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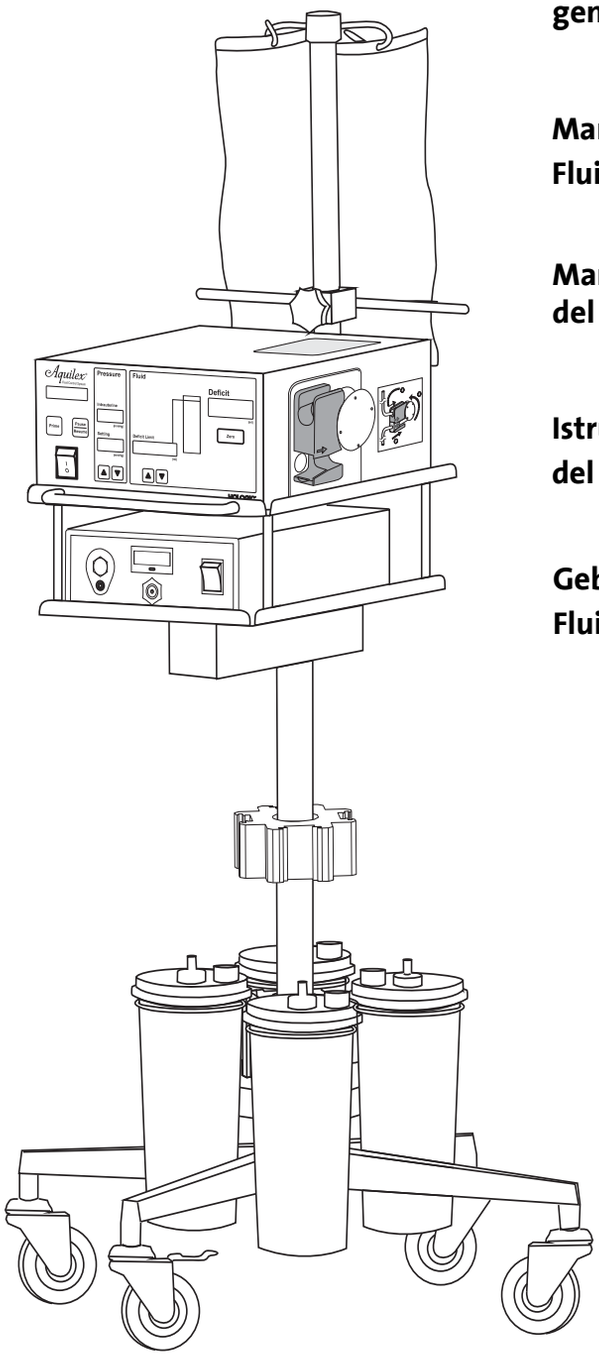
Aquilex®
Fluid Control System



Instructions for Use and Fluid Control System Operator's Manual EN

Gebrauchs- und Bedienungsanweisungen für Fluid Control System DE

Manuel d'instruction et d'utilisation du Fluid Control System FR

Manual de Instrucciones y de Utilización del Fluid Control System ES

Istruzioni per l'uso e istruzioni operative del Fluid Control System IT

Gebruiks- en bedieningsinstructies voor Fluid Control System NL

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CE 0197

CE marking according to Directive 93/42/EEC
CE-Kennzeichnung gemäß Richtlinie 93/42/CEE
Marquage CE conforme à la directive 93/42/CEE
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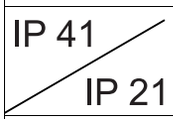
MAN-02570-4320 Rev.009
Model: H112/1201048/10000011593 07/2016-04/endefresitnl/marik

