MAGNAMED

INSTRUCTION MANUAL

Ventilator Analyzer

VentMeter

Part Number: 1901509 Rev:05

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1 Definitions and Information

Warning

- ***Warns the user about the possibility of injury, death or other serious adverse reaction due to the misuse of the equipment.***

Caution

- ***Warns the user about the possibility of equipment failure associated with the use or misuse. Like equipment malfunction, damage or third-party property damage and indirectly to patient injury.***

Notes

- *Important Information.*

The VentMeter Gas Flow Analyzer is a device designed to carry out lung ventilator evaluation. The measured parameters are: Flow, Volume, Pressure, Times, Frequency, Compliance, and Resistance, among others. For these measurements, the analyzer counts with a flow sensor and transducer set extremely precise that grants measurement precision.
This analyzer coupled to lung ventilator under test and a lung simulator allows its complete characterization.
Basic Characteristics:

- AC Input 100 ~ 240 V_{AC} – 50 ~ 60 Hz;
- Internal battery with intelligent charger;
- Graphic LCD display to show monitored parameters and pressure curve, flow curve and volume curve;
- FiO_2 monitor, maximum pressure, mean pressure and PEEP/CPAP pressure, respiration frequency (rate) and I:E ratio;
- Key to navigate among many available screens;
- Key to select the monitored parameters to be visualized;
- Allows – serial communication to a PC for registering results.
- PulmoTrend Software – to register data and best visualization.

Warning

- ***This symbol***  ***indicates to read the instruction manual to get more information.***
- ***This equipment should be used exclusively to evaluate lung ventilators performance. It should not be used to monitor patient ventilation in Intensive Care Units.***
- ***This manual should be completely read, to safely and correct use of the equipment and to get maximum performance.***
- ***Disconnect the equipment from electrical power source before cleaning.***
- ***Do not expose this equipment to liquids to avoid electrical shock hazards. Do not use the equipment if the internal components were being exposed to liquids.***

Caution

- ***The Ventilator Analyzer don't emit electromagnetically waves that interfere in the functioning of the equipment's in its proximity.***
- ***The Ventilator Analyzer should be CALIBRATED yearly. All the maintenance service procedure should be done by trained personnel only.***
- ***Use only parts, pieces, cables and sensors specified and acquired from* MAGNAMED*. Part Number in chapter 12.***
- ***Turn on the equipment and proceed to the verification and basic adjustments – follow the instructions;***
- ***Wait at least 30 minutes to get temperature stabilization in order to have stable pressure and flow readings.***
- ***Observe the correct connection of the flow sensor and verify that no obstruction is present inside the sensor.***
- ***Do not expose the equipment to extreme temperatures. To get correct measurements be sure that the ambient temperature is between 18 and 40 ºC during its use.***
- ***Do not use the equipment if any problem cannot be solved.***

- ***The Ventilator Analyzer has an independent power supply unit. Keep it connected to the electrical power source to charge the internal batteries.***
    - ***Plug the power cord into a three pin, NBR 14136 standard (Chapter 5.2);***
    - ***Keep the equipment connected to a power source even when it is turned off so that the internal batteries are permanently charged.***
    - ***Recharge the batteries completely after use or after a long period of storage;***

Notes

- *Dispose of removed parts in accordance with the institution's parts and parts disposal protocol and follow local governmental recommendations for environmental protection, especially in the case of electronic waste or electronic parts (e.g. batteries).*
- *The technical specifications of* **MAGNAMED***'s products are subject to change without previous notice.*
- *Pressure units:*

1 mbar (millibar) = 1 hPa (hectoPascal) = 1,016 cmH_2O (centimeters of water)

Practically these units can be used as:

1 mbar = 1 hPa ≈ 1 cmH_2O

2 Index

3 Description

3.1 Intended Use

The Ventilator Analyzer – VentMeter is an instrument to be used in evaluation and test of lung ventilators. The measurements are done by flow sensors and pressure sensors.
The flow measurement is bidirectional and is carried out by three kind of flow sensors calibrated to neonatal to adult range of flows.
The Ventilator Analyzer measures 17 mechanical ventilation parameters, besides measuring the oxygen concentration of the gas output from the ventilator.
The Ventilator Analyzer can be used to pre-evaluate lung ventilators before its acquisition, as well as for periodical performance evaluation of the equipment in service and is extremely useful during training courses to interpret ventilation curves.

Basic Characteristics:

- AC Input 100 ~ 240 VAC – 50 ~ 60 Hz;
- Internal battery with intelligent charger;
- LCD Display to show pressure curve, flow curve, volume curve and monitored values;
- FiO_2 monitoring, maximum pressure, mean pressure, PEEP/CPAP, respiration rate and I: E Ratio;
- Keys to navigate between many available screens;
- Keys to select monitored parameters to be visualized;
- Allows serial communication to a PC to register all the results
- PulmoTrend software to register all data and to better visualization (basic version available to download and is free)

3.2 Operating Principles

The ventilation parameters measurements are done by a flow sensor connected proximally to the lung simulator.

Through this flow sensor the equipment gets the basic readings of:

- Flow
- Pressure

These data are continuously monitored

The other parameters are calculated from these two data:

- Maximum Flow
- Minimum Flow
- Exhaled Volume (Tidal Volume)
- Inspired Volume
- Minute Volume

- Inspiratory Time
- Expiratory Time
- I: E Ratio
- Respiration Frequency (Respiration Rate)
- Maximum Inspiratory Pressure (Peak Inspiratory Pressure)
- PEEP (Positive End Expiratory Pressure)
- Mean Pressure
- Plateau Pressure
- Minimum Pressure
- Static Compliance
- Dynamic Compliance
- Airway Resistance

Beside these monitored data by the flow sensor, it is possible to measure the oxygen concentration of the gas mixture from the lung ventilator under test (FiO_2 – Oxygen Inspired Fraction).

The available flow sensors are:

- NEONATAL Sensor – NEO - Flow from 0 to 20 $L.min^{-1}$
- INFANT Sensor – INF - Flow from 0 to 50 $L.min^{-1}$
- ADULT Sensor – ADU - Flow from 0 to 150 $L.min^{-1}$

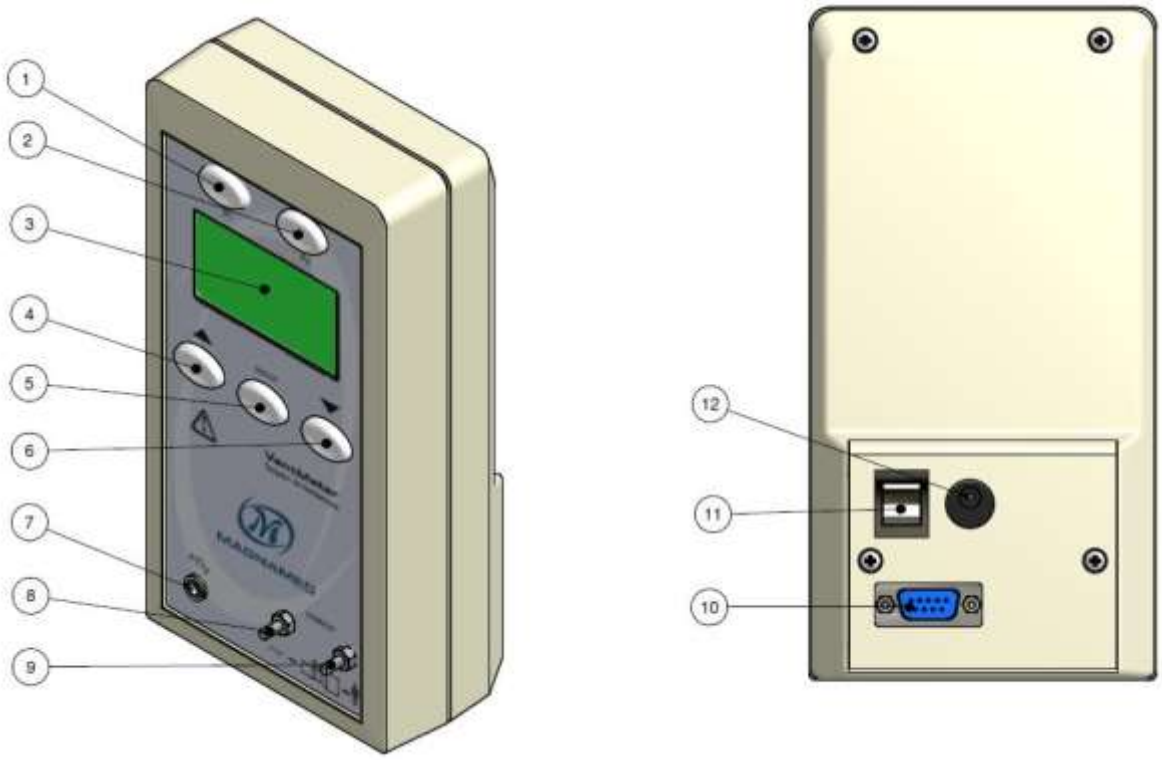
4 Part Identification

4.1 Parts and Components

The following items are supplied integrating the equipment.

