"** procedure (see previous cfr.).

WARNING! ! Risk of injuries for the patient

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

6.5.4 Preliminary tests - Alarms

To perform the preliminary tests on lung ventilator alarms it is necessary to have knowledge of the keypad and alarm logic operation (see cf. 5 and/or cfr. 8).

The choice of the entries needed to modify the alarms activation limits, is made by setting of values through the MENU.

Through the MENU function, verify the alarm setting and eventually vary the limit (see cfr 5. and/or cfr. 9).

VC/VAC operative mode - Alarms Test

For additional information on alarm operation logic consult cfr. 8.

Low pressure	• Set thelow pressure alarm limit at 5 cmH_2O. • During anaesthesia unit operation discounnect the patient simulator from patient circuit (SIARE type). • After around 15 seconds the low airways pressure alarm occurs: silence the alarm. • Re-connect the patient simulator.
High pressure	• Set the high pressure alarm limit at 45 cmH_2O. • During the anaesthesia unit operation block (wit the hands) the patient simulator. • The high airways pressure alarm occurs: silence the alarm. • Unlock the patient simulator.
High/low oxygen concentration	See cfr. 6.5.2
Power failure	• During the anaesthesia unit operation place on OFF (**0**) the main switch (cfr. 6.3.10). • The power failure alarm occurs: silence the alarm. • Replace the main switch in ON position (**I**).
Gas failure	• During anaesthesia unit operation close the medical gas supply • The gas supplì failure alarm occurs: silence the alarm. • Restore the medical gas supply.

WARNING! ! Risk of injuries for the patient

The alarms must be activated in the correct times and modes.

Verify the correct activation of the visual and acoustic indications.

6.6 Conclusions

Before connecting a patient to the anaesthesia unit it is necessari to perform and overcome all the preliminary tests.

If the preliminary tests phase is not overcome:

- see cfr. 8 (Alarms) and cfr. 9 (Troubleshooting);
- contact the nearest Siare Service Center or authorize by Siare.

WARNING! ! Risk of injuries for the patient

Before connecting a patient to the anaesthesia unit check the alarms set vlaues (cfr. 8).

Modify the alarmi settings in function of clinical situation.

WARNING! ! Risk of injuries for the user / patient

The MORPHEUS anaesthesia unit must be inspected and maintained once the 1000 hours operation are reached or, in case of limited use, every 6 months at least.

All maintenance interventions and/or repairing require a perfect knowledge of equipment, so they must be effected by highly qualified, specifically trained personnel, formally authorized by SIARE.

Inadequate interventions or not authorized modifications can compromise safety and be dangerous for the patient.

6.7 Preliminary tests sequence table

7 VENTILATOR USE

In this chapter the use of ventilator module is illustrated, and some operation modes and physiological patient parameters are taken into consideration.

WARNING! Risk of injury to the patient

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

7.1 Introduction

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

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.

For the safety of users and patients, before making operative the MORPHEUS anaesthesia unit, you should have performed a series of checks and inspections.

WARNING! Risk of injury to the user / patient

- Consult the present User's Manual
- Perform correctly all the foreseen preliminary controls (cfr. 6)
- Prepare the flowmeter box for operation
- Set the respiratory physiological parameters most suitable for the patient's clinical conditions.
- Set the logic and the limits of the alarms
- Set the patient data

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.

Before submitting a patient to lung ventilation, it is good practice to:

- set the limit of airways pressure (high PAW at values not higher than 30 cmH_2O; this to avoid problems due to a wrong setting of volume or respiratory rate (the pressure could be increased whenever required by the pathology and the patient's conditions);
- always verify the set oxygen concentration (FiO_2) since high concentrations could cause injury to the patient.

7.2 Flowmeter box

7.2.1 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 of injury to the user / patient

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 litter 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).

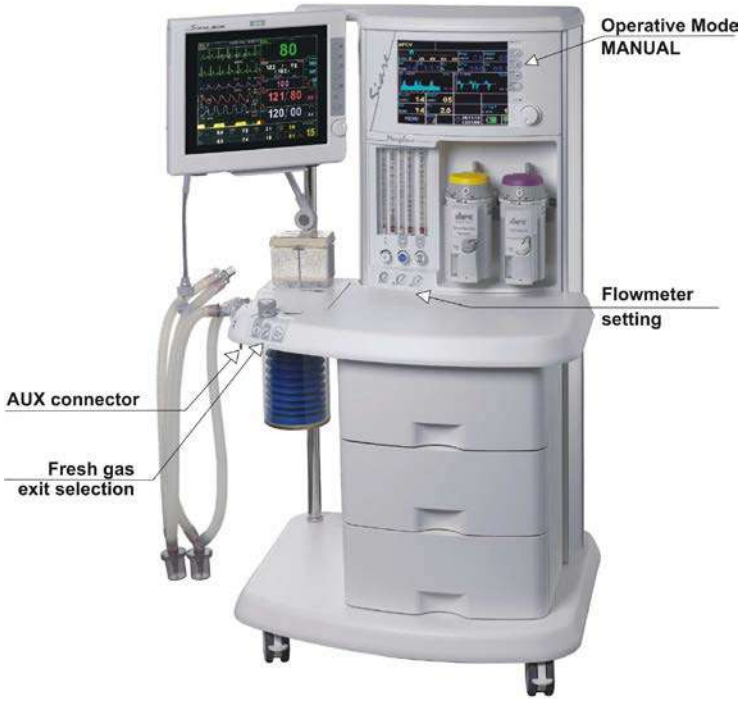
7.2.2 Administration of fresh gas in the "TO and FRO" system

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

- the lung ventilator is in MANUAL operative mode;

- the TO and FRO patient circuit is connected to the AUX connector;
- that the fresh gas exit selection is activated : enabling of fresh gas exit connector (AUX) on control panel for manual ventilation;

- that the flowmeter box is correctly set.



CAUTION. Risk of injury to the patient.

In this operative modality there is no monitoring of respiratory vital parameters: all the patient ventilation phase is entrusted to the User's sensitivity.

The fresh gas flow must be high to avoid CO_2 accumulation.

7.2.3 Mechanical flowmeter box 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.

- Enable and open the Air regulator or that of N_2O.

CAUTION. Risk of injury for the patient.

The two gas cannot be used at the same time.

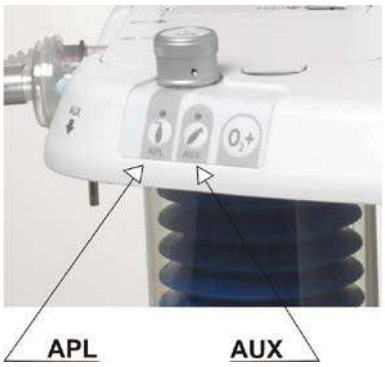
- Ad just the Air flow or that of N_2O.

The opening of N_2O regulator determines the automatic opening of O_2 in the measure of 20-30% (MIX-LIFE).

- Adjust the O_2 flow.
- Verify that the sum of the flows read on all flowmeters corresponds the foreseen value.
- Adjust the concentration of anaesthetic agent onto the vaporiser.

On the control panel for manual ventilation, select the type of desired breathing circuit:

- AUX: control of fresh gas exit selection
- 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.

Electric control.

The activation 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.

7.3 Lung ventilator

7.3.1 Operative mode selection

At start-up the system restores the previous display state (mode and ventilation parameters) before shut-down.

Description of the start-up phase of Morpheus anaesthesia unit: see on cfr. 5.

Press the encoder to activate the **MENU** box.

TURN the encoder until selecting the **Operative Mode** box.

Press the encoder to activate the **Operative Mode**.

TURN the encoder until selecting **Operative Mode.**

- **APCV**
- **APCV-TV**
- **PSV**
- **VC/VAC**
- **VC/VAC BABY**
- **SIMV**

Press the encoder to confirm the selection of **Operative Mode**.

7.3.2 Respiratory physiological parameters [hereinafter PRF] setting

Press the encoder to activate the **MENU** box**.**

TURN the encoder until selecting the box of **PRF parameter** to be set.

Press the encoder to activate the **PRF parameter** to be set.

TURN the encoder clockwise (counter-clockwise) until selecting the value of desired **PRF parameter**.

- **20**
- **19**
- **……**
- **15**

Press the encoder to confirm the selection of the desired value of **PRF parameter**.

To set the necessary respiratory physiological parameters, proceed as described.

DEFAULT PARAMETERS – following page

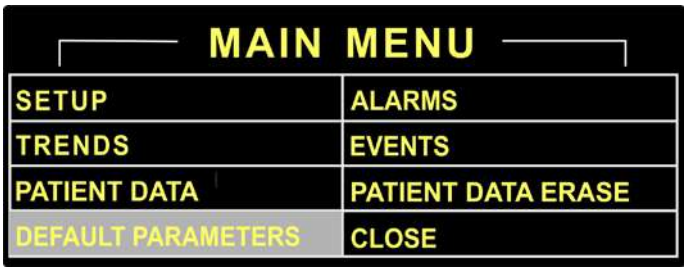
Select **MENU – DEFAULT PARAMETERS** – to set the standard PRF pre-set.

7.3.3 DEFAULT parameters setting

Press the encoder to activate the **MENU** box.

Press the encoder to activate the **MAIN MENU** selection**.**

TURN the encoder until selecting the **DEFAULT PARAMETERS** box.

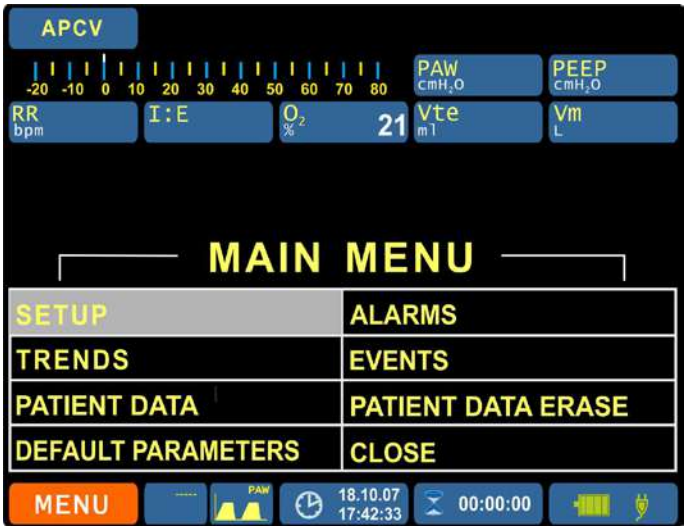


Press the encoder to enable the **DEFAULT PARAMETERS.**

To **NOT** load the **DEFAULT PARAMETERS**, press the **STAND BY / ON-OFF** membrane key: returns to MAIN MENU view.

Press the encoder to confirm the **ENTERING OF DEFAULT PARAMETERS.**

The **MAIN MENU** window appears.



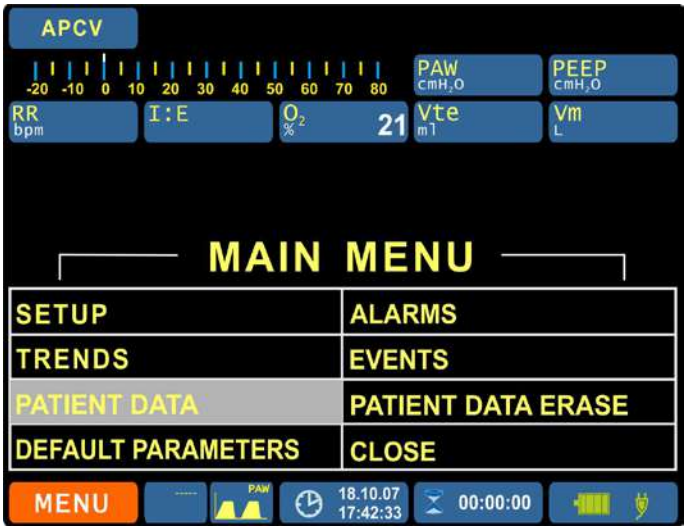
To return to **STAND-BY** view

- press the **STAND BY / ON-OFF** key
- or select the box **CLOSE**

WARNING! Risk of injury for the patient

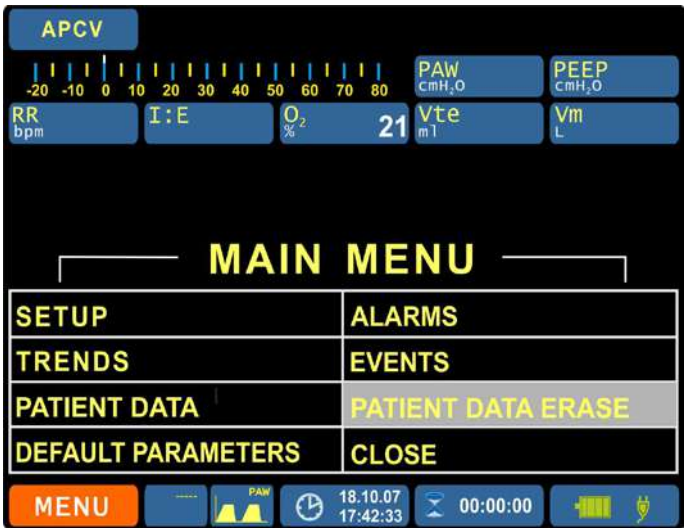
The load of **DEFAULT PARAMETERS enable** the MORPHEUS medical gas driven.

7.3.4 PATIENT DATA setting



For further details or information on **PATIENT DATA SETTING** see cfr. 5.9.5.

7.3.5 PATIENT DATA erase



For further details and information on **PATIENT DATA ERASING**, see cfr. 5.9.6.

7.4 Operative Modes

Automatic Ventilation

- Rotate the encoder knob to select the required operative mode ; press the button AUT to enable the ventilation.
- Press the STAND BY soft key to interrupt the ventilation.

APCV	Assisted pressure controlled ventilation, synchronised with patient's breathing.
APCV - TV	(Volume Targeted) Assisted pressure controlled ventilation, synchronised with patient's breathing and with assured current volume.
PSV	Assisted pressure support ventilation with assured respiratory rate set by the clinician (Apnoea Back Up).
VC/VAC	Volume controlled ventilation synchronised with the patient if the inspiratory trigger is activated.
VC/VAC BABY	Volume controlled ventilation synchronised with the patient if the inspiratory trigger for neonates and premature births is activated.
SIMV	Synchronized Intermittent Mandatory Ventilation.
MAN	Manual ventilation

Manual ventilation

- Press the **MAN** soft key to activate the manual ventilation.
- Press the **STAND BY** soft key to interrupt the ventilation.

7.4.1 STAND-BY

STAND-BY is the state condition in which the equipment is positioned at start-up (or for switch-off), on hold for start of ventilation in selected ventilation modality.

In STAND-BY select the operative mode, set and/or modify all the ventilation parameters (PRF) relevant to the concerned operative mode.

The PRF can be adjusted also during the operation of lung ventilator, adapting them to the patient clinical conditions.

