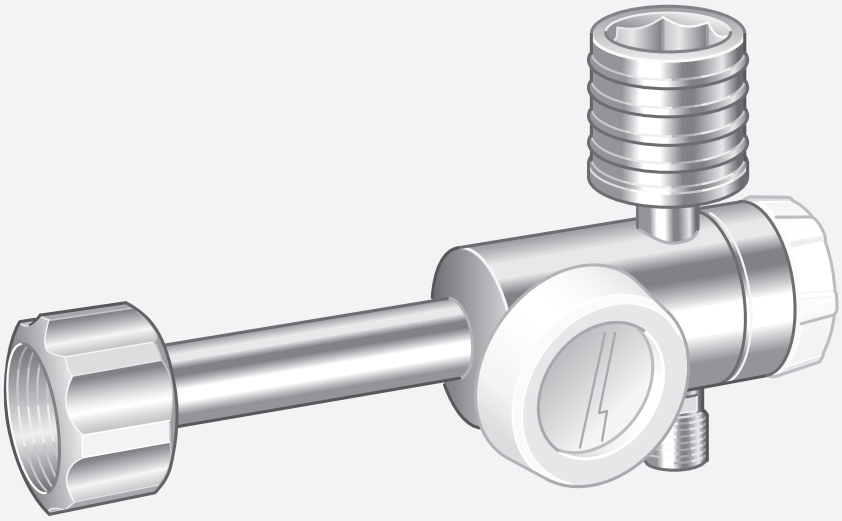
OPERATING INSTRUCTIONS

PRESSURE REGULATOR

MEDAP



GA 5752 5554 GB 11

Subject to technical modification!

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

V11 2023-08

CE 0124

Table of contents

1 Introduction

1.1 Foreword

Your facility has selected 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
	**DANGER!** Indicates a direct and immediate risk to persons which may be fatal or result in most serious injury. Observe the necessary measures.
	**WARNING!** Warning of a risk that can cause death or seriously injure you. Observe the necessary measures.
	**CAUTION!** Warning of a risk that can easily injure you. Observe the necessary measures.
	**ATTENTION!** Indicates a risk that may cause damage to the product or other objects. Observe the necessary measures.

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
	Consult operating instructions
	Warning; pay special attention

Symbols	Identification
CE	This device complies with the relevant requirements of the EU regulations.
CE 0124	This device complies with the relevant requirements of the EU regulations.
REF	Reference number
SN	Serial number
	Manufacturer
	Date of manufacture Country of manufacture
UDI	Unique Device Identifier of a medical device
MD	Medical device
LOT	Batch code
>PA<	Material designation for PA (polyamide) plastic
	Keep dry
	Fragile, handle with care

Symbols	Identification
	This side up
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Symbol for ‘Oil- and fat-free"

Tab. 3: Symbols

1.3 Disposal

1.3.1 General

Used products or parts thereof may be contaminated. To prevent potential infection, please clean and disinfect the product prior to return/disposal.

1.3.2 Packaging

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

1.3.3 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.

