





User Manual English Software version V3.6.x







YL072800 - Revision 9A - 2021-06 - EN

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1 Before use

1.1 Definitions of user warnings

CAUTION: Warns the user of the risks associated with the use or misuse of the device:

- · occurrence of a technical problem or device malfunction,
- slight or serious injury to the patient.



Note: Highlights a particular item of information.

1.2 Intended use

Monnal T75 is a standalone turbine ventilator used to treat infants (weighing at least 3 kg), children and adults. It is used for patient ventilation to compensate for or mitigate respiratory failure. Contact with the patient is made via an adequate patient interface (e.g., mask or endotracheal tube), which allows air to flow from the ventilator into the lungs.

It is for use by hospital personnel (doctors, nurses, etc.):

- · In the intensive care unit,
- In the post-operative recovery room,
- · When transporting patients in the hospital area.

Medical electrical system

Monnal **T75** is part of the medical electrical system along with the CO2 measuring probe (IRMA[™]) (Ref. KB033600).

It can also be operated with various accessories, such as:

- a Monnal Clean'in HEPA filter,
- a nebulizer,
- a humidifier,
- · oxygen from a supply network, cylinder, or concentrator,
- an alarm transfer system.

Monnal **T75** is used to monitor two respiratory gases – oxygen (02) and carbon dioxide (C02) (applies to product reference KB033600).

1.3 Brief description of the device

Monnal **T75** can supply tidal volumes from 20 to 2000 mL in volume-controlled mode, and insufflation pressures from 0 to 99 cmH20 in pressure-controlled mode.

It can also supply FiO2 adjustable from 21 to 100% under continuous monitoring.

It has the following ventilation modes:

Monnal T75 user manual

VCV (controlled ventilation or assisted volume-controlled ventilation)

PCV (controlled ventilation or assisted pressure-controlled ventilation)

PSV (spontaneous ventilation with inspiratory assistance and PEEP)

SIMV (intermittent assisted controlled ventilation)

PSIMV (intermittent assisted pressure-controlled ventilation)

PSV NIV (non-invasive ventilation).

CPAP (continuous positive airway pressure)

Duo Levels (alternation between two levels of CPAP).

PRVC (Pressure-regulated volume controlled ventilation)

PS-Pro: interlocked barometric mode, intended for use in resuscitation

APRV: Airway Pressure Release Ventilation

The device is equipped with a 10.4-inch color touch screen, an ergonomic control wheel and a functional interface for easy adjustment of the various settings and ventilation parameters.

The ventilator may be used with a mobile stand, making it more convenient to move around, and can be placed on a wall tablet.



CAUTION: The user is responsible for ensuring that the use of accessories does not affect the safety and the expected performance of the device.

Patient environment

Under normal use, the patient is in a hospital bed and the *Monnal T75* equipment is placed nearby. All parts of the medical electrical system are suitable for use in the patient environment.

User's position

The equipment is positioned with the display facing towards the user allowing them to make the necessary adjustments with the coder wheel and read the information displayed on the screen. The recommended distance depends on the environment, the ambient light and the user's visual acuity. The rear of the equipment remains, however, within the user's reach.

Options

Monnal T75- reference KB033600 - comes with the option of purchasing CO2 monitoring.

1.4 Requisite knowledge

Persons intending to operate this ventilator must be trained in its use.

Only persons who have fully read and understood this manual are authorised to handle and use this ventilator. The present manual is intended to give all information necessary for the correct utilisation of this ventilator, but is in no way intended to replace the medical prescription that is essential for adjusting the apparatus according to patient needs.

1.4.1 Training

There are two main types of training:

- training in the use of the ventilator,
- · training in the routine maintenance of the ventilator.

Training in the use of the ventilator

Training in the use of the ventilator takes around thirty minutes. It is carried out during installation in the hospital department by *Air Liquide Medical Systems* staff or by an authorized *Air Liquide Medical Systems* distributor. This training includes:

- · validation of the intended use and description of the ventilator,
- · installation and commissioning,
- · comprehensive presentation of the operating functions of the ventilator,
- practice on a test lung, adapted to the type of hospital service.

This training can be repeated or covered in more depth at the request of the users, by contacting the usual *Air Liquide Medical Systems* representative.

Training in routine maintenance

Training in the routine maintenance of the ventilator takes around thirty minutes. It is carried out during delivery to the biomedical department, or during installation in the hospital department by *Air Liquide Medical Systems* staff or by an authorized *Air Liquide Medical Systems* distributor. It is intended for biomedical teams and equipment supervisors in the department.

The training includes:

- consumables management
- daily recommended maintenance practices
- monitoring minor alarms

1.5 Symbols and markings on the device

100 - 240 V ~ 50 - 60 Hz 255 VA 🖈 💭	Weight and rated output of prod- uct	\odot	ON button
Ä	Weight of Monnal T75 device	ß	Weight of the system (Monnal T75 , mobile stand, articulated arm, sock- et base, external battery pack and pa- tient circuit)
	Manufacturer	O2 280 - 600 kPa 105 - 130 L / min	High pressure oxygen inlet fitting
\bigotimes	Do not push	O2 0 - 150 kPa 0 - 85 L / min	Low pressure oxygen inlet fitting
C € 0459	Complies with European Direc- tive 93/42/CEE Notified Body No. 0459.	\square	Patient circuit inspiratory fitting
REF	Device catalog number	P	Patient circuit expiratory fitting
SN	Serial Number of the device		IRMA [™] CO2 probe connector
M	Date of manufacture: YYYY-MM		Nebulizer fitting
(Caution: refer to the user manual.	• 1	02 cell cover locked
	Protective earth (ground)	• 🗊	02 cell cover unlocked
*	Type B applied part		Expiratory valve eject button
\sim	Alternating current		Video output VGA

IP3X (if serial num- ber below MT75-05000) IP31 (for serial numbers from MT75-05000)	Protection Index according to the EN 60529 standard 3: protection from the penetration of solid bodies of diameter ≥ 2.5 mm. 1: protection against vertically falling water drops X: no particular protection from the penetration of liquids, but compliant with EN 60601-1.		This logo means that the equipment must not be disposed of via ordinary waste channels. It must receive ap- propriate end-of-life handling, in ac- cordance with European Directive 2012/19/UE (WEEE). This device was manufactured after the 13th of August 2005.	
	Electrical protection fuse	COM 1	RS232 connectors	
	Alarm transfer outlet	O	External power supply connector	
Ð~	AC power supply indicator light			
Specific symbo	Specific symbols for IRMA™ CO2 measurement probe (ref. KB033600)			
IP44	 Protection Index according to the EN 60529 standard 4: protection from the penetration of solid bodies of diameter ≥ 1 mm. 4: protection from water splashing from any direction 	*	Type BF device	

1.6 General safety instructions

Oxygen use

Precautions in case of oxygen leak:

- No smoking
- Avoid any flame or source of sparks
- Disconnect the oxygen source
- Fully air the room throughout the duration of the leak and for at least 20 minutes afterwards.
- · Air one's own clothing.
- The device must not be in operation near any incandescent source.

The device must not be used with inflammable anaesthetic agents or explosive products.

Do not use the equipment with helium or helium mixed with another gas.

The ventilator does not directly administer nitric oxide but can be used concomitantly with a Nitric Oxide administration system, provided that the manufacturer of the nitric oxide delivery system has validated its use.

Do not use the device with components contaminated by inflammable substances (e.g. grease, oil, etc.).

The internal components of the device were degreased before delivery and use a type of grease which is compatible with oxygen. Do not grease or lubricate any part of the device.

Medical quality oxygen, which is dust-free and dry, must be used (H2O < 20 mg/m3).

The supply pressure on the high pressure oxygen inlet must be between 280 kPa (2.8 bar) and 600 kPa (6 bar).

The supply pressure on the low pressure oxygen inlet must be less than 150 kPa (1.5 bar).

Power supply



CAUTION: To avoid the risk of electric shock, this equipment must only be connected to a grounded power outlet.

Check that the voltage in the mains socket used matches the electrical characteristics of the ventilator (indicated on the rear panel of the power supply adaptor).

Electrical isolation is accomplished by disconnecting the equipment from the power outlet. Accordingly, do not place the equipment in a position that would make it difficult to use this disconnect device.

The ventilator has an internal battery. It must be plugged into the mains on a regular basis in order to keep the internal battery sufficiently charged.

In the event of any doubt about the condition of the mains power supply cable, use the device on its internal battery.

Do not use antistatic or electrically conductive tubing.

The user must not touch the patient and the equipment enclosures at the same time.

Modifications to the EM system require an assessment of their compliance with the requirements of standard IEC60601-1.

IP Protection

To ensure the IP protection level of the device is maintained during normal use, it is essential that the power cable is plugged in and all removable components (air filter, expiratory assembly, O2 sensor cover and the rear plastic panel) are fitted in place.

Electromagnetic compatibility

Monnal **T75** complies with the EN 60601-1-2 standard on the electromagnetic compatibility of medical devices.

This device requires specific precautions as regards EMC. It must be installed and put into operation in accordance with the EMC information provided in this user manual.

The ventilator functioning can be impaired by the use of appliances in its immediate proximity, such as diathermic devices, high frequency electro-surgery units, defibrillators, cell phones or, more generally, by electromagnetic interference that exceeds the levels specified in the EN 60601-1-2 standard.

Monnal **T75** should not be placed next to or on top of this equipment. If it is not possible to do otherwise, *Monnal* **T75** should be monitored to make sure that it operates correctly where placed.

Do not use this ventilator in a specifically magnetic environment (MRI, etc.).

Replacing a cable or internal component that is not provided by *Air Liquide Medical Systems*, may lead to a rise in emissions or a decrease in the immunity of the device.

Connection to other electrical devices

Do not connect the device to other electrical appliances not mentioned in this user manual without first consulting the manufacturers or technical support.

Devices connected to the inputs and signal outputs must comply with the 60601-1 Standard, Edition 2.

Commissioning

The device must not be put into service immediately after storage or transportation where the temperature and humidity were different from the recommended operating conditions.

Before each use, check that the audible and visual alarms are working correctly and carry out the checking process in the appendix (see <u>Checklist</u> on page 135).

Use

The manufacturer has provided solutions for most of the possible malfunctions of the ventilator, and these are normally covered by the internal monitoring system. It is nevertheless recommended, in case of complete patient dependence to provide an additional and fully autonomous system which can be used to check the effectiveness of ventilation, as well as a back-up device, such as a suitable manual insufflator. Lack of an alternative means of ventilation may result in patient death should the ventilator fail.

If the accessories used are not compliant with the manufacturer's recommendations, the manufacturer accepts no responsibility in the event of an incident.

Do not expose the device to direct sunlight.

Do not use the **Monnal T75** in a hyperbaric chamber. It is not reccommended to push the pulmonary ventilator by its top when fitted on its trolley. To move, push using the handle (at the base of the ventilator)

The device and its accessories (masks, circuits, etc.) are Latex Free in order to avoid the risk of allergic reactions.

The air inlets behind and under the device must be completely unobstructed.

To operate the device from ambient air, a **Monnal Clean'In** (HEPA) filter must be used at the ventilator inlet. This filter is recommended by *Air Liquide Medical Systems*.

Do not use the ventilator in an explosive or nicotine-laden atmosphere (cigarette smoke, fire, etc.).

Risk of cross-contamination

Reusing single-use accessories or consumables carries the risk of patient cross-contamination. This risk also arises if reusable accessories or consumables are not sterilized between each use.

The endotracheal tube, mask, patient circuit, expiratory valve, humidification chamber, and the probe or nebulizer adapters are part of the air pathway that may be contaminated under normal and single-fault conditions by body fluids, secretions or gases exhaled by the patient.

Maintenance

• The ventilator must be checked regularly. To schedule and record maintenance operations, refer to the maintenance form in the appendix.

In accordance with IEC 60601-1 (Annex A, Subclause 7.9.2.6):

"The instructions for use can contain a statement saying that the Manufacturer, assembler, installer or importer considers himself responsible for the effect on basic safety, reliability and performance of the ME equipment or ME system only if:

- appropriately trained personnel carry out assembly operations, extensions, readjustments, modifications or repairs;
- · the electrical installation of the relevant room complies with the appropriate requirements;
- · the ME equipment or ME system is used in accordance with the instructions for use.»"

The qualified technician must use only *Air Liquide Medical Systems* spare parts when carrying out routine maintenance on the device.

Do not use abrasive powders, alcohol, acetone or other easily flammable solvents.

The device must be disconnected from the mains during any procedure such as maintenance or cleaning

Recommendations for the use of the CO2 measurement probe MASIMO IRMA™ (REF. KB033600)

See CO2 Option on page 43.

2 Description of the device

2.1 Terminology used

The expiratory assembly corresponds to the expiratory flow sensor and the Monnal EVA expiratory valve.

The Monnal EVA expiratory valve corresponds to the valve body, the membrane, and the silicone disc.

2.2 Front panel



1. Alarm indicator light

It turns red to inform the user that an ultra or high alarm has been activated.

2. Color touch screen (10.4 inches)

This is the user interface and it enables to adjust all the ventilation parameters.

3. Control wheel

This is used to adjust and validate the parameters

4. AC power supply indicator light

It illuminates when the device is connected to the mains.

5. CO2 measurement probe connection (only for KB033600)

- 6. Expiratory assembly and expiratory limb connection
- 7. Expiratory assembly eject button
- 8. Ambiant air intake
- 9. Pneumatic nebulizer supply connection
- 10. Inspiratory limb connection

2.3 Right-hand side

Oxygen Cell

11. 02 sensor access cover

Oxygen access closed :



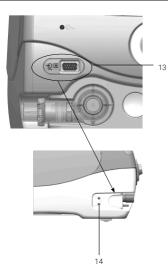
12. O2 sensor position

Oxygen access closed :



2.4 Left-hand side

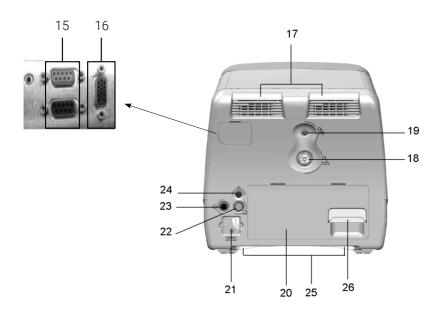
Expiratory assembly



13. Expiratory assembly built into the device

14. Electrical connection with the hot wire flow sensor (expiratory assembly withdrawn)

2.5 Rear panel



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15	RS232 connections	16	Video output connection
17	Low pressure oxygen inlet	18	Cooling wings
19	High pressure oxygen inlet	20	Access to internal battery
21	AC power supply connector	22	AC power supply connector
23	Alarm transfer connector	24	On/Off button
25	Patient air intake filter	26	Monnal Clean' in filter

3 Installation and commissioning

3.1 Unpacking

Take the ventilator out of the packaging and place it on a table.

Unwrap the accessories supplied with the ventilator (see <u>Items included in the package</u> on page 96).

CAUTION: The ventilator weighs approximately 16 kg:

- · Apply safe lifting procedures when installing it.
- For installation on a horizontal support, ensure that the horizontal support can bear the weight of the unit. Check that the assembly is stable.

3.2 Connections and commissioning

3.2.1 Power supply

This ventilator may be used with various sources of electrical power (see <u>Electrical power sources</u> on page 105):

- AC power supply;
- · Power supply connected to an external DC source (external battery);
- Power supply connected to an internal DC source (internal battery).

To turn on the ventilator, plug it into a grounded AC power outlet.



CAUTION: Always check that the electrical network is compatible with the specifications in this manual.

Check that the device preventing the mains plug from being pulled out is operative.

3.2.2 Oxygen supply

To supply FiO2 above 21%, connect the low or high pressure inlet of the ventilator oxygen to an available source, via an appropriate connection.

If this oxygen source is a cylinder, it must be equipped with a pressure reducer to suit the allowable pressure range (2.8 to 6 bar).



CAUTION: Start by connecting the O2 connection hose to the ventilator before connecting it to the oxygen network. Check the capacity of the oxygen cylinder before using the ventilator for intra-hospital transport.



CAUTION: To prevent the low pressure 02 fitting becoming detached, ensure the input pressure applied to the low pressure oxygen inlet is less than 150 kPa (1.5 bar).

3.2.3 Assembly of patient circuit and accessories

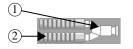
Connect the patient circuit to the ventilator and the humidifier (if used):



- Connect the expiratory limb of the patient circuit to the expiratory valve of the ventilator: 🕆 (27).
- Connect the inspiratory limb of the patient circuit to the inspiratory outlet cone of the ventilator: \checkmark (28).

CAUTION: Make sure to limit dead space while installing patient circuit and accessories.

Air Liquide Medical Systems recommends the use of a bacteriological filter at the inspiratory outlet of the ventilator or, preferably, at the Y-piece. It is also recommended to use patient circuits equipped with water traps when using a humidifier.



 1
 Y-piece
 2
 Double-limb patient circuit

CAUTION: Empty the water traps regularly during ventilation.

When using the equipment on a patient for the first time, make sure that you follow the hospital's hygiene protocol for new single-use equipment or adequately sterilized reusable equipment. The accessories and consumables (patient circuit, masks, expiratory valves, adapters, nebulizer, etc.) are generally available in single-use and autoclavable versions.



CAUTION: Reusing single-use accessories or consumables carries the risk of patient crosscontamination.

3.2.4 CO2 Measurement Probe

See CO2 Option on page 43 (for ref. KB033600).

3.2.5 Humidifier

If the ventilator is used with a humidifier ensure that it is always placed lower than the ventilator and the patient.

Empty the water traps regularly in order to limit condensation in the pipes.



CAUTION: Ensure that water does not enter the unit during handling of the patient circuit or the humidifier (if used). If this occurs, immediately stop using the device, and contact the Technical Department.



CAUTION: Humidification may increase the resistance of the filters used in the patient circuit. The filters should be tested frequently to check for an increase in resistance or blockage.

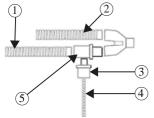
3.2.6 Nebulization

The ventilator operates with pneumatic nebulization. It supplies a reduction pressure of 1.2 bar.



The nebulization outlet is located at the front of the unit and identified by the following symbol:

To set up a nebulizer:



- 1. Install a connector (5) upstream from the Y-piece, in the inspiratory limb of the patient circuit (1).
- 2. Connect the body of the nebulizer (3) to this connector (5).
- 3. Connect the nebulizer pipe (4) to the nebulizer output of the ventilator.



CAUTION: The nebulization output (front panel) and the low-pressure inlet (rear panel) are similar. Beware of not confusing them.



CAUTION: Nebulization with the ventilator includes certain constraints which must be taken into consideration:

- Do not conduct treatment sessions with inflammable agents,
- Y-piece respiratory filters can prevent medication from being effective: their use is therefore not recommended,
- The precision of the expired volume can be impaired: a protective filter can then be used at the expiration end.



CAUTION: Nebulization may increase the resistance of the filters placed in the patient circuit. The filters should be checked frequently for an increase in resistance or blockage.

Refer to <u>Nebulization</u> on page 70 Nebulization for a more detailed description of the nebulization function and to <u>Accessories</u> on page 96 for different types of nebulizers available.

3.2.7 Applying power

Turn on the unit using the switch button (green) at the back of the unit.



The buzzers sound and the alarm lights light up.

After the initialization tests (duration: < 10 s), the ventilator goes into Stand-by Mode.

Select the appropriate language (see <u>Ventilator configuration</u> on page 30) and carry out the checking phase (see <u>Checklist</u> on page 135).



Note: *Monnal* **775** is equipped with an absolute pressure sensor to compensate the effects of altitude. In case of an installation in a high altitude area, an alarm tells the user to start the automatic tests; the atmospheric pressure is therefore measured and the device compensated.



CAUTION: Do not obstruct the openings under and behind the ventilator, as this may compromise patient safety.

3.2.8 Automatic tests

The **[Automatic tests]** button checks the integrity and correct operation of the unit's internal components. In particular, it calibrates certain sensors, including the expiratory flow sensor and the oxygen cell. Without the automatic test, the precision of ventilation parameters and measurements cannot be guaranteed.



Note: Air Liquide Medical Systems recommends to run the automatic test before each use of the device on a patient.

To run the automatic tests, press the [Automatic tests] button.

Automatic tests	Automatic tests
Select adapted patient category Use circuit adapted to patient category and compliant with utilization	Tests initialization Circuit rinsing Pneumatic check Mixer check End of tests
with utilization Install a filter on inspiratory branch and other accessories compliant with utilization Seal patient circuit Confirm launch of autotests	Clear the patient circuit
Cancel ²¹¹ Validate ²¹¹	Cancel

1. To confirm, press [Validate];

Note: Remember to seal off the Y-piece of the patient circuit.

- Otherwise, press [Cancel].
- 2. To interrupt the test, press [Stop] and then [Finish].
- **3.** To start the test again, press the **[Restart]** button, and then **[Validate]**. At the point where tests have been completed, a window opens, indicating that the plug should be removed from the patient circuit Y-piece, accompanied by an audible reminder every 2 minutes.



Note: If the user does not unblock the patient circuit after 20 minutes, the test is stopped. Press **[Re-start]** to resume the last step of the automatic tests.

If the automatic tests fail with the message «Circuit resistance not evaluated»:

- · check the consistency between the patient category selected and the patient circuit used,
- · check that the patient circuit is properly connected to the device,
- · check that the filters and other accessories used do not cause too high a resistance.



CAUTION: Make sure that the patient category selected corresponds to the patient circuit and the accessories used (see <u>New patient / Category selection</u> on page 29).

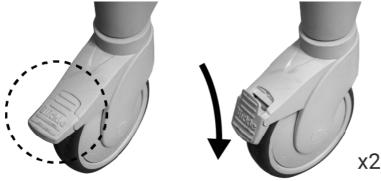
For a full description of the automatic test, see <u>Technical description</u> on page 102.

3.2.9 Transport on the rolling stand

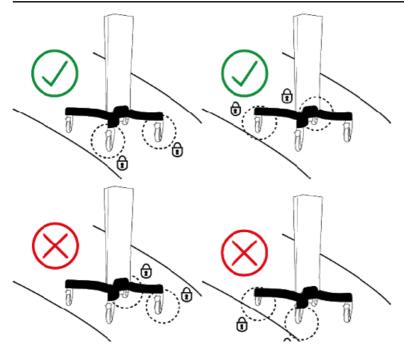
When moving *Monnal T75* Monnal T75 on its stand, place both hands on the handle to push it safely:



Once *Monnal T75* is in place, activate the 2 brakes on the wheels:



CAUTION: When the floor is sloping, you must place both foot brakes on the same side: either on the side sloping upwards or on the side sloping downwards. Placing one foot brake on side sloping upwards and one brake on the side sloping downwards may imbalance *Monnal* **T75**.



4 Use

The ventilator is controlled mainly via the touch screen and the control wheel.

CAUTION: Do not use any object that might scratch the screen.



The device starts up in Standby mode.

In the display zone, the message is "Unit on stand-by".

The stand-by mode allows the user:

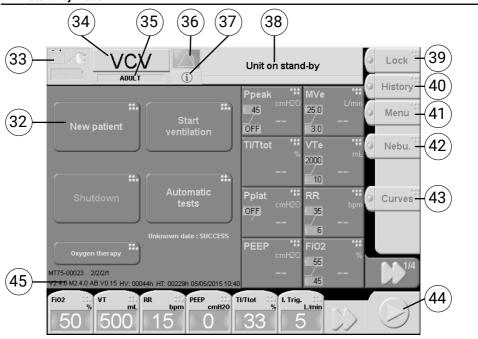
- · to select the ventilation mode,
- · to configure set-points and alarm thresholds for the selected mode,
- to start ventilation (green),
- · to choose a patient category,
- · to start automatic tests,
- to shut down the device (red).

In the stand-by mode screen, the following information is displayed:

- · the current software version,
- the ventilation time counter,
- · the power-on time counter,
- · the current time and date,
- the time and date of the latest automatic tests and their result.

4.1 Screen description

4.1.1 Stand-by mode

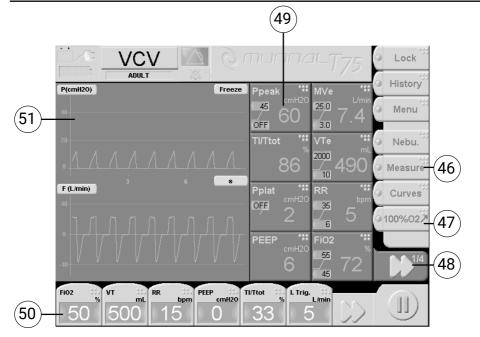


32	 Stand-by screen zone: [New Patient] key to select a patient category [Start ventilation] key [Shutdown] key [Automatic tests] key [Oxygen therapy] function key 	33	Symbol status of external battery / indica- tion of mains connection /status internal battery
34	Ventilation mode and access to mode change	35	Patient category
36	Software alarm indicator	37	Audible alarm silence button
38	Alarm display zone	39	Screen lock key
40	Alarm history access key	41	Menu access key
42	Nebulization access key	43	Curves access key

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44	Ventilation start key 🔘 or ventila- tion pause key 🕕	45	Indications: serial number; software version / counters / time and
			today's date.

