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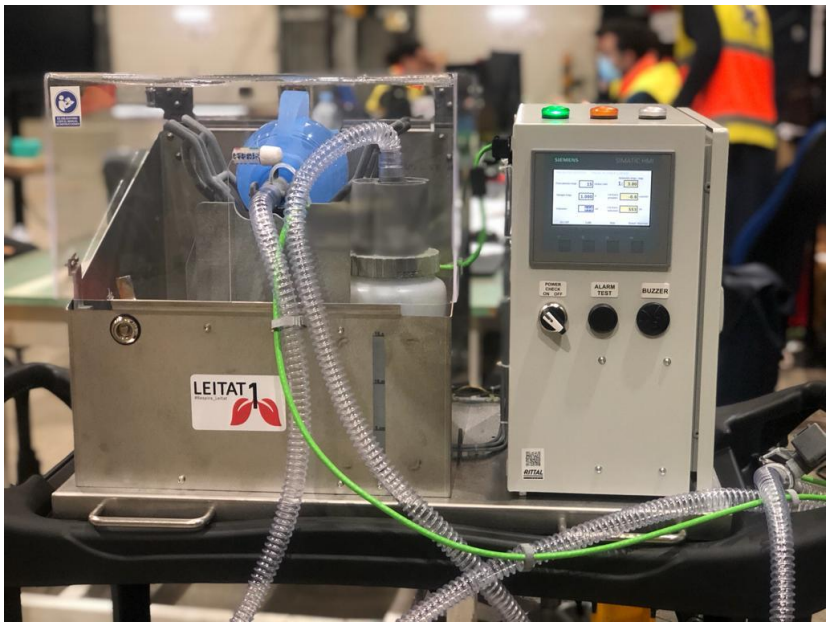

LEITAT 1

AUTOMATED RESUSCITATOR

USER GUIDE

Manufacturer: **LEITAT & CZFB**
Model: **LT-RSP1 V.00**

Access to the online content:

- Explanatory video
- Instructions manual
- Data collection form
- FAQs
- Contacts

NOTE: Please address any questions or queries about this *User Guide* through the QR code.

This project has been carried out by the following alliance of companies:

- **LEITAT**
- **Consorcio de la Zona Franca**
- **Hewlett-Packard**

Scientific leadership by Hospital Parc Taulí de Sabadell

User guide version 15 (07/05/2020)

CONTENTS

1.INTRODUCTION

The mechanical ventilation system **LEITAT 1** is a device designed to keep in vital support the patient in a situation of severe respiratory failure who requires intubation and invasive mechanical ventilation. It should not be considered as a partial ventilatory support system (non-invasive mechanical ventilation - NIMV) in patients who ventilate spontaneously. It is not a therapy, it is a support intervention, a medical device for ventilatory and temporary support therapy that ventilates the patient while correcting the originating problem.

In its entirety, the device allows to apply a mandatory ventilation mode with a programmable volume to a patient through the mechanical actuation of a conventional resuscitation balloon system (AMBU).

The use of this equipment is exclusively for clinical research and only in a hospital setting.

