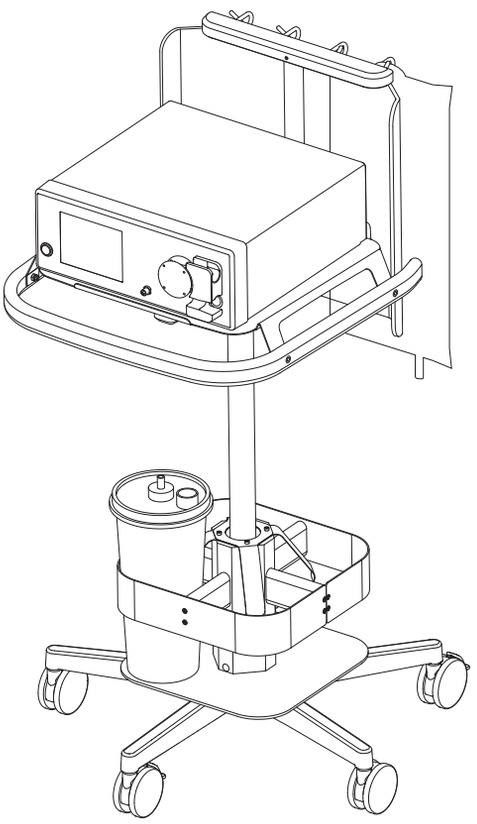
CALDERA MEDICAL

Instructions for Use en



GYN-Pump

Consisting of:
CAL-FM1741 GYN-Pump (PH304), and
CAL-FM1751 Fluid Monitoring Unit (PS304)

en

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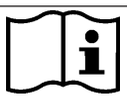
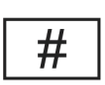
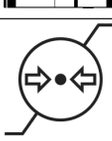
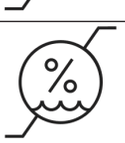
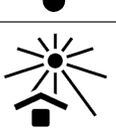
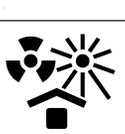
PH304, PS304 / 1201963 / 10000030314 00 / TW Issued: 2024-05-27

en

Symbols and Descriptions

	Caution
	Follow instructions for use
	Consult instructions for use
 eifu.novanta.com	Consult electronic instructions for use
	Manufacturer
	Distributor
	Service
	Authorized for Sale or use by Physician only
	Certification Mark
	Model number
	Catalogue number
	Medical Device
	Serial number
	Batch code

	Quantity
	Use by date (YYYY-MM-DD)
	Country (CC) and date of manufacture (YYYY-MM-DD)
	Date of manufacture (YYYY-MM-DD)
	Unique device identifier
	Transport conditions
	Storage conditions
	Atmospheric pressure limitation
	Humidity limitation
	Temperature limit
	Keep away from sunlight
	Protect from heat and radioactive sources
	Keep dry
	This way up

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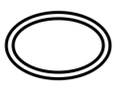
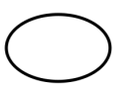
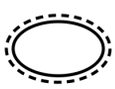
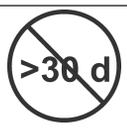
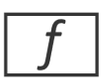
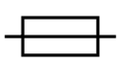
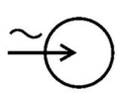
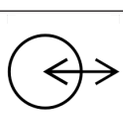
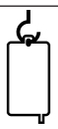
	Fragile, handle with care
	Do not use if package is damaged
	Stacking limit by number
	Quality Seal. Unbroken seal indicates the product has not been tampered with or serviced.
	Non sterile
	Do not reuse
	Sterilized using ethylene oxide
	Do not resterilize
	Double sterile barrier system
	Single sterile barrier system
	Single sterile barrier system with protective packaging outside
	Single sterile barrier system with protective packaging inside
	Maximum use 30 days
	Contains hazardous substances

	Made with phthalates
	Not made with natural rubber latex
	Type BF applied part
	RFID tag, general
	ON/OFF (push-push)
	Equipotentiality
	Mains voltage range (alternating current)
	Supply frequency
	Flow rate
	Fuse
	Rated power input AC (power consumption)
	Input/Output
	Air out
	Waste management

	Scale connection
	Maximum load/maximum weighing capacity of bag scale
	Maximum load/maximum weighing capacity of canister scale
	Weight
	No pushing
	No leaning against

You can find a complete list of all standardized symbols and descriptions on our eIFU website in addition to the Symbols and Descriptions in this document.

Please go to: eifu.novanta.com

Table of Contents

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1 Important User Notes

Read the Instructions for Use carefully to make sure you are familiar with the operation and functions of the device and its accessories before using the device during surgical procedures.

Non-observance of the instructions included in this manual can result in:

- Life-threatening injuries of the patient
- Severe injuries of the OR personnel (surgeons, nurses, service personnel)
- Damages or malfunction of device and/or accessories

To request further copies of the Instructions for Use, please contact the manufacturer.

Safety and warning messages

Sections marked with WARNING, CAUTION, and NOTE are related to safety and proper use of the device. Carefully read the warnings, precautions, and notes before use of the device.

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.

en

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 indirect, incidental and consequential damages, including, but not limited to, loss of profit. Any liability and applicable warranty becomes null and void if:

- the device and/or the accessories/ peripherals 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/peripherals;
- 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, adjustments or alterations to the device or accessories/ peripherals.

WARNING! Modification of the device GYN-Pump is not permitted.

Authorized service technician

Only an authorized service technician may perform repairs, adjustments, or alterations on the device or accessories/ peripherals and use the service menu. Any violation will void any applicable 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/ peripherals 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 surgery or operation of the device.

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

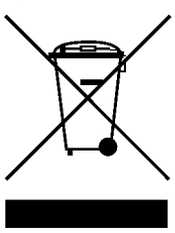
Contamination

Before shipping, decontaminate the device and accessories/ peripherals 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 refuse the repair of contaminated devices or accessories/peripherals.

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 Device Description

The **GYN-Pump** is a system providing a suction and irrigation function for the indication hysteroscopy.

The device is non-invasive and designed for use in non-sterile areas. It pumps medically sterile distension fluid through a sterile tube. These fluids are used to distend and irrigate the uterus to provide space and improve visibility for the physician. The device can be used with electrolyte-free media (e.g., glycine 1.5 % and sorbitol 3.0 %) and with isotonic, electrolyte containing media (e.g., saline 0.9 % and Lactated Ringer's). The device is equipped with a vacuum suction function used to suction off fluid and tissue from the cavity. The device functions only with the tube sets described in the accessory list (see Chapter Accessory List [▷ 74]). The control unit is equipped with a scale that monitors the volume differential between the distension fluid flowing in and out of the uterus during hysteroscopic procedures.

The device can be operated at a maximum flow rate of 800 ml/min. Pressure settings of up to 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 taken by integrating the pressure chamber into the tube system. 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 to maintain the nominal pressure. If the nominal flow rate is set too low, the nominal pressure cannot be reached. Pay attention to possible leaks.

3.2 Clinical Benefit

The **GYN-Pump** enables Minimally Invasive Surgery (MIS) to be carried out. MIS has become the standard method for the treatment for many conditions that cannot be treated by non-invasive methods and were previously treated using open surgery techniques involving much larger incisions. All necessary instruments and equipment required for MIS are standard hospital surgical equipment.

A peristaltic hysteroscopic pump enables a pressure-controlled creation of the necessary space in the uterus to perform these procedures.

In conjunction with the use of the associated scale, the pump is also able to calculate the fluid deficit during hysteroscopic procedures.

Compared to open surgery, MIS has been demonstrated to have the following clinical benefits:

- Reduction of surgical/operative trauma
- Faster patient recovery (e.g. shorter hospital stay, return to daily activities)
- Less postoperative pain
- Fewer postoperative complications (e.g. infection rates)
- Better cosmetic outcome

3.3 Intended Purpose

3.3.1 Intended Use/ Indications for Use

The **GYN-Pump** is a combined suction and irrigation control unit for use in hysteroscopic interventions. The **GYN-Pump** is intended to provide liquid distension of the uterus during diagnostic and operative hysteroscopy, and to monitor the volume differential between the distension fluid flowing into and out of the uterus.

3.3.2 Intended User

The device must only be used by surgeons or operating room personnel with the necessary professional qualifications and product training.

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3.3.3 Target Patient Group

The target patient group includes:

Patient group hysteroscopy	
Age	As of 12 years
Sex	Biological female
Weight	From 40 kg
Site in the body	Uterus

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.

3.3.4 Contraindications

Use of the **GYN-Pump** for intrauterine distension is contraindicated whenever hysteroscopy is contraindicated. See the operators manual of your hysteroscope for absolute and relative contraindications.

3.4 Warnings and Precautions

3.4.1 General Warnings

WARNING!

Use only with necessary training

The device is intended to be used only by surgeons and support personnel with the necessary training in the appropriate indication - technical terms may be used.

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!

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!

Changing factory settings of device for surgical procedures

The physician can change the factory settings of the device.

The physician is responsible for all settings affecting surgical procedures.

WARNING!

Parameters and tolerances exceeded

An authorized service technician must check the device if the specific parameters and tolerances are exceeded.

WARNING!

Irrigation fluid

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

WARNING!

Sterile media and accessories

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

WARNING!

Reprocessing of sterile single-use/disposable products

Reuse of sterile single-use/disposable products can lead to patient and/or user infection hazards. Product functionality might be impaired. Risk of injury, illness, or death due to contamination and/or impaired functionality of the product. Do not reprocess the product.

WARNING!

Preventing infections

Sterilize reusable instruments and reusable tubes (NOT FOR SALE IN USA) 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!

Loss of distension

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

WARNING!

Function test

The function test must be performed prior to each device use.

WARNING!

Scale test

The scale test must be performed at the beginning of the day prior to device use and whenever the scale has been exposed to shock (e.g. due to movement).

WARNING!

Device defects

For the safety of the patient and operating personnel, make sure that the device is complete and fully functional before each use of the device.

Do not use the device if defects are suspected during use or confirmed by device check/tests. Defects include obvious defects of power supply (e.g. power plugs, power cords).

Make sure that the device cannot be used until a qualified service technician conducts the applicable tests and repairs.

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!

Device settings

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.

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!

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

Check the warning signals prior to each device use. Set up the system so that all warning signals can be perceived.

WARNING!

Use in proximity to other devices

The GYN-Pump should not be used directly next to other devices as this could result in malfunctions.

The GYN-Pump was tested for compliance with IEC 60601-1-2 as a stand-alone system. Do not stack other devices on the system.

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.

WARNING!

Portable HF communication equipment

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

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!

Condensation / Water penetration

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

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!

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!

Checking the fuse

Unplug the power cord from the device before checking the fuse.

WARNING!

ON/OFF button

For electrical safety reasons, do not touch the patient and the ON/OFF button at the same time.

WARNING!

Disconnecting device from mains power supply

The ON/OFF push button does not disconnect the device from the mains power supply. This requires pulling the plug located in the rear of the device.

WARNING!

Irrigation fluid bags

Only use the device with flexible irrigation fluid bags. Do not use glass containers as they may break. With rigid containers, the liquid cannot flow fast enough because a vacuum is created inside the container, thus there is a risk of implosion.

WARNING!

Incorrect height of the bag setting

Incorrect height of the bag setting may lead to a deviation of the flow in comparison to the specification of the device. Deficit calculation could be incorrect in this case!

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.

WARNING!

Fluid bag and canister change during surgery

A fluid bag or canister change during surgery is only allowed, if the fluid bag or canister holds at least 0.5 l of fluid or waste. Otherwise, the deficit value may be inaccurate. In this case, the manufacturer recommends manual deficit calculation.

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!

Instrument replacement during surgery

If you replace the device during surgery, you must stop the procedure.

Use the Stop button of the indication display to stop the device and continue the procedure by using the Start button after replacement of the instrument.

WARNING!

Original accessories

For your own safety and that of your patient, use only original accessories (see Chapter Accessory List [▷ 74]).

WARNING!

Unauthorized device changes

Only authorized service technicians are permitted to repair, calibrate, or modify the device or its equipment.

Service technicians must be trained, certified, and authorized by the manufacturer.

Calibration or maintenance by the user are not permitted.

Do not open the device.

WARNING!

ME System (Medical Electrical System)

Use only parts and/or devices from ME systems (see Chapter Electromagnetic Compatibility [▷ 68]) 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!

This product contains phthalates!

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.

PHT

DEHP

3.4.2 Hysteroscopy Specific Warnings

WARNING!

Loss of intra-cavity distension pressure

When tissue removal is used, the combination of low nominal pressures and a too high vacuum pressures may result in a significant loss of intra-cavity distension pressure, which has the potential to affect the visibility of the surgical field. Conversely, when employing high distension pressures, the deactivation of the morcellator system can lead to pressure spikes exceeding 150 mmHg.

WARNING!

Fluid Overload

There is a risk of irrigation fluid reaching the circulatory system of the patient's soft tissue. This can be affected by distention pressure, flow rate, perforation of the distended body cavity and duration of the endoscopic surgery. It is critical to closely monitor the input and outflow of the distending liquid at all times.

WARNING!

Hypothermia (monitoring body temperature)

Continuous flow of distention fluids can lead to a lowering of the patient's body temperature. Lower body temperatures can cause coronary and cardiovascular problems. Always monitor the patient's body temperature during the entire surgery 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.**

WARNING!

Air embolism

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

WARNING!

Touching the canisters and their holders as well as vibrations of the balancing system should be avoided during surgery to prevent triggering a false detection of the canister change and not negatively affect the accuracy of the deficit calculation.

WARNING!

Changing canisters

Canisters should be changed quickly to avoid affecting the accuracy of the deficit calculation.

WARNING!

Loss of deficit and inflow value

The deficit display value is lost in case of a power loss or "brownout."

WARNING!

