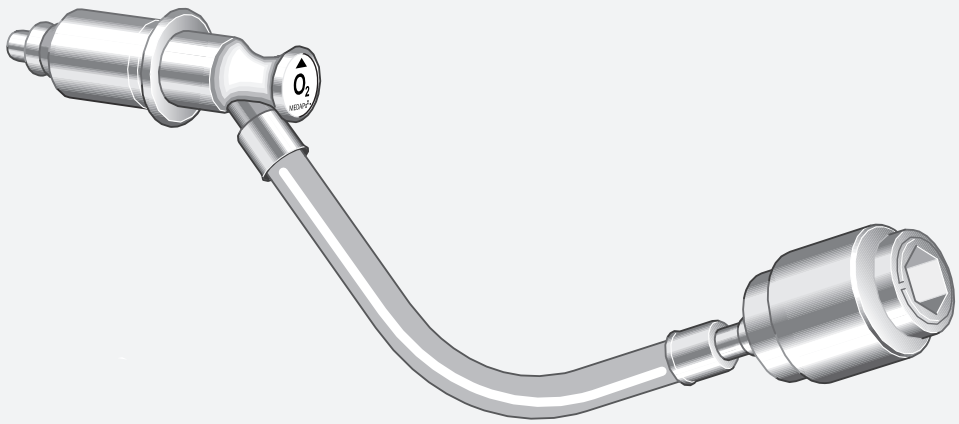
OPERATING INSTRUCTIONS

MEDAP
ADAPTER COUPLING



GA 5752 5123 GB 08

Subject to technical modification!

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

V08 2020-07

CE
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1 Introduction

1.1 How to use these operating instructions

1.1.1 General

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.

1.1.2 Symbols

1.1.2.1 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.

1.1.3 Definitions

1.1.3.1 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

1.1.3.2 Structure of notes

Pictogram	Descriptor	Text
	**NOTE**	Supplementary assistance or further useful information without potential injury to persons or property damage is described in the text of the note.

Tab. 2: Structure of notes

1.2 Disposal

WARNING!

Infection hazard!

The product or some of its components may be contaminated after use.

Clean and disinfect the product before disposal.

1.2.1 Packaging

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

1.2.2 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.

1.3 Symbols used

Symbols	Identification
CE 0124	Labelling for products which were developed and are marketed in compliance with the 93/42/EEC Medial Products Directive. Class Is, Im, IIa, IIb and III products are also marked with the identifying number of the Notified Body.
	Labelling in compliance with the ISO 15223-1 standard. Symbol for ‘Name and address of the manufacturer as well as date of manufacture’.
	Labelling in compliance with the ISO 15223-1 standard. Symbol for ‘Date of manufacture’.
	Labelling in compliance with the ISO 15223-1 standard. Symbol for ‘Follow operating instructions’.
REF	Labelling in compliance with the ISO 15223-1 standard. Symbol for ‘Product number’.

Symbols	Identification
LOT	Labelling in compliance with the ISO 15223-1 standard. Symbol for ‘Batch number‘.
	Packaging label. Symbol for ‘Keep dry‘.
	Labelling in compliance with the ISO 15223-1 standard. Symbol for ‘Temperature limitations’.
	Labelling in compliance with the ISO 15223-1 standard. Symbol for ‘Relative humidity’.
	Labelling in compliance with the ISO 15223-1 standard. Symbol for ‘Atmospheric pressure’.

Tab. 3: Symbols

1.4 Basic requirements

1.4.1 Use in accordance with the intended purpose

Product

As per Annex IX of the Medical Products Directive 93/42/EC this product belongs to class IIa. In accordance with this directive, the product may only be used by persons who have been instructed how to use this product by an authorised person. This product is to be used exclusively for human medicine. When employed in a 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. Other accessories, combinations of accessories and consumable items may be used only if they have a valid certification, are intended expressly for the particular use and will not adversely affect performance, the prescribed ambient conditions or safety requirements.

