**OPERATING INSTRUCTIONS**

MEDAP
HOLDER FOR SEPTIC FLUID JARS

MEDAP
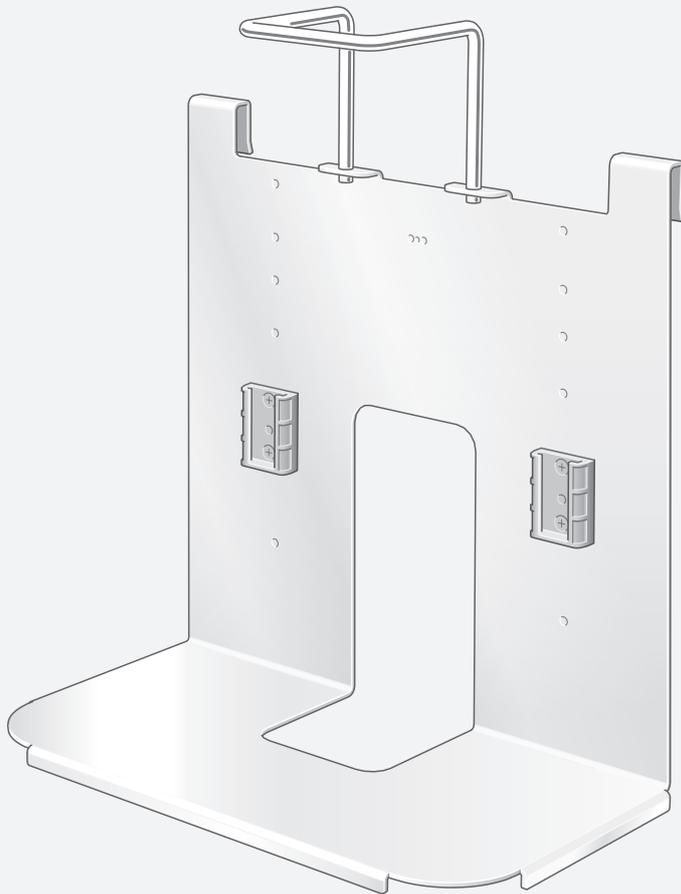
Subject to technical modification!

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

V06 2017-07

CE

Table of contents

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 Environmental protection

1.2.1 Packing

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

1.2.3 Disposal

⚠️ **WARNING!**

Infection hazard!

Follow hygiene regulations when disposing of fluids such as blood and secretion as well as parts contaminated by it.

1.3 How to use these operating instructions

1.3.1 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.

1.3.2 Symbols

1.3.2.1 Cross-references

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

1.3.2.2 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.

1.3.3 Definitions

1.3.3.1 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

1.3.3.2 Design of other notes

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.

Tab. 2:   Design of other notes

1.3.4 Symbols used

Symbols	Identification
CE	Labelling for Class I products, developed and marketed in compliance with Medical Device Directive 93/42/EEC.
♳ 07 PSU	Material designation for the plastic PSU (polysulfone).
📖	Labelling in compliance with the IEC 60601-1 standard. Symbol for "Follow Operating Instructions".
☂	Packaging label. Symbol for "Keep dry".

Symbols	Identification
	Packaging label. Symbol for "Fragile! Handle with care".
	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".
REF	Labelling in compliance with the ISO 15223-1 standard. Symbol for "Product number".
	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 IEC 60601-1 standard. Symbol for "Follow Operating Instructions".
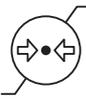
Tab. 3:   Symbols