Intrauterine distension

Intrauterine distension is usually possible with pressure values between 35 to 70 mmHg. A pressure above 75 mmHg is required only in rare cases or if the patient has an excessively high blood pressure.

WARNING!

Fluid intake and output surveillance

Strict fluid intake and output surveillance should be maintained due to the risk of fluid overload. For healthy patients, the maximum fluid deficit of 1,000 ml is suggested when using a hypotonic solution (e.g. glycine, sorbitol and mannitol). If isotonic solutions (e.g. saline, Lactated Ringer's) are used, the fluid deficit should not exceed 2,500 ml.

WARNING!

Hyponatremia

Some distension fluids may lead to fluid overload and, consequently, hyponatremia with its attending sequelae. This can be affected by the distending pressure, flow rate, and duration of hysteroscopic procedure. It is critical to closely monitor the input and outflow of the distending liquid at all times.

WARNING!

Pulmonary edema

A surgical procedure is associated with a risk of developing pulmonary edema resulting from fluid overload with isotonic fluids. It is critical to closely monitor the input and outflow of the distending liquid at all times.

WARNING!

Cerebral edema

Hysteroscopic surgery is associated with a risk of developing cerebral edema resulting from fluid overload and electrolyte disturbances with hypoosmolar (non-ionic) fluids such as glycine 1.5 % and sorbitol 3.0 %. It is critical to closely monitor the input and outflow of the distending liquid at all times.

WARNING!

Idiosyncratic reactions

In rare cases, idiosyncratic reactions such as

• intravascular coagulopathy

• allergic reaction including anaphylaxis may occur during a surgical procedure if a liquid distension medium is used. Specifically, idiosyncratic anaphylactic reactions have been reported when using Hyskon as an distension fluid during a surgical procedure. These should be managed like any other allergic reaction.

WARNING!

Rupture of the fallopian tube secondary to tubal obstruction

Distention of the uterus may lead to a tear of the fallopian tube should there be an obstruction or permanent occlusion. The rupture could lead to irrigation fluid flowing into the patient's peritoneal cavity, resulting in a fluid overload. It is critical to closely monitor the input and outflow of the distending liquid at all times.

WARNING!

Deficit displays and warnings

Deficit displays and warnings serve as a tool for the treating physician and do not replace the monitoring of the patient's condition.

WARNING!

Fluid volume/sodium concentration

The fluid left in the patient and the concentration of sodium in the blood serum must both be monitored. The deficit amount is the entire amount of fluid lost by or to the system. Take note of the measurement tolerance of the system. While the system provides fluid deficit estimation, it is ultimately the physician’s responsibility to monitor fluid deficit.

WARNING!

Pressure

The pressure should be kept as low as possible to allow for a sufficient intrauterine distention and to reduce the forces that could allow fluid, ambient air, and/or gas into the circulatory system.

WARNING!

Fluid inflow limit

If the scale is in use, the GYN-Pump has a permitted maximum fluid inflow volume.

If the fluid inflow limit is reached, fluid inflow stops, the fluid inflow and fluid deficit values freeze.

If the physician decides to continue the procedure, the device does not continue to calculate the fluid deficit. Fluid inflow and fluid deficit values must be counted manually.

WARNING!

Resetting the deficit display

Filling the tubing with irrigation fluid and resetting the deficit display to zero are to be done at the physician’s discretion.

WARNING!

Fluid bags

Make sure the fluid bags hang freely, are not resting on something, and do not touch other objects except the bag deflectors. Failure to follow these instructions means the deficit cannot be calculated correctly.

WARNING!

Maximum use of vacuum tube with filter

The vacuum tube with integrated filter is designed for a maximum use of 30 days.

Replace the vacuum tube if it is obviously contaminated.

The filter prevents that body fluids enter the interior of the device. Note that the filter can reduce suction capacity.

3.4.3 Precautions

CAUTION!

In case of serious incident

Please report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the State in which the user and/or patient is established.

CAUTION!

Continuous operation

After 24 hours of continuous operation, switch the device off and then on again so that the device self test can be carried out.

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!

Using tissue removal device/shaver

When a tissue removal device/shaver system is used, the combination of low nominal pressures and a too high vacuum pressures may result in a significant loss of intra-cavity distension pressure, which has the potential to affect the visibility of the surgical field. Conversely, when employing high distension pressures, the deactivation of the tissue removal device can lead to pressure spikes exceeding 150 mmHg.

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!

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!

Mains power cord

Any power cords 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!

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/3.94 in).**

CAUTION!

Hysteroscope

The device may only be connected with hysteroscopes designed for and featuring the technical specification permitting such a combined use. Any utilized hysteroscopes 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.

CAUTION!

Instrument recognition

The instrument recognition must be performed outside of the patient and at the same level as the patient.

CAUTION!

Electrical interference

(See Chapter Electromagnetic Compatibility [▷ 68]). 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 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!

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!

Adapting device to operating environment

Before the device is unpacked, the device must be allowed to slowly adapt to the indoor climate of the operating environment.

If the device is not adapted to the indoor climate after transport or storage, the device can become damaged when switched on.

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/EN 60601-2-18 for endoscopic devices and IEC/EN 60601-1 for electrical medical devices. All configurations have to comply with IEC/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/EN 60601-1.

CAUTION!

Connecting the scale

Connect the scale to the device before you start the device. If the scale is connected after starting the device, the device does not detect the scale.

CAUTION!

Transport

The device is transportable. The rollers of the cart/scale system are used for positioning at the usage site. To transport the device, remove all fluid bags from the hooks and make sure there are no containers or only completely emptied containers on the cart/scale. Inflow and outflow tubes must be completely removed. Make sure power supply line does not touch the ground and there are no other objects located on the pump or on the scale. Always use the handle to move the system safely.

CAUTION!

Accuracy of the deficit

To avoid affecting the accuracy of the deficit calculation, ensure that the first step of the canister change is to disconnect tubing from the full canisters. Reconnect tubing to the new canisters only if they are already inserted into the scale.

CAUTION!

Collecting the fluid

Try to collect all the fluid that runs out of the uterus during the procedure in order to achieve the most exact balancing possible.

CAUTION!

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

CAUTION!

To avoid incorrect values or damage, do not apply physical weight to the scale:

- Do note lean against the scale.

- Do not step on the scale.

CAUTION!

Height-settings of fluid bags

Make sure that the height of the fluid bags is set correctly in the general menu of the device if you do not use a scale. See Chapter Fluid Bag Configuration (Use without Scale) [▷ 54].

CAUTION!

Equipment should be positioned such that power cable can be easily disconnected.

CAUTION!

Position of the device

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

CAUTION!

Sterile field

Place the device outside the sterile field.

CAUTION!

Critical overpressure

The warning message Critical Overpressure! overwrites all other status messages.

Overpressure warning functions help the physician to respond appropriately to excess pressure conditions.

If possible, the physician should reduce the intrauterine pressure by opening the outflow cannula.

CAUTION!

Pre-evacuated tube system

Only if the tube system is pre-evacuated (building a vacuum), the full suction capacity is available. Pre-evacuation takes about 30 to 60 seconds depending on the volume of the container.

CAUTION!

Approved accessories

To ensure compliance with the requirements of IEC/EN 60601-1-2 in the current version, the device GYN-Pump must be used only with the accessories listed in Chapter Accessory List [▷ 74].

CAUTION!

Replacing the fuse

Before replacing the fuse, make sure the values of the fuse to be inserted are in accordance with Chapter Technical Data [▶ 71]. Only use a fuse provided by the manufacturer (see Chapter Accessory List [▶ 74]).

4 Initial Setup

NOTE!

Locations

The device is only to be used in a professional facility healthcare environment.

4.1 Scope of Delivery

- CAL-FM1741 GYN-Pump (PH304)
- CAL-FM1751 Fluid Monitoring Unit (PS304)
- Instructions for Use
- Power cord

Delivery inspection

CAUTION!

Adapting device to operating environment

Before the device is unpacked, the device must be allowed to slowly adapt to the indoor climate of the operating environment.

If the device is not adapted to the indoor climate after transport or storage, the device can become damaged when switched on.

WARNING!

Preventing infections

Sterilize reusable instruments and reusable tubes sets (NOT FOR SALE IN USA AND JAPAN) 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.

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

The manufacturer does not claim responsibility for transport damage resulting from insufficient or improper packaging.

If it becomes necessary to return the device, always use the original packaging.

Please fill out the return form enclosed at the end of this Instructions for Use (see Chapter Appendix [▶ 75]) and include the Instructions for Use in your return.

Make sure the following information is 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

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 Technical Data [▶ 71].

WARNING!

ME System (Medical Electrical System)

Use only parts and/or devices from ME systems (see Chapter Electromagnetic Compatibility [▷ 68]) in patient environments in compliance with the standard IEC60601-1 in the respective currently valid version.

WARNING!

Use in proximity to other devices

The GYN-Pump should not be used directly next to other devices as this could result in malfunctions.

The GYN-Pump was tested for compliance with IEC 60601-1-2 as a stand-alone system. Do not stack other devices on the system.

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.

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!

Equipment should be positioned such that power cable can be easily disconnected.

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/3.94 in).**

CAUTION!

Switching on the device

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

CAUTION!

Position of the device

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

CAUTION!

Sterile field

Place the device outside the sterile field.

CAUTION!

Position of the user

To ensure safe operations of the device, the user must be positioned correctly towards the device

- **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.**

Mains connection

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 (if included in scope of delivery) to establish a connection between the mains wall socket and the non-heating device plug located in the rear of the device.

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 Setup and Connection of Pump and Fluid Monitoring Unit

CAUTION!

Connecting the scale

Connect the scale to the device before you start the device. If the scale is connected after starting the device, the device does not detect the scale.

CAUTION!

Sterilization of device not permitted

Do not sterilize the pump or the fluid monitoring unit.

The fluid monitoring unit is a cart system that has a weighing unit (for distension fluid bags and canisters) and a roller wheel base.

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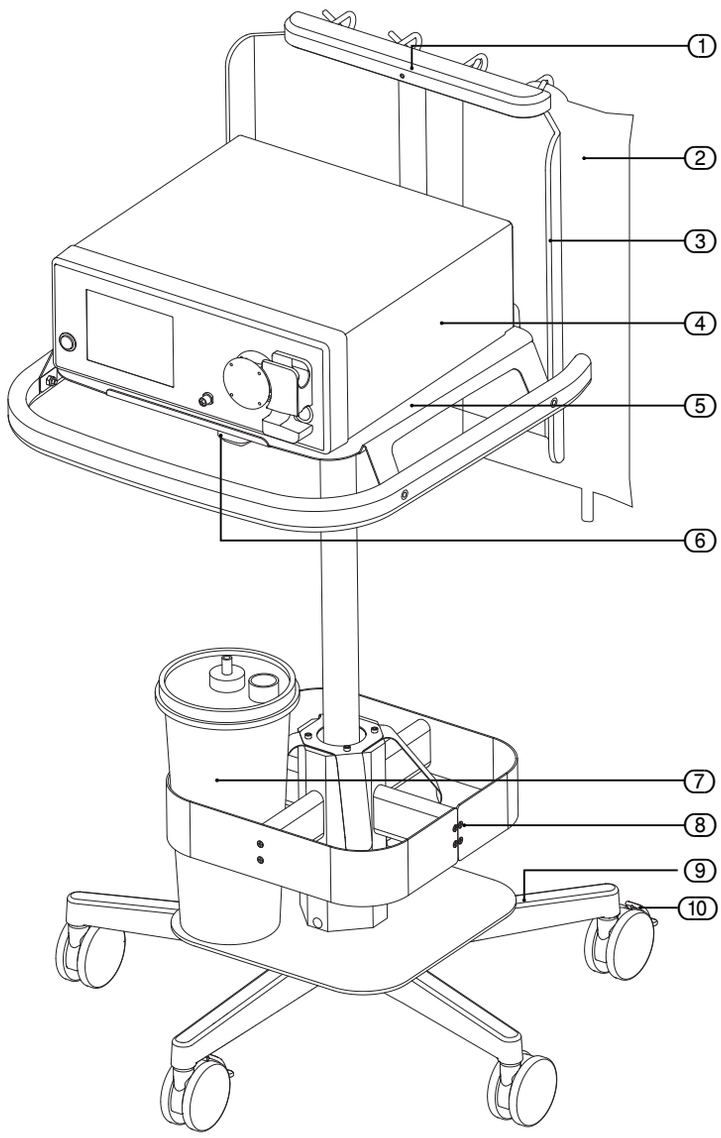
Fig. 4–1 Setup of pump and Fluid Monitoring Unit

① Holder with bag hooks
② Irrigation fluid bags
③ Bag deflector
④ Pump
⑤ Pump tray
⑥ Weighing cells for bags and canisters
⑦ Canister (e.g. Bemis, Medela, Serres, Abbott)
⑧ Canister holder
⑨ Roller wheel base
⑩ Locking foot brake



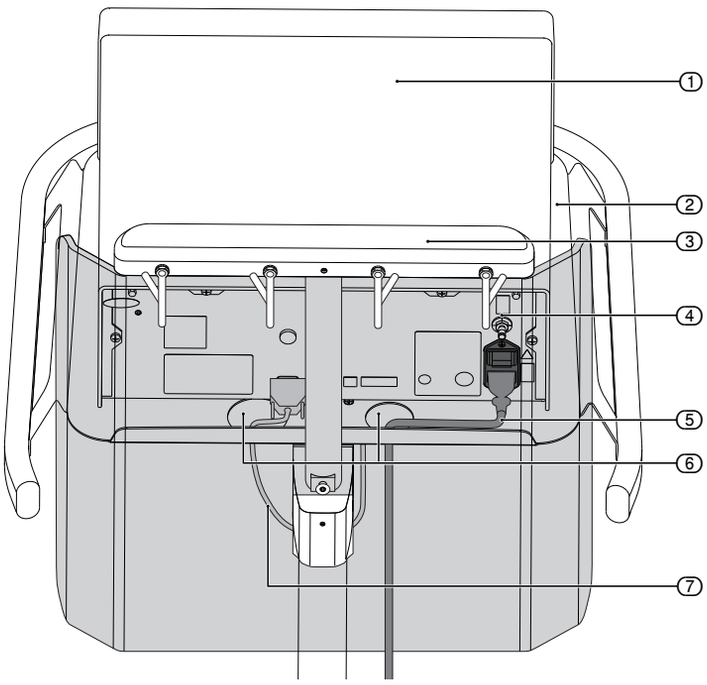


Fig. 4–2 Connecting pump and Fluid Monitoring Unit

1. Pump
2. Pump tray
3. Holder with bag hooks
4. Bag deflector
5. Power cord (pump connection)
6. Pump tray notch
7. Scale cord (pump connection)

CAUTION!

