ENGINEERING
INTERNATIONAL GROUP s.r.l.

PULSAR

User's manual

GENERAL INFORMATION

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The information contained in this manual refers to PULSAR produced or updated after July 2011. 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 DU3980106

Revision 6 - 21.07.2011

Observations

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Any comments 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 your comments to the following address:

SIARE ENGINEERING INTERNATIONAL GROUP s.r.l.

Tel.: +39 051 969802 - Fax: +39 051 969366

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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.

N.B.

This indicates information worthy of note, making the operation of the PULSAR more efficient or practical.

Warnings, cautions and notes

You are advised to carefully read the information given alongside the three symbols shown on the previous page, since it contains considerations on the safety, the special requirements for the use of the PULSAR and the relative safety regulations.

- In order to understand how the PULSAR 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 PULSAR 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 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 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 PULSAR 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 the (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 machine in a safe and correct manner.
- To prevent the risk of fire, keep the 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.
- The use of flexible connectors, antistatic or conductive hose is not admitted in any applications with this device.
- In the event of fire or an unpleasant smell (e.g. a smell of burning), the PULSAR should immediately be disconnected from the electrical power supply and from the battery (if fitted).

- Concerning cleaning, sterilization and disinfection of product components, keep into consideration the directives in force in the country where the equipment is installed.
- Before using the Pulsar 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 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.
- The correct functioning of the 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 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.
- This equipment is part of the range of products manufactured by SIARE ENGINEERING INTERNATIONAL GROUP s.r.l.

WARNING !!

This equipment is not approved for operation in places where there is any risk of explosion.

WARNING !!

Do not use the equipment in the presence of flammable gases.

WARNING !!

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

WARNING !!

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

WARNING !!

Qualified staff must make the regulation of ventilation parameters.

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

- If the is used in conditions and for purposes not stated or described in this manual.
- If the 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 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 equipment not in accordance with the instructions contained in the users and maintenance manual.

Year of manufacture

Check the identification data label of the equipment in the relative chapter.

Manufacturer

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Electromagnetic Compatibility

The PULSAR is designed to operate in the specified electromagnetic environment (see warning below). The customer or the user of the PULSAR should ensure that it is used in such an electromagnetic environment

The PULSAR 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 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. If it is necessary to use the PULSAR in the vicinity of other units, it should be kept under observation to check its normal functioning according to the chosen configuration..

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 PULSAR user’s manual.

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Table of contents

1 INTRODUCTION

The Pulsar is a new generation device designed both for use during recovery and at home.

The unit controls breathings; offers various ventilation methods and simplifies the selection of the most appropriate settings by the operator.

The purposes of cough stimulation are:

- Broncho-pulmonary secretions removal
- Improvement of the quality of the life
- Reduction in relapses
- Neuropsychic improvement

1.1 Intended use

The PULSAR is designed for patients who have difficulty in removing the broncho-pulmonary secretions.

The PULSAR assists the patients to facilitate the bronco-pulmonary secretion through the gradual application of a positive pressure followed by a negative pressure.

The PULSAR can be used on adults or children, varying the breathing parameters which can be set by the graphic user's interface (GUI).

The PULSAR has different modalities and through the graphic user's interface (GUI) simplifies the selection of the most appropriate settings by the operator.

The main modalities offered by the Pulsar are the following:

- AUTO (automatic modality),
- AUTO + V (automatic modality with vibration),
- MAN (manual modality),
- MAN + V (manual modality with vibration),
- AST (assisted mode synchronized with the patient)
- AST + V (assisted mode synchronized with the patient with vibration)

In order to correctly understand how the Pulsar works at negative pressure, the recommendations and instructions contained in this user's manual must be read with care and understood.

1.1.1 Contraindications

Possible contraindications for the treatment with the PULSAR device:

- After thoracic operations, in order to avoid injury to the internal organs, consult the doctor.
- After “open-heart” operations, pay attention to ventilation parameters setting in order not to negatively affect the patient hemodynamic functions.
- After maxillo-facial operations consult the doctor before using the device.
- In case the patient has inconveniences due to emphysema, bronco-pneumothoracic or barotrauma, a widen clinic survey is recommended before use.

1.2 Technical features

The PULSAR is composed or the following main units.

- The graphic user’s interface (GUI) includes: the monochromatic TFT 5.7’’ display, the side keyboard and the encoder knob. The screen displays the pressure trend and the parameters which can be set by the user.
- To make using the device more simple and intuitive, the operator can act directly with all the functions available on the graphic user’s interface (GUI), by means of the keyboard and the Encoder knob on the front of the monitor.

For anyone who already has basic knowledge of the Pulsar, the use of the user’s interface is intuitive. So, to correctly use the unit, simply consult the user’s manual.

The screen of the graphical interface (GUI) is divided into areas displaying:

- operator set parameters which are associated to a system of acoustic and visual alarms;
- the pressure bar on which it is possible to display the values;
- the visual indication for the alarms;
- the “real-time” ventilatory phase: INSP (INHALE), EXP (EXHALE), PAUSE, STAND-BY

The device user’s interface has been designed for a simple and intuitive use.

The electronic management and control portion are controlled by a single mother board, which manages all the information received from the peripherals.

The PULSAR also fitted with a series of sensors for continuous patient monitoring:

- A pressure sensor for airways pressure control.
- A temperature sensor can monitor the temperature in the blower.

The sensors operation should be verified by the operator before using the device, in order to avoid wrong evaluations of the patient conditions.

The pneumatic part of the Pulsar consists in various internal pneumatic circuits as well as an actuator designed to control the pressure of the air coming out from the blower.

The device does not need to be connected to any high pressure medical gas distribution sources, since this is done independently by an internal blower.

The following is required for correct operation:

- correct connection to the patient circuit;
- connected to a main power supply with the same voltage as specified on the identification plate of the device's power supply meeting the general standard for medical equipment **IEC 60601-1**.

The connections with the mains power supply must comply with the instructions given in this manual.

In order to guarantee maximum reliability and to ensure patient and operator safety the Pulsar was designed and manufactured to ensure the total quality of the products and its components.

The present manual explains how to use the Pulsar and how to perform simple maintenance interventions.

To ensure the best performance of the Pulsar it is recommended that qualified technical personnel perform periodic maintenance on the device.

Is recommended careful reading of this manual and the relative labels before operating the Pulsar or carrying out any maintenance.

1.3 Applicable standards

The Pulsar for home care and hospital use was manufactured in compliance with the following standards:

IEC 601-1	Medical electrical equipment. Part 1: General requirements for safety
IEC 601-1-2	Medical electrical equipment. Part 1: General requirements for safety 2. Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 601-1-4	Medical electrical equipment. Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
UNI EN 1281-1	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
ISO 10651-2	Lung ventilators for medical use. Particular requirements for basic safety and essential performance - Part 2: Home care ventilators for ventilator-dependent patients
UNI EN 475	Medical devices. Electrically-generated alarm signals
UNI EN ISO 9703-3	Anaesthesia and respiratory care alarm signals - Part 3: Guidance on application of alarms
UNI EN ISO 4135	Anaesthetic and respiratory equipment - Vocabulary
93/42/EEC	Medical devices directive

2 PULSAR DESCRIPTION

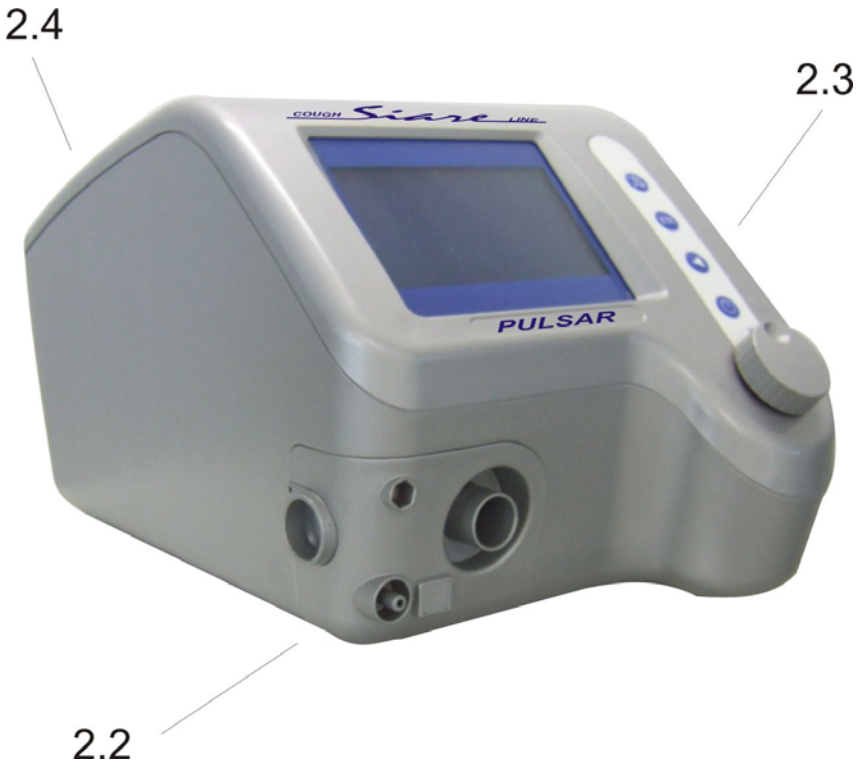
This chapter describes the Pulsar in its main parts.

- Pulsar, total view
- Side view
- Front view
- User's controls interface (UCI)
- Back view
- Back connectors panel
- User's qualification

As far as assembling, interfacing and maintenance are concerned, make reference to the present manual or contact the authorized agent for technical service.

2.1 Pulsar, total view

The images are just indicative and they illustrate a possible device configuration.



