Air Liquide
HEALTHCARE | MONNAL T60

User Manual

English

Software Version V2.7.x

LOT

V2.7.xI10

YL068000

www.device.airliquidehealthcare.com

YL068000 - Revision 10 - 2021-05

Contents

1 Before use

1.1 Symbols used in this manual

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 T60 is a standalone ventilator using air (propelled by a blower) used to treat infants (3 kg and above), 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.) and is used:

- for pre-admission transportation[1],
- for transportation within a hospital,
- for transportation between hospitals[1],
- for intra-hospital emergencies,
- in post-operative recovery rooms,
- in intensive care.

Medical electrical system

Monnal T60 is part of the medical electrical system consisting of the following components:

- a CO2 measurement probe (IRMA™)
- a Monnal Clean'In (HEPA) filter
- a humidifier
- a nebulizer
- an extractable battery
- an external power supply
- oxygen from a supply network, cylinder, or concentrator.

Monnal T60 provides monitoring for the following respiratory gases: oxygen and carbon dioxide (using the optional IRMA probe).

1 Land transportation and air ambulances.

1.3 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 authorized 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.

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 daily recommended maintenance practices.

1.4 Brief description of the device

Monnal T60 can supply tidal volumes from 20 to 2000 mL in volume-controlled mode, and insufflation pressures from 5 to 60 cmH2O in pressure-controlled mode.

It can also supply FiO2 from 21 to 100%. This is continuously monitored.

It features the following ventilation modes and functions:

VCV (controlled ventilation or assisted volume-controlled ventilation)

PCV (controlled ventilation or assisted pressure-controlled ventilation)

PSV (spontaneous ventilation with inspiratory assistance and PEEP)

CPAP (Continuous Positive Airway Pressure)

SIMV (intermittent assisted controlled ventilation)

PSIMV (intermittent assisted pressure-controlled ventilation)

Duo-Levels (Alternation of two CPAP levels)

Pre-oxygenation NIV

PRVC (Pressure-regulated volume controlled ventilation)

PS-Pro (Spontaneous ventilation with inspiratory assistance, PEEP and servomechanism frequency)

Oxygen therapy

CPV (Cardio-Pulmonary Ventilation)

Some of the ventilation modes are available in non-invasive ventilation. See Start / stop ventilation on page 37.

The device is equipped with an 8.4-inch colour touch screen, an ergonomic control wheel and a functional interface for adjustment of the various settings and ventilation parameters.

Patient environment

During normal use, the patient is lying on a hospital bed with the ***Monnal T60*** device placed close by. All parts of the medical electrical system are suitable for use in the patient environment.

User position

The human machine interface of the device faces the user so that the user can make the necessary adjustments with the control wheel and read the information displayed on the screen. The recommended distance depends on the environment, the ambient lighting and the user's visual acuity. The back of the device is accessible to the user.

1.5 Symbols and markings on the device

	Weight and rated output of product		Oxygen cell hatch open
	Manufacturer	CE 0459	Complies with European Directive 93/42/CEE Notified Body No. 0459.
	Weight of ***Monnal T60*** device		Expiratory valve eject button
REF	Device Catalogue Number		Weight of complete system (***Monnal T60***, mobile stand, articulated arm, extractable battery and patient circuit)
SN	Serial Number of the device		
	Date of manufacture: YYYY-MM		High pressure oxygen inlet fitting

	Class II		Low pressure oxygen inlet fitting
IP34	**Protection Index** according to the EN 60529 standard **3:** protection from the penetration of solid bodies of diameter ≥ 2,5 mm. **4:** protection from water splashing from any direction		IRMA™ CO2 probe connector
			Patient circuit inspiratory fitting
			Patient circuit expiratory fitting
	Type BF applied part protects against defibrillation shocks.		This logo means that the equipment must not be disposed of through ordinary waste channels. It must receive appropriate end-of-life handling, in accordance with European Directive 2012/19/EU (WEEE). This device was manufactured after 13.08.05.
	ON button		
	DC power supply connector		
	USB connector		Internal battery status indicator
	VGA video output		Removable battery status indicator
	Do not let liquid enter this area.		Lithium-ion extractable battery
	Direct current		Mains power supply or DC voltage
	Alternating current		Caution: refer to the user manual On the device, the symbol is shown in blue.

Symbols and markings relating to accessories			
	Universal Device Identifier.		Medical Device.

Storage information - Indications on the packaging			
	Fragile. Handle with care.		Keep dry. Do not expose to rain.
	Up. Maintain in up position.		Stacking limit. Do not stack more than three boxes.
	Minimum and maximum temperature.		Minimum and maximum humidity.
	Minimum and maximum atmospheric pressure.		

Specific symbols for IRMA™ CO_2 measurement probe			
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

Use of oxygen

- Precautions in case of oxygen leak:
  - No smoking
  - Avoid any flame or source of sparks
  - Disconnect the oxygen source
  - Ventilate room during leakage and at least 20 minutes after leakage.
  - Air one's own clothing.
- The device must not be in operation near any incandescent source.
- This ventilator must not be used with inflammable anesthetic 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 that have been contaminated by inflammable substances (e.g. grease, oil, etc.).

- The internal components of the device were degreased before delivery or use a type of grease which is compatible with oxygen. Do not grease or lubricate any part of the device.
- Medical grade oxygen must be used (i.e. dust-free and dry, H2O < 20 mg/m3).
- The supply pressure must be between 280 kPa (2.8 bars) and 600 kPa (6 bars).
- When the device is not in use, it is recommended that you disconnect all oxygen sources from it.

Use with a defibrillator

- When using the ***Monnal T60*** and a defibrillator simultaneously, the defibrillation shock in the presence of enriched oxygen and combustibles (such as textiles) can cause an explosion or fire which could injure the patient and bystanders.
- It is recommended to use adhesive electrodes.
- During the defibrillation:
- remove the oxygen mask or the nasal cannula and keep it at least 1 m from the patient's torso;
- if the patient is intubated, leave the ventilator connected;
- ensure that the oxygen-enriched air at the outlet of the expiratory valve is not facing the patient's torso.

Electrical power supply

- 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 adapter).
- Use only the mains cable and mains power supply box supplied with the device.
- If an external power supply is used, check that the voltage and current used match the electrical characteristics of the ventilator (indicated on the side of the ventilator).
- The mains power supply adapter is not protected from splashes of water (IPX0), unlike the device itself, which complies with IPX4 during battery-powered operation.
- This ventilator has an internal battery and an extractable battery. The device must be connected to the mains regularly to maintain the battery charge at a suitable level.
- In the event of any doubt about the condition of the mains power supply cable, use the device on its internal battery only.
- In case of long battery-powered operation, we recommend keeping a spare extractable battery on hand.
- Do not use antistatic or electrically conductive pipes.
- The user must not touch the patient and the equipment enclosures at the same time.

Internal battery electrical power supply

The internal battery is a backup power source only. If connection to the mains power supply (primary power source) is impossible, an extractable battery (secondary power source) must be used. Using the internal battery as the main power source can cause ventilation to stop unexpectedly.

IP Protection

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

Electromagnetic compatibility

- The presence of equipment as diathermy units, high frequency electro-surgical equipment, defibrillators and cellular telephones or of electromagnetic interferences exceeding IEC 60601-1-2 levels in its vicinity may interfere with the normal operation of the ventilator.
- The ***Monnal T60*** should not be placed next to or on top of this equipment. If such use is necessary, the ***Monnal T60*** should be observed together with the other ventilators to ensure that they are operating normally.

- Do not use this ventilator in a specifically magnetic environment (MRI, NMR, etc.).
- ***Monnal T60*** is compliant with the requirements defined in standard IEC 60601-1-2 relating to the electromagnetic compatibility of medical devices. Precautionary measures are required with this device in terms of EMC and the devices must be installed and put into operation in accordance with the EMC information provided in this user manual.
- The replacing of cables or internal components with cables or components that are not supplied by *Air Liquide Medical Systems* may result in an increase 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 concerned or a specialist.
- Devices connected to the inputs and signal outputs must comply with the 60601-1 Standard.

Set-up

- 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 checks listed in the appendix (*see section* "Checklist on page 138).
- The ventilator should not be covered or positioned in such a way that its functioning or performance are affected. Always leave some space around the device: for example, never place the ventilator close to a curtain which could impede the fresh air flow and cause overheating.
- If the ***Monnal T60*** is installed on the universal support (KA010400), follow the instructions in the assembly manual. Ensure that the structure or unit (bed rail, for example) onto which the universal support is mounted can support the weight of the ***Monnal T60***.

Use

- The manufacturer has tried to anticipate most of the possible malfunction scenarios of this ventilator, and these are normally monitored by the internal monitoring system. It is nevertheless recommended, in cases of complete patient dependence, that you provide an additional, fully autonomous system which can be used to check the effectiveness of the 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 ***Monnal T60*** in a hyperbaric chamber.
- The device and its accessories (masks, circuits, etc.) are Latex-free.
- The air inlets located at the back and side of 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.).
- In order to prevent dust from entering:
    - between ventilator uses in the bag, close the inspiratory limb cap;
    - between ventilator uses in the bag, leave a bacteriological filter or patient circuit on the inspiratory outlet of the ventilator;
    - during cleaning, leave a bacteriological filter or a patient circuit on the inspiratory outlet of the ventilator;
    - clean the inside of the bag regularly.

Transportation

- During transportation, we recommend that you use the device in its protective carry bag. The case must be securely fastened in the vehicle using the strap loops provided for the purpose.
- The device must not be subjected to violent impact.
- Use the carry bag recommended by *Air Liquide Medical Systems* only.
- During transport, the use of ***Monnal T60*** outside of its bag does not ensure compliance with EN 13718-1, EN 1789 and EN 794-3 standards.

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 disinfected between each use.
- The breathing tube, mask, patient circuit, bacteriological filters, expiratory valve, humidification chamber, CO2 probe or nebulizer adapters are part of the air path and can be contaminated under normal operating conditions, and in the event of a single fault condition by bodily fluids, secretions or gas exhaled by the patient.

Maintenance

- This ventilator must be checked regularly. To plan and keep a record of all maintenance, operations, refer to the maintenance sheet in the appendix.
- The safety of the patient and of users, and the performance of the ventilator, are no longer guaranteed in the following cases:
- assembly operations, adjustment of the settings, modifications or repairs not carried out by trained individuals;
- the electrical installation is not compliant with the specifications defined in this manual and the regulations in force;
- the ***Monnal T60*** system is not used in accordance with the user instructions of this manual.
- The approved technician must use only *Air Liquide Medical Systems* spare parts when carrying out routine maintenance of 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 aspiration

- Aspiration may be carried out according to different methods: fully unplugging the circuit, opening a respiratory circuit connection, or closed system.
- When using a breathing tube in a closed system, it is advised to use the PCV mode with the parameters adjusted to the patient and, if tolerated, a PEEP of at least 3 cmH2O.

Medical Contraindications

- Certain diseases require appropriate treatment before the ventilator is used. Failure to provide such treatment may adversely affect the patient's health.
- ***Monnal T60*** is not appropriate for patients whose weight is very low (premature newborns, and newborns under 3 kg).
- ***Monnal T60*** cannot be used in magnetic resonance imaging (MRI) rooms, unless a sufficiently long circuit is added.
- ***Monnal T60*** is not intended for hyperbaric ventilation.
- The CPV (cardiopulmonary ventilation, optional) ventilation function is not suitable for children and newborns.

Recommendations for using the MASIMO IRMA™ CO2 measurement probe

See CO2 option on page 53.

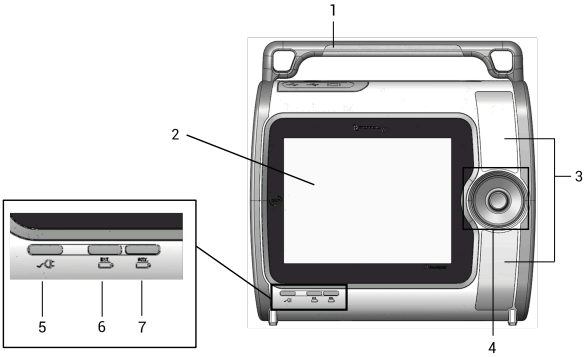
2 Description of the device

2.1 Terminology Used

The **expiratory assembly** denotes the **expiratory flow sensor** and the **expiratory valve.**

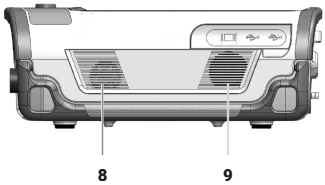
The **expiratory valve** designates the **valve body**, the **membrane** and the **silicone discs**.

2.2 Front view



1.	Handle: To carry the machine easily.	**2.**	Touch screen (8.4 inches) • Interface between the user and the device • Permits adjustment of all ventilation settings.
3.	Alarm indicators: Illuminates to inform the user that an alarm has been activated. • Red fast flashing = high priority • Yellow slow flashing = medium priority • Steady yellow = low priority	**4.**	Control wheel: To adjust and confirm the parameters.
5.	AC power supply indicator light	**6.**	Internal battery status indicator
7.	Extractable battery status indicator		

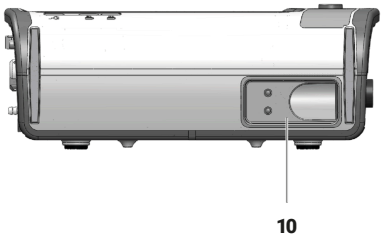
2.3 Handle side



8. Secondary air inlet

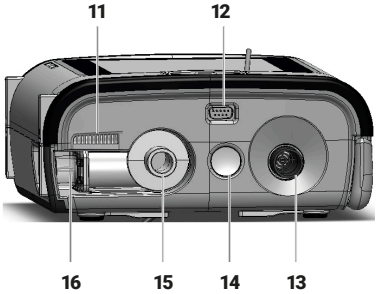
9. Speaker

2.4 Base side



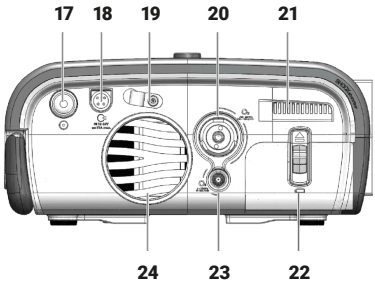
10. Electrical connection with the hot wire expiratory flow sensor (expiratory assembly withdrawn)

2.5 Right-hand side: Patient circuit connection panel



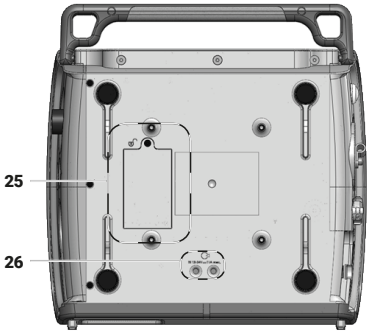
11.	Cooling vent	**12.**	IRMA™ CO_2 probe connector socket
13.	Inspiratory circuit connection	**14.**	Expiratory valve eject button
15.	Expiratory circuit connection	**16.**	Hot wire expiratory flow sensor

2.6 Left-hand side: Turbine air inlet panel



17.	ON/OFF button	**18.**	Electrical power supply connector
19.	Anti-pull cable protection clip	**20.**	High-pressure oxygen inlet
21.	Cooling vent	**22.**	Removable battery housing
23.	Low-pressure oxygen inlet	**24.**	Air inlet

2.7 Rear panel



25. FiO_2 cell

26. Electrical connections for a wall-mounted charging station

3 Installation and commissioning

3.1 Unpacking

Remove the ventilator from the packaging and place it horizontally on a table.

Unwrap the accessories supplied with the ventilator.

CAUTION: Before using on a new patient, and before the first use of this device, you must clean and disinfect the accessories (see section Maintenance on page 98).

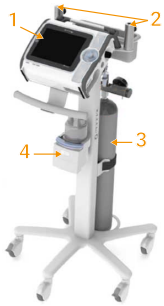
3.2 Items included in the package

1 ***Monnal T60*** KA010000 ventilator, including:

- 1 internal battery
- 1 external power supply
- 1 O2 sensor
- 1 ***Monnal EVA*** expiratory valve
- 1 expiratory flow sensor
- 1 ***Monnal Clean'In*** (HEPA) filter
- 1 user manual
- 1 power cable (2.5 m)
- 1 specific gas connector (according to model)

3.3 Installation on the wheel stand

Installation example of ***Monnal T60*** **(1)** on the wheel stand, with the humidifier **(4)** and the oxygen cylinder **(3)**:



Note: The articulated arm for the patient circuit is installed on one of the fastening points **(2)**.

System with wheel stand

The ***Monnal T60*** system and wheel stand (shown as weight B on the label) comprises the following elements:

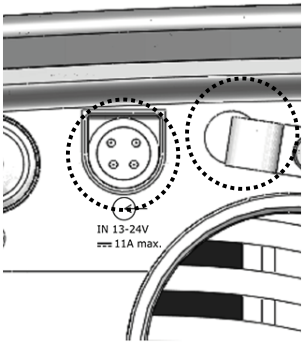
- ***Monnal T60***
- wheel stand
- articulated arm
- humidifier
- oxygen cylinder

3.4 Connections and commissioning

3.4.1 Electrical power supply

Connect the electrical power supply cable to the ventilator, and then connect it to an AC power supply socket.

Location of power cable with anti-pull cable protection clip :



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

Check that the power cable is not damaged.

CAUTION: Leave enough space behind the device for removing the cord from the power outlet when stopping the machine.

Note: The power cord enables ***Monnal T60*** to be disconnected from the power supply on all poles simultaneously.

3.4.2 Oxygen supply

To use a mixture with more than 21% oxygen, connect the ventilator's high- or low-pressure O_2 inlet to a valid source via an appropriate connector.

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

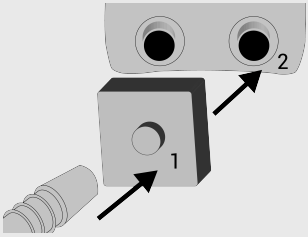
CAUTION: Start by connecting the O_2 connection hose to the ventilator before connecting it to the oxygen network.

CAUTION: Check the capacity of the oxygen cylinder before using the ventilator.

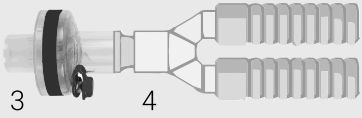
3.4.3 Assembly of patient circuit and accessories

CAUTION: Make sure that the use of accessories does not affect the safety and the expected performance of the device. Only use the accessories described below with the ***Monnal T60***. ***Monnal T60*** is compatible with double-branch, adult and pediatric circuits.

CAUTION: It is **necessary** to use a hydrophobic bacterial filter **(1)** on the ventilator's inspiratory outlet **(2)**.



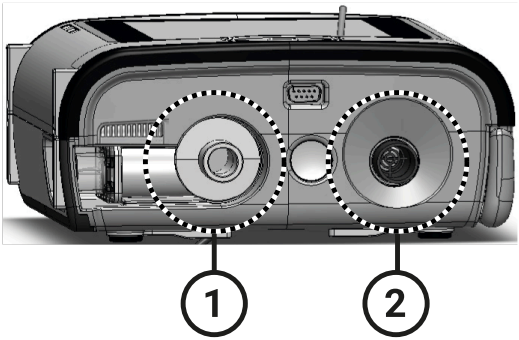
CAUTION: An HME **(3)** (heat and moisture exchanger) filter can be used in addition to the hydrophobic bacteriological filter **(1)**. It must be placed on the Y-shaped part**(4)**.



CAUTION: Air Liquide Medical Systems recommends using the patient circuits listed in Chapter List of options and accessories. If not, the use of patient circuits containing phthalates or bisphenol A poses risks for pregnant women, lactating women and children.

In a case where the expiratory valve is not fitted, assemble the expiratory valve as shown in Expiratory assembly cleaning protocol on page 140 then insert it into the housing until you here it click into place.

Double-branch patient circuit



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

- Connect the expiratory branch to the expiratory valve of the ventilator:

  (1)
- Connect the inspiratory branch to the inspiratory outlet cone of the ventilator:

  (2)

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

CAUTION: 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 disinfected 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 cross-contamination. This risk also arises if reusable accessories or consumables are not disinfected between each use.

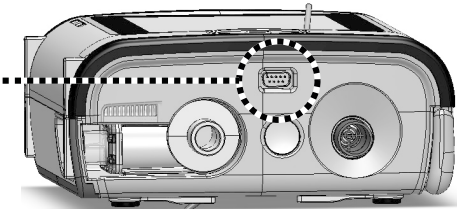
3.4.4 CO_2 Measurement Probe (IRMA™)

Note: CO_2 monitoring requires a software option that can be enabled using a code. To use this option, contact your Air Liquide Medical Systems representative

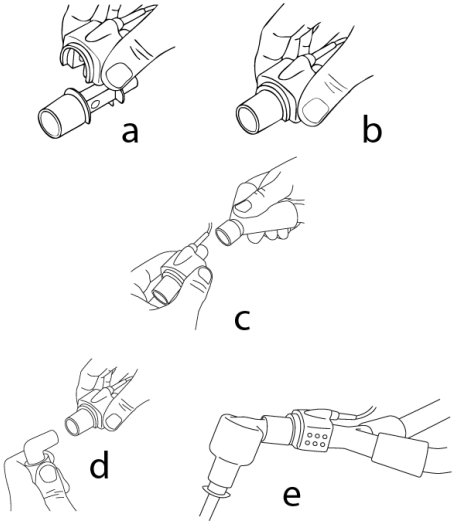
After purchasing this option, *Air Liquide Medical Systems* provides:

- 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.

1. Connect the IRMA™ probe to the etCO2 connection socket.



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. Wait at least 10 seconds. If the etCO2 monitoring block does not show 0%, or if the error 'CO2 measurement incorrect' is displayed, a calibration test should be carried out. See Display of measurements on page 60.
5. The LED flashes and then goes green. This means that the IRMA™ probe is ready for use (b).

Pre-use checks (for each new patient)

1. Connect the sensor to the patient adapter (a). A click should be heard when the sensor is properly connected to the adapter.
2. Ensure that the etCO2 monitoring block is displaying data.
3. Connect the IRMA™ probe, equipped with its adapter, to the Y-piece on the patient circuit (c).
4. Connect the IRMA™ probe to the patient's endotracheal tube (d).
5. Position the IRMA™ probe (e) (see photo opposite).

Note: The probe sends information and alarms to the ***Monnal T60***. The probe has an LED indicating the following statuses:

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

3.4.5 Humidifier

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

It is also recommended that you use patient circuits equipped with water traps when using a humidifier.

CAUTION: Remember to empty the water traps regularly during ventilation.

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.

3.4.6 Nebulizer

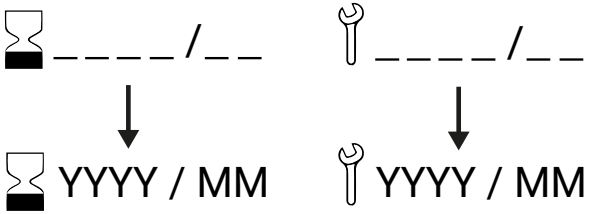
CAUTION: Y-piece respiratory filters can prevent medication from being effective: their use is therefore not recommended,

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

CAUTION: If a nebulizer is used, it is necessary to use a filter on the expiratory limb to avoid damage to the expiratory flow sensor.

3.4.7 Removable battery

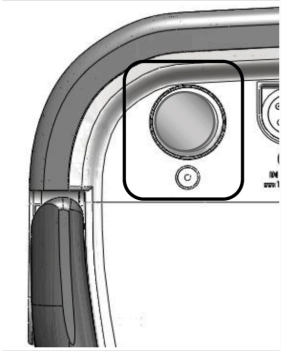


Prior to using the extractable battery for the first time, please complete the blank expiration date label supplied with the battery (2 years after date of first use).

3.4.8 Applying power

CAUTION: Do not obstruct the vents located on the left- and right-hand sides of the device and underneath it, as this could compromise patient safety.

Apply power to the device using the ON/OFF button located on the left-hand side of the unit.



The initialization tests start up (duration: up to 5 s). The buzzers sound and the alarm indicators light up.

After the initialization tests, the machine displays the start-up screen.

Note: When switching the device on using internal/external battery (no mains supply connected), the ON/OFF button may need to be pressed for an extended period of time than normal to start the device (approximately 3 seconds).

CAUTION: Ensure that the two batteries (internal and removable) are charged fully before using the ventilator.

3.4.9 Automatic tests

The automatic tests check the integrity and correct operation of the unit's internal components.

In particular, they calibrate certain sensors, including the expiratory flow sensor and the oxygen cell.

Without these tests, the precision of ventilation parameters and measurements cannot be guaranteed.