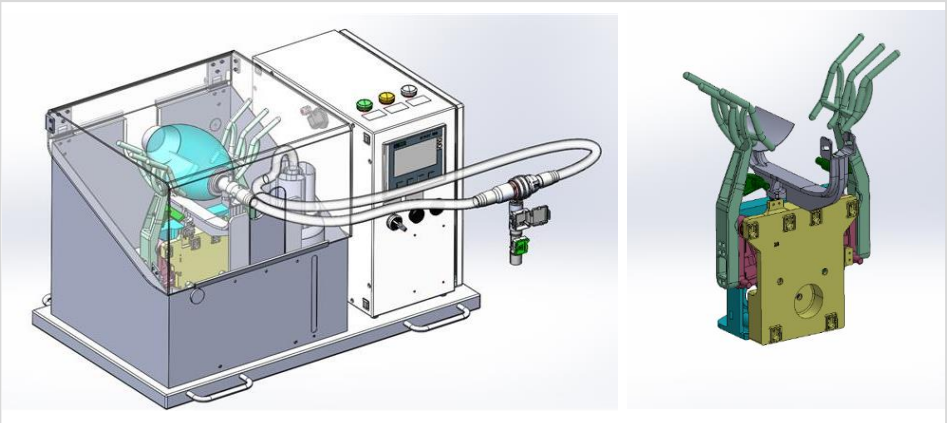

Figure 1: Illustration of the device

2.INSTALLATION AND SET UP

2.1. GENERAL INFORMATION

LEITAT 1 works as Volume-Controlled Ventilation and mode of operation is mandatory.
In each ventilation cycle, the inspiratory time (in seconds) can be adjusted, allowing the desired inspiration: expiration (I: E) ratio to be selected.
In normal operating mode, the user can control the number of ventilatory cycles per minute (respiratory rate), as well as the amount of air blown by controlling the actioning blades. In the case of detecting a pressure greater than 50 cmH2O, a sound and light warning alarm is activated and, automatically, the operating mode changes from "Volume-Controlled Mode" to "Pressure-Controlled Mode", maintaining a breath cycle of 1 inspiration for 2 expiration but applying a volume of air that does not exceed the pressure of 50 cmH2O.

The technical specifications of the equipment are as follows:

GENERAL DATA	
Manufacturer	LEITAT & CZFB
Model	LT-RSP1 V.00

MODULE DIMENSIONS	
Width	710 mm
Height	460 mm
Depth	500 mm
Weight	27 kg

ELECTRICAL VALUES	
Voltage	220-240 VAC (50Hz)
Power	100 VA (Max. 350VA)

CLINICAL VALUES	
Tidal volume	150 ml to 600 mL
Maximum flow (VMAX)	9 – 18 L/min
Respiratory rate (rpm)	12 to 30 rpm
Inspiratory pressure	15 to 50 cmH_2O
PEEP pressure	0 to 20 cmH_2O
Inspiratory time	0.6 - 1.5 seconds
O_2 percentage	21% to 100%

PERMITTED BREATHING MODE	
Mandatory	Yes
Spontaneous	No

TYPE OF PERMITTED VENTILATION	
Non-invasive (NIV)	Not designed for it
Invasive (INV)	Yes

Table 1. LEITAT 1 technical specifications

POWER SUPPLY

The equipment has a 2m grounded Schuko (CEE 7/7) power cable that connects at one end to the rear base of the appliance, equipped with a 1.5A fuse protection; and on the other hand, to a 220-240V power outlet at the facilities.

CONTROL CONSOLE

The equipment has a digital screen for parameterization and control of the equipment. At the bottom of the screen, there following function buttons can be found: power on/off, navigation through the different screens, and alarm management.

The parameters that can be set by the medical personnel who is authorized to operate the equipment are: inspiratory volume, inspiratory time and the respiratory rate.

In addition, in the control console there is also the safety switch to prevent electrical failure, a button for checking the correct operation of the alarm, and the buzzer that sends out the audible alarm.

Finally, at the top, light indicators are found, which show the status of the equipment.

CONFIGURABLE PARAMETERS

- Inspiratory volume: 150 – 600 cm^3
- Inspiratory time: 0,6 – 1,5 s
- Inspiratory rate: 12 – 30 rpm
- Positive end-expiratory pressure (PEEP): 0 - 20 cmH_2O

MONITORING AND ALARM

The equipment has various sensors that monitor its operation, supervising parameters such as volume, pressure, times and other algorithms that allow detecting any anomaly.
In summary, the monitored alarms are as follows:

- Volumetric deviation
- Maximum pressure, greater than 50 cmH2O
- Pressure less than 15 cmH2O
- Deviation of respiratory rate
- Mechanical failure
- Power supply failure

All alarms are manifested visually and through the piezoelectric buzzer.

2.2. INDICATIONS OF USE

Patient who requires mechanical ventilation and that the benefits are sufficient to ventilate him/her adequately.

Patients must meet all the criteria mentioned below:

- Patients who in clinical judgment require mechanical ventilation
- No access to a certified mechanical ventilator * due to lack of availability due to a health crisis situation
- Have been given an informed consent to participate in the study

* Therefore, physical non –availability in a specific hospital unit and temporary at a given time is accepted as non-availability.