2.2 Side view

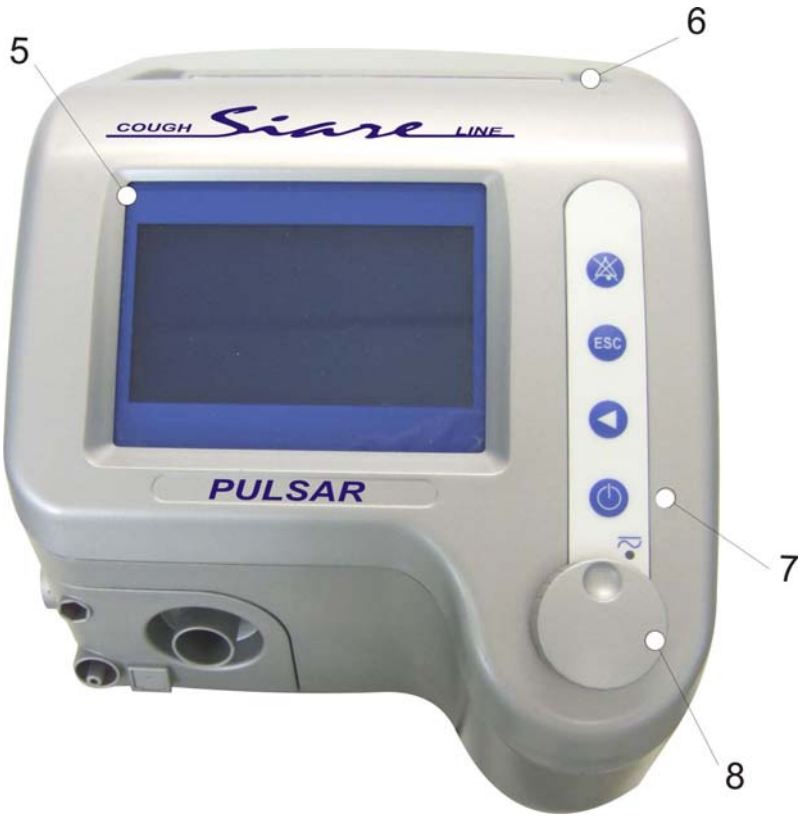
2.3 Front view

2.4 Back view

2.2 Side view

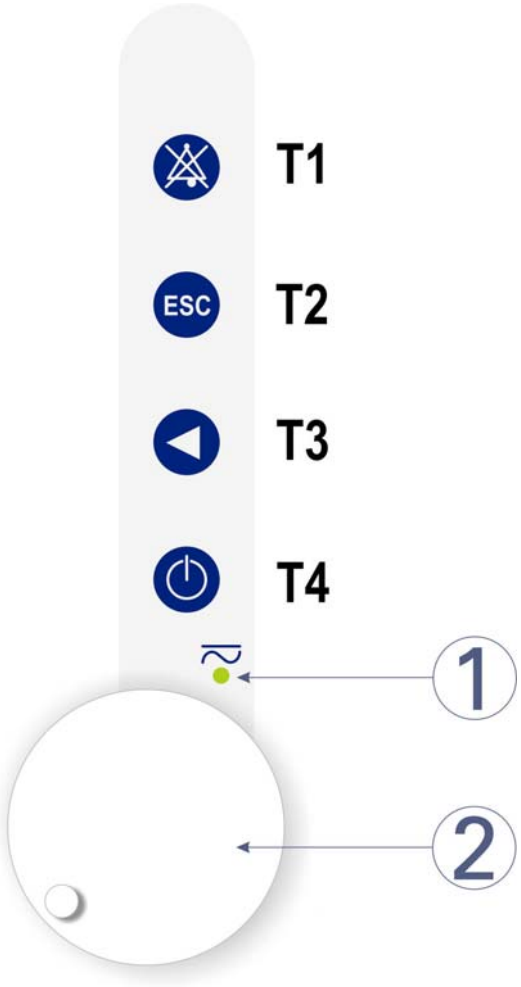
1. EXP. Line
2. INSP. Line
3. Unused connectors

2.3 Front view



5. Graphic display 240x128px
6. Transport handle
7. Control keyboard with membrane keys
8. Encoder knob

2.3.1 User's controls interface (UCI)



T1 Audible alarm silencer key

T2 Return key to previous menu window

T3 Start ventilation key (START)

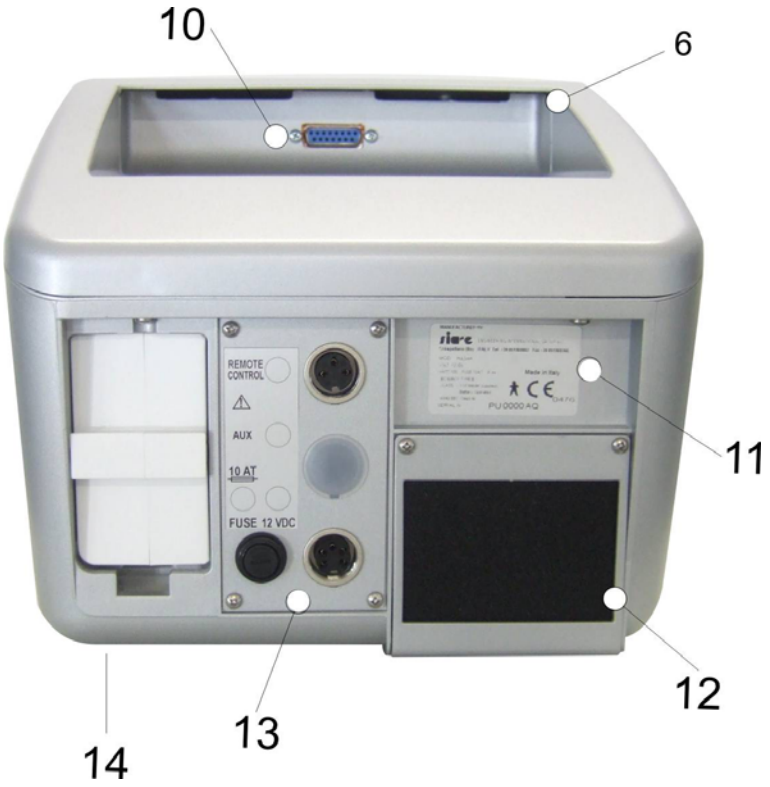
T4 STANDBY, ON/OFF

1 Power led indicator

2 Selection Encoder knob

For the description of the rapid control keyboard and Encoder knob see chapter 3.

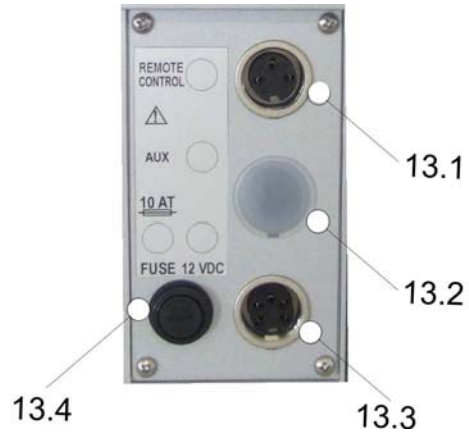
2.4 Back view



10. Programming Connector
11. PULSAR identification data label
12. Anti-dust and anti-pollution air aspiration filter for turbine
13. Back connectors panel
14. Fan air aspiration filter

On the identification data label, are indicated: the model, the power supply, the power consumption, the number and the fuses value, the serial number of the equipment.

2.4.1 Back connectors panel



13.1 External control connection

13.2 Future uses

13.3 Connector for external 12Vdc power supply

13.4 Protection fuse for 12Vdc power circuit

For the description of the electrical and pneumatic connections see the relevant section of the present manual.

2.5 User's qualification

The medical device should be exclusively regulated by a doctor.

At the moment of delivery to the patient, the doctor or the health worker should instruct him on equipment operation.

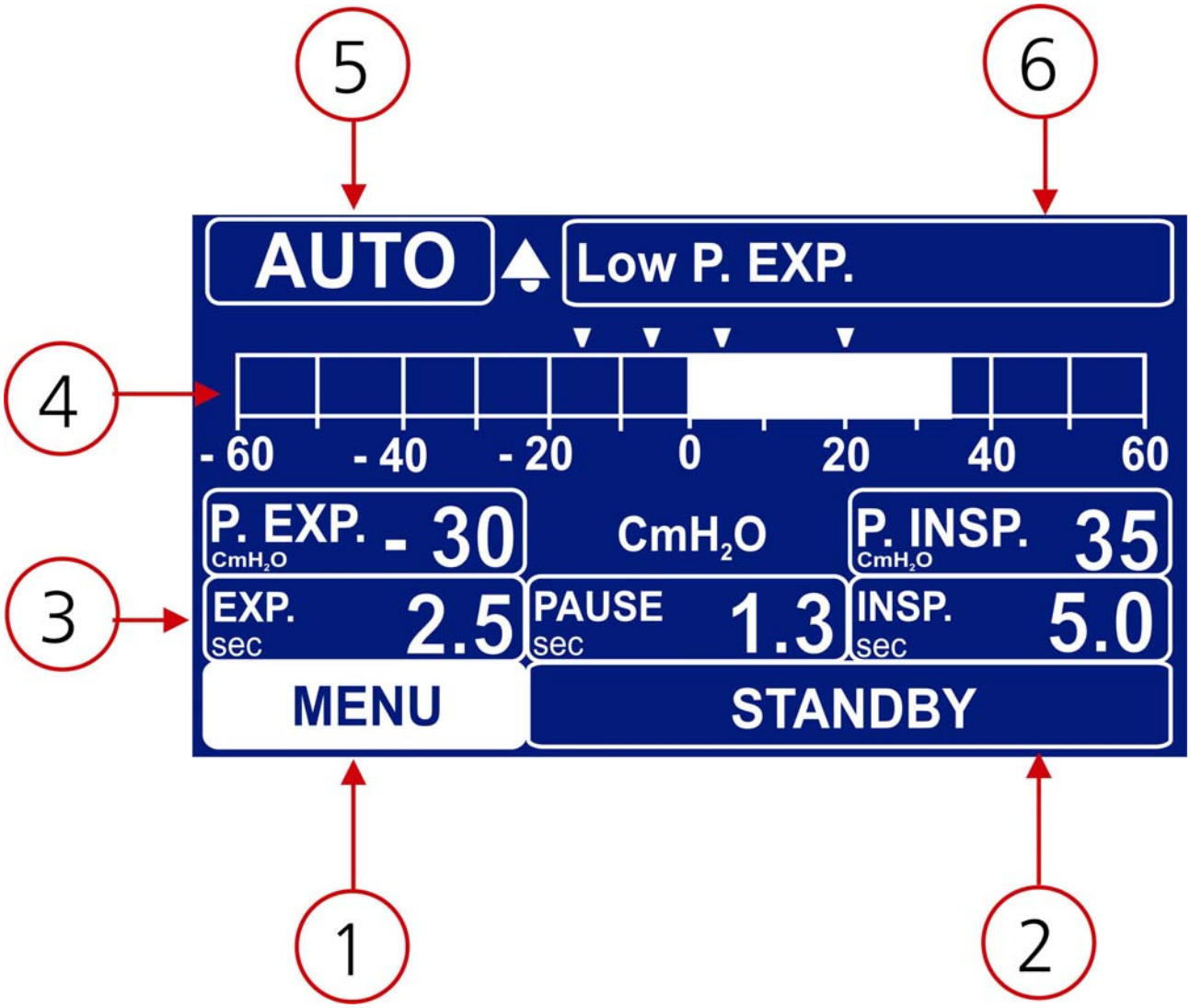
3 USER'S INTERFACE

This chapter contains a widen description of the graphic user's interface (following as GUI) dividing and illustrating the screen in areas and using zones, and a description of the user's controls interface with indication of keys and selecting encoder knob functions.

- Graphic user's interface (GUI)
- Menu area
- Operative modalities setting zone
- Set parameters display zone
- "Real time" pressure bar
- Alarms zone
- "Real time" phase displaying zone
- User's controls interface (UCI)
- Remote control: push-button panel

Each described part, put in evidence the setting and regulations to be performed, allowing to the user to use the PULSAR at best.