1.4.2 Applicable standards

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

1.4.3 Intended purpose

Name:	Adapter couplings
Main function:	Adapter between DIN and MEDAP standards
Medical indications / application:	For connection of a gas probe MEDAP with a terminal unit DIN
Specification of the main function:	Adapter couplings consist of a gas probe MEDAP and a coupling DIN. For connection of a gas probe DIN with a terminal unit of a central gas supply in MEDAP standard, an adapter coupling with gas probe MEDAP and coupling DIN is needed. The gas probe MEDAP of the adapter coupling is inserted to the terminal unit MEDAP of the central gas supply. The gas probe DIN is inserted into the coupling DIN of the adapter coupling. The permitted nominal supply pressure is 400 kPa to 500 kPa +/-10%.
User profile:	Doctor, medically trained staff
Patient groups:	Patients of all ages
Application organ:	No specific organ
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 which do have a central gas supply system. The application of the product may only be performed by medically trained and instructed staff.
Contraindications:	The adapter couplings may not be used: • Outside the medical sector • In MR areas • For ultra-pure gases • For liquids • For corrosive, aggressive and toxic gases, acetylene, propane, butane and other flammable gases • At a nominal supply pressure of the central gas supply system other than 400 kPa to 500 kPa +/–10%.
The product is:	Not active
Sterility:	Not a sterile product
Single-use product / reprocessing:	The product and parts of the accessories are reusable. For information on reprocessing, cleaning and disinfection please see the operating instructions.

1.4.4 Versions

Products and accessories are only permitted with the ISO colour coding.

NOTE

The gas probe is rotatable for adapter couplings with DIN gas probes.

- MEDAP gas probe DIN plug-in coupling; compressed air; ISO colour coding; REF 5752 5093
- MEDAP gas probe, DIN plug-in coupling; oxygen; ISO colour coding; REF 5752 5095

2 Safety notes

2.1 General

DANGER!

Fire/explosion hazard!

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

Keep product, in particular for oxygen, free of oils, greases, lubricants and hand cream. Only use lubricants which are approved by ATMOS. Observe fire protection regulations when dealing with flammable gases. Contact Technical Service about any leakages in the product.

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 fitt when mounting accessories.

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!

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!

Worn or damaged products can cause injuries.

Use only products which are in perfect condition.

WARNING!

Malfunction!

To avoid malfunctions or damage, do not apply any mechanical forces to the product from the plug-in connection.

WARNING!

Malfunction!

Do not expose the product to torsion, as this might impair its proper function.

Mount accessories in such a way that they remain torsion-free and tension-free.

WARNING!

Impact!

Sensitive precision components may be damaged if the product is exposed to impact.

WARNING!

Permissible load!

Leakages may occur at the point of connection of ‘terminal unit and gas probe‘.

In accordance with DIN EN ISO 9170-1, the overall weight of the units directly connected to the terminal unit may not exceed 2 kg.

WARNING!

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 during operation.

CAUTION!

Property damage!

The plug-in coupling may be damaged if the wrong gas probe is connected.

Compare coding of the gas probe with plug-in coupling. Only use gas probes corresponding to DIN EN 13260-2 or the MEDAP works standard. Never use contaminated gas probes.

CAUTION!

Property damage!

During preparation no liquid must enter the product, as it may become inoperative.

CAUTION!

Property damage!

Do not insert pointed or sharp objects, as this may damage the product.

Do not insert pointed or sharp objects into the product.

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.

DANGER!

Danger to life!

When using oxygen, a kink in the connection tube may cause the oxygen supply to be interrupted.

Ensure that there are no kinks in the connection tube.

CAUTION!

Property damage!

Condensate in the interior of the valve may lead to a loss in functionality.

100% air humidity must be avoided.

CAUTION!

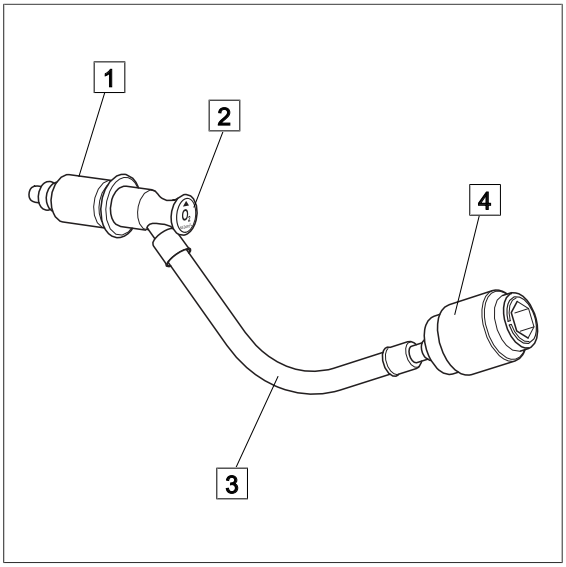
Reduced performance!

Length and inner diameter of the product used may impair the maximum available gas volume.

Check the gas volume available at the tapping unit.

3 Initial operation, operation and use

3.1 General



- Gas probe MEDAP (1)
- Gas type (2)
- Connection tube (3)
- Plug-in coupling DIN (4) without park position

Fig. 1: Connector plug MEDAP, plug-in coupling DIN

3.2 Equipment inspection

NOTE

Before using the product for the first time perform a disinfection.