The most important factor when making any decision is the continuous observation of the patient and his/her evolutionary trend. Therefore, the indication to intubate or ventilate a patient is generally a clinical decision based more on the signs of respiratory distress than on parameters of gas exchange or pulmonary mechanics, which are only indicative.

2.3. ASSEMBLY OF THE DEVICE

Needed equipment for mechanical ventilation:

Ventilation accessories

- HEPA Filter.
- Heat and moisture exchanger.

For the intubation

- Endotracheal tube (TET): the size depends on the age of the patient and the route of entry (mouth, nose). It features a balloon in adults and in some paediatric.
- Intubation introducers of different sizes.
- Laryngoscope with blades of different sizes and curvatures.
- Maguill's clamp.
- Syringe to blow the balloon.
- Tube fixing system (for instance: Haid).

Support equipment

- AMBU with reservoir and connection to flowmeter.
- Two O2 sources: One for the ventilator and one for the AMBU.
- Aspiration equipment (sterile) and aspirator.
- Guedel cannula.
- Ball pressure gauge: inflatable to measure its pressure.

Assembly

- *Inspiratory part*: tube from ventilator (end of resuscitative balloon) to patient, with intermediate connection to a one-way valve through its inhalation end.
- *Expiratory part:* from one-way valve (exhalatory end) -with option to ambient air (PEEP 0) or with connection to the tube- to container with water column to generate PEEP from 0 to 20 cm.
    - *Warning: to be used only with distilled water to avoid the growth of bacteria.*
- Flow sensor, placed between the two-way valve and the filter.
- High-efficiency filter placed between flow sensor and patient.
- Humidifier placed between filter and patient.

- Oxygen connection line from resuscitative balloon to wall-mounted flow meter.

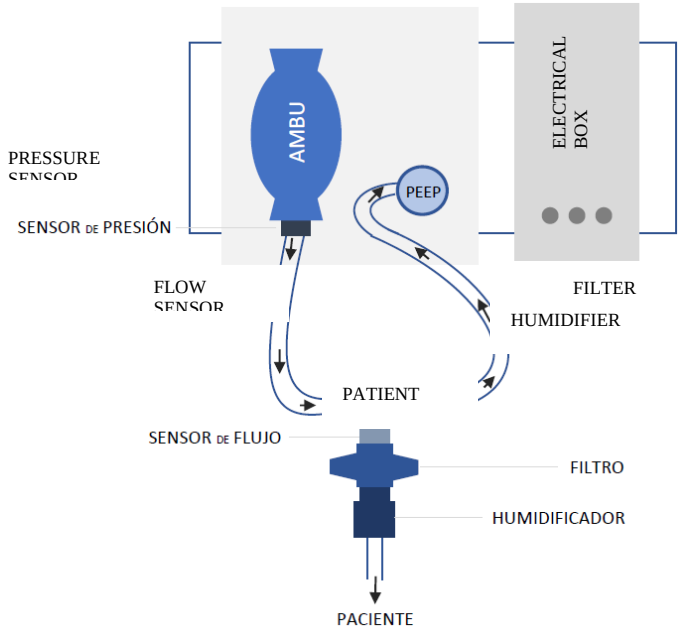

Figure 2: LEITAT 1 assembly diagram

Starting the equipment

Once assembly is complete, connect the equipment to the socket. After 5 seconds, the system will load and the safety mechanisms will be activated. An alarm will sound, warning that the supervision of the electrical failure must be activated and, at the same time, will allow checking the proper functioning of the acoustic alarm warning. The position of the “Power check” switch must be changed to ON to turn off the alarm.
After that, the functional ventilation parameters should be set and the equipment should be turned on.
For disconnection, the same procedure applies.
When disconnecting the equipment from the socket, the power failure alarm will warn that there is no current. At that time, change the position from "Power check" to OFF and the alarm will stop sounding.
For equipment storage, the switch must be OFF. Otherwise the alarm will sound until the battery is drained.
Whenever considered, the operation of the acoustic alarm can be verified by pressing the "Alarm Test" button.