3.1 Graphic user's interface (GUI)

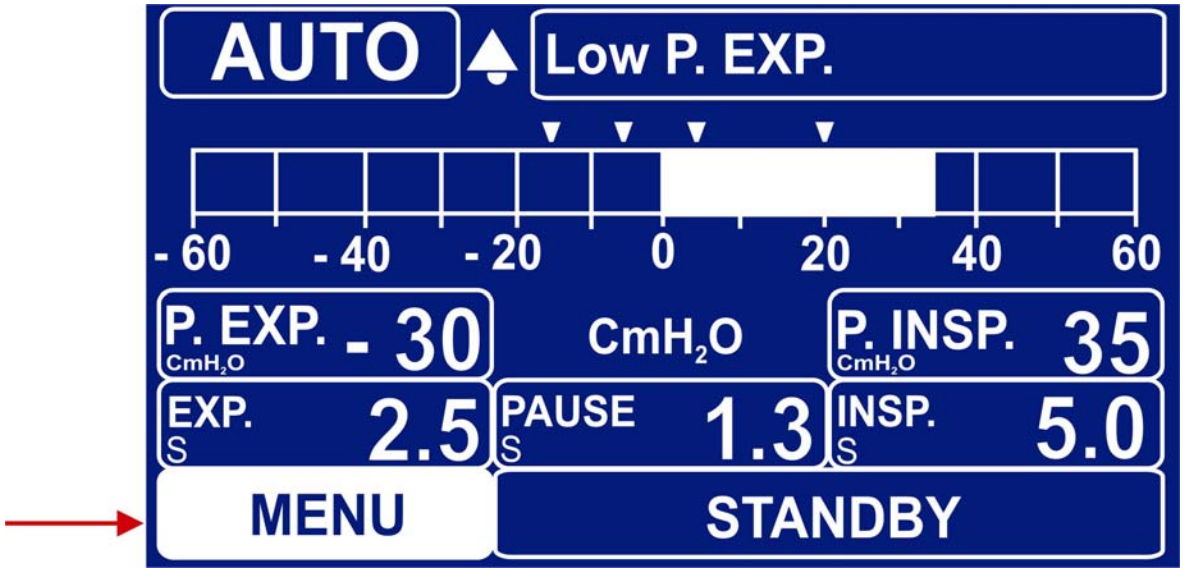


1. Menu Area
2. "Operative condition" area
3. Parameters setting zone
4. "Real time" pressure bar
5. Adjustable operative mode zone
6. Alarms zone

3.1.1 Menu area

Proceed with the following operations to activate the **MAIN MENÙ**.

1. Press the Encoder knob
2. Turn the Encoder knob and position the cursor on **Menu** item
3. Press the Encoder knob again (the indication **Menu** will start flashing)
4. Turn the encoder knob and select the desired sub-menu (ex. **Menu 1**) and press to confirm (now the **Menu 1** indication will become fix)



When the **MENU** function has been enabled, the **Menu 1** window opens, as seen in the GUI.

To enter one item of the a.m. menu, press again the encoder knob to confirm, in alternative it is possible to enter to next menus by turning clockwise the encoder knob.

Select an entry from **Menu 1** to open the " lower level " windows with additional items and parameters that can be set.

- o Turn the encoder knob and position the cursor on the desired menu entry (high lightened with a white background) and confirm the selection by pressing the encoder.

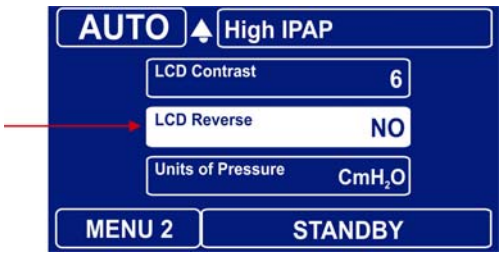
The **MENU** function includes the following lower levels:

Menu 1

- Language
  - Italian
  - English
  - German
- Sound Volume %
  - 0 – 100%

Menu 2

- LCD contrast — 0 - 10
- LCD reverse — YES / NO
- Units of pressure — cmH2O / mbar / hPa



Menu 3

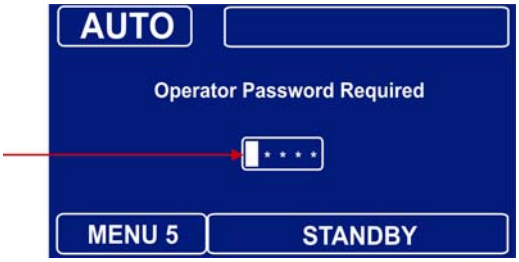
- P. EXP. min — [-30, -10]
- P. EXP. Max — [10, 30]
- P. INSP. min — [-30, -10]
- P. INSP. Max — [10, 30]

Menu 4

- INSP — [0.5, 5] s
- Vibration Time — [0.2, 4.8] s
- Vibration Frequency — [180, 600] bpm

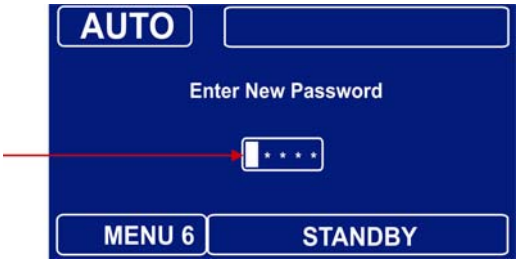
Menu 5

- Password — **00000 (DEFAULT)**



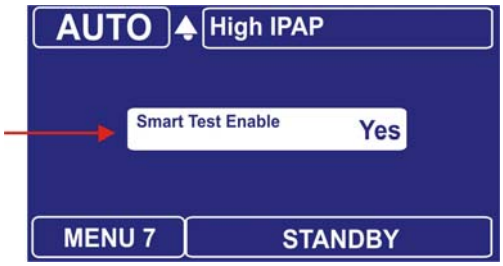
Menu 6

- New Password



Menu 7

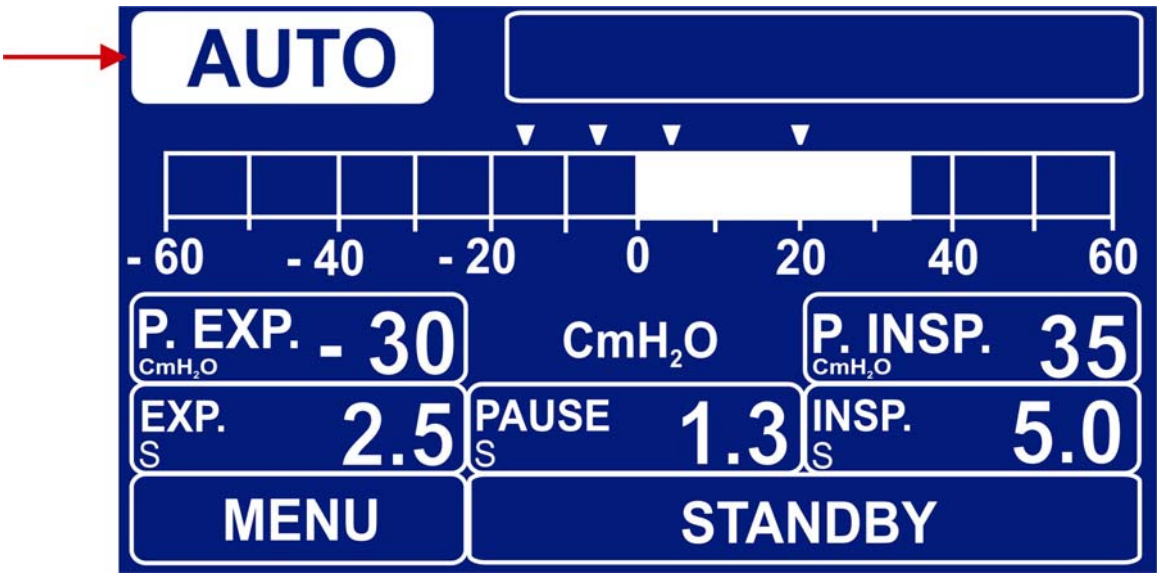
- Smart Test Enable
  - YES
  - NO



The two sub-menus (**6, 7**) are enabled only after the corrected password is entered in the menu 5.

3.1.2 Operative modalities setting zone

The selected operative mode is shown in the upper side of the main screen.



AUTO

Indication of Operative Mode type selected by the MENU function.

- AUTO
- AUTO + V (automatic modality with vibration enabled)
- MAN
- MAN + V (manual modality with vibration enabled)
- AST (assisted mode synchronized with the patient)
- AST + V (assisted mode synchronized with the patient with vibration)

3.1.3 Set parameters display zone

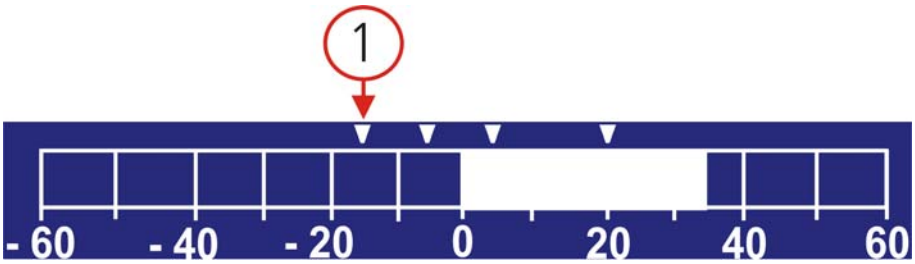
The ventilation parameters area is the zone of main interest where all the physiological breathing parameters of the system can be set [**PRF**].

Description of the adjustable parameters:

P. EXP.	**EXPIRATORY PRESSURE** With this parameter it is possible to set the negative airways pressure value in the expiratory phase. The parameter can be set at values from **0 to - 60 cmH_2O** with steps of 1 cmH_2O.
P. INSP.	**INSPIRATORY PRESSURE** With this parameter it's possible to set the positive airways pressure value in inspiratory phase. This parameter can be set at values from **5 to 60 cmH_2O** with steps of 1 cmH_2O.
INSP	**INSPIRATORY PHASE** With this parameter it is possible to set the duration of the inspiratory phase. This parameter can be set at values from **0.5 to 5 seconds** with steps of 0.1 s.
EXP	**EXPIRATORY PHASE** With this parameter it is possible to set the duration of expiratory phase. This parameter can be set at values from **0 to 5 seconds** with steps of 0.1 s.
PAUSE	**PAUSE** With this parameter it is possible to set a time pause between the end of an act and the next one: At termination of expiratory phase, the next inspiratory phase start will be delayed upon set time. This parameter can be set at values from **0 to 5 seconds** with steps of 0.1 s.

3.1.4 "Real time" pressure bar

In the upper side of the screen there is a "pressure bar" indicator showing the real-time airways pressure (**PAW)**.



As per above figure (**1**), some identification marker are displayed upon set alarm limits (see chapter 6 of the present manual).

3.1.5 Alarms zone

The unit is equipped with audible and visual alarms.

