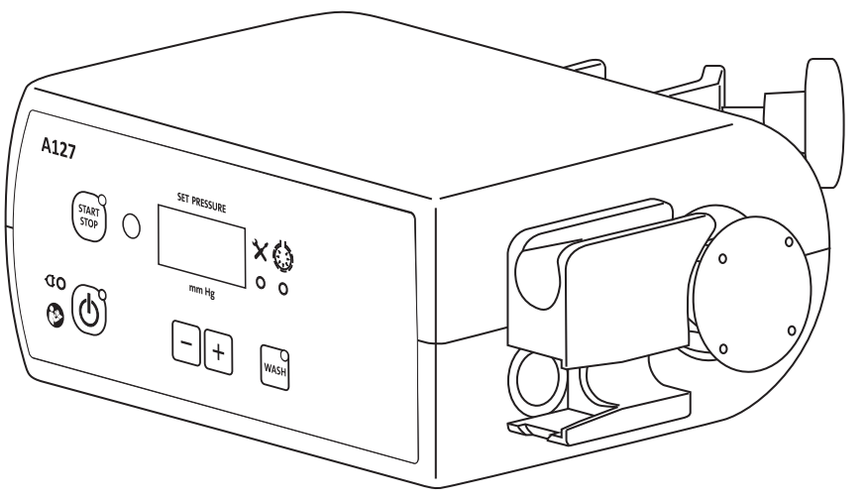
# A127

Instructions for Use en




## Pump for Arthroscopy A127

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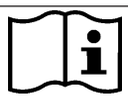
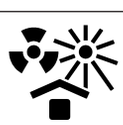
CE 0197 CE marking according to Directive 93/42/EEC

Type: A127 / 1201161 / 10000012999 07 Issued: 2020-01

## Symbols and Description

| | |
|---|---|
|  | Follow instructions for use (white image on a blue background) |
|  | Caution |
|  | Consult instructions for use |
|   | Authorized for Sale or use by Physician only |
|  | Type BF applied part |
|  | Equipotentiality |
| IP 41 | Degrees of protection provided by enclosures (IP-Code) |
|  | Protective earth (Ground) |
|  | Alternating current |
|  | Service |
|  | Service |
| REF | Catalogue number |
| LOT | Batch code |
| SN | Serial number |

| | |
|---|---|
|  | Do not reuse |
|   | Do not resterilize |
| STERILE EO | Sterilized using ethylene oxide |
|   | Non sterile |
|  | Date of manufacture (YYYY-MM-DD) |
|  | Manufacturer |
|  | Use by date (YYYY-MM-DD) |
| QTY | Quantity |
|   | Not made with phthalates |
| 134 °C 3 bar 5 min XX | Number of autoclaving cycles |
|  | Keep dry |
|  | Top-Bottom |
|  | Fragile |
|  | Keep away from sunlight |
|  | Protect from heat and radioactive sources |

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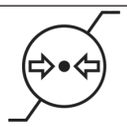
|---|---|
|  | Temperature limit |
|  | Humidity limitation |
|  | Atmospheric pressure limitation |
|  | Do not use if package is damaged |
|  | Waste management |
|  | Transport conditions |
|  | Storage conditions |
|  | Recyclable packaging (Greendot symbol) |
|   | Recycling PAP PE |
|   | RFID tag, general |
|  | Non-ionizing electomagnetic radiation |

## Table of Contents

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# 1 Important User Notes

Read the manual carefully and become familiar with the operation and function of the device and the accessories before use during surgical procedures. Non-observance of the instructions listed in this manual can lead

- to life-threatening injuries of the patient,
- to severe injuries of the surgical team, nursing or service personnel, or
- damages or malfunction of device and/or accessories.

**Subject to technical changes**

The manufacturer reserves the right to modify the appearance, graphics, and technical data of the product through continued development of its products.

**Please note**

Paragraphs marked with the words WARNING, CAUTION, and NOTE carry special meanings. Sections marked with these words must be given special attention.

**WARNING!**

**The safety and/or health of the patient, user, or a third party are at risk. Comply with this warning to avoid injury to the patient, user, or third party.**

**CAUTION!**

**These paragraphs include information provided to the operator concerning the intended and proper use of the device or accessories.**

**NOTE!**

**These paragraphs contain information to clarify the instructions or provide additional useful information.**

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## 2 Safety Information

**Federal Law (only for U.S. market)**

**CAUTION! Federal law restricts this device to sale by or on the order of a physician.**

**Exclusion of liability**

The manufacturer is not liable for direct or consequential damages, and the warranty becomes null and void if:

- the device and/or the accessories are improperly used, transported, stored, prepared, or maintained;
- the instructions and rules in the instructions for use are not adhered to;
- unauthorized persons perform repairs, adjustments, or alterations on the device or accessories;
- unauthorized persons open the device;
- the prescribed inspection and maintenance schedules are not adhered to.

The handing over of technical documents does not constitute authorization to make repairs or alterations to the device or accessories.

**WARNING! Modification of the devices A127 is not permitted.**

**Authorized service technician**

Only an authorized service technician may perform repairs, adjustments, or alterations on the device or accessories and use the service menu. Any violation will void the manufacturer's warranty. Authorized service technicians are only trained and certified by the manufacturer.

**Care and maintenance**

The service and maintenance of the device and its accessories has to be carried out as per instructions to ensure the safe operation of the device. For the protection of the patient and the operating team, check that the device is complete and functional before each use. Maintenance of the device may not be performed during the operation.

**NOTE! Service or maintenance work may not be carried out during surgery.**

**Contamination**

Before shipping, decontaminate device and accessories in order to protect the service personnel. Follow the instructions listed in these instructions for use. If this is not possible,

- the product must be clearly marked with a contamination warning and
- is to be double-sealed in safety foil.

The manufacturer has the right to reject contaminated products for repair.

**Waste management**

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. For disposal of the device and its accessories, please consult the manufacturer or an authorized disposal company, in compliance with legal or national regulations.

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# 3 General Information

## 3.1 Description of the Device

The device itself is non-invasive and designed for use in non-sterile areas. It pumps medically sterile irrigation fluids through a sterile tube. These fluids are used to distend and irrigate corresponding body cavities to provide space and improve visibility for the attending physician. The device can be used with electrolyte-free media (e.g., glycine 1.5 % or sorbitol 3.0 %) and with isotonic, electrolyte-containing media (e.g., saline 0.9 % or Ringer's lactate). The device functions only with the tube sets described in the accessory list (see Chapter Accessory List [▶ 48]).

During arthroscopic procedures the device can be operated at nominal flow rates of up to 1.5 l/min and a maximum pressure of 150 mmHg can be selected.

The device operates with a completely non-contact pressure measurement of the irrigation medium. The contact-free pressure measurement is achieved by integrating the pressure membrane into the tube set. The pressure membrane transfers the tube pressure to the electronics of the device via a pressure sensor. The pressure control circuit continuously compares the actual pressure with the nominal pressure. The function of the device is to maintain the nominal pressure.

## 3.2 Intended Use and Contraindications

### 3.2.1 Intended Use

**WARNING!**

**Use only with necessary training**

**The device is intended to be used only by surgeons and support personnel with the necessary training in arthroscopic procedures.**

The product **A127** is an irrigation pump for diagnostic and/or surgical arthroscopic procedures. Such procedures may include:

- Ligament injuries
- Meniscus injures
- Cartilage injures
- Operating planning and re-examination

The irrigation pump serves to distend and irrigate joints in the knee, shoulder, hip and elbow, as well the wrist and ankle joint.

The user can select the desired joint pressure.

The pump attempts to reach and maintain the preset pressure in the joint by supplying irrigation fluid. If the joint cannot be drained (e.g., because closed valve at instrument), and if the pre-selected pressure has been reached, the pump reduces the inflow of the fluid and attempts to maintain the preset pressure. If the intraarticular pressure falls below the selected value, fluid automatically continues to be supplied.

The device is used in the non-sterile area of a lit or darkened operating room and can be attached with a toggle bolt to the rear side of the device on a tripod, or can be set up in an equipment rack as well. The positioning should be at the height of the joint to be irrigate.

**Patient population**

There are no restrictions to consider specifically concerning the patient population.

**Recommended pressure**

The nominal pressure can be preset to between 5 and 150 mmHg. The preset pressure should be based on the average blood pressure of the patient to prevent bleeding in the joint. The manufacturer recommends the following pressure settings for the following application areas:

| | |
|---|---|
| Knee joint | 50 mmHg |
| Shoulder joint | 50 mmHg |
| Hip joint | 60 mmHg |
| Elbow joint | 30 mmHg |
| Ankle joint | 70 mmHg |

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| | |
|---|---|
| Wrist joint | 30 mmHg |

Each surgery and each patient require different parameters. The values indicated by manufacturer are therefore only recommendations and are not intended to substitute or replace the expertise of the surgeon.

The maximum flow is limited to 1.5 l/min on the device side and is automatically reduced by the pump once the nominal pressure has been reached.

**Clinical use**

When performing monopolar electrosurgery, only non-conductive irrigation fluids may be used. Examples include glycine, sorbitol, mannitol, sorbitol plus mannitol, and dextran.

### 3.2.2 Contraindications

Use of this device to inject fluid into a joint is prohibited whenever arthroscopy is contraindicated. Refer to your endoscope's manual for absolute and relative contraindications.

Arthroscopy is contraindicated in the following cases:

- Ankylosis
- Inflammation or bacterial contamination

The device may not be used to inject medication.

The device is not designed or intended for use with gas.

## 3.3 General Warnings and Precautions

### 3.3.1 General Warnings

**WARNING!**

**Risk of electrical shock**

**To prevent electrical shock, do not open this device. Never open this device yourself. Notify the authorized service technicians of any required repairs.**

**WARNING!**

**Risk of electrical shock**

**To avoid the risk of electrical shock, only use this device when connected to a properly grounded power supply network.**

**WARNING!**

**Maintenance and calibration**

**Do not open the device. The device may not be opened or calibrated by the user. Only authorized service technicians are permitted to repair, calibrate, or modify the device or its equipment.**

**WARNING!**

**Power supply**

**Disconnection from the power supply is only guaranteed if the mains plug is pulled from the mains wall socket.**

**WARNING!**

**Technique and procedures**

**Only the physician can evaluate the clinical factors involved with each patient and determine if the use of this device is indicated. The physician must determine the specific technique and procedure that will accomplish the desired clinical effect.**

**WARNING!**

**Check all factory settings**

**Factory settings are not mandatory settings for the physician. The physician is responsible for all settings affecting the surgical procedure.**

**WARNING!**

**Original accessories**

**For your own safety and that of your patient, use only original accessories.**

**WARNING!**

**Acoustic signals**

**Different default settings of the warning message for identical or similar devices in the operating room may cause a risk due to conflicting acoustic signals.**

**WARNING!**

**Checking the warning signals**

**The warning signals must be checking prior to each device use. The system is to be set up so that all warning signals can be perceived.**

**WARNING!**

**Not explosion-proof**

**The device is not explosion-proof. Do not operate the device in the vicinity of explosive anesthetic gases and not in the vicinity of oxygen-enriched environments.**

**WARNING!**

**Professional qualification**

**The instructions for use do not include descriptions or instructions for surgical procedures/techniques. It is not suitable for training physicians in the use of surgical techniques. Medical peripherals and devices may be used only by physicians or medical assistants with the appropriate technical/medical qualifications working under the direction and supervision of a physician.**

**WARNING!**

**Functional test**

**The functional test must be performed by the user prior to each surgery.**

**WARNING!**

**Sterile media and accessories**

**Always work exclusively with sterile substances and media, sterile fluids, and sterile accessories if so indicated.**

**WARNING!**

**Replacement device and accessories**

**In case the device or any of the accessories fail during surgery, a replacement device and replacement accessories should be kept within close proximity to be able to finish the operation with the replacement components.**

**WARNING!**

**Contamination**

**Do not use device and/or accessories if signs of contamination are detected. Make sure the device or/and accessories can no longer be operated until a qualified service technician conducts the appropriate tests and repairs.**

**WARNING!**

**Condensation / Water penetration**

**Protect device from moisture. Do not use if moisture has penetrated the device.**

**WARNING!**

**Replace the fuse**

**Replace the fuse only with a fuse of the same type and rating (see Chapter Technical Data [▶ 52]).**

**WARNING!**

**Touching patient and device**

**The operating team must not touch both patient and device while the patient is in sterile area and device is in non sterile area of the operating theatre.**