7.4.2 APCV

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

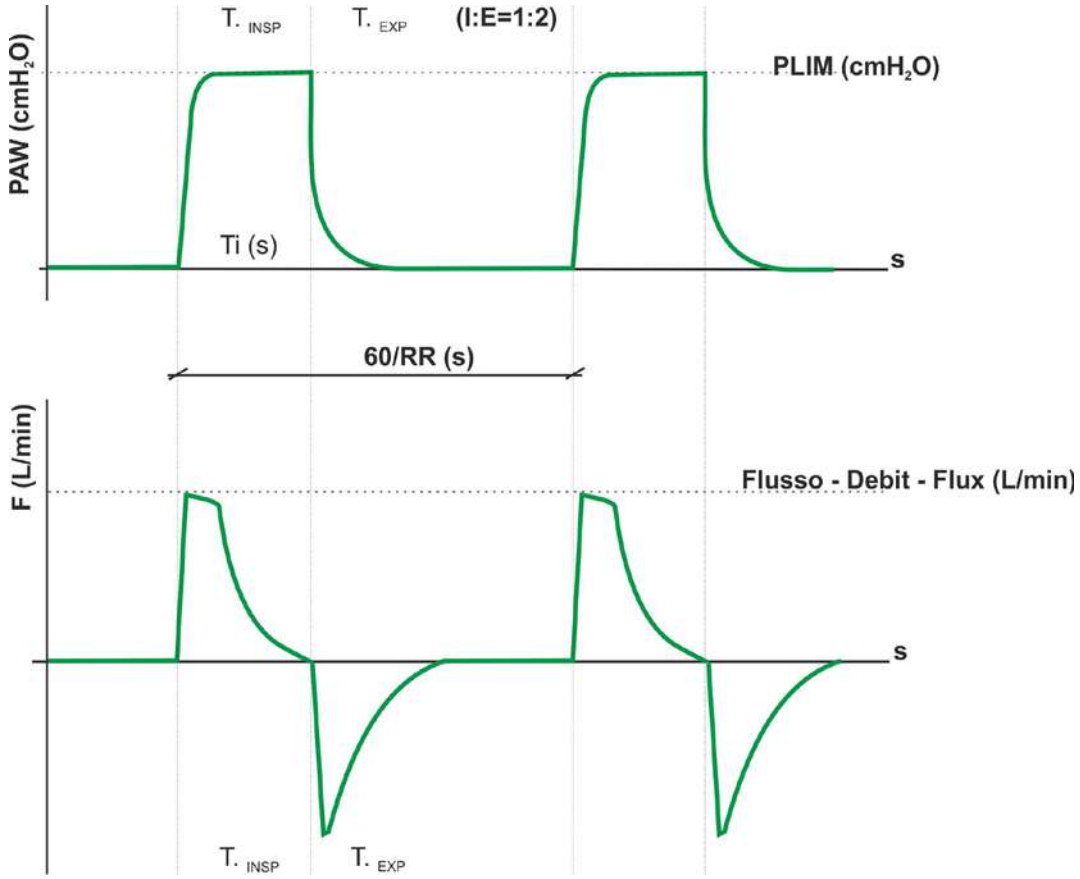
With this parameters configuration, APCV is a pressure controlled ventilation, synchronised with the patient's breathing, during which the system generates a ventilates the patient at a pre-set inspiratory pressure (PLIM), a pre-set flow (Flow), a calculated I:E ratio and a settable respiratory rate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

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

During the inspiratory phase, the ventilator generates a settable flow (Flow). When the airway pressure reaches the control value (PLIM), this pressure level is kept constant by the ventilator until the end of the inspiration that you can set using (RR) and a I:E ratio.

Use the settable parameters to define an inspiratory trigger (Trig. 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.


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

7.4.3 APCV-TV

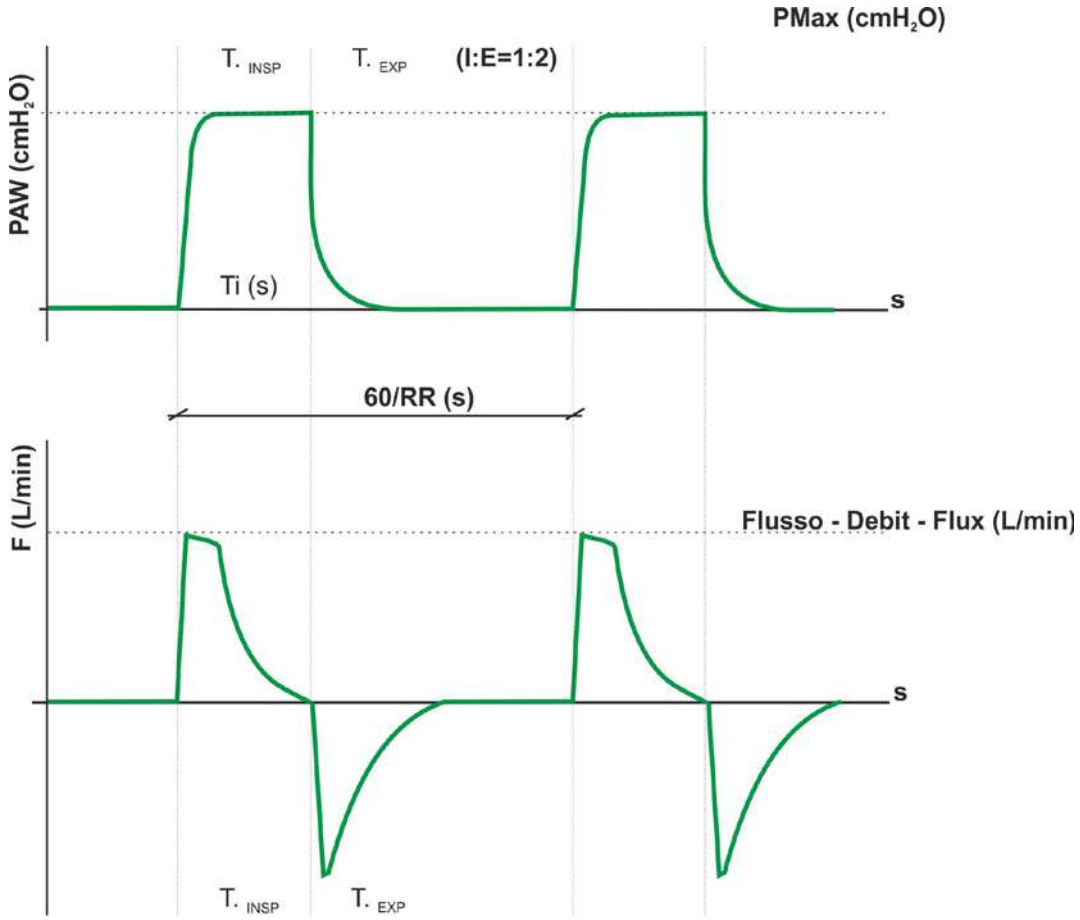
APCV-TV is a pressure controlled ventilation, synchronised with the patient's breathing (automatic PLIM) with assured current volume (Vte).

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

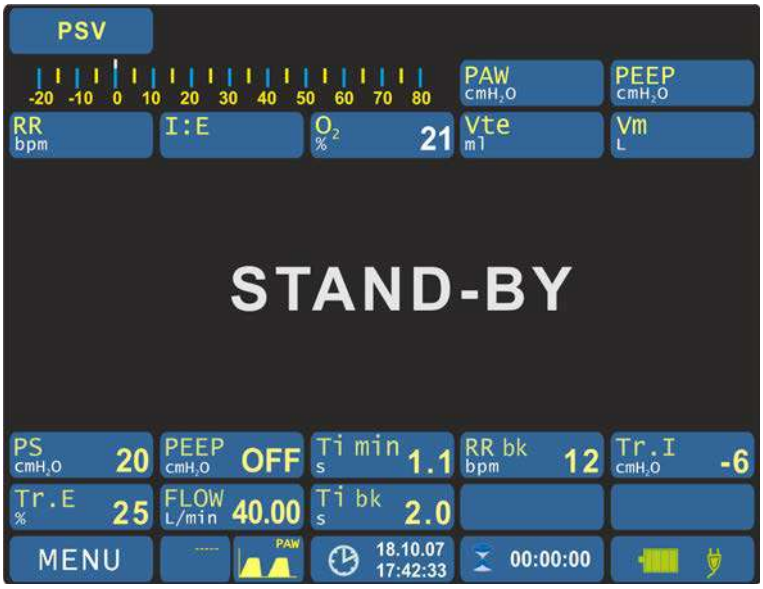
During the inspiratory phase, the ventilator generates an automatic flow. When the pressure reaches the control value inside the airway, this pressure level is kept constant by the ventilator until the end of the inspiration that you can set using the (RR) and a I:E ratio.

Use the settable parameters to define an inspiratory trigger (Trig. 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 more the value configured is high, the bigger is the patient’s effort to get an inspiratory act.


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

7.4.4 PSV



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

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

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

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

When the set support pressure is reached (according to T min), the expiration takes the place of the inspiration (according to Trig E - percentage of the inspiratory flow peak beyond which the expiration can begin).

This technique saves the patient from the work of breathing, as he only has to reach the small quota necessary to enable the ventilator trigger (Trig I). This way, the patient is the one who sets the respiratory rate, the current volume (based on the physiological characteristics) and the beginning of the inspiratory and expiratory phases.

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

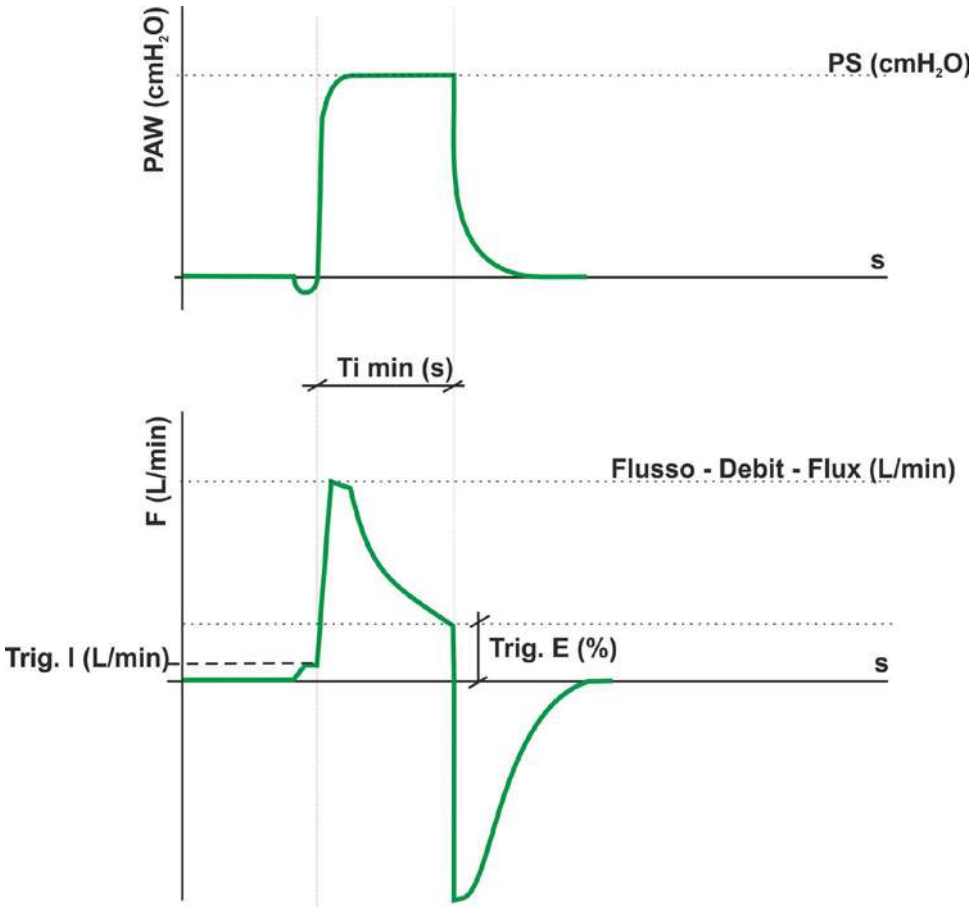
In this mode the patient's work of breathing is assumed by the ventilator. Each breath initiated by the patient (Trig I activated) is supported by the ventilator, that sends a gas flow inside the airway, at a certain pre-set pressure, called support pressure (PS).

The other parameters available in PSV determine:

- Trig E (%), is the percentage of inspiratory flow peak beyond which the expiratory act can start.
- Ti min (s), minimum duration time of the inspiratory phase; the patient cannot breathe out before this time.

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

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



7.4.5 VC/VAC

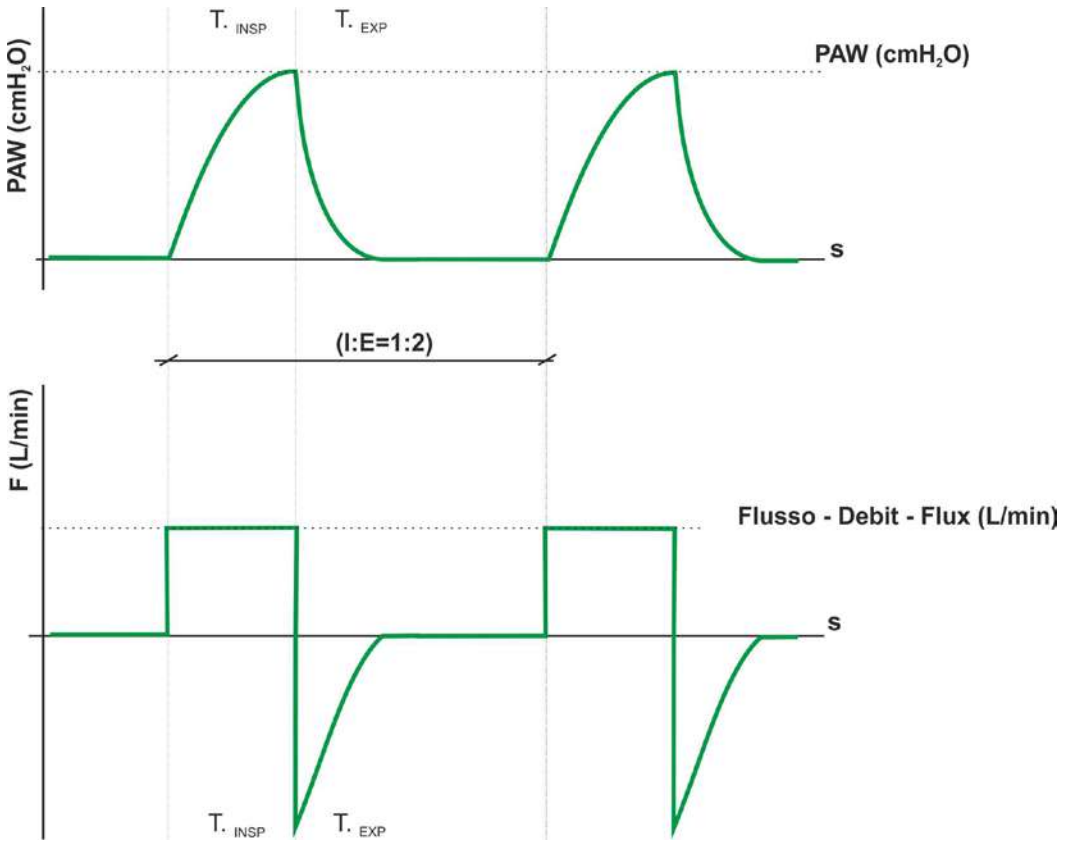
The VC/VAC is a volume controlled ventilation (Vti), synchronized with the patient breaths if the inspiratory trigger is active (Trig. I).

This type of ventilation, being completely made by the device, is used when the patient is not able to breathe autonomously, or, to assure an effective pre-set tidal volume, it is necessary to ventilate the patient in a fully mechanical way.

The inspired volume (Vti) is pre-set and it is delivered in a preset time (RR and I/E) and determines the characteristics and the width of the necessary pressure to reach the preset quantity of gas mixture to be delivered. A tented inspiratory act of the patient is detected by the system (Trig I) which automatically provides to send a gas flow to the airways at a preset volume (Vti).

To reduce the barotrauma risk it is necessary to set the alarm on the maximum limit of inspiratory pressure, once reached such limit the machine stops the inspiratory phase and pass to expiratory one.

To combine the assisted modality to controlled modality, it is necessary to ad just the trigger sensitivity (Trig. I) at a value suitable for the patient. If the patient, during the expiratory phase, effects a spontaneous breath able to activate the trigger, the ventilator synchronizes the respiratory activity with such spontaneous act, calculating the times of I:E ratio from such synchronism event and showing them on ventilator display.


