

**Taema**

---

---

***MONNAL D2***  
**User Manual**



## GENERAL SAFETY GUIDELINES

### Use of oxygen

Follow the safety guidelines for the use of oxygen:

- Do not smoke
- Do not use near a source of sparks or incandescent objects
- Do not lubricate working parts.



### Use and maintenance of the device

Conformity with NFC 74010 (§6.8.2.b):

"The manufacturer, assembler, installer or importer are not to be considered responsible themselves for the consequences on safety, reliability, and characteristics of a device unless:

- The assembly, extensions, modifications or repairs have been carried out by persons authorised by the party concerned, and
- The electrical installation of the corresponding premises complies with IEC regulations,
- The device is used in accordance with the instructions for use."

If the replacement parts used for the periodic servicing do not comply with the manufacturer's specifications, the latter is absolved from all responsibility in the event of an accident.

- Do not open the device whilst in operation.
- Do not use ether-type solvents when washing patients
- Do not use conduits or tubes which are antistatic or conductors of electricity.
- Do not use in a specifically magnetic environment (MRI, etc.)

The **MONNAL D2** pulmonary ventilator must not be used with inflammable anaesthetic agents or explosive substances.

### Electromagnetic compatibility

- The **MONNAL D2** ventilator is a medical device complying with the safety requirements of the 93/42/ EEC European directive.
- The operation of this device may be affected by other devices being used nearby, such as diathermy and high frequency electro-surgical equipment, defibrillators, short wave therapy equipment, mobile telephones and more generally by electromagnetic interference exceeding the levels specified by the EN 60601-1-2 standard.

- The **MONNAL D2** ventilator must be used in conjunction with the necessary complementary monitoring system (FiO<sub>2</sub>, flow measurement, etc.) in compliance with the current regulations.

**It is recommended that a manual ventilation system (of the Taema IM5 type) be kept nearby, together with an emergency medical oxygen tank equipped with a low-pressure reducing valve.**

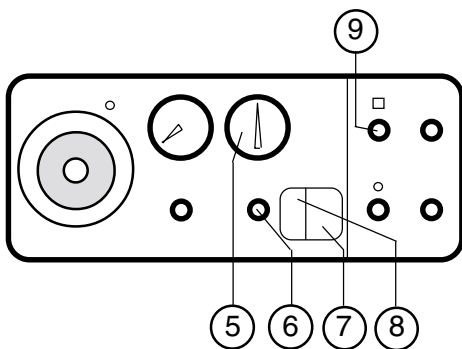
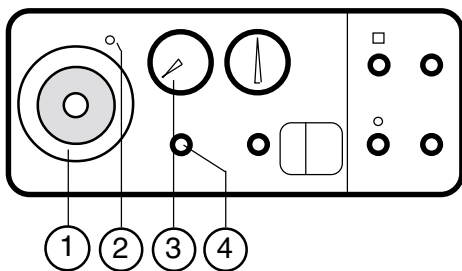
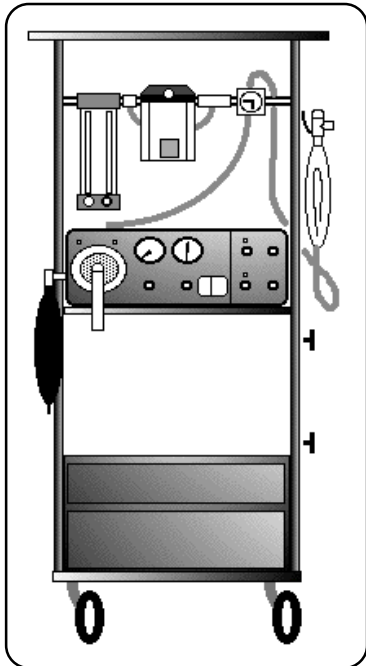
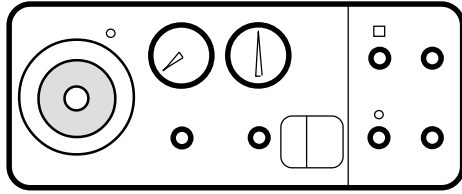
**The *MONNAL D2* ventilator must be used in conjunction with a system for monitoring the pressure in the patient's airways (of the Taema P*MAX* Module type).**

**Only persons who have read and understood this entire manual are authorised to use the *MONNAL D2* ventilator.**

**The audible alarm of the *MONNAL D2* ventilator is designed to be heard by a practitioner situated close to the patient. The maximum distance that the user can move away from it and the volume level of the alarm must therefore be determined by the user to suit the environment.**