2.4. OPERATION OF THE CONTROL CONSOLE

The HMI (initials of Human-Machine Interface) is the graphical control panel through which the device operator can control the ventilation process, through the following screens:

- 4 physical buttons (F1 to F4) for the functions:
  - F1: *Start/Stop*
  - F2: Switch between user screens
  - F3: Access to the screen “Más” (More)
  - F4: Alarm reset

- 9 user screens:
  - Principal (Main)
  - Calibración (Calibration)
  - Configuración médica (Medical settings)
  - Alarmas (Alarms)
  - Más (More)
  - Versión (Version)
  - Reloj (Clock)
  - Monitorización 1 (Monitoring 1)
  - Monitorización 2 (Monitoring 2)

The main areas of the HMI are the following:

Figure 3: Screen areas

The different available screens are described below:

1 | ALARM AREA

In the alarm area, the excessive pressure ("Presión excesiva") and insufficient pressure ("Presión insuficiente") alarms are represented.
When alarms are NOT ACTIVE, the labels "Presión excesiva" and "Presión insuficiente" appear in **gray**.
When alarms are ACTIVE, the labels "Presión excesiva" and "Presión insuficiente" appear in flashing **red**.
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Figure 4: Alarm zone with alarms NOT active

Figure 5: Alarm area with the insufficient pressure alarm active

2 | MAIN SCREEN

On this screen the operator controls the main process of the ventilator.

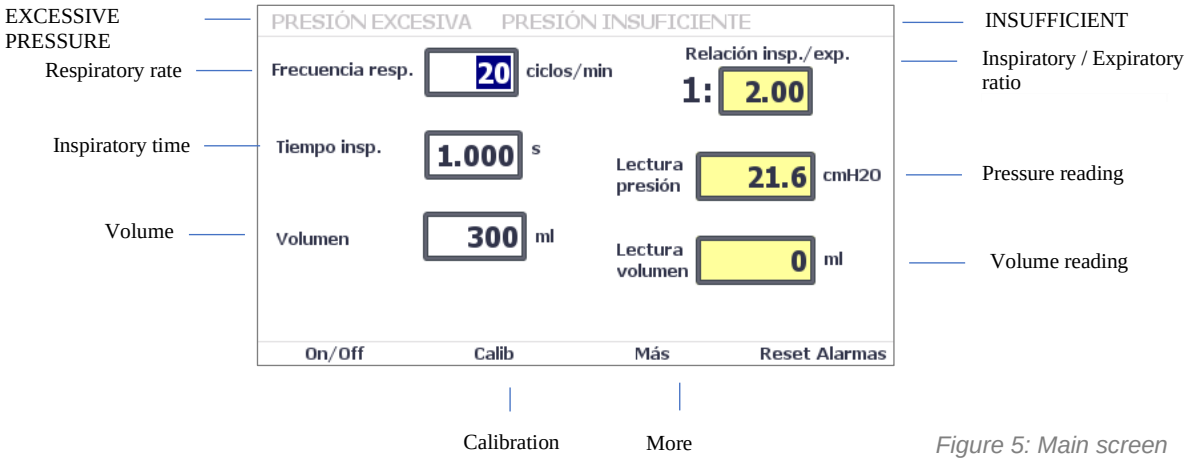

Figure 5: Main screen

On this screen the operator can enter values in the control parameters, as well as monitor the pressure and volume values that the system is registering.

Control parameters

- Respiratory rate: number of respiratory cycles per minute.
  - Min value: 12 cycles/min
  - Max value: 30 cycles/min
- Respiratory time: time interval that the inspiration movement lasts.
  - Min value: 0.6 seconds
  - Max value: 1.5 seconds
- Delivering volume:
  - Min value: 150 ml
  - Max value: 600 ml

Monitoring values

- Inspiratory time – Expiratory time ratio
- Maximum pressure reading delivered in the last cycle, in centimetres of water (cmH2O)
- Volume reading delivered in the last cycle, in millilitres (ml)

Once the control parameters have been entered, the user must press the F1 (On / Off) key to start the process.

Floating buttons on the screen

On the main screen there are 2 floating buttons that are used to access the 2 monitoring screens of the respiratory system. These screens serve to increase the values of the most important values for healthcare personnel.

