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- 412 8.26-inch x 11.69-inch (A4) sheets attached.

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REV DRAFTED BY R MISTRY DATE 08/18/23	TITLE: TEXT, IFU, AQUILEX FLUID MANAGEMENT SYSTEM, 4320	DOCUMENT NUMBER: AW-07059-4320	REV: 012
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REV. RELEASE DATE: 08/28/23			

Aquilex®
Fluid Control System

Instructions for Use and Fluid Control System Operator's Manual

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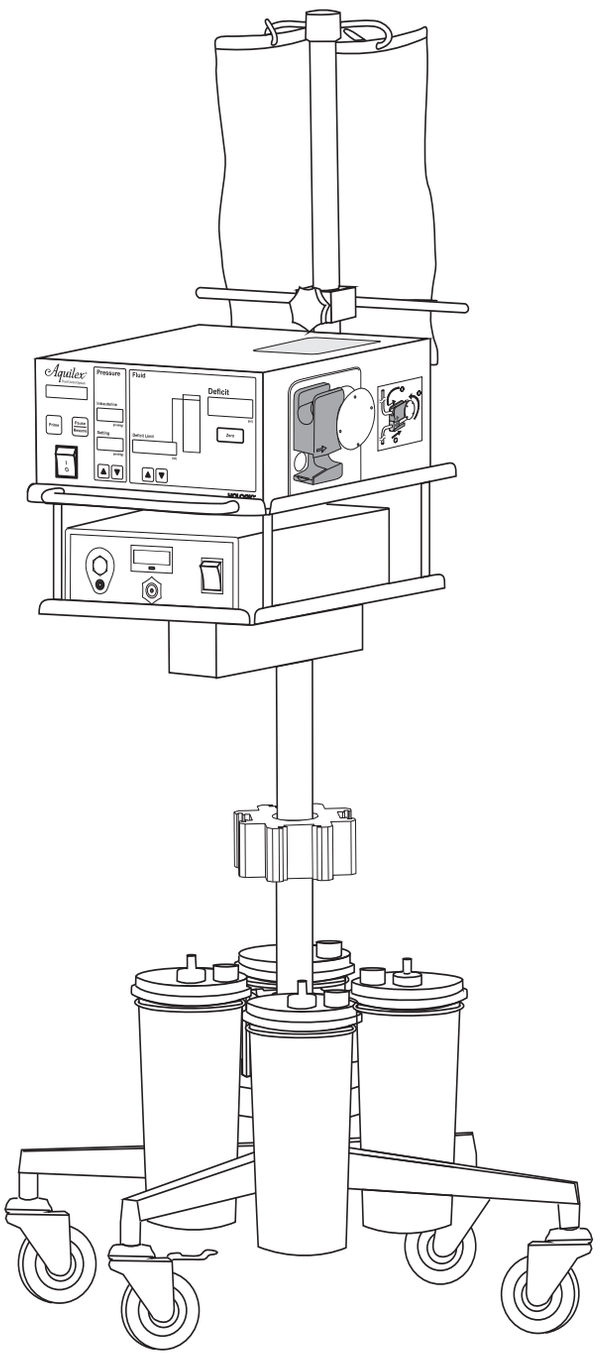

HOLOGIC®

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Federal Law (only for U.S. market)

Caution: Federal law restricts this device to sale by or on the order of a physician.

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

MAN-02570-4320 Rev. 012

Type: H112 / 1201048 / 10000011593 12 / TR

Issued: 2023-03

Symbols

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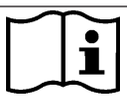	Consult instructions for use
	Type BF applied part
	Equipotentiality
IP 41	Degrees of protection provided by enclosures (IP-Code)
IP 21	Degrees of protection provided by enclosures (IP-Code)
	Alternating current
	Service
	Catalogue number
	Do not reuse
	Do not resterilize
	Sterilized using ethylene oxide
	Batch code
	Serial number

	Manufacturer
	Date of manufacture (YYYY-MM-DD)
	Use by date (YYYY-MM-DD)
	Quantity
	Not made with natural rubber latex
	Not made with phthalates
	Made with phthalates
	Keep dry
	This way up
	Fragile
	Stacking limit by number
	Keep away from sunlight
	Protect from heat and radioactive sources
	Non-ionizing electromagnetic radiation

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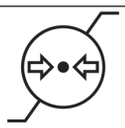
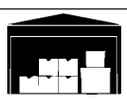
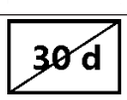
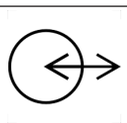
	Do not use if package is damaged
	Authorized for Sale or use by Physician only
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Storage conditions
	Transport conditions
	Waste management
	ON/OFF (push-push)
	Max. use 30 days
	Non sterile
	Scale connection
	Data transmission port (see Using Device Control instructions for detail)
	No pushing
	Caution

	SGS USTC Certification Mark
	RFID tag, general

Table of Contents

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1 Important User Notes

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

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

Subject to technical changes

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

Please note

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

WARNING!

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

CAUTION!

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

NOTE!

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

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2 Safety Information

Exclusion of liability

Hologic is not liable for indirect, incidental and consequential damages, including, but not limited to, loss of profit. Any liability and applicable warranty become null and void if:

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

Receipt of technical documentation from Hologic does not authorize individuals to perform repairs, adjustments, or alterations on or to the system or accessories.

WARNING! Modification of the Aquilex Fluid Control System is not permitted.

Authorized service technician

Only an authorized service technician may perform repairs, adjustments, or alterations on the system 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.

Normal Use

The system may be used only as intended.

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.

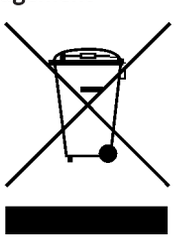
Contamination

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 Hologic or an authorized disposal company, in compliance with legal or national regulations.

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3 Purpose

Intended Use

The Aquilex Fluid Control System is intended to provide fluid distension of the uterus during diagnostic and operative hysteroscopies and to monitor the volume differential between the irrigation fluid flowing into and out of the uterus.

Contraindications

The system may not be used to introduce fluids into the uterus when hysteroscopy is contraindicated. See the operator's manual of your hysteroscope for absolute and relative contraindications.

Relative contraindications to endometrial ablation:

Hysteroscopic endometrial ablation, whether by laser or electrosurgery, should not be undertaken before adequate training, preceptorship, and clinical experience. Additionally, tissue sampling is required prior to destruction of the endometrium. The following are clinical conditions that can significantly complicate hysteroscopic endometrial ablation:

- Adenomatous endometrial hyperplasia
- Uterine leiomyoma
- Severe adenomyosis
- Pelvic pain (subtle PID)
- Uterine anomalies
- Surgical skill (see above)
- Severe anemia
- Inability to circumnavigate the myoma (re: myoma size) - predominantly intramural myomas with small submucous components.

3.1 Warnings and Precautions

3.1.1 General Warnings

WARNING!

Failure of scale connection

If the message "Check Scale Connection" appears, the deficit must be calculated manually. The pump keeps displaying the last known deficit value determined prior to the failure of the scale connection.

WARNING!

Scale error

Make sure that screw connections at cable and pump are fixed hand-tight to avoid loosening of connection during move or use.

WARNING!

Scale error

Ensure that nothing weighs down the scale during system start-up. Doing so may result in an inaccurate deficit value.

WARNING!

Instrument replacement

Stop the device using the Pause/Resume and Prime button if replacing the instrument during surgery.

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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!

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!

Flow rate test

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

WARNING!

Obvious defects

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

WARNING!

System error

Do not use the Aquilex System if a defect is suspected or detected during the function test. This also applies to any obvious defects, especially defects on the power connector or plug and power cord.

WARNING!

Device setup

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

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

WARNING!

ON/OFF switch

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

WARNING!

Disconnect the power cord

Pressing the ON/OFF switch does not disconnect the system from the wall power outlet. This requires pulling the power cord located in the rear of the system.

WARNING!

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

WARNING!

Technique and procedures

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

WARNING!

Check all factory settings

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

WARNING!

Original accessories

For your own safety and that of your patient, use only Aquilexaccessories (see Chapter Accessory List [▷ 60]).

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!

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!

Not explosion-proof

The system is not explosion-proof. Do not use in an area where flammable anesthetic gases are present.

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WARNING!

Risk of electrical shock

To avoid risk of electrical shock, this system may only be connected to a supply mains with protective earth.

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!

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!

Sterile media and accessories

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

WARNING!

Reprocessing of sterile disposable products

Reuse of inflow or outflow tube can cause an infection hazard for patients and/or users as well as impair of product functionality. Contamination and/or impaired functionality of the system can cause risk of injury, illness, or death. Do not re-process or reuse single-use inflow or outflow tube sets.

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!

Replacement device and accessories

In case the system or any of the accessories fail during a procedure, an alternative system and replacement accessories should be kept within easy reach to be able to finish the operation with the replacement components.

WARNING!

Parameters and tolerances exceeded

If the specified parameters and tolerances are exceeded, the system must be returned to Hologic for evaluation.

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.

WARNING!

Condensation / Water penetration

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

WARNING!

Replace the fuse

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

WARNING!

Electromagnetic emissions

Electromagnetic emissions may increase and rise above the permissible limits if other equipment (e.g. MyoSure® Control Unit) is stacked onto or placed directly next to the Aquilex Fluid Control System. The user is responsible for monitoring the devices to make sure they function properly.

WARNING!

Portable HF communication equipment

Portable HF communication equipment can affect the performance characteristics of the device Aquilex Fluid Control System. Such equipment must therefore com-ply with a minimum distance of 30 cm (regardless of all calculations) from the device Aquilex Fluid Control System, its components and cables.

WARNING!

If the Aquilex Fluid Control System is configured as part of a ME SYSTEM, the en-tire ME SYSTEM should be tested for compliance with IEC 60601-1-1, and any equipment used with the Aquilex Fluid Control System should be Type BF.

WARNING!

If the leakage current of the configured ME SYSTEM exceeds the limits of IEC 60601-1-1, install an appropriately rated UL 2601-1/IEC 60601-1 approved isolation transformer and retest the system.

WARNING!

Touching containers and their holders

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

3.1.2 Hysterosocopy Specific Warnings

WARNING!

Distension media

When performing monopolar hysteroscopic electrosurgery, the distension medium must be electrically non-conductive. Examples include glycine, sorbitol and mannitol. Isotonic saline irrigation fluids may only be used when performing bipolar electrosurgical resective procedures.

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 to enter the circulatory system.

WARNING!

Risk of intravasation

If the intrauterine pressure does not react to an increase in the pressure setting during the procedure, a perforation of the uterine cavity might be the cause. This results in an increased risk of intravasation. Examine the uterine cavity for injuries.

WARNING!

Intrauterine distension

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

WARNING!

Fluid overload

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

WARNING!

Fluid deficit

The fluid left in the patient must be monitored. The deficit is the total amount of fluid left in the patient or unaccounted for otherwise. Take notice of the measurement tolerance of the system (see Chapter Technical Data [▶ 52]). Estimating the fluid volume remaining in the patient is the physician’s responsibility.

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!

Containers and fluid bags

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

WARNING!

Containers and fluid bags

Make sure the containers and 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!

Accuracy of the deficit

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

WARNING!

Changing fluid bags

Fluid bags should be changed quickly to avoid affecting the accuracy of the deficit calculation. Observe the occurrence of acoustic signals and message to avoid unrecognized bag changes during procedure which can affect the displayed deficit value.

WARNING!

Touching containers and their holders

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

WARNING!

Change of the containers

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

WARNING!

Serum sodium concentration

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

WARNING!

Idiosyncratic reactions

In rare cases, idiosyncratic reactions including

- **intravascular coagulopathy**
- **allergic reaction including anaphylaxis**

may occur while performing a hysteroscopy if a liquid distention medium is used.

WARNING!

Loss of deficit and inflow value

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

WARNING!

Fluid bag and container change during surgery

A fluid bag or container change during surgery is only allowed, if the fluid bag or container holds at least 0,5 liters of fluid or waste. Otherwise, the deficit value may be falsified. In this case, the manufacturer recommends manual deficit calculation.

WARNING!

Irrigation fluid bags

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

WARNING!

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!

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!

Incorrect determination of fluid deficit

Always use the hooks of the bag scale to hang the fluid bags to ensure an accurate determination of the fluid deficit. In addition, leave the empty fluid bags hanging on the bag scale until the end of surgery.

WARNING!

Inflow volume limit

The Aquilex Fluid Control System has a maximum allowable fluid inflow volume of 30,000 ml. When the inflow volume reaches 30,000 ml, the inflow volume drops abruptly to zero, while the deficit increases continuously as per the roller wheel rotation.

When an inflow volume of 30,000 ml is reached, the current procedure should be concluded as quickly and safely as possible.

If the physician decides to continue the operation, manual count for continued deficit monitoring must be performed.

WARNING!

Combination of low set pressures and excessive vacuum pressures

When using the Aquilex Fluid Control System with tissue removal systems, e.g. MyoSure®, the combination of low set pressures and excessive vacuum pressures may result in a significant loss of intrauterine distension pressure which has the potential to affect the visibility of the surgical field. Conversely, when employing a high distension pressure, the deactivation of the tissue removal system can lead to pressure peaks that can exceed 150 mmHg.

