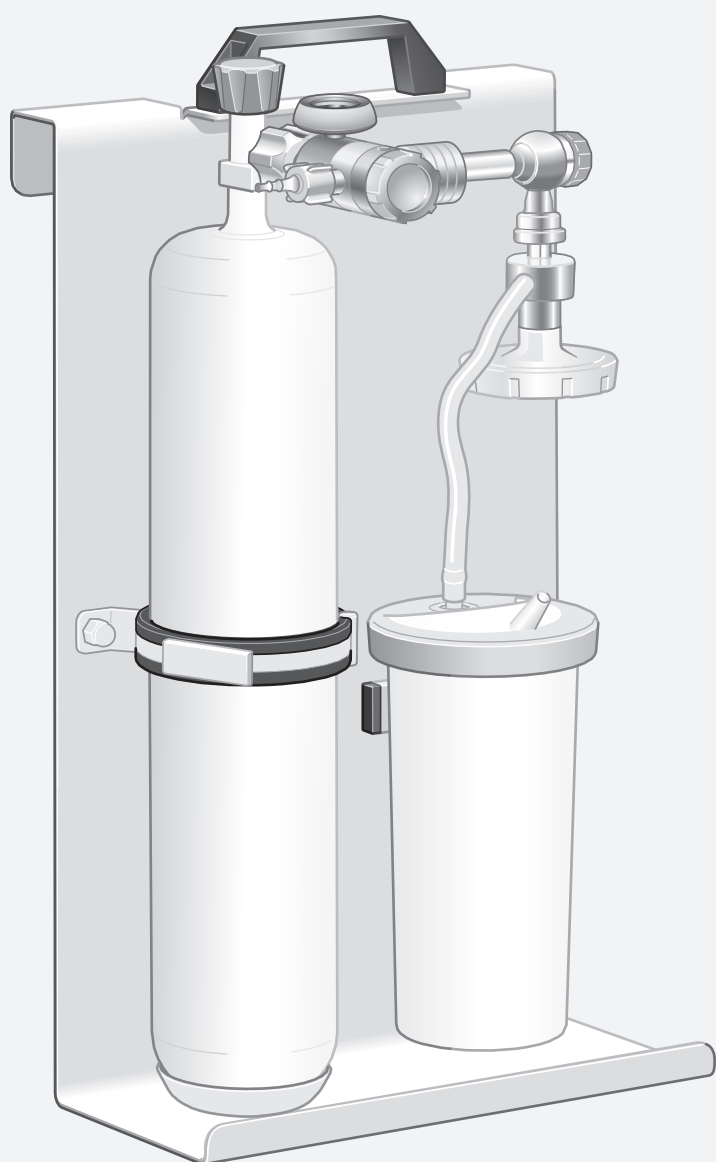


OPERATING INSTRUCTIONS
EMERGENCY OXYGEN UNIT

MEDAP 



Subject to technical modification!

Illustrations and technical specifications may vary slightly from those in these Operating Instructions as a result of ongoing product development.

V06 2025-04



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1 Introduction

1.1 Foreword

Your facility has selected the leading-edge medical technology made by ATMOS. We sincerely appreciate the trust you have placed in us.

1.2 How to use these operating instructions

These operating instructions are provided to familiarise you with the features of this ATMOS product.

They are subdivided into several chapters.

Please note:

- Please read these operating instructions carefully and completely before using the product for the first time.
- Always proceed in accordance with the information contained herein.
- Store these operating instructions in a location near the product.

1.2.1 Abbreviations

EN	European standard
EEC	European Economic Community
VDE	Verband der Elektrotechnik Elektronik Informationstechnik (Association for Electrical, Electronic & Information Technology)

1.2.2 Symbols

1.2.2.1 Cross-references

References to other pages in these operating instructions are identified with a double arrow symbol '»»'.

1.2.2.2 Actions and responses




The '☒' symbol identifies an action taken by the user while the '✓' symbol identifies the reaction that this will induce in the system.

Example:

- ☒ Turn on the light switch.
 - ✓ Lamp lights up.

1.2.3 Definitions



1.2.3.1 Design of safety notes

Pictogram	Descriptor	Text
	DANGER! Indicates a direct and immediate risk to persons which may be fatal or result in most serious injury.	The text for the safety note describes the type of risk and how to avert it.
	WARNING! Indicates a potential risk to persons or property which may result in health hazard or grave property damage.	
	CAUTION! Indicates a potential risk to property which may result in property damage.	

Tab. 1: Design of safety notes

1.2.3.2 Structure of notes





Notes not referring to personal injury or property damage are structured as follows:











Pictogram	Descriptor	Reference to
	NOTE	Supplementary assistance or further useful information without potential injury to persons or property damage is described in the text of the note.
	ENVIRONMENT	Information regarding proper disposal.

Tab. 2: Structure of notes

1.2.4 Symbols used

Symbols are attached to products, type plates and packaging.

Symbols	Identification
	This device complies with the relevant requirements of EU regulations.
	Consult operating instructions
	Manufacturer
	Warning; pay special attention

Symbols	Identification
	Reference number
	Unique Device Identifier of a medical device
	Medical device
	Professional disposal
	Fragile, handle with care
	Keep dry
	Keep away from sunlight
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

Tab. 3: Symbols

1.3 UDI application identifier

(01)	UDI-DI: Identification of the manufacturer and the device
(10)	Batch code
(11)	Date of manufacture
(13)	Packing date
(21)	Serial number

Tab. 4: UDI application identifier

1.4 Disposal

1.4.1 Packaging

The packaging is made of materials compatible with the environment. ATMOS will dispose of the packaging materials upon request.