Quantity	Description	Picture
01	VentMeter – Ventilator Analyzer	
01	Kit Flow Sensors	
01	Resistance Kit	

Quantity	Description	Picture
01	Testing bag set	
01	Handbag	
01	CD – Instruction Manual and PulmoTrend Software for PC – basic version	
01	Source AC/DC 90 – 2source 60 Vac to +12 Vdc	



4.2 Identification

1 F1 Key

This key assumes the functions indicated by a highlighted text in the screen: Config. and Return

2 F2 Key

This key assumes the functions indicated by a highlighted text in the screen: Cal. and Next

3 LCD Display

Show graphs and monitored parameters.

4 UP Key or Increment Key

This key increments or UP ARROW to allow navigation within the screen.

5 Confirm Key

This key selects the function or parameter to be monitored.

6 Decrement Key or Down Key

This key decrements or DOWN ARROW to allow navigation within the screen.

7 Galvanic Cell Connector to measure O_2 Concentration

It allows a galvanic cell connection to measure O_2 concentration in the respiratory circuit.

Caution

- ***Use only cables and sensors specified and acquired from* MAGNAMED*. Acquisition and part number information see chapter 12.***

8 Distal Flow Sensor Connector

Distal flow sensor pressure measurement port connector.

Caution

- ***Connect the tubing according to the picture shown in the front panel of the VentMeter.***

9 Proximal Flow Sensor Connector

Proximal flow sensor pressure measurement port connector.

10 PC Serial RS-232 connectors

PC Serial communication connector (RS-232). It communicates exclusively to Magnamed's PulmoTrend Software (basic version available for download).

Caution

- ***Use cable specified by* MAGNAMED*. Use SERIAL TO USB converter cable with appropriate driver for PC.***

11 ON / OFF Switch

This key allows turning power on or off the Ventilator Analyzer.

12 DC Power connector

The power supply unit is an AC/DC Converter that can be connected to an electrical power source as shown in the figure.

Tension	1	2	3
$110V_{AC}$	NEUTRAL	PHASE	GROUND
$220V_{AC}$	PHASE	PHASE	GROUND

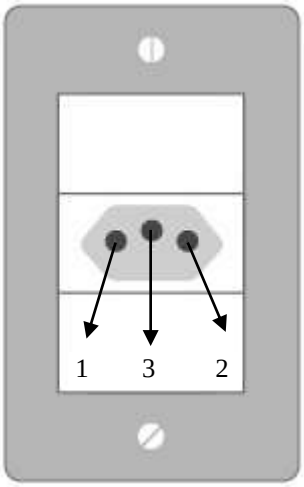


Figure - socket pattern NBR 14136

Notes

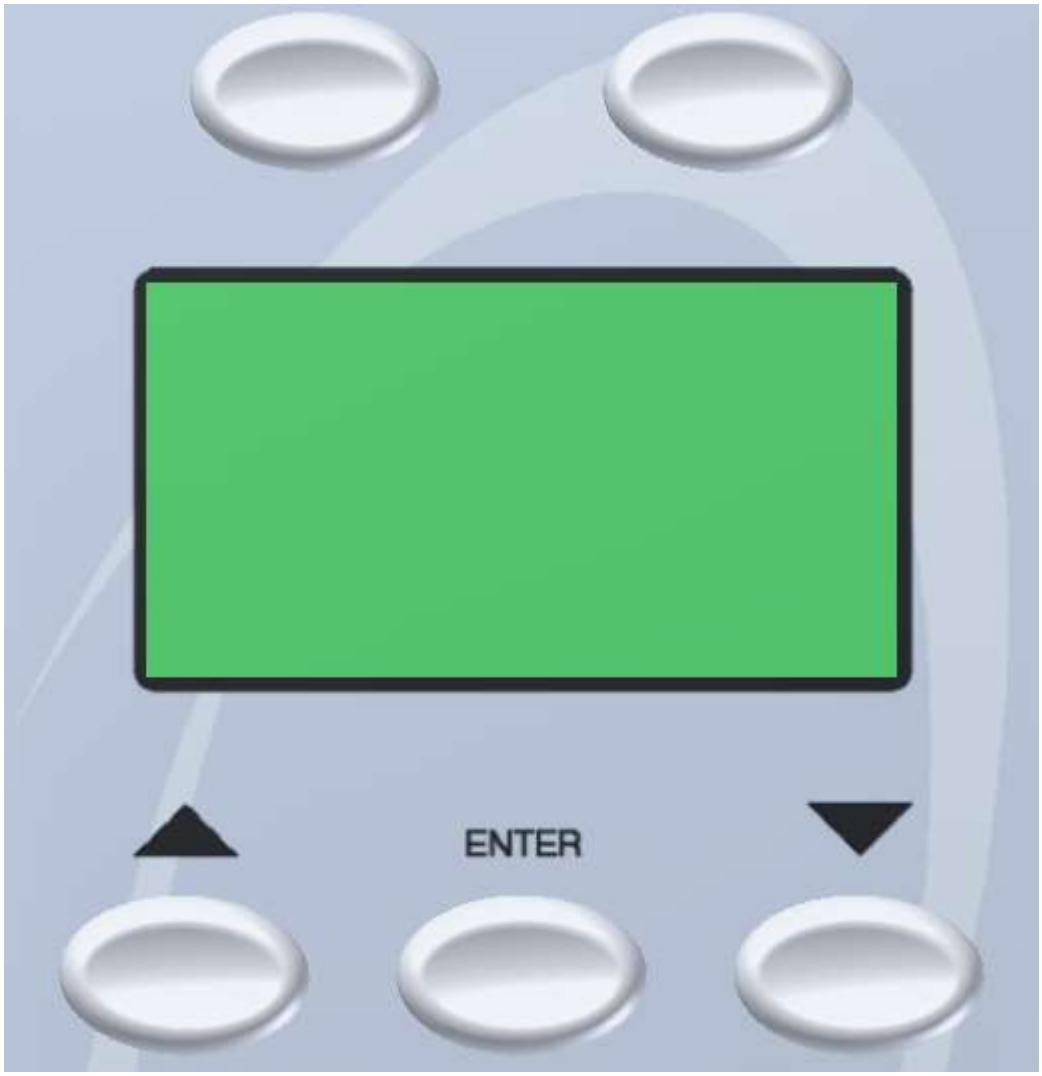
- *Plug and Socket Standard: ABNT NBR-14136 - Plugues e tomadas para uso doméstico e análogo até 20 A/250 V em corrente alternada - Padronização ”*

The internal battery of the Ventilator Analyzer – should be always charged and ready to use in eventual electrical power failure, to achieve it this cable should be kept connected to the mains. This carries out battery charging even if the VentMeter is turned off.
After long use of the Ventilator Analyzer in battery operated mode it is advisable that a complete recharging cycle be done preparing it to the next use.

Caution

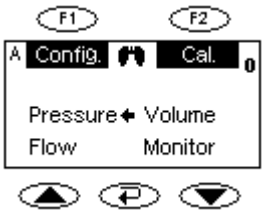
- ***If the Ventilator Analyzer - VentMeter remains disconnected from the electrical power supply for a period greater than one month, it is recommended to recharge it before use.***

5 Command and Adjustment



All the measurements are selected from the main screen through the selection button (UP and DOWN arrows) and CONFIRM . The F1 and F2 have variable function according to highlighted text shown in the screen bellow each button.