Note: *Air Liquide Medical Systems* therefore recommends the running of these automatic tests before each use on a patient.

1. To launch the automatic tests, press the **Automatic tests** key.
2. Follow the instructions on the screen.
3. Press **Validate** to confirm the launching of tests.

   At the end of testing, a window is displayed with the instruction to remove the plug from the Y-piece on the patient circuit, accompanied by an audible reminder every 2 minutes.

Note: If the user does not disconnect the patient circuit, the test stops after 20 minutes. Press "Restart "to resume the last stage of the autotests.

The automatic tests end a few seconds after the cap is taken off the Y-piece. When the tests are over, press **End**.

To interrupt the tests, press **Stop** and then **Finish**.

To resume the tests, press **Restart** and then **Validate**.

If the autotests fail with the message "Circuit resistance not evaluated":

- check that the selected patient category matches the patient circuit used,
- check that the patient circuit is correctly connected to the device,

- check that the filters and other accessories used do not generate too high a resistance.

CAUTION: Make sure that the patient category selected corresponds to the patient circuit and the accessories used (see section Selecting the patient category on page 34).

4 Use

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

CAUTION: Avoid using any object that might scratch the screen.

4.1 Start-up screen

This screen is displayed when the machine starts up.

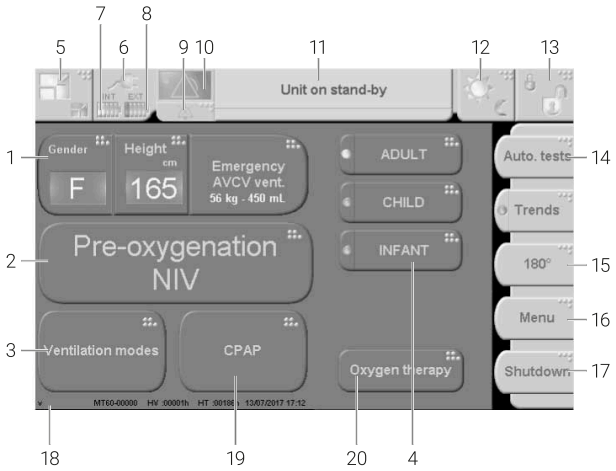
The display zone (green band) says **'Unit on stand-by'.**

The start-up screen is used to:

- Select the ventilation mode,
- Start ventilation,
- Choose the patient category,
- Start the automatic tests,
- Shut down the unit.

It also displays:

- The current software version,
- Ventilation time counter,
- The power-on time counter,
- The time and date.

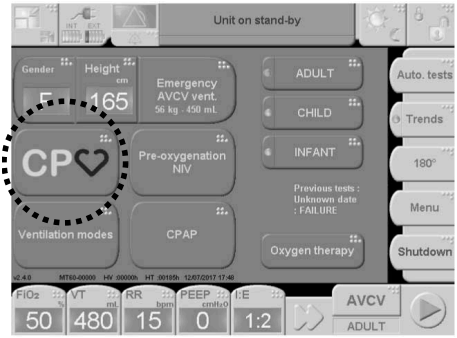


1	Zone to define the patient characteristics. See section New patient on page 34. Emergency ventilation access key in VC mode.	**11**	Alarm banner: Alarm display and software version zone
2	Key to access 100% O2 in PSV non-invasive ventilation (NIV) mode	**12**	**Day / Night** key (brightness setting). See Day/Night key on page 64.
3	Key to access other available ventilation Modes.	**13**	**Screen lock** key. See Screen lock key (Lock) on page 64.
4	Zone to define the category of patient to be ventilated (adult, child or infant)	**14**	Automatic test launch key
5	**Monitoring screen** key: to increase the display area of curves and trends	**15**	**180°** key: rotates the screen through 180°. See 180° Key on page 64.
6	AC power connection status	**16**	**Menu** access key
7	Internal battery status symbol	**17**	Unit **Shutdown** key
8	Removable battery status symbol	**18**	Software version / serial number / counters / current date & time
9	Audible alarm inhibit key	**19**	CPAP mode access button.
10	Alarm indicator	**20**	**Oxygen therapy** function key

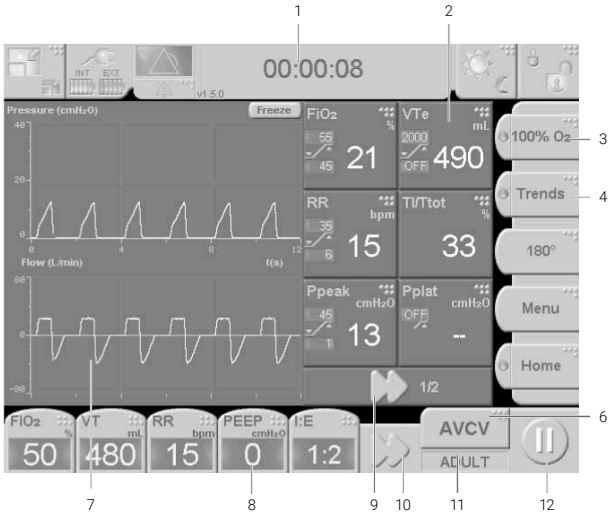
Note: Buttons **(2)** and **(19)** can be configured. The illustration above shows their default configuration. See Key configuration on the home screen on page 66.

Screen - CPV option enabled

If the CPV option is enabled, the ventilation mode is displayed on the home page, as shown here.


Unit on stand-by
Gender
Height
cm
165
Emergency
AVCV vent.
56 kg - 450 mL
ADULT
CHILD
INFANT
Auto. tests
Trends
180°
Menu
Shutdown
CPR
Pre-oxygenation
NIV
Ventilation modes
CPAP
Oxygen therapy
Previous tests :
Unknown date
: FAILURE
FIO2
%
VT
mL
RR
bpm
PEEP
cmH2O
I:E
50
480
15
0
1:2
AVCV
ADULT

4.2 Ventilation screen

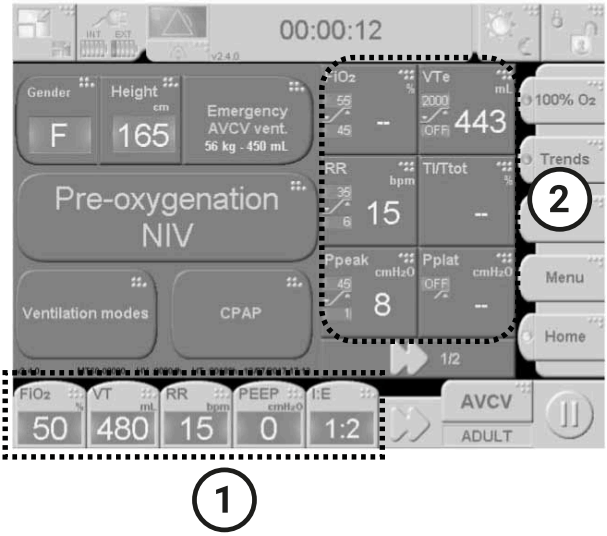


1	Display of the time elapsed since a ventilation mode was first activated. The counter resets to zero for each new patient, and after 18h ventilation. The counter display turns red after one hour's ventilation.	**7**	Display curves (1 to 8 configurable)
2	Monitored ventilation parameters	**8**	Ventilation settings
3	**100% O2** key	**9**	Arrow to access the rest of the settings for the current ventilation mode
4	**Trends** access key	**10**	Arrow to access the rest of the monitored ventilation parameters
5	**Home** screen access key: returns you to the home screen. Saves the ventilation-related functions: settings and measured parameters	**11**	Display type of patient ventilated (adult, child, or infant)
6	Current ventilation mode and key to access the change of ventilation modes	**12**	Ventilation start key **[**  **]** or ventilation pause key **[**  **]**

Note: The settings are not displayed when the device is started up. They are displayed when the Ventilation Modes button is selected or when a ventilation has already been launched.

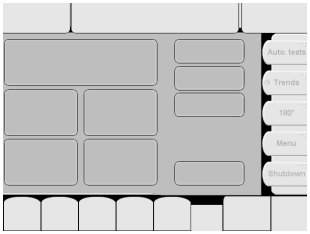
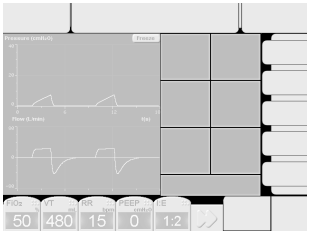
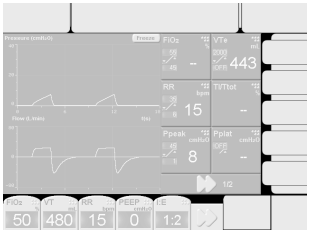
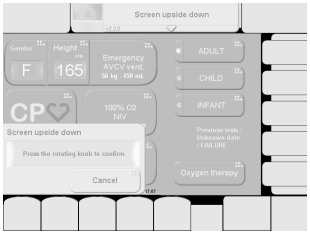
4.3 Home screen (current ventilation)

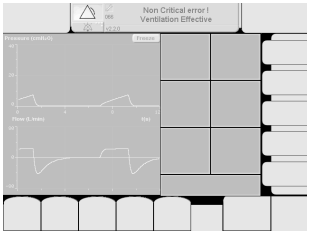
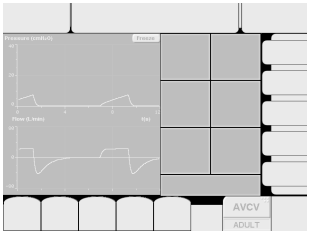
This screen is displayed when you press the **Home** key. It is the same as the start-up screen, but it keeps the ventilation-related functions: settings and monitored parameters. Ventilation continues.



1	Set parameters of the ventilation mode in progress.	2	Monitored parameters.

4.4 Ventilator controls

Function buttons 	Each function is activated by pressing the appropriate key. Its activation is indicated by a yellow LED. Press again to deactivate the function: the yellow LED is OFF.
Ventilation settings 	Settings of each more are entered or modified by pressing the screen. The value is highlighted. To change the value, turn the control wheel and confirm by pressing the control wheel. The set-points are displayed on two pages. Press  to move from one page to another. The key can be accessed when the device is locked.
Monitoring blocks 	Alarm thresholds are represented by the following symbol:  . Each threshold is selected by pressing this up or down symbol. Adjust the value by turning the control wheel, and press the control wheel to validate. The monitoring blocks are displayed on two pages. Press  to move from one page to another. The  key can be accessed when the device is locked.
Validation and information box 	This dialog box informs the user of the interaction between the parameters when they are being adjusted, or asks for confirmation for an action.

Alarm header panel 	The alarm header panel shows the alarm status and level. Its color changes depending on the importance: red, yellow, cyan, green (in decreasing order of importance). The arrow indicates the presence of several alarms at the same time (where the highest one is always displayed). Press this arrow to display the rest of the current alarms.
Ventilation Mode 	The current ventilation mode is displayed on screen. To change the ventilation mode, press the current mode key, select the desired mode (a yellow LED illuminates), and confirm by pressing **Validate**.

4.5 New patient

CAUTION: For the safety of the patient and to optimize ventilation performance, the patient characteristics should be appropriate to the patient being ventilated.

4.5.1 Selecting the patient category

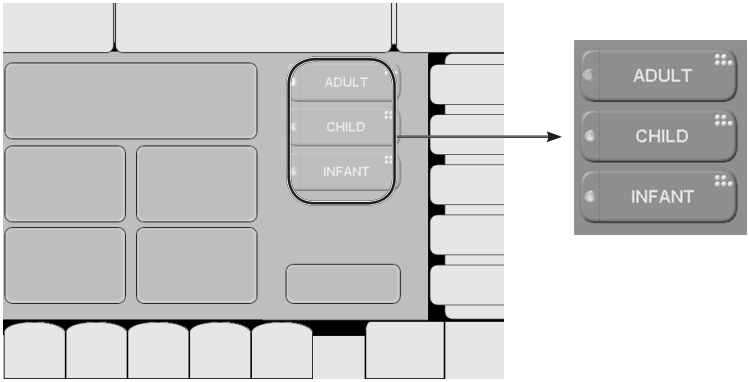
The choice of patient category allows adaptation of each of the following elements to the condition of the patient:

- 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.

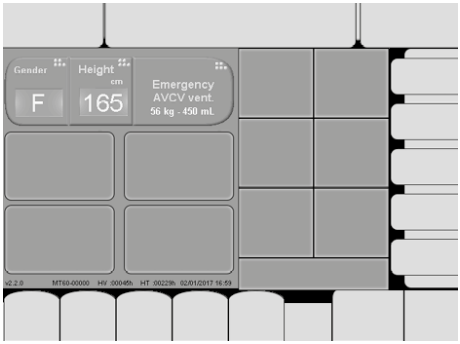
The patient category is selected from the start-up screen or the stand-by screen.

To define the patient category, press the appropriate button



4.5.2 Selecting the patient height and gender

The choice of height and gender enables the default volume supplied to the patient in emergency **Volume-Controlled (VC)** Ventilation mode to be adjusted and the predicted Weight/VT coefficient to be shown in the help window for setting volume modes.



To enter the height, press the **"Height"** button, turn the control wheel to change the value, and press the control wheel to confirm the highlighted option.

To enter the gender, press the **"Gender"** button, turn the control wheel to change the value, and press control wheel to confirm the highlighted option.

The predicted body weight and corresponding VT are displayed on the AVCV Emergency Ventilation mode start button.

Note: The predicted body weight of the patient is calculated using the patient's characteristics.

For more information on predicted weight, refer to Calculation of predicted body weight on page 129.

Note: The default gender is "Female" and the corresponding default height is:

- 165 cm for adults
- 100 cm for children
- 55 cm for infants

CAUTION: The diameter of the pipes in the patient circuit tubing must also be appropriate.

See the table below:

Patient category	VT range (mL)	Internal diameter of patient circuit tubing (mm)
Adult	100 - 2000	22 mm
Child	50 - 500	VT > 100 mL: 22 or 15 mm VT < 100 mL: 15 mm or less
Infant ≥3kg	20 - 75	Between 10 and 12 mm

Note: The user can only change the patient category via the start-up or stand-by screen.

Note: If the **"Save patient settings"** functionality is enabled, when the ventilator is started up, the **"Height"** and**"Gender"** settings correspond to those of the last patient that was ventilated.

4.6 Emergency ventilation start-up

For requirements arising in critical emergency situations, ***Monnal T60*** allows you to launch ventilation from the start-up screen with predefined ventilation parameters.

The proposed emergency ventilation mode is Volume Controlled Ventilation. As advised by clinicians, the following applications could be considered for the modes available. Examples of conditions involved: coma, respiratory distress and cardiac arrest (if the CPV option is not activated).

To launch emergency ventilation:

1. Enter the patient category (see New patient on page 34).
2. Enter the patient's height and gender.
3. Launch emergency ventilation by pressing **VC Emergency ventilation.**

   The default volume delivered will be 8 ml/kg. This ratio can be configured from 6 to 8 ml/kg.

Note: The volume is indicated on the emergency ventilation button. The weight displayed is the patient's predicted body weight. See Calculation of predicted body weight on page 129.

Note: The inspiratory trigger values return to their default values: when switching from emergency VCV ventilation mode to another mode, and when switching from another mode to emergency VCV ventilation mode.

The user can also launch a mode of 100% O_2 Pre-Oxygenation directly from the start-up or home screen in PSV mode / NIV (Non Invasive Ventilation). The pathology example concerned is asthma.

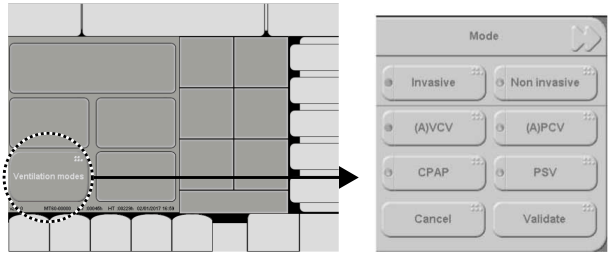
To launch this pre-oxygenation in NIV: press the **Pre-Oxygenation / NIV key**.

If the CPV Cardio-Pulmonary Ventilation software option is enabled, the user can also launch the CPV function directly from the start-up screen.

Note: If the CPV Cardio-Pulmonary Ventilation software option is enabled, the ventilation parameters are modified by default. See Settings tables on page 124.

4.7 Start / stop ventilation

The various ventilation modes are accessible via the start-up screen using the **Ventilation Modes** key.



The following modes are available:

- (A)VCV; (A)VCV / NIV
- (A)PCV; (A)PCV / NIV
- PSV; PSV / NIV
- CPAP
- SIMV; SIMV NIV

In option:

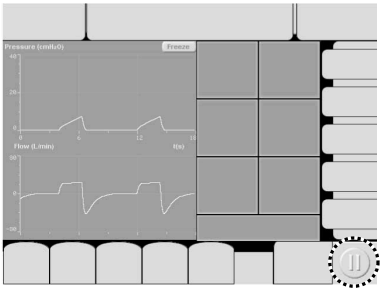
- Duo-Levels
- PSIMV; PSIMV NIV
- PS-Pro
- PRVC

To start ventilation:

1. Define the desired patient category (adult, child, or infant) from the start-up screen (see section New patient on page 34).
2. Press the **Ventilation Modes** key.
3. Select the desired mode by pressing the appropriate key (the yellow LED tells the user that the mode has been selected).
4. Press the **Validate** key.

Note: Adjust the parameters before starting ventilation.

The standard settings are restored every time the unit is started up, unless the **Save patient settings** functionality is enabled. In this case, when the ventilator is started up, the default settings correspond to those of the last patient that was ventilated.



To stop the ventilation in progress:

- Press the **Pause** [ ] key: a query alarm sounds and a dialog box is displayed;
- Validate or cancel using the control wheel.

Following validation, the machine stops ventilation and resumes the stand-by screen.

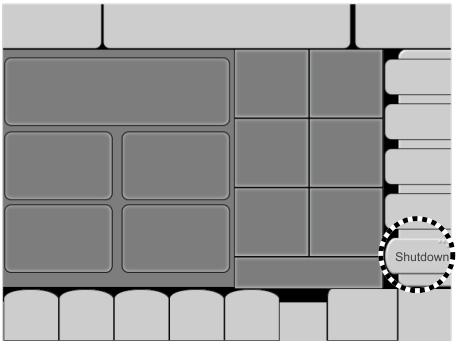
By pressing the **Play** [ ] key, the user restarts ventilation including the same parameters as the previous ventilation.

4.8 Shutting down the unit

There are two ways to shut down the unit from the stand-by screen:

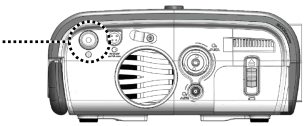
Press the **Shutdown** key;

- press the control wheel to confirm or press **Cancel** to cancel the shutdown.



Press the ON/OFF button (left-hand panel of the unit), for more than 10 seconds,

- press the control wheel to confirm or press **Cancel** to cancel the shutdown.



4.9 Ventilation modes and functions

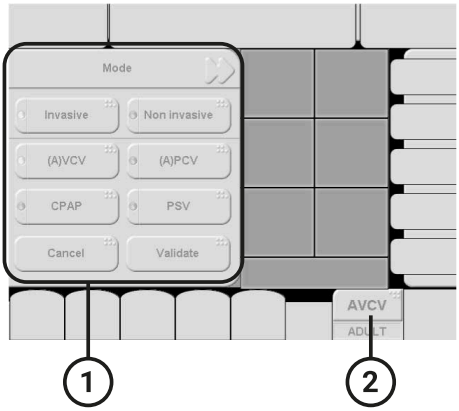
4.9.1 Mode selection

From the start-up screen or home screen (ventilation in progress)

1. Press the **Ventilation Modes** key.
2. Press the desired ventilation mode. The corresponding yellow LED lights up.
3. Press the **Validate** key.

From the ventilation screen

See Ventilator controls on page 32.



1	Mode selection	2	Current ventilation mode key

4.9.2 Ventilation settings

There are several series of settings for each ventilation mode.

The screen always displays five set-points.

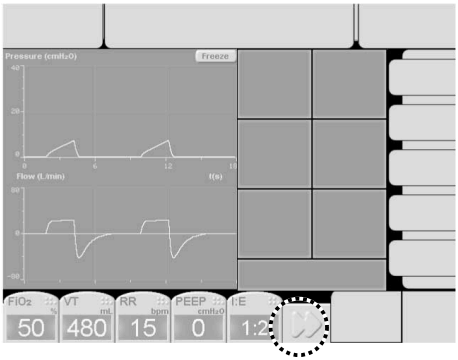
These settings can be adjusted using the **Ventilation Modes** key or on the Stand-by screen or during ventilation.

They are accessible on one or two pages using the arrow according to the ventilation mode selected.

To adjust a ventilation setting:

See Ventilator controls on page 32.

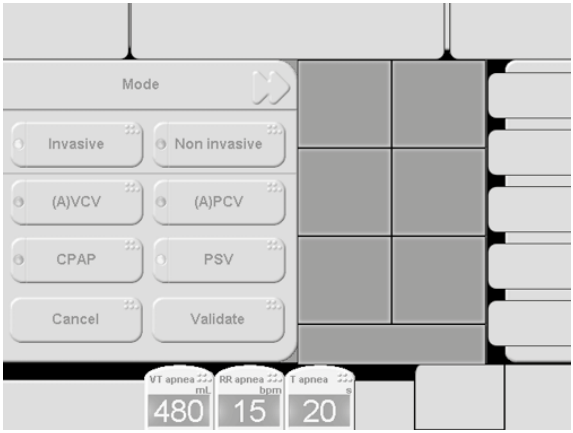
Arrow to access the second page of ventilation settings :



4.9.3 Apnea ventilation adjustment

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

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 stop apnea ventilation button or changes ventilation mode.

Apnea ventilation can be deactivated in CPAP mode, by setting T apnea to OFF. In this case, an alarm that can be cleared is triggered, to confirm the deactivation.

CAUTION: For safety reasons, apnea ventilation should only be deactivated when the clinical situation so permits. *Air Liquide Medical Systems* recommends activating apnea ventilation.

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

CAUTION: Apnea ventilation is not available in VCV, PCV, PS-Pro, PRVC modes and oxygen therapy function.

Note: Apnea ventilation is deactivated for two minutes when the following modes are launched: CPAP, Duo-Levels. It is also deactivated for two minutes when the PSV mode is launched, only in non-invasive ventilation mode.

4.9.4 VCV (controlled ventilation or assisted 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 ventilation cycles. During expiration, the ventilator regulates the pressure in order to maintain the set PEEP level.

If the inspiratory trigger value is set, this mode denotes (A) to show that it is now also assisted.

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

Set-points

FiO2	inspired oxygen fraction
VT	tidal volume (mL)
RR	minimum respiratory frequency (bpm)
PEEP	positive end of expiration pressure
I:E	ratio of inspiration time to expiration time
Trig.I	inspiratory trigger (L/min)
Tplat	adjustment of inspiratory plateau time (% TI)
Flow shape	form of flow rate insufflated to the patient: Constant or decelerated
VTsigh	enabling the sigh function if ≠ OFF sigh amplitude (unit x VT; e.g. VT sigh = 1.5 VT)
Sigh	sigh periodicity (1 sigh every x cycles)

Note: In VCV, there is no apnea ventilation.

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

4.9.5 PCV (controlled ventilation or assisted pressure-controlled ventilation)

[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 ventilation cycles. During expiration, the ventilator regulates the pressure in order to maintain the set PEEP level.

If the inspiratory trigger value is set, this mode denotes (A) to show that it is now also assisted.

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

Set-points

FiO2	inspired oxygen fraction
PI	inspiratory pressure (cmH2O)
RR	minimum respiratory frequency (bpm)
PEEP	positive end of expiration pressure (cmH2O)
I:E	ratio of inspiration time to expiration time
Trig.I	inspiratory trigger (L/min)
Slope	inspiratory pressure slope (cmH2O/s)
PIsigh	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)

Note: The PI value corresponds to the total inspiratory pressure applied to the patient. 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.

4.9.6 PSV (spontaneous ventilation with inspiratory assistance and PEEP)

[PSV = Pressure Support Ventilation]

Principle

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

The switch to the expiratory phase can be triggered:

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

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

Set-points

FiO2	inspired oxygen fraction

PSV	pressure support ventilation (cmH2O)
RR mini	minimum respiratory frequency (bpm) (if the function is enabled)
PEEP	positive end of expiration pressure (cmH2O)
Trig.I	inspiratory trigger (L/min)
TImax	maximum inspiration time of cycles (s)
Slope	pressure support pressure rise slope (cmH2O/s)
Trig.E	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 min' parameter: in the absence of inspiratory demand for a time exceeding '1/RR minimum' of a minute. 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 min.
- Use of the 'TI max' parameter: in the event of a leak in the circuit, the flow rate expiratory trigger may not be activated; in this case, the limitation on inspiration time allows the patient to enter the expiratory phase.