**WARNING!**

**Touching patient and device**

**Do not touch patient and the Standby/ON key at the same time.**

**WARNING!**

**ME System (Medical Electrical System)**

**Use only parts and/or devices from ME systems (see Chapter Glossary) in patient environments in compliance with the standard IEC60601-1 in the respective currently valid version.**

**WARNING!**

**ME System (Medical Electrical System)**

**Connect only items that have been specified as part of the ME system or specified as being compatible with ME system.**

**WARNING!**

**Additional equipment**

**Additional equipment connected to medical electrical devices must be demonstrated to be compliant with their respective IEC or ISO standards (IEC 60601-1, IEC 60950 or IEC 62368 for data processing equipment). Furthermore, all configurations must comply with the normative requirements for medical systems (see section 16 of the last valid edition of IEC 60601-1). Anyone who connects additional devices to medical electrical equipment is a system configurator and as such is responsible for the system's compliance with the normative requirements for systems. Please contact the technical service if you have additional questions.**

**WARNING!**

**Obvious defects**

**Never use the device if it has suspected or confirmed defects, especially if these involve the power plugs or the mains power supply connection cables. In this case have the device repaired by authorized service personnel.**

**WARNING!**

**Instrument replacement**

**Stop the device using the START/STOP key if replacing the instrument during surgery.**

**WARNING!**

**Preventing infections**

**Sterilize reusable instruments and reusable tubes sets (NOT FOR SALE IN USA) before surgery to prevent infections. Check all the single-use/disposable items before removing them from the package to ensure that the packaging is intact and that the expiration date is still valid.**

**WARNING!**

**Reprocessing of sterile disposable products**

**Infection hazard for patients and/or users and impairment of product functionality due to reuse. Risk of injury, illness or death due to contamination and/or impaired functionality of the product! Do not reprocess the product.**

**WARNING!**

**Falls and crashes**

**Place the device on a stable and level surface. Cables must be laid safely. Tubes between the device and the patient must not create any obstruction.**

### 3.3.2 Precautions

**CAUTION!**

**Incorrect voltage**

**Check to make sure the available mains voltage matches the data listed on the type label attached to the back of the device. Incorrect voltage can cause errors and malfunctions and may destroy the device.**

**CAUTION!**

**ME systems**

**The medical electrical (ME) device is suitable for integration in ME equipment systems (see Chapter Glossary). Operation of the ME device in vicinity of non-ME devices may result in voiding the intended use of the ME device.**

**CAUTION!**

**ME Device in Rack**

**The ME device may not be used when stacked or stored directly adjacent to or with other devices. If it should be necessary to operate the device close to stacked with other devices, the ME device or ME system should be monitored to ensure it works properly as configured.**

CAUTION!

Endoscope

The device may only be connected with endoscopes designed for and featuring the technical specification permitting such a combined use. Any utilized endoscopes must comply with the most recent versions of EC 60601-2-18 and ISO 8600. Combining/connecting with other devices generates a medical electrical system (MES). The system configurator is responsible for compliance with the standard IEC 60601-1 / EN 60601-1 in its latest version.

CAUTION!

Peripheral Devices

Additional peripheral equipment connected to interfaces of the medical monitor has to meet the requirements of the following specifications in the respective current valid version: IEC 60601-2-18 / EN 60601-2-18 for endoscopic devices and IEC 60601-1 / EN 60601-1 for electrical medical devices. All configurations have to comply with IEC 60601-1 / EN 60601-1 specifications. Whoever connects additional equipment to signal output or signal input is considered the system configurator and as such is responsible for complying with requirements of the standard IEC 60601-1 / EN 60601-1.

CAUTION!

Electrical interference

(See Chapter Electromagnetic Compatibility [▷ 49]). Care was taken during the development and testing of this device that electrical interference of or from other devices or instruments was practically eliminated. However, if you still detect or suspect such interference, please follow these suggestions:

- Move this, the other, or both devices to a different location
- Increase distance between used devices
- Consult an electro-medical expert

CAUTION!

Use of other accessories, other transducers and cables

The device may only be connected with endoscopes designed for and featuring the technical specification permitting such a combined use. Any utilized endoscope must comply with the most recent versions of IEC 60601-2-18 and ISO 8600. Combining/connecting with other devices generates a medical electrical system (MES). The system configurator is responsible for compliance with the standard IEC 60601-1 / EN 60601-1 in its last version. The use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM (see Chapter Glossary) as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the ME EQUIPMENT or ME SYSTEM.

CAUTION!

Not to be used with a defibrillator

The device may not be used in conjunction with a defibrillator since it is not equipped with corresponding safety elements. The manufacturer accepts no liability in this case for ensuing damage.

CAUTION!

Indoor climate

Before switching on the device, sufficient time must have passed to adjust to the indoor climate.

**CAUTION!**

**Ventilation of the device**

- **Avoid device overheating.**
- **Ensure free air circulation especially to the bottom and rear of the device (rear panel distance of at least 10 cm).**

**CAUTION!**

**Patient group**

**There are no restrictions as to the specification of the patient group when using the device as intended and its use does not endanger the patient's health.**

**CAUTION!**

**Cleaning the Device**

**Do not sterilize the device.**

**CAUTION!**

**Overheating**

**To avoid overheating,**

- **the device must not be operated for more than 10 minutes at maximum speed.**
- **the device must not be operated without fluid in the tube system.**

**CAUTION!**

**Mains Power Cable**

**Any power cables employed by the user that are not provided by the manufacturer must meet the safety requirements of the national standards in the respective current valid version.**

**CAUTION!**

**Device setup**

**Device should be positioned outside of the sterile area in such a way that**

- **it can be easily disconnected,**
- **it is easy to use and switch off and on,**
- **it allows an easy monitoring of the display values, device functions, and access to the control elements.**

## 3.4 Device-Specific Warnings: Arthroscopy Indication

**WARNING!**

**Irrigation fluid bags**

**The device is only intended for use with flexible fluid bags. Do not use glass containers as they might break. With rigid containers, fluid cannot flow quickly enough due to the vacuum being generated inside of the containers. Risk of implosion with rigid containers.**

**WARNING!**

**Pressure settings**

**The nominal pressure of the described device can be preset to values described in these Instructions for Use. Select the optimum pressure based on the patient profile, including but not limited to blood pressure, height, weight and age. The manufacturer recommends pressure settings for different areas of application; however these are suggestions only and are not intended to substitute or replace the expertise of the surgeon.**

**WARNING!**

**In case of an overpressure**

**In case of an overpressure situation, the here described device is equipped with safety measures to assist in reducing the overpressure. The pump may display warning signs and start turning the inflow spindle backwards, in an attempt to decrease the intra-articular pressure by removing fluid from the joint. Please refer to the descriptions of various warnings described in these Instructions for Use.**

**WARNING!**

**Loss of distension**

**Distension may be lost when resetting the nominal flow or nominal pressure settings.**

**WARNING!**

**Fluid extravasation**

**Fluid irrigation pumps used in Arthroscopy may cause fluid extravasation into the surrounding tissue. In severe cases, the resulting pulmonary edema may result in a serious adverse patient event which may include compartment syndrome, neuropraxia, tachycardia, pneumothorax, tissue tearing or nerve compromise. Should extravasation be observed, it is recommended to reduce pressure settings and closely observe the excess fluid build up.**

**WARNING!**

**Height difference**

**The height difference between the device and the patient must be adjusted correctly in order to ensure exact pressure measurement.**

**WARNING!**

**Keep fluid bags ready for use**

**Always keep a full fluid bag on hand to replace an empty one. This avoid having to interrupt surgery due to a lack of distention fluid.**

# 4 Device Setup

The operation of the device is reserved for medical staff with the relevant professional qualifications trained to use the device.

**Setting up**

## 4.1 Scope of Delivery

- Device **A127**
- Instructions for Use
- Power cable

**Delivery inspection**

**WARNING!**

**Check for defects**

**Check the product and the packaging for defects prior to use. Do not use if package is damaged.**

**CAUTION!**

**Premature unpacking**

**Do not premature unpack the devices, until sufficient time must have passed to adapt to the room climate**

Always check all parts and accessories of the device immediately after receiving the shipment. The manufacturer considers only replacement claims that have been immediately submitted or reported to a sales representative or an authorized service company.

**WARNING!**

**Preventing infections**

**Sterilize reusable instruments and reusable tubes sets (NOT FOR SALE IN USA) before surgery to prevent infections. Check all the single-use/disposable items before removing them from the package to ensure that the packaging is intact and that the expiration date is still valid.**

**Returning the device**

If it becomes necessary to return the device, always use the original packaging. The manufacturer does not take responsibility for damage that has occurred during transportation if the damage was caused by inadequate transport packaging.

Please fill out the return form enclosed at the end of these Instructions for Use. Enclose the Instructions for Use with the device.

Please make sure that all required information has been supplied:

- Name of owner
- Address of owner
- Device type and model
- Serial number (see identification plate)
- Description of defect

## 4.2 Setting up and Connecting the Device

**NOTE!**

**Locations**

**The device may be used only in the hospital or operating rooms.**

After unpacking, place the device **A127** on a flat surface free of vibration located in a dry environment. The ambient temperature and humidity must meet the requirements mentioned in Chapter Technical Data [▸ 52].

**WARNING!**

**Falls and crashes**

**Place the device on a stable and level surface. Cables must be laid safely. Tubes between the device and the patient must not create any obstruction.**

**WARNING!**

**Condensation / Water penetration**

**Protect device from moisture. Do not use if moisture has penetrated the device.**

**WARNING!**

**Not explosion-proof**

**The device is not explosion-proof. Do not operate the device in the vicinity of explosive anesthetic gases and not in the vicinity of oxygen-enriched environments.**

**WARNING!**

**Functional test**

**The functional test must be performed by the user prior to each surgery.**

**WARNING!**

**Original accessories**

**For your own safety and that of your patient, use only original accessories.**

**WARNING!**

**ME System (Medical Electrical System)**

**Use only parts and/or devices from ME systems (see Chapter Glossary) in patient environments in compliance with the standard IEC60601-1 in the respective currently valid version.**

**CAUTION!**

**ME systems**

**The medical electrical (ME) device is suitable for integration in ME equipment systems (see Chapter Glossary). Operation of the ME device in vicinity of non-ME devices may result in voiding the intended use of the ME device.**

**CAUTION!**

**ME Device in Rack**

**The ME device may not be used when stacked or stored directly adjacent to or with other devices. If it should be necessary to operate the device close to stacked with other devices, the ME device or ME system should be monitored to ensure it works properly as configured.**

**CAUTION!**

**Switching on the device**

**Before switching on the device, sufficient time must have passed to adapt to the room climate.**

CAUTION!

Ventilation of the device

- Avoid device overheating.
- Ensure free air circulation especially to the bottom and rear of the device (rear panel distance of at least 10 cm).

CAUTION!

Device setup

Device should be positioned outside of the sterile area in such a way that

- it can be easily disconnected,
- it is easy to use and switch off and on,
- it allows an easy monitoring of the display values, device functions, and access to the control elements.

CAUTION!

Position of the user

To avoid a malfunction, the user must be positioned correctly

- within a display viewing angle of ±50° to operate the device,
- up to 2 m/6.5 ft from the device front for monitoring the actual values.

CAUTION!

To avoid malfunctions

The device A127 should not be used directly next to other devices as this could result in malfunctions. The device A127 was tested for compliance with IEC 60601-1-2 as a stand alone system. Therefore, do not stack other devices on the system or the pump. If usage in the manner described above is nevertheless required, this system and the other devices should be monitored to make sure they function properly.

## Mains connection

WARNING!

Cable pulling

Always grasp the plug of the power cable when unplugging; never pull on the cable itself.

CAUTION!

Connection to mains

Do not connect this device or system to a multiple socket-outlet or an extension cord.

**CAUTION!**

**Mains connection**

- **Make sure the available mains voltage matches the data listed on the type label attached to the back of the device. Incorrect voltage can cause errors and malfunctions and may destroy the device.**
- **Make sure the connection data and technical specifications of the power supply comply with DIN VDE or national requirements. The mains connection cable may be plugged only into a properly installed, grounded safety wall socket (shockproof socket) (see DIN VDE 0100-710).**
- **Read the device label located in rear of device (type plate) to determine the operating voltage of the device.**

**Grounding contact**

The power connection must be equipped with a grounding contact. Use the original power cable to establish a connection between the mains wall socket and the non-heating device plug located in the rear of the device.