Main Screen:



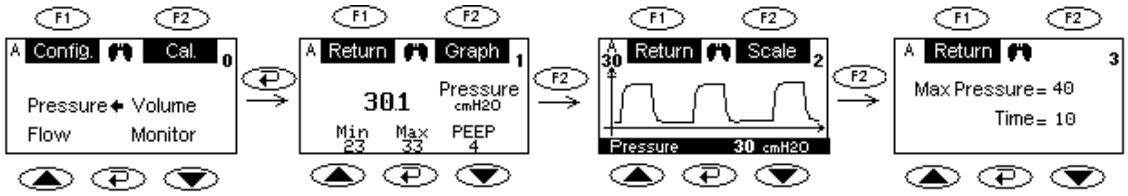
In the **Main Screen** if INCREMENT  or DECREMENT  key is pressed the arrow moves to Pressure, Flow, Volume or Monitor

In the figure above if the ENTER  key is pressed the Display will show the **Pressure Measurement Screen**.

Notes

- ***The number at superior right corner indicates the distance in screen from the main screen. Zero = Main screen.***
- ***The letter at superior left corner indicates which flow sensor is selected:***
  A = Adult Sensor;
  I = Infant Sensor;
  N = Neonatal Sensor.

Pressure Measurement Screens:

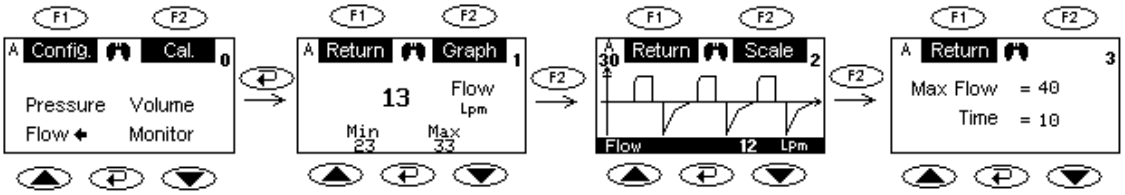


The F1 and F2 keys allows navigation between pressure screens, notice that as the F2 key is pressed the number at the superior right corner is incremented, indicating greater distance from the **Main Screen**.

- **Pressure Screen (1):** Pressure Numerical Values
  - **Screen Central –** Instantaneous Pressure
  - **Screen Inferior –** Minimum Pressure, Maximum Pressure, PEEP
- **Screen Pressure (2):** Pressure Graph
  - **Screen Central –** Pressure Graph
  - **Screen Inferior –** Instantaneous Pressure Value
- **Pressure Screen (3):** Graph Scale
  - **Max Pressure –** Maximum pressure value in the graph (adjusts from 20 to 120 cmH_2O with steps of 5 cmH_2O)
  - **Time –** One screen sweep time (adjusted from 1 to 15 seconds with steps of 1 second).

When adjusted in 1, it is possible to see a complete respiration cycle with 60 min^{-1} (respiration rate) rate. Adjusting in 12, it is possible to see a complete respiration cycle with 5 min^{-1} respiration rates.

Flow Measurement Screens:

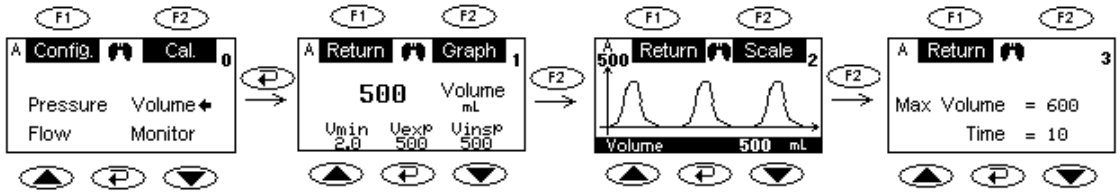


By pressing the ENTER 

key, in the **Main Screen**, when the arrow is pointing to Flow, the display will show the **Flow Measurement Screen**.
The F1 and F2 key allows navigation between flow screens, notice that as the F2 key is pressed the number at the superior right corner is incremented, indicating greater distance from the **Main Screen**.

- **Flow Screen (1):** Flow Numerical Values
  - **Central Screen –** Instantaneous Flow
  - **Inferior Screen –** Minimum Flow and Maximum Flow
- **Flow Screen (2):** Flow Graph
  - **Central Screen –** Flow Graph
  - **Inferior Screen –** Instantaneous Flow Value
- **Flow Screen (3):** Graph's Scale
  - **Max Flow –** Maximum value of flow in the graph (adjusted from 10 to 150 $L.min^{-1}$ with steps of 10 $L.min^{-1}$)
  - **Time –** One screen sweep time (adjusted from 1 to 15 seconds with steps of 1 second). When adjusted in 1, it is possible to see a complete respiration cycle with 60 min^{-1} (respiration rate) rate. Adjusting in 12, it is possible to see a complete respiration cycle with 5 min^{-1} respiration rates.

Volume Measurement Screens:



By pressing the ENTER 

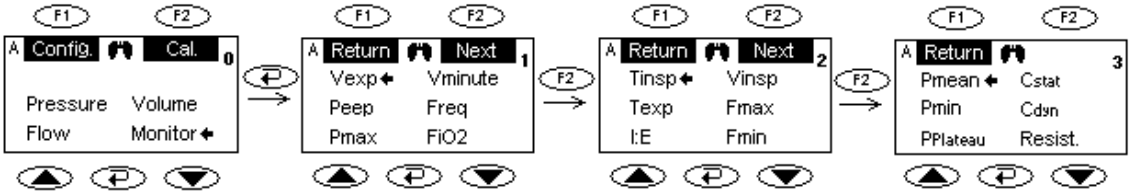
key, in the **Main Screen**, when the arrow is pointing to Volume, the display will show the **Volume Measurement Screen**.
The F1 and F2 key allows navigation between volume screens, notice that as the F2 key is pressed the number at the superior right corner is incremented, indicating greater distance from the **Main Screen**.

- **Volume Screen (1):** Volume Numerical Values
  - **Central Screen –** Instantaneous Volume
  - **Inferior Screen –** Vmin: Minute Volume; Vexp: Expired Volume; Vinsp: Inspired Volume
- **Volume Screen (2):** Volume Graph
  - **Central Screen –** Volume Graph
  - **Inferior Screen –** Instantaneous Volume Value
- **Volume Screen (3):** Graph's Scale

- **Max Volume –** Maximum value of volume in the graph (adjusted from 50 to 2000 mL with steps of 50 mL)
- **Time –** One screen sweep time (adjusted from 1 to 15 seconds with steps of 1 second). When adjusted in 1, it is possible to see a complete respiration cycle with 60 min^{-1} (respiration rate) rate. Adjusting in 12, it is possible to see a complete respiration cycle with 5 min^{-1} respiration rates.

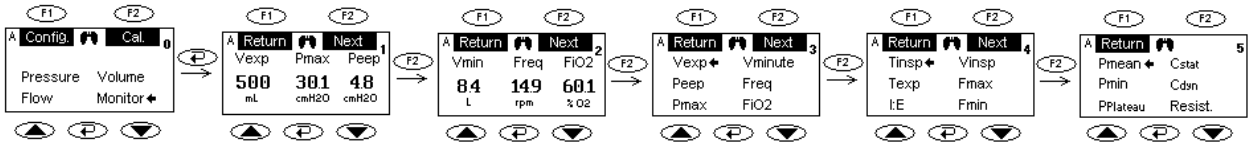
Monitor Screen:

In the monitor screen it will be possible to select up to 6 parameters with two screens of 3 parameters simultaneously.
Screen sequence without any parameter selected:



Screen sequence with up to 3 parameters selected:

Screen sequence with up to 6 parameters selected:



By pressing the ENTER 

key, in the **Main Screen**, when the arrow is pointing to Monitor the display will show the **Monitor Screen**.
The F1 and F2 key allows navigation between monitor screens, notice that as the F2 key is pressed the number at the superior right corner is incremented, indicating greater distance from the **Main Screen**.
.