Note: When this mode is launched during non-invasive ventilation, apnea ventilation is deactivated for two minutes.

4.9.7 SIMV

[SIMV = Synchronized Intermittent Mandatory Ventilation]

Principle

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

Set-points

FiO2	Inspired oxygen fraction
VT	Tidal volume (mL)
RR SIMV	Determines the frequency of the mandatory cycles (bpm)
PEEP	Positive end of expiration pressure (cmH2O)
Tins	Determines the inspiratory time of the mandatory cycles (bpm)
Tplat	Inspiratory plateau time of the mandatory cycles (% TI)
Trig.I	Inspiratory trigger (L/min)
Flow rate	Form of flow rate insufflated to the patient: Constant or decelerated
PSV	Pressure support ventilation delivered during the spontaneous cycles (cmH2O)

TImax	Maximum inspiration time of spontaneous cycles (s)
Slope	Pressure support pressure rise slope (cmH2O/s)
Trig.E	Expiratory trigger (% of peak inspiratory flow).

In this ventilation mode, the controlled cycle (VCV) delivers a fixed volume at the set frequency RR SIMV. 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.

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 decreases after a spontaneous cycle, the unit waits for the SIMV period to expire before triggering a controlled cycle (VCV).

4.9.8 Pre-oxygenation NIV (non-invasive ventilation)

[NIV = Non Invasive Ventilation]

Principle

NIV is initiated by pressing the **Non invasive** key.

The **Pre-oxygenation NIV** mode allows you to ventilate a patient via a non-airtight interface: eg. Facial, oral, nasal mask or a NIV headset.

For this reason, the range of the ventilation settings and alarm thresholds ranges are adapted to NIV, i.e.:

- The PEEP set-point is limited to 20 cmH2O;
- The PSV set-point is limited to 25 cmH2O;
- The Trig.E set-point is set to 50% by default;
- The high and low VTi alarms are deactivated;
- The low MVe threshold is set at 3 L/min (adult), 1.5 L/min (child), 1 L/min (infant).

Note: NIV generally involves a variable leakage, which the unit estimates. This estimate is then input into the inspiratory demand detection algorithm to limit self-triggering. It may be necessary, however, to increase the level of the inspiratory trigger slightly, if self-triggering occurs too often. It may be necessary, however, to increase the level of the inspiratory trigger slightly if self-triggering occurs too often.

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

Note: CPAP and Duo-Levels modes are used in NIV only.

4.9.9 CPAP (Continuous Positive Airway Pressure)

[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.

Set-points

FiO2	Inspired oxygen fraction
CPAP	Continuous Positive Airway Pressure (cmH2O)

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

Note: When this mode is launched, apnea ventilation is deactivated for two minutes.

Note: The inspiratory and expiratory plateaus and pauses are disabled in CPAP mode.

4.9.10 Duo-Levels (Alternation of two CPAP levels)

Principle

Duo-Levels mode is characterised by pressure-controlled ventilation combined with the patient having the ability to breathe spontaneously throughout the cycle.

Duo-Levels mode is used to maintain a constant pressure (PI) for a time T high, and then a lower pressure (PEEP) for a time T low. The duration of the high-pressure phase and the minimum frequency are adjustable.

Trigger windows

To enable the patient's spontaneous breathing to adapt correctly to the ventilator, trigger windows are present to synchronize the inspiratory and expiratory phases:

- From low pressure to high pressure, the start of the trigger window is launched at T1. T1 takes the highest of the following two values: 30% of T low, or T low - 4 seconds.
- From high pressure to low pressure, the trigger window is launched at T2. T2 takes the highest of the following two values: 70% of T high, or T high - 2 seconds. At the end of the T high phase, if an inspiration is in progress, the T high phase is extended by a maximum of one second.

Set-points

FiO2	Inspired oxygen fraction
PI	Insufflation pressure (cmH2O)
PEEP	Positive end of expiration pressure (cmH2O)

RR mini	minimum respiratory frequency (bpm)
T high	duration at high level (s)
Trig. I	inspiratory trigger (L/min)
Trig. E	Expiratory Trigger (% of peak inspiratory flow)
Slope	pressure support pressure rise slope (cmH2O/s)

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

Note: When this mode is launched, apnea ventilation is deactivated for two minutes.

4.9.11 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 cmH2O 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.

  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 cmH2O
- Furthermore if the Ppeak, VTi Max or patient disconnection alarm is set off, the adaptation of the PI is inhibited until the alarm stops.

Set-points

FiO2	inspired oxygen fraction (%)
VT Target	volume target (mL);
RR	minimum respiratory frequency (bpm)
PEEP	positive end of expiration pressure (cmH2O)
I:E	ratio of inspiration time to expiration 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.

Note: In PRVC mode, there is no apnea ventilation.

4.9.12 PS-Pro (Pressure Support - Pro)

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 breathes spontaneously in such a way as to set off the inspiratory trigger, at a frequency above the set minimum frequency, the assistance frequency is then equal to the minimum frequency.

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.

It is therefore necessary to set a maintenance frequency equivalent to the frequency set in AVCV or APVC mode.

When ventilation is launched, 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.

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 (bpm)
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 (bpm)
PI max	maximum inspiratory pressure (cmH2O)
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 inhaled by the patient. Any adaptation of the pressure is therefore inappropriate.

Note: In PS-Pro mode, there is no apnea ventilation.

4.9.13 PSIMV (Synchronized Intermittent Mandatory Pressure Monitored Ventilation)

[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.

Set-points

FiO2	inspired oxygen fraction;
PI	inspiratory pressure (cmH2O);
RR SIMV	determines the frequency of the imposed cycles (bpm);
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 (cmH2O);
TImax	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 (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.

4.9.14 CPV: Cardio-Pulmonary Ventilation

4.9.14.1 Principle

The CPV function is a solution for assisting ventilation with ADULT patients in cardiac arrest.

It combines ventilation, monitoring and functionalities specifically for cardiopulmonary resuscitation.

The CPV function has two ventilation phases:

- the “chest compression” phase, enabling compressions to continue with appropriate ventilation and monitoring
- the “ROSC” (Return of Spontaneous Circulation) phase, during a prolonged cessation of chest compressions, allowing standard ventilation to be resumed.

To switch between these phases, press the **ROSC** key during chest compressions and the **CPV** key in ROSC.

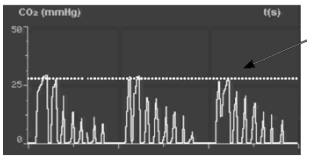
4.9.14.2 Measurements specific to chest compressions

RR CC	Chest compression rate measured by the ventilator (bpm)
% CC	Duration of cardiac massage in relation to time spent in the chest compression phase (%)
CO2	Maximum CO2 value between two ventilation cycles.

Timer	Time elapsed since CPV mode was launched. The counter is stopped during the ROSC phase in order only count the time spent in the CPV phase.
P-P	Maximum pressure variation generated by the chest compressions (cmH2O) 

4.9.14.3 Average CO_2 concentration

The maximum instantaneous CO2 values are averaged over 2 minutes, and then displayed as a horizontal dotted line.



It enables comparison of the instantaneous CO2 value with the average CO2 concentration line, in order to reveal a sudden variation in the CO2 level.

4.9.14.4 Chest compression phase set-points

FiO_2	fraction of oxygen inhaled
RR CPV	respiratory rate (bpm)
PL sync	synchronized low pressure (cmH2O)
PH sync	synchronized high pressure (cmH2O)
T high	high-level duration (s)

4.9.14.5 ROSC phase set-points

FiO2	fraction of oxygen inhaled
RR	minimum respiratory rate (bpm)
PEEP	Positive exhalation pressure (cmH2O)
PI	Insufflation pressure (cmH2O)
Trig.I	Inspiratory Trigger (L/min)

4.9.14.6 Operation

Chest compression phase

At the start of the CPV function, the “Chest compressions” phase is enabled, and remains so until the **ROSC**. key is pressed. Detection of the first chest compressions is confirmed by the sound of 5 audible beeps.

During this phase, the set-point panel is pink and 3 measurement blocks specific to cardiopulmonary resuscitation are available.

These measurement blocks are indicated by the following symbol :

During this phase, ventilation alternates between a level of high pressure and low pressure triggered by the ventilator. The pressure is specifically regulated to optimize the chest compressions.

ROSC (Return of Spontaneous Circulation) phase

The “ROSC” phase is activated by pressing the **ROSC** key.

The following message “ROSC Phase: Return to standard ventilation” displays in the alarm panel. The set-point panel turns back to blue. The measurement blocks specific to CPR have moved to the second monitoring page.

The ventilation delivered in the ROSC phase is pressure assisted and controlled. The default respiratory rate in the ROSC phase is greater than that of the previous phase to compensate for the loss of ventilation introduced by the chest compressions.

To resume chest compressions, pressing the **CPV** keys causes the immediate return to the “Chest compressions” phase.

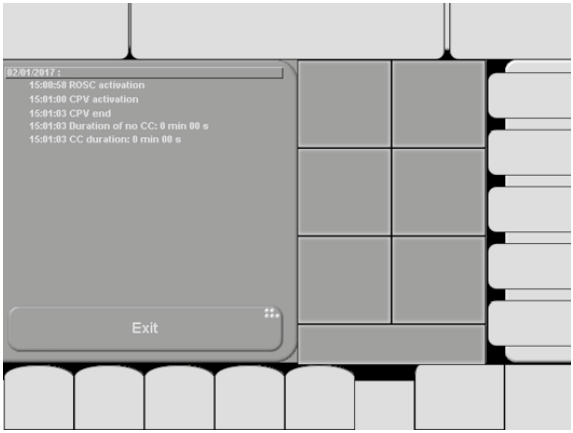
Note: The set-point panel and monitoring page visible by default on the first page always correspond to the current phase. The set-point panel and the monitoring page of the pending phase are accessible on the second page.

Note: The CPV function is only suitable for adult patients and is not available if the selected patient category is “Child” or “Infant”.

4.9.14.7 CPV report

The **“CPV Report”** function displays a chronological list of the most recent events of the CPV operating mode:

- activation of the mode
- stopping the ventilation
- activation of the “Chest compressions” stage
- activation of the “ROSC” stage
- cumulated duration of chest compressions for the ventilation period observed
- cumulated duration of “no CC” for the ventilation period observed (see Chapter CPV: Cardio-Pulmonary Ventilation on page 49)



To access the CPV Report, see section Patient monitoring on page 72.

Use the knob to browse the list.

Note: When the memory capacity of the log is full, the oldest entries will be replaced by the new entries.

4.9.14.8 Airway Opening Index (AOI)

Percentage of the opening of the airway, based on the measurement of instantaneous CO2. See Trends on page 61.

4.9.15 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 T60*** (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 T60*** 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 section Automatic tests on page 25);
3. Disconnect the dual branch circuit and set up the required patient circuit on the inspiratory branch of the ventilator 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.

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 FiO_2 is the FiO_2 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 FiO_2 is potentially higher than that inhaled by the patient.

Note: The Ppeak threshold can be adjusted. Its default setting is 45 cmH_2O.

4.9.16 CO2 option

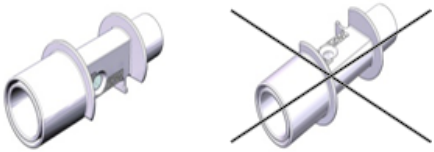
4.9.16.1 Recommendations for using the MASIMO IRMA CO2 measurement probe

- 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 probe must not be in direct contact with the patient.
- The IRMA™ probe must not be used with flammable anesthetic agents.
- IRMA™ adapters are a single-use product and must not be re-used for different patients. Used adapters must be disposed of via the appropriate hospital waste disposal channels. Reusing single-use adapters can lead to patient cross-contamination.
- Do not use adapters for adult patients or children on infants, as this carries the risk of adding dead space.
- Do not use adapters for infants on adult patients or children, as this carries the risk of increasing resistance.
- 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 humidity is observed on the inside.
- Do not use the IRMA™ airway adapter with nebulized medications as this may affect the light transmission of the airway adapter windows.
- 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.

4.9.17 Keeping alarm settings and thresholds

When changing ventilation mode, and depending on the case, the alarm settings and thresholds can be kept or discarded.

There are 3 scenarios:

Oxygen therapy

When an oxygen therapy session is started, the settings and thresholds for this function are applied, and no longer take the settings from the previous mode into account. However, the previous settings are not erased.

When the user stops the oxygen therapy session and starts another mode, the patient setting and threshold values return to the previous configuration.

In this example, an oxygen therapy session follows the PSV mode:

PSV	→	**Oxygen therapy**	→	**PSV**
FiO2 : 30%		FiO2 : **50%**		FiO2 : **30%**

1. Ventilation in **PSV mode** with FiO2 set at 30%.
2. Switch to **Oxygen therapy** with FiO2 at 50%.
3. When the **Oxygen therapy** session is finished, the user starts PSV mode again. FiO2 returns to the previous setting (30%).

Note: The oxygen therapy FiO2 settings are not saved for the next launch.

Emergency modes

The following ventilation functions are in this category: **CPV**, **Emergency AVCV Ventilation** and **100% O2 NIV**.

These functions do not take the settings and thresholds for previous ventilation modes. The settings and thresholds are erased and are replaced by default values.

In this example, **CPV** follows the **AVCV** mode:

VCV	→	**CPV**	→	**VCV**
FiO2 : 30%		FiO2 : **50%**		FiO2 : **50%**

1. Ventilation in **AVCV** mode with FiO2 set at 30%.
2. Switch to **CPV** with FiO2 at 50%.
3. When the cardiopulmonary ventilation session is finished, the user starts **AVCV** mode again. FiO2 is reset to the mode default setting (50%), and not to the previous setting (30%).

Other modes

When switching from one ventilation mode to another (not including emergency modes and oxygen therapy), the setting and threshold values are kept. For settings and thresholds that are not shared by the two modes (i.e. VT in pressure-controlled mode), the values are stored in memory but are not applied.

In this example, a **pressure**-controlled mode (PSV) follows a **volume**-controlled mode (AVCV):

VCV	→	**PSV**	→	**PSV**	→	**VCV**
VT: 460 mL PEEP: 4 cmH_2O		PEEP: 4 cmH_2O		**PEEP: 6 cmH_2O**		**VT: 460 mL** **PEEP: 4 cmH_2O**

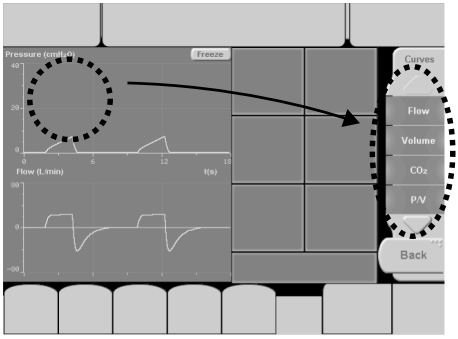
1. Ventilation in **AVCV** mode with VT set at 460 mL and PEEP at 4 cmH2O.
2. Switch to **PSV** mode: since the VT is not used in this mode, the setting is not applied, but it remains in the memory. However, the PEEP is applied.
3. Set PEEP at 6 cmH2O.
4. Switch to **AVCV** mode: the PEEP setting is kept. The VT setting is applied once again.

4.9.18 Displaying the curves

The following curves are available: Pressure, flow rate, volume, pressure / volume, flow rate / pressure, volume / CO2 and CO2 (if the etCO2 software option is enabled).

Two curves are displayed continuously and in real time. Only one is displayed in the case of loop curves.

To change the curve display, press the area of the curve to be replaced and select the desired curve from the menu on the right.

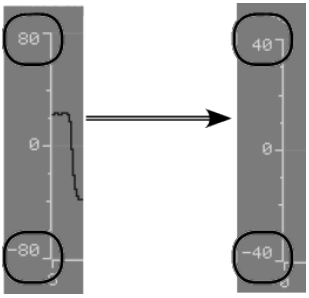


Press **Back** to cancel.

Note: If the selected curve is already displayed in the curve area, the two curves are inverted.

Note: When the respiratory cycle comes from a patient demand, the curves are green, but a controlled cycle is displayed in yellow.

4.9.18.1 Adjustment of scales



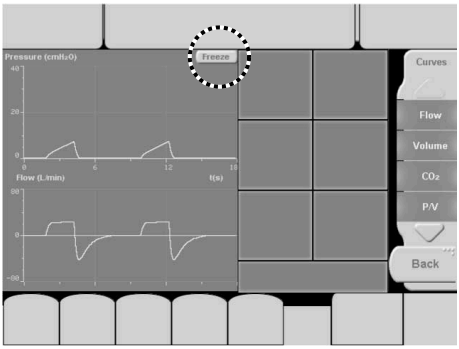
To adjust the time scale, press the t(s) (abscissa) (X) axis.

To adjust the pressure, flow rate, volume, or CO2 scale, press the corresponding ordinate (Y) axis.

Pressing the center of the curve automatically adjusts the ordinate (Y) axis.

4.9.18.2 Freezing the curves

Press the **Freeze** key to freeze the curves.



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

The cursor is selected, modified and moved using the control wheel.

The symbol Δ indicates the difference in pressure, flow, volume, CO2 and time between the two cursors for the two curves displayed.

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

Note: While the curves are frozen, the numerical values of the patient parameters continue to be refreshed on-screen.

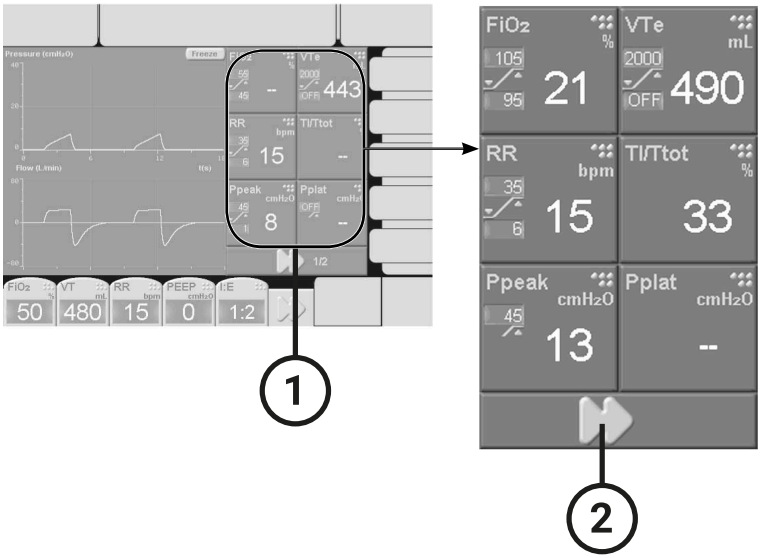
4.9.19 Monitoring

Several monitored ventilation parameters (measurements) are available for each ventilation mode.

Each parameter displays the value of the measurement for the current ventilation mode.

These values are accessible on two pages using the arrow.

Six measurements per page are continuously displayed on the screen, six on the clinical screen, and four on the waveform monitoring screen.



1	Monitored respiratory parameters	2	Arrow to access the second page of monitored parameters

The position of each block is configurable (see Display of measurements on page 60).

Each measurement is displayed in a block containing:

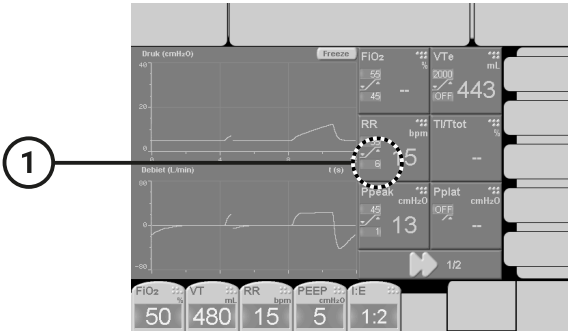
- the name, unit of measurement, and current value along with
- the upper and lower alarm thresholds.

The measurement blocks can also be used to adjust the alarm thresholds.

4.9.19.1 Adjustment of alarm thresholds

The alarm thresholds can be accessed and adjusted directly via the ventilation screen.

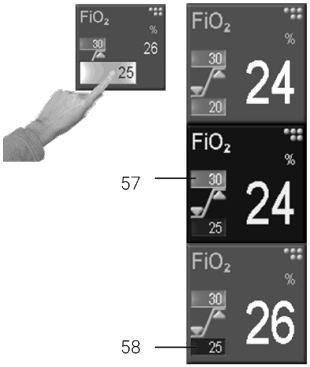
To adjust a threshold:



- Select the value to be adjusted, upper or lower threshold of the desired block **(1)**. The value is highlighted.
- Adjust the value by turning the control wheel, and press the control wheel again to confirm.

When an alarm threshold has been breached, the block and the associated alarm threshold turn red **(57).** This display is maintained for as long as the alarm is present.

When the alarm is resolved, the block resumes its original appearance, but the threshold concerned remains red (**58**): this indicates that the alarm took place.



CAUTION: After restarting the unit or changing the patient category, the alarm thresholds are automatically reset to their standard value.

CAUTION: It is necessary to set these alarm thresholds to ensure that they are suitable for the patient and his/her ventilation. For example: the high-pressure threshold is very important to protect the patient from excessive airway pressure.

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

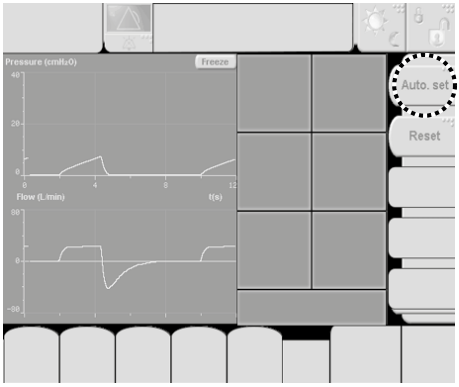
Particular case of peak airway pressure (Ppeak) and maximum tidal volume (MTV)

In all modes, exceeding the upper Ppeak threshold switches off the current inspiration and is forced to change to expiration. Furthermore, in non-invasive pressure-controlled ventilation modes, exceeding the upper insufflated tidal volume (Vti) threshold also switches off the current inspiration and is forced to change to expiration.

4.9.19.2 Automatic thresholds

The **Auto. set** button is used to automatically configure all of the alarm thresholds according to the values measured at the time when the button is pressed (see Adjustment of alarm thresholds on page 58).

To adjust the automatic thresholds, press a monitoring block. The **Auto. set** button appears on the right-hand side of the screen.



Press the **Auto. set** button, then confirm by pressing the rotating knob: all of the alarm thresholds update automatically.

CAUTION: After pressing the **Auto. set** button, check that the thresholds obtained in this way are appropriate for the clinical condition of the patient.

Resetting

When an alarm threshold has been exceeded, it remains highlighted in red, as do the other thresholds, even when the alarm is resolved.

To reset all the thresholds highlighted in red, press the **Reset** key.

4.9.19.3 Display of measurements

List of measured parameters (those with alarm thresholds must be present) on two pages:

Measurements	Type of information
FiO2	Insufflated oxygen fraction measured every second
VTe	Volume exhaled during the cycle
RR	Respiratory rate averaged over 4 cycles
I:E	Ratio of inspiration time to total cycle time
Ppeak	Peak inspiratory pressure of the cycle
Pplat	Pressure measured at the end of the plateau or inspiratory pause
PEEP	Pressure measured 80 ms before the end of expiration
VTi	Volume insufflated during the cycle (invasive ventilation)
MVe	Expiratory volume per minute averaged over 30 s
MVi	Inspiratory volume per minute averaged over 30 s.
Leak	Leak percentage (non-invasive ventilation)

Measure-ments	Type of information
Pmean	Mean pressure of respiratory cycle
etCO2	Expired CO2 fraction at end of expiration [2].
CO2	Highest instantaneous CO2 value between two ventilation cycles. [3].
% CC	Duration of cardiac massage in relation to time spent in the chest compression phase (%) [3].
Timer	Time since CPV mode started [3].
P-P	Maximum pressure variation generated by the chest compressions (cmH2O) [3].

4.9.19.4 Trends

This function allows the user to track the following measured ventilation parameters:

CO2[4]	VTe	MVe	Ppeak
PEEP	Pmean	RR	TI/Ttot
FiO2	Pplat	VTi	Leak
P-P[4]	RR CC[4]	% CC[4]	AOI[4]

This screen can display two trend curves at the same time.

To replace the trends curve displayed on-screen with another measured parameter, press the curve to be replaced and select the desired parameter from the right-hand menu.

