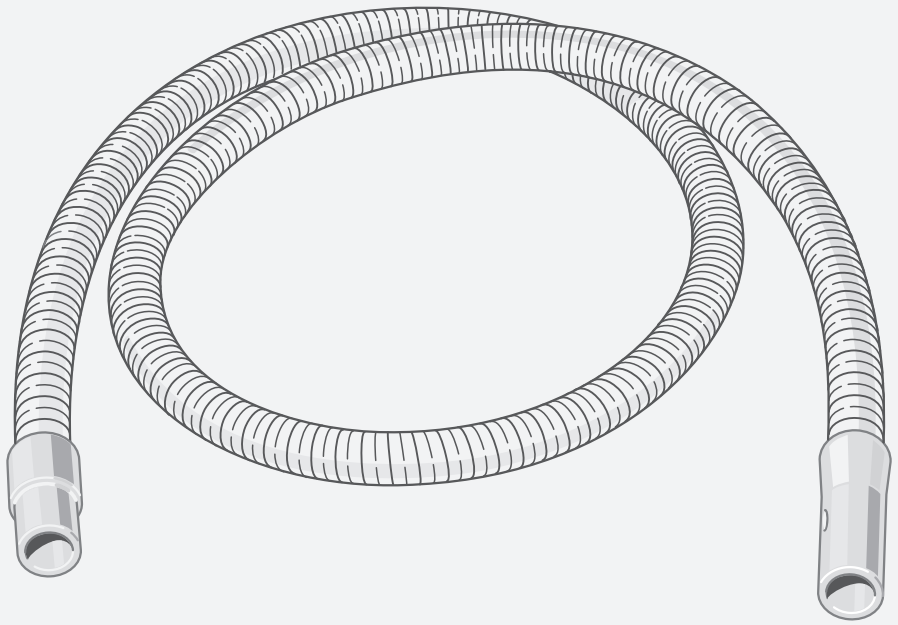
OPERATING INSTRUCTIONS

MEDAP
CONNECTION TUBE ANAESTHETIC GAS SCAVENGING SYSTEMS

MEDAP



GA 5752 4411 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 2022-08

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 in the operating instructions.
- Store these operating instructions in a location near the product.

1.1.2 Symbols

1.1.2.1 Cross-references

References to other pages in these operating instructions are identified with a double arrow symbol „⏩“.

1.1.2.2 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.

1.1.3 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 Design for other 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: Design for other notes

1.1.4 Explanation of pictograms, symbols and codes

Symbols are attached to products, type plates and packaging.

Symbols	Identification
	This product complies with the relevant requirements of the EU regulations.
	Follow operating instructions
	Manufacturer
	Country of manufacture: Germany Date of manufacture
	Article number
	Unique Device Identifier of a medical device
	Medical device
	Batch code
	Fragile, handle with care
	Keep dry
	Temperature limit

Symbols	Identification
	Humidity limitation
	Atmospheric pressure limitation

UDI-Code

(01)	UDI-DI: Identification of the manufacturer and the device
(10)	Batch code
(11)	Date of manufacture

Tab. 3: Pictograms, symbols, codes

1.2 Disposal

1.2.1 General

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

1.2.2 Packing

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

1.2.3 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.

1.3 Basic requirements

1.3.1 Use in accordance with the intended purpose

The product bears the CE marking CE in accordance with the European Regulation for Medical Devices (MDR) No. 2017/745.

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.

