Manual

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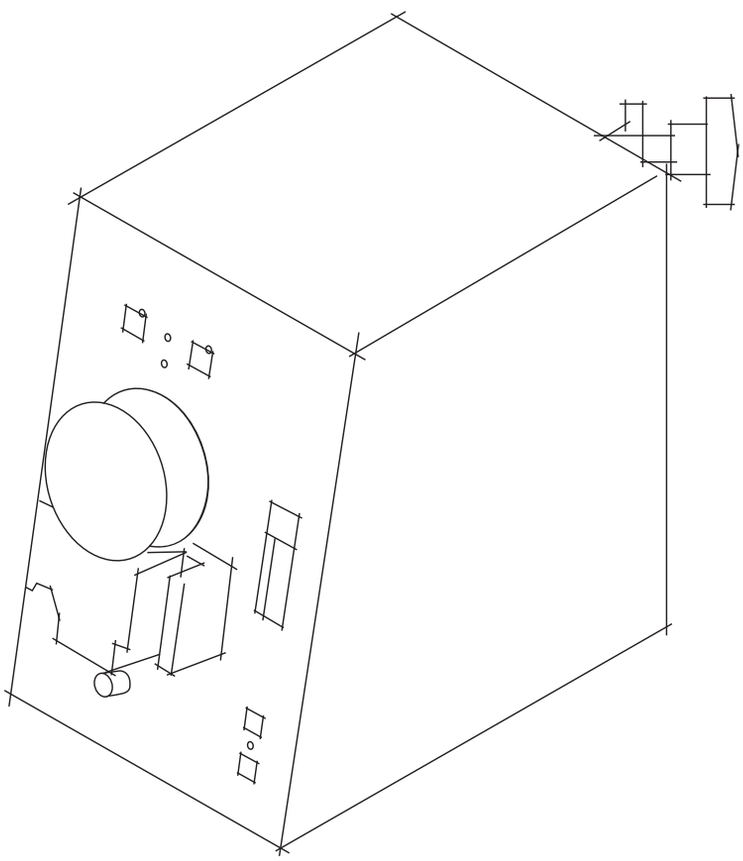

FLUID CONTROL Lap 2216

RICHARD WOLF

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Manufacturer:
RICHARD WOLF GmbH
Pforzheimer Straße 32
75438 Knittlingen, Germany
www.richard-wolf.com

CE 0124 CE-Marking according to directive 93/42/EEC

GA-A 276 /en/2020-11 V3.0

Type: P106

10000021595 01/2020-11/TR

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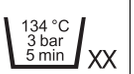
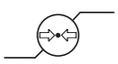
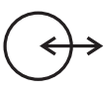
Symbols	Description
	Follow instructions for use (white image on a blue background)
	Consult instructions for use
	Caution
	Type BF applied part
	Equipotentiality
IP 41	Degrees of protection provided by enclosures (IP-Code)
~	Alternating current
	Service
REF	Catalogue number
	Non sterile
	Do not resterilize
	Do not reuse
STERILE EO	Sterilized using ethylene oxide
LOT	Batch code
SN	Serial number
	Herstellungsdatum (JJJJ-MM-TT)

Symbols	Description
	Verwendbar bis (JJJJ-MM-TT)
	Quantity
	Number of autoclaving cycles
	Keep dry
	Not made with phthalates
	Contains DEHP
	Top-Bottom
	Fragile
	Waste management
	Manufacturer
	Authorized for Sale or use by Physician only
	Suction
	Irrigation
	Keep away from sunlight
	Protect from heat and radioactive sources
	Recyclable packaging (Green dot symbol)

Symbols	Description
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Do not use if package is damaged
	Recycling PAP PE
	Non-ionizing electromagnetic radiation
	Protective earth (Ground)
	Input/Output
	No hazardous substances contained in the device
	Air Out
	RFID tag. general

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1 Important User Notes

Read the instructions for use 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 staff or service personnel, or
- to damage 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

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

DANGER!
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.

WARNING!
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 General Safety Notes

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, 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 schedule is not adhered to.

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

WARNING: Modifying the device FLUID CONTROL Lap 2216 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.

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
- must be double-sealed in safety foil.

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

Disposal

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 Device Description

The device **FLUID CONTROL Lap 2216** is a pump with an irrigation and suction function for laparoscopy.

The device itself is non-invasive and designed for use in multi-unit racks (non-sterile area). It pumps medical sterile irrigation fluid through a sterile tube. This flushes the corresponding fluids into the body cavity. The device can be used with electrolyte-free media (such as glycine 1.5% or sorbitol 3.0%) and with isotonic electrolyte-containing media (such as saline 0.9% or Ringer's Lactate solution). The device is equipped with a vacuum suction function used to suction off secreted fluids. The secretion liquid is sucked through a tube into the container. The device functions only with the tube sets described in the accessory list (see chapter 10 "Accessory List").

Essential Performance

The essential performance of the device in the laparoscopy indication consists of providing an irrigation pressure to produce an irrigation flow. Another key performance characteristic of the device is to provide suction pressure to suction the fluid from the patient.

3.2 Used as Intended and Contraindications

3.2.1 Intended Use

The device **FLUID CONTROL Lap 2216** is a suction and irrigation pump for Minimally Invasive Surgeries (MIS). It flushes fluid into and suctions fluid from the abdomen.

3.2.2 Contraindication

Do not use the device **FLUID CONTROL Lap 2216** for procedures where a specific pressure has to be preset and reached such as a hysteroscopy or an arthroscopy.

3.3 General Warnings and Precautions

3.3.1 General Warnings

DANGER!
Condensation / Water penetration
Protect device from moisture. Do not use if moisture has penetrated the device.

DANGER!
Do not use this system if a defect is suspected or detected during the function check. This also applies to obvious defects, especially defects and damage to the power plug and power cord.

DANGER!
Device Errors
Do not use this device if a defect is suspected or detected during the function check. It is prohibited to use the device in the case of obvious defects.

DANGER!
An authorized service technician must check the device if the specified parameters and tolerances are exceeded.

DANGER!
Do not touch
Avoid touching the roller wheel. Risk of injury!

DANGER!
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.

DANGER!
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.

DANGER!
Original accessories
For your own safety and that of your patient, use only original accessories.

DANGER!
Make sure the tubes for the suction-irrigation instrument do not have any kinks when installed. Make sure the tubes are not crimped or clamped off.

DANGER!
Hygiene filter
Use a new filter for each patient. Please use a hydrophobic filter between patient and device suction. The filter prevents bodily fluids from entering the inside of the device and possible contaminants from the device reaching the patient.

DANGER!
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.

DANGER!
Keep full fluid bags ready for use
Always keep a full fluid bag on hand to replace an empty one. This avoids having to interrupt surgery due to a lack of irrigation fluid.

DANGER!
Sterile mediums and accessories
Always work exclusively with sterile substances and mediums, sterile fluids, and sterile accessories if so indicated.

DANGER!
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.

DANGER!
Sterilize reusable instruments and tubing 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.

DANGER!
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.

DANGER!
Device defect
If a device defect is suspected or confirmed, do not use it. Make sure the device can no longer be used until a qualified service technician conducts the appropriate tests and repairs.

DANGER!
Disconnect device from power supply
Pressing the ON/OFF key does not disconnect the device from the power supply. This requires pulling the plug located in the rear of the device.

DANGER!
Replacing fuse
Replace the fuse only with a fuse of the same type and rating.

DANGER!
Risk of electrical shock
To prevent electrical shock, do not open this device. Never open this device yourself. Refer servicing to qualified service personnel.

DANGER!
Cleaning the device
Do not sterilize the device.

DANGER!

The product may be used only by doctors or health care professional in accordance with the intended use. Personnel must have training that qualifies them to operate laparoscopy pumps. In addition, personnel must read the user manual and operating instructions and become familiar with handling the device before first use. Personnel must have mastered handling and operation of the product before first use during a surgery. This user manual does not include descriptions or instructions for surgical procedures/techniques. It is also not intended to introduce to or train physicians in the use of surgical techniques.

DANGER!

The vacuum tube sets for this device contain diethylhexylphthalate (DEHP), which is classified as toxic to reproduction according to the EU Directive 1272/2008/EEC on Classification, Labeling and Packaging of Dangerous Substances. DEHP may impair fertility and may cause harm to the unborn child. Therefore, this product must not be used for unauthorized applications. When applied within the intended use, the potential risk to pregnant or breastfeeding women as well as to children resulting from the DEHP contained in this product is not critical.

DANGER!

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.

DANGER!

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.

DANGER!

Set up the device in such a way as to allow for easy monitoring of the display values, device functions, and access to the control elements.

DANGER!

Position the device in such a way that it is easy to operate and switch off.

DANGER!

Risk of electrical shock

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

DANGER!

Use only parts and/or devices from ME systems (see chapter 14 "Glossary") in patient environments in compliance with the standard IEC 60601-1 in the respective currently valid version

DANGER!
Connect only items, that have been specified as part of the ME system or specified as being compatible with ME systems.

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

DANGER!
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.

DANGER!
Please read the instruction manual for the device cart before mounting the pump on the cart.