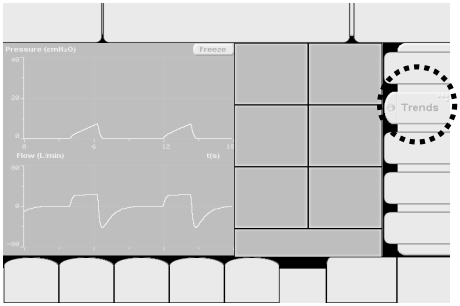
Note: If the selected curve is already displayed in the curve area, the two curves are inverted.

Access to trends from the ventilation screen :

2 If the etCO2 software option is enabled and etCO2 monitoring is activated .

3 If the CPV software option is enabled. Only available in CPV.

4 If the CPV software option is activated.



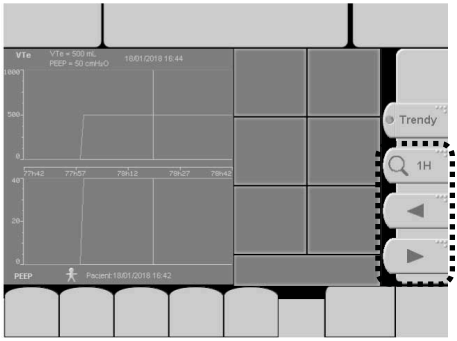
The trend curves can be displayed for 5, 20, 40 or 80 hours. To change the time scales, press the **zoom + or -** buttons.

To scroll through time in the trend curves, press the arrows.

The user can display the exact values at a given instant of ventilation parameters selected using the cursor. The patient treatment date corresponding to the cursor position is shown when it falls within the last 80 hours of ventilation.

The user can thus move in the trend curve and read the values of the two predefined measured parameters.

Note: Measured ventilation parameters are also stored in memory when the device is in stand-by mode.

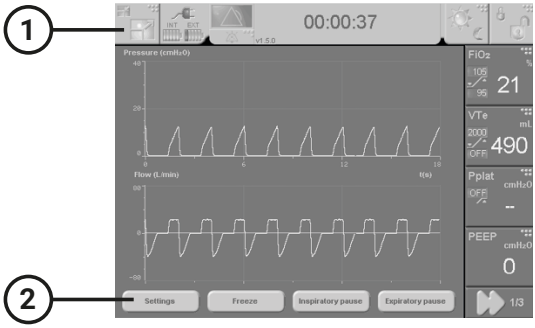


4.9.19.5 Monitoring screen

The **Monitoring screen** key lets you increase the curve display area.

When this function is enabled:

- The ventilation settings are no longer displayed, and are replaced by the curve **Freeze**, **Inspiratory pause** and **Expiratory pause** functions.
- The panel of functions on the right is no longer displayed,
- Four blocks of measurements are displayed instead of six.



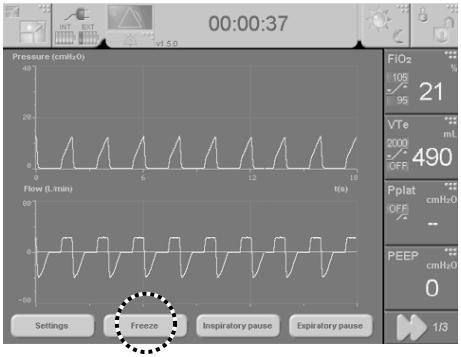
1	Monitoring screen key	2	Back to ventilation screen

Press the **Ventilation screen** key again or the **Settings** function in the lower left-hand corner to display the ventilation screen with standard monitoring and access to the settings.

Note: The **Inspiratory pause** and **Expiratory pause** keys are not accessible in CPV, CPAP and Duo-Levels modes.

Freezing the curves

Press the **Freeze** key to freeze the curves. For instructions on using the **Freeze** function, see Freezing the curves on page 56.



Inspiratory pause

The **Inspiratory pause** key is used to perform an inspiratory pause (limited to 40 seconds). The pause continues for as long as the user holds down the key. When the user stops the hold, the ventilator resumes ventilation with the parameters set previously.

Expiratory pause

The **Expiratory pause** key is used to perform an expiratory pause (limited to 60 seconds). The pause continues for as long as the user holds down the key. When the user stops the hold, the ventilator resumes ventilation with the parameters set previously.

Note: The inspiratory and expiratory pauses are not available in CPV, CPAP and Duo-Levels.

Note: After the execution of a pause, a curve freeze can be performed in order to measure the plateau pressure and the auto PEEP value using cursors.

Note: The plateau pressure value is refreshed:

- After an inspiratory pause;
- In the event of an inspiratory plateau lasting longer than 0.3 s (in VCV)
- When the inspiratory plateau is not activated, the Pplat measurement is displayed as follows: --.

4.9.20 Other functions

4.9.20.1 Screen lock key (Lock)

Press this key to lock the screen.

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

4.9.20.2 Day/Night key

This function adjusts the brightness of the screen.

4.9.20.3 180° Key

This function rotates the screen 180°.

4.9.21 Personalizing the device

All of the machine settings described below are accessible in stand-by via the configuration menu (press the control wheel and press the sound inhibition key).

Ventilator	Home screen first button Home screen second button Activate options Patient Weight/VT coeff. (mL/kg) SI units Size unit Protocol
Settings	VCV setting APCMV setting Tplat unit Help setting Fmin setting
Monitoring	Clinical screen measurements Restore clinical screen Monit. screen measurements Restore monit. screen
Language	
Modes	(A)PCV CPAP SIMV, PSIMV, PRVC Duo-Levels, PS-Pro
Settings back-up	Ventilation settings back-up Alarm thresholds back-up Ventilation settings restoration Alarm thresholds restoration Copy machine parameters (usb) Patient settings back-up

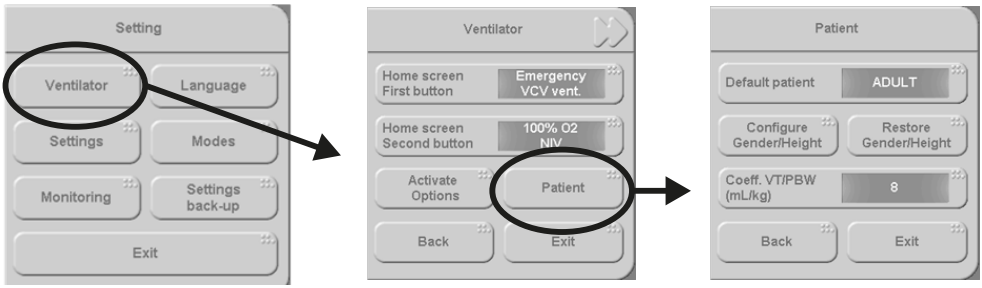
4.9.21.1 Default patient

The **Default patient** function is used to choose the type of patient (adult, child, or infant) selected by default on device start-up.

The default patient is ADULT.

This is accessed from the **"Ventilator"** tab, then **"Patient"**.

If the **"Patient sett. back-up"** functionality is enabled, when the ventilator is started up, the category corresponds to the last patient who was ventilated. See Saving the ventilation settings and alarm thresholds on page 68.



4.9.21.2 Gender /Height configuration

The **"Configure Gender/Height"** function is for configuring the gender and height suggested by default for each category of patient.

To configure the default sex and height for a patient category:

1. From the **"Patient"** menu, select the **"Default Patient"** corresponding to the category concerned.
2. Press **"Configure Gender/Height"** to display the configuration window.

Note: This operation can be repeated for the Adult, Child and Baby categories.

The **"Restore Gender/Height"** key resets the default parameters (see Settings tables on page 124). Restoration applies to all patient categories.

4.9.21.3 VT/PBW coefficient

The **VT/PBW coefficient** function is used to select the coefficient applied to the predicted body weight for the volume calculation when the **VC Emergency Ventilation** key is pressed (6, 7, or 8 mL/kg).

The default coefficient is 8 mL/kg.

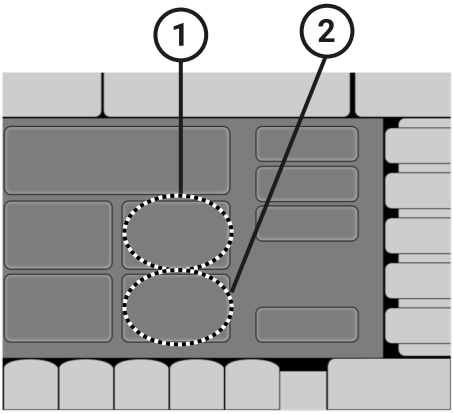
To access, use the **"Ventilator"** tab then **"Patient"**.

4.9.21.4 SI Unit

The **"SI Unit"** function enables the cmH2O unit of pressure measurement to be replaced by hPa.

4.9.21.5 Key configuration on the home screen

The **"Key configuration"** function enables the available ventilation modes to be selected from the home screen.



1	Key 1	2	Key 2

The configuration is available from the Ventilator menu.

Keys 1 and 2 can be configured. By default, key 1 is attributed to 100% O2 NIV and key 2 to CPAP mode.

CAUTION: If the **100% O2 NIV** function is not showing on the home screen, it will not be possible to start it from the **Other modes** window.

4.9.21.6 Selecting the height display unit

The **"Height unit"** function enables the height measurement unit used for emergency ventilation to be selected.

It is accessed using the ⏩ arrow key on the Ventilator menu.

4.9.21.7 Choice of communication protocol

This function allows you to select the protocol used for transmitting data from the ***Monnal T60***. See Connectivity to hospital networks on page 106.

4.9.21.8 Display of the ventilation timer

This function allows you to enable or disable the display of the ventilation timer.

It is available on page 3 of the Ventilator menu.

By default, the timer is displayed.

Note: The timer function cannot be deactivated. This function only changes whether the timer is displayed on the screen or not.

4.9.21.9 Mains disconnection alarm

This function allows you to activate an alarm in the case where the mains cable is disconnected, even if both batteries (internal and extractable) are connected.

Please see Table of alarms on page 77 for the alarm details.

This function is available on the 3rd page of the **Ventilator** menu.

By default, this alarm is deactivated.

4.9.21.10 Saving the ventilation settings and alarm thresholds

Settings can be saved for each category and each type of ventilation:

- Invasive ventilation
- Non-invasive ventilation
- Emergency ventilation VCV
- 100% O2 NIV
- CPV (if enabled)

Likewise, the alarm threshold settings for each category and for the following two types of ventilation can be saved:

- Invasive ventilation
- Non-invasive ventilation

These are accessed directly via the first page of the configuration menu.

The **Restore** keys are used to reset the set-points and/or thresholds to the default values. Restoration applies to all configurations and all patient categories.

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.

If the device is shut down, the **"Save patient settings"** key allows the device to be restarted using the settings of the last ventilation.

Note: If it is started up without a patient category selection, the following settings are retained:

- Patient type (category, height and gender)
- Ventilation mode (set-points, alarm thresholds)

4.9.21.11 Set-point selection

The **Set-points** function is used to select the set-points to be used according to application:

- I:E, Ti/Ttot, Ti or Flow rate in VCV
- I:E, Ti/Ttot or Ti in PCV
- Tplat in % or seconds in VCV and SIMV
- PS or PI in PSV and SIMV
- RR min enabled or disabled in PSV

4.9.21.12 Display of the monitoring blocks

The **Monitoring** function allows the user to change the display order of the monitoring blocks in the clinical display **(measures clinic screen)** and in the monitoring display **(measures wide screen)**. The configurations are independent between the screens.

The **Restoration** keys allow you to reset the order of the monitoring blocks on each screen.

These functions are available from the **Ventilator** menu.

Note: In clinical mode, the display of the Pplat and Leak monitoring blocks on the first page change according to the ventilation type. In invasive ventilation, Leak is replaced by Pplat, and vice versa in non-invasive ventilation.

4.9.21.13 Display modes in the 'other modes' window

The **Ventilation modes** function is used to choose the modes that will appear in the **Other modes** window, and therefore to remove unused modes if necessary.

Note: VCV and PSV modes cannot be disabled.

Note: To transfer all of the configurations from one machine to another, use a USB key and go into the **Save settings tab**, and then **Copy machine parameters (USB)**.

The **'Monnal => USB Key'** key is used to save all the settings on a machine to the USB key.

The **'USB key => Monnal'** key is used to load onto the machine all the settings entered into another machine and then stored on the USB key.

4.10 Menu

4.10.1 Description

The Menu key is on the right, at the bottom of the screen. It gives access to functions or commands via a two-level structure.

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

The menu items give access to:

- Apnea ventilation adjustment,
- Patient monitoring,
- Activation of the FiO2, CO2 and expiratory flow monitoring sensors,
- Activation of the low-pressure O2,
- Ventilator configuration,
- The command to transfer data via a USB key (not accessible during ventilation).

Press the **Exit** button to return to the previous screen.

4.10.2 Menu structure

Patient monitoring	History Trends CPV report
Sensors	FiO_2 monitoring (ON/OFF) $etCO_2$ monitoring (ON/OFF) Exp monitoring (ON/OFF) CO_2 sensor calibration
Low-pressure O2	ON/OFF
Configuration	Alarm sound volume Brightness Alarm flash (ON/OFF) Alarm inhibition (ON/OFF) Keypad tone (ON/OFF) Date and time
Data transfer	History (log.csv) Black box (blackbox.his) Trends (trends.csv) CPV report (cpv.csv)

4.10.3 Sensors

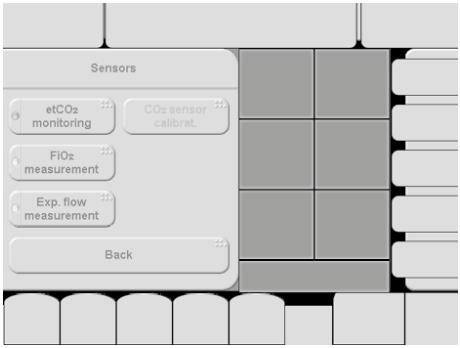
This key is used to enable or disable monitoring.

Three monitoring sensors can be selected or de-selected:

- FiO_2 monitoring
- $etCO_2$ monitoring
- Expiratory flow monitoring.

To enable a sensor:

- Press the **Menu** key,
- Press the **Sensors** key,
- Press the desired sensor to enable it (yellow LED).



Note: By default, FiO_2 monitoring and monitoring of the expiratory flow are enabled (yellow LEDs).

$etCO_2$ monitoring is enabled automatically when the CO_2 probe is connected to the ventilator.

When the CO_2 probe is connected or enabled, the **CO2 sensor calibrat.** key is used to calibrate the probe.

Note: If the CO_2 probe is connected but the user does not require it, the user may disable it.

CO_2sensor calibration

The IRMA™ probe must be calibrated whenever an offset is found in the measurements or when the **Calibrate CO2 sensor** alarm is triggered.

The probe cannot be calibrated until approximately 10 seconds after it has been connected to the ventilator.

Probe calibration must be performed with a new adapter on the sensor. This must be disconnected from the Y-piece of the patient circuit and from the patient. Next, press the **CO_2 sensor calibrat**. key to launch probe calibration. The green LED on the probe flashes for about five seconds during calibration.

Special care must be taken to avoid any breathing into the adapter during probe calibration. The presence of ambient air (21% O_2 and 0% CO_2) in the probe is crucial for a successful calibration.

4.10.4 Low-pressure O_2

This function allows the machine to enrich the O_2 mixture from a low-pressure source, typically a low flow meter on an O_2 cylinder or a concentrator.

This is different from connecting it to a high-pressure source, as it involves lower quantities (pressure generally below 1 bar, flow less than 10 L/min); According to the nature of the source and the ventilation settings, certain FiO2 values cannot be guaranteed. An alignment chart is provided for information in Section Technical description on page 100.

To enable the low-pressure O_2 function, press **Menu** and then **Low-pressure O_2**.

The message **'Low-pressure O_2 enabled'** (information) then appears in the alarm panel.

The gas mixture is O_2-enriched and monitored in conjunction with the FiO_2 setting parameter, and the machine supplies the desired concentration insofar as possible.

If the ventilation and low-pressure source settings are incompatible, the FiO_2 will not be reached, and the **Low FiO_2!!!** alarm will be triggered. The user will then be informed that the settings need to be modified.

Note: During operation with a high-pressure source, the 100% O_2function can be enabled. This possibility is maintained in low-pressure operation dependent on the O_2 supply flow and the patient's ventilation. The maximum concentration that can be achieved nonetheless depends on the source and the ventilation settings.

CAUTION: To guarantee satisfactory operation from a low flow O_2 supply on a concentrator, the high-pressure O*2* hose must be disconnected from the machine.

4.10.5 Patient monitoring

The **"Patient monitoring"** function is for accessing the patient's data such as History (see section History on page 77), Trends (see section Trends on page 61) and the CPV report (see section CPV: Cardio-Pulmonary Ventilation on page 49).

Note: The trends can also be accessed via the ventilation, start-up, and stand-by screens.

4.10.6 Data transfer

This function is accessible via the start-up screen and the stand-by screen. This allows you to transfer the data (history, trends) from the patient's ventilation session to a USB key. This also allows data to be transferred from the machine technical memory (black box).

4.10.7 Configuration of the ventilator

Press the **Menu** key: the list of menu parameters is displayed.

Press the **Configuration** key.

Volume

To adjust the device's audible alarms:

- Press the **Volume** key,
- Turn the control wheel to display the desired value,
- Press the control wheel again to validate.

Note: The audible alarm is for a health professional near the patient. The maximum distance away and the volume of the alarm must therefore be determined by the user according to the situation.

CAUTION: You must set a higher volume than the ambient noise. A volume that is too low may prevent users from hearing the alarm.

Brightness

To adjust the brightness of the screen backlighting:

- Press the **Brightness** key,
- Turn the control wheel to display the desired value,
- Press the control wheel again to validate.

Keypad tone

The **Keypad tone** function causes a beep to sound whenever a key is pressed on the screen:

- Press the **Alarm flash key** to activate the function: a yellow LED is displayed (this function is enabled by default).
- Press the **Alarm flash key** again to disable the function (yellow LED off).

Alarm flash

The **Alarm flash** function allows you to enable the presence of the casing indicator light on the front panel of the machine.

- Press the **Alarm flash** key to activate the function: a yellow LED is displayed (this function is enabled by default).
- Press the **Alarm flash** key again to disable the function (yellow LED off).

Alarm inhibition

The **“Preventive Alarm Inhibition”** function silences the audible alarms on the ***Monnal T60*** for 2 minutes.

Press the **“Alarm Inhibition”** key to enable the function: a yellow LED is displayed (this function is disabled by default).

Date / Time (In stand-by only)

To set the date and time on the machine, press the **Date/Time** key.

To adjust each parameter (day / month / year / hour / minute):

- Turn the control wheel to display the desired value,
- Press the control wheel to confirm and proceed to the next value.

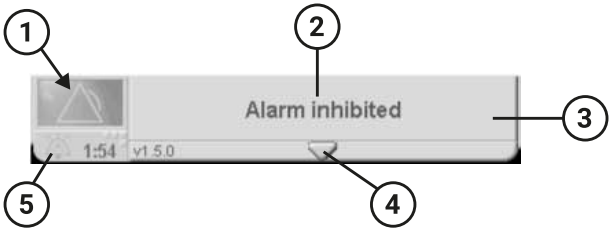
5 Alarms and other messages

In some circumstances, ***Monnal T60*** warns the user that action is required using audible and visual alarms. ***Monnal T60*** can also display information messages on the screen.

There are 5 categories of alarms and messages:

- Info category: information messages;
- Low, Medium, High categories: low, medium, and high priority alarm;
- Ultra category: high-priority alarm caused by the ventilation stopping.

5.1 Display



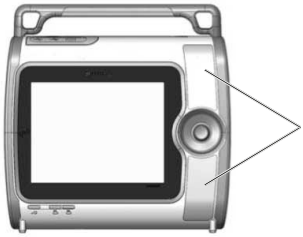
1	Alarm indicator	2	Alarm text or information message
3	Alarm banner	4	Arrow (indicates several active alarms)
5	Disable button		

The color of the alarm indicator, the disable button and the banner depends on the message category:

Category	Disable button and indicator	Banner
ULTRA	Red	Red
HIGH		
MEDIUM	Yellow	Yellow
LOW	Cyan	Cyan
INFO	Grey	Green
No alarm or message	Grey	Grey

Note: The alarm indicator flashes when a HIGH or MEDIUM priority alarm is on.

The alarm lights on the front of the device also indicate an alarm:

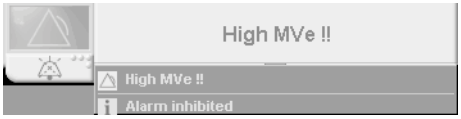


Category	Alarm lights
Ultra and high	Fast flashing red (twice per second)
Medium	Slow flashing yellow (once every two seconds)
Low	Continuous yellow

Simultaneous alarms display

The arrow indicates that several alarms are active at the same time:

Press on the arrow to display all the active alarms:



Note: In cases where two (or more) alarms of the same priority are triggered at the same time, the alarm with the lowest No. is visible.

Technical alarms

To indicate a technical error, the alarm also displays the symbol (“ ”) and a number so that the technical department can identify the exact source of the alarm.

Priority and trigger

The priority level of some alarms can increase according to repeated conditions (number of cycles and/or number of seconds).

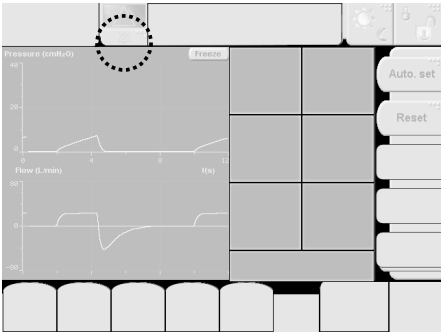
5.2 Alarm Acknowledgement

Certain alarms open a dialog 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 confirm using the control wheel; the dialog box then disappears.

5.3 Alarm inhibition

Pressing the alarm inhibition key interrupts the alarms for 2 minutes.



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

However, if another audible alarm with a higher priority replaces it, the sound inhibition is automatically disabled and the audible emission of the new alarm begins. The previous alarm is then automatically archived in the history.

5.4 Preventive alarm inhibition

Holding down the alarm inhibition key interrupts the alarms for 2 minutes.

On the screen, the panel shows “Alarm inhibited”. A counter next to the alarm inhibition key shows the remaining activation time.

If there is an alarm during this time, the alarm message displays on the screen.

Pressing this key a second time cancels the preventive inhibition.

The inhibited alarms concern the alarms relating to monitoring and patient disconnection.

In the event of a technical alarm (mains disconnection, etc.) or Pmax alarm, inhibition is disabled.

5.5 Reset

When an alarm threshold has been breached, it remains highlighted in red, as do any other breached thresholds, even when the alarm is resolved.

To reset all the thresholds highlighted in red, press the Reset key (see paragraph Automatic thresholds on page 59, Reset on page 76).

5.6 History

This function displays the chronological list of the last 200 alarms or events recorded by the ventilator.

To access the history, see Patient monitoring on page 72.

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 by turning it clockwise or anti-clockwise.

To exit the alarm history, press the control wheel.