The grounded, shockproof safety wall socket should be near the device and within easy reach. Disconnect the device from the mains power supply (pull cable out off the grounded safety wall socket) if the device is not being used for several days or an extended period. The device is ready for use as soon as all connections are established and all cables have been plugged in.

**Only for U.S. operators**

Only use a certified (UL-listed), removable mains connection cable, type SJT, minimal 18 AWG, 3 leads. The plug connectors must comply with NEMA 5-15 and IEC 60320-C13. Grounding will only be reliable if the equipment is connected to a corresponding hospital grade socket.

**Potential equalization**

The equipotential bonding is used as a protective measure against the failure of the protective conductor according to requirements of IEC 60601-1 in the respectively valid version. The installation must be according to the relevant local safety regulations.

## 4.3 Mounting the Pump

The device is designed to be suspended from a portable stand or upright placement in a device rack. Installation and initial startup of the device are to be carried out by a correspondingly trained service technician authorized by the manufacturer. The device is installed horizontally with the upper side of the device pointing up. The height of the installation position of the device above the floor should correspond with height of the joint.

### 4.3.1 Mounting on Stand

**CAUTION!**

**Read instructions**

**Please read the instruction manual for the stand before mounting the pump on the stand.**

**CAUTION!**

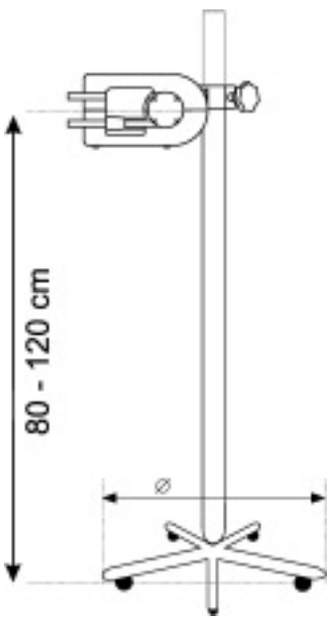
**Stability**

**The position of the device on the stand can affect the stand's stability. If the device is mounted too high on the stand, the stand may tilt or topple. The user/operator of the device is responsible for making sure the device cannot be tipped over or otherwise become unstable.**

**CAUTION!**

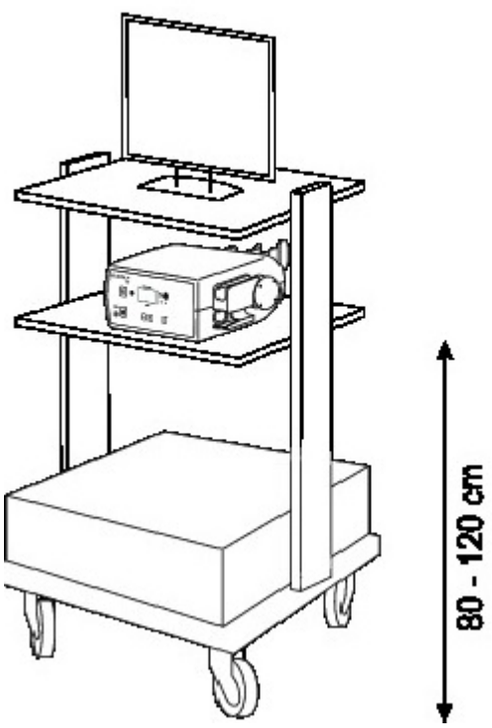
**Pump in place**

**Make sure the toggle screw is tightened sufficiently to fasten the pump securely in place. Also check that the toggle screw remains tightened.**




1. Position the pump on the rod of the stand at the desired height, usually between 80 and 120 cm (example: Base of stand ø = 65 cm, maximum height of h < 100 cm recommended).
2. Tighten the toggle screw on the rear of the pump.

### 4.3.2 Positioning in Device Rack



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# 5 Operating the Device

**CAUTION!**

**Combination of devices**

**Comply with the relevant standards IEC 60601-1 / EN 60601-1 when combining several devices.**

## 5.1 Front of the Device

Familiarize yourself with the control and function elements at the front of the device.

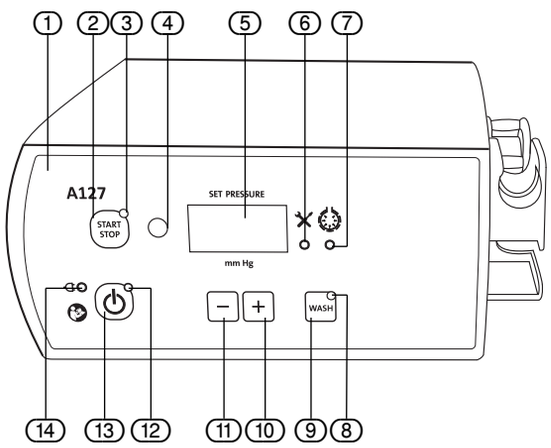


**Fig. 5–1 Front of the device**

1. Control foil
2. START/STOP key
3. START operating mode LED
4. Remote operation interface
5. Operating states and warnings display
6. Service LED
7. Overpressure LED
8. WASH operating mode LED
9. WASH key
10. Increase pressure key (PLUS)
11. Decrease pressure key (MINUS)
12. ON operating mode LED
13. Standby/ON key
14. Mains voltage LED

## 5.2 Device Side

Familiarize yourself with the connection elements at the side of the device.

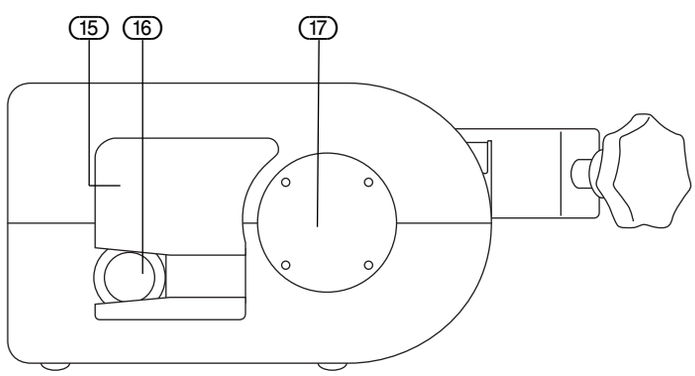


**Fig. 5–2 Device side**

15. Tube retainer
16. Pressure sensor
17. Roller wheel

## 5.3 Rear of the Device

Familiarize yourself with the connection elements at the rear of the device.

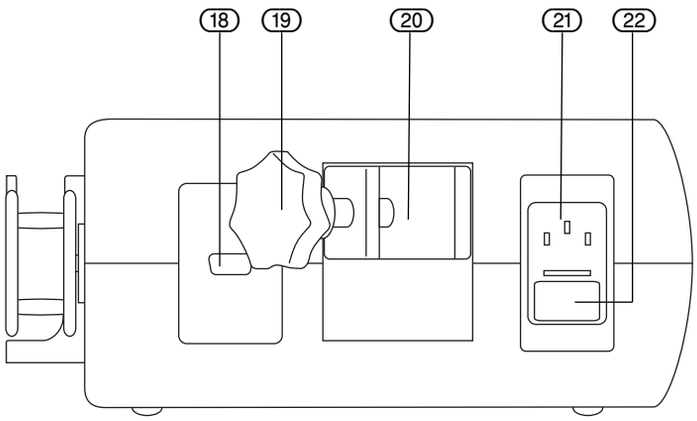


**Fig. 5–3 Rear of the device**

(18) Service interface
(19) Toggle screw
(20) Tripod mount
(21) Mains socket
(22) Fuse holder

## 5.4 Turning the Device On

1. Plug the device into the power outlet. The mains voltage LED lights up green (Front of the device [▸ 22] (14)).
2. Make sure a tube set is **not** inserted into the tube retainer.
3. Press "ON" key (Front of the device [▸ 22] (13)). The device switches on.
4. The "ON" operating mode LED lights up green (Front of the device [▸ 22] (12)). A device self-test is carried out automatically.

If a tube set is in the tube retainer of the device when the device is being switched on, the display for operating states and warnings (Front of the device [▸ 22] (5)) depicts "----" and a warning acoustic signal (beep) is emitted once. The self-test continues once the tube set is removed.

If the device check is unsuccessful, the corresponding error messages are displayed on the Operating States and Warnings display ("ERROR" see Chapter Error and Warning Messages [▸ 54]).

A low volume acoustic signal (beep) indicates the device self-test completed successfully.

## 5.5 Irrigation Tube Sets Overview

A total of 2 different tube sets can be inserted into the tube retainer on the device side (Device side [▸ 22] (15)). The following table lists the usability of each type of tube set.

| Art. No. | Tube description |
|---|---|
| T0449-01 | Disposable tube set, Luer lock connector and spikes, only inflow |
| T0454-01 | Reusable tube set **(NOT FOR SALE IN USA)**, Luer lock connector and spikes, only inflow |

**WARNING!**

**Preventing infections**

**Sterilize reusable instruments and reusable tubes sets before surgery to prevent infections. Check all the single-use/disposable items before removing them from the package to ensure that the packaging is intact and that the expiration date is still valid.**

**WARNING!**

**Reprocessing of sterile disposable products**

**Infection hazard for patients and/or users and impairment of product functionality due to reuse. Risk of injury, illness or death due to contamination and/or impaired functionality of the product! Do not reprocess the product.**

**CAUTION!**

**Check of the reprocessed tube set**

**After each cleaning / reprocessing, the cleaned / reprocessed tube set must be checked for possible damages caused by the process before it is stored / used properly and professionally for the following use!**

**CAUTION!**

**Pressure chamber diaphragm**

**The pressure chamber diaphragm is fragile and can be replaced if damaged. The reusable tube sets (NOT FOR SALE IN USA) must be prepared before each use. See Chapter Care of the Reusable Tube Set (NOT FOR SALE IN USA) [▶ 39].**

**NOTE!**

**Tube set storage**

**The tube sets must be stored at room temperature. The shelf life for tube sets is 5 years.**

**NOTE!**

**Hygiene regulations**

**Observe applicable hygiene regulations when disposing of the tube set.**

## 5.6 Using the Irrigation Tube Sets

The **A127** is designed to be used with a disposable tube set as well as a reusable tube set **(NOT FOR SALE IN USA)**.

**RFID technology (transponder technology)**

All irrigation tube sets are equipped with a transponder. The transponder technology detects the tube type, the validity and reliability of a tube set automatically and a corresponding message is output in the display of the device. This eliminates virtually all "operating errors" since non fitting, invalid, and not approved tube sets are reliably detected and not released for use. The corresponding transponder is located in every approved tube set (see Chapter Irrigation Tube Sets Overview [▶ 23]).

If a valid tube set has been inserted into the device ready to be operated, a low volume acoustic signal is emitted and the operating states and warnings display (Fig. Front of the device [▶ 22] ⑤) depicts for 3 seconds the number of cycles remaining after the current surgery (000 for disposable tube set and for reusable tube set during last remaining cycle, xxx for reusable tube set).

**Invalidating a tube set**

If an approved and valid tube set is located in the device, the transponder technology automatically invalidates this tube set when the device is started. Depending on the tube set, this has the following consequences:

- **Disposable tube set:**

*Display 000 (3 s) -> remaining cycles after this use*

  - The tube set can be removed/inserted as often as desired without invalidating the tube set as long as the pump is not started.
  - The tube set is invalidated 1 minute after starting the pump.

- The pump can be started/stopped as often as desired with a tube set invalidated during the current application if the tube set is not removed. Once the tube set is removed, it can no longer be used.
- If the inserted tube set has already been invalidated, an error message **E02** is displayed until the tube set is removed.
- If an invalid tube set is inserted, an error message **E03** is displayed until the tube set is removed.
- If the inserted tube set has been inserted incorrectly and the pump is started, an error message **E04** is displayed for 3 seconds.
- If no tube set has been inserted and the pump is started, an error message **E01** is displayed for 3 seconds.
- If an invalid tube set has been inserted and the pump is started, **E03** flashes 3 times.
- If an invalidated tube set has been inserted and the pump is started, **E02** flashes 3 times.