## CONTENTS

<b>GENERAL SAFETY GUIDELINES</b> ..... page 1	6. Alarms ..... page 6
<b>CONTENTS</b> ..... page 1	7. Maintenance ..... page 7
<b>I. INTRODUCTION</b> ..... page 2	8. Maintenance by a technician ..... page 7
<b>II. DESCRIPTION AND ADJUSTMENTS</b> ..... page 2	9. Method for disposing of waste ..... page 7
1. Description of front panel ..... page 2	10. Method for disposing of device ..... page 7
2. Description of rear panel ..... page 3	11. Troubleshooting ..... page 8
3. Upper cover controls ..... page 3	<b>TECHNICAL DESCRIPTION</b> ..... page 9
<b>III. USEFUL INFORMATION</b> ..... page 4	1. Operating Principles ..... page 9
1. Installation ..... page 4	2. Technical Characteristics ..... page 9
2. Starting up ..... page 4	<b>V. APPENDICES</b> ..... page 10
3. Compressed air flow to anaesthesia rack ..... page 5	Symbols - Abbreviations ..... page 10
4. Ventilation modes ..... page 5	Check-list for start-up / on return from maintenance ..... page 10
5. Safety ..... page 5	Service sheet ..... page 11



## I. INTRODUCTION

The **MONNAL D2** ventilator is a device specially designed to fulfil the requirements of anaesthetists or resuscitation personnel wishing to use a flexible and multi-purpose ventilator.

- in observation wards and recovery rooms
- in (open circuit) anaesthesia

The **MONNAL D2** ventilator can ventilate a patient with a gas or gas mixture (with or without a halogenated agent present).

To provide a **complete anaesthetic**, it can be supplied with O<sub>2</sub> and N<sub>2</sub>O gas from a source of O<sub>2</sub> under pressure (or from an oxygen concentrator) and of N<sub>2</sub>O under pressure, and with air from the ventilator.

The **MONNAL D2** ventilator is generally used in conjunction with:

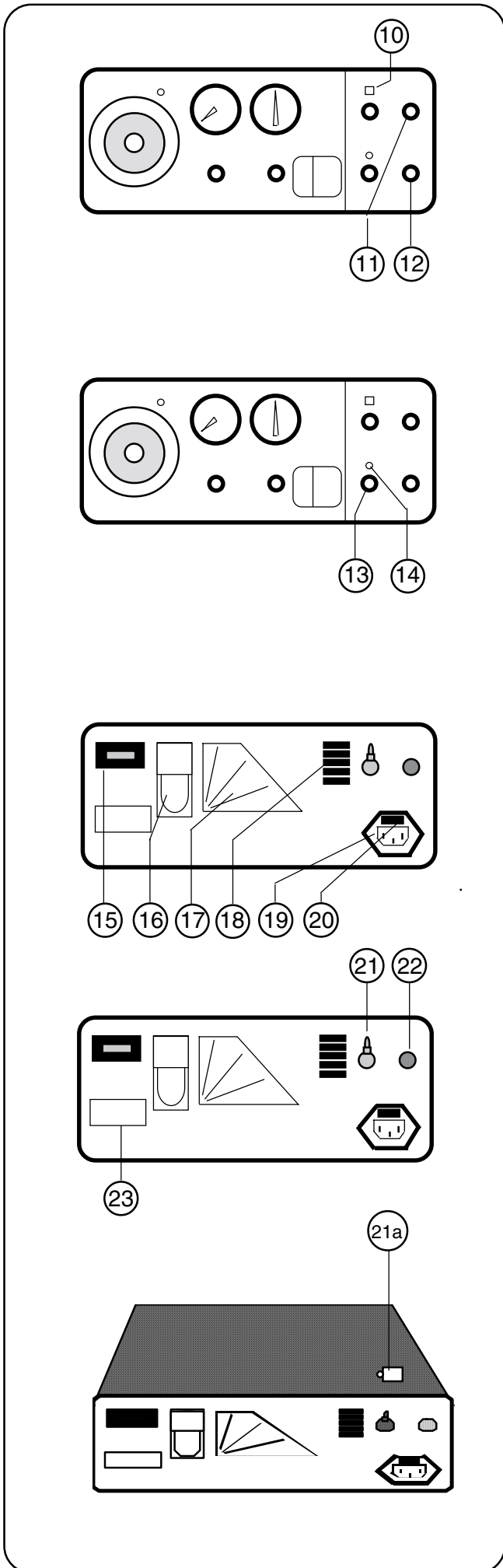
- a halogenated agent evaporator
- a safety O<sub>2</sub> / N<sub>2</sub>O mixer
- a manual induction circuit
- an anaesthesia table.