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

Hysteroscopic surgery 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!

Hypothermia (monitoring body temperature)

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

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!

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!

Hysteroscope

The system 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.

3.1.3 Precautions

CAUTION!

Federal Law (only for U.S. market)

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

CAUTION!

Indoor climate

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

CAUTION!

Instrument recognition

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

CAUTION!

Continuous operation

After 24 hours of continuous operation, a device self-test must be carried out.

Switch device off and on again.

CAUTION!

Accessories

To ensure compliance with the requirements of IEC 60601-1-2 in the current ver-sion, the device Aquilex Fluid Control System must be used only with the ac-cessories listed in Chapter Accessory List [▷ 60].

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!

Mains Power Cable

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

CAUTION!

Ventilation of the device

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

CAUTION!

Modifying the system

Modifying the system and/or its accessories is not permitted.

CAUTION!

Electrical interference

(see Chapter Electromagnetic Compatibility [▷ 56]): Electrical interference with other devices or instruments was considered when developing this system and none was detected during testing. However, if you still detect or suspect such interference, please follow these suggestions:

- **Move the Aquilex System, the other device, or both devices to a different location.**
- **Increase distance between devices used.**
- **Consult an electro-medical expert.**

CAUTION!

Wall outlet voltage

Check to ensure the available wall outlet voltage matches the data listed on the label attached to the back of the pump. Incorrect voltage can cause errors and malfunctions and may destroy the system.

CAUTION!

Transport

The device is transportable. The roller wheels of the Fluid Monitoring Unit (cart/scale) are used for positioning at the place of use. 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 the power supply line does not touch the ground and there are no other objects located on the Aquilex Fluid Control System. Always use the handle to move the system safely.

CAUTION!

Combination of AQL-100P with AQL-100CS

The irrigation pump unit AQL-100P may only be used with the fluid monitoring unit AQL-100CS as only this combination is approved to bear the SGS NRTL mark.

CAUTION!

Cleaning the system / Sterilization not allowed

The pump and the cart/scale can be disinfected by wiping off the outer surfaces. Do not sterilize the pump and the cart/scale.

CAUTION!

Filter

The vacuum tube with integrated filter is designed for maximum 30 days. The vacuum tube may not be sterilized. Replace the vacuum tube sooner if it is obviously contaminated. The filter prevents body fluids from entering the interior of the device.

3.2 Description of the Aquilex Fluid Control System

Technical application scope of the system

The intrauterine pressure can be adjusted on the front of the pump. It can be pre-set to a range between 40 and 150 mmHg. The maximum inflow rate is 800 ml/min and is reduced automatically by the pump once the pre-set intrauterine pressure setting has been reached.

The system has been designed to provide both fluid and vacuum systems that maximize the performance of the MyoSure® Tissue Removal System.

Suggested distension media

The **Aquilex Fluid Control System** can be used with hypotonic, electrolyte-free media (e.g., glycine 1.5 % and sorbitol 3.0 %) and isotonic, electrolyte containing media (e.g., saline 0.9 % and Lactated Ringer's).

Pressure measuring and regulating

The system operates with a completely non-contact pressure measurement of the irrigation medium. The contact-free pressure measurement is achieved by integrating the pressure chamber into the tubing system. The pressure chamber transmits the irrigation fluid pressure to the electronics of the device via a pressure sensor. The pressure control circuit continuously compares the desired preset intrauterine pressure with the actual intrauterine pressure. The function of this algorithm is to maintain the pre-set intrauterine pressure. Check for possible leaks if the pre-set intrauterine pressure cannot be achieved.

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4 Initial System Set-Up

Always check all parts and accessories of the system when performing initial setup. If the system has obvious defects, contact Hologic Technical Support (Chapter Warranty Information [▷ 61]).

Initial system set-up

Place the system on a level surface and install in a dry environment. The ambient temperature and humidity must meet the requirements mentioned in Chapter Technical Data [▷ 52].

WARNING!

Device setup

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

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

CAUTION!

Indoor climate

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

4.1 Preparing the System for Use

Connection to the wall outlet

CAUTION!

Possible malfunctions

The device Aquilex Fluid Control System should not be used directly next to other devices as this could result in malfunctions. The device Aquilex Fluid Control System was tested for compliance with IEC 60601-1-2 as a standalone system. Therefore, do not stack other devices (e.g. MyoSure® Control Unit) on the system or the Irrigation Pump Unit. In particular, do not place any other device than the AQL-100PBS on the trays of the AQL-100CBS. 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!

Combination of AQL-100P with AQL-100CS

The irrigation pump unit AQL-100P may only be used with the fluid monitoring unit AQL-100CS as only this combination is approved to bear the SGS NRTL mark.

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.**

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Grounding contact

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

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

Only for U.S. operators

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

Potential equalization

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

Precautionary measures

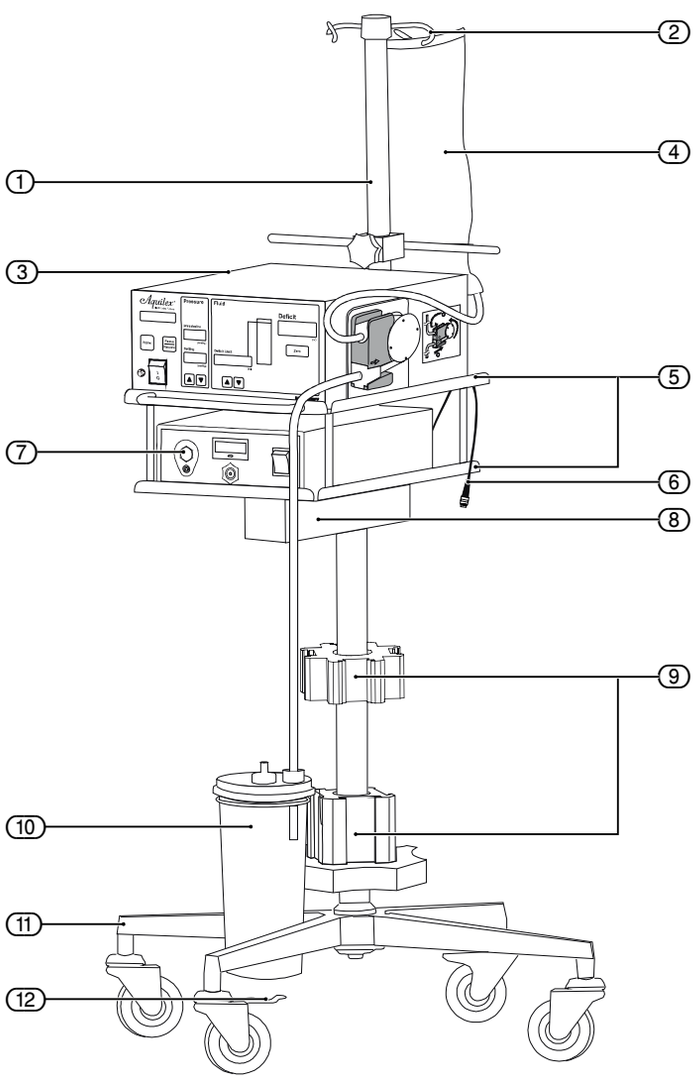
Medical devices are subject to special safety and protective measures concerning electromagnetic compatibility (hereafter abbreviated as EMC).

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

4.2 System Components

Fig. 4–1 System components

① Cart
② Bag holder
③ Irrigation Pump Unit
④ Fluid bag
⑤ Trays
⑥ Container scale cable/connector
⑦ MyoSure® Control Unit
⑧ Container scale
⑨ Container holders
⑩ Container
⑪ Roller wheel base
⑫ Locking foot brake



The **Aquilex Fluid Control System** is divided into two separate boxes for shipping:

Box 1 contains:

- Irrigation Pump Unit
- Instructions for Use
- Power cord
- **Aquilex Fluid Control System** vacuum tube set (low and high vacuum)
- MyoSure® Control Unit power cord
- 1000 g weight

Box 2 contains:

- Cart/Scale
- Container rings

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5 System Operation

Make sure that the function tests have been performed according to chapter Function Tests [▷ 41].

5.1 Front of Irrigation Pump Unit

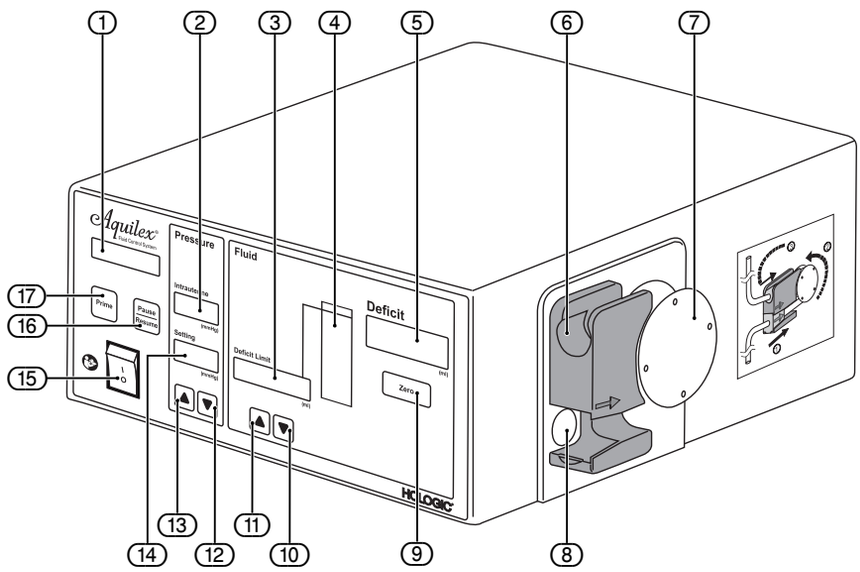

Fig. 5–1 Front of irrigation pump unit

1. Pump display
2. Intrauterine pressure display
3. Fluid deficit limit display
4. Deficit meter
5. Deficit display
6. Inflow tube holder
7. Roller wheel
8. Pressure sensor
9. Reset deficit button (Zero)
10. Decrease deficit limit
11. Increase deficit limit
12. Decrease intrauterine pressure setting
13. Increase intrauterine pressure setting
14. Intrauterine pressure setting display
15. ON/OFF switch
16. Pause/Resume button
17. Prime button

Please familiarize yourself with the layout of the individual elements on the front of the irrigation pump unit.

5.2 Rear of Irrigation Pump Unit

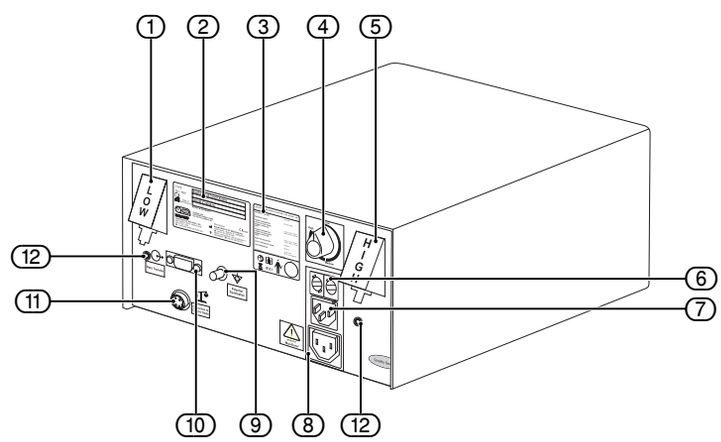

Fig. 5–2 Rear of irrigation pump unit

1. Connection for low vacuum (white)
2. Product label
3. Performance data of the device
4. Adjustment controller for high vacuum
5. Connection for high vacuum (green)
6. Fuse holder(s)
7. Power cord connection
8. MyoSure® control unit power connection
9. Potential equalization connection
10. Service interface
11. Connection for scale
12. Suction opening

Please familiarize yourself with the layout of the individual elements at the rear of the irrigation pump unit.

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.