- **Reusable tube set (max. 20 cycles, NOT FOR SALE IN USA):**

*Display xxx (3 s) -> remaining cycles after this use*

- After the last remaining cycle, 000 is displayed for an additional 3 seconds with every stop and a low volume acoustic signal (beep) is emitted.
- The tube set is invalidated 1 minute after starting the pump.
- The pump can be started/stopped as often as desired with a tube set invalidated during the current application if the tube set is not removed. Once the tube set is removed during the last remaining cycle, this tube set can no longer be used.
- If the inserted tube set has already been invalidated, an error message **E02** is displayed until the tube set is removed.
- If an invalid tube set is inserted, an error message **E03** is displayed until the tube set is removed.
- If the inserted tube set has been inserted incorrectly and the pump is started, an error message **E04** is displayed for 3 seconds.
- If no tube set has been inserted and the pump is started, an error message **E01** is displayed for 3 seconds.
- If an invalid tube set has been inserted and the pump is started, **E03** flashes 3 times.
- If an invalidated tube set has been inserted and the pump is started, **E02** flashes 3 times.

**Transponder signal loss**

The device stops and cannot be restarted if the transponder loses its signal during current operation (e.g. defective electronic component). If the signal is automatically restored within 1 second, it is possible to continue using the tube set for additional applications.

## 5.7 Inserting the Irrigation Tube Sets

The irrigation tube set is available as a disposable or reusable tube set (autoclavable, **NOT FOR SALE IN USA)** (see Chapter Irrigation Tube Sets Overview [▷ 23]).

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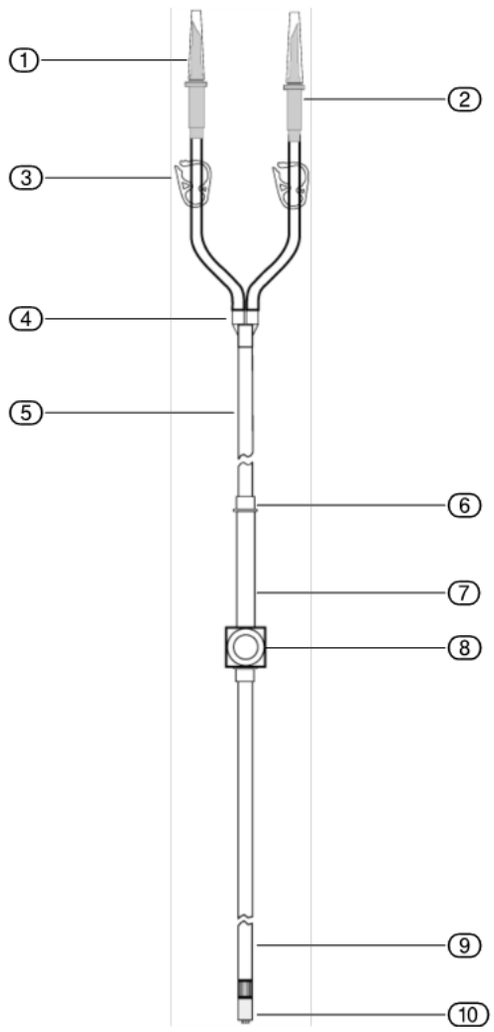
**Fig. 5–4 Tube set elements**

① Protect[illegible]aps
② Spikes
③ Tube clamps
④ Y-connector
⑤ Inflow tube
⑥ Ring
⑦ Roller tube
⑧ Pressure chamber with membrane and transponder
⑨ Instrument tube
⑩ Luer lock connector




The irrigation tube set consists of three tube sections (roller tube, inflow tube, and instrument tube), a Y-connector, 2 spikes with protective caps, 2 tube clamps and a pressure chamber with membrane and transponder.

The spikes are used to connect the tube sections with the irrigation fluid bags.

The Luer lock connector connects the instrument tube with the instrument.

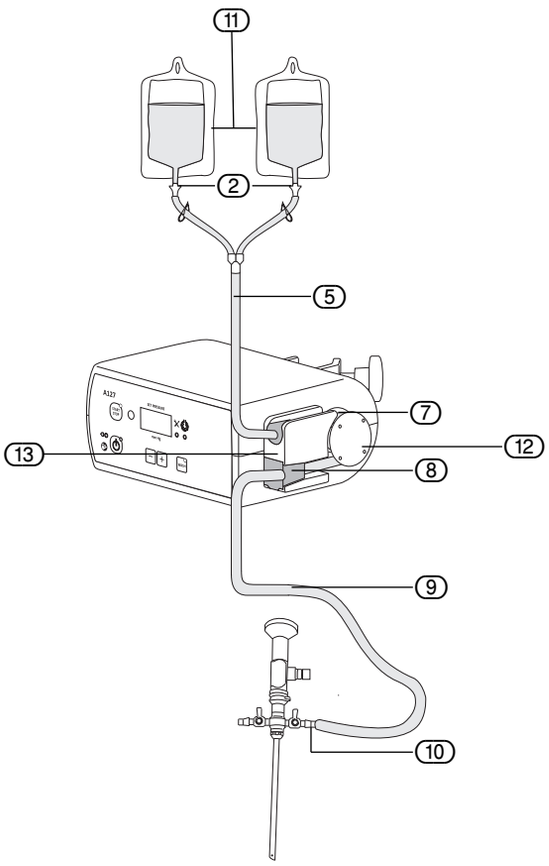



**Fig. 5–5 Inserting tube set**

(2) Spikes
(5) Inflow tube
(7) Roller tube
(8) Pressure chamber with membrane and transponder
(9) Instrument tube
(10) Luer lock connector
(11) Irrigation fluid bags
(12) Roller wheel
(13) Tube retainer

**1a. Disposable tube set - To be carried out by non-sterile technician:**

**Open outer packaging**

- Open outer packaging of the tube set.
- A sterile technician then removes the inner tube set package and opens it.

**1b. Reusable tube set (NOT FOR SALE IN USA) - To be carried out by non-sterile technician:**

**Open sterile autoclavable container**

- Open the sterile autoclavable container of the tube set.
- A sterile technician then removes the tube set from the inside of the package.

**2. To be carried out by sterile technician:**

**Connecting the instrument**

- Keep the Luer lock connector (10) in the sterile area and hand the tube end with the spikes (2) to the non-sterile technician (see Fig. Inserting tube set [▷ 27]).
- Connect the Luer lock connector (10) with the instrument (inflow). Open inflow valve of the instrument.

**3. To be carried out by non-sterile technician:**

**Inserting the tube set**

- Switch device on. Insert the tube set. Inserting the roller tube is depicted in Fig. Position roller tube [▷ 28].
- Place the roller tube (7) around the roller wheel (12).
- When inserting the roller tube, make sure not to damage the membranes of the pressure chamber. Insert the pressure chamber (8) only if chamber is not pressurized.
- Carefully insert the unpressurized pressure chamber (8) into the lower notch of the tube retainer (13) up to the stop.
- Connect the fluid bags (see Chapter Connecting the Irrigation Fluid Bags [▷ 28]).

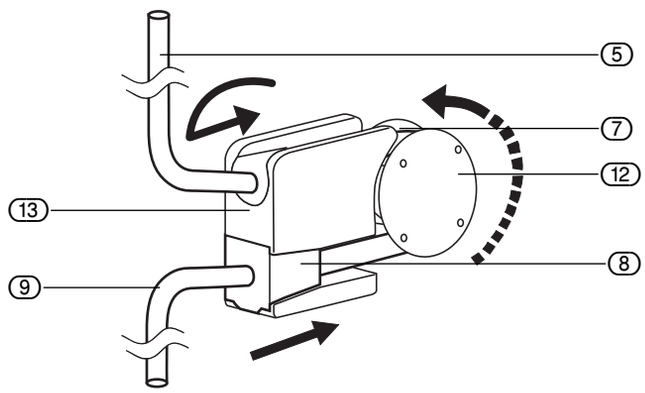
**Fig. 5–6 Position roller tube**

- (5) Roller tube
- (2) Pressure chamber
- (5) Inflow tube
- (7) Roller tube
- (9) Instrument tube
- (12) Roller wheel
- (13) Tube retainer

**CAUTION!**

**Inserting the tubes**

**Instrument tube (9) and inflow tube (5) must be inserted horizontally towards the front without twisting the roller tube.**




The device is now ready for use.

## 5.8 Connecting the Irrigation Fluid Bags

**WARNING!**

**Irrigation fluid bags**

**The device is only intended for use with flexible fluid bags. Do not use glass containers as they might break. With rigid containers, fluid cannot flow quickly enough due to the vacuum being generated inside of the containers. Risk of implosion with rigid containers.**

The fluid bags must be suspended at a height of h between 0.7 to 1.0 m above the pump (see Fig. Hanging fluid bags [▷ 29]).

1. The irrigation tube can take irrigation fluid from two fluid bags (1). Close both clamps (3) at the branches of the inflow tube.
2. Grasp the tap (2) at the provided handle when connecting or disconnecting.
3. Comply with sterile precautions when inserting the spike into a bag (optional safe lock connection).
4. Open at least one tube clamp (3) at the irrigation tube.
5. The surgeon has to select an irrigation fluid suitable for the application and medical procedure.

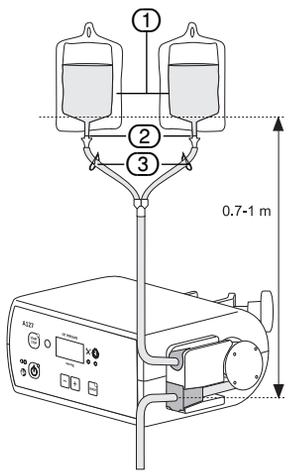



**Fig. 5–7 Hanging fluid bags**

① Irrigation fluid bags
② Spikes
③ Tube clamps

## 5.9 Setting Nominal Values

**Preselecting the nominal pressure**

The nominal pressure can be set while the device is being operated or while stopped. Adjust settings by tapping the **INCREASE** or **DECREASE** key on the control foil (Fig. Front of the device [▷ 22]).

Tap the **INCREASE** or **DECREASE** key on the control foil to change the nominal pressure values. Tap the **INCREASE** or **DECREASE** key once to increase or decrease the nominal pressure value in increments of 5 mmHg. Keeping the keys depressed longer than 1 second activates scrolling in increments of 20 mmHg. Tapping the keys is confirmed with a low volume acoustic signal (beep).

| Minimum nominal pressure | Maximum nominal pressure | Factory settings |
|---|---|---|
| 5 mmHg | 150 mmHg | 50 mmHg |

The last set value is not saved. The preset factory setting is always restored when the device is restarted.

**Preselecting the nominal flow**

The nominal flow cannot be adjusted. The maximum flow is limited to 1.5 l/min.

## 5.10 Starting the Device

Once the tube set has been inserted and the irrigation fluid bags are connected, tap the **START/STOP** key ② (see Fig. Front of the device [▷ 22]) to start the pump. The "START" ③ operating mode LED lights up green.

If the attempted start is unsuccessful, the corresponding error messages are displayed on the operating states and warnings display ("ERROR" see Chapter Error and Warning Messages [▷ 54]).

**Instrument recognition**

The device is equipped with an instrument recognition function. The pump determines the flow resistance of the instrument connected to the tube. If the instrument recognition was successful, this resistance is considered when the device is used for an optimized flow performance.

For an optimal resistance measurement, it is advised to perform the instrument recognition outside the joint prior to surgery.

For best results, follow these instructions prior to beginning the surgical procedure:

1. Connect the instrument tube to the instrument required for the surgical procedure.
2. Close the outflow valve if installed.
3. Open the inflow valve completely.
4. The instrument recognition should be carried out outside of the joint at a working height of ± 10 cm. The process takes about 15 seconds.
5. Start the irrigation with the **START** key. The device will first fill the tube with fluid.

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6. The pump detects when the tube is filled. The device starts the instrument recognition process automatically as soon as pressure conditions have stabilized. This may take a few seconds..
7. This is followed by three short irrigation cycles.
8. Close the inflow valve. Do not press the **START/STOP** key. The instrument recognition is lost if the **START/STOP** key is pressed.
9. Continue with the surgical procedure.

**WARNING!**

**Erroneous measurements**

**Incompletely opened inflow valve and incompletely closed outflow valve during the instrument recognition phase can lead to erroneous measurements of the intra-articulate pressure.**

**Intraoperative instrument change**

**NOTE!**

**Instrument recognition**

**The instrument recognition has to be performed once more if the instrument is changed during surgery.**

How to:

1. Press the **START/STOP** key to stop the pumping process ("**START** " operating mode LED goes out).
2. Change the instrument, open the inflow valve completely, and close the outflow valve (drain valve).
3. The instrument recognition should be carried out outside of the joint at a working height of ± 10 cm. The process takes about 15 seconds.
4. Start the irrigation with the **START** key. The device will first fill the tube with fluid.
5. The pump detects when the tube is filled. The device starts the instrument recognition process automatically as soon as pressure conditions have stabilized. This may take from a few seconds..
6. This is followed by three short irrigation cycles.
7. Close the inflow valve. Do not press the **START/STOP** key. The instrument recognition is lost if the **START/STOP** key is pressed.
8. Continue with the surgical procedure.