1.4.2 ATMOS products

ATMOS will take back used products or those which are no longer in service.
Please contact your ATMOS representative for more detailed information.

1.5 Overview

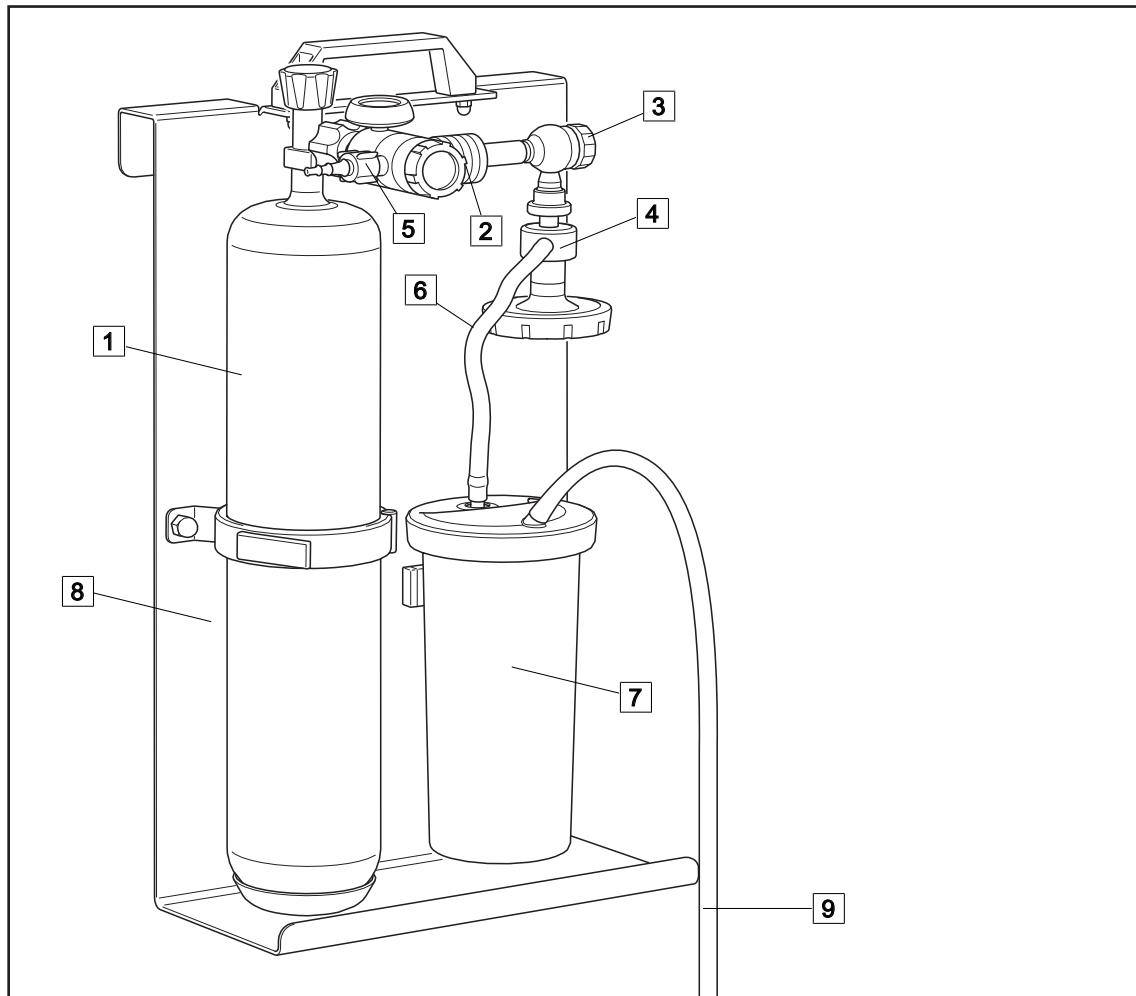


Fig. 1: Overview of emergency oxygen unit

- | | |
|----------------------|-------------------|
| 1 Oxygen cylinder | 6 Connection tube |
| 2 Pressure regulator | 7 Aspiration set |
| 3 Fine regulator | 8 Carrying board |
| 4 Gas-jet pump | 9 Suction tube |
| 5 Tube adapter | |

1.6 Basic requirements

1.6.1 Use in accordance with the intended purpose

This product is a medical device according to the Medical Devices Directive 93/42/EEC.

This product is to be used exclusively in human medicine.

Patients may be placed on the device and put in position only under the supervision of medical personnel.

Accessories

Accessories or combinations of accessories may be utilised only as and when indicated in these operating instructions.

Use other accessories, combinations and parts subject to wear only if these are intended expressly for the application and will not adversely affect performance features or safety requirements.

1.6.2 Applicable standards

The product fulfils the essential requirements according to Annex I of Council Directive 93/42/EEC concerning medical devices (Medical Devices Directive).

1.6.3 Treatment system as per Article 12

The product consists of several components which together comprise one treatment system as per Article 12 of the Medical Devices Directive 93/42/EEC.