When an alarm is activated the operator will see information and signals which appear in the Alarms Area in the upper right side of GUI.

See chapter 6 for more information on present alarms.

The alarms area shows both an information message relevant to the type of activated alarm and displays the alarm "bell".

For additional information see chapter 6 about present alarms whose settings, use and interpretation of available information are deeply illustrated.

The "bell" symbol lights up and flashes when an alarm condition occurs.

- Active Alarm 
- Suspended alarm: "bell" symbol crossed through 

The alarms signalled in this zone of GUI are:

- **P. EXP. min**
- **P. EXP. Max**
- **P. INSP. min**
- **P. INSP. Max**

3.1.6 "Real time" phase displaying zone

In the "real time" phase zone is displayed the current operating condition.

See the below figure to note the indication of the standby phase.

The conditions which can be displayed in such zone are :

STANDBY

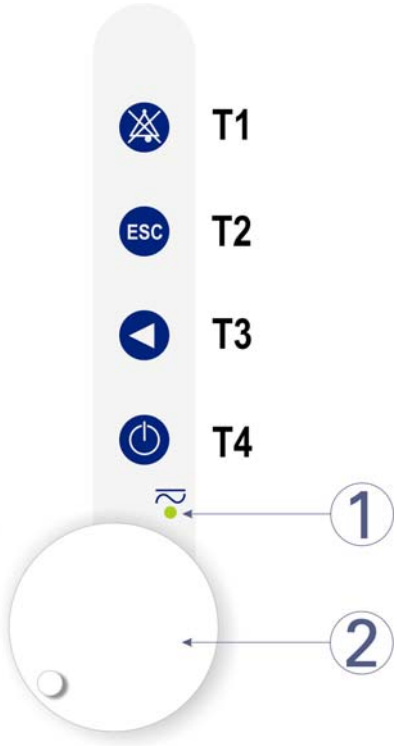
Inspiration

Expiration

Pause

3.2 User's controls interface (UCI)

The user's command interface, shown here below (**UCI**), consists of a keyboard with four membrane keys, a power indication led and an encoder knob, which allows navigation within the GUI and parameters selection/setting.



T1. Audible alarm silencing key

T2. Key to return to the previous menu

T3. Ventilation start key

T4. STANDBY, ON/OFF key

1 Electrical power indication LED

2 Selection Encoder

3.2.1 UCI Description

Audible alarm silencing key

T1

When an alarm condition occurs, an audible alarm is activated for the period described in the alarm section of the present manual (chapter 6) and it can be silenced by pressing the T1 membrane key. When the condition which caused the alarm stops, it is possible to cancel the visual indication on the GUI window by pressing again the same key.

ESC escape key

T2

By pressing this key it is possible to escape from the "current" screen and return to the "previous" screen.

Ventilation starting key

T3

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

Stand-by On/Off key

T4

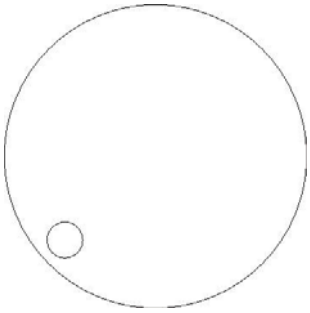
This key has a double function:

- **ON/OFF:** by a prolonged pressure on the key (3 sec.) the device can be turned on and off.
- **STAND-BY:** by a pressure of the key during the ventilation the operator or the patient can temporarily stop the equipment and put it in a stand-by condition (STANDBY).

2- Electric power indication

Electric Power Led

When the green led under the electric power symbol lights up, as in the figure alongside, this means that the equipment is connected to the electric power supply.



1- Selection Encoder knob

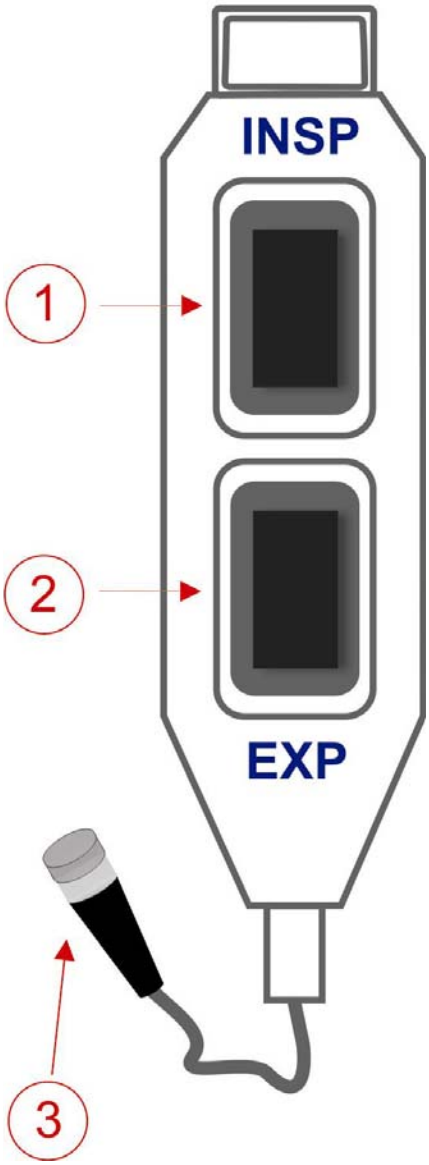
Selection encoder knob

You can navigate inside the GUI by turning the encoder knob. To access the selection modality, select the parameter field to be set and press the encoder knob: when a parameter is changed, the field background will change colour. Press again the encoder knob to confirm the selection (see the description of the parameters setting chapter 5).

It is also possible to access to the main menu by selecting the Menu box on the GUI and navigating within the menu following the desired path.

3.3 Remote control: push-button panel

The device is equipped with an external push-button panel, for the control of ventilation in manual modality.



1. **INSP key**: with this key the operator can activate the inspiratory phase in *MAN, MAN+V modality*. The end of the inspiratory phase is determined by the release of the same key.

2. **EXP key**: with this key the operator can activate the expiratory phase in *MAN, MAN+V modality*. The end of the expiratory phase is determined by the release of the same key.

3. **Connection Cable**: with this cable you provide to connect the remote control to the Pulsar.

For your notes

4 PREPARATION FOR USE

This chapter illustrates how installing the PULSAR.

- Preliminary operations
- Connection of the patient circuit
- Connection to main power sources
- Remote control
- PULSAR start-up
- PULSAR turn-off

4.1 Preliminary operations

- Unpack carefully; lift the PULSAR by means of carrying handle.
- To avoid damaging the components or malfunctioning, position the PULSAR correctly on the trolley (if supplied) or on a flat surface.
- The assembly and connection of all components must be carried out by highly qualified technical personnel, trained and formally authorized by the Manufacturer.
- This type of medical device is not suitable to be used in a hyperbaric chamber and magnetic resonance areas.
- Do not connect or disconnect parts or components when the PULSAR is on or connected to the main power supply.

- Before using the PULSAR, it is suggested to clean the external surfaces and sterilize the components, following the maintenance instructions provided in this manual and respecting the regulations in force in the country where the unit is sold.

4.2 Connection of the patient circuit

- Mount the filters on the EXP. and INSP lines of the PULSAR.

- Apply the filters to the patient circuit.

- To reduce risks of bacterial contamination and component damage, the antibacterial filters must always be handled with care and connected to the unit during its use.
- Do not connect the device to the patient by means of antistatic conductive hoses; the use of such hoses is not allowed under any circumstances with this unit.

The figure shows a connection example of a disposable PVC dual limb patient circuit for adult code A36.049041.

4.2.1 Antibacterial filter

The antibacterial filter (code A36.049011) as shown above is positioned between the Pulsar and the patient circuit.

The filter is equipped with a 0.3 micron antibacterial membrane, which guarantees high efficiency up to 99%. The flow resistance is lower than 1cmH2O/50lpm. The filter is made of polycarbonate and has a 22 mm female connector and a 22F/15M mm connector.

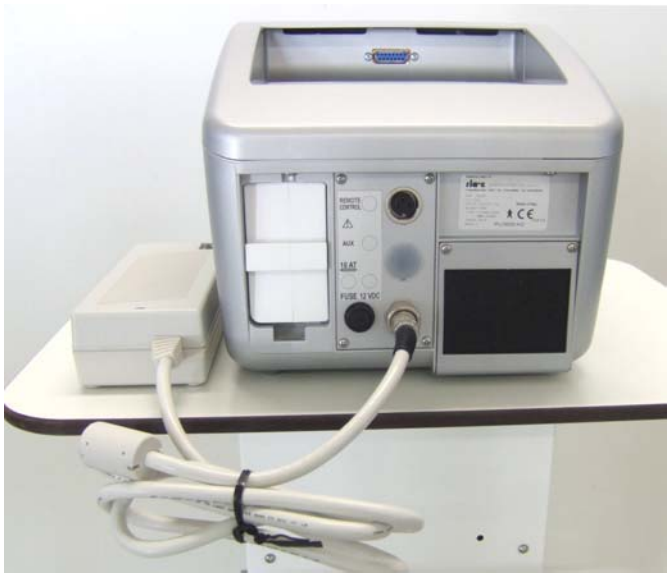
It complies with ISO-5356-1 standard.

4.3 Connection to main power sources

The power supply connection is a very important phase of the installation of the PULSAR.

Wrong connections or connections to not appropriate main power sources can compromise the patient and operator safety.

The main power sources must be compliant with the IEC 601-1 standards for electric safety in environments for civil use.



Verify that data indicated on the equipment identification label are compatible with the electric main source.

The equipment is conform to the **IEC 601-1-2** standard for the electromagnetic compatibility.

As a further guarantee of good operation of the PULSAR, it is advisable to install it in combination with equipment which are complying with the above mentioned standards.

- Position the PULSAR on a trolley (type Castor LT) or on a flat surface.

- Connect the 220 VAC power cable supplied to the main supply line and to the supplied feeder.

- Connect the 12 Vdc power cable supplied to the connector positioned on the rear side of the PULSAR (alongside figure).

- Screw the ring nut to hold up the connector.

- Device start-up: press the **I / O** switch located on the 220 Vac / 12 Vdc power unit.

- Press the **ON / OFF** key on the front keyboard.

At PULSAR start-up also a series of machine tests will be performed to verify the correct functioning of its main components, in order to allow a correct patient ventilation (see following chapter).

To avoid electro-shock risk, connect the power cable of the PULSAR to a electric outlet equipped with earth pin.

4.3.1 Protection fuses

Replace the protection fuse respecting the values indicated on the label; fuses with wrong values can compromise the integrity and the safety of equipment.

One fuse protects the unit main board. To access the mentioned fuse of the 12Vdc power supply line it is necessary to turn and remove the fuse support (see alongside figure).

Fuse value, *12 Vdc circuit : 10 Amperes.*

4.4 Remote control

The external push-button panel allows to control the Pulsar manually (INSP. and EXP. phase).

See Chap. 5 for use.