## 5.11 Using the WASH Function

To improve visibility within the joint, activate the **WASH** function. This function increases the pressure by 50 % of the set nominal pressure value for 20 seconds. However, the maximum pressure of 150 mmHg is not exceeded.

**Starting the WASH function**

While the device is running, press the **WASH** key (Fig. Front of the device [▶ 22] (9)). Tapping the key is confirmed with a low volume acoustic signal (beep).

The **WASH** LED to visualize the current operating state **WASH** lights up green.

**Stopping the WASH function**

The pump automatically returns to the previously set operating values after 20 seconds.

To end the **WASH** function before 20 seconds of **WASH** time are over, press the **WASH** key again. This returns the pump immediately to the previously set operating value.

## 5.12 Switching the Device Off

1. Press the **Standby/ON** key (Fig. Front of the device [▶ 22] (13)) to turn the device off.
2. Remove the power connection cable (power cord) from mains socket (Fig. Rear of the device [▶ 23] (21)).

**NOTE!**

**Safe disconnection from power supply**

**A safe and all-pole disconnection of the product from the power supply is only ensured by disconnecting the power cord.**

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# 6 Safety Functions

The electronic components continuously monitor the proper function of the device. Device malfunctions are indicated with audible warning signals (beeps), error messages, and/or the blocking of device functions. A table listing a summary of possible error and warning messages is provided in Chapter Error and Warning Messages [▷ 54].

## 6.1 Device Self-Test

After being switched on, the device performs a self-test of the sensors, the motor, and electronic components. All LEDs light up during the self-test. Chapter Error and Warning Messages [▷ 54] describes the messages for defects of the individual modules or components.

## 6.2 Exceeding Nominal Pressure

In case of arthroscopic surgical procedures, it is possible that temporary overpressures occur (up to more than 300 mmHg in extreme cases), especially when the joint is being moved. The pump is therefore equipped with safety control mechanisms.

**Exceeding nominal pressure during operation**

The pump reduces any possible overpressure within the joint.

If the actual pressure exceeds the nominal pressure by more than 30 mmHg for at least 5 seconds, the pump tries to reverse the roller wheel to reduce the overpressure. A visual or acoustic warning is not provided.

If the pump is unable to reduce the overpressure, the Overpressure LED flashes red (Fig. Front of the device [▷ 22] ⑦) and an acoustic warning signal is emitted (10 beeps). The motor shuts down as well. Once the overpressure is eliminated, the motor starts again and the visual and acoustic warnings are removed.

**Pressure > 200 mmHg**

If the actual pressure exceeds the safety threshold of 200 mmHg, the device immediately activates the roller wheel in reverse motion to attempt a reduction of the overpressure.

The Overpressure LED (Fig. Front of the device [▷ 22] ⑦) flashes yellow. If the value does not drop below the safety threshold of 200 mmHg within 2 seconds, an acoustic warning signal is emitted (3 beeps).

**Pressure > 250 mmHg**

If the value exceeds the safety threshold of 250 mmHg, the device immediately activates the roller wheel in reverse motion to attempt a reduction of the overpressure. The Overpressure LED (Fig. Front of the device [▷ 22] ⑦) flashes red. If the value does not drop below the safety threshold of 250 mmHg within 0.5 seconds, an acoustic warning signal is emitted (10 beeps).

If the pump continuously moves the wheel in reverse for more than 5 seconds and is still unable to reduce the pressure to less than 250 mmHg, the motor is switched off until the pressure value drops below <250 mmHg.

# 7 Function Test

**WARNING!**

**Functional test**

**The functional test must be performed by the user prior to each surgery.**

**WARNING!**

**Checking the warning signals**

**The warning signals must be checking prior to each device use. The system is to be set up so that all warning signals can be perceived.**

**WARNING!**

**Original accessories**

**For your own safety and that of your patient, use only original accessories.**

**WARNING!**

**Obvious defects**

**Never use the device if it has suspected or confirmed defects, especially if these involve the power plugs or the mains power supply connection cables. In this case have the device repaired by authorized service personnel.**

**WARNING!**

**Preventing infections**

**Sterilize reusable instruments and reusable tubes sets (NOT FOR SALE IN USA) before surgery to prevent infections. Check all the single-use/disposable items before removing them from the package to ensure that the packaging is intact and that the expiration date is still valid.**

**NOTE!**

**Fastening the pump**

**Make sure the toggle screw is tightened sufficiently to fasten the pump securely in place. Also check that the toggle screw remains tightened.**

## 7.1 Preparing the Function Test

Check to make sure the fluid bags meet the listed specifications (see Chapter Connecting the Irrigation Fluid Bags [▶ 28]) and are suspended properly.

## 7.2 Performing the Function Test

The fluid bags and the instrument are connected to the pump (see Chapter Starting the Device [▶ 29]). The pump is turned on.

**NOTE!**

**Performing the tests**

**These tests must be performed out of the joints.**

1. Select a nominal pressure = 100 mmHg
2. Open the inflow valve at instrument and close the outflow valve.

3. Start the pump with the **START/STOP** key. The START operating mode LED (Fig. Front of the device [▶ 22] ③) lights up. Wait until the instrument recognition is finished (the instrument is outside of the joint and at a working height of ± 10 cm of the operation height, see Chapter Starting the Device [▶ 29]).
4. Close the inflow valve after the instrument recognition is finished.

## 7.3 Checking the WASH Function

1. Start the Wash function by pressing the **WASH** key on the device (or the corresponding key on the remote control). The pressure increase for the **WASH** function, in this case 150 mmHg, is depicted in the nominal pressure display. The roller wheel must pump briefly and then stops.
2. Stop the Wash function by pressing the **WASH** key on the device once more (or the corresponding key on the remote control). The pressure display depicts the last set values, in this case 100 mmHg. The roller wheel must reverse briefly and then stops.

## 7.4 Ending the Function Test

Stop the device by pressing the **START/STOP** key (see Fig. Front of the device [▶ 22] ②).

The function test has now been successfully completed. The device is now ready for surgical use. Position the device as needed for surgery.

# 8 Using the Device during Surgery

**WARNING!**

**Functional test**

**The functional test must be performed by the user prior to each surgery.**

**WARNING!**

**Irrigation fluid**

**The physician must determinate a distension fluid suitable for the application and medical procedure.**

## Before surgery

Make sure the device is at the same height as the instrument. A difference in height affects the pressure readings due to hydrostatic pressure.

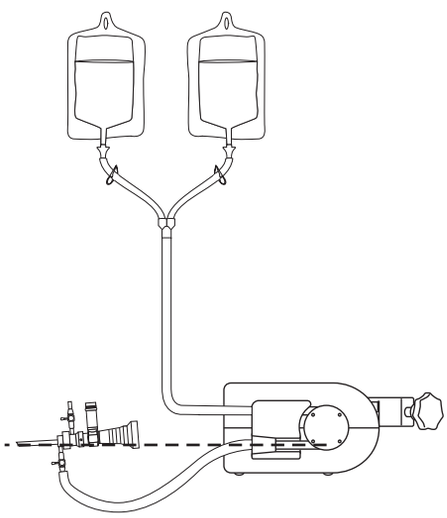

**Fig. 8–1 Before surgery**

1. Select the desired nominal pressure.
2. Open the inflow valve at the instrument and close the outflow valve (drain valve).
3. Press the **START/STOP** key. The START operating mode LED (Fig. Front of the device [▷ 22] ③) lights up. Wait until the instrument recognition is finished (the instrument is outside of the joint and at a working height of ± 10 cm of the operation height.
4. Close the inflow valve after the instrument recognition is finished.
5. Insert instrument into joint.
6. Open the inflow valve on the instrument.
7. The device ensures the joint is distended according to the preset nominal pressure. The flow is automatically reduced once the nominal pressure has been reached.

## After surgery

**WARNING!**

**Emptying the tube set**

**The manufacturer recommends emptying the tube set using the pump when employing saccharine irrigation fluids (HF use). Remove fluid bag and instrument first.**

1. Stop the irrigation process.
2. Close the valve on the instrument. Press the **START/STOP** key.
3. User the power switch to turn device off.
4. Remove standard tube set.

**NOTE!**

**Disposal**

**Comply with hygiene rules and regulations when disposing of the tube set, collected fluid, and the suction container.**

# 9 Care and Maintenance

Special care is necessary when servicing, maintaining, and storing the device and its accessories to maintain the functionality of the device and its accessories.

**NOTE!**

**Service or maintenance work**

**Service or maintenance work may not be carried out during surgery.**

## 9.1 Maintenance Intervals

**Manufacturer's specifications**

The manufacturer stipulates that qualified personnel or hospital technicians must regularly test the device to assess its functionality and technical safety. This inspection must be carried out once a year. The tests are described in Chapter Annual Inspection [▷ 46].

Regular inspections will assist in early detection of possible malfunctions. This helps to preserve the device and increases its safety and service life.

## 9.2 Cleaning the Device

1. Use the **Standby/ON** key to turn the device off.
2. Remove the power cable.
3. Wipe the surface of the device with a soft lint-free cloth moistened with the surface disinfectant (for example Meliseptol® rapid). The concentration and the time the disinfectant must be applied, depends on the information provided by the manufacturer of the disinfectant. Make sure moisture does not enter the device.

**CAUTION!**

**Cleaning the Device**

**Do not sterilize the device.**

## 9.3 Maintenance by Authorized Service Technician

**Two-year maintenance interval**

An authorized service technician has to inspect and service the device at appropriate intervals to ensure its safety and functionality. The service interval is two years. If the service interval is not maintained, the manufacturer does not assume any liability for the functional safety of the device.

A sticker located on the rear panel of the device states the latest date for the next service or maintenance check.

**Authorized trained personnel**

Authorized service technicians are only trained and certified by the manufacturer.

All of the service tasks, such as changes, modifications, repairs, calibrations, etc. may be carried out only by the manufacturer or manufacturer-approved trained and skilled technicians.

**Unauthorized personnel**

The manufacturer is not liable for the operational safety of the device if unauthorized persons conduct this maintenance or any other service tasks.

**Liability**

Unauthorized opening of the device and repairs performed by unauthorized personnel or third parties and/or changes or modifications release the manufacturer of any liability concerning the operational safety of the device.

**Technical documents**

Receiving technical documentation from the manufacturer does not authorize individuals to perform repairs, adjustments, or alterations on the device or accessories/peripherals.

**Technical report**

Ask the service technician for a technical report after the service technician has inspected the device or performed any service tasks. This technical report lists the type, the scope and the results of the service as well as the date and name of the servicing company together with the signature of the service technician.

**WARNING!**

**Risk of electrical shock**

**To prevent electrical shock, do not open this device. Never open this device yourself. Notify the authorized service technicians of any required repairs.**

**WARNING!**

**Modification of the device**

**This device may not be modified without the permission of the manufacturer.**

**WARNING!**

**Modified device**

**If the device is modified, suitable examinations and tests must be carried out to ensure further safe use of the device.**

## 9.4 Replacing the Fuse

**WARNING!**

**Replace the fuse**

**Replace the fuse only with a fuse of the same type and rating (see Chapter Technical Data [▶ 52]).**

The fuse may be defective and is in need of replacement if:

- displays and LEDs (if available on your equipment) do not light up,
- the device does not function.

Check to make sure

- the main power supply cable is properly connected to the power supply input and to a safety socket,
- the house power supply fuse is functioning.

**WARNING!**

**Checking the fuse**

**Unplug the power cable from the device before checking the fuse.**

The device does **not** have to be opened to replace the fuse.

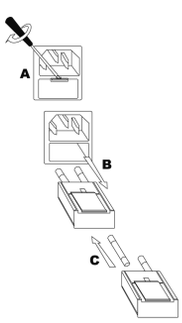


**Fig. 9–1 Opening the fuse holder**

1. Switch device off.
2. Disconnect device from power supply.
3. Remove power connection cable from mains socket.
4. The fuse holder is located next to the mains socket.
5. Remove fuse holder as depicted in Fig. Opening the fuse holder [▶ 38].
6. **A** Undo the latch of the fuse holder with a small screwdriver.
7. **B** Remove the fuse holder.
8. **C** Check fuse.
9. Insert a new fuse. Use only the specified type of fuse (see Chapter Technical Data [▶ 52]).
10. Insert the fuse holder until it can be heard snapping into place.