4.1.2 Ventilation mode



46	Measurement access key	47	xx% O2 key
48	Access to other monitored parameters	49	Monitored respiratory parameters and ac- cess to alarm settings
50	Ventilation set-points	51	Pressure and flow rate curves
52	Access key to the rest of the set-points a ventilation mode in progress		

4.2 Start/stop ventilation



Note: Adjust the parameters before starting ventilation.

To restore the standard settings, press the [New Patient] key.

To start ventilation, press the [Start ventilation] key.

To stop ventilation in progress, press button **[43]**. A pop-up window appears telling the user whether to cancel or validate by pressing the control wheel. In case of validation the unit then goes directly to stand-by mode.



Note: If the unit was suddenly shut off during ventilation (e.g. battery exhausted), it automatically resumes ventilation with the last parameters saved when restarted.

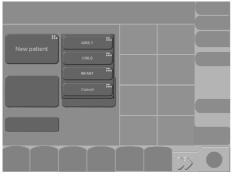
4.3 Shutting down the unit

The [Shutdown] key is accessible from the stand-by screen, and is used to switch the unit off.

To switch the unit off, press the **[Shutdown]** key. To confirm, press the control wheel. To cancel, press the **[Cancel]** key.

4.4 New patient / Category selection

Press the [New patient] button to reinitialize all of the ventilation and alarm settings.



The choice of a patient category enables the prescriber to adapt each of the following elements to the condition of the patient:

- · Initial values of ventilation parameters and alarms,
- · Ventilation parameter and alarm adjustment ranges.

Each of these values or ranges is given in the appendix of this manual.



CAUTION: For the safety of the patient and to optimize ventilation performance, the category selected must be appropriate for the patient being ventilated. The diameter of the tubing in the patient circuit must also be appropriate:

Patient category	VT range (mL)	Internal diameter of tubes in patient cir- cuit (mm)
Adult	100-2000	22 mm
Child	50-500	VT > 100mL: 22 or 15 mm VT < 100 mL: 12 mm

Patient category	VT range (mL)	Internal diameter of tubes in patient cir- cuit (mm)
Infant	20-75	12 mm
≥ 3kg		

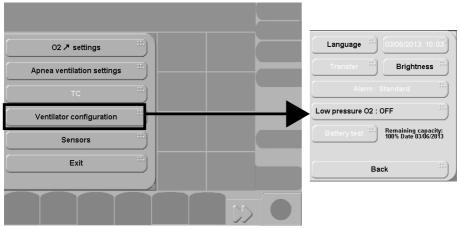


Note: The patient category can only be changed in Stand-by Mode.

Note: Administrator Configuration (see <u>Administrator configuration</u> on page 75) can be used to configure the set-points.

4.5 Ventilator configuration

Users may access the configurations at any time by pressing the **[Menu]** and **[Ventilator Configura**tion] keys.



The following parameters can be accessed:

4.5.1 Language

Monnal T75 offers several languages.

To change the language, press the [Language] keys.

Press the key for the desired language, then press [Back] twice, and [Exit].

4.5.2 Date and time

To change the date or time:

- · Click on the display key: use the control wheel to increment or decrement a value.
- Press the control wheel to validate the number and go on to the next parameter.



Note: If the date selected does not exist (e.g. 30 February), it will be displayed in red on the screen and will not be taken into account. The previous date will be restored.

4.5.3 Transfer

This function can be reached from the stand-by screen. It allows the maintenance technician to transfer data from the unit to a PC.

4.5.4 Brightness

To change the contrast of the screen:

· Press the [Brightness] button. A new window is displayed.

Turn the control wheel to increase or decrease the contrast until optimum visibility is obtained.

4.5.5 Audible alarm

Monnal T75 provides 2 different audible alarms to the user:

The first alarm is standard. It cannot be modified by the user. It is selected by default.

The second alarm (Custom) can be customized with another tone and its volume can be modified.



Note: This adjustment must be performed by a technician: contact your representative if you want the alarm volume to be modified.

The alarm volume adjustment is for the convenience of the doctor. The maximum distance and the volume of the alarm must therefore be determined by the user according to the surroundings.

Access to the alarm list can only be made when the unit is in stand-by mode.

To choose an alarm:

- · Press the [Alarm: ...] button and turn the control wheel to select [Standard] or [Custom];
- Validate to confirm.

An audible display of the alarm is then performed so that the user is aware of the new setting.



Note: Whatever the operation done on the device (shutdown, software update...), every selected alarm remains.



Note: It is possible to select standard or custom alarm melody in the Administrator Configuration.

4.6 Ventilation modes

4.6.1 Mode selection

\bigcirc		SIMV 33	
(2)	PCV ⁸⁸	PSIMV 32	
	PSV **	PRVC 35	
	PSV NIV	PS-Pro	
	Duo-Levels	APRV 33.	
	СРАР		
	Cancel 88	Validate	

The ventilation mode is selected from the ventilation mode display button in the upper left-hand part of the screen (1).

To select or change the ventilation mode, press the display button, select the desired ventilation mode (2), and press [Validate].

4.6.2 Ventilation set-points

There are several series of set-points for each ventilation mode.

These ventilation set-points can be adjusted either in Stand-by mode, or in ventilation mode. They are displayed on one or two pages using the arrow according to the selected ventilation mode.



To adjust a set-point, touch it to select, set the desired value by turning the control wheel, and validate by pressing the control wheel.

4.7 Description of ventilation modes

4.7.1 VCV (Volume-Controlled Ventilation)

[VCV = Volume-controlled Ventilation]

Principle

VCV mode is used to control the tidal volume delivered to the patient on inspiration and the frequency of the respiratory cycles. During expiration, the ventilator regulates the pressure in order to maintain the set PEEP level.

The respiratory frequency can be increased as soon as the ventilator detects that the patient is making a respiratory effort.

Fi02	inspired oxygen fraction
VT	tidal volume (mL)
RR	minimum respiratory frequency (c/min)
PEEP	positive end of expiration pressure (cmH20)
TI/Ttot	ratio of inspiration time to total cycle time (%)
Tplat	adjustment of inspiratory plateau time (% du TI)
I. Trig	inspiratory trigger (L/min)
Flow	form of flow rate insufflated to the patient: constant, decelerated
Sigh	sigh periodicity (1 sigh every x cycles)
VTsigh	enabling the sigh function if ≠0FF
	sigh amplitude (unit x VT; e.g.: VT sigh = 1.5 VT)
Sigh Period	sigh period (1 sigh every "sigh period" cycles)

Ventilation set-points

Note: If the patient tries to inhale at a greater flow rate than the flow rate set point, the ventilator will deliver the desired flow rate to the patient but will switch to expiration when the volume has been delivered (TI will not be observed in this case). The "Patient demand greater than peak flow rate setting" alarm will then be triggered. In this case, it is advisable to increase the peak flow rate (or reduce the inspiration time) and/or increase the VT setting.

Note: In VCV, there is no apnea ventilation (or "backup ventilation").

Safety is guaranteed by the lower limit on the frequency and tidal volume according to each patient category.

4.7.2 PCV (Pressure-Controlled Ventilation)

Principle

PCV mode is used to control the pressure delivered to the patient, the inspiration time, and the frequency of the respiratory cycles. During expiration, the ventilator regulates the pressure in order to maintain the set PEEP level. The respiratory frequency can be increased as soon as the ventilator detects that the patient is making a respiratory effort.

Table 1: Ventilation set-points

FiO2	inspired oxygen fraction
PI	tidal volume (mL)
RR	minimum respiratory frequency (c/min)
PEEP	positive end of expiration pressure (cmH2O)
TI/Ttot	ratio of inspiration time to total cycle time (%)
I.Trig	inspiratory trigger (L/min or cmH2O)
Slope	Pressure support pressure rise slope (cmH2O/s)
Plsigh	enabling the sigh function if ≠OFF
	pressure supplied during a sigh (unit x PI; e.g.: PI sigh = 1.4 PI)
Sigh	sigh periodicity (1 sigh every x cycles)
Sigh Pe- riod	sigh period (1 sigh every "sigh period" cycles)



Note:

The value of PI corresponds to the pressure added to the current PEEP value. The PEEP value is incorporated in the PI.

In PCV mode, unlike VCV, the pressure delivered to the patient is controlled but the tidal and minute volumes are not.

4.7.3 PCV (Pressure-Controlled Ventilation)

Principle

A constant positive pressure is maintained above PEEP level in the patient circuit each time the patient makes an inspiratory effort.

The switch to the expiratory phase can be triggered:

- If the flow rate falls below the set expiratory threshold (E. Trig),
- · By an expiratory effort from the patient,
- If the maximum set insufflation time is reached (TImax).

If there is no inspiratory effort, the machine provides the minimum set frequency.

Ventilation set-points

FiO2	inspired oxygen fraction
PS	pressure support ventilation (cmH2O)
RR mini	Minimum respiratory frequency (c/min) (if the function is enabled)

PEEP	positive end of expiration pressure (cmH20)
TImax	Maximum inspiration time of cycles (s)
I.Trig	Inspiratory trigger (L/min or cmH2O)
Slope	pressure support pressure rise slope (cmH2O/s)
E.Trig	Expiratory trigger (% of peak inspiratory flow)



Note: Apnea ventilation can be activated. The apnea parameters should be suited to the condition and requirements of the patient.

- Use of the "RR mini" parameter. In the absence of inspiratory demand for a time longer than "1/RR mini", the ventilator initiates a pressure support cycle. The RR low alarm can be associated with this safety feature by setting it to a value above "RR mini".
- Use of the "TImax" parameter. In the event of a leak in the circuit, the flow rate expiratory trigger might not be activated. In this case, the limitation on inspiration time allows the patient to enter the expiratory phase.

4.7.4 SIMV (Synchronized Intermittent Mandatory Ventilation)

Principle

SIMV mode combines mandatory assisted controlled ventilation and pressure supports spontaneous patient ventilation between the controlled cycles.

Ventilation set-points

Fi02	inspired oxygen fraction
VT	tidal volume (mL)
RR SIMV	determines the frequency of the mandatory cycles (c/min)
PEEP	positive end of expiration pressure (cmH2O)
Tins	determines the inspiration time of the mandatory cycles (c/min)
Tplat	inspiratory plateau time of the mandatory cycles (%TI)
I. Trig	inspiratory trigger (L/min or cmH2O)
Flow	form of flow rate insufflated to the patient: constant or decelerated.
PS	pressure support ventilation delivered during the spontaneous cycles (s)
Tlmax	maximum inspiration time of spontaneous cycles (s)
Slope	pressure support pressure rise slope (cmH2O/s)
E.Trig	expiratory trigger (% of peak inspiratory flow)

Operation

In this ventilation mode, the "controlled" cycle (VCV) delivers a fixed volume at the set frequency RRSIMV. A SIMV period arises from this frequency.

E.g. for a SIMV frequency set to 10 cycles per minute, the SIMV period between two "controlled" (VCV) cycles is 6 seconds.

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In the event of absence of patient respiratory activity, this mode provides the guarantee of controlled ventilation (VCV).

When the patient has regular and detectable respiratory activity, the unit responds by:

- supplying a "spontaneous" cycle (PSV) if the time elapsed since the last "controlled" cycle is less than the SIMV period.
- supplying a "controlled" cycle (VCV) if the time elapsed since the last "controlled" cycle is greater than the SIMV period. If patient respiratory activity declines again after a "spontaneous" cycle, the unit waits for the SIMV period - set TiMax to expire before triggering a "controlled cycle" (VCV) itself.

Insufflation in a spontaneous cycle with pressure support ends:

- If the flow rate falls below the set expiratory threshold (E. Trig);
- · If the patient makes an expiratory effort,
- or if the insufflation time reaches the maximum Ti setting (Timax).



Note: Apnea ventilation can be activated. The apnea parameters should be suited to the condition and requirements of the patient.

4.7.5 PSIMV (Synchronized Intermittent Mandatory Pressure Monitored Ventilation)

Principle

PSIMV Mode combines mandatory assisted pressure-controlled ventilation and spontaneous patient ventilation between the assisted controlled cycles.

FiO2	inspired oxygen fraction
PI	inspiratory pressure (cmH2O)
RR SIMV	determines the frequency of the imposed cycles
	(c/min)
PEEP	positive end of expiration pressure (cmH2O)
Tins	inspiration time of intermittent controlled assisted cycles (s)
I.Trig	inspiratory trigger (L/min or cmH2O)
PS	pressure support ventilation delivered during the spontaneous cycles (cmH20)
TImax	maximum inspiration time of spontaneous cycles (s)
Slope	pressure support pressure rise slope (cmH2O/s)
E.Trig	expiratory trigger (% of peak inspiratory flow).

Ventilation set-points

Operation

In this ventilation mode, the "controlled" cycle (PCV) delivers a fixed pressure at the set frequency RRSIMV. A SIMV period arises from this frequency.

E.g. for a SIMV frequency set to 10 cycles per minute, the SIMV period between two "controlled" (PCV) cycles is 6 seconds.

In the event of absence of patient respiratory activity, this mode provides the guarantee of controlled ventilation (PCV).

When the patient has regular and detectable respiratory activity, the unit responds by:

- supplying a "spontaneous" cycle (PSV) if the time elapsed since the last "controlled" cycle is less than the SIMV period,
- supplying a "controlled" cycle (PCV) if the time elapsed since the last "controlled" cycle is greater than the SIMV period.

If patient respiratory activity declines again after a "spontaneous" cycle, the unit waits for the SIMV period - set TiMax to expire before triggering a "controlled" cycle (PCV) itself.

Insufflation in a spontaneous cycle with pressure support ends:

- If the flow rate falls below the set expiratory threshold (E. Trig);
- · If the patient makes an expiratory effort,
- or if the insufflation time reaches the maximum Ti setting (Timax).



Note: Apnea ventilation can be activated; the apnea parameters should be suited to the condition and requirements of the patient.

4.7.6 PSV NIV (Non Invasive ventilation)

[NIV = Non Invasive ventilation]

Principle

NIV is started by pressing the PSV NIV key.

PSV NIV mode enables the prescriber to ventilate a patient via a non-airtight interface: facial or nasal mask, NIV headset.

Likewise, the ventilation setting ranges and the alarm thresholds and ranges are suited to NIV.

- the PEEP setting is limited to 15 cmH20,
- the PS setting is limited to 25 cmH20,
- the E. Trig set-point is set at 50% by default,
- the high and low VTi alarms are disabled;
- the low MVe threshold is preset to 3 L/min (ADULT), 1.5 L/min (CHILD) and 1 L/min (INFANT).



Note: NIV generally involves more or less variable leakage, which the unit estimates. Estimates are then input into the inspiratory demand detection algorithm to limit self-triggering. It may be necessary, however, to increase the level of this inspiratory trigger slightly if self-triggering occurs too often.

In the volume-controlled modes used in NIV, the insufflated volume does not take leaks into account. The user must also take special care to monitor the NIV volumes. Especially the difference between the VT insufflated by the ventilator (VTi) and the VT measured at the expiratory valve outlet (VTe) must be monitored. The difference indicates the level of leakage.



Ventilation set-points

FiO2	inspired oxygen fraction
PS	pressure support ventilation (cmH20)

IP	insufflation pressure (cmH2O)
RR mini	minimum respiratory frequency (c/min)
PEEP	positive end of expiration pressure (cmH2O)
I.Trig	inspiratory trigger (L/min or cmH2O)
TImax	maximum inspiration time of cycles (s)
Slope	pressure support pressure rise slope (cmH20/s)
E.Trig	expiratory trigger (% of peak inspiratory flow)

4.7.7 CPAP (Continuous Positive Airway Pressure)

Principle

In CPAP mode, the ventilator regulates the pressure in the airways to the set CPAP value.

The patient breathes spontaneously through the device in this mode of operation.

Ventilation set-points

Fi02	Inspired oxygen fraction
CPAP	Continuous positive airway pressure (cmH20)



Note: Apnea ventilation can be activated; the apnea parameters should be suited to the condition and requirements of the patient.

Note: Loops curves, inspiratory and expiratory plateau are deactivated in CPAP mode.

4.7.8 Duo levels (Alternation of two CPAP levels)

Principle

The Duo-Levels mode is characterized by controlled-pressure ventilation, combined with the patient having the option of breathing spontaneously throughout the entire cycle.

Duo-Levels mode enables the prescriber to maintain a constant level of pressure (PI) for a period of time T high, then a lower level of pressure (PEEP) for a period of time T low. The duration of the high-pressure phase can be set, as can the minimum frequency. However, in order to enable the patient's spontaneous breathing to properly adapt with the ventilator, there are trigger windows for synchronizing the inspiratory and expiratory phases:

- from low pressure to high pressure, the trigger window is 60% of T low, 4 seconds maximum,
- from high pressure to low pressure, the trigger window is 30% of T high, 2 seconds maximum. If at the end of T high, inspiration is underway, inspiration is extended for up to 1 second.



Note: The value of PI corresponds to the pressure added to the current PEEP value. The PEEP value is incorporated in the PI.

Ventilation set-points

PI	inspiratory pressure (cmH2O)
----	------------------------------

4	Use

PEEP	positive end of expiration pressure (cmH20)
RR mini	minimum respiratory frequency (bpm)
T high	high-level duration (s)
I. Trig.	inspiratory trigger (L/min or cmH2O)
E. Trig.	expiratory trigger (% of peak inspiratory flow)
Slope	pressure support's pressure rise slope (cmH2O/s)

4.7.9 APRV (Airway Presure Release Ventilation)

Principle

APRV mode is characterised by spontaneous ventilation, alternating between a constant high pressure level and a short period at a lower pressure.

Ventilation set-points

FiO2	inspired oxygen fraction
P high	high pressure (cmH2O)
P low	low pressure (cmH20)
T high	duration at high level (s)
T low	duration at low level (s)
Slope	pressure support pressure rise slope (cmH2O/s)



Note: An absence of inspiratory demand during the apnea time (Tapnea) activates apnea ventilation.



Note: The value of Phigh is absolute, meaning that the pressure on the high level will be equal to Phigh, independent of the PEEP setting.

4.7.10 PRVC (Pressure-Regulated Volume Controlled)

[PRVC = Pressure-Regulated Volume Controlled]

Principle

PRVC mode is a pressure-regulated ventilation mode that guarantees the volume delivered to the patient. The ventilator automatically adapts the inspiratory pressure delivered so that the monitored Vti is equal to the set Vt Target.

The adaptation interval of the PI is between 0.1 cmH2O and 3 cmH2O. It depends on the gap between the Vt Target and the monitored Vti.



Note:

It is possible to activate or disable the set Vt Target:

- When the Vt Target is activated, the PI delivered to the patient is between the PEEP + 5 cmH20 and the PI max.
- The set PI then indicates Auto.

- When the Vt Target is OFF, the delivered PI is the set PI. The mode is then equivalent to PCV mode.
- If the Vt Target is disabled during ventilation, the set pressure takes the current regulation value.

The PI value corresponds to the pressure added to the current PEEP value. The pressure applied to the patient is then equal to PI + PEEP.

Whatever the circumstances, the delivered PI should never exceed the PI Max.

CAUTION: The "Vt target and regulated pressure incompatibility!!!" alarm is activated when:

- Monitored volume < 90% of the Vt Target and delivered PI = PI Max;
- Monitored volume > 110% of the Vt Target and delivered PI = PEEP + 5 cmH20.

Furthermore if the Ppeak, Vti Max or patient disconnection alarm is set off, the adaptation of the PI is inhibited until the alarm stops.

Ventilation set-points

FiO2	inspired oxygen fraction (%)
Vt Target	volume target (mL);
RR	minimum respiratory frequency (c/min);
PEEP	positive end of expiration pressure (cmH20);
TI/Ttot	ratio of inspiration time to total cycle time (%);
PI	inspiratory pressure (cmH2O);
PI max	maximum inspiratory pressure (cmH2O);
I.Trig	inspiratory trigger (L/min or cmH2O);
Slope	inspiratory pressure slope (cmH2O/s);

CAUTION: The Vt Target should not be used in NIV. If there is a leak, the tidal volume monitored by the ventilator no longer represents the tidal volume inhaled by the patient. Any adaptation of the pressure is therefore inappropriate.

4.7.11 PS - PRO (interlocked barometric mode, intended for use in resuscitation)

Principle

The PS Pro mode is a PSV type pressure-regulated ventilation whose assistance frequency evolves automatically between two set frequencies: RR min and RR support (minimum frequency and maintained frequency).

The aim of automatic adaptation of the frequency is to let the patient breathe autonomously when his or her respiratory reflexes are active and allow the ventilator to take over when his or reflexes are inactive.

Furthermore, the PS Pro mode can be combined with the Vt Target function. The inspiratory assistance pressure is then adapted, cycle to cycle, so that the monitored Vt may converge towards the set Vt Target.

If the patient spontaneously triggers above RR mini, each patient effort will be assisted. The set frequency will then be the frequency of the patient.

If the patient frequency reduces to the RR mini safety threshold, the ventilator will start the fixed cycles to gradually reach the maintenance frequency, thus leaving the patient the opportunity of triggering a new spontaneous cycle.

In the case of insufficient or no inspiratory effort (the patient's respiratory frequency is lower than the set minimum frequency), the ventilator guarantees an assistance frequency equal to the set maintenance frequency.

A maintenance frequency equivalent to that set in VAC or PAC mode should therefore be set.

At the start of ventilation, the assistance frequency is equal to the maintenance frequency.

The maximum insufflation time (Ti max) is automatically set at 40% of the total time of a cycle with an assistance frequency not exceeding 3.5 seconds.



Note: For operation of the Vt Target function, refer to PRVC mode.



CAUTION: The set minimum frequency is a safety threshold below which the ventilator provides controlled ventilation based on the set patient frequency.

If the patient is disconnected, the frequency is no longer adapted until the patient is reconnected.

Safety features of the Vt target function are applied when the function is activated.

Ventilation set-points

FiO2	inspired oxygen fraction (%)
PS	inspiratory assistance (cmH2O);
RR support	maintenance frequency at which the patient is ventilated when he or she no longer breathes spontaneously (c/min);
PEEP	positive end of expiration pressure (cmH2O);
Vt Target	target volume (mL);
I. Trig.	inspiratory trigger (L/min or cmH2O);
RR mini	minimum respiratory frequency (c/min);
PI max	maximum inspiratory pressure (cmH20);
Slope	inspiratory pressure slope (cmH2O/s);
E. Trig.	expiratory trigger (% of inspiratory peak flow).



CAUTION: The Vt Target function should not be used in NIV. If there is a leak, the tidal volume monitored by the ventilator no longer represents the tidal volume inhalted by the patient. Any adaptation of the pressure is therefore inappropriate.

4.8 Oxygen therapy

The oxygen therapy function delivers a mixture of air/O2 to the patient at a given rate and FiO2. This function is used for non-ventilation dependent patients and may be used before NIV. It has adjustable flow rates which are able to cover the patient's peak inspiratory flow and consequently control the FiO2 delivered.

The oxygen therapy function is available for all categories of patients treated with **Monnal T75** (adults, children and infants) where they are connected to the high pressure O2 network (the function is disabled in low pressure O2). It requires the use of a humidifier and nasal cannula (or tracheotomy tube) specific to high throughput oxygen therapy.



Note: Please refer to the patient/machine interface manual.

Set-up

1. Install the humidifier on the Monnal T75 stand;

Note: Place the humidifier lower than the patient to prevent water flowing into the circuit.

- 2. Perform an automatic test with a dual branch circuit (see <u>Automatic tests</u> on page 22).
- **3.** Disconnect the double-limb circuit and set up the required patient circuit on the inspiratory limb of the ventilator **(52)** and on the humidifier.



- 4. Connect the patient/machine interface between the humidifier and the patient.
- 5. Check that the humidifier is in working order before switching it on.
- 6. Enable the Oxygen therapy function and set the desired flow rate.

Oxygen therapy ADULT	
Oxygen therapy This function is not a ventilation mode. You must use a humidifier and need cannuls. Apnee ventilation is disabled.	
00:00:00	
Back Th Start Th	



Note: Humidify the flow generated by the device.



CAUTION: Oxygen therapy is not a ventilation mode and must be used under supervision. The patient breathes in a fully autonomous manner, this is why:

- Apnea ventilation is not ensured in the event of a patient's respiratory arrest.
- No alarm is set off if the patient circuit is disconnected.