- Connect the supplied push-button panel cable to the connector positioned on the back side of the PULSAR (alongside figure).
- Screw the ring nut to hold up the connector.

4.5 PULSAR start-up

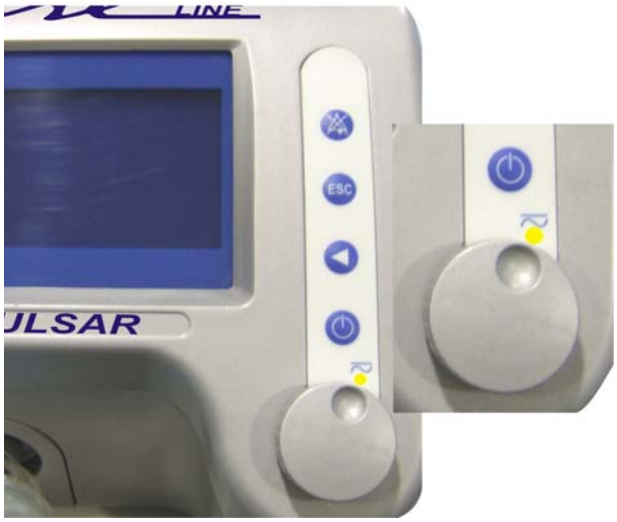
The PULSAR activates at start-up, a series of machine tests to verify the correct functioning of its components, in order to allow a correct patient ventilation.

- Before connecting the PULSAR to the patient it is necessary to perform a rapid preliminary checking on the equipment to verify its perfect functioning.
- Connect and/or verify that the PULSAR is ready for start-up.

After checking that all component parts are correctly connected, proceed to the unit start-up:

- Position the power switch on **" I "** (the power presence led on the Pulsar lights on).

- Keep pressed for around 3 sec. the **T4** "ON/OFF" **membrane** key (see image alongside) located on the control keyboard on the front of PULSAR.



- On the display the initial test screen is shown.

- Keep manually closed the Y connector of patient circuit to perform the smart test: ***" Close Patient Circuit and press START to begin the Smart Test ".***

- Press the **T3** ventilation start key (**START**). The smart test will take few seconds.

The PULSAR activates the checking test for the correct operation of the INSP. and EXP. phases of patient ventilation.

- The screen of passed test is shown on the display.

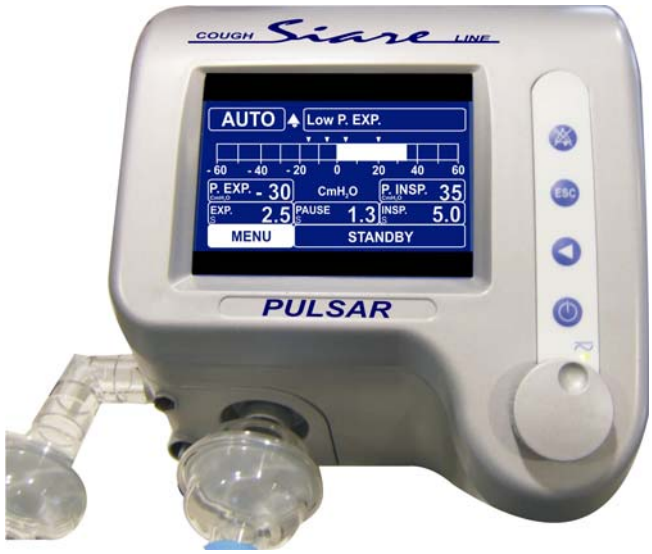
- The screen of NOT passed test is shown on the display.

In case the checking test on correct operation of the INSP. and EXP. phases of the patient ventilation is **NOT PASSED,** check:

- the connections of patient circuit
- if the procedure has been correctly performed
- consult the chapter 7 for troubleshooting

At the end of the checking test on the correct operation of INSP. and EXP. phases, the device displays the operation screen in STANDBY.

Set the desired ventilation parameters, then the PULSAR is ready to ventilate the patient.



If these tests are completed or passed and the PULSAR stops, contact the nearest service centre authorized by SIARE.

4.6 PULSAR turn-off

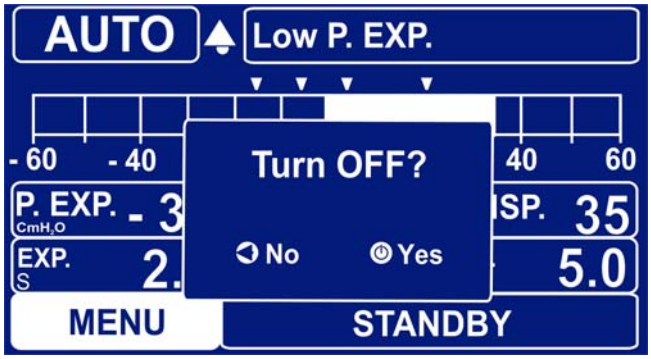
To turn-off the PULSAR follow the instructions and the operations here below listed.

To turn-off the device it is necessary to pass through the STANDBY condition and then proceed with manual turning-off.

- Keep pressed for around 3 sec. the “ON/OFF“ **T4 membrane key** (see alongside figure) located on the control keyboard on the front side of the PULSAR.

- On the monitor two options are highlighted
  - o **No**
  - o **Yes**

- Pressing the **T4 = No** (ON/OFF) key the PULSAR returns in STANDBY condition.
- Pressing the **T3 = Yes** key the PULSAR turns-off.



5 USE

This chapter describes how the operator can make the most of the characteristics of the PULSAR ventilator.

- Turning the equipment on
- Setting of physiological respiratory parameters
- Operative modalities setting
- Description of the operative modes
- Setting of alarm limits
- Setting the function: “vibration”

Before ventilating a patient it is necessary to:

- consult the previous chapters of User’s Manual
- in STANDBY, set the physiological respiratory parameters most suited for the clinical condition of the patient
- in STANDBY, select the operative mode to be used
- set the suitable ventilation parameters for the patient
- set the alarms limits (see chapter Alarms)

5.1 Turning the equipment on

For more information and details on turning on and of procedures consult the previous chapter.

- Check that all the component parts are correctly connected.
- Position the power switch supplied in position " I " (the power presence led on the PULSAR lights on).
- Keep pressed for around 3 sec. the T4 "ON/OFF" membrane key located on the control keyboard on the front of PULSAR ventilator.
- Keep manually close the Y connector of the patient circuit to perform the smart test: " *Close Patient Circuit and press START to begin the Smart Test ".*
- Press the T3 (START) key for ventilation start-up.
- At the end of the test checking on correct operation of the INSP. and EXP. phases the ventilator displays the screen of operation in STANDBY.
- Set the desired ventilation parameters and then the PULSAR ventilator is ready to ventilate the patient.

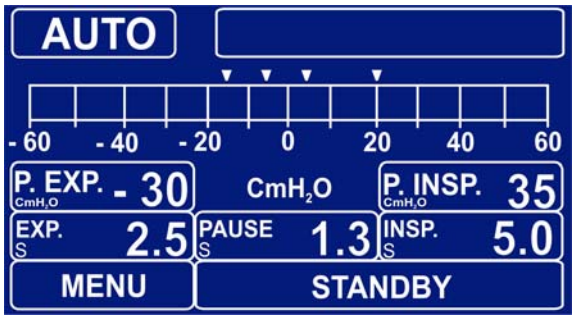
5.2 Setting of physiological respiratory parameters

All the physiological respiratory parameters can be selected, modified and confirmed at the same way, by the encoder knob.

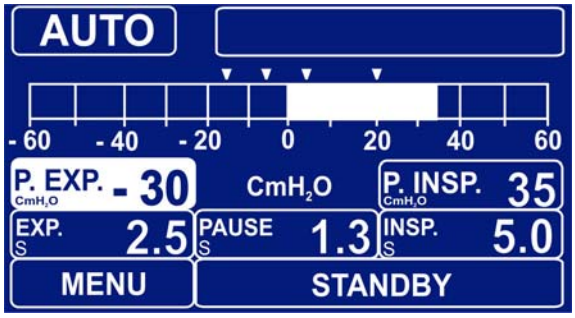
The figure and the indications of physiological respiratory parameters are merely an example.

5.2.1 P. EXP. parameter setting

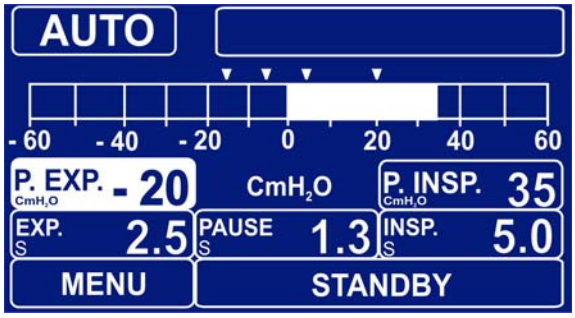
- PULSAR ventilator in STANDBY.



- Rotate the Encoder until positioning the cursor on **P. EXP. - 30**.
- Press the Encoder: the numeric value of the "physiological parameter " (**P. EXP. – 30**) will become flashing.



- Rotate the encoder until setting the numeric value of the desired "physiological parameter" (**P. EXP. - 20**).
- Press to confirm the numeric value of the set "physiological parameter" (**P. EXP. – 20**).



Proceed like described to set also the other numeric values of "physiological parameters" if necessary.

The physiological respiratory parameters should be set before activating the ventilation.

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

As far as the detailed description of the adjustable physiological parameters, make reference to **Chapter 3** "User's Interface".

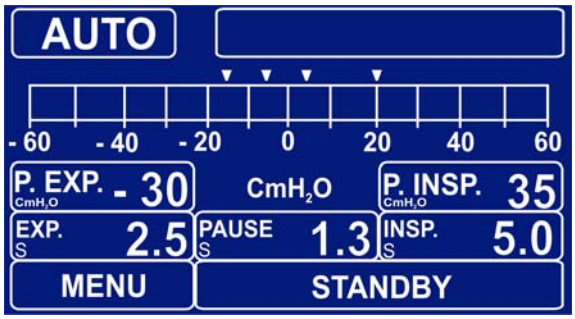
5.3 Operative modalities setting

In the upper side of the main screen is shown the selected ventilation modality.