DANGER!
The device is only intended for use with flexible fluid containers. Do not use glass containers as they might break. Fluid cannot flow quickly enough due to the vacuum being generated inside of the bottle. Risk of implosion.

DANGER!
Functional test
The functional test must be performed prior to each surgery.

DANGER!
Sterilize reusable instruments and tubing 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.

DANGER!
The irrigation fluid bags must not be stored on the device or hung up directly above the device.

DANGER!
Select an irrigation fluid suitable for the subsequent medical procedure.

DANGER!
Checking the warning signals
The warning signals must be checked prior to each operation. The system is to be set up so that all warning signals can be perceived.

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DANGER!

The reusable tube set is made of silicone, polysulfone (PSU), and stainless steel. For cleaning and disinfection, use only pH-neutral or slightly alkaline cleaning agents (e.g. neodisher MediClean 2.0 %), disinfectants (e.g. Lysetol V 8 %), and drying and rinsing agents approved for the tube set materials.

Using unsuitable agents (e.g. neodisher MediKlar rinsing agent) may damage the tube system and especially the PSU connectors.

DANGER!

Always check the reusable tube set for signs of deterioration before use and after sterilization. Never use a tube set which shows signs of deterioration, including cracking, or perforation.

DANGER!

Make sure to connect tubes as indicated by the matching connection pieces (connectors).

DANGER!

The day tube remains connected to the device after each surgery. The patient tube must be disposed of immediately after surgery. A new sterile cap (included with the patient tube) must be screwed onto the hygiene connector at the day tube after each surgery. This sterile protector remains connected to the day tube until the next surgery.

DANGER!

Do not touch patient and the ON/OFF switch at the same time.

DANGER!

Serum sodium concentration

It is also necessary to monitor the concentration of sodium in the blood of the patient to prevent electrolyte disturbances. Monitoring of the concentration of sodium in the blood must be performed by the physician and is not performed or supported by the system.

DANGER!

Air Embolisms

An air embolism can be the result of air contained in the tube set or connected instrument reaching the patient. Make sure that there is always fluid in the bag to prevent air from being aspirated into the patient.

DANGER!
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.

DANGER!
Hypothermia (monitoring body temperature)
The continuous flow of the distension liquid may lower the body temperature of the patient. Lower body temperatures can cause coronary and cardiovascular problems. Always monitor the patient's body temperature during the entire surgical procedure. Make especially sure that the following, hypothermia promoting, operation conditions are avoided as best as possible:
- **longer operating times**
- **use of cold irrigation fluid.**

3.3.2 Precautionary Measures

WARNING!
The pressure chamber diaphragm is fragile and can be replaced if damaged. Replacement diaphragms are supplied with reusable tubes. The reusable tube sets must be prepared before each use. See chapter 7.2 Care and Maintenance of Reusable Tube Set for further instructions.

WARNING!
Connecting the tube
The tube outlet may only be connected to instruments which are intended for intra-abdominal fluid suction and irrigation.

WARNING!
The day tube must be replaced at the end of the day of surgery but not later than after 24 hrs.

WARNING!
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 yields dry surgical equipment when using the method of saturated steam sterilization described here.

WARNING!
Connecting the tube
The tube outlet may only be connected to instruments which are intended for intra-abdominal fluid suction and irrigation.

WARNING!
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.

WARNING!
Electrical Interference
(See chapter 11 "Electromagnetic Compatibility"). Electrical interference with other devices or instruments was practically eliminated when developing this devices and none was detected during testing. 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**

WARNING!
Use of other accessories, other transducers and cables
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 14 "Glossary") as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the ME EQUIPMENT or ME SYSTEM.

WARNING!
Power cables
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.

WARNING!
Service connection
Access to the service menu is restricted to authorized service personnel.The connected equipment must comply with the standard EN 60950 in the currently valid version. Do not connect a device to the service connection during surgery.

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4 Device Startup

DANGER!
The product may be used only by doctors or health care professional in accordance with the intended use. Personnel must have training that qualifies them to operate laparoscopy pumps. In addition, personnel must read the user manual and operating instructions and become familiar with handling the device before first use. Personnel must have mastered handling and operation of the product before first use during a surgery. This user manual does not include descriptions or instructions for surgical procedures/techniques. It is also not intended to introduce to or train physicians in the use of surgical techniques.

NOTE!
Locations
The device is only to be used in a professional facility healthcare enviroment.

4.1 Delivery Scope

- Device FLUID CONTROL Lap 2216
- Instructions for Use
- Power cord

Delivery inspection

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.

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 the instructions. Enclose the manual 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

Setting up

Place the device on a flat surface free of vibration located in a dry environment. The ambient temperature and humidity must meet the requirements mentioned in Chapter 9 "Technical Data".

DANGER!
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.

DANGER!
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.

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DANGER!
Set up the device in such a way as to allow for easy monitoring of the display values, device functions, and access to the control elements.

DANGER!
Position the device in such a way that it is easy to operate and switch off.

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

DANGER!
Use only parts and/or devices from ME systems (see chapter 14 "Glossary") in patient environments in compliance with the standard IEC 60601-1 in the respective currently valid version

WARNING!
The ME device is suitable for arrangement in ME device systems (see chapter14 "Glossary"). Operation of the ME device in close proximity to non-ME devices may result in the intended use of the ME device no longer being guaranteed.

WARNING!
Equipment should be positioned such that power cord can be easily disconnected.

WARNING!
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).

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

WARNING!
Place the device outside the sterile field.

WARNING!
Position of the user
To avoid a malfunction, the user must be positioned correctly
- **for observation up to 2 m from the front of the device.**

Power connection

WARNING!
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.

Make sure the connection data and technical specifications of the power supply comply with DIN VDE or national requirements. The mains connection cable must be plugged into a properly installed, grounded shockproof safety wall socket.

Protective contact

The power connection must be equipped with ground contact (protective contact). Use the original power cable (included in scope of delivery) to establish a connection between the mains wall socket and the mains socket located in the rear of the device.

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

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 for upright placement on a device cart.

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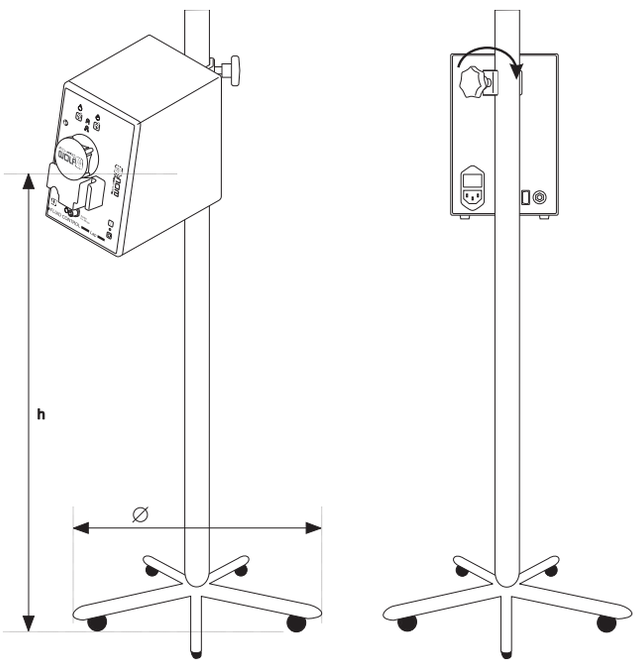
4.3.1 Mounting on Stand

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

NOTE!
Make sure the rod of the stand has a diameter of 20-30 mm.

Abb. 4-1 Mounting on the stand



DANGER!
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.

1. Slide the pump onto the rod of the stand at the desired height. Please pay attention to sufficient stability.
2. Tighten the toggle screw on the rear of the pump.

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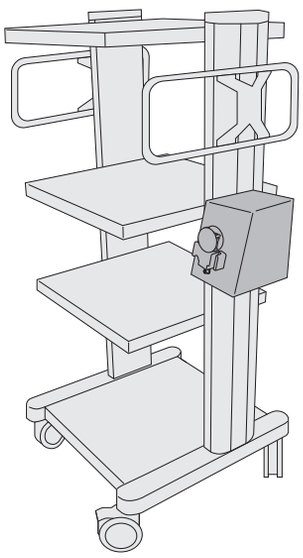
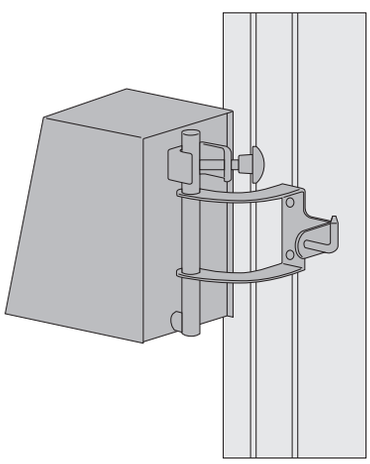
4.3.2 Mounting on Device Cart

DANGER!
Please read the instruction manual for the device cart before mounting the pump on the cart.



