ATMOS MedizinTechnik

Instructions for Use

Connection hose

English



GA1GB.230501.0

2026-04 Index 01

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1 Introduction

1.1 Notes on Instructions for Use



These Instructions for Use are part of the products listed (see chapter '1.2 These Instructions for Use are valid for the following products:' on page 3) and remain valid until they are replaced by a later revision of the Instructions for Use.

These Instructions for Use are designed for training and instructing new operating personnel in the use of the system and also for use as a reference manual. This document may be reprinted, either in part or in whole, only with written permission of ATMOS.

These Instructions for Use must always be kept available near the product.



Care, periodic tests, regular cleaning, and proper application are essential. They ensure the operational safety and usability of the product.

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Read chapter '2 Notes for your safety' on page 7 before using the product for the first time. This will help you to avoid potentially dangerous situations.

The products bear the CE marking CE in accordance with the European Medical Device Regulation (MDR) 2017/745.

The Declarations of Conformity and our General Terms and Conditions can be viewed on our website at www.atmosmed.com.

The quality management system applied at ATMOS has been certified according to the international standard EN ISO 13485.

1.2 These Instructions for Use are valid for the following products:

Name	REF
Connection hose-D (orange-standard), 5 m	UT 1187-500
Connection hose-A (standard-orange), 5 m	UT 1188-500
Connection hose-A (orange-orange), 3 m	UT 1277-300
Connection hose-A (orange-orange), 5 m	UT 1277-500
Connection hose-D (orange-orange), 3 m	UT 1276-300
Connection hose-D (orange-orange), 5 m	UT 1276-500
Connection hose-D (standard-standard), 3 m	UT 1321-300
Connection hose-D (standard-standard), 5 m	UT 1321-500

1.3 Explanation of pictograms and symbols

In the Instructions for Use

⚠ DANGER Warning of a hazard that will result in death or serious injury. Observe the necessary measures.
⚠ WARNING Warning of a hazard that could result in death or serious injury. Observe the necessary measures.
⚠ CAUTION Warning of a hazard that may result in minor or moderate injury. Observe the necessary measures.
NOTICE Indicates a hazard that may result in damage to the product or other property if not avoided. Observe the necessary measures.
⚠ Warning of a hazard that could cause serious injury or death.

On device and type plate

	Follow instructions for use (blue)
	Consult instructions for use
	Warning; pay special attention
	This device complies with the relevant requirements of EU regulations.
	Manufacturer
	Date of manufacture Country of manufacture
REF	Reference number
UDI	Unique Device Identifier of a medical device
MD	Medical device
LOT	Batch code
	Keep dry

	Keep away from sunlight
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

UDI application identifier

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

1.4 Intended purpose

Product name:	• Connection hose-D (orange-standard), 5 m • Connection hose-A (standard-orange), 5 m • Connection hose-A (orange-orange), 3 m • Connection hose-A (orange-orange), 5 m • Connection hose-D (orange-orange), 3 m • Connection hose-D (orange-orange), 5 m • Connection hose-D (standard-standard), 3 m • Connection hose-D (standard-standard), 5 m
Main functions:	The connection hose is used to transmit the pressure from a pneumatic tourniquet to the cuff.
Intended use:	The connection hose is intended to be used to connect tourniquet cuffs to tourniquets to create an artificial blood arrest in the upper or lower extremities in order to achieve a relatively bloodless surgical site.
Intended users / user profile:	Trained healthcare professionals (e.g. operating theatre assistants). Users must not be hard of hearing or deaf and must have adequate eyesight.
User training:	The connection hose may only be used by persons who have received medical training.
Intended patient target groups:	Patients of all age groups with and without restrictions. There are no restrictions apart from the contraindications. The typical patient group consists of patients undergoing surgery on the extremity.
Medical conditions to be diagnosed, treated or monitored:	Not applicable.
Organ(s) applied to:	Not applicable.

Duration of application:	For short-term use on the patient.
Use environment:	The connection hose is used in the surgical environment of a professional healthcare facility. The connection hose is used in surgery/orthopaedics of the extremities in the fields of vascular surgery, trauma surgery, neurosurgery, and plastic surgery.
Patient selection criteria:	The patient group consists of patients undergoing surgery on one or more extremities.
Indications:	Patients who benefit from tourniquet application.
Medical contra--indications:	Not applicable.
Other contra-indications:	• No application in emergency and rescue situations • No use in the homecare area that is not supervised by healthcare professionals • No use in non-medical areas
Undesirable side-effects:	Not applicable.
Warnings:	See chapter '2 Notes for your safety' on page 7 in the valid instructions for use of the product.
The product is:	not active
Sterility / specific microbial state:	Non-sterile product
Single-use device / reprocessing:	• The connection hose is intended for multiple use. • For information on reprocessing, cleaning and disinfection, please see chapter '4 Reprocessing' on page 10.