1.4 Overview

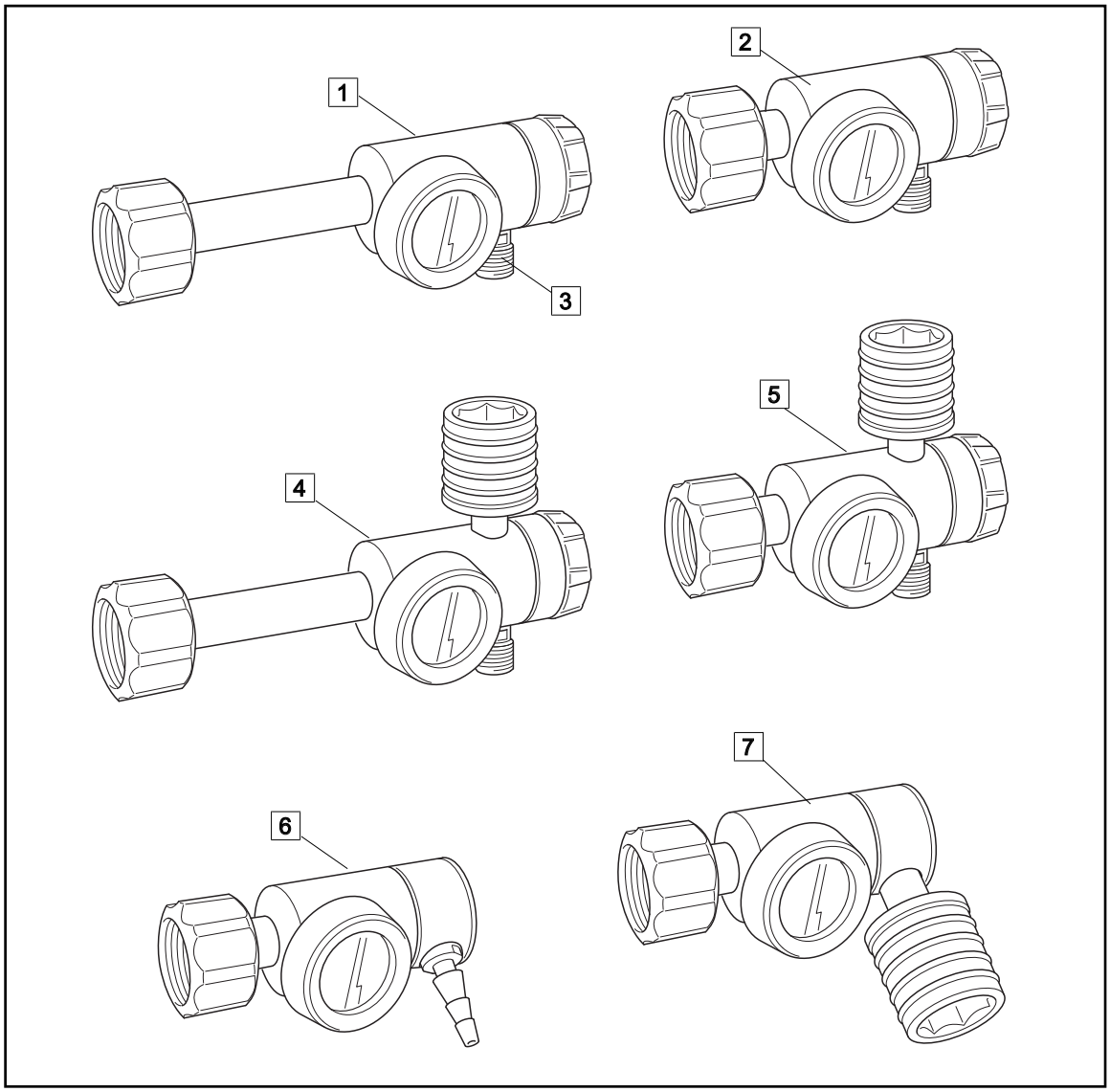


Fig. 1: Overview of pressure regulator

1	Pressure regulator with flowmeter (long axle)	HM57525543
2	Pressure regulator with flowmeter (short axle)	HM57525618
3	Tube connector flowmeter outlet	
4	Pressure regulator with flowmeter and coupling (long axle)	HM57525544
5	Pressure regulator with flowmeter and coupling (short axle)	HM57525545
6	Pressure regulator with fixed set flow rate (short axle)	HM57525546
7	Pressure regulator with coupling (short axle)	HM57525547

1.5 Basic requirements

1.5.1 Use in accordance with the intended purpose

Product

This device may only be used by medically trained staff who have been instructed in its use by an authorised person.

This product is to be used exclusively for human medicine.

When employed in commercial or business use, this product must be entered in the inventory.

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.

1.5.2 Applicable standards

The product satisfies the basic requirements set forth in Annex I to Council Directive 93/42/EEC concerning medical devices (Medical Devices Directive) as well as the applicable national (German) codes and the Medical Devices Act (MPG) in Germany. This has also been demonstrated through the application of the corresponding standards which have been harmonised with Directive 93/42/EEC.