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

5.7 Table of alarms

No.	Alarms	Priority	Alarm activation	Alarm activation delay	Actions
1	STANDBY mode?	MEDIUM	Device switched to Stand-by Mode	Immediate triggering	Press the control wheel to stop ventilation. Press **Cancel** to maintain ventilation.
2	Ventilator shutdown?	MEDIUM	Unit Off request	Immediate triggering	Press the control wheel to shut down the unit. Press **Cancel** to leave the unit in Standby.
3	Expiratory branch may be obstructed!!!	HIGH	Patient circuit obstructed, or expiratory valve membrane stuck, or an electronic fault has occurred	Triggering after two ventilation cycles with high pressure and PEEP + 5 cmH2O or PEEP + 5 cmH2O for 15 consecutive seconds	Check the patient circuit. Check the expiratory valve membrane. Contact your technical department if the problem persists Expiration is prolonged for a maximum of 15 s, until the measured PEEP returns below the PEEP setting.
4	Ventilation Interrupted!!!use an alternative ventilator	HIGH (ULTRA category)	Electronics failure	Immediate triggering	Use a different unit and contact your technical department Patient circuit vented to atmosphere
5	Ventilation Interrupted!!! use an alternative ventilator	HIGH (ULTRA category)	Electronics failure	Immediate triggering	Use a different unit and contact your technical department Patient circuit vented to atmosphere
6	Ventilation Interrupted!!! use an alternative ventilator	HIGH (ULTRA category)	Electronics failure	Immediate triggering	Use a different unit and contact your technical department Patient circuit vented to atmosphere

No.	Alarms	Priority	Alarm activation	Alarm activation delay	Actions
7	Safety Ventilation!!! Recommend switching ventilator	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact your technical department
8	Patient disconnection!!!	HIGH	Patient disconnection or leak level too high, or an electronics failure has occurred	Inhibition for 60 s on ventilation start-up. Inhibition during a pause and 30 s after a pause. Otherwise, triggering within 17 s.	Check the level of leakage Check the Adult/Child patient setting. Check that the ventilation settings are appropriate for the patient's needs. Contact your technical department if the problem persists
9	High pressure!!!	HIGH	Peak pressure above alarm threshold	Triggered after 3 consecutive ventilation cycles with a Pmax pressure above the alarm limit	Check the coherence of alarm levels with ventilation settings When the pressure threshold is reached, the machine switches to the expiration phase.
10	Error detected!!! Contact the technical department	HIGH	Electronics failure	Connectivity tests performed every second	Use a different unit and contact your technical department
11	Error detected!!! Contact the technical department	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact your technical department
12	Screen fault!!! Ventilation Effective	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact your technical department
13	Incorrect Settings!!!	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact your technical department Ventilation continues in VCV mode with the default settings.
14	Incorrect Settings!!!	HIGH	Ventilation settings are not technically achievable, or a software error has occurred	Immediate triggering	Check and amend the settings if necessary. Contact your technical department if the problem persists or is recurrent. Ventilation continues but the new settings are not adopted.
15	Incorrect alarms settings!!!	HIGH	Alarm settings are not technically achievable, or a software error has occurred	Immediate triggering	Check and amend the alarm thresholds if necessary. Contact your technical department if the problem persists or is recurrent. Ventilation continues with the default alarm settings.
16	Low MVi!!!	HIGH	Inhaled volume per minute below the alarm threshold	Inhibition for 60 s on ventilation start-up. Inhibition during a pause and 30 s after a pause. Triggering within 1 ventilation cycle.	Check the suitability of alarm level settings with the ventilation settings in progress

No.	Alarms	Priority	Alarm activation	Alarm activation delay	Actions
17	Low MVe!!!	HIGH	Exhaled volume per minute below the alarm threshold	Inhibition for 60 s on ventilation start-up. Inhibition during a pause and 30 s after a pause. Triggering within 1 ventilation cycle.	Check the level of leakage Check the suitability of alarm level settings with the ventilation settings in progress
18	Low respiratory rate!!	MEDIUM	Measured frequency below the alarm threshold	Inhibition for 60 s on ventilation start-up. Inhibition during a pause and 30 s after a pause. Triggered after 3 consecutive ventilation cycles with Fmin.	Check the suitability of alarm level settings with the ventilation settings in progress
19	Safety Ventilation!!! Recommend switching ventilator	HIGH	Electronics failure	1.5 s	Use a different unit and contact your technical department
20	Delivered gases temperature too high!!!	HIGH	Temperature of gases delivered to the patient above 40°C	15 s	Check that the unit is being used according to specifications Contact your technical department if the problem persists
21	PEEP greater than set PEEP + 5 cmH2O!!!	HIGH	Measured PEEP at least 5 cmH2O greater than the PEEP setting	Immediate triggering	Ventilation continues, but extended expiration will take place if the high-pressure alarm is also triggered or if the alarm persists for longer than 15 s.
22	High respiratory rate!!	MEDIUM	Measured frequency above the alarm threshold or automatic triggering of the inspiratory trigger	Inhibition for 60 s on ventilation start-up. Inhibition during a pause and 30s after the pause. Triggered after 3 consecutive ventilation cycles with Fmax.	Check the suitability of alarm level settings with the ventilation settings in progress Reduce the sensitivity of the inspiratory trigger if required.
23	High MVi!!!	HIGH	Inhaled volume per minute above the set threshold	Inhibition for 60 s on ventilation start-up. Triggering within 1 ventilation cycle.	Check the level of leakage Check the suitability of alarm level settings with the ventilation settings in progress
24	High MVe!!	MEDIUM	Exhaled volume per minute above the set threshold	Inhibition for 60 s on ventilation start-up. Triggering within 1 ventilation cycle.	Check the suitability of alarm level settings with the ventilation settings in progress

No.	Alarms	Priority	Alarm activation	Alarm activation delay	Actions
25	Low FiO2!!!	HIGH	Measured FiO2 below the set threshold	Inhibition for 60 s on ventilation start-up. Immediate triggering Inhibition for 60 s in adult and child mode, and 120 s in infant mode, at each change of FiO2 set-point or change of ventilation mode. Inhibition during a pause and 30 s after a pause.	Check the presence of the oxygen supply. Check the suitability of alarm level settings with the ventilation settings in progress If not resolved: Provide an alternative means of ventilation and run the automatic tests
26	High FiO2!!!	HIGH	Measured FiO2 above the set threshold	Inhibition for 60 s in adult and child mode, and 120 s in infant mode, at each change of FiO2 set-point or change of ventilation mode. Inhibition during a pause and 30 s after a pause. Immediate triggering.	Check the suitability of alarm level settings with the ventilation settings in progress. If not resolved: Provide an alternative means of ventilation and run the automatic tests procedure.
28	Empty Battery !!! Recharge the battery	HIGH	The internal battery life at full charge is insufficient.	Immediate triggering	Insert a charged, replacement removable battery or connect the unit to AC mains.
29	Batteries nearly discharged!!! Connect AC power.	MEDIUM	The remaining time available on the internal battery is low.	Immediate triggering	Insert a charged, replacement removable battery or connect the unit to AC mains. As the internal battery approaches the end of its life time, certain ventilation parameters can be adjusted to optimize the ventilation time.
31	Battery charger ineffective!!! Ventilation Effective	HIGH	The battery charger is faulty.	Triggering within 10 s	Use a different unit and contact your technical department
33	Apnea ventilation!!!	HIGH	No patient respiratory activity for a time greater than the set T apnea	T Apnea Immediate triggering	Check patient safety and verify the switch to back-up ventilation
34	Safety Ventilation!!! Recommend switching ventilator	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact your technical department
36	Safety Ventilation!!! Recommend switching ventilator	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact your technical department
37	Safety Ventilation!!! Recommend switching ventilator	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact your technical department

No.	Alarms	Priority	Alarm activation	Alarm activation delay	Actions
38	Safety Ventilation!!! Recommend switching ventilator	HIGH	Electronics failure	Triggering during automatic tests	Use a different unit and contact your technical department
39	Patient circuit leak detected during automatic tests!!!	HIGH	Patient circuit connection problem	Triggering on exit from automatic tests	Check and re-connect the patient circuit components carefully and repeat the automatic tests. If the problem persists, change the patient circuit.
40	Safety Ventilation!!! Recommend switching ventilator	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact your technical department
41	Safety Ventilation!!! Recommend switching ventilator	HIGH	Electronics failure	1 s in stand-by	Use a different unit and contact your technical department
42	Safety Ventilation!!! Recommend switching ventilator	HIGH	Electronics failure	Triggering during automatic tests	Re-run the automatic tests. If the problem persists: Use a different unit and contact your technical department
43	Sounder failure!!! Ventilation Effective	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact your technical department
44	Expiratory flow measurement inoperative!!!	HIGH	Expiratory flow sensor problem, e.g. Breakage, poor connection, or absence of hot wire sensor	Immediate triggering	Double branch: check that the flow sensor is in position, or replace the flow sensor, or disable expiratory measurement (in the Menu). Caution: in this case, Vte and MVe will not be monitored.
45	FiO2 sensor inoperative!!!	HIGH	O2 Sensor problem, e.g. poor connection or absence of the O2 sensor or the measured FiO2 is below 18%	Immediate triggering	Check that the O2 sensor is installed, check its connection, and re-run the automatic tests. Replace the O2 sensor and re-run the automatic tests. During ventilation, disable FiO2 measurement (in the Menu). Caution: in this case, FiO2 will not be monitored.
46	Screen fault!!! Ventilation Effective	HIGH	Long press on screen or broken screen	Triggering beyond 65 s	Stop pressing the screen. If the problem persists: use a different unit, and contact the technical department.
48	Low VTi!!!	MEDIUM	Insufflated tidal volume below the set threshold	Inhibition for 60 s on ventilation start-up. Triggered after 3 consecutive ventilation cycles with low VTi.	Check the suitability of alarm level settings with the ventilation settings in progress
49	Low VTe!!!	MEDIUM	Exhaled tidal volume below the set threshold	Inhibition for 60 s on ventilation start-up. Triggered after 3 consecutive ventilation cycles with low VTe.	Check the level of leakage Check the suitability of alarm level settings with the ventilation settings in progress

No.	Alarms	Priority	Alarm activation	Alarm activation delay	Actions
51	High VTi!!	MEDIUM	Insufflated tidal volume above the set threshold	Triggered after 3 consecutive ventilation cycles with low VTi.	Check the level of leakage Check the suitability of alarm level settings with the ventilation settings in progress. In pressure-control ventilation mode, when the VTi high alarm threshold is reached, the unit switches to the expiration phase.
52	High Vte!!	MEDIUM	Exhaled tidal volume above the set threshold	Inhibition for 60 s on ventilation start-up. Triggered after 3 consecutive ventilation cycles with high VTe.	Check the suitability of alarm level settings with the ventilation settings in progress
53	Sounder failure!! Ventilation Effective	MEDIUM	Electronics failure	Immediate triggering	Use a different unit and contact your technical department
54	Sounder failure!! Ventilation Effective	MEDIUM	Electronics failure	Immediate triggering	Use a different unit and contact your technical department
56	High pressure!	LOW	Peak pressure above alarm threshold	Immediate triggering	Check the suitability of alarm level settings with the ventilation settings in progress. When the high pressure alarm threshold is reached, the unit switches to the expiration phase
57	Low VTi!	LOW	Insufflated tidal volume below the set threshold	Inhibition for 60 s on ventilation start-up. Triggering within 1 ventilation cycle.	Check the suitability of alarm level settings with the ventilation settings in progress.
58	Low VTe!	LOW	Exhaled tidal volume below the set threshold	Inhibition for 60 s on ventilation start-up. Triggering within 1 ventilation cycle.	Check the level of leakage Check the suitability of alarm level settings with the ventilation settings in progress
59	Low respiratory rate!	LOW	Measured frequency below the alarm threshold	Inhibition for 60 s on ventilation start-up. Inhibition during a pause and 30 s after a pause. Triggering within 1 ventilation cycle.	Check the suitability of alarm level settings with the ventilation settings in progress.
60	VT or PI not reached! Check settings	LOW	In volumetric mode, the measured VTi is less than 2/3 of the setting. In pressure-controlled mode, Ppeak is less than 2/3 of the setting	Inhibition for 60 s on ventilation start-up. Inhibition during a pause and 30 s after a pause. Triggering within 3 ventilation cycles.	Check the ventilator settings and patient circuit. Check the air inlet and the filter at the back of the unit for obstruction. Use a different unit and contact your technical department

No.	Alarms	Priority	Alarm activation	Alarm activation delay	Actions
62	High VTi!	LOW	Insufflated tidal volume above the set threshold	Triggering within 1 ventilation cycle.	Check the level of leakage Check the suitability of alarm level settings with the ventilation settings in progress. In pressure-control ventilation mode, when the VTi high alarm threshold is reached, the unit switches to the expiration phase.
63	High Vte!	LOW	Exhaled tidal volume above the set threshold	Inhibition for 60 s on ventilation start-up. Triggering within 1 ventilation cycle.	Check the suitability of alarm level settings with the ventilation settings in progress.
64	High respiratory rate!	LOW	Measured frequency above the alarm threshold or auto-triggering of the inspiratory trigger	Inhibition for 60 s on ventilation start-up. Inhibition during a pause and 30s after the pause. Triggering within 1 ventilation cycle.	Check the suitability of alarm level settings with the ventilation settings in progress. Reduce the sensitivity of the inspiratory trigger if required.
65	Non Critical error! Ventilation Effective	LOW	Electronics failure	Immediate triggering in stand-by only	Use a different unit and contact your technical department
66	Non Critical error! Ventilation Effective	LOW	Electronics failure	Immediate triggering in stand-by only	Use a different unit and contact your technical department
67	Ventilator operating on internal battery!!	MEDIUM	The machine is operating on internal battery	Immediate triggering	Replace the removable battery or connect the machine to AC mains.
69	FiO2 sensor requires replacement soon!	LOW	O2 sensor at end of life	Immediate triggering	Press the control wheel to acknowledge the alarm. Replace the O2 sensor before you next put the unit in use.
70	Non Critical error! Ventilation Effective	LOW	Electronics failure	Triggering during automatic tests	Re-run the automatic tests. If the problem persists: Use a different unit and contact your technical department
71	Screen locked	None (INFO category)	Pressing the screen when it is locked	Immediate triggering	Follow the on-screen instructions to unlock if necessary
72	Unit on stand-by	None (INFO category)	Unit on stand-by	Immediate triggering when ventilation shuts down or when unit is started up	Not applicable

No.	Alarms	Priority	Alarm activation	Alarm activation delay	Actions
73	Screen upside down	None (INFO category)	Press the 180° key	Immediate triggering	Press the control wheel to confirm screen inversion. Press 'cancel' to leave the screen in the same orientation.
74	Ventilation Interrupted!!! use an alternative ventilator	HIGH (ULTRA category)	Turbine temperature too high	Immediate triggering	Check the machine air inlet. Replace the filters. Use a different unit and contact your technical department
75	Non Critical error! Ventilation Effective	LOW	Electronics failure	Immediate triggering	Use a different unit and contact the technical department
76	CO2 apnea!!!	MEDIUM	No patient exhalation gas been detected for more than 20 s.	Immediate triggering	A resuscitation specialist must re-evaluate the patient's ventilation.
77	Check the adapter of the IRMA™ (CO2) probe	MEDIUM	UU adapter poorly fitted on the probe (The red LED on the probe flashes)	Immediate triggering	Check the UU adapter.
78	Replace the adapter of the IRMA™ (CO2) probe	MEDIUM	UU adapter obstructed or blocked	Immediate triggering	Change the adapter.
79	CO2 concentration out of tolerance	MEDIUM	Measured CO2 > 15%	Immediate triggering	If CO2 actually < 15% then calibrate the probe.
80	Calibrate the IRMA™ probe(CO2)	MEDIUM	Probe drift	Immediate triggering	Calibrate the probe.
81	IRMA™ (CO2) probe error	MEDIUM	Probe hardware or software error	Immediate triggering	Disconnect and reconnect the probe. If the problem persists, replace the probe.
82	CO2 measurement inoperative	MEDIUM	Probe not connected	Immediate triggering	Connect the IRMA probe.
83	IRMA™ (CO2)probe: Internal temperature out of tolerance!!!	MEDIUM	The internal temperature of the probe has exceeded the maximum measurement threshold	Immediate triggering	If the ambient temperature is normal, replace the probe.
84	IRMA™ (CO2)probe: ambient pressure out of tolerance	MEDIUM	The atmospheric pressure measured by the probe has exceeded the maximum measurement threshold	Immediate triggering	If the atmospheric pressure is normal, replace the probe.
85	etCO2 high!!!	MEDIUM	etCO2 measurement above the threshold setting	Immediate triggering	Check the suitability of alarm level settings with the ventilation settings in progress.
86	etCO2 low!!!	MEDIUM	etCO2 measurement below the threshold setting	Immediate triggering	Check the suitability of alarm level settings with the ventilation settings in progress.
89	O2 mixer defect!!! Ventilation Effective to 21%	HIGH	Electronics failure Inhibit if FiO2 set-point = 21%	Immediate triggering	Set the FiO2 set-point = 21% Use a different unit and contact your technical department

No.	Alarms	Priority	Alarm activation	Alarm activation delay	Actions
90	High oxygen supply pressure!!!	HIGH	O2 supply pressure > 7 bar	Immediate triggering	Check pressure in supply network or cylinder
91	Loss of oxygen supply pressure!!!	HIGH	O2 supply pressure is too low	Triggering within 10 s	Check remaining O2 level in cylinder or pressure in supply network. For operation on a low-pressure source, ensure that the high-pressure O2 connection hose is disconnected from the machine.
92	O2 mixer defect!!! Ventilation Effective to 21%	HIGH	Electronics failure	Immediate triggering	Set the FiO2 set-point = 21% Re-run the automatic tests with an O2 source. Use a different unit and contact your technical department Note: O2 leakage inside the machine is possible.
93	O2 mixer defect!!! Ventilation Effective to 21%	HIGH	Electronics failure	Immediate triggering	Set the FiO2 set-point = 21% Use a different unit and contact your technical department
94	Low oxygen supply pressure!!!	MEDIUM	O2 supply pressure < 2.8 bars	Triggered within 2 s	Check remaining O2 level in cylinder or pressure in supply network. For operation on a low-pressure source, select 'Low-pressure O2' from the configuration menu.
95	O2 maximum for 2 min!	None (INFO category)	Press the "100% O2" key	Start of next ventilation cycle	Not applicable
96	O2 low pressure	None (INFO category)	Press the "Low-pressure O2" key	Immediate triggering	Not applicable
97	O2 mixer defect!!! Safety Ventilation	HIGH	Electronics failure	Immediate triggering	Use a different unit and contact your technical department
98	No internal battery!!!	HIGH	No internal battery or internal battery fully discharged	Immediate triggering	Use a different unit and contact your technical department. The alarm is active until the internal battery starts charging.

No.	Alarms	Priority	Alarm activation	Alarm activation delay	Actions
100	Excessive internal battery temperature!	HIGH	Mean temperature of internal battery: - Discharging: above 75°C or below -40°C - Charging: above 70°C or below -20°C	Immediate triggering	Use a different unit and contact your technical department
101	Excessive removable battery temperature!	HIGH	Mean temperature of auxiliary battery: - Discharging: above 75°C or below -40°C - Charging: above 70°C or below -20°C	Immediate triggering	Replace the removable battery.
102	Excessive PCB supply temperature!	HIGH	Power supply PCB temperature above 95°C	Immediate triggering	Use a different unit and contact your technical department
103	Internal battery temperature measurement error!!!	HIGH	Correct voltage at internal battery terminals, but zero current or temperature outside tolerance	Triggering within 10 s	Use a different unit and contact your technical department
104	Removable battery temperature measurement error!!!	HIGH	Correct voltage at auxiliary battery terminals, but zero current or temperature outside tolerance	Triggering within 10 s	Replace the removable battery.
105	Internal battery defective!	LOW	Actual capacity of the internal battery too low compared to its initial capacity or battery older than 2 years	Immediate triggering	Isolate the device. Fully discharge the internal battery, then fully charge it. If the alarm still occurs, use a different unit and contact your technical department.
108	Inspiratory pause occlusion in progress	None (INFO category)	**Inspiratory pause** respiratory function selected	Triggering at the start of the expiratory phase	Not applicable
109	Expiratory pause occlusion in progress	None (INFO category)	**Expiratory pause** respiratory function selected	Triggering at the start of the inspiratory phase	Not applicable
110	Time pre-oxygenation > 3 min	LOW	Ventilation in 100% O2 mode with the FiO2 setting at 100%	Triggering after more than 3 minutes of ventilation	Select a mode other than '100% O2' or reduce the FiO2 setting if appropriate

No.	Alarms	Priority	Alarm activation	Alarm activation delay	Actions
111	High turbine temperature!!! Ventilation potential stop	HIGH	High turbine temperature	Immediate triggering	Check that the unit is being used according to specifications Check the unit air inlet. Replace the filters. Contact your technical department if the problem persists
112	O2 sensor disabled. Use an external O2 monitor.	MEDIUM	“O2 monitoring” key disabled	Immediate triggering	Acknowledge the alarm. Re-enable the “O2 monitoring” sensor.
113	Slight leak detected during automatic tests!	LOW	Sealing problem in the patient circuit or the machine.	Triggering on exit from automatic tests	Check and re-connect patient circuit, connect patient circuit components carefully, and repeat automatic tests If the problem persists: Change the patient circuit This error affects Auto. Tests pauses only.
114	Rebreathing detected!	MEDIUM	Inspiratory CO2 above threshold (4 mmHg)	Immediate triggering	Check ventilation settings and dead space in the patient circuit.
115	DC input voltage greater than 30 V!!!	HIGH	DC input voltage greater than 31 V for longer than 10 s	10 s during which the fault is observed	IMMEDIATELY replace the machine’s power supply unit (AC Adaptor). Use a DC power supply that is compatible with the machine.
117	Imminent shutdown!!!	HIGH	When operating on internal battery, the machine is about to shut down because the excessive internal battery temperature alarm has been triggered.	30 s after triggering of the ‘Excessive internal battery temperature’ alarm	Immediately replace the removable battery or connect to AC mains power.
118	Low Pressure!!!	HIGH	Peak pressure below alarm threshold	Inhibition for 60 s on ventilation start-up. Immediate triggering	Check the coherence of alarm levels with ventilation settings.
119	High plateau pressure!!	MEDIUM	Plateau pressure greater than alarm threshold	Immediate triggering	Check the coherence of alarm levels with ventilation settings.
120	Incompatibility between VT target and settled pressure!!	MEDIUM	VT target not reached	3 cycles	Check the coherence between the target VT and the patient. Check the coherence between the target VT and the Pimax set. Check there are no leaks between the machine and the patient.

No.	Alarms	Priority	Alarm activation	Alarm activation delay	Actions
121	Oxygen therapy enabled Apnea ventilation disabled	None (INFO category)	Activation of the oxygen therapy function	Immediate triggering	Stop the oxygen therapy function
122	Oxygen therapy branch may be obstructed!!!	HIGH	Ventilator output pressure > 45cmH2O	4s after Ppeak > 45cmH2O	Check the patient circuit. Check the humidifier. Check the patient interface.
128	Alarms inhibited	None (INFO category)	Press the alarm inhibition key if enabled and there is no current alarm	3 seconds	Not applicable
129	Error detected! Contact the technical department	LOW	Electronics failure	Triggering during automatic tests	Run the automatic tests procedure. Backup ventilation. Contact the technical department.
130	Obstructed expiratory branch!!! Safety ventilation	HIGH	Expiratory airway pressure greater than the threshold during expiration	Triggering after 2 cycles, or after 5 seconds in the case of low frequency.	Checking the status of the expiratory limb and eliminating the cause of the obstruction. Backup ventilation. Contact the technical department.
131	Low CC rate!	LOW	Measured cardiac massage rate below the alarm threshold	Inhibition for 60 s at ventilation start-up. Starts after 6 s	Check the consistency of the alarm levels in relation to the cardiac massage rate. Check that the patient's airways are not obstructed.
132	High CC rate!	LOW	Measured cardiac massage rate greater than the alarm threshold	Inhibition for 60 s at ventilation start-up. Starts after 6 s	Check the consistency of the alarm levels in relation to the cardiac massage rate
133	ROSC phase: return to standard ventilation	None (INFO category)	Pressing the ROSC key	Immediate triggering	None
134	Apnea ventilation disabled!	LOW	Setting T apnea to OFF or changing to CPAP mode with T apnea set to OFF.	Immediate triggering	Press the rotating knob to clear the alarm.
135	Emergency VCV vent' VT not applicable!!!	HIGH	The VT resulting from the height and gender settings is incompatible with the other settings when the AVCV Emergency Ventilation mode is launched	Immediate triggering	Change RR, I:E (or Ti/Ttot or Flow Rate or Ti), Tplat settings to set the desired VT. Press the rotating knob to start ventilation with the pre-settings displayed at the bottom of the screen. Press 'Cancel' to stop ventilation from starting.

No.	Alarms	Priority	Alarm activation	Alarm activation delay	Actions
136	Auto. set?	None (INFO category)	Pressing the 'Auto. thresholds' button	Immediate triggering	Not applicable
137	Preventive maintenance to be provided!	LOW	Preventive maintenance not performed for 13 months	Immediate triggering	Contact the technical department to carry out preventive maintenance. The alarm can be acknowledged.
138	Safety Ventilation!!! Recommend switching ventilator	HIGH	Turbine's tachymeter out of order	15s	Contact the technical department.
139	Mains cable unplugged	LOW	Disconnection from the mains	Immediate triggering	Check whether the mains plug is plugged in. This alarm is deactivated by default. See Mains disconnection alarm on page 67

Activation delay: Sum of the maximum alarm condition delay and the delay to activation of the audible or visual alarm

Note: Delay in the activation of certain alarms can vary according to the status of the machine (in stand-by, during ventilation, during automatic tests), the type of patient and the elapsed duration of ventilation.

6 Care and upkeep

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

Re-usable elements must be regularly cleaned and disinfected to prevent cross-contamination.

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

6.1 Surface of the ventilator

Products

The following products may be used to regularly disinfect the external surfaces of ***Monnal T60***:

- Mikrozid PAA wipes;
- Mikrozid sensitive wipes;
- Mikrozid universal wipes.

Note: Any other equivalent disinfectant may be used as long as the product's manufacturer demonstrates its compatibility with ***Monnal T60***.

CAUTION: Follow the instructions of the product's manufacturer.