The emergency oxygen unit consists of the following components:

- PR O₂, short fitt, flowmeter 15 l/min, DIN coupl (REF HM57525545)
- Carrying board for emergency oxy unit (REF HM57524678)
- FINA RV O Wall DIN (REF HM57523705)
- Gas-jet pump oxygen LF/HV (REF HM57507540)
- AS Aspiration (REF HM57524681)

1.6.4 Intended purpose

Name:	Emergency oxygen unit
Main function:	Treatment system consisting of several components for administration of oxygen and for bronchial aspiration
Medical indications / application:	Supply of patients with medical oxygen and bronchial aspiration if a central gas supply is not available (e.g. inter-hospital transport)
Specification of the main function:	<p>The emergency oxygen unit is a treatment system as per Article 12 of the Medical Devices Directive 93/42/EEC.</p> <p>The components are listed in the following chapter of these operating instructions.</p> <p>The carrying board provides a basis for a 2 / 3 l oxygen cylinder. A pressure reducer is connected to the oxygen cylinder and reduces the pressure to the usual pressure of central gas supply systems. An integrated flowmeter in the pressure reducer can be used for inhalation or insufflation of oxygen within the scope of oxygen enrichment for patients breathing by themselves. In the coupling DIN of the pressure regulator a fine regulator oxygen can be inserted. A gas-jet pump can be connected to the outlet of the fine regulator, converting the oxygen into vacuum via Venturi principle. The application set aspiration consists of a septic fluid jar with lid for bronchial aspiration. The permitted pressure in the oxygen cylinder is 200 bar.</p>
User profile:	Doctor, medically trained staff
Patient groups:	Patients of all ages
Application organ:	<p>Outlet flowmeter: Lung</p> <p>Outlet coupling: No specific organ</p>

Application time:	For continuous operation; in practice short-term use on the patient (< 30 days)
Application site:	The application site is the clinical environment and doctor's practices. The application of the product may only be performed by medically trained and instructed staff.
Contraindications:	<p>The emergency oxygen unit may not be used for the following purposes:</p> <ul style="list-style-type: none"> • Outside the medical sector • In MR areas • For ultra-pure gases • For corrosive, aggressive and toxic gases, acetylene, propane, butane and other flammable gases • With a supply pressure higher than 200 bar • The undosed supply of medical oxygen (connection of tapping units intended for this purpose is strictly necessary) • When applying oxygen in its function as a medication, it is absolutely necessary to measure the flow rate.
The product is:	Active
Sterility:	No sterile product
Single-use product / reprocessing:	The treatment system and parts of the accessories are reusable. For information on reprocessing, cleaning and disinfection, please see the operating instructions.

1.6.5 Interface description

1.6.5.1 Oxygen cylinder

The oxygen cylinder is mounted to the carrying board with a clamp bracket and supplies oxygen to the emergency oxygen unit.

Technical specifications

- 2 or 3 l
- Cylinder diameter 100 mm
- Cylinder height at least 250 mm
- Ball-shaped bottom
- Weight maximum 6 kg
- 200 bar / 20000 kPa
- Connection DIN 477-1

1.6.5.2 Vacuum connection tube

The vacuum connection tube is used to connect the tapping unit and the septic fluid jar.

Technical specifications

- Shore hardness of 60
- Inner diameter 6 mm
- Length 50 cm (±10 cm)
- Vacuum resistant down to -95 kPa (may not collapse)

Prerequisites

- The inner diameter of the vacuum connection tube should match the outer diameter of the tube connector on the septic fluid jar cap of the pump.

The vacuum connection tube will be referred to only as 'connection tube' below.

1.6.5.3 Suction tube

The suction tube is used to connect the tube connector on the septic fluid jar on the patient side and the fingertip or the utensil.

Technical specifications

- Shore hardness of 60
- Inner diameter 6–8 mm
- Length of 1.3 m to 3.0 m
- Vacuum resistant down to –95 kPa (may not collapse)

Prerequisites

- The outer diameter of the tube connector on the patient side of the septic fluid jar cap must match the inner diameter of the suction tube.

1.6.5.4 Connection tube

The connection tube is used to connect the tube adapter on the flowmeter outlet of the pressure regulator to the inhalation mask.

Technical specifications

- Inner diameter 5 mm

Prerequisites

- The inner diameter of the connection tube should match the tube connector on the flowmeter outlet of the pressure regulator and the tube connector of the inhalation mask.

1.6.5.5 Bubble humidifier (REF HM57525315)

The bubble humidifier can be integrated between the flowmeter outlet of the pressure regulator and the connection tube of the inhalation mask to humidify the oxygen. Instead of the tube adapter, the angled adapter (REF HM57525606) is connected to the flowmeter outlet of the pressure regulator for this purpose. The bubble humidifier is connected at the outlet of the angled adapter and the connection tube to the inhalation mask is connected at the outlet of the bubble humidifier [►► Page 16].

2 Safety notes

2.1 General safety notes

**DANGER!**

Danger to life!

The undosed supply of gases is hazardous to the patient.

Use only tapping units with dosing system.

**DANGER!**

Danger to life!

Danger due to unauthorised modifications.

The product may not be modified.

**WARNING!**

Risk of injury!

Hazard resulting from incorrect handling.

Be absolutely sure to observe the operating instructions for all the products used in the configuration.

**WARNING!**

Risk of injury!

ATMOS products may be used only when fully functional.

Check to ensure that the ATMOS product is fully functional and in good working order prior to use.

**CAUTION!**

Observe ambient conditions

The precision, operation, mechanical stability and tightness of the product cannot be guaranteed if the maximum upper and lower ambient temperatures are exceeded.

**DANGER!**

Danger to life!

Danger due to improper configuration of the system.

The configuration of the overall system as well as the functional testing are subject to the overall responsibility of the medical staff. The operator must check the proper functionality and suitability of the connected accessories for each intended application prior to every use, in particular, connection parts, sealing properties and suitability with regard to material, work pressure and flow.



Report all serious incidents that have occurred in connection with this product to the manufacturer and your national competent authority.

3 Initial operation

3.1 General

**NOTE**

The oxygen cylinder, connection tube to inhalation mask and inhalation mask are not included in the scope of delivery.

**NOTE**

Please refer to the operating instructions of the carrying board (REF HM57524733) for information on mounting the oxygen cylinder to the carrying board.