CAUTION: Monitored FiO2 is the FiO2 delivered by the ventilator. If the patient's inspiratory flow is greater than the flow set-point or if the nasal cannula are not properly positioned, then monitored FiO2 is potentially higher than that inhaled by the patient.

Note: Ppeak threshold can be adjusted. Its default setting is 45 cmH20.

4.9 CO2 Option

4.9.1 Introduction

CO2 monitoring on the Monnal T75 (only for KB033600) is a fee-based software option.

After purchasing this option, Air Liquide Medical Systems provides:

- the activation code for the option,
- the CO2 probe for measuring the concentration of exhaled carbon dioxide (in accordance with ISO 80601-2-55),
- the necessary adapters.

The CO2 measurement probe is mounted on an airway adapter. This adapter is connected to patient flow as close as possible to the intubation tube.

The IRMA[™] CO2 measurement probe generates an infrared signal and transmits it to the receiver on the opposite side, across the airway adapter. The measurement principle is based on the energy that the CO2 absorbs. The probe sends the CO2 concentration measurement to the *Monnal T75*.

The *Monnal T75* then displays the CO2 monitoring information that is received, in the form of a monitoring tile, time curve, trends curve and loop curve.

This information provides clinical support and can be used to assess the integrity of the patient's airways, as well as to check that accurate intubation has been successful.

4.9.2 Installing the CO2 software option

CO2 monitoring requires installation of the software option with a code. If you would like this option, contact your Air Liquide Medical Systems representative.

- 1. Go to the [Administrator configuration] menu.
- 2. Press the [Activate options] key.
- 3. Enter the code that your Air Liquide Medical Systems representative has provided.
- 4. Quit the **[Administrator configuration]** menu. The CO2 option is enabled.

4.9.3 Display of pressure and flow rate curves

The pressure and flow rate curves are displayed in real time by default. The volume and CO2 curves may also be displayed (if the software option is present).



Note: Spontaneous patient activity is represented by the curves displayed on-screen changing color. When the respiratory cycle comes from a patient demand, the curves are green, but a controlled cycle is displayed in yellow.

Changing curves

To change curves:

- 1. Press the curve to be replaced. A menu appears in the bar on the right-hand side of the screen.
- 2. Select the desired curve in the menu. The curve is displayed automatically.

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3. Press the [Back] key to quit the change curve menu.

Adjustment of scales

To adjust the time scale, press the [s] key.

To adjust the pressure scale, press the ordinate axis of the pressure curve or the [cmH20] key.

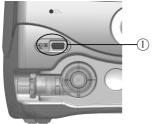
To adjust the flow rate scale, press the ordinate axis of the flow rate curve or the **[L/min]** key.

To adjust the volume scale, press the y-axis of the volume curve or the [mL] key.

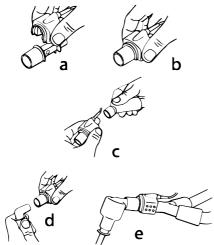
To adjust the CO2 scale, press the y-axis of the CO2 curve, the [mmHg] key, the [kPa] key or the [%] key.

4.9.4 Setting up the CO2 measurement probe

1. Connect the IRMA[™] probe to the etCO2 connection socket (1).



- **2.** Apply power to the ventilator.
- **3.** Connect the probe to its patient adapter (a). The probe is correctly connected to its adapter when you hear it click into position.



- 4. The LED flashes and then goes green. This means that the IRMA[™] probe is ready for use (b).
- 5. Connect the IRMA[™] probe, equipped with its adapter, to the Y-piece on the patient circuit (c).
- 6. Connect the IRMA[™] probe to the patient's endotracheal tube (d).
- 7. Position the IRMA[™] probe (e) (see photo opposite).



Note: The probe sends information and alarms to *Monnal T75*. The probe has an LED indicating the following statuses:

LED status	Description
Continuous green	ОК
Flashing green	Calibration in progress
Continuous red	Probe error
Flashing red	Checking the adapter



Note: For more information, please refer to the IRMA[™] user manual from MASIMO.

4.9.5 Adjusting the CO2 unit

Several measurement units can be configured for CO2 measurement:

1. Go to the [Administrator configuration] menu.

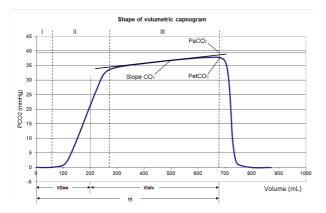
VCV settings : I:E	Save current ventilation setting
PCV and PRVC settings : I:E	Retrieve default settings
Monitoring : TI/Ttot	Support Setting : PS
etCO2 monitoring : mmHg	ОТР
Setting RR mini : Enabled	Save current alarms settings
02 supply altered : Disabled	Retrieve default settings
Volume setting	Modes selection
Activate Options	Retrieve default settings

- 2. Press the [EtCO2 Monitoring] key.
- **3.** Choose between mmHg, kPa and%.
- 4. Validate with the control wheel.

This configuration will be saved when you press the [Exit Administrator config.] key.

4.9.6 Monitored CO2 parameters

The following CO2 parameters result from the interpretation of the temporal or volumetric capnography curve. The volumetric capnography curve is the loop curve that gives the values of the exhaled CO2 as a function of the exhaled volume.



CO2 at the end of expiration (PetCO2 or FetCO2)

The maximum CO2 value measured during expiration is considered as being the CO2 value at the end of expiration. This value can be expressed as partial pressure (PetCO2 in mmHg or kPa), or as a fraction of the CO2 concentration of the gas (FetCO2 as a%).

As there is the risk that the intubation tube may not be properly sited or that it could move; evaluating CO2 at the end of expiration is a way to confirm that the intubation has been performed correctly.

Note: EtCO2 measurement should not be used as a substitute for blood gas analysis.

CO2 Minute volume (VMCO2)

The CO2 minute volume is the volume of CO2 produced by the patient in 1 minute.

The volume of CO2 produced by the patient is expressed as the difference between the volume of CO2 exhaled

during expiration, and the volume of CO2 inhaled during inspiration.

Measuring VMCO2 enables medical staff to evaluate the level of gaseous exchange in the lung. It also indicates how the patient is responding to treatment.

Dead space (VDaw)

The physiological dead space is the part of the air volume inhaled by the patient that is not part of the gaseous exchanges in the lung.

The physiological dead space is the sum of the anatomical dead space (airways) and the alveolar dead space (in the lung).

The value of the VDaw dead space that **Monnal T75** monitors is an estimation of the volume lost in the airways (anatomical dead space). This value is interpreted from the volumetric capnography curve.

Ratio of dead space to tidal volume (VDaw/Vt)

The anatomical dead space is usually compared to tidal volume, to define the ratio of anatomical dead space volume to tidal volume (VDaw/VT).

This ratio is a way to show the fraction of tidal volume that is not part of the gaseous exchanges in the lung.

Standard monitoring of the ventilation per minute not only includes lung ventilation, but also the ventilation of the parts that are not part of the gaseous exchanges airways, alveoli that are not perfused).

Alveolar ventilation per minute (VMalv) is a way to refine the information provided by the ventilation per minute calculation (MVe). The VMalv estimates the volume of air that is actually involved in gaseous exchanges in one minute.

For example, a patient with an anatomic dead space of 100 mL could achieve a minute volume of 8L/min, with the two settings below:

- tidal volume of 100 mL, and a frequency of 80 c/min, or....
- tidal volume of 500 mL, and a frequency of 16 c/min.

However, the alveolar ventilation would be completely different:

- For 100 mL of anatomic dead space, 100 mL of tidal volume, and a frequency of 80 c/min, the VMalv is 0 L/min. Thus the air in the patient's lungs is not being replaced,
- For 100 mL of anatomic dead space, 500 mL of tidal volume, and a frequency of 16 c/min, the VMalv is 6.4 L/min. Thus the air in the patient's lungs is being replaced.

The alveolar ventilation in one minute is calculated as:

VMalv = f * (Vt - VDaw)

Where f is the respiratory frequency, Vt is the tidal volume, and VDaw is the anatomical dead space.

Not all of the alveolar volume is involved in gaseous exchanges because some alveoli are only partially perfused. The volume not involved in gas exchange is called the alveolar dead space. To evaluate it, the blood gas must be measured. This is used to calculate the CO2 arterial partial pressure (PaCO2).

Alveolar plateau slope (CO2 slope)

The alveolar plateau slope is the slope of the «plateau» of the CO2 loop curve after the initial rise. It describes the appearance of the volumetric capnography, and can provides an indication of the quality of the ventilation-to-perfusion ratio.

A sharp slope can be observed in obstructive pulmonary diseases for example (asthma, COPD).

4.9.7 Activation or deactivation of CO2 monitoring

To activate or deactivate CO2 monitoring:

- 1. Go to the [Menu]
- 2. Press the [Sensors] key
- 3. Then press the [CO2 Monitoring] key.

Activating this option allows you to measure and display CO2 related monitoring. If this option is deactivated, the CO2 monitoring values are replaced by "--".



Note: When CO2 monitoring is activated, a CO2 probe must be connected. If there is no probe, an alarm is triggered.

When a CO2 probe is connected to the device, CO2 monitoring is automatically activated, and the CO2 curve is displayed on the screen.



Note: If the CO2 probe is connected and the user does not require monitoring, the user may deactivate it.

When the CO2 probe is connected or activated, the [Calibration] key can be used to calibrate the probe.

4.9.8 Calibrating the CO2 probe

The IRMA[™] probe must be calibrated when a significant shift in measurement is observed, or when the **[Calibrate the IRMA probe]** alarm is triggered.

After the probe is connected to the device, you must wait approximately ten seconds before calibrating it.

If calibration is not an available option, the key is grayed out and unavailable.

To calibrate the CO2 probe:

- 1. Go to the [Menu].
- 2. Press the [Sensors] key.
- 3. Press the [Calibration] key.

The probe must be calibrated when using a new airway adapter on the sensor.

This must be disconnected from the Y-piece of the patient circuit and the patient. Then click on the **[Calibration]** key to start calibrating the probe. The probe's green indicator blinks for approximately 5 seconds during calibration. When the calibration is finished, the message **[Calibration OK]** is displayed.

Care must be taken to avoid breathing into the adapter when the probe is being calibrated. For the calibration to succeed, it is extremely important for ambient air (21% O2 and 0% CO2) to be in the adapter/ probe combination.



Note: If the calibration is not done correctly, the measurement values will be skewed.

4.9.9 Recommendations for the use of the MASIMO IRMA[™] CO2 measurement probe

- The IRMA[™] probe may only be used by qualified, authorized medical personnel.
- The mainstream IRMA[™] multi-gas probe is intended to be connected to a patient circuit to monitor the gases inhaled/exhaled by adult or pediatric patients in emergency or intensive care situations.
- The probe must not be the sole patient monitoring device. It must always be used with other devices to monitor vital signs and/or in addition to medical advice given by a qualified person. The IRMA™ probe must be used by qualified, authorized medical personnel only.
- · The probe must not be in direct contact with the patient.
- The IRMA[™] probe must not be used with flammable anesthetic agents.
- IRMA[™] airway adapters are single-use, and must not be re-used from one patient to another. Used
 adapters must be disposed of via the appropriate hospital waste disposal channels. Reusing single-use adapters can lead to patient cross-contamination.
- Used adapters must be disposed of via the appropriate hospital waste disposal channels.
- Do not use adapters intended for adult patients or children on infant patients, because such adapters add 6 mL of dead volume to the patient circuit.
- Do not use adapters intended for infant patients on adult patients, because such adapters add 6 mL of dead volume to the patient circuit.
- The IRMA[™] probe can give poor-quality measurements in the presence of devices that emit electromagnetic interference exceeding the levels mentioned in Standard 60601-1-2. Ensure that it is used in a suitable environment.
- Only Air Liquide Medical Systems adapters may be used with the IRMA[™] probe.



CAUTION: Use only IRMA[™] probes sold by Air Liquide Medical Systems: Cat. No.: KB020400.

Do not connect the IRMA[™] at the outlet of an elbow connector, in order to avoid an accumulation
of patient secretions in the adapter and the obstruction of XTP[™] windows.



• When using the IRMA[™] probe, place the adapter so that its XTP[™] windows are vertical, to avoid an accumulation of patient secretions on these windows:

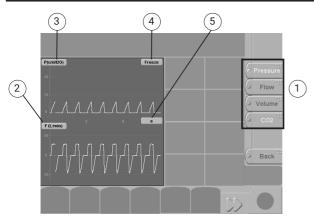


- When using the IRMA[™] probe, position the adapter so that moisture and secretions do not accumulate inside it due to the effect of gravity. Replace the adapter if it has been rained on or if it is damp.
- Do not use any aerosol medication with the IRMA[™] probe, to avoid a deterioration of IR transmission through the windows of the adapter.
- If the calibration is not done properly, the measurement values will be skewed.
- Never sterilize the IRMA[™] probe or immerse it in liquid.
- Do not pull on the cable of the IRMA[™] probe.
- Do not use the IRMA[™] probe at a temperature below 0°C or above 40°C.
- During use, ensure that the IRMA[™] probe is connected to the ventilator before you connect it to the patient.
- The probe can be cleaned using a cloth dipped in alcohol (maximum 70% ethanol or 70% isopropanol).
- Remove the adapter before cleaning the probe.
- · The adapters are not autoclavable.
- The gas measurements supplied by the probe must be checked regularly using a reference instrument. We recommend that this check be performed annually.

4.10 Display of pressure and flow rate curves

The pressure and flow rate curves are displayed in real time by default. The volume and CO2 curves may also be displayed (if the software option is present).

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Note: Spontaneous patient activity is represented by the curves displayed on-screen changing color. When the respiratory cycle comes from a patient demand, the curves are green, but a controlled cycle is displayed in yellow.

Changing curves

To change curves:

- Press the curve to be replaced. A menu appears in the bar on the right-hand side of the screen (1).
- 2. Select the desired curve in the menu. The curve is displayed automatically.
- 3. Press the [Back] key to quit the change curve menu.

Adjustment of scales

To adjust the time scale, press the [s] key (5).

To adjust the pressure scale, press the ordinate axis of the pressure curve or the [cmH20] key (3).

To adjust the flow rate scale, press the ordinate axis of the flow rate curve or the [L/min] key (2).

To adjust the volume scale, press the y-axis of the volume curve or the **[mL]** key.

To adjust the CO2 scale, press the y-axis of the CO2 curve, the [mmHg] key, the [kPa] key or the [%] key.

Freezing the curves

Pressing the [Freeze] key immediately freezes the curves (4).

Two cursors (vertical lines) are then available in order to measure and display the values of each curve. The cursor currently selected appears in green.

Use the control wheel to select, modify or move the cursor.

The symbol Δ indicates the pressure, flow rate, volume, CO2, and time interval between the two cursors.

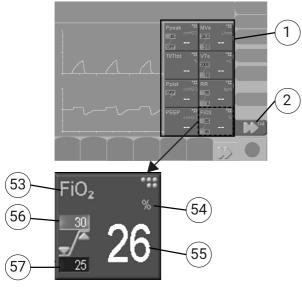
To exit from frozen curve mode, press the [Back] key.



Note: The digital display of patient parameters continues to be refreshed on-screen whilst the frozen are being displayed.

4.11 Monitoring

Eight respiratory parameters (1) are continuously displayed on the screen.



Each measurement is displayed in a block containing:

53	Name	54	Unit of measurement
55	Current value	56	Upper alarm threshold
57	Lower alarm threshold		

4.11.1 Display of measurements

The display of measurements varies according to the chosen ventilation mode.

The respiratory parameters are displayed over 2 or 3 pages. If the CO2 software option is present, an additional page specifically for CO2 monitoring is displayed.

Press on the arrow to access the different pages.

	AVCV, APCV, SIMV, PSIMV, PRVC Modes		AVCV, APCV, SIMV, PSIMV, PRVC Modes		PSV NIV, CPAP and Duo- Levels Modes	
Page 1	Ppeak	MVe	Ppeak	MVe	Ppeak	MVe
	TI/Ttot*	VTe	TI/Ttot*	VTe	%leak	VTe
	Pplat	RR	RR spont	RR	RR spont	RR
	PEEP	FiO2 or et- CO2**	PEEP	FiO2 or et- CO2**	PEEP	FiO2 or et- CO2**
Page 2	%leak	MVe spont	%leak	MVe spont	RR/VTe	MVe spont
	Pmean	VTi	Pmean	VTi	Ti/Ttot*	VTi
	RR spont	% spont	Pplat	%spont	Pmean	%spont
	\dot{V}_{peakl}	VpeakE	peakl	VpeakE	\dot{V}_{leak}	VmaxE
Page 3	Rdyn	Cdyn	Rdyn	Cdyn	etCO2	VMC02
	WOB	RR spont	WOB	RR spont	VMalv	MVe
	P0.1	NIF	P0.1	NIF	Vdaw/Vt	Vdaw
	RR/VTe	Auto-PEEP	RR/VTe	Auto-PEEP	CO2 slope	FiO2
Page 4	etCO2	VMC02	etCO2	VMC02		
	VMalv	MVe	VMalv	MVe		
	Vdaw/Vt	Vdaw	Vdaw/Vt	Vdaw		
	CO2 slope	FiO2	CO2 slope	FiO2		

* TI/Ttot or I:E ratio according to monitoring configuration selected.

** If the CO2 monitoring option is present.

*** Static values displayed during an RC stat measurement. Dynamic values otherwise.

Measurements	Definition	IV	NIV
Ppeak	Inspiratory peak pressure of the cycle	\checkmark	\checkmark
Inspiratory peak pressure of the cycle	Volume insufflated during the cycle (invasive ventilation)	\checkmark	
%leak	Leak rate (non-invasive ventilation) (i-e)/i	\checkmark	
PEEP	Positive end-of-expiration pressure	\checkmark	\checkmark
Auto-PEEP	Intrinsic PEEP	\checkmark	

Measurements	Definition	IV	NIV
VTe	Tidal volume exhaled	\checkmark	\checkmark
Pplat	Pressure measured at the end of a plateau or in- spiratory pause	\checkmark	
MVe	Expiratory volume per minute	\checkmark	\checkmark
Spont MVe	Spontaneous expiratory volume per minute	\checkmark	\checkmark
RR	Respiratory frequency	\checkmark	\checkmark
Spont RR	Spontaneous respiratory frequency	\checkmark	\checkmark
Spont%	Percentage of spontaneous respiratory cycles	\checkmark	\checkmark
FiO2	Insufflated oxygen fraction	\checkmark	\checkmark
TI/Ttot	Ratio of inspiration time to total cycle time	\checkmark	\checkmark
I:E	Ratio of inspiratory time to expiratory time	\checkmark	\checkmark
\dot{V} peak insp	Peak insufflated flow	\checkmark	
\dot{V} peak exp	Peak exhaled flow	\checkmark	\checkmark
f/VTe	Ratio of frequency to exhaled tidal volume	\checkmark	
Pmean	Average cycle pressure	\checkmark	\checkmark
P0.1	Obstruction pressure	\checkmark	
Rstat	Calculated static resistance	\checkmark	1
Cstat	Calculated static compliance	\checkmark	
Rdyn	Calculated dynamic resistance	\checkmark	

Measurements	Definition	IV	NIV
Cdyn	Calculated dynamic compliance	\checkmark	
WOB	Respiratory effort (inspiratory)	\checkmark	
NIF	Negative inspiratory force	\checkmark	
V leak	Leak rate during expiration		\checkmark

CO2 monitoring if this option is present				
etCO2	Fraction of CO2 at the end of expiration	\checkmark	\checkmark	
VMC02	CO2 minute volume	\checkmark	\checkmark	
VMalv	Alveolar minute volume	\checkmark	\checkmark	
VDaw/VT	Ratio of airway dead space to tidal volume	\checkmark	\checkmark	
Vdaw	Airway dead space	\checkmark	\checkmark	
SlopeCO2	Slope of the volumetric capnogram on the alveo- lar plateau	\checkmark	\checkmark	

The value of Pplat is updated:

- After an inspiratory pause;
- In the event of an inspiratory plateau lasting longer than 0.3 s (in VCV and SIMV).

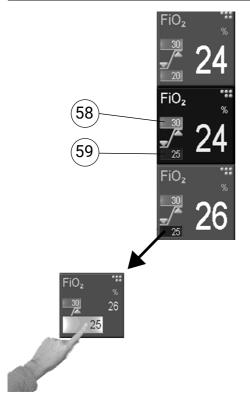
When the inspiratory plateau is not activated, the Pplat measurement is displayed as follows:

The static and dynamic resistance and compliance values are displayed in the same monitoring panels and in the context of invasive ventilation only.

- When the RC stat function (see [<u>R&C stat] key</u> on page 58) is disabled, the dynamic resistance and compliance values are displayed;
- When an RC stat measurement has been taken, the static values are displayed for a certain time before the dynamic values reappear.

4.11.2 Alarm settings

The alarm thresholds can be adjusted directly via the screen.



- To set a threshold:
- · Select the value to be adjusted: it is highlighted.

Adjust the desired value by turning the control wheel, and press the control wheel to validate.

When an alarm threshold has been exceeded, the block and the associated alarm threshold turn red **(58)**. This display is maintained as long as the alarm is present.

When the alarm disappears, the block resumes its original appearance, but the threshold concerned remains red **(59)**: this indicates that the alarm took place.



CAUTION: After a new patient selection, the alarm thresholds are automatically reset to their standard value.

These threshold settings must be systematically re-assessed in order to ensure that they suit the patient and his ventilation.

The upper pressure threshold is especially important to protect the patient from excessive airway pressure.

The setting of alarm thresholds to the extreme values in the adjustment ranges can render the alarm system ineffective.

The alarm thresholds can also be adjusted automatically according to the values measured. Refer to the next section.

Note: During a total power outage (AC power, external and internal batteries) the alarm threshold settings are retained in memory and may be displayed after the electrical power is restored. The settings are saved by a backup battery with a life of approx. 2 years. An alarm is issued when the battery life becomes too short. The battery must be replaced. A power outage of more than 2 years will cause the settings to be lost. At the next startup, the alarm thresholds will be automatically restored to their default values.

MVe low threshold settings

In PSV NIV mode, the user has the option of setting the lower threshold of the expiratory minute volume (MVe) in the OFF position.

This setting is used to inhibit the alarms associated with the low expiratory minute volume (MVe) particularly in the event of non-invasive ventilation with major leaks.

4.11.3 Automatic thresholds

The **[Auto set]** button automatically configures the alarm thresholds according to the values measured at the time when it is pressed.



To adjust the automatic thresholds, press on a monitoring pad and the **[Auto. threshold]** button will appear on the right of the screen

Press the **[Auto setting of alarm thresholds?]** button, then confirm by pressing the dial: all the alarm thresholds will update automatically.



CAUTION: After pressing the **[Auto. Set]** button, verify that the thresholds obtained in this way are appropriate for the clinical condition of the patient.



Note: The [Auto set] key is deactivated when the screen is locked.

4.11.4 Resetting

As soon as an alarm threshold has been exceeded, it is highlighted in red, and remains highlighted even when the alarm disappears.

To reset all the thresholds highlighted in red, press the [Reset] button.

4.11.5 Alarm history

The alarm history shows the latest alarm-related events recorded by the ventilator.

2285/2015 :	Lock History
E 14:36:21 ON Unit on stand-by E 14:36:24 OFF Unit on stand-by	Menu ⁵⁵
14:37:02 ON Unit on stand-by 14:41:42 OFF	Nebu. ³³
Unit on stand-by	Measure H
	Curves"
Exit **	

The [History] key opens a window which displays a chronological list of the last 200 alarms.

For each alarm there is a date, priority (color), time, activation or deactivation (ON or OFF), name, and for physiological alarms, the alarm threshold setting at the time of activation.

Use the control wheel to browse the list.

To exit the alarm history, press the control wheel.



Note: When a complete power cut occurs (mains, external and internal batteries), the history is preserved and can be displayed after the power supply has been restored. These data are preserved thanks to a back-up battery with a working life of approximately two years. An alarm is triggered when this battery runs low. The battery should then be replaced.

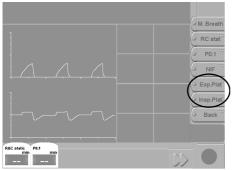


Note: When the log reaches its maximum size, the oldest events will be overwritten by incoming events.

5 Measurements

5.1 Expiratory plateau

The **[Exp. Plat]** key is used to create an expiratory pause (limited to 60 seconds). The pause continues as long as the user holds down the button. As soon as the user stops pressing the button, the ventilator resumes normal ventilation.





Note: A curve freeze can be applied in order to measure the autoPEEP value via the cursors (See <u>Display of pressure and flow rate curves</u> on page 49).