Modell Richard Wolf



Detail mounting on device cart, rear

4.4 Front of the Device

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

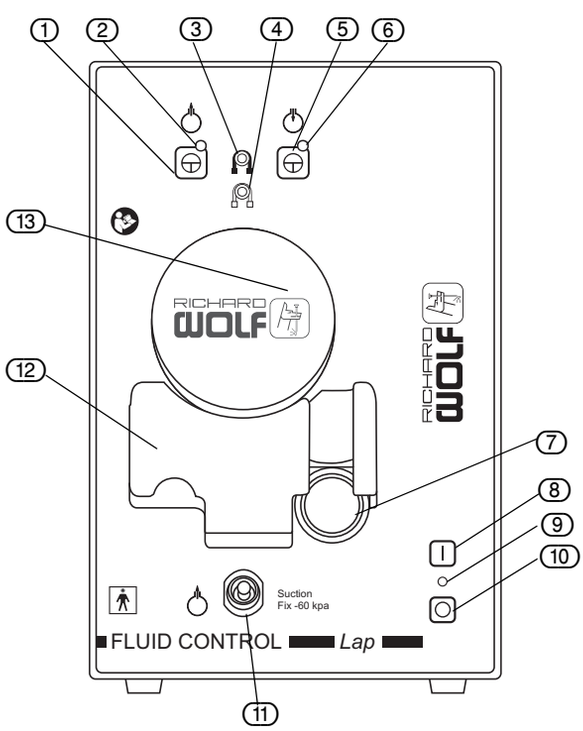


Abb. 4-2 Device front

1. Suction start/stop key
2. Suction status LED
3. LED tube status green
4. LED tube status red
5. Irrigation start/stop key
6. Irrigation status LED
7. Pressure sensor
8. Power switch ON
9. Power switch status LED
10. Power switch OFF
11. Connection for hygiene filter and vacuum tube
12. Tube clamp
13. Roller wheel

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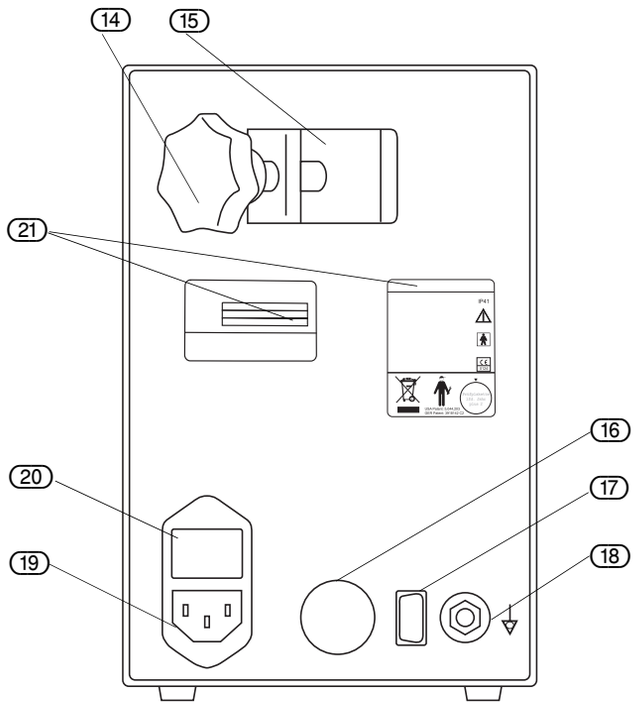
4.5 Rear of the Device

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

Abb. 4-3 Device rear



(14) Toggle screw
(15) Clamp
(16) Spacer
(17) Service interface
(18) Connection for potential equalization
(19) Mains socket
(20) Fuse holder
(21) Labels

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5 Operating the Device

5.1 Function test

DANGER!
Functional test
The functional test must be performed prior to each surgery.

DANGER!
Sterilize reusable instruments and tubing 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.

DANGER!
Original accessories
For your own safety and that of your patient, use only original accessories.

5.1.1 Preparing the Function Test

1. The device is switched off and without an inserted tube set.
2. Switch device on using the power switch.
3. The device carries out a self-check. A long beep is emitted after the successful device check.
4. Insert the tube set (see chapter 5.4 "Inserting a Tube Set"). Connect the suction (see chapter 5.6 "Irrigation").

5.1.2 Irrigation Test

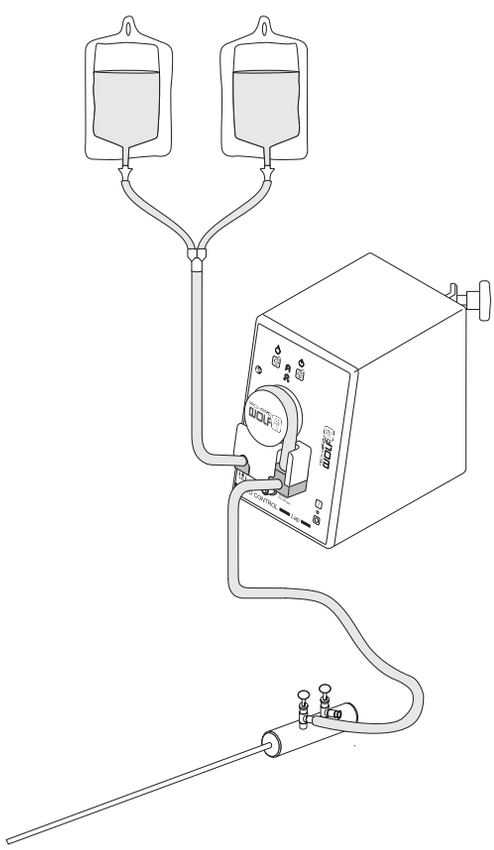

Abb. 5-1 Irrigation test

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1. Connect the instrument.
   Close stopcock if using instrument with stopcock.
2. Press the irrigation start/stop key. The irrigation LED lights up.
3. Operate the trumpet valve or open the stopcock. Make sure tube set and instrument are completely filled with fluid. Remove all air from tube and instrument.
4. Release the trumpet valve or close the instrument stopcock.

5.1.3 Suction Test

1. Close stopcock if using instrument with stopcock.
2. Press the suction start/stop key (LED lights up).
   The device generates a negative pressure inside of the suction system. The vacuum pump is deactivated once a low pressure of max. -60 kpa is reached.

WARNING!
The suction system has a leak if the vacuum pump does not stop. Check the suction system for leaks and repeat function test. Do not use device, if vacuum pump is not operating or not operating correctly.

3. Open the instrument. Suction starts. The vacuum pump is automatically reactivated if the min. negative pressure is exceeded.
4. Press the suction start/stop key again (LED goes out).

This concludes the function check. The device has been checked and is ready for surgery.

DANGER!
Device defect
Do not use this device if a defect is suspected or detected during the function check. This also applies to obvious defects, especially defects and damage of the power plug and power cable.

5.2 Use of the Device During Surgery

DANGER!
Functional test
The functional test must be performed prior to each surgery.

DANGER!
The irrigation fluid bags must not be stored on the device or hung up directly above the device.

DANGER!
Select an irrigation fluid suitable for the subsequent medical procedure.

DANGER!
Checking the warning signals
The warning signals must be checked prior to each operation. The system is to be set up so that all warning signals can be perceived.

Before surgery

1. Tube set and instrument are filled with irrigation fluid. The suction system is connected. The stopcocks are closed.
2. Press the suction start/stop key (LED lights up).
   The suction system is pre-evacuated.
   Only then can the suction procedure be started with the instrument.

During surgery

1. Press the irrigation start/stop key (LED lights up).
2. Insert instrument into abdomen.
   Start irrigating wash:
   Operate the trumpet valve or open the stopcock.
3. Starting the suction process:
   Operate the trumpet valve or open the stopcock.

After surgery

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

1. Press the irrigation start/stop key and the suction start/stop key (LED goes out).
2. Use the power switch to turn device off.
3. Remove the tube sets.

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

5.3 Overview of the Usable Tube Sets

The following table shows an overview FLUID CONTROL Lap 2216 of the tube sets that can be used.