3.2 Connecting the pressure regulator

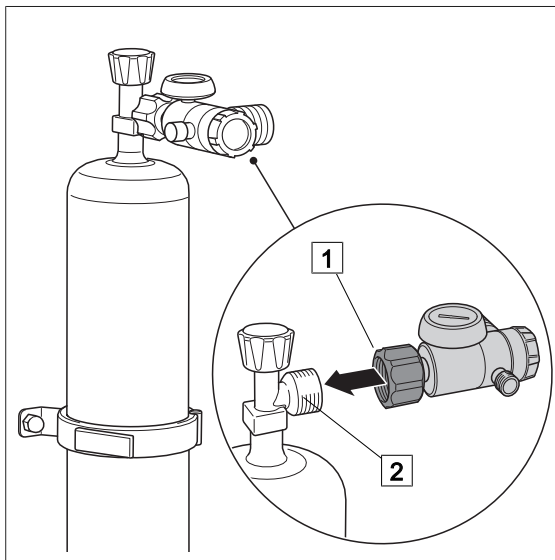


Fig. 2: Connecting the pressure regulator

Connecting the pressure regulator

- Ensure that the pressure regulator is closed.
- Plug the cap nut (1) of the pressure regulator onto the thread of the connection thread (2) of the oxygen cylinder.
- Tighten the cap nut by hand.
 - ✓ The pressure regulator is mounted.

3.3 Oxygen supply via tube adapter

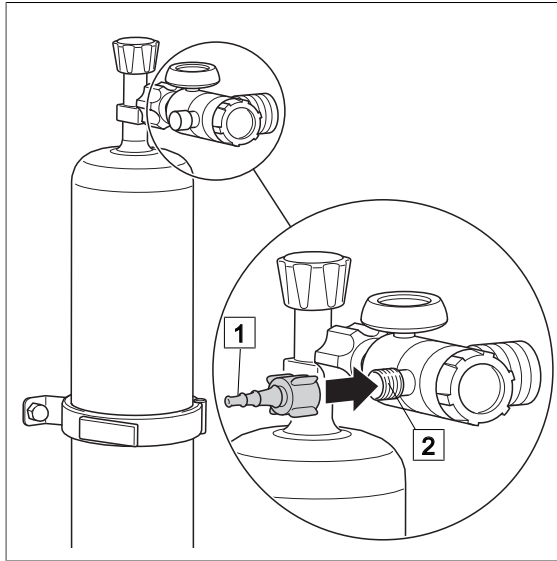


Fig. 3: Providing oxygen supply

Screwing on the tube adapter

- ☒ Screw the tube adapter (1) onto the tube connector (2) of the pressure regulator.

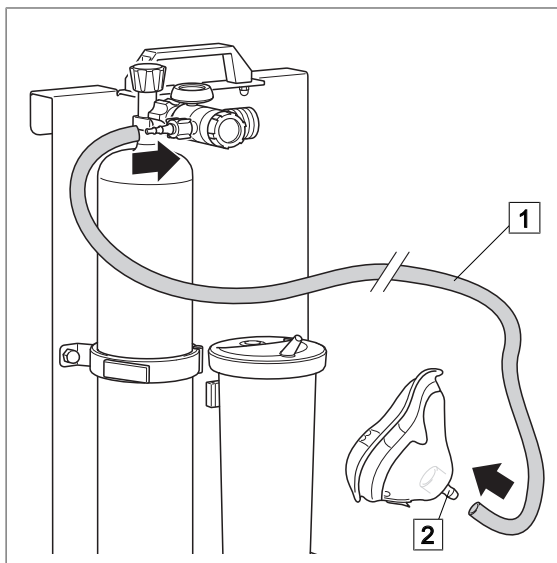


Fig. 4: Connecting the connection tube

Connecting the connection tube

- ☒ Attach the connection tube (1) to the tube adapter.
- ☒ Attach the other end of the connection tube to the inhalation mask (2).
- ✓ Oxygen supply is functional.

3.4 Connecting the fine regulator

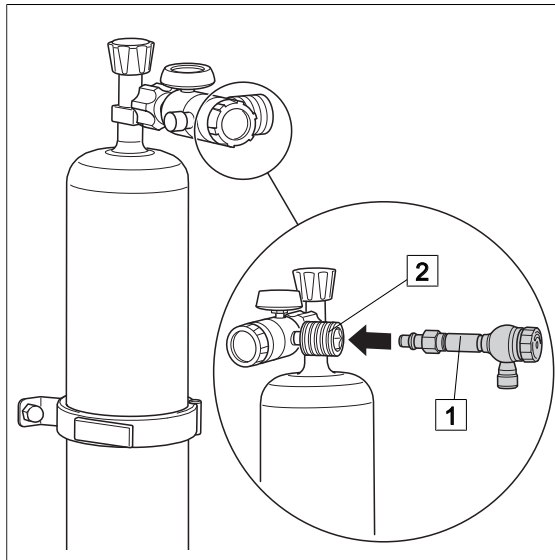


Fig. 5: Connecting the fine regulator

Connecting the fine regulator

- ☒ Insert the fine regulator (1) into the DIN coupling (2) on the pressure regulator.