1.4 Overview

1.4.1 Overview of holder for septic fluid jar
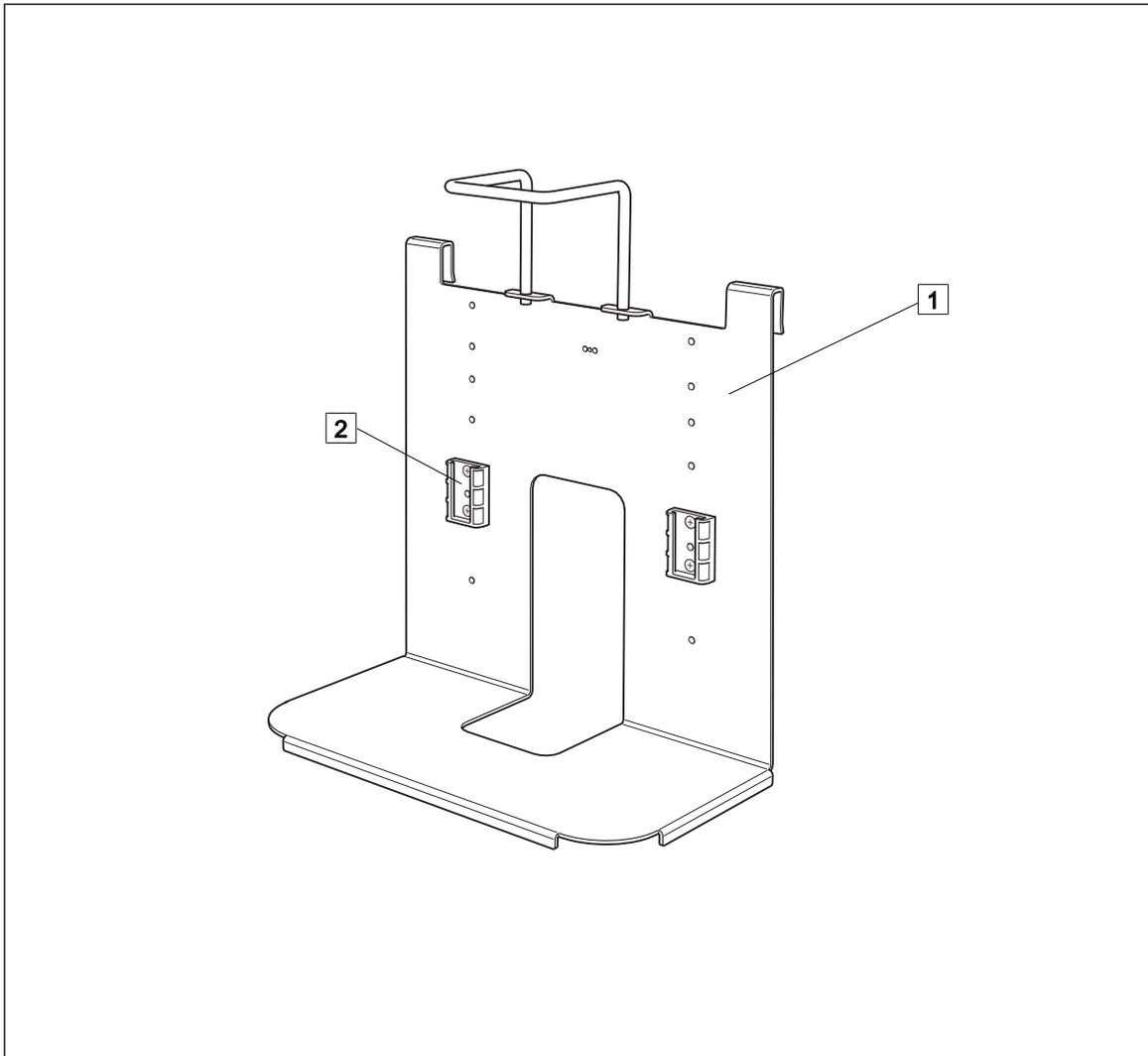
Fig. 1: Overview of holder for septic fluid jar

1 Aspiration set carrier frame solo (REF 5752 5256)
2 Equipment carrier

1.5 Basic requirements

1.5.1 Use in accordance with the intended purpose

This product is a medical device according to the Medical Device Directive 93/42/EEC. This product is to be used exclusively for human medicine.

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 the 93/42/EU 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 is certified by compliance with harmonised standards such as IEC 60601-1 and related standards and the respective special sections.