5.2 Inspiratory plateau

The **[Insp.Plat]** button is used to create an inspiratory pause (limited to 40 seconds). The pause continues as long as the user holds down the button. As soon as the user stops pressing the button, the ventilator resumes normal ventilation.

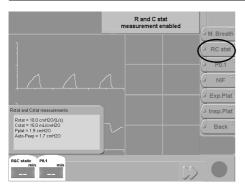


Note: A curve freeze can be applied in order to measure the Pplat pressure value via the cursors (See <u>CO2 Option</u> on page 43).

5.3 [R&C stat] key

Calculated patient resistance and compliance values consist of selectively or periodically evaluating resistance (in cmH2O/L/s) of the patient's airways, along with their pulmonary compliance (in mL/ cmH2O). Changes in these measurements over time may provide information about the patient's condition (lessening of compliance, beneficial effect of a bronchodilator, etc.)

The result is shown on the monitoring pad and in the trends, and in a window which is displayed at the end of the selective measurement.





Note: This window also displays the Pplat and Auto-PEEP results.

To start the static resistance and static compliance measurement:

- Press the [Measures] key;
- A new window opens with the [R&C stat] and [P0.1] functions.

The static R&C measurement can be performed automatically when required (–) or according to the following frequencies (min): 1, 2, 3, 4, 5, 10, 20, and 30.

- 1. Press on the 'R&C stat' set-point on the bottom row,
- 2. Select the required value with the control wheel and press on the control wheel to validate.

To enable the function, press on the **[R&C stat]** key. The indicator light comes on and the measurement begins. The following is displayed in the alarm banner: 'R and C stat measurement enabled'.



Note:

Pressing on the [R&C stat] button again disables the function.

Measurement principle

The ventilator generates:

- · end-expiratory occlusion;
- · inspiration (consistent with the current mode), delivering a Vt;
- · end-inspiratory occlusion.



Note: Inspiration between the two occlusions can be shortened to ensure that the flow rate at end of inspiration is not zero. The measurement is interrupted in the event of Ppeak.

The Rstat and Cstat values result from the following calculations:

- Cstat = VT / (Pplat total PEEP);
- Rstat = (Ppeak Pplat) / end of inspiration flow rate.

Measurement accuracy is ± 20%.



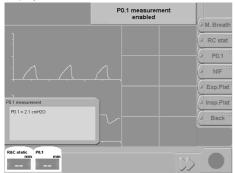
Note: This function is only available in VCV, PCV and PRVC. In these modes, the patient is sufficiently passive for the end-inspiratory and end-expiratory occlusion pressures to be stable.

Note: The set periodicity remains in the memory when the function is disabled.

5.4 P0.1 measurement key

P0.1 measurement can be useful to determine whether extubation will be successful. The procedure begins with detection of an inspiratory demand by creating end-expiratory occlusion and by measuring the drop in pressure after 0.1 seconds. The inspiratory cycle then continues normally.

The measurement result is shown on the monitoring pad and in the trends, and in a window which is displayed at the end of the selective measurement.



To begin occlusion pressure measurement:

- Press the [Measures] button;
- A new window opens with the [R&C stat] and [P0.1]' functions.

The occlusion pressure measurement can be performed automatically when required (--) or according to the following frequencies (min): 1, 2, 3, 4, 5, 10, 20, and 30.

- 1. Press on the [P0.1] set-point on the bottom line;
- 2. Select the required value with the control wheel and press on the control wheel to validate.

To enable the function, press on the **[P0.1]** button. The indicator light comes on and the measurement begins. The following is displayed in the alarm banner: 'P0.1 measurement enabled'.



Note: Pressing on the [P0.1] button again disables the function.



Note: P0.1 measurement is accessible in all modes in invasive ventilation except CPAP and Duo-Levels. It is not available in non-invasive ventilation, where the risk of leakage does not guarantee a reliable measurement.

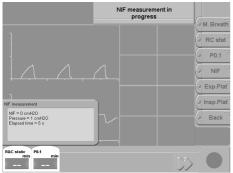


Note: The set periodicity remains in the memory when the function is disabled.

5.5 NIF (negative inspiratory force)

The NIF measurement can be useful in determining the possibility of a successful extubation.

During the NIF operation, the patient circuit is blocked, and the low pressure generated by the patient with respect to PEEP is measured. NIF is the patient's maximum inspiratory effort. When the pressure drop is less than -30 cmH20, the probability of a successful extubation is higher.



The measurement result is written in the monitoring panel and in the trends, as well as a window present during measurement.

The pressure curve is displayed on the upper part and the scale is changed so that it displays the negative pressures.

To activate the function, press the [Measurements] key and then press and hold the [NIF] key.

The LED lights up, and measurement begins, indicating the following message in the alarm panel: 'NIF measurement in progress'.



Note: As long as the key is pressed, the procedure takes place, the circuit is blocked, and the pressure drop generated by the patient is measured.

When the key is released, ventilation is resumed.



Note: The maximum measurement duration is 30 s.



Note: NIF measurement is accessible in all ventilation modes except CPAP, Duo-Levels and APRV. It is not available in non-invasive ventilation, where the risk of leaks does not guarantee reliable measurement.



Note: The procedure may be interrupted by the raising of alarms such as Ppeak.

5.6 Manual Cycle

When the patient is in expiratory phase, an inspiratory cycle can be triggered manually (manual cycle).

To activate this function, press the **[Measurements]** key and then select **[Cycle.M]** when the patient is in expiratory phase. The LED lights up and an inspiratory cycle is automatically launched, indicating the following message in the alarm panel: 'Manual cycle in progress'.



Note: If the **[Cycle.M]** key is still pressed at the end of the inspiratory cycle, an inspiratory plateau is then automatically applied.

Note: The manual cycle is not available in CPAP or APRV.

5.7 Work of Breathing (WOB)

The WOB is the quantity of energy required to carry out ventilation.

Monnal T75 can calculate the work contributed by the patient to overcome the resistance of the circuit and the intubation probe and obtain a sufficient flow rate generated by the machine after the trigger is started. The value displayed on the monitoring unit equates to the Work Of Breathing Imposed (WOBi).



Note: Monitoring is not available for modes CPAP, Duo-Levels, APRV and PSV VNI.

6 Menu

6.1 Description

The **[Menu]** key is on the right-hand side of the screen. It gives access to functions or commands via a two-level structure.

The menu is accessible via the start-up, stand-by, and ventilation screens.

02 ≯ settings	**		
Apnea ventilation settings			
тс			
Ventilator configuration			
Sensors	<u> </u>		
Exit			

The menu items give access to:

- · the oxygenation/aspiration function,
- · apnea ventilation adjustment,
- · tube Compensation settings,
- machine configuration
- sensor settings.

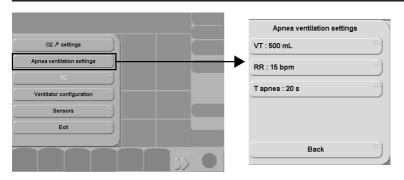
Press the [Exit] key to return to the previous screen.

6.2 Menu structure

1st level	2nd level				
02 setting	O2 boost: xx%				
	Oxygenation period:	- before aspiration			
		- after aspiration			
Apnea ventilation settings	VT				
	RR				
	T apnea				
тс	Compensation level				
	Tube type:	- Endotracheal			
		- Tracheostomy			
Ventilator config-	Language				
uration	Battery test				
	Date/hour				
	Transfer				
	Brightness				
	Alarm				
	Low pressure 02	Low pressure 02: ON/OFF			
Sensors	CO2 monitoring				
	Calibration				

6.2.1 Apnea ventilation adjustment

Apnea ventilation uses an assisted volume-controlled mode with a frequency and tidal volume to be adjusted. It keeps the PEEP and inspiratory trigger set in the current mode, Ti/Ttot of 33% and a decreasing flow rate form.



Apnea ventilation is triggered when no inspiration has been triggered for a time greater than T apnea.

It stops when:

- · The patient triggers more than three consecutive cycles,
- · The user presses the apnea ventilation Off key,
- · The user changes ventilation modes.

The ventilation of apnoea may be deactivated in CPAP mode by setting the apnoea T set-point to OFF. In such a case, an alarm sounds to confirm deactivation and should be acknowledged.



CAUTION: For safety reasons, the ventilation of apnoea should only be deactivated where the clinical situation allows. Air Liquide Medical Systems recommends that apnoea ventilation is activated.



Note: Ideally, the apnea ventilation adjustment should be performed before starting ventilation.

To access the apnea ventilation adjustments, press the **[Menu]** key and then **[Apnea ventilation set-**tings].

6.2.2 TC (Tube Compensation)

[Patient circuit compensation]

In invasive ventilation, the tube compensation function is used to estimate tube end pressure (at the tip of the tube) by making up for pressure loss in the intubation tube (tube resistance according to flow rate). By therefore applying the pressure level, set not at the pressure measured in the Y piece but at bottom pressure, the patient's physiological needs will be met.

When the function is enabled, two pressure curves are displayed: Y piece pressure (unbroken line) and bottom pressure (dotted line).



Note: The TC function is only available for the following pressure modes: PCV, PSV, SIMV, and for spontaneous PSIMV, PRVC and PS-Pro cycles. Compensation only applies during the inspiratory phase. The function remains enabled when users change modes during ventilation, but becomes disabled when the device returns to Standby mode.

To enable the function, press the [Menu] button then the [TC] key.

Three parameters are available:

- Compensation level;
- Tube type;
- Tube diameter.

Compensation level

Compensation level varies from 'none' to 100%. If compensation level is 100%, loss of tube pressure will be fully compensated. Inversely, 'none' means that no compensation takes place and that the Compensation Tube function is not enabled.

As an example, 50% compensation means that only half of loss of tube pressure will be compensated.



CAUTION: If a compensation level is set, an information message indicating that the function is enabled is displayed in the alarm banner: «intubation tube compensation enabled».

Tube type

There are 2 types: endotracheal or tracheostomy.

Tube diameter

Internal tube diameter varies from 2.5 mm to 11 mm. According to the patient category selected (adult, child, infant), suitable minimum and maximum setting limits are available.



CAUTION: Users must check that the type but also the internal diameter of the tube match that attached to the patient.



CAUTION: Compensation is limited to 10 cmH20.



CAUTION: For tubes of a diameter smaller than 3 mm, compensation is deliberately under-estimated to avoid barotrauma. Bottom pressure is actually lower than the value displayed.



CAUTION: Ensure there are no leaks in order to prevent barotrauma.

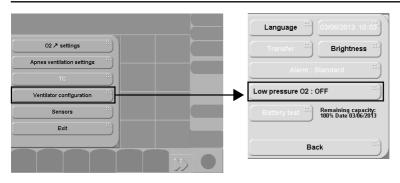
6.2.3 O2 low pressure

This function allows the device to enrich the O2 mix from a low-pressure source (typically, a concentrator).

This is different from a high-pressure source connection since it works on a lower scale (pressure generally less than 1 bar, flow rate less than 10 L/min):

- Depending on the nature of the source and the ventilation settings, certain FiO2 values cannot be guaranteed. A chart is provided for information purposes in <u>Technical description</u> on page 102).
- · The mechanisms for monitoring the presence/absence of the source must be adapted.

To activate the "Low Pressure" function, press **[Menu]**, then **[Ventilator configuration]**, then **[Low Pressure 02]** then set the position to "ON". The "Low Pressure FiO2" descriptive label then appears on the alarm panel.



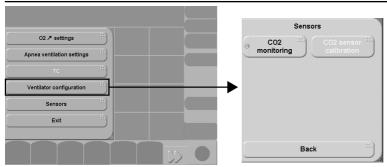
The enrichment of the O2 mix then takes place according to the FiO2 parameter, and the device then delivers, as far as possible, the desired concentration. If the ventilation and low-pressure source settings are incompatible, the FiO2 will not be reached and the "low FiO2" alarm will be generated. The user will then be informed that these settings need to be modified.



CAUTION: To have efficient operation on a low O2 pressure source, the high pressure O2 connection hose must be disconnected from the device.

To prevent the low pressure 02 fitting becoming detached, ensure the pressure applied to the low pressure oxygen inlet is less than 150 kPa (1.5 bar).

6.2.4 Sensors



CO2 monitoring

The [CO2Monitoring] key activates and deactivates CO2 monitoring.

See <u>CO2 Option</u> on page 43 for more information.

Calibration

The [CO2 sensor calibration] key calibrates the CO2 probe.

See <u>CO2 Option</u> on page 43 for more information.

6.3 Other functions

6.3.1 Oxygenation function-suction

The **[xx% 02** \nearrow] key is used to ensure the patient has oxygenation, at a FiO2 greater than the current FiO2. It also makes it possible to inhibit the alarms and ventilation in order to carry out pulmonary aspiration.



Note: If the oxygenation FiO2 is lower than the current FiO2 (see Settings), the button is disabled.

During suction, the PEEP level is maintained to the extent possible, depending on the size of the leak, in order to limit alveolar derecruitment.



Note: Suction may be carried out according to different methods (fully unplugging the circuit, opening a connection from the respiratory circuit, or "closed system").

Low-leak methods will be preferred in order to limit alveolar derecruitment.

The Oxygenation-Suction function is organized into three steps:

1- Oxygenation

Once you press the [xx% O27] key, the FiO2 that is delivered increases to the value set for oxygenation.

A countdown indicates the time remaining for oxygenation.

If the patient circuit is disconnected or opened to carry out pulmonary aspiration during this oxygenation step (#1), the Suction step (#2) is activated.

Otherwise, the oxygenation turns off and the

[xx% O2 ↗] key turns off.

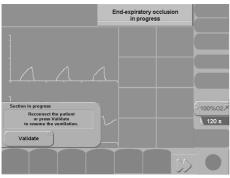
Note: It is possible to shut down the function at any time by pressing the [xx% 02 7] key.

2- Suction

During this step, the ventilator no longer generates ventilation-related alarms.

Additionally, ventilation is interrupted, thereby preventing the secretions contained in this circuit from spreading. PEEP, however, is maintained, which is improved since the circuit's leak is minimal.

Once aspiration is complete and the patient circuit has been reconnected, the ventilator automatically detects the reconnection and activates the end-of-suction oxygenation phase.





Note: The suction time is limited to 40 seconds. Afterward, the end-of-aspiration oxygenation phase (N°3) is automatically started.



Note: The user can also restart the ordinary ventilation by pressing the **[Validate]** button in the dialogue box.

3- End-of-suction oxygenation

This step is used to re-oxygenate the patient after his or her disconnection during pulmonary suction.

A countdown indicates the time remaining for oxygenation.

At the end of this countdown, oxygenation shuts down and the **[xx% 02** 7] key turns off.



Note: It is possible to shut down the function at any time by pressing the **[xx% 02** \nearrow] key.



Note: Throughout the entire oxygenation-aspiration function, nebulization is suspended. It automatically resumes at the end of the function.

Settings

The different oxygenation settings can be adjusted via a window of the [02 > Settings] [Menu].

This menu is used to set:

- Target 02: Fi02 applied to the whole oxygenation-suction period.
- Duration of oxygenation before suction (step 1 "Oxygenation")
- Duration of oxygenation after suction (step 3 "End-of-aspiration oxygenation")

For more information, refer to Checklist on page 135.

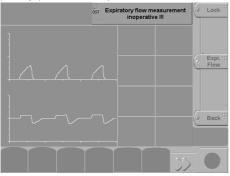
6.3.2 Screen lock key (lock)

Press this button to lock the screen.

To unlock the screen, press this key again, and then validate using the control wheel.

6.3.3 Inhibiting the spirometry sensor

Whenever alarm #57 "Expiratory flow measurement inoperative" triggers, it appears as a high priority (red color code).



The user has the ability to inhibit this alarm:

- 1. Touch the alarm banner. The "Choice of sensors" area appears on the right of the screen,
- 2. Disable the expiratory flow sensor by pressing the [Expi. Flow].

The active alarm disappears, then an informative message comes up: "Expiratory flow measurement inactive, use an external monitor".

This message stays displayed.

3. Press the [Back] button to return to the previous screen.

6.3.4 Nebulization

The ventilator can be used with a pneumatic nebulizer. It supplies a constant outlet pressure of 1.2 bar (see <u>Nebulization</u> on page 21). The nebulization flow rate then depends on the choice of the nebulizer.

Because the only high-pressure source available in the ventilator is the high-pressure O2 inlet, nebulization is possible only with the machine connected to the network (or a cylinder). The flow from the nebulizer is then oxygen: FiO2 can therefore vary in the event of nebulization.



CAUTION: The accuracy of the *Monnal T75* may be degraded by gases added during the use of the nebulizer.

In order to limit these FiO2 variations and keep the ventilation parameters (such as tidal volume) constant, the ventilator applies systematic compensation of the nebulization flow rate by reducing its own outlet flow rate by an equivalent amount (and by prioritizing the reduction of its oxygen flow rate).

The FiO2 reading is displayed on screen; the value shown represents the concentration in the Y-piece (i.e., it includes the nebulization flow).



Note: The display of the FiO2 value is an estimation of the gas concentration and cannot substitute external monitor precision.

There are several mechanisms to alert the user to any changes in ventilation:

Oxygen concentration not observed

When the estimated FiO2 measurement in the Y-piece is more than 30% greater than the concentration setting on the ventilator, an acknowledgeable HIGH alarm is triggered: "High FiO2!!! Nebuliza-tion stopped".

Nebulization is then shut off.

Nebulization flow greater than the machine output flow rate.

When the flow rate from the nebulizer is greater than the output flow rate of the machine, nebulization is automatically shut off. This occurs, for example, in pressure-controlled cycles where the end-of-in-spiration flow rate can be zero.

If nebulization is shut off for more than half the inspiratory cycle, an acknowledgeable MEDIUM alarm is triggered: "Nebulization ineffective!!".

Nebulization continues in spite of this.



CAUTION: Nebulization is deactivated for the pediatric use of the device.

To start a nebulization session:

			6	Lock ***
Nebu. : OFF	**.)			History ³³ Menu ³³³
Flow : 7.0 L/min			Ć	Nebu.
Nebulization duration : 1 min			\succ	Measure
Periodicity : none			61	00%02
Back	**			
				0

- Press the [Nebulization] key displayed in the right-hand panel.
- The following settings should be adjusted in the nebulization screen:
- · Activation or deactivation of nebulization (ON/OFF),
- Nebulization flow rate (L/min),
- · Duration of the nebulization session (in minutes),
- Periodicity (frequency) of the sessions (in hours).

Activation/Deactivation

To activate nebulization, press the [Nebulization] key.

Turn the control wheel: the button says [ON].

Press the control wheel to validate.

To stop or disable nebulization, press the [Nebulization] key.

Turn the control wheel: the button says [OFF].

Press the control wheel to validate.

Flow rate

This parameter is used to define the nebulizer flow rate so that the ventilator can compensate for it.

There are various possible ways to define this flow rate: automatic adjustment or manual adjustment.

Automatic adjustment

This is the preferred mode.

When the automatic test is launched, the user is asked to integrate the nebulizer in the inspiratory limb (see <u>Nebulization</u> on page 21) and to connect the device to the oxygen network (or cylinder).

The flow rate from the nebulizer can then be measured, and the flow rate parameter can be adjusted automatically in the settings screen.

This flow rate will be taken into account for the next nebulization session so that it can be compensated.



Note: If the automatic test is running in the absence of a nebulizer (or if the device is not connected to the oxygen network), a warning is triggered to inform the user. If a nebulization session is subsequently requested, an acknowledgeable LOW alarm is triggered: "Did you start the automatic tests with the Nebulizer?".

If the user does not wish to interrupt ventilation, the nebulization flow rate can then be adjusted manually.

Manual adjustment

The device supplies a nebulization pressure of 1.2 bar. The user must refer to the nebulizer instructions to find out the correct nebulization flow rate for this pressure, and then adjust it accordingly on screen.

Nebulization time

This defines the duration of the nebulization session.

Periodicity

This defines the frequency of the nebulization sessions.

Press the [Periodicity] button to set the frequency of nebulization (hours).

If necessary, you can activate just one nebulization session which will not be repeated periodically. To do this, set the PERIODICITY parameter to "NONE".

To go back to the previous screen, press [Back].

6.3.5 Loop curves

The following types of loop curves can be displayed:

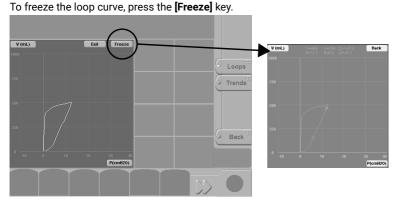
- Volume / Pressure;
- Flow rate / Pressure;
- Volume / Flow rate;
- CO2 / Volume (if the CO software option is present).

To access the loop curves:

- 1. Press the [Curves] key in the right-hand bar
- 2. Press the [Loops] key.

To access these various types of loop curve, touch the curves zone until the desired curve is displayed.

To adjust the volume, pressure, flow rate, or CO2 scale, press the appropriate key (V mL, P cmH20, D L/min, CO2 mmHg, CO2% or CO2 kPa) until the desired scale is displayed.



When the loop curve is frozen, two cursors appear and allow the value of the curve to be measured at the point defined by the cursor.

To select the cursor, press the control wheel.

Turn the control wheel to move the cursor.

The values measured on each curve are displayed under the frozen curve.

The symbol Δ indicates the volume, pressure, flow rate, or CO2 interval between the two cursors.

To exit from frozen curve mode, press [Back].

6.3.6 Trends

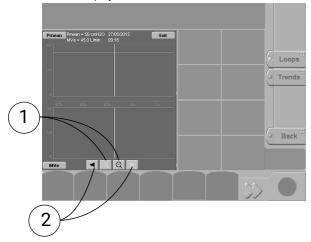
This function allows the user to monitor the development of the following ventilation settings over a maximum 80 hours:

RR	VTi	Vte	MVe
Pplat	Ppeak	Pmean	PEEP
Ti/Ttot	%Leak	Auto-PEEP	spont. MVe
spont. RR	spont.%	peak ins	peak exp
P0.1	Rstat	Cstat	Rdyn
Cdyn	NIF	WOB	leak
I:E	FiO2	etCO2	

To access the trends:

- press the [Curves] key in the right-hand bar.
- press the [Trends] key.

This screen can display two trend curves.



To change the top trend and display another parameter, press the current parameter button (top-left of the graph) and choose the desired parameter.

To change the top trend and display another parameter, press the current parameter button (top-left of the graph) and choose the desired parameter.

The trend curves can be displayed every 2, 5, 10, 20 or 40 hours. To modify the time scales, use the zoom + or - buttons (1).

To scroll the trends curves from left to right, use the arrows (2).

The user can display the precise values at a given moment (date and time) of the selected ventilation parameters using the vertical line.

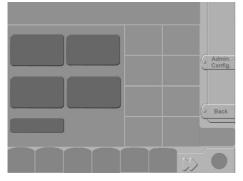
The user can thus move the line along the trends curve and read off the values of the two previously defined parameters.

7 Administrator configuration

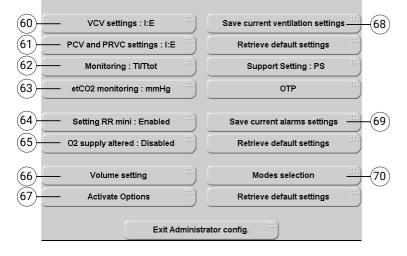
7.1 Access

The **[Administrator config.]** menu is accessible from the Stand-by mode. It is only accessible to authorized persons.

After a special access procedure by authorized persons, press the **[Administrator config.]** button in the right-hand bar to display the **[Administrator config.]** screen.



To close the [Administrator config.] menu, press the [Exit Administrator config.] button.



7.2 Presentation

The **[Administrator config]** menu enables the prescriber to customize the configuration of default ventilation parameters (set-points, alarms, etc.)

The new parameters are applied whenever a new patient is selected.

Note: The defined parameters will be specific to each category (adult/child/infant).

7.3 Setting inspiratory time in VCV mode (60)

Several types of settings can be configured for inspiratory time.

- Setting the TI/Ttot ratio
- Setting the I:E ratio
- · Setting the peak inspiratory flow
- Setting the Ti.

Configurations are saved when you press the [Exit Administrator config.] key.

7.4 Setting inspiratory time in PCV mode (61)

Several types of settings can be configured for inspiratory time:

- Setting the TI/Ttot
- Setting the I:E ratio
- Setting the Ti.

Configurations are saved when you press the [Exit Administrator config.] key.

7.5 Inspiratory time monitoring (62)

Several types of measures are available to measure inspiratory time:

- I:E ratio measurement;
- TI/Ttot ratio measurement.

7.6 Monitoring etCO2 (63)

See CO2 Option on page 43.