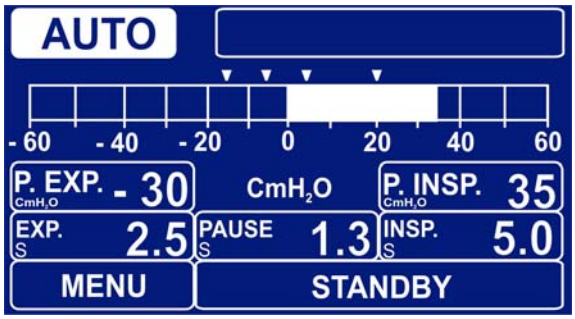
The Operator can select among 6 different operative modes:

- **AUTO**
- **AUTO + V** (automatic modality with active vibration)
- **MAN**
- **MAN + V** (manual modality with active vibration)
- **AST** (assisted mode synchronized with the patient)
- **AST + V** (assisted mode synchronized with the patient with vibration)

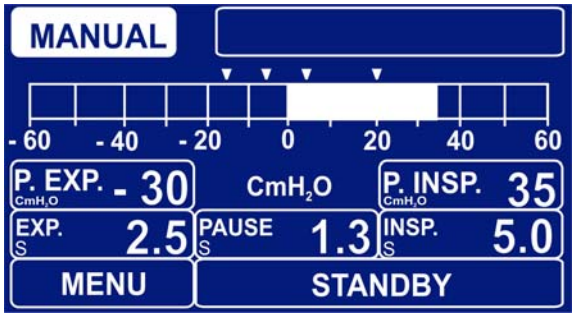
- PULSAR in STANDBY.



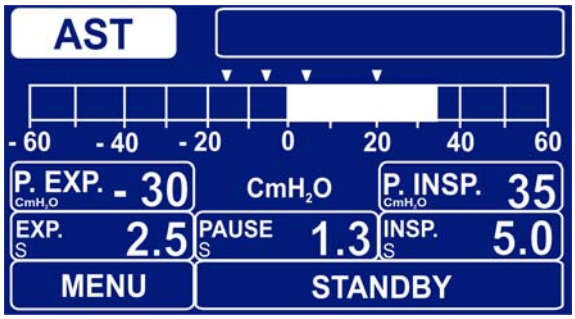
- Rotate the Encoder until positioning the cursor on the **AUTO.**
- Press the Encoder: the operative modality (**AUTO**) will become flashing.



- Rotate the encoder until setting the desired operative modality (**MANUAL**).
- Press to confirm the set operative modality (**MANUAL**).
- Rotate the Encoder until positioning the cursor on **Menu .**



- Rotate the encoder until setting the desired operative modality (**AST**).
- Press to confirm the set operative modality (**AST**).
- Rotate the Encoder until positioning the cursor on **Menu .**



5.4 Description of the operative modes

In this paragraph are described in detail the available operative modes.

- **STAND-BY** This is the operating status in which the PULSAR is in immediately after being turned on (if in operator mode) or when the current ventilation mode was disabled by pressing of the START/STOP key.

  In this phase, it is possible to modify all the parameters relative to the selected operating mode.

  Press the START/STOP key to restart ventilation.

- **AUTO** **Automatic modality:**

  In such modality the device supplies an automatic therapy : during the inspiratory phase an P. INSP. pressure is generated as settings for the selected time (INSP), then an P. EXP. negative pressure is delivered for a period like EXP. After a waiting time equal to the pause (PAUSE) the next act is generated.

- **AUTO + V** **Automatic modality with vibration:**

  The operation principle of such modality is the same as previous one. Furthermore, it is possible to set the duration and the frequency of a vibration during the inspiratory phase (see paragraph of general settings of the present chapter).

- **MANUAL** **Manual modality:**

  In such modality the device supplies a manual therapy controlled by the external keyboard supplied with the ventilator.

  INSP phase: pressing the INSP key on the external keyboard, the INSP phase starts and it terminates when the same key is released or, for patient safety, when the set inspiration time is reached.

  EXP phase: pressing the EXP key on the external keyboard, the EXP phase starts and terminates when the same key is released or, for patient safety, when the set expiration time is reached.

- **MAN + V** **Manual modality with vibration:**

  In such modality the device supplies a manual therapy controlled by the external keyboard supplied with the ventilator. Furthermore it is possible to set the duration and a vibration frequency during the inspiratory phase (see paragraph on general settings of the present chapter).

- **AST** **Assisted mode:**

  In this mode, the device provides an assisted therapy: during the Inspiratory phase is generated a P. INSP. pressure as settings for the inspiratory time, then a negative pressure is delivered for the expiratory time. In this mode, you will synchronise with the patient: the breath will be provided when there is a request by the patient. The pressure trigger is fixed on -2 cm H2O.

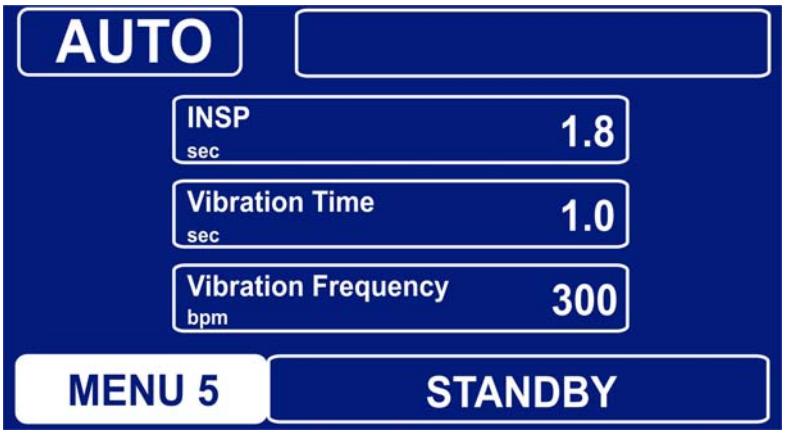
- **AST + V** **Assisted mode with vibration:**

  In this mode, the device provides an assisted therapy: during the Inspiratory phase is generated a P. INSP. pressure as settings for the inspiratory time, then a negative pressure is delivered for the expiratory time. In this mode, you will synchronize with the patient: the breath will be provided when there is a request by the patient. Furthermore it is possible to set the duration and a vibration frequency during the inspiratory phase (see paragraph on general settings of the present chapter).

5.5 Setting of alarm limits

As far as the detailed description of alarm limits setting is concerned, make reference to the relevant chapter 6.

5.6 Setting the function: “vibration”



Menu 4

- **INSP**

  With this parameter is possible to adjust the inspiratory phase time.

  Such parameter is adjustable in the following interval: [0.5 : 5] s.

- **Vibration Time** (Vibration T.)

  With this parameter is possible to adjust the vibration time during the inspiratory phase.

  Such parameter is adjustable in the following interval: [0.2 : 4.8] s as a fraction of the insp. time.

- **Vibration Freq** (Vibration F.)

  With this parameter is possible to adjust the vibration frequency during the inspiratory phase.

  Such parameter is adjustable in the following interval: [180 : 600] bpm .

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6 ALARMS

This chapter describes the part of the system that deals with the alarms, their functioning logic and their causes, focussing on the following points:

- Alarm logic
- Symbols
- Division of the alarms
- Alarm settings

A brief description was provided in chapter **3** "**User Interface**" in order to introduce the subject.

Before using the Pulsar, it is recommended that the MENU function be used to set the items necessary for the correct operation of the device.

6.1 Alarm logic

The PULSAR is equipped with a series of acoustic and visual alarms.

At alarm activation the operator will find a series of information and signals which appear in the zone Alarm Area in the upper right side of IGU (see the example in the following figure).

The alarm area evidences both an information line relevant to the activated alarm type and the displaying of the alarm “bell”.

As far as the acoustic alarms are concerned, the ***acoustic signals*** comply with the provisions of the UNI EN 475 standard..

If two or more alarms with the same priority levels become active, the message of the last alarm activated will be displayed.

Then, the other alarm conditions that are active will recurrently displayed every 4 seconds.

6.2 Symbols

The “bell” alarm symbol lights on and flashes when an alarm conditions occurs.

- Active alarm 
- Suspended alarm: bell crossed through 

During normal functioning, the T1 key is used to silence an active alarm. 

6.3 Division of the alarms

The alarms foreseen on the unit can be divided into two families.

- Alarms with limits that can be set by the operator (high and low limit for each alarm)
  - P. EXP. min
  - P. EXP. Max
  - P. INSP. min
  - P. INSP. Max
- System alarms
  - Turbine (motor malfunctioning – blower failure)
  - Turbine (operative over temperature – blower over temperature)

The alarms listed above are all displayed on the GUI in the alarm area with specific messages.

The figure and alarm indication is merely an example, since the alarm message depends on the type of alarm that has been activated.

6.3.1 Alarms with limits that can be set by the operator

P. INSP. Max **[10, 30]**	This alarm indicates the violation of the high limit of airways inspiratory peak pressure. Such alarm limit is compared to the set value (P. INSP). It is reported by an acoustic signal and a flashing message in the alarm area similar to a visual signal.
P. INSP. Min **[-30, -10]**	This alarm indicates the violation of the low limit of airways inspiratory peak pressure. Such alarm limit is compared to the set value (P. INSP). It is reported by an acoustic signal and a flashing message in the alarm area similar to a visual signal.
P. EXP. Max **[10, 30]**	This alarm indicates the violation of the high limit of airways expiratory peak pressure. Such alarm limit is compared to the set value (P. EXP.). It is reported by an acoustic signal and a flashing message in the alarm area similar to a visual signal.
P. EXP. Min **[-30, -10]**	This alarm indicates the violation of the low limit of airways expiratory peak pressure. Such alarm limit is compared to the set value (P. EXP.). It is reported by an acoustic signal and a flashing message in the alarm area similar to a visual signal.

6.3.2 System alarms and those that cannot be set by the operator

Blower fault	This is a high priority alarm that activates after a delay of 0 sec. and indicates a malfunction in the BLOWER. This alarm is indicated by an acoustic and visual signal. It cannot be silenced or inhibited.

Immediately contact technical assistance for servicing.

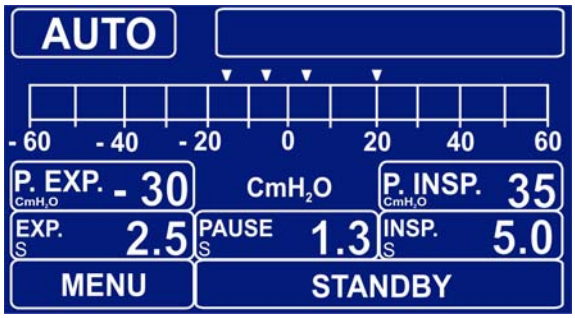
Blower overheating	This is a high priority alarm that activates after a delay of 0 s from the time the maximum operating temperature of the blower is reached (85°C). It is indicated by an acoustic and a visual signal. It can be silenced, but not inhibited.

Immediately turn off the device and promptly contact technical assistance.

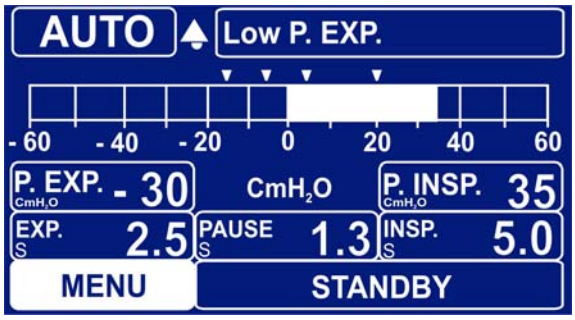
6.4 Alarm settings

The figure and the indications of the alarms, are just for illustrative purposes, because the message is a function of the relevant activated alarm type.