1.5.3 **Intended purpose**

Name:	Holder for septic fluid jar
Main function:	The holder for septic fluid jars is used for fixation of a vacuum controller and for firm fastening of up to two septic fluid jars with equipment mount each up to a volume of two litres.
Medical indications / application:	For all applications which require aspiration
Specification of the main function:	The holder for the septic fluid jar has two equipment carriers for septic fluid jars with equipment mount 30 x 5 mm. As an accessory equipment carriers for septic fluid jars with equipment mount 45 x 5 mm are available. Depending on the height of the septic fluid jars the equipment carriers can be adjusted in height. Septic fluid jars with equipment mount and a volume of up to two litres can be attached to the holder for septic fluid jar. The holder for the septic fluid jar has special holes for fixation of a vacuum controller screw connection from the MEDAP product range. The holder for the septic fluid jar has a special chamfer for fixation to an equipment rail with a thickness of 10 mm.
User profile:	Doctor, medically trained staff
Patient groups:	Patients of all ages
Application organ:	Natural and artificial body orifices
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 introduced staff.
Contraindications:	The holder for the septic fluid jar may not be used for the following purposes:

- Outside the medical sector
- In MR areas
- In the home care sector
- Being operated directly by the patient
- With septic fluid jars which do not have an equipment mount either 30 x 5 mm or 45 x 5 mm
- With septic fluid jars with a volume of more than 2 litres
- With vacuum controllers which do not have the appropriate screw connection

The product is:	Not active
Sterility:	No sterile product

| Single-use product / reprocessing: | For information on reprocessing and cleaning please see the operating instructions. |

1.5.4   Interface description

1.5.4.1   Septic fluid jar

The septic fluid jar (REF 5752 5431) can be used with the suction set carrier frame solo.

1.5.4.2   Equipment mount

The suction set carrier frame solo (REF 5752 5256) is equipped with an adjustable fastening set. Septic fluid jars with equipment mounts 30 x 5 mm according to DIN EN ISO 19054 can be safely mounted to the carrier frame. Septic fluid jars or holders for septic fluid jar with an equipment mount of 45 x 5 mm may be safely mounted to the carrier frame using the fastening set (REF 5752 5288). In addition the suction set carrier frame solo has an interface for screwing in vacuum controllers FINA VAC / AIR, S VAC and S AIR.

2 Safety notes

	WARNING!
⚠	Risk of injury!
	ATMOS products may be used only if they are in perfect working order.
	Check to ensure that the ATMOS product is fully functional and in good working order prior to use.

3 Initial operation

3.1 General

⚠️ **DANGER!**

Product testing!

Only product parts in perfect condition will ensure the proper functionality.

The product parts will thus have to be carefully inspected before putting the unit into service.

⚠️ **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.

☒ Check, whether all product parts are undamaged. Do not use damaged parts.

☒ Check whether the product has been properly cleaned and that there are no residues or soiling.

3.2 Attaching the aspiration set carrier frame solo (REF 5752 5256)

The aspiration set carrier frame solo is equipped with two adjustable equipment carriers. Septic fluid jars with equipment mounts may be safely mounted to the aspiration set carrier frame solo.


Fig. 2: Aspiration set carrier frame solo
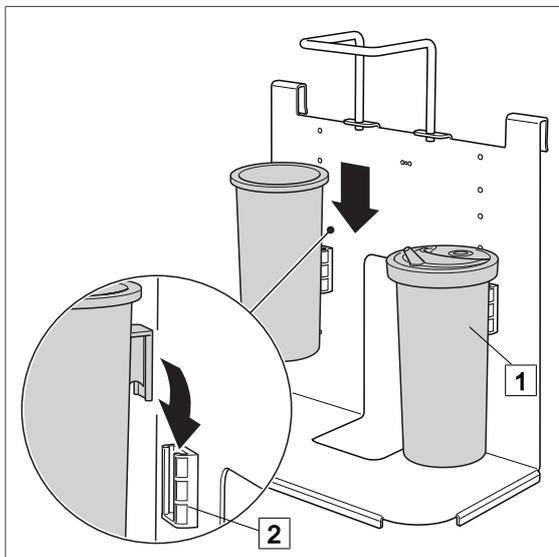
Fitting suction sets

☒ Insert aspirations sets (1) into the equipment carrier (2) of the carrier frame from above.