T. INSP
T. EXP
PAW (cmH2O)
PAW (cmH2O)
s
(I:E=1:2)
F (L/min)
Flusso - Debit - Flux (L/min)
s
T. INSP
T. EXP

7.4.6 VC/VAC BABY

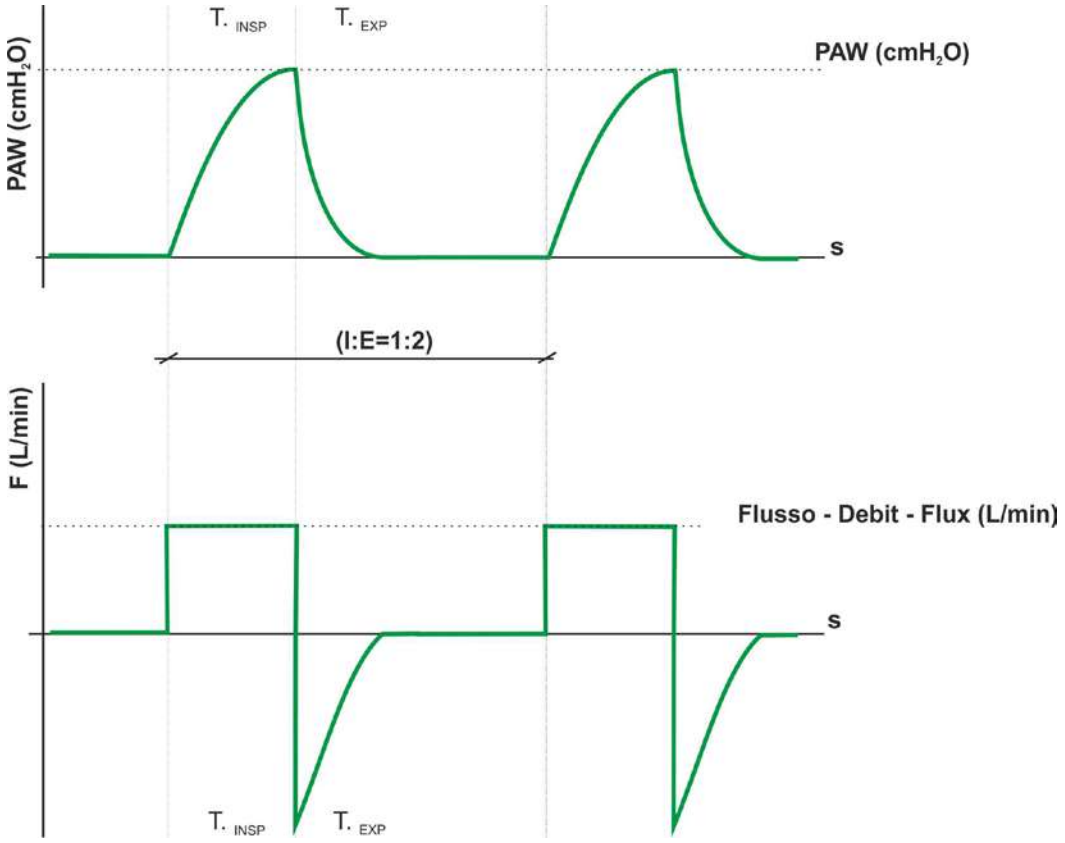
The VC/VAC BABY is a volume controlled ventilation (Vte), synchronized with the patient breathing acts if the inspiratory trigger is activated (Trig. I).

In this operative mode specifically for neonatal patient, respect to the previous VAC, it has been introduced a parameter identifying the max pressure limit which can be reached during ventilation.

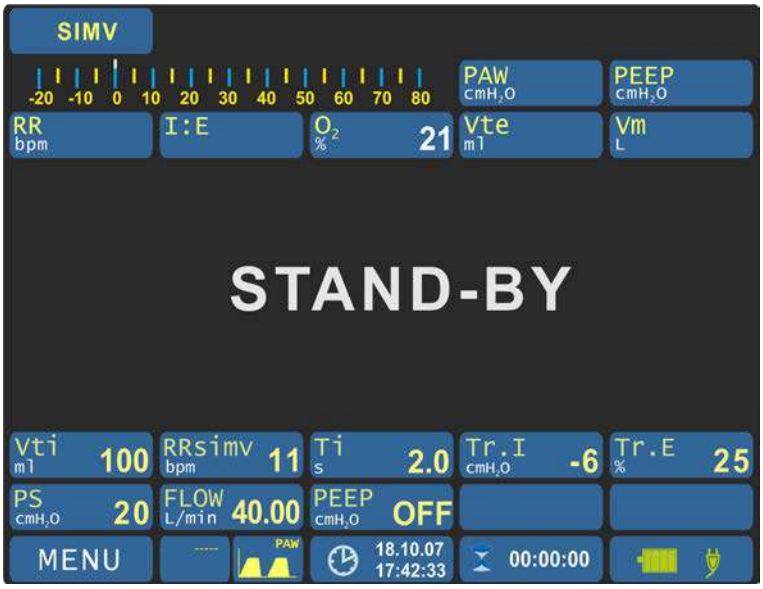
Being totally carried out by the equipment, this type of ventilation is used when the patient is unable to breathe autonomously, or to ensure an effective pre-set tidal volume, it is necessary to ventilate the patient in a completely mechanic mode.

The inspired tidal volume (Vte) is pre-set and is supplied in a pre-fixed time (RR and I/E) and it determines the characteristics and the width of the necessary pressure to reach the preset quantity of mixture to be delivered. A tended inspiratory act of the patient is detected by the system (Trig I) which automatically provides to send to the airways a gas flow at a preset volume (Vte).

To combine the assisted modality to the controlled one, it is necessary to adjust the trigger sensitivity (Trig. I) at the appropriate value to the patient. If the patient, during expiratory phase, makes a spontaneous breathing able to activate the trigger, the ventilator synchronizes the breathing activity with such spontaneous act, recalculating the times of the I:E ratio such event of synchronism, showing them on ventilator display.


T. INSP
T. EXP
PAW (cmH2O)
PAW (cmH2O)
s
(I:E=1:2)
F (L/min)
Flusso - Debit - Flux (L/min)
s
T. INSP
T. EXP

7.4.7 SIMV (+PS / SPONT)



The SIMV is a Synchronized Intermitted Mandatory Ventilation, where the equipment delivers a certain number of breaths per minute (RRsimv) at a set volume (Vti).

Furthermore, the SIMV allows to the patient to breathe spontaneously between the mandatory breaths with positive pressure support set (PS) if the patient inspiratory act is enough to activate the flow trigger (Trig. I). The spontaneous phase is characterized by the inspiratory time set (Ti) whom, once reached the pressure support value set (PS), gives way to the expiratory phase (Trig E).

Therefore, in SIMV modality, the ventilator can deliver a combination of controlled and spontaneous breaths. The ventilator, the user or the patient can activate the controlled breaths. The patient can also activate spontaneous breaths: these last ones can be supported with pressometric modalities (PSV).

The SIMV is frequently used like a ventilatory mode of passage from a total dependence on ventilator to the removal of ventilatory assistance (weaning).

With RRsimv set to NO (RRsimv equal to 0) we obtain the real SPONT modality (spontaneous ventilation). The equipment aids the patient spontaneous activity like in assisted modality (PSV), respecting the airways set pressure limit.

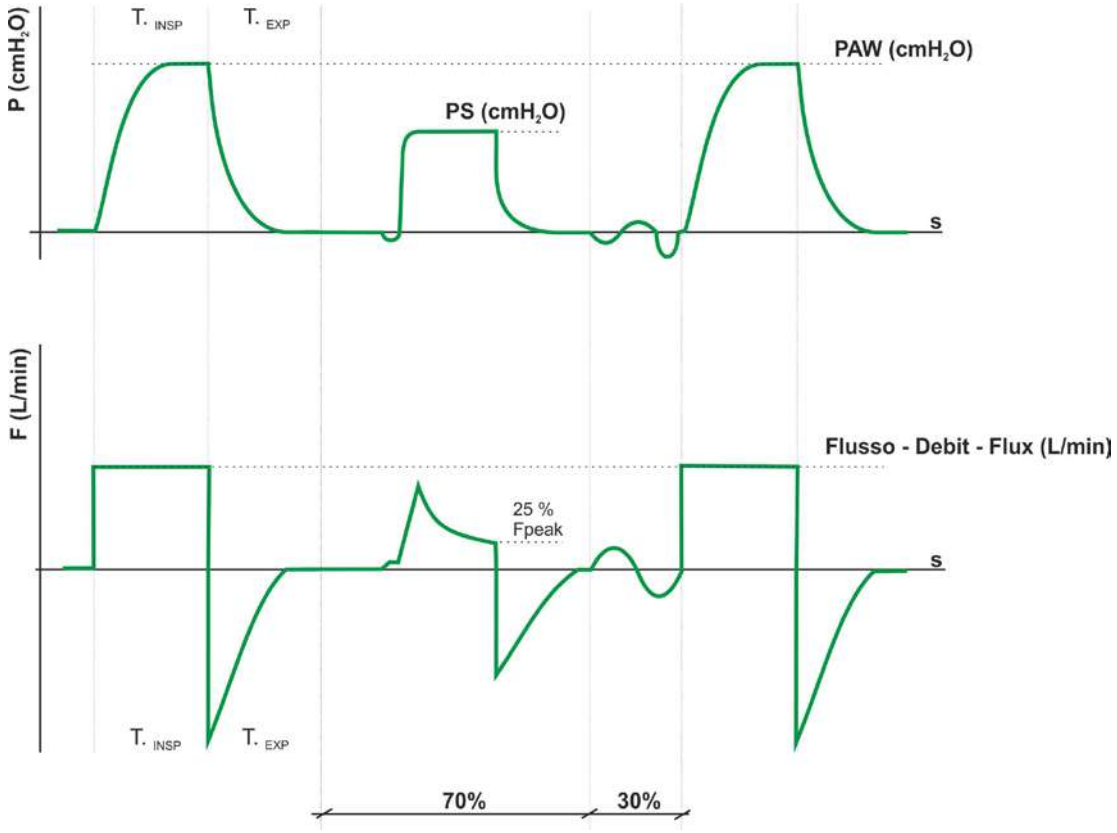
At this point the weaning is finished, the patient is weaned and autonomous in breathing functionality.

Pay particular attention in setting the trigger: in fact, it it should be too high, or completely excluded, the patient should have full respiratory efficiency to survive.

With RRsimv set to NO (RRsimv equal to 0) the patient can breath spontaneously in the circuit.

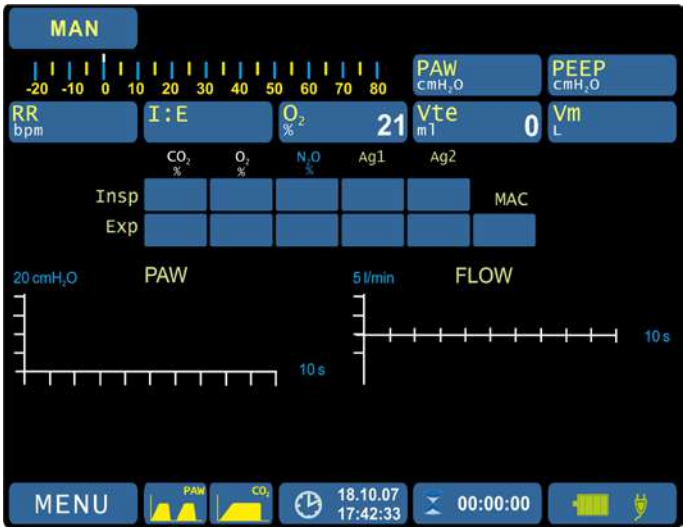
In case the patient does not require a spontaneous act during the apnoea time (set in the SETUP MENU), the audible and visual alarm of low PAW occurs (low pressure in the airways) and simultaneously the APNOEA function starts.

The system will automatically supply an **APCV** ventilation with a pre-set respiratory rate (RR).



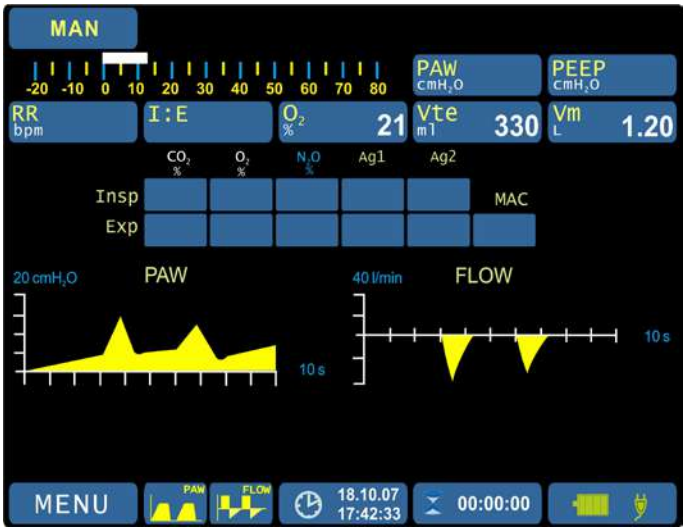
In the graphic is schematized the functioning of SIMV+PS operative mode. The spontaneous activity between a synchronized act and the other is 70% managed by pressure (PS) while the remaining 30% represents the window for the activation of synchronized forced breath.

7.4.8 MAN



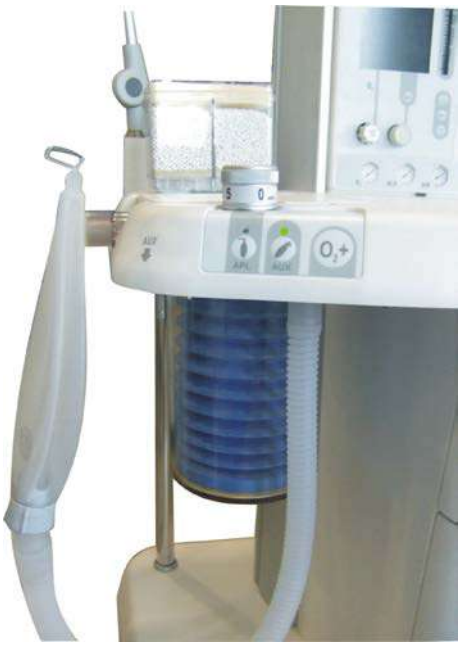
To activate the MAN operative mode it is necessary to press the MAN key on the membrane keyboard.

The ventilator is ready for manual ventilation (MAN).



During the manual ventilation (MAN) the ventilator displays the graphic of both the pressure and the Vte value of the Minute Volume.

The manual ventilation can be effected by the bag connected to the “BAG” connector positioned on the breathing system through the supplied manual circuit.



On the work-shelf keyboard must be selected the APL key (green led on).

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

Set on flowmeter box enough fresh gases for the correct ventilation of the patient.

APL – Airways pressure limit regulator

In the manual ventilation the APL regulator is used for determine the maximum value of such pressure in the airways.

A manual ventilation can be effected also with an auxiliary ventilation system, Mapleson C type (to and fro), connected to the “**AUX**” connector placed on the valves group.

On the work-shelf keyboard must be selected the AUX key.

Set on flowmeter box enough fresh gases for the correct ventilation of the patient.

With this type of manual ventilation (**AUX** key activated), the system (even if the MAN operative mode is selected) **DOES NOT** displays the parameters monitoring.

In MAN operative mode, press on the membrane keyboard the **STAND BY / ON-OFF** key to return to STAND-BY operative mode.

In MAN operative mode press on the membrane keyboard the **AUT** key to return to the last functioning operative mode used (i.e.: VA/VAC).

7.4.9 APNOEA BACK-UP

The apnoea BACK-UP is a safety feature for the patient which can be activated in the operative modes: PSV e SIMV+PS / SPONT (RR=0).

The apnoea BACK-UP function is activated in case the patient, ventilated in one of the above mentioned operative modes, stops generating breaths.

After a time preset in the SETUP MENU, the relevant alarms occur and the system automatically starts patient ventilation.

When the ventilator automatically commutates in this safety modality, the user CANNOT act on ventilation parameters.

The equipment continues to ventilate and the user take note of the emergency state that has been created.

When the apnoea BACK-UP function is activated the ventilation parameters used are those set in STAND-BY according with the selected operative mode.

To return to initial ventilation conditions (operative modes, PSV e SIMV+PS / SPONT).) press the membrane key for silencing the audible alarm.

7.5 Respiratory physiological parameters [PRF]

In the picture the displayed parameters are referred to the APCV-TV operative modality and have the mere purpose of being an example and they do not make any reference to real clinical cases.

- According to the preferred mode of ventilation, the same respiratory physiological parameter can be a dependent variable (i.e. variable as a result of changing other parameters) or independent (i.e. quantity whose change is to change values of other parameters).
- The **PRF** can be adjusted also during lung ventilator operation, adapting them to the patient clinical conditions.

The respiratory physiological parameters can be set **manually in STAND-BY** before activating any Operative Mode.

The system allows to set the default respiratory physiological parameters in **STAND-BY mode** suitable for the ventilation of an adult patient.

7.5.1 Description of PRF parameters

I:E	**RESPIRATORY TIME RELATION** With this parameter it is possible to set the relation between inspiratory and expiratory time. It can be set differently, according with the type of breathing and the different modes. It is possible to select the following values: **1:1, 1:1.5, 1:2, 1:3, 2:1, 3:1.** This parameter is used in the following operative modality: VA/VAC.