Surface cleaning and disinfection precautions

CAUTION: Before the operation:

- power off ***Monnal T60***;
- insert the USB cover to stop liquid from entering the ventilator.

CAUTION: During cleaning or disinfection: Do not let any liquid penetrate the inside of the machine or come into contact with the connectors.

CAUTION: After the operation, let the product dry completely before reusing ***Monnal T60***.

6.2 Bacteriological filter

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

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

CAUTION: A clogged bacteriological filter can lead to an increase in inspiratory and expiratory resistance.

6.3 Air inlet filter (Monnal Clean'In)

The **Monnal Clean'In** HEPA air inlet filter must be checked and replaced regularly (every six months).

To replace it, loosen and remove by turning anticlockwise. Insert the new filter and turn clockwise to secure the fit.

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

Characteristics	
Reference	KY691400
Resistance at 60 L/min	1.15 mbar
Filtration	99.97%
Particles	> 0.5µm

6.4 Expiratory assembly: Flow sensor + expiratory valve

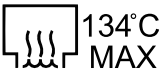
There are two types of expiratory assembly: single-use assemblies and autoclavable assemblies (re-usable).

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:

The sensor and the **autoclavable** expiratory assembly valve are blue. Both of these components bear a unit Serial Number, a Part Number, and the 'autoclavable' logo:

Refer to the summary of markings below

Markings	Autoclavable	Single-use
Expiratory valve	134°C MAX	
	SN serial number	REF catalog number
	REF catalog number	LOT batch number

Markings	Autoclavable	Single-use
Expiratory flow sensor		
	 serial number	 catalog number
	 catalog number	 batch number

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.

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

Autoclavable version

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

CAUTION: The expiratory flow sensor requires special precautions during pre-disinfection, cleaning, and disinfection. It contains 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 any impacts or dropping it.

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, and connected to the ventilator.

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

CAUTION: Disinfection of the autoclavable expiratory valve flow sensor and autoclavable expiratory valve before the first use is recommended.

Expiratory assembly cleaning protocol

See Expiratory assembly cleaning protocol on page 140.

7 Accessories

7.1 Regulatory requirements

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

Accessories from the *Air Liquide Medical Systems* catalogue 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 are taken during the automatic tests. In the absence of automatic tests, the resistances retained correspond to those of the ventilator fitted with a standard adult patient circuit and a bacteriological filter (KV103300).

The prescriber must also ensure that the configuration thus obtained, complies with ISO 80601-2-12.

7.2 List of options and accessories

Note: Some of the items mentioned below may not be available in every country. Contact your *Air Liquide Medical Systems*reseller for more information.

Description		Catalog Number
Capnography option		
	etCO2 software option	KA010700
	IRMA™ CO2 probe	KB020400
Single use	IRMA™ CO2 adaptors x25 (adult/child)	KB020300
	IRMA™ CO2 adaptors x10 (infant/new-born)	KB032800

Optional ventilation and complementary monitoring	
Duo-Levels mode option	KA012300
P/V, D/P, D/V and V/CO2 loop curves	KA012400
SIMV/PSIMV-NIV mode	KA014900
PS-Pro mode	KA015000
PRVC mode	KA015100
Pack modes SIMV / PS-Pro / PRVC / Duo-Levels	KA015200

Optional ventilation and complementary monitoring	
CPV – Cardio-Pulmonary Ventilation	KA015700

Expiratory assemblies		
Single use	Monnal Eva expiratory valve x5 (valve body and membrane)	KY694800
	Monnal Eva expiratory valve x20 (valve body and membrane)	KY694900
	Expiratory flow sensor x5	KY664500
	Expiratory flow sensor x20	KY664600
Auto-clavable	Monnal Eva expiratory valve x1 (valve body and membrane)	KY694500
	Expiratory flow sensor x1	KY632200
Single use	Membrane x5 (for autoclavable valve KY694500)	KY665300

Patient circuits and accessories		
Single use	Adult patient circuit dual limb smooth inside surface x20 1.6 m Ø22 (without water-trap)	KG020100
	Adult patient circuit dual limb smooth inside surface x12 1.6 m Ø22 (without water-trap)	KG501516
	Child patient circuit dual limb smooth inside surface x20 1.5 m Ø15 (without water-trap)	KG020200
	Adult patient circuit dual limb corrugated inside surface x15 1.6 m Ø22 (with water trap)	VD315100
	Child patient circuit dual limb corrugated inside surface x10 1.6 m Ø15 (with water trap)	VD317600
Autoclavable	Adult patient circuit dual limb smooth inside surface x1 1.5 m Ø22 (with water-trap)	KG020400
	Child patient circuit dual limb smooth inside surface x1 1.5 m Ø22 (with water-trap)	VD317600

Masks and accessories		
Single use	Non-vented full-face mask size S	KM222100
	Non-vented full-face mask size M	KM222200
	Non-vented full-face mask size L	KM222300
Autoclavable	Non-vented full-face mask size S	KM218800
	Non-vented full-face mask size M	KM218900
	Non-vented full-face mask size L	KM219000
	Respireo cushion size S x10	KM218500

Masks and accessories		
	Respireo cushion size M x10	KM218600
	Respireo cushion size L x10	KM218700
	Disposable harness x10	KM222400

Test lungs	
1 liter test lung (adult/child)	VS206103
0.3 liter test lung (infant)	KV103500

Filters		
Single use	Bacteriological filters for inspiratory output x50	KV103300
	Monnal Clean'In filter ***Monnal T60***(HEPA filter)	KY691400

Articulated arms for patient circuits	
1-m articulated arm with quick central fixation and rail support (with collet fixture adjustment)	KB019200
1-m articulated arm (without tightening nut)	KA017105

Humidification		
Heating humidifier MR850* (230 V EUR plug)		VD324500
Single use	Optiflow nasal cannula (x20)	VD341000
	Sensor adapter and respiratory circuit kit for MR850 humidifier	VD340900

Nebulization		
Single use	Aerogen Solo international nebulizer	According to country
Autoclavable	Aerogen Pro international nebulizer	According to country

Medical arm systems	
Assembly on normalized sliding rail	
Sliding rail arm length 30.5 cm	KA016900

Assembly on vertical tube	
Tube arm length 20.3 cm (tube diam 38 mm)	KA017000
Tube arm length 20.3 cm (tube diam 38 mm) with clip diam 19-51 mm	KA017100

Assembly on vertical rail (thickness: 10 x width: 25-40 mm)	
Vertical rail arm 30.5 cm long	KA016500

Assembly on horizontal rail (depth: 10 x width: 25-40 mm)	
Horizontal rail arm length 30.5 cm	KA016700
Horizontal rail double arm length 30.5 x 30.5 cm	KA016800
VESA plate interface (100x100) MT60 for articulated arm	KA016400

Fixing and transfer systems	
Carry bag	KF007800
Wall-mounted charging station	KA010300
Kit for wall-mounted charging station	KA011100
Universal support rail	PE750003
Collet fixture for recharging mount on vertical tube	KB016800
Intra-hospital universal support	KA010400
Rolling stand	KA010100
Table top stand	KA012600
Snap-hooks (x2)	KA013300

Oxygen supply hoses and accessories	
Emboufix O2 1.5 m NF	BF030600
Emboufix O2 3 m NF	BF030200
Filtrabloc O2 NF	KB002800
5 microns Filter	KV103600

Electrical power supply	
Removable battery	KY692800
Vehicle power adapter	YR123700
External power supply 2.5 m	YR115700
2.5 m mains cable	Reference varies according to country
Battery charger ***Monnal T60***	KA012700

Oxygen monitoring	
O2 Cell	YR049700

Information transfer	
USB key 2 GB	YR112900
Connection dongle / USB cable	YR135600

8 Maintenance

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

For any operation requiring the machine to be opened, call on a trained, qualified technician.

Note: *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.

8.1 By the user

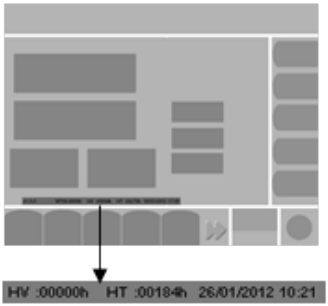
The user must:

- If using a patient circuit with water trap, empty the patient circuit water traps as often as necessary,
- Clean and disinfect the re-usable components after each patient: The patient circuit, autoclavable expiratory flow sensor, and the autoclavable expiratory valve (see Expiratory assembly: Flow sensor + expiratory valve on page 91),
- Between patients, replace the non-reusable elements (circuit, filters, single use expiratory valve, single use expiratory flow sensor, IRMA™ CO2 measurement probe adapter),
- Replace the bacteriological filter at the ventilator output according to manufacturer recommendations,
- Replace the Monnal Clean'In HEPA air intake filter every six months,
- Replace the O2 sensor (see O2 Cell on page 99) and expiratory flow sensor in the event of failure,
- Check the remaining battery capacity approximately every six months (connect a test lung to the ventilator, start ventilation, and check that battery capacity is adequate),
- Replace the extractable battery after 2 years. The date of entry into service of the extractable battery is indicated on the label (see Removable battery on page 24).
- Go through a checklist before each use (see Checklist on page 138).

8.2 By the technician

Annual maintenance with a check of machine operation and performance. Access to maintenance is protected by a code. This code is provided to the qualified technician via a call to the hotline, following technical training by *Air Liquide Medical Systems* or their authorized representative. 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 start-up and stand-by screen:

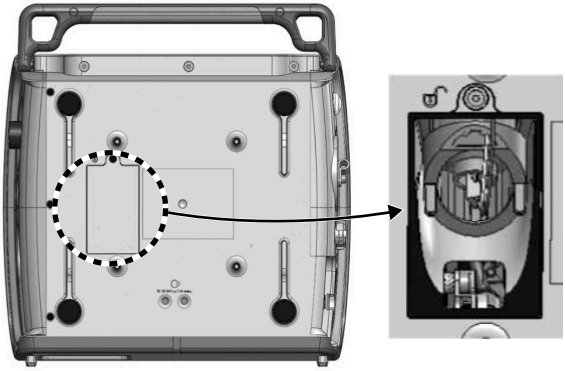


The internal battery must be replaced after 300 charge/discharge cycles or 2 years (whichever comes first), and this replacement must be performed by a qualified technician. For more information, refer to the maintenance manual.

8.3 O_2 Cell

Note: The life time of the O_2cell is approximately 5000 hours, but this can vary according to the oxygen concentration used and the ambient temperature.

- To open the compartment, turn and loosen the hatch.



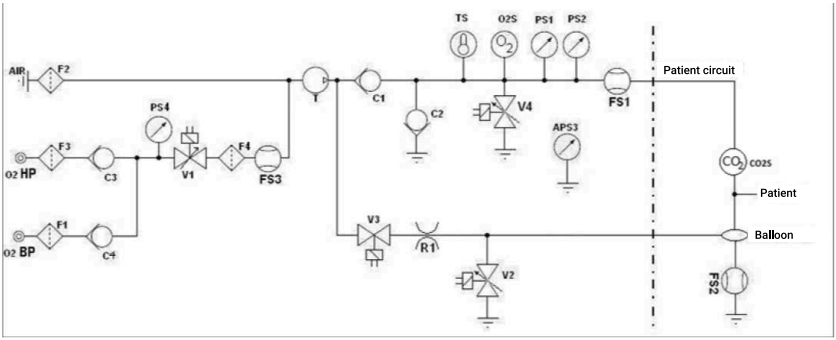
- Disconnect the used sensor and then unscrew it using the tool provided to remove it from its housing.
- Replace it with a new sensor, referring to the instructions on the packaging of the new sensor if necessary.
- Fully re-tighten the sensor to prevent any leaks, return the disassembly tool to its housing, and then connect the sensor.
- To close the hatch, use the screw that was removed earlier.
- Run the sensor calibration automatic tests.

Note: It is recommended that you calibrate the $O2_2$ sensor frequently via the automatic tests.

9 Technical description

9.1 Operation

9.1.1 Pneumatic system



AIR	Ambient air intake	**Patient**	Patient
O2 LP	Low-pressure oxygen inlet (concentrator)	**Balloon**	Expiratory valve equipped with a membrane
O2 HP	High-pressure O2 inlet(network, cylinder)		
C1	Non-return valve	**PS1**	Airway inspiratory pressure sensor
C2	Non-return valve	**PS2**	Airway inspiratory pressure sensor (secondary)
C3	Non-return valve	**APS3**	Atmospheric pressure sensor
C4	Non-return valve	**PS4**	O2 pressure sensor
F1	O2 inlet filter (oxygen low pressure supply)	**T**	Turbine
F2	Air intake filter (HEPA filter)	**TS**	Patient gas temperature sensor
F3	O2 inlet filter (compressed gas)	**V1**	Oxygen regulating proportional solenoid valve
F4	Bronze filter (laminar flow)	**V2**	PEEP control proportional solenoid valve
FS1	Patient flow rate sensor	**V3**	Pause on/off solenoid valve
FS2	Hot wire expiratory flow sensor	**V4**	On/off obstruction management solenoid valve[5]
FS3	O2 flow sensor	**R1**	Calibrated opening
CO2S	Carbon dioxide sensor (optional)	**O2 s**	Oxygen sensor

Note: The balloon and hot wire expiratory flow sensor can be replaced. Refer to the maintenance manual for more information.

[5] Solenoid valve V4 is found on the ***Monnal T60*** devices from No. 3000.

9.1.2 Ventilation function

The turbine **(T)** of the ventilator entrains ambient air via the ***Monnal Clean'In*** (HEPA) **(F2)** filter and provides sufficient compression according to the patient's flow requirement and the settings. 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 turbine **(T)**, which allows the adjustment of:

- Flow via the flow sensor **(FS1)** when a volume-controlled mode is selected,
- Pressurised via the pressure sensor **(PS1)** when the selected mode is pressure-controlled.

  At the same time, the solenoid valves **(V3)** and **(V2)** are open and closed respectively such that the blower pressure is applied to the membrane **(M1)** of the expiratory valve, thus forcing the air sent via the turbine **(T)** to flow towards the patient only

Expiratory phase

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

With this in mind, the PEEP control proportional solenoid valve **(V2)** regulates the expiration pressure via the pressure sensor **(PS1)**.

At the same time, the turbine **(T)** regulates the flow via the flow sensor **(FS1)** for a flow-by rate of 5 L/min. This flow limits reinhalation and allows quick detection of an inspiratory demand.

Note: During ventilation with leakage, such as NIV, the turbine **(T)** is liable to increase the rinse flow (flow-by); 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.

Safety mechanisms

Venting in the event the machine stops

In normal operation, the turbine T generates pressure in the inspiratory limb, which keeps the non-return valve C2 closed.

If the patient needs to be vented to atmosphere, the turbine shuts down, and no longer generates pressure in the inspiratory limb. Therefore, with every inspiratory demand, the non-return valve C2 opens, which allows the patient to breathe freely through the device.

Obstruction management

In the event of an obstruction in the expiratory branch, the solenoid valve V4 opens, which depressurizes the patient's airways. The ventilation continues with zero PEEP. Expiration takes place through solenoid valve V4. The machine tests for the presence of an obstruction in the expiratory branch at regular intervals. When the obstruction disappears, normal ventilation resumes.

In the absence of solenoid valve V4, the pressure in the patient airway can remain elevated. A high priority alarm will be raised in the event of obstruction, with or without a solenoid valve.

9.1.3 Air/O_2 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 high pressure operation and O2 low pressure operation.

Operation on an O2 high pressure 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 with oxygen by regulating the flow via the flow sensor **(FS3)**, where the set-point is proportional to the upstream flow rate **(FS1)** 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 may 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.

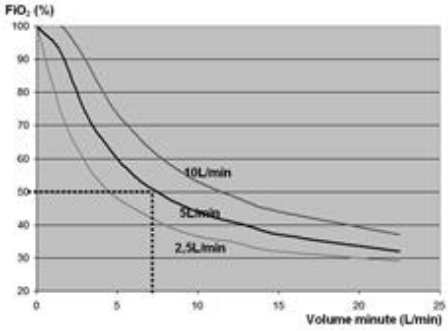
Low O2 pressure operation

The unit has a “low pressure” connector to operate with a low O2 pressure supply system (inlet via the filter **(F1)**). The concept of finely controlling the O2 pressure that is applied at high pressure is still applied when operating on a low-pressure source: the machine continuously supplies a mixture at the correct FiO2 level.

The concentration of the mixture may however not be reached, because this depends on:

- The type of low O2 pressure supply system and its settings (the O2 flow supplied is often low, and its O2 concentration varies between 90 and 100%)
- And the ventilation parameters.

  Below are the maximum concentrations obtainable with different flow rates (assuming their O2 concentration is 100%) according to the volume per minute of a patient ventilated at a frequency of 15 breaths per minute:



For example, for an O2 supply of 5 L/min and a patient ventilated in volume-controlled mode with a VT of 0.5 L and a frequency of 15 bpm (volume per minute 0.5 x 15 = 7.5 L/min), the maximum obtainable concentration will be approximately 50%. The machine will then be able to supply any desired concentration below this value.

Note: Because the machine consumes only the flow rate it needs to provide the correct mixture concentration, *Air Liquide Medical Systems* recommends that the low-pressure source should be set to its maximum flow rate. This will allow a wider range of possible FiO2 values.

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 launched. Ambient humidity also affects the oxygen measurement at the rate of -0.03% per %Hr, at 25°C (see Measured parameters on page 114).

9.1.4 CO2 monitoring

The CO2 **(CO2S)** sensor monitors the CO2 concentration when the patient exhales.

9.2 Electrical power sources

This ventilator is compatible with various electrical power sources:

- AC power supply via the mains power supply device supplied with the machine,
- Power supply on an external DC source
- Power supply on two internal DC sources (internal battery and auxiliary battery.

The electrical characteristics of each of these sources are described in Section Electrical specifications on page 111.

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.

Note: The alarm settings, history and observance are retained when the device is shut down.

Note: When a complete power loss occurs with both AC mains or the auxiliary/internal batteries, the machine history is preserved and can be displayed after the power supply has been restored. This data is preserved due to a secondary internal battery back-up battery with a life time of approximately ten years. Note that this secondary internal battery does not power any ventilation modes.

An alarm is triggered when this battery runs low and technical support should be contacted.

Note: When the battery is completely exhausted, the machine is reset to the factory settings. The alarm thresholds are reset and the alarm history is erased.

9.2.1 Managing the power supply

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

- AC power supply or external DC power supply,
- In the event of external failure, power supply from extractable battery,
- In the event of auxiliary failure, power supply from internal battery.

Note: During a power supply switchover, the screen may turn off and briefly turn back on again.

9.2.2 AC power supply

The presence or absence of AC power or the external DC supply is indicated by two pictograms:

	Mains present
	Mains absent

Presence of the mains (AC supply) is also indicated by a blue LED on the front panel of the machine. This LED is extinguished in the absence of mains or during battery-powered operation.

9.2.3 Removable battery and internal battery

The ventilator is equipped with two batteries: an internal battery (INT), which is not accessible to the user, and an extractable battery (EXT), which can be replaced during the operation of the ventilator.

The ventilator is equipped with one or two batteries:

- an internal battery (INT) that cannot be accessed by the user.
- an extractable battery (EXT) that can be replaced while the ventilator is in operation.

In the event of absence of mains or the external DC source, switching over to the removable battery has top priority. When the extractable battery is completely discharged, or if no extractable battery has been installed, the device switches automatically to the internal battery.

The internal and extractable batteries have the same capacity.

The charge status of both batteries is then indicated in the upper left-hand part of the screen:

	Full battery charge
	Comfortable battery charge
	Medium battery charge
	Battery low—connect the unit to the mains power supply. For the internal battery, the pictogram is associated with a medium-priority acknowledgeable alarm “Batteries nearly discharged!!! Connect AC power.”
	Battery dangerously low—imminent shutdown For the internal battery, the pictogram is associated with a high-priority, non-acknowledgeable alarm “Batteries inoperative!!! Connect AC power.” It is then urgent to connect the ventilator to the mains or to replace the extractable battery to prevent it from shutting down due to a lack of power.

When the unit is connected to the mains or an extractable battery, the unit’s internal battery recharges. When internal battery charging is complete, the machine charges the extractable battery, if any. A special pictogram appears on the screen, representing the progress of light segments:

	Battery discharged
	Battery half-charged
	Battery fully charged

CAUTION: When operating the device at very high or low temperatures an alarm may be triggered “Excessive Battery Temperature”. This is a safety feature of the battery charging system and may interrupt the charging and discharging process of the battery, this can significantly affect the charging time and autonomy of the battery.

Note: The charging time per battery is approximately 2 h 20 min (at 25°C ambient temperature) if the machine is not ventilating, and approximately 5 h 30 min if the machine is ventilating.

When the machine is switched off but connected to the mains or an external DC power source, battery charging automatically takes place.

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

	Battery unavailable For the internal battery, the pictogram is associated with a high-priority alarm, ‘Internal battery absent!’.

CAUTION: The batteries must not come into contact with water, as this could damage the batteries or injure the user.

Note: The integrity of the internal battery should be checked during annual maintenance.

9.2.4 Battery status indicator LED

The status of the internal and auxiliary batteries is also indicated by two LEDs on the front panel of the machine. These LEDs allow the user to view the machine charge status when the machine is connected to the mains and the screen is switched off (the LEDs show the battery status when on or in standby mode).

If an LED is:

- Off: it indicates battery absence
- Steady red: indicates that the battery is empty (inoperative)
- Flashing red: indicates that the battery is dangerously low
- Flashing green: indicates that the battery is charging
- Steady green: indicates that the battery is fully charged or in use at the start of discharging.

Note: When one of the two batteries is charging and the other one is low, the LEDs of both batteries flash green.

CAUTION: Both LEDs flashing red with the mains power supply on means the battery charger is malfunctioning.

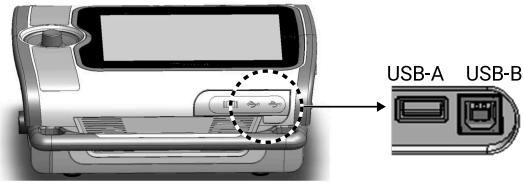
9.3 Inputs and outputs

9.3.1 Video output

The video output is located on the side of the machine where the handle is situated. A remote screen can be connected via this output in order to display an image of the ventilator screen.

9.3.2 USB Connections

The USB connectors on this ventilator provide data inputs (software updates using the USB-B port) and outputs (transmission of patient data on USB key using the USB-A port).



Software updates

The ventilator software is updated simply via the USB connection using standard computer tools.

CAUTION: The USB ports are protected by a removable cover. When the USB protector cover is removed, IP protection is no longer guaranteed. When cleaning, it is necessary to replace the USB cover to prevent liquid from getting into the ventilator.

Note: With regard to the USB 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
- The assurance that its safety certification was carried out in compliance with the local standards in force and/or the EN 60601-1 standard,
- Do not apply any abnormal voltage to the USB connectors.

9.3.3 Connectivity to hospital networks

This ventilator incorporates communication protocols which allow data to be sent to data-collection applications and external monitoring systems.

Choosing protocol

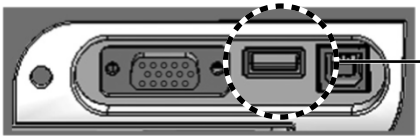
1. In the **"Config. Admin"** select the **"Ventilator"** menu and access the second page using the arrow at the top right.
2. Press **"Protocol"**, then select the protocol which corresponds to the external device using the coding whee:

   - OTP
   - Monnal Link
   - VueLink/Intellibridge EC10

Note: Contact the IT manager to select the appropriate protocol.

Connecting the communication module

Connect the YR135600 cable to the type A USB socket of the ***Monnal T60***, then connect the other end of the cable to the external device.



CAUTION: A galvanised cable should be used to ensure the electrical safety class of the ***Monnal T60***.

CAUTION: Do not leave the cable connected to the ***Monnal T60*** without connecting it to an external device, so as to avoid electromagnetic interference.

CAUTION: When the ventilator is connected to the hospital network via the USB port (with the cover removed), IP protection is no longer guaranteed. When cleaning, it is necessary to replace the USB cover to prevent liquid from getting into the ventilator.

Air Liquide Medical Systems protocols

Monnal T60 has the following *Air Liquide Medical Systems* communication protocols:

- OTP
- Monnal Link

These protocols are available on request. For more information, contact almedicalsystems.services@airliquide.com.

Data sent

The following data is sent:

- ventilation set-points
- alarms
- alarm thresholds
- all measurements excluding temporal curves

Data use

CAUTION: Since data can be altered after transmission, transmitted data should not be used for diagnostic purposes.

Compatible communication modules

Contact *Air Liquide Medical Systems* to obtain the full list of communication modules compatible with ***Monnal T60***.