## II. DESCRIPTION AND ADJUSTMENT

### 1. DESCRIPTION OF FRONT PANEL

Description of Items

- ① **Bacteriological filter cover**
- ② **Collector switch**  
Controls the working of the expiration valve
- ③ **Flowmeter for ambient air supplied by compressor**
- ④ **Airflow regulator**
- ⑤ **Insufflation pressure gauge**
- ⑥ **Safety pressure regulator**  
To adjust, it is necessary to:
  - block the patient circuit at Y
  - read off the maximum P that appears on the pressure gauge during insufflation
  - adjust the regulator by turning towards + or -
- Note:** The user may keep the maximum P value constant by removing the detachable button
- ⑦ **Luminous green On/Off switch**
- ⑧ **Luminous yellow compressor operating switch**  
When the switch is on the On position, the **MONNAL D2** ventilator delivers compressed ambient air. Otherwise only the mixture coming from the anaesthesia rack is used.
- ⑨ **Minimum P alarm regulator**  
Adjustment is by potentiometer.



**10 Audible maximum P alarm red monitor and stop button**  
 When the luminous and audible alarm is activated, pressing on the button stops the audible alarm for two minutes but the flashing red luminous signal continues to operate.

**11 I / E ratio regulator**  
 From 1/3 to 1/1.

**12 Frequency regulator**  
 Adjustment of the minimum controlled cycle frequency from 8 to 40 bpm

**13 CV and CAV trigger threshold (TT) regulator**  
 The trigger threshold allows Controlled Assisted Ventilation. The detection of a call generates a controlled cycle. If no call is detected, a controlled cycle is generated by the machine to ensure the minimum set frequency.

The standard TT settings for CAV are from -1 to -5 mbar. A higher setting requires a respiratory effort from the patient and generates extra inspiratory effort. To enter CV mode, set the trigger threshold to -20 mbar.

**14 Inspiratory effort trigger monitor**

**2. DESCRIPTION OF REAR PANEL**

Description of Items:

**15 Timer**  
 Allows scheduling of preventive maintenance

**16 Water trap**

**17 Abacus: air and oxygen mixtures**

**18 Aeration**

**19 Mains electricity supply**

**20 Fuses**  
 2 fuses for protection of main supply.

**21 Ambient compressed air outlet**  
 Outlet used for setting up of autonomous anaesthesia

**22 Fresh gas inlet**

**23 Manufacturer's name plate**

**3. UPPER COVER CONTROL**

**21a Compressed ambient air outlet control switch**

Control switch for flow of air from compressor to outlet (21) used for the setting up of autonomous anaesthesia.

The AIR DIRECT position corresponds to standard functioning; AIR INDIRECT corresponds to the autonomous system configuration.

### III. USEFUL INFORMATION

#### 1. INSTALLATION

##### 1.1. Integrator balloon

Attach the integrator balloon (24) to the side, observing the following precautions:

- attach the rotating elbow to the side of the device by means of the ring nut (26) which must be tightened but not locked. Make sure the seal is in place.
- then slide **the latex** integrator balloon (24) onto the elbow, which is free to move in every direction

##### 1.2. Expiratory valve

- Attach the valve support (29).
- Place the expiratory valve on its support (with the flow sensor if necessary)
- Connect the valve balloon to the collector.

*Note: The expiratory valve must be inserted in the patient circuit, at the end of the expiratory branch.*

##### 1.3. Bacteriological filter

Check for the presence of the bacteriological filter (27) (white plastic grille, visible in the cap opening (1)).

- When the filter has to be fitted or replaced, proceed with care in the following manner:
  - Unscrew the cap,
  - Change the filter (27),
  - Insert it in the housing (28) attached to the device (it can only be placed in one position),
  - Replace the cap firmly,
  - Screw it in.

**Note: The cap must be correctly engaged. It should screw in freely and without effort (if not, the cap is badly positioned).**

- when you are sure that the cap has been correctly installed, airtightness is achieved by tightening firmly but not excessively.