3 | CALIBRATION SCREEN

On the Calibration screen, the user can adjust the system parameters. It is accessible from the Main screen using the F2 button.

The device is calibrated in the manufacturing process. Therefore, this screen should not be used, unless deviations are detected or when the AMBU is broken or needs to be repaired. In such case, it is recommended to immediately contact the technical service.

System calibration establishes the connection between the actuator open and close positions, and the delivered volume, which the user can observe during the calibration process. This procedure must be performed at least once before starting normal device operation.

Note: On this screen, the position value 0 (zero) corresponds to the maximum opening position of the actuator; that is, the position in which the actuator is furthest from the balloon.

Figure 6: Calibration screen

Calibration process of the actioning mechanism

As a preventive measure, each time a calibration process is started, please press the "Clear All" button.

1 | The “initial position” will be the same throughout the calibration process. To determine it, use the “Abrir” (Open) and "Cerrar” (Close) buttons to bring the actuator to the closest position to the balloon but without pressing it, and write down the value shown in "Pos. actual" (Current position).

2 | Press “*On/Off*” to start the cycles.

3 | While the device is operating, enter in the field “Pos. Inicial” (Starting position) the value previously noted. This number will not vary during the entire calibration process.

4 | Choose a final position setpoint and enter it in the “Pos. Final" (End position) field.

5 | The cycles that the actuator will perform at this time will correspond to the values entered in “Pos. Inicial ”and“ Pos. Final".

6 | The field “Lectura vol.” (Volume reading) will be updated at the end of every cycle with the delivered flow value. Such reading must be entered in the “Consigna volumen” (Volume setpoint) field.

7 | Press the "Guardar” (Save) button to enter the calibration point.

8 | If between 3 and 50 calibration points have been entered, proceed to the next step. Otherwise, return to step 5, bearing in mind that the end position of the actuator should not be repeated.

9 | If between 3 and 50 calibration points have been entered, proceed to the next step. Otherwise, return to step 5, bearing in mind that the end position of the actuator should not be repeated. Please note that the last entered point should be as close as possible to the actuator’s maximum closing position.

10 | Press the ‘Apply’ button and confirm that the calibration has been carried out correctly.

11 | It is necessary to disconnect the device from the grid power after completing the present calibration.

4 | MEDICAL SETTINGS SCREEN

On this screen, medical personnel can set up the internal system parameters, such as tolerances or thresholds. It is accessible from the "Calibration" button F2.

IMPORTANT:

The displayed and editable values in this screen should not be modified during the normal operation of the device. A trained technician may modify such values when needed while adjustment, start-up or maintenance operations.