3.5 Connecting the gas-jet pump

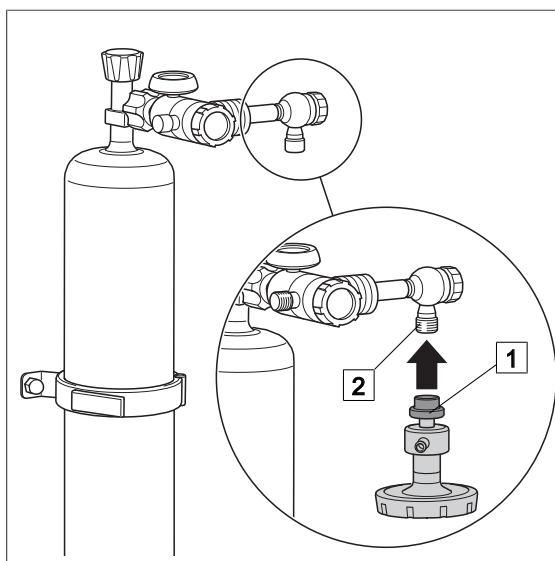


Fig. 6: Connecting the gas-jet pump

Connecting the gas-jet pump

- ☒ Fit the cap nut (1) of the gas-jet pump onto the connection thread (2) of the fine regulator.
- ☒ Tighten the cap nut.
 - ✓ The gas-jet pump is mounted.

3.6 Mounting the tubes



NOTE

Use the hydrophobic bacterial and viral filter (REF HM57522557) instead of the tube adapter (REF HM57522295) to increase safety.

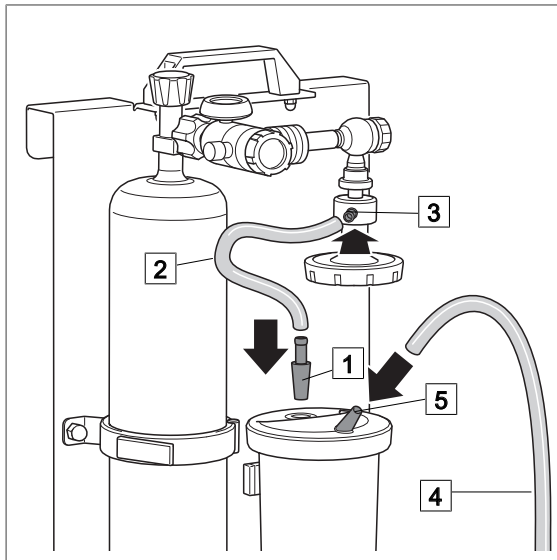


Fig. 7: Mounting the tubes

Mounting the tubes

- ☒ Fit the adapter (1) into the septic fluid jar cap.
 - ☒ Attach the connection tube (2) to the adapter.
 - ☒ Attach the other end of the connection tube to the tube connector (3) on the gas-jet pump.
 - ☒ Attach the suction tube (4) to the patient-side connector (5) on the septic fluid jar cap.
- ✓ Aspiration set is functional.

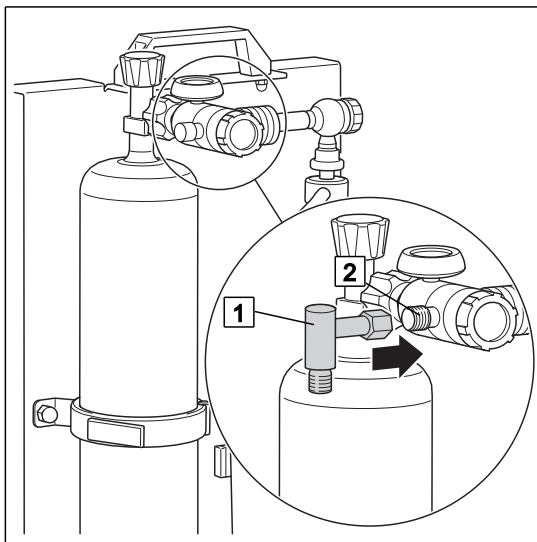
3.7 Aspiration and oxygen therapy**3.7.1 Connecting the accessories (optional)****3.7.1.1 Connection of bubble humidifier MEDAP (REF HM57525315)**

Fig. 8: Connecting the angled adapter

Connecting the angled adapter

- ☒ Screw the angled adapter (1) onto the tube connector (2) of the pressure regulator.

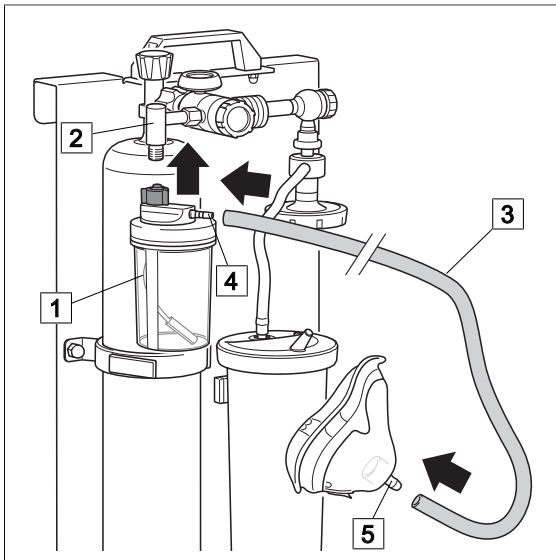


Fig. 9: Connection of bubble humidifier

Connecting the bubble humidifier

- ☒ Ensure that the tube connector of the bubble humidifier has two seals.
- ☒ Screw the bubble humidifier (1) directly to the angled adapter (2) and tighten finger-tight as far as it will go.
- ☒ Attach the connection tube (3) to the tube connector (4) of the bubble humidifier.
- ☒ Attach the other end of the connection tube to the inhalation mask (5).
 - ✓ Oxygen supply is functional.
- ☒ Pay attention that no tensile forces affect the bubble humidifier.

3.7.1.2 Connection of disposable humidifiers from other manufacturers

Disposable humidifiers may be connected to the flowmeter outlet. An angled adapter must be used for disposable humidifiers.

- ☒ Screw the disposable humidifier directly to the flowmeter output (2) and tighten finger-tight as far as it will go.