Tube category	Art. No.	Tube type
Irrigation tube set with tapping spike	8171223	Reusable (autoclavable)
Irrigation tube set with tapping spike L 3 m	4171223	Disposable (sterile)
Irrigation tube set with Care-Lock L 3 m	4171224	Disposable (sterile)
Suction tube set NL 3 m	4171225	Disposable (sterile)
Vacuum tube set	8170.401	Reusable (autoclavable)

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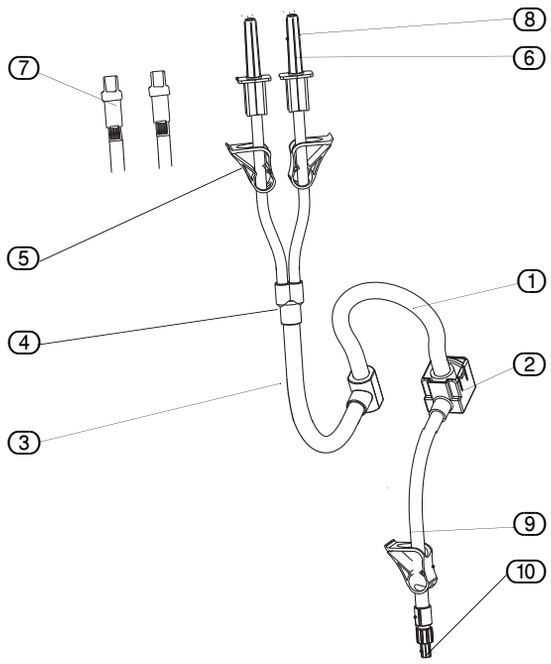
5.4 Inserting a Tube Set

Abb. 5-2 Tube set irrigation elements



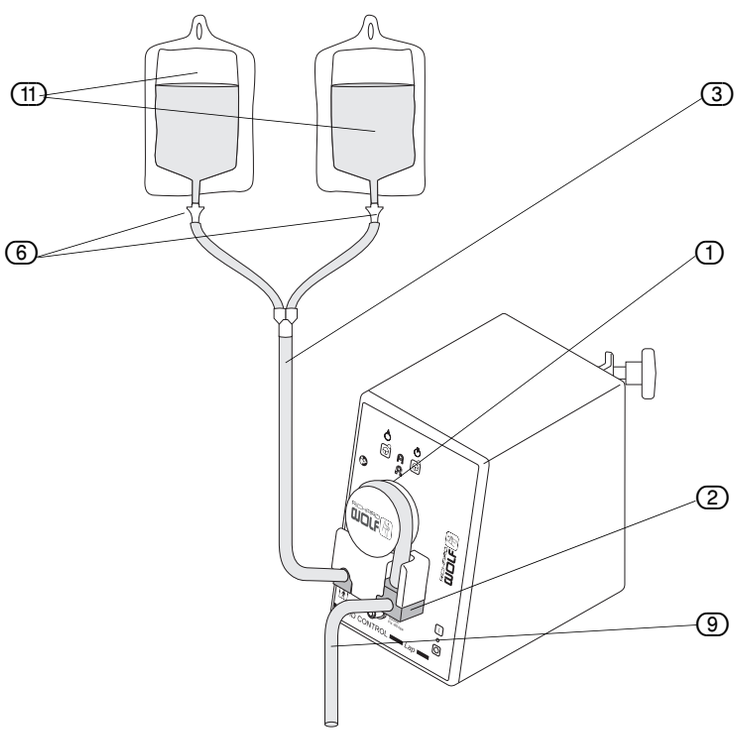
① Roller tube
② Pressure chamber with membrane
③ Irrigation tube
④ Y-connector
⑤ Tubing clamps
⑥ Tap spikes
⑦ Care-Lock® connectors
⑧ Protective caps
⑨ Instrument tube
⑩ Luer lock connection with protective cap

The **irrigation tube set** is available as a disposable or reusable tube set (autoclavable).

The tube set consists of three tube parts, (roller tube ①, irrigation tube ③ and instrument tube ⑨),), a Y-connector ④ and two tap spikes ⑥ or Care-Lock® connectors ⑦. The tube sections are connected to the irrigation fluid bags with the help of the tap spikes ⑥ or Care-Lock® connectors ⑦.

The Luer lock connector ⑩ connects the instrument tube with the instrument.

Abb. 5-3 Inserting the tube set



① Roller tube
② Pressure chamber
③ Irrigation tube
⑥ Tap spikes/Care-Lock® connector
⑨ Instrument tube
⑪ Irrigation fluid bag

Open outer packaging

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

▶ Open outer packaging of the tube set.

- A sterile technician then removes the inner tube set package and opens it.

1b. Reusable tube set - 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. Sterile tasks

Connect instrument

- Keep the Luer lock connector (10) in the sterile area and hand the tube end with the tap spikes (6)/Care-Lock® (7) to the non-sterile personnel.
- Remove the protective cap on the Luer lock connector.
- Connect the Luer lock connector (10) with the instrument (e.g., inflow cannula). Open inflow valve at instrument.

3. To be carried out by non-sterile personnel:

Insert tube set

- Before inserting the tube, connect both tube clamps (5) (Abb. 5-2 "Tube set irrigation elements") to the bags.
- Switch the device on. The power status LED on the ON switch lights up. Make sure all tube sets are removed from the pump before switching the device on. A long beep is emitted to signal the successful completion of the device test and the tube can now be inserted.
  Inserting the roller tube is depicted in Abb. 5-4 "Inserting the roller tube".
- When inserting the roller tube, make sure not to damage the membranes of the pressure chamber. Insert the pressure chamber (2) only if chamber is not pressurized.
- Insert the unpressurized pressure chamber (2) carefully into the lower notch of the tube retainer (12) up to the stop.
- Place the roller tube (1) around the roller wheel.
- Insert the tube adapter into the left section of the tube retainer by (13) tightening the tube.
- Make sure the tube adapter is firmly snapped into place! Irrigation and drain tube must point straight to the front from the tube retainer.

Connect an instrument and the corresponding bags (see also chapter 5.5 "Connecting the Irrigation Fluid Bags").

WARNING!
Instrument tube (9) and irrigation tube (3) must be inserted vertically towards the front without twisting the roller tube.

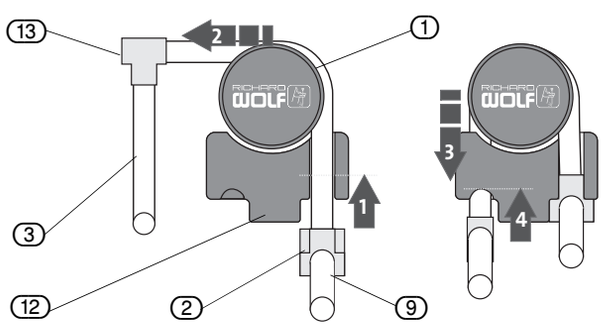


Abb. 5-4 Inserting the roller tube

(1) Roller tube
(2) Pressure chamber with membrane
(3) Irrigation tube
(9) Instrument tube
(12) Tube clamp
(13) Tube adapter

RFID technology (transponder technology)

Transponder technology detects the tube type, the validity and reliability of a tube set automatically. This eliminates virtually all "operating errors" since non fitting, invalid, and not approved tube sets are reliably detected.

The tube status LED lights up green if a valid tube is inserted. Irrigation can be started.

Invalidating a tube set

If an approved tube set is in the device, the transponder technology automatically invalidates this tube set after 60 seconds when the device is started. Depending on the tube set, this has the following consequences:

- **Disposable tube set**: After inserting the tube set and starting the irrigation cycle, the tube set is invalidated. If the irrigation cycle is stopped, the device can be restarted within 45 minutes. If the device is switched off or in case of a power failure, the tube set is invalidated. The irrigation cycle can no longer be started. If this is the case, you must insert a new, valid, and approved tube set.

  If an invalid tube is inserted into the pump, the tube status LED lights up red and three short warning beeps are emitted. The red LED flashes if irrigation is still started. Irrigation can no longer be started.
- **Reusable tube set**: The reusable tube set can be used about 20 times. After inserting and starting irrigation, one use cycle is invalidated. If irrigating is stopped during the use cycle, irrigation can be restarted within 45 minutes. If the device is switched off or in case of a power failure, the current use cycle is invalidated. Once the last use cycle has been invalidated, irrigation can no longer be started. If this is the case, you must insert a new, valid, and approved tube set.

  If the tube set is used for the last time (20 times), the green tube status LED flashes, i.e. the tube can no longer be used once the current procedure is finished.

NOTE!

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

Transponder signal loss

The device stops and cannot be restarted if the transponder loses its signal during current use. If the signal is restored with 60 seconds, it is possible to continue using the tube set.

Diethylhexylphthalate (DEHP)

DANGER!

The vacuum tube sets for this device contain diethylhexylphthalate (DEHP), which is classified as toxic to reproduction according to the EU Directive 1272/2008/EEC on Classification, Labeling and Packaging of Dangerous Substances. DEHP may impair fertility and may cause harm to the unborn child. Therefore, this product must not be used for unauthorized applications. When applied within the intended use, the potential risk to pregnant or breastfeeding women as well as to children resulting from the DEHP contained in this product is not critical.

5.5 Connecting the Irrigation Fluid Bags

DANGER!
The device is only intended for use with flexible fluid containers. Do not use glass containers as they might break. Fluid cannot flow quickly enough due to the vacuum being generated inside of the bottle. Risk of implosion.

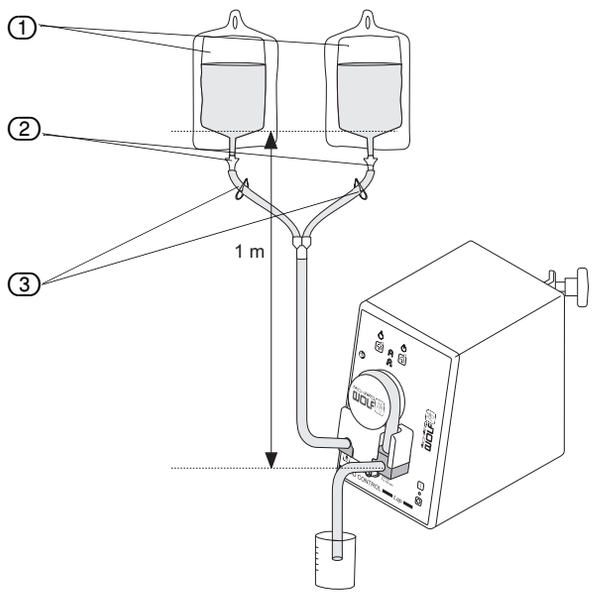


Abb. 5-5 Hanging the irrigation fluid bags

① Irrigation fluid bag
② Tap spikes/Care-Lock® connector
③ Tubing clamps

The irrigation fluid bags should be suspended at a height of **h** between 0.7-1.0 m above the pump (Abb. 5-5 "Hanging the irrigation fluid bags") (pump inflow at center of fluid level in bag).