1.5.3 Intended purpose

Product name:	Pressure regulator • PR, O2, short connection, without flowmeter • PR, O2, short connection, fixed flow 4 l/min • PR, O2, long connection, flowmeter 15 l/min • PR, O2, short connection, flowmeter 15 l/min • PR, O2, short connection., flowmeter 15 l/min, DIN coupling • PR, O2, long connection., flowmeter 15 l/min, DIN coupling
Main functions:	Reducing the pressure of gas cylinders with compressed medical gases to a lower pressure and supplying the compressed gases to patients either via an integrated flowmeter or via a media-coded coupling to a device or a regulator for compressed gases
Intended use:	Connection of the pressure regulator with a gas cylinder. The pressure regulator has an integrated flowmeter with fixed or variable flow rate and/or media-coded coupling. The flowmeter outlet can be used for inhalation or insufflation of oxygen within the scope of oxygen enrichment for patients breathing by themselves. The media-coded coupling can be used for inserting regulators directly. As an alternative, the connection to a regulator (e.g., fine regulator) or a device (e.g., anaesthetic machine) can be made via a connection tube with gas probe. The permitted pressure in the gas cylinders is depending on the coding 200 bar or 300 bar.
Intended users / user profile:	• Doctors • Healthcare professionals Users must have adequate visual faculty

User training:	The product may only be used by persons who have received medical training
Intended patient target groups:	Patients of all age groups with and without restrictions
Medical conditions to be diagnosed, treated or monitored:	Oxygen deficiency (hypoxia/hypoxaemia)
Organ(s) applied to:	• Outlet flowmeter: lung • Outlet coupling: no specific organ
Duration of application:	Device designed for continuous application; in practice, short-term use on the patient (< 30 days)
Use environment:	Environments for use are the hospital/clinic environment and doctor's practices.
Patient selection criteria:	All patients needing additional oxygen or water-soluble drugs via an inhalation mask.
Indications:	Supply of patients with compressed medical gases if a central gas supply is not available (e.g., inter hospital transport). • Inhalation and insufflation of oxygen within the scope of oxygen enrichment via an inhalation mask or a nasal cannula for patients breathing by themselves. • Together with a hand-held nebuliser, administration of water-soluble drugs via an inhalation mask.
Medical contra-indications:	• Dosed supply of medical gases
Other contra-indications:	• Outside the medical field • MR area • Homecare area • For ultra-pure gases • For corrosive, aggressive, and toxic gases, acetylene, propane, butane, and other flammable gases • With an input pressure higher than 200 bar or 300 bar, depending on the media-coding. • When applying oxygen in its function as a medication, it is necessary to measure the flow rate
Undesirable side-effects:	The following complications may arise during supply of oxygen: • Drying of the mucous membranes in the nose • Increased concentration of oxygen in the blood • Skin irritation or allergic reactions
Warnings:	See chapter „2 Safety notes“ on page 13 in the valid operating instructions of the product.
The product is:	active
Sterility / specific microbial state:	Non-sterile device
Single-use device / reprocessing:	The device is intended for multiple use. The device and part of the accessories are reusable. For information on reprocessing, cleaning and disinfection, please see the operating instructions.

1.5.4 Versions

The product is available in the following versions:

• PR, O2, short connection, without flowmeter	REF HM57525547
• PR, O2, short connection, fixed flow 4 l/min	REF HM57525546
• PR, O2, long connection, flowmeter 15 l/min	REF HM57525543
• PR, O2, short connection, flowmeter 15 l/min	REF HM57525618
• PR, O2, short connection., flowmeter 15 l/min, DIN coupling	REF HM57525545
• PR, O2, long connection., flowmeter 15 l/min, DIN coupling	REF HM57525544

2 Safety notes

DANGER!

Fire/explosion hazard!

Air, oxygen and oxygen compounds react explosively with oils, greases and lubricants. Fire and explosion hazard due to compressed gases.

Always keep the product free of oils, greases and lubricants. Only use sliding means (lubricants) approved by ATMOS for this product.

DANGER!

Fire hazard!

The product may ignite if the maximum operating pressure or the maximum operating temperature is exceeded.

Do not exceed the maximum operating pressure or maximum operating temperature.

DANGER!

Fire hazard!

Fire hazard as a result of escaping oxygen.

Never smoke near equipment which carries oxygen and avoid using open fires or glowing objects. Check the connector for leaks and tight fit when mounting accessories.

DANGER!