## 9.5 Care of the Reusable Tube Set (NOT FOR SALE IN USA)

All reusable inflow tubes must be cleaned, disinfected, and sterilized before use. This applies in particular to the first use after delivery since the product is delivered non-sterile. Effective cleaning and disinfection are an essential prerequisite for effective sterilization.

The device **A127** can be used with a reusable tube set listed as an accessory (see Chapter Accessory List [▷ 48]). Please comply with the following information when using a reusable tube set.

### 9.5.1 General Notes

**WARNING!**

**Reprocessing**

**Only reprocess after training has been completed.**

**The reusable tube set may only be reprocessed by trained personnel.**

Within the scope of your responsibility for the sterility of the product in the application of material compatibility, please note the following:

- Only cleaning/disinfection and sterilization methods sufficiently validated and specifically designed for the tube set are to be used.
- The equipment used (washer-disinfector, sterilizer) must be regularly maintained and checked.
- Adherence to the validated parameters during each cycle must be ensured.

Please also comply with the legal or statutory requirements applicable to your country as well as the hygiene rules of the physician's office or hospital. This applies in particular to the differing requirements regarding effective prion deactivation.

**Products for cleaning and disinfection**

**WARNING!**

**Cleaning and disinfection**

**The reusable tube set (NOT FOR SALE IN USA) consists of silicone, polysulfone (PSU), POM (Polyoxymethylene) and stainless steel. For cleaning and disinfection, use pH-neutral or slightly alkaline cleaners and disinfectants approved for the utilized materials. If using unsuitable substances (e.g., Neodisher® Mediklar rinsing agent), the tube set and especially connectors made of PSU may become damaged.**

Examples for cleaning agents and disinfectants which have been used for validation by the manufacturer:

| Steps | | Manufacturer | Product | Concentration [%] |
|---|---|---|---|---|
| Pretreatment | | Dr. Weigert | Neodisher MediZym | 0.5 |
| Automated | Cleaning | Dr. Weigert | Neodisher MediClean | 0.5 |
| | Neutralization | Dr. Weigert | Neodisher Z | 0.1 |
| Manual | Cleaning | Dr. Weigert | Neodisher MediZym | 0.5 |
| | Disinfection | ASP | Cidex OPA | - |

When selecting the cleaning and disinfecting agents, please ensure that the following ingredients are not included:

- Organic, mineral, and oxidizing acids with pH-value < 6.5
- Alkalis (pH value > 9.5, neutral/enzymatic or slightly alkaline cleaner recommended)
- Organic solvents (alcohols, ethers, ketones, petroleum)
- Oxidizing agents (such as hydrogen peroxide)
- Halogens (chlorine, iodine, bromine)
- Aromatic/halogenated hydrocarbons

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It is imperative to comply with the concentrations, temperatures, and exposure times, as well as the post-rinsing requirements specified by the manufacturer of the cleaning agent and/or disinfectant.

Make sure that the entire tube set is rinsed and dried. If necessary, rinse or dry the tube set both from the Luer lock side and from the side of the spikes.

Never clean the product with metal brushes or steel wool but with a soft cloth.

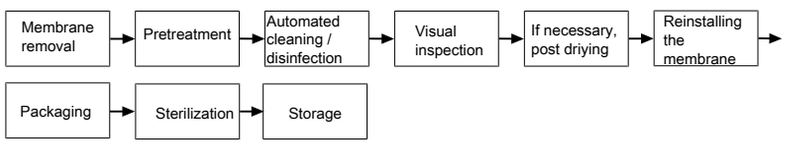
Rinse aids and / or acid neutralizers are not permitted.

The product shall not be exposed to temperatures exceeding 142 °C (288 °F)!

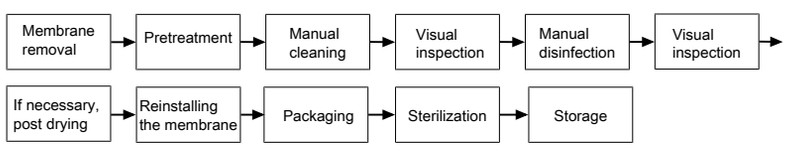
Instrument oils or greases must not be used to used to maintain the product.

**Workflow**

Automated reprocessing




Manual reprocessing




## 9.5.2 Reprocessing

### 9.5.2.1 Preparation

**WARNING!**

**Membrane**

**Remove the membrane before cleaning.**

**Removing the membrane from the product**

1. Before cleaning: Carefully remove the membrane (2) from the pressure chamber (1) (see Fig. Pressure chamber membrane and its position in the inflow tube set [▶ 41]). This is done by pulling the strap of the membrane (6) towards the top. Make sure not to damage the membrane. Damaged membranes must be replaced.
2. Before starting sterilization, the membrane must be reattached to the pressure chamber according to the instructions in Chapter Reinstalling the Membrane [▶ 44].

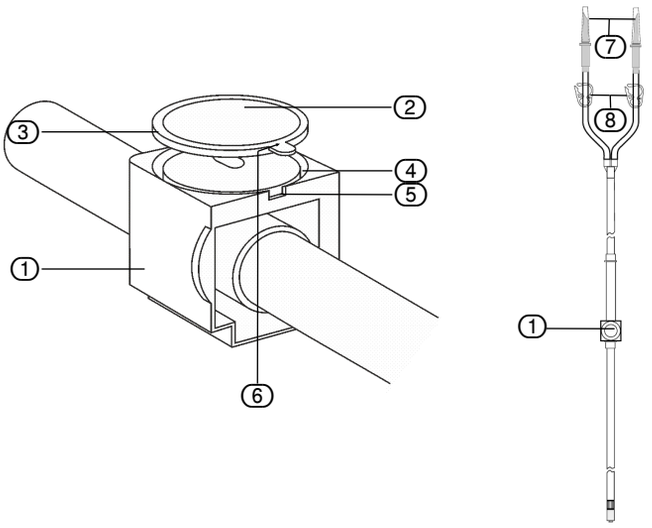



**Fig. 9–2 Pressure chamber membrane and its position in the inflow tube set**

1. Pressure chamber
2. Membrane
3. Lip of the membrane
4. Groove
5. Notch
6. Strap
7. Spikes with protective caps
8. Tube clamps

### 9.5.2.2 Pretreatment

Pretreatment must be carried out both during automated and manual cleaning and disinfection. Please note that the disinfectant used for the pretreatment serves only personal protection against contamination and cannot replace the subsequent disinfection carried out after the cleaning step.

Directly after the application (no later than within 2 hrs), large impurities must be removed from the reusable tube set.

**Instruction**

1. If necessary, remove the protective caps of the spikes (7) (see Fig. Pressure chamber membrane and its position in the inflow tube set [▷ 41]).
2. Open the tube clamps (8).
3. Rinse the tube set and the membrane for at least 1 min under running water (temperature < 35 °C/95 °F). Rinse all lumina of the tube set three times using a disposable syringe filled with water (minimum volume 100 ml).
4. Place the tube set and membrane in a freshly prepared cleaning solution. Observe relevant requirements as listed in Chapter General Notes [▷ 39] concerning the selection, concentration, temperature, and exposure time.
5. Rinse all lumina of the tube set three times using a disposable syringe filled with cleaning solution (minimum volume 100 ml).
6. Manually remove all externally visible particles with a clean soft cloth and soft brush that is used only for this purpose and that does not scratch the surface.
7. Rinse the tube set and the membrane for at least 1 min under running water (temperature < 35 °C/95 °F). Rinse all lumina of the tube set three times using a disposable syringe filled with water (minimum volume 100 ml).

If you use a combined cleaning and disinfecting agent for this purpose - e.g., for reasons of occupational safety - please take into account the following:

- They should be aldehyde-free (otherwise fixation of blood contamination)
- They must have a tested efficacy (e.g., VAH/DGHM or FDA/EPA approval/ clearance/registration, or a CE marking)
- They must be suitable for disinfecting the product
- They must not contain any of the components listed under General Notes [▷ 39] and are compatible with the product.

### 9.5.2.3 Cleaning and Disinfection

An automated process (cleaning and disinfecting equipment) should be used if possible. A manual process - even when using an ultrasonic bath - should be used only if an automated process is not available or not possible due to the significantly reduced efficiency and reproducibility.

Suitability of the cleaning device used in the context of automated cleaning and disinfection, the selected program, and the used cleaning or disinfecting agent, as well as a guarantee with respect to the attainable hygiene status and material compatibility are the sole responsibility of the operator!

#### 9.5.2.3.1 Automated Cleaning and Disinfection

When selecting a washer-disinfector, make sure of the following:

- The washer-disinfector has a tested effectiveness (e.g., DGHM (German Society for Hygiene and Microbiology and Compliance with EN ISO 15883-1) - or FDA approval/ clearance/registration; CE marking according to medical device directive or regulation).
- If possible, a tested thermal disinfection program is used (see Vario TD Program of Miele & Cie. KG, type: G 7836 CD with mobile injection unit E450 for MIS instruments; A0 value (scale for the inactivation of microorganisms of a disinfection process; > 3000 or - for older devices - at least 5 min at 90 °C/194 °F) (chemical disinfection may leave residues of disinfectant on the products).
- The used program is suitable for the product.
- The used program contains sufficient rinsing cycles.
- Only sterile or low-germ (max. 10 germs/ml) and low endotoxin (max. 0.25 endotoxin units/ml) water (e.g., purified water/high purity water) is used for rinsing.
- The air used for drying is filtered (oil-free, low in particles and germs).
- The washer-disinfector is regularly maintained and checked.

When choosing the cleaning agent system, make sure of the following:

- It is generally suitable for the cleaning of instruments made of metal and plastics.
- If no thermal disinfection is used, additionally a suitable disinfectant with tested effectiveness (e.g., VAH (Association for Applied Hygiene)/ DGHM - or FDA/EPA (environmental protection agency) approval/clearance/registration or CE-marking) is used and that this is compatible with the cleaning agent used.
- The chemicals used are compatible with the products.

**Instruction**

1. Place tube set and membrane into the cleaning and disinfecting equipment. Make sure the tube set and membrane do not touch one another. Use a tubing connector to connect all lumina of the tubing set to the rinsing connectors of the washer-disinfector.
2. Start the verified thermal disinfection program (see Vario TD Program from Miele; A0 value > 3000 or - for older devices - at least 5 min at 90 °C/194 °F).
3. Remove the tube set from the washer-disinfector after the end of the program.
4. If necessary, check and dry the tube set and the membrane (see Chapter Visual Inspection [▷ 43] and Chapter Subsequent Drying [▷ 43]).

#### 9.5.2.3.2 Manual Cleaning and Disinfection

Manual cleaning and disinfection should only be used if an automated process is not available.

When choosing the cleaning and disinfecting agent to be used, make sure of the following:

- It is generally suitable for the cleaning or disinfection of instruments made of metals and plastics.

- A disinfectant with tested effectiveness (e.g. VAH/DGHM or FDA/EPA approva/ clearance/Registration or CE marking) is used which is compatible with the cleaning agent used.
- The chemicals used are compatible with the products.

Combined cleaning/disinfecting agents should not be used if possible. Combined cleaning/disinfecting agents can be used only in cases of very low contamination (no visible impurities).

It is imperative to comply with the concentrations, temperatures, and exposure times, as well as the post-rinsing requirements specified by the manufacturer of the cleaning agent and disinfectant. Use only freshly prepared solutions, only sterile or low-germ (max. 10 germs/ml) and low endotoxin (max. 0.25 endotoxin units/ml) water (e.g., purified water/high-purity water), or only a soft, clean and lint-free cloth and/or filtered air for drying.

**Manual cleaning**

**Instruction**

1. Place the tube set and the membrane in the cleaning bath for the specified exposure time of the cleaning agent so that they are sufficiently covered and do not touch each other.
2. Rinse all lumina of the products at least five times at the beginning and at the end of the exposure time using a disposable syringe filled with the cleaning agent (minimum volume 100 ml). Clean the exterior surfaces with a clean, soft cloth and a soft brush that is only used for this purpose.
3. Remove the tube set and the membrane from the cleaning bath and rinse them at least three times thoroughly (at least 1 min) with water.
4. Rinse all lumina of the tube set at least five times using a disposable syringe filled with water (minimum volume 100 ml).
5. Inspect the tube set and the membrane (see Chapter Visual Inspection [▸ 43]).