Pause

INSPIRATORY PAUSE

Through this parameter it is possible to adjust the inspiratory pause timing, which is measured on display by the % of inspiratory time.; furthermore it is used for calculation of the respiratory mechanics parameters (compliance and resistance).
Its duration can be extended from **0% to 60%** of inspiratory time with steps of 1%.

This parameter is used in the following operative modality: VA/VAC.

PEEP

END EXPIRATION POSITIVE PRESSURE

With this parameter it is possible to set the value of positive airways pressure in expiratory phase. The PEEP is the positive pressure maintained in patient circuit during the expiratory phase.

It is possible to ad just this parameter on values from **OFF, 3 a 30 cmH_2O** with steps of 1 cmH_2O.

This parameter is used in all foreseen operative modalities.

The introduction of PEEP during the automatic ventilation requires caution since it determines the increase of max and mean airways pressure.

This change requires probably also the modification of alarm limits.

PLIM

LIMIT PRESSURE

With this parameter it is possible to set the value of max airways pressure. The parameter is used in the pressure controlled modalities and it is used to fix an insuperable safety limit on the airways pressure.

It is possible to adjust this parameter on values from **6 to 60 cmH_2O** with steps of 1 cmH_2O.

This parameter is used in the following operative modality: APCV

PMax

MAXIMUM PRESSURE

With this parameter it is possible to set, in APCV and VC/VAC BABY modalities, the max value of the pressure which can be reached to deliver the set volume.

It is possible to select value from: **6 to 60 cmH_2O.**

PS

PRESSURE SUPPORT

With this parameter it is possible to set the value of the positive pressure of airways in inspiratory phase.

It is possible to adjust this parameter on values from **6 to 60 cmH_2O** with steps of 1 cmH_2O

This parameter is used in the following operative modalities: PSV, SIMV.

RR

RESPIRATORY RATE

With this parameter it is possible to set the number of breaths to be effected by the patient in one minute.

The set values are from **4 to 120 bpm** with step of 1. In APCV pressometric modality, the set RR values vary upon the set Ti.

With Ti = 0.5 s from 24 to 50 bpm

With Ti = 1.0 s from 12 to 48 bpm

With Ti = 1.5 s from 08 to 32 bpm

With Ti = 2.0 s from 06 to 24 bpm

With Ti = 2.5 s from 05 to 19 bpm

With Ti = 3.0 s from 05 to 16 bpm

RR bk

BACKUP RESPIRATORY RATE

With this parameter it is possible to set the back up respiratory rate in PSV, used when the APNOEA condition occurs to activate a ventilation modality controlled by the ventilator.

The values can be set from **5 to 50 bpm** with steps of 1 in the pressometric modalities (PSV) according with Ti set.

PSV

With Ti = 0.5 s from 24 to 50 bpm

With Ti = 1.0 s from 12 to 48 bpm

With Ti = 1.5 s from 08 to 32 bpm

With Ti = 2.0 s from 06 to 24 bpm

With Ti = 2.5 s from 05 to 19 bpm

With Ti = 3.0 s from 05 to 16 bpm

RR simv	**RESPIRATORY RATE OF SIMV** With this parameter it is possible to set the respiratory rate in SIMV operative modality. Between a set breaths and the other it is possible to breathe in spontaneous way. The values can be set from **NO, 1 a 119 bpm** with steps of 1 according with Ti set. The parameter can be also disabled: NO

The max respiratory rate **RR simv** which can be set, depends on the RR value set in VA/VAC ; **RR simv = RR -1 (also verify the set Ti)**.

FLOW	**FLOW ACCELERATION RAMP** With this parameter it is possible to pre-set the generated flow value: the interval is from **10 to 78**. This parameter is used in all operative modalities except VC/VAC – VC/VAC BABY.
Trig. E	**EXPIRATORY FLOW TRIGGER** With this parameter it is possible to set the inspiratory flow peak percentage beyond which the expiratory act can start It is possible to select percentages from: **4 a 90%** with steps of 1% . This parameter is combined operative modes, PSV and SIMV.
Trig. I	**INSPIRATORY FLOW TRIGGER** With this parameter it is possible to set the sensitivity in L/min with which it is possible to recognize the patient spontaneous activity. The ventilator, once recognized such threshold, provides to deliver a synchronized inspiratory act with the tended patient breath. **Flow Trigger** : it is possible to select sensitivity values from: **OFF**, **1 to 15 l/min** with steps of 1 L/min. **Pressure Trigger**: it is possible to select sensitivity values from: **-1 to -9 cmH_2O** under the PEEP level, with step 1 cmH_2O. The activation of the trigger is visually indicated by a fix red point in the Trig. I box. This parameter is used in all the foreseen operative modalities.

Ti

INSPIRATION TIME

With this parameter it is possible to set the time establishing the duration of the ventilator inspiration period.

It is possible to select values from **0.2 a 5.0 sec.** sec. with steps of 0.1 seconds according with RR parameter set.

This parameter is combined with APCV, VC/VAC BABY, and SIMV operative modes.

Ti bk

BACKUP INSPIRATORY TIME

With this parameter it is possible to set the back-up time in PSV, used in case of APNOEA condition to activate a ventilation modality controlled by the ventilator.

It is possible to select values from **0.2 to 5.0 sec**. with step of 0.1 seconds in function of set RRbk parameter.

Ti min

MINIMUM INSPIRATORY TIME

With this parameter it is possible to set the time establishing the minimum duration of inspiratory period. Therefore, in case the inspiratory phase has a duration lower than such set value, the patient will be **forced** to remain in the inspiratory phase for that time.

Through this parameter it is possible to set the minimum duration of inspiratory phase of the assisted spontaneous breaths.

It is possible to select values from **0.3 to 2.5 sec.** with steps of 0.1 sec.

This parameter is combined with the PSV modalities.

Vte

TIDAL VOLUME

With this parameter it is possible to set the quantity of gas mixture volume guaranteed at each breath.

This parameter is used in the foreseen operative modalities: APCV-TV and VA/VAC BABY.

It is possible to select values from: **0.005 a 1.0 L.** (<50ml: step 1ml / 50-100ml: step 5ml / >100ml step 10ml).

Vti

TIDAL VOLUME

With this parameter it is possible to set the quantity of gas mixture volume guaranteed at each breath.

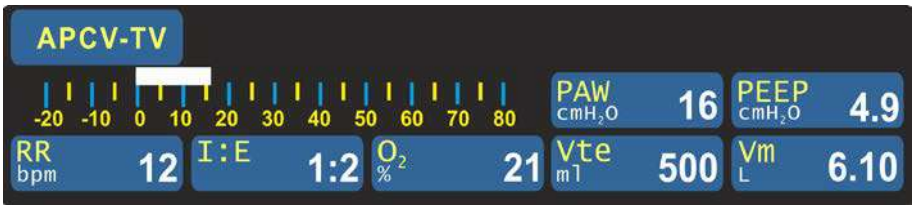
This parameter is used in the foreseen operative modalities: SIMV and VA/VAC.

It is possible to select values from: **0.05 to 1.5 L.** with steps of 10mL.

7.6 Monitoring

7.6.1 Parameters monitoring

The picture shows parameters referred to APCV-TV operative modality and they have the mere purpose of being an example and they do not make any reference to real clinical cases.



PAW (cmH_2O)

Airways pressure

The measurement of airways pressure in cmH_2O is displayed in two different ways.

- Through the lighting bar indicator (with scale from – 20 to + 80 cmH_2O) which displays in real-time the airways pressure.
- Through the numeric indication reporting the peak value measured and reached by the airways during the ventilation phase.

For a better detection of abnormalities on the airways pressure, it is suggested to set the value of: PAW HIGH is 10 cmH2O over peak pressure reached by the patient and the PAW LOW value at 5 cmH2O.

In such way any obstruction of patient airways or any leak in patient circuit, it is probably immediately detected by the ventilator.

PEEP (cmH2O)

Positive expiratory airways pressure

It indicates the end expiration positive pressure: the measuring unit is the cmH_2O.

Through this value, the user can check if the ventilator is able to reach and maintain the level of PEEP pressure set.

RR (bpm)

Respiratory rate

It indicates the real respiratory rate value (breaths per time unit), considering in the calculation, also the eventual spontaneous activity.

This measure allows to control that the ventilator respects the set rate and, in assisted modality, allows to evaluate the patient spontaneous activity.

In case the set rate value is not respected, within certain tolerance limits manually or automatically set, the ventilator generates an visual and audible alarm.

I/E

Inspiratory / Expiratory ratio

It indicates the relation between inspiratory time and expiratory time.

The measured value allows to evaluate the accuracy of the ventilator to respect the set ratio.

O2 (%)

FiO2

Indicates the percentage oxygen concentration inspired by the patient. The value of inspired oxygen concentration is read by the system, through the oxygen cell on the inspiratory line.

The measured oxygen concentration is compared with the alarm limits automatically or manually set; if the limits are not respected the corresponding alarms occur.

The oxygen cell is subject to two checks: the ventilator verifies both the connection of the cell and the exhaustion of reagents.

In case of negative result of that checks the corresponding alarms occur.

Vte (ml)

Tidal expired volume

It indicates the value of tidal volume during expiratory phase of the patient: the measuring unit is the ml.

This size represents the measure of the expired volume obtained integrating over time the curve of the expired flow. The measure is obtained through the flow sensor on the expiratory line.

If the expired tidal volume does not correspond to the set one, within certain limits of tolerance which can be set manually or automatically, the ventilator generates a visual and audible alarm.

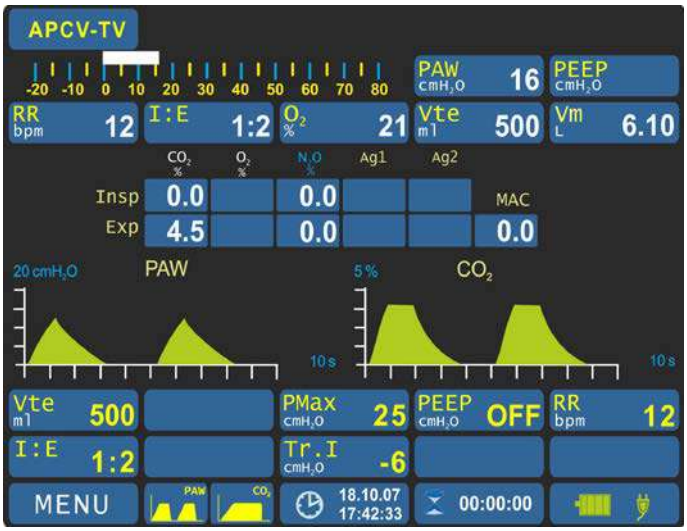
VM (L)

Minute volume

It indicates the value of minute volume expired by the patient: the measuring unit is the L/min. The value is obtained also with the formula: tidal volume (Vte) x respiratory rate (RR).

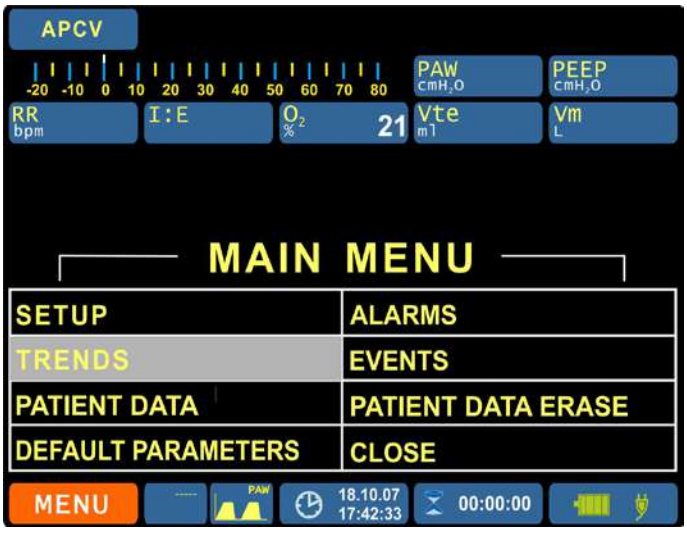
The ventilator measures the Minute Volume expired by the patient and compares it with the alarm limits automatically or manually set. If the check generates an alarm situation the ventilator indicates the limits violation with a visual and audible indication.

7.6.2 Monitoring of curves and loops



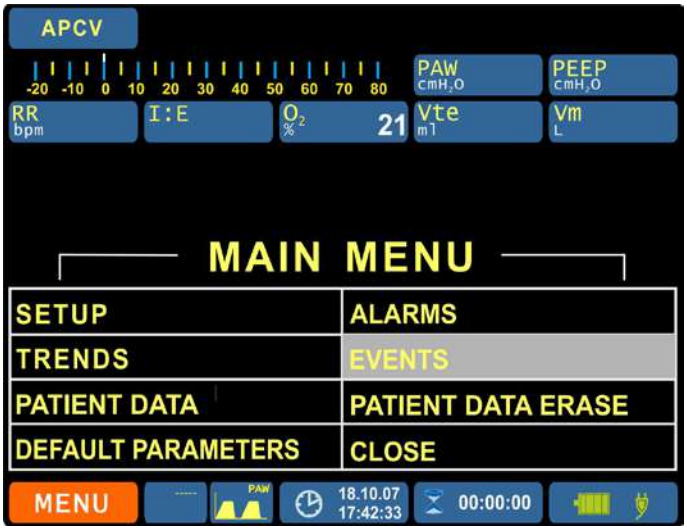
For further details and information on the **Monitoring – Graphics**, see cfr. 5.11

7.6.3 TRENDS



For further details and information on the **Monitoring – TRENDS**, see cfr. 5.9.3.

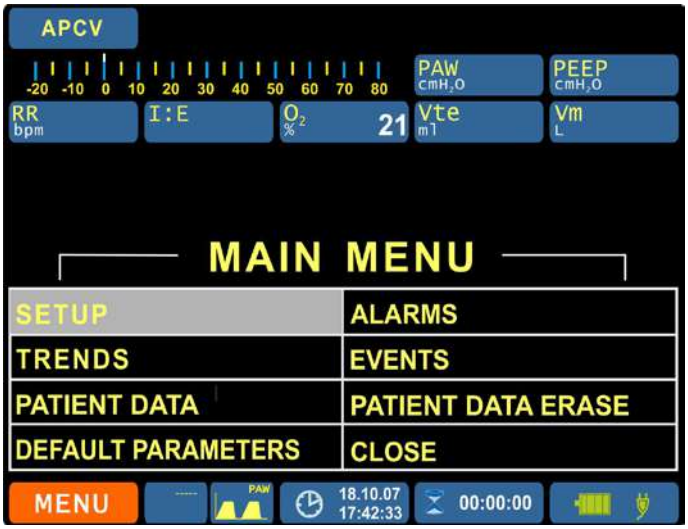
7.6.4 EVENTS



For further details and information on the **Monitoring – EVENTS,** see CFR. 5.9.4.

7.7 MAIN MENU

7.7.1 MENU (first level)



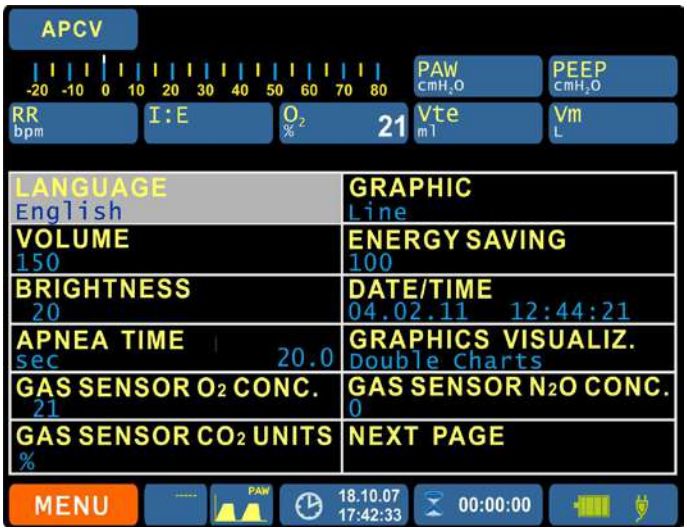
The user at **MENU** first level can choose among the following entries.