	Read Instructions Before Use	Bedienungsanleitung befolgen	Lire la documentation jointe !	Observe la documentación adjunta	Leggere la documentazione allegata	Lees de begeleidende documentatie
	BF Type Equipment	System des Typs BF	Système de type BF	Sistema del tipo BF	Sistema tipo BF	Syteem van het type BF
	Symbol for Potential Equalization	Symbol für Potentialausgleich	Symbole pour la fiche équipotentielle	Símbolo para la conexión equipotencial	Simbolo per il collegamento equipotenziale	Symbool voor de potentiaalvereffening
	Degrees of Protection Provided by Enclosures (IP-Code)	Gehäuseschutzklasse (IP-Code)	Degrés de protection procurés parles enveloppes (Code IP)	Grado de protección proporcionado por los envolventes (Código IP)	Grado di protezione degli involucri (Codice IP)	Beschermingsklasse (IP-code) behuizing
	Alternating Current	Wechselstrom	Courant alternatif	Corriente alterna	Corrente alternata	Wisselstroom
	Service	Service	Service	Servicio	Servizio	Service
REF	Order Number	Bestellnummer	Numéro de commande	Número de pedido	Numero di ordinazione	Bestelnummer
	Do not Reuse	Nicht zur Wiederverwendung	Usage unique	No reutilizable	Non riutilizzabile	Niet voor hergebruik
STERILE EO	Sterilized using Ethylene Oxide	Sterilisiert mit Ethylenoxid	Stérilisés à l'éthylène oxide	Esterilizado con óxido de etileno	Sterilizzato con ossido di etilene	Sterilisatie met ethyleenoxide
LOT	Lot Number	Chargenbezeichnung	Numéro de lot	Número de lote	Numero di lotto	Chargenummer
SN	Serial Number	Seriennummer	Numéro de série	Número de serie	Numero di serie	Serienummer
	Date of Manufacture	Herstellungsdatum	Date de fabrication	Fecha de fabricación	Data di produzione	Fabricagedatum
	Expiration Date	Verwendbar bis	Date limite d'utilisation	Utilizable hasta	Da utilizzarsi entro il	Te gebruiken tot
Pieces	Pieces	Stück	Unités	Unidades	Pezzi	Eenheden
QTY	Quantity	Menge	Quantité	Cantidad	Quantità	Hoeveelheid
	Not Made with Natural Rubber Latex	Nicht aus Naturkautschuklatex hergestellt	Ce produit ne contient pas de latex de caoutchouc naturel	Producto no producido con látex de caucho natural	Non prodotto in lattice di caucciù naturale	Niet vervaardigd van natuurlijke rubberlatex

EN DE FR ES IT NL

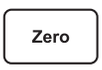
	Not Made with Phthalates	Dieses Produkt enthält kein Diethylhexylphthalat (DEHP)	Ce produit ne contient pas du diethylhexyl phtalate (DEHP)	Este producto no contiene dietilhexilftalato (DEHP)	Questo prodotto non contiene diethylhexylftalato (DEHP)	Dit product bevat geen di-ethylftalaat (DEHP)
	Made with Phthalates	Dieses Produkt enthält Diethylhexylphthalat (DEHP)	Ce produit contient du diethylhexyl phtalate (DEHP)	Este producto contiene dietilhexilftalato (DEHP)	Questo prodotto contiene diethylhexylftalato (DEHP)	Dit product bevat di-ethylftalaat (DEHP
	Do Not Get Wet	Vor Nässe schützen	Protéger de l'humidité	Proteger contra la humedad	Proteggere dall'umidità	Beschermen tegen vocht
	Top-Bottom	Oben-Unten	Haut-bas	Arriba-abajo	Alto - basso	Boven-Beneden
	Fragile	Zerbrechlich	Fragile	Frágil	Fragile	Breekbaar
	Waste Management	Entsorgung	Élimination des déchets	Gestión de residuos	Smaltimento	Verwijdering
	Reset Deficit Button	Taste Reset Deficit	Touche de remise à zéro du déficit	Tecla de reseteo del déficit	Tasto di reset per deficit	Resettoets voor deficit
	Prime Button	Taste Prime	Touche Prime	Tecla Prime	Tasto Prime	Toets Prime
	Pause/Resume Button	Taste Pause/Resume	Touche Pause/ Resume	Tecla Pause/ Resume	Tasto Pause/ Resume	Toets Pause/ Resume
	Increase	Erhöhen	Croissant	Aumento	Crescente	Verhogen
	Decrease	Verringern	Décroissant	Disminución	Decrescente	Verlagen
	Fluid Bags	Flüssigkeitsbeutel	Poche de liquide	Bolsa de líquido	Sacche di liquido	Vloeistofzak
	Non-Sterile	Nicht steril	Non stérile	No estéril	Non è sterile	Niet steriel
	Connection for Canister Scale	Anschluss Containewaage	Raccord pour unité de pesage à container	Conexión para la balanza de cubetas	Attacco per unità di pesatura contenitori	Aansluiting reservoirweegsysteem
	Data Transfer	Datenübertragung	Transmission de données	Transmisión de datos	Trasmissione dati	Datatransmissie
	Do not push!	Schieben verboten	Interdit de pousser!	¡No empujar!	Non spingere!	Duwen verboden
	General Warning Sign	Warnzeichen für allgemeine Gefahr	Signalisation générale de danger	Señal de advertencia general	Segnale generale di pericolo	Waarschuwingsteken voor algemeen gevaar
	SGS USTC Certification Mark	SGS USTC Produktzertifizierung	Marque de certification SGS USTC	Marca de certificación SGS USTC	Marquio de certificazione SGS USTC	Kwaliteitsmerk SGS USTC

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Table of contents

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1 Important User Notes

Read the manual carefully and become familiar with the operation and function of the Aquilex® Fluid Control System (Aquilex System) and the accessories before use during surgical procedures. Non-observance of the instructions listed in this manual can lead to:

- life-threatening injuries to the patient,
- severe injuries of the surgical team, nursing staff or service personnel, or
- damage or malfunction of the system 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 the product.