1. The inflow 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 spike/Care-Lock® connector ② at the provided handle when connecting or disconnecting.
3. Comply with sterile precautions when inserting the tap spike (or Care-Lock® connector) into a bag.
4. Open at least one tube clamp ③ at the irrigation tube.

5.6 Irrigation

The device is designed to work with an instrument featuring a trumpet valve or stopcock. Make sure tube set and instrument are completely filled with fluid. Fill with fluid until the air is completely removed from the tube and instrument.

1. Insert the tube set (see chapter 5.4 "Inserting a Tube Set").
2. Connect the irrigation fluid bag (see chapter 5.5 "Connecting the Irrigation Fluid Bags").
3. Connect the instrument tube to the instrument.
   Close stopcock if using instrument with stopcock.
4. Press the irrigation start/stop key (LED lights up).
   An admission pressure of 400 mmHg is generated in the tube. This admission pressure is necessary to provide the full irrigation volume/output.
5. Start irrigating wash:
   Operate the trumpet valve or open the stopcock.
6. Stopping the irrigation process:
   Release the trumpet valve or close the stopcock.
   The admission pressure begins to be rebuilt so that the full irrigation volume/output is available for the next irrigation procedure.

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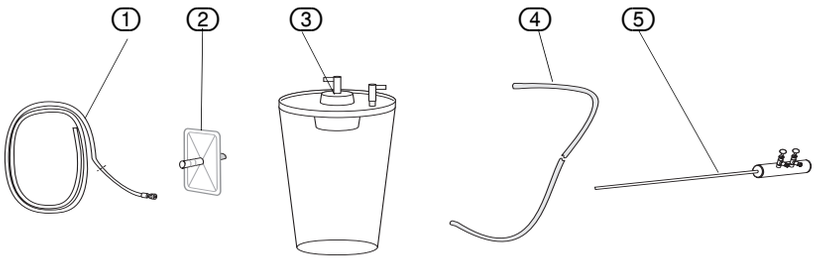
7. Press the irrigation start/stop key again (LED goes out).
   The tube is now relieved of pressure. The roller wheel turns backwards to relieve the pressure in the tube. After that it stops.

5.7 Suction

Abb. 5-6 Suction system

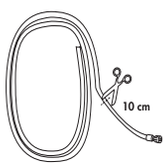


① Vacuum tube
② Hygiene filter
③ Suction container
④ Drain tube
⑤ Instrument

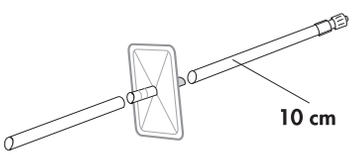
The suction system consists of the following:

- Vacuum tube
- Hygiene filter
- Suction container
- Drain tube
- Instrument

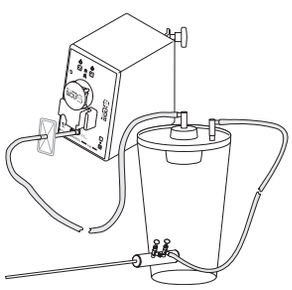
1.



2.



3.-4.



1. Cut 10 cm of the vacuum tube off.
2. Connect the hygiene filter with the vacuum tube.
3. Connect device with the suction container (using vacuum tube and hygiene filter).
4. Connect suction container with instrument (using drain tube).
   Close stopcock if using instrument with stopcock.
5. Press the suction start/stop key (LED lights up).
   The device generates a negative pressure inside of the suction system. The vacuum pump stops when a negative pressure of max. -60 kpa (-0.60 bar) has been reached.
   The vacuum pump automatically reactivates, if the min. negative pressure is reached.
6. Starting suction:
   Operate the trumpet valve or open the stopcock.
7. Stopping suction:
   Release the trumpet valve or close the stopcock.
8. Press the suction start/stop key again (LED goes out). Suction is stopped.

WARNING!
The full suction output/volume is available only, if the suction system is pre-evacuated (vacuum generation). Pre-evacuation takes about 20 to 60 seconds depending on the volume of the secretion container.

NOTE!
Only use suction containers with overflow protection.

5.8 Replacing the Suction Container

WARNING!
Full secretion containers must be replaced immediately without stopping surgery. If the overflow protection of the secretion containers is triggered, suction is stopped to prevent the ingress of fluids.

1. Stop the suction (see chapter 5.7 "Suction").
   Press the suction start/stop key (LED goes out).
2. Actuate the trumpet valve or open the stopcock to vent the system.
3. Remove tubes from filled suction container.
4. Reattach tubes to empty suction container.
   Close stopcock if using instrument with stopcock.
5. Press the suction start/stop key (LED lights up).
6. Starting suction:
   Operate the trumpet valve or open the stopcock.

5.9 Removing a Vacuum Tube System

1. Remove the drain tube (4) from the instrument (5) (see Abb. 5-6 "Suction system").
2. Remove the suction container (3) from the drain tube (4).
3. Remove the vacuum tube (1) from the suction container (3).
4. Remove the hygiene filter from the vacuum tube (1).
5. Remove the vacuum tube from the device.

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 by blocking device functions.

6.1 Pressure Limitation at 400 mmHg

The pump generates a max. pressure of 400 mmHg to reach the max. flow capacity during the irrigation mode. If external factors, for example, cause the pressure to exceed the pressure limits, the roller wheel reverses in an attempt to reduce the pressure.

6.2 Motor Cutout at 500 mmHg

The roller wheel is stopped if the pressure exceeds 500 mmHg for more than 5 seconds. The suction pump is also stopped in this state. Further irrigation is not possible. The roller wheel and suction pump automatically restart when the pressure has fallen below 500 mmHg.

6.3 Device Self-Test

The device performs a self-test after being switched on. All LEDs light up during the test. A long beep is emitted after the successful device test.

A table listing a summary of possible error and warning messages is provided in Chapter 12 "Error and Warning Messages".

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7 Care and Maintenance

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

7.1 Cleaning the Device

1. Use the **ON/OFF** button to turn the device off.
2. Remove the power cable.
3. Wipe the surface of the device with a soft cloth moistened with the surface disinfectant based on alcohol or aldehyde (for example Meliseptol® rapid). The concentration of the used disinfectant depends on the information provided by the manufacturer of the disinfectant. Make sure moisture does not enter the device.

NOTE!
Do not sterilize the device.

7.2 Care and Maintenance of Reusable Tube Set

The device can be used with reusable tube set validated for this purpose. Please comply with the following information when using a reusable tube set.

DANGER!
Remove the membrane before cleaning.

1. Before cleaning: Carefully remove the membrane (2) from the pressure chamber (1). Make sure not to damage the membrane. This is done by pulling the strap of the membrane (6) towards the top.
2. Reinstalling membranes before sterilization: Place lip (3) of membrane into ring groove (1) of pressure chamber. The strap (6) must be positioned above the provided notch (5).
3. Press lip of membrane into groove (4). A properly inserted membrane is flush with the pressure chamber and exhibits no wrinkles.

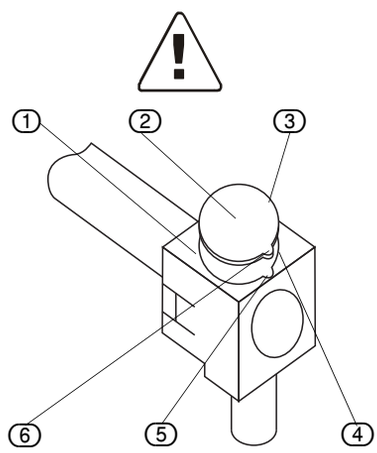
7.2.1 Cleaning the Reusable Tube Set

1. Dismantle the tubing set.
2. Use a soft brush or cleaning gun with a pressure of 3 to 4 bar to flush and rinse the individual parts.
3. Rinse individual parts with demineralized water.
4. Use compressed air or a sterile soft cloth to dry all parts.

7.2.2 Disinfecting the Reusable Tube Set

1. Only disinfect a thoroughly cleaned tube set.
2. Place all tube set components into an enzymatic (e.g. Neodisher® medizym) or slightly alkaline (e.g. Neodisher® mediclean) disinfectant solution for a short period. Do not stack parts. The concentration and the application duration of the disinfectant depends on the information provided by the manufacturer of the disinfectant. The tube set can be damaged if the concentration is set too high.
3. Remove the parts from the solution using forceps with a soft edge.
4. Remove all disinfectant residues.
5. Make sure all disinfectant residue is removed from the individual parts.
6. Dry all parts with a sterile cloth and wrap each part in a separate sterile cloth.
7. Assemble all parts before sterilization.