- **SETUP** See next paragraph
- **ALLARMI** See chapter 8
- **TRENDS** See paragraph in the present chapter
- **EVENTS** See paragraph in the present chapter
- **PATIENT DATA** See paragraph in the present chapter
- **PATIENT DATA CANC.** See paragraph in the present chapter
- **DEFAULT PARAMETERS** See paragraph in the present chapter
- **CLOSE** This entry allows to return to previous view

7.7.2 MENU (second level)

Turn the encoder until activating the box of the **desired entry** (e.g., SETUP).

Press the encoder: the view of **selected entry** (e.g., SETUP – see next page) appears.



How select and modify an entry from menu

Turn the encoder until activating the **desired entry** box (e.g., LANGUAGE).

Press the encoder: **the box for parameter modification** is activated**.**

Turn the encoder **to modify the language parameter**.

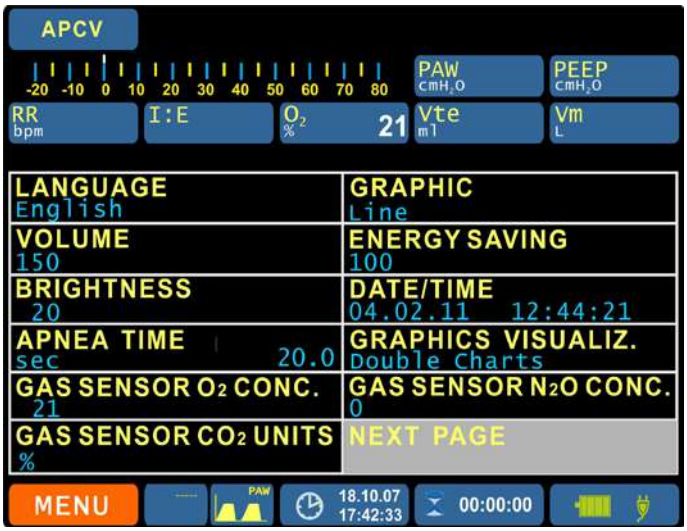
Turn the encoder **to activate the modification of desired language parameter**.

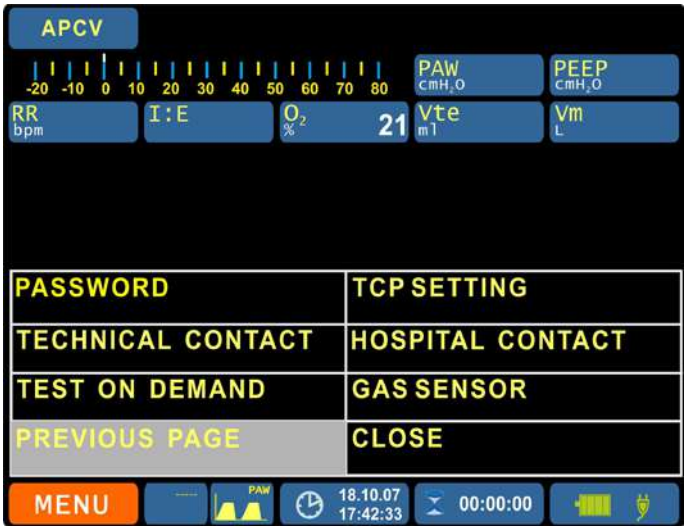
To return to initial view, press:

- the **STAND BY / ON-OFF** key
- or select the **CLOSE** box

CLOSE

The User at second level of **SETUP MENU** can choose among the following entries:

LANGUAGE	It is possible to set the language
GRAPHIC	It is possible to select the type of graph
VOLUME	It is possible to choose the acoustic intensity of the alarm signal.
ENERGY SAVING	It is possible to set the percentage value of the energy consumption of the machine.
BRIGHTNESS	It is possible to set the brightness of the screen
DATE/TIME	It is possible to set the data and hour field.
APNOEA TIME	Selecting the **"Apnoea Time"** it is possible to set the time after which the apnoea back-up function to support patient ventilation, will be activated.
GRAPHS VISUALIZZATION	It is possible to select the graphs displaying modality:
O_2 CONCENTRATION	Parameter for O_2 measurement
N_2O CONCENTRATION	Parameter for N_2O measurement
CO_2 MEASUREMENT UNIT	It is possible to select the measurement unit of **CO_2**
NEST PAGE	

PASSWORD	Function NOT enabled: future uses
TCP SETTING	Optional function: it is not available in the present HW version
TECHNICAL CONTACT	It is possible to access to a screen where setting the data relevant to the service contact developed in 6 lines of text.
HOSPITAL CONTACT	It is possible to access to a screen where setting the data relevant to the hospital contact developed in 6 lines of text.
TESTS ON DEMAND	It is possible to access to a screen where activating the functional tests.
GAS PROBE	To access screens where it is possible to display the state of gas analyzer in use, select the **"Gas probe** " box.
PREVIOUS PAGE	
CLOSE	Return to **MAIN MENU** view.

For further details and information on the SETUP parameters, see cfr. 5.9.1.

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8 ALARMS

In this chapter the part of the system relevant to the alarms of ventilator module is illustrated; also the operating logic and issues for alarms action are taken into consideration.

WARNING! Risk of injury for the user / patient

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

WARNING! Risk of injury for the patient

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

8.1 Definitions

Disable an alarm	Inactivate an alarm function.
Alarm inhibition	Abolition of alarm signals which persists unless intentionally revocated.
Alarm restore	Make that the alarm function is restored to its default initial state.
Alarm stop and silencing	Causing the cessation and restore of an acoustic alarm by a deliberate action.
Alarm suspension	Abolition of alarm signals which persists unless automatically cancelled
Alarm signal	It indicates an occurring condition and/or the duration of a condition which requires a reply by the user.
High priority alarm signal; warning	It indicates the need of an immediate reply by the user.
Medium priority signal; precautionary	It indicates the need of a prompt reply by the user.
Low priority signal; warning	It indicates the need of attention by the user.
Information signal.	An acoustic visual signal or a combination of both, whose aim is to supply technical or physiological information.

The ventilator module is in accordance to what is provided by the EN 475 standard (Electrically-generated alarm signals) and EN ISO 9703-3 standard (Anaesthetic and respiratory care alarm signals. Guidance on application of alarms).

8.2 General

The ventilator module is equipped with automatic means for detection and identification of serious and sudden events through alarm 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; they differ for:

Level or urgency, divided into:	• Immediate, the event is potentially able to develop in a period of time which generally is not enough to undertake a corrective manual action; • brief, the event is potentially able to develop in a period of time which generally is enough to undertake a corrective manual action; • delayed, i.e. that the event is potentially able to develop in a not specified period of time.
Level of severity, divided into:	• 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 aim of the **information signal** is to send a message which may require more supervision by the user; contrary to alarm signals, they do not require the user's intervention.

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.

8.2.1 Logic on alarm management

- The system checks the status of each alarm in every verification cycle identified in the software.
- Each alarm starts from an inactive status corresponding to: false alarm condition.
- The indication of an active status of an alarm occurs after a delay time, during which the alarm condition must persist (the delay time varies according to the type of alarm and the operating mode being used).
- Each alarm has a visual signal (multi-language message and icon in the alarm area).

- Some alarms can be suspended by means of the relative key (the suspension interval of the acoustic signal depends on the type of alarm).
- Only the power supply failure alarm can be inhibited by the operator through a specific selection window in MENU.
- The alarm condition will be stored in the EEPROM of the motherboard and will be recorded in the event registry, which can be consulted by the operator.

- If two or more alarms with different priority levels become active, the acoustic signal with the highest priority is enabled.
- If two or more alarms with the same priority levels become active, the message of the last alarm activated will be displayed. Subsequently, the other activated alarm conditions will be cyclically re-proposed.
- In case of concomitance of more than one alarm the level of acoustic signalling will correspond to that with major priority; the suspension is for all the alarm which are active in that moment.
- If, on the contrary, the trigger condition is no more real, the alarms come back to the inactive state prior suspension of the alarm.

As far as visual alarms are concerned, the visual signals consist of a multi-language message and a bell (yellow or red depending on the priority level of the alarm).

WARNING. Alarms setting after a power failure and restore of electric power supply.

When the device electric power supply is restored after a total power failure (from mains or battery) of a duration higher than 5 min or less, the alarms regulations set before the power failure should remain memorized for what the regulations of the fault condition alarms are concerned.

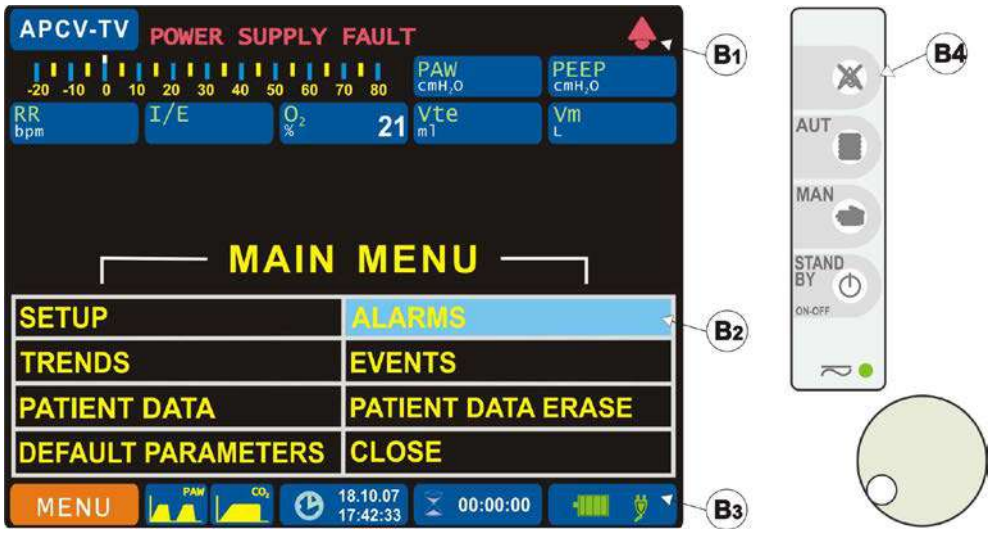
Visual indications of high, medium and low priority

- High priority: Red
- Medium priority: Yellow
- Low priority: Yellow

The power failure signal is evidenced by the network symbol flashing with the inside that changes colour: from green to red.

8.3 Displaying and used symbols

Alarms display area



Alarm area: this area of the monitor provides the following indications:

B1

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

ALARMS parameter, MAIN MENU

B2 Through the encoder it is possible to select the entry of the ALARMS area - MAIN MENU to access the Min and Max. alarms value setting

General information area: this monitor area, through a series of symbols, provides the indications on:

B3

- battery charge level
- the main power presence (failure)

B4 Membrane key for acoustic alarm silencing

8.3.1 Alarm area

This area of the monitor provides the following indications:

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

Configurable alarms (displayed alarms - text string)

Lung Ventilator	• Low Pressure • Low Frequency • Low Exp. Vte • Low FiO_2 • Power Supply Fault	• High Pressure • High Frequency • High Exp. Vte • High FiO_2
Gas Sensor (if provided)	• Low FiO_2 • Low $FiCO_2$ • Low $EtCO_2$ • Low FiN_2O • Low EtN_2O • Low FiAg1 • Low EtAg1 • Low FiAg2 • Low EtAg2	• Low EtO_2 • High $FiCO_2$ • High $EtCO_2$ • High FiN_2O • High EtN_2O • High FiAg1 • High EtAg1 • High FiAg2 • High EtAg2

Symbol “alarm bell”

Medium priority: yellow bell	Suspended alarm: yellow bell crossed through	High priority: red bell
		

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

System alarms	
Lung Ventilator	• Apnoea • Power Supply Failure • Low Battery 50% Rem. • Low Battery 25% Rem. • Low Battery 10 Min. Rem. • *Turbine Failure (available with turbine driven, only)* • *Turbine Overcurrent (available with turbine driven, only)* • *Turbine Overtemperature (available with turbine driven, only)* • Disconnected Circuit • Low Gas Supply • Can-Bus Failure
Gas Sensor (if provided)	• Sampling Line Clogged • No Sampling Line • Replace Adapter • No Adapter • O_2 Port Failure • O_2 Sensor Error • Unspecified Accuracy (….) • Gas Sensor error (….) • No Breaths • Replace O_2 Sensor • O_2 Calibration Required • 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.

8.3.2 ALARMS parameter, MAIN MENU

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

Alarms with limits that can be set by the operator		
Lung Ventilator	• **Low Pressure**	*From 2 to 20 cmH_2O*
	• **High Pressure**	*From 20 to 80 cmH_2O*
	• **Low Frequency**	*From 1 to 11 rpm*
	• **High Frequency**	*From 13 to 130 bpm*
	• **Low Exp. Vte**	*From 0 to 1400 ml (10 ml steps)*
	• **High Exp. Vte**	*From 1 to 1700 ml (10 ml steps)*
	• **Low FiO_2**	*From 20 to 98 %*
	• **High FiO_2**	*From 21 to 99 %*
	• **Power Supply Fault**	*Enable / Disable*

Alarms with limits that can be set by the operator		
Gas Sensor (if provided)	• **Gas Sensor Low FiO_2**	*From 18 to 100 %*
	• **Gas Sensor Low EtO_2**	*From 18 to 100 %*
	• **Gas Sensor Low $FiCO_2$**	*From 0.0 to 12.9 %*
	• **Gas Sensor High $FiCO_2$**	*From 0.1 to 13.0 %*
	• **Gas Sensor Low $EtCO_2$**	*From 0.4 to 12.9 %*
	• **Gas Sensor High $EtCO_2$**	*From 0.5 to 13.0 %*
	• **Gas Sensor Low FiN_2O**	*From 0 to 79 %*
	• **Gas Sensor High FiN_2O**	*From 0 to 79 %*
	• **Gas Sensor Low EtN_2O**	*From 0 to 79 %*
	• **Gas Sensor High EtN_2O**	*From 0 to 79 %*
	• **Gas Sensor Low FiAg1**	*From 0.0 to 25 %*
	• **Gas Sensor High FiAg1**	*From 0.1 to 25 %*
	• **Gas Sensor Low EtAg1**	*From 0.0 to 25 %*
	• **Gas Sensor High EtAg1**	*From 0.1 to 25 %*
	• **Gas Sensor Low FiAg2**	*From 0.0 to 25 %*
	• **Gas Sensor High FiAg2**	*From 0.1 to 25 %*
	• **Gas Sensor Low EtAg2**	*From 0.0 to 25 %*
	• **Gas Sensor High EtAg2**	*From 0.1 to 25 %*

8.3.3 General information area

For further details and information on **'General information Area',** see cfr.5.7

8.3.4 Acoustic alarm silencing

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

- Pushing the ALARM RESET button will stop the acoustic alarm for a defined time.
- During the alarm silencing the alarm text is showed on the panel.
- Pushing further the ALARM RESET button will cancel the alarm text only if the alarm conditions is disappeared.
- If during the alarm silencing a new high priority alarm occur, the alarm silencing is cancelled and the acoustic signal and the visual texts are activated again.

