ATMOS
MedizinTechnik

Instructions for Use

Tourniquet sophie

English



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1 Introduction

1.1 Notes on Instructions for Use



These Instructions for Use contain important information on how to operate your product safely, correctly, and effectively.

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 only be reprinted, either in part or in whole, 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.

Maintenance, repairs, and periodic tests may only be carried out by persons who have the appropriate technical knowledge and are familiar with the product. The person must have the necessary test equipment and original spare parts to carry out these measures.

§

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

The sophie tourniquet complies with all applicable requirements of Directive 2011/65/EU restricting the use of certain hazardous substances in electrical and electronic equipment ('RoHS').

The Declarations of Conformity and our General Standard Terms and Conditions can be obtained 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.

Prior to initial start-up, read chapter '2 Notes for your safety' on page 10 to avoid any potentially dangerous situations.

These Instructions for Use are valid for the following products:

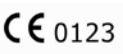
sophie, mein Tourniquet 2 channel (CGS)	REF UT 1380-S
sophie, mein Tourniquet 2 channel, printer (CGS)	REF UT 1380-SP

1.2 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.
ⓘ	Notice of potential material damage.
☞	Useful information on handling the device.
1.	Call for action. Proceed step by step.
»	Result of an action.
→	Move/plug in this direction.

On device, type plate, and packaging

	Follow instructions for use (blue)
	Consult instructions for use
	Warning; pay special attention
	This device complies with the relevant requirements of EU regulations.
	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
SN	Serial number
IPX1	Protection against vertically falling drops of water
	Type B applied part
	Professional disposal
	Do not reuse
	Protection class II device
	Potential equalisation
	Protective earth connection
AIR	Connection for compressed air (AIR)
	(On/Off) Standby
	This side up
	Fragile, handle with care
	Keep dry
	Keep away from sunlight
	Stacking limit by number: 5
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Do not use if the packaging is damaged

UDI application identifier

(01)	UDI-DI: Identification of the manufacturer and the device
(11)	Date of manufacture
(21)	Serial number

1.3 Intended purpose

1.3.1 sophie tourniquet

Product name:
- sophie, mein Tourniquet 2 channel (CGS)
- sophie, mein Tourniquet 2 channel, printer (CGS)

Main functions:
The tourniquets function by means of a pneumatic device in combination with a tourniquet cuff.

During surgical procedures on the extremities (limbs), the blood supply of the arteries and veins is blocked by compressing the respective arm or leg.

Intended use:
The intended use of the tourniquets in conjunction with tourniquet accessories is the temporary regulation of arterial blood flow in the upper and lower extremities, including complete blood arrest. The duration and amount of applied pressure are the sole responsibility of the physician according to current knowledge obtained from research and technology.

Intended users / user profile:
Trained healthcare professionals (e.g., operating theatre assistants (OTA) and anaesthetists).

Users must not be hard of hearing or deaf and must have adequate eyesight.

User training:
The tourniquets 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. The indications show examples of such patient groups.

Medical conditions to be diagnosed, treated or monitored:
Not applicable.

Use of the tourniquets is not dependent on a medical condition. Use of the tourniquets is defined by the indication.

Organ(s) applied to:
Upper and lower extremities

Duration of application:
For short-term use (< 30 days) on the patient

Use environment:	Tourniquets are used in the surgical environment of a professional healthcare facility. Tourniquets are used in surgery/orthopaedics of the extremities in the fields of vascular surgery, trauma surgery, neurosurgery, and plastic surgery. An additional application in anaesthesia is intravenous regional anaesthesia (IVRA).
Patient selection criteria:	The patient group consists of patients undergoing surgery on one or more extremities.
Indications:	Tourniquets are used for the following indications: • Fractures • Removal of metal or implants • Finger, knee, and elbow prostheses • Arthroscopy • Tendon correction • Carpal tunnel syndrome • Hammer toes • Amputation • Varicose veins • Removal of benign tumours • Removal of cysts
Medical contra-- indications:	Tourniquets may only be used on patients who do not have any of the following contraindications: • Inflammations • Malignant tumours • Severe arteriosclerosis • Severe crush injury • Severe hypertension • Diabetes mellitus • Thrombosis • Compound fractures of the extremities • Fresh skin transplants • Severe brain injury • Neuromuscular damage • Crush injuries • Peripheral arterial disease • Patients carrying the sickle cell gene • Tissue ischaemia
Use environments and applications that are outside the device's intended purpose:	• 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:	The following complications may occur during or after use of tourniquets: • Hyperaemia with a risk of haemorrhage • Muscle oedema • Paralyses • Acid-base regulation disorder • Shock due to metabolite influx after spontaneous return of blood flow • Crushed nerve (especially the peroneal or ulnar nerve); consequence: paralysis
Warnings:	See chapter 2.0 ‘Notices for your safety’ in the valid instructions for use of the product.
The product is:	active
Sterility / specific microbial state:	• The devices are used in non-sterile condition. • Sterile disposable cuffs or reusable multiple-use cuffs can be used.
Single-use device / reprocessing:	• The devices are intended for multiple use. • The devices and part of the accessories are reusable. For information on reprocessing, cleaning and disinfection, please see: ‘6 Cleaning and disinfection’ on page 47. • Disposable cuffs are single-use devices.

1.4 Function

The pneumatic tourniquet is used during surgical procedures on the upper and lower extremities.

The device features an On / Off button, a touch display with user guidance, an integrated hose holder, a handle, notification and status indicators, and smooth, hygienic surfaces. The devices are available with an optional protocol printer or can be retrofitted with one if required. A mobile stand or a standard rail bracket can be purchased as an alternative mounting option to the stationary device.

The device is powered by compressed air from a central gas supply (CGS).

1.5 Transport and storage

Transport the product only in a shipping box that is padded and 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 device to ATMOS; see section ‘7.1 Sending in the device’ on page 51.

Environmental conditions for transport and storage: see chapter ‘12 Technical Data’ on page 65.

2 Notes for your safety

The safety and performance of the ATMOS tourniquet sophie 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 have occurred 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 operate the device 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.

2.2 Danger to users, patients, and third parties

⚠ WARNING

Electric shock due to unsuitable mains power connection, incorrect handling of the product, or damage to product components.

Burns and cardiac arrhythmias, which may be fatal, are possible.

- Do not operate the device if it has been dropped. In this case, clean and disinfect the device and send it to ATMOS for repair.
- Before use, check the device and power cable for any damage. Do not operate the device if you notice any damage. In this case, clean and disinfect the device and send it to ATMOS for repair.
- Damaged cables must be replaced.
- The device can only be disconnected from the power supply by unplugging the power plug.
- Position the device so that it can be easily disconnected from the power supply at any time.
- When disconnecting the device from the power supply, disconnect the power plug first and then the device plug.
- Disconnect the device from the power supply before cleaning or disinfecting it.
- Never touch the plug or power cable with wet hands.
- Never immerse the device in water or other liquids.
- The device is not sterilisable.
- Use the power cable only in dry surroundings. The surroundings must be non-conductive.
- Do not allow liquids (such as disinfectants) to enter the device or power cable.
- Ensure that no liquid enters the device. If liquid has entered the device, stop operating it immediately; it must no longer be used. In this case, clean and disinfect the device and send it to ATMOS or an authorised service partner for repair.
- Use only original accessories and original spare parts from ATMOS. This applies to the power cable in particular.
- Observe the information on periodic tests in chapter ‘7 Maintenance and service’ on page 51.
- Assembly, new settings, modifications, extensions, and repairs may only be carried out by authorised persons.
- Do not modify the device without the manufacturer’s permission.

⚠ WARNING

Risk of infection from non-sterile products.

Deadly diseases may be transmitted.

- Never use components marked with ⓧ more than once. These components are intended for single use only.
- Reuse of components marked with ⓧ is prohibited. This product cannot be resterilised. If reused, these components lose their function.
- Use sterile-packed parts only if the packaging is undamaged.
- Before use, check that the packaging of the sterile products is intact.
- Reuse of sterile products can lead to infection.

⚠ WARNING

Risk of infection due to patient secretion on the device!

Deadly diseases may be transmitted.

- Always wear disposable gloves if you might come into contact with bodily secretions.
- Clean and disinfect the device after every use.
- Clean and disinfect the device according to the Instructions for Use.

⚠ WARNING

Ensure that the device is always functional and ready for use.

Your patient can be severely injured.

- Ensure that the device is always ready for use.
- ATMOS recommends always having an alternative method of tourniquet application available.
- Place the device where it is easily accessible.
- Perform a function check after each use.
- Observe the notes on the electromagnetic compatibility (EMC) of the device.
- If the device has been dropped, check it for visible damage. If the housing is damaged, the device is defective and must not be operated. In this case, clean and disinfect the device and send it to ATMOS for repair.
- The sophie tourniquet is a medical device for which special safety precautions apply. They must be installed and put into operation in accordance with the EMC regulations. Portable and mobile RF communication devices (mobile phones) may affect the performance of the tourniquets.

⚠ WARNING

Avoid improper use.

Your patient can be severely injured.

- Use the device only according to its intended purpose.
- The product may only be used by medically trained persons who have been instructed in its medical application.
- Observe the valid guidelines.
- Observe the notes on hygiene and cleaning.
- Faulty or damaged system components must be replaced immediately.

⚠ WARNING

Explosion and fire hazard.

Burns and injuries are possible.

- Use only original accessories and original spare parts from ATMOS. This applies to the power cable in particular.
- Never operate the product in potentially explosive areas or in areas that are oxygenated.
- Explosion-hazardous areas may be caused by the use of flammable anaesthetics, skin cleansing products, and skin disinfectants. The environmental conditions specified in the Technical Data (see chapter '12 Technical Data' on page 65) must be strictly observed.

⚠ CAUTION

Contact may cause allergic reactions.

You or your patient can be injured.

- The materials used have been tested for their tolerability. In very rare cases, contact with accessible materials on the device and its accessories may cause allergic reactions. This applies in particular to contact injuries caused by prolonged contact. If this occurs, seek medical attention immediately.

⚠ CAUTION

Tripping hazard due to cables.

Injuries and fractures are possible.

- Lay the power cable and connection hoses properly.

2.3 Important safety information

Training in the use of the tourniquet

- Training in the use of the tourniquet may only be provided by the manufacturer or by persons authorised by the manufacturer.
- The sophie tourniquet may be operated only by trained personnel who are familiar with and comply with these Instructions for Use.
- Following training, the applicable regulations governing the operation of medical devices apply.
- All applicable national regulations relating to the installation, training, documentation and operation of a medical device must be observed.

⚠ WARNING

Explosion and fire hazard

- Use of the tourniquet, including all accessories, in potentially explosive environments or in the presence of flammable anaesthetics or cleaning agents may result in serious injury to persons and damage to the sophie tourniquet.
- Use the sophie tourniquet, including all accessories, only in environments without an explosion hazard and in the presence of non-flammable anaesthetics or cleaning agents.

⚠ CAUTION

Comply with applicable national regulations for medical gases.

If the tourniquet is supplied from a central compressed air system, this system must comply with applicable national regulations for medical gases.

- Additional equipment connected to the device's electrical interfaces must be shown to comply with the system standard EN 60601-1-1.

⚠ WARNING

Potential equalisation

- To protect against touch voltages between accessible conductive parts of the tourniquet and other devices in the patient environment, the tourniquet must be connected to the hospital's potential equalisation system by means of a potential equalisation cable.
- Do not touch the patient and the protocol printer at the same time.

2.4 Safety for users and patients

The tourniquet has a microcontroller-controlled safety concept. This prevents, for example, a sudden pressure drop in the cuff in exceptional circumstances (e.g., loss of power). If a fault occurs, the tourniquet provides a visual and audible warning.

⚠ DANGER

Device functionality

- Before starting the application, ensure that the tourniquet and accessories are functioning properly.

⚠ WARNING

The duration and level of applied pressure are the sole responsibility of the physician, based on current scientific and technical knowledge.

Excessive pressure or prolonged tourniquet application may result in injury to the patient.

- Use the minimum pressure required to ensure a safe tourniquet application in the surgical field.
- Pay particular attention to this during tourniquet application in paediatric patients.

⚠ WARNING

Monitoring tourniquet duration

To monitor the duration of tourniquet application, the elapsed time or the remaining time until the set countdown expires is displayed during the procedure.