1.5 Function

The connection hose is intended to be used to connect tourniquet cuffs to tourniquet devices. A connection hose has two connectors: one for connecting to the cuff, and one for connecting to the device. The connection hose differs with regard to its length, the possibility of sterilisation (connection hose with protection cap on the connector), and its combination of connectors that can be selected based on the tourniquet and the cuff (see chapter '3.2 Using the connection hose' on page 9).

1.6 Transport and storage

Transport the product only in packaging that offers sufficient protection.

If you notice transport damage:

1. Document and report the transport damage.
2. Fill in the form QD 434 'Product Complaint / Return Shipment'.
3. Send the product to ATMOS.

Environmental conditions for transport and storage: see chapter '7 Technical Data' on page 17.

2 Notes for your safety

The safety and performance of the connection hose comply with the relevant General Safety and Performance Requirements in accordance with Regulation (EU) 2017/745 on medical devices (MDR) as well as with the generally accepted state of the art.

2.1 General safety instructions

Report any serious incidents that occur in connection with this product to the manufacturer and your national competent authority.

Familiarise yourself with the product early on so that you can use it at any time.

Never use the product if it shows any obvious safety defects.

Only a fully functional product meets the safety requirements of users, patients, and third parties. Therefore, observe the following instructions on your product.

Please read and pay attention to the safety instructions carefully prior to using the product.

2.2 Danger for users, patients, and third parties

⚠ DANGER

Your patient can be severely injured!

- Read and follow the safety instructions before using the product.
- A lack of expertise regarding the product or procedure can result in the patient's death.
- Ensure that the connection hose is connected only by qualified medical staff with sufficient knowledge.
- Monitor the connection hose and tourniquet while blood flow is occluded.

⚠ WARNING

Ensure that the product is functional and ready for use at all times!

Your patient can be severely injured.

- Ensure that the product is always ready for use.
- Always carry out a function check before each use.
- ATMOS recommends always keeping a spare connection hose to hand.

⚠ WARNING

Risk of injury due to tripping!

Improper routing of a connected connection hose may create a tripping hazard.

⚠ CAUTION

Risk of injury from infection, contamination, or material fatigue!

- Handle the reprocessed connection hose carefully to avoid contamination.
- Check the connection hose for damage before each use.
- Do not use a connection hose if it has any damaged components.

⚠ CAUTION

An improperly routed connection hose can impair functionality. Increased risk of infection due to extended surgery time.

Ensure that the connection hose is not kinked or clamped.

⚠ CAUTION

Incompatible accessories or hose combinations result in loss of function. Increased risk of infection due to extended surgery time.

Use only accessories that are listed in the accessory list.

Do not use hose combinations consisting of multiple hoses or connectors.

NOTICE

Risk of injury

The use of hose combinations or systems not approved by ATMOS endangers the safety of the patient and/or the user and the proper functioning of the tourniquet.

NOTICE

Frequent cleaning, disinfection, sterilisation, and prolonged storage times reduce the ageing resistance of the connection hose. Damage to the product due to improper handling!

The product may become damaged.

- Reprocess the product in accordance with the instructions (see chapter ‘4 Reprocessing’ on page 10).
- Always carry out a function check before each use.
- ATMOS recommends always keeping a spare connection hose to hand.

3 Application

3.1 Visual and functional inspection before use

⚠ WARNING

External influences may damage the connection hose, which may lead to loss of function during use. Increased risk of infection due to extended surgery time!

Your patient can be injured.

- Check the product for proper condition and functionality before each use.

Before each use, perform a visual and functional inspection of the connection hose:

1. Ensure that the connection hose has no damaged areas.
2. Do not use a damaged or defective connection hose any longer.
3. Perform a functional test using the tourniquet. Observe the tourniquet's Instructions for Use.

3.2 Using the connection hose



Once the tourniquet is ready for operation, the connection hose may be connected to both the tourniquet and the cuff.

☞ Observe the tourniquet's Instructions for Use.

Connect the male end of the hose to the tourniquet and the female end of the hose to the cuff. Ensure that you hear the connection hose click into place when plugging it in.

To disconnect the connection, detach the male hose end (see chapter '7.1 Illustration of connection hose' on page 18).