8.4 List of alarms and priorities

8.4.1 Lung Ventilator – configurable alarms

Alarm type	Priority	Delay time (s)	Suspendable	Delay (s)	Inhibition
High Pressure	*HIGH*	*3 patient breaths*	*YES*	*30*	*NO*
Low Pressure	*HIGH*	*15*	*YES*	*30*	*NO*
High Frequency	*HIGH*	*3 patient breaths*	*YES*	*30*	*NO*
Low Frequency	*HIGH*	*15*	*YES*	*30*	*NO*
Min. Exp. Volume	*HIGH*	*0*	*YES*	*30*	*NO*
Max. Volume Exp.	*HIGH*	*0*	*YES*	*30*	*NO*
FiO_2 Min.	*HIGH*	*15*	*YES*	*30*	*YES (auto if FiO2<21%)*
FiO_2 Max.	*HIGH*	*15*	*YES*	*30*	*YES (auto if FiO2<21%)*
Power Supply Fault	*HIGH*	*0*	*YES*	*120*	*YES*

8.4.2 System alarms

Alarm type	Priority	Delay time (s)	Suspendable	Delay (s)	Inhibition
APNOEA	*HIGH*	*0*	*YES*	*30*	*NO*
BATTERY LOW 50% REM.	*MEDIUM*	*0*	*YES*	*120*	*YES*
BATTERY LOW 25% REM.	*HIGH*	*0*	*YES*	*60*	*YES*
LOW BATTERY 10 MIN. REM.	*HIGH*	*0*	*NO*	*-*	*NO*
TURBINE FAILURE	*HIGH*	*0*	*YES*	*30*	*NO*
TURBINE OVERTEMPERATURE	*HIGH*	*0*	*NO*	*-*	*NO*
TURBINE OVERCURRENT	*HIGH*	*0*	*YES*	*30*	*NO*
LOW GAS SUPPLY	*HIGH*	*5*	*YES*	*120*	*YES (auto if FiO2<21%)*
DISCONNECTED CIRCUIT	*MEDIUM*	*0*	*YES*	*120*	*YES*
CAN-BUS FAILURE	*HIGH*	*0*	*NO*	*-*	*NO*

The following series of SYSTEM STATE INDICATIONS are displayed in the EVENTS

- **POWER ON**
- **STAND BY**
- **VENTILATION START**
- **POWER OFF**

8.4.3 Gas Sensor (if provided) – configurable alarms

Alarm type	Priority	Delay time (s)	Suspendable	Delay (s)	Note
Low FiO_2	*HIGH*	*0*	*YES*	*30*	
Low EtO_2	*HIGH*	*0*	*YES*	*30*	
Low $FiCO_2$	*HIGH*	*0*	*YES*	*30*	
High $FiCO_2$	*HIGH*	*0*	*YES*	*30*	
Low $EtCO_2$	*HIGH*	*0*	*YES*	*30*	
High $EtCO_2$	*HIGH*	*0*	*YES*	*30*	
Low FiN_2O	*HIGH*	*0*	*YES*	*30*	
High FiN_2O	*HIGH*	*0*	*YES*	*30*	
Low EtN_2O	*HIGH*	*0*	*YES*	*30*	
High EtN_2O	*HIGH*	*0*	*YES*	*30*	
Low FiAg1	*HIGH*	*0*	*YES*	*30*	
High FiAg1	*HIGH*	*0*	*YES*	*30*	
Low EtAg1	*HIGH*	*0*	*YES*	*30*	
High EtAg1	*HIGH*	*0*	*YES*	*30*	
Low FiAg2	*HIGH*	*0*	*YES*	*30*	
High FiAg2	*HIGH*	*0*	*YES*	*30*	
Low EtAg2	*HIGH*	*0*	*YES*	*30*	
High EtAg2	*HIGH*	*0*	*YES*	*30*	

8.4.4 Gas Sensor (if provided) – system alarms

Alarm type	Priority	Delay time (s)	Suspendable	Delay (s)	Note
Sampling Line Clogged	*HIGH*	*0*	*YES*	*30*	
No Sampling Line	*HIGH*	*0*	*YES*	*30*	
Replace Adapter	*HIGH*	*0*	*YES*	*30*	
No Adapter	*HIGH*	*0*	*YES*	*30*	
O_2 Port Failure	*HIGH*	*0*	*YES*	*30*	
O_2 Sensor Error	*HIGH*	*0*	*YES*	*30*	
Unspecified Accuracy	*HIGH*	*0*	*YES*	*30*	
Gas Sensor error	*HIGH*	*0*	*YES*	*30*	
No Breaths	*HIGH*	*0*	*YES*	*30*	
Replace O_2 Sensor	*HIGH*	*0*	*YES*	*30*	
O_2 Calibration Required	*HIGH*	*0*	*YES*	*30*	

8.5 Alarms adjustment

8.5.1 How setting the ALAMRS-MENU entries

WARNING !! Risk of injury for the patient

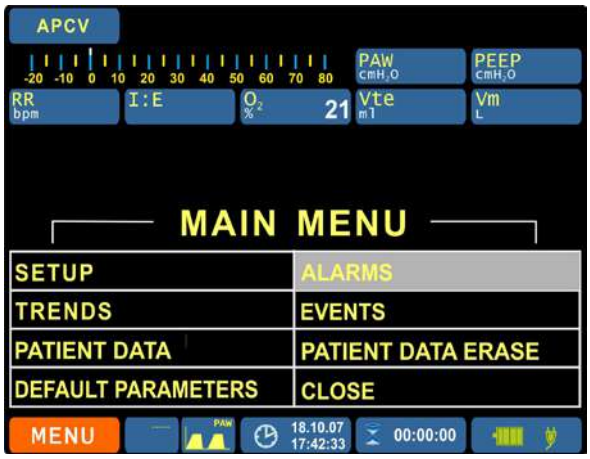
Using in the same area more than one medical device having different alarm limits setting, the User could have a potential false misinterpretation.

- Before using the anaesthesia unit it is suggested to use the MENU function to adjust the items necessary for the correct operation of the equipment.
- During operation it is possible to adapt the alarm setting in function of the patient clinical situation.

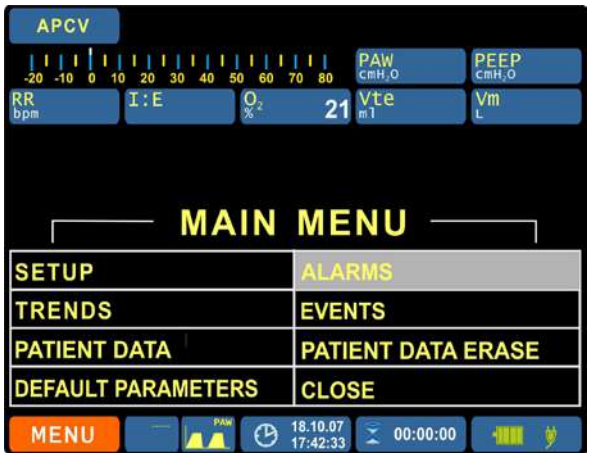
Press (turn) the encoder until to activate the **MENU** box.

Press the encoder: the **MAIN MENU** view is displayed.

Turn the encoder until selecting the **ALARMS** box.



Press the encoder to enable the **ALARMS** function.



- Turn the encoder to **select** the box of the alarm to be modified.
- Press the encoder to **activate** the box if the alarm to be modified.

- Turn the encoder to modify the numerical value of the alarm.
- Press the encoder to **confirm** the numerical value of the alarm.

To return back to the **STAND-BY** view:

- Press the **STANDBY / ON-OFF** key
- or select the **CLOSE** box

8.5.2 How to adjust the alarm volume

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

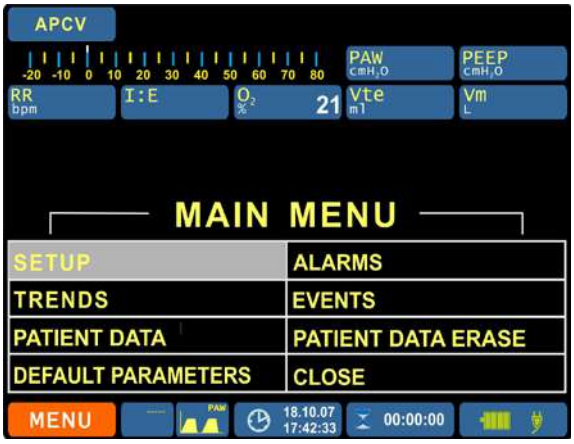
Acoustic intensity value at 1 mt distance

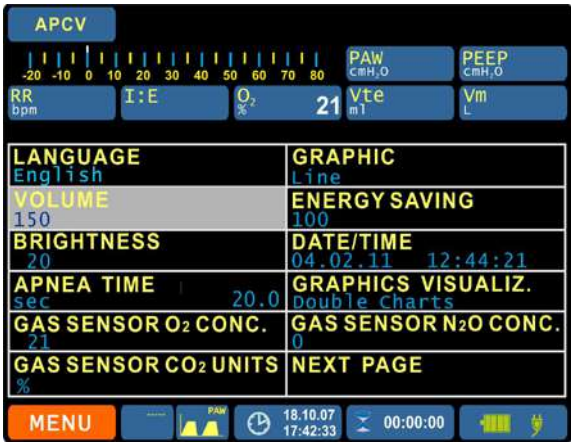
- Minimum level Acoustic Volume setting at 1 = 54dBA
- Maximum level Acoustic Volume setting at 20 = 84dBA

Press (turn) the encoder until activating the **MENU** box.

Press the encoder: **MAIN MENU** view appears.

Rotate (press) the encoder to set the options available in the MAIN MENU (Volume).





Turn the encoder until activating the box of **VOLUME** entry.

Press the encoder: the **box for parameter modification** is activated.

Turn the encoder **to modify the VOLUME parameter value**.

Turn the encoder **to activate the modification of desired VOLUME value**.

WARNING !! Risk of injury for the patient

When the alarm Sound Volume is set to the minimum value (Setting = 1), its intelligibility can be lost.

To return to the **STAND-BY** view:

- press the **STANDBY / ON-OFF** key
- or select the **CLOSE** box

8.6 Regulations and default values table

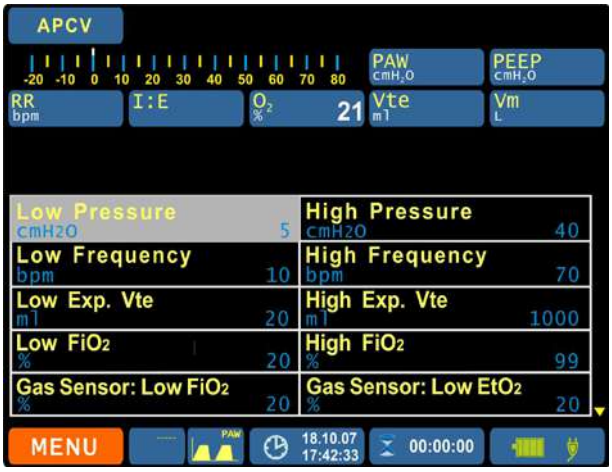
8.6.1 Lung Ventilator

WARNING! Risk of injury for the user / patient

The anaesthesia units 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 or adjust the alarm limits on values suitable to the new condition of use. .
- 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.

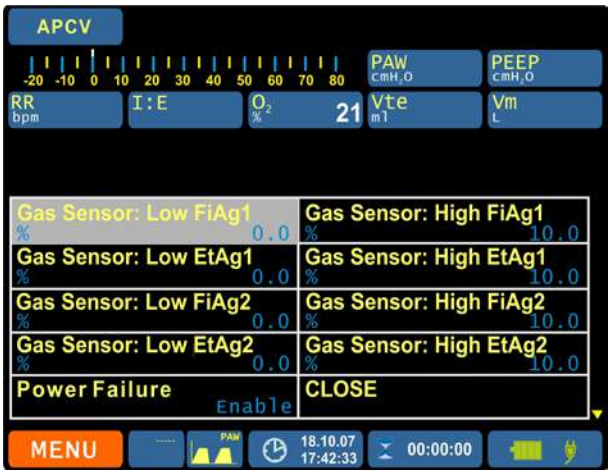
The available regulations and the default regulations which can be selected by the operator are listed here below.



Low pressure	This entry is used to set the low pressure alarm limit • 02 – 20 cmH_2O
High pressure	This entry is used to set the high pressure alarm limit • 20 – 80 cmH_2O
Low frequency	This entry is used to set the low respiratory frequency alarm limit • 01 – 11 bpm
High frequency	This entry is used to set the high respiratory frequency alarm limit • 13 – 130 bpm
Min. Exp. Volume	This entry is used to set the alarm limit for the low expiratory tidal volume • 0 – 1400 ml
Max. Volume Exp.	This entry is used to set the alarm limit for the high expiratory tidal volume • 1 – 1700 ml
FiO_2 Min.	This entry is used to set the limit for the low FiO_2% • 20 – 98 %
FiO_2 Max.	This entry is used to set the limit for the high FiO_2%: • 21 – 99 %
Power failure (electric power supply)	This entry permits to enable or disable the acoustic signal of power failure • Enabled / Disabled

8.6.2 Gas Sensor (if provided)

The available regulations and the default regulations which can be selected by the operator are listed here below.



Low FiO_2

This entry is used to set the low FiO_2 alarm limit

- *From 18 to 100 %*

Low EtO_2

This entry is used to set the low EtO_2 alarm limit

- *From 18 to 100 %*

Low $FiCO_2$

This entry is used to set the low $FiCO_2$ alarm limit

- *From 0.0 to 12.9 %*

High $FiCO_2$

This entry is used to set the high $FiCO_2$ alarm limit

- *From 0.1 to 13.0 %*

Low $EtCO_2$

This entry is used to set the low $EtCO_2$ alarm limit

- *From 0.4 to 12.9 %*

High $EtCO_2$

This entry is used to set the high $EtCO_2$ alarm limit

- *From 0.5 to 13.0 %*

Low FiN_2O	This entry is used to set the low FiN_2O alarm limit • *From 0 to 79 %*
High FiN_2O	This entry is used to set the high FiN_2O alarm limit • *From 0 to 79 %*
Low EtN_2O	This entry is used to set the low EtN_2O alarm limit: • *From 0 to 79 %*
High EtN_2O	This entry is used to set the high EtN_2O alarm limit • *From 0 to 79 %*
Low FiAg1	This entry is used to set the low FiAg1 alarm limit • *From 0.0 to 25 %*
High FiAg1	This entry is used to set the high FiAg1 alarm limit • *From 0.1 to 25 %*
Low EtAg1	This entry is used to set the low EtAg1 alarm limit: • *From 0.0 to 25 %*
High EtAg1	This entry is used to set the high EtAg1 alarm limit: • *From 0.1 to 25 %*
Low FiAg2	This entry is used to set the low FiAg2 alarm limit: • *From 0.0 to 25 %*
High FiAg2	This entry is used to set the high FiAg2 alarm limit: • *From 0.1 to 25 %*
Low EtAg2	This entry is used to set the low EtAg2 alarm limit: • *From 0.0 to 25 %*
High EtAg2	This entry is used to set the high EtAg2 alarm limit: • *From 0.1 to 25 %*

8.7 Description

8.7.1 Alarms with limits that can be set by the operator

High Pressure	This alarm detects when the airway pressure rises above the upper limit (set in automatic or manual operative mode). This is a high priority alarm activated when the alarm limit for the inspiratory pressure is reached in no more than 3 consecutive breaths: in this situation, the expiratory valve will be immediately opened. This prevents the alarm from activating from a cough. An acoustic indicator and a flashing string in the alarms zone, as visual signal, are provided. The sound can be silenced and suspended for 30 s; the inhibition is not foreseen.
Low Pressure	This alarm detects when the airway pressure falls below the lower limit (set in automatic or manual operative mode). This is a high priority alarm activated in automatic and manual modalities after 15 s. The alarm limit of low pressure is meant with respect to the set PEEP value. An acoustic indicator and a flashing string in the alarms zone, as visual signal, are provided. The sound can be silenced and suspended for 30 s; the inhibition is not foreseen.
High Frequency	This alarm indicates that the respiratory rate has risen above the upper limit. This is a high priority alarm activated when the alarm level for the respiratory rate is reached in no more than three consecutive breaths. An acoustic indicator and a flashing string in the alarms zone, as visual signal, are provided. The sound can be silenced and suspended for 30 s; the inhibition is not foreseen.
Low Frequency	This alarm indicates that the respiratory rate has fallen below the lower limit. It is a high priority alarm, activated after 15 s. An acoustic indicator and a flashing string in the alarms zone, as visual signal, are provided. The sound can be silenced and suspended for 30 s; the inhibition is not foreseen.

Min. Exp. Volume	This alarm signals the overcoming of the low limit of the corresponding parameter. This is a high priority alarm, activated after a delay of 15 s. An acoustic indicator and a flashing string in the alarms zone, as visual signal, are provided. The sound can be silenced and suspended for 30 s; the inhibition is not foreseen.
Max. Volume Exp.	This alarm signals the overcoming of the high limit of the corresponding parameter. This is a high priority alarm, activated after a delay of 15 s. An acoustic indicator and a flashing string in the alarms zone, as visual signal, are provided. The sound can be silenced and suspended for 30 s; the inhibition is not foreseen.
FiO_2 Min.	This alarm signals the overcoming of the low limit of the corresponding parameter. This is a high priority alarm, activated after a delay of 15 s. An acoustic indicator and a flashing string in the alarms zone, as visual signal, are provided. The sound can be silenced and suspended for 30 s; the inhibition is not foreseen. If you set a FiO2 at 21%, the alarm is automatically disabled. This High priority alarm, can be enabled even if the system detects the cell disconnection. The value of the cell disconnected bring to a displaying of the 0 value on the display in the box of the O2 %.
FiO_2 Max.	This alarm signals the overcoming of the low limit of the corresponding parameter. This is a high priority alarm, activated after a delay of 15 s. An acoustic indicator and a flashing string in the alarms zone, as visual signal, are provided. The sound can be silenced and suspended for 30 s; the inhibition is not foreseen. If you set FiO2 at 21%, the alarm is automatically disabled.