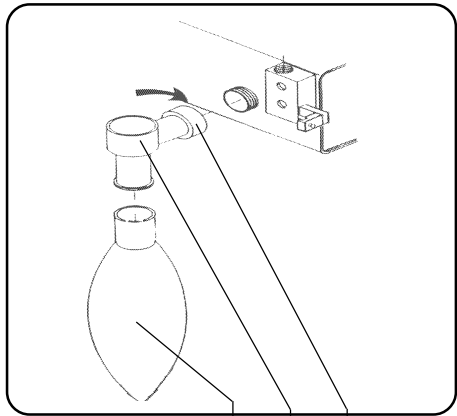
#### 2. STARTING UP

- Check that the voltage of the power outlet used is the same as the voltage of the device as indicated on the rear panel. Then connect the device to the electricity supply.

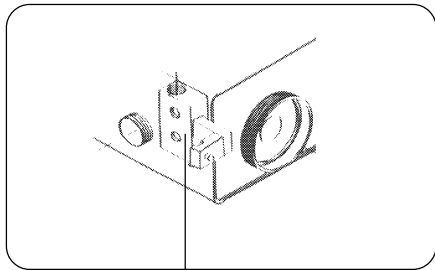
To start the device, press the On/Off button, which will stay pressed down: the integrator balloon will inflate and deflate alternately.

To stop the device, press the On/Off button, which will return to the Off position.

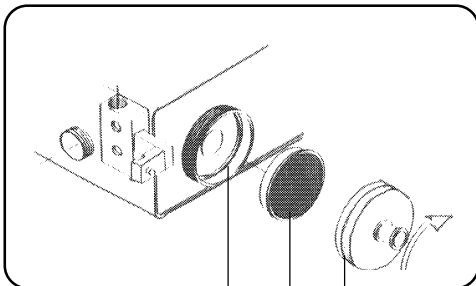
- Check that there is no leakage. If necessary:
  - tighten the integrator balloon elbow,
  - tighten the cap.



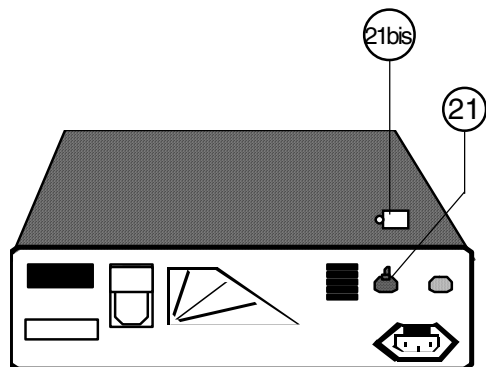
24 25 26

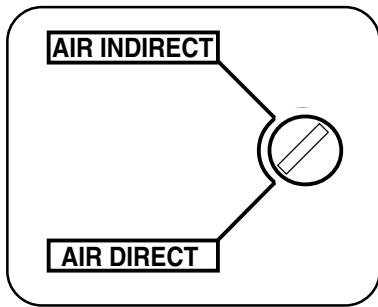


29

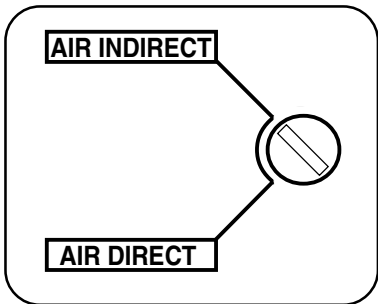


28 27 1

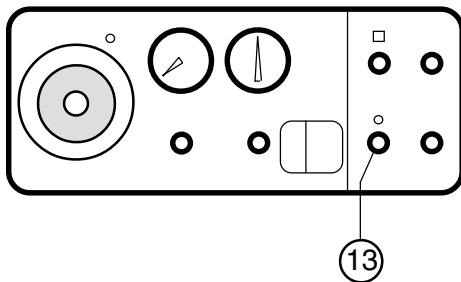




Label and Switch for air flow (21A) standard position



Label and Switch for air flow (21A) autonomous position



### 3. COMPRESSED AIR FLOW TOWARDS THE ANAESTHESIA RACK

- The **MONNAL D2** ventilator's compressor can be used as an autonomous air generator. In standard configuration, AIR DIRECT position, the air whose rate of flow is read on the flowmeter (3) supplies the patient circuit directly. Bypass is achieved by turning the control switch (21A) to AIR INDIRECT. This is used via the outlet (21) on the rear panel.