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

CAUTION: Connection to a hospital network supplying other units could give rise to previously unidentified risks to patients, operators or third parties.

The user should identify, analyse, evaluate and manage such risks. Subsequent modifications made to the hospital network could lead to new risks and require further analysis. Modifications to the hospital network include:

- modifications to the configuration of the external system;
- connection of additional units to the external system;
- disconnection of units from the external system;

- updating of units connected to the external system;
- upgrade of units connected to the external system.

Cybersecurity

To ensure the security of our device and of the hospital's information systems, access to the ***Monnal T60*** must be controlled. Only physical access to ***Monnal T60*** might introduce a cybersecurity risk.

9.4 Performance and characteristics

9.4.1 Regulatory requirements

Directives

Directive 93/42/EEC

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

Date on which the marking was awarded to the ***Monnal T60*** ventilator: 2011.

Life time of the ***Monnal T60*** ventilator: 10 years.

Standards

The compliance of ***Monnal T60*** with the essential requirements of Directive 93/42 is based on the following standards:

EN ISO 14971 Application of risk management to medical devices

IEC 60601-1 and its amendments | Electromedical devices – Part One: General requirements for safety

IEC 60601-1-2 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

EN 60601-1-6 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability

ISO 80601-2-12 | Medical electrical equipment - Part 2-12: Specific requirements for basic safety and essential performance for pulmonary ventilators for use in intensive care

EN 794-3 + A2 | Pulmonary ventilators - Part 3: Specific recommendations for emergency and transport ventilators

EN 1789 + A1 | Medical vehicles and their equipment - Road ambulances

EN 13718-1 | Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances

RTCA-DO160F – Environmental conditions and test procedures for airborne equipment. Sections 7, 8, 20 and 21

IEC 62304 - Medical device software – Software life cycle processes

EN 62366 - Application of usability engineering to medical devices

9.4.2 Recovery of the components of the medical device

Characteristics of the packaging

Box for transportation (800 g) and wedge (200 g):

- Recycled paper
- Recyclable

Protective foam (1 kg):

- 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 T60*** equipment.

CAUTION: Altering the patient circuit (e.g., addition of a humidifier) may lead to variations in the inspiratory and expiratory resistances. These variations may negatively affect the performance of the ventilator.

9.4.3 Technical Characteristics

9.4.3.1 General specifications

Dimensions (L x l x h)	**29 x 25 x 11 cm**
Audible operating sound level	48 dB(A) at 1 m
Weight	Weight A: 3.7 kg Weight with two batteries: 4 kg Weight B: 20 kg

Operating conditions	
Relative humidity	0 à 95% without condensation at 40°C max.
Atmospheric pressure	600 to 1150 hPa (from -500 m to +4,000 m approximately)
Temperature	On the mains: -20°C to +40°C (-4°F to +104°F) On batteries: -10°C to +40°C (14°F to +104°F)

Storage conditions	
Relative humidity	0 à 95% without condensation at 40°C max.

Storage conditions	
Atmospheric pressure	600 to 1150 hPa (from -500 m to +4,000 m approximately)
Temperature	-20°C to +50°C (-4°F to +122°F)

Storage condition for internal battery and extractable battery	
Temperature	-20°C to +50°C (-4°F to +122°F)

Interface	
Check	Resistive tactile pad
Screen	Color 8.4", 640*480 pixels

Protection	
Protection index	IP34

9.4.3.2 Alarm sound level

Priority [6]	Acoustic pressure level measured [7]	Accuracy
High	Min : 62 dB (A) Max : 97 dB (A)	± 3 dB (A)
Medium	Min : 60 dB (A) Max : 87 dB (A)	
low	Min : 46 dB (A) Max : 69 dB (A)	
Microphone position	1 meter, opposite the speaker (position where the acoustic pressure is highest in the horizontal plane)	

6 Includes the high, medium, and low-priority conditions

7 The values shown correspond to the device's sound volume settings: Min corresponds to a setting of 20% and Max corresponds to a setting of 100%.

9.4.3.3 Electrical specifications

Main Power Supply	
Input voltage	100 - 240 V AC (tolerance -10%; +10%)
Frequency	50 to 60 Hz
Electrical power consumption	120 VA max. (0.12 kW)
Electrical class	II
Type	BF
Leak current	IEC 60601-1 compliant
Protection following a loss of power	Continuous audible alarm and patient vented to atmosphere
Cable type	2-point mains cable having max. length of 2.50 m Note: The use of cables other than those mentioned in this manual may lead to an increase in emissions or a decrease in the immunity of the device as specified in the following paragraph: Electromagnetic Compatibility

External DC source (ambulance, aeroplane, helicopter)	
Type	Rated voltage: 13-24 VDC (tolerance: 11.1-30 VDC) Permissible voltage: 11.1V to 30V for use with the ***Monnal T60*** power cable Maximum current: 11 A
Cable type	2.5m ***Monnal T60*** power cable (YR123700)

Internal [8] (YR115100) and auxiliary (KY692800) battery	
Type	Lithium-ion Rated voltage: 22.2 V Rated capacity: 2600 mAh Peak current: 5.5 A
Battery capacity (new and charged battery) with the standard ADULT ventilation configuration	Typically 2.5 hours per battery, or a total of 5 hours (at 25°C ambient temperature

Internal [8] (YR115100) and auxiliary (KY692800) battery	
Charging time (h)	Typically 2 hours 20 minutes per battery (quick charge with machine in stand-by), Typically 5.5 hours per battery (slow charge with machine ventilating) according to environmental conditions and type of power supply

Note: The internal battery has a life of around 300 charge and discharge cycles or two years, whichever happens first.

9.4.3.4 Specifications of accessories

IRMA™ probe

For more information, please refer to the IRMA™ user manual from MASIMO.

Components of the ventilation system

Components of the ventilator's ventilation system that meet the requirements of the following standards may be used:

- ISO 5367 (patient circuits)
- ISO 23328-1 and ISO 23328-2 (filters)
- ISO 8185 or ISO 80601-2-74 (humidifiers)
- ISO 9360-1 or ISO 9360-2 (HME filters)

It is also necessary to carry out the automatic tests with the combination of all of the components of the ventilator's ventilation system foreseen for the patient and to obtain faultless test results.

Patient circuit

Adult single-use patient circuit with water trap	
Catalogue Number	KG019300
Resistance at 60 L/min	1.2 cmH_2O
Compliance	1.2 mL/cmH_2O
Volume	1050 cm3

Adult single-use patient	
Catalogue Number	KG020100
Resistance at 60 L/min	0.4 cmH2O
Compliance	1 ml/cmH2O
Volume	1216 cm3

[8] The internal battery is a spare part. For more information, please contact the technical department.

Pediatric single-use patient circuit with water trap	
Catalogue Number	KG019400
Resistance at 30L/min	5 cmH2O
Compliance	0.6 mL/cmH2O
Volume	760 cm3

Pediatric single-use patient circuit without water trap	
Catalogue Number	KG020200
Resistance at 5 L/min	0.32 cmH2O
Compliance	0.8 ml/cmH2O
Volume	530 cm3

Bacteriological filter

Ventilator outlet bacteriological filter	
Catalogue Number	KV103300
Resistance at 60L/min	1.7 cmH2O
Compliance	0.1 mL/cmH2O
Volume	120 cm3
Filtration	99.99999% bacterial retention at 0.3 µm 99.9999% viral retention at 0.02 µm

9.4.3.5 Oxygen sensor specifications

Lifespan	Approximately 5000 h (variable time according to concentration and temperature)
Conditions of storage and use	Identical to those of the machine
Power supply	Supplied by the ventilator, including when operating on internal battery
Calibration	Calibration is performed automatically during the interactive tests. Only frequent calibration (at least once a week) will guarantee precision.
Minimum flow rate to guarantee precision	5 L/min
Drift of measuring precision over six hours	< ±3 Vol.%

Response time at 90% (extreme conditions)	60 s (if volume > 300ml) 90 s (if volume between 50 and 300ml) 110 s (if volume < 50mL)
Response time at 90% according to ISO 80601-2-55 standard	< 12 s
Start-up time	Immediate
Sampling rate of the O2 cell data	5 ms
Effect of humidity on oxygen measurements	-0.03 (% per %RH at 25°C)
Effect of pressure	Compensation of the measurement according to atmospheric pressure. Compensation of measurement at average pressure of respiratory cycle
Effect of ambient temperature	Compensation of the measurement according to ambient temperature. Note: Extreme temperatures damage the accuracy of the measurements.

9.4.3.6 Measured parameters

Flow rate and volume measurement condition: BTPS

Measured parameters	Measurement	Resolution	Precision [9]	Filtering [10]
Peak airway pressure (Ppeak, cmH2O)	0 - 100	0.1	± (2 cmH2O + 4%)	15 ms
Positive expiratory pressure (PEEP, cmH2O).	0 - 100	0.1	± (2 cmH2O + 4%)	15 ms
Plateau pressure (Pplat, cmH2O)	0 - 100	0.1	± (2 cmH2O + 4%)	15 ms
Average pressure (Pmean, cmH2O)	0 - 100	0.1	± (2 cmH2O + 4%)	1 cycle
Frequency (RR, bpm)	1 - 120	0.1	±1	4 cycles
Ratio of inspiratory time to total time (Ti/Ttot, %)	10 - 50	1	±1	1 cycle
Ratio of inspiratory time to expiratory time (I:E)	1:1 - 1:9	0.1	±0.1	1 cycle
Insufflated tidal volume (VTi, L/min)	20 - 3000	1	VTi < 50 mL: 11.5 mL VTi ≥ 50 mL: ± (4 mL + 15%)	-
Leak (%)	0 - 100	1	±10	-
Expired tidal volume (VTe, mL)	20 - 3000	1	VTe < 50 mL: 20% VTe ≥ 50 mL: ± (2.5 mL + 15%)	-

Measured parameters	Measurement	Resolution	Precision [9]	Filtering [10]
Expired volume per minute (MVe, L/min)	0 - 99	0.1	±20%	30 s
Inspired volume per minute (MVi, L/min)	0 - 99	0.1	±23%	30 s
Inspired oxygen fraction FiO2 [11] (Vol.%)	21 - 100	1	±(2,5 % + 2,5 % of set value)	5 s
Expired fraction of CO2 EtCO2 [12] (mmHg)	0 - 100	0.1	< ±8 mmHg	-
CO2 [13]	0 - 100	0.1	< ±(8 mmHg +8%)	
Chest compression rate [13] (fCC, bpm)	55 - 145	1	±10%	4 s + 5 cycles
Maximum pressure variation [13] (P-P, cmH2O)	5 - 20	0.1	± 4 cmH2O + 30%	5 cycles
CPV timer [13]	--	--	±2s	-
%CC (%) [13]	0 - 100	1	15%	-

9 These precision values are guaranteed in the most unfavorable ventilation system configuration, composed of a bacteriological filter, an adult patient circuit with water trap, an empty humidifier and an IRMA™ probe.

10 Filtering is performed via a sliding average of n samples.

11 The FIO2 sensor complies with the standards concerning oxygen monitors and satisfies the specifications set out below.

12 CO2 monitoring is performed by the IRMA™ probe, whose characteristics are described in Specifications of accessories.

13 In CPV mode only, only if the CPV option is active. See CPV: Cardio-Pulmonary Ventilation on page 49.

9.4.3.7 Monitoring specifications

Curves	
Flow rate (L/min)	Adjustable on successive scales: -10 to +10, -20 to +20, -40 to +40, -80 to +80, -160 to +160
Pressure (cmH2O)	Adjustable on successive scales: 0 to +20, 0 to +40, 0 to +60, 0 to +100
Volume (ml)	Adjustable on successive scales: 0 to 100, 0 to 500, 0 to 1000, 0 to 3000
Instantaneous CO2 / Average CO2 concentration (mmHg)	Adjustable on successive scales: 0 to +50, 0 to +100
Time (s)	Adjustable on successive scales: 0 to +6, 0 to +12, 0 to +18 in the ventilation screen and 0 to +9, 0 to +18, 0 to +27 in the monitoring screen
Loop curves	P/V, D/P, D/V and V/CO2

Data storage	
Trends	Simultaneous display of two parameters measured 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 [14])

9.4.3.8 Ventilation specifications

Ventilation modes	
VCV (controlled ventilation or assisted volume-controlled ventilation)	(A) VCV
PCV (controlled ventilation or assisted pressure-controlled ventilation)	(A) PCV
PSV (spontaneous ventilation with inspiratory assistance and PEEP)	PSV

[14] The unit records a maximum of 4000 events. An event is represented by a set-point or an alarm threshold when an adjustment is made and an alarm if triggered.

Ventilation modes	
CPAP mode (Continuous Positive Airway Pressure)	CPAP
Synchronized Intermittent Mandatory Ventilation	SIMV
Alternation of two CPAP levels	Duo Levels
Synchronized Intermittent Mandatory Pressure Monitored Ventilation	PSIMV
Pressure-regulated volume-controlled ventilation	PRVC
Spontaneous ventilation with inspiratory assistance, PEEP and servomechanism frequency	PS-Pro

Inspiratory trigger system	
Inspiratory trigger system	Primary inspiratory trigger is flow rate, secondary is pressure: The inspiratory trigger setting is between 0.5 and 10 L/min. A pressure threshold varying from 0.2 to 5 cmH2O is correlated to the flow trigger. At the time of a patient demand, satisfying one of the conditions (flow rate or pressure) will trigger an inspiratory cycle.
Expiratory trigger system	During any spontaneous cycle, the switch to expiration occurs as soon as one of the following criteria 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 tests	
Initialization of tests	Checking the integrity of sensors to begin the tests
Rinsing the circuit	Eliminating the oxygen present in the system
Pneumatic tests	Checking the integrity of the actuators of the inspiratory and expiratory branches Calibrating the oxygen and expiratory flow sensors
Checking the mixer	Checking the mixer
Conclusion of tests	Checking the safety mechanisms Compliance measurement

9.4.3.9 Pneumatic specifications

High-pressure (HP) and low-pressure (LP) O2 intakes	
Type of gas fitting	NF, DISS, NIST (HP) Spiral fitting (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 bars / 130 L/min at 6 bars (HP), 85 L/min at 1.5 bar (LP)
Standalone mode	Cylinder (HP) Low flow O2 metered supply e.g. Concentrator (LP)
Mixer	Electronic, electrochemical O2 sensor
Precision (% of set value)	± 5 percentage points under the conditions specified by standard, ISO 80601-2-12
Gas consumption [15]	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[16]	
Resistances at 60L/min (cmH2O) (machine + single-use adult patient circuit KG020100+ filter KV103300)	Inspiratory: 4.73 Expiratory: 4.89
Resistances at 30L/min (cmH2O) (machine + single-use child patient circuit KG020200+ filter KV103300)	Inspiratory: 2.62 Expiratory: 2.52
Resistances at 5 L/min (cmH2O) (machine + single-use child patient circuit KG020200 + filter KV103300)	Inspiratory: 0.28 Expiratory: 1.39

Pressure	
Maximum limited pressure (Plimmax)	90 cmH2O: blower performance limitation
Maximum working pressure (P w max)	70 cmH2O
Minimum working pressure (P w min)	0 cmH2O
Minimum limited pressure (P lim min)	Back-up ambient air intake preventing a pressure drop in the patient circuit

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 @ 2,5 L/min
Expiratory resistance	Adult: max 6 cmH2O @ 30 L/min Child: max 6 cmH2O @ 15 L/min Infant: max 6 cmH2O @ 2,5 L/min
Compliance	12 mL/cmH2O

9.4.3.10 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.

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.

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15 Consumption example:

- For an adult, average consumption is 6 l/min of gas (air or oxygen),
- The flow-by and own consumption of the unit is fixed at 5 L/min;

  In the case of a B5 compact-type cylinder being used. Its volume is 5 litres. Because the gas is compressed to 200 bars, in this case we have 1000 litres of gas. In our example, we will therefore have approximately 1 hour 15 minutes of operating time if ventilation is carried out at 100% oxygen concentration.

16 The above-mentioned resistances take the ventilator, an inspiratory filter, 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.

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.

The main performance requirement is the continuity of the patient's ventilation within the limits of the alarm set by the operator or the generation of an audible and visual alarm.

Note: The emission characteristics of this device allow it to be used in industrial areas and in a hospital environment (class A as defined in CISPR 11). If used in a domestic environment (for which class B as defined in CISPR 11 is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user may be required to take mitigation measures, such as relocating or re-orienting the ventilator.

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 T60***, including the cables specified by the manufacturer. Otherwise, the performance of this equipment may be impaired.

Length of cables

CAUTION: ***Monnal T60*** must be used with these accessories. The use of other accessories may result in increased emissions or decreased immunity of the ventilator.

Cables and accessories	Maximum length	Test type	In compliance with
Monnal T60 **Ventilator** Power cable (2.50 m) YR094100 **CO2 Monitoring probe** ***Monnal T60*** connection cable (2.5m) KB020400	< 3 m	RF Emission	CISPR 11, Class A
		Emission of harmonic currents	IEC 61000-3-2
		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 interruptions and voltage variations	IEC 61000-4-1

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 T60***, 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 disturbance(Radiated emissions) (CISPR 11)	Group1	The medical device uses RF energy for its internal`operation. Consequently, its radio frequency emissions are very low and are not likely to create any interference with neighboring equipment.
Power terminal disturbance voltage (Conducted emissions) (CISPR 11	Class A	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 environment/comments
Electrostatic discharges (ESD) (IEC 61000-4-2)	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	Home health care environment and a professional health care establishment environment
Electrical Fast Transient/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 frequency magnetic field (IEC 61000-4-8)	30 A/m	30 A/m	

Immunity test	Test level according to IEC 60601	Compliance level	Electromagnetic environment/comments
Voltage dips, short interruptions and voltage variations (IEC 61000-4-11)	0% UT for 0.5 cycles A 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0% UT for 0.5 cycles A 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Home health care environment and a professional health care establishment environment. If use of the system requires continued operation during power supply cuts, the use of a separate power source to power the medical device is recommended (UPS, etc.).
	0% UT for 1 cycle	0% UT for 1 cycle	
	70% UT for 25 cycles at 50 Hz For 30 cycles at 60 Hz Single phase: at 0°	70% UT for 25 cycles at 50 Hz For 30 cycles at 60 Hz Single phase: at 0°	
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	Home health care environment and a professional health care establishment environment. If use of the system requires continued operation during power supply cuts, the use of a separate power source to power the medical device is recommended (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 environment/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 T60***, including the cables specified by the manufacturer. Otherwise, the performance of this equipment may be impaired.			
Radiated, radio-frequency, electromagnetic 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	Home health care environment and a professional health care establishment environment.

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

9.4.4 Settings tables

Name	Mode	Label	Unit	Adult				Child				Infant			
				Range		Resolution	Default value	Range		Resolution	Default value	Range		Resolution	Default value
				Min.	Max.			Min.	Max.			Min.	Max.		
FiO2	All	FiO2	%	21	100	5 as from 25[18]	50	21	100	5 as from 25[18]	50	21	100	1 as from 25[18]	35
	VC Emergency Ventilation[17]						100								
	Oxygen therapy						50								50
Inspired volume	VCV square VCV decelerated SIMV	VT	mL	100	2000	10	480	50	500	5	120	20	75	5	50
Target volume	PSV PRVC	VT target	mL	OFF,100	2000	10	480	OFF, 50	500	5	120	OFF, 20	75	5	35
Insufflation pressure[19]	PCV PSIMV	PI	cmH2O	5	60	1	15	5	60	1	15	5	60	1	15
	PSV SIMV PS-Pro	PS[19]	cmH2O	5	40	1	15	5	40	1	15	5	40	1	15
	Duo-Levels	PI	cmH2O	5	40	1	13	5	40	1	13	5	40	1	13
	PSV / NIV	PS[19]	cmH2O	5	25	1	8	5	25	1	8	5	25	1	8
Max. insufflation pressure	PS-Pro PRVC	Pi max	cmH2O	5	60	1	25	5	60	1	25	5	60	1	25
Frequency	VCV square VCV decelerated PCV	RR	bpm	5	40	1	15	5	60	1	25	10	80	1	40
	SIMV PSIMV	RR SIMV	bpm	1	40	1	15	5	60	1	25	10	80	1	40
	PCV PRVC	RR mini	bpm	1	40	1	15	1	60	1	10	1	80	1	20
	PSV PSV / NIV Duo-Level	RR mini	bpm	1	40	1	5	1	60	1	10	1	80	1	20
Maintenance intervals	PS-Pro	RR support	bpm	5	40	1	15	5	60	1	25	10	80	1	40

Name	Mode	Label	Unit	Adult				Child				Infant			
				Range		Resolution	Default value	Range		Resolution	Default value	Range		Resolution	Default value
				Min.	Max.			Min.	Max.			Min.	Max.		
Expiratory pressure	VCV square VCV decelerated SIMV PSV PSIMV PCV PRVC PS-Pro	PEEP	cmH2O	0	20	1	5	0	20	1	5	0	20	1	5
	PSV / NIV Duo-Levels	PEEP	cmH2O	0	15	1	5	0	15	1	5	0	15	1	5
	CPAP	CPAP	cmH2O	2	20	1	5	2	20	1	5	2	20	1	5
I:E ratio	VCV square VCV decelerated PCV PRVC	I:E		1:1	1:9	0,1	1:2	1:1	1:9	0,1	1:2	1	9	0,1	2
Inspiratory time	PCV SIMV	Ti	s	0,3	5	0,1	1,3	0,3	5	0,1	0,8	0,25	3	0,05 then 0,1	0,5
	SIMV	Ti	s	0,3	5	0,1	1,2	0,3	5	0,1	0,7	0,25	3	0,05 then 0,1	0,5
	PSV PSV / NIV	TImax	s	0,3	5	0,1	1,3	0,3	5	0,1	1	0,25	5	0,05 then 0,1	1
	Duo-Levels	THigh	s	0,3	30	0,1	1,3	0,3	30	0,1	1	0,25	30	0,05 then 0,1	1
Plateau time	VCV square VCV decelerated SIMV	Tplat	%	0	60	5	10	0	40	5	10	0	40	5	0
Inspiratory trigger	VCV square VCV decelerated PCV PRVC	I Trig.	L/min	OFF-0,5	10	1	3	OFF-0,5	10	1	3	OFF-0,5	10	1	3
	PSV PSV / NIV SIMV Duo-Levels PS-Pro PSIMV	I Trig.	L/min	0.5	10	1	3	0.5	10	1	3	0,5	10	1	3

Name	Mode	Label	Unit	Adult				Child				Infant			
				Range		Resolution	Default value	Range		Resolution	Default value	Range		Resolution	Default value
				Min.	Max.			Min.	Max.			Min.	Max.		
	Emergency VCV vent (with CPV option)	I Trig.	L/min	OFF-0,5	10	1	OFF	OFF- 0,5	10	1	OFF	OFF-0,5	10	1	OFF
	Emergency VCV vent (without CPV option)	I Trig.	L/min	OFF-0,5	10	1	5	OFF- 0,5	10	1	5	OFF-0,5	10	1	5
Expiratory trigger	PSV SIMV PSIMV PS-Pro	E Trig.	%	10	90	10	30	10	90	10	30	10	90	10	30
	PSV / NIV Duo- Levels	E Trig.	%	10	90	10	50	10	90	10	50	10	90	10	50
Pressure rise slope	PSV PSV / NIV PCV SIMV PSIMV Duo- Levels PS-Pro PRVC	Slope	cmH2O / s	60	120	20	100	60	120	20	100	60	120	20	100
Form of flow	Emergency ventil.	Flow rate		CONST	DE-CEL		DE-CEL	CONST	DE-CEL		DECEL	CONST	DECEL		DECEL
	VCV square VCV decelerated SIMV						CONST				CONST				CONST
Peak flow	Oxygen therapy	Flow	L/min	4	80	1	40	4	60	1	25	2	60	1	15
	VCV Square VCV decelerated SIMV			4	150	1	24	4	150	1	10	2	36	1	4
Sigh amplitude	VCV square VCV decelerated	VT sigh	x VT	OFF, 1.1	2.0	0.1	OFF	OFF-1.1	2.0	0.1	OFF	OFF-1.1	2.0	0.1	OFF, 1.1
	PCV	PI sigh	x PI	OFF, 1.1	2.0	0.1	OFF	OFF-1.1	2.0	0.1	OFF	OFF-1.1	2.0	0.1	OFF, 1.1

Name	Mode	Label	Unit	Adult				Child				Infant			
				Range		Resolution	Default value	Range		Resolution	Default value	Range		Resolution	Default value
				Min.	Max.			Min.	Max.			Min.	Max.		
Sigh frequency	VCV square VCV decelerated PCV	Sigh	Period	9	200	1	20	9	200	1	20	9	200	1	20
Ti/Ttot	VCV PCV PRVC	Ti/Ttot	%	10	50	1	33	10	50	1	33	10	50	1	33
Apnea ventilation volume	All except VCV, PCV PS-Pro PRVC	VT	mL	100	2000	10	480	50	500	5	120	20	75	5	35
Apnea ventilation frequency	All except VCV, PCV PS-Pro PRVC	RR	bpm	5	40	1	15	5	60	1	25	10	80	1	40
Triggering duration	All except VCV, PCV PS-Pro PRVC	Tapnea	s	15	60	1	20	4	60	1	20	2	60	1	10
Height	Emergency ventilation	Height	Cm	106	235	1	M : 175 F : 165	73	166	1	100	45	77	1	55
			Inches	42	92	1	M : 68 F : 64	29	65	1	39	17	30	1	21
Gender	Emergency ventilation	Gender		M-F			F	M-F			F	M-F			F

Accuracy of the delivered values compared to the set values :

- VTi < 50 mL : 11.5 mL
- VTi ≥ 50 mL: ± (4 mL + 15%)
- Pressures (PEEP, IP, PS): ± (2 cmH2O + 4%)
- 5 percentage points under the conditions specified by standard ISO 80601-2-12

17 If CPV option is not enabled.

18 4 between 21 and 25.