- When the countdown has elapsed, an audible warning is issued, and the time can be adjusted if required.
- In consultation with the responsible physician, decide whether to continue or release the tourniquet.

2.5 Avoiding damage to the device

⚠ CAUTION

Safety check

ATMOS recommends performing the safety check (see section ‘9.3 Safety check’ on page 60) after 3000 operating hours.

- This check may only be performed by the manufacturer or by service personnel authorised by the manufacturer.

⚠ DANGER

Repairs

- Repairs may only be carried out by the manufacturer or by service personnel authorised by the manufacturer.

Storage and operation in an unsuitable environment.

The product may become damaged.

☞ Observe the environmental conditions for transport, storage, and operation; see chapter ‘12 Technical Data’ on page 65.

3 Setup and settings

3.1 Front of the device

The 2-channel tourniquet sophie has two connections for using two cuffs. This tourniquet allows you to perform a tourniquet application on two extremities at the same time in the following ways:

- 2x arm
- 2x leg
- Arm and leg

In addition, intravenous regional anaesthesia (IVRA application) can be performed using a double-chamber cuff.



1. Notification indicator (red LED)
2. Power supply indicator (green LED)
3. Notice: Observe the Instructions for Use
4. Connection for cuff, blue (leg / distal cuff chamber)
5. Touch display
6. Connection for cuff red (arm / proximal cuff chamber)
7. On / Off button
8. Hose holder
9. Handle

When using with one channel:

The left connection (red channel) is always used for the arm, and the right connection (blue channel) is always used for the leg.

When using with both channels:

In this case, both connections (channels) can be used for arms or legs. When they are used for both arms or both legs, it does not matter which connection (channel) is selected for which limb. When used for one arm and one leg, the left connection (red channel) must be used for the arm and the right connection (blue channel) for the leg.

Connections with colour coding for IVRA applications

To make an IVRA application easier with the 2-channel sophie tourniquet, the connections on the tourniquet are colour coded.

When using a double-chamber cuff for an IVRA application, connect the distal and proximal cuff chambers as follows:

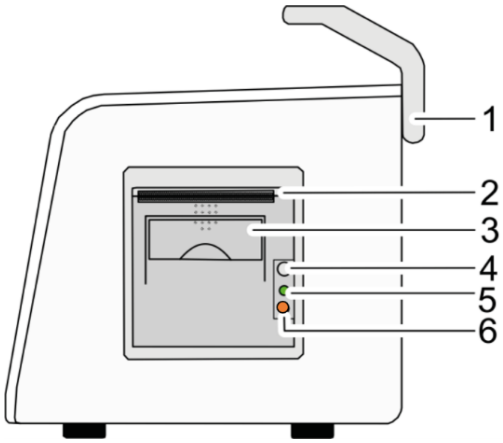
- The left connection is marked in red and stands for the proximal cuff chamber.
- The right connection is marked in blue and stands for the distal cuff chamber.
- The colours red and blue are shown in the safety messages. This helps you to more quickly identify which channel has a possible fault.

3.2 Rear side



1. IEC connector inlet (power supply connection)
2. Hose holder
3. Connection for potential equalisation (POAG)
4. Strain relief with test plugs (REF SP000698)
5. Type plate
6. Handle

3.3 Side view (right)



1. Handle
2. Protocol printer
3. Lever for opening the protocol printer
4. Paper feed button
5. Status indicator: ready for operation (green LED)
6. Status indicator: not ready for operation (orange LED)

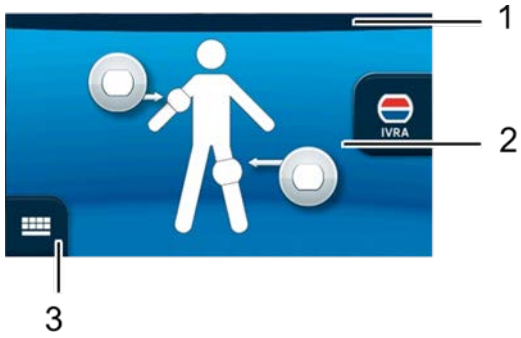
☞ Tourniquets can be retrofitted with the protocol printer at a later time (UT 1381).

☞ Contact your medical device specialist.

3.4 Display and buttons

The sophie tourniquet is operated via the touch display.

Information on the touch display (selection of tourniquet application)



1 Status line
2 Control panel
3 Menu

3.4.1 Buttons, symbols, and functions

Selection of tourniquet application

	Select extremity
	IVRA selection

Before starting surgery

	Set time and pressure (Press and hold the button to adjust the set values more quickly.)
	Set countdown
	Start tourniquet application

During surgery

	Adjust pressure
	Indicator for remaining time (countdown)
	Indicator for time that has already passed (counter)
	Stop tourniquet application

General buttons

	Open menu
	Confirm selection/action
	Cancel selection/action
	Indicator for the selected extremity Upper body green = arm Lower body green = leg

The status line is located in the upper part of the display and contains the following status information:

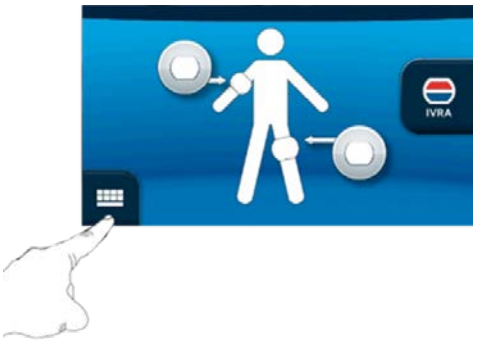
Left	Date and time
Middle	Placeholder for safety messages and fault indicators
Right	Power connection available Service symbol

3.5 Menu settings

3.5.1 Presetting the pressure

The preset values are retained when the device is switched off.

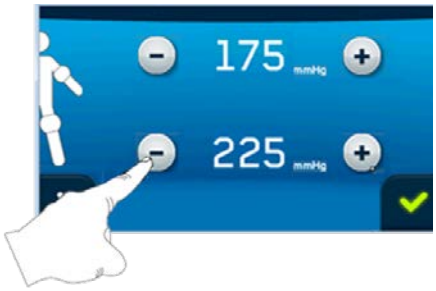
1



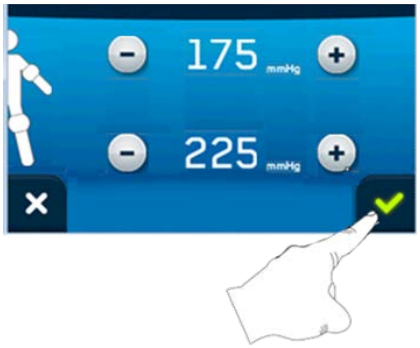
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3



4

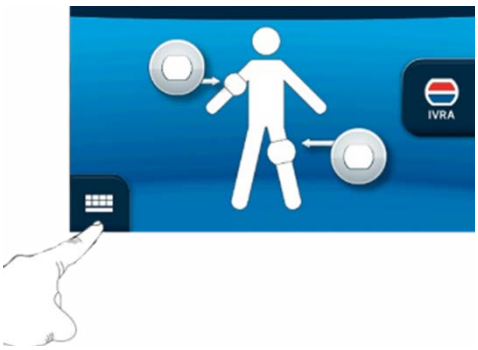


5

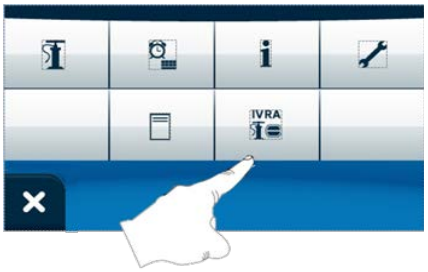


3.5.2 Adjusting the pressure for IVRA application

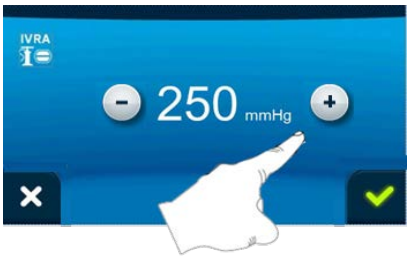
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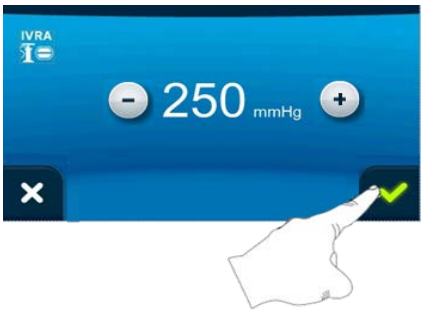
2



3



4



5



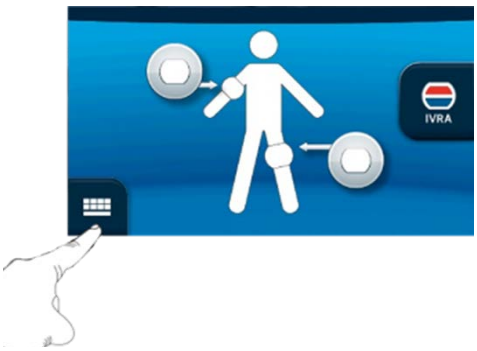
3.5.3 Presetting the tourniquet duration (ascending/descending)

☞ You can choose between a **countdown** and a **counter** :

- **Countdown:** The set tourniquet duration is displayed, for example, starting from 90 minutes and counting down.
- **Counter:** The set tourniquet duration counts up starting from 0 minutes.

The tourniquet duration can be temporarily changed before starting the tourniquet application (when starting the application).

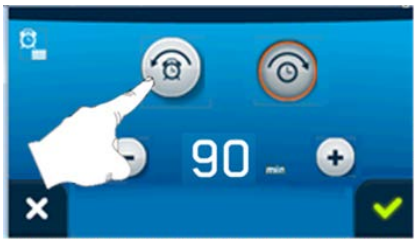
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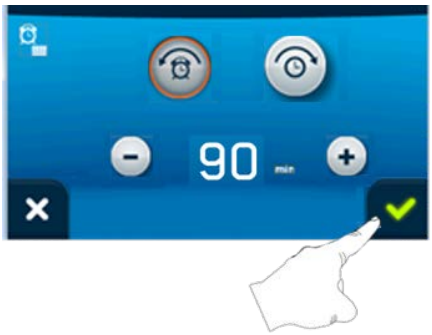
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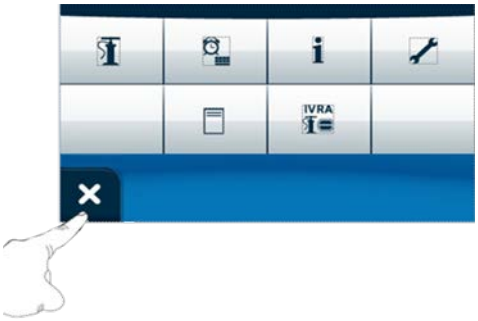
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3.5.4 Enabling and disabling the protocol printer

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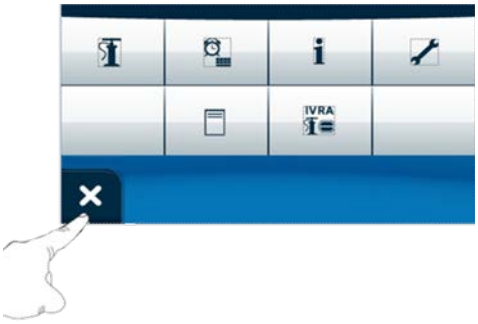
3



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5



3.5.5 Setting the date and time

☞ Two different formats are available for displaying dates. MM-DD-YYYY for 08.23.2024, for example, or DD-MM-YYYY for 23.08.2024, for example.