**Note.** The control switch (21A) must not be placed in an intermediate position. Only positions AIR DIRECT and AIR INDIRECT are operational.

- Flow start-up

### 4. VENTILATION MODES

The **MONNAL D2** ventilator has a trigger threshold regulator (potentiometer 13) which allows it to ventilate in controlled mode or in assisted controlled mode.

#### 4.1. Controlled Ventilation CV

The characteristics of the respiratory cycle are entirely determined by the ventilator, without the patient being able to intervene.

This mode is recommended in the following situations:

- during anaesthesia
- in all cases of additional ventilation
- for the great majority of the usual indications for artificial respiration

However, the lack of adaptability of this mode gives rise to discomfort, i.e. coughing or resistance.

#### 4.2. Controlled Assisted Ventilation

The patient sets off respiratory cycles which are controlled by the ventilator. Only the frequency is determined by the patient; the ventilator ensures a minimum frequency.

This mode is recommended when ventilation requirements are variable when patient is conscious or in resuscitation and controlled ventilation with or without PEEP does not allow satisfactory adaptation to the respirator.

### 5. SAFETY AND PROTECTION

#### 5.1. Safety devices and electrical protection

- Fuses protecting the general supply (2 fuses) (on rear panel (20)).
- Internal fuse to protect 100 mA electronic board.
- Thermal circuit breaker of compressor: Triggered when the compressor temperature reaches 135°C. In this way excessive overheating of the compressor is avoided.

**5.2. Safety devices and pneumatic protection**

- **Safety valve:**  
Limits the pressure in the patient circuit to a pressure adjustable to 80 mbar.
- **Integrator balloon protection valve:**  
This valve is situated inside the device and limits pressure to 90 mbar.
- **Aeration of the device:**  
An internal fan ventilates the case and the compressor.
- **Gas filtration:**  
This is carried out by a bacteriological filter between the device and the patient.

**6. ALARMS**

**6.1. Electricity supply fault**

In the case of a power cut while the **MONNAL D2** ventilator is in operation, a continuous audible alarm is triggered (minimum time 5 minutes).

**Note :** This alarm may also be triggered if there is a fault in supply to the electronic part.

**6.2. P minimum alarm**

An audible and luminous alarm is triggered in the following situations:

- If, for more than 10 seconds, the pressure in the patient circuit does not achieve the set value (adjustable from 0 to 60 mbar) (see diagrams A and B opposite);
- If, in "CONTROL" mode, the minimum P is set at 0 mbar. To avoid triggering the alarm in this way, set P minimum at a few mbar.

This alarm can be suppressed for two minutes by pressing on the sound inhibition button.

**7. MAINTENANCE**

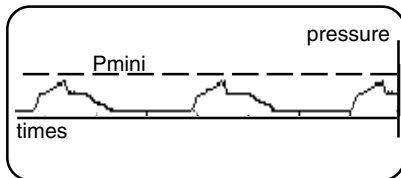
**7.1. Cleaning / Disinfection**

Wash the entire patient circuit by immersion in a cleaning solution such as Surfanios (trade mark). Rinse in hot water and dry. It can be disinfected / decontaminated with a solution such as Hexanios G+R (trade mark).

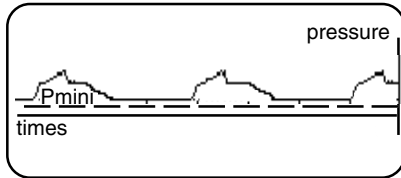
Clean or replace the patient circuit for each new patient and whenever necessary (damaged or soiled circuit, etc).

The respirator can be washed in soapy water by means of a cloth (well wrung out) dipped in soapy water and wiped with a dry rag or a towelette impregnated with an aqueous alcohol-based solution.

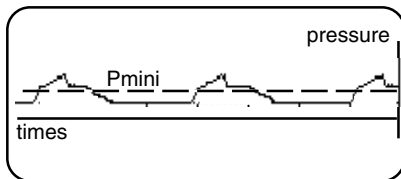
A - example: Pmini sounds



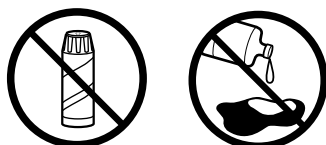
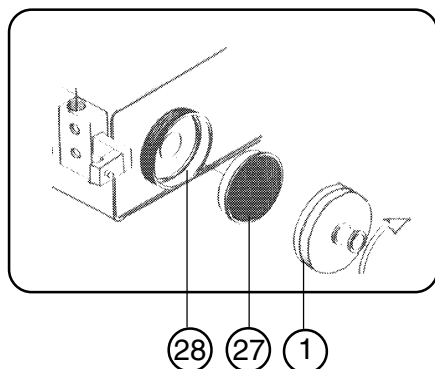
B - example: Pmini sounds



C - example: Pmini does not sound







## 7.2. Continuous sterilisation

The bacteriological filter at the device outlet allows sterilisation to be limited to the patient circuit only. Change the bacteriological filter every 600 hours.