Art. no.	Sterilisable	Length	Weight	Hose colour	Material	Connector device-side (male)	Connector cuff-side (female)
UT 1187-500	no	5 m	0.44 kg	white	silicone	orange	standard
UT 1188-500	yes	5 m	0.44 kg	white	silicone	standard	orange
UT 1277-300	yes	3 m	0.28 kg	white	silicone	orange	orange
UT 1277-500	yes	5 m	0.22 kg	white	silicone	orange	orange
UT 1276-300	no	3 m	0.19 kg	black	polyurethane	orange	orange
UT 1276-500	no	5 m	0.16 kg	black	polyurethane	orange	orange
UT 1321-300	no	3 m	0.10 kg	black	polyurethane	standard	standard
UT 1321-500	no	5 m	0.16 kg	black	polyurethane	standard	standard

4 Reprocessing

4.1 Safety instructions for reprocessing

4.1.1 General safety instructions

We recommend that you always document all maintenance work and part replacements in writing. Observe national legal regulations, national and international standards and guidelines, and adhere to your facility's hygiene regulations for reprocessing.

It is the responsibility of the user to ensure that the required results of cleaning and disinfection are achieved. Validation and routine monitoring of the procedure will generally be necessary.

Reprocessing may be carried out only by persons who have the appropriate expertise. To carry out these measures, the person must have the necessary equipment.

4.1.2 Material compatibility

NOTICE

Unsuitable cleaning agents and disinfectants.

The product may become damaged.

Do not use any:

- cleaning agents containing solvent-based components.
- cleaning agents with a pH value >10.5.
- disinfectants that contain hydrogen peroxide.
- disinfectants containing organic or inorganic acids or bases, as these may cause corrosion damage.
- disinfectants containing chloramines or phenol derivatives, as these may cause stress cracks in the plastic materials used.

NOTICE

Unsuitable cleaning agents and disinfectants.

The product may become damaged.

Follow the manufacturers' instructions for cleaning agents and disinfectants regarding material compatibility, concentration, and contact time.

Use only cleaning agents and disinfectants that are suitable for the reprocessing of medical devices. Use only disinfectants whose effectiveness has been confirmed by recognised test methods (e.g., according to VAH, DGHM, or RKI listings).

Use only suitable cleaning agents (neutral, enzymatic, or mildly alkaline cleaning agents up to pH 10.5).

The cleaning procedure for surface disinfection as prescribed by the respective facility applies to the non-sterilisable connection hose.

4.2 Procedure

	Instructions
Warnings	
⚠ WARNING	**Danger for users, patients, and third parties** • The connection hose must be reprocessed before first use and after each use. • Use only a clinically reprocessed connection hose. • Ensure that a validated reprocessing procedure is in place.
⚠ WARNING	**Risk of infection due to unsuitable aids** Pathogens may be transmitted. • Wear disposable gloves during all cleaning and disinfection procedures. • Use only aids that can be suitably reprocessed or disposable products.
⚠ WARNING	**Risk of infection due to unsuitable reprocessing** Pathogens may be transmitted. • Ensure that all areas of the product are accessible during reprocessing. • Use only suitable load carriers for automated reprocessing. • Always use demineralised water for the final rinse. • Effective cleaning and disinfection are prerequisites for successful sterilisation.
NOTICE	**Prevent product damage** • Frequent cleaning, disinfection, sterilisation, and prolonged storage times reduce the ageing resistance of the sterilisable connection hose. • Unsuitable aids: Use only lint-free, soft cloths.

4.2.1 Procedure for the non-sterilisable connection hose

Valid for the following article numbers: UT 1187-500; UT 1276-300; UT 1276-500; UT 1321-300; UT 1321-500

	Instructions
Manual cleaning ***NOTICE***	Ensure that no water or other liquids enter the connection hose. 1. Clean the surfaces of the non-sterilisable connection hose evenly with a clean, lint-free cloth that is slightly damp (not wet) and moistened with warm water or a mild soap solution. 2. If visible contamination remains, repeat the cleaning process to avoid impairing the effectiveness of disinfection. 3. Allow the non-sterilisable connection hose to dry completely before disinfection.
	Instructions
Manual disinfection **⚠ WARNING**	1. Wipe evenly over the surfaces of the non-sterilisable connection hose with a damp (never wet), clean and lint-free cloth moistened with disinfectant. Ensure complete wetting to achieve effective disinfection. 2. Allow the disinfectant to act for the full contact time.
	Instructions
Drying	Allow the connection hose to air-dry or wipe it dry with a soft, lint-free cloth.
	Instructions
Maintenance, checks, and inspection	1. Verify successful reprocessing by performing a visual inspection. 2. If reprocessing was not successful, reprocess the product again. 3. If damaged: Do not use the connection hose any longer and dispose of it in accordance with local regulations.
	Instructions
Storage	Store the non-sterilisable connection hose in a clean environment.
	Instructions
Service life	Inspect the non-sterilisable connection hose for damage such as cracks, porous areas, and loose connectors. Frequent cleaning and disinfection reduce the ageing resistance of the connection hose. Over-concentrated cleaning agents may attack the material.