1.3.2 Intended purpose

Name:	Connection tubes anaesthetic gas scavenging systems
Main function:	Removal of anaesthetic gases
Intended purpose:	The connection tube anaesthetic gas scavenging systems removes no longer required anaesthetic gases from the operating room.
Intended Users / User profile:	Doctor, medically trained staff
Intended Patient population:	Patients of all ages
Medical condition to be diagnosed, treated or monitored:	The connection tube anaesthetic gas scavenging system connects the expiration outlet of an anaesthetic machine with a connection plug for the anaesthetic gas scavenging system which, in turn is plugged into the terminal unit for the anaesthetic gas scavenging system (AGSS) of a central gas supply. A distinction is made between the two versions • Connection tube anaesthetic gas scavenging system with shunt air opening at the patient side connection • Connection tube anaesthetic gas scavenging system without shunt air opening at the patient side connection
Application organ:	Lung
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.
Criteria for patient selection:	None
Indication:	Removal of anaesthetic gases
Medical contraindications:	The connection tubes anaesthetic gas scavenging systems may not be used • For liquids
Other contra-indications:	The connection tubes anaesthetic gas scavenging systems may not be used: • Outside the medical sector
Warnings:	None
The product is:	Not active
Sterility/specific microbial status:	No 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.

1.3.3 Versions

These operating instructions apply to the versions listed below.

Connection ASS NGA with shunt air opening, 3 m	REF HM57508095
Connection ASS NGA with shunt air opening, 5 m	REF HM57508096
Connection ASS NGA with shunt air opening, 7 m	REF HM57524448
Connection ASS NGA without shunt air opening, 3 m	REF HM57521281
Connection ASS NGA without shunt air opening, 5 m	REF HM57521282

1.3.4 Function

The connection tubes anaesthetic gas scavenging systems is for removal of anaesthetic gases from anaesthesia equipment in operating rooms. The anaesthetic gases coming from the anaesthetic machine are conducted through the connection tubes of the anaesthetic gas scavenging systems to the connector for anaesthetic gas scavenging systems. The connector for anaesthetic gas scavenging systems is plugged into the terminal unit for anaesthetic gas scavenging systems of the central gas supply system. The anaesthetic gases are extracted via a Venturi principle through the terminal unit for anaesthetic gas scavenging systems and conducted out of the operating room.

2 Safety notes

2.1 Principal safety notes

DANGER!

Danger to life!

Hazard resulting from incorrect handling.

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

DANGER!

Risk of suffocation!

If the connection tube **without** shunt air opening is used in connection with anaesthetic machines according to older standards, the breathing air is extracted by means of vacuum by the anaesthetic gas scavenging system.

When using older anaesthetic machines, no vacuum may be permitted to form at the expiration outlet.

A flow rate of a maximum of 50 l/min must be ensured.

In conjunction with older anaesthetic machines only use connection tubes **with** a shunt air opening at the patient-side connector.

DANGER!

Risk of suffocation!

If the connection tube with shunt air opening is used in connection **with** anaesthetic machines according to the current standard, the required vacuum is not reached at the expiration outlet.

There must be sufficient vacuum on the expiration outlet ensuring a flow rate of 50 l/min, at a resistance of 1 kPa in the anaesthetic machine.

In conjunction with current anaesthetic machines, only use connection tubes **without** shunt air openings.

WARNING!

Tube is not connected!

Ensure correct seat of the connection tube at the anaesthetic machine and connector.

WARNING!

Risk of injury!

Worn or damaged products can cause injuries.

Use only products which are in perfect condition.

DANGER!

Defective device!

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

Only use original accessories or spare parts.

WARNING!

Infection hazard!

Contaminated components may endanger the health of the staff and the patients.

Ensure the product is prepared as per hygiene standards before using it for the first time.