5.3 Cart/Scale

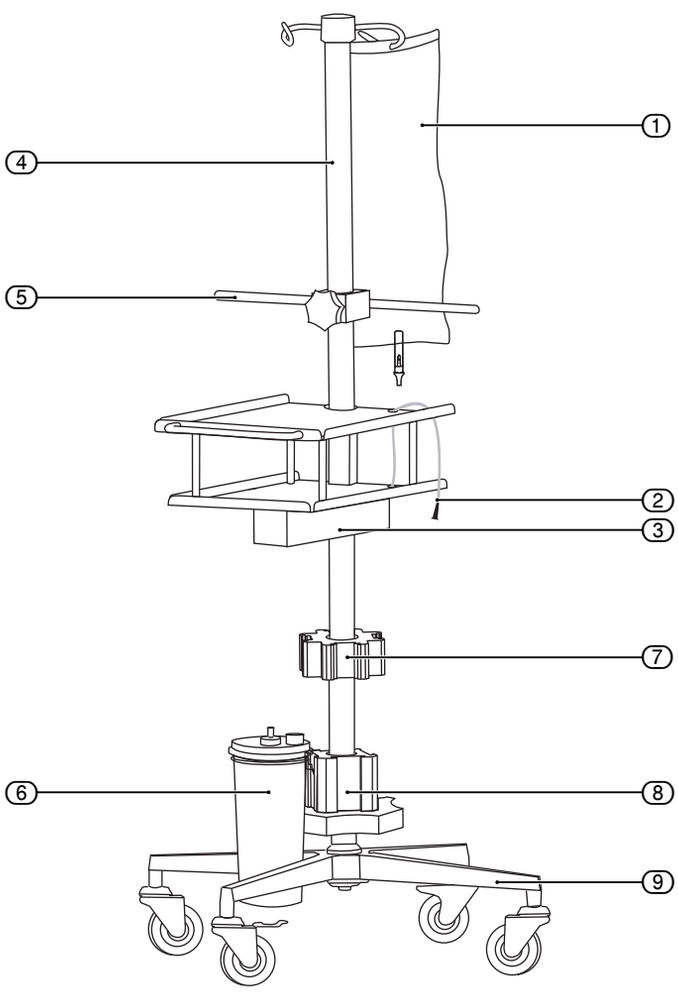

Fig. 5–3 Fluid monitoring unit (cart with scale)

① Fluid bag
② Container scale cable/connector
③ Container scale
④ Pole with bag hooks
⑤ Bag deflector
⑥ Container
⑦ Holder for upper container (Serres, Medela, Baxter, Baxter flex)
⑧ Holder for lower container (Abbott, Bemis®, Medi-Vac®, DeRoyal®)
⑨ Roller wheel base

The cart/scale consists of a weighing scale for the containers, a pole with hooks for irrigation fluid bags, and a roller wheel base.

1. Remove the cart/scale from the cardboard shipping box.
2. Remove the pump and the power cords from the first cardboard box.
3. Loosen the handwheel ④ (Fig. Scale and pump connection [▷ 26]) and extend the pole to stop position. Extend the bag deflector to stop position. The screw ⑤ (Fig. Scale and pump connection [▷ 26]) must be inserted into the provided opening. Secure the bag scale with the handwheel.
4. Depending on the type of container used, attach the container rings (included in the second box) to the upper ⑦ or lower ⑧ container holders (Fig. Fluid monitoring unit (cart with scale) [▷ 25]).

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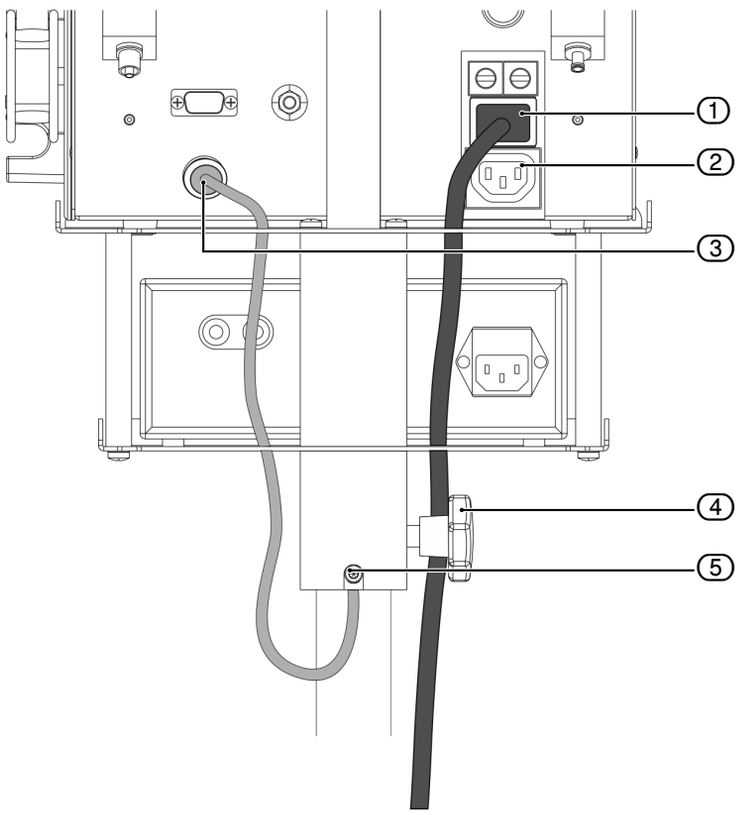
5. Guide the power cord through the holes provided for this purpose and connect to pump ① (Fig. Scale and pump connection [▶ 26]) and plug into grounded, shockproof safety wall socket.
6. Attach the scale to the pump by connecting and screwing the connector of the container scale ③ (Fig. Scale and pump connection [▶ 26]) and fix the connected cables below the lower pump tray by means of the provided wire clips.

Fig. 5–4 Scale and pump connection

① Power cord/pump connection
② Power output
③ Plug connection pump with container scale
④ Handwheel
⑤ Screw



WARNING!

Scale error

Ensure that nothing weighs down the scale during system start-up. Doing so may result in an inaccurate deficit value.

WARNING!

Scale error

Make sure that screw connections at cable and pump are fixed hand-tight to avoid loosening of connection during move or use.

WARNING!

Fluid deficit

The fluid left in the patient must be monitored. The deficit is the total amount of fluid left in the patient or unaccounted for otherwise. Take notice of the measurement tolerance of the system (see Chapter Technical Data [▶ 52]). Estimating the fluid volume remaining in the patient is the physician's responsibility.

WARNING!

Serum sodium concentration

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

WARNING!

Incorrect measurement of the deficit (inflow tube)

Air located in the inflow tube results in an incorrect measurement of the deficit. Make sure to replace the bag in a timely manner.

WARNING!

Incorrect measurement of the deficit (bag clamp)

Make sure the clamp of the active bag is always open during operation of the pump. Otherwise, this will lead to an incorrect measurement of the deficit.

NOTE!

Deficit accuracy

The greater the consumption of irrigation fluid, the greater the deviation between the actual and displayed deficit (see "Technical Data", accuracy: deficit ±10 %).

Precise balancing

Try to collect all the fluid running out of the uterine cavity during the procedure to achieve the most exact deficit value possible.

Scale capacity

The scale can be loaded with a weight of up to 65 lbs (~30 kg). Weight above this value triggers the **Scale Overloaded/Check Scale** message. Three audible warning signals are emitted (see Chapter Error and Warning Messages [▷ 54]).

WARNING!

Containers and fluid bags

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

NOTE!

Scale recognition

Connect the scale to the pump before turning the system on to ensure the system recognizes the scale.

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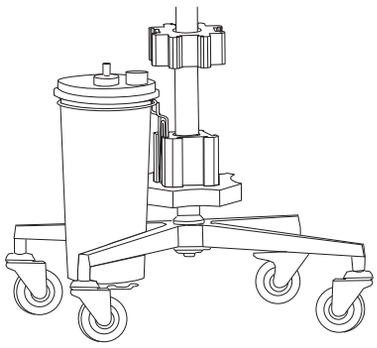
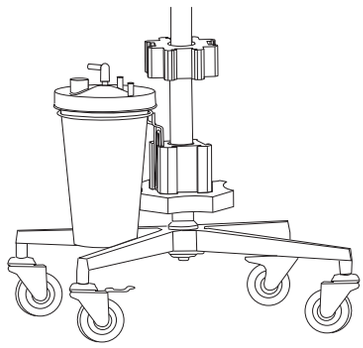
5.3.1 Setting of the Container Scale

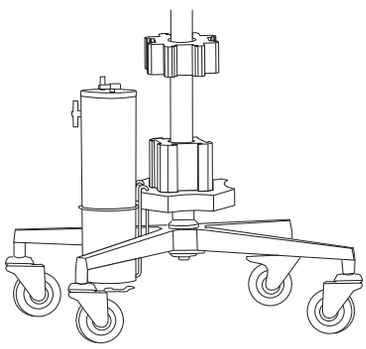
The container scale can be used with containers from different manufacturers.



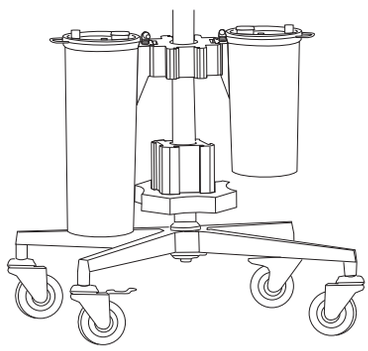
Bemis® 3 liters



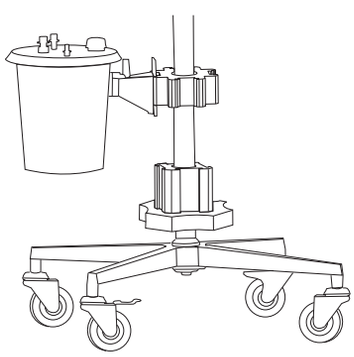
DeRoyal® Crystaline™ 2.1 l



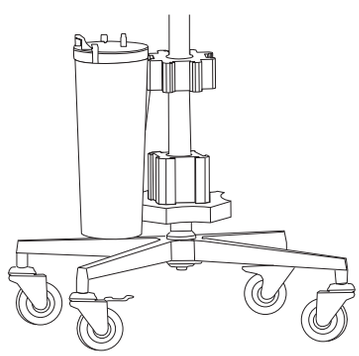
Abbott 2 liters



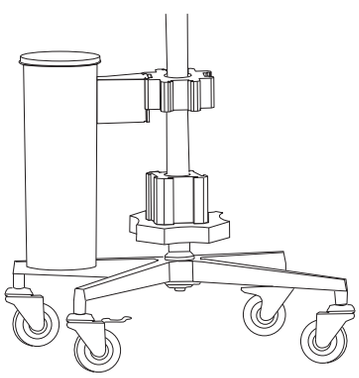
Serres 2 & 3 liters



Medi-Vac® 3 liters



Medela 3 liters



Medi-Vac® Flex Advantage 3000 cc

NOTE!

Container position

Ensure containers are positioned properly in the respective holders.

NOTE!

Containers with overflow protection

Only use suction containers with overflow protection.

5.3.2 Connecting the Vacuum Tube

WARNING!

Combination of low set pressures and excessive vacuum pressures

When using the Aquilex Fluid Control System with tissue removal systems, e.g. MyoSure®, the combination of low set pressures and excessive vacuum pressures may result in a significant loss of intrauterine distension pressure which has the potential to affect the visibility of the surgical field. Conversely, when employing a high distension pressure, the deactivation of the tissue removal system can lead to pressure peaks that can exceed 150 mmHg.

Connect vacuum tube with hygiene filter to suction containers. The vacuum tube with hygiene filter must be replaced when dirty and after 30 days at the latest. The vacuum tube with hygiene filter should not be cleaned.

Connection for low vacuum (white)

- Connect vacuum tube with white connector to low vacuum port (white) ① Fig. Low vacuum tube [▶ 29]. This vacuum pump has a fixed vacuum pressure (~225 mmHg).
- Use the connecting tube (⑤ Fig. Low vacuum tube [▶ 29]) when two containers are serially connected to the same vacuum port.

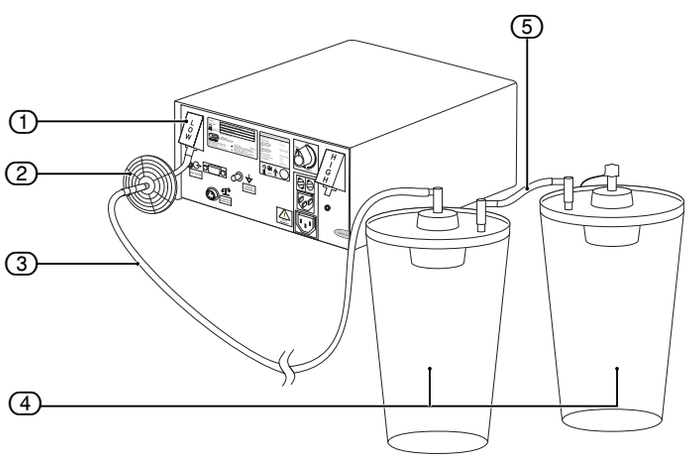


Fig. 5–5 Low vacuum tube

① Connection for low vacuum (white)
② Hygiene filter
③ Vacuum tube
④ Container
⑤ Connecting tube

Connection for high vacuum (green)

- Connect vacuum tube set with the green connectors to the high vacuum port (green) ⑧ in Fig. High vacuum tube [▶ 30]. This vacuum can be adjusted to a maximum 500 mmHg using adjustment controller.
- Use the connecting tube (⑫ Fig. High vacuum tube [▶ 30]) when two containers are serially connected to the same vacuum port.