**Manual disinfection**

**Instruction**

1. Place the cleaned and inspected tube set and the membrane in the disinfection bath for the specified exposure time so that they are sufficiently covered and do not touch each other.
2. Rinse all lumina of the tube set at least five times at the beginning and at the end of the exposure time using a disposable syringe filled with the disinfection solution (minimum volume 100 ml).
3. Remove the tube set and the membrane from the disinfecting bath and rinse at least five times thoroughly (at least 1 min) with water.
4. Rinse all lumina of the tube set at least five times using a disposable syringe filled with water (minimum volume 100 ml).
5. Inspect and dry the product if necessary (see Chapter Visual Inspection [▸ 43] and Chapter Subsequent Drying [▸ 43]).

### 9.5.2.4 Visual Inspection

After cleaning or cleaning/disinfecting, inspect the tube set and the membrane for corrosion, damaged surfaces, splinters, dirt and discoloration, and inspect for damaged products (see Chapter Reusability [▸ 45] for numerical restrictions on reuse). If the chrome-plated components of the Luer lock adapter or the spike are damaged (scratches, detachments), the product must be replaced immediately (no further use permitted).

A product that is still dirty must be cleaned and disinfected again.

### 9.5.2.5 Subsequent Drying

After cleaning, the tube set and membrane must be dried before packing. For this purpose, the tube set and membrane must be placed in an appropriate tray and drained or dried with an air pistol and filtered compressed air; if necessary, the individual components must be dried with a soft, clean and lint-free cloth. Alternatively, the components can be treated in an air dryer (10 minutes at 100 °C/212 °F).

Check the tube set and the membrane after drying as described in Chapter Visual Inspection [▸ 43].

### 9.5.2.6 Reinstalling the Membrane

Reinstalling membrane before sterilization (see Fig. Pressure chamber membrane and its position in the inflow tube set [▶ 41]): Place the lip of the membrane (3) into the ring groove (4) of the pressure chamber. The strap (6) must be positioned in the notch (5) provided for this purpose. Press the lip of the membrane into the groove (4). A properly inserted membrane is flush with the pressure chamber and exhibits no wrinkles.

### 9.5.2.7 Packaging

Pack the reassembled, dry product (see Chapter Reinstalling the Membrane [▶ 44]) in disposable sterilization packaging (single or double packaging) which meets the following requirements (material/process):

- Conform to EN ISO 11607-1 and -2 /ANSI AAMI ISO 11607-1 and -2.
- Suitable for steam sterilization (temperature resistance up to at least 142 °C (288 °F) with sufficient steam permeability).
- Sufficient protection of the product or the sterilization packaging against mechanical damage (e.g., from the spikes).

### 9.5.2.8 Sterilization

Only a clean, dry and disinfected as well as correctly assembled product (see Chapter Subsequent Drying [▶ 43], Chapter Reinstalling the Membrane [▶ 44] and Chapter Packaging [▶ 44]) may be sterilized. Only the sterilization procedures listed below are to be used for sterilization. Other sterilization methods are not permitted.

Steam Sterilization

- Fractionated vacuum process with at least three vacuum steps (with sufficient product drying >20 minutes).
- Steam sterilizer according to EN 13060 and EN 285. ANSI AAMI ST79.
- Validated according to EN ISO 17665-1 (valid commissioning (installation/operational qualification/IQ/OQ, and product-specific performance evaluation (PQ).
- Maximum sterilization temperature 138 °C (280 °F; plus tolerance according to EN ISO 17665-1).
- Sterilization time (exposure time at sterilization temperature) between 5 and 18 min (for prion deactivation) at 132 °C (270 °F)/134 °C (273 °F).

Use of the less effective gravitation procedure is allowed only in case of non-availability of the fractionated vacuum procedure; requires significantly longer sterilization times and must be validated specifically for the products, devices, and parameters in sole responsibility of the user.

The actual required drying time depends on parameters, which are the sole responsibility of the user (loading configuration and density, sterilizer condition, etc.) and must therefore be determined by the user. However, drying times should never be less than 20 minutes.

**CAUTION!**

**Drying time**

**The indicated drying time depends on several variables, including the following: Altitude, humidity, type of packaging, preconditioning, size of chamber, mass of load, and placement in chamber. Users must verify that the drying time set in their autoclave results in dry surgical equipment when using the method of saturated steam sterilization described here.**

**Other sterilization methods**

The flash sterilization process is generally not permitted.

Do not use hot air sterilization, radiation sterilization, formaldehyde or plasma sterilization.

Individual automated processing methods must be independently validated by the operator.

Ethylene oxide sterilization is possible but not validated by the manufacturer.

### 9.5.2.9 Storage

After sterilization, the products in the sterilization packaging must be stored dry and dust-free.

### 9.5.2.10 Reusability

The products can be reused up to 20 times, provided they are undamaged and uncontaminated, and used with due care; any further use or the use of damaged and/or contaminated products is the responsibility of the user.

If disregarded, any liability is excluded.

**WARNING!**

**Signs of damage**

**Please check the reusable tube (NOT FOR SALE IN USA) for signs of damage after sterilization and before use. Never use a tube showing signs of damage, especially brittleness and perforation.**

**WARNING!**

**Contamination**

**Do not use the tube set if signs or indications of a contamination are detected.**

**CAUTION!**

**Maximal cleaning / reprocessing cycles**

**Do not clean / reprocess the reusable tube sets for more than 20 cycles as indicated on the label.**

**CAUTION!**

**Check of the reprocessed tube set**

**After each cleaning / reprocessing, the cleaned / reprocessed tube set must be checked for possible damages caused by the process before it is stored / used properly and professionally for the following use!**

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# 10 Annual Inspection

**Inspection tests**

The following tests are designed specifically for trained personnel or a hospital technician. The operation of the device as well as its functionality and serviceability are easily checked. Each test conducted has to be documented with date and signature in the test log.

Each test conducted must be documented with date and signature on the test log (Chapter Test log [▷ 56]).

**Measured values and tolerances**

The following measuring tools and resources were used by the manufacturer to determine the listed measurements and tolerances:

- Disposable irrigation tube set
- Measuring beaker with scaling up to at least 0.26 gal (1.5 l)
- 2 irrigation fluid bags with 3 l each
- Length measuring device (e.g. folding rule or measuring tape)
- Stopwatch

**WARNING!**

**Measured values and tolerance exceeded**

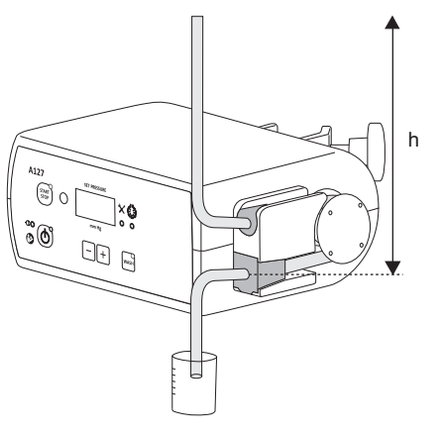
**An authorized service technician must check the device if the specified measured values and tolerances are exceeded during the individual tests.**

## 10.1 Electrical Safety Test

1. Perform a visual inspection. Make sure that
   - the fuse corresponds with the specifications indicated by the manufacturer,
   - labels and stickers on device are legible,
   - the mechanical condition of the device allows for its safe use,
   - the device is clean to ensure proper and safe functionality.
2. Carry out the measurements for the ground leakage current, short-circuit current/housing leakage current, and the protective conductor resistance as per IEC 62353 in the current version or according to the applicable national standard.

## 10.2 Basic Function Test

**Fig. 10–1 Basic function test**




**Prepare basic function test**

A basic function test checks the displays, keys, and performance of the device.

The layout of the test and its setup are depicted in Fig. Basic function test [▷ 46].

1. Switch device on.
2. Insert the tube set.
3. Hang the fluid bags onto the hooks of the bag holder at a height of h = 0.7 to 1 m and connect with inflow tube.
4. Insert instrument tube into measuring beaker.

5. Select the following values: Nominal pressure: 150 mmHg
6. Press the **START/STOP** key. The START operating mode LED (Fig. Front of the device [▶ 22] (3)) lights up. The roller wheel starts to turn.
7. Fill tube set completely with fluid. Wait until the instrument recognition has finished.
8. Close the clamp (Fig. Tube set elements [▶ 26] (3)).

**Performing the basic function test**

1. Empty measuring beaker.
2. Open clamp (Fig. Tube set elements [▶ 26] (3)) and stop after 30 seconds.
3. Press the **START/STOP** key once this time has passed. The graduated measuring beaker must contain approx. 0.75 l (±10 %) of fluid.

The basic function test has been successfully completed once these values have been reached.

## 10.3 Pressure Measuring Test

The pressure test checks the pressure chamber, the pressure sensors, and the pressure measuring to ensure all elements are functioning properly.

**Preparing the pressure measuring test**

1. Insert a test tube set into the device (without connected instrument).
2. Connect the tube set with a fluid bag.
3. If necessary, open the clamps on the fluid bag and press the **START/STOP** key to completely ventilate the tube set.
4. After ventilating the tube set, press the **START/STOP** key again.

**Performing the pressure measuring test**

- Press the "Reduce Pressure" (Fig. Front of the device [▶ 22] (11)) and "**WASH**" (Fig. Front of the device [▶ 22] (9)) keys simultaneously for 3 seconds.
- Set the display to "P" by pressing the "Increase Pressure" (Fig. 5-1 Front of the device [▶ 22] (10)) or "Decrease Pressure" key (Fig. 5-1 Front of the device [▶ 22] (11)).
- Press the **START/STOP** key to confirm.
- Hold the fluid-filled tube end with the Luer Lock connection exactly 1 m higher than the pressure chamber of the tube set.
- Read the measured pressure value. The value should be 74 ±5 mmHg.
- Exit test mode by pressing the **WASH** key.

The familiar nominal pressure display is now depicted again in normal operating mode.

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## 11 Accessory List

| Article description | Order number |
|---|---|
| Disposable tube set*, Luer lock connector, and spikes, only inflow | T0449-01 |
| Reusable tube set*, Luer lock connector, and spikes, only inflow **(NOT FOR SALE IN USA)** | T0454-01 |
| Power cable 2.0 m, EU | Z0101-01 |
| Power cable 2.5 m, US | Z0102-01 |
| Power cable 1.8 m, UK | Z0176-00 |
| Power cable 1.8 m, CN | Z0178-00 |

* = Applied part

# 12 Electromagnetic Compatibility

**CAUTION!**

**Accessories**

**To ensure compliance with the requirements of IEC 60601-1-2 in the current version, the device A127 must be used only with the accessories listed in Chapter Accessory List [▶ 48].**

**Precautionary measures**

Medical devices are subject to special safety and protective measures concerning electromagnetic compatibility (hereafter abbreviated as EMC).

The device is to be used only for the purposes described in the Instructions for Use and is intended for use in environments in Professional Healthcare Facility Environment. This applies even if individual requirements meet the conditions for deviating electromagnetic environments. During installation and commissioning as well as during operation of the device, the compliance with the notes and instructions for EMC must be strictly observed.

To ensure the basic safety and essential functionality in relation to electromagnetic interference over the life of the device, the device must be restarted after 24 hours so that a diagnostic self-test can be performed. The maintenance intervals indicated in Chapter Maintenance Intervals [▶ 37] must also be observed.

This device complies with the electromagnetic compatibility (EMC) requirements for medical electrical devices as defined by IEC 60601-1-2. The limits used in testing provide a basic level of safety against typical electromagnetic interference likely to occur in professional health care facilities. Nevertheless, it can happen that individual performance features are no longer available or only to a limited extent due to the presence of EM interference.

## 12.1 Electrical Connections

**ESD (Electrostatic Discharge) precautionary measures**

The following are ESD precautionary measures:

- Apply potential equalization (PE), if available on your equipment, to all devices to be connected.
- Use only the listed equipment and accessories.

Hospital employees should be informed about and trained in ESD precautionary measures.