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

3 Operation

3.1 Patient side connection

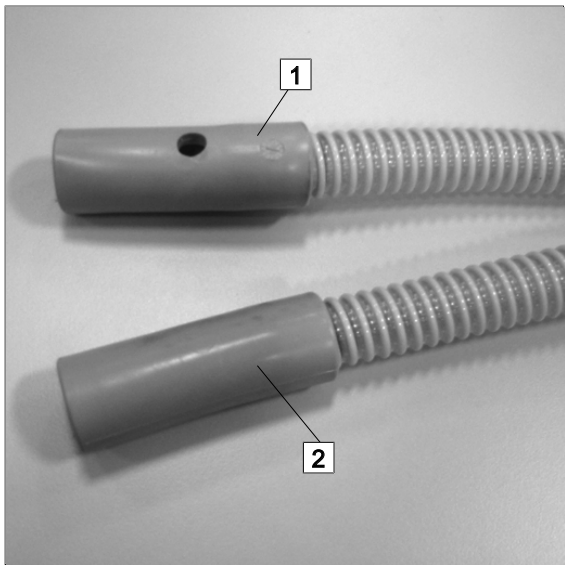

Fig. 1: Patient side connection

Connect the connection tube at the patient side

☒ Connect the patient side connection with shunt air opening (1) or the patient side connection without shunt air opening (2) to the expiration outlet according to the type of connection tube.

3.2 Wall connection side connection

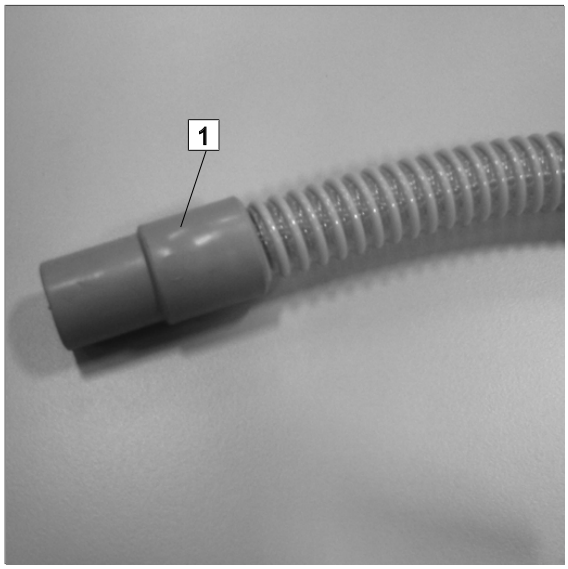

Fig. 2: Wall connection side connection

Connect the connection tube at the wall side

☒ Connect the wall side connection (1) at the connector AGSS-C, AGSS-E, AGSS EN Type 1L or AGSS-EN Type 1H.

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 the valid hospital hygiene rules.

WARNING!

Infection hazard!

Product may be contaminated.

Always wear gloves for cleaning and disinfection.

WARNING!

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.

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. Do not sterilise the product using live steam.

CAUTION!

Property damage!

Using non-colour-fast drapes can cause discolouration of surfaces.

Always 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 tensides and phosphates as the active cleaning agents.

In the event of heavily contaminated surfaces, use concentrated multi-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 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.

DANGER!

Risk of injury!

Disinfectants may contain substances hazardous to health, which may cause injuries on contact with skin and eyes. Protect your skin and eyes, and strictly follow hygiene guidelines when working with disinfectants. Follow the instructions of the disinfectant manufacturer and the hygiene specialist.

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
- Quarternary 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 Period tests

Observe the country specific requirements regarding period tests.

5.3 Repairs

The following may require repairs from the manufacturer or an authorized service partner:

- The performance has significantly decreased.
- Abnormal noises occur.

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

Make a note of the deficiencies and the REF number on the data plate and inform the responsible ATMOS Service.

Observe the information in chapter 5.5 on page 16.

5.4 Service hotline:

+49 7653 689-0

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 and approved accessories

6.1 General

Classification as per Annex IX of the 2017/745/EEC Directive	Class I

6.2 Ambient conditions

Ambient conditions Shipping / storage	
• Temperature	-15...+50 °C
• Humidity without condensation	10...95 %
• Atmospheric pressure	700...1060 hPa
Ambient conditions	
• Temperature	+10...+40 °C
• Humidity without condensation	30...75 %
• Atmospheric pressure	700...1060 hPa
CE mark	CE

6.3 Approved accessories

HM57508097	Gas probe NGA_C, according to MEDAP factory standard
HM57508098	Gas probe NGA_E, according to DRÄGER factory standard
HM57525084	Gas probe NGA_EN, Type 1L Standard Type 1L

Tab. 5: Approved accessories

Notes

Notes

MEDAP

Manufacturer:

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