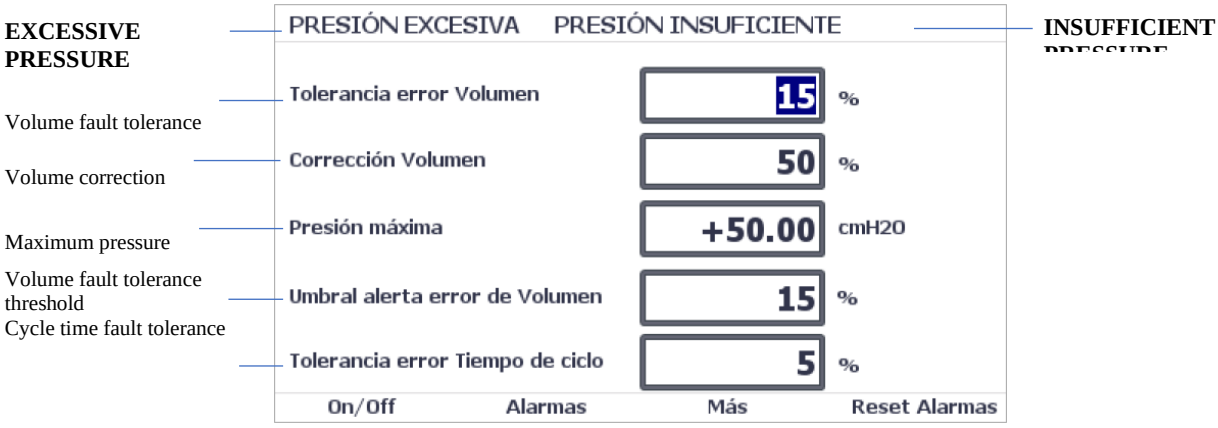

Figure 7: Medical settings screen

- Volume fault tolerance: Acceptable percentage difference between desired and measured delivered volume. If the value measured in one cycle is within the range, the setpoint is maintained in the next cycle.
- Volume correction: If the difference between the desired and measured delivered volume exceeds the tolerance described in the previous point, the next cycle will add or subtract the setpoint from this percentage of the resulting difference, without affecting the Volume field of the “Main” screen. "
- Maximum pressure: Maximum accepted pressure value. Whenever this pressure is exceeded, the device will understand that the inspiration has ended (actuator will close) and proceed to perform the expiration (actuator will open). It is now in pressure control mode.
- Volume fault tolerance threshold: Tolerance of the measured volume with respect to the desired value to trigger the corresponding alarm (%).
- Cycle time fault tolerance: Tolerance of the measured cycle time with respect to the desired value to trigger the corresponding alarm (%).

5 | ALARM CONTROL SCREEN

On this screen the user can check both active alarms and active warnings.
All alarms and warnings remain on this screen even when they are no longer active, until they are cleared using the F4 button, Reset Alarms, which can be pressed from any screen.

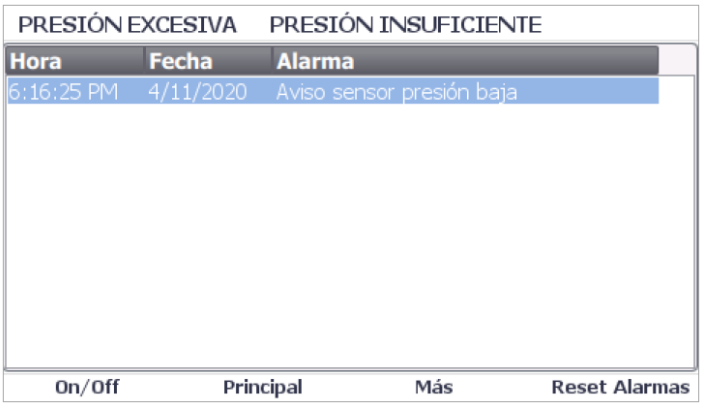

Figure 8: Alarm screen

The different alarms and warnings generated by the device are described below. In the case of alarms, an acoustic signal will sound. In the case of warnings, there is no acoustic signal.

	Eventos	# Ciclos Continuos	Generar Alarma	Generar Warning
Volumen	Volumen Leido > Volumen Target + 15%	1	NO	YES
	Volumen Leido < Volumen Target - 15%	1	NO	YES
	Volumen Leido > Volumen Target + 15%	10	YES	NO
	Volumen Leido < Volumen Target - 15%	10	YES	NO
	Volumen leido constante	3	YES	NO
uSwitches	Deteccion Sensor Final Carrera (1 o los 2)	1	NO	YES
	Deteccion Sensor Final Carrera (1 o los 2)	5	YES	NO
	Deteccion Home (1 o los 2)	1	NO	YES
	Deteccion Home (1 o los 2)	5	YES	NO
Presion	Presion actual > 50cm columna agua	1	YES	NO
	Presion Max Durante el Ciclo < 15cm columna agua	1	YES	NO
	Lectura presion constante	3	YES	NO
Tiempo	Tiempo inspiracion > Tiempo inspiracion target + 5%	1	NO	YES
	Tiempo inspiracion < Tiempo inspiracion target - 5%	1	NO	YES
	Tiempo inspiracion > Tiempo inspiracion target + 5%	10	YES	NO
	Tiempo inspiracion < Tiempo inspiracion target - 5%	10	YES	NO
	# Ciclos x min != # Ciclos Target x min	1	NO	YES
	# Ciclos x min != # Ciclos Target x min	3	YES	NO
	Cada 10min de bombeo	1	NO	NO
ON/OFF	Encendido del sistema previamente apagado cuando estaba bombeando	1	YES	NO
Home	No se detecta sensor home durante el homing en medio de un ciclo de bombeo	1	NO	YES
	No se detecta sensor home durante el homing en medio de un ciclo de bombeo	3	YES	NO

Figure 9: Alarms and warnings of the LEITAT 1 device

6 | VERSION SCREEN

On this screen it is possible to check the firmware version loaded in each of the components of the device. It is accessible by pressing the "Versión" button on the "Más" screen. The latter is accessible from any screen by pressing F3.