• Sterilisation in an autoclave: the autoclavable patient circuit in the **Taema** catalogue is compatible with the following AFNOR cycles:

- . 134°C, 18 minutes (cf prions)
- . 121°C, 30 minutes.

Recommended frequency of sterilisation in autoclave: after each patient or after each cleaning / disinfection cycle.

The patient circuit is also sterilisable by all normal procedures (gaseous formaldehyde etc).

**Note: Do not use abrasive powders, pure alcohol, acetone, or other powerful solvents.**

## 8. MAINTENANCE BY A TECHNICIAN

- Every 1500 hours or annually
  - replace filter compressors, collector block membranes.
  - check pressure gauge, drive pressure, cocks and valves
- Every 5000 hours
  - replace integrator balloon
- Every 10,000 hours or every 5 years:
  - return device to factory for complete service (see maintenance manual to carry out these operations).

## 9. ACCESSORIES

The accessories used with the **MONNAL D2** ventilator must be:

- oxygen compatible
- biocompatible
- compliant with the general requirements of EN 60 601-1 and directive 93/42/EEC.

They must also be non-antistatic (or not conductive of electricity).

The use of accessories not compliant with the requirements set out above discharges the manufacturer of responsibility in case of accident.

Accessories manufactured by **Taema** or included in the accessories package supplied with the device are compliant with these requirements.

Electro-medical devices linked to, or used jointly with the **MONNAL D2** ventilator must not interfere with it, in compliance with the essential requirements of directive 93/94/EEC.

## 10. METHOD FOR DISPOSING OF WASTE

All waste arising from the use of the **MONNAL D2** ventilator (patient circuit, filters, etc) must be disposed of by the appropriate channels in the healthcare establishment.

## 11. METHOD FOR DISPOSING OF THE DEVICE

In order to protect the environment, if the device is disposed of, it must be done through the proper channels of the healthcare establishment.

Furthermore, the traceability system required by **CE** labelling makes it mandatory to inform the **TAEMA** technical department of the serial number of the device disposed of.

**11. TROUBLESHOOTING**

<b>Observations</b>	<b>Causes probables</b>	<b>Remède</b>
<b>No Ventilation</b> -Compressor does not work and the clock does not function	- On/Off button not pressed	- Press the On/Off button
Compressor does not work and clock does not function	-No electrical power	- Check electrical power connection
On/Off button is in On position 'Power fault' alarm on	- Device supply fuse(s) out of order -100 mA fuse out of order	- Change the main supply fuse(s) - Change the 100 mA fuse
Compressor does not work, but the clock functions	- Compressor overheating (thermal circuit breaker cut in)	- Check air intakes - Contact after-sales service
Compressor works, clock functions and Pmini alarm sounding	-Ventilation button off (flowmeter indicating 0) - Defective pneumatic circuit - Control 21A in wrong position	- Open ventilation valve - Contact after-sales service - Check by-pass control (21A)
Compressor works, but clock does not function	- Defective electronic unit	- Contact after-sales service
<b>Ventilation still insufficient</b>	- Patient circuit not airtight or defective	- Check connection: The expiratory valve membrane inflates and deflates <b>alternately</b>
	- Filter assembly badly fitted, not airtight	- Remove and reinstall the assembly with care
<b>Controlled Assisted Ventilation (CAV) breakdown</b>  "TRIGGER" LED permanently flashing	- Self-activated	- Adjust the trigger threshold correctly
	- Defective electronics	- Contact after-sales service
"Trigger" LED does not light up	- Trigger threshold set at about - 20 mbar	- Correct the trigger threshold setting
<b>Pmini</b>  Pmini alarm activated continuously	- Wrongly adjusted	- Adjust the Pmini threshold correctly
Pmini alarm does not trigger	- Defective electronics	- Contact ( <b>TAEMA</b> ) after-sales service

## IV. TECHNICAL DESCRIPTION

### 1. OPERATING PRINCIPLES

The collector / electronically controlled valve is supplied:

- with air through a compressor
- and / or
- with a mixture of anaesthetic gas or with pure oxygen.