4 Operation



NOTE

Unscrew manual tightening only after pressure has been fully released from the pressure regulator. First, close the valve on the oxygen cylinder; then release the pressure on the click-stop flowmeter.

4.1 Functional test

Prior to using the system, the operator must check that the product is fully functional and in good condition. Prior to each use, carry out the following functionality checks:

Pressure regulator

- State of manual tightening
- State of seal in cap nut
- Ease of movement at the connection threads (difficulty of movement is an indication of damage or soiling to the threads)
- Damage to supply tubes
- Airtightness
- Intact connection thread for accessories

Suction unit

- Damage of seal rims of float in the overflow protection device
- Any cracks in septic fluid jar
- Splintering at the contact surfaces of the septic fluid jar
- Damage to seal of the septic fluid jar cap
- Cracked or hardened connection tubes
- State of seal in cap nut of gas-jet pump
- Free movement of control valve of fine regulator for gas-jet pump

Oxygen cylinder

- Sufficient filling level

4.2 Check the filling level of the oxygen cylinder



NOTE

Check airtightness of all accessory connections before beginning treatment.

Manually retighten connecting nuts as necessary and readjust to the amount of oxygen required.

The duration of use in the treatment depends on the filling level of the oxygen cylinder. The filling level may be checked as follows:

Cylinder pressure (kPa) * cylinder volume (V) / O₂ dosage (l/min)

Example of calculation:

- Cylinder pressure = 200 kPa
- Cylinder volume = 2 l
- O₂ dosage = 4 (l/min)
- $200 * 2 / 4 = 100$ min

The cylinder contents will last for approximately 1.5 hours.

Checking filling level

- Open cylinder valve.
- Set hand wheel of the click-stop flowmeter at the pressure regulator.
- Check gauge to see whether the cylinder contains sufficient oxygen for the treatment.

4.3 Oxygen extraction

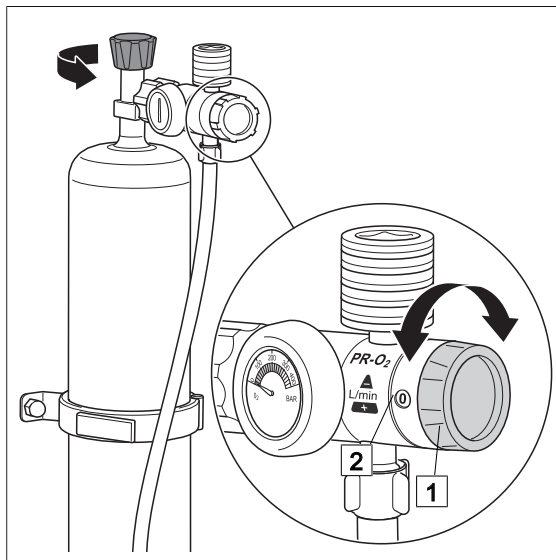


Fig. 10: Setting the flow

Setting the flow

- Set hand wheel (1) of the click-stop flowmeter to [0].
- Open the cylinder valve of the oxygen cylinder counter-clockwise and check whether the cylinder contains sufficient content for the treatment [▶ Page 18].
- Set the desired flow quantity on the hand wheel.
 - ✓ The arrow (2) on the pressure regulator indicates flow quantity.

4.4 Setting the vacuum level



NOTE

Check airtightness of all accessory connections before beginning treatment. Manually retighten connecting nuts as necessary and readjust to the amount of oxygen required.

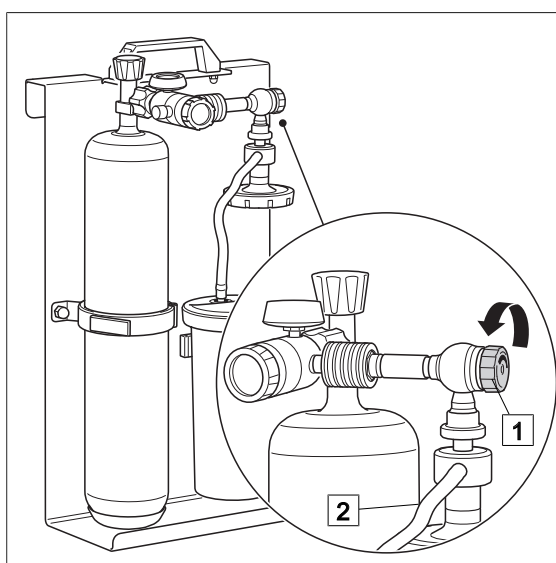


Fig. 11: Setting the vacuum level

Setting the vacuum level

- Close the control valve (1) on the fine regulator.
- Open the cylinder valve of the oxygen cylinder and check whether the cylinder contains sufficient content for the treatment [▶ Page 18].
- Turn the control valve of the fine regulator slowly one full rotation in an anticlockwise direction.
- Bend the suction tube (2).
- Set the suction rate required using the control valve.

5 Taking the unit out of operation

5.1 Stopping oxygen extraction

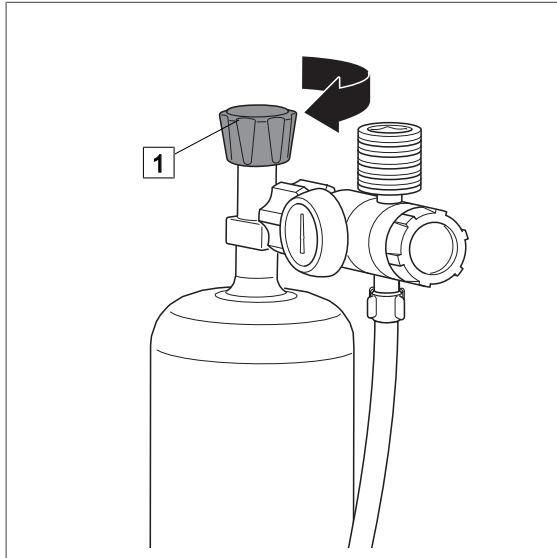


Fig. 12: Closing the cylinder valve

Closing the cylinder valve

- Turn the hand wheel (1) of the cylinder valve slowly in a clockwise direction.
 - ✓ Cylinder valve is closed.
 - ✓ Oxygen supply is interrupted.