Figure 10: Version screen

7 | CLOCK SCREEN

On this screen it is possible to set up the date and time of the device. It is accessible by pressing the "Reloj" button on the "Más" screen. The latter is accessible from any screen by pressing F3.
To modify the time and / or date, click on the field where such values are displayed and use the keyboard displayed on the screen for this purpose. When finished, it is possible to finish entering data using the "enter" button and it will only be necessary to press the "Apply" button to make the change effective.

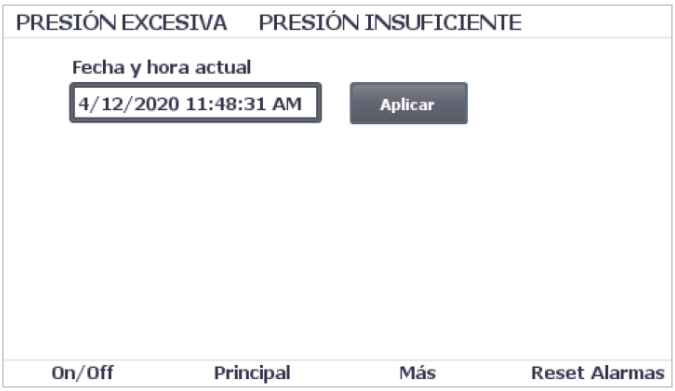

Figure 11: Clock screen

8 | MONITORING SCREEN 1

Monitoring screen 1 is a screen used to monitor the following 3 values:

- Delivered volume
- Delivered pressure
- Respiratory rate

The purpose of this screen is to make the values easily seen from far, about 2.5 meters.

This screen also has a floating button that navigates to the main screen. From this screen, changes to the desired objectives are not allowed. These must be done from the main screen.

Figure 12: Monitoring screen 1

9 | MONITORING SCREEN 2

Monitoring screen 2 is a screen used to monitor the following 2 values:

- Delivered volume
- Delivered pressure

The purpose of this screen is to make the values easily seen from far, about 2.5 meters.
This screen also has a floating button that navigates to the main screen. From this screen, changes to the desired objectives are not allowed. These must be done from the main screen.

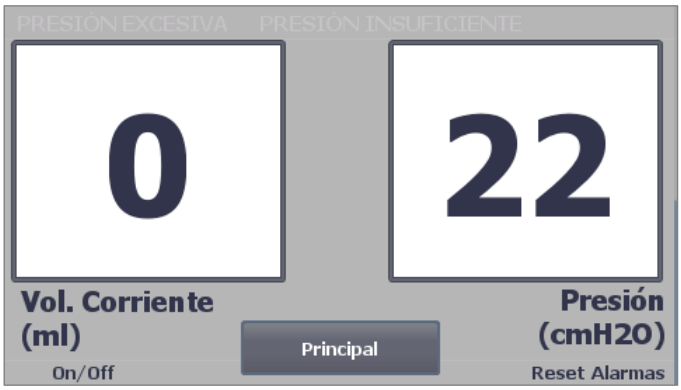

Figure 13: Monitoring screen 2

3.WARNING OR PRECAUTIONS OF USE

The objective of this section is to collect information regarding the risks resulting from the incorrect use of the automated resuscitator.

Three levels of information are established according to their degree of criticality.

- **Warnings:** They indicate conditions that may result in risks for the patient or for the operator.
- **Precautions:** They indicate conditions that may affect or damage the equipment or its accessories.
- **Additional Information:** They collect complementary information, which help in understanding the operation of the equipment.

3.1. WARNINGS

The following information shows the conditions that may cause a risk to the safety of the patient and / or operator.

The mechanized ventilation system **LEITAT 1** is a temporary aid to the ventilatory function of the inspiratory muscles. It is not a therapy, it is a support intervention, an equipment which aims to provide ventilatory and temporary support that ventilates the patient while correcting the originating problem.