Power Supply Fault	This is a high priority alarm activated after a delay time of 0 sec. from the moment the mains power supply is disconnected. It is indicated by an acoustic and a visual signal. It can be silenced (suspended) for 120 s and inhibited. The internal part of the electrical power symbol changes from steady green to flashing red. It can be silenced (see procedure for inhibiting the power supply failure alarm – cfr 8.5).

Low FiO_2	Alarms are active and present in function of the type and model of the gas sensor which has been used.
……	These alarms indicate the overcoming of the higher (lower) limit of the specifically parameter in all the operative modes used by the ventilator.
……	
…… **High EtAg2**	These are high priority alarms activated when is reached the alarm level. An acoustic indicator and a flashing strings in the alarm zone, as visual signal, are provided. The sound can be silenced and suspended for 30 s; the inhibition is not foreseen.

8.7.2 System alarms and those that cannot be set by the operator

Apnoea	The APNEA BACKUP alarm condition is activated in PSV and SIMV+PS / SPONT modality, in case of absence of patient inspiratory demand (RATE=0) within a preset time interval (apnoea time which can be set from 5 to 60 seconds). After such time the device provides a ventilation according to the operative mode type with a rate equal to the set safety one (RR bk). Such alarm is present only in PSV and SIMV+PS / SPONT modalities, because in other assisted modalities a minimum rate is guaranteed. It is an high priority acoustic and visual alarm, which can be silenced (suspended) for the same preset time (apnoea time which can be set from 5 to 60 seconds); the alarm inhibition is not foreseen.

Battery Low 50% rem.	This alarm is activated 0 sec. after the battery voltage falls below **50%** of the fully charged level. It is a medium priority alarm indicated by an acoustic and visual signal. It can be silenced. Inhibiting the acoustic signal of this alarm is the same as that for the power supply failure alarm (there is however a visual signal in the alarm area).
Battery Low 25% rem.	This alarm is activated 0 sec. after the battery voltage falls below **25%** of the fully charged level. It is a high priority alarm indicated by an acoustic and visual signal. It can be silenced. Inhibiting the acoustic signal of this alarm is the same as that for the power supply failure alarm (there is however a visual signal in the alarm area).
Low Battery 10 Min. rem.	This is an alarm that is activated after a delay of 0 sec. by the moment in which the residual autonomy of the battery is of about 10 minutes. Is an alarm of high priority, signalled by an acoustic and visual device. He cannot be reset and even inhibited.

WARNING! Risk of injury for the unit

When this alarm signal is activated only 10 minutes of autonomy are available and the machine will stop to ventilate.

Turbine Failure	*This high priority alarm which is enabled after a 0 sec delay and highlights the malfunctioning of the TURBINE.*

WARNING! Risk of injury for the unit

Switch off immediately the device and get in touch with the Technical service urgently.

Turbine Over-temperature	*This is a high priority alarm which is activated after a 0 sec delay starting from the max limit of the turbine temperature (105°C) and it is restored once the temperature goes under the 100°C.* *It is indicated by an acoustic and visual alarm and it can be silenced but not inhibited.*

WARNING! Risk of injury for the unit

Switch off the device immediately and get in touch with the technical service urgently.

Turbine Over-current	*This is a high priority alarm which is activated after a 700 ms delay starting from the max limit of the voltage during the turbine operation.* *It is indicated by an acoustic and visual alarm and it can be silenced but not inhibited.*

WARNING! Risk of injury for the unit

Switch off immediately the device and get in touch with the technical service urgently.

Low Gas Supply	This high priority alarm occurs in case the supply pressure of the gas channel remains for more than 5 sec. (delay time) at a lower value than the minimum necessary one to allow the equipment operation. It is indicated by an acoustic and visual alarm. It can be silenced (suspended) for 120 sec. If the FiO2 % is set on 21% such alarm will be automatically inhibited.
Can-Bus Failure	This high priority alarm occurs in case when the CAN system doesn't recognise the correct adjustments in the electronic boards.

WARNING! Risk of injury for the patient

An auxiliary system of ventilation must be always available for the patient when the ventilator is for a total life support.

8.7.3 Gas Sensor (if provided)

Sampling Line Clogged	This alarm occurs in case the sampling line is obstructed.
No Sampling Line	This alarm occurs in case the sampling line has not been correctly connected.
Replace Adapter	This alarm occurs in case the used adaptor for the gas sensor doesn't properly work ; replace the gas sensor adaptor.
No Adapter	This alarm occurs in case the adaptor is not properly inserted on the relevant gas sensor
O_2 Port Failure	This alarm occurs in case a malfunction is detected in the oxygen inlet inside the sensor.
O_2 Sensor Error	This alarm occurs in case a malfunction is detected in the oxygen sensor; replace the oxygen sensor.
Unspecified Accuracy	This alarm occurs in case the measurement detected by the gas sensor is not inside the normal operating field.
Gas Sensor Error	This alarm occurs in case a a malfunction is detected on the gas sensor; replace the gas sensor.
No Breaths	This alarm occurs in case the sensor doesn't detect any patient breath.
Replace O_2 Sensor	This alarm occurs in case the oxygen sensor doesn't properly work; replace the oxygen sensor.

O_2 Calibration Required	This alarm occurs in case the oxygen sensor calibration has not been properly done; the oxygen calibration has to be repeated.

The alarms are active and present in function of the type and model of the gas sensor which has been used.

The high priority alarm are activated when the specifically alarm condition is started.

An acoustic indicator and a flashing strings in the alarm zone, as visual signal, are provided. The sound can be silenced and suspended for 30 s; the inhibition is not foreseen.

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9 TROUBLESHOOTING

This chapter is a guide for the operator and the technician, providing indications for eliminating, as quickly as possible, most of the problems that may have caused malfunctioning or alarm signals.

This chapter describes the possible causes of problems, indicated by alarms that are activated during normal functioning.

If the problem persists, carry out a complete check of the MORPHEUS anaesthesia unit to identify any irregularities.

If the problem cannot be resolved, contact the Siare Service Centre or a Centre authorised by Siare.

9.1 List of malfunctioning

No power	The anaesthesia unit does not switch on
	• Check that it is connected to the main power supply • Check that the main switch is turned to the I position (ON) • Check the main fuses • Contact the Siare Service Centre or a Centre authorised by Siare.
Power supply	There is a power supply fault and the anaesthesia unit is operating on the battery
	• Check that it is connected to the main power supply • Check that the main switch is turned to the I position (ON) • Check the correct connections of the plug, the fuses and the connector, and the condition of the cable (if necessary, restore the connections and replace the cable if it is damaged). • Check that power is present at the relative socket by plugging in another electrical device. If there is no power, use another socket or check the overload switch on the electrical panel of the room.

Initialization phase	The initialization phase is not completed and the system is blocked.
	• Verify and intervene in function on the error messages and indications evidenced during the “SELF TEST” phase. • Turn off and on the anaesthesia unit and repeat “SELF TEST” phase. • Contact the Siare Service Centre or a Centre authorised by Siare.
Keys and encoder knob	The keys or the encoder knob do not work
	• Switch the anaesthesia unit OFF and then switch back ON. • Contact the Siare Service Centre or a Centre authorised by Siare.
Error in the bus “CAN”	This alarm condition occurs in case of system failure (electronic boards).
	• Contact the Siare Service Centre or a Centre authorised by Siare
Patient circuit disconnected	This alarm conditions occurs in case of pneumatic circuit malfunctioning.
	• Check that the 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 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. • If this is not the case, contact the Siare Service Centre or a Centre authorised by Siare.

Low 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.
Battery charge level 25% (50%)	This alarm is activated when the charge level of the battery is at 25% (50%) of the fully charged level: no more than 30 (60) minutes of operating autonomy is guaranteed.
	• 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.
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 correct connection of power supply. • To 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.
Exhausted O2 sensor	Low O_2 concentration - This alarm is activated when the reagents in the oxygen sensor are exhausted.
	• 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	Low O_2 concentration - This alarm indicates the connection status of the oxygen sensor.
	• Check that the oxygen cell is correctly connected. • Replace the oxygen sensor with a new one. • Check the condition of the cable and the connector (if necessary, restore the connection and replace the cable if damaged). • If the problem persists, contact the Siare Service Centre or a Centre authorised by Siare.
FiO_2 high	This alarm is activated when the measured concentration of oxygen exceeds the set limit.
	• Check that the corresponding alarm limits are set correctly. • Calibrate the oxygen cell: if the problem occurs again after a short time, replace the oxygen cell. • Contact the Siare Service Centre or a Centre authorised by Siare.
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. • 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. • Contact the Siare Service Centre or a Centre authorised by Siare.

Minimum expired volume	This alarm condition occurs in case the expired volume 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. • If this is not the case, contact the Siare Service Centre or a Centre authorised by Siare.
Max expired volume	This alarm condition occurs in case the expired volume 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). • If this is not the case, 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, 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 luminous PAW bar on ventilator (the airways pressure curve) correctly follows the inspiration / expiration cycle.
- Check that nothing is limiting the patient's respiratory capacity.
- If this is not the case, 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, 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 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 ventilator (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 anaesthesia unit delivers the gas mixture correctly.
- Check that the low pressure level is higher than the PEEP level set. If not, increase it above the PEEP level.
- If this is not the case, contact the Siare Service Centre or a Centre authorised by Siare.

Rate high	This alarm is activated when the breathing rate volume 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.
- Contact the Siare Service Centre or a Centre authorised by Siare

Rate low	This alarm is activated when the breathing rate volume 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, 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 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.
- Contact the Siare Service Centre or a Centre authorised by Siare

Apnoea	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, 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 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.

Gas Sensor	Malfunctioning
	• Check that the patient's respiratory parameters are set correctly. • Check that the gas sensor is connected correctly to the anaesthesia unit and to the patient. • 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 Gas Sensor User’s Manuals.

10 MAINTENANCE

To ensure correct functioning of the MORPHEUS anaesthesia unit, carry out the following maintenance operations at the scheduled intervals.

All the operations must be adapted to the regulations in force in the individual health structures.

The instructions for carrying out more detailed tests, for troubleshooting and for other interventional procedures, information intended for qualified technical personnel, are contained in the relative chapter.

WARNING! Risk of injury for the user / patient

To ensure the safety of the patient and the operator, 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 must therefore only be carried out by highly qualified personnel, specifically trained and formally authorised by SIARE.

Inappropriate intervention or unauthorised modifications can compromise safety and cause danger to the patient.

To avoid the danger of electric shock during maintenance and/or repair operations, make sure that all power supplies have been disconnected, disconnect the power supply source (positioning the special danger signs) and disable all the protection switches of the equipment.

On completion of the maintenance operations, all removed components should be disposed of according to current waste disposal regulations.

Components that cannot be destroyed should be sterilised before disposal.

Follow current regulations for the disposal or recycling of all removed components.

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.

10.1 Cleaning, disinfection and sterilisation

The operator 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 operator safety.

WARNING! Risk of personal injury

Do not attempt to dismantle, clean or rinse parts or components, such as the screen or knobs, with liquids or compressed air.

To avoid exposing the patient to sterilizing substances, these parts must be sterilized as described below. Remember that exposure to sterilizing substances can reduce the working life of some components.

Always use filters to protect circuits and 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 ventilator is sold.

Siare is aware that working procedures can differ considerably from one health structure to another: it is therefore impossible to indicate specific procedures that are suitable for all requirements.

SIARE cannot be held responsible for the efficacy of the cleaning, disinfection and 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 operator’s responsibility to ensure the validity and efficacy of the methods used.

Before carrying out maintenance and/or repair operations on the anaesthesia unit, and also in the event of shipment of the machine to our premises, clean and disinfect the equipment.

10.2 General instructions

10.2.1 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.

10.2.2 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 machine is used and in any case at least once a month.

Siare recommends:

- 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.

10.2.3 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.

Siare recommends:

- 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.

10.2.4 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 operator may use disinfectants (e.g. Buraton 10 F, diluted according to the manufacturer's instructions or VPRO 60C°) to clean the components. Disinfectants based on the following substances can cause damage: • halogen-releasing compounds; • strong organic acids; • oxygen-releasing compounds. Remove any dust from the surfaces or in openings using a vacuum cleaner or a soft cloth.	Make sure that no sprays or liquids penetrate inside the equipment and the connectors.
Screen	See above	Do not use cloths or sponges that could scratch the surface.

To avoid damaging the labels and outer surfaces of the ventilator, use only the chemical substances listed.

Patient circuit (silicone tubes)	Dismantle and clean, then 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.

- Do not clean or re-use disposable circuit tubes.
- Do not clean or re-use if the filters are the disposable type.

WARNING! Risk of injury for the patient

It is necessary to have at least one spare patient circuit in stock for routine use and /or accidental breaks.

Couplings and connectors	Dismantle and clean, then sterilize in an autoclave, disinfect with steam or chemically.	Check that there are no splits and replace them if they are damaged. Before using again, eliminate any humidity inside the components by means of compressed air.

Breathing system	Dismantle and clean, then sterilize in an autoclave, disinfect with steam or chemically.	Check that there are no splits and replace them if they are damaged. Before using again, eliminate any humidity inside the components by means of compressed air.

Flow sensor	Disinfect with steam or chemically.	

WARNING. Risk of device failure.

Do not attempt to dismantle or clean with compressed air.

The flow sensor can be washed and disinfected by immersing it in a bowl with 3 centimetres of liquid, keeping the connector for the electrical connections facing upwards.

Electrical connections	On the aim to guarantee patient and operator safety it is necessary to keep the power supply cable in perfect conditions.	Perform daily checking's of cable condition; any damage, also a minimum damage, must be promptly eliminated, eventually replacing the whole cable.

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

Other accessories	Carefully follow the manufacturer's instructions.	Refer to the accompanying documentation.

10.3 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 ventilator is sold.

- Inspections and periodic maintenance are ensured by taking out a maintenance contract with SIARE or an authorised dealer.
- Contact SIARE for information regarding authorised Service Centres in your area.
- When you require service, please indicate the serial number of the unit and the problem to SIARE or to your authorised technicians.
- SIARE assumes responsibility for all provisions foreseen by the law, if the equipment is used and maintained as per the instructions in this manual and the technical manual
- The Technical Assistance Report, signed by the authorised SIARE technician, is proof of the completion of the scheduled maintenance.

10.3.1 Maintenance operations

WARNING. Risk of injury for the patient

Always refer to the instructions contained in the previous section: cleaning, disinfection and sterilization of the components.

The table summarizes the preventive maintenance frequency and procedures to be carried out on the anaesthesia unit.

Frequency	Component	Procedure / Action
Several times a day Every day / when necessary	Patient circuit	Check for any water collection, drain and clean the tubes when necessary.
	Condensation trap filter	
According to local practice and standards	Filters	Check for wear.
	Anaesthesia unit	General cleaning and checks.
	Breathing system	Dismount the components and clean, then sterilize in autoclave, disinfect by steam or chemically.
	Flow sensor	Disinfect with steam or chemically.
Every week / when necessary	Breathing system	Dismount the components and clean, then sterilize in autoclave, disinfect by steam or chemically.
	Oxygen sensor	Calibrate according to the procedures described in this manual.
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.
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.
	Filters	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.
	Patient circuit	
	Washers / O-Rings	

Frequency	Component	Procedure / Action
Every year	Anaesthesia unit	Check the performance. This includes an electrical safety test and inspection of the ventilator 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.

To avoid damage to components due to excessive wear, carry out preventive maintenance and replace parts following the recommended frequency.

10.3.2 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 anaesthesia unit every time is used with another patient.

10.4 Repairs and spare parts

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

10.4.1 Annual kit for MORPHEUS anaesthesia workstation

Code: R062003A1

Spare parts kit for annual maintenance to be used with the MORPHEUS anaesthesia workstation.

10.5 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.

10.6 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.

10.7 Disposal

Batteries, accumulators, O2 cells and electronic parts in general:

- do not put them in the fire, explosion risk
- do not open them, corrosion danger
- do not recharge batteries
- do not throw them away with normal waste.

The batteries and the accumulators are special waste materials and they must be disposed of in appropriate containers in accordance with local regulations for the disposal of such waste materials.