Setting the date

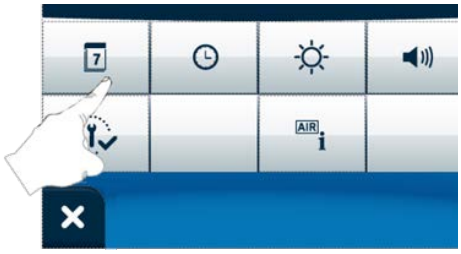
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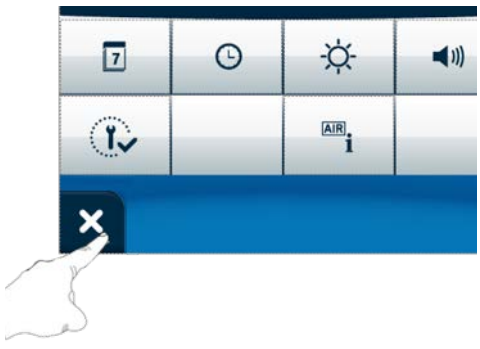
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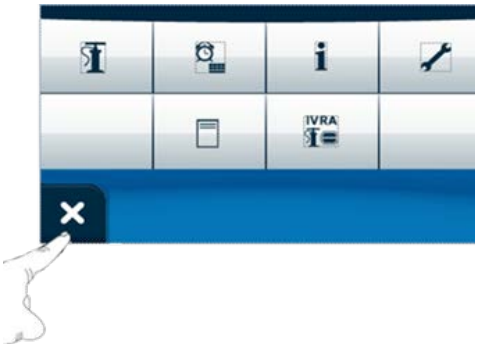
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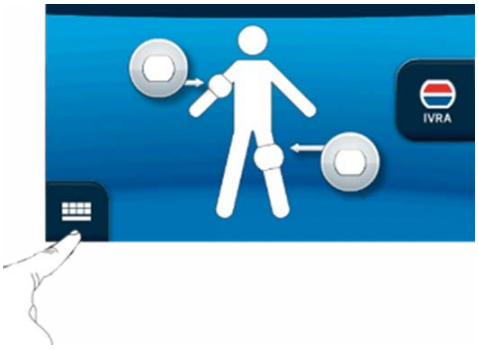
6



3.5.6 Setting the time

☞ The system does not automatically switch between standard time and daylight saving time. This setting must be made manually by the user.

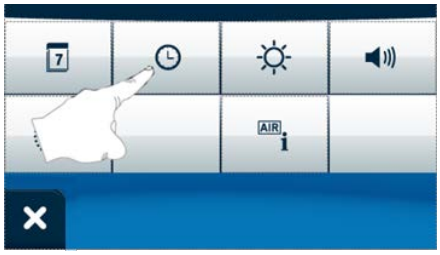
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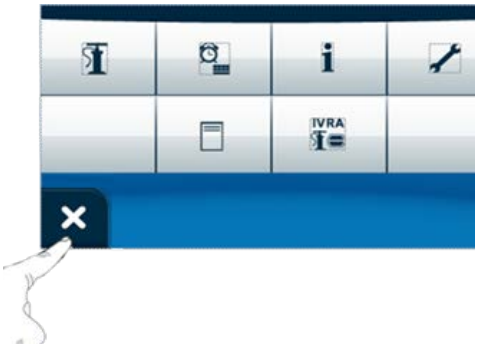
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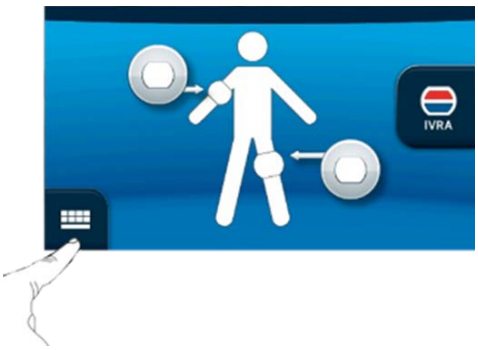


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3.5.7 Adjusting the display brightness

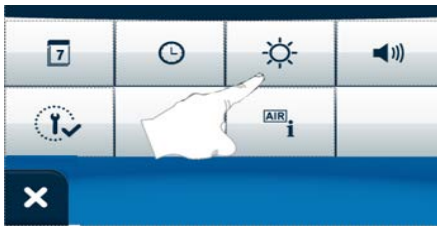
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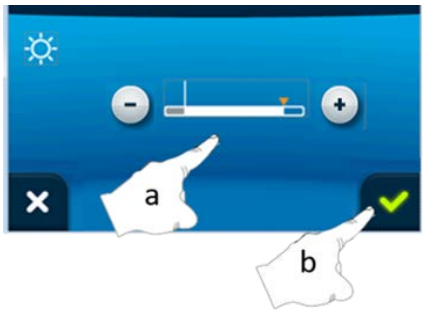
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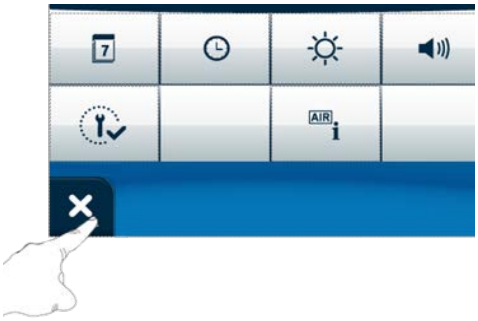
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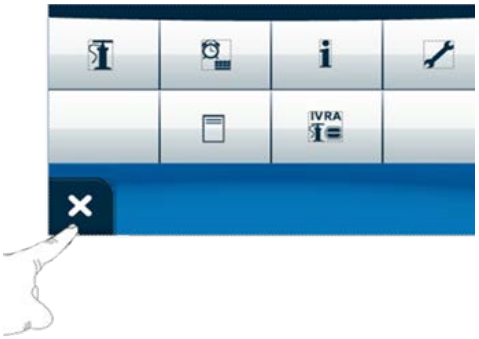
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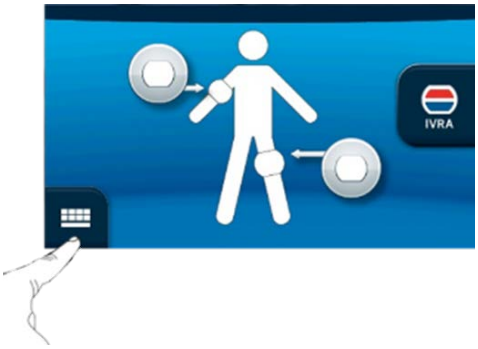
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3.5.8 Adjusting the volume

☞ The device volume cannot be completely turned off to ensure that warning and fault messages can still be heard.

1



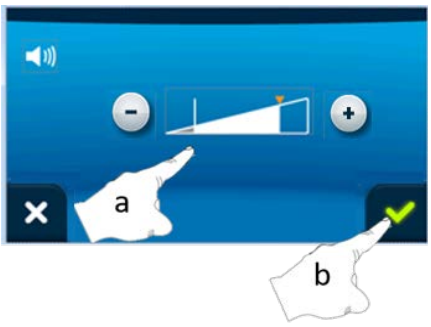
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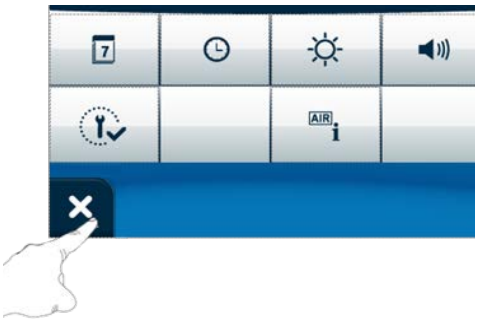
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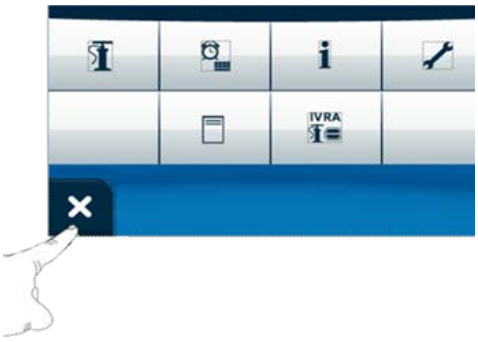
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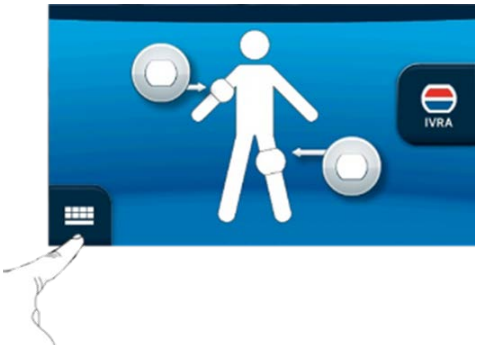
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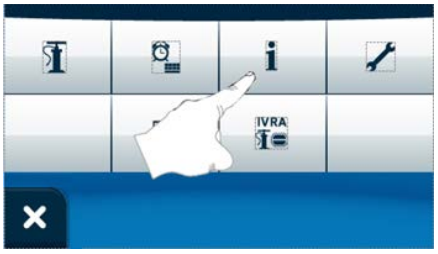
3.5.9 Viewing device information

☞ On the device information screen, the total operating hours or the software version number can also be viewed.

1



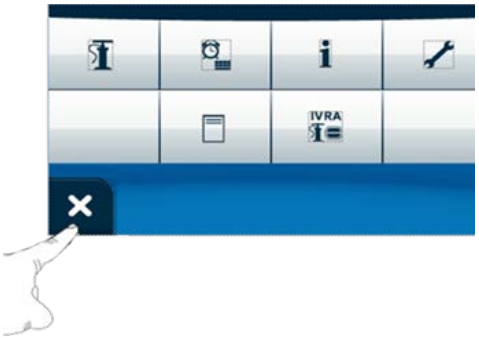
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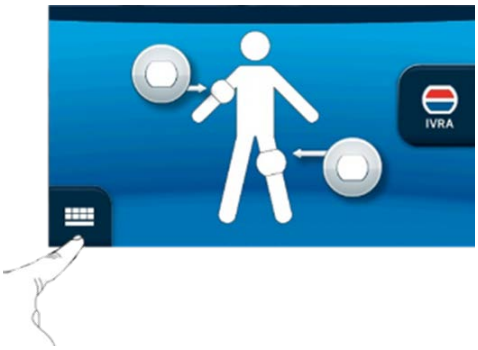


3.5.10 Reading the internal operating pressure of the device

⚠ DANGER

The internal operating pressure of the device must be between 1200 mmHg and 1800 mmHg.

1



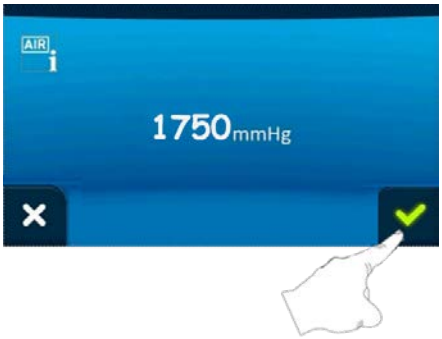
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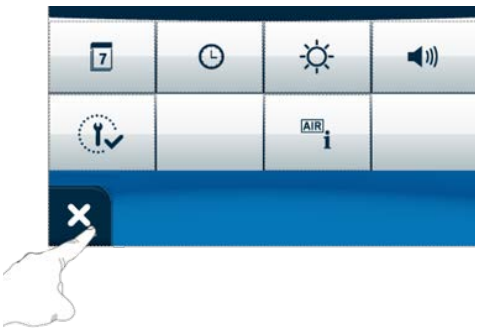
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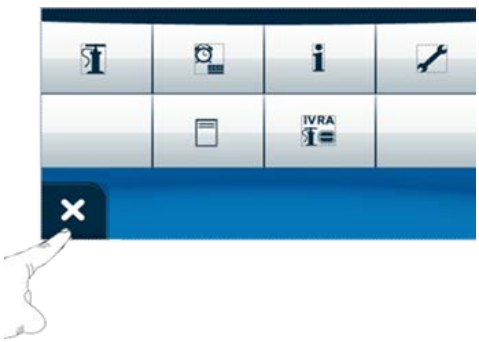
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6



4 Initial start-up

Read the Instructions for Use carefully before using the sophie tourniquet for the first time. The contents of these Instructions for Use must be fully understood in order to perform the described procedures correctly and conscientiously.

ATMOS Tourniquets may be used only after training has been provided by an ATMOS medical device specialist or by an authorised person.

⚠ DANGER

If the device is transported from a cool environment (for example after prolonged storage) into the room where it will be used, a significant temperature difference may cause the display to appear dark when the device is switched on.