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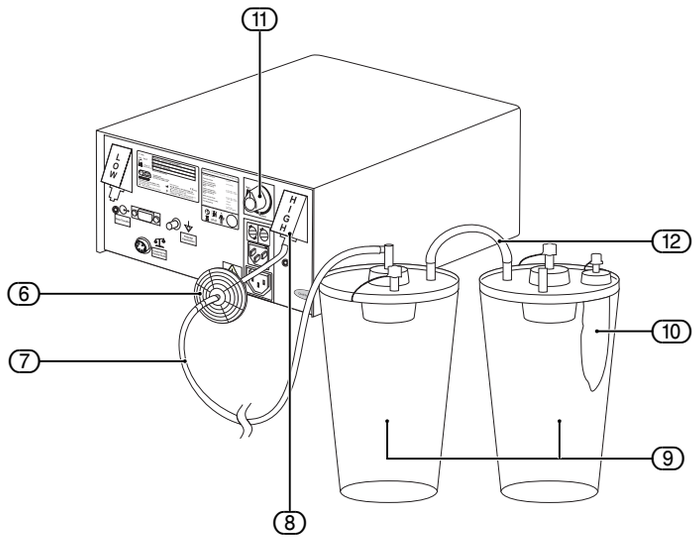
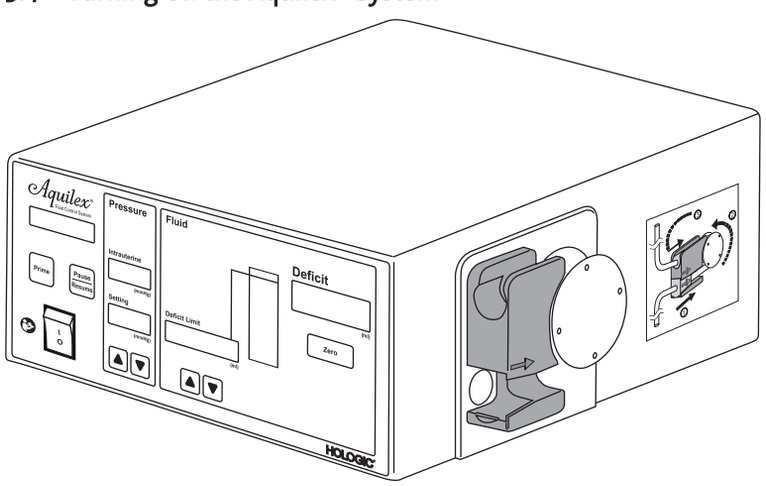
Fig. 5–6 High vacuum tube

⑥ Hygiene filter
⑦ Vacuum tube (green connectors)
⑧ Connection for high vacuum (green)
⑨ Container
⑩ Tissue trap (MyoSure® procedures)
⑪ Adjustment controller
⑫ Connecting tube



5.4 Turning On the Aquilex® System

Fig. 5–7 Front of Device



1. Press the ON/OFF switch. The displays and indicators light up and system turns on.
2. The system now performs a device self-test.
3. If a tube set is in the inflow tube holder when the pump is switched on, the pump display (Fig. Front of irrigation pump unit [▶ 24] ①) shows the message **Remove Tube Set**. The device self-test resumes once the tube set is removed from the roller wheel.

   If the device self-test is unsuccessful, the corresponding error messages are displayed (see Chapter Error and Warning Messages [▶ 54]).

The system has successfully completed the device self-test when a single audible warning signal is heard. The message **System OK** is displayed for 5 seconds followed by the message **Insert Tube Set**.

WARNING!

Obvious defects

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

5.5 Hanging the Fluid Bags

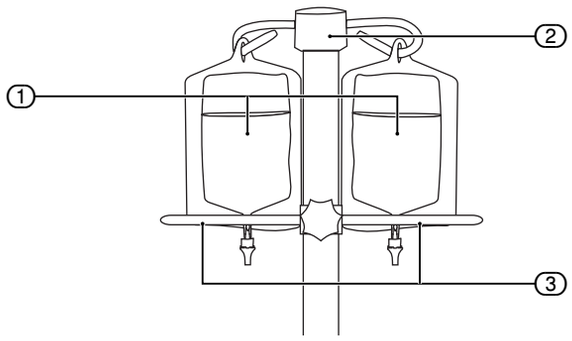


Fig. 5–8 Fluid bag suspension

① Fluid bags
② Pole with bag hooks
③ Bag deflector

WARNING!

Distension media

When performing monopolar hysteroscopic electrosurgery, the distension medium must be electrically non-conductive. Examples include glycine, sorbitol and mannitol. Isotonic saline irrigation fluids may only be used when performing bipolar electrosurgical resective procedures.

Hang one or two fluid bags with distension media appropriate for procedure. (A MyoSure® procedure utilizes one or two 3000 cc saline bags.)

WARNING!

Irrigation fluid bags

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

5.6 Using Tube Sets

The **Aquilex Fluid Control System** is designed for use with sterile disposable inflow and outflow tube sets.

Tube set recognition

Each inflow tube set is equipped with tube set recognition technology. An RFID transponder detects the type of tube, whether it has been used, and its reliability automatically.

The pump display indicates this information. This eliminates accidental reuse of tube sets on more than one patient (see chapter Tube Sets Overview [▶ 32]).

WARNING!

Visual inspection of the tube set

Before the operation, perform a visual inspection of the tube set and its packaging.

Damaged tube sets or tube sets from damaged packagings may not be used.

WARNING!

Reprocessing of sterile disposable products

Reuse of inflow or outflow tube can cause an infection hazard for patients and/or users as well as impair of product functionality. Contamination and/or impaired functionality of the system can cause risk of injury, illness, or death. Do not re-process or reuse single-use inflow or outflow tube sets.

NOTE!

Disposing tube sets

Observe applicable hygiene rules and regulations when disposing tube sets, collected fluids, and waste containers.

5.7 Tube Sets Overview

Three different tube sets are necessary to operate the system. The following table lists each type of tube set and its application.

Article number	Description
AQL-110	Tube set for irrigation, single-use, for **Aquilex Fluid Control System**
AQL-111	Tube set for suction, single-use, for **Aquilex Fluid Control System**
AQL-112	**Aquilex Fluid Control System** complete tube set (inflow and outflow), disposable, sterilized using ethylene oxide
AQL-114	Tube set for vacuum incl. filter, 30-day use, for **Aquilex Fluid Control System**

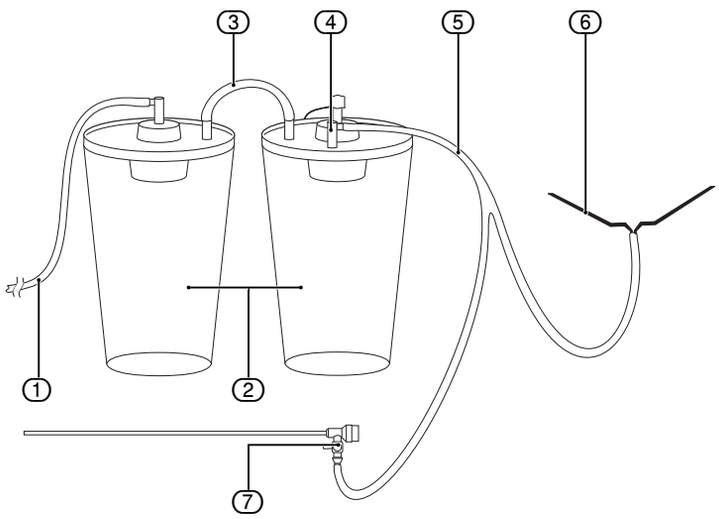
Table 1: Tube sets

5.8 Connecting the Outflow Tube Set

WARNING!

Combination of low set pressures and excessive vacuum pressures

When using the Aquilex Fluid Control System with tissue removal systems, e.g. MyoSure®, the combination of low set pressures and excessive vacuum pressures may result in a significant loss of intrauterine distension pressure which has the potential to affect the visibility of the surgical field. Conversely, when employing a high distension pressure, the deactivation of the tissue removal system can lead to pressure peaks that can exceed 150 mmHg.



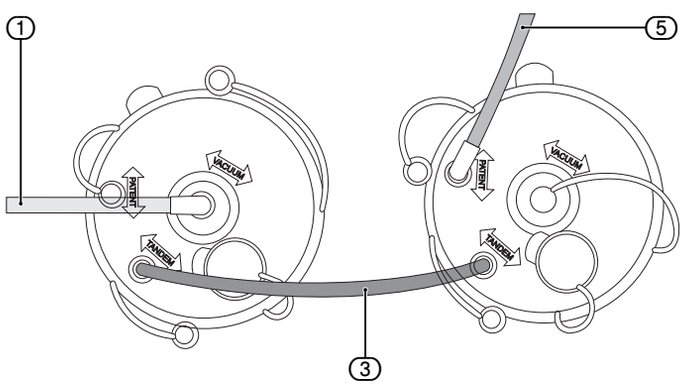


Fig. 5–9 Outflow tube set

① To low vacuum port (white)
② Container
③ Connecting tube
④ Patient port
⑤ Outflow tube set
⑥ Drape
⑦ Removable outflow channel or hysteroscope outflow sheath Luer lock

Using low vacuum configuration of Fig. Outflow tube set [▷ 33], connect outflow tube set (Y-tube) to patient port ④ of second container. Yellow flexible connector attaches to drape ⑥. Yellow Luer lock of outflow tube set connects to Luer lock ⑦ of removable outflow channel or hysteroscope outflow sheath.

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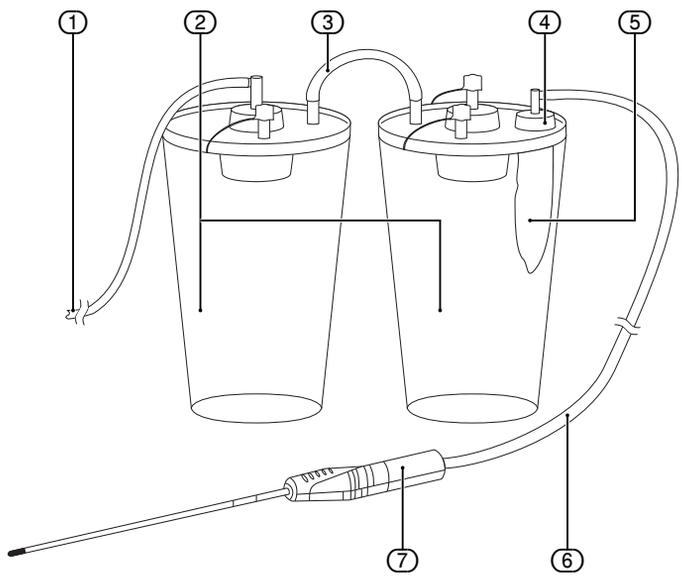
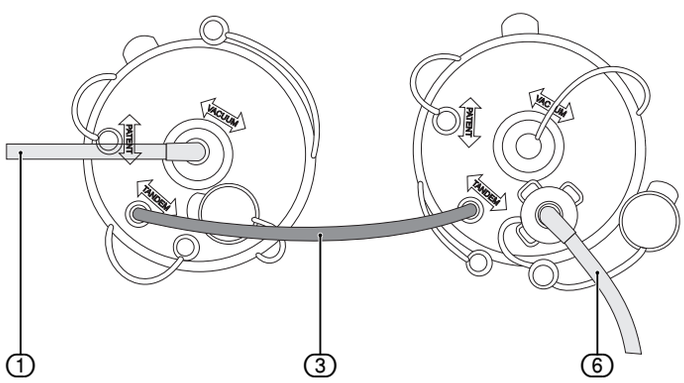
Fig. 5–10 Port for tissue removal systems

① To high vacuum port (green)
② Container
③ Connecting tube
④ Specimen tissue port
⑤ Tissue trap
⑥ Vacuum tube of tissue removal handpiece (yellow)
⑦ Tissue removal handpiece

5.8.1 Connecting Outflow Tube of Tissue Removal Handpiece (e.g. MyoSure®)





If intrauterine pathology is identified, the outflow tube of a tissue removal handpiece ⑥ is connected to the tissue trap ⑤ located in the second container.

5.9 Inserting the Inflow Tube Set

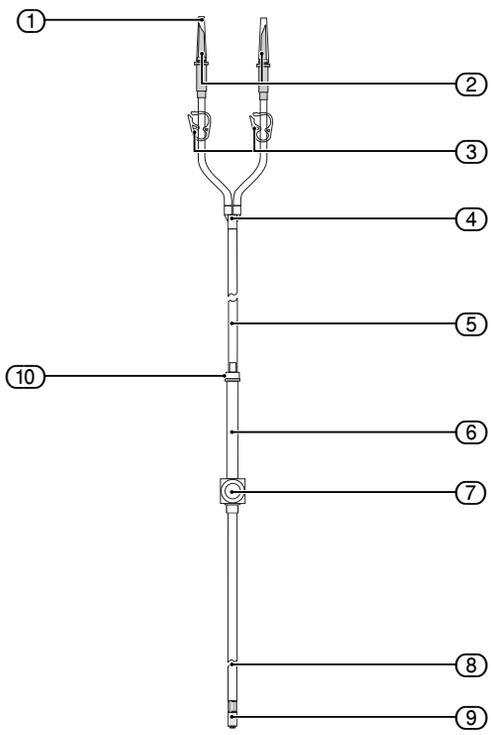


Fig. 5–11 Tube set elements

1. Protective caps
2. Spikes
3. Clamps
4. Y-connector
5. Inflow tube
6. Roller wheel tube
7. Pressure chamber with membrane and RFID transponder
8. Hysteroscope tube
9. Luer lock connector (blue)
10. Roller wheel connector

(See Fig. Tube set elements [▷ 35]) The inflow tube set consists of three tubes, a Luer lock connector (blue) ⑨ and two spikes ②. The three tubes are: Roller wheel tube ⑥, inflow tube ⑤, and hysteroscope tube ⑧. The spikes ② are used to connect the tubes to the fluid bags.