Fig. 3: Aspiration set carrier frame solo
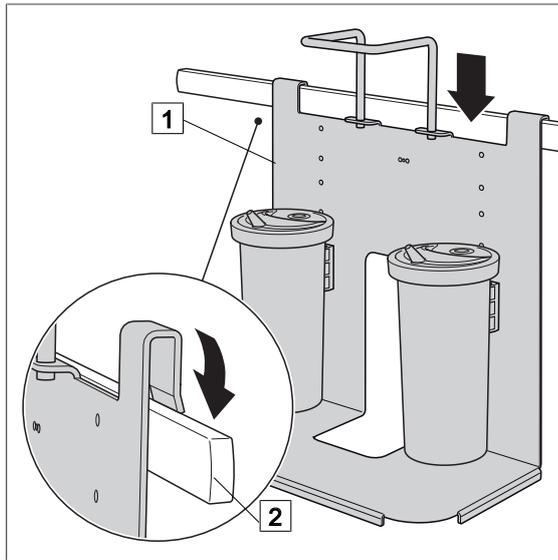
Attaching the carrier frame to the equipment rail

☒ Attach the carrier frame (1) from above onto the equipment rail (2).

Offsetting the equipment carrier

The already screw-fitted equipment carriers on the aspiration set carrier frame solo can be offset for the use of larger septic fluid jars.

Fig. 4: Offsetting the equipment carrier
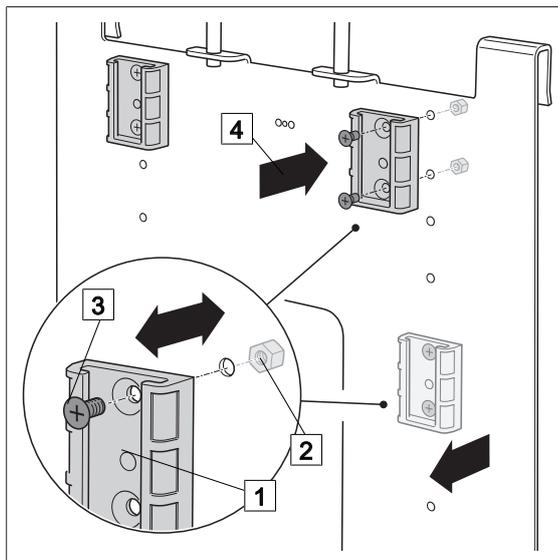
Offsetting the equipment carrier

☒ Hold the equipment carrier (1) and remove the acorn nut (2) from the countersunk screw.

☒ Remove the countersunk screw (3) from the drilled hole.

☒ Offset the equipment carrier upwards (4).

✓ The drilled holes of the equipment carrier are positioned over the drilled holes of the carrier frame.

☒ Insert the countersunk screw into the drilled holes and screw the acorn nut onto the countersunk screw.

Attaching the fastening set (REF 5752 5288) to the carrier frame

The fastening set (REF 5752 5288) is not supplied and must be ordered separately. The fastening set is used to mount the septic fluid jars or holders for septic fluid jar with an equipment mount of 45 x 5 mm.


Fig. 5: Attaching the fastening set
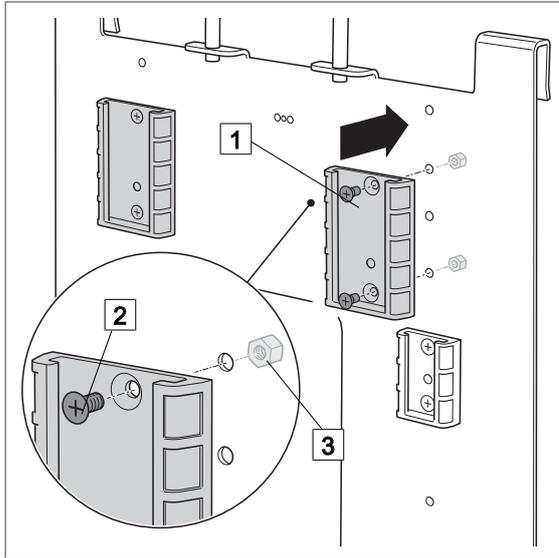
Attaching the fastening set to the carrier frame

☒ Fitting the equipment carrier (1) to the carrier frame.