To avoid incorrect values or damage, do not apply physical weight to the scale:

- Do note lean against the scale.

- Do not step on the scale.

Preparation

- Make sure only bags with distension fluid are attached to the bag scale.
- Only attach canisters with connected tubes to the canister holder.
- Use a maximum weighing load of 23 kg for the bag scale and a maximum weighing load of 16 kg for the canister scale. See: Technical Data - Fluid Monitoring Unit [▷ 72]

Procedure

1. Place the pump on the pump tray of the fluid monitoring unit (scale).
2. Put the power cord through the pump tray notch.
3. Connect the power cord to the pump and a grounded safety wall socket.
4. Put the scale cord through the notch of the pump tray notch.
5. Connect the scale cord to the connection on the rear of the pump.
6. Make a loop with the scale cord to prevent bending and kinking.
7. Position the cord above the pump support.
8. Do the scale test according to chapter Scale Test [▷ 59].

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5 Device Interfaces

5.1 Front of Device

Familiarize yourself with the control and display elements of the device.

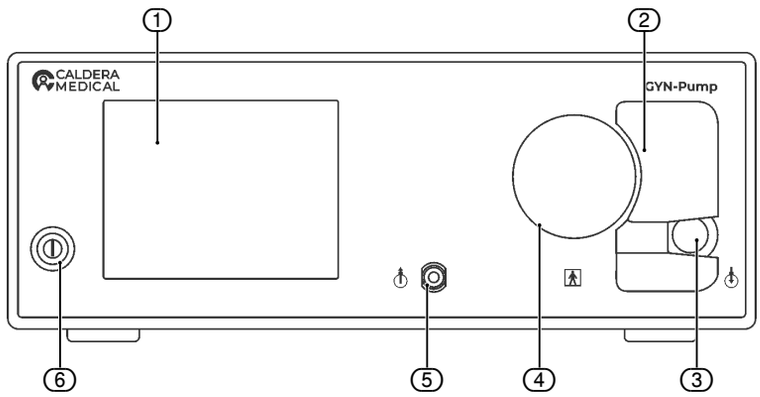

Fig. 5–1 Front of device

① Touchscreen
② Tube retainer
③ Pressure sensor
④ Roller wheel
⑤ Vacuum connection
⑥ ON/OFF button

5.2 Rear of Device

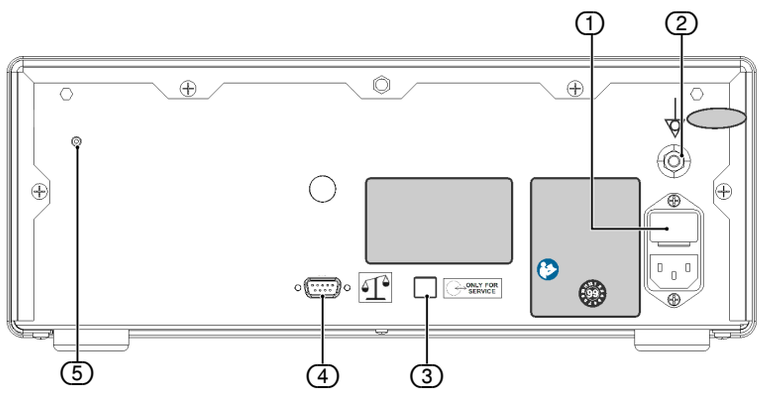

Fig. 5–2 Rear of device

① Mains power connection with fuse holder
② Potential equalization plug
③ USB service interface (for service only)
④ Scale connection
⑤ Vacuum output

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.

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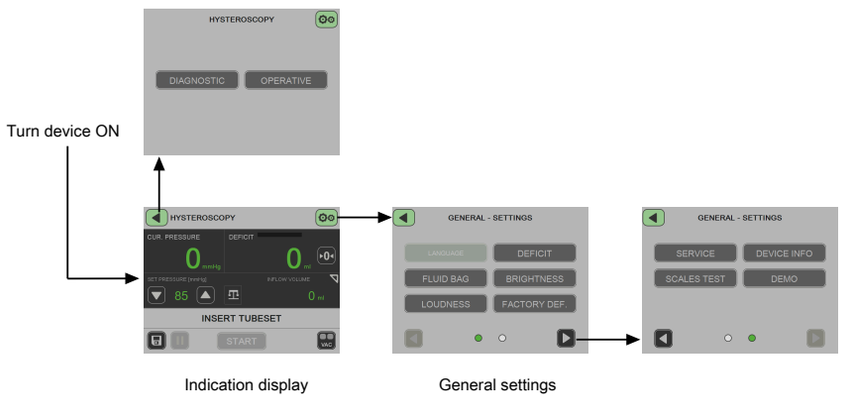
5.3 Touchscreen

The touchscreen of the device front connects the display with control elements for intuitive use of the pump.

Fig. 5–3 User interface - menu overview

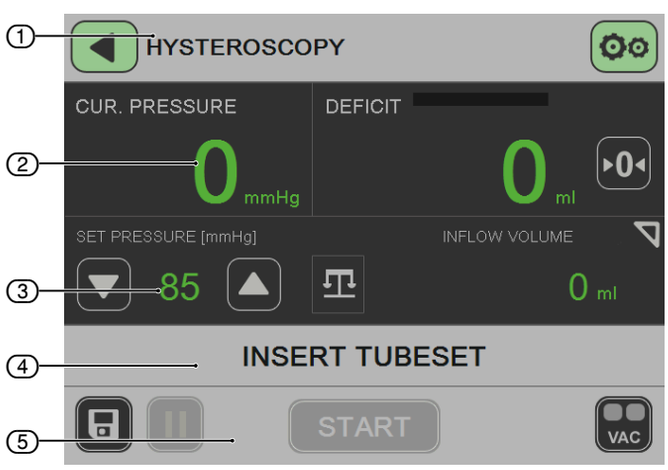


See also Indication Display - Hysteroscopy [▷ 44] for details.

The following general displays are available:

- Indication display
- General settings

Fig. 5–4 Indication display



①	Indication line	Shows selected indication
②	Actual value	Shows actual pressure and deficit values
③	Nominal value	Shows the set nominal pressure
④	Status line	Shows current status, warnings/error messages
⑤	Footer	Control elements

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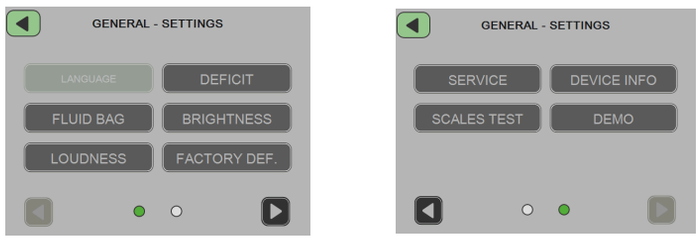
Fig. 5–5 General settings display



6 Operating the Device

WARNING!

Use only with necessary training

The device is intended to be used only by surgeons and support personnel with the necessary training in the appropriate indication - technical terms may be used.

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.

6.1 Switching the Device On

WARNING!

Touching patient and device

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

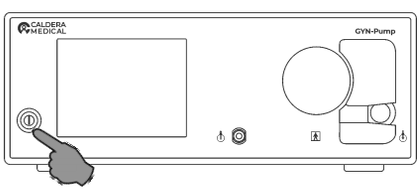


Fig. 6–1 Starting the device - ON/OFF button

1. Plug the device into the power outlet.
2. Make sure a tube set is not inserted into the tube retainer.
3. Press the ON/OFF button to switch the device on.
   - The device performs a device check.
   - Company logo and the progress bar are shown on the display.
   - If a scale is connected, the system directly enters the **Operative** mode after successful completion of device check.
   - If a scale is not connected, the system directly enters the **Diagnostic** mode.
   - If a tube set is inserted in the tube retainer before the device is switched on, the status line shows the message: **Remove tube set**
   - If the device check is not successful, corresponding error messages show on the display. For more information, see section: Automatic Device Check [▷ 56]

Press the ON/OFF button to shut the device off.

en

6.2 Using the Tube Sets

6.2.1 Tube Sets Overview

The following table shows the available approved tube sets for use with the system. See also Accessory List [▷ 74]

Type	Catalogue number	Product name	Intended use
Disposable (disposable/ single-use)	T0505-01	Tube set for irrigation, single-use	The Tube set for irrigation, single-use is intended to transport irrigation fluid to the patient in endoscopic surgeries.
Disposable (disposable/ single-use)	T0503-01	Tube set for suction (with 2 ports), single-use	The Tube set for suction (with 2 ports), single-use is intended to transport irrigation and waste fluid to a suitable waste container.
30-days use	T0504-01	Tube set for vacuum incl. filter, 30-day use	The Tube set for vacuum incl. filter, 30-day use is intended to provide suction to a suitable waste container.

WARNING!

The vacuum tube sets and the outflow 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. In regard to the short exposure time and the physical characteristics, the eventuality of critical quantities of DEHP being dissolved from the tube sets is negligible.

WARNING!

Preventing infections

Sterilize reusable instruments and reusable tubes (NOT FOR SALE IN USA) 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

Reprocessing of sterile disposable products can lead to infection hazards for patients and/or users and impairment of product functionality due to reuse. This could lead to the risk of injury, illness or death due to contamination and/or impaired functionality of the product! Do not reprocess the product.

NOTE!

Tubes must be stored at room temperature. The shelf life of the tubes may not exceed the expiration date indicated on the label.

NOTE!

Disposing tube sets

Observe applicable hygiene rules and regulations when disposing tube sets.

6.2.2 Tube Set Functions

RFID detection

The RFID transponder detects the tube type, the validity and reliability of a tube set automatically and a corresponding message is output in the status line of the display.

This eliminates virtually all operating errors since non fitting, invalid, and not allowed tube sets are reliably detected.

The corresponding transponder is located underneath the tube retainer in each allowed tube set (see chapter Accessory List [▷ 74]).

Invalidating a tube set

If an approved tube set is located in the device, the transponder technology automatically marks this tube set as used when the device is started.

Disposable tube set:

After inserting the tube set and starting the irrigation cycle, the tube set is marked as used after 10 minutes. If irrigation is paused, the device can be restarted. If the irrigation cycle is stopped, the device can be restarted within 30 minutes.

If the device is switched off or in case of a power failure, the tube set is marked as used and the irrigation cycle can no longer be started. If this is the case, you must insert a new, unused, and approved tube set.

Transponder signal loss

The device stops and cannot be restarted if the transponder loses its signal during current use. If the signal is restored within 20 seconds, it is possible to continue using the tube set.

6.2.3 Irrigation Tube Set Connection

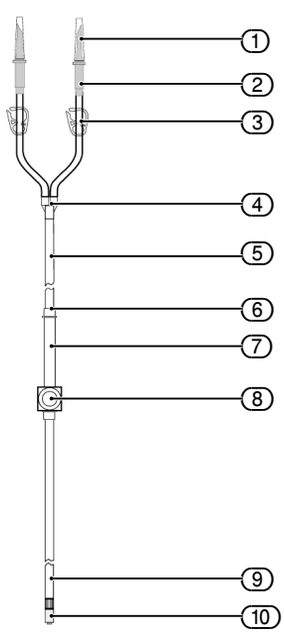


Fig. 6–2 Components of irrigation tube set

1. Protective caps
2. Spikes
3. Tube clamps
4. Y-connector
5. Irrigation tube
6. Ring
7. Roller tube
8. Pressure chamber with membrane and transponder
9. Instrument tube
10. Luer lock connector (blue)

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The irrigation tube set is available as a one-time use disposable tube set with the following components:

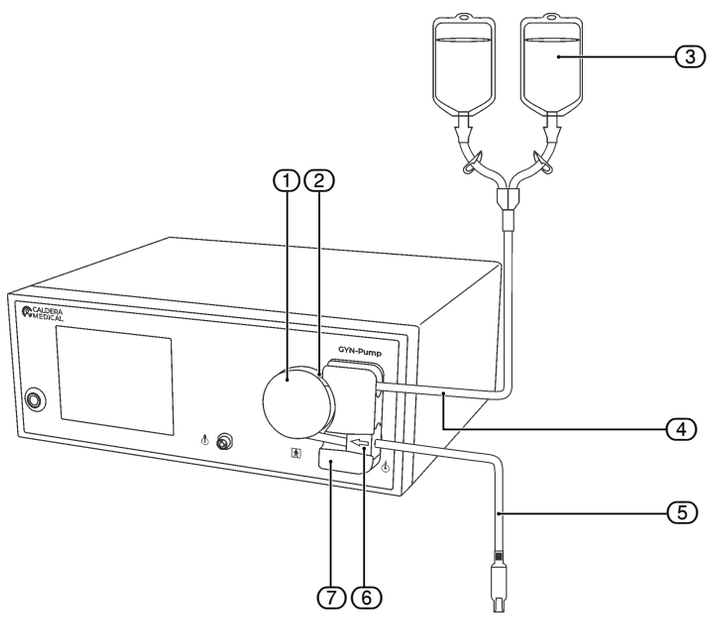
- Tube components: irrigation tube, roller tube, instrument tube
- Y-connector
- Spikes (for connection of tube components with the fluid bags)

See also: Tube Sets Overview [▷ 34]

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

Fig. 6–3 Setup for inserting the irrigation tube set

① Roller wheel
② Roller tube
③ Fluid bags
④ Irrigation tube
⑤ Instrument tube
⑥ Pressure chamber (with membrane and transponder)
⑦ Tube retainer



To separate sterile from non-sterile components and areas, assign the following tasks to sterile and non-sterile medical OR personnel (OR nurse, OR technician).