19 PI = PS + PEEP

9.4.5 Settings table (CPV)

CPV phase	Set-point	Label	Unit	Settings			
				Range		Resolution	Default value
				Min	Max		
Chest compression	FiO2	FiO2	%	21	100	5	100
	Respiratory rate	RR CPV	bpm	5	25	1	10
	Synchronized low pressure	PL sync	cmH2O	0	15	1	5
	Synchronized high pressure	PH sync	cmH2O	5	40	1	20
	High-level duration	T high	s	0,3	3	0,1	1
Return of Spontaneous Circulation	FiO2	FiO2	%	21	100	5	50
	Respiratory rate	RR CPV	bpm	5	25	1	15
	Expiratory pressure	PEEP	cmH2O	0	15	1	5
	Insufflation pressure	PI	cmH2O	5	40	1	15
	Inspiratory trigger	Trig. I	L/min	OFF	10	1	5

9.4.6 Calculation of predicted body weight

Height		Predicted body weight (kg)		Category
Inch	cm	Female	Male	
17	45	3		Infant
19	50	4		
21	54	5		
23	59	6		
25	64	7		
27	69	8		
28	73	9		
30	78	10		Child
32	82	11		
37	93	14	15	
40	101	15	17	
43	109	17	20	
46	116	20	22	
49	124	23	26	
51	129	25	28	
52	132	26	31	Adult
54	137	31	35	
56	142	36	40	
58	147	40	45	
60	152	45	49	
62	157	49	54	
64	162	54	58	
66	167	58	63	
68	172	63	67	
70	177	67	72	
72	182	72	76	
74	187	76	81	
76	193	82	86	
78	198	86	91	
80	203	91	96	
82	208	96	100	
84	213	100	105	
86	218	105	109	
87	220	107	111	
88	225	111	116	
90	230	116	120	
92	235	120	125	

Predicted weight based on:

- Height <= 84 cm: WHO child growth standards
- 84 cm < Height <=144 cm: Adults and Pediatrics. Peck Formula. Tech. Report. 10. Div. Clin. Pharmacol. Uniformed Services University of the Health Sciences.

Predicted weight (man) = 59.6035 + [5.2878 x height] - [0.1239 x height2] + [0.0013 x height3]

Predicted weight (woman) = -77.5580 + [6.9373 x height] - [0.1717 x height2]+ [0.0017 x height3]

Height > 144 cm: Adults. Devine Formula. Drug. Intell. Clin. Pharm. 8: 650

Predicted weight (man) = 50 + 2.3 [height - 60]

Predicted weight (woman) = 45.5 + 2.3 [height - 60]

9.4.7 Interdependency of settings

PCV Mode

Pressure Support Ventilation minimum of 5 cmH2O

PI - PEEP > 5 cmH2O

PSV, PSV / NIV Modes

Maximum insufflation pressure of 60 cmH2O → PSV + PEEP < 60 cmH2O

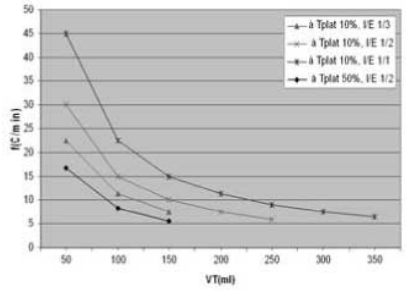
VCV Mode:

Minimum peak rate of 2 L/min.

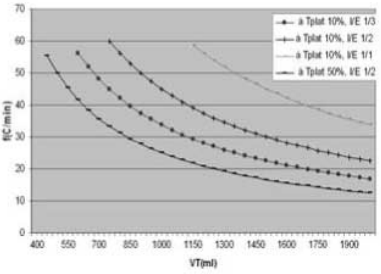
Maximum peak rate of 150 L/min.

The form of the flow rate, the VT, and the parameters RR, I:E and Tplat are interdependent in order to comply with the conditions given above.

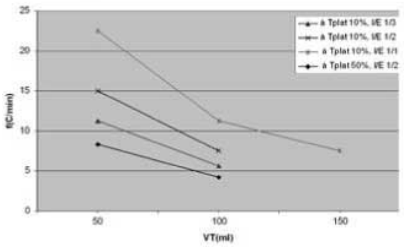
Frequence minimum en fonction du volume en VAC carré



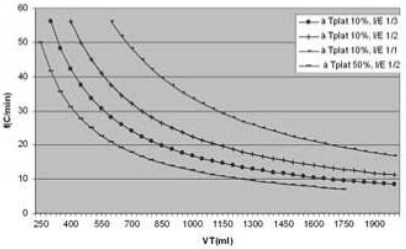
Frequence maximum en fonction du volume en VAC carré



Frequence minimum en fonction du volume en VAC décéléré



Frequence maximum en fonction du volume en VAC décéléré



9.4.8 Alarm thresholds

Name	Modes concerned	label	adult			child			infant		
			setting		Default value	setting		Default value	setting		Default value
			min	max		min	max		min	max.	
Peak pressure	PSV PSV / NIV PCV PSIMV PRVC	Ppeak	10	80	45 auto threshold: Pmeasured + max. (20%, 5)	10	80	45 auto threshold: Pmeasured + max. (20%, 5)	10	80	45 auto threshold: P measured + max. (20%, 5)
	SIMV Duo- Levels CPAP Oxygen therapy	Ppeak	max (10, Pi + 5)	80	45 No auto threshold	max (10, Pi + 5)	80	45 No auto threshold	max (10, Pi + 5)	80	45 No auto threshold
	VCV square VCV decelerated	Ppeak	10	80	45 auto threshold: Pmeasured + 33%	10	80	45 auto threshold: Pmeasured + 33%	10	80	45 auto threshold: Pmeasured + 33%
Low pressure	PSV PSV / NIV PCV PSIMV PRVC	Pmin	OFF, 1	75	1, auto threshold: Pmeasured - max. (20%, 5)	OFF, 1	75	1, auto threshold: Pmeasured - max. (20%, 5)	OFF, 1	75	1, auto threshold: Pmeasured - max. (20%, 5)
	Oxygen therapy	Pmin	Non-adjustable		OFF	Non-adjustable		OFF	Non-adjustable		OFF
	SIMV Duo- Levels CPAP	Pmin	OFF, 1	min(75, PI)	1, No auto threshold	OFF, 1	min(75, PI)	1, No auto threshold	OFF, 1	min(75, PI)	1, No auto threshold
	VCV square VCV decelerated	Pmin	OFF, 1	75	1, auto threshold: Pmeasured - 33%	OFF, 1	75	1, auto threshold: Pmeasured - 33%	OFF, 1	75	1, auto threshold: Pmeasured - 33%
Low frequency	All except oxygen therapy	RR	1	50	6 auto threshold: RR measured + 50% (limited to 40 bpm)	1	80	10 auto threshold: RR measured + 50% (limited to 40 bpm)	1	80	20 auto threshold: RR measured + 50% (limited to 40 bpm)
High frequency	All except oxygen therapy	RR	11	60	35 auto threshold: RR measured + 50% (limited to 90 bpm)	11	100	40 auto threshold: RR measured + 50% (limited to 90 bpm)	11	120	60 auto threshold: RR measured + 50% (limited to 90 bpm)

Name	Modes concerned	label	adult			child			infant		
			setting		Default value	setting		Default value	setting		Default value
			min	max		min	max		min	max.	
Low exp.volume	VCV square VCV decelerated PCV	Low VTe	OFF, 10	min(2000, Vt setting)	OFF auto threshold: VTe measured - 50% (limited to 10 mL)	OFF, 10	min(1950, Vt setting)	OFF auto threshold: VTe measured - 50% (limited to 10 mL)	OFF, 10	min(790, Vt setting)	OFF auto threshold: VTe measured - 50% (limited to 10 mL)
	PSV PSV / NIV	Low VTe	OFF, 10	min(2000, VTe high threshold - 50)	OFF auto threshold: VTe measured - 75% (limited to 10 mL)	OFF, 10	min(1950, VTe high threshold - 50)	OFF auto threshold: VTe measured - 75% (limited to 10 mL)	OFF, 10	min(790, VTe high threshold - 10)	OFF auto threshold: VTe measured - 75% (limited to 10 mL)
	SIMV	Low VTe	OFF, 10	min(2000, Vt setting)	OFF No auto threshold	OFF, 10	min(1950, Vt setting)	OFF No auto threshold	OFF, 10	min(790, Vt setting)	OFF No auto threshold
	CPAP Duo- Levels PS-Pro PRVC PSIMV	Low VTe	OFF, 10	min(2000, VTe high threshold - 50)	OFF auto threshold: OFF	OFF, 10	min(1950, VTe high threshold - 50)	OFF auto threshold: OFF	OFF, 10	min(790, VTe high threshold - 10)	OFF auto threshold: OFF
High exp.volume	VCV square VCV decelerated PCV	High VTe	max (50, Vt setting + 50)	3000	2000 auto threshold: VTe measured + 100% (limited to 3000 mL)	max (50, Vt setting + 50)	2000	1000 auto threshold: VTe measured + 100% (limited to 3000 mL)	max (20, Vt setting + 10)	800	OFF auto threshold: VTe measured - 50% (limited to 10 mL)
	PSV / NIV PSV	High VTe	max(50, VTe low threshold + 50)	3000	2000 auto threshold: VTe measured + 100% (limited to 3000 mL)	max(50, VTe low threshold + 50)	2000	1000 auto threshold: VTe measured + 100% (limited to 3000 mL)	max(20, VTe low threshold + 10)	800	OFF auto threshold: VTe measured - 50% (limited to 10 mL)
	CPAP Duo- Levels PS-Pro PRVC PSIMV	High VTe	max (50, Vt setting + 50)	2000	CPAP Duo-Levels	max (50, Vt setting + 50)	2000	OFF No auto threshold	max (20, Vt setting + 10)	800	OFF No auto threshold
	SIMV	High VTe	max(50, VTe low threshold + 50)	3000	2000 auto threshold: 2000	max(50, VTe low threshold + 50)	2000	1000 auto threshold: 1000	max(20, VTe low threshold + 10)	800	OFF auto threshold: OFF
Low insp. volume	VCV square VCV decelerated PCV	Low VTi	OFF, 10	min(2000, Vt setting)	OFF auto threshold: VTi measured - 50% (limited to 10 mL)	OFF, 10	min(1950, Vt setting)	OFF auto threshold: VTi measured - 50% (limited to 10 mL)	OFF, 10	min(790, Vt setting)	OFF auto threshold: VTi measured - 50% (limited to 10 mL)

Name	Modes concerned	label	adult			child			infant		
			setting		Default value	setting		Default value	setting		Default value
			min	max		min	max		min	max.	
	PSV PSV / NIV	Low VTi	OFF, 10	min(2000, high VTi threshold - 50)	OFF auto threshold: VTi measured - 75% (limited to 10 mL)	OFF, 10	min(1950, high VTi threshold - 50)	OFF auto threshold: VTi measured - 75% (limited to 10 mL)	OFF, 10	min(790, high VTi threshold - 10)	OFF auto threshold: VTi measured - 75% (limited to 10 mL)
	CPAP Duo- Levels PS-Pro PRVC PSIMV	Low VTi	OFF, 10	min(2000, Vt setting)	2000 No auto threshold	OFF, 10	min(1950, Vt setting)	OFF, 10	OFF, 10	min(790, Vt setting)	OFF No auto threshold
	SIMV	Low VTi	OFF, 10	min(2000, high VTi threshold - 50)	OFF auto threshold: OFF	OFF, 10	min(1950, high VTi threshold - 50)	OFF auto threshold: OFF	OFF, 10	min(790, high VTi threshold - 10)	OFF auto threshold: OFF
High insp. volume	VCV square VCV decelerated PCV	VTi high	max (50, Vt setting + 50)	3000	2000 auto threshold: VTi measured + 50% (limited to 3000 mL)	max (50, Vt setting + 50)	2000	1000 auto threshold: VTi measured + 50% (limited to 2000 mL)	max (20, Vt setting + 10)	800	100 auto threshold: VTi measured + 50% (limited to 800 mL)
	PSV PSV / NIV	VTi high	max(50, low VTi threshold + 50)	3000	2000 auto threshold: VTi measured + 100% (limited to 3000 mL)	max(50, low VTi threshold + 50)	2000	1000 auto threshold: VTi measured + 100% (limited to 2000 mL)	max(20, low VTi threshold + 10)	800	100 auto threshold: VTi measured + 100% (limited to 800 mL)
	CPAP Duo- Levels PS-Pro PRVC PSIMV	High VTi	max (50, Vt setting + 50)	3000	2000 No auto threshold	max (50, Vt setting + 50)	2000	1000 No auto threshold	max (20, Vt setting + 10)	800	100 No auto threshold
	SIMV	High VTi	max(50, low VTi threshold + 50)	3000	2000 auto threshold: 2000	max(50, low VTi threshold + 50)	2000	1000 auto threshold: 1000	max(20, low VTi threshold + 10)	800	100 auto threshold: 100
Low expired volume per minute	All except oxygen therapy	Low MVe	OFF, 0.1	39	3 auto threshold: Measured MVe - 50%	OFF, 0.1	39	1.5 auto threshold: MVe measured - 50%	OFF, 0.1	39	OFF, 0.1
High expired volume per minute	All except oxygen therapy	High MVe	1.5	40	25 auto threshold: MVe measured + 50%	1	40	10 auto threshold: MVe measured + 50%	1	40	5 auto threshold: MVe measured + 50%
Low inspired volume per minute	All except oxygen therapy	Low MVi	0.5	39	3 auto threshold: MVi measured - 50%	0.5	39	1.5 auto threshold: MVe measured - 50%	0.5	39	1 auto threshold: MVe measured - 50%

Name	Modes concerned	label	adult			child			infant		
			setting		Default value	setting		Default value	setting		Default value
			min	max		min	max		min	max.	
High inspired volume per minute	All except oxygen therapy	High MVi	1.5	40	25 auto threshold: MVi measured + 50%	1	40	10 auto threshold: MVi measured + 50%	1	40	5 auto threshold: MVi measured + 50%
FiO2 low	All	FiO2	18	95	FiO2 setting - 5	18	95	FiO2 setting - 5	18	95	FiO2 setting - 5
FiO2 high	All	FiO2	24	105	FiO2 setting + 5	24	105	FiO2 setting + 5	24	105	FiO2 setting + 5
etCO2 low	All	etCO2	OFF, 1	98	30 auto threshold: no impact	OFF, 1	98	30 auto threshold: no impact	OFF, 1	98	30 auto threshold: no impact
etCO2 high	All	etCO2	5	99	49 auto threshold: no impact	5	99	49 auto threshold: no impact	5	99	49 auto threshold: no impact
High Pplat	VCV	Pplat	1	50, OFF	OFF auto threshold: Pplat +5	1	50, OFF	OFF auto threshold: Pplat +5	1	50, OFF	OFF auto threshold: Pplat +5
	Other modes except oxygen therapy	Pplat	1	50, OFF	OFF auto threshold OFF	1	50, OFF	OFF auto threshold OFF	1	50, OFF	OFF auto threshold OFF

9.4.9 Alarm thresholds – CPV

Name	Label	Range		Resolution	Default value
		Min	Max		
Peak pressure	Ppeak	10	80	1	60
					auto threshold: Pmeasured + max. (20%, 5)
Low pressure	Pmin	OFF, 1	75	1	1
					No auto threshold
Low frequency	RR	1	50	1	6
					Auto threshold: RR measured - 50% (limited to 4 bpm)
High frequency	RR	11	60	1	35
					auto threshold: RR measured + 50% (limited to 90 bpm)
Low exp.volume[20]	Low Vte	OFF, 10	2000	10	OFF
					auto threshold: measured VTe - 50% (limited to 10 mL)
High exp.volume[20]	High VTe	50	3000	10	2000
					auto threshold: measured VTe + 50% (limited to 3000 mL)
Low insp. volume	Low VTi	OFF, 10	2000	10	OFF
					auto threshold: measured VTi - 50% (limited to 10 mL)
High insp. volume	High VTi	50	3000	10	2000
					auto threshold: measured VTi + 50% (limited to 3000 mL)
Low expired volume per minute[20]	Low MVe	OFF, 0.1	39	0.1	3
					auto threshold: measured MVe - 50%
High expired volume per minute[20]	High MVe	1.5	40	0.1	40
					auto threshold: measured MVe + 50%
FiO2 low	FiO2	18	95	1	FiO2 setting - 5
FiO2 high	FiO2	24	105	1	FiO2 setting + 5
etCO2 low[20]	etCO2	OFF, 1	98	1	OFF
					auto threshold: no impact
etCO2 high[20]	etCO2	5	99	1	OFF
					auto threshold: no impact
Low Chest Compression rate	Low fCC	70	100	5	90

Name	Label	Range		Resolution	Default value
		Min	Max		
High Chest Compression rate	High fCC	110	140	5	120

20 This monitored parameter is available only during the ROSC phase.

10 Appendix

10.1 Checklist

When a device is commissioned and after any maintenance operation, carry out the sequence of actions below:

	Yes, done
Connect the unit to the O2 wall outlet or an oxygen cylinder. Check that the supply pressure is correct (between 2.8 and 6 bar).	☐
Install the patient circuit on the machine and connect a test lung.	☐
Connect the unit to the mains power supply and check that the blue indicator light on the front panel lights up.	☐
Press the ON/OFF button on left-hand side of the machine to switch on the ventilator. You should hear a BEEP from the audible alarm, and the ventilator screen should light up.	☐
Select **"Emergency ventilation"** in the machine stand-by screen (FiO2 setting = 21%). After one minute of ventilation, check that no technical alarm is present (this test is used to purge oxygen before performing the autotests).	☐
Close off the Y-piece and run the automatic test procedure. The message 'Test successful' appears, as well as a compliance value	☐
Select **"Emergency ventilation"** in the machine stand-by screen (FiO2 setting = 100%). After one minute of ventilation, check that no technical alarm is present (this test is used to check the addition of oxygen).	☐
Test the functioning of the alarms: adjust the thresholds to trigger the alarms (follow the method described in Adjustment of alarm thresholds on page 58) To trigger the obstruction alarm: using a tool, simulate an obstruction in the expiratory limb during ventilation (for example: by clamping the expiratory limb).	☐
Battery operation: During ventilation on the test lung, disconnect the electrical connection. Check that the ventilator is ventilating on the extractable battery and indicates this on the screen. Check that the battery is sufficiently charged (at least four squares). Reconnect the AC power supply.	☐
Alarm volume: Press the **'Pause'** key. A dialog box is displayed and asks the user to confirm stopping ventilation. Check that the sound level of the alarm associated with the ventilation stop request is sufficient. If not, refer to Configuration of the ventilator on page 72. Confirm that you wish to stop ventilation.	☐

10.2 Maintenance sheet

1 year	2 years
Date : Technician name: Signature and stamp:	Date : Technician name: Signature and stamp:
3 years	**4 years**
Date : Technician name: Signature and stamp:	Date : Technician name: Signature and stamp:
5 years	**6 years**
Date : Technician name: Signature and stamp:	Date : Technician name: Signature and stamp:
7 years	**8 years**
Date : Technician name: Signature and stamp:	Date : Technician name: Signature and stamp:
9 years	**10 years**
Date : Technician name: Signature and stamp:	Date : Technician name: Signature and stamp:

Monnal T60 No:
Installation date:
Maintenance Service done by:

Distributor name:
Address:

Telephone:

Preventive maintenance of devices should be carried out according to the manufacturer's instructions as given in the maintenance manual and updates (if any).
All technicians trained by Air Liquide Medical Systems are given a copy of the maintenance manual.
Use only authorized spare parts.
Air Liquide Medical Systems is an activity of the Healthcare Division of Air Liquide

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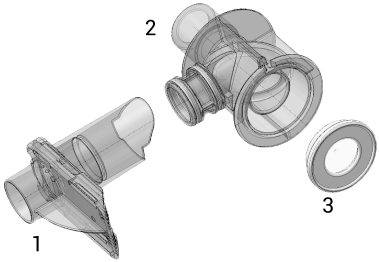
10.3 Expiratory assembly cleaning protocol

Disassembly

1. Disassemble the patient circuit by removing its components: pipes, fittings, water traps, and Y-piece.
2. Remove the expiratory assembly from its housing by pressing the eject push-button.
3. Disassemble the expiratory assembly according to the diagram below:



4. Remove the expiratory flow hot wire sensor **(1)**, the valve body **(2)**.
5. Remove and dispose of the membrane **(3)**.

CAUTION: The membrane is for single use.

6. 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

1. Immerse the expiratory assembly components in a pre-disinfectant solution.

Note: Air Liquide Medical Systems recommends the use of products: neodisher Multi-Zym, Anios Clean Excel D (follow the instructions of the product manufacturer).

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

2. Rinse the parts under running water, except for the expiratory flow sensor **(1)**, which should only be dipped in water.
3. Leave the components to dry on absorbent paper.

PRION cycle 134°/18 min

CAUTION: Disinfection must be performed with care by certified personnel.

Condition the components removed from the expiratory assembly before the procedure.

CAUTION: The expiratory valve (except the membrane) can tolerate 50 disinfection cycles. The membrane is single use.

Note: 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.

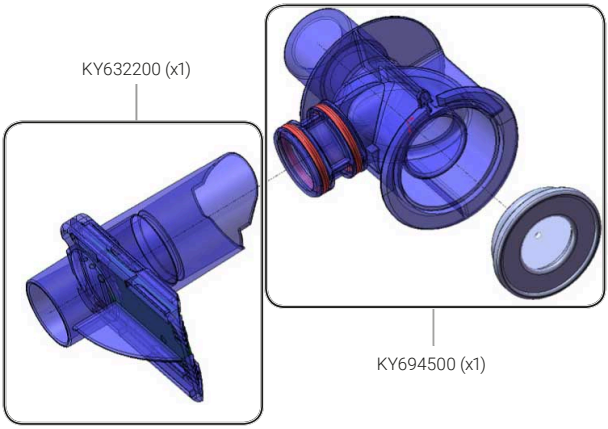
Reassembly

Reassemble the expiratory assembly wearing gloves: place a new membrane in the valve body.

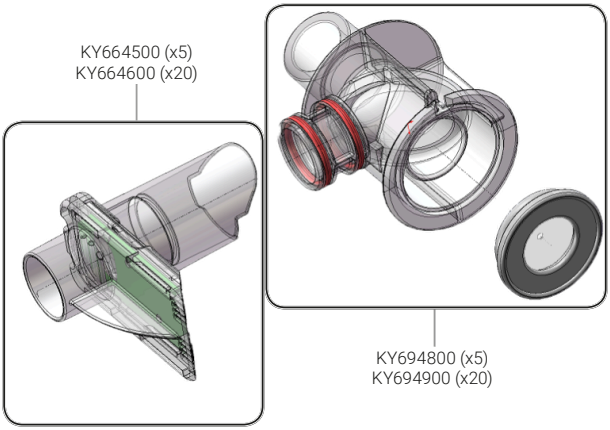
CAUTION: It is necessary to perform an automatic test after each assembly of the expiratory valve and the flow sensor.

CAUTION: Incorrect reassembly of the expiratory assembly (wrong positioning of the membrane in the valve body, removal or addition of an additional silicon disc, etc.) can lead to degraded performance of the device (risk of leaks, incorrect pressurization, failure to respect the volume – hypoventilation).

10.3.1 Monnal EVA autoclavable expiratory assembly



10.3.2 Monnal EVA single-use expiratory assembly



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