- **Monitor Screen (1):** Monitored Numerical Value I
  - **Superior Screen –** Monitored Parameter Name
  - **Central Screen –** Param 1, Param 2, Param 3
  - **Inferior Screen –** Unity of measurement
- **Monitor Screen (2):** Monitored Numerical Values II
  - **Superior Screen –** Monitored Parameter Name
  - **Central Screen –** Param 4, Param 5, Param 6
  - **Inferior Screen –** Unity of Measurement
- **Monitor Screen (3):** Monitored Parameters Selection I
  - **Vexp – Expired Volume (Tidal Volume)**

  - **PEEP – Positive Expiratory End Pressure**
  - **Pmax – Maximum Pressure**
  - **Vminuto – Minute Volume**
  - **Freq – Respiration Frequency (Rate)**
  - **FiO2 – Inspired O_2 Fraction**
- **Monitor Screen (4):** Monitored Parameters Selection II
  - **Tinsp – Inspiratory Time**
  - **Texp – Expiratory Time**
  - **I:E –I:E Ratio**
  - **Vinsp – Inspired Volume**
  - **Fmax – Maximum Flow**
  - **Fmin – Minimum Flow**
- **Monitor Screen (5):** Monitored Parameter Selection III
  - **Pmean – Mean Pressure**
  - **Pmin – Minimum Pressure**
  - **Pplat – Plateau Pressure**
  - **Csta – Static Compliance**
  - **Cdyn – Dynamic Compliance**
  - **Raw – Airway Resistance**

The 3, 4 and 5 monitor screen allows to select the parameters to be shown continuously. In these screens the position of the arrow and the ENTER key selects or inhibits the parameter to be shown in the monitor screen. The selected parameters will be blinking and the inhibit ones will not. To navigate between these parameters, use the UP and DOWN keys.
It is possible to choose up to 6 (six) parameters to be shown in two monitor screens. Each monitor screen (1 or 2) can show up to 3 parameters simultaneously.

Example:

a. Vexp selection

In this case there will be only Monitor Screen (1) with the expired volume centralized in the screen. By pressing F2, the presented screen will be Monitor Screen (3) and at superior right corner of the screen will show number 2 indicating the distance in screens to the **Main Screen**.

b. Selecting Vexp and Vinsp

In this case there will be only Monitor Screen (1) with the expired volume in the left side of the screen and the inspired volume in the right side of the screen.

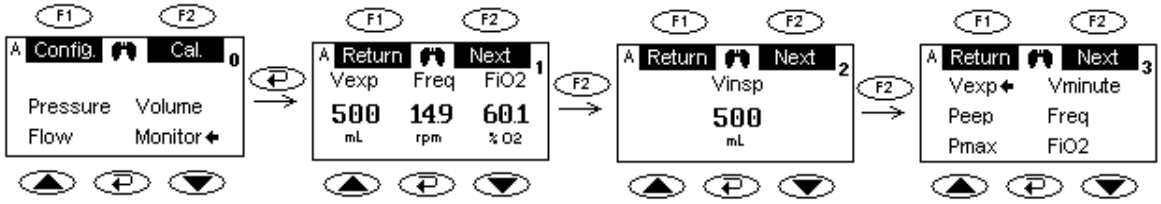
c. Selecting Vexp, Vinsp and Freq

In this case there will be only Monitor Screen (1) with the expired volume in the left side of the screen, frequency (rate) in the middle of the screen and the inspired volume in the right side of the screen.

Note

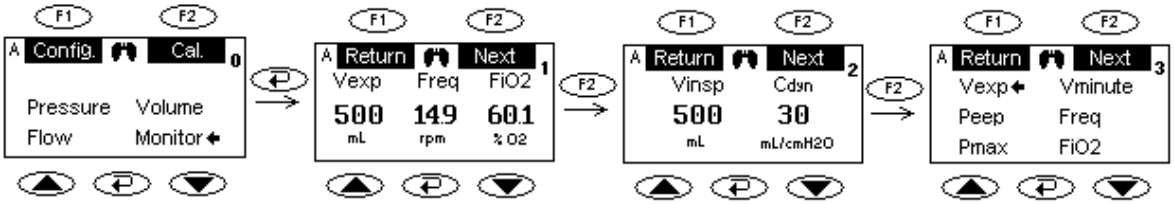
- ***The parameters will always be shown in the sequence presented in the Monitor Screens (3,4 and 5).***
- ***In example (c) instead of Vexp, Vinsp and Freq order it will show Vexp, Freq e Vinsp.***

d. Selecting Vexp, Vinsp, Freq and FiO2



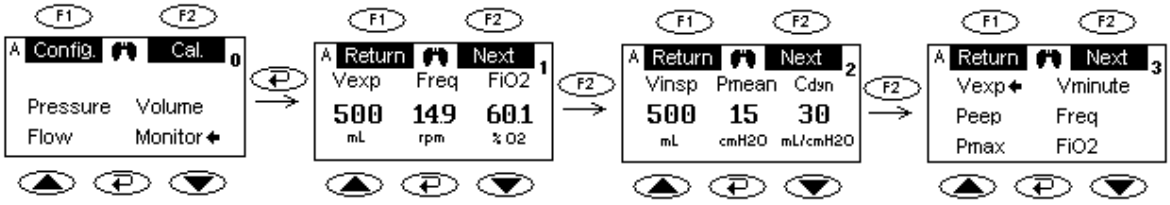
In this case there are four parameters to be shown in two screens. Screen Monitor (1) with three parameters (Vexp, Freq and FiO_2) and Monitor Screen (2) with Vinsp in the middle of the screen. Notice that in this situation the Monitor Screen (2) will show in its superior right corner the number 2 indicating that it is two screens of distance from the **Main Screen** and the Monitor Screen (3) will show in its superior right corner the number 3 indicating that it is three screens from the **Main Screen**.

e. Selecting Vexp, Vinsp, Freq, FiO2 and Cdyn



The Monitor Screen (1) will show (Vexp, Freq, FiO_2) and the Monitor Screen (2) will show the inspired volume (Vinsp) in the left side and the dynamic compliance (Cdyn) value in the left side of the screen.

f. Selecting Vexp, Vinsp, Freq, FiO2, Cdyn and Pmean

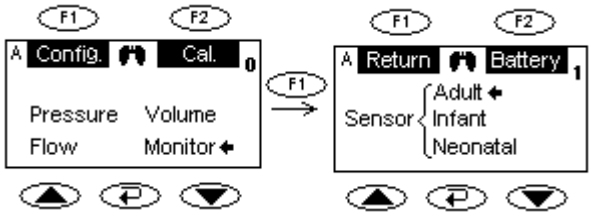


The Monitor Screen (1) will show (Vexp, Freq, FiO_2) and the Monitor Screen (2) will show (Vinsp, Pmean, Cdyn).

Note

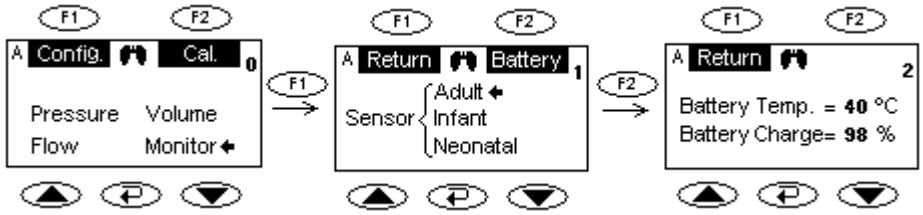
- ***Attempting to select a seventh parameter to be shown it will not blink, because the maximum parameters that can be shown is six.***
- ***If this new parameter must be shown, then first deselect one of the parameters and select this new parameter.***
- ***To observe inspiratory and expiratory cycles watch the lung drawing between the F1 and F2 key.***
- ***To carry out continuous pressure or flow monitoring observe that the lung between F1 and F2 key will remain static.***

Configurations (F1 key from the main screen):



By pressing F1 in the **Main Screen** it will present a screen with three flow sensors. The blinking flow sensor is the one selected. To select another flow sensor, use the UP and DOWN keys to reach the new sensor and press ENTER key to select it. This new sensor will start to blink indicating that it is the one selected.

Battery (F2 key from the Configuration Screen):



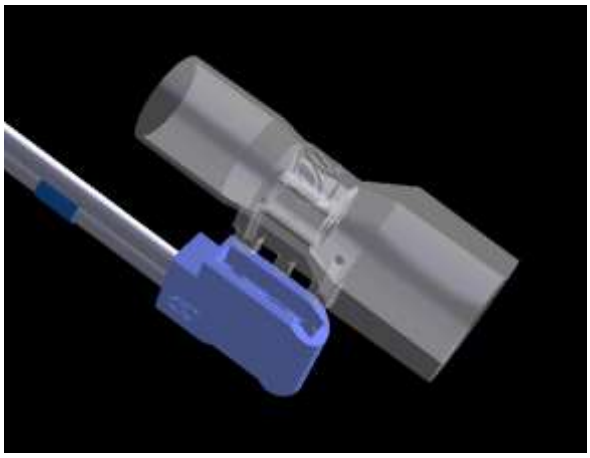
By pressing F2 in the configuration screen it is possible to visualize the charging situation and the battery temperature.