Information about the pressure chamber membrane



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7.2.3 Sterilizing the Reusable Tube Set

The maximum number of sterilization cycles for the tube set is determined by the manufacturer (see tube packaging).

WARNING!
Never exceed the number of uses recommended by the manufacturer.

NOTE!
The last (20th) use of the tube set is indicated by the flashing green tube status LED after pressing the stop key. This tube set cannot be reused even if sterilized.

DANGER!
Always check the reusable tube set for signs of deterioration before use and after sterilization. Never use a tube set which shows signs of deterioration, including cracking, or perforation.

Autoclave sterilization

Only clean, dry, and assembled tube sets should be sterilized in an autoclave. Please follow the instruction manual of the autoclave you use.

The manufacturer has validated the following sterilization methods:

Saturated steam sterilization using a pre-vacuum cycle at 134°C/3 bar and an exposure time of 5 minutes with a subsequent 20 minutes drying time.

Gas sterilization

Sterilization with ethylene oxide (ETO) is possible but has not been approved by the manufacturer. Only gas-sterilize a clean, dry, disinfected, and assembled tube set. Please follow your gas sterilizer's instruction manual for proper use when using gas sterilization.

7.3 Care and Maintenance of Reusable Tube Sets

The device can be used with a reusable vacuum tube set validated for this purpose. Please comply with the following information when using a reusable vacuum tube set.

7.3.1 Cleaning Reusable Tube Sets

DANGER!
The reusable tube set is made of silicone and chromed brass. For cleaning and disinfection, use only pH-neutral or slightly alkaline cleaners (e.g., neodic MediClean 2.0 %), disinfectants (e.g., Lysetol V 8%), drying, and clear rinsing substances approved for the utilized materials. If using unsuitable substances (e.g., the neodic clear rinsing agent MediKlar), the tube set may be damaged.

The reusable tube set should be reconditioned as soon as possible after use (recommended: max 30 minutes). In case of heavy contamination, it is recommended to remove these residues with a soft cloth while still at the site of the surgery. This cloth may be moistened with a slightly alkaline cleaner. The tube set is then transported, preferably in a dry basket, to the actual reconditioning location where the complete process is carried out.

1. Preparing for cleaning at the reconditioning site: Disassemble the vacuum tube set and discard the previously used hygiene filter.
2. **Prepare for cleaning:** Use a soft cloth to carefully wipe off each tube set component. Remove any remaining residue. The cloth to be used may be moistened with a slightly alkaline cleaner.

Automatic cleaning and disinfecting:

The cleaning and subsequent disinfection of the individual components of the tube sets can be carried out with the appropriate programmable cleaning and disinfecting equipment for medical devices. The manufacturer has validated the applicability of this method in terms of hygiene success and material compatibility using the "Vario" program of the disinfector manufactured by the company Miele.

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!

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

Manual Cleaning

1. Place the prepared individual components of the tube set in demineralized water (room temperature, 20 °C to 30 °C) for a period of at least 3 minutes to 5 minutes and then rinse them off under running water. Remaining residues should be removed with a cleaning brush at 3-4 bar or by using a soft brush.
2. Use a soft cloth to thoroughly dry the components.
3. The completely dry tube set components must now soak for a period of 25 minutes to 30 minutes in a suitable cleaning agent (e.g., neodisher Mediclean 2.0% or equivalents). Comply with the instructions and notes of the manufacturer of the used cleaning agent. Make sure the components are fully immersed in the cleaning agent.
4. Flush the silicone tube for 15 seconds with demineralized water. Then use a high-pressure cleaning gun to emit 10 pressure surges, each one with a length of one second (1 second) into the silicone tube.
5. The individual parts must be dried after cleaning. For this purpose, they are to be placed in an appropriate tray and allowed to drip dry or use an air gun to dry the components. It is also possible to use, where appropriate, a sterile, soft cloth. Or, the components can be dried in an air dryer (10 minutes at 100 °C).

7.3.2 Disinfecting Reusable Tube Sets

After cleaning, the individual tube set components must be disinfected. Only a thoroughly cleaned tube set may be disinfected.

Automatic disinfection

The cleaning and subsequent disinfection of the individual components of the tube sets can be carried out with the appropriate programmable cleaning and disinfecting equipment for medical devices. Observe the instructions in chapter 7.3.1 "Cleaning Reusable Tube Sets" for the automatic cleaning and disinfecting of the reusable vacuum tube set.

Manual Disinfection

1. The cleaned and completely dried tube set components are to be soaked in a suitable disinfectant for a period of 25 minutes to 30 minutes or as specified by the manufacturer (e.g., Lysetol 8% or equivalent), enzymatic disinfectant (e.g., Neodisher® medizym), or weakly alkaline disinfectant (e.g., Neodisher® mediclean). Make sure the components are fully immersed in the cleaning agent and are not stacked on top of one another. Comply with the instructions and notes of the manufacturer of the used cleaning agent. The tube set can be damaged if the concentration is too high or the components are soaked too long.
2. After the soaking time, the individual tube set components should be removed from the disinfectant liquid with pliers with soft jaws.

3. Place the components once more in demineralized water (room temperature, 20 °C to 30 °C) for a period of at least 3 minutes to 5 minutes and then rinse them off under running water. Make sure all disinfectant residue is removed from the individual parts of the tube set.
4. Flush the silicone tube for 15 seconds with demineralized water. Then use a high-pressure cleaning gun to emit 10 pressure surges, each one with a length of one second (1 second) into the silicone tube.
5. The individual parts must be dried after cleaning. For this purpose, they are to be placed in an appropriate tray and allowed to drip dry or use an air gun to dry the components. It is also possible to use, where appropriate, a sterile, soft cloth. Or, the components can be dried in an air dryer (10 minutes at 100 °C).

7.3.3 Sterilizing Reusable Tube Sets

The manufacturer has approved the reusable tube set for a specific number of recycling cycles. Always comply with the instructions on the label.

Never exceed the number of uses indicated by the manufacturer.

DANGER!
Please check the reusable tube for signs of damage after sterilization and before use. Never use a tube showing signs of damage, especially brittleness and perforation. Tube sets with evidence of or suspected of damage must be blocked from further use.

Only sterilize a clean, disinfected, and dry tube set. In order not to humidify or damage the hygiene filter during the sterilization process, the filter is connected to the vacuum tube only before the next application.

• Packaging

Pack the dry tube set in suitable sterile packaging for sterilization (cloth, bag or tray).

• Sterilization

The manufacturer has validated saturated steam sterilization based on the parameters listed below using the pre-vacuum process as a suitable method of sterilization for the tube set. Sterilize the tube set according to these specifications.

	Pre-vac
Sterilization Methods	Pre-vacuum sterilization
Packaging	Packed
Cycle time	5 min (273 °F/134°C, 3 bar)
Drying time	10 min

WARNING!
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 yields dry surgical equipment when using the method of saturated steam sterilization described here.

Please follow the instruction manual of the autoclave you use.

• Storage

Always store the tube set after sterilization in a suitable sterile packaging or in a suitable environment to avoid contamination.

- Additional information

When sterilizing several tube sets, instruments, etc. with one sterilization cycle, make sure not to exceed the max. load of the sterilizer.

Sterilization with ethylene oxide (ETO) is possible but has not been approved by the manufacturer.

7.4 Annual Inspection

Manufacturer's specifications

The manufacturer stipulates that qualified personnel or hospital technicians must regularly test the device to assess its functionality. These tests must be performed on an annual basis. The tests are described in chapter 8 "Annual Inspection".

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

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

7.5 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 the safety and functionality of the unit. The minimum service interval is two years, depending on frequency and duration of use. 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 will remind you of the latest date for the next service or maintenance check.

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

Authorized trained personnel

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.

Certification

Ask the service technician for a certificate after he or she has inspected the unit or performed any service tasks. This certificate lists the type and scope of the service as well as the date and name of the servicing company together wit the signature of the service technician.

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7.6 Changing the Fuse

DANGER!
Replacing fuse
Replace the fuse only with a fuse of the same type and rating.

WARNING!
Before replacing the fuse, check the values of the fuse to be inserted acc. to chapter 9 "Technical Data".

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

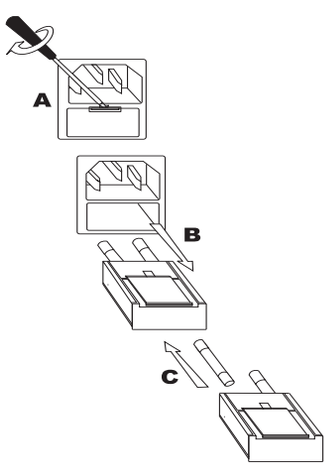
- the main power supply cable is properly connected to the power supply input and to a safety socket,
- the house power supply fuse is functioning.

DANGER!
Unplug the power cable from the device before checking the fuse.

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

1. Switch device off.
2. Disconnect device from power supply by pulling the mains plug from the mains socket.
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 Abb. 7-1 "Open the fuse holder".
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 9 "Technical Data").
10. Insert the fuse holder until it can be heard snapping into place.
11. Use the power cable to reconnect the shockproof safety socket with the rear mains socket.