Please note

The words WARNING, CAUTION, and NOTE carry special meanings. Read these sections with special attention.

WARNING!
Warnings indicate risks to the safety of the patient or user. Failure to follow warnings may result in injury to the patient or user.

CAUTION!
Warnings indicate risks to the equipment. Failure to follow cautions may result in damage to the system.

NOTE!
Notes provide special information to clarify instructions or present additional information.

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2 Safety Information

Federal Law (only for U.S. market)

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

Exclusion of liability

Hologic is not liable for direct or consequential damage and the warranty is null and void if:

- the system and/or the accessories are improperly used, prepared, or maintained,
- the instructions in the manual are not adhered to,
- non-authorized persons perform repairs, adjustments, or alterations on or to the system or accessories,
- non-authorized persons open the pump housing,
- 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.

Authorized service technician

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

Intended use

The system may be used only as intended.

Care and maintenance

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

Waste management

In the European Community, this symbol indicates that the waste of electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately instead. Please contact Hologic or an accordingly authorized disposal or waste management company for further information.

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3 Purpose of the System

Indication for use

Aquilex® Fluid Control System is intended to provide liquid distension of the uterus during diagnostic and operative hysteroscopy, 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 operators 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 Warnings

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

WARNING!
Intrauterine distention is usually possible with pressure values between 35 to 70 mmHg. A pressure above 75 to 80 mmHg is required only in rare cases or if the patient has an excessively high blood pressure.

WARNING!
When using the cart/scale, follow the exact operating instructions in this manual.

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 hystero-

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scopic 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 10, Technical Data). 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. If a low viscosity liquid distention medium is used, intrauterine instillation exceeding 2 liters should be followed with great care due to the possibility of fluid overload. If a high viscosity fluid (e. g. Hyskon) is used, the use of more than 500 ml should be followed with great care. See labeling for Hyskon for additional information.

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

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!
Idiosyncratic reactions
In rare cases, idiosyncratic reactions, including:
- **intravascular coagulopathy**
- **allergic reaction including anaphylaxis**

may occur while performing hysteroscopy if a liquid distention medium is used. Specifically, idiosynatric anaphylactoid reactions have been reported when using Hyskon as an irrigation fluid during hysteroscopy. These should be managed like any allergic reaction.

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!
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!
The system is only intended for use with flexible fluid containers. 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!
Filling the tubing with irrigation fluid and resetting the deficit display to zero are to be done at the physician’s discretion.

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WARNING!
Place the system in such a way as to allow for easy visualization of the display values, system functions, and access to the control elements.

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

WARNING!
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!
Technique and procedures
Only the physician can evaluate the clinical factors involved with each patient and determine if the use of this system is indicated. The physician must determine the specific technique and procedure that will accomplish the desired clinical outcome.

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 Aquilex accessories.

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

WARNING!
No modification of this equipment is allowed.

WARNING!
To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

WARNING!
Professional qualification
This manual does not include descriptions or instructions for surgical procedures/techniques. It is also not suitable for training physicians in the use of surgical techniques. Medical instruments and systems may be used only by physicians or medical assistants with the appropriate technical/medical qualification 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!
Replacement system 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!
Cleaning the system
Do not sterilize the system.

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

WARNING!
System defect
If a system defect is suspected or confirmed, do not use the system. Ensure the system will no longer be used until a qualified service technician conducts the appropriate tests and repairs.

WARNING!
Replacing fuse
Replace the fuse only with a fuse of the same type and rating (see Chapter 10, Technical Data).

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

3.1.2 Precautions

CAUTION!
Federal Law (only for U.S. market)
Federal law restricts this device to sale by or on the order of a physician.

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CAUTION!
When using the Aquilex System with MyoSure® or other morcellation systems, the combination of low set pressures and high 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 high distension pressures, the deactivation of the MyoSure® or other morcellator system can lead to pressure spikes that can exceed 150 mmHg. These situations may occur for a short time as the system automatically adjusts the flow rate to return to the set intrauterine pressure.

CAUTION!
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 EC 60601-2-18 and ISO 8600.

CAUTION!
Electrical Interference: (See Chapter 11, Guidelines and manufacturer's statement - electromagnetic compatibility). Electrical interference with other devices or instruments was practically eliminated 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!
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.

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 preset to a range between 40 and 150 mmHg. The maximun 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.

4 Initial System Set-up

Always check all parts and accessories of the system when performing initial set-up. If the system should show obvious defects, contact Hologic Technical Support (Chapter 13, Warranty Information).

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 10, Technical Data.

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

4.1 Preparing the System For Use

Connection to the wall outlet

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

Ensure the connection data and technical specifications of the power supply comply with DIN VDE or national requirements. The wall outlet power supply cord must be plugged into a properly installed safety wall plug (see DIN VDE 0107). Read the device label located in rear of