☞ Allow the tourniquet to acclimate to room temperature before operating it. Depending on the temperature difference, this can take approximately 30 minutes to several hours.

Follow these steps for initial start-up:

4.1 Unpacking and setting up the device

1. Unpack the tourniquet.
2. Store the packaging in a suitable location.
3. Position or mount the tourniquet at the desired location.
4. If necessary, allow the tourniquet to acclimate to room temperature.

4.2 Connecting the device to the power supply

1. Use the provided power cable to connect the tourniquet to the power supply (power outlet).

☞ Refer to the information about the power supply; see chapter ‘12 Technical Data’ on page 65. The power outlet must remain accessible at all times.

2. Route the power cable through the strain relief clamp on the rear of the device to prevent it from being accidentally pulled out.

4.3 Switching on the device

1. Switch on the tourniquet.
   - A self-test is carried out.
   - If the self-test fails, a safety message appears (E 140, E 145, E 155 or E 180 appears); see section ‘8.4.1 Troubleshooting messages’ on page 53.
   - The tourniquet is ready for use when the selection screen appears.

4.4 Switching off the device

1. Switch off the tourniquet.

4.5 Setup

⚠ CAUTION

Reduction of performance characteristics or functional impairment due to damaged device.

☞ The device must not be put into operation if it is damaged.

4.5.1 Placement in the operating theatre environment

☞ Verify that the initial start-up was carried out correctly; see chapter '5 Operation' on page 32.

☞ Place or mount the tourniquet in the desired location:
- Use as a stationary device
- Mounting on a standard rail
- Mounting on a mobile stand

⚠ WARNING

Risk of injury due to tripping.

Improper routing of the connected power cable may create a tripping hazard.

☞ Avoid tripping hazards or places where feet could be trapped when laying the cables and connection hoses.

4.5.2 Use as a stationary device

The tourniquet can be used as stationary device.

☞ Ensure that the tourniquet is stable and place it only on a level surface.

☞ Protect the tourniquet from direct sunlight and moisture.

☞ Avoid placing the tourniquet directly in front of radiators and other heat sources.

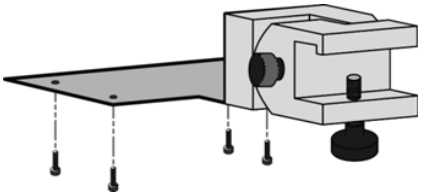
4.5.3 Mounting on a standard rail (optional)

The tourniquet can be mounted on a horizontal standard rail using the adjustable standard rail bracket for tourniquets (UT 1383), available as an optional accessory.

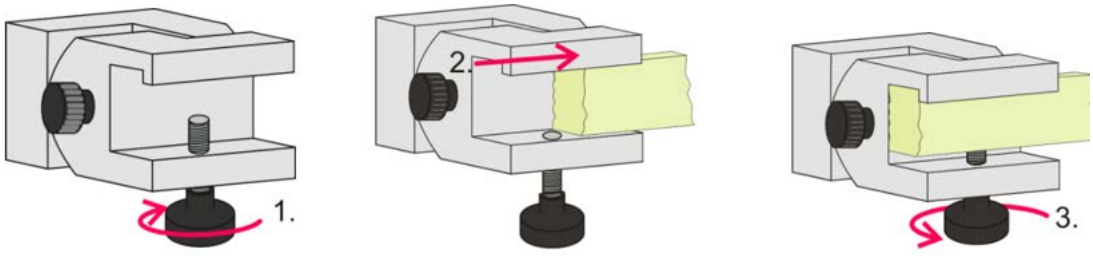
The standard rail bracket allows positioning of the tourniquet at various angles.

4.5.4 Mounting the standard rail bracket on the tourniquet

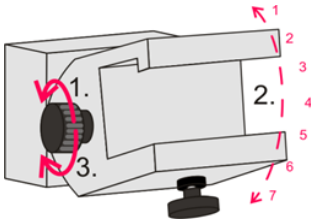
1. Secure the standard rail bracket to the base of the tourniquet using the four screws supplied.



2. Align the standard rail bracket.



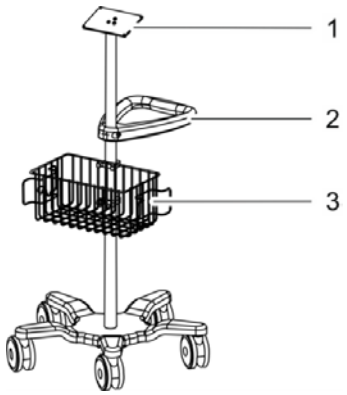
3. Set the desired position. The position can be adjusted to seven different angles.



4.5.5 Mounting on the mobile stand (optional)

The tourniquet can optionally be mounted on a mobile stand (UT 1382). The mobile stand is equipped with a basket for storing connection hoses, cuffs, and accessories.

☞ The handle and basket can be mounted on the mobile stand and can be positioned as required. The installation instructions for the mobile stand are supplied with the product.



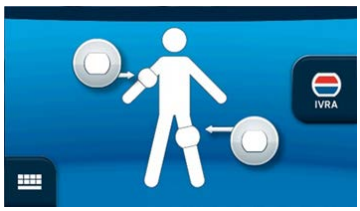
1 Mount for tourniquet (facing user)
2 Handle
3 Basket for storing cuffs with hose holders on the side

Using the locking brake

☞ Release the locking brake before moving the mobile stand.

☞ Prevent the tourniquet from accidentally moving by engaging the locking brake.

4.5.6 Connecting the device to the supply



1 Establish the CGS-NIST connection.
2 Plug in the power cable.
3 Switch on the tourniquet and observe the self-test. The tourniquet is ready for use when the selection screen appears.

5 Operation

⚠ DANGER

Large difference in temperature.

If the device is transported from a cool environment (for example after prolonged storage) into the room where it will be used, a significant temperature difference may cause the display to appear dark when the device is switched on.

☞ Allow the tourniquet to acclimate to room temperature before operating it. Depending on the temperature difference, this can take approximately 30 minutes to several hours.

5.1 Connecting and switching on the tourniquet

- Position or mount the tourniquet at the desired location.
- Follow the instructions for safe positioning in the operating theatre environment.
- If necessary, allow the tourniquet to acclimate to room temperature.

☞ Follow the instruction on the front of the tourniquet: ‘Connect cuff AFTER the self-test’.



5.1.1 Switching on the device

Switch on the tourniquet.

- A self-test is carried out.
- If the self-test fails, a safety message appears (E 140, E 145, E 155, or E 180); see section ‘8.4.1 Troubleshooting messages’ on page 53.
- The tourniquet is ready for use when the selection screen appears.

5.2 Cuff size tape

The cuff size tape (UT 1315) is used to determine the size of the ATMOS Cuff to use on the patient’s extremity to be operated on. The cuff size tape measures 1200 mm × 35 mm and is divided into ranges corresponding to cuff sizes 2XS to 3XL. The different size ranges correspond to the colour coding of the ATMOS Cuffs (refer to the respective Instructions for Use of the cuffs).

5.2.1 Using the cuff size tape

Place the cuff size tape around the patient’s extremity, centrally at the position where the cuff is to be applied. Ensure that the cuff size tape is oriented correctly for reading. At the point of overlap, the appropriate cuff size can be selected based on the marking. Ensure that the cuff size tape is placed around the padding underneath and that the correct cuff is selected. If in doubt, select the larger cuff size.

5.3 Applying the tourniquet

Select one of the following tourniquet applications:

- Tourniquet application on the leg (see section ‘5.3.1 Performing a tourniquet application on the leg’ on page 33)
- Tourniquet application on the arm (see section ‘5.3.2 Performing a tourniquet application on the arm’ on page 34)
- Tourniquet application on different extremities (see section ‘5.7 Additional selection options for tourniquet application’ on page 42).
- Intravenous regional anaesthesia with a tourniquet (see section ‘5.7 Additional selection options for tourniquet application’ on page 42).

5.3.1 Performing a tourniquet application on the leg

1. Select **Leg**.
2. Confirm your selection using the ‘Confirm‘ button .

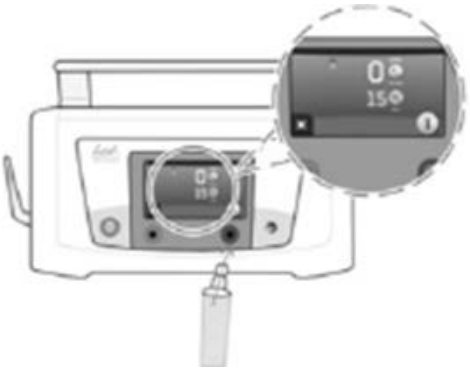
If you have made the wrong selection, click the ‘Cancel’ button to cancel and make your selection again.

» Type of tourniquet application selected.



Attaching the cuff

1. Use the connection hose to connect the cuff to the connection on the right (blue).



☞ Refer to the instructions for use of the cuffs for more information on how to apply them.

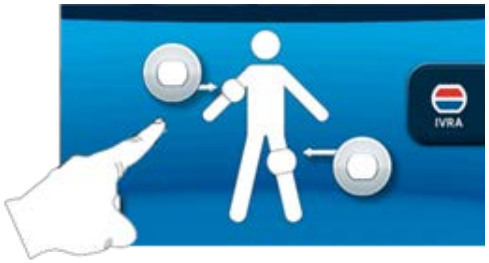
The tourniquet application can now be started in the next step; see section ‘5.5 Starting the tourniquet application’ on page 37.

5.3.2 Performing a tourniquet application on the arm

1. Select **Arm**.
2. Confirm your selection using the ‘Confirm‘ button .

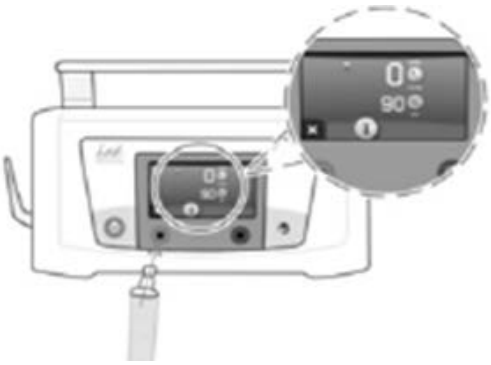
If you have made the wrong selection, click the ‘Cancel’ button to cancel and make your selection again.

» Type of tourniquet application selected.



Attaching the cuff

1. Use the connection hose to connect the cuff to the connection on the tourniquet.
   - Left channel, first arm.
   - Right channel, second arm.



☞ Refer to the instructions for use of the cuffs for more information on how to apply them.

The tourniquet application can now be started in the next step; see section ‘5.5 Starting the tourniquet application’ on page 37.

5.4 Preparing the tourniquet application

⚠ WARNING

Before starting the application, check the settings and ensure that the tourniquet and accessories are functioning properly.

	**1-channel** 1 Preset pressure 2 Countdown or counter (depending on preset setting) 3 Start tourniquet application 4 Cancel selection 5 Current pressure in the cuff 6 Display of selected extremity (green)
	**2-channel** 1 Leg (blue) 2 Arm (red)
	**IVRA** 1 Distal chamber (blue) 2 Proximal chamber (red)

5.4.1 Changing the tourniquet duration before surgery

The tourniquet duration can be changed before surgery starts. This temporary change applies only to the subsequent tourniquet application and does not affect the preset values defined in the menu. For the next tourniquet application, the selection of the tourniquet duration defaults to the preset value specified in the menu.

The time cannot be changed while the application is in process. The time cannot be extended until after the set tourniquet duration expires without cuff pressure being lost.

Changing the countdown

1



2



Information on tourniquet duration

Throughout the entire tourniquet duration, you can access information on the remaining and elapsed tourniquet duration.

1



2



5.4.2 Adjusting the pressure

The preset pressure can be changed before surgery starts. This temporary change applies only to the subsequent tourniquet application and does not affect the preset values defined in the menu. For the next tourniquet application, the selection of the pressure defaults to the preset value specified in the menu.

☞ In the case of 2-channel application, the pressure can be separately adjusted for each channel. In the case of IVRA application, the set pressure values always apply to both channels.

1



2



3



5.5 Starting the tourniquet application

1. Start the tourniquet application using the 'Start tourniquet application' button on the display.
2. Confirm your selection using the 'Confirm' button or 'Start tourniquet application' button .