The components of the electronic boards can contain compounds, such as arsenic, lead, cadmium, mutagenic and cancerogenous agents, that are a health hazard if dispersed in the environment in an uncontrolled way.

For further information contact the relevant authorities for environmental and public health monitoring.

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11 APPENDIX - MORPHEUS OM3.S5

This chapter includes all the information and data necessary to provide full knowledge and interpretation of the manual for the MORPHEUS M anaesthesia unit.

11.1 Technical sheet

11.1.1 MORPHEUS M - cod. OM3.S5

INTENDED USE	The MORPHEUS M is an anaesthesia unit and it can be used on adult, children and newborn patients. The MORPHEUS M is suitable for administration of Oxygen - Air - Nitrous Oxide - Halothane - Enflurane - Isoflurane - Sevoflurane - Desflurane mixtures.
GENERAL DESCRIPTION	The MORPHEUS M anaesthesia unit is completed with: • mechanic gas mixing system, • electronic lung ventilator with 12” TFT colour 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 • gas supply group, • gas analysis system (optional function).

TECHNICAL DATA	
Structure	Light aluminium alloy and plastic moulds
Wheels	Pivoting antistatic wheels, diameter 100 mm (2 with brakes)
Drawer	No. 3 full extension drawers
Cylinder support	No. 2 vertical cylinders supports, on the back side (for cylinders up to 10 litres capacity) and round rubber pads
Support for 2 vaporizers	On horizontal guide (SIARETEX rapid connection device, Selectatec compatible for 2 vaporizers)
Auxiliary power supply outlets	No. 1 SCHUKO 220 Vac outlet (max. 6 A)
Work shelf lighting	12Vdc by led
Dimensions	71 x 77 x 138 (L x P x H) cm (without monitor).
Weight	72 kg (without accessories)
Environmental conditions	• Temperature from +10 to +40°C • Relative humidity from 10 to 90% non-condensing

GAS MIXING SYSTEM

It has the function to regulate the capacity and the concentration of gas mixture (Air, O_2, N_2O) as well as to 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 O_2 enrichment for delivered mixture in case of emergency.

The anaesthesia module includes a device which guarantees a minimum concentration of 25% oxygen in all conditions (MIX-LIFE device).

The three pressure gauges on the front panel allow the continuous control of medical gas feeding pressure coming from the gas pipelines system.

Oxygen rotameter	Scale: 0.1 - 15 L/min. Resolution: 0.1 L/min up to 1 L/min and 1 L/min up to 15 L/min Accuracy: ± 10% of read value or: ± 1% of end scale whichever is the worse case.
Nitrous oxide rotameter	Scale : 0.2 - 12 L/min. Resolution: 0.1 L/min up to 1 L/min and 0.5 L/min up to 12 L/min Accuracy: ± 10% of read value or: ± 1% of end scale whichever is the worse case.
Air rotameter	Scale: 0.1 - 15 L/min. Resolution: 0.1 L/min up to 1 L/min and 1 L/min up to 15 L/min Accuracy: ± 10% of read value or: ± 1% of end scale whichever is the worse case.
Low flows oxygen rotameter	Scale 0.1 - 1 L/min. Resolution: 0.05 L/min Accuracy: ± 10% of read value or: ± 1% of end scale whichever is the worse case.
Low flow nitrous oxide rotameter	Scale: 0.1 - 1 L/min. Resolution: 0.05 L/min Accuracy: ± 10% of read value or: ± 1% of end scale whichever is the worse case.

Medical gas supply	OXYGEN • Pressure included between 280 kPa and 600 kPa (2,8 – 6 bar) • Max. required flow 90 L/min.
	NITROUS OXIDE • Pressure included between 280 kPa and 600 kPa (2,8 – 6 bar) • Max. required flow 15 L/min.
	MEDICAL COMPRESSED AIR • Pressure included between 280 kPa and 600 kPa (2,8 – 6 bar) • Max. required flow 90 L/min.
Gauges	No. 3 on front panel (O_2 - N_2O - AIR), scale 0 - 6 bar
Alarms	Lack or low oxygen pressure with consequent cut-off of nitrous oxide delivery
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 LACK OR LOW OXYGEN PRESSURE CUT-OFF: audible alarm with immediate cut-off of nitrous oxide delivery. AGAINST OVERPRESSURE IN FLOWMETER BOX: Safety valve calibrated at 0.8 bar for the protection of the glass rotameters. 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 N_2O: Selection by membrane key on the flowmeter front panel.
Control for activation of exit of fresh gas for manual ventilations	Setting of MANUAL modality on ventilator (MAN) 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, max flow 35 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)

OUT gas sockets on gas supply group	• No. 1 sockets for O_2 • No. 1 sockets O_2 - AIR for active scavenger feeding • 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)

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	12" TFT high resolution colour display with membrane keyboard and encoder
Control modality	Electronic by microprocessor
Dead space compensation system	Automatic
Automatic compensation of atmospheric pressure	Automatic compensation of atmospheric pressure on measured pressure: present (max. 5000 mt)
Flow generation	Electronic system
Gas feeding	▪ Medical compressed Air or Oxygen supply with pressure included between 280 kPa and 600 kPa (2,8 – 6 bar) ▪ Turbine driven: independent from the gas supply system (in this case it's necessary a pneumatic Oxygen supply only).

Self-Test	**Primary test:** at anaesthesia unit's start-up, a control test of Turbine presence, Medical Gas Supply presence, INSP and EXP flow sensors operation, pressure sensor, patient circuit losses, back-up battery state, oxygen cell, 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.
Ventilation modalities	▪ APCV ▪ APCV-TV ▪ PSV ▪ APNEA BACK-UP ▪ SIMV (Volumetric +PS; SPONT) ▪ VC/VAC ▪ VC/VAC BABY (integrated NEONATAL ventilation mode) ▪ MANUAL
Breathing rate	From 4 to 120 bpm (step 1 bpm)
I:E Ratio	1:1, 1:1.5, 1:2, 1:3, 2:1, 3:1
Inspiratory time	From 0.2 to 5 sec.
Inspiratory pause	From 0 to 60% of inspiratory time
SIMV rate	From 1 to 119 bpm
Tidal volume	From 5 to 1500 ml (< 50ml: step 1ml / 50-100ml: step 5ml / >100ml step 10ml)
Minute volume	From 1 to 30 liters
Airways pressure limit (PLIM)	From 6 to 60 cmH_2O
Support pressure (PS)	From 5 to 60 cmH_2O
PEEP	OFF, 3 to 30 cmH_2O (step 1 cmH_2O)
Inspiratory Flow (FLOW)	Selectable ramp from 10 to 80 L/min (step 10 L/min)
Oximeter	Minimum resolution 1% - Automatic calibration procedure
Bronchomanometer	-20 to 80 cmH_2O

Flow trigger	From OFF, 1 to 15 L/min (step 1 L/min)
Pressure trigger	From -1 to -9 cmH_2O under the PEEP level
Safety	Electronic and mechanical limit of airways pressure - Self-diagnosis system
Alarms	• Low / High Airways Pressure, Low / High Breathing Rate, Low / High O_2 Concentration, Low / High Tidal Volume, Electric Power Supply • Apnoea, Low Battery, Low Gas Supply, Disconnected Patient Circuit, Can-Bus Failure
Flow sensor	Internal to the valves group, by magnetic perturbance, reusable.
Measured parameters	• PAW; PEEP; Rate; I:E; FiO_2; Vte; ExpMV • MAP; Pplateau; Tpause; Ti; Te; Fi; Fe; Cs; Ri;
Ventilation Curves	CURVES: Pressure - Flow - Volume LOOPs: Volume / Pressure and Flow / Volume Measurement RANGE: automatic
Trend	Scale and 72 hours trend period setting Foreseen Trends: PAW; PEEP; VTe; ExpMV; Rate
Events	Memory storage up to 100 events per machine including the alarms.

GAS ANALYSIS - (Optional Function)

Gas analysis	Integrated software for analysis of CO_2, O_2, N_2O, AG automatic identification, MAC.
Mainstream device	• IRMA AX+ (CO_2, N_2O, primary and secondary agents, HAL, ISO, ENF, SEV, DES). • IRMA CO_2 (CO_2)
Sidestream device	• ISA AX+ (CO_2, N_2O, Agents) • ISA CO_2 (CO_2) • ISA OR+ (CO_2, N_2O, Agents, O_2)
Technical characteristics	Consult the relevant technical data sheets for mainstream and sidestream modules.

ELECTRIC POWER SUPPLY

Electric power supply	100 ÷ 240Vac / 45 ÷ 60Hz
Maximum power	120 Watt
Back-up battery	12Vdc - 3 Ah Pb battery which guarantees an autonomy of around 120 minutes
Charging time	Around 10 hours

CONFORMITY TO DIRECTIVES

Class and type according with IEC 601-1	Class I Type B
Class according with 93/42/EEC Dir.ve.	Class IIb

EN 60601-1:2006/A1:2011/A1:2013; EN 60601-1-2:2015; IEC 60601-1-6:2013; IEC 60601-1-8:2012; EN 62304:2006/AC:2008; ISO 10993-1:2009; IEC 62353:2014; DIR.2011/65/CE; D.Lgs 49/2014; EN ISO 14971:2012; ISO 4135:2001; ISO 15223-1:2016; EN 60601-2-13:2006;

ACCESSORIES

Standard accessories

- User's Manual
- O_2 supply hose
- N_2O supply hose
- Air supply hose
- O_2 cylinder supply hose
- N_2O cylinder supply hose
- Top Special CO_2 absorber canister of 1 kg (no. 1 / canister with metal cover)
- O_2 cell
- Adult silicone patient circuit
- Adult Mapleson C adult patient circuit
- Manual ventilation KIT
- Electric power supply cable

Optional accessories See current export price list

11.1.2 Table for Identification of medical gas hose colours

GAS	SYMBOL	ISO & UK	USA	GERMANY
OXYGEN	O_2	White	Green	Blue
NITROUS OXIDE	N_2O	Blue	Blue	Grey
CARBON DIOXIDE	CO_2	Grey	Grey	-
CYCLOPROPANE	C_3H_6	Orange	Orange	-
MEDICAL AIR	AIR	White & Black	Yellow	Yellow
ENTONOX 50/50 N_2O/O_2	$N_2O + O_2$	Blue & White	-	-
EMPTY	-	Yellow	-	-

11.2 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 apnea and starts the corresponding ventilation when the interval between the two respiratory cycles exceeds the set apnoea time.
Automatic alarm resetting	This occurs when an alarm is disabled, i.e. when the alarm conditions are no longer present, without pressing the alarm reset key. ALARM RESET
Basic flow	Constant flow (depending on the sensitivity value set in the “trigger value” parameter) circulating in the patient circuit with respect to which the ventilator measures the Flow Trigger value.
CE	A certificate of origin issued by the European Economic Community indicating that the equipment conforms to the Medical Device Directive (MDD), 93/42/EEC.
Clinical alarm	An alarm that can indicate an abnormal physiological condition
cm	Centimetre (unit of length).
cmH_2O	Centimetres of water (unit of pressure = 0.98068 mbar = 1 hPa).
Compliance (Cs)	This term defines the variation in volume of the respiratory tract determined by a variation in pressure; it is measured in ml/cmH_2O. It provides an indication of the elastic properties of the respiratory system and its components (Inspiratory Tidal Volume / Pause Pressure).
Compressor	The Compressor (optional) provides the system with compressed air and can be used instead of the mains or cylinder supply of compressed air.
CPU	Central processing unit
DISS	Diameter Index Safety Standard: a standard for high pressure gas input connectors.
EMC	Electromagnetic Compatibility

EN	European norm referring to the European Economic Community
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 operator which closes the inspiratory and expiratory valves during the expiratory phase of a breath.
FiO_2	Parameter set by the operator and monitored. The % setting of FiO_2 determines the percentage of oxygen in the gas delivered to the patient. The monitored data of the % of FiO_2 indicate the percentage of oxygen delivered to the patient, measured on the inspiratory line.
Flow Trigger	Method of recognition of the inspiratory effort of the patient, during which the ventilator controls the basic flow circulating in the patient circuit. An inspiratory attempt by the patient is translated into a decrease of the basic flow, which the ventilator recognizes as a spontaneous breath and delivers a synchronized breath.
GUI	Graphics user interface, the part of the ventilator which comprises the screen, the keys and the knob. The GUI is equipped with an independent CPU which monitors the data of the ventilator and the patient. The screen displays the monitored information, including the alarms, the monitored parameters, the graphs, the ventilator settings and the messages.
High priority alarm	As defined by the international standards organizations, this is an alarm which requires immediate intervention to ensure the safety of the patient. During a high priority alarm, the corresponding red signal flashes rapidly, a high priority acoustic alarm signal is emitted (a series of five tones repeated twice, followed by a pause, then repeated again) and an alarm message is displayed in the upper part of the screen.
hPa	Hectopascal (unit of pressure, approximately equal to 1 cmH_2O).
Hz	Hertz (unit of measurement of frequency, indicating cycles per second).
I:E ratio	The ratio between inspiratory time and expiratory time
IEC	International Electrotechnical Commission: international organisation for the definition of standards.
INSP. PAUSE	Inspiratory pause, a manoeuvre started by the operator which closes the inspiratory and expiratory valves during the inspiratory phase of a breath. This manoeuvre can be used to determine the static compliance (C) and the resistance (R).

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 operator) 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 operator for an inspiratory time also set by the operator.
PEEP	Positive end expiratory pressure: the minimum level of pressure maintained in the patient circuit during ventilation. Parameter set by the operator and monitored.
Pressure Trigger	Method of recognition of the inspiratory effort of the patient, in which the ventilator controls the pressure in the patient circuit. The ventilator enables ventilation when the airways pressure decreases by an amount at least equal to the selected threshold value in a defined period of time.
PSV	Pressure support ventilation: a type of spontaneous ventilation in which the ventilator delivers pressure set by the operator 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 operator which determines the volume delivered to the patient during controlled volume ventilation. Tidal volume includes the compensation for compliance and for pressure and body temperature.
TREND	Medium and long-term monitoring of the respiratory parameters.
VA	Volt -Ampere (unit of power).
Vac	Alternate current voltage
VC-VAC	Intermitted ventilation by assisted positive pressure: a ventilation mode which allows to deliver controlled ventilations only (started by the patient, by the ventilator or by operator) basing on current settings.
Vdc	Direct current voltage
Ventilations per minute (bpm)	Respiratory rate unit (Resp/min).

11.3 Electromagnetic compatibility tables

11.3.1 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>

11.3.2 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.

11.3.3 ANNEX C: Table 3

<table>
<tr><th colspan="5">Guidance and manufacturer’s declaration – electromagnetic immunity</th></tr>
<tr><td colspan="5">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>IMMUNITY test</th><th>IEC 60601 TEST LEVEL</th><th>Compliance level effective</th><th>Compliance level</th><th>Electromagnetic environment – guidance
Recommended separation distances</th></tr>
<tr><td rowspan="2">Conducted RF
IEC 61000-4-6</td><td>3 Vrms 150 kHz to 80 MHz outside ISM bands</td><td>VRMS</td><td>[V1] VRMS</td><td>SEE ANNEX E</td></tr>
<tr><td>10 Vrms 150 kHz to 80 MHz in ISM bands</td><td>VRMS</td><td>[V2] VRMS</td><td>SEE ANNEX E</td></tr>
<tr><td rowspan="2">Radiated RF
IEC 61000-4-3</td><td rowspan="2">10 V/m 80 MHz to 2,5 GHz</td><td rowspan="2">V/m</td><td rowspan="2">[E1] V/m</td><td>80 ÷ 800 MHz
SEE ANNEX E</td></tr>
<tr><td>800 ÷ 2500 MHz
SEE ANNEX E</td></tr>
<tr><td colspan="5">Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol:

  </td></tr>
<tr><td colspan="5">Note:

1. At 80 MHz and 800 MHz, the higher frequency range applies.

2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
</table>

11.3.4 ANNEX E: Table 5

Recommended separation distances between portable and mobile RF communications equipment and the Morpheus E

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 :

1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
2. 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.
3. 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 V_1 and 10V for V_2

11.4 Preliminary tests

In the following table:

List of preliminary tests - MORPHEUS ANAESTHESIA UNIT

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 operator.**			
Has the periodic maintenance (that should be performed by the operator) 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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Anaesthesia Unit

Morpheus M

User's Manual

Version DU3300105

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