7.7 Disabling the RRmini set-point (64)

It is possible to deactivate the RRmini set-point for the following modes: PSV, PSV NIV and Duo-levels.

Press RRmini set-point key and modify and validate with the control wheel.

Configurations are saved when you press the [Exit Administrator config.] Key.

7.8 Altered O2 network (65)

Users may choose to use *Monnal T75* on a so-called 'altered' 02 network, where 02 concentration is lower than 100%. E.g., a network supplied by oxygen generators.

In order to enable optimum operation in these conditions, it must be indicated that *Monnal T75* is connected to such a network. Select the O2 network to do this:

- · Go to the 'Administrator configuration' menu;
- · Press the [O2 supply altered] button and select [Enabled];
- Quit the [Administrator configuration] menu.



Note: An information message on green background 'Operating on altered network' is displayed in the alarm display area when the device is in Standby mode.

Monnal **T75** automatically measures the purity of the network, during the automatic test and adjusts its algorithms accordingly.



Note: The automatic test must be launched before use on patients.



CAUTION: It must be ensured that the *Monnal T75* mode of operation matches the actual network oxygen concentration to prevent dysfunction (notably the appearance of technical alarms)

Depending on oxygen concentration, the algorithms monitoring technical failures of the mixer may be less sensitive.



Note: Depending on network concentration, certain set-points may not be available.



Note: The estimated FiO2 for nebulisation may be subject to error, up to the natural variations in network purity.

7.9 Volume setting (66)

It is possible to customize the alarm sound level.

Press the **[Volume Setting]** button, set the volume to between 0 and 100 using the control wheel, and then validate.

Configurations are saved when you press the **[Exit Administrator config.]** button.



CAUTION: Adjusting the volume to a level below the ambient noise level may prevent medical staff from hearing the alarms and render the alarm system ineffective.

7.10 Enabling Options (67)

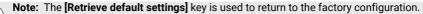
See CO2 Option on page 43.

7.11 Saving the ventilation set-points (68)

The **[Save current ventilation settings]** key is used to save a ventilation mode with preferred settings for each patient category. This ventilation mode with customized settings is applied by selecting **[New patient]**.



Note: The operation must be repeated for each patient category (adult/child/infant).





Note: See notes and procedure below.

7.12 Pressure Support Setting (69)

The function « Support Setting » allows the user to select the behavior of pressure setpoint depending on how it is used. The default setting is PS.

7.13 Setting the ventilation set-points (70)

The **[Save current ventilation settings]** button is used to save a ventilation mode with preferred settings for each patient category. This ventilation mode with customized settings is applied by selecting **[New patient]**.



CAUTION: Confusion may arise if different alarm settings are used on different devices within the same zone, for example an intensive care unit or a heart surgery room.

Procedure for saving ventilation and alarm set point:

- 1. In standby mode, choose a category of patient (adult, child or infant);
- 2. Configure the chosen mode with the desired settings and alarm;
- 3. Go to the [Administrator Configuration] menu and press the save button(s);
- 4. Exit the [Administrator Configuration] menu;
- 5. Change the patient category and repeat the same operation.

7.14 Selecting ventilation modes (71)

The available ventilation modes are not always all used by all prescribers.

Therefore, the user has the option to define in advance, those modes that will be used most frequently.

To disable modes: press the desired mode, turn the control wheel and validate by pressing the control wheel again.

Disabled and unused modes are no longer displayed.



Note: VCV mode is not accessible and cannot be disabled.

To reactivate the modes: press the desired mode, turn the control wheel and validate by pressing the control wheel again.

The reactivated modes are then displayed on the screen.

Configurations are saved when you press the [Exit Modes selection] key.

To restore default configuration mode, press the **[Retrieve default settings]** key.

8 Alarms

Alarms are indicated by on-screen displays and the emission of audible sequences.

The header panel indicates the alarm status and level. Its color varies according to the importance: red, yellow, cyan or green.

On the left of the alarm band is a software alarm indicator and an alarm silence button. The two buttons are displayed as follows:

Alarms	Priority	Software alarm indica- tor	Inhibition key
ULTRA	High	Red	Red
HIGH	High	Red	Red
MEDIUM	Medium	Yellow	Yellow
LOW	Low	Cyan	Cyan
INFO	None	Green	None



Note: The software alarm signal flashes when an ULTRA, HIGH or MEDIUM alarm is raised.

The arrow means that there are several alarms at the same time.



8.1 Parameters

Alarms are ranked according to 3 priority levels, with different sounds and colors.

Alarms	Background color	Text color	Sound
ULTRA	Red	White	Intermittent
HIGH	Red	Black	Intermittent
MEDIUM	Yellow	Black	Intermittent
LOW	Cyan	Black	Intermittent
INFO	Green	Black	None

ULTRA alarms are high priority alarms referring to a device or power supply failure. HIGH alarms are high priority alarms referring to a ventilation failure.

The INFO priority is displayed on a green background with the symbol .

To indicated a technical error, the alarm also displays the symbol \checkmark and a number so that the technical department can identify the exact source of the alarm.

If several alarms are triggered, a small arrow appears on the right-hand side of the panel, and only the highest-priority alarm is visible. Press the panel to display the list of current alarms.

If multiple alarms are displayed in this list, the user can browse all alarms using the control wheel.



Note: The audible alarm is for a doctor working near the patient. The maximum distance away and the volume of the alarm must therefore be determined by this person according to the situation.

8.2 Acknowledgement of alarms

Certain alarms open a dialogue box. These are "acknowledgeable" alarms, which are specifically intended to inform the user of a particular event.

A stand-by request or switching to internal battery are examples of acknowledgeable alarms. The user must validate using the control wheel; the dialogue box then disappears.

8.3 Inhibition of alarms

Press _____ to interrupt the audible signal for two minutes.

This greys out the inhibit button.

Press to cancel the alarm inhibition. The alarm message remains on the screen.

If this alarm is replaced by another audible alarm with a higher priority, the inhibit function is automatically disabled and the new alarm begins to sound. The previous alarm is then automatically archived in the history.

8.4 List of alarms

N°	Alarm	Priority	Alarm activation	Alarm onset delay	Actions
0	Shut off ventilation?	HIGH [acknowledgeable]	Placing on STAND- BY mode	Immediate triggering	Validate using the control wheel to stop ventilation
1	Ventilator shutdown?	HIGH [acknowledgeable]	Unit Off request	Immediate triggering	Validate using con- trol wheel to switch off the unit
2	Expiratory limb might be obstructed!!!	HIGH	Electronic failure or expiratory valve membrane is stuck	Triggered within 15 s (and 2 cycles with high pressure)	Check expiratory limb membrane and accessories Contact the techni- cal department if the problem persists

N°	Alarm	Priority	Alarm activation	Alarm onset delay	Actions
3-7	Machine out of service!!! Use a back- up ventilator	HIGH (ULTRA)	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department Patient vented to at- mosphere
8	Error detected!!! Contact the tech. department	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department Patient vented to at- mosphere
9	Machine out of service!!! Use a back- up ventilator	HIGH (ULTRA)	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department Patient vented to at- mosphere
10	Patient disconnection!!!	HIGH	The patient is dis- connected	Triggered within 15 s	Check the level of leakage
11	High pressure!!!	HIGH	Pressure in pa- tient circuit > alarm threshold	Triggered after 3 consecutive ventila- tion cycles	When the pressure threshold is reached, the machine goes into expiration mode. Check the suitability of alarm levels with ventilation settings
12	Error detected!!! Contact the tech. department	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department
13 - 14	Screen fault!!! Ventilation Effective	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department
15	Incorrect Settings!!!	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department
16	Incorrect alarms settings!!!	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department
17	Low minute volume!!!	HIGH	Expired ventilation per minute MVe is below the set alarm threshold	Immediate triggering	Check for leaks in the patient circuit. Check the suitability of alarm levels with ventilation settings
18	Low frequency!!	MEDIUM	Measured frequen- cy below the alarm threshold	Immediate triggering	Check the suitability of alarm levels with ventilation settings
19 - 20	Ventilation downgraded! Replace the machine ASAP.	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department

N°	Alarm	Priority	Alarm activation	Alarm onset delay	Actions
21	O2 supply pressure too low!!!	нідн	O2 supply pressure < 1.5 bar	Immediate triggering	Check remaining supply in cylinder or pressure in wall net- work.
					In case of opera- tion on low pressure source, check that the high pressure O2 connection hose is disconnected from the device.
22	O2 supply pressure too high!!!	HIGH	02 supply pressure > 7 bar	Immediate triggering	Check pressure in wall network.
23	Safety Ventilation!!! recommend switching ventilator	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department
24				T	
25	PEEP greater than set PEEP + 5 cmH20!!!	HIGH	Measured PEEP is 5 cmH2O above the PEEP setting	Triggered within 15 s	Ventilation contin- ues, but extended expiration will occur if the high pressure alarm is activated
26	High respiratory rate!!	MEDIUM	The frequency mea- sured by the ventila- tor is above the set threshold	Triggered after 5 s	Check the suitability of alarm levels with ventilation settings
			Self-triggering of in- spiratory trigger	Triggered after 5 s	Lower the inpiratory trigger sensitivity
27	High minute volume!!	MEDIUM	MVe > set threshold	Immediate triggering	Check the suitability of alarm levels with ventilation settings
28	High FiO2!!!	HIGH	Measured FiO2 > set threshold	Immediate triggering	
				Inhibition for 2 min after change of set- point	
29 - 30	Error detected!!! Contact the tech. department	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department
30	Error detected!!! Contact the tech.	HIGH	Draumatia	Immediate triggering	
	department		Pneumatic problem Electronics failure		- Check the position of the expiratory valve and its mem- brane.
					- Verify that the membrane is not punctured.
					- Replace the lip seal (Chapter XI, Mainte- nance)
					Contact the technical department.

N°	Alarm	Priority	Alarm activation	Alarm onset delay	Actions
32 - 33	Error detected!!! Contact the tech. department	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department
34	Low FiO2!!!	HIGH	Measured FiO2 < set threshold	Immediate triggering Inhibition for 2 min after change of set- point	
35	Internal battery inoperative!!! Connect AC power	HIGH (ULTRA)	The battery is empty.	Immediate triggering	Immediately connect to mains power sup- ply.
36	Internal battery discharged!!! Connect AC power	HIGH [acknowledgeable]	Internal battery al- most empty	Immediate triggering	Connect the unit to mains (battery will charge
37	Internal battery unavailable!!! Check battery	HIGH [acknowledgeable]	Electronics failure	Immediate triggering	Check battery
38 - 39	Power Fault, connect to external source!!! Ventilation Effective	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department
40	Apnea ventilation!!!	HIGH	No respiratory activ- ity for a time > T ap- nea	T apnea Immediate triggering	Switch to back-up ventilation, associat- ed alarm
41	Delivered gases too hot!!!	HIGH	Temperature of gas- es supplied to pa- tient is approaching 41°C	Immediate triggering	Check that the unit is being used accord- ing to specifications If problem persists, use a different unit and contact the tech- nical department
42 - 45	Safety Ventilation!!! recommend switching ventilator	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department
46	Patient circuit leak detected during automatic tests!!!	HIGH	Patient circuit con- nection problem	Triggering on exit from the automatic test	Change the patient circuit, connect pa- tient circuit compo- nents carefully, and repeat the automatic test
47	High FiO2 too!!! Nebulization stopped	HIGH [acknowledgeable]	Incompatibility be- tween settings and the nebulization function	Immediate triggering	Readjust the set- points
48	Safety Ventilation!!! recommend switching ventilator	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department

N°	Alarm	Priority	Alarm activation	Alarm onset delay	Actions
49	Restart the automatic tests!!!	HIGH	The atmospher- ic pressure has changed of more than 50 mB since the last automatic test	Triggering when the ventilator is started	Start the automatic test in order to cali- brate to the new at- mospheric pressure
50 - 52	Safety Ventilation!!! recommend switching ventilator	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department
53	FiO2 sensor inoperative!!!	нісн	Bad O2 sensor con- nection, defective O2 sensor	Immediate triggering	Replace the O2 sen- sor (see <u>O2 cell</u> on page 100) Check O2 sensor connection
54	Safety Ventilation!!! recommend switching ventilator	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department
55	Sounder failure !!! Ventilation Effec- tive	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department
56	Expiratory flow measurement inoper- ative!!!	HIGH	Hot Wire Sensor bro- ken	Immediate triggering	Replace the expira- tion flow rate sensor
57	Safety Ventilation!!! recommend switching ventilator	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department
58	Safety Ventilation!!! recommend switching ventilator	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department
59	Low VTe!!	MEDIUM	Exsufflated volume < set threshold	Triggered after 6 consecutive ventila- tion cycles	Check the suitability of alarm levels with ventilation settings
60	High VTe!!	MEDIUM	Exsufflated volume > set threshold	Triggered after 6 consecutive ventila- tion cycles	Check the suitability of alarm levels with ventilation settings
61	Screen fault!!! Ventilation Effective	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department
62	High plateau pressure!!	MEDIUM	Lung pressure > alarm threshold	Triggering at an in- spiratory plateau	Check the suitability of alarm levels with ventilation settings
63	Low VTi!!	MEDIUM	Insufflated volume < set threshold	Triggered after 3 consecutive ventila- tion cycles	Check the suitability of alarm levels with ventilation settings
65	High VTi!!	MEDIUM	Actual insufflated volume > VT setting	Triggered after 3 consecutive ventila- tion cycles	The machine goes into expiration mode when the threshold is reached. Check the suitability of alarm levels with ventilation settings In pressure-control mode, check leakage level

N°	Alarm	Priority	Alarm activation	Alarm onset delay	Actions
66	Nebulization ineffective	MEDIUM	Setting is incompati- ble with nebulization	Immediate triggering	Check the nebuliza- tion flow setting Change the settings
67 - 69	Safety Ventilation!! recommend switching ventilator	MEDIUM	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department
70	Screen fault!! Ventilation Effective	MEDIUM	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department
71	Internal battery nearly discharged!!	MEDIUM [acknowledgeable]	Battery low	Immediate triggering	Ventilation can con- tinue but the unit could stop at any time. Immediately connect the unit to the mains power supply
72	Error detected!! Contact the tech. de- partment	MEDIUM	Electronics failure	Triggering when the ventilator is started	Use a different unit and contact the tech- nical department
73	High pressure!	LOW	Ppeak > threshold	Immediate triggering	When the high pres- sure threshold is reached, the ma- chine goes into expi- ration mode. Check the suitability of alarm levels with ventilation settings
74	O2 supply pressure low!	LOW	O2 supply pressure is too low	Immediate triggering	Check remaining supply in cylinder or pressure in wall net- work. In case of opera- tion on low pressure source, check that the high pressure 02 connection hose is disconnected from the device.
75	Low VTi!	LOW	Insufflated volume < set threshold	Immediate triggering	Check the suitability of alarm levels with ventilation settings
76	Low respiratory rate!	LOW	The measured fre- quency is below the set threshold	Immediate triggering	Check the suitability of alarm levels with ventilation settings
77	VT not reached! Check settings	LOW	The blower is on maximum and the volume reached is 30% below the vol- ume setting	Immediate triggering	Check the set-points
78	Patient demand higher than set peak flow!	LOW	Settings are below patient capacity	Triggered after 5 consecutive ventila- tion cycles	Adjust ventilation settings to suit the patient

N°	Alarm	Priority	Alarm activation	Alarm onset delay	Actions
79	High VTi!	LOW	Insufflated volume > set threshold	Immediate triggering	The machine goes into expiration mode when the threshold is reached.
					Check the suitability of alarm levels with ventilation settings
					In pressure-control mode, check leakage level
80	High respiratory rate!	LOW	The measured fre- quency is above the threshold	Immediate triggering	Check the suitability of alarm levels with ventilation settings
			Self-triggering of in- spiratory trigger	Immediate triggering	Lower the inspiratory trigger sensitivity
81 - 86	Non Critical error! Ventilation Effec- tive	LOW	Electronics failure	Immediate triggering	Use a different unit and contact the tech- nical department
87	Ventilator operates from internal bat- tery!	LOW [acknowledgeable]	Loss of mains power supply	Immediate triggering	Battery life (see <u>Bat-</u> <u>tery life check</u> on page 99)
					Connect the unit to the mains if internal power is not neces- sary
88	Ventilator operates from external bat- tery!	LOW [acknowledge- able]	Loss of mains power supply	Immediate triggering	Monitor the remain- ing charge in the ex- ternal battery and connect the unit to the mains if the bat- tery is low
89	FiO2 sensor to be soon replaced!	LOW	Voltage below a threshold	Immediate triggering	Replace the O2 sen- sor the next time you put the unit in ser- vice.
90	Perform a battery test! (Machine Configuration menu)	LOW [acknowledgeable]		Every 6 months	Conduct battery test
91	Did you start the automatic tests with the nebulizer?	LOW [acknowledgeable]	Nebulization activat- ed without having run automatic test with nebulizer con- nected	Immediate triggering	Run the automatic test
92	End-inspiratory occlusion in progress	INFO	"Inspiratory pause" respiratory function selected	Triggering at the start of the expirato- ry phase	
93	End-expiratory occlusion in progress	INFO	"Expiratory pause" respiratory function selected	Triggering at the start of the inspirato- ry phase	
96	Low pressure O2 activated	INFO	Press the "O2 low presure" button	Immediate triggering	
97	Nebulization in progress	INFO	Nebulization in progress	Immediate triggering	

N°	Alarm	Priority	Alarm activation	Alarm onset delay	Actions
98	Nebulization due to start	INFO	Nebulization due to start	Triggering 15 min before the start of a nebulization cycle	
99	Screen locked	INFO	The user has locked the screen	Immediate triggering	
100	Unit on	INFO	Unit in stand-by	Immediate	
	Stand-by			triggering at ventila- tion stop or at the starting of the device	
101	FiO2 sensor calibration: plan to restart the automatic tests!	LOW [acknowledgeable]	Deviation from the O2 sensor measure- ment	Immediate triggering	
102	Suction; patient disconnection in progress	MEDIUM	Disconnecting the patient with the "Suc- tion" function active	Triggering within 15 s	Validate to acknowl- edge the alarm Conduct the auto- matic test as soon as possible
103	Oxygenation in progress – Suction possible	INFO	Press the "xx% O2 ↗ " button	Immediate triggering	Reconnect the pa- tient
104	End-of-suction oxygenation in progress	INFO	Reconnecting the cir- cuit after aspiration	Triggering within 10 s	
105	Expi. flow measurement disabled, use an external monitor	INFO	Disable the hot wire sensor	Immediate triggering	Use an external mon- itor
106	Low minute volume alarm disabled	LOW		Immediate triggering	Set a low MVe alarm threshold different from OFF
107	Press detected on \nthe touch screen!	LOW	Electronic fault	Immediate triggering	Change the ventila- tion and contact the tech. department
108	Vt target and set pressure incompat- ibility!!	MEDIUM	Exhaled volume < Vt target and Delivered pressure = Ppeak	Immediate triggering	Check that settings of Vt target and Ppeak are consistent
			Exhaled volume > Vt target and delivered pressure = PEEP + 5 cmH2O	Immediate triggering	Check that settings of Vt targe (Pressure delivered cannot be lower than PEEP
					+ 5 cmH2O)
109	Oxygen therapy enabled, Apnea venti- lation disabled	INFO	Press the 'Oxygen therapy' button	Starts after pressing the 'Start' button	
110	Oxygen therapy branch may be ob- structed!!!	HIGH	Pressure in pa- tient circuit > alarm threshold	Starts after 4 s	Check the patient cir- cuit, the patient/ma- chine interface and the inspiratory limb of the ventilator.
					Check that the alarm levels match the set- tings.
111	R and C stat measurement enabled	INFO	Press the 'R&C stat' button	Immediate triggering	
112	'P0.1 measurement enabled'	INFO	Press the 'P0.1' but- ton	Immediate triggering	

N°	Alarm	Priority	Alarm activation	Alarm onset delay	Actions
113	Intubation tube compensation en- abled	INFO	Press the 'TC' button	Immediate triggering	
114	Operate on altered O2 supply	INFO	'Enabled' setting of altered O2 network in administrator con- figuration	Immediate triggering	
115	NIF measurement in progress	INFO	Press the NIF key	Immediate triggering	
116	Low pressure!!!	HIGH	Pressure in pa- tient circuit < alarm threshold	Triggered after 3 consecutive ventila- tion cycles	Check the level of leakage
117	Low pressure!	LOW	Pressure in pa- tient circuit < alarm threshold	Immediate triggering	Check the level of leakage
118	Manual cycle in progress	INFO	Press the Cycle.M key	Immediate triggering	
119	CO2 apnea!!!	HIGH	CO2 sensor: No pa- tient breaths have been detected for more than 20 sec- onds	Immediate triggering	A clinician must re- evaluate the patient's ventilation
120	Check IRMA probe (CO2) adapter!	LOW	CO2 sensor: UU adapter is not prop- erly placed on the probe	Immediate triggering	Check the UU adapter
121	Replace IRMA probe (CO2) adapter!	LOW	CO2 sensor: UU adapter is obstruct- ed or blocked	Immediate triggering	Change the adapter
122	CO2 concentration is outside toler- ance!	LOW	CO2 measured > 15%	Immediate triggering	If CO2 is correctly < 15%, calibrate the probe
123	Calibrate the IRMA probe (CO2)!	LOW	CO2 sensor: Probe drift	Immediate triggering	Calibrate the probe
124	IRMA probe error (CO2)!	LOW	CO2 sensor: probe hardware or soft- ware error	Immediate triggering	Disconnect and re- connect the probe. If the problem persists, change probes.
125	CO2 measurement is inoperative!	LOW	CO2 sensor: Probe is not connected	Immediate triggering	Connect the IRMA probe
126	IRMA probe (CO2): Internal tempera- ture outside tolerance!	LOW	CO2 sensor: The in- ternal probe temper- ature exceeds the maximum measure- ment threshold	Immediate triggering	If the ambient tem- perature is normal, change probes
127	IRMA probe (CO2 Ambient pressure is out of tolerance!	LOW	CO2 sensor: The at- mospheric pressure measured by the probe exceeds the maximum measure- ment threshold	Immediate triggering	If the ambient pres- sure is normal, change probes

N°	Alarm	Priority	Alarm activation	Alarm onset delay	Actions
128	EtCO2 high!!	MEDIUM	EtCO2 measurement greater than the set threshold	Immediate triggering	Check the suitability of the alarm levels with the ventilation settings. Check the patient's condition and the ab- sence of secretions in the adapter and the patient circuit.
129	EtCO2 low!!	MEDIUM	EtCO2 measure- ment is below the set threshold	Immediate triggering	Check the suitability of the alarm levels with the ventilation settings. Check the patient's condition and the absence of leaks in the patient circuit.
130	Re-breathing detected!!	MEDIUM	re-breathing > thresh- old (4 mmHg)	Immediate triggering	Reduce the dead space
131	VMalv high!!	MEDIUM	VMalv value is above the set threshold	Immediate triggering	Check the suitability of the alarm levels with the ventilation settings.
132	VMalv low!!	MEDIUM	VMalv value is below the set threshold	Immediate triggering	Check the suitability of the alarm levels with the ventilation settings.
133	VMCO2 high!!	MEDIUM	VMCO2 value is above the set thresh- old	Immediate triggering	Check the suitability of the alarm levels with the ventilation settings.
134	VMCO2 low!!	MEDIUM	VMCO2 value is be- low the set threshold	Immediate triggering	Check the suitability of the alarm levels with the ventilation settings.
135	Perform Preventive Maintenance	LOW	Perform Preventive Maintenance	Immediate triggering	Contact the technical department The alarm can be acknowledged.
136	Expiratory limb obstructed!!! Emer- gency ventilation	HIGH	Respiratory-tract pressure during ex- halation > threshold during exhalation	Sounded after 5 s in the event of low frequency; otherwise after 2 cycles.	Check the condition of the expiratory limb and eliminate the cause of the obstruc- tion. Backup ventila- tion. Contact Techni- cal Support.
137	Safety Ventilation!! recommend switching ventilator	HIGH	Electronic fault or mechanical jam	Immediate triggering	Change the ventila- tion device and con- tact the tech. depart- ment Patient respiratory contact with room air as backup ventila- tion.

N°	Alarm	Priority	Alarm activation	Alarm onset delay	Actions
138	Apnoea ventilation deactivated!	LOW	The Tapnea set-point switches OFF during CPAP ventilator, or the mode starts up with Tapnea set to OFF	Immediate triggering	The Tapnea set-point switches to a value other than OFF dur- ing CPAP Ventilator or ventilation other than CPAP.
139	Reduced battery power for transfer!!	MEDIUM [acknowledgeable]	Battery capacity 50%	Immediate triggering	See battery (see <u>Bat-</u> <u>tery life check</u> on page 99)
140	Insufficient battery power for transfer	HIGH [acknowledgeable]	Battery capacity 25%	Immediate triggering	The battery has reached its operating limit. Please replace it.