» Tourniquet application started.

☞ Ensure that the tourniquet cuff is inflated and exerts sufficient counter-pressure when two fingers are placed under the (proximal) inner edge of the cuff.

☞ Monitor the cuff pressure at regular intervals during tourniquet application.

5.5.1 Interrupting the tourniquet application

A tourniquet application that is in process can be interrupted and continued at any time.

⚠ CAUTION

Interruptions

Interrupting the application can result in bleeding in the surgical field.

- Do not interrupt the tourniquet application unless instructed to do so by a physician.

1



2



» The tourniquet application is interrupted.

Continuing the tourniquet application

1. Start the tourniquet application using the 'Start tourniquet application' button on the display.



2. Confirm your selection using the 'Confirm' button or 'Start tourniquet application' button .



» The tourniquet application resumes.

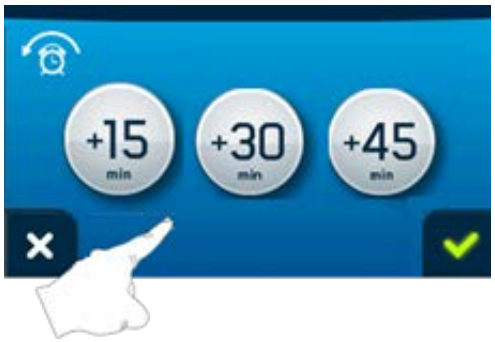
5.5.2 Extending the tourniquet duration

After the set tourniquet duration has elapsed, a pop-up appears on the display and a warning sound is emitted. You can extend the tourniquet duration in this pop-up.

If no new setting is made on the display, the tourniquet duration is automatically extended by 3 minutes. The warning sound is emitted again and the pop-up reappears.

☞ In consultation with the responsible physician, decide whether to continue or release the tourniquet.

1



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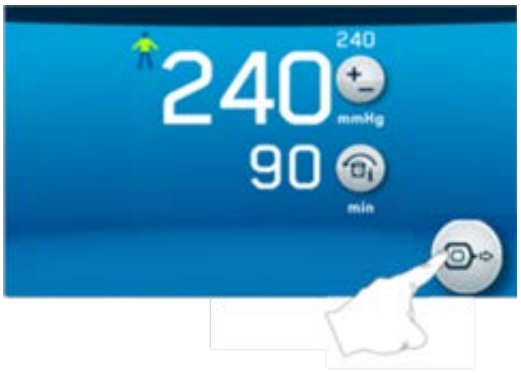
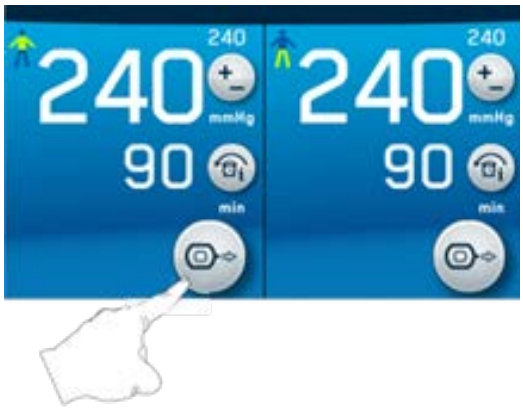
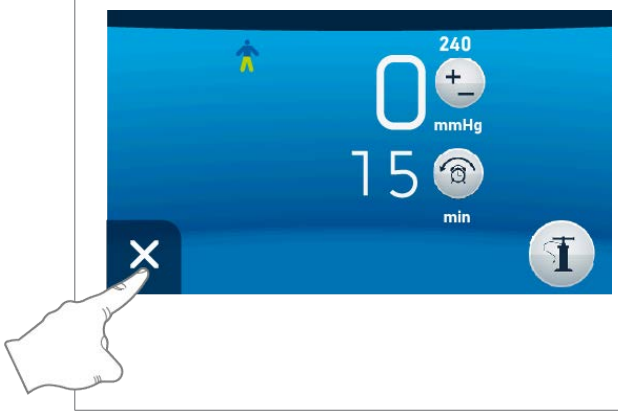
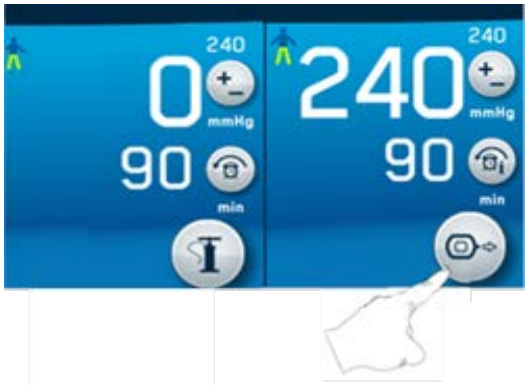


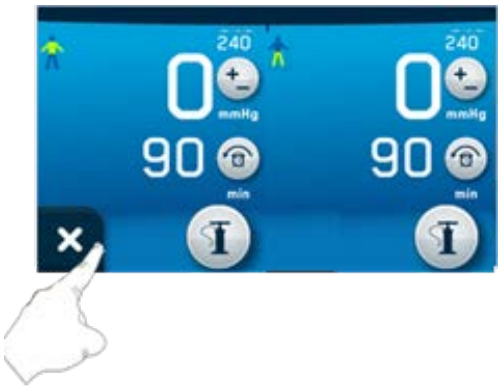
☞ Confirm your selection using the ‘Confirm‘ button .

» The tourniquet application resumes.

5.6 Ending and repeating the tourniquet application

5.6.1 Ending the tourniquet application

1-channel	2-channel
1.1 Release air from the cuff.	1.1 Release air from the cuff connected on the left.
	
1.2 Confirm that air was released.	1.2 Confirm that air was released.
	
2. Exit the application using the 'Cancel' button ✕.	1.3 Release air from the cuff connected on the right.
	

1-channel	2-channel
3 Display for 1-channel application	1.4 Confirm that air was released.
	
1 Date 2 Time (start and end of tourniquet application) 3 Last pressure used 4 Tourniquet duration	2 Exit the application using the 'Cancel' button ✕.
	
	3 Display for 2-channel application
	
	1 Date 2 Time (start and end of tourniquet application) 3 Last pressure used 4 Tourniquet duration

- ☞ Press the 'Confirm' button ✓ or 'Cancel' button ✕ to switch to the selection screen.
- ☞ If no confirmation takes place, the tourniquet automatically switches to the selection screen after 10 minutes.
- ☞ Disconnect the connection hose and the cuff.

5.6.2 Repeating the tourniquet application

If the cuff should need to be reinflated on the same patient, the application can be restarted at any time.

5.7 Additional selection options for tourniquet application

5.7.1 Arm–arm

1 2 3



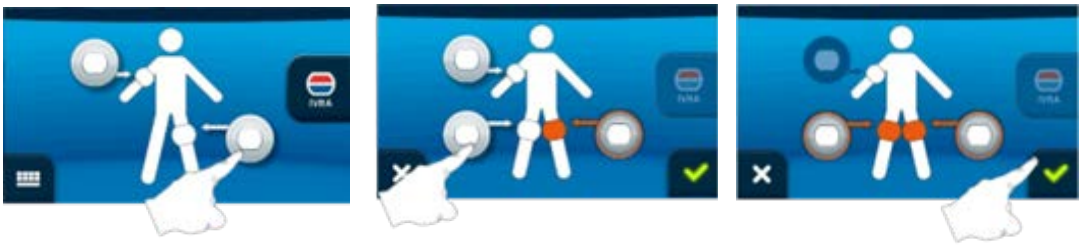
5.7.2 Arm–leg

1 2 3



5.7.3 Leg–leg

1 2 3

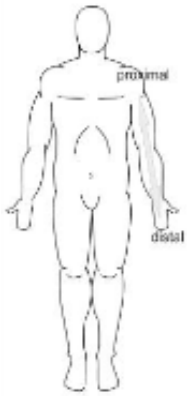


5.7.4 IVRA

Intravenous regional anaesthesia (IVRA) is a method for regional anaesthesia that is generally used in the case of outpatient surgical procedures on the extremities.

During IVRA application, the extremity to be operated on is first drained and then the proximal chamber of the cuff is inflated. A local anaesthetic is then injected into the vein, which prevents the spread of pain in the ligated extremity. The distal chamber can then be inflated, after which the proximal chamber is deflated.

IVRA applications can be performed using the sophie tourniquet.

	**Term**	**Meaning**	**Assigned colour**
	proximal	Towards the torso (closer to the heart)	red
	distal	Away from the torso (farther from the heart)	blue

Start IVRA

1. Select the IVRA application.



2. Confirm your selection by pressing the ‘Confirm‘ button .



3. Start the left (red) side using the ‘Start tourniquet application’ button on the display.



4. Confirm your selection by pressing the ‘Confirm‘ button or the ‘Start tourniquet application’ button .



5. Administer the anaesthetic and allow the required onset time to elapse.

6. Start the right (blue) side using the ‘Start tourniquet application’ button on the display.



7. Confirm your selection by pressing the ‘Confirm‘ button or the ‘Start tourniquet application’ button .
8. Deflate the left (red) side.

» The surgical procedure can now be performed.



5.8 Protocol printer

5.8.1 Protocol printout

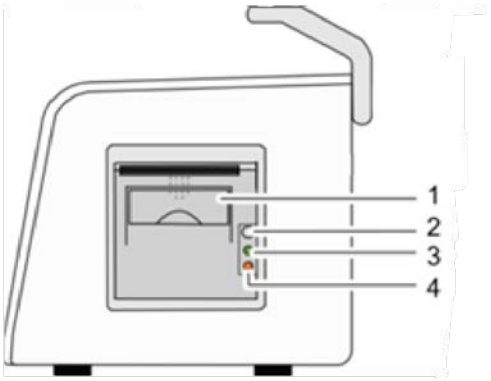
If your tourniquet is equipped with a protocol printer, the printout starts automatically at the beginning of the tourniquet application and records all events (e.g., pressure changes, safety messages) until the end of the application.

☞ The red (left) and blue (right) connections are also shown accordingly on the left and right sides of the protocol printout. This layout helps you quickly distinguish the values for the individual connections.

Protocol printout	Entries on the protocol printout
ATMOS MedizinTechnik **SOPHIE** - mein Tourniquet SW **1.08** (**S1302001**) Patient ID _ _ _ _ _ _ Surgery_ _ _ _ _ _ _ OR No. _ _ _ _ _ _ _ Date: 13.08.2012 Female: [ ] Male: [ ] Arm: L [ ] R [ ] Leg: L [ ] R [ ] IVRA: L [ ] R [ ]	Patient ID Surgical procedure OT number Date: Female: Male: Arm: Left Right Leg: Left Right IVRA: Left Right
Start: 08:00 Time Pressure Pressure [h:min] [mmHg] [mmHg] 08:01 --- 250 08:30 --- 280 Stop: 08:40	Start time Time Pressure Pressure End time
History: Pressure: --- 280 [mmHg] Time: --- 40 [h:min] Signature: _ _ _ _ _ _ Notes:	History: Pressure: Duration: Signature: Notes:

5.8.2 Changing the printer paper

1. Lever for opening the protocol printer
2. Paper feed button
3. Status indicator: ready for operation (green LED)
4. Status indicator: not ready for operation (orange LED)



☞ If the printer runs out of printer paper, warning W 301 appears. The device displays the error and the printer status indicator lights up orange (not ready for use).

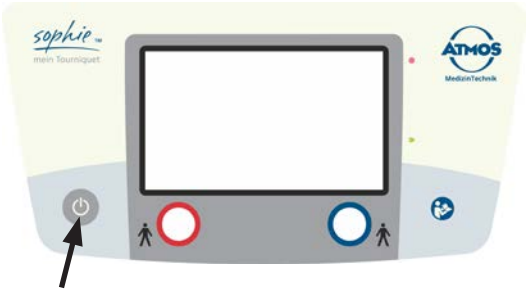
To change the printer paper (UT 1381-01):

1. Open the cover of the protocol printer using the lever.
2. Insert the printer paper so that approximately 10 cm of the loose end (at the top) extends away from the device.
3. Position the loose end of the paper centrally on top of the cover.
4. Close the cover. A small amount of paper should now protrude from the printer.
5. The orange LED goes out and the printer status indicator lights up green (ready for use).
6. Briefly press the paper feed button to test whether the paper feeds correctly. The paper can now be torn off.
7. Acknowledge the warning using the 'Acknowledge message' button.