Calibrations (F2 key from the main screen):

By pressing F2 key in the Main Screen it will present the Transducers Calibration Screen. In this screen, by pressing ENTER key, the transducers will be calibrated. It will present the message: Calibrating… and in this condition F1 and F2 will be inactive. After the calibration process the message will be cleared and the F1 and F2 keys will return to the active state.

Caution

- ***To carry out the transducers CALIBRATION it is necessary that the flow sensor is disconnected from the respiratory circuit. Another way is to disconnect the line from the flow sensor.***



Being at Transducers Calibration Screen, by pressing F2 key it will show the Oxygen Sensor Calibrating Screen. In this screen it is shown two values (21% and 100%), the arrow indicates which oxygen concentration will be used to calibrate the sensor. If the arrow is pointing to 21% and the ENTER key is pressed, then it will blink and the message Calibrating… will appear, in this situation the F1 and F2 keys will be inactive. After finishing the calibration, the message will be cleared and the F1 and F2 keys will return to its active state. Similar process occurs when calibrating with 100% oxygen concentration.

Caution

- ***To carry out oxygen sensor CALIBRATION certify to use the correct concentration, otherwise the oxygen concentration measurement will be INCORRECT.***

6 Ventilation Parameters

Parameter	Name	Description
Vexp	Expired Volume or Tidal Volume	It is the tidal volume calculated by the expiratory flow integration during the expiratory time
PEEP	Positive End Expiratory Pressure)	Is the pressure value at the end of the expiration
Pmax	Maximum Pressure	Is the absolute maximum pressure value during the inspiratory cycle
Vminute	Minute Volume	Is the tidal (expiratory) volume multiplied by the respiratory frequency
Freq	Frequency (Respiration Rate)	Is the respiration frequency (rate). $(Tinsp + Texp)^{-1}$
FiO_2	Inspired Fraction of Oxygen Concentration	Is the oxygen concentration value in the gas mixture in the measuring point (It is denominated FiO_2 – Inspired O_2 Fraction when the measuring point is in the gas mixture output connection of the ventilator to the patient)
Tinsp	Inspiratory Time	Is the inspiratory time value (Positive Flow)
Texp	Expiratory Time	Is the expiratory time value (Negative Flow)
I:E	I:E Ratio	Is the result of Tins divided by Texp
Vinsp	Inspired Volume	Is the volume resulting from the integration of inspired flow during the inspiratory time
Fmax	Maximum Flow	Is the maximum value of flow registered during the inspiratory time
Fmin	Minimum Flow	Is the minimum flow registered during the expiratory time
Pmean	Mean Pressure	Is the mean pressure during the entire respiration cycle (Tins+Texp)
Pmin	Minimum Pressure	Is the minimum pressure value registered during the expiratory time
Pplat	Plateau Pressure	Is the pressure value registered at the end of the inspiratory flow
Csta	Static Compliance	Is the result from the division of expiratory volume by plateau pressure value
Cdyn	Dynamic Compliance	Is the result from the division of expiratory volume by maximum pressure value
Raw	Airway Resistance	Is the value of the airway resistance

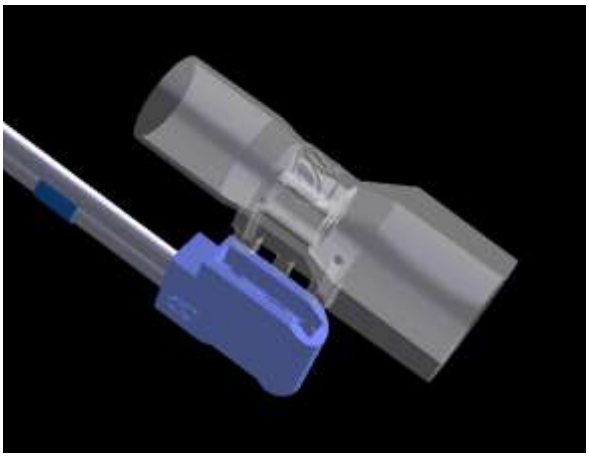
7 Preparing to Use

7.1 Ventilator Analyzer Setup

1 Connect the flow sensor tubing according to the following figure:

2 Connect the oxygen sensor to VentMeter using appropriate cable (audio cable).

3 Turn on the VentMeter and wait for the initialization screen.
4 Select the flow sensor to carry out the tests and connect the pressure line as shown in the figure bellow

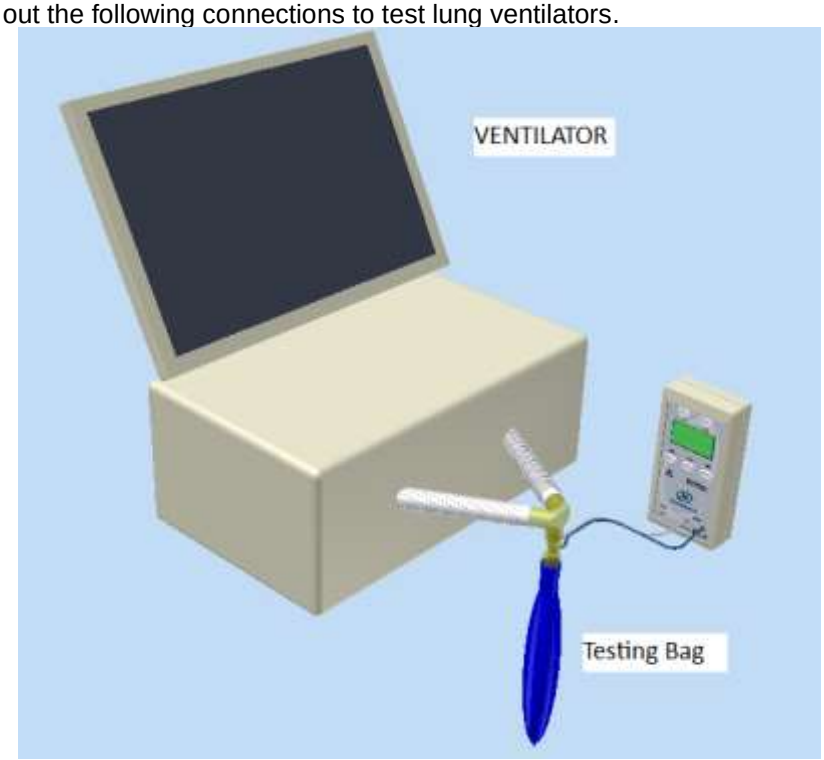


5 Prepare the respiratory circuits to test the ventilator.

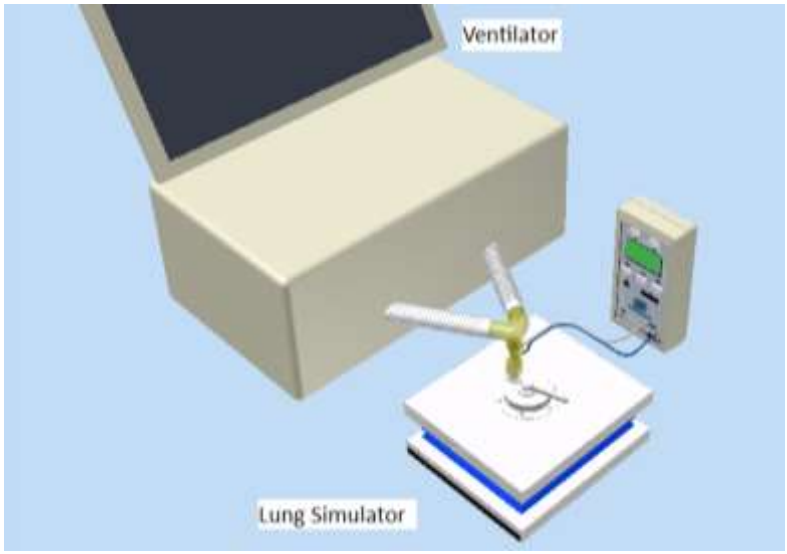
Warning

- ***The respiratory circuit should be STERILIZED, otherwise there is risk of contamination***

6 Carry out the following connections to test lung ventilators.



Test System with Bag



Test System with Lung Simulator

7.2 Electrical Power Connection

The internal battery should be charged and ready to use in the event of an electrical power failure. Keep the AC/DC converter connected to the VentMeter, this will charge continuously the battery even if the VentMeter is turned off.