9 Maintenance

Accessories can be re-usable (autoclavable) or single-use (disposable).

Re-usable elements must be regularly cleaned and sterilized to prevent infection.

This procedure, which is mandatory and extremely important, is the responsibility of the user.

9.1 Definitions

Cleaning

The act of removing all traces of soiling from a place, a surface, or an element.

Sterilization

Total destruction of all germ strains, viruses, and yeasts.

A sterilization or disinfection procedure is never possible on dirty or soiled elements.

A complete procedure includes:

- 1. Disassembly, pre-disinfection, rinsing and drying;
- 2. Cleaning, rinsing and drying;
- 3. Disinfection, rinsing and drying, or sterilization;
- 4. Reassembly and functional tests



CAUTION: Never use abrasive powders, acetone, or other powerful solvents.



Note: The following instructions have been approved by the manufacturer of the medical equipment as ENABLING a medical device to be prepared for re-use.

It is always the responsibility of the department concerned to ensure that the sterilization procedure actually implemented via the equipment, materials and personnel of the reprocessing facility achieves the expected result.

This generally requires the validation and routine inspection of procedures.

9.2 Routine maintenance

The surface of the ventilator can be cleaned.

Air Liquide Medical Systems recommends the following cleaning products for this purpose: ANIOS TSA or ANIOS SURFA'safe.

Obey the instructions of the product manufacturer, and do not allow any liquid to penetrate inside the unit.



CAUTION: Maintenance must be carried out with the ventilator disconnected from the electrical power supply.

9.3 Expiratory assembly: flow sensor + expiratory valve Monnal EVA

There are two types of expiratory assembly: single-use assemblies and autoclavable assemblies (reusable).

The sensor and the single-use expiratory assembly valve are transparent. Both of these components

bear a Part Number, Batch Number, and the following logo: 2

The sensor and the autoclavable expiratory assembly valve are colored blue. Both of these compo-

nents bear a unit Serial Number, a Part Number, and the 'autoclavable' logo:

(Refer to the summary of markings below).

Single-use version

The expiratory assembly is delivered by Air Liquide Medical Systems clean and ready for clinical use. The exchange interval depends on hospital infection-control protocols, the presence of secretions and the nebulization of drugs.

Reusing single-use accessories or consumables carries the risk of patient cross-contamination.

Autoclavable version

The expiratory assembly is intended to undergo at least 50 sterilization cycles.

To help track the number of cycles, the sensor and valve are marked with a unit serial number (SN).

The expiratory flow sensor (67) requires special precautions during pre-disinfection, cleaning, and disinfection. It consists of a very fine, fragile platinum wire.

It is therefore important to:

- · Avoid inserting any object into the flow sensor,
- · Avoid exposing it to a jet of water or air,
- Avoid bumping or dropping it.

Summary of markings

Markings	Autoclavable	Single-use
Expiratory valve		2
	SN serial number	REF part number
	REF part number	LOT batch number
Expiratory flow sensor		2
	SN serial number	REF part number

Markings	Autoclavable	Single-use
	REF	LOT batch number

After a cleaning / disinfection cycle (immersion, autoclave, etc.), the hot wire expiratory flow sensor must be thoroughly dried before being reinstalled, connected to the expiratory valve Monnal EVA, and connected to the ventilator.

Make a visual check to ensure that the various components are in good condition.

Sterilization of the reusable expiratory flow sensor and expiratory valve assembly before the first use is recommended.

Preparation

Remove the expiratory assembly from its housing by pressing the eject pushbutton.

Separate the expiratory flow sensor (67) from the expiratory valve Monnal EVA, and then remove the valve body (68) and the membrane (69).

Pre-disinfection / Cleaning

- 1. Immerse the expiratory assembly components (67,68,69) in a pre-disinfectant solution: Air Liquide Medical Systems recommends the use of ANIOS products: ANIOSYME DD1, SALVANIOS PH7, HEXANIOS G+R (obey product manufacturer instructions).
- 2. Shake the pre-disinfected components thoroughly in a cleaning solution*,
- 3. Rinse under running water*,
- **4.** Dry the components fully.

*except the expiratory flow sensor

Sterilization

If necessary, sterilize the following parts of the expiratory assembly (compatible with sterilization for 18 min at 134°C and 1 bar above atmospheric pressure): expiratory flow sensor, valve body and membrane.

Reassembly

Reassemble the expiratory assembly.



CAUTION: Incorrect reassembly of the expiratory assembly (incorrect positioning of the diaphragm in the valve body, omission of the silicone disc, placement of an additional silicone disc, etc.) may result in degraded equipment performance.

9.4 Monnal Clean'in filter (Type filtre HEPA: High- Efficiency Particulate Air)

The Monnal Clean'in filter is an air filter that is used to purify the air at the turbine's intake.

It blocks 99.97% of all particles.

Air Liquide Medical Systems recommends checking this filter every three months.

A place on the filter's label enables the user to indicate an installation date.

The Monnal Clean'in filter must be replaced at least once per year.

CAUTION: The Monnal Clean'in filter may not be disinfected, cleaned, or sterilized.

Replacing the filter

Remove the filter assembly from its housing with the help of the drawer and replace it.

9.5 Air intake filter

The air intake filter must be managed and cleaned every three months.

To access to the filter, remove the rear panel.



Two cleaning methods are recommended:

- Remove the filter from its housing, and wash it using warm soapy water. Rinse under running water. Make sure that the filter is fully dry before reinstalling it.
- Remove the filter from its housing and use an air jet to remove any particles trapped in it, and then reinstall the filter.

9.6 Bacteriological filter

Apply manufacturer recommendations concerning the frequency of replacement of the bacteriological filter. Refer to the user instructions supplied with the filter.

10 Accessories

Air Liquide Medical Systems recommends using the following consumables and accessories with the *Monnal 175*.



CAUTION: The use of non-recommended parts may result in degraded performance. It is the user's responsibility to verify the compatibility of the ventilator and all parts used to connect the patient prior to using the ventilator.

10.1 Items included in the package

Package contents:

- 1 × Monnal T75 ventilator
- 1 Monnal Clean'In (HEPA) filter
- 1 user manual
- 1 Monnal EVA expiratory valve
- 1 expiratory flow sensor
- 1 power cable
- 1 specific gas connector

10.2 List of consumables

Consumables	Reference
Expiratory assembly	
Autoclavable expiratory flow sensor	KY632200
Autoclavable expiratory valve Monnal EVA (per unit)	KY694500
Group of 5 single-use expiratory valves Monnal EVA	KY694800
Group of 20 single-use expiratory valves Monnal EVA	KY694900
Group of 5 single-use expiratory flow sensors	KY664500
Group of 20 single-use expiratory flow sensors	KY664600
Membrane Monnal EVA x 5	KY665300
Batch of five lip seals	YJ073300
02 Cell	
Oxygen cell (electrochemical O2 sensor)	YR049700
Filters	
Oxygen filtrabloc	KB002800
Monnal Clean'In filter (HEPA filter, per-unit)	KB030100

Consumables	Reference
Group of 6 air intake filters	KY650300
Group of 50 bacteria filters (inspiratory output)	KV103300
Air intake filter mount	KY652700
Patient circuits	
Group of 20 single-use adult-patient circuits, 1.6 meter without any water-trap, but with a smooth inside surface	KG020100
Can be connected to a pneumatic nebulizer	
Group of 20 single-use child-patient circuits, 1.6 meter without any water-trap, but with a smooth inside surface	KG020200
Can be connected to a pneumatic nebulizer	
Group of 10 single-use adult-patient circuits, 1.6 meter	KG019300
with inspiratory/expiratory water trap	
Group of 12 single-use child-patient circuits, 1.6 meter with inspiratory/expirato- ry water trap	KG019400
Can be connected to a pneumatic nebulizer	
Group of 15 single-use adult-patient circuits, 1.6 meter with a water-trap on the inspiratory circuit and a corrugated surface expiratory circuit	VD315100
Cannot be connected to a pneumatic nebulizer	
Group of 10 single-use child-patient circuits 1.5 meter	VD317600
With a water-trap on the inspiratory circuit and a corrugated surface expiratory surface	
Cannot be connected to a pneumatic nebulizer	

10.3 List of accessories

Accessories of the EM system	Reference
IRMA™ probe	KB020400

Other accessories	Reference
For other available accessories, please contact Air Liquide Medical Systems for a catalogue	KY665000

Pneumatic nebulizers	Reference
Group of 20 single-use pneumatic nebulizer	KB025200
Ultrasonic nebulizer	
Autoclavable Aerogen nebulizer, France	KB028600
Single-use Aerogen nebulizer, FR/DE/NL/IT	KB029300

Humidifiers	Reference
Heating humidifier MR850 230V EU, FR / ES / EN	VD324500
Heating humidifier MR850 115V US, PT / ES / EN	VD324600
Heating humidifier MR850 230V EU, IT / ES / PT	VD324700

CO2 monitoring option	Reference
Monnal T75 IRMA [™] CO2 probe	KB020400
Monnal T75 CO2 monitoring software option	KB034000
UU adult / pediatric adapters for the IRMA [™] CO2 probe (x25)	KB020300
UU infant adapters for the IRMA [™] CO2 probe (x10)	KB032800

10.4 List of available documents

User manuals	Reference
Addition to Philips' communication protocol	YL075500

11 Maintenance

Certain maintenance operations are the responsibility of the user, whilst others must be performed by a technician.

For any operation requiring the ventilator to be opened, call on a technician.

Air Liquide Medical Systems holds available to maintenance staff a maintenance manual containing the circuit diagrams, component lists, descriptions, calibration instructions and all other information relevant to maintenance staff.

11.1 By the user

The user must:

- · Drain the patient circuit water traps as often as necessary,
- Clean, disinfect and sterilize the re-usable components after each patient: the patient circuit, the expiratory flow sensor and the expiratory valve Monnal EVA (see <u>Expiratory assembly: flow sensor</u> + expiratory valve Monnal EVA on page 93);
- After each patient, change the items that are not re-usable (circuit, filters, expiratory valve, expiration flow rate sensor, CO2 IRMA[™] measurement probe airway adapter)
- · Replace the bacteriological filter according to manufacturer recommendations,
- · Replace the O2 sensor and expiratory flow sensor in the event of failure
- Replace the Monnal Clean'in filter (see <u>Monnal Clean'in filter (Type filtre HEPA: High- Efficiency</u> <u>Particulate Air)</u> on page 94;
- · Replace the air intake filter (see Air intake filter on page 95);
- Check the remaining battery capacity approximately every six months (start ventilation, and check that battery capacity is adequate) (see below),
- The battery must be replaced after 500 charge/discharge cycles.
- · Replace lip seal every three months.
- Go through a checklist before each use (see <u>Checklist</u> on page 135).

11.1.1 Battery life check

In order to assist users to check battery life, an acknowledgeable alarm 'Perform battery test!' is triggered every 6 months, and prompts users to perform a battery test.

This test is accessible in Standby mode by pressing the [Menu] and [Machine Configuration] keys.



Note: To access the test, the device must be connected to the AC power supply, and the battery must be fully charged. The test may last for more than 3 hours.

Once the test selected, a window is displayed, and users may start or cancel the test.



Note: Do not connect to other devices (patient circuit). Do not disconnect the device from the AC power supply.

When the test starts, the device will automatically switch to its internal battery. Discharge it completely then automatically switch to the AC power supply. A window displays a figure indicating the remaining battery life, compared to a new battery (3 hours' battery life on standard ventilation as indicated in the technical description in this manual).

100%	The battery is fully operational
75%	75% battery life remaining, does not need to be replaced.
50%	50% battery life remaining.The conditions of use of the battery must be taken into consideration when deciding whether to replace it or not:If the battery is never used apart from in the test (permanently connected to the AC power supply, back-up supply), the remaining battery life may be sufficient.If the battery is used often, during intra-hospital transfer of variable duration, it may be necessary to replace it.
25%	The battery has reached its operating limit. Please replace it.

In order to preserve a record of the test performed, the information is permanently displayed next to the **[Battery test]** access key, and includes remaining battery life and test date.



Note: This test resizes the battery charge indicator displayed on-screen: for example, if the battery is down to 50% of its initial charge, no more than three of the five pictogram cells can be lit. This function keeps the user aware of the overall state of the battery.

11.2 By the technician

Servicing once a year and checking the operation and performance of the unit.

The ventilator counts two operational parameters: number of hours of ventilation, and number of hours that the machine is powered up.

These times can be viewed at any time in the stand-by screen.

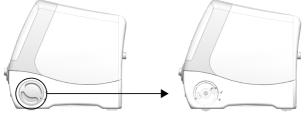
The internal battery must be replaced after 500 charge/discharge cycles or 3 years (whichever comes first), and this replacement must be performed by a qualified technician. For more information, refer to the maintenance manual.

11.3 O2 cell



Note: The working life of the O2 cell is approximately 5000 hours, but this can vary according to the oxygen concentration used and the ambient temperature.

1. To open the compartment, press the cover down slightly and turn towards the • I symbol.



- 2. Disconnect the used sensor and then unscrew it to remove it from its housing.
- **3.** Replace it with a new sensor, referring to the instructions on the packaging of the new sensor if necessary.
- 4. Tighten the sensor properly in order to prevent leakage, and then connect it.
- 5. To close the cover, press it down slightly (with the arrow pointing to $\bullet \textcircled{1}$) and turn it until the arrow points to $\bullet \textcircled{1}$.
- 6. Run the sensor calibration automatic test.

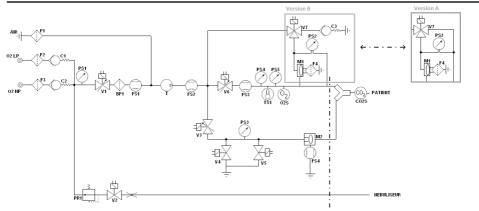
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Note: It is recommended that you calibrate the O2 sensor frequently via the automatic test.

12 Technical description

12.1 Operation

12.1.1 Pneumatic system



AIR	Ambient air intake	PATIENT	Patient
02 LP	Low-pressure oxygen inlet (concentrator)	NEBULISEUR	Nebulization outlet (calibrated coupler) to which the nebulizer is connected
02 HP	High-pressure O2 inlet (network, cylinder)		
BF1	Bronze filter (laminar flow)	PS1	02 pressure sensor
C1	Non-return valve	PS2	Differential pressure sensor
C2	Non-return valve	PS3	Balloon pressure sensor
C3	Non-return valve		
F1	Air intake filter (microfilter)	PS4	Airway inspiratory pressure sensor
F2	O2 inlet filter (oxygen concentrator)	PS5	Airway inspiratory pressure sensor (redun- dancy
F3	02 inlet filter (compressed gas)	Т	Turbine
F4	Air intake filter	TS1	Patient gas temperature sensor
FS1	O2 flow sensor	V1	Oxygen regulating proportional solenoid valve
FS2	Blower flow sensor	V2	Nebulization on/off solenoid valve
FS3	Patient flow sensor	V3	PEEP control proportional solenoid valve
FS4	Hot wire expiratory flow sensor	V4	PEEP control on/off solenoid valve

M1	Membrane	V5	Bleed on/off solenoid valve (redundancy)
M2	Membrane	V6	Inspiratory phase control proportional sole- noid valve
02S	Oxygen sensor	V7	3/2 on/off patient venting solenoid valve (MAP)
PR1	Pressure regulator (reducer):	C02S	Carbon dioxide sensor

12.1.2 Ventilation operation

The blower (T) of the ventilator entrains ambient air via the microfilter (F1) and compresses it according to the patient and the settings concerned. The compressed gas is then distributed via a pneumatic network according to whether an inspiratory or expiratory phase is being delivered.

Inspiratory phase

The main component during the inspiratory phase is the solenoid valve (V6) which regulates the flow rate via the flow sensor (FS3) when the selected mode is volume-controlled, or via the pressure sensor (PS4) when the selected mode is pressure-controlled.

At the same time, the solenoid valves (V3), (V4) and (V5) are open, closed, and closed respectively such that the blower pressure is applied to the membrane (M2) of the expiratory valve, thus forcing the air sent via the solenoid valve (V6) to flow towards the patient only.

Expiratory phase

In this phase, the patient exhales the gases inhaled in the previous phase, and the unit is expected to regulate to a pressure determined by the settings (PEEP).

With this in mind, the solenoid valve (V4) opens to depressurise the membrane (M2) and the PEEP control proportional solenoid valve (V3) regulates the expiration pressure via the pressure sensor (PS4).

At the same time, the inspiratory electromagnet regulates the flow via the flow sensor (FS3) for a rinse flow of 3 L/min. This flow limits reinhalation and allows quick detection of an inspiratory demand.



Note: During ventilation with leakage, such as NIV, the solenoid valve (V6) is liable to increase the rinse flow; it then enters an "on-demand valve" mode. The purpose of this function is to compensate for leaks in order to maintain the PEEP in the circuit.

Obstruction management

Version A:

In normal operation, solenoid valve (V7) connects the turbine pressure to diaphragm (M1), which plugs the safety ambient air intake. If the patient needs to be vented to atmosphere, solenoid valve (V7) connects diaphragm (M1) to the patient. On each inspiratory effort by the patient, the safety ambient air intake opens and the patient can breath freely through the device.

Version B:

In normal operation, solenoid valve (V7) connects the turbine pressure to diaphragm (M1), which plugs the safety ambient air intake. If the patient needs to be vented to atmosphere, solenoid valve (V7) connects diaphragm (M1) to the atmosphere, which opens the ambient air intake and depressurises the patient's airways. In the special case of an obstruction in the expiratory limb, once the pressure in the airways reaches atmospheric pressure, ventilation continues in accordance with the mode selected by the operator. This is the backup ventilation system: the patient exhales through the ambient air intake valve. Patient exhalation periodically occurs through the expiratory valve, to check how it is functioning and permit normal ventilation when there is no longer an obstruction.

Note: Because it is possible to exhale through the ambient air intake valve in backup ventilation mode, Air Liquide Medical Systems recommends that a bacteria filter always be inserted at the point of connection with the inspiratory limb to avoid contamination of the ventilator. Since exhalation occurs through the inspiratory limb in backup mode, part of the expired gas is reinhaled. The inspiratory trigger is disabled and a minimum backup frequency is maintained. Oversight and monitoring linked to the exhaled flow are altered.

Version B of patient venting applies from Monnal T75 device no. MT75-05000.

- · A lower serial number identifies the device as version A.
- A higher serial number identifies the device as version B.



Note: For more information, contact Air Liquide Medical Systems.

12.1.3 Air/O2 mixture

The O2 concentration of the gases administered to the patient depends on the source connected to the unit. A distinction is made between O2 network operation and concentrator operation.

Operation on an O2 network

For proper operation, the pressure at the O2 inlet terminals (O2 HP) must be between 2.8 and 6 bar. The O2 is then filtered via F3.

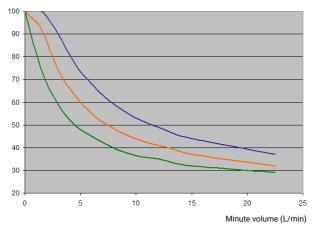
The proportional solenoid valve (V1) enriches the mixture in oxygen by regulating the flow via the flow sensor (FS1), where the set-point is proportional to the upstream flow rate (FS2) and depends on the FiO2 setting.



Note: Operation at a network pressure between 1.5 and 2.8 bar or between 6 and 7 bar is possible, but the quality of enrichment might be affected. If the pressure falls below 1.5 bar or goes above 7 bar, the oxygen supply is cut off by the proportional solenoid valve (V1) and an oxygen supply error alarm is triggered.

Operation with a concentrator

The ventilator is equipped with a "low pressure" connector for working with a flow meter (intake via the filter (F2)). The principle of precise control of the O2 concentration applied at high pressure is maintained when operating with a low-pressure source, with the device constantly delivering a mix at the correct FiO2.



However, it may well be that the mix concentration cannot be achieved since it depends:

- on the type of concentrator and its settings (the 02 flow rate delivered by the concentrator is often low and its 02 concentration variable [between 90 and 100%]);
- on the ventilation parameters.

The following graph shows the maximum concentrations that can be obtained with different concentrator flow rates (based on an O2 concentration of 100%) according to the minute volume of a patient ventilated at the frequency of 15 bpm.

For example, for a concentrator delivering 5 L/min and a patient ventilated in volumetric mode with a Vt of 0.5 L and a frequency of 15 bpm (i.e.: a minute volume of 0.5x15 = 7.5 L/min), the maximum concentration that may be obtained will be approximately 50%. The device will then be capable of delivering any required concentration below this value.



Note: Since the device only consumes the flow that it needs to ensure correct concentration of the mixture, Air Liquide Medical Systems recommends that the low-pressure source be adjusted to its maximum flow rate. This will make it possible to obtain a wider range of possible Fi02.

Whatever the function mode for the device, the oxygen sensor (O2S) ensures monitoring of the FiO2 concentration in the circuit.

This sensor is a chemical cell where an electrolytic reaction occurs. The current produced is proportional to the partial pressure of oxygen.

However a compensation of this pressure is applied each time the automatic tests are lauched. Ambient humidity also affects the oxygen measurement at the rate of -0.03% per%Hr, at 25°C (see <u>Measured parameters</u> on page 122).

12.1.4 Special characteristics of nebulization

The O2 supply pressure (O2 HP) is reduced in the nebulization branch by the pressure reducer (PR1) at a pressure of 1 bar.

The nebulization on/off solenoid valve (V2) provides nebulization via its open and closed positions. The nebulization flow rate then depends on the nebulizer used.

12.1.5 CO2 monitoring

The CO2 (CO2S) sensor ensures monitoring of the CO2 concentration during the expiration of the patient.

12.2 Electrical power sources

he ventilator is compatible with various electrical power sources:

- Mains supply;
- Power supply on an external DC source (external battery);
- Power supply on an internal DC source (internal battery).

The electrical characteristics of each of these sources are described in <u>Electrical specifications</u> on page 112.



Note: If the unit suddenly shuts down during ventilation (e.g. battery empty), when the unit is reconnected to the external or auxiliary power and restarted, it automatically resumes ventilation with the last parameters saved.

12.2.1 Power supply management

The supply board manages the energy source changeover automatically according to the hierarchy as follows:

- 1. Mains supply;
- 2. In the event of failure, power supply from external battery;
- 3. In the event of failure, power supply from internal battery.

12.2.2 Mains supply

Two pictograms indicate whether or not the mains power supply is present.

∠	Mains present
/	Mains absent

12.2.3 Internal battery

In the event of absence of the mains and the external source, the switch to internal battery is indicated by a low-priority acknowledgeable alarm "Ventilator operates from internal battery!".

The charge status of the internal battery is then indicated in the upper left-hand part of the screen (example based on a new battery):

Full battery charge
Comfortable battery charge
Medium battery charge
Battery low - connect the unit to the mains power supply. Associated with a medium-priority acknowledgeable alarm "Internal battery nearly dis- charged!"
Battery dangerously low - imminent shutdown Associated with high-priority acknowledgeable alarms "Internal battery discharged!!! Connect AC power" and then "Internal battery inoperative!!! Connect AC power" It is then urgent to connect the ventilator to the mains or to an external battery to prevent it from shutting down due to a lack of power.

When the unit is connected to the mains or an external battery, the unit's internal battery recharges. A special pictogram appears on the screen to show the progress of light segments (example based on a new battery):

3 3 3 3 3	Battery discharged
	Battery half-charged
	Battery fully charged

In the event of operation at a high ambient temperature, a safety device might limit the battery charge. This can have a significant effect on the charging time and operating duration of the battery.

 (\mathbf{i})

Note: The battery takes about 10 hours to charge (at ambient 25°C).

When the unit is switched off but connected to the mains or an external battery, the internal battery automatically recharges.

If the unit cannot recharge the battery because the battery is absent or defective, the following pictogram appears on screen:

Battery unavailable
Associated with a high-priority alarm 'Internal battery unavailable!!! Check battery'

12.2.4 External battery

The *Monnal T75* medical electrical equipment may be connected to a separate external power supply to create a medical electrical system.

Two icons indicates the absence or presence of an external source.

Ū.	Presence of an external battery
	Presence of an external battery

In case of a power-supply disconnection, the changeover to the external battery is indicated with a lowpriority acknowledgeable alarm "Ventilator operates from external battery".

12.3 Inputs and outputs

12.3.1 Alarm transfer

Description of the alarm transfer function

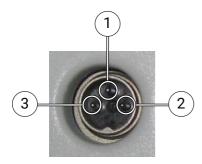
The alarm transfer function uses a dry contact to send an alarm from the ventilator to an external module. The contact is either closed, allowing the flow of a current generated by the external module, or open, preventing the current from flowing. This contact is accessible via the three-pin socket located at the back of the unit.