Abb. 7-1 Open the fuse holder



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8 Annual Inspection

Each test conducted must be documented with date and signature on the test log (chapter 13 "Test Record").

Measured values and tolerances

The following measuring tools and resources were used by the manufacturer to determine the measurements and tolerance levels:

Tube set	
Beaker/meas. cup	With scaling up to 2.0 l
2 irrigation fluid bags	
Suction tubes	Vacuum tube, drain tube
Suction container	3.0 l
Instrument	Trumpet valve or stopcock
Stop-watch	

An authorized service technician has to check the device if the specified parameters and tolerances are exceeded.

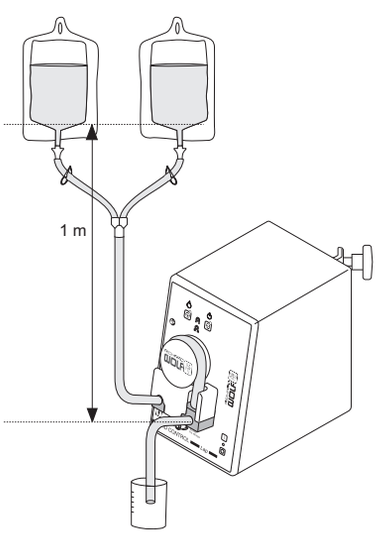
An authorized service technician must inspect and service the device at appropriate intervals to ensure the safety and functionality of the device. The minimum service interval is two years, depending on frequency and duration of use.

8.1 Safety Test

1. Perform a visual inspection of the device. Make sure
   - the fuse matches the specifications indicated by the manufacturer,
   - text and labels on the device are legible,
   - the mechanical condition of the system allows for its safe use,
   - the system is clean to ensure proper and safe functionality.
2. Conduct measurements of earth leakage current, contact current/housing leakage current/protective conductor resistance and insulation resistance according to IEC 62353 in the current version or in accordance with the applicable national standard.

As an alternative, perform safety test according to IEC 62353/EN 62353.

8.2 Irrigation Test



Preparation

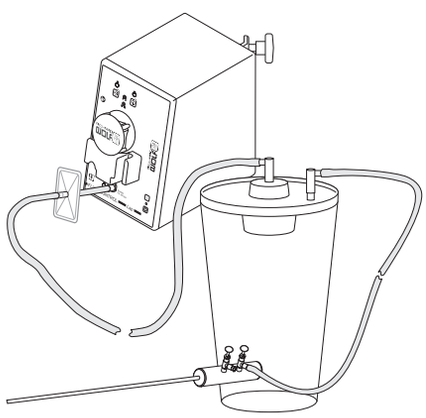
1. Switch device on using the power switch.
2. Insert the tube set.

3. Connect the irrigation tube with both irrigation fluid bags. The fluid bags have to be suspended 1.0 m above the device. Do not connect an instrument.
4. Start irrigating wash:
   Press the irrigation start/stop key (LED lights up).
5. Fill tube set completely with fluid.
6. Clamp off tube set at instrument outlet.
7. Keep the tube set disconnected until the pump stops and thus the pressure limit of the pump works.

Testing

1. Empty measuring cup.
2. Hold tube into measuring cup, open outlet, and stop at 30 seconds.
3. End test:
   Press the irrigation start/stop key (LED goes out). The graduated beaker must contain approx. 1.0 l (±10%) water.

8.3 Suction Test



1. Connect the suction system including suction container and instrument.
   Close stopcock if using instrument with stopcock.
2. Press the suction start/stop key (LED lights up). The device generates a negative pressure inside of the suction system.
   The vacuum pump stops when a negative pressure of max. -60 kPa (-0.60 bar) has been reached.
   The suction system has a leak, if the vacuum pump is not deactivated. Check the suction system for leaks and repeat test.
3. Starting suction:
   Open the instrument.
   The vacuum pump automatically reactivates, if the min. negative pressure is exceeded.
4. End suction:
   Press the suction start/stop key again (LED goes out).

Each successfully conducted test must documented with the test log.

9 Technical Data

Type designation:	FLUID CONTROL Lap 2216	
Manufacturer Information	RICHARD WOLF GmbH Pforzheimer Straße 32 75438 Knittlingen, Germany www.richard-wolf.com info@richard-wolf.com	
Software version	The software can be read by certified service technicians.	
Mains voltage range [V~]:	100-240	
Supply frequencies [Hz]	50/60	
Fuse designation:	T3,15 AH, 250 V, UL-recognized, slow blow	
Power consumption:	Current [A]	Power consumption [VA]
Normal operation 100 V	0.65	65
Normal operation 240 V	0.42	96
Protection class [I, II]:	I	
Application part(s) [Type B, Type BF, Type CF]:	Type BF[1]	
Defibrillator protected application part [yes/No]	No	
Type of protection (IP code):	41	
Classification according to Medical Device Directive 93/42/EEC, [I, IIa, IIb, III]:	IIa	
Tested to the following standards (in the respectively valid version):	IEC 60601-1/EN 60601-1 IEC 60601-1-2/EN 60601-1-2	
Operating conditions:		
	Temperature [°C/°F]	10-40/50-104
	Relative humidity [%]	30-75
	Air pressure [kPa]	70-106
	Max. usage altitude above sea level [m]	3000
Suitable operating environment (EMC)	Professional	
Suitability for use in environments with flammable mixtures of anesthetics (class AP or APG).	This device is not designed for use with flammable anesthetic agents (Class AP) or flammable anesthetic agents with oxidants (Class APG).	
Suitability for use in an oxygenated environment [Yes/No]	No	
Storage conditions:		
	Temperature [°C/°F]	5-40/41-104
	Relative humidity [%]	5-90
	Air pressure [kPa]	70-106
Transport conditions:		
	Temperature [°C/°F]	-20–60/-4–140
	Relative humidity [%]	5-90
	Air pressure [kPa]	70-106
Max. sound pressure level [dB (A)]	57	
Max. dimensions (Width x Height x Depth) [mm[3]]		
	with toggle screw	140 x 210 x 295
	without toggle screw	140 x 210 x 200
Weight [kg]	4	
Approved sterilization, cleaning, and disinfection procedures	Clean with soft cloth and surface disinfectant based on alcohol or aldehyde	

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Max. negative suction pressure [kPa]	-60	
Max. suction power [l/min]	2.0	
Max. outlet pressure [mmHg]	400	
Max. irrigation output [l/min]	2.0	
Interfaces/ports:		
	Signal input/output	Service interface (D-Sub female 9-pin DE-9, only for service, no ESD protection)
	Power supply	IEC-60320-1 C14
RFID transponder technology		
	Transmit/Receive Frequency Range	13.56 MHz ± 0.424 MHz
	Transceiver class	Class I
	RF Output Power	-10.83 dBµA/m at 10 m/32.8 ft
	Type of Antenna	Inductive Loop Antenna
	Antenna loop area	0.00032 m²
	Modulation	Amplitude-shift keying (ASK)
	Mode of Operation (Simplex/Duplex)	Duplex
Essential performance	Irrigation flow generation (LAP) up to 2.0 l min, tolerance +/- 10%.	
	Generate suction pressure up to 60 kPa for fluid suction	

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

10 Accessory List

Accessories	Order Number
Irrigation tube set with tapping spike, with Luer lock connection, autoclavable, incl. 10 replacement diaphragms	8171223
Irrigation tube set with tap spike L 3M, with Luer lock connector, sterile disposable item, 10 units in sale pack	4171223
Hygiene tube set with Care-Lock L 3M, sterile disposable item, 10 units in sale pack	4171224
Suction tube set L 3M, with connection piece for handle 8385.901, incl. frainage tube, sterile disposable item, 10 units in sale pack	4171225
Tube set for vacuum, reusable	8170.401
Protective filter for gas filtration, hydrophobic (hygiene filter)	4171.121
Suction container PSU, 3 liters, autoclavable	8170.981
Suction container, 3 liters, disposable item, 2 units in sale pack	2215.971
Holder to fasten suction container to irrigation stand or MUT scales	2215.992
Universal holder for FLUID CONTROL Lap 2216 on RIWOmobil	32114605

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11 Electromagnetic Compatibility

Precautionary measures

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

This device is to be used only for the purposes described in the manual and has to be installed, set up, and operated in compliance with the EMC notes and instructions.

WARNING!
Accessories
To ensure compliance with the requirements of IEC 60601-1-2 in the current version, the device FLUID CONTROL Lap 2216 must be used only with the accessories listed in chapter 10 "Accessory List".

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 self-test can be performed. In addition, the specified maintenance intervals (see chapter 7 "Care and Maintenance") must be observed.

11.1 Impact of Mobile and Portable HF Communication Devices

The emission of high frequency energy by mobile communication devices may impact the function of the electrical medical device. Operating such devices (e.g., cell phones, GSM phones) in the proximity of the electrical medical device is prohibited.

11.2 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.

11.3 Guidelines and Manufacturer's Statement – Electromagnetic Emissions

The FLUID CONTROL Lap 2216 is intended for use in an environment as described below. The user/operator of the FLUID CONTROL Lap 2216 should make sure the device is operated within such an environment.