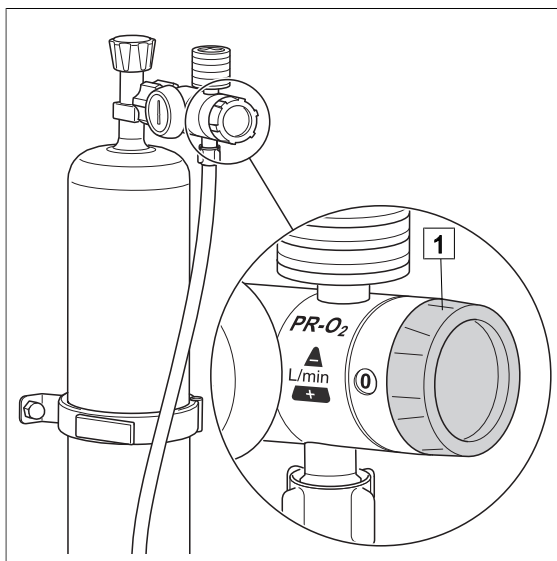


Fig. 13: Closing the pressure regulator

Releasing the pressure

- Set hand wheel (1) of the click-stop flowmeter to [15].
 - ✓ Pressure is released.

Closing the pressure regulator

- Set hand wheel (1) of the click-stop flowmeter to [0].

5.2 Replacing the oxygen cylinder



NOTE

Unscrew manual tightening only after pressure has been fully released from the pressure regulator. First, close the valve on the oxygen cylinder; then release the pressure on the click-stop flowmeter.



NOTE

Please refer to the operating instructions of the carrying board (REF HM57524733) for information on mounting the oxygen cylinder to the carrying board.

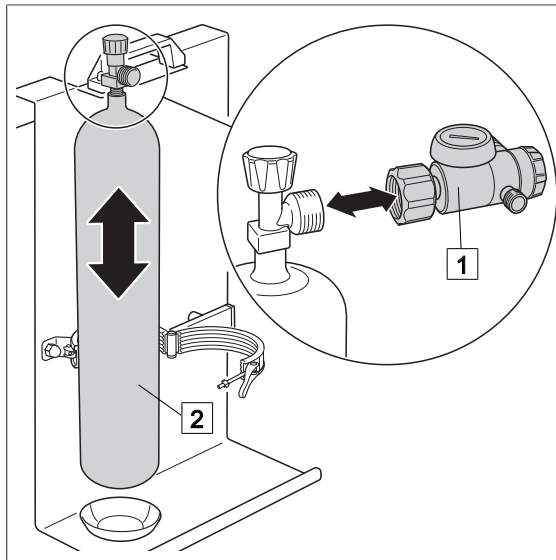


Fig. 14: Replacing the oxygen cylinder

Replacing the oxygen cylinder

- Release the pressure.
- Close the pressure regulator.
- Unscrew the pressure regulator (1).
- Replace the oxygen cylinder (2).
- Screw the pressure regulator back into place.

5.3 Detaching tubes

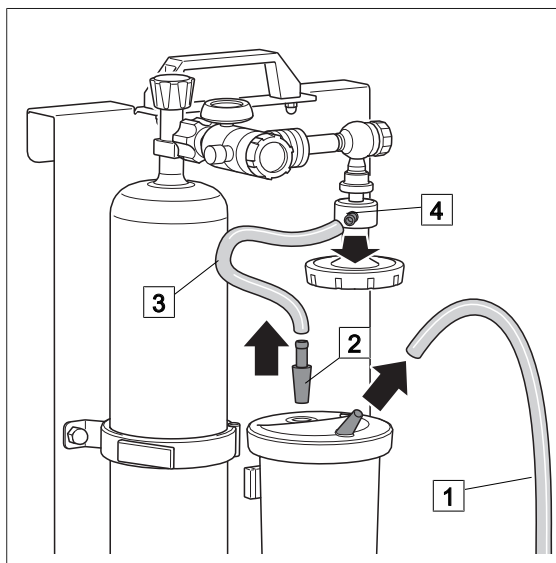


Fig. 15: Detaching tubes

Detaching tubes

- Remove the suction tube (1) from the patient-side tube connector (5) on the septic fluid jar cap.
- Detach the adapter (2) and connection tube (3) from the septic fluid jar cap.
- Remove the other end of the connection tube from the connector (4) on the gas-jet pump.

6 Cleaning and disinfection

6.1 General

The product must be cleaned as well as wipe disinfected after every use. Perform visual and functional inspections after each cleaning and disinfection process. Please strictly observe the cleaning instructions in the operating instructions of the connected products.

**DANGER!**

Risk due to incorrect use of detergents and disinfectants!

It is strictly advised to observe the manufacturer's instructions regarding how to use the detergents and disinfectants as well as the valid hospital hygiene rules.

**DANGER!**

Infection hazard!

Product may be contaminated.

Always wear gloves for cleaning and disinfection.

7 Maintenance

7.1 General

Maintenance, repairs and periodic tests may only be carried out by persons who have the appropriate technical knowledge and are familiar with the product. To carry out these measures, the person must have the necessary test devices and original spare parts.