The Luer lock connector ⑨ connects the hysteroscope tube with the hysteroscope.

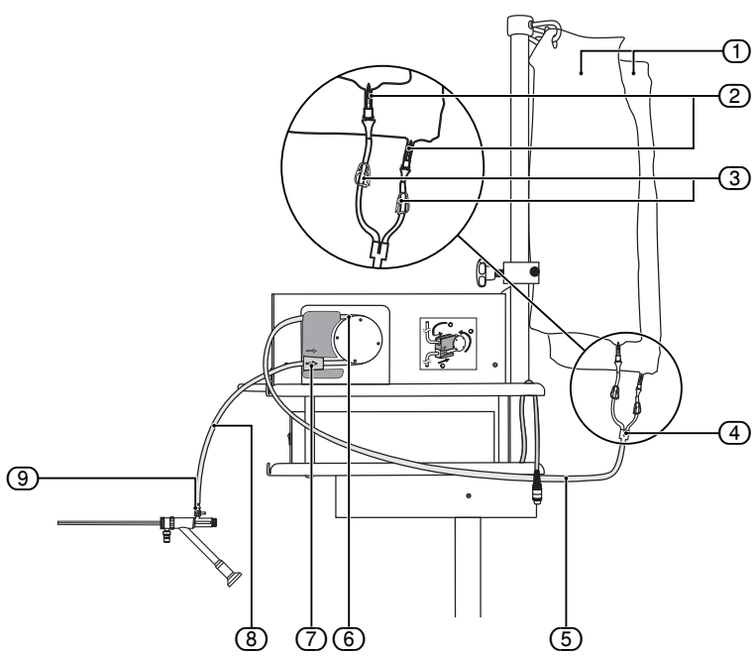


Fig. 5–12 Inserting the tube set

1. Fluid bags
2. Bag spikes
3. Bag clamps
4. Y-connector
5. Inflow tube
6. Roller wheel tube
7. Pressure chamber with membrane and RFID transponder
8. Hysteroscope tube
9. Luer lock connector (blue)

Open outer packaging

- To be carried out by non-sterile nurse:
  - Ensure system is turned on.
  - Open outer packaging of the inflow tube set.

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Connect to hysteroscope

- To be carried out by sterile nurse:
  - Remove the inner tube set package and open it.
  - Keep the blue Luer lock connector (9) in the sterile area and hand the tube ends with the spikes (2) to the non-sterile nurse.
  - Connect the blue Luer lock connector (9) with the hysteroscope inflow Luer lock. Open stopcock.

Inserting the tube set

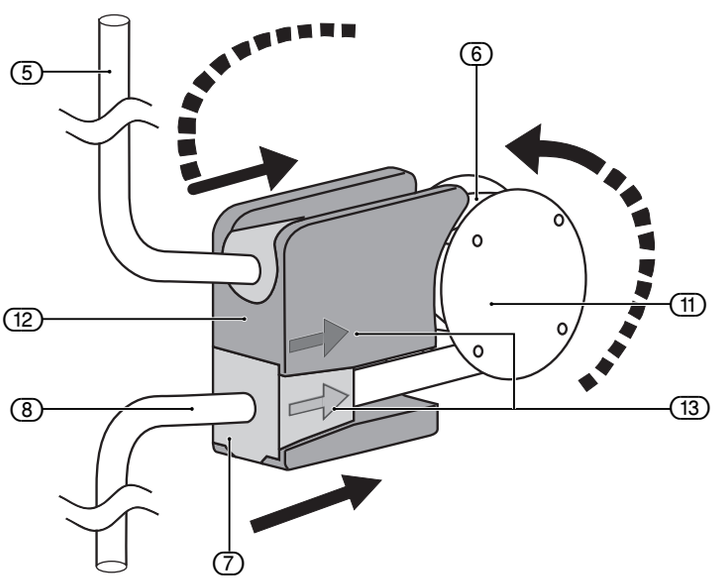
- To be carried out by non-sterile nurse:
  - Close the clamps (3) on the inflow tube below the spikes (2).
  - Carefully insert the pressure chamber (7) into the lower notch of the inflow tube holder (12) until you feel resistance. Insert the pressure chamber (7) only if chamber is not pressurized and make sure not to damage the membranes of the pressure chamber. Align pressure chamber and inflow tube holder using arrows (see Fig. Attach roller wheel tube [▷ 36]).
  - Place the roller wheel tube (6) around the roller wheel (11) and insert the roller wheel connector (see Fig.Tube set elements [▷ 35], (10)) into the upper notch of the inflow tube holder (12).

Connect the fluid bags

- To be carried out by non-sterile nurse:
  - When connecting or removing the tube to or from the irrigation fluid bags, always grasp the spike at the provided handle. Observe aseptic technique when inserting the spike(s) into the fluid bag(s). The surgeon must select a distension fluid suitable for the type of procedure.

Fig. 5–13 Attach roller wheel tube

(5) Inflow tube
(6) Roller wheel tube
(7) Pressure chamber with membrane and RFID transponder
(8) Hysteroscope tube
(11) Roller wheel
(12) Inflow tube holder
(13) Alignment arrows



5.10 Presetting the Intrauterine Pressure

Intrauterine pressure setting

The intrauterine pressure setting can be adjusted while the system is in operation. The initial default pressure is 70 mmHg. Use the ▲ and ▼ buttons (Fig. Front of irrigation pump unit [▷ 24]). The pressure setting can be adjusted to between 40 to 150 mmHg in steps of 5 mmHg or by scrolling if the button is pressed longer. Between two ON/OFF cycles of the device, the previous pressure value will be remembered, if it was less or equal to 80 mmHg. If the previous intrauterine pressure exceeded 80 mmHg, its value will reset to 80 mmHg upon restarting the device.

The intrauterine pressure is shown on the intrauterine pressure display (2).

Safety threshold

If when scrolling with the ▲ button (Fig. Front of irrigation pump unit [▷ 24]) the safety threshold of 100 mmHg is reached, the text message **Safety Threshold** is displayed accompanied by an audible warning signal. After this you could proceed with the pressure setting using the ▲ button again to set higher values up to 100 mmHg.

CAUTION!

Risk of intravasation

If the intrauterine pressure does not react to an increase in the pressure setting during the procedure, a perforation of the uterine cavity might be the cause. This results in an increased risk of intravasation. Examine the uterine cavity for injuries.

5.11 Deficit Limit Setting

Setting the deficit limit

The deficit limit can be adjusted while the system is in operation. Use the ▲ and ▼ buttons (see Fig. Front of irrigation pump unit [▶ 24]). The deficit limit can be adjusted to between 600 and 2500 ml in steps of 100 ml or by scrolling if the button is pressed longer. The deficit limit is shown on the deficit limit display (3). The default value for the deficit limit is 1000 ml.

The deficit meter is designed to help the operator track the deficit volume. The color of the deficit meter changes as the deficit limit is approached. If the deficit limit set by the operator is exceeded, this is marked by a red LED at the top of the deficit meter. If during surgery the actual deficit rises, the LEDs will light up sequentially every 10 % of the set deficit limit to represent the actual deficit volume until the deficit limit is reached (see section **Deficit Limit** in Chapter Safety Functions [▶ 45]).

5.12 Using the Pump during Surgery

Start lumen calibration

- Open clamps on the fluid bags ((3) Fig. Inserting the tube set [▶ 35]).
- Fully open hysteroscope inflow stopcock.
- If drainage stopcock is available: Fully close drainage stopcock.
- Keep the hysteroscope at the height of the patient and above the drape to ensure the fluid can be collected. Do not insert the hysteroscope into the uterus at this time.
- Press the button **Prime** ((17) Fig. Front of irrigation pump unit [▶ 24]).
- Pump will run for approximately 20 seconds to purge air from tubes and run the automatic lumen calibration function.
- Pump will display **Calibration Running**.

Automatic lumen calibration

The pump is equipped with an automatic lumen calibration function. The system determines the flow resistance of the hysteroscope. This resistance is used to calculate the pump pressure necessary to maintain the pre-set intrauterine pressure. To overcome this resistance, the pump allows a pressure of up to 80 mmHg during calibration. This will be shown in the display of the actual intrauterine pressure. If calibration fails due to high resistance, calibration is repeated with a permissible pressure of up to 150 mmHg. If calibration is then still not completed, the pump displays **Prime Fail - Open Stopcock, Clamps**.

The automatic lumen calibration starts once the **Prime** button is pressed.

- Three audible warning signals are heard once the automatic lumen calibration is finished. The pump display will show **Prime Successful Close Stopcock** for 5 seconds followed by **Pump Operating**.
- Close hysteroscope inflow stopcock to stop fluid flow. Once all fluid has been removed from the drape, zero the deficit display.
- Check to see if fluid has leaked in the area of the pressure chamber. If you find leaked irrigation fluid in the area of the pump, change the tube set and retry the automatic lumen calibration.

CAUTION!

Instrument recognition

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

NOTE!

To stop the pump

The pump continues to operate after automatic lumen calibration is complete. The pump should be stopped by closing hysteroscope inflow stopcock.

System operation

- Open stopcock and guide the hysteroscope with fluid flowing into the uterus.
- Adjust intrauterine pressure setting as necessary to obtain adequate distension and visualization.

Completing system operation

- After the medical procedure, if system operation is complete close the hysteroscope inflow stopcock.
- Wait until the entire fluid volume from the drape and the tube set has been collected in both containers.
- Press the **Pause/Resume** button.
- Note the deficit volume indicated on the deficit display. This is the total fluid volume that was absorbed by the patient.

WARNING!

System error

Do not use the Aquilex System if a defect is suspected or detected during the function test. This also applies to any obvious defects, especially defects on the power connector or plug and power cord.

WARNING!

Failure of scale connection

If the message “Check Scale Connection” appears, the deficit must be calculated manually. The pump keeps displaying the last known deficit value determined prior to the failure of the scale connection.

NOTE!

Change the containers and bags during surgery

It is possible to change the containers and bags during surgery without losing the previously measured deficit.

5.13 Changing Bags during Surgery

Bag change during surgery

If the replacement of a fluid bag during surgery is necessary follow the steps below:

- Close the clamp of the empty fluid bag.
- Hang a new fluid bag to a bag hook (see Chapter Hanging the Fluid Bags [▷ 31]).
- Reconnect the new fluid bag with the inflow tube set.
- Open the clamp of the new bag.

WARNING!

Fluid bag and container change during surgery

A fluid bag or container change during surgery is only allowed, if the fluid bag or container holds at least 0,5 liters of fluid or waste. Otherwise, the deficit value may be falsified. In this case, the manufacturer recommends manual deficit calculation.

5.14 Changing Container during Surgery

Container change during surgery

The device system detects automatically the replacement of a container. The pump will stop immediately, and the deficit display is locked to insure an accurate deficit count is maintained. Brief fluctuations in the deficit calculation (< 10 s) may occur when a container is replaced. The replacement of a container is indicated with the message **Container Change, Press Resume**.

- Disconnect tubing from full containers.
- Immediately remove full containers from scale.
- Install new containers.
- Reconnect tubing to new containers.
- Press **Pause/Resume** button to resume procedure.

WARNING!

Fluid bag and container change during surgery

A fluid bag or container change during surgery is only allowed, if the fluid bag or container holds at least 0,5 liters of fluid or waste. Otherwise, the deficit value may be falsified. In this case, the manufacturer recommends manual deficit calculation.

WARNING!

Touching containers and their holders

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

WARNING!

Change of the containers

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

WARNING!

Accuracy of the deficit

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

5.15 Changing Instrument during Surgery

NOTE!

Correct lumen calibration and deficit calculation

The calibration must be performed outside of the patient to ensure a correct lumen calibration and deficit calculation.

NOTE!

Change the containers and bags during surgery

It is possible to change the containers and bags during surgery without losing the previously measured deficit.

Instrument change during surgery

- Pause the pump by pressing **Pause/Resume** button.
- Press the **Prime** button for 2 seconds.
- Change the instrument.
- Fully open hysteroscope inflow stopcock.

- Keep the hysteroscope at the height of the patient and above the drape to ensure the fluid can be collected. Do not insert the hysteroscope into the uterus at this time.
- Press the **Prime** (17) button (Fig. Front of irrigation pump unit [▸ 24]).
- Pump is running to carry out the automatic lumen calibration. The pump display depicts **Calibration Running**.
- Three audible warning signals are heard once the automatic lumen calibration is finished.
- The pump display depicts **Prime Successful Close Stopcock** for 5 seconds, followed by **Pump Operating**.
- Close the stopcock for the hysteroscope inflow to stop the inflow.

5.16 Total Inflow Volume Displayed

Total inflow volume displayed

If a manual check of the fluid deficit is desired, the total fluid volume supplied from the fluid bags can be obtained by simultaneously pressing and holding both the up and down arrows ((10) and (11) Fig. Front of irrigation pump unit [▸ 24]). The number in the deficit display is the total inflow fluid volume in ml. Once one or both of these buttons is released, the deficit display will return to the fluid deficit value.