## 12.2 Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The device **A127** is intended for use in an environment as described below. The user/operator of the device **A127** should make sure the device is operated within such an environment.

| Emissions test | Compliance | Electromagnetic environment - guidance |
|---|---|---|
| RF emissions CISPR 11 | Group 1 | The device **A127** uses RF energy solely for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | The device **A127** is suitable for use in all establishments, other than public establishments and those directly connected to the public mains network that supplies buildings used for public purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | |

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## 12.3 Guidelines and Manufacturer's Statement - Electromagnetic Interference Immunity

The device **A127** is intended for use in an electromagnetic environment as described below. The user/operator of the device **A127** should make sure the device is operated within such an environment.

| Electromagnetic interference immunity tests | IEC 60601 test level | Compliance levels | Electromagnetic environment guidelines |
|---|---|---|---|
| Electrostatic discharges (ESD) IEC 61000-4-2 | ± 8 kV contact<br>± 2, ± 4, ± 8, ± 15 kV air | ± 8 kV contact<br>± 2, ± 4, ± 8, ± 15 kV air | Floors should be made from wood or concrete or covered with ceramic tiles. If the floor covering consists of synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transients/bursts according to IEC 61000-4-4 | ± 2 kV for power lines<br>Modulation 100 kHz | ± 2 kV for power lines<br>Modulation 100 kHz | The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment. |
| Surges according to IEC 61000-4-5 | ±1 kV line(s) to line(s)<br>± 2 kV line(s) to earth | ±1 kV line(s) to line(s)<br>± 2 kV line(s) to earth | The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment. |
| Blackouts, brownouts, and fluctuations of the power supply according to IEC 61000-4-11 | 0 % UT; 0.5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° | 0 % UT; 0.5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° | |
| | 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° | 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° | |
| | 0 % UT; 250/300 cycles | 0 % UT; 250/300 cycles | |
| Supply frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m | 30 A/m | Magnetic fields of the mains power frequency should comply with the typical values of business and hospital environments. |
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>0.15 MHz to 80 MHz<br>6 Vrms in ISM bands between 0.15 MHz and 80 MHz<br>80 % AM at 1 kHz | 3 Vrms<br>0.15 MHz to 80 MHz<br>6 Vrms in ISM bands between 0.15 MHz and 80 MHz<br>80 % AM at 1 kHz | |
| Transients RF<br>IEC 61000-4-3 | 3 V/m 0.15 MHz to 80 MHz<br>80 % AM by 1 kHz | 3 V/m 0.15 MHz to 80 MHz<br>80 % AM by 1 kHz | |

**IMMUNITY to proximity fields from RF wireless communications equipment**

**Test method IEC 61000-4-3**

| Test frequency (MHz) | Band (MHz) | Service | Modulation | Maximum power (W) | Distance (m) | IMMUNITY TEST LEVEL (V/m) |
|---|---|---|---|---|---|---|
| 385 | 380-390 | TETRA 400 | Pulse modulation<br>18 Hz | 1.8 | 0.3 | 27 |
| 450 | 430-470 | GMRS 460, FRS 460 | FM<br>±5 kHz deviation<br>1 kHz sinus | 2 | 0.3 | 28 |
| 710 | 704-787 | LTE Band 13, 17 | Pulse modulation<br>217 Hz | 0.2 | 0.3 | 9 |
| 745 | | | | | | |
| 780 | | | | | | |
| 810 | 800-960 | GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5 | Pulse modulation<br>18 Hz | 2 | 0.3 | 28 |
| 870 | | | | | | |
| 930 | | | | | | |

| Test frequency (MHz) | Band (MHz) | Service | Modulation | Maximum power (W) | Distance (m) | IMMUNITY TEST LEVEL (V/m) |
|---|---|---|---|---|---|---|
| 1720 | 1700-1990 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | Pulse modulation 217 Hz | 2 | 0.3 | 28 |
| 1845 | | | | | | |
| 1970 | | | | | | |
| 2450 | 2400-2570 | Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation 217 Hz | 2 | 0.3 | 28 |
| 5240 | 5100-5800 | WLAN WLAN 802.11 a/n | Pulse modulation 217 Hz | 0.2 | 0.3 | 9 |
| 5500 | | | | | | |
| 5785 | | | | | | |

**WARNING!**

**Portable HF communication equipment**

**Portable HF communication equipment can affect the performance characteristics of the device A127. Such equipment must therefore comply with a minimum distance of 30 cm (regardless of all calculations) from the device A127, its components and cables.**

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## 13 Technical Data

| | | | |
|---|---|---|---|
| Type designation | | A127 | |
| Product name | | **A127** | |
| Manufacturer information: | | W.O.M. WORLD OF MEDICINE GmbH<br>Salzufer 8, 10587 Berlin | |
| Software version | | Can be determined by the authorized service technician | |
| Mains voltage range [V] | | 100-240 | |
| Supply frequency range [Hz] | | 50 / 60 | |
| Fuse designation | | 2x T 3.15 A H 250 V | |
| Power consumption | | Current [A] | Power [VA] |
| Normal operation 100 V/60 Hz | | 1.15 | 115 |
| Normal operation 240 V/50 Hz | | 0.59 | 141 |
| Protection class (I, II) | | I | |
| Application part type (B, BF, CF) | | BF [a] | |
| Defibrillator protection (yes/no) | | No | |
| Protection class (IP code) | | IP41 | |
| Classification according to Medical Device Directive 93/42/EEC, (I, IIa, IIb, III) | | IIa | |
| Conformity with the following standards: (in the currently valid version) | | IEC 60601-1/EN 60601-1<br>IEC 60601-1-2/EN 60601-1-2 | |
| Operating conditions | | | |
| | Temperature [°C] / [°F] | 10 to 40 / 50 to 104 | |
| | Relative air humidity [%] | 30 to 75 | |
| | Air pressure [kPa] | 70 to 106 | |
| | Max. altitude above sea level [m] | 3000 | |
| Transport conditions | | | |
| | Temperature [°C] / [°F] | -25 to +70 / -13 to +158 | |
| | Relative air humidity [%] | 10 to 95 | |
| | Air pressure [kPa] | 70 to 106 | |
| Storage conditions | | | |
| | Temperature [°C] / [°F] | -25 to +70 / -13 to +158 | |
| | Relative air humidity [%] | 10 to 95 | |
| | Air pressure [kPa] | 70 to 106 | |
| Maximum sound level [dB] | | < 80 dB(A) (with acoustic signals) | |
| Suitable operating conditions (EMC) | | Professional healthcare facility environment, | |
| Suitability for use in environments with flammable anaesthetic mixtures (Category AP or APG) | | This device is not designed for use with flammable anesthetic agents (Category AP) or flammable anesthetic agents with oxidants (Category APG) | |
| Suitability for use in an oxygen rich environment [Yes / No] | | No | |
| Mode of operation | | Continuous operation | |
| Approved sterilization / cleaning / disinfection method(s) | | Wipe the surface of the device with a soft lint-free cloth moistened with the surface disinfectant (for example Meliseptol® rapid). The concentration and the time the disinfectant must be applied, depends on the information provided by the manufacturer of the disinfectant. Make sure moisture does not enter the device.<br>Do not sterilize the device! | |
| Max. time interval of safety check [a] | | 1 | |
| Max. output pressure [mmHg] | | 150 | |
| Max. irrigation rate [l/min] | | 1.5 | |
| Adjustable values/ranges | | | |

| | | |
|---|---|---|
| Set output pressure range [mmHg] | | 5 to 150 |
| Measurement range | | |
| Flow [l/min] | | 0.5 to 1.5 |
| Pressure [mmHg] | | 0 to 300 |
| Accuracy | | |
| Flow [%] | | ±10 % |
| Output pressure [mmHg] | | ±4.5 |
| Maximum dimensions (Width x Height x Depth) (with toggle screw, projecting as much as possible): | | 240 x 103 x 255 [mm] |
| Maximum dimensions (Width x Height x Depth) (without toggle screw): | | 240 x 103 x 221 [mm] |
| Weight | | 2.8 kg |
| Interfaces: | | |
| | Signal input / -output | 1x service interface (9-pin D-sub port) |
| | Mains power connection | IEC 60320-1 C14 |
| | RFID transponder technology | Transmit/Receive Frequency Range: 13.56 MHz ± 0.424 MHz<br>Transceiver class: Class I<br>RF Output Power: -10.83 dBµA/m at 10 m/ 32.8 ft<br>Type of Antenna: Inductive Loop Antenna<br>Antenna loop area: 0.00032 m²<br>Modulation: Amplitude-shift keying (ASK)<br>Mode of Operation (Simplex / Duplex): Duplex |
| | Remote control | NIR (near infrared), 880 nm |
| **Essential performance** | | No essential performance defined for this device. |

[a] A tube set is not an applied part in terms of the standard. However, it meets all the technical requirements for an applied part.

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## 14 Error and Warning Messages

| Informational signals | | | |
|---|---|---|---|
| **Optical** | **Acoustic** | **Priority** | **Cause** |
| 000 (for 3 s) | 1 low volume beep | Information | Disposable/reusable tube was accepted<br>number of remaining cycles: 0 |
| xxx (for 3 s) | 1 low volume beep | Information | Disposable/reusable tube was accepted<br>Number of remaining cycles: xxx |
| n/a | 1 low volume beep | Information | Self-test successfully completed |
| n/a | 1 low volume beep | Information | Key confirmation |

| Physiological warnings | | | |
|---|---|---|---|
| **Optical** | **Acoustic** | **Priority** | **Cause** |
| Overpressure indicator<br>(flashing, yellow), immediately until remedied | 3 beeps<br>(after 2 s, alarm condition prevails until remedied) | Medium | Safety threshold for pressure (200 mmHg) exceeded |
| Overpressure indicator<br>(flashing, red), immediately until condition remedied | 10 beeps<br>(after 0.5 s, alarm condition prevails until remedied) | High | Critical safety threshold for pressure (250 mmHg) exceeded<br>OR<br>Reversing the roller wheel did not reduce the overpressure |

| Technical warnings – user error | | | |
|---|---|---|---|
| **Optical** | **Acoustic** | **Priority** | **Cause** |
| ---<br>(constant until tube set is removed) | 1 beep | Low | Device was switched on with tube set inserted, the sensor could not be checked |
| E01<br>(3 s) | 1 beep | Low | Attempted pump activation without tube set inserted |
| E02<br>(constant until tube set is removed) | 1 beep | Low | Invalidated tube set has been inserted |
| E03<br>(constant until tube set is removed) | 1 beep | Low | Invalidated tube set has been inserted |
| E04 (3 s) | 1 beep | Low | Tube set incorrectly inserted |
| E02/E03<br>(3x flashing) | 1 beep | Medium | Attempted pump activation with invalid (invalidated or not approved) tube set inserted |

| Technical warnings – device error | | | |
|---|---|---|---|
| **Optical** | **Acoustic** | **Priority** | **Cause** |
| E05<br>service icon, red<br>(constant) | 5 beeps | High | Sensor error |
| E06<br>service icon, red<br>(constant) | 5 beeps | High | Motor error |
| E07<br>service icon, red<br>(constant) | 5 beeps | High | RFID module defective |

| Technical warnings – device error | | | |
|---|---|---|---|
| **Optical** | **Acoustic** | **Priority** | **Cause** |
| E50<br>service icon, red<br>(constant) | 5 beeps | High | Communication error |
| E55<br>service icon, red<br>(constant) | 5 beeps | High | Electronics error |
| E58<br>service icon, red<br>(constant) | 5 beeps | High | Keyboard error |
| E59<br>service icon, red<br>(constant) | 5 beeps | High | Calibration error |

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# 15 Appendix

## 15.1 Test log

| Date | Result | Comment | Signature |
|---|---|---|---|
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## 15.2 Return form

**Please fill out this form when returning the device:**

**Name of owner:**

**Sales partner:**

**Address of person returning unit:**

| **Street:** | **House number:** |
|---|---|
| | |

| **ZIP/Postal code:** | **City:** |
|---|---|
| | |

**Country:**

**IMPORTANT!**

**Serial number (see identification plate):**

**Device type:**

**Description of defect:**

| | | |
|---|---|---|
| **Contact** | **Signature** | **Date** |

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## Glossary

### Basic function test

The basic function test checks the basic function of the device and is part of the annual inspection.

### EMC

The electromagnetic compatibility describes the ability of a device to function satisfactorily within an electromagnetic environment without adding unacceptable electromagnetic interferences/disturbances to the environment that may cause problems for other devices or equipment located nearby.

### Functional test

The function test must be carried out before each surgery to ensure the respective device is fully functional.

### ME Device

Medical electrical device used for therapy, monitoring or diagnosis of patients, equipped with no more than one connection to a supply network and which necessarily comes into physical or electrical contact with the patient or which transfers energy to or from the patient or which records or captures such energy transfer to or from the patient.

### ME System

Medical electrical system consisting of a combination of devices, of which at least one is classified as a medical electrical device and specified by the manufacturer as such and which are joined together by a functional connection or by using a power strip.

### Safety test

The safety test is part of the annual inspection.

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## List of Figures

en

# Index