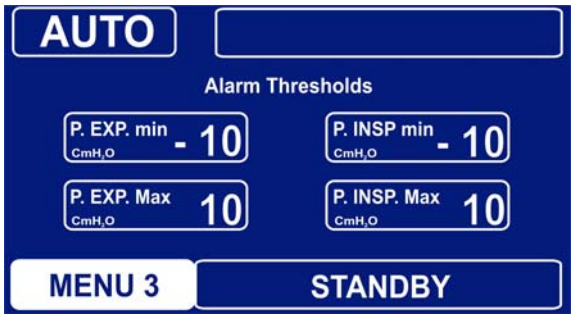
- STANDBY condition.



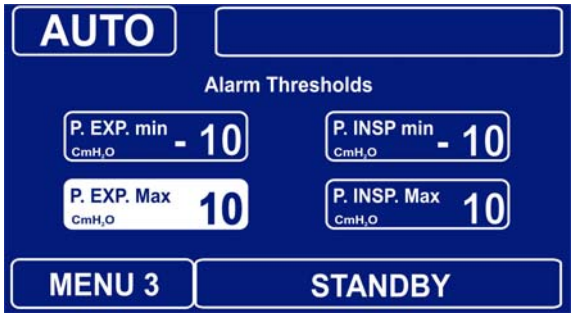
- Turn the Encoder knob to position the cursor on **Menu**.
- Press the Encoder knob again (the indication of **Menu** will start flashing).



- Turn the encoder knob to select the desired sub-menu (**Menu 3**).
- Press to confirm (now the indication of **Menu 3** will become fix).



- Turn the encoder knob to select the sub-menu “alarm parameter” (P. EXP. Max 10) to be set.
- Press the Encoder knob: the numeric value of the “alarm parameter” (P. EXP. Max 10) will start flashing.

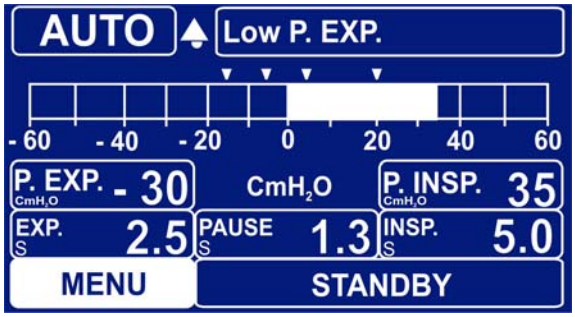


- Turn the encoder knob to set a numeric value of the desired “alarm parameter” (P. EXP. Max 20).
- Press to confirm the numeric value of the set “alarm parameter” (P. EXP. Max 20).

Proceed as described to set also the other numeric values of “alarm parameter” if necessary.

- To return in STANBY modality, turn the knob to position the cursor on **Menu 3**.
- Press the Encoder knob (the indication **Menu 3** will start flashing).

- Turn the Encoder knob to position the cursor on **Menu**
- Press the Encoder knob again (the indication **Menu** will become fix).



In alternative, for quick returning to main menu press **ESC.**

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7 FAULTY CONDITIONS AND TROUBLESHOOTING

This chapter is a guide for the Operator and for Technician, providing indications for eliminating, as quick as possible, most of the problems that may have caused of the malfunctioning or alarm signals.

This chapter describes the possible causes of problems, indicated by alarms that are activated during the normal functioning.

If the problem persists, carry out a complete check of the device to identify any irregularities.

If the problem cannot be solved, contact the nearest Service Centre of a Centre authorized by Manufacturer.

No power	The PULSAR does not switch on
	• Check that it is connected to the main power supply • Check the correct connections of the plug, the fuses and the connector, and the cable conditions (if necessary, restore the connections and replace the cable if it is damaged). • Check that power is present at the relative socket by plugging in another electrical device. (if there is no power, use another socket or check the overload switch on the electrical panel of the room). • Check that the main switch is turned to the I position (ON) • Check the power supply fuses • Contact the nearest Authorized Service Centre
Initialisation Phase	The initialization phase is not completed and the system is blocked.
	• Contact the nearest Authorized Service Centre.
Blower temperature	The safety limit for the blower operating temperature has been exceeded.
	• The PULSAR will automatically shut off in order to avoid serious risks to the patient
Blower malfunction	A malfunction is occurred in the motor that operates the blower.
	• The PULSAR is switched off automatically to avoid serious risks to the patient.

Control keyboard and Encoder	The control keyboard/ encoder do not function
	• Check the connections • Switch the unit off and then switch back on the PULSAR • Contact the nearest Authorized Service Centre.
Overcoming P. INSP. P. EXP.	In this condition the patient circuit + patient system presents a higher resistance than expected or a lower compliance. This causes an airways pressure that exceeds the set limit of the inspiratory/expiratory pressure.
	• Check if the corresponding alarm limits are set correctly. • Check that the mask / endotracheal tube / 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 setting of the respiratory parameters of the patient. • Check that nothing limits the respiratory capacity of the patient • If it is not the case contact the nearest Authorized Service Centre.
Low P. INSP.	In this condition the patient circuit + patient system presents a lower resistance than expected or an higher compliance. This causes an insufficient ventilation pressure.
	• Check the filters are not obstructed • Check the correct setting of corresponding alarm limits. • Check that, the mask / endotracheal tube / patient circuit are not in some way broken or not correctly connected. If this is the case, eliminate the problem or replace them. • Check the correct setting of the respiratory parameters of the patient. • Check that the patient circuit is correctly connected to the equipment and to the patient. • If it is not the case contact the nearest Authorized Service Centre.
Low P. EXP.	In this condition the patient circuit + patient system presents a resistance that avoid the achievement of the expiratory pressure. This causes an insufficient ventilation pressure.
	• Check the filters are not obstructed • Check the correct setting of corresponding alarm limits. • Check that, the mask / endotracheal tube / patient circuit are not in some way broken or not correctly connected. If this is the case, eliminate the problem or replace them. • Check the correct setting of the respiratory parameters of the patient. • Check that the patient circuit is correctly connected to the equipment and to the patient. • Check that the expiration window on the device bottom is not obstructed • If it is not the case contact the nearest Authorized Service Centre.

NOTES

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8 MAINTENANCE

To ensure correct functioning of PULSAR, 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.

This section describes the operations regarding:

- Cleaning, disinfection and sterilisation
- General instructions
- Repairs and spare parts
- Disposal
- Storage
- Repackaging and shipment

To ensure the safety of the patient and the operator, the Pulsar must be inspected and checked **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, trained/authorized by Manufacturer..

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 disposed of, should be sterilised before disposal.

Follow current regulations for the disposal or recycling of all removed components.

8.1 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!

- 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 antibacterial 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 PULSAR 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 device is sold.

The factory 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.

The factory 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 PULSAR, and also in the event of shipment of the machine to our premises, clean and disinfect the equipment.

8.2 General instructions

8.2.1 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 or single patient use 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 completely.
- Is recommended 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.

8.2.2 Clinical disinfection and sterilization

For external cleaning of PULSAR, proceed in the following way: do not sterilize the equipment in autoclave; clean the equipment externally with a cloth and neutral detergent (disinfecting solution for external surfaces); do not allow to any liquid or humidity to enter inside the PULSAR.

The compounds based on the following agents do not damage the materials:

- Aldehydes

The compounds based on the following active agents can damage the materials:

- Compounds that release halogens
- Strong organic acids
- Compounds that release oxygen

Follow carefully the Instructions for Use recommended by Manufacturer.

8.2.3 Domestic cleaning and disinfection

For cleaning of all the parts in contact with the breathing gas, the following procedures should be performed:

- immerse the removed parts in hot water and clean them
- remove dirt with a brush.
- rinse carefully the parts with hot current water .
- eliminate all water from the parts.
- dry the parts carefully.
- store the equipment in a dust-protected place

The eventual disinfection of parts can be effected by immersing them in Virkon® or equivalent detergent. Rinse the parts with clean water carefully and dry them completely.

Follow carefully the instructions for use recommended by the Manufacturer.

8.2.4 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) 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 device, use only the chemical substances listed.

Patient circuit tubes (silicon tube)	Dismantle and clean, then sterilize in an autoclave, disinfect with steam or chemically	Before using again, eliminate any humidity inside the tubes by means of compressed air. Check that there are no splits in the tubes and replace them if they are damaged.

The silicon 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 or single patient use tubes.

Couplings and connectors	Dismantle and clean, disinfect with steam or chemically.	Before using again, eliminate any humidity inside the components by means of compressed air. Check that there are no splits and replace them if they are damaged.
Aspiration, pollen and fan filters	Dismantle and wash the component with hot water or neutral detergent solution.	Before reinstalling, dry them and eliminate any humidity inside the filters by means of compressed air. Check that there are no splits and replace them if they are damaged.
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 PULSAR must be used with a different patient • If the PULSAR 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.

8.2.5 Periodic maintenance

The PULSAR does not require particular maintenance and preventive operations other than those indicated in this manual or in order to respect standards applied in the specific country where the unit is sold.

- Taking out a maintenance contract ensures inspections and periodic maintenance.
- Contact the manufacturer 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 the manufacturer.
- The manufacturer 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 technician, is proof of the completion of the scheduled maintenance.

8.2.6 Maintenance operations table

WARNING!

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 PULSAR.

To avoid damage to components due to excessive wear, carry out preventive maintenance and replace parts following the recommended frequency.

Frequency	Component	Procedure / Action
Several times a day / according to local practice and standards	Patient circuit	Check for any water collection, drain and clean the tubes when necessary.
	Filters	Check for wear or obstructions.
Every day / when necessary	PULSAR	General cleaning and checks.
Every week / when necessary	Aspiration, pollen and fan filters	Dismantle and wash the component with hot water or neutral detergent solution. Replace if damaged.
Every 6 months	PULSAR	Check the performance. This includes an electrical safety test and inspection of the device for mechanical damage and legibility of the labels Furthermore, the PULSAR must also be inspected and checked in general and worn parts must be replaced, using the appropriate preventive maintenance kit. Qualified technical personnel only, according to the instructions contained in the relative service and maintenance manual should carry out this operation.
	Aspiration, pollen and fan filters	Replace
	Patient circuit	

To avoid damage to components due to excessive wear, carry out preventive maintenance and replace parts following the recommended frequency.

8.2.6.1 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 machine.

WARNING !!

It is recommended to sterilize / disinfect the PULSAR every time is used with another patient.

8.3 Repairs and spare parts

Use only original spare parts or spare parts checked and approved by the manufacturer.

The table shows the parts (components) that should be **R**eplaced periodically or **R**eplaced if broken or worn and those that should be **M**aintained.

If no indications are given, the parts should be replaced in the event of failure or wear.

The table provides all the indications so as to make consultation easier, showing the following data:

- the reference number used in the figures and the description
- the order code
- the no. of the spare parts kit and the quantity
- the maintenance interval (in months) of the parts subject to wear.