4.2.2 Procedure for the sterilisable connection hose

Valid for the following article numbers: UT 1188-500; UT 1277-300; UT 1277-500

	Instructions
Preparation before cleaning ⚠ WARNING	Ensure that each connector is closed with the protection cap so that no liquid can enter the connection hose. 1. Close the protection cap on the connector of the sterilisable connection hose. 2. For stubborn contamination: remove deposits with a soft cloth moistened with warm water or a mild soap solution.
	Instructions
Automated cleaning and disinfection	Automated reprocessing is intended exclusively for the sterilisable connection hose and must be carried out in a washer-disinfector compliant with DIN EN ISO 15883. The following parameters for automated cleaning and disinfection have been validated: • Secure the product on a suitable load carrier so that the cleaning agent reaches all surfaces. • Clean and disinfect using a suitable programme. **Automated cleaning:** • Pre-rinse: with cold water • Cleaning: 10 min, 60 °C with neodisher® MediClean forte (concentration: 0.65%) • Neutralisation: with neodisher® Z (concentration: 0.1%) • Intermediate rinse: with cold, demineralised water **Automated disinfection:** • Disinfection: 5 min, 93 °C with demineralised water
NOTICE	Ensure that no visible contamination remains. Repeat reprocessing if necessary.
	Instructions
Packaging	Pack the product. Use suitable sterile packaging for steam sterilisation (see DIN EN ISO 11607 / EN 868-2). ☞ Ensure that the sterilising agent reaches all surfaces.

	Instructions
Sterilisation	Sterilisation is intended exclusively for the sterilisable connection hose. Use a steam steriliser in accordance with DIN EN 13060 or DIN EN 285. The following cycle for steam sterilisation using a 3-pulse fractionated vacuum process has been validated: • Temperature and holding time: 134 °C for 8 minutes • Drying time: 15 minutes When using other temperatures, adjust the holding times accordingly.
	Instructions
Storage	Store the sterilisable connection hose in a dry place and protected from direct sunlight.
	Instructions
Service life	The sterilisable connection hose has a service life of 50 reprocessing cycles. Once the specified number of cycles has been exceeded, responsibility and liability for their functionality and condition rest with the operator.

5 Maintenance and repair

Damaged connection hose

- Replace the connection hose and dispose of the damaged one.

Repair

The product contains no parts that the user could repair themselves.

- Dispose of the defective connection hose.

6 Disposal

Packaging

Please recycle the product packaging.

ATMOS Connection Hose

The product does not contain any hazardous materials.

Clean and disinfect the product.

Dispose of the product professionally and in accordance with country-specific laws and regulations.

6.1 Expected service life

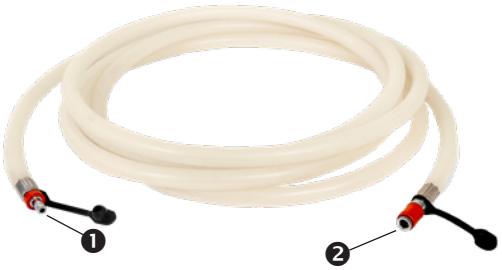
The ATMOS Connection Hose has an expected service life of 50 reprocessing cycles. Regular, thorough cleaning and disinfection of the connection hose according to the Instructions for Use are a prerequisite.

7 Technical Data

Connection to	• ATMOS Tourniquets elsa, heidi, sophie • Tourniquets from third-party suppliers • Cuffs with orange connector or standard connector
Dimensions	See table ‘3.2 Using the connection hose’ on page 9
Weight	See table ‘3.2 Using the connection hose’ on page 9
Material	See table ‘3.2 Using the connection hose’ on page 9
Colour	See table ‘3.2 Using the connection hose’ on page 9
Packaging unit	1 piece
Reuse	Reusable
Reprocessing	Wipe disinfection or steam sterilisation: see chapter ‘3.2 Using the connection hose’ on page 9
Risk classification	Class I according to Rule 1
CE marking	CE
Environmental conditions Transport/storage • Temperature range • Air humidity without condensation • Air pressure	 −30…+60 °C 5…95% 700…1060 hPa
Environmental conditions Operation • Temperature range • Air humidity without condensation • Air pressure	 +5…+40 °C 5…95% 700…1060 hPa
Reference number (REF)	UT 1276-300 UT 1276-500 UT 1321-300 UT 1321-500 UT 1187-500 UT 1188-500 UT 1277-300 UT 1277-500 UT 1278-500

7.1 Illustration of connection hose

Connection hose with orange connector (e.g., UT 1277-300)



Connection hose with standard connector (e.g., UT 1321-300)



❶ Male hose end
❷ Female hose end

8 Notes

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