✓ The drilled holes of the equipment carrier are positioned over the drilled holes of the carrier frame.

☒ Insert the countersunk screw into the drilled holes and screw the acorn nut onto the countersunk screw.

4 Cleaning and disinfection

4.1 General

The product must be cleaned and wipe or spray 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.
ℹ	**NOTE** The product can be reused after cleaning and disinfection.

4.2 Cleaning

4.2.1 General

NOTE

In case the product is very dirty, carry out prior cleaning procedure before disinfecting the product.

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 high-pressure 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 or spray disinfect the product after every cleaning.

4.3 Disinfection

4.3.1 General

WARNING!

Risk of injury!

Disinfectants may contain substances hazardous to health, which may cause injuries on contact with skin and eyes.

Protect the skin and eyes and observe the hygiene rules when working with disinfectants.

⚠️ **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.

ℹ️ NOTE

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

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

☒ After each cleaning process, wipe or spray disinfect the product in accordance with the instructions of the disinfectant manufacturer.

☒ Ensure that the product is free of disinfectant residue.

☒ Perform visual and functional inspections.

4.4　Special safety notes

DANGER!

Material damage!

Various components in the product are made of plastic materials. Solvents and some disinfectants and some cleaning agents can soften plastic or cause tension fissures.

Never use detergents that contain alcohol. Observe cleaning and disinfection standards.

CAUTION!

Property damage!

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

Always use colour-fast drapes.

5 Maintenance

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 authorized ATMOS service partner. This ensures that repairs and testing are carried out professionally, original spare parts are used and warranty claims remain unaffected.

5.1 Repairs

The following may require repairs from the manufacturer or an authorized 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 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 19].

5.2 Service hotline:

+49 7653 689-0

5.3 Type plate position
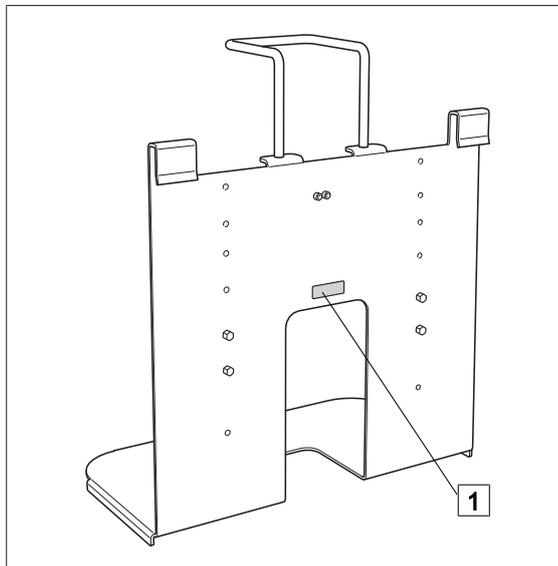
Position of the type plate (1).

Fig. 6: Type plate position

5.4 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 Classification as per Annex IX of the 93/42/EEC Directive

Aspiration set carrier frame solo (REF 5752 5256)	Class I

6.2 Ambient conditions

Temperature	-15 °C to +50 °C (shipping)
	+5 °C to +35 °C (operation)
Relative humidity	10 % to 95 % (shipping)
	30 % to 75 % (operation)
Atmospheric pressure	700 hPa to 1060 hPa (shipping)
	700 hPa to 1060 hPa (operation)

6.3 Dimensions and weights

Product name	REF	Dimensions in mm (L x W x H)	Weight
Aspiration set carrier frame solo	5752 5256	approximately 210 x 390 x 473	1.61 kg

Tab. 5: Dimensions and weights

7 Approved accessories

7.1 Accessories

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

Fastening set for aspiration set carrier frame solo	5752 5288

Tab. 6:   Accessories

Notes

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