WARNING!

Inflow volume limit

The Aquilex Fluid Control System has a maximum allowable fluid inflow volume of 30,000 ml. When the inflow volume reaches 30,000 ml, the inflow volume drops abruptly to zero, while the deficit increases continuously as per the roller wheel rotation.

When an inflow volume of 30,000 ml is reached, the current procedure should be concluded as quickly and safely as possible.

If the physician decides to continue the operation, manual count for continued deficit monitoring must be performed.

5.17 Turning System Off

Turning off

Press the **ON/OFF** switch to turn pump off. The displays and indicators are no longer illuminated.

WARNING!

Disconnect the power cord

Pressing the ON/OFF switch does not disconnect the system from the wall power outlet. This requires pulling the power cord located in the rear of the system.

6 Function Tests

WARNING!

Device defect

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

Do the general function test before each procedure.

Do the flow rate test and scale test at the beginning of the day prior to device use.

You need the following items for the function tests:

- **Aquilex Fluid Control System** inflow tube set
- Fluid bag containing at least 1.5 l of fluid (to prevent the bag from running empty during the test procedure)
- Measuring cup with marked scale (1 liter)
- Stopwatch
- 1000 g weight (included with each pump)

6.1 General Function Test

WARNING!

Function test

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

Doing 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 that all tube connections (vacuum/inflow/outflow) are correct and intact.
6. 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.
7. Make sure that the automatic lumen calibration is successful (no error messages are displayed). See chapter Using the Pump during Surgery [▷ 37].
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.

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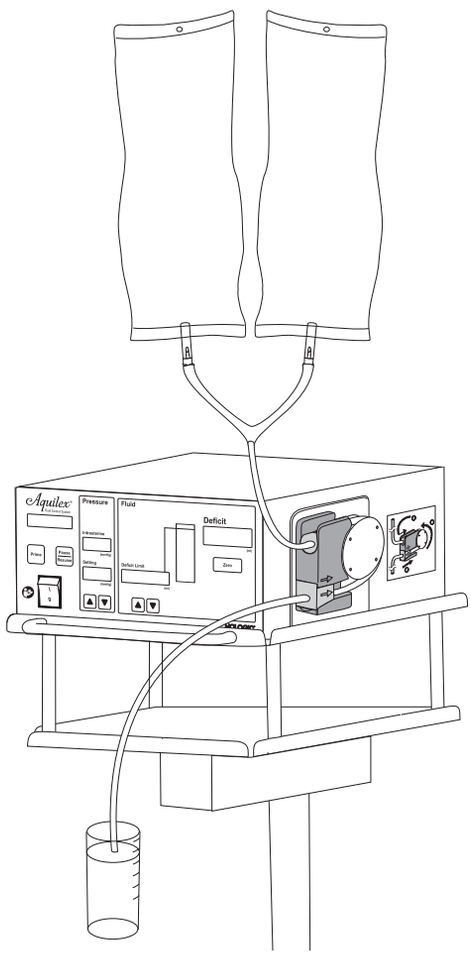
6.2 Flow Rate Test

WARNING!

Flow rate test

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

Fig. 6–1 Setup of the flow rate test



Testing the flow rate

1. Switch system on (see Chapter Turning On the Aquilex System [▷ 30]).
2. Insert tube set into pump and close clamps on the bags.
3. Hang the fluid bags onto the fluid bag hooks.
4. Insert spikes into the fluid bags and open clamps on the fluid bags.
5. Insert hysteroscope tube into the measuring cup.
6. Set intrauterine nominal pressure to 150 mmHg.
7. Press the **Prime** button
8. The roller wheel starts to rotate in order to remove the air from the tubes and to carry out the automatic lumen calibration.
9. When the automatic lumen calibration is completed, press **Pause/Resume** button.
10. Empty the measuring cup.
11. Place hysteroscope tube back into the measuring cup.
12. Press the **Pause/Resume** button.

13. Press **Pause/Resume** button after one minute. The measuring cup should contain approximately 800 ml ± 80 ml of fluid.

Enter the results into the Test log [▷ 62] in Section Appendix [▷ 62]. The test is successfully completed when the results are within the permissible tolerance limit.

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6.3 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).

Doing the scale test

1. Turn the system on.
2. Once the message **Insert Tube Set** appears, press the **Pause/Resume** button and the **Zero** button simultaneously.
3. The pump display depicts the message **Scale Test.**
   - The first option is the test of the container scale.
4. Place the 1000 g weight (included with each pump) on the container scale.
   - The display of the fluid deficit limit depicts the weight.
   - The displayed value should be 1000 g.
   - The acceptable tolerance is ±20 g.
   - If the displayed value is outside the tolerance range, the scale must be calibrated by a service technician.
5. Remove the weight from container scale.
6. Press the **Pause/Resume** button to conclude this test.
7. Record results in the test log in the Appendix [▶ 62].
   - The test is successful if results are within the acceptable tolerance limits.

7 Safety Functions

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

Intrauterine pressure reaches 150 mmHg

The message **Maximum Pressure** is displayed for 3 seconds once the intrauterine pressure exceeds 150 mmHg. The maximum permissible pressure has now been reached.

Intrauterine pressure 10 mmHg above preset intrauterine pressure setting

If the intrauterine pressure exceeds the intrauterine pressure setting by 10 mmHg for longer than 5 seconds, the message **Overpressure Open Stopcock** is displayed and three audible warning signals are emitted. The pressure reduction function is activated and the roller wheel will move forward or backward a few times during the pressure reduction process. If the pressure cannot be reduced, the roller wheel stops, the message **Overpressure Check Stopcock** is displayed and five short continuous audible warning signals are emitted until the overpressure is reduced..

Intrauterine pressure > 200 mmHg

If the intrauterine pressure exceeds 200 mmHg for longer than 5 seconds, the roller wheel stops, and the message **Overpressure Check Stopcock** is displayed. Five short continuous audible warning signals are emitted until the pressure is reduced. Once the intrauterine pressure falls below 200 mmHg, the audible warning signals stop and the pump wheel resumes turning automatically.

Check Tube Set Installation

If the inflow tube set is not inserted properly into the roller wheel, pressing the **Prime** button results in a short audible warning signals and **Check Tube Set Installation** is displayed. The roller wheel does not start to turn.

Pressure measuring system malfunctions

If a malfunction is detected in the pressure measurement electronics, **Sensor Error** is displayed, and five short audible warning signals are emitted. The roller wheel stops turning.

Scale overload

If the maximum permissible weight of the scale is exceeded (container scale), three audible warning signals are emitted, and **Scale Overloaded Check Scale** is displayed. The warning stops once the excess weight is removed from the scale.

Loading/unloading scale while in operation

The following messages are displayed when a container is removed from the scale or a new fluid bag is added during operation of the system: **Container Change, Press Resume** as long as the container change is ongoing accompanied by three audible warning signals or **Bag Change, Please Proceed** for 5 seconds accompanied by one audible warning signal.

Pressure setting at restart

If the last pre-set intrauterine pressure setting is greater than 80 mmHg, this value is reset to the default value of 80 mmHg.

Deficit limit

If the preset deficit threshold is reached and also for each additional deficit increase by 100 ml above the threshold the message **Deficit Limit Exceeded** is displayed together with 3 audible warning signals. After 2 seconds this message is replaced by the continuous message **Deficit Limit Reached** accompanied by three audible warning signals again.

Deficit rate >300 ml/min

If the deficit rate exceeds 300 ml/min, 3 audible warning signals are emitted, and the message **High Fluid Loss Check Leakage** is displayed. If no obvious source of high fluid loss can be identified, an assessment of potential cervical or uterine perforation should be made.

Serious system defect

Some components of the system will be observed during operating and at the startup sequence. Five short audible warning signals are emitted and a message **"Component" Error** is displayed. Please refer to Error and Warning Messages [▷ 54] for details about components linked to this error. It is possible that errors can occur in the startup sequence prior to the enabling of the pump display. In this situation, the pump display will remain blank.

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8 Care and Maintenance

NOTE!

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

Care and maintenance

The service and maintenance of the system and its accessories has to be carried out as per instructions to ensure the safe operation of the system. For the protection of the patient and the operating team, check that the system is complete and functional before each use.

Special care is necessary when servicing, maintaining, and storing the system and its accessories to maintain the functionality of the equipment and any attached devices.

8.1 Cleaning the System

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

CAUTION!

Cleaning the system / Sterilization not allowed

The pump and the cart/scale can be disinfected by wiping off the outer surfaces. Do not sterilize the pump and the cart/scale.

8.2 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. This inspection must be carried out once a year. The tests are described in Chapter Annual Inspection [▷ 48].

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

8.3 Maintenance by Authorized Service Technician

Two-year maintenance interval

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

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

Authorized trained personnel

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

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

Unauthorized personnel

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

Liability

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

Technical documents

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

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

Technical report

WARNING!

Risk of electrical shock

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

WARNING!

Modification of the device

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

WARNING!

Modified device

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

8.4 Replacing of 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 [▷ 52].

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

- displays and LEDs do not light up,
- the system does not function.

Check whether

- the power cord is properly connected to the power cord connection (Figure Opening the fuse holder [▷ 47]) and to a grounded safety wall outlet,
- the wall outlet has power.

WARNING!

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

The system does not have to be opened to replace the fuse.

1. Turn system off.
2. Disconnect system from wall power outlet.
3. The fuse holder is located on the back of the pump, next to the male connection.
4. Remove both fuse holders as depicted in Fig. Opening the fuse holder [▷ 47], using small flathead screwdriver.
5. Pull out the fuse holders.
6. Check the fuses.
7. Insert new fuses. Use only the specified type of fuse (see Technical Data [▷ 52]).
8. Insert the fuse holders.

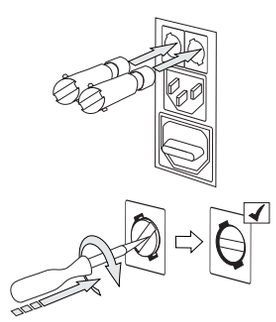

Fig. 8–1 Opening the fuse holder

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

WARNING!

Parameters and tolerances exceeded

If the specified parameters and tolerances are exceeded, the system must be returned to Hologic for evaluation.

9.1 Electrical Safety Test

1. Perform a visual inspection. Ensure:
   - the fuse corresponds with the specifications indicated by the manufacturer,
   - labels and stickers on system are legible,
   - the mechanical condition of the system allows for its safe use,
   - the system is clean to ensure proper and safe functionality.
2. Perform the measurement of the ground leakage current (max. 500 µA) and contact current (max. 100 µA in normal state and max. 500 µA on first error) according to IEC 60601-1/EN 60601-1.
3. Measure protective conductor resistance according to IEC 60601-1/EN 60601-1. The protective conductor resistance is measured while the system is connected to the power supply. The max. value is 0.2 Ω. As an alternative, perform safety test according to DIN EN 62353.

9.2 Basic Function Tests

The basic function tests check displays, buttons, and overall system performance.

You need the following for this test:

- Aquilex inflow tube set
- Fluid bag containing at least 1.5 l of fluid, to prevent the bag from running empty during the test procedure
- Measuring cup with marked scale (1 Liter)
- Stopwatch
- 1000 g weight (included with each pump)

NOTE!

Function test fails

If the device does not work as described and the test fails the device must be sent to the service.

9.2.1 Flow Rate Test

The flow rate test must be carried out as part of the annual inspection. See section Flow Rate Test [▶ 42] for details.

The test is successfully completed when the results are within the permissible tolerance limit.

Enter the results into the test log (see Appendix [▶ 62]).

9.2.2 Scale Test

The scale test must be carried out as part of the annual inspection. See section Scale Test for details.

The test is successfully completed when the results are within the permissible tolerance limit.

Enter the results into the test log (see Appendix [▷ 62]).

9.2.3 Pressure Measuring Test

The test setup is depicted in Fig. Set-up of pressure measuring test [▷ 49].