See also: Components of irrigation tube set [▷ 35], Setup for inserting the irrigation tube set [▷ 36]

Connecting the irrigation tube set

Non-sterile OR technician:

Open the outer packaging of the tube set.

Sterile OR technician:

1. Remove tube set from outer packaging.
2. Open inner packaging of tube set.

Sterile OR technician:

1. Give the tube end with the spikes to a non-sterile technician. Keep the Luer lock connector in the sterile area.
2. Connect the Luer lock connector to the instrument or tubing adapter, as applicable.
3. Open inflow valve at instrument.

Non-sterile OR technician:

1. Turn the device on.
   – The indication screen shows the status: **Insert tube set**
2. Insert the unpressurized pressure chamber carefully into the lower notch of the tube retainer up to the stop.

- Make sure that you do not damage the membranes of the pressure chamber when inserting the roller tube.
- Insert the pressure chamber only if chamber is not pressurized.

3. Put the roller tube around the roller wheel. See also: Roller wheel - position of roller tube [▷ 37]
4. Pull the tube until the tube ring fits in the upper part of the tube retainer.
   - The device starts a check of the tube set validity.
   - If the tube set is invalid, the status line shows: **Tube set not valid** and **Remove tube set**
   - If the tube is invalid, 3 acoustic warning signals are emitted. Repeat the full procedure with a valid tube set.
5. Connect the tube end with the spikes to the full fluid bags.
   - The device is now ready for instrument recognition.

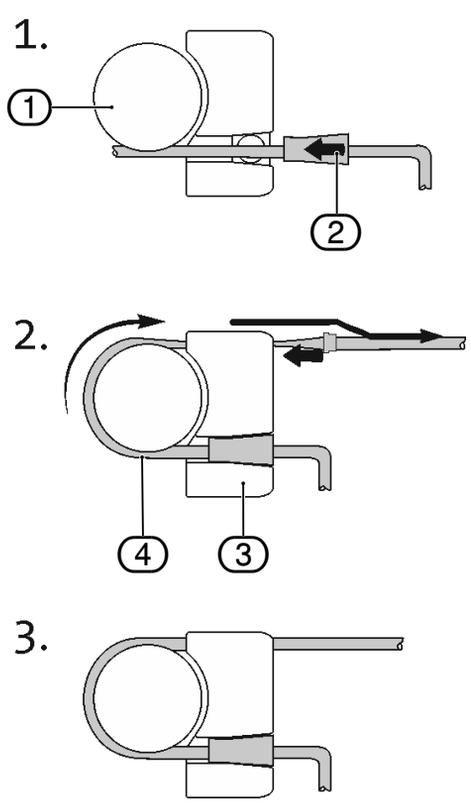


Fig. 6–4 Roller wheel - position of roller tube

① Roller wheel
② Pressure chamber
③ Tube retainer
④ Roller tube

6.2.4 Removing a Tube Set

To separate sterile from non-sterile components and areas, assign the following tasks to sterile and non-sterile medical OR personnel (OR nurse, OR technician).

Sterile OR technician:

1. Disconnect the Luer lock connector from the instrument or tubing adapter, as applicable.
2. Give the Luer lock connector to a non-sterile OR technician.

Non-sterile OR technician:

1. Disconnect the tube end with the spikes from the fluid bags.
2. Remove the tube from the tube retainer.

en

6.3 Attaching and Connecting the Irrigation Fluid Bags

WARNING!

Irrigation fluid

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

WARNING!

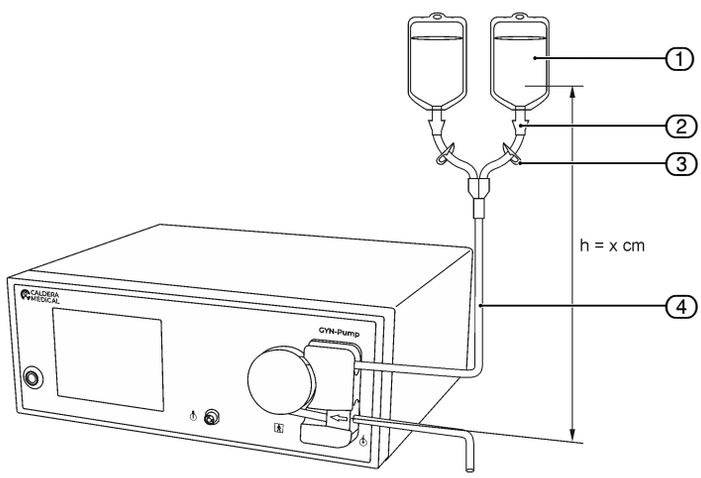
Distension media

When performing monopolar electrosurgery, the distension medium must be electrically non-conductive. Examples include glycine, sorbitol and mannitol. Electrically conductive distension fluid (saline, Lactated Ringer's) may only be used when performing bipolar electrosurgical resective procedures and when using mechanical tissue removal devices.

The inflow tube can receive distension fluid from 2 fluid bags.

Fig. 6–5 Attaching the fluid bags

① Fluid bag
② Spikes
③ Tube clamps
④ Inflow tube



To separate sterile from non-sterile components and areas, assign the following tasks to sterile and non-sterile medical OR personnel (OR nurse, OR technician).

Non-sterile OR technician:

1. Make sure that both tube clamps are connected to the branches of the inflow tube (see Fig. Attaching the fluid bags [▷ 38]).
2. Attach the fluid bags to the bag hooks of the scale (see Fig. Setup of pump and Fluid Monitoring Unit [▷ 28]).
3. If the scale is not used: Hang the bags at a height (h) between 0 and 1.5 m on a pole and set the height h in the settings of the operating menu.
4. Use the spikes to connect the tube ends of the tube set to the fluid bags.
   - Always hold the spikes with the provided handle.
   - Always comply with sterile conditions when inserting the spikes into the fluid bags.
5. Open one of the two tube clamps of the inflow/irrigation tube.

en

7 Using the Suction Function

The device is equipped with a vacuum pump.

The vacuum pump removes patient secretions with a suction tube and a secretion canister.

The suction system has the following components:

- Vacuum tube (with filter)
- Suction instrument tube
- Tandem tubes (for use with more than one secretion canister)
- Secretion canister
- Suction instrument
- Patient drape

Suction tubes can be used with all available indications.

The vacuum pump has 2 different vacuum levels:

Suction level	Vacuum
Low	30 kPa
High	60 kPa

The suction level is shown in the lower right corner of the indication display.

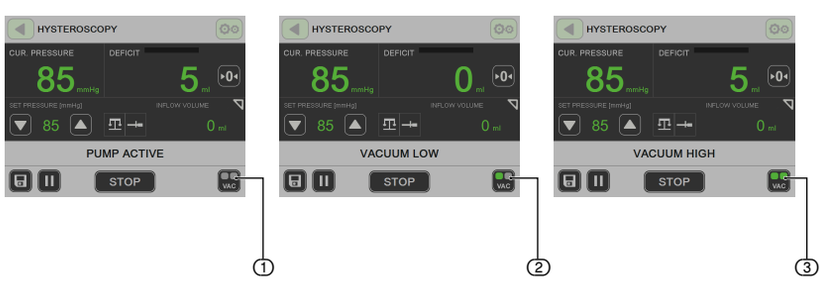


Fig. 7–1 Suction level display

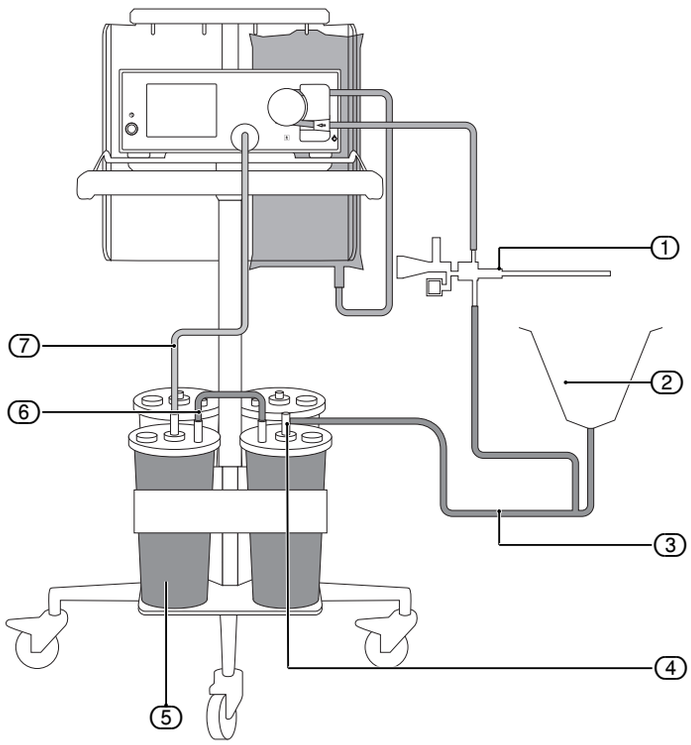
① Vacuum off
② Vacuum low
③ Vacuum high

en

7.1 Setup and Connection of Suction Tube Set

Fig. 7–2 Suction tube set connection

① Suction instrument
② Patient drape
③ Suction tube (Y-tube)
④ Patient port (connection to vacuum canister)
⑤ Secretion canister
⑥ Tandem tube
⑦ Vacuum tube (with filter)



7.2 Connecting Suction and Vacuum Tube Sets

WARNING!

Maximum use of vacuum tube with filter

The vacuum tube with integrated filter is designed for a maximum use of 30 days.

Replace the vacuum tube if it is obviously contaminated.

The filter prevents that body fluids enter the interior of the device. Note that the filter can reduce suction capacity.

CAUTION!

Pre-evacuated tube system

Only if the tube system is pre-evacuated (building a vacuum), the full suction capacity is available. Pre-evacuation takes about 30 to 60 seconds depending on the volume of the container.

CAUTION!

Containers with overflow protection

Only use secretion containers with overflow protection.

1. Connect the vacuum tube to the vacuum port of the device.
2. Connect the vacuum tube to the secretion canister.
   - Use tandem tubes if more than one secretion canister is connected to the vacuum source.
3. Connect the secretion canister to the suction tube (instrument tube).
4. Connect the suction tube to the suction instrument.

5. Close the inflow valve of the suction instrument.
6. Connect flexible white connector of suction tube (Y-tube) to patient port of secretion canister.
7. Attach the flexible blue connector of the suction tube to the drape.
8. Connect the red Luer connector of the suction tube to the suction instrument.

7.3 Starting/Stopping Suction

In the indication display, press the suction function button **VAC** to activate suction.

- The vacuum pump generates a negative pressure.
- When a negative pressure matching the suction level is reached, the vacuum pump stops.
- When the negative pressure falls below the suction level, the vacuum pump starts again.

7.4 Safety Functions – Vacuum Pump

WARNING!

Device defects

For the safety of the patient and operating personnel, make sure that the device is complete and fully functional before each use of the device.

Do not use the device if defects are suspected during use or confirmed by device check/tests. Defects include obvious defects of power supply (e.g. power plugs, power cords).

Make sure that the device cannot be used until a qualified service technician conducts the applicable tests and repairs.

If a malfunction of the suction function or the vacuum pump occurs:

- The status line shows the warning message: **Vacuum pump defective**
- The device emits 3 warning sounds

Surgery can be continued. After completion of the surgery, make sure the device is not used before it has been checked by an authorized service technician.

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8 Using the GYN-Pump for Hysteroscopy

NOTE!

Perform Function Test

Before using the device perform the function tests as described in chapter Function Tests [▷ 58]

Only use the device within the scope of the intended use.

See section: Intended Use/ Indications for Use [▷ 11]

The device has the following characteristics in hysteroscopy indication mode:

- Operative and diagnostic mode
- Instrument recognition function
- Maximum fluid inflow volume: 30,000 ml
- Safety features communicate important status messages related to total fluid inflow. See section: Fluid Inflow Limit [▷ 51]
- Nominal pressure range: 15–150 mmHg
- Maximum flow range: 30–800 ml/min
- Safety threshold for nominal pressure
- Acoustic warning sounds for control of nominal pressure, deficit limit, and high fluid loss

8.1 Device-Inherent Risks – Hysteroscopy

WARNING!

Distension media

When performing monopolar electrosurgery, the distension medium must be electrically non-conductive. Examples include glycine, sorbitol and mannitol. Electrically conductive distension fluid (saline, Lactated Ringer's) may only be used when performing bipolar electrosurgical resective procedures and when using mechanical tissue removal devices.

WARNING!

Fluid Overload

There is a risk of irrigation fluid reaching the circulatory system of the patient's soft tissue. This can be affected by distention pressure, flow rate, perforation of the distended body cavity and duration of the endoscopic surgery. It is critical to closely monitor the input and outflow of the distending liquid at all times.

WARNING!

Hypothermia (monitoring body temperature)

Continuous flow of distention fluids can lead to a lowering of the patient's body temperature. Lower body temperatures can cause coronary and cardiovascular problems. Always monitor the patient's body temperature during the entire surgery 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.**

WARNING!

Air embolism

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

WARNING!

Loss of deficit and inflow value

The deficit display value is lost in case of a power loss or "brownout."