WARNING!

The table shows a maintenance package over the use of 6 months.

The replacement of the filters of the PULSAR depends on environment/ambient conditions (dust, etc.), and it is recommended for the correct operation.

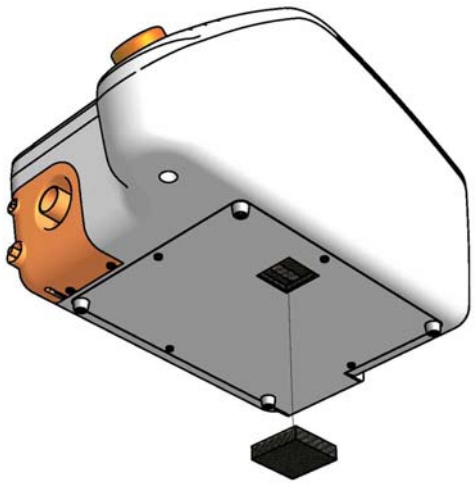
Ref.	Description	R980001S0			6 months
		Code	KIT	Q.ty	
1	Aspiration filter	M53550309	S0	1	R
2	Pollen filter	M53550409	S0	1	R
3	Cooling fan air filter	M53551109	S0	1	R

8.3.1 Maintenance KIT

Code : R980001S0

KIT for 6 months

1	**M53550309 Aspiration filter**	**No. 1**	**6 months**
2	**M53550409 Pollen filter**	**No. 1**	**6 months**



3	**M53551109 Cooling fan air filter**	**No. 1**	**6 months**

8.4 Disposal

Batteries, accumulators, electronic parts in general:

- do not put them in the fire, explosion risk
- do not open them, corrosion danger
- do not recharge batteries
- do not throw them away with normal waste.

The batteries and the accumulators are special waste materials and they must be disposed of in appropriate containers in accordance with local regulations for the disposal of such waste materials.

The components of the electronic boards can contain compounds, such as arsenic, lead, cadmium, mutagenic and cancerogenous agents, that are a health hazard if dispersed in the environment in an uncontrolled way.

For further information contact the relevant authorities for environmental and public health monitoring.

8.5 Storage

If for any reason the PULSAR is not used, we suggest leaving it in its original packaging and storing it in a safe and dry place.

8.6 Repackaging and shipment

If it is necessary to return the equipment to the Manufacturer 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.

9 APPENDIX

This chapter includes all the information and data necessary to provide full knowledge and interpretation of the manual for the PULSAR.

- Technical sheet
- Electromagnetic compatibility tables

9.1 Technical sheet

Application	Positive and negative pressure ventilator for home and hospital use.
Patients	Adults / Children
SPECIFICATIONS	
Operation modes	AUT, AUT+V, MAN, MAN+V, AST, AST + V (V = vibration)
Positive pressure (P.INSP.)	[5 ÷ 60] (cmH_2O, hPa, mbar) during the inspiratory phase.
Negative pressure (P.EXP.)	[- 60 ÷ 0] (cmH_2O, hPa, mbar) during the expiratory phase.
Inspiratory time (INSP.)	[0,5 ÷ 5] (sec)
Expiratory time (ESP.)	[0 ÷ 5] (sec)
Pause time (PAUSE)	[0 ÷ 5] (sec)
Vibration time	[0.2 ÷ 5] (sec)
Vibration rate	[180 ÷ 600] (bpm)
Pression trigger	- 2 (cmH_2O)
Remote control	INSP, EXP manual
Power supply	12,8 Vdc / 100 - 240 Vac; Imax= 9,4 A; Pmax= 120 W
SYSTEM SETTINGS	
Contrast	[0 ÷ 100] (%)
LCD reverse	ON/OFF
Units of pressure	cmH_2O, hPa, mbar.
Sound volume	[0 ÷ 100] (%)
ALLARMS	
P.INSP. min, P.EXP. min	[-30 ÷ -10] (cmH_2O) referred to the setting values P.INSP. e P.EXP.
P.INSP. max, P.EXP. max	[10 ÷ 30] (cmH_2O) referred to the setting values P.INSP. e P.EXP.
PHYSICAL CHARACTERISTICS	
Dimensions (L x P x H)	240 x 330 x 210 mm
Weight	3,9 Kg

Protection IP degree	IP 44
Conformity to norms	IEC 601-1, IEC 601-1-2, IEC 601-1-4, UNI EN 1281-1, ISO 10651-2, UNI EN 475, UNI EN ISO 9703-3, UNI EN ISO 4135, 93/42/CEE
Class and type according to IEC 601-1	Class 1 Type B
Class according to 93/42 EEC Dir.	Class II b
Environmental conditions	Temperature from -10 to 40 °C Non condensing relative Humidity from 15 to 95 % Atmospheric pressure from 70 to 110 Kpa
STANDARD ACCESSORIES	
	Operator user manual Power supply 12,8 Vdc / 100 - 240 Vac; Imax= 9,4 A; Pmax= 120 W SHUKO-VDE power cable Remote control (push button) Bi-tube PVC patient circuit adult cm 180x22 +Y single use Turbine antidust aspiration filter (n.1 pc supplied with the unit) Turbine pollen aspiration filter (n.1 pc supplied with the unit) Air fan cooling filter (n. 1 pc supplied with the unit) Patient circuit HEPA 15M-22F filter (n.1 pc supplied with the unit) 22 mm straight connector

9.2 Electromagnetic compatibility tables

<table>
<tr><th colspan="3">ELECTROMAGNETIC EMISSIONS</th></tr>
<tr><td colspan="3">The unit is suitable for use in the electromagnetic environment as specified below. The customer or the user of the Pulsar should ensure that it is used in such an electromagnetic environment.</td></tr>
<tr><td>EMISSION TEST</td><td>TEST LEVEL

IEC 60601-1-2</td><td>GUIDANCE ON ELECTROMAGNETIC ENVIRONMENT</td></tr>
<tr><td>RF Emissions

CISPR 11</td><td>Group 1</td><td>The device uses RF energy only for its internal functions.

Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF Emissions

CISPR 11</td><td>Class B</td><td rowspan="3">The unit is suitable for use in all domestic environments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions

IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuation/flicker

IEC 61000-3-3</td><td>Complies</td></tr>
<tr><td></td><td colspan="2">The Pulsar complies with norm CEI EN 60601-1-2 on Electro-magnetic Compliance of electro-medical equipment. It is in any case strongly recommended not to use the equipment adjacent to high-powered equipment or to units, which emit strong electro-magnetic fields.

Cellular and cordless phones or other radio transmitters used in the vicinity of the equipment could influence its operation.

If it is necessary to use the equipment in the vicinity of other units, it is advisable to check it and verify the normal functioning according to the chosen configuration.

Avoid using extension cables or adapters with the power supply cable. The ground contact to the power plug should not be cut or removed.

The equipment must be connected to the mains power supply using the supplied 2 mt cable only. The unit complete with such cable complies with Electro-magnetic Compliance Norms. The use of cables of different length may cause an increase in emissions or a decrease in immunity to radio disturbance.</td></tr>
</table>

ELECTROMAGNETIC IMMUNITY			
The unit is suitable for use in the electromagnetic environment specified below. The customer or operator should ensure that it is used in such an electro-magnetic environment.			
IMMUNITY TEST	TEST LEVEL IEC 60601-1-2	COMPLIANCE LEVEL	GUIDANCE ON ELECTRO-MAGNETC ENVIRONMENT
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be made of wood, concrete or ceramic tiles. If floors are covered with synthetic material, relative humidity should be at least 30%.
Transient/electrical trains Fast 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	Mains power quality should be the same as a typical domestic environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be the same as a typical domestic environment.
Voltage dips, short interruptions and voltage variations IEC 61000-4-11	<5% U_T (Dip >95% U_T) for 0,5 cycles 40% U_T (Dips of 60% U_T) for 5 cycles 70% U_T (Dips of 30% U_T) for 25 cycles <5% U_T (Dip >of 95% U_T) for 5 seconds	<5% U_T (Dip >95% U_T) for 0,5 cycles 40% U_T (Dip of 60% U_T) for 5 cycles 70% U_T (Dip of 30% U_T) for 25 cycles <5% U_T (Dip > of 95% U_T) for 5 seconds	Mains power quality should be the same as a typical domestic environment. . If the operator of the unit needs continuous functioning, even during mains power failures, the device should be powered with a UPS device or with emergency systems (batteries, generators with piston engine). It is also recommended to keep one or more back-up batteries.

Power frequency magnetic field (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should have the typical levels of those in domestic environments.
	U_T is the a.c. mains voltage prior to the application of the test level.		
Conducted RF 61000-4-6	3 V/m from 150 kHz to 80 MHz	3 V eff	Portable and mobile RF equipment should not be used closer to any part of the unit, including cables, with respect to the recommended distance calculated on the equation applicable to the frequency of the transmitter. **Recommended operational distance:** ***d* = 1,2√*P***
Radiated RF IEC 61000-4-3	10 V/m from 80 MHz to 2,5 GHz	3 V/m	
Radiated RF IEC 61000-4-3	10 V/m from 80 MHz to 2,5 GHz	3 V/m	**from 150 kHz to 80 MHz** ***d* = 1,2√*P*** **from 80 MHz to 800 MHz** ***d* = 2,3√*P*** **from 800 MHz to 2,5 GHz** where ***P*** is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and ***d*** is the recommended separation distance in meters (m). Disturbances may occur in the vicinity of equipment marked with the following symbol: 

	These guidelines may not apply to all situations. Electromagnetic propagation is influenced by the absorption and reflection of structures, objects and people. Due to the impossibility to evaluate with extreme precision the field strengths issued by the various transmitters (AM/FM radio, mobile phones, cordless phones, televisions), an electromagnetic site survey should be considered. If the field strength measured where the unit is used exceeds the indicated level of compliance it is necessary to test the unit and verify the normal functioning. If abnormal performances are detected, additional measures may be needed, such as relocating the device. The fixed RF transmitter field intensity, as determined by an electromagnetic survey at the site, should be less than 3 V in the frequency interval from 150 kHz to 80 MHz.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF EQUIPMENT AND THE DEVICE

The customer or operator of the unit may help in preventing interference by maintaining a minimum distance between RF mobile and portable equipment (transmitters) and the device as recommended below, according to the maximum output power of the RF communications equipment..

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER - Watt (W)	SEPARATION DISTANCE FROM THE FREQUENCY TRANSMITTER - m (meters)		
	From 150 kHz to 80 MHz $d = 1,2\sqrt{P}$	*From 80 MHz to 800 MHz* $d = 1,2\sqrt{P}$	*From 800 MHz to 2,5 GHz* $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

	For transmitters rated at a maximum output power not listed above, the recommended separation distance in meters (m) may be calculated by using the equation applicable to the transmitter frequency, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer. These guidelines may not apply to all situations. The electromagnetic propagation is influenced by the absorption and reflection of structures, objects and people.

NOTES

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