After prolonged use of the VentMeter only with the power of the internal battery, it must be fully recharged and ready for further use.

If the VentMeter remains unplugged for more than one month, the battery must be fully recharged.

7.3 Oxygen Sensor (Optional)

The oxygen sensor is an element that allows monitoring the FiO_2 in the gas mixture from the ventilator to the patient. Its use is extremely useful in evaluation of the oxygen concentration administered to the patient. Its working principle is by electrochemical reaction and should be connected to the flow source to be sent to the patient.

Caution

- ***Follow the central command instructions to calibrate the oxygen concentration measurement.***
- ***Replacements should be done with the recommended oxygen sensor.***
- ***OXYGEN SENSOR REPLACEMENT:***
    - **MAXTEC – MAX-13 – O2 SENSOR**
    - **MAXTEC - RP16P02 – Tee Adaptor**
    - **MAXTEC - R110P10 – Flow Diverting**

7.4 Before Use

This inspection routine is intended to orient the user to carry out a simple procedure and quick equipment test before each use or at least at the beginning of each working period, assuring high reliability to the measurements.

7.4.1 Initial Procedures

- The equipment should be turned off.
- Integrity of all accessories and the equipment – visual inspection.
- Check if all the accessories are correctly and firmly connected.

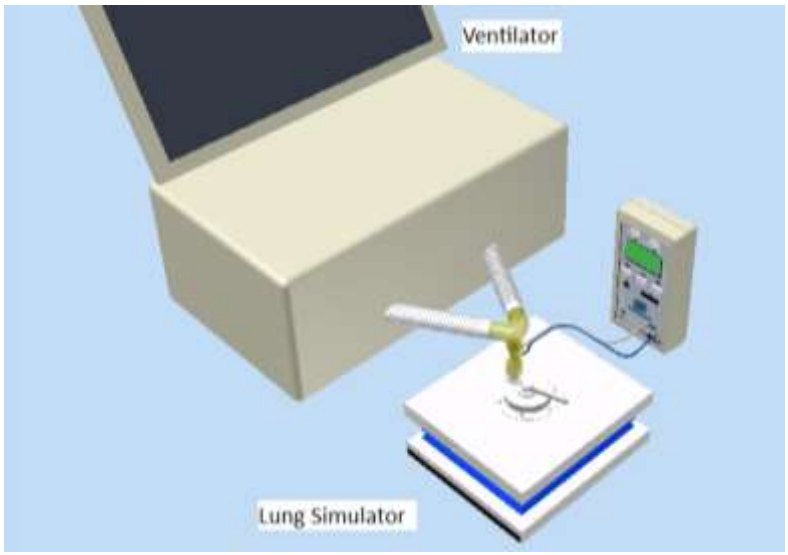
8 Ventilator Test Samples

In this chapter there are some ventilation test procedure samples, instructions and forms.

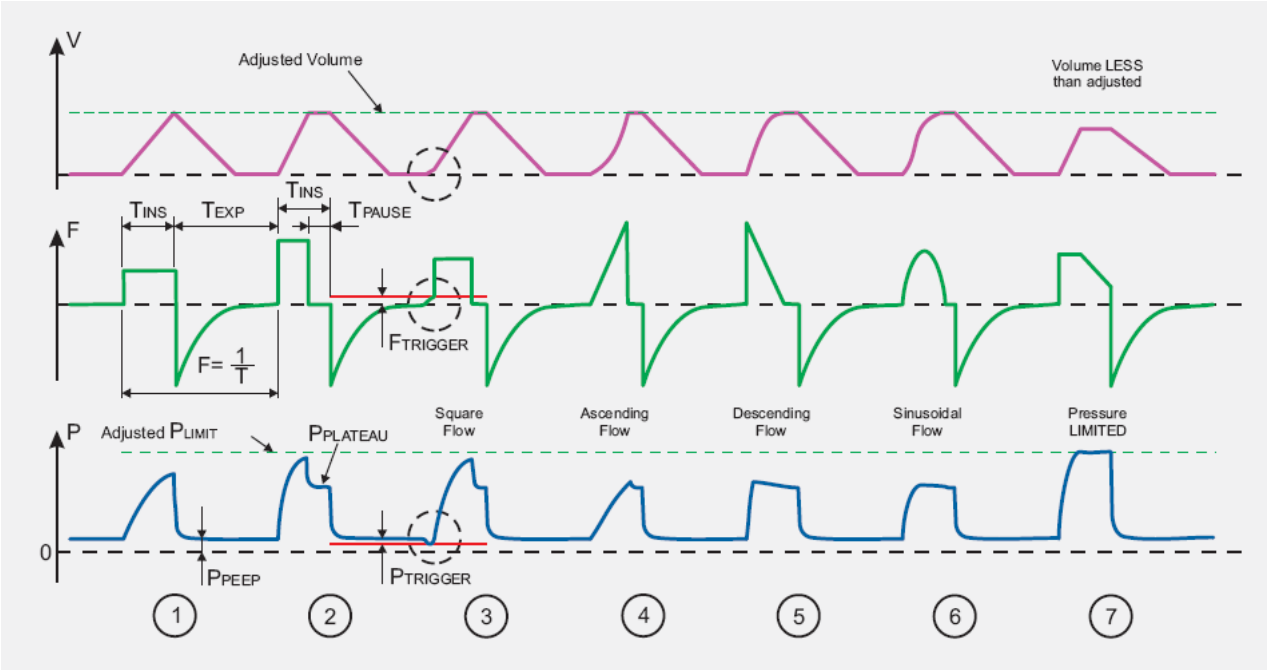
Sample 1:

Evaluating an adult ventilator in VCV (Volume Controlled Ventilation) mode.

a. Connect the system as shown in the figure bellow.



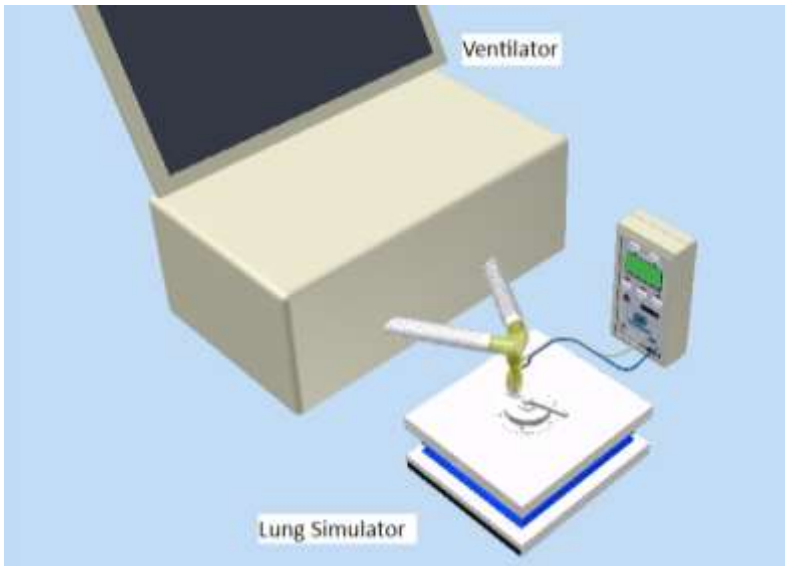
b. Calibrate the Ventilator Analyzer - VentMeter
c. Calibrate or carry out the initialization procedures of the ventilator according to the manufacturer's recommendation
d. Adjust the lung simulator:
   - Compliance = 20 mL/cmH_2O
   - Resistance = 20 cmH_2O/L/s
e. Adjust the lung ventilator with the following parameters:
   - Volume = 500 mL
   - Frequency (Rate) = 12 min^{-1}
   - Flow = 30 $L.min^{-1}$
   - Maximum Pressure ≥ 30 cmH_2O
   - PEEP = 0 cmH_2O
f. See the curves Pressure x Time, Flow x Time, Volume x Time (sample in the figure bellow)



g. Monitor the following parameters with VentMeter's Monitor Screen
   - Vexp – Expiratory Volume
   - Freq – Frequency - Rate
   - I:E – I:E Ratio
   - Pmax – Maximum Pressure
   - Pplat – Plateau Pressure
   - PEEP – Positive Expiratory End Pressure

Evaluating adult ventilator in PCV (Pressure Controlled Ventilation) mode.

a. Connect the system as shown in the figure bellow.