WARNING!

Intrauterine distension

Intrauterine distension is usually possible with pressure values between 35 to 70 mmHg. A pressure above 75 mmHg is required only in rare cases or if the patient has an excessively high blood pressure.

WARNING!

Fluid intake and output surveillance

Strict fluid intake and output surveillance should be maintained due to the risk of fluid overload. For healthy patients, the maximum fluid deficit of 1,000 ml is suggested when using a hypotonic solution (e.g. glycine, sorbitol and mannitol). If isotonic solutions (e.g. saline, Lactated Ringer's) are used, the fluid deficit should not exceed 2,500 ml.

WARNING!

Hyponatremia

Some distension fluids may lead to fluid overload and, consequently, hyponatremia with its attending sequelae. This can be affected by the distending pressure, flow rate, and duration of hysteroscopic procedure. It is critical to closely monitor the input and outflow of the distending liquid at all times.

WARNING!

Pulmonary edema

A surgical procedure is associated with a risk of developing pulmonary edema resulting from fluid overload with isotonic fluids. It is critical to closely monitor the input and outflow of the distending liquid at all times.

WARNING!

Cerebral edema

A surgical procedure is associated with a risk of developing cerebral edema resulting from fluid overload and electrolyte disturbances with hypoosmolar (non-ionic) fluids such as glycine 1.5 % and sorbitol 3.0 %. It is critical to closely monitor the input and outflow of the distending liquid at all times.

WARNING!

Rupture of the fallopian tube secondary to tubal obstruction

Distention of the uterus may lead to a tear of the fallopian tube should there be an obstruction or permanent occlusion. The rupture could lead to irrigation fluid flowing into the patient's peritoneal cavity, resulting in a fluid overload. It is critical to closely monitor the input and outflow of the distending liquid at all times.

WARNING!

Instrument replacement during surgery

If you replace the device during surgery, you must stop the procedure.

Use the Stop button of the indication display to stop the device and continue the procedure by using the Start button after replacement of the instrument.

WARNING!

Deficit displays and warnings

Deficit displays and warnings serve as a tool for the treating physician and do not replace the monitoring of the patient's condition.

WARNING!

Fluid volume/sodium concentration

The fluid left in the patient and the concentration of sodium in the blood serum must both be monitored. The deficit amount is the entire amount of fluid lost by or to the system. Take note of the measurement tolerance of the system. While the system provides fluid deficit estimation, it is ultimately the physician's responsibility to monitor fluid deficit.

WARNING!

Pressure

The pressure should be kept as low as possible to allow for a sufficient intrauterine distention and to reduce the forces that could allow fluid, ambient air, and/or gas into the circulatory system.

WARNING!

Resetting the deficit display

Filling the tubing with irrigation fluid and resetting the deficit display to zero are to be done at the physician's discretion.

WARNING!

Fluid bags

Make sure the fluid bags hang freely, are not resting on something, and do not touch other objects except the bag deflectors. Failure to follow these instructions means the deficit cannot be calculated correctly.

8.2 Indication Display – Hysteroscopy

When the device is started, the **Hysteroscopy** indication display is shown as default.

The device has a operative mode and a diagnostic mode.

- When the scale is connected, the device automatically enters the **Operative** mode.
  - Fluid deficit is measured and shown on the display.
  - You can change the mode back to **Diagnostic** mode with the back/return button.
- When the scale is not connected, the device automatically enters **Diagnostic** mode.
  - The inflow volume is displayed.
  - The fluid deficit is not displayed.

For safety reasons, some buttons (for example **Stop**, **Deficit Reset**, **Save**) must be held down for 1.5 seconds to be activated.

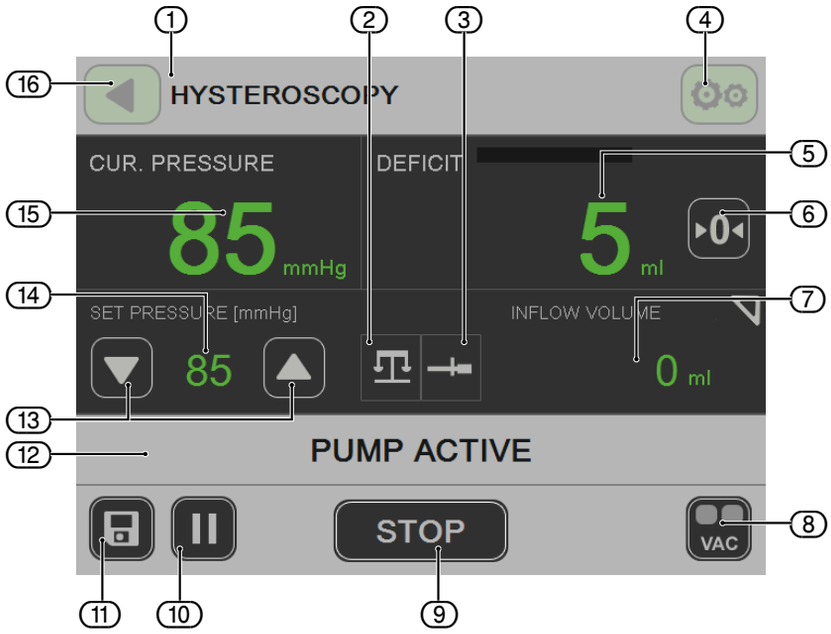

Fig. 8–1 Display operative mode – scale connected

1. Indication display
2. Scale display (scale connected)
3. Instrument recognition
4. Menu button
5. Fluid deficit display
6. Deficit reset button
7. Nominal flow display
8. Suction function button (ON/OFF)
9. Start/Stop button
10. Pause/Continue button
11. Save button
12. Status display
13. Nominal pressure setting button
14. Nominal pressure display
15. Actual pressure display
16. Back/Return button

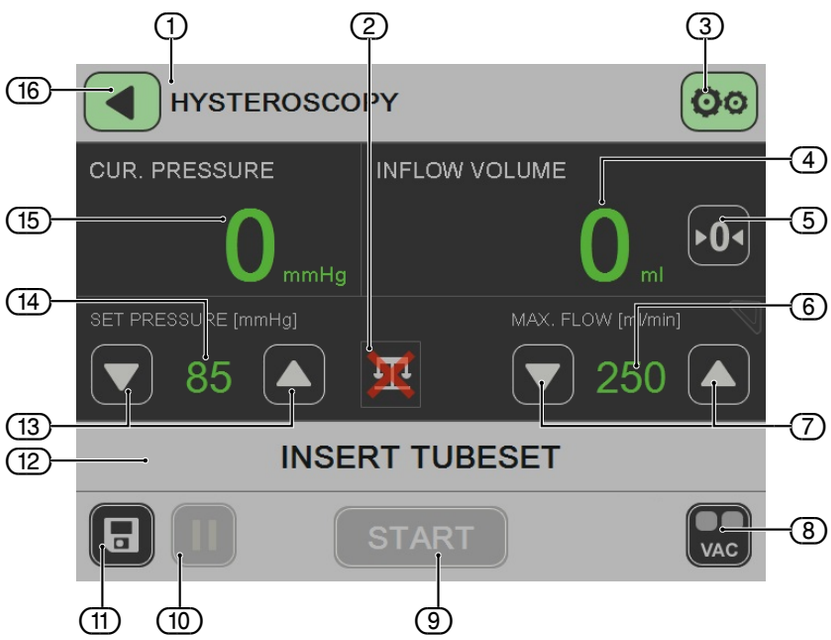

Fig. 8–2 Display diagnostic mode – no scale connected

1. Indication display
2. Scale display (no scale connected)
3. Menu button
4. Inflow volume display
5. Deficit reset button
6. Nominal flow display
7. Nominal flow setting button
8. Suction function button
9. Start/Stop button
10. Pause/Continue button
11. Save button
12. Status display
13. Nominal pressure setting button
14. Nominal pressure display
15. Actual pressure display
16. Back/return button

If the scale is not connected to the device, the display shows inflow volume but not the fluid deficit.

No deficit measurement

8.2.1 Maximum Flow Rate Display

In operative mode, the inflow volume is displayed below the deficit volume.

Use the Shift key to toggle between the inflow volume and maximum flow rate display. See also: Fig. Hysteroscopy screen display in operative mode [▷ 45]

8.2.2 Fluid Deficit Volume Display

In operative mode, the fluid **Deficit** is measured by the device and shown in the indication display.

The fluid deficit is the difference between the consumed irrigation fluid volume and the fluid volume collected in the canisters.

The deficit indicates the fluid that is lost during surgery.

WARNING!

Fluid inflow limit

If the scale is in use, the GYN-Pump has a permitted maximum fluid inflow volume.

If the fluid inflow limit is reached, fluid inflow stops, the fluid inflow and fluid deficit values freeze.

If the physician decides to continue the procedure, the device does not continue to calculate the fluid deficit. Fluid inflow and fluid deficit values must be counted manually.

CAUTION!

Collecting the fluid

Try to collect all the fluid that runs out of the uterus during the procedure in order to achieve the most exact balancing possible.

8.3 Instrument Recognition

The device has an instrument recognition function that allows compensation for pressure loss due flow through the narrow working channel.

The instrument recognition function runs each time a new procedure is started. Make sure that the inflow stopcock is opened for the procedure.

The pressure drop at the instrument is included in the measured actual pressure to ensure accurate pressure control.

Instrument recognition must be done again each time the instrument is changed and the procedure is stopped using the Stop button of the indication display. For details, see section: Changing the Instrument [▷ 48]

8.4 Setting the Nominal Pressure

WARNING!

Risk for bacteria entering the body

If the current pressure does not react to an increase of the flow value during surgery, a perforation of the cavum uteri might be the cause. This results in an increased risk for bacteria entering the body. Examine the uterus for injuries.

The nominal pressure can be set in active or inactive state of the device.

Nominal pressure values can be set in the range of 15 to 150 mmHg (factory setting: 60 mmHg). See also: Technical Data [▷ 71]

1. Use the nominal pressure setting buttons to increase/decrease the nominal pressure in increments of 5 mmHg. See: Indication Display – Hysteroscopy [▷ 44]
2. Hold the nominal pressure setting buttons for more than 1.5 seconds to activate the scroll function with values of 10 mmHg increments.

8.5 Setting the Maximum Flow Rate

You can set the maximum flow rate when operating the device. You can also set the maximum flow rate when not operating the device.

Maximum flow rate values can be set in the range of 30–800 ml/min (factory setting: 800 ml/min). See also: Technical Data [▷ 71]

1. If the scale is in use, use the shift key to navigate to the flow rate setting.
2. Use the maximum flow-rate setting buttons to increase or decrease the maximum flow rate in increments of 50 ml/min.
3. Press and hold the maximum flow-rate setting button for more than 1.5 seconds to activate the scroll function with increments of 100 ml/min.
4. Press and hold the save button for 1.5 seconds to save the entered value.

Increase/decrease maximum nominal flow

CAUTION!

If the maximum flow rate is set too low, the nominal pressure cannot be reached.

8.6 Saving Nominal Pressure and Maximum Flow Values

Press and hold the save button for 1.5 s to save the nominal pressure and maximum flow rate values for next use of the hysteroscopy indication.

See: Indication Display – Hysteroscopy [▶ 44]

If the nominal pressure exceeds 80 mmHg, the nominal pressure is automatically reset to 80 mmHg for the next hysteroscopy procedure.

8.7 Resetting the Fluid Deficit

- Press and hold the deficit reset button for 1.5 s to reset the fluid deficit to 0 (zero).
  - The status line shows the following message: **Fluid deficit reset**
  - The inflow volume is reset to 0 (zero) at the same time.

8.8 Starting/Stopping Irrigation

CAUTION!

Instrument recognition

The instrument recognition must be performed outside of the patient and at the same level as the patient.

1. Insert the inflow tube set. See also: Tube Set Functions [▶ 35]
2. Open one of the two tube clamps at the inflow tube.
3. Fully open the inflow valve of the instrument.
4. Use the **Start** button to start the instrument recognition.
   - The actual pressure display shows the current measured value.
   - The roller wheel starts to turn.
   - The instrument recognition starts.
5. The status dispay shows: **Instrument recognition**
   - Wait until the instrument recognition is completed.
   - 1x acoustic signal indicates completion of the instrument recognition.
   - The status changes to: **Instrument recognition completed**
6. Check the deficit value and reset it if necessary.
7. Press **Start** to start the procedure.
8. Use **Pause** to pause the fluid flow or press and hold the **Stop** button for 1.5 s to stop the procedure.
   - If you pause the procedure with **Pause**, you can continue using **Start** without doing instrument recognition again.
   - You must do the instrument recognition again after stopping the procedure with the **Stop** button.

WARNING!

Instrument replacement during surgery

If you replace the device during surgery, you must stop the procedure.

Use the Stop button of the indication display to stop the device and continue the procedure by using the Start button after replacement of the instrument.

NOTE!

The device checks during operation if the performed instrument recognition is still valid. If this check yields an error, the instrument characteristic is rejected. The device then uses standard values.

8.9 Changing the Instrument

If the instrument (hysteroscope) is changed, the instrument recognition must be done again to ensure accurate pressure measurement.

A change of the instrument can be necessary when changing from a diagnostic to a surgical procedure, for example.

1. Press and hold the **Stop** button for 1.5 seconds to stop the procedure.
2. Change the instrument.
3. Press **Start** to start the procedure.
   - The instrument recognition process starts again.

See also section: Starting/Stopping Irrigation [▸ 47]

8.10 Changing Fluid Bags during Surgery

WARNING!

Fluid bag and canister change during surgery

A fluid bag or canister change during surgery is only allowed, if the fluid bag or canister holds at least 0.5 l of fluid or waste. Otherwise, the deficit value may be inaccurate. In this case, the manufacturer recommends manual deficit calculation.

WARNING!