Explosion hazard!

The oxygen cylinder can ignite as a result of extreme heat.

Do not expose the oxygen cylinder to intense heat.

Do not position oxygen cylinder close to radiators and protect from high solar radiation.

DANGER!

Fire hazard!

Compressed oxygen is very dense. Opening the cylinder valve quickly may produce a pressure surge which can spark an explosive flame by igniting dirt particles or residues of disinfectants.

Open the cylinder valve of the oxygen cylinder slowly.

DANGER!

Fire/explosion hazard!

Pressure regulators are equipped with a safety valve. Manipulation of the safety valve may impair the accuracy of the flow rate or cause an uncontrolled release of gas.

The safety valve are factory-set and may not be adjusted.

DANGER!

Danger to life!

Danger due to improper configuration of the system!

Configuration of the overall system as well as 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.

WARNING!

Defective product!

Using incorrect spare parts and accessories can cause injuries or equipment failure.

Only use original accessories or spare parts.

WARNING!

Risk of injury!

The tube connector of the flowmeter outlet may not be used for operation in conjunction with medical devices connected in series.

WARNING!

Risk of injury!

ATMOS products may be used only when fully functional.

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

WARNING!

Allergic reactions due to contact!

The materials used were examined for their compatibility. In exceptional cases, allergic reactions to accessible materials on the unit and its accessories can occur. This applies to contact injuries in the event of prolonged contact. In this case, consult a doctor immediately.

ATTENTION!

Tensile forces!

The connected accessories must not exert any mechanical forces which could adversely affect the secure fit of the product.

ATTENTION!

Impacts!

Impacts may cause damage to sensitive, precision mechanical components.

Do not expose the product to impacts.

ATTENTION!

Property damage!

Exposure to UV rays can cause material fatigue. The stability would no longer be ensured.

Do not expose the product to strong UV light.

ATTENTION!

Property damage!

Using tools is likely to damage the cap nuts of the gas cylinder connections or the connecting part of the application component. The cap nuts may leak and become useless.

Do not use any tools or tool-like devices for unscrewing or tightening the cap nuts.

ATMOS recommends, always having another pressure regulator ready to hand. This allows you to continue working even in the event of product failure.

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

3 Operation and use

3.1 Connecting the pressure regulator

☒ Remove the seal of the valve on the gas cylinder.

☒ Ensure that there is no dirt, oil or grease residue present.

☒ Screw the pressure regulator connector to the gas cylinder and tighten by hand.

☒ Screw accessories to the outlets of the pressure regulator.

3.2 Function test

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

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

3.3 Operation

☒ Slowly open the valve of the gas cylinder.

☒ Check the flowmeter to see whether the pressure is gradually increasing and stabilises when the valve is completely open.

☒ Should any leak be detected, close the valve on the gas cylinder immediately. Check the seal on the gas cylinder connection, if there is one.

☒ In the event of pressure regulators with a flowmeter, turn the pressure regulator anticlockwise to increase the flow rate.

3.4 Taking the unit out of operation

☒ To remove the pressure regulator, close the valve on the gas cylinder.

☒ In the event of pressure regulators with a pressure flowmeter, close the pressure regulator by turning the hand wheel clockwise and ensure that it is closed.

4 Cleaning and disinfection

4.1 General

DANGER!

Fire hazard!

Cleaning agents and disinfectants may contain flammable substances which form a highly flammable compound together with oxygen. Fire hazard is increased with use of oxygen.

Do not use flammable cleaning agents and disinfectants. Make sure that neither cleaning agents nor disinfectants are able to enter the high-pressure area of the gas cylinder connection nor penetrate the pressure regulator.

WARNING!

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 to observe the valid hospital hygiene rules.

WARNING!

Health hazard!

Do not disassemble the product and do not clean it by gas sterilisation or any other mechanical cleaning or sterilisation method. Disinfectant and cleaning agents may not enter the product.

ATTENTION!

Improper cleaning and disinfection can cause property damage!

Use only as much detergent and disinfectant as required.

ATTENTION!

Improper cleaning and disinfection can cause property damage!