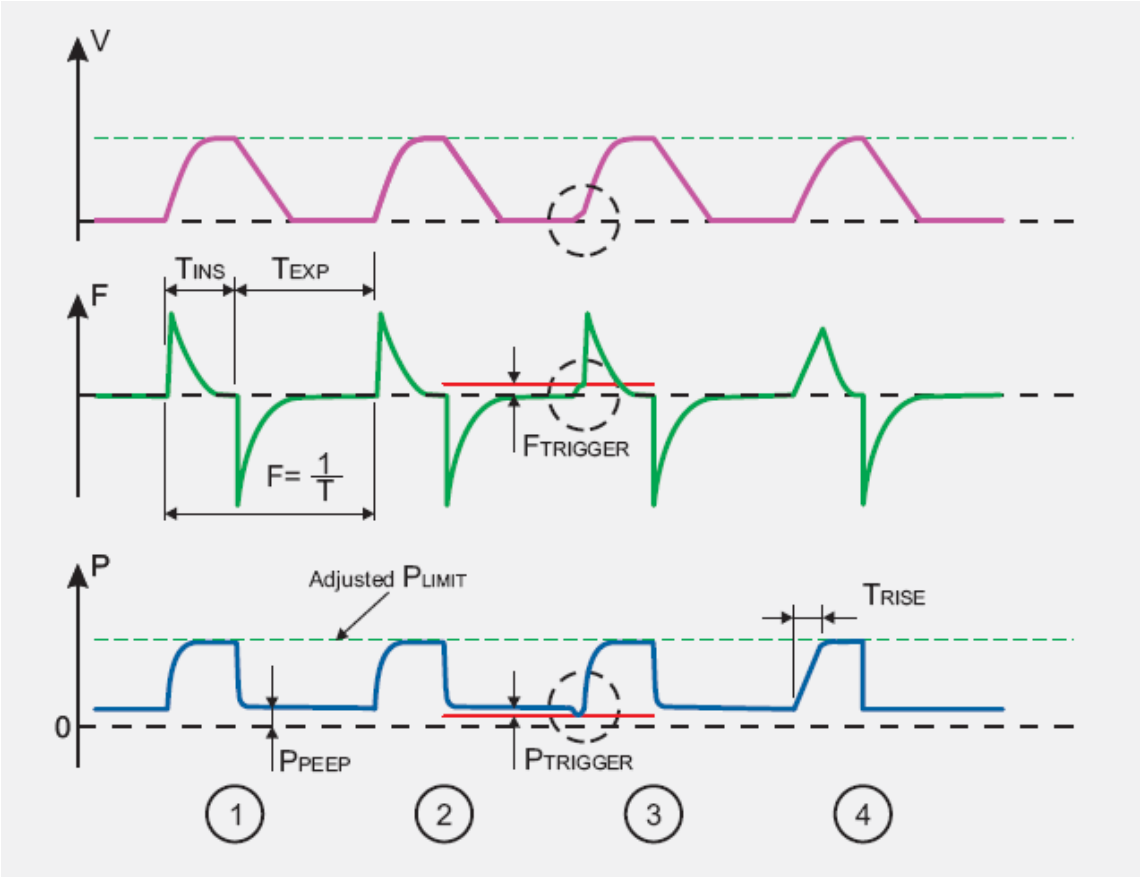


b. Calibrate the Ventilator Analyzer - VentMeter
c. Calibrate or carry out the initialization procedures of the ventilator according to the manufacturers recommendation
d. Adjust the lung simulator:

- Compliance = 20 mL/cmH_2O
- Resistance = 20 cmH_2O/L/s

e. Adjust the lung ventilator with the following parameters:
- Pressure = 25 cmH_2O
- Frequency (Respiration Rate) = 12 min^{-1}
- Inspiratory Time = 1,7 s
- PEEP = 5 cmH_2O

f. See the curves Pressure x Time, Flow x Time, Volume x Time (sample in the figure bellow)



g. Monitor the following parameters with VentMeter's Monitor Screen
- Vexp – Expiratory Volume
- Freq – Frequency - Rate
- I:E – I:E Ratio
- Pmax – Maximum Pressure
- Pplat – Plateau Pressure
- PEEP – Positive Expiratory End Pressure

Sample 3:

Test x Result Table

	SIMULATOR		VENTILATOR									VentMeter					
TEST	C [mL/kPa]	R [kPa/L/s]	Mode	Volume [mL]	Freq [1/min]	Flow [L/min]	Tins [s]	Pmax [hPa]	PEEP/CPAP [hPa]	Pause [s]	FiO2	Flow Type	Tidal Volume [mL]	Freq [1/min]	I:E Ratio	Pmax [hPa]	PEEP/CPAP [hPa]	FiO2
1	500	0.5	VCV	500	10	30		50	0	1.0	40	SQUARE						
2	500	0.5	PCV		10		2.0	25	5		60							
3	200	2.0	VCV	300	20	30		50	0	0.4	40	SQUARE						
4	200	2.0	PCV		20		1.0	25	5		60							
5	10	5.0	PCV		30		0.67	30	0		40							

Reference: IEC-60601-2-12 Table 101

9 Troubleshooting

In this chapter it is shown the main problems and its possible solutions. The majority is of simple solution that can be done by the equipment operator.

Warning

- ***DO NOT USE the equipment if a problem should be not be solved.***

Problem	Possible Causes	Solutions
Display doesn't show anything or cannot be turned on	1. Low battery 2. No electrical power	1. Recharge the battery. 2. Connect to mains
No pressure curve	1. Respiratory circuit disconnection. 2. Simulated respiratory mechanics changed. 3. Defective internal pressure transducer.	1. Find it and reconnect it firmly. 2. Verify the simulation condition. 3. Ask for technical service assistance
No flow curve	1. Respiratory circuit disconnection. 2. Simulated respiratory mechanics changed. 3. Defective internal pressure transducer.	1. Find it and reconnect it firmly. 2. Verify the simulation condition. 3. Ask for technical service assistance
Flow readings incompatible	1. Selected Flow sensor incompatible. 2. Upside down flow curve.	1. Select and connect the correct flow sensor. 2. Check if the pressure measuring tubing is correctly connected.
No Volume Curve	1. Respiratory circuit disconnection. 2. Simulated respiratory mechanics changed. 3. Defective internal pressure transducer.	1. Find it and reconnect it firmly. 2. Verify the simulation condition. 3. Ask for technical service assistance

Problem	Possible Causes	Solutions
Volume does not return to zero	1. Leakage in the respiratory circuit or in the lung simulator. 2. Calibration 3. Defective internal pressure transducer.	1. Find any leakage and eliminate it. 2. Carry out the calibration procedure according to chapter 6. 3. Ask for technical service assistance
FiO_2 cell doesn't read correctly	1. Electrical cable connection to the oxygen cell. 2. Pneumatic connection of the oxygen sensor. 3. Cell is consumed. 4. Calibration. 5. Internal Problem.	1. Check any disconnection of the cable at each side of it (cell or VentMeter). 2. Check if the cell is firmly connected to the respiratory circuit. 3. Acquire new oxygen cell. 4. Calibrate according to the procedures in chapter 6. 5. Ask for technical service assistance

10 Parts and Accessories

Caution

- ***Always use original parts and accessories to assure safety and efficacy of the equipment.***

Product:

Item	Part Number	Description	QTY	UN
1	6001874	PULMONARY VENTILATOR TESTER	01	PC
2	1701956	HANDBAG FOR VENTMETER	01	PC
3	1702105	O2 CONCENTRATION MEASUREMENT CELL	01	PC
4	1702986	NEONATAL LUNG SIMULATOR 40ML 15F	01	PC
5	2401860	SERIAL - USB CABLE	01	PC
6	2402021	CD DOCUMENTATION AND PULMOTREND BASIC	01	PC
7	2701886	POWER SUPPLY AC/DC - 12V/1A - 90 TO 260 VAC	01	PC
8	3102183	CONNECTOR 90° 15M 15F	01	PC
9	3201471	NEONATAL FLOW SENSOR POLICARBONATE	01	PC
10	3201472	PEDIATRIC FLOW SENSOR POLICARBONATE	01	PC
11	3201473	ADULT FLOW SENSOR POLICARBONATE	01	PC
12	3802195	FLOW RESISTANCE RP 5 WITH LABEL	01	PC
13	3802196	FLOW RESISTANCE RP 20 WITH LABEL	01	PC
14	3802197	FLOW RESISTANCE RP 50 WITH LABEL	01	PC
15	3802198	FLOW RESISTANCE RP 200 WITH LABEL	01	PC
16	3804363	UNIVERSAL CONNECTOR WITH SILICONE LINE 1,3 M	01	PC
17	3901839	TEST BALLOOM INFANT 500ML 22MM	01	PC
18	3901840	TEST BALLOOM ADULT 1000ML 22MM	01	PC
19	7002970	QUICK REFERENCE GUIDE - VENTMETER	01	PC