Changing fluid bags and containers

Change canisters and fluid bags quickly to avoid affecting the accuracy of the deficit calculation.

WARNING!

Empty fluid bags

Do not remove empty fluid bags from the bag hooks so that fluid deficit values continue to be accurate.

CAUTION!

Height-settings of fluid bags

Make sure that the height of the fluid bags is set correctly in the general menu of the device if you do not use a scale. See Chapter Fluid Bag Configuration (Use without Scale) [▸ 54].

If a connected scale is used, the device system automatically senses a bag change.

Short fluctuations in the deficit calculation (up to 30 seconds) can occur when replacing a fluid bag.

The status of the display shows the following message to indicate the change: **Bag Change**

To separate sterile from non-sterile components and areas, assign the following tasks to sterile and non-sterile medical OR personnel (OR nurse, OR technician).

Non-sterile OR technician:

1. Open tube clamp of the full fluid bag.
2. Close tube clamp of the empty fluid bag.
3. Hang a full fluid bag on the same bag hook as the empty fluid bag.
   - Do not remove empty bags from the bag hooks so that fluid deficit values continue to be accurate.
4. Close the tube clamp of the new, full fluid bag.
   - Keep the tube clamp of the new, full fluid bag closed until this bag is also in need of replacement.

This procedure must be carried out each time a fluid bag is replaced.

8.11 Changing Canisters during Surgery

WARNING!

Fluid bag and canister change during surgery

A fluid bag or canister change during surgery is only allowed, if the fluid bag or canister holds at least 0.5 l of fluid or waste. Otherwise, the deficit value may be inaccurate. In this case, the manufacturer recommends manual deficit calculation.

WARNING!

Touching the canisters and their holders as well as vibrations of the balancing system should be avoided during surgery to prevent triggering a false detection of the canister change and not negatively affect the accuracy of the deficit calculation.

WARNING!

Changing canisters

Canisters should be changed quickly to avoid affecting the accuracy of the deficit calculation.

CAUTION!

To avoid affecting the accuracy of the deficit calculation ensure that the first step of the canister change is to disconnect tubing from the full canisters. Reconnect tubing to the new canisters only if they are already inserted into the scale.

CAUTION!

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

If a connected scale is used, the device system automatically senses a canister change.

The pump continues to operate during a canister change.

Short fluctuations in the deficit calculation (up to 30 seconds) can occur when replacing a canister.

The status of the display shows the following message to indicate the change: **Canister change**

1. Disconnect the tubing from full canisters.
2. Remove full canisters from the scale.

Changing canisters

3. Insert new canisters.
4. Connect tubing to the new canisters.

8.12 Safety Functions – Hysteroscopy

8.12.1 General Safety Functions

The device has safety functions for different levels of criticality that include:

- Warning messages shown on the status line of the display
- Warning sounds emitted by the device
- Automatic device responses

For general safety functions of the device, see: Safety Functions [▸ 56]

For an overview of warning messages and troubleshooting instructions, see: Error and Warning Messages [▸ 57]

8.12.2 High Fluid Loss

If the fluid deficit rate of 300 ml/min is exceeded:

- The device emits 3 acoustic warning signals.
- The status line shows the following warning message for 15 seconds, unless the deficit rate returns to a lower value before: **High Fluid Loss!**

See also: Fluid Deficit Safety Threshold [▸ 50]

8.12.3 Fluid Deficit Safety Threshold

The deficit threshold triggers fluid-deficit related warning messages in case of high fluid loss. See also section: Setting the Deficit Threshold [▸ 53]

Deficit reached

If the differential volume reaches the set threshold value (0.1–2.5 l):

- The device emits 3 acoustic warning signals.
- The status line shows the following warning message: **Deficit reached!**

The progress bar changes to red and shows the deficit value on the display.

Deficit exceeded

If the deficit volume exceeds the value of the fluid-deficit threshold:

- The device emits 5 acoustic warning signals
- The status line shows the following warning message: **Deficit exceeded!**

The device emits a warning signal with every additional 100 ml that exceed the deficit threshold.

8.12.4 Overpressure

Overpressures can occur during device operation. Safety-functions of the device help the physician during surgery in the following conditions:

1. The actual pressure exceeds the nominal pressure by more than 10 mmHg.
2. The actual pressure exceeds 150 mmHg.
   - The status line shows the following warning message: **Overpressure!**
   - The device emits 3 warning sounds.
   - A pressure-relief function is activated that turns the roller wheel backwards.
     - If the actual pressure falls below the nominal pressure, the roller wheel starts turning forward again and irrigation is continued.
     - The warning functions stop.

Actual pressure > 200 mmHg

CAUTION!

Critical overpressure

The warning message Critical Overpressure! overwrites all other status messages.

Overpressure warning functions help the physician to respond appropriately to excess pressure conditions.

If possible, the physician should reduce the intrauterine pressure by opening the outflow cannula.

If the actual pressure exceeds 200 mmHg:

- The status line shows the following warning message: **Critical overpressure!**
- The device emits 5 warning sounds.
- A pressure relief function is activated that turns the roller wheel backwards.
  - If pressure relief is not successful after 5 seconds, the roller wheel stops.
  - If the actual pressure falls below the nominal pressure, the roller wheel starts turning forward again and irrigation is continued.
  - The warning functions stop.

8.12.5 Pressure Safety Threshold

To prevent dangerous pressures, the device has a safety threshold for nominal pressures over 100 mmHg.

- An acoustic warning sound is emitted
- The status line shows the following warning message: **Pressure over 100 mmHg?**
- After 2 seconds, the pressure can be set to a value exceeding the 100 mmHg threshold.

8.12.6 Fluid Inflow Limit

WARNING!

Fluid inflow limit

If the scale is in use, the GYN-Pump has a permitted maximum fluid inflow volume.

If the fluid inflow limit is reached, fluid inflow stops, the fluid inflow and fluid deficit values freeze.

If the physician decides to continue the procedure, the device does not continue to calculate the fluid deficit. Fluid inflow and fluid deficit values must be counted manually.

If the scale is in use, the **GYN-Pump** has a permitted maximum fluid inflow volume of 30,000 ml.

- If the fluid inflow volume reaches 28,000 ml:
  - The device emits 3 warning sounds.
  - The status line shows the warning message: **High inflow volume reached!**
- For every additional 500 ml above 28,000 ml fluid inflow:
  - The device emits 5 warning sounds.
  - The status line shows the warning message: **High inflow volume exceeded!**
- If the fluid inflow volume reaches 30,000 ml:
  - The device emits 5 warning sounds.
  - The status line shows the warning message: **Inflow volume limit reached! / Pump paused.**
  - The pump stops fluid inflow.

- The fluid inflow volume and the deficit freeze at the current values.
- The deficit value flashes on the display.
- The procedure can be continued with the **Start** button. The status line continues to show the warning message: **Inflow volume limit reached!**

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9 Settings Menu

In the settings menu you can:

- Change the general device parameters
- Change the indication-specific parameters
- Open the service menu (authorized service personnel only)

To enter the settings menu, the device and the vacuum pump must be stopped.

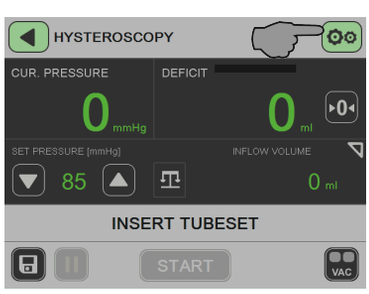
9.1 General Settings – Overview

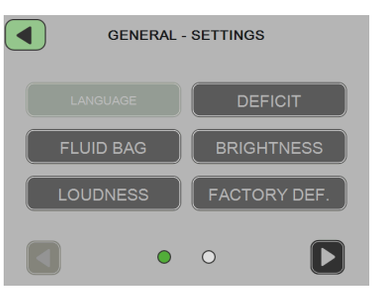
General settings	Languages	English	
	Deficit (range: 0.1–2.5l)	[-]	Default setting: 1.5 l
		[+]	
	Fluid bag height (range: 0–1.5m)	[-]	Default setting:1 m
		[+]	
	Brightness (levels 1–11)	[-]	Default setting: 6
		[+]	
	Loudness (levels 1–7)	[-]	Default setting: 4
		[+]	
	Factory settings		
	Service	Calibration	Pressure sensor
			Inflow monitor
			Touch screen
			Scale 1
			Scale 2
		Device info	
	Device info		
	Scale test		
	Demo		

9.2 General Settings Menu

Opening the general settings menu

1. Switch the device on.





2. To navigate to the general device settings, press the menu button in the indication display or in the mode selection display.
3. Select one of the available parameters (see General Settings – Overview [▷ 53]).

The following sections give a detailed description of the general device parameters.

9.2.1 Setting the Deficit Threshold

The fluid-deficit threshold specifies the deficit value that triggers deficit-related warning messages.

The deficit threshold can be set within a range of 0.1 to 2.5 l.

Default setting: 1.5 l

1. Select **Threshold** in the general settings.
2. Use the increase/decrease buttons (**+/-**) to set the deficit threshold.
   - Pressing the buttons briefly increases/decreases the value in increments of 0.1 l.
   - By pressing and holding the buttons you can change to increments of 0.2 l/min.
3. Press the return button to save the values and to return to the previous menu.

9.2.2 Fluid Bag Configuration (Use without Scale)

In the fluid bag configuration you can set the height difference between device and fluid bag. For details, see Attaching and Connecting the Irrigation Fluid Bags [▷ 38].

Factory setting: 0 m

1. Select **Fluid bag** in the general settings.
2. Use the increase/decrease buttons (**+/-**) to set the height between device and fluid bag.
   - Pressing the buttons briefly increases/decreases the value in increments of 0.1 m.
   - By pressing and holding the buttons you can change to increments of 0.5 l/m.
3. Press the return arrow-button to save the values and to return to the general settings menu.

WARNING!

Settings of fluid bags incorrect

If the height of fluid bags is set incorrectly in the general settings of the device, deviation of the flow in comparison to the specification of the device can occur.

Deficit calculation can be incorrect in this case.

NOTE!

The adjustment of the bag height is inactive when using a scale since the height of the bags is predetermined by the scale.

9.2.3 Setting the Display Brightness

Factory setting: 6

1. Select **Brightness** in the general settings.
2. Use the increase/decrease buttons (**+/-**) to set the brightness value in a range between 1 and 11.
3. Press the return arrow-button to save the values and to return to the general settings menu.

9.2.4 Setting the Loudness of Warning Sounds

Factory setting: 4

1. Select **Loudness** in the general settings.
2. Use the increase/decrease buttons (**+/-**) to set the volume in a range between 1 and 7.
3. Press the return arrow-button to save the values and to return to the general settings menu.

9.2.5 Resetting to Factory Default

1. Select **Factory Default** in the general settings.
2. Press the **OK** reset all general and all indication-specific device parameters.

– If you do not want to reset the settings to factory default, you can use the return arrow-button to return to the general settings menu without saving.

9.2.6 Service Menu

The **Service** menu is password protected and access is intended for qualified service technicians only.

The following functions are available in the service menu:

- Pressure sensor calibration
- Inflow motor calibration
- Touchscreen calibration
- Scale 1
- Scale 2

9.2.7 Device Information

Select **Device Info** in the general settings.

The serial number and software version are shown.

9.2.8 Scales Test Menu

See Chapter Scale Test [▶ 59].

9.2.9 Demo Mode

Select **Demo** in the general settings.

The **Demo** mode shows the control unit functionalities.

The irrigation stops after 2 minutes and is disabled for another 30 seconds.

If the pump is stopped before 2 minutes, you have to wait 30 seconds before restarting.

Tubes are not invalidated during demo mode.

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10 Safety Functions

WARNING!

Device defects

For the safety of the patient and operating personnel, make sure that the device is complete and fully functional before each use of the device.

Do not use the device if defects are suspected during use or confirmed by device check/tests. Defects include obvious defects of power supply (e.g. power plugs, power cords).

Make sure that the device cannot be used until a qualified service technician conducts the applicable tests and repairs.

The correct operation of the device is continuously monitored by the electronic components.

The device has safety functions for different levels of criticality that include:

- Warning messages shown on the status line of the display
- Warning sounds emitted by the device
- Automatic functional device responses

If more than one error occurs at the same time, warning messages are processed according to an internal priority ranking.

On-screen warning messages have different formats:

Level	Criticality of message	Format
1	High	Red letters, exclamation mark, 5 warning sounds
2	Medium	Black letters, exclamation mark, 3 warning sounds
3	Low	Black letters, 1 warning sound
4	None (general operating messages)	Black letters, 1 system sound

For an overview of warning messages, see: Error and Warning Messages [▷ 57]

For safety functions related to Hysteroscopy, see: Safety Functions – Hysteroscopy [▷ 50]

10.1 Automatic Device Check

When you start the device, the device runs an automatic device check. The check includes pressure sensors, motor, and electronic components.

The following errors and responses can occur. For details and troubleshooting instructions, see section: Error and Warning Messages [▷ 57]

Sensor Error

If an sensor error occurs in the pressure-measurement system:

- The device emits 5 warning sounds.
- The status line shows the warning message: **Sensor error**

Motor Error

If a motor error occurs:

- The device emits 5 warning sounds.
- The status line shows the warning message: **Motor error**

Electronics Error

If a system electronics error occurs:

- The device emits 5 warning sounds.
- The status line shows the warning message: **Electronics error**

Calibration Error

If a calibration error occurs:

- The device emits 5 warning sounds.
- The status line shows the warning message: **Calibration error**

10.2 Error and Warning Messages

Criticality: High		
Message	**Cause**	**Troubleshooting**
Electronic error! Call service	Electronic error	Restart the device. If the malfunction or error occurs again, please contact the service department.
Sensor error! Call service	Pressure sensor defective	Restart the device. If the malfunction or error occurs again, please contact the service department.
Motor error! Call service	Motor error	Restart the device. If the malfunction or error occurs again, please contact the service department.
Calibration error! Call service	The device is not calibrated properly.	The device must be recalibrated. Please contact the service department.
Critical overpressure!	Hysteroscopy: Actual pressure above 200 mmHg	The physician must reduce the pressure, for example, by opening the outflow valve.
Deficit limit exceeded!	In increments of 100 ml above the preset value	Physician must respond appropriately.
High inflow volume exceeded!	500 ml increments above 28,000 ml and below 30,000 ml inflow volume reached	End case quickly and safely.
Inflow volume limit reached! / Pump paused	30,000 ml inflow volume limit reached	End case; if case is continued, perform manual count to monitor deficit.