NOTE

Please refer to the manufacturer's instructions for the particular terminal unit for information on connecting the gas probe to the terminal unit.

☒ Examine the plug-in coupling for correct functioning and contamination or damages.

☒ Check the connection tube for leaks.

3.3 Connect plug-in coupling

3.3.1 Connect/disconnect gas probe adapter coupling

CAUTION!

Property damage!

The plug-in coupling does not have a park position. When plugging in the connection device, the preset pressure is on immediately.

Only connect accessories via gas probe with tube.

3.3.1.1 Connector plug MEDAP, plug-in coupling DIN

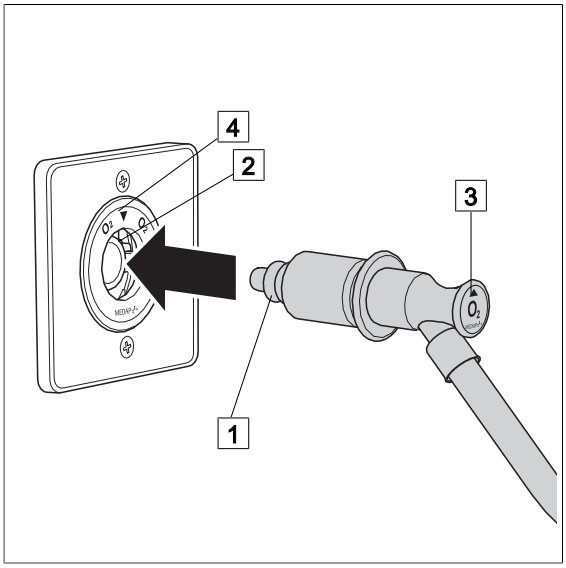


Fig. 2: Couple adapter coupling

Couple gas probe

☒ Press in gas probe (1) until it stops in the terminal unit (2) or press until the sliding sleeve snaps.

✓ The arrow (3) on the label of the gas probe corresponds to the axis of the arrow (4) on the cover plate of the terminal unit.

✓ Operating position for gas supply is achieved.

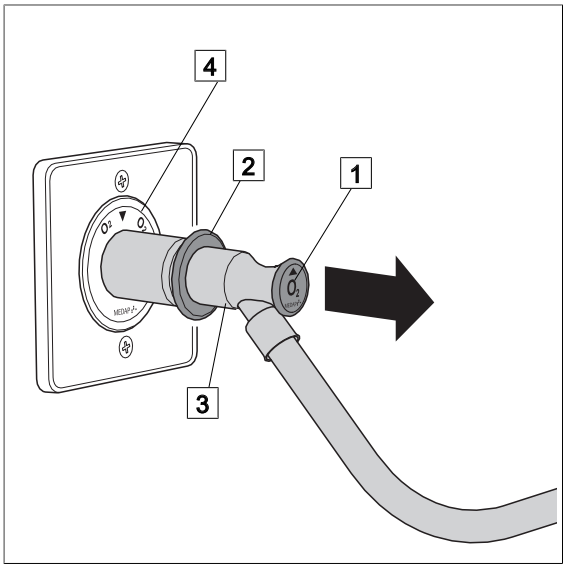


Fig. 3: Decouple adapter coupling

Release gas probe

☒ Press thumbs on the plate (1) of the gas probe.

☒ Use two fingers to pull the slide sleeve (2) of the gas probe (3) to the back.

☒ Pull out gas probe from terminal unit (4).

4 Cleaning and disinfection

4.1 Basic instructions

The product must be cleaned as well as wipe disinfected after every use.

DANGER!

Risk due to incorrect use of detergents and disinfectants!

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

DANGER!

Infection hazard!

Product may be contaminated.

Always wear gloves for cleaning / disinfection.

DANGER!

Infection hazard!

Particles of grime may become encapsulated and lead to the product not reaching the desired germ reduction after disinfection.

Before disinfection, the product must be cleaned thoroughly of contamination and encapsulated particles of grime.

DANGER!

Health hazard!

The product is also used to administer respiratory gas. Residues of sterilisation gases or other substances in the unit could endanger the patient's health.

Do not disassemble the product and do not clean it by gas sterilisation or any other mechanical cleaning or sterilisation method. Ensure that no disinfectant or cleaning agent enters the product.

CAUTION!

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. fluorids, 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.

CAUTION!

Improper cleaning and disinfection can cause property damage!

Use only as much detergent and disinfectant as required.

CAUTION!
Improper cleaning and disinfection can cause property damage!
Perform visual and functional inspections after each cleaning and disinfection process.