Emitted interference measurements	Compliance	Electromagnetic environment guidelines
HF emission according to CISPR 11	Group 1	The FLUID CONTROL Lap 2216 uses HF energy solely for its internal functions. Therefore, the camera's HF emission is very low and it is unlikely that devices in close proximity will experience interference.
HF emission according to CISPR 11	Class B	The FLUID CONTROL Lap 2216 is suitable for use in all facilities including those in residential areas and those directly connected to a public utility network supplying buildings used for residential purposes as well.
Emission of harmonic oscillations according to IEC 61000-3-2	Class A	
Emission of voltage fluctuations / flickers according to IEC 61000-3-3	In compliance	

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11.4 Guidelines and Manufacturer's Statement/Electromagnetic Interference Immunity

The deviceFLUID CONTROL Lap 2216 is intended for use in an electromagnetic environment as described below. The user/operator of the device FLUID CONTROL Lap 2216 must make sure the device is operated within such an environment.

Electromagnetic Interference Immunity Tests	**IEC 60601-1-2 test level**	**Concordance Level**	**Electromagnetic environment/guidelines**
Discharge of static electricity (ESD) according to IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 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 AC power lines ± 1 kV for input and output lines Modulation 100 KHz	± 2 kV for AC power lines ± 1 kV for input and output lines Modulation 100 KHz	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment.
Voltage surges according to IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to ground	± 1 kV line(s) to line(s) ± 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	< 5% U_T* (> 95% dip in the U_T) for ½ cycle < 40% U_T (> 60% dip in the U_T) for 5 cycles < 70% U_T (> 30% dip in the U_T) for 25 cycles < 5% U_T (> 95% dip in the U_T) for 5 cycles	< 5% U_T * (> 95% dip in the UT) for 1/2 cycle 40% U_T (60% dip in the U_T) for 5 cycles 70% U_T (30% dip in the U_T) for 25 cycles < 5% U_T (> 95% dip in the U_T) for 5 seconds 0% U_T; ½ cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles single phase: at 0° 0% U_T; 250/300 cycles	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment. If the user/operator of the system requires the continuation of functionality after power interruptions/disruptions, it is recommended to supply the device with power from an uninterruptible power supply.
Supply frequency magnetic field (50/60 Hz) according to 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.

*Note: U_T is the mains alternating voltage before applying the test levels.

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11.5 Guidelines and Manufacturer's Statement/Electromagnetic Interference Immunity

The device FLUID CONTROL Lap 2216 is intended for operation in an electromagnetic environment as described below. The user of the device FLUID CONTROL Lap 2216 should make sure the device is operated within such an environment.

Electromagnetic interference immunity tests	**IEC 60601-1-2 test level**	**Compliance levels**	**Electromagnetic environment/guidelines**
Conducted HF interference quantities according to IEC 61000-4-6 Radiated HF interference quantities according to IEC 61000-4-3	3 V_{eff} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz	3 V_{eff} 80 MHz to 800 MHz 3 V/m 80 MHz to 2.7 GHz	Portable and mobile wireless devices should not be used in closer proximity to the device FLUID CONTROL Lap 2216 (including cables/lines) than the recommended safety distance calculated based on the transmitting frequency and the applicable formula. Recommended safety distances: $d = 1.2\sqrt{P}$ for 150 KHz to 80 MHz $d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 800 MHz to 2.7 GHz P is the max. rated output of the transmitter in watt (W) according to the information provided by the manufacturer of the transmitter. The recommended separation distance in meters (m) is d. The field strength of stationary transmitters for all frequencies tested on site [a] should be lower than the concordance level. [b] Interference is possible in the proximity of devices featuring the following pictograph. 

Note 1: The higher frequency range applies at 80 MHz and 800 MHz.

Note 2: These guidelines are probably not realizable in all cases. The distribution and spread of electromagnetic quantities differs depending on the absorption and reflection of buildings, objects, and people.

[a] The field strength of stationary transmitters, such as base stations of wireless phones and cell phones, ham radio operators, AM and FM radio and TV stations theoretically cannot always be determined in advance. A study of the installation site should be considered to determine the electromagnetic environment concerning the stationary transmitter. If the field strength measured at the usage site of the device FLUID CONTROL Lap 2216 exceeds the compliance levels listed above, the device FLUID CONTROL Lap 2216 should be monitored for proper function. If unusual performance characteristics are observed, additional measures may be required such as changing orientation or the location of the device FLUID CONTROL Lap 2216.

[b] The field strength should be less than 3 V/m for the frequency range of 150 kHz to 80 MHz.

IMMUNITY TESTS

Transients HF IEC 61000-4-3

Test frequency (MHz)	Band (MHz)	Service	Modulation	Max. power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ±5 kHz deviation	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 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 18 Hz	2	0.3	28
870						
930						
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 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

DANGER!
Portable HF communication devices can have an effect on the performance characteristics of the device FLUID CONTROL Lap 2216. Therefore, such devices must be kept at a minimum distance of 30 cm (independent of any calculation) from the device FLUID CONTROL Lap 2216, its accessories, and the cables.

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12 Error and Warning Messages

Error and Warning Messages	Cause	Troubleshooting
Device error		
All LEDs flash rapidly Short warning beeps, 1x or 2x, are continuously repeated	Electronics defective	Turn the device off and back on after approx. 10 seconds. If the error message is displayed again, the device may not be used any longer. Make sure the device can no longer be operated until a qualified service technician conducts the appropriate tests and repairs.
All LEDs flash rapidly Short 4 warning beeps are continuously repeated	Sensor errors: Impermissible deviation or error in the electronics components measuring the pressure. Pressure on sensor while no tube is inserted.	
All LEDs flash rapidly Short 5 warning beeps are continuously repeated	Motor error: Defective motor control. The motor error warning can also occur during the operation of the device due to a jammed roller wheel.	
All LEDs flash rapidly Short 7x warning beeps are continuously repeated	RFID error: Errors in the transponder electronics	
All LEDs flash rapidly Short 10x warning beeps are continuously repeated	Calibration error: The device is not calibrated properly.	
Suction does not start Suction status LED flashes slowly Short 3x warning beeps repeated 3 times	Vacuum pump defective	Turn the device off and back on after approx. 10 seconds. If the error message is displayed again, the device can be used without the integrated vacuum pump. In this case, use external suction. After the surgical procedure, have the device checked by an authorized service technician.
Tube warning		
Irrigation cannot be started Red and green tube status LEDs flash slowly Irrigation and suction status LEDs light up Warning beeps, 3x short beeps	The pump was switched on while a tube was inserted.	Remove tube. Reinsert tube after a successful device test. A tube may not be inserted while starting.
The red tube status LED lights up after inserting the tube Warning beeps, 3x short beeps	The tube has no remaining uses left or the tube is not approved for this pump.	Reinsert the tube. If the tube is not detected again, remove tube and insert a new one into the pump.
The red LED flashes slowly after pressing the start key while a tube is inserted Warning beeps, 3x short beeps Irrigation cannot be started	The tube has no remaining uses left or the tube is not approved for this pump. Start key was pressed.	Reinsert the tube. If the tube is not detected again, remove tube and insert a new one into the pump.
Roller wheel stops Red and green tube status LEDs light up Warning beeps, 3x short beeps	The tube was detected by the transponder but the roller tube is not correctly tensioned over the roller wheel. Then the pump was started.	Remove tube and reinsert. Check the correct fit of the tube on the left side of the roller wheel. The roller wheel must be tensioned across the roller wheel.
Green tube status LED is flashing Warning beep, 1x short	Last cycle for reusable tube After the surgical procedure is finished, the inserted tube cannot be used any longer.	Make sure a new tube is available for the subsequent surgical procedure.

Error and Warning Messages	Cause	Troubleshooting
After pressing the start key: Red and green tube status LEDs flash slowly Warning beep, 1x short	The pump was started without an inserted tube or the tube was not detected by the pump, e.g. defective transponder.	Insert a new tube into pump before starting.
Device information		
Green tube status LED lights up	Tube OK - irrigation can be started	
All LEDs light up briefly and then go out Warning beep, 1x long	Self-test concluded successfully. The pump is ready	
Suction does not automatically shut off when instrument is closed	Leakage in tube system or defective vacuum suction	Check the tube system and suction container for leaks. If there is no leakage, suction is defective and must be switched off. It is possible to continue using the device without integrated vacuum pump. In this case, use external suction. After the surgical procedure, have the device checked by an authorized service technician.

13 Test Record

13.1 Test Log

Date	Results	Comment	Signature

13.2 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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14 Glossary

Term	Explanation
Transponder	RFID transponders are wireless communication and monitoring devices that receive and automatically respond to signals. The term transponder is a mixture of "transmitter" and "responder." Transponders can be active or passive.
RFID	RFID (Radio Frequency Identification) is an automated identification process that makes it possible to detect objects without touching them and to log or acquire and save data automatically. A RFID system usually consists of a transponder and a reading device. While the transponder marks objects, the reading device makes it possible to read out data, which are then further processed.
Pressure sensor	The pressure sensor measures the pressure applied to the pressure membrane.
Pressure membrane	The pressure membrane is located in the tube retainer of a tube set and transfers the pressure to the pressure sensor.
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.
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.

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