☞ The printer paper can be changed during tourniquet application. Printing resumes only after the paper has been changed. Data recorded before the paper change are no longer printed.

5.9 Switching off the tourniquet

Hold down the On / Off button for 2 seconds to turn off the tourniquet.



6 Cleaning and disinfection

⚠ WARNING	**Risk of electric shock and short circuit during cleaning and disinfection.** • Switch off the tourniquet and disconnect it from the power supply before carrying out any cleaning work. • Clean and disinfect the surfaces using only a damp (not wet) cloth. • The device must never be autoclaved, rinsed under running water, or immersed in liquids. • Prevent liquids from entering the device, especially in the connections on the rear of the device.
⚠ WARNING	**Risk of infection due to inadequate reprocessing.** • The tourniquet and the cuff size tape must be cleaned and disinfected before first use and after each use. • The cleaning and disinfection measures described do not replace the applicable regulations at the place of use. • Remove all accessories before carrying out complete cleaning.
NOTICE	**Damage to the product due to unsuitable cleaning agents, disinfectants, and aids.** • Never clean the device using metal brushes or steel wool. • Some disinfectant solutions may cause discolouration of the plastic surfaces. • When selecting cleaning agents and disinfectants, avoid products containing organic or inorganic acids or bases. • When selecting disinfectants, avoid products containing chloramines or phenol derivatives, as they could cause stress cracks in the plastic materials used. • Follow the disinfectant manufacturer's instructions for use, especially regarding concentration, material compatibility, and contact time.
Limitations with regard to reprocessing	**Tourniquet:** Regularly inspect the tourniquet for damage to its surfaces (e.g., cracks, discolouration, or other changes). Ensure that the display and all labels and markings on the device are always present and clearly legible. If any changes or damage are identified, contact the manufacturer. **Cuff size tape:** Inspect the cuff size tape for damage such as tears or cracks, poor legibility, and deformation. Frequent cleaning and disinfection reduce the ageing resistance of the cuff size tape. Excessively concentrated cleaning agents and disinfectants may attack the material. ☞ If damaged, do not continue to use the cuff size tape and dispose of it in accordance with local regulations.

Instructions	
Preparation before cleaning	Put on personal protective equipment before cleaning. Disinfect your hands first, and then put on chemical-resistant disposable gloves and a protective gown. Switch off the tourniquet and disconnect it from the power supply before carrying out any cleaning work. Before reprocessing, remove all accessories: • Disposable cuffs (dispose of) • Reusable cuffs • Connection hoses After this step, put on new gloves and clean and disinfect your hands. Prepare the cleaning and disinfection solutions as required and follow the manufacturer's specifications for concentration, contact time, and material compatibility. Remove any coarse contamination first.
Cleaning • **Accessories: lint-free disposable wipes, soft brush** • **Water quality: drinking water** • **Process chemicals: e.g., mikrozid® sensitive wipes**	For stubborn soiling, clean the cuff size tape with a soft cloth moistened with warm water or a mild soap solution. As a general rule, the entire device surface must be cleaned between patients using a clean, damp (never wet) disposable wipe and the recommended cleaning agent. Wipe all surfaces using light pressure, ensuring that no areas are left untreated. Continue cleaning the surfaces until they are visibly clean, ensuring that no areas are left untreated. Follow the instructions for the different surfaces below. **Front of the device:** The resistive touch display may only be wiped using gentle pressure. Do not omit the On / Off button on the front of the device; wipe it thoroughly. Thoroughly wipe both cuff connections of the tourniquet. Ensure that no liquid enters the connections. **Handle and hose holder:** Thoroughly wipe all surfaces of the handle and the hose holder. For hard-to-reach areas on the underside of the handle and the inner side of the hose holder, use a soft brush if necessary. This can also be used to remove stubborn soiling from all surfaces. To do this, dip the soft brush in the cleaning solution and clean the surfaces carefully. **Rear of the device:** Do not wipe over the connections and openings on the rear of the device. Prevent liquids from entering the device during cleaning. In addition to the surfaces, thoroughly wipe the strain relief, including the test plugs.

	Protocol printer (only for option with protocol printer): Do not wipe over the openings of the protocol printer when cleaning. When wiping over the lever for opening the protocol printer, ensure that no liquids enter the gaps. Otherwise, wipe the printer surface and the paper feed button. For hard-to-reach areas on the protocol printer, use a soft brush previously dipped in the cleaning solution. Ensure thorough removal of all soiling from all surfaces so that the effectiveness of disinfection is not impaired. Use a soft brush for hard-to-reach areas. Repeat the cleaning process if any visible soiling remains after cleaning. After cleaning, an intermediate rinse with drinking water should be carried out. To do this, wipe the surfaces with a lint-free, damp disposable wipe to remove any cleaning agent residues. After this step, put on new gloves and clean and disinfect your hands. If the device is not in use, clean the device surface once a week.
Disinfection • **Accessories: lint-free disposable wipes, soft brush** • **Water quality: drinking water** • **Process chemicals: Incidin™ Pro (concentration 1%, contact time 15 min)**	As a general rule, the entire device surface and the cuff size tape must be wipe disinfected between patients using a clean, damp (never wet) disposable wipe and one of the recommended surface disinfectants. **Front of the device:** The resistive touch display may only be wiped using gentle pressure. Do not omit the On / Off button on the front of the device; wipe it thoroughly. Thoroughly wipe both cuff connections of the tourniquet. Ensure that no liquid enters the connections. **Handle and hose holder:** Thoroughly wipe all surfaces of the handle and the hose holder. For hard-to-reach areas on the underside of the handle and the inner side of the hose holder, use a soft brush if necessary. To do this, dip the soft brush in the disinfectant solution and clean the surfaces carefully. **Rear of the device:** Do not wipe over the connections and openings on the rear of the device. Prevent liquids from entering the device during disinfection. In addition to the surfaces, thoroughly wipe the strain relief, including the test plugs. **Protocol printer (only for option with protocol printer):** Do not wipe over the openings of the protocol printer when disinfecting. When wiping over the lever for opening the protocol printer, ensure that no liquids enter the gaps. Otherwise, wipe the printer surface and the paper feed button. For hard-to-reach areas on the protocol printer, use a soft brush previously dipped in the disinfectant solution. During this process, ensure that the disinfectant is applied evenly. The disinfectant solution must completely and uniformly wet all device surfaces to achieve the desired disinfecting effect. If the device is not in use, disinfect the device surface once a week.
Drying	Allow the tourniquet to air-dry after cleaning and disinfection. Ensure that all surfaces are completely dry before the next use.

Storage	**Tourniquets:** Store clean and dry; see chapter '12 Technical Data' on page 65. **Cuff size tape:** After disinfection, store in a suitable clean environment; see chapter '12 Technical Data' on page 65.
Additional information	Other disinfectants listed by VAH (Association for Applied Hygiene) and RKI (Robert Koch Institute) may also be used, provided they are suitable for plastic surfaces and metals. Observe the manufacturer's information on material compatibility. Contact the manufacturer for approval.

6.1 Unsuitable cleaning agents and disinfectants

NOTICE

Unsuitable cleaning agents and disinfectants.

The product may become damaged.

Do not use any process chemicals that contain the following ingredients on plastic parts and the cuff size tape:

- Chloramines or phenol derivatives
- Hydrogen peroxide (causes stress cracks and embrittlement)

Do not use any process chemicals that contain the following ingredients on metal:

Stainless steel:

- Organic or inorganic bases
- Alkaline solutions

Brass:

- Organic or inorganic acids
- Strong oxidising agents, including hydrogen peroxide

6.2 Recommended cleaning agents and disinfectants for the device surface

☞ Lukewarm water with a mild soap solution may be used to clean the device surfaces.

Agent (manufacturer)	Ingredients	In 100 g
Cleaning		
mikrozid® sensitive wipes (Schülke & Mayr)*	Alkyl (C12–16) dimethylbenzylammonium chloride Didecyldimethylammonium chloride Alkyl (C12–14) ethylbenzylammonium chloride	0.25 g 0.25 g 0.25 g
Disinfection		
Incidin™ Pro (Ecolab)*	2-Phenoxyethanol N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine (diamine) Alkyl (C12–16) dimethylbenzyl ammonium chloride	10.0 g 8.0 g 7.5 g

*Validation of efficacy has been performed using these cleaning agents and disinfectants.

☞ Follow the manufacturer's specifications for concentration, contact time, and material compatibility.

7 Maintenance and service

Maintenance, repairs, and periodic tests may only be carried out by persons who have the appropriate technical knowledge and are familiar with the product. The person must have the necessary test equipment and original spare parts to carry out these measures. ATMOS recommends that the work 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.

- Perform a repeat test of the electrical safety in accordance with IEC 62353 at least every 12 months. In this context, ATMOS recommends carrying out an inspection in accordance with the manufacturer's specifications.

7.1 Sending in the device

- Remove all consumables and dispose of them properly.
- Clean and disinfect the product and accessories according to the Instructions for Use.
- Enclose any used accessories with the product.
- Fill in the form QD 434 'Delivery complaint / return shipment' and the corresponding **Decontamination certificate**.

☞ This form is enclosed with the product and can be found at www.atmosmed.com.

- Pack the product in suitable packaging with adequate padding.
- Place the form QD 434 'Delivery complaint / return shipment' and the corresponding **Decontamination certificate** in an envelope.
- Affix the envelope to the outside of the package.
- Send the product to ATMOS or your dealer.

8 Troubleshooting

8.1 Detecting faults

Messages

If a deviation from proper device operation is detected, a pop-up with the corresponding **message** is displayed. The message categories are described in the following section.

Error

If a fault occurs that does not generate a message, there is an **error** in the device. The errors are described here: see section ‘8.5 Errors and troubleshooting’ on page 58.

Warning sound

Depending on the priority of the fault and the message, a warning sound is emitted. All warning sounds can be muted by pressing the button.

8.2 Message categories

Messages occurring during operation are prioritised by the tourniquet and divided into the categories Warnings and Faults.

8.2.1 Warning

Warnings are events that may impair the intended function of the tourniquet. Warnings are displayed as pop-ups with a turquoise background and are identified by a warning number preceded by ‘W’. Additional icons are displayed to make them easier to distinguish.

☞ For a description of all warnings and information on how to resolve them, see section ‘8.4.1 Troubleshooting messages’ on page 53.



☞ Warnings displayed in a narrow pop-up bar can be acknowledged using a button.

8.3 Fault

In the event of a fault, the intended function of the tourniquet can no longer be ensured safely due to the occurrence of an event.

Faults are displayed as pop-ups with a yellow background and are identified by a fault number preceded by ‘E’.

☞ For a description of all faults and information on how to resolve them, see section ‘8.4.1 Troubleshooting messages’ on page 53.



Faults that can usually be resolved quickly and easily are additionally indicated by an icon.

Examples:

- E 530 'No cuff connected'
- E 650 'The device detects a leakage or pressure loss'

8.4 Messages and troubleshooting

☞ Before contacting service, follow the troubleshooting steps described in the list below.

☞ The colour of the safety message number indicates which channel is affected.

Colours:

- Red: The left channel is affected.
- Blue: The right channel is affected.
- Black: Both channels are affected.

8.4.1 Troubleshooting messages

Category 'W' – Warning

Description	Cause	Resolution
W 301	Recording 	Is your tourniquet equipped with a printer? Check whether the printer cover is closed. Check whether enough paper is inserted. Add paper if necessary (see section '5.8.2 Changing the printer paper' on page 46). Acknowledge the warning using the 'Acknowledge message' button . The red LED goes out immediately and the warning is cleared. If the warning continues to appear, permanently disable the printer after completing the tourniquet application (see section '3.5.4 Enabling and disabling the protocol printer' on page 22).
W 311	Safety check required	The tourniquet has been used for over 3000 operating hours. Perform the safety check (see section '9.3 Safety check' on page 60). This warning appears once. If the safety message is confirmed, the tourniquet can continue to be operated. The service symbol is displayed in the status line until the safety check has been performed. When the tourniquet is switched on, the service screen with the service symbol still appears.