CAUTION!
Property damage!
The product is not suitable for live steam sterilisation or spray disinfection! Do not clean the product by live steam sterilisation or spray disinfection.

CAUTION!
Property damage!
Using non-colour-fast surgical drapes can cause discolouration of surfaces.
Only use colour-fast drapes.

4.2 Cleaning

4.2.1 General

CAUTION!
Improper cleaning can cause property damage!
Residues of physiological saline solutions (e.g. sodium chloride) can attack the surfaces of the product.
Remove residues of physiological saline solutions with a cloth dipped in clean water. Then dry the product with a dry, lint free cloth.

CAUTION!
Improper cleaning can cause property damage!
Do not spray cleaning agent directly into the joints or gaps and never use a high-pressure cleaning unit!

NOTE
Use only all-purpose cleaners which are slightly alkaline (soap solution) and contain surfactants and phosphates as the active cleaning agents. In the event that surfaces are heavily contaminated, use concentrated all-purpose detergent.

4.2.2 Cleaning procedure

☒ Use the correct dose of multi-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 wetted in a multi-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 General

NOTE

In the event of product surfaces that are very dirty, carry out an additional cleaning procedure before disinfecting the product.

CAUTION!

Material damage due to excessive exposure times!

Exceeding the specified exposure time of the disinfectant may damage the surfaces.

Observe the specified exposure time of the disinfectant manufacturer.

4.3.2 Suitable disinfectants

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

- Aldehydes
- Quaternary compounds
- Guanidine derivatives

Ingredient group	Active ingredients
Aldehydes	2-ethyl-1-hexanal, formaldehyde, glutardialdehyde, glyoxal, o-phthaldialdehyde, succinaldehyde
Quarternary compounds	Alkyl-didecyl-polyoxethyl ammonium propionate, alkyl-dimethyl-alkylbenzyl ammonium chloride, alkyl-dimethyl-ethyl ammonium chloride, alkyl-dimethyl-ethylbenzyl ammonium chloride, benzalkonium propionate, benzalkonium chloride (alkyl-dimethyl-benzyl ammonium chloride, coco-dimethyl-benzyl ammonium chloride, lauryl-dimethylbenzyl ammonium chloride, myristyl-dimethyl-benzyl ammonium chloride), benzethonium chloride, benzyl-dihydroxyethyl-coco-alkyl ammonium chloride, dialkyl-dimethyl ammonium chloride (didecyldimethyl ammonium chloride), didecyl-methyl-oxyethyl ammonium propionate, mecetronium-ethyl sulfate, methyl-benzethonium chloride, n-octyl-dimethyl-benzyl ammonium chloride
Guanidine derivatives	Alkyl-biguanide, chlorhexidine-digluconate, cocospropylene-diamine guanidinium diacetate, oliogomeric biguanide, polyhexamethylene biguanide hydrochloride (oligo-diimino imiodo-carbonyl imino-hexamethylene, polyhexanide)

Tab. 4: Active ingredients of disinfectants

4.3.3 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 Malfunctions and troubleshooting

Defect	Source of malfunction	Corrective actions
Gas escapes with connected gas probe	Plug-in coupling defective	Inform Technical Service.
Gas probe cannot be inserted	Gas probe is designed for different gas types than the adapter coupling	Only use gas probes designed for same gas type as the adapter coupling.
	The coding of the gas probe differs to that of the adapter coupling	Use MEDAP gas probe for MEDAP adapter coupling and use DIN gas probe for DIN adapter coupling.
	Gas probe is deformed	Inspect gas probe and have it replaced, if required
Gas probe is difficult to insert	Gas probe is defective as a result of tension or torsion forces in terms of function	Remove mechanical load and have plug-in coupling checked if necessary.

Tab. 5: Corrective actions

5.4 Repairs

The following may require repairs from 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 18].

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

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

Observe the information in chapter Sending in the device [⏩ page 19].

5.5 Service hotline:

+49 7653 689-0

5.6 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

6.1 General

Classification as per Medical Products Directive 93/42/EEC	Class IIa
Nominal supply pressure for compressed gases	400 - 500 kPa ± 10%

6.2 Ambient conditions

Temperature: Shipping / storage	–15 °C to +50 °C
Temperature: Operation	–10 °C to +40 °C
Relative humidity: Shipping / storage	10% to 90%
Relative humidity: Operation	30% to 75%
Atmospheric pressure: Shipping / storage	700 hPa to 1060 hPa
Atmospheric pressure: Operation	700 hPa to 1060 hPa

Notes

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MEDAP

Manufacturer:

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