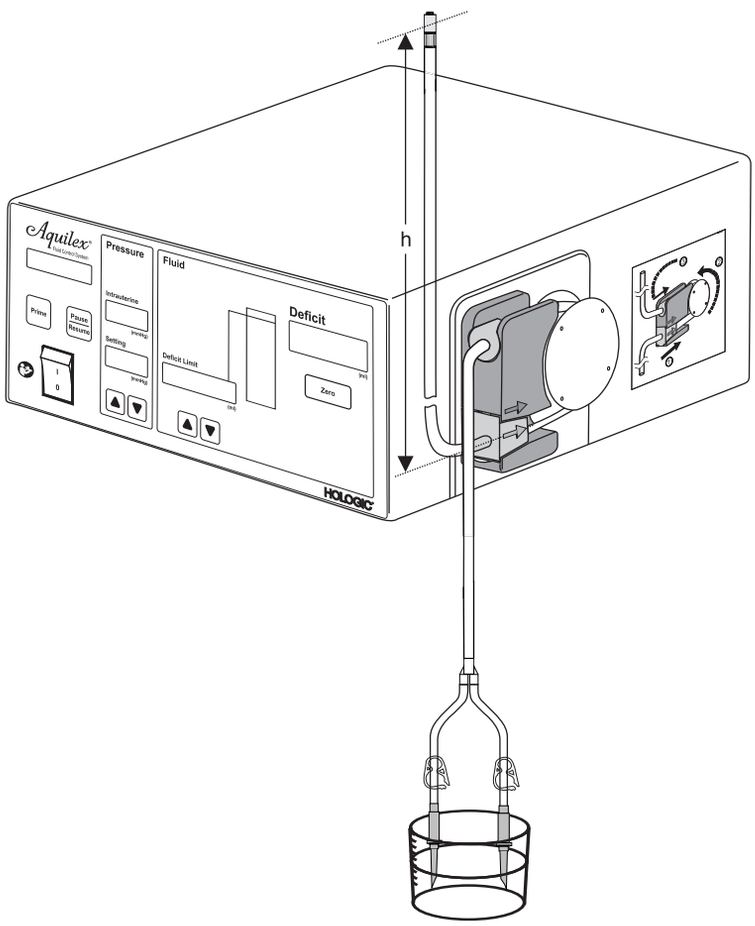

Fig. 9–1 Set-up of pressure measuring test

h Height of the water line

The pressure test checks the pressure chamber, the pressure sensor, and the accuracy of the pressure measurement, to ensure that all elements function correctly. For this test, an inflow tube set, and a water-filled container is required. The height of the water column (hydrostatic pressure) is used to test the pressure transducer.

1. Hang the inflow end of the tube with the spikes for the fluid bags into a container filled with water.
2. Fill the tube end completely with water by running the pump with the Prime button. Let the pump run until the calibration is complete. Press the **Pause/ Resume** button to stop the roller wheel. The intrauterine actual pressure display depicts 0 mmHg.
3. Seal the end of the hysteroscope tube (with finger on the tip of the luer connector).
4. Hold the water level at the end of the hysteroscope tube (h) 30 cm above the pressure chamber. The water column exerts a hydrostatic pressure on the pressure transducer.
5. Remove your finger from the end of the hysteroscope tube.

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6. The intrauterine actual pressure display should depict 20 mmHg (± 10 mmHg).
7. Change the water column height by changing the height of the water filled end of the tube set. The value depicted on the intrauterine actual pressure display should change accordingly.

Enter the results into the test log in section Test log [▷ 62]. The test is successfully completed when the results are within the permissible tolerance limit.

9.2.4 Fluid Deficit Measurement Test

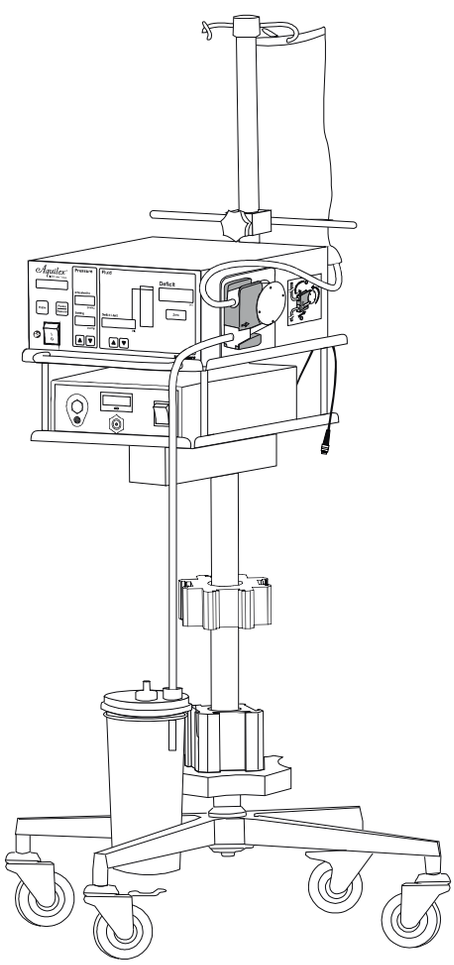
The test setup is depicted in Fig. Fluid deficit measurement test [▷ 50]. It is critical that the collection container be placed on the scale as shown in Fig. Fluid deficit measurement test [▷ 50].

1. If the basic function tests described in the Chapters Scale Test [▷ 44], Flow Rate Test [▷ 42] and Pressure Measuring Test [▷ 49] have been conducted, skip to step 2. If not, conduct the Basic Function Tests described in Chapter Flow Rate Test [▷ 42] steps 1 to 11.
2. "Zero" the fluid deficit display by pressing the **Zero** button (see Fig. Front of irrigation pump unit [▷ 24], item (9)).
3. Press the **Pause/Resume** button.
4. Let the system run for 1 minute. The container should have ~800 ml of fluid but the fluid deficit display should stay at ~0 ml.

The acceptable tolerance is ± 100 ml for AQL-100 respectively ± 60 ml for AQL-100S.

Record results in the test log in the Appendix [▷ 62]. The test is successful if results are within acceptable tolerance limits.

Fig. 9–2 Fluid deficit measurement test



9.2.5 Testing the Vacuum Pump

This test is not designed as a performance test for the measurement of negative pressure. The test only indicates whether or not the vacuum pump is operational.

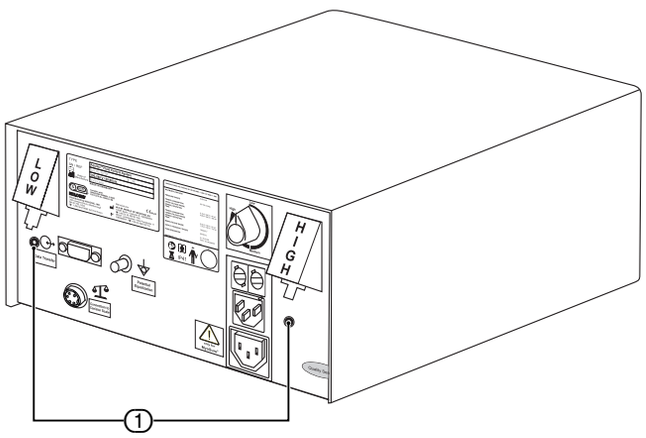


Fig. 9–3 Vacuum pump exhaust ports

① Suction openings

1. Check to be sure at least one port is opened into the container.
2. Press the **Pause/Resume** button.
3. Place a finger lightly over the suction openings (Fig. Vacuum pump exhaust ports [▷ 51], ①) and check whether you can feel a sucking air flow.

Enter the results into the test log in section Test log [▷ 62]. The test is successfully completed when a stream of air can be demonstrated.

9.3 Determine the Software Version

The software version of the pump may be required for further analysis.

Follow these steps to determine the software version:

1. Turn device on and wait for the device self-test.
2. Press the Pause/Resume button for at least 1 second.
3. The software version of the pump is depicted in the "Deficit Limit" display and consists of a 5-digit numerical sequence.

Enter the determined software version into the test log in Section Test log [▷ 62].

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10 Technical Data

Model or type designation		Aquilex Fluid Control System (REF: AQL-100) consisting of: Irrigation Pump Unit (REF: AQL-100P) Fluid Monitoring Unit (REF: AQL-100CS)		
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		
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		
Max. allowed load of the additional socket / more than one sockets [A or VA]		1.6 A		
Power consumption Upper voltage range		Current [A]	Voltage [V]	Power consumption [VA/W]
	Normal operation	0.19 A	240 V	45 VA
	Peak	0.69 A	240 V	165 VA
Lower voltage range				
	Normal operation	0.52 A	100 V	52 VA
	Peak	1.70 A	100 V	170 VA
Protection class (I, II, III)		I		
Application part type (B, BF, CF)		BF (with Aquilex Fluid Control System inflow tube set)[1]		
Defibrillator protected (yes/no)		No		
Protection type (IP code)		IP41 (AQL-100P), IP21 (AQL-100CS)		
Classification (I, IIa, IIb, III) acc. to Appendix IX of European MDD		IIb		
Conformity with the following standards		EN 60601-1:2006 / IEC 60601-1:2005 EN 60601-1-2:2007 / IEC 60601-1-2:2007		
Operating conditions		10 to 40 °C / 50 to 104 °F 30 to 75 % rel. humidity 70 to 106 kPa air pressure 3000 m max. altitude above sea level for device use		
Use possible with flammable anesthetic gases		This system is not designed for use with flammable anesthetic agents (Class AP) or flammable anesthetic agents with oxidants (Class APG).		
Storage conditions [°C] [°F], [%], [kPa]		5 to 40 °C/41 to 140 °F 5 to 85 % rel. humidity 70 to 106 kPa air pressure		
Transport conditions [°C] [°F], [%], [kPa]		-20 to 70 °C/-4 to 158 °F 5 to 90 % rel. humidity at 30 °C/86 °F 70 to 106 kPa air pressure		
Max. sound level		< 80 dB(A)		
Maximum flow rate [l/min]		0.8 l/min ± 10 %		
Maximum load		65 lbs/30 kg		
Maximum negative suction pressure		-67 kPa		

Adjustable values		
	Pressure range [mmHg]	40 - 150 mmHg
	Deficit limit [l]	0.6 – 2.5 l
	Suction pressure [kPa]	0, LOW: -30 kPa (fixed value), HIGH: -40 to -67 kPa
Measurement range		
	Pressure [mmHg]	0 - 500 mmHg
	Deficit [ml]	-999/+9999 ml
	Inflow volume [ml]	0 - 30000 ml
Dimensions	Width x Height x Depth [in]/[mm]	12 in x 6 in x 12 in / 300 mm x 140 mm x 300 mm (AQL-100P), 26 in x 52 in x 26 in / 670 mm x 1320 mm x 670 mm (AQL-100CS)
Weight [lbs], [kg]		13 lbs [5.8 kg] (AQL-100P), 23 lbs [10.5 kg] (AQL-100CS)
Accuracy		
	Flow [% measured value]	± 10 %
	Pressure [mmHg]	± 10 mmHg
	Deficit [% measured value]	< 1 l: ±100 ml > 1 l: ± 10 %
	Suction pressure	± 20 %
Interfaces		
	Signal IN/OUT	1 x scale connection (round flanged connection socket with 5 pins) 1 x service port (RS232 socket D-SUB9)
	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	Pressure: build up, measure and control in a body cavity NC: Maximum value: 150 mmHg ± 10 mmHg SFC: Maximum value: 200 mmHg ± 10 mmHg for maximum 5 s Suction pressure High: NC: -67 kPa ± 20 % SFC: 0 kPa (no function) or -84 kPa ± 20 % (constructional limit) Suction pressure Low: NC: -30 kPa ± 20 % SFC: 0 kPa (no function) or -84 kPa ± 20 % (constructional limit)	

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

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11 Error and Warning Messages

The messages appear in the pump display and audible warning signals are heard. Audible warning signals indicating a warning or operating message are sounded several times.

Message in the pump display	audible warning signals	Method
Communication Error	5 audible warning signals	Contact Hologic Technical Support.
Calibration Error	5 audible warning signals	Contact Hologic Technical Support.
Electronics Error	5 audible warning signals	Contact Hologic Technical Support.
Motor Error	5 audible warning signals	Contact Hologic Technical Support.
Sensor Error	5 audible warning signals	Contact Hologic Technical Support.
Defective Key	5 audible warning signals	Contact Hologic Technical Support.
Overpressure Check Stopcock	5 audible warning signals, constantly repeating until pressure is reduced	Pressure has exceeded the 200 mmHg safety limit and must be reduced. The most common cause is a closed hysteroscope stopcock while the pump operates at the highest flow rate.
Check Flow Path Stopcock, Clamps	3 audible warning signals	Flow path is blocked. Check that clamps and hysteroscope stopcock are open. Make sure the tube set is not blocked.
Overpressure Open Stopcock	3 audible warning signals	Most commonly triggered when hysteroscope stopcock is closed while pump is operating at peak flow rate. Open hysteroscope stopcock or remove other closure to relieve pressure.
Deficit Limit Reached	3 audible warning signals	Actions are at the discretion of the physician.
Deficit Limit Exceeded	3 audible warning signals	Actions are at the discretion of the physician. If necessary, perform manual deficit control.
Scale Test	3 audible warning signals	The scale test is active. Please proceed as described in -Ref to Scale Test Description-.
Check Scale Connection	3 audible warning signals, constantly repeating until connection is reestablished	Check scale connection. Reconnect scale, restart device. If the message reappears, contact Hologic.
Scale Overloaded Check Scale	3 audible warning signals	Weight on the **container scale** exceeds 25 kg (55 lbs). The weight must be reduced. System function will resume when the excess weight has been removed.
Prime Fail-Open Stopcock, Clamps	3 audible warning signals	Check clamp(s) and hysteroscope inflow stopcock are open. Press the **Prime** button to restart.
High Fluid Loss Check Leakage	3 audible warning signals	Actions are at the discretion of the physician. If necessary, perform manual deficit control.
Low Vac Failed Use Alternative	3 audible warning signals, constantly repeating as long as the error occurs	An alternative low vacuum source must be used in order to continue the procedure. Contact Hologic Technical Support.
High Vac Failed Use Alternative	3 audible warning signals, constantly repeating as long as the error occurs	An alternative high vacuum source must be used in order to continue the procedure. Contact Hologic Technical Support.
Vac Systems Out Use Alternative	3 audible warning signals, constantly repeating as long as the error occurs	An alternative low vacuum source must be used in order to continue the procedure. Contact Hologic Technical Support.
Container Change, Press Resume	3 audible warning signals	The system has recognized an ongoing container change and is waiting for user action to proceed.
Prime Successful Close Stopcock	3 audible warning signals	The lumen calibration was finished successful. Please close the Stopcock at the instrument and proceed by inserting the instrument.
System OK	1 audible warning signal	The system check was finished successful. All system components are ready to use, no error detected.
Check Tube Set Installation	1 audible warning signal	Remove and re-insert tube set. If the message reappears, insert a new tube set.
Tube Set Over Usage Limits	1 audible warning signal	Tube set detection indicates that the tube set has been used already. Insert new tube set.