Breaking capacity

The relay is used to switch from a maximum voltage of 24 V with a maximum current of 250 mA.

Pin configuration of the "alarm transfer" connector

Mechanical arrangement (view from rear of ventilator)



Idle (without alarm)

- The contact located between the "NC" (3) output and "Common" (2) is closed.
- The contact located between the "NO" (3) output and "Common" (2) is open.

12.3.2 RS232 link

The RS232 link of this ventilator allows data input ((1), software updates) and output ((2), sending of machine data).



Software updates

The ventilator software is updated via the RS232 link using standard IT tools.

Technical features:

- Speed: 115200 bps
- Parity: none
- Format: 8 bits; 1 start bit; 1 stop bit
- Flow check: No



Note: With regard to the RS232 link, the use of an accessory that is not compliant with the safety requirements of this ventilator can bring about a reduction in the safety level of the resulting system.

The following factors should be considered when choosing the accessory:

- · Its use near the patient
- Certainty that its safety certification was carried out in compliance with the local standards in force and/or the EN 60601-1 standard as well as IEC 60950-1
- Do not apply any abnormal voltage to the RS232 connector (15 V max.).

12.3.3 Connectivity to hospital networks

This ventilator incorporates a communication protocol for sending data to data-collection software or external monitoring systems.

Choice of protocol

From the "Admin Config" menu, select the protocol which corresponds to the external device, using the encoder wheel:

- OTP,
- Monnal Link,
- VueLink/Intellibridge EC10.

Contact the information system manager to select the appropriate protocol.

Connecting the communication module

Connect the cable supplied by the manufacturer of the communication module to RS232 connector no. 1 on the *Monnal* **T75** and then connect the other end of the cable to the external device.

Do not leave the cable connected to the *Monnal T75* without connecting it to an external device, in order to prevent electromagnetic interference.

Air Liquide Medical Systems protocols

The Monnal T75 includes the following Air Liquide Medical Systems communication protocols:

- OTP,
- Monnal Link.

These protocols are available upon request.

For more information, contact almedicalsystems.services@airliquide.com.

Information transmitted

The information transmitted is as follows:

- · ventilation set-points,
- alarms,
- · alarm thresholds,
- · all measurements apart from time curves.

Compatible communication modules

- Capsuletech Datacaptor (OTP protocol),
- · Philips monitors (VueLink/Intellibridge Protocol EC10),
- Mindray (OTP protocol).

To obtain a full list of the communication modules compatible with the *Monnal T75*, contact the manufacturer.

A hospital network failure can result in no data being transmitted (alarms and monitoring) to the external device.

Connection to a hospital network which includes other apparatus could give rise to previously unidentified risks to patients, operators or third parties.

The user should identify, analyze, evaluate and control such risks. Subsequent modifications made to the hospital network could introduce new risks and require additional analysis. Modifications to the hospital network include:

- · modifications to the configuration of the external device;
- · the connection of additional units to the external device;
- · the disconnection of units from the external device;
- the updating of devices connected to the external device;

• the correction of devices connected to the external device.

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12.3.4 Video output

The video output is located on the back panel of the unit: a remote screen can be connected via this output in order to display an image of the ventilator screen.



12.4 Performances and characteristics

12.4.1 Regulatory requirements

Directives

European Council Directive 93/42/CEE concerning medical devices.

Directive 2012/19/EU of the European Parliament and Council concerning Waste Electrical and Electronic Equipment (WEEE).

Standards

The compliance of *Monnal T75* with the essential requirements of Directive 93/42 is based on the following standards:

EN ISO 14971 | Application of risk management to medical devices

EN ISO 60601-1 | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

EN ISO 80601-2-12 | Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical-care ventilators.

EN ISO 80601-2-55 | Medical electrical equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors.

Device class: IIb

Service life of Monnal T75: 7 years.

Year of Monnal T75 (Ref. KB022600) CE marking: 2008

Year of Monnal T75 with CO2 option (Ref. KB033600) CE marking: 2013

12.4.2 Recovery of the components of the medical device

Recovery of the components of the medical device

Characteristics of the packaging

Box for transportation (993 g) and wedge (650 g):

- Recycled paper
- Recyclable

Protective foam (1580 g):

- Polyethylene
- Recyclable

Method of recovery for consumable items

All used consumable items from use of this ventilator (the patient circuit, the bacteriological filters, etc.) must be collected in the hospital's appropriate disposal channels. The packaging waste for the device and for its accessories must be disposed of in the hospital's appropriate disposal channels.

Shipping equipment

Air Liquide Medical Systems recommends that the user keep the original packaging.

If the medical device is returned, always use the original packaging. Otherwise, contact your Air Liquide Medical Systems representative to obtain replacement packaging.

Equipment modifications



CAUTION: It is prohibited to alter the Monnal T75 equipment.

Accessories

The accessories used with this ventilator must comply with the general requirements of European directive 93/42/CEE, as well as EN 60601-1 and collateral standards.

Accessories from the Air Liquide Medical Systems catalog or included in the accessories kit delivered with the ventilator comply with these requirements. The use of accessories not recommended by Air Liquide Medical Systems releases Air Liquide Medical Systems from all liability in the event of an incident.

The user is responsible for ensuring that the use of accessories does not affect the safety and the expected performance of the ventilator.

The inspiratory and expiratory resistance measurements of this respiratory were taken using a standard adult patient circuit and a bacteriological filter (KV103300).



CAUTION: The addition of intermediate parts or other components or assemblies to the respiration system of the ventilator may change the pressure gradient of the system which may have a negative impact on the performance of the ventilator.

The prescriber must ensure that the assembly thus obtained complies with IEC 80601-2-12. Items included in the package.

12.4.3 Technical characteristics

12.4.3.1 General specifications

Dimensions (Lxwxh)	40x30x35 cm
Mass	16 kg
Audible sound level	48 dB at 1 m
Operating conditions	

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	-
Temperature	+10°C to +40°C (+50°F to +104°F) (See warning under table)
Relative humidity	0 to 90% without condensation at 40°C max.
Atmospheric pressure	700 to 1060 hPa
Storage and transport condition	ons
Temperature	-20°C to +70°C (-4°F to +158°F)
Relative humidity	0 à 90% without condensation at 40°C max
Atmospheric pressure	500 to 1060 hPa
Turbine and screen	•
Turbine warranty	40000h or 5 years (whichever comes first)
Control	Resistive tactile pad
Screen	Color 10.4", 640*480 pixels
Protection	•
Protection index	IP3X (if the serial number is less than MT75-05000)
	IP31(if the serial number is greater than MT75-05000)
Applied parts according to IEC	60601-1
Applied parts	The respiratory system of the Monnal T75 ventilator is a type B applied part.
	The CO2 probe of the <i>Monnal T75</i> is a type BF applied part

CAUTION: Ambient temperature warning: the temperature of the *Monnal T75* delivery flow can exceed that of the room. Exercise extreme caution when using the *Monnal T75* at ambient temperatures above 38 C (100.4° F).

At an ambient temperature of 38 C or higher, gas temperature can climb as high as 43 C, depending on the settings. The 43°C limit can never be exceeded. In such conditions, humidification or nebulization may not be effective. When ambient temperature exceeds 38°C, Air Liquide Medical Systems recommends use of HME filters.

12.4.3.2 Electrical specifications

Main power supply		
Input voltage	100 - 240 V AC +/- 5%	
Frequency	50 to 60 Hz	
Electrical power consumption	250 VA	
250 VA	T 16 A	
External power supply fuse (x1)	T 3,15 A, 250 V	
Т 16 А	0,25 A FST	

Main power supply	
Main fuses (x2)	T 3,15 A L, 250 V
Electrical class	I
Туре	A
Leak current	IEC 60601-1 compliant
Protection following a loss of power	Continuous audible alarm and patient vented to atmosphere
Internal battery (Air Liquide ref. KY633300)	
Туре	NiMh
	Rated voltage: 24 V
	Rated capacity 2X4500 mAh
Battery capacity (new and charged battery) with	3 h typical
the standard ADULT configuration	Ambient temperature: 25°C
Charging time (h)	10 h typical (according to environmental condi- tions)
Isolation	
Separation from the power supply	To electrically separate the Monnal T75 from the power supply, disconnect the flexible power cable.

12.4.3.3 Electromagnetic Compatibility

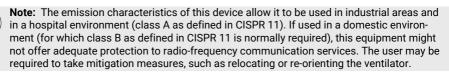
All of the information set out below was obtained from the normative requirements to which the manufacturers of electro-medical devices are subject, within the meaning of standard IEC 60601-1-2 Ed4.

The medical device is compliant with the electromagnetic compatibility standards in force; nevertheless the user shall ensure that any electromagnetic interference does not create an additional risk, such as radio-frequency transmitters or other electronic devices.

In this section you will find the information required to ensure that the installation and putting into operation of your medical device is carried out under the best possible conditions in terms of electromagnetic compatibility. The various leads attached to the medical device must be separated from each other.

Certain types of telecommunications mobile devices such as mobile phones may interfere with the medical device. The recommended separation distances in this section must therefore be strictly observed.

The medical device must not be used in close proximity to other equipment or placed on top of other equipment. If this cannot be avoided, its operation under the conditions of use must be checked beforehand. The use of accessories other than those specified or sold by *Air Liquide Medical Systems* as replacement parts may have the consequence of increasing the emissions or decreasing the immunity of the medical device.





CAUTION: Exceptional electromagnetic disturbance may degrade ventilation performance.



CAUTION: RF hand-held communication devices should not be used (including peripherals such as antenna cables and external cables) within a radius of 30 cm (12 inches) of any part of the *Monnal T75*, including the cables specified by the manufacturer. Otherwise, the performance of this equipment may be impaired.

Length of cables



CAUTION: These accessories and cables must be used with the *Monnal* **T75**. Their use with other medical electrical equipment may increase the emissions of the equipment or decrease its immunity.

Accessories and ca- bles used during test- ing	Max- imal length	Test type	in compliance with
Monnal T75 equip-	3 m	RF Emission	CISPR 11, Class B
ment:		Emission of harmonic currents	IEC 61000-3-2
Power cable (3 m) - KY120500		Voltage fluctuation and voltage flickers	IEC 61000-3-3
		Electrostatic discharge immunity	IEC 61000-4-2
		Radiated immunity – Electromagnetic fields	IEC 61000-4-3
		Electrical fast transient/burst immunity	IEC 61000-4-4
		Surge immunity	IEC 61000-4-5
	Immunity to conducted disturbances, induced by radio-frequency fields	IEC 61000-4-6	
	Radiated immunity - Magnetic fields	IEC 61000-4-8	
		Immunity to voltage dips, short inter- ruptions and voltage variations	IEC 61000-4-11

Recommended separation distances

The medical device is intended for use in an electromagnetic environment in which the disturbances due to RF radiation are controlled.

The user or installer of the medical device can help prevent electromagnetic interference by maintaining a minimum distance, according to the maximum output power of the radio-frequency transmission equipment. RF hand-held communication devices should not be used (including peripherals such as antenna cables and external cables) within a radius of 30 cm (12 inches) of any part of the **Monnal 775**, including the cables specified by the manufacturer. Otherwise, the performance of this equipment may be impaired.

Electromagnetic emissions

The medical device is intended for use in an electromagnetic environment described in the table below. The user and installer must ensure that the medical device is used in the environment described below.

Emission test	Compliance	Electromagnetic environment - comments
Electromagnetic radiation dis- turbance(Radiated emissions) (CISPR 11)	Group1	The medical device uses RF en- ergy for its internal operation. Consequently, its radio frequen- cy emissions are very low and are not likely to create any inter- ference with neighboring equip- ment.
Power terminal disturbance voltage (Conducted emissions) (CISPR 11)	Class B	Home health care environment and a professional health care establishment environment.
Emission of harmonic currents (IEC 61000-3-2)	Class A	
Voltage changes, voltage fluctuations and flicker (IEC 61000-3-3)	Compliant	

Magnetic and electromagnetic immunity

The medical device is intended for use in a magnetic and electromagnetic environment described in the table below. The user and installer must ensure compliance of the electromagnetic environment.

Immunity test	Test level according to IEC 60601	Compliance level	Electromagnetic envi- ronment/comments
Electrostatic dis- charges (ESD) (IEC 61000-4-2)	± 8 kV contact dis- charge ± 15 kV air discharge	± 8 kV contact dis- charge ± 15 kV air discharge	Professional health care establishment en- vironment.
Electrical Fast Tran- sient/Burst (IEC 61000-4-4)	± 2 kV for electrical power lines	± 2 kV for electrical power lines ± 1 kV for signal ports	
Surges (IEC 61000-4-5)	± 1 kV in Differential mode	± 1 kV in Differential mode	
	± 2 kV in common mode	± 2 kV in common mode	
Assigned industrial fre- quency magnetic field (IEC 61000-4-8)	30 A/m	30 A/m	

Immunity test	Test level according to IEC 60601	Compliance level	Electromagnetic envi- ronment/comments
Voltage dips, short in- terruptions and volt- age variations (IEC 61000-4-11)	0% UT for 0.5 cycles A 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle 70% UT for 25 cycles at 50 Hz For 30 cycles at 60 Hz Single phase: at 0°	0% UT for 0.5 cycles A 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle 70% UT for 25 cycles at 50 Hz For 30 cycles at 60 Hz Single phase: at 0°	Professional health care establishment en- vironment. If use of the system re- quires continued oper- ation during power sup- ply cuts, the use of a separate power source to power the medical device is recommend- ed (UPS, etc.).
Voltage interruptions (IEC 61000-4-11)	0 % UT; for 250 cycles at 50 Hz for 300 cycles at 60 Hz	0 % UT; for 250 cycles at 50Hz for 300 cycles at 60 Hz	Professional health care establishment en- vironment. If use of the system re- quires continued oper- ation during power sup- ply cuts, the use of a separate power source to power the medical device is recommend- ed (UPS, etc.).

Electromagnetic immunity, portable radio-frequency equipment

The medical device is intended for use in a magnetic and electromagnetic environment as described in the table below. The user and installer must ensure compliance of the electromagnetic environment.

Immunity test	Test level	Compliance level	Electromagnetic envi- ronment/comments
WARNING: RF hand-held communication devices should not be used (including peripherals such as antenna cables and external cables) within a radius of 30 cm (12 inches) of any part of the Monnal 775 , including the cables specified by the manufacturer. Otherwise, the performance of this equipment may be impaired.			
Radiated, radio-fre- quency, electro- magnetic fields (IEC 61000-4-3)	3 V/m 80 MHz to 2.7 GHz 80 % MA to 1 kHz 10 V/m 80 MHz to 2.7 GHz 80 % MA to 1 kHz	3 V/m 80 MHz to 2.7 GHz 80 % MA to 1 kHz 10 V/m 80 MHz to 2.7 GHz 80 % MA to 1 kHz	Professional health care establishment en- vironment.

Immunity test	Test level	Compliance level	Electromagnetic envi- ronment/comments
Proximity fields from RF wireless commu-	9 V/m	9 V/m	
nications equipment	710 MHz, 745 MHz,	710 MHz, 745 MHz,	
(IEC 61000-4-3 interim method)	780 MHZ, 5240 MHz,	780 MHZ, 5240 MHz,	
,	5550 MHz, 5785 MHz	5550 MHz, 5785 MHz	
	27 V/m	27 V/m	
	385 MHz	385 MHz	
	28 V/m	28 V/m	
	450 MHz, 810 MHz,	450 MHz, 810 MHz,	
	870 MHz, 930 MHz,	870 MHz, 930 MHz,	
	1720 MHz, 1845 MHz,	1720 MHz, 1845 MHz,	
	1970 MHz, 2450 MHz	1970 MHz, 2450 MHz	
Conducted distur- bances, induced by ra-	3 V	3 V	
dio-frequency fields (IEC 610004-6)	150KHz to 80MHz	150KHz to 80MHz	
	6 V ISM bandwidth and bandwidths between 0.15 MHZ and 80 MHZ, including amateur ra- dio bandwidths 80% MA to 1 KHZ	6 V ISM bandwidth and bandwidths between 0.15 MHZ and 80 MHZ, including amateur ra- dio bandwidths 80% MA to 1 KHz	

The electromagnetic field strengths of fixed radio-frequency transmitters, as determined by a survey of the electromagnetic environment (a), must be below the compliance level for each frequency range. Interference may occur close to equipment identified by the following symbol:



Comment: These specifications may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

(a) The electromagnetic field strengths of fixed radio-frequency transmitters, such as base stations for mobile phones (cellular/wireless), mobile radios, amateur radio operators, AM/FM radio broadcasts and TV broadcasts cannot be determined accurately through theory. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be carried out. If the intensity level of the radio-frequency field in the immediate environment in which the product is being

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used exceeds the radio-frequency compliance level specified above, the product performance must be tested in order to check whether or not it is compliant with the specifications. In the case of any abnormal performance of the device, additional measures may be necessary, such as reorienting or relocating the product.

12.4.3.4 Pneumatic specifications

High pressure (HP) and low pressure (LP) 02 inlets		
Type of gas fitting	NF, DISS, NIST (HP) Connector (LP)	
O2 pneumatic supply	2.8 - 6 bar / 280 - 600 kPa / 40 - 86 psi (HP) 0 – 1.5 bar / 0 – 150 kPa / 0 – 22 psi (LP)	
Required maximum flow rate (at atmospheric pressure)	105 L/min at 2.8 bar / 130 L/min at 6 bar (HP) 85 L/min at 1.5 bar (LP)	
Standalone mode	Cylinder (HP) Concentrator (LP)	
Mixer	Electronic, electrochemical O2 sensor	
Precision (% of set value)	< 3%	
Gas consumption(1)	Patient ventilation + 4 L/min. (flow-by + internal consumption)	
Connectors		
Inspiratory hose connector	ISO 22 mm male	
Expiratory hose connector	ISO 22 mm male	
Inspiratory and expiratory resistances(2)		
Resistances at 60 L/min (cmH2O)	Inspiratory: 3.9	
(Unit + single-use adult patient circuit KG019300)	Expiratory: 3.2	
Resistances at 30 L/min (cmH2O)	Inspiratory: 5.7	
(Unit + single-use paediatric patient circuit KG019400)	Expiratory: 4.9	
Pressure	·	
Maximum limited pressure (P lim max)	100 cmH20; blower performance limitation	
Maximum working pressure (P w max)	0-100 cmH2O	

High pressure (HP) and low pressure (LP) 02 inlets	
Minimum limited pressure (P lim min)	Back-up ambient air intake preventing a pressure drop in the patient circuit

(1) Consumption example:

- · For an adult, average consumption is 6 l/min of gas (air or oxygen;
- The flow-by + internal consumption of the unit is fixed at 4 l/min.

In the case of a B5 type cylinder being used, its volume is 5 litres. Because the gas is compressed to 200 bar, in this case we have 1000 litres of gas. In our example, we will therefore have approximately 1 hour 40 minutes of operating time if the ventilation is carried out at 100% oxygen concentration.

(2) The above-mentioned resistances take the ventilator and the circuit into account, but exclude any other intermediate accessory. For accessories other than those mentioned in this manual, please contact us. The test method is also available on request.

Compatibility of accessories (parts of the respiration system which can be removed and assembled by the operator)

Inspiratory resistance	Adult: max 5,5 cmH2O @ 30 L/min Child: max 5,5 cmH2O @ 15 L/min Infant: max 5,5 cmH2O @ 7,5 L/min
Expiratory resistance	Adult: max 10 cmH2O @ 30 L/min Child: max 6 cmH2O @ 15 L/min Infant: max 6 cmH2O @ 7,5 L/min
Compliance	6 mL/cmH20

12.4.3.5 Ventilation specifications

Ventilation modes	
VCV (controlled ventilation or assisted vol- ume-controlled ventilation)	VCV
PCV (controlled ventilation or assisted pres- sure-controlled ventilation)	PCV
SIMV (Synchronised Intermittent Mandatory Ven- tilation)	SIMV
PSIMV (synchronised intermittent mandatory pressure-monitored ventilation)	PSIMV
PSV (spontaneous ventilation with inspiratory as- sistance and PEEP)	PSV
Non-invasive ventilation	PSV NIV

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CPAP MODE (Continuous Positive Airway Pres- sure)	СРАР		
Ventilation at two pressure levels	Duo-Levels		
Pressure-regulated volume controlled ventilation	PRVC		
Spontaneous ventilation with inspiratory assis- tance, PEEP and servomechanism frequency	PS-Pro		
Airway Pressure Release Ventilation	APRV		
Inspiratory trigger system			
Main inspiratory trigger in flow rate, secondary in p	pressure:		
Turn the control wheel to set the inspiratory trigger cmH20. A pressure threshold	r to between 1 and 15 L/min or between 0.2 and 3 $$		
varying from 0.2 to 5 cmH2O is associated with it.			
At the time of a patient demand, satisfying one of an inspiratory cycle.	the conditions (flow rate or pressure) will trigger		
Expiratory trigger system			
During any spontaneous cycle, the switch to expiration occurs as soon as one of the following crite- ria is encountered:			
- expiratory flow trigger (Trig. E); Expiration as soon as the inspiratory flow rate reaches x% of peak inspiratory flow rate			
- expiratory pressure trigger (not adjustable): expiration as soon as an overpressure of 3 cmH2O is detected on the inspiratory			
pressure signal			
- expiratory time trigger (TI max.): expiration as soon as the insufflation time reaches the maximum Ti setting (Timax).			
Automatic Test			
Tests initialization	Checking the integrity of sensors to begin the tests		
Circuit rinsing	Eliminating the oxygen present in the system		
Pneumatic check	Checking the integrity of the actuators of the in- spiratory		
	and expiratory branches		
	Calibrating the oxygen and expiratory flow sen- sors		
Mixer check	Checking the mixer		

End of tests	Checking the safety mechanisms
	Compliance measurement
	Measurement of the resistance of the inspiratory and
	expiratory circuits and their accessories

12.4.3.6 Monitoring specifications

Adjustable on successive scales:
-10 to +10,
-20 to +20,
-40 to +40,
-80 to +80,
-160 to +160
Adjustable on successive scales:
0 to +20,
0 to +40,
0 to +60,
0 to +100
Adjustable on successive scales:
0 to +80,
0 to +100,
0 to +500,
0 to +1000
Adjustable on successive scales:
In mmHg in kPa in%
0 to +50, 0 to +7, 0 to +7,
0 to +150, 0 to +15, 0 to +15
Adjustable on successive scales:
0 to +3,
0 to +9,
0 to +24

Curves	
Loop curves	Pressure / Volume
	Volume / Flow rate
	Flow rate / Pressure
	CO2/Volume (only for KB033600)
Monitoring	·
Conditions for measurement of flows and vol- umes	BTPS
Data storage	
Trends	Simultaneous display of two parameters mea- sured during a maximum period of 80 h. All measured parameters are accessible.
Alarm log	List of alarms triggered during the use of the unit (4000 events recorded (1))

(1) The unit records 4000 events. An event is represented by a set-point or an alarm threshold when an adjustment is made and an alarm if triggered. Because the alarm log reports only alarm-related events, the maximum number of events recorded can be below 4000.