Criticality: Medium		
Message	**Cause**	**Troubleshooting**
Overpressure!	Hysteroscopy: Actual pressure > nominal pressure + 10 mmHg and > 150 mmHg	The physician must reduce the pressure, for example, by opening the outflow valve.
High fluid loss	Deficit change >300 ml/min	Physician must respond appropriately.
Deficit limit reached!	Deficit exceeds the preset value	Physician must respond appropriately.
Scales defective!	Incorrect scale values or communication with scale interrupted	Connect new scale, restart device.
Scales overloaded!	Bag scale overloaded with more than 23 kg Canister scale overloaded with more than 16 kg	The weight must be reduced.
Instrument recognition failed!	A valid instrument was not detected	The instrument recognition must be carried out again.
Defective vacuum pump	Defective vacuum pump	Restart the device. If the malfunction or error occurs again, please contact the service department.
Tube set incorrectly inserted	Incorrect position of tube set	Insert tube set correctly.
High inflow volume reached!	28,000 ml inflow volume reached	End case quickly and safely.

Criticality: Low		
Message	**Cause**	**Troubleshooting**
Pressure over 100 mmHg?	Nominal pressure setting	Physician must respond appropriately.
Tubeset not valid	Tube set consumed or not valid	Insert new tube set.

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11 Function Tests

WARNING!

Device defects

For the safety of the patient and operating personnel, make sure that the device is complete and fully functional before each use of the device.

Do not use the device if defects are suspected during use or confirmed by device check/tests. Defects include obvious defects of power supply (e.g. power plugs, power cords).

Make sure that the device cannot be used until a qualified service technician conducts the applicable tests and repairs.

WARNING!

Checking the warning signals

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

WARNING!

Preventing infections

Sterilize reusable instruments and reusable tubes sets (NOT FOR SALE IN USA AND JAPAN) 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.

11.1 General Function Test

WARNING!

Function test

The function test must be performed prior to each device use.

Performing the general function test

1. Do a visual check of the device.
   - Do not use the system in case of obvious damage.
2. Check the rollers of the roller wheel and make sure they move easily and smoothly.
3. Turn on the device.
4. Check whether power switch, indicators, and displays light up.
5. Make sure the irrigation fluid bags hang freely and the bags do not touch the scale.
6. Make sure that all tube connections (vacuum/inflow/outflow) are correct and intact.
7. Make sure that all tube connections are free of mechanical stresses and are routed without snagging.
   - The tube connections must not touch the scale. Non-observance can lead to a distortion of the deficit calculation.
8. Make sure that there is no leaking irrigation fluid in the area of the pressure chamber.
9. Change the relative height between Luer lock (blue) of the connected inflow tube and the pressure sensor by moving the Luer lock connector up or down. Monitor the intrauterine pressure value.
   - When moving the Luer lock up, the pressure value must increase.
   - When moving the Luer lock down, the pressure value must decrease.

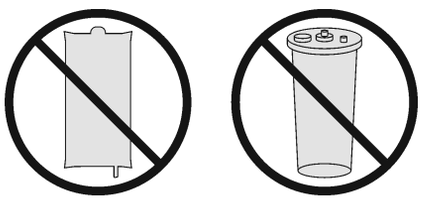
10. Check whether the roller wheel rotates as long as the set pressure does not reach the actual pressure.

11.2 Scale Test

WARNING!

Scale test

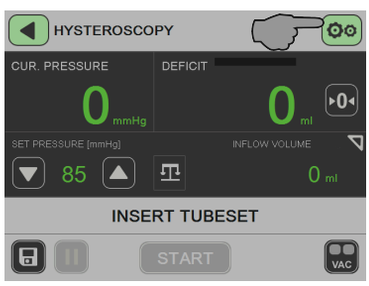
The scale test must be performed at the beginning of the day prior to device use and whenever the scale has been exposed to shock (e.g. due to movement).

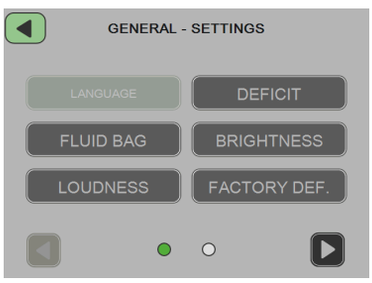


The device must be switched on and connected to the scale (see chapter Initial Setup [▷ 25]).

Make sure that there is no weight on the bag hooks and the canisters are not inserted.

1. Press the menu button.





2. Select **Scales Test**.
   - The current weights of the two scale modules are displayed.
3. Record the starting values of the bag scale and the canister scale.

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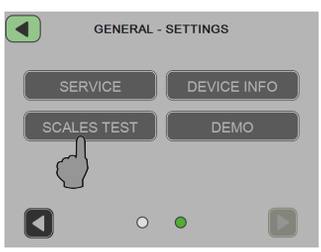

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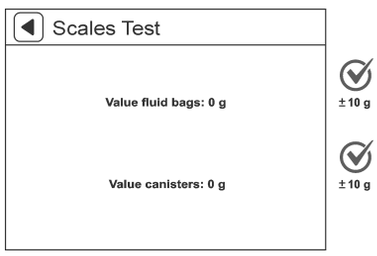

Bag scale

1. Put a test weight between 1 and 5 kg on the bag scale.
2. Record the displayed test value of the fluid bag.
   - The weight difference between the starting value and the test value should be equal to the weight added to the bag scale (acceptable tolerance: ± 100 g).

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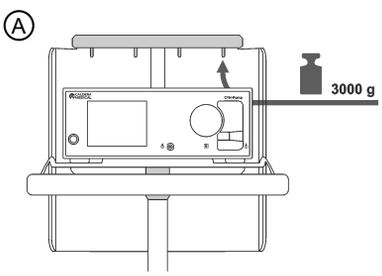

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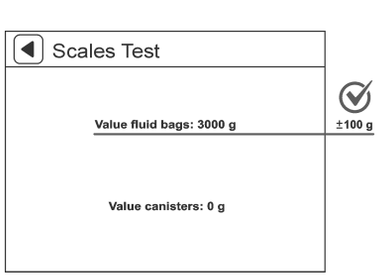

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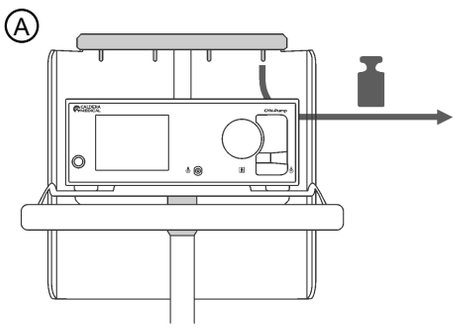
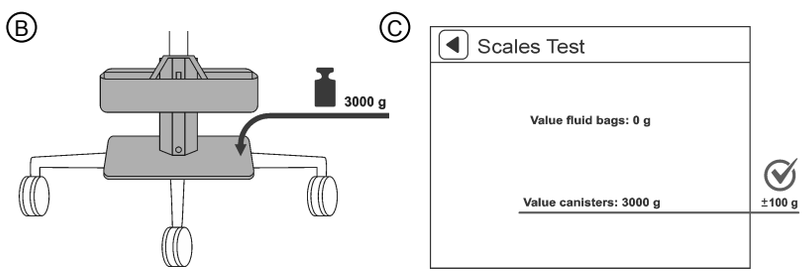
Canister scale

1. Remove weight from the bag scale.
2. Put a weight between 1 and 5 kg into the receptacle of the canisters.
3. Record the changed test value of the canisters.
   - The weight difference between the starting value and the test value should be equal to the weight added to the canister scale (acceptable tolerance: ± 100 g).





The function test of the scale is successfully completed when the value of the weight detected does not exceed the permitted tolerance of ± 100 g.

Example: The permitted range is 2,950–3,150 g for a starting value of 50 g and an added test weight of 3,000 g.

If one or both of the scales do not detect the weight added within the permitted tolerance, an authorized service technician must calibrate the scale again.

12 Care and Maintenance

WARNING!

Maintenance not permitted when operating the device

Maintenance of the device must not be performed during surgery or operation of the device.

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

12.1 Cleaning the Device

CAUTION!

Sterilization of device not permitted

Do not sterilize the pump or the fluid monitoring unit.

Before you clean the device:

1. Switch device OFF.
2. Disconnect device from power supply.

The concentration of the used disinfectant depends on the information provided by the manufacturer of the disinfectant.

Wipe the surface of the device with a soft cloth moistened with the disinfectant. Make sure moisture does not enter the device.

The manufacturer recommends **Meliseptol® rapid** as disinfectant.

12.2 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. The device has to be inspected every year. The accordant tests are described in Chapter Annual Inspection [▷ 64].

Furthermore, an authorized service technician has to inspect and service the device at least every two years, see Sectionv Maintenance by Authorized Service Technician [▷ 61].

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

NOTE!

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

12.3 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 the safety and functionality of the unit. The device needs to be serviced at least every 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 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.

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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 with the signature of the service technician.

12.4 Changing the Fuse

The fuse can be defective and needs to be replaced if:

- Displays and LEDs do not light up.
- The device does not operate.

Make sure that:

- The main power supply cable is correctly connected to the power supply input and to a safety socket,
- The fuse of the house power supply is operating. You do not need to open the device when replacing the fuse.

CAUTION!

Replacing the fuse

Before replacing the fuse, make sure the values of the fuse to be inserted are in accordance with Chapter Technical Data [▷ 71]. Only use a fuse provided by the manufacturer (see Chapter Accessory List [▷ 74]).

WARNING!

Unplug the power cable from the device before checking 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 shown in Fig. Opening the fuse holder [▷ 63].
6. Undo the latch of the fuse holder with a small screwdriver (A).
7. Remove the fuse holder (B).
8. Check fuse (C).
9. Insert a new fuse. Use only the specified type of fuse (see Technical Data - Pump [▷ 71]).

10. Insert the fuse holder until it can be heard snapping into place.

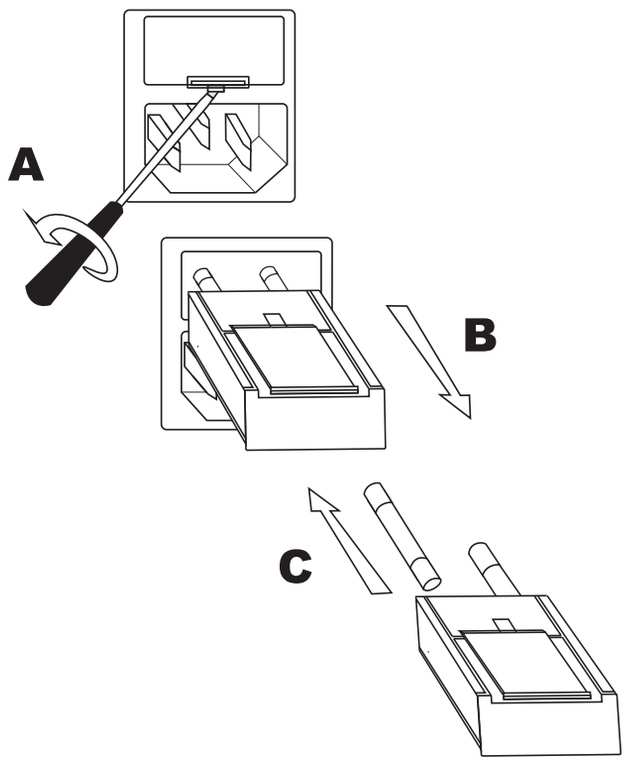

Fig. 12–1 Opening the fuse holder

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13 Annual Inspection

Manufacturer's specification

The manufacturer stipulates that qualified personnel or hospital technicians must regularly test the device to assess its functionality and technical safety. These inspections have to be carried out on an annual basis. Regular inspections will assist in early detection of possible malfunctions. This helps preserve the device and increases its safety and service life.

Inspection tests

The tests described in this chapter 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 must be documented with date and signature in Chapter Appendix [75] .

Measured values and tolerances

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

- Original Hysteroscopic Inflow Tube Set
- Fluid bag (3 l)
- 1-liter measuring cup (100 ml scaling)
- Stopwatch

WARNING!

Parameters and tolerances exceeded

An authorized service technician must check the device if the specific parameters and tolerances are exceeded.

13.1 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 earth leakage current, short-circuit current/equipment leakage current and protective earth resistance by using an accessible conductive part as per IEC 62353 in the current version or according to the applicable national standard .
3. If specific electrical safety tests are required for this device, please refer to the corresponding section below in this chapter. Only required specific electrical safety tests are described.