11 Preventive Maintenance

Warning

- ***Corrective or preventive maintenance should be done only by authorized personnel.***
- ***DO NOT USE the equipment if it is not working accordingly to the specifications in this instruction manual.***

11.1 Check List

Daily Verification or Before Use

- Equipment Cleanliness
- Integrity of the AC/DC converter and its electrical power cords
- LCD display readability
- Key operation (F1, F2, UP, ENTER, DOWN)
- Integrity of the flow sensor connection tubing
- Integrity of the flow sensors
- Integrity of the oxygen sensor cable (optional)

Annual Check-up

- Ask for preventive maintenance to carry out complete check-up, adjustments and equipment calibration.

11.2 Internal Lithium-Ion Battery

This battery is responsible to keep the equipment working even if the electrical power is not connected and its duration is specified in chapter 13. To assure that it is fully charged it is recommended that the equipment be kept CONNECTED to the mains.

12 Technical Specification

12.1 Technical Specifications

12.1.1 Specifications

The Ventilator Analyzer consists of the following components:

- LCD display 128 x 64 pixels
- Electronic Control Board:
  - Show data in the display
  - RS-232C serial interface
  - Keyboard
  - Pressure readings
  - Flow readings
  - O_2 concentration readings
  - Internal battery back-up system
- AC/DC Converter (100 – 240 V_{AC}) to +12V_{DC} ;
- On/Off Switch;
- O_2 Cell sensor (OPTIONAL);
- O_2 Cell connection cable (OPTIONAL);
- One 20L.min^{-1} flow sensor;
- One 50L.min^{-1} flow sensor;
- One 150L.min^{-1} flow sensor;

12.1.2 Electrical Characteristics

Item	Parameter	Unity	Specification	Tolerance
1	Electrical Power (50/60Hz) (1)	V_{AC}	100 a 240	± 10%
2	Maximum Power Consumption	W	12	± 10%
3	Internal Battery Li-Ion 7,6V_{DC}	mAh	1400	± 15%
4	Internal battery back-up system duration	h	4.0	± 15%
5	Complete recharging time (VentMeter in operation)	h	2.5	± 15%

(1) External AC/DC Converter

12.1.3 Environment and Physical Specifications:

Item	Parameter	Unity	Specification	Tolerance (4)
	Dimension			
1	Height	mm	199.4	± 2
2	Width	mm	100.6	± 2

3	Length	mm	135	± 2
4	Weight	kgf	1.3	± 0.1
	Operation			
5	Temperature	ºC	5 a 50	---
6	Barometric Pressure	hPa	700 a 1060	---
7	Humidity (no condensation)	%	20 a 90	---
	Storage			
8	Temperature	ºC	-5 a 60	---
9	Barometric Pressure	hPa	500 a 1060	---
10	Humidity (no condensation)	%	0 a 99	---

12.1.4 Measurement and Presentation Specification

Item	Parameter		Unit	Range	Resolution	Tolerance
1	Instantaneous Measured Pressure (1)		hPa	-50 to 200	0,1	± (0,4 hPa or 1% of reading)
2	Maximum Inspiratory Pressure (1)		hPa	0 to 200	0,1	± (0,4 hPa or 1% of reading)
3	Mean Pressure (1)		hPa	0 to 120	0,1	± (0,4 hPa or 1% of reading)
4	Plateau Pressure (1)		hPa	0 to 120	0,1	± (0,4 hPa or 1% of reading)
5	PEEP (1)		hPa	-50 to 120	0,1	± (0,4 hPa or 1% of reading)
6	Measured Volume	(Adult Sensor – ADU)	mL	100 to 2000	5	± (15 mL or 3% of reading)
		(Infant Sensor – INF) (2)	mL	10 to 400	2	± (5 mL or 5% of reading)
		(Neonate Sensor – NEO) (2)	mL	1 to 100	0,1	± (2 mL or 5% of reading)
7	Minute Volume	(Adult Sensor – ADU)	L	0,1 to 50,0	0,001	± (0,18 L or 3% of reading) (3)
		(Infant Sensor – INF) (2)	L	0,01 to 50,0	0,001	± (0,10 L or 5% of reading) (3)
		(Neonate Sensor – NEO) (2)	L	0,001 to 20,0	0,001	± (0,06 L or 5% of reading) (3)
8	Inspiratory Time		s	0,05 to 60,00	0,01	± 0,01s
9	Expiratory Time		s	0,05 to 60,00	0,01	± 0,01s
10	Respiration Frequency (Rate)		Rpm	1,0 to 200,0	0,1	± 0,2 Rpm
11	Respiration Frequency (Rate)		hPa /L/s	0 to 200,0	1	± 10%
12	Airway Resistance		mL. hPa^{-1}	0 to 200,0	1	± 10%
13	FiO_2		$\%O_2$	15 to 100	0,1	± (2% + 1% of reading)
14	NEONATAL Flow Sensor – NEO		$L.min^{-1}$	-20,0 to 20,0	0,1	± (0,15 $L.min^{-1}$ or 2% of reading)
15	INFANT Flow Sensor – INF		$L.min^{-1}$	-50,0 to 50,0	0,5	± (0,5 $L.min^{-1}$ or 2% of reading)
16	ADULT Flow Sensor – ADU		$L.min^{-1}$	-150,0 to 150,0	1,0	± (1,0 $L.min^{-1}$ or 2% of reading)

(1) 1 mbar (millibar) = 1 hPa (hectoPascal) = 1,016 cmH_2O (centimeter of water). Practically these units can be used as:

1 mbar = 1 hPa ≈ 1 cmH_2O

(2) To resistances greater than 150 $cmH_2O/L/s$ the exhaled monitored volume tolerance to be considered is ± 10% or ± 50mL the greater. In this condition, the inspired volume sent by the ventilator to the respiratory circuit will be according to the specification.

(3) The tolerance is calculated by frequencies 12, 20 and 30 Rpm, respectively to adult, infant and neonate sensor. The tolerance is a function of volume uncertainty multiplied by the frequency.

(4) When two tolerances are indicated, consider the one with the highest value.

Important: Parameters related to the volume are expressed under environmental conditions of temperature, pressure and volume (ATPD).

12.1.5 Calibration and Maintenance Specification:

Item	Description	Unit	Specification	Tolerance
1	Revision	Year	1	1 month
2	Calibration	Year	1	1 month

13 Warranty

The products manufactured and commercialized by Magnamed Tecnologia Médica S.A. are guaranteed against material and manufacture defect according to the paragraphs below.

The guarantee responsibility limits to the replacement, repair and labor, for parts that are defective or do not complies with the specification contained in this instruction manual. And the warranty is limited to the products used under normal conditions and which preventive maintenance and part substitutions and repairs are carried out accordingly to the procedures contained in this instruction manual.

The warranty does not cover defects caused by inappropriate use or installation, accidents, inadequate sterilization, service, installation, operation or modifications carried out by non-authorized or disqualified personnel.

The lack of sealing label or its rupture by non-authorized or disqualified personnel voids this warranty.

The warranty is valid for a period of 365 days for the equipment, 90 days for batteries and 60 days for accessories, if its original characteristics are maintained, and is counted from the Magnamed Tecnologia Médica S.A. Commercial Invoice issue date to the first owner of the equipment.

Parts subject to degradation or deterioration under normal use conditions, adverse use conditions, and inappropriate use or fortuity accidents are not covered by this warranty.

This warranty does not cover eventual costs and risks with equipment transportation.

Magnamed Tecnologia Médica S.A. cannot be considered by any means for any damage including beside others, eventual, consequential or specials. There is no other explicit or implicit guarantee other than the stated above.

This product shall be used exclusively to evaluate lung ventilators performances and shall be operated by qualified personnel.

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