12.4.3.7 Measured parameters

Measured para- meters	Measurement range	Resolution	Precision	Filtering
Peak airway pres- sure (Ppeak, cmH2O)	0 - 100	1	+/- (2 cmH2O + 4%)	15 ms
Positive end of ex- piratory pressure (PEEP, cmH2O)	0 - 99	1	+/- (2 cmH2O + 4%)	15 ms
Plateau pressure (Pplat, cmH2O)	2 - 99	1	+/- (2 cmH20 + 4%)	15 ms
Frequency (RR, bpm)	0 - 120	1	+/-1 bpm	4 cycles
Insufflated tidal volume (VTi, mL)	0 - 3000	1	+/- (4 mL + 15%)	-
Leak (%)	0 - 100	1	+/- 20%	-
Expired tidal vol- ume (VTe, mL)	0 - 5000	1	+/- (20 mL + 15%)	-
Expired volume per minute (MVe, L/min)	0 - 40	0.1	+/- (0.5 L/min + 15%)	30 s

Measured para- meters	Measurement range	Resolution	Precision	Filtering
FiO2 (Vol.%)	18 - 100	1	< +/- 3 abs	5 s
Intrinsic PEEP(1) (Auto-PEEP, cmH20)	0 - 99	1	+/- (2 cmH2O + 4%)	
Spontaneous ex- haled volume per minute (Spont MVe, L/min)	0.5 - 40	0.1	+/- (0.5 L/min + 15%)	30 s
Ratio of inspira- tion time to total time (TI/Tot)	0 – 100	1	+/- 5%	-
Spontaneous fre- quency (spont. RR, bpm)	0 – 120	1	+/-1 bpm	4 cycles spon- tanés
Percentage of spontaneous cy- cles (spont%)	0 - 100	1	+/- 5 %	-
Peak insufflated flow rate (max ins, L/min)	0 – 120	0,1	+/- (1 L/min + 10%)	125 ms
Peak exhaled flow rate (max exp, L/ min)	0 - 150	0,1	+/- (2 L/min + 15%)	125 ms
Ratio of frequen- cy to exhaled tidal volume (RR/VTe, bpm/L)	0 - 5000	1	+/- 20%	-
Mean cycle pres- sure (Pmean, cmH2O)	0-99	1	+/- (2 cmH2O + 4%)	-
Occlusion pres- sure(1) (P0.1, cmH2O)	0-20	1	+/- (2 cmH2O + 4%)	-
Estimated pa- tient resistance(1) (Rstat, cmH2O/(L/ s))	5 - 200	0,1	+/- (5 cmH2O/(L/ s) + 20%)	-
Estimated pa- tient compli- ance(1) (Cstat, mL/cmH2O)	10 - 150	0,1	+/- (5 mL/cmH20 + 20%)	-

Measured para- meters	Measurement range	Resolution	Precision	Filtering
Estimated patient resistance (Rdyn, cmH2O/(L/s))	5 - 200	0,1	+/- (5 cmH2O/(L/ s) + 30%)	-
Estimated patient compliance (Cdyn, mL/cmH2O)	10 - 150	0,1	+/- (5 mL/cmH20 + 30%)	-
WOB (Joule/L)	0 - 2	0,001	+/- 0,7	-
NIF (cmH2O)	0 - 30	1	+/- (2 cmH2O + 4%)	-
Ratio of inspira- tion time to expi- ration time (I:E)	1/20 - 1/0.3	1/0.1	+/- (1/0.3)	-
Leak rate (leak, L/ min))	0 -120	1	+/- (2 L/min + 15%)	-
Measured paramet	ers related to the IRI	MA™ CO2 measurem	ent probe	
Fraction of CO2 at the end of expira- tion	0 – 15	0,1	+/- (0,43% abs. + 8 % rel.)	-
(etCO2,%)				
CO2 pressure at the end of expira- tion	0-100	1	+/- (3 mmHg abs. + 8 % rel.)	-
(etCO2, mmHg)				
CO2 minute vol- ume (VMCO2, mL/min))	0 - 9999	1	-	30s
Alveolar minute volume (Vmalv, L/ min)	0 – 99	0,1	-	30s
Ratio of airway dead space to tidal volume (Vdaw/Vt,%)	0 – 100	1	-	-
Airway dead space volume (Vdaw, mL)	0 – 5000	1	-	-

Measured para- meters	Measurement range	Resolution	Precision	Filtering
Slope of the vol- umetric capno- gram on the alveolar plateau (SlopeCO2,%CO2/ L)	0 – 99	0,1	-	-

1) Filtering is performed with a rolling average of n samples.

Oxygen sensor specifications	
Service life	Approximately 5000 h (variable duration as a function of concentration and temperature)
Conditions of use and storage	Same as those of the device
Power supply	Provided by the device, including during battery operation
Calibration	Calibration is automatically conducted during in- teractive testing.
	Precision is guaranteed only when there is fre- quent calibration
	(at least weekly).
Minimum flow rate to guarantee precision.	5 L/min
Drift of measurement accuracy over 6 hours	< +/-3 Vol.%
Response time at 90% (extreme conditions)	45s
Response time at 90% according to the EN ISO 80601-2-55 standard	< 10 s
Start time	Immediate
Sampling rate of the O2 cell data	5 ms
Influence of humidity on the oxygen measure- ment	- 0.03 (% per%RH at 25°C)
Effect of pressure	Compensation of the measurement as a function of atmospheric pressure.
	Compensation of the measurement at average pressure of the respiratory cycle.

12.4.3.8 Specifications of accessories

Single-use adult patient circuit	
Part No.	KG019300

Single-use adult patient circuit	
Resistance at 60 L/min	1.2 cmH20
Compliance	1.2 mL/ cmH20
Volume	1050 cm3
Single use pediatric patient circuit	
Part No.	KG019400
Resistance at 30 L/min	5 cmH20
Compliance	0.6 mL/cmH20
Volume	760 cm3
Ventilator outlet bacteriological filter	
Part No.	KV103300
Resistance at 30 L/min	1.7 cmH20
Compliance	0.1 mL/cmH20
Volume	120 cm3

12.4.3.9 IRMA[™] Probe

For more information, please refer to the IRMA[™] user manual from MASIMO.

12.4.4 Settings tables

Invasive ventilation

Set- points	Unit	Adult				Child				Infant			
points		Min.	Max.	Incr.	Default	Min.	Max.	Incr.	Default	Min.	Max.	Incr.	Default
VT	mL	100	2000	10	450	50	500	5	200	20	75	1	35
RR	bpm	4	80	1	15	5	120	1	25	10	120	1	40
TI/Ttot	%	5	80	1	33	5	60	1	33	5	60	1	33
I/E	-	1/19	1/0.3	1/0.1	1/2t	1/19	1/0.7	1/0.1	1/2	1/19	1/0.7	1/0.1	1/2
Flow	L/min	2	150	1	20	2	150	1	15	2	150	1	4
Tplat	%	0	60	5	20	0	60	5	0	0	40	5	0
RR SIMV	bpm	1	80	1	10	1	120	1	15	1	120	1	30
I. Trig	L/min	OFF, 1*	15	1	3	OFF, 1*	15	1	3	OFF, 1*	15	1	3
-	cmH20	0FF, 0,2*	3	0,2	0,6	OFF, 0,2*	3	0,2	0,6	OFF, 0,2*	3	0,2	0,6
PEEP	cmH2O	0	50	1	4	0	50	1	4	0	50	1	4
Tins	s	0.2	10.0	0.1	1.3	0.2	8.0	0.1	0.8	0.2	3.0	0.1	0.5
PS	cmH2O	2	40	1	10	2	40	1	10	2	40	1	10
PI	cmH2O	2	99	1	10	2	99	1	10	2	99	1	10

Set-	Unit	Adult				Child				Infant			
points		Min.	Max.	Incr.	Default	Min.	Max.	Incr.	Default	Min.	Max.	Incr.	Default
Fi02	%	21	100	1	60	21	100	1	50	21	100	1	35
Timax	s	0.3	5	0.1	1.5	0.3	5.0	0.1	1.5	0.2	2.5	0.1	1
E. Trig	%	5	90	5	30	0	90	5	30	0	90	5	30
Slope	cmH2O/ s	20	200	10	150	20	200	10	150	20	200	10	150
RR mi- ni	bpm	1	80	1	6	1	100	1	10	1	100	1	15
Sighs		OFF	ON		OFF	OFF	ON		OFF	OFF	ON		OFF
Vtsigh	x VT	1	2	0.1	1,2	1	2	0.1	1,2	1	2	0.1	1,2
PiSigh	x Pl	1	2	0.1	1,2	1	2	0.1	1,2	1	2	0.1	1,2
Sighs	Period	9	200	1	20	9	200	1	20	9	200	1	20
T high	s	0,3	30	0,1	1,5	0,2	30	0,1	1,5	0,2	30	0,1	0,5
T low	s	0,1	30	0,1	0,6	0,1	30	0,1	0,5	0,1	30	0,1	0,3
P high	cmH2O	2	99	1	15	2	99	1	15	2	99	1	15
P low	cmH2O	0	50	1	0	0	50	1	0	0	50	1	0

according to ventilation mode

Alarms	Unit	Adult				Child				Infant			
		Min.	Max.	Incr.	Default	Min.	Max.	Incr.	Default	Min.	Max.	Incr.	Default
Ppeak high	cmH20	10	100	1	45	10	100	1	45	10	100	1	45
Pplat high	cmH20	0FF, 1	50	1	OFF	OFF, 1	50	1	OFF	OFF, 1	50	1	OFF
Pplat high	cmH20	0FF, 1	50	1	30	OFF, 1	50	1	OFF	OFF, 1	50	1	OFF
RR low	bpm	1	70	1	6	1	110	1	10	1	110	1	20
RR high	bpm	11	80	1	45	11	120	1	50	11	120	1	70
Low VTi	mL	OFF	2900	10	OFF	OFF	1900	10	OFF	OFF	500	10	OFF
High VTi	mL	100	3000	10	3000	100	2000	10	1000	100	800	10	100
Low VTe	mL	OFF, 10	2000	10	OFF	OFF, 10	2000	10	10	OFF, 10	500	10	10
High VTe	mL	10	3000	10	3000	10	3000	10	1000	10	800	10	100
Low MVe	L/min	0.5	39.0	0.5	3.0	0.5	39.0	0.5	1.5	0.1	39.0	0.1	1
High MVe	L/min	1.5	30.0	0.5	25.0	1.5	40.0	0.5	10.0	1.0	40.0	0.1	5.0
FiO2 low	%	1,8	95	1	55	18	95	1	45	18	95	1	30
FiO2 high	%	23	100	1	65	23	100	1	55	23	100	1	40

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Alarms	Unit	Adult				Child				Infant			
		Min.	Max.	Incr.	Default	Min.	Max.	Incr.	Default	Min.	Max.	Incr.	Default
T ap- nea	s	15	60	1	20	4	60	1	20	2	30	1	10
CO2 alar	ms (if the	CO2 monit	toring soft	ware optio	n is enable	d)					•		
etCO2 low low	mmHg	OFF, 1	98	1	27	OFF, 1	98	1	30	OFF, 1	98	1	30
IOW IOW	%	OFF, 1	14	1	4	OFF, 1	14	1	4	OFF, 1	14	1	4
etCO2	mmHg	1	99	1	49	1	99	1	49	1	99	1	49
haut	%	1	15	1	6	1	15	1	6	1	15	1	6
VM- CO2 high	mL/ min	OFF	990	10	OFF	OFF	990	10	OFF	OFF	990	10	OFF
VM- CO2 high	mL/ min	10	1000	10	1000	10	1000	10	1000	10	1000	10	1000
VMalv low	L/min	OFF	39	0,5	OFF	OFF	39	0,5	OFF	OFF	39	0,5	OFF
VMalv high	L/min	1	40	0,5	40	1	40	0,5	40	1	40	0,5	40

Settings: PRVC and PS-PRO (Invasive ventilation)

De- scrip-	Min.	Max.	Incr.	Adult				Child				Infant			
tion				De- fault	Min.	Max.	Incr.	De- fault	Min.	Max.	Incr.	De- fault	Maxi	Pas	Incr.
Expi- ratory pres- sure	PRVC PS PRO	PEP	cmH2O	0	50	1	0	0	50	1	0	0	50	1	0
FI02	PRVC PS PRO	FiO2	%	21	100	1	50	21	100	1	50	21	100	1	35
Fre- quen- cy	PRVC	f	c/min	4	80	1	15	5	120	1	25	5	120	1	40
Insuf- fla- tion	VCRP	PI	cmH2O	AUTO 2	AUTO 99	1	AUTO 15	AUTO 2	AUTO 99	1	AUTO 15	AUTO 2	AUTO 99	1	AUTO 15
pres- sure	PS PRO	AI		AUTO 2	AUTO 40			AUTO 2	AUTO 40			AUTO 2	AUTO 40		
Pres- sure In- crease slope	PRVC PS PRO	Pente	cmH20 s	/ AUTO	AUTO	10	150	20	200	10	150	20	200	10	150
l:E ratio	VCRP	Ti/ Ttot	%	2	40	1	33	5	60	1	33	5	60	1	33

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De-	Min.	Max.	Incr.	Adult				Child				Infant			
scrip- tion				De- fault	Min.	Max.	Incr.	De- fault	Min.	Max.	Incr.	De- fault	Maxi	Pas	Incr.
Inspi- ratory	VCRP	Trig.l	L/min	OFF	15	1	5	OFF	15	1	5	OFF	15	1	5
trig- ger			cmH20		3	0.2	1		3	0.2	1		3	0.2	1
gei	PS PRO		L/min	1	15	1	5	1	15	1	5	1	15	1	5
			cmH20	0.2	3	0.2	1	0.2	3	0.2	1	0.2	3	0.2	1
Expi- ratory trig- ger	PS PRO	Trig. E	%	5	90	5	30	5	90	5	30	0	90	5	30
Mini fre- quen- cy	PS PRO	f min	c/min	1	80	1	8	1	100	1	15	1	100	1	20
Main- te- nance fre- quen- cy	PS PRO	f ent.	c/min	4	99	1	15	5	120	1	25	5	120	1	40
Vt Tar- get	PRVC PS PRO	Vt Cible	mL	OFF 100	2000	10	500	OFF 50	500	5	200	OFF 20	75	1	35
PI max	PRVC	PI max	cmH20	2	99	1	20	2	99	1	20	2	99	1	20
IIIdA	PS PRO			2	99			2	99			2	99		

Non-invasive ventilation

Set- points	Unit	Adult				Child				Infant			
points		Min	Max	Incr.	Default	Min	Max	Incr.	Default	Min	Max	Incr.	Default
PS	cmH2O	2	25	1	15	2	25	1	15	2	25	1	15
PEP	cmH2O	0	15	1	5	0	15	1	5	0	15	1	5
RR mi- ni	c/min	1	80	1	8	1	100	1	15	1	100	1	20
Timax	s	0.3	5.0	0.1	1,3	0.3	5.0	0.1	1.2	0.2	2.5	0.1	0.5
I. Trig	L/min	1	15	1	5	1	15	1	5	1	15	1	5
	cmH2O	0,2	3	0,2	1	0,2	3	0,2	1	0,2	3	0,2	1
E. Trig	%	10	90	5	50	10	90	5	50	5	90	5	50
Slope	cmH20 / s	20	200	10	150	20	200	10	150	20	200	10	150
CPAP	cmH2O	2	50	1	5	2	25	1	5	2	25	1	5
Pi	cmH2O	2	99	1	15	2	99	1	15	2	99	1	15
T high	s	0.3	30	0.1	1.5	0.2	30	0.1	1.5	0.2	30	0.1	0.5
T low	s	0,1	30	0,1	0,6	0,1	30	0,1	0,5	0,1	30	0,1	0,3
P high	cmH2O	2	99	1	15	2	99	1	15	2	99	1	15

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Set- points	Unit	Adult				Child				Infant			
points		Min	lin Max Incr. Default			Min	Max	Incr.	Default	Min	Max	Incr.	Default
P low	cmH20	0	50	1	0	0	50	1	0	0	50	1	0

Alarms	Unit	Adult				Child				Infant			
		Min	Max	Incr.	Default	Min	Max	Incr.	Default	Min	Мах	Incr.	Default
Ppeak high	cmH2O	10	100	1	45	10	100	1	45	10	100	1	45
RR low	c/min	1	70	1	6	1	110	1	10	1	110	1	20
RR high	c/min	11	80	1	35	11	120	1	40	11	120	1	70
Low VTi	mL	Non-adju	stable ala	rm		Non-adju	istable alai	m		Non-adju	istable alai	rm	
High VTi	mL	Non-adju	istable alai	rm		Non-adju	istable alai	m		Non-adju	istable alai	rm	
Low VTe	mL	OFF, 10	2900	10	10	OFF, 10	2900	10	10	OFF, 10	500	10	10
High VTe	mL	100	3000	10	3000	100	3000	10	1000	10	800	10	100
Low MVe	L/min	OFF, 0.5	59.0	0.1	2.0	OFF, 0.1	59.0	0.1	1.5	OFF, 0.1	39	0.1	1
High MVe	L/min	1.0	60.0	0.1	30.0	1.0	60.0	0.1	10.0	0,9	40	0.1	5
FiO2 low	%	18	95	1	55	18	95	1	45	18	95	1	30*
FiO2 high	%	23	100	1	65	23	100	1	55	23	100	1	40*
T ap- nea	s	15	60	1	20	4	60	1	20	2	30	1	10

*If FiO2 set-point =35%

CO2 ALA	RMS (IF T	HE CO2 M	ONITORIN	G SOFTWA	RE OPTIO	N IS ENAB	LED)						
etCO2 low	mmHg	OFF, 1	98	1	30	OFF, 1	98	1	30	OFF, 1	98	1	30
1010	%	OFF, 1	14	1	4	OFF, 1	14	1	4	OFF, 1	14	1	4
etCO2 high	mmHg	1	99	1	49	1	99	1	49	1	99	1	49
nign	%	1	15	1	6	1	15	1	6	1	15	1	6
VM- CO2 low	mL/ min	OFF	990	10	OFF	OFF	990	10	OFF	OFF	990	10	OFF
VM- CO2 high	mL/ min	10	1000	10	1000	10	1000	10	1000	10	1000	10	1000
VMalv low	L/min	OFF	39	0,5	OFF	OFF	39	0,5	OFF	OFF	39	0,5	OFF
VMalv high	L/min	1	40	0,5	40	1	40	0,5	40	1	40	0,5	40

Suction settings

Suc- tion	Unit	Adult				Child				Infant			
		Min	Max	Incr.	Default	Min	Max	Incr.	Default	Min	Max	Incr.	Default
O2 Tar- get	% (Vol 02)"	21	100	1	100	21	100	1	100	21	100	1	60
Oxy- gena- tion time	s	30	900	10	120	30	900	10	120	30	900	10	120
Post- oxy- gena- tion time	s	30	300	5	120	30	300	5	120	30	300	5	120

Nebulization settings

Nebu- lization	Unit	Adult				Child	Infant		
lization		Min	Max	Incr.	Default				
Flow	L/min	1.0	20.0	0.5	6.0	Inactive function	Inactive function		
Nebu- lization dura- tion	min	1	60	1	10				
Fre- quency	h	1	24 / none	1	none				

Oxygen therapy settings

Oxygen	Unit	Adult			Child				Infant				
		Min	Max	Incr.	Default	Min	Max	Incr.	Default	Min	Max	Incr.	Default
FiO2	%	21	100	1	50	21	100	1	50	21	100	1	50
Flow rate	L/min	2	80	1	60	2	60	1	25	2	60	1	15

Automatic alarm thresholds

		vcv	VPC	SIMV	PSIMV	PSV	PSV NIV	CPAP APRV	Duo Levels	PRVC	PS PRO
P peak (cmH2O)	cmH2O	P peak mea- sured + 33%	P peak mea- sured +max. (20%, +5)		P peak measure	d +max. (2	0%, +5)			P peak measured +max. (20%, +5)	
Pmin (cmH2O)	cmH2O	P peak mea- sured - 33%	P peak mea- sured - max (20%, 5)	-	P peak measured - max (20%, 5)			-		P peak measured - max (20%, 5)	
P plat (cmH2O)	cmH2O	P plat mea- sured + 5			OFF -				OFF	OFF	
VTi low (mL)	mL	VTi measured	d - 75%	OFF	VTi measured - 75%					VTi measured - 75%	
VTi high (mL)	mL	VTi 2000 mL measured + 50%			VTi - measured + 50%				VTi measured	VTi measured + 50%	
MVe low (L/ min)	L/min	MVe measured - 50%									
MVe high (L/ min)	L/min	MVe mea 50%	/e measured + MVe measured + 75%						MVe mea- sured + 50%	MVe mea- sured + 75%	
RR low (c/min)	c/min	RR measured - 50%									
RR high (c/min)	c/min	RR measured + 50%									
VMC02 low	mL/min	VMCO2 n	VMC02 measured – max(- 50%, 10)								
VMCO2 high	mL/min	VMCO2 n	VMCO2 measured - max(+ 50%, 30)								
VMalv low	L/min	VMCO2 n	VMC02 measured – max(- 50%, 10)								
high VMalv	L/min	VMalv measured – max(+ 50%, 5)									

12.5 Testing the alarms

Alarm testing methods	
Power supply failure alarm	Disconnect the AC power cord.
High FiO2 alarm	Temporarily change the threshold to activate the corresponding alarm.
Low exhaled volume alarm	Temporarily change the threshold to activate the corresponding alarm.
High pressure alarm	Temporarily change the threshold to activate the corresponding alarm.
High PEEP alarm	Temporarily change the threshold to activate the corresponding alarm.
Obstruction alarm	Use a suitable device to simulate obstruction of the expiratory branch during ventilation (e.g. by clamping the expiratory branch).
O2 supply failure alarm	Disconnect the oxygen supply.
Means of testing an alarm in each category	
LOW ALARM	Adjust a min VTe threshold to below the mea- sured value.
MEDIUM ALARM	Adjust a min VTe threshold to below the mea- sured value and wait three cycles. This same alarm switches to MEDIUM.
HIGH ALARM	Disconnect the hot-wire sensor in standby or ven- tilation mode.
ULTRA ALARM	Cannot be simulated without opening the equip- ment.

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14 Appendix

14.1 Checklist

The following actions must be applied when commissioning a unit after every maintenance operation:

	Done
Connect the unit to the O2 wall outlet	
Check that the supply pressure is correct (between 2.8 and 6 bar).	
Install the patient circuit on the device and connect a test lung.	
Connect the unit to the mains power supply and check that the indicator light on the front panel lights up.	
Apply power to the unit pressing the On/Off button at the back of the device.	
You should hear a BEEP and the ventilator screen should light up.	
Select [New Patient], "Adult" type, in the stand-by screen, and start ventilation.	
Check there is no technical alarm after 1 minute of ventilation.	
Power supply	
During ventilation on a test lung, disconnect the electrical connection	
Check that the ventilator ventilates on its internal battery and announces this fact on screen.	
Check the battery is charged enough (3 squares at least) if an intra-hospital transport is programmed. Reconnect the AC power supply. (See also <u>Testing the alarms</u> on page 133)	
Alarm level tone	
Press the [Stand-by] key, a dialog box is displayed asking for confirmation of venti- lation stop. Check that the alarm level tone associated to the demand of ventilation stop is sufficient. If it's not, see <u>Audible alarm</u> on page 31. Confirm the ventilation stop.	
Seal off the Y-piece and run the automatic test sequence; the message "test success- fully completed" appears, with a compliance value.	
Check that alarm transfer is operative (if used).	
Select [New Patient] and the appropriate type of patient (ADULT or CHILD or INFANT) from the stand-by screen.	

14.2 Expiratory assembly cleaning protocol

Complete operation:

- 1. Disassembly
- 2. Pre-disinfection
- 3. Sterilisation
- 4. Reassembly

Disassembly



- Disassemble the patient circuit by removing its components: pipes, fittings, water traps, and Ypiece.
- Disassemble the expiratory assembly according to the diagram below.
- Remove the expiratory assembly from its housing by pressing the eject pushbutton.
- Remove the expiratory flow hot wire sensor (1), the valve body (2), the membrane (3), and the silicone disc (4). Do not remove the two seals from the valve body (2).

CAUTION: The flow sensor requires special precautions:

- · Avoid inserting any object into the flow sensor,
- · Avoid exposing it to a jet of water or air,
- Avoid impacts or dropping it.

Pre-disinfection / cleaning

Immerse the expiratory assembly components in a pre-disinfectant solution: *Air Liquide Medical Systems* recommends the use of ANIOS products: ANIOSYME DD1, SALVANIOS PH7, HEXANIOS G+R (obey the instructions of the product manufacturer).

Rinse the parts under running water, except for the expiratory flow sensor (1), which should only be dipped in water.

Leave the components to dry on absorbent paper.

Sterilisation: prion cycle 134°/18 min/ 1 bar above atmospheric pressure

CAUTION: Sterilisation must be performed with care by certified personnel.

Condition the components removed from the expiratory assembly before the procedure.

The expiratory assembly can tolerate 50 sterilisation cycles. A unique serial number on the expiratory flow sensor (1) and the valve body (2) gives the date of manufacture of the components and can be used to track the number of cycles they have undergone.

Reassembly

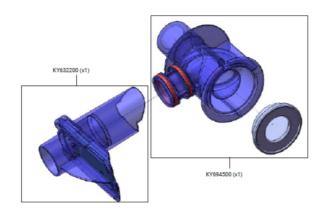
Reassemble the expiratory assembly (wear sterile gloves to do this):

- install the silicone disc in the membrane,
- reposition the membrane in the valve body.

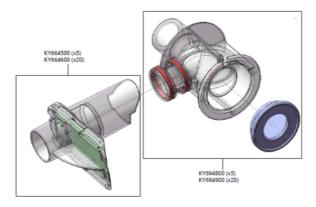


CAUTION: Before any further use of the expiratory assembly, check that it was correctly reassembled by connecting it to the ventilator and performing the automatic tests.

Monnal EVA autoclavable expiratory assembly



Monnal EVA single-use expiratory assembly











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