Category ‘E‘ – Fault

If this safety message continues to appear despite following the troubleshooting steps:

» Contact service.

Code	Meaning	Resolution
E 99 (black)	Device check was not passed. 	1. Ensure that the CGS pressure is present. 2. Insert the test plugs. 3. Perform the device check again (see section ‘9.2 Device check’ on page 59).
E 120 (black)	Internal memory error	This safety message may appear during the self-test. We recommend restarting the device. 1. Switch off the tourniquet using the On / Off button. 2. Disconnect the tourniquet from the power supply. 3. Wait 10 seconds and reconnect the power plug. 4. Switch the tourniquet on again using the On / Off button.
E 135	CGS operating pressure too low 	This safety message may appear during the self-test. 1. Switch off the tourniquet using the On / Off button. 2. Ensure that the CGS pressure is present. 3. Switch the tourniquet on again using the On / Off button.
E 140 (black)	Pressure measurement inconsistent	During the self-test, a deviation in the pressure measurement was detected; this indicates a malfunction. 1. Switch off the tourniquet using the On / Off button. 2. Disconnect the tourniquet from the power supply. 3. Wait 10 seconds and reconnect the power plug. 4. Switch the tourniquet on again using the On / Off button.
E 145 (blue/red)	Malfunction of the switching behaviour of the valves 	1. The device connections are not free during the self-test. 2. Disconnect all hoses, cuffs, and test plugs before the self-test. 3. Switch off the tourniquet. 4. Wait about 10 seconds. 5. Switch the tourniquet on again.
E 420 (black)	Internal memory error	Values changed in the menu cannot be saved. We recommend restarting the device. 1. Switch off the tourniquet. 2. Wait about 10 seconds. 3. Switch the tourniquet on again. 4. Check in the menu whether your changes have been applied.

Code	Meaning	Resolution
E 435	CGS operating pressure too low 	☞ Ensure that the CGS hose is connected correctly and pressure is present. The safety message is cleared once the issue has been resolved. The application cannot be started until the fault is resolved.
E 530 (blue/red)	No cuff connected 	1. Ensure that a cuff or hose is attached and connected to the correct connection. 2. Ensure that the cuffs or hoses are properly engaged in the cuff connection. 3. Ensure that the cuff is not applied too loosely to the patient extremity. If necessary, change the cuff size. 4. Acknowledge the safety message using the 'Mute warning' button . The safety message is closed, and the tourniquet application can be restarted immediately.
E 635	CGS operating pressure too low 	This fault may appear during surgery. The pressure in the cuff is maintained. Adjustment of the pressure is not possible. 1. Acknowledge the safety message using the 'Mute warning' button . 2. Ensure that the CGS hose is connected correctly and pressure is present. The safety message is cleared once the issue has been resolved. The application cannot be started until the fault is resolved. If the fault persists for more than 9 minutes, the device switches to E 880.
E 645 (blue/red)	Malfunction of the switching and control behaviour of the valves	A malfunction of the proportional valve or the venting valve is possible. If the fault should occur during surgery when you wish to adjust the pressure, the device cannot perform the pressure adjustment. If the fault appears after you wish to release the pressure, the tourniquet cannot release the pressure in the cuff. 1. Switch off the tourniquet. 2. Manually disconnect the connection hose from the tourniquet so that the pressure is released from the cuff. In both cases, the tourniquet requires a device check.

Code	Meaning	Resolution
E 650 (blue/red)	Leakage message 	The tourniquet detects a continuous pressure loss (target pressure –20 mmHg for 3 seconds). Leakage in the cuffs or hoses is suspected. 1. The message can be muted using the 'Mute warning' button . 2. Check that the hoses and cuffs are connected correctly. If the leakage persists, the safety message is issued visually and audibly after 3 minutes. If the leakage has not been eliminated after 9 minutes, the valves are closed and the cuff pressure is maintained, provided there is no leakage in the cuff itself. This is followed by safety message E 880. ☞ Always end the tourniquet application first on the tourniquet device. ☞ Do not disconnect the cuffs or connection hoses from the tourniquet until the tourniquet application has ended.
E 665 (blue/red)	Excessive pressure in the cuff	Excessive pressure enters the cuff and can no longer be reduced by the tourniquet. Yellow warning with blue text (small): 20 mmHg above target pressure for at least 3 seconds, right channel. Yellow warning with red text (small): 20 mmHg above target pressure for at least 3 seconds, left channel. Red warning with white text (small): 50 mmHg above target pressure. The valves are closed and the cuff pressure is maintained. 1. Visually check the actual pressure in the cuff. 2. End the tourniquet application and switch off the tourniquet. The tourniquet requires a device check (see section '9.2 Device check' on page 59).
E 870	CGS operating pressure too high	This fault may appear during surgery. The pressure in the cuff is maintained. Adjustment of the pressure is not possible. 1. Switch off the tourniquet (after completing surgery) using the On / Off button. 2. Restart the tourniquet. » After the self-test, the tourniquet requires a device check. 3. Perform the device check (see section '9.2 Device check' on page 59).

Code	Meaning	Resolution
E 875 (black)	Internal power supply fault	If the tourniquet is in use during surgery, the pressure in the cuff is maintained. 1. Switch off the tourniquet (after completing surgery) using the On / Off button. 2. Disconnect the tourniquet from the power supply. 3. Wait 10 seconds and reconnect the power plug. 4. Switch the tourniquet on again using the On / Off button. 5. If a device check is required, perform it (see section '9.2 Device check' on page 59).
E 880 (black)	Safety message in pressure measurement	The tourniquet detects deviations in the pressure measurement system. This fault may appear during surgery. The pressure in the cuff is maintained. Adjustment of the pressure is not possible. 1. Switch off the tourniquet (after completing surgery) using the On / Off button. 2. Disconnect the tourniquet from the power supply. 3. Wait 10 seconds and reconnect the power plug. 4. Switch the tourniquet on again using the On / Off button. 5. If a device check is required, perform it (see section '9.2 Device check' on page 59). If the device check is passed, you may start the tourniquet application.
E 890	Software error	If this fault appears during surgery, the pressure in the cuff is maintained. Adjustment of the pressure is not possible. The software is no longer functioning correctly. 1. Switch off the tourniquet (after completing surgery) using the On / Off button. 2. We recommend disconnecting the tourniquet from the power supply. 3. Wait 10 seconds and reconnect the power plug. 4. Switch the tourniquet on again using the On / Off button. 5. If a device check is required, perform it (see section '9.2 Device check' on page 59). If the device check is passed, you may start the tourniquet application.

Code	Meaning	Resolution
E 895	Over-temperature-message (> 65 °C)	The tourniquet measures an internal temperature of more than 65 °C and switches off automatically after 30 seconds to prevent a risk of fire. If this safety message occurs during a tourniquet application, the pressure in the cuff is maintained. 1. Check that the tourniquet is not exposed to sources of heat. 2. Switch off the tourniquet. 3. Disconnect the tourniquet from the power supply. 4. Allow the tourniquet to cool down. 5. If necessary, contact the person responsible for the device to have the tourniquet and its environment checked for possible causes. 6. Switch the tourniquet on again.

8.5 Errors and troubleshooting

Description	Cause	Resolution
The touch display remains dark after the device is switched on.	Device not adequately acclimated to room temperature.	1. Switch off the tourniquet again. 2. Allow the tourniquet to acclimate to room temperature. 3. Switch the tourniquet on again.
The touch display is dark and the red LED is flashing. A warning sound is emitted.	Software error	1. Press and hold the On / Off button until the warning sound stops and the red LED goes out. If this malfunction occurs during surgery, the valves are closed and the cuff pressure is maintained. 2. End the tourniquet application manually. 3. Disconnect the connection hose from the device connection. » The device check is required (see section ‘9.2 Device check’ on page 59). The tourniquet application cannot be started until the device check is passed.

9 Maintenance

9.1 Self-test

The sophie tourniquet performs a self-test each time it is switched on. The device connections must be kept clear during this process (i.e., no hoses or cuffs must be connected). These initial system tests ensure safe start-up and provide a function check of all critical components.

☞ Do not connect the cuffs and hoses until the selection screen appears (observe the notice on the front of the sophie tourniquet).



If the self-test fails, safety message E 120, E 135, E 140 or E 145 appears (see section ‘8.4.1 Troubleshooting messages’ on page 53).

9.2 Device check

A device check is automatically required after the tourniquet has detected a major fault during the tourniquet application.

The device check ensures proper functioning of the tourniquet following faults E 645, E 665, E 870, E 875, E 880, E 890, E 895, E 99 (see section ‘8.4.1 Troubleshooting messages’ on page 53).

During the device check, the tourniquet automatically checks all important internal device functions in a fully automated test sequence.

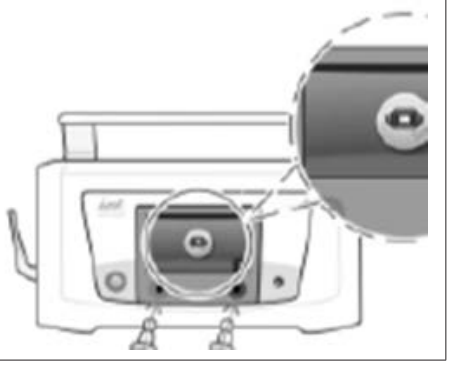
To perform the device check, the test plugs located on the rear of the tourniquet are required (see section ‘3.2 Rear side’ on page 16).

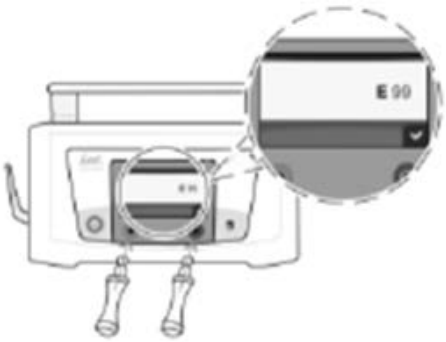
If the device check is passed, the product is free from faults and can be used in accordance with its intended purpose.

If the device check is successfully completed following a fault, the likely cause of the fault is the accessories (e.g., defective cuff or connection hoses).

9.2.1 Performing the device check

If the following icon appears on the tourniquet, this indicates that a device check is required.

1. Insert the test plugs (REF SP000698) into the cuff connections. 2. Start the device check using the ‘Confirm’ button ✓. The device check is performed. The time counts down (10 seconds).	

After the device check has been completed successfully, a white ‘Device check’ icon appears in the centre of the display. 3. Confirm using the ‘Confirm’ button  and exit the menu. » The device check has been passed.	
If the device check is not passed, safety message E 99 appears (see section ‘8.4.1 Troubleshooting messages’ on page 53). 4. Ensure that the test plugs are inserted correctly and that the CGS pressure is present. Restart the test from within the safety message.	

☞ If the device check has not been passed three times: Contact service.

9.3 Safety check

⚠ CAUTION

ATMOS recommends performing the safety check after 3000 operating hours.

- This check may only be performed by the manufacturer or by service personnel authorised by the manufacturer.

When 3000 operating hours are reached, safety message W 311 appears.

The current operating hours of the tourniquet can be viewed in the information field in the menu (see section ‘3.5.9 Viewing device information’ on page 27).

1. Acknowledge safety message W 311.

» The safety message is closed and the service symbol appears in the status line.

☞ After each restart of the tourniquet, the service screen appears as a reminder. The tourniquet application is not affected by this.



10 Accessories

Customers can order all listed accessory parts from their authorised distributor or ATMOS MedizinTechnik.