Do **not** use the following products for cleaning and disinfection:

- Products containing alcohol (e.g. hand disinfectants)
- Halogenides (e.g. fluorides, chlorides, bromides, iodides)
- Dehalogenating compounds (e.g. fluorine, chlorine, bromine, iodine)
- Products that may scratch the surface (e.g. scouring agents, wire brushes, wire wool)
- Standard commercial solvents (e.g. benzene, thinner)
- Water containing iron particles
- Cleaning sponges containing iron
- Products containing hydrochloric acid

Use a soft, lint-free cloth or a soft nylon brush to clean the product.

NOTE

Use only all-purpose cleaners which are slightly alkaline (soap solution) and which contain surfactants and phosphates as the active cleaning agents.

In the event of heavily contaminated surfaces, use concentrated all-purpose detergent.

4.2 Cleaning

4.2.1 Cleaning procedure

☒ Use the correct dose of all-purpose detergent with water for the degree of surface contamination and in accordance with the instructions of the detergent manufacturer.

☒ Thoroughly wipe off the product with a soft cloth slightly dampened in an all-purpose detergent solution.

☒ Ensure that the product is free of contamination and encapsulated particles of grime.

☒ Thoroughly wipe off the product with a soft cloth dipped in clean water.

☒ Ensure that the product is free of detergent residues.

☒ Dry the product with a dry, absorbent and lint-free cloth.

✓ This will help to reduce pathogen growth on the product's surface.

☒ Wipe disinfect the product after every cleaning process.

4.3 Disinfection

4.3.1 Suitable disinfectants

Only surface disinfectants based on the following combinations of active ingredients may be used for disinfection:

- Aldehydes
- Quaternary compounds
- Guanidine derivatives

4.3.2 Disinfection procedure

☒ Wipe disinfect the product in accordance with the instructions of the disinfectant manufacturer after every cleaning process.

☒ Ensure that the product is free of disinfectant residue.

☒ Perform visual and functional inspections.

5 Maintenance

5.1 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.

5.2 Periodic tests

At least every 5 years a test must be performed.

5.3 Repairs

The following 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.

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

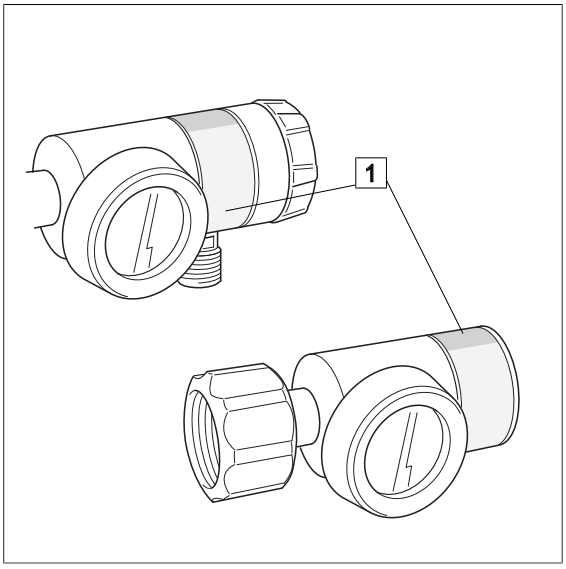
Make a note of the defects and the REF number on the type plate and inform your ATMOS representative.

Observe the information in chapter Sending in the device [⏩ page 20].

5.4 Service hotline

+49 7653 689-0

5.4.1 Type plate position



Position of the type plate (1) on the product.

Fig. 2: Type plate position

5.5 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.