Message in the pump display	audible warning signals	Method
Remove Tube Set for System Check	1 audible warning signal	Make sure all tube sets are removed from the roller wheel during the system test. Remove tube set and wait until you hear an audible warning signal and the message "Insert Tube Set" appears.
Incorrect Tube Set	1 audible warning signal	Replace tube set. The tube set does not match the type approved for the **Aquilex Fluid Control System** .
Pump Paused, Press Resume	1 audible warning signal	Pause/Resume button has been activated. Press **Pause/Resume** button again to resume surgery.
Pressure Threshold	1 audible warning signal	For a hysteroscopy, pressures above 100 mmHg are usually not necessary. Careful monitoring of the fluid deficit is recommended.
Press Prime Button	1 audible warning signal	The system is waiting for user action to proceed. Please press **Prime** to start the lumen calibration.
Service Menu	No audible warning signal	The service menu is entered. Only relevant for service technicians, no user access allowed. Please refer to the service manual for detailed information.
System Check Running	No audible warning signal	The system check is running. No user action required until message "System OK" appears.
Calibration Running	No audible warning signal	The system is proceeding the lumen calibration. No user action required until the message "Prime Successful Close Stopcock" appears.
Pump Operating	No audible warning signal	The system is ready to use and operating as intended.
Maximum Pressure	No audible warning signal	The message "Maximum Pressure" is depicted when the intrauterine pressure is greater than 150 mmHg.
Insert Tube Set	No audible warning signal	The system is waiting for user action to proceed. Please insert a valid tube set to operate the system as intended.

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12 Electromagnetic Compatibility

CAUTION!

Accessories

To ensure compliance with the requirements of IEC 60601-1-2 in the current ver-sion, the device Aquilex Fluid Control System must be used only with the ac-cessories listed in Chapter Accessory List [▷ 60].

CAUTION!

Possible malfunctions

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

Precautionary measures

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

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

To ensure the basic safety and essential functionality in relation to electromagnetic interference over the life of the device, the device must be restarted after 24 hours so that a diagnostic self-test can be performed. The maintenance intervals indicated in Chapter Maintenance Intervals [▷ 46] must also be observed.

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

12.1 Impact of Mobile and Portable HF Communication Devices

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

12.2 Electrical Connections

Do not touch electrical connections identified with this warning label. Do not establish a connection between these plugs and sockets without first implementing precautionary ESD (electrostatic discharge) measures.

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.

Employees have to be informed about and trained in ESD precautionary measures.

12.3 Guidelines and Manufacturer's Statement – Electromagnetic Emissions

The **Aquilex Fluid Control System** is intended for use in an environment as described below. The user/operator of the **Aquilex Fluid Control System** 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 **Aquilex Fluid Control System** uses HF energy solely for its internal func-tions. Therefore, its 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 **Aquilex Fluid Control System** 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	

12.4 Guidelines and Manufacturer's Statement/Electromagnetic Interference Immunity

The **Aquilex Fluid Control System** is intended for use in an electromagnetic environment as described below. The user/operator of the **Aquilex Fluid Control System** must make sure the device is operated within such an environment.

Electromagnetic interference immunity tests	Test level	Compliance	Electromagnetic environment guidelines
Discharge of static electricity (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	In compliance	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 ± 1 kV for input and output lines	In compliance	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	In compliance	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment.
Blackouts, brownouts, and fluctuations of the power supply according to IEC 61000-4-11	< 5 % U_T* (> 95 % dip in the U_T) for ½ cycle	In compliance	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment. If the user/operator of the system requires the continuation of functionality after power interruptions/disruptions, it is recommended to supply the device with power from an uninterruptible power supply.
	< 40 % U_T (> 60 % dip in the U_T) for 5 cycles		
	< 70 % U_T (> 30 % dip in the U_T) for 25 cycles		
	< 5 % U_T (> 95 % dip in the U_T) for 5 cycles		
Supply frequency magnetic field (50/60 Hz) according to IEC 61000-4-8	3 A/m	In compliance	Magnetic fields of the mains power frequency should comply with the typical values of business and hospital environments.
Conducted HF interference quantities according to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	In compliance	Portable and mobile wireless devices should not be used in closer proximity to the device **Aquilex Fluid Control System** (including cables/lines) than the recommended safety

Electromagnetic interference immunity tests	Test level	Compliance	Electromagnetic environment guidelines
Radiated HF interference quantities according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	In compliance	distance calculated based on the transmitting frequency and the applicable formula. Recommended safety distances: d = 1.2√P for 150 kHz to 80 MHz d = 1.2√P for 80 MHz to 800 MHz d = 2.3√P for 800 MHz to 2.5 GHz With P as the rated output of the transmitter in watts [W] according to the information provided by the manufacturer of the transmitter and **d** as recommended safety distance in meters [m]. The field strength of stationary transmitters for all frequencies tested on site[a] should be lower than the concordance level[b]. Interference is possible in the proximity of devices featuring the following pictograph. 

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

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

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

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

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

12.5 Recommended safety distances between portable and mobile HF telecommunications devices and the Aquilex Fluid Control System

The **Aquilex Fluid Control System** is intended for use in an electromagnetic environment where HF interferences are controlled. The user/operator of the **Aquilex Fluid Control System** can contribute to lowering electromagnetic emissions by complying with the minimum distance between portable and mobile HF telecommunications devices (transmitters) and the **Aquilex Fluid Control System** - depending on the output power of the communication device listed below.

Rated output of the transmitter [W]	Safety distance [m] based on the transmitting frequency		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

The safety distance d in meters [m] for transmitters with a maximum rated output not listed in the table above can be calculated by applying the corresponding formula in the respective column. P is the max. rated output of the transmitter in watts [W] according to the information provided by the manufacturer of the transmitter.

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

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

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13 Accessory List

The following accessories and peripherals are available:

Article	Order No.
Tube set for irrigation, single-use, for **Aquilex Fluid Control System**	AQL-110
Tube set for suction, single-use, for **Aquilex Fluid Control System**	AQL-111
Aquilex Fluid Control System complete tube set (inflow and outflow), disposable, sterilized using ethylene oxide	AQL-112
Tube set for vacuum incl. filter, 30-day use, for **Aquilex Fluid Control System**	AQL-114
Aquilex Fluid Control System container rings	AQL-200
Aquilex Fluid Control System MyoSure® Power Cord	AQL-213
Aquilex Fluid Control System power cord (US)	AQL-215
Aquilex Fluid Control System power cord (UK)	AQL-216
Aquilex Fluid Control System power cord (EU)	AQL-217
Aquilex Fluid Control System spare calibration weight	AQL-218

14 Warranty Information

Hologic warrants to the original purchaser of the **Aquilex Fluid Control System** that it shall be free of defects in material and workmanship when used as intended under normal surgical conditions and in conformance with its instructions for use and maintenance instructions. The obligation of Hologic under this warranty shall be limited to the repair or replacement, each at no charge, at the option of Hologic within one year from the date of purchase. Alternatively, Hologic may elect to repay or credit the original purchaser an amount equal to the purchase price of the defective equipment.

THIS WARRANTY IS MADE IN LIEU OF ALL OTHER WARRANTIES EXPRESSED OR IMPLIED INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR USE AND ALL OTHER OBLIGATIONS AND LIABILITIES ON THE PART OF HOLOGIC. HOLOGIC'S ENTIRE WARRANTY RESPONSIBILITY IS EXPRESSLY LIMITED TO REPAIR OR REPLACEMENT (AT HOLOGIC'S OPTION AND IN THE FORM ORIGINALLY SHIPPED) OF PRODUCT OR CORRECTION OF SERVICE SUBJECT TO ANY CLAIM, OR, AT HOLOGIC'S ELECTION, REPAYMENT OF, OR CREDITING CUSTOMER WITH, AN AMOUNT EQUAL TO THE HOLOGIC PRICE, FEE OR CHARGE THEREFOR. SUCH LIMITED WARRANTY IS GIVEN SOLELY TO THE ORIGINAL PURCHASER AND IS NOT GIVEN TO, NOR MAY IT BE RELIED UPON BY, ANY THIRD PARTY, INCLUDING, WITHOUT LIMITATION, CUSTOMERS OF PURCHASER. THIS WARRANTY IS VOID UPON TRANSFER OF PRODUCT BY PURCHASER TO ANY ENTITY WHO HAS LESS THAN FIFTY (50) PERCENT OWNERSHIP IN THE PRODUCT. THIS WARRANTY SHALL NOT APPLY TO AN AQUILEX SYSTEM OR TO THE AQUILEX FLUID CONTROL SYSTEM WHICH HAS BEEN SUBJECT TO ACCIDENT, NEGLIGENCE, ALTERATION, ABUSE, OR MISUSE, OR THAT HAS BEEN REPAIRED, MOVED, OR ALTERED BY ANYONE OTHER THAN AN AUTHORIZED HOLOGIC SERVICE PERSON. HOLOGIC MAKES NO WARRANTY WHATSOEVER WITH REGARD TO ACCESSORIES OR PARTS USED IN CONJUNCTION WITH THE AQUILEX FLUID CONTROL SYSTEM NOT SUPPLIED AND/OR MANUFACTURED BY HOLOGIC. THE TERM “ORIGINAL PURCHASER”, AS USED IN THE WARRANTY, SHALL BE DEEMED TO MEAN THAT PERSON OR ORGANIZATION AND ITS EMPLOYEES, IF APPLICABLE, TO WHOM THE AQUILEX SYSTEM WAS SOLD BY HOLOGIC.

Technical Support and Product Return Information

Contact Hologic Technical Support if the **Aquilex Fluid Control System** fails to operate as intended. If product is to be returned to Hologic for any reason, Technical Support will issue a Returned Materials Authorization (RMA) number. Return **Aquilex Fluid Control System** according to the instructions provided by Technical Support. Be sure to clean the **Aquilex Fluid Control System** with a clean damp cloth and germicide or isopropyl alcohol before returning it and include all accessories in the box with the returned unit.

Hologic and its distributors and customers in the European Community are required to comply with the Waste Electrical and Electronic Equipment (WEEE) Directive (2012/19/EC). Hologic is dedicated to meeting country specific requirements related to the environmentally sound treatment of its products. Hologic’s objective is to reduce the waste resulting from the disposal of its electrical and electronic equipment. Hologic realizes the benefits of subjecting such WEEE to potential reuse, treatment, recycling or recovery to minimize the amount of hazardous substances entering the environment. Hologic customers in the European Community are responsible for ensuring that medical devices marked with the following symbol, indicating that the WEEE Directive applies, are not placed into a municipal waste system unless authorized to do so by local authorities.

Contact Hologic Technical Support to arrange for proper disposal of the **Aquilex Fluid Control System** in accordance with the WEEE Directive.

Hologic Technical Support

United States and Canada:

Phone: 1 800 442 9892 (toll-free) or 1 508 263 2900

Fax: 1 508 229 2795

Authorized European Representative:

Phone: +32 2 255 17 74

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15 Appendix

15.1 Test log

Date	Result	Comment	Signature

15.2 Return form

Please fill out this form when returning the device:

Name of owner:

Sales partner:

Address of person returning unit:

Street:	**House number:**

ZIP/Postal code:	**City:**

Country:

IMPORTANT!

Serial number (see identification plate):

Device type:

Description of defect:

Contact	**Signature**	**Date**

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Glossary

Contamination Soiling

Pollution of rooms, water, foods, objects, or persons due to microorganisms or radioactive materials, biological poisons or chemical agents

Contraindication

Circumstances (e.g., age, pregnancy, certain illness, medication) prohibiting the use of an otherwise indicated measure (contrary to an indication

Embolism

Sudden capillary blockage due to embolus

Flow rate

Quantity (in ml) of irrigation fluid flowing through tube set per minute

Hypervolemia

An increased volume of circulating blood

Hyponatremia

A low concentration (< 130 mmol/l) of sodium in the patient's bloodstream

Hysteroscope

Endoscope to look inside the uterus

Intrauterine pressure

Pressure in uterine cavity

Intravasation

Entry of foreign matter into a blood vessel

Saline

Isotonic saline solution, i.e., one liter (l) contains 9.0 grams of sodium chloride.

TUR syndrome

Transurethral Resection Syndrome

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