REF	Description
Accessories	
Documentation	
UT 1381	Protocol printer for mein Tourniquet (retrofit)
UT 1381-01	Paper for protocol printer UT 1381, 58 mm width
Mounting the tourniquet	
UT 1382	Mobile stand for tourniquets elsa, heidi, sophie, with basket and cable holder
UT 1383	Standard rail bracket for tourniquets
Power cables, plugs	
XD 2068-01	Power cable CEE 7 Europe 2 m
XD 2068-02	Power cable BS1363 GB 2 m
XD 2068-03	Power cable GB2099 CN 2 m
XD 2068-04	Power cable NBR14136 BR 2.5 m
XD 2068-05	Power cable SANS164 RSA 1.5 m
XD 2068-06	Power cable NEMA5-15P US 3 m hospital grade
XD 2068-07	Power cable SEV type 12 CH 2.5 m
XD 2068-08	Power cable CEI 23-50 ITA 1.5 m
XD 2068-09	Power cable AS3112 AUS 2 m
Reusable cuffs	
UT 1317-2XS	Cuff 2XS, orange connector
UT 1317-XS	Cuff XS, orange connector
UT 1317-S	Cuff S, orange connector
UT 1317-M	Cuff M, orange connector
UT 1317-L	Cuff L, orange connector
UT 1317-XL	Cuff XL, orange connector
UT 1317-2XL	Cuff 2XL, orange connector
UT 1317-3XL	Cuff 3XL, orange connector
UT 1321-2XS	Cuff 2XS, standard connector
UT 1321-XS	Cuff XS, standard connector
UT 1321-S	Cuff S, standard connector
UT 1321-M	Cuff M, standard connector
UT 1321-L	Cuff L, standard connector
UT 1321-XL	Cuff XL, standard connector
UT 1321-2XL	Cuff 2XL, standard connector
UT 1321-3XL	Cuff 3XL, standard connector
Disposable cuffs	
UT 1332-2XS	Disposable cuff 2XS, orange connector, 10 pcs.
UT 1332-XS	Disposable cuff XS, orange connector, 10 pcs.
UT 1332-S	Disposable cuff S, orange connector, 10 pcs.

UT 1332-M	Disposable cuff M, orange connector, 10 pcs.
UT 1332-L	Disposable cuff L, orange connector, 10 pcs.
UT 1332-XL	Disposable cuff XL, orange connector, 10 pcs.
UT 1332-XL-P	Disposable cuff XL parallel, orange connector, 10 pcs.
UT 1332-2XL	Disposable cuff 2XL, orange connector, 10 pcs.
UT 1330-2XS	Disposable cuff 2XS, standard connector, 10 pcs.
UT 1330-XS	Disposable cuff XS, standard connector, 10 pcs.
UT 1330-S	Disposable cuff S, standard connector, 10 pcs.
UT 1330-M	Disposable cuff M, standard connector, 10 pcs.
UT 1330-L	Disposable cuff L, standard connector, 10 pcs.
UT 1330-XL	Disposable cuff XL, standard connector, 10 pcs.
UT 1330-XL-P	Disposable cuff XL parallel, standard connector, 10 pcs.
UT 1330-2XL	Disposable cuff 2XL, standard connector, 10 pcs.
Connection hoses	
UT 1187-500	Connection hose-D (orange-standard), 5 m
UT 1188-500	Connection hose-A (standard-orange), 5 m
UT 1277-300	Connection hose-A (orange-orange), 3 m
UT 1277-500	Connection hose-A (orange-orange), 5 m
UT 1276-300	Connection hose-D (orange-orange), 3 m
UT 1276-500	Connection hose-D (orange-orange), 5 m
UT 1321-300	Connection hose-D (standard-standard), 3 m
UT 1321-500	Connection hose-D (standard-standard), 5 m
Hoses for central gas supply (CGS)	
UT 1270-080	Connection hose for central compressed air, neutral model
UT 1270-150	Connection hose for central compressed air, neutral model
UT 1270-300	Connection hose for central compressed air, neutral model
UT 1270-500	Connection hose for central compressed air, neutral model
UT 1272-150	CGS-NIST hose, 1.5 m neutral
UT 1272-300	CGS-NIST hose, 3 m neutral
UT 1273-150	CGS-NIST hose, 1.5 m ISO
UT 1273-150-01	CGS-NIST hose, angled, 1.5 m ISO
UT 1273-150-02	CGS-NIST hose, angled, 1.5 m neutral
UT 1273-300	CGS-NIST hose, 3 m ISO
UT 1273-300-01	CGS-NIST hose, angled, 3 m ISO
UT 1273-300-02	CGS-NIST hose, angled, 3 m neutral
UT 1273-500-01	CGS-NIST hose, angled, 5 m ISO
HM57525019	Connection tube AIR DIN 1.5 m / neutral colour
HM57525020	Connection tube AIR DIN 3 m / neutral colour
HM57525021	Connection tube AIR DIN 1.5 m / ISO
Other cuff accessories	
UT 1315	Cuff size tape
UT 1355	Plug for connector
300.001	Hook-and-loop cleaning comb

11 Disposal and environmental specification

Packaging

1. Recycle any device packaging you no longer need.

Hoses and disposable cuffs

Disposable products may not be reprocessed and may not be reused! Dispose of single-use products properly.

sophie tourniquet



Do not dispose of the device with household waste.

1. Clean and disinfect the device.
2. In Germany: return the device to ATMOS or your specialist dealer. They will recycle the device properly.
3. In other countries: recycle the device properly and in accordance with applicable national laws and regulations.

11.1 Expected service life

When the sophie tourniquet is operated according to the Instructions for Use, it has an expected service life of 6 years. This assumes regular, thorough cleaning and disinfection of the device and its applied parts, as well as operation in accordance with the Instructions for Use.

11.2 Environmental specification

Within the framework of applicable statutory provisions (in Germany: the Electrical and Electronic Equipment Act (ElektroG)), ATMOS generally organises the take-back and disposal of devices that were first placed on the market on or after 24 March 2006 and are intended for disposal. Provision of the serial number is required for take-back. Naturally, the system or system components may also be disposed of via the hospital's internal waste disposal system.

The basis for the disposal of medical waste in the European Union is the European Waste Catalogue. Where applicable, countries down to the municipal level may issue their own waste disposal regulations, which must be complied with.

Outside the European Union, the relevant country-specific regulations for the disposal of medical waste must be observed.

Type of disposal	Includes	Waste code*
Electronic waste	Display, printed circuit boards, motor, power supply units, switches, sensors, terminal	20 01 36
Batteries Note: Return batteries to the manufacturer for disposal in accordance with applicable regulations.	Lead	20 01 33
Metal recycling and plastic recycling	Structural attachments, cables, housing, tray	20 01 39 20 01 40

Type of disposal	Includes	Waste code*
Packaging	Separation of cardboard, paper, and plastics	15 01 01 15 01 02 15 01 05 15 01 06
Items with patient contact	Single-use items, cuffs	16 03 04 16 10 02 18 01 04 18 01 01 20 01 11
Items without patient contact	Single-use items, cuffs	16 03 04 20 01 11 18 01 01

* Waste codes according to the currently applicable European List of Waste.

12 Technical Data

Input voltage	100–240 VAC; 50/60 Hz
Power consumption	62 VA
Fuses	mains: F1 and F2: 2 AT; 250 V
Other safety devices	pressure reducing valve
minimum / maximum cuff pressure	30 mmHg / 600 mmHg
Accuracy	± 10 mmHg
CGS-NIST connection [AIR]	4–6 bar
Type of documentation	Integrated log printer (optional)
Display	LCD Touchscreen 4.3" (resistive, reacts on pressure, can be operated with gloves)
Monitoring microprocessor	yes, dual (Main/Safety CPU)
Environmental conditions Transport/storage • Temperature range • Air humidity without condensation • Air pressure	 –15...+40 °C 5...90 % 700...1060 hPa
Environmental conditions Operation • Temperature range • Air humidity without condensation • Air pressure	 +15...+30 °C 5...90 % 700...1060 hPa
Maximum operating altitude	3000 m
Contamination level	Class 2
Overvoltage category	II
Dimensions (H x W x D)	179 x 313 x 156 mm (without hose holder and printer)
Weight (without log printer)	3.8 kg
Periodic tests	Recommended: Safety check after 3000 operating hours
Protection class against electric shock (acc. to EN 60601-1)	I
Classification of applied parts	Type B applied parts The applied part is the contact surface of the cuff
Degree of protection	IPX1
CE marking	CE 0123

Reference number (REF)	UT 1380-S sophie, mein Tourniquet 2 channel (CGS) UT 1380-SP sophie, mein Tourniquet 2 channel, printer (CGS)

12.1 Mobile stand UT 1382 (optional accessory)

Operating height	Approx. 1160 mm
Device base diameter	Approx. 533 mm
Weight	Approx. 10 kg
Maximum load basket	Approx. 2.4 kg

13 Notes on EMC

Requirements that apply to all devices and systems:

- ☞ Note that the tourniquet must be installed and commissioned in accordance with the following EMC information, since medical electrical devices are subject to special precautions regarding electromagnetic compatibility (EMC).
- ☞ In addition, mobile RF communications equipment may affect the performance of the tourniquet.

If special requirements apply with regard to electromagnetic immunity for operation in the intended operating theatre:

contact ATMOS to obtain further information.

The electromagnetic (EM) environment for the sophie tourniquet is defined in accordance with the EMC standard DIN EN 60601-1-2:2022-01 as follows:

- Hospitals with corresponding operating departments:
  Environment in professional healthcare facilities
- Outpatient surgery centres or corresponding practices:
  Environment in areas of home healthcare
- The sophie tourniquet is suitable for use in special electromagnetic environments:
  Areas used for medical treatment with high-power medical electrical equipment and RF surgical equipment

The sophie tourniquet has been tested in accordance with the EMC standard DIN EN 60601-1-2:2022-01.

All emission limits specified in this standard are met.

All immunity test levels defined in this standard are reliably tolerated by the sophie tourniquet, so that no impairment of function occurs.

⚠ WARNING

Reduction of performance characteristics or functional impairment due to the use of unauthorised cables.

Risk of increased electromagnetic emissions, reduced electromagnetic immunity of the tourniquets, or malfunction.

- Use only accessories and cables specified by ATMOS as replacement parts for internal components.

⚠ WARNING

Reduction of performance characteristics or functional impairment due to portable RF communications equipment.

- Maintain a minimum distance of 30 cm between the tourniquets and portable RF communications equipment to prevent a reduction in performance characteristics or functional impairment.

⚠ WARNING

Reduction of performance characteristics or functional impairment due to the use of unauthorised power cables.

- Use only power cables specified by ATMOS. Only these power cables have been tested in accordance with this EMC standard, including ad hoc testing with RF surgical equipment, and do not cause undefined electromagnetic emissions or result in a reduction in performance characteristics or functional impairment due to electromagnetic interference.

Electromagnetic EMISSIONS – sophie tourniquet		
The sophie tourniquet is intended for use in the ELECTROMAGNETIC ENVIRONMENT specified below. The customer or user[N3)] of the tourniquet must ensure that it is operated in such an environment.		
Emission measurements	**Compliance**	**Description**
HF emissions according to DIN EN 55011 / CISPR 11	Group 1	The sophie tourniquet uses RF energy only for its internal FUNCTION. RF emissions are therefore very low and are not likely to cause interference in nearby electronic equipment.
	Class B	
Harmonic emissions according to DIN EN 61000-3-2 / IEC 61000-3-2	Class A	The sophie tourniquet is suitable for use in all establishments, including domestic and those connected directly to the PUBLIC LOW-VOLTAGE POWER SUPPLY NETWORK that supplies buildings used for residential purposes.
Voltage fluctuations/flicker according to DIN EN 61000-3-3 / IEC 61000-3-3	Complies	

Electromagnetic IMMUNITY – sophie tourniquet
The sophie tourniquet is intended for use in the ELECTROMAGNETIC ENVIRONMENT specified below. The customer or user[N4)] of the tourniquet must ensure that it is used in such an environment.
IMMUNITY tests
Electrostatic discharge (ESD) according to DIN EN 61000-4-2
Radiated RF electromagnetic fields according to DIN EN 61000-4-3
Test level: 3 V/m (professional healthcare facilities)
Test level: 10 V/m (home healthcare environments)
Electrical fast transient/burst according to DIN EN 61000-4-4
Surge immunity according to DIN EN 61000-4-5
Conducted RF disturbances induced by RF fields according to DIN EN 61000-4-6
Voltage dips, short interruptions and voltage variations on power supply input lines according to DIN EN 61000-4-11
Power-frequency magnetic field (50/60 Hz) according to DIN EN 61000-4-8
Frequency variations according to DIN EN 60601-1

[N3) N4)] National footnote: In this context, the term user refers to the ‘RESPONSIBLE ORGANISATION’.

14 Notes

ATMOS
MedizinTechnik

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