ATMOS recommends: Work should be carried out by an authorised ATMOS service partner. This ensures that repairs and testing are carried out professionally, original spare parts are used and warranty claims remain unaffected.



DANGER!

Health hazard!

The product is used in the treatment of patients. The product or some of its components may be contaminated.

Clean and disinfect the product before maintenance and repair.

Repair work may be performed by personnel authorised by ATMOS.

7.2 Periodic tests

Observe the instructions for the individual components.

7.3 Visual and functional inspections

To ensure correct operation, it is necessary to have visual and functional inspections performed by a trained person prior to each use.

Documentation of the results of the visual and functional inspections is recommended and should include the date and signature of the person who performed the inspections. The following table can be used as a template.

Suggestion:

No.	Inspection	Defects are present		No defects
1	Has the product been cleaned and disinfected according to the hygiene guideline?	<input type="checkbox"/>	<input checked="" type="checkbox"/> Do not use the product any longer. <input checked="" type="checkbox"/> Clean and disinfect the product according to the guidelines.	<input type="checkbox"/>
	Comment:			
2	Is the product sealed?	<input type="checkbox"/>	<input checked="" type="checkbox"/> Do not use the product any longer.	<input type="checkbox"/>
	Comment:			
3	Are there damages to mechanical parts?	<input type="checkbox"/>	<input checked="" type="checkbox"/> Do not use the product any longer. <input checked="" type="checkbox"/> Inform service personnel.	<input type="checkbox"/>
	Comment:			
4	(Space for other tests)	<input type="checkbox"/>		<input type="checkbox"/>

No.	Inspection	Defects are present	No defects
	Comment:		

Tab. 5: Visual and functional inspections

7.4 Malfunctions and troubleshooting

Defect	Source of malfunction	Troubleshooting		
No or reduced flow rate.	No pressure available	Check the contents of the oxygen cylinder; if necessary, replace the oxygen cylinder		
		Open the oxygen cylinder		
		Fit the fine regulator correctly		
		Open the fine regulator		
	Gas-jet pump is defective	Pressure regulator is defective	Contact technical service	
				Fine regulator defective
				Oxygen cylinder is empty
	Fine regulator is not seated properly in DIN coupling of the pressure regulator	Oxygen cylinder is not open	Replace the oxygen cylinder	
			Fine regulator is not open	Fit the fine regulator correctly
Open the oxygen cylinder				
Open the fine regulator				
Cylinder pressure gauge is not working	Oxygen cylinder is empty	Replace the oxygen cylinder		
	Oxygen cylinder is not open	Open the oxygen cylinder		
	Pressure regulator is defective	Contact technical service		
No or only little oxygen released	No oxygen pressure	Check the contents of the oxygen cylinder; if necessary, replace the oxygen cylinder		
	Pressure regulator with flowmeter clogged	Contact technical service		
	Leaking manual tightening	Check seal in DIN 477-1 connection of pressure regulator Retighten manual tightening		
	Leaking or contaminated accessories	Replace or clean accessories		

Tab. 6: Troubleshooting

7.5 Repairs

The following issues may require repairs by the manufacturer or an authorised service partner:

- Liquid has penetrated the device.
- The performance has significantly decreased.
- Inexplicable notifications appear.
- Abnormal noises occur.
- Functional faults cannot be rectified according to the measures in chapter Malfunctions and troubleshooting [▶▶ page 24].

If defects are detected, the product may not be used any longer.

Make a note of the defects and the REF number on the type plate and inform your ATMOS representative.

Observe the information in chapter Sending in the device [▶▶ page 25].

7.6 Service hotline

+49 7653 689-0

7.7 Spare parts

HM57506522	Humidifier bottle for bubble humidifier MEDAP
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Tab. 7: Spare parts

7.8 Sending in the device

- Remove and properly dispose of consumables.
 - Clean and disinfect the product and accessories according to the operating instructions.
 - Place used accessories with the product.
 - Fill in the form QD 434 'Delivery complaint / return shipment' and the respective **decontamination certificate**.
- This form is enclosed with each delivery and can be found at www.atmosmed.com.
- The device must be well padded and packed in suitable packaging.
 - Place the form QD 434 'Delivery complaint / return shipment' and the respective **decontamination certificate** in an envelope.
 - Affix the envelope to the outside of the package.
 - Send the product to ATMOS or to your dealer.

8 Technical specifications

8.1 Ambient conditions

Temperature: Shipping / storage	-20 °C to +60 °C
Temperature: Operation	-20 °C to +60 °C
Relative humidity: Shipping / storage	10 % to 95 %
Relative humidity: Operation	10 % to 95 %
Atmospheric pressure: Shipping / storage	700 hPa to 1060 hPa
Atmospheric pressure: Operation	700 hPa to 1060 hPa

8.2 Technical specifications

Observe the instructions for the individual components in the respective operating instructions.

8.3 Dimensions and weights

Dimensions (W x H x D)	250 x 545 x 200 mm
Weight without cylinder	4.3 kg
Maximum weight (with 3 l cylinder)	9.2 kg

8.4 Expected service life

When used according to the operating instructions, the device has an expected service life of 8 years. Regular thorough cleaning and disinfection of the device and its applied parts as well as operation of the device according to the operating instructions are assumed.

9 Accessories

9.1 Accessories

5752 5606	Angled adapter UNF 9/16"
5752 5315	Bubble humidifier

Tab. 8: Accessories

9.2 Consumables

5750 5045	Hydrophobic bacterial filter paper (100 pieces)
5752 2557	Hydrophobic bacterial and viral filter (pore size 1 µm)
000.0347.0	Fingertip
5750 5467	Vacuum connection tube, 6 x 12 mm, by the metre

Tab. 9: Consumables



■ **Manufacturer:**

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