13.2 Basic Function Tests

The basic function tests check the displays, touch keys, and performance of the device. For these tests, you will need the following:

- One Hysteroscopic inflow tube set
- Fluid bag (3 l)
- Stopwatch
- One 1-liter measuring cup (100 ml scaling)

13.2.1 Flow Rate Test

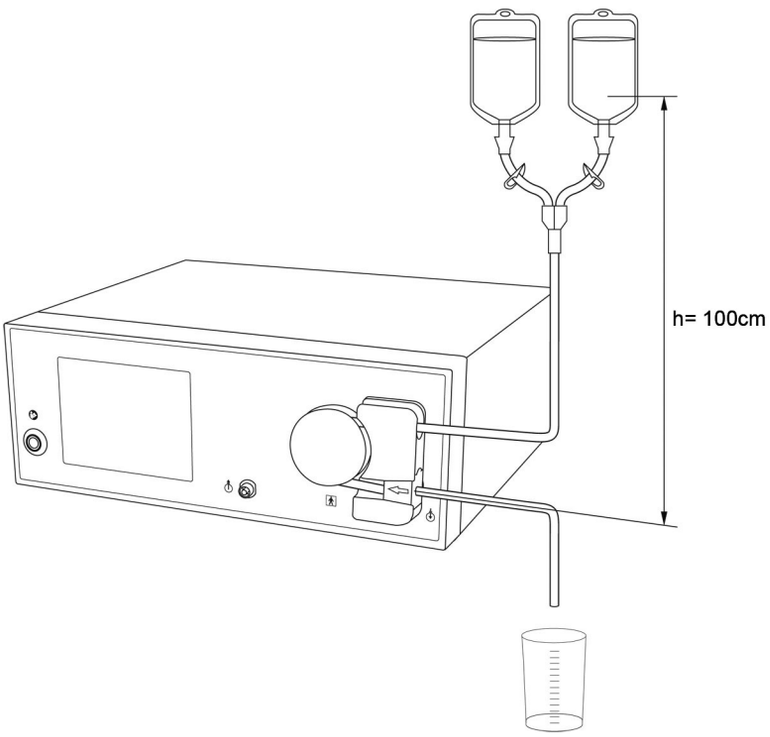

Fig. 13–1 Setup of flow rate test

1. Turn device ON.
   - Wait until the device check has finished.
2. Insert an irrigation tube set into the tube retainer.
3. Attach the fluid bag to one of the fluid bag hooks of the scale as shown in Fig. Setup of flow rate test [▶ 65]
4. Connect the fluid bag with the inflow tube.
5. Put the tube end with the Luer lock into the measuring cup.
6. Set the following nominal values:

   Nominal pressure: **150 mmHg**

   Nominal flow: **800 ml/min**
7. Press **Start**.
   - Wait until the tube set is completely filled with distension fluid.
   - Let the device pump fluid for at least 1 minute to do the instrument recognition.
8. Clamp off the instrument tube end in the measuring cup without stopping the pump.
9. Empty the measuring cup and place the end of the tube back into the measuring cup.
10. Release the tube end.
    - The irrigation process runs.
11. Press the start button of the stopwatch.
12. After 1 minute, press **Stop**.
    - The measuring cup must contain approximately 800 ml (± 60 ml) of fluid.
    - The flow rate test is successfully completed when 800 ml (± 60 ml) are reached.

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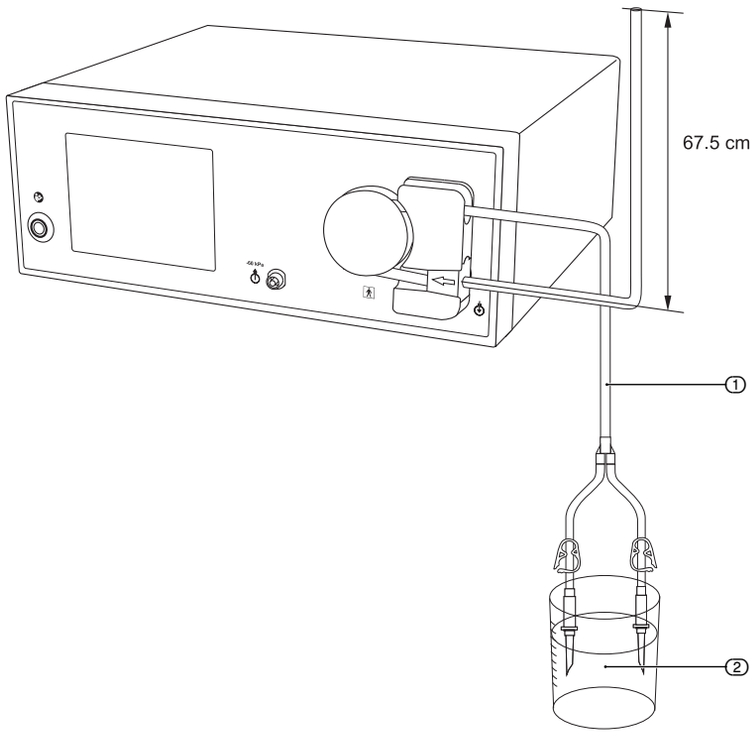
13.2.2 Pressure Measuring Test

Fig. 13–2 Setup of pressure measuring test

① 1x Irrigation/Inflow tube set
② 1x Measuring cup (1 l volume, 100 ml scaling)



The pressure measurement test checks the proper functioning of the pressure measurement.

- Required:
  - 1x complete tube set
  - Canister (measuring cup), filled with water

The height of the water column (hydrostatic pressure) is measured and then converted to mercury column (mmHg).

The height of the water column above the pressure chamber must match the value of the actual pressure display after conversion.

Conversion formula: p (cm H2O) x 0.74 = p (mmHg)

Procedure

1. Turn the device on.
   - Wait until the device check is completed.
2. Select the indication.
3. Press **Start**.
   - Wait until the inflow tube set is completely filled with fluid.

NOTE!

- **The fluid in the inflow tube set must contain no bubbles.**
- **The tube set behind the roller wheel bust be completely filled with fluid.**

4. Press **Stop**.
5. Hold the end of the inflow tube set at a level of approximately 67.5 cm above the pressure sensor.
   - Make sure the tube segment between this point and the cartridge is completely filled with fluid.

- Make sure that no part of the cartridge is at a higher point than the indicated value.

6. Use the height of the water column to calculate the generated hydrostatic (water) pressure with the following formula: 67.5 cm H2O x 0.74 = 50 mmHg
   - The actual pressure shown on the display should be approximately 50 mmHg (± 10 mmHg).
   - When you change the height of the tube set above the roller wheel, the actual pressure display also changes accordingly.

The test of the pressure measurement is successfully completed when the values of the displayed actual pressure correspond to those of the converted water column height.

Enter each completed test into the test log (see Test log [▷ 75]).

13.2.3 Scale Function Test

See section Scale Test [▷ 59].

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14 Electromagnetic Compatibility

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.

WARNING!

Use in proximity to other devices

The GYN-Pump should not be used directly next to other devices as this could result in malfunctions.

The GYN-Pump was tested for compliance with IEC 60601-1-2 as a stand-alone system. Do not stack other devices on the system.

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.

CAUTION!

Approved accessories

To ensure compliance with the requirements of IEC/EN 60601-1-2 in the current version, the device GYN-Pump must be used only with the accessories listed in Chapter Accessory List [▷ 74].

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 [▷ 61] must also be observed.

This device complies with the 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.

14.1 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.

14.2 Electromagnetic Emissions – Guidelines and Manufacturer's Statement

The device **GYN-Pump** is intended for use in the electromagnetic environment specified below. The user/operator of the **GYN-Pump** 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 device **GYN-Pump** uses HF energy solely for its internal functions. Therefore, the 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 device **GYN-Pump** 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	

14.3 Electromagnetic Interference Immunity – Guidelines and Manufacturer's Statement

The device **GYN-Pump** is intended for use in an electromagnetic environment as described below. The user/operator of the device **GYN-Pump** 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 ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 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 Repetition frequency 100 kHz	± 2 kV for power lines Repetition frequency 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) ± 2 kV line(s) to earth	± 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	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % UT; 0.5 cycle 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 IEC 61000-4-6	3 Vrms 0.15 MHz to 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0.15 MHz to 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	
Transients RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80 % AM by 1 kHz	3 V/m 80 MHz to 2.7 GHz 80 % AM by 1 kHz	

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 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sinus	2	0.3	28

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Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
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 WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

Table 1: IMMUNITY to proximity fields from RF wireless communications equipment - **Test method IEC 61000-4-3**

WARNING!

HF devices – minimum distance 30 cm

Portable HF communication devices can have an effect on the performance characteristics of the device GYN-Pump.

Always keep portable HF communication devices away from the GYN-Pump, its accessories, and the cables (minimum distance: 30 cm).

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15 Technical Data

15.1 Technical Data - Pump

Model		PH304	
Product name		GYN-Pump	
Manufacturer information		W.O.M. WORLD OF MEDICINE GmbH Salzufer 8, 10587 Berlin, Germany	
Software version		See user manual/operator instructions to determine software version. See Device Information [▸ 55]	
Mains voltage range [V]		100–240 V	
Supply frequency range [Hz]		50/60 Hz	
Fuse designation		2x T 3.15 AH 250 V, UL-recognized	
Internal voltage supply		No	
Power consumption		Current	Power
	Normal operation 100 V/60 Hz	0.85 A	85 VA
	Normal operation 240 V/50 Hz	0.50 A	120 VA
Protection class (I, II)		I	
Application part type (B, BF, CF)		BF	
Defibrillator protection (yes/no)		No	
Protection class (IP code)		IP21	
Classification according to Medical Device Directive 93/42/EEC, (I, IIa, IIb, III)		IIb	
Conformity with the following standards: (in the currently valid version)		IEC 60601-1/EN 60601-1 IEC 60601-1-2/EN 60601-1-2	
Operating conditions [°C] [°F], [%], [kPa]		10 to 40 °C/ 50 to 104 °F 30 to 70 % relative humidity 70 to 106 kPa air pressure 3000 m maximum altitude above sea level for device use	
Possible use with explosive anesthetic gases		This device is not designed for use with flammable anesthetic gases (Class AP) or flammable anesthetic gases with oxygen (Class APG).	
Storage conditions [°C] [°F], [%], [kPa]		5–40 °C (41–104 °F) 5–85 % relative humidity 70–106 kPa air pressure	
Transport conditions [° C] [° F], [%], [kPa]		-20 to 60 °C (-4 to 140 °F) 10–90 % relative humidity 70–106 kPa air pressure	
Maximum sound level		< 80 dB(A) (with acoustic signals)	
Maximum negative suction pressure		-60 kPa	
Adjustable values/ranges			
	Maximum flow	30–800 ml/min	
	Suction power	-60 kPa/-450 mmHg	
	Nominal pressure range	15–150 mmHg	
Measurement range			
	Flow	0 to 2.0 l/min	
	Pressure	0 to 300 mmHg	
	Inflow volume	0 to 30,000 ml	
	Deficit volume	0 to ±30,000 ml	
Accuracy			
	Flow	± 10 %	
	Pressure	± 5 % (of final value)	

	Deficit/inflow volume	> 1 l: ± 6 % deficit accuracy related to provided inflow volume, but maximum 300 ml ≤ 1 l: ± 60 ml
Maximum dimensions	Width x Height x Depth	380 mm x 148 mm x 388 mm
Weight		6.3 kg
Interfaces		
	IN/OUT signal for components	1x scale connection (DSUB plug, DE-9) 1x service connection (USB port, USB 2.0)
	Mains power socket	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		**Normal condition:** Pressure build-up in the body cavity, control and measurement. Limit: 150 mmHg ± 5 First error: 200 mmHg ± 5 for maximum 5 seconds Deficit measurement: ≤ 1 l: ± 60 ml > 1 l: ± 6 % deficit accuracy related to provided inflow volume, but maximum 300 ml **Single Fault Condition 1:** No function of deficit measurement. Limit: 150 mmHg ± 5 Single Fault Condition 2: ≤ 1 l: greater deviation than ± 60 ml, > 1 l: greater deviation than ± 6 % deficit accuracy related to provided inflow volume, or greater/over 300 ml
Hazardous substances		This product includes components in which the following SVHC substance is contained at a concentration of above 0.1 percent by weight: Lead (CAS-Nr. 7439-92-1)

15.2 Technical Data - Fluid Monitoring Unit

Model	PS304
Manufacturer	W.O.M. WORLD OF MEDICINE GmbH Salzufer 8, 10587 Berlin, Germany
Software version	The software version is shown in the general settings of the GYN-Pump (see Device Information [▷ 55]).
Enclosure protection (IP code)	IP21
Tested as per following standards (in the respectively valid version)	IEC 60601-1/EN 60601-1
Maximum load of canister scale	16 kg (35.3 lbs), 4 canisters
Maximum load of bag scale	23 kg (50.7 lbs), 4 bags with 5 l each
Weight	22 kg
Maximum dimensions (Width x Height x Depth)	634 mm x 1159 mm x 634 mm

Operating conditions	Temperature: 10–40 °C (50–104 °F) Relative humidity: 30–70 % Air pressure: 70–106 kPa Maximum altitude above sea level: 3000 m
Storage conditions	Temperature: 5–40 °C (41–104 °F) Relative humidity: 5–85 % Air pressure: 70–106 kPa
Transport conditions	Temperature: -20 to 60 °C (-4 to 140 °F) Relative humidity: 10–90 % Air pressure: 70–106 kPa
Interfaces/ports	
Signal input/output	1x data connection (D-Sub-connector, DE-9) for connection to pump.

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16 Accessory List

Catalogue number	Product name
T0505-01	Tube set for irrigation, single use[1]
T0504-01	Tube set for vacuum incl. filter, 30 day use[2]
T0503-01	Tube set for suction (with 2 ports), single use[1]

Applied parts classification:

[1] The tube set is not an applied part in terms of the standard IEC 60601-1. However, it meets all the technical requirements for an applied part.

[2] Not applicable

Fluid monitoring unit	
Catalogue number	**Product name**
CAL-FM1751	Fluid Monitoring Unit (PS304)

Power cord	
Catalogue number	**Product name**
Z4102-01	Power cord US, 5 m

17 Appendix

17.1 Test log

Date	Result	Comment	Signature

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17.2 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 Model:

Description of defect:

Contact Signature Date

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List of Figures

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