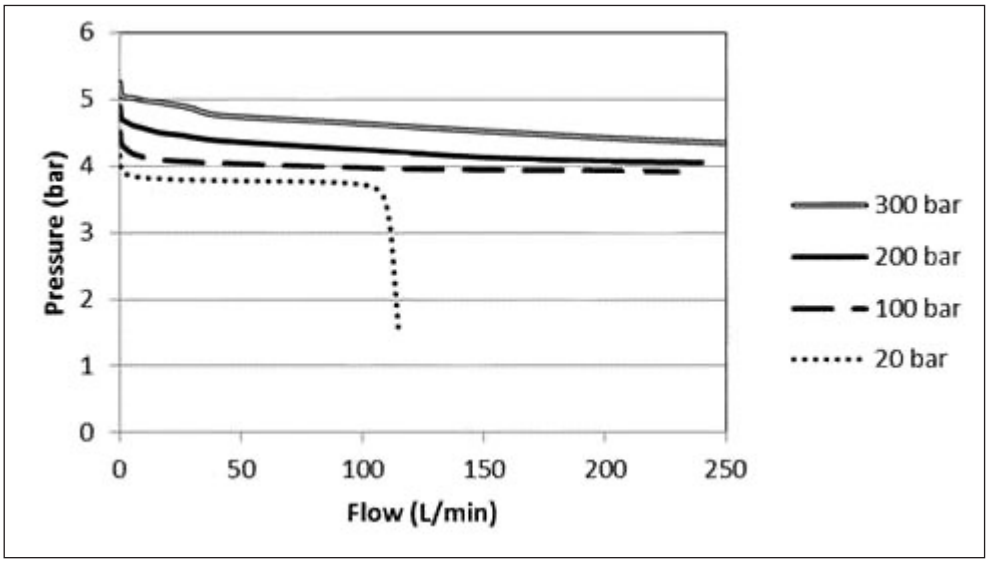
☒ Affix the envelope to the outside of the package.

☒ Send the product to ATMOS or to your dealer.

6 Technical specifications

Supply pressure P1 (maximum)	30,000 kPa
Supply pressure P1 for DIN 477-1 connection	20,000 kPa
Rated operating pressure	450 kPa ± 50 kPa
Pressure regulator version A: adjustable flow rate	0–15 l/min
Pressure regulator version B: fixed set flow rate	4 l/min
Environmental conditions: Transport/storage • Temperature range • Air humidity without condensation • Air pressure	 –20...+60 °C 10...95% 700...1060 hPa
Environmental conditions: Operation • Temperature range • Air humidity without condensation • Air pressure	 –20...+60 °C 10...95% 700...1060 hPa
Pressure regulator with flowmeter (long axle)	Dimensions: 160 x 57 x 51 mm Weight: 590 g
Pressure regulator with flowmeter (short axle)	Dimensions: 105 x 57 x 51 mm Weight: 500 g
Pressure regulator with flowmeter and coupling (long axle)	Dimensions: 160 x 57 x 92 mm Weight: 655 g
Pressure regulator with flowmeter and coupling (short axle)	Dimensions: 105 x 57 x 92 mm Weight: 565 g
Pressure regulator with flowmeter; fixed set flow rate 4 l/min (short axle)	Dimensions: 86 x 57 x 62 mm Weight: 450 g
Pressure regulator with coupling (short axle)	Dimensions: 86 x 57 x 74 mm Weight: 510 g
Periodic tests	Testing every 5 years.
CE marking	CE 0124
Reference number (REF)	• HM57525543 • HM57525544 • HM57525545 • HM57525546 • HM57525547 • HM57525618

6.1 Nominal flow depends on the pressure



7 Approved accessories

7.1 Accessories

The following accessories are not part of the scope of delivery and must be ordered separately:

HM57522746	Tube adapter 4.6, 8 mm, connection UNF 9/16‘‘
HM57525316	Tube adapter,, 4, 6, 8 mm, plastic UNF 9/16''
HM57525315	Bubble humidifier
HM57525707	Flow selector
HM57525606	Angled adapter (UNF 9/16'' – UNF 9/16'')

Tab. 4: Accessories

8 Disposal/Recycling

Packaging

Recycle the product packaging if no longer required.

Pressure regulator

Do not dispose of the product with household waste.

☒ Clean and disinfect the product.

☒ In Germany, send the product to ATMOS or to your dealer. They will recycle the product properly.

☒ In other countries: Recycle the product properly and in accordance with country-specific laws and regulations.

8.1 Expected service life

When used according to the instructions for use, the product has an expected service life of 8 years. Regular thorough cleaning and disinfection, as well as operation of the product according to the instructions for use, are assumed.

Notes

Notes

Notes

MEDAP

Manufacturer:

ATMOS
MedizinTechnik GmbH & Co. KG
Ludwig-Kegel-Str. 16
79853 Lenzkirch
GERMANY
Phone: +49 7653 689-0
www.atmosmed.com