3.1.1 | Responsibilities of the operator

Before using the automated resuscitator, this manual should be read and fully understood. The use of the equipment before the full understanding of its characteristics and functions may result in risky conditions for the patient, the operator and the equipment itself.

After reading and understanding this manual, it should be kept in an accessible place for quick reference if necessary.

This automated resuscitator should ALWAYS be used in accordance with the specifications contained in this manual.

This equipment should be handled and operated only by properly trained professionals.

Automated resuscitator alarms indicate a hazardous situation, requiring operator attention and should NEVER be ignored.

3.1.2 | Maintenance

This automated resuscitator is a life support equipment. In the event of any problem or malfunction with the use or operation of the equipment, it MUST be replaced by another while its operation is supervised at all times.

For cleaning the equipment, the same cleaning protocols established in the hospital will be applied for cleaning medical equipment in the intensive care unit.

The pressure regulator (PEEP) bottle should only be filled with distilled water to avoid bacteria generation problems.

3.1.3 | Accessories

Always use accessories, parts and original equipment parts. Modification or replacement by non-original parts may cause this equipment to malfunction. Furthermore, failure to comply with this point could put the safety of the patient and the operator at risk.

3.1.4 | Batteries

The automated resuscitator alarm system has a battery so that, in case of failure of the electrical power system, it ensures its operation for at least 20 minutes. Verify when starting up the equipment that the battery is not exhausted, turning the alarm ON and pressing the "Test Alarm" button to verify that it works. In case of low battery detection of the alarm system, it should be replaced immediately, supervising the equipment at all times between detection until the battery is replaced.

If the alarm system battery needs to be replaced, it must be replaced by one with identical characteristics. Replacing the battery with one of different characteristics could lead to improper operation of the alarm system.

3.1.5 | Elimination

All replaced parts and pieces must be disposed of as determined by the local legislation where the equipment is installed.

Special attention should be paid to the battery of the alarm system, and electronic components, which must be treated as special waste and disposed of independently from the rest of the equipment as they can present a risk to the environment.

3.1.6 | Electrical safety

ALWAYS use an AC power supply that provides a grounding pin connection.

Never disassemble the box containing the electrical system of the automated resuscitator. This operation presents a risk of electric shock.

The leakage current measured in the equipment is 0.58 mA, so there is no risk of causing untimely trips of the differentials due to the accumulation of equipment.

3.1.7 | Electromagnetic compatibility

The use of this equipment requires special precautions regarding its electromagnetic compatibility.

- Only connect this equipment to a grounded electrical outlet.
- Never disconnect the grounding cable from the equipment.

3.2. PRECAUTIONS OF USE

The following are conditions that may affect or damage the equipment or its accessories.

3.2.1 | Installation

When in operation, this automated resuscitator:

- NEVER be covered or placed in such a way that it blocks your access or covers the ventilation openings. These entrances are located on the sides of the team.
- NEVER place this equipment exposed directly to heat sources or in places where it can get wet or splashed.
- Place this equipment on a firm, level surface.

3.2.2 | Maintenance

To ensure the correct operation of the equipment, the following actions must be carried out:

- **Initial verification *Check List*:**

  Carry out a verification of the general condition of the equipment, as well as aspects of cleaning, assembly and connections with an electrical power source.
  It is recommended to be done daily or before use.

- **Functional Verification Test – PVF:**

  Perform the functional verification of the equipment, as well as the operation of the alarm and monitoring resources, by means of fault simulations, using a pulmonary simulator.
  It is recommended to perform before the use of the equipment in a patient or when there are doubts about the operation of the equipment.

3.2.3 | Cleaning, disinfection and sterilization

When cleaning the equipment, the same cleaning protocols established in the hospital for cleaning medical equipment in the intensive care unit will be used.

Never immerse the equipment in liquid solution, nor allow liquids to enter its internal part.

Never use abrasives on the surface of the automated resuscitator, especially on your screen.

The tubes supplied with this equipment may be sterilized by autoclave.
The flow sensor can be sterilized by ethylene oxide (ETO).