Air ventilation is displayed on a flowmeter and controlled by a valve.

The collector block comprising diaphragms linked to electronically controlled valves, controlled by the electronic unit, distributes the continuous flow:

- on one hand, towards the integrator balloon during the expiratory phase,
- on the other, added to the gas stored by the balloon, towards the patient through a bacteriological filter during the inspiratory phase.

The insufflation pressure is visually represented on a pressure meter and can be limited by adjusting a safety valve.

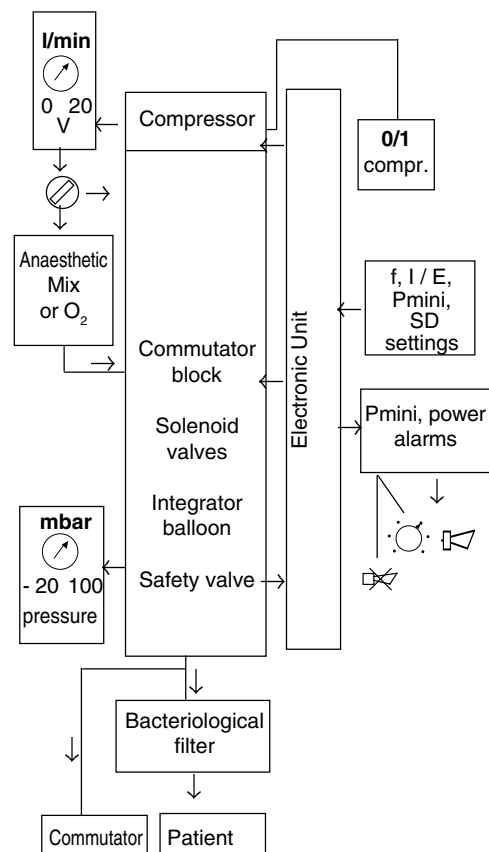
The electronic unit allows adjustment of frequency, the I / E ratio, the SD activation threshold (in VAC mode) and the Pmini threshold. It also provides visual indication of the SD activation threshold, an audible and visual indication of Pmini, audible indication of electric power failure.

### 2. TECHNICAL CHARACTERISTICS







- Power supply: 220 V - 50 Hz
- Power consumption: 160 VA
- Class I device
- Class B device
- Maximum current protection:
  - Mains supply protection: 2 F1A fuses (rear panel)
  - Electronic card protection: 1 internal 100 mA fuse
- Protection against lack of power:
  - Audible alarm (discharge time: 10 minutes)
- Dimensions: L x B x H = 470 x 308 x 150 mm
- Mass: 14 kg.
- Extreme storage temperatures: from -40°C to +70°C
- Extreme operation temperatures: from +10°C to +40°C
- Atmospheric pressure (use): from 700 to 1060 mbars
- Relative humidity (use and storage): from 30 to 75%
- Degree of protection: IP20 (protected against solid bodies greater than 12 mm and not protected against liquids).
- Performance:
  - Respiratory frequency: from 8 to 40 bpm
  - I / E ratio: from 1/1 to 1/3
  - Mean flow (insufflated per minute): from 0 to 20 l / min
  - Pmini pressure threshold: from 0 to 60 hPa
  - Activation threshold (VAC): from 0 to -20 hPa.
- Instantaneous pressure display: from -20 to 100 hPa
- Materials in contact with the patient and the breathed gases: Silicon (autoclavable patient circuit), **Latex** (accumulator balloon), PVC, and aluminium.


- Standards / Directives:
  - NFC 74350 - Artificial respiration and treatment devices
  - NFS 90-118 Ventilators for medical use
  - NFEN 601 - 1 Safety of electro-medical devices
  - NFEN 60-601-1-2 Electromagnetic compatibility of medical devices.

