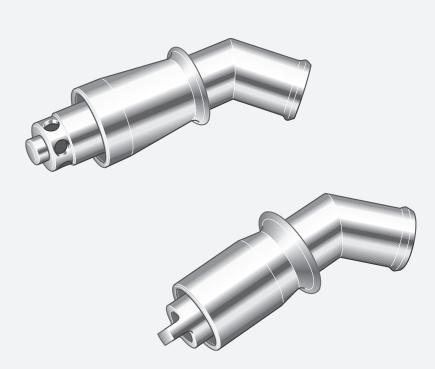
# **OPERATING INSTRUCTIONS**

MEDAP
CONNECTOR FOR ANAESTHETIC GAS
SCAVENGING SYSTEMS

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.

V11 2022-08





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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 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 " $\boxtimes$ " symbol identifies an action taken by the user while the " $\checkmark$ " symbol identifies the reaction that this will induce in the system.

#### **Example:**

✓ Lamp lights up.

#### 1.1.3 Definitions

### 1.1.3.1 Design of safety notes

Pictogram	Descriptor	Text
<u> </u>	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.
<u> </u>	WARNING! Indicates a potential risk to persons or property which may result in health hazard or grave property damage.	
<u> </u>	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	Reference to
i	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 the 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.
[i	Follow operating instructions
	Manufacturer
) DE	Country of manufacture: Germany Date of manufacture
REF	Article number
UDI	Unique Device Identifier of a medical device
MD	Medical device
LOT	Batch code
Ţ	Fragile, handle with care
**	Keep dry
1	Temperature limit
<u>%</u>	Humidity limitation



Symbols	Identification
( <del>+</del> )•( <del>+</del> )	Atmospheric pressure limitation

### **UDI-Code**

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

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

This device bears the CE marking CE in accordance with the European Medical Device Regulation (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: Connector for anaesthetic gas scavenging systems

Main function: Connector for removal of anaesthetic gases

Intended purpose: The connector for 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 conditions to be diagnosed, treated or

monitored:

The connector for anaesthetic gas scavenging systems connects the wall side tube connector of the connection tube and the terminal unit for anaesthetic gas aspiration, also called anaesthetic gas scavenging system.

A distinction is made between the two versions:

Connector AGSS-C (REF HM57508097) for connection to terminal units according to MEDAP standard

Connector AGSS-E (REF HM57508098) for connection to termi-

nal units according to Dräger standard

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 introduced staff.

Patient selection criteria: None

Indications: The connector for anaesthetic gas scavenging systems removes no

longer required anaesthetic gases from the operating room.

Medical contra-indications: The connectors for anaesthetic gas scavenging systems may not

be used:

· For liquids

Other contra-indications: Outside the medical sector

Warnings: No warnings

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.

Gas probe AGSS-C, according to MEDAP factory standard REF HM57508097

Gas probe AGSS-C, according to DRÄGER factory standard REF HM57508098



# 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.



#### **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 Gas probe AGSS-C

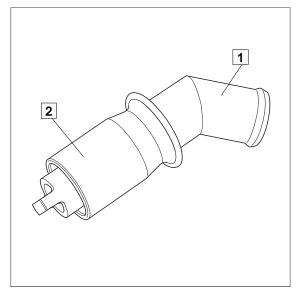


Fig. 1: Gas probe AGSS-C

### Connect the connection tube

- ☑ Plug connection tube on tube connector (1).
- ☑ Plug the connector AGSS-C (2) into the terminal unit AGSS-C.

## 3.2 Gas probe AGSS-E

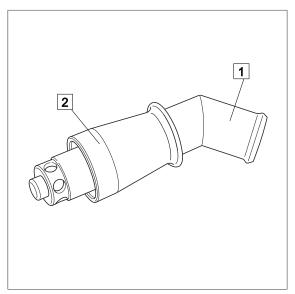


Fig. 2: Gas probe AGSS-E

### Connect the connection tube

- ☑ Plug connection tube on tube connector (1).
- ☑ Plug the connector AGSS-E (2) into the terminal unit AGSS-E.



# 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!

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

- · Products containing alcohol (e. g. hand disinfectants)
- Halogenides (e. g. fluorites, 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 drapes can cause discolouration of surfaces.

Always use colour-fast drapes.

### 4.2 Cleaning

#### 4.2.1 General



#### **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.



#### **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 highpressure cleaning unit!

### 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 imiodocarbonyl 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.
- ${\color{orange}oxed{\boxtimes}}$  Ensure that the product is free of disinfectant residue.
- ☑ Perform visual and functional inspections.



## 5 Maintenance

#### 5.1 General

Maintenance, repairs and period 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 Sending in the device [ >> 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.



#### Technical specifications and approved accessories 6

#### 6.1 General

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

#### 6.2 **Ambient conditions**

Ambient conditions		
Shipping / storage		
Temperature	-15+50 °C	
Humidity without condensation	1095 %	
Atmospheric pressure	7001060 hPa	
Ambient conditions		
Temperature	+10+40 °C	
Humidity without condensation	3075 %	
Atmospheric pressure	7001060 hPa	
CE mark	( (	

#### Approved accessories 6.3

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

Tab. 5: Accessories

## Notes

## Notes



## ■Manufacturer:

www.atmosmed.com

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