### OPERATION BLOCK DIAGRAM



**SYMBOLS AND ABBREVIATIONS**

	: Off (power off)	SD/Trigger	: Trigger threshold
I	: On (power on)		: Earth protection
	: Suspension of audible Pmini alarm		: Equipotential
I/E	: Inspiration / Expiration phase ratio		: Refer to accompanying documents
f	: Frequency		: Type B device

 **0459**: Compliance with directive 93 / 42 EEC  
(established by notified organisation no. 0459)

**CHECK-LIST FOR START-UP / ON RETURN FROM MAINTENANCE**

Before each use and after every return from maintenance, carry out the sequence below:

- Set the On/Off switch to Off
- Check that the voltage of the electric plug used corresponds to the voltage of the device. Then plug the device in.
- Start the compressor by pressing the On/Off button (7) situated on the front panel. Make sure the button lights up (colour yellow).
- Start the ventilator by pressing on the On/Off button situated on the front panel. Make sure the button lights up (colour green).
- Check that the Pmini audible and luminous alarm (flashing red) is activated through a few cycles (in the time for the balloon to inflate).
- Check that the humidifier (if used) is correctly filled and that the heating temperature complies with the prescription.
- Check that the integrator balloon is in good condition (no leakage etc).
- Fit a clean patient circuit, having checked beforehand that it is in good condition.
- Adjust the settings according to the prescription and check that the values displayed correspond to the settings.
- Adjust the Pmax safety valve. Then block the patient circuit at the Y piece (with the thumb, for example) and check that the pressure limitation in the patient circuit is functioning correctly.
- Connect the patient to the ventilator. Check that the integrator balloon inflates and deflates correctly.
- Check that the appropriate monitoring (flow measurement, FiO<sub>2</sub>, airways pressure, halogen etc) is operational.
- Check that the machine is generally functioning properly.

**MAINTENANCE SHEET**

**2 500 Hours**

Carried out on: .....

No. of hours: .....

Name of technician : .....

.....

Signature  
and  
stamp:

**5 000 Hours**

Carried out on: .....

No. of hours: .....

Name of technician : .....

.....

Signature  
and  
stamp:

**7 500 Hours**

Carried out on: .....

No. of hours: .....

Name of technician : .....

.....

Signature  
and  
stamp:

**10 000 Hours**

Carried out on: .....

No. of hours: .....

Name of technician : .....

.....

Signature  
and  
stamp:

**12 500 Hours**

Carried out on: .....

No. of hours: .....

Name of technician : .....

.....

Signature  
and  
stamp:

**15 000 Hours**

Carried out on: .....

No. of hours: .....

Name of technician : .....

.....

Signature  
and  
stamp:

**17 500 Hours**

Carried out on: .....

No. of hours: .....

Name of technician : .....

.....

Signature  
and  
stamp:

**20 000 Hours**

Carried out on: .....

No. of hours: .....

Name of technician : .....

.....

Signature  
and  
stamp:

**22 500 Hours**

Carried out on: .....

No. of hours: .....

Name of technician : .....

.....

Signature  
and  
stamp:

**25 000 Hours**

Carried out on: .....

No. of hours: .....

Name of technician : .....

.....

Signature  
and  
stamp:

**27 500 Hours**

Carried out on: .....

No. of hours: .....

Name of technician : .....

.....

Signature  
and  
stamp:

**30 000 Hours**

Carried out on: .....

No. of hours: .....

Name of technician : .....

.....

Signature  
and  
stamp:

**MONNAL D2 VENTILATOR** no: .....

**Commissioned on:** .....

**Maintenance provided by:** .....

.....

**Your distributor:** .....

**Address:** .....

.....

.....

**Telephone:** .....

**Preventive maintenance** of the devices must be carried out keeping to the manufacturer's directions set out in the maintenance manual and any updates thereof. The work must be carried out by technicians who have received the appropriate training.

**Only use original components.**

On request, the supplier provides circuit diagrams, lists of components, technical descriptions and all other information useful to personnel qualified to repair those parts of the device which have been designated as repairable by the manufacturer.

**Taema**

AIR LIQUIDE *Santé*: AIR LIQUIDE. One mission, one ethic, one ambition. In more than 40 countries the mission of AIR LIQUIDE Healthcare's staff is to contribute to the improvement of care given to patients, at hospital and at home. Their ethic is the constant attention given to patients and to stand side by side with those who care for them. Their ambition is to promote the development of the AIR LIQUIDE Group in the healthcare profession



**Taema is a division of AIR LIQUIDE Santé INTERNATIONAL**

Taema  
Parc de Haute Technologie  
6 rue Georges Besse CE 80  
92182 Antony CEDEX - FRANCE  
Tel.: (33) 01 40 96 66 00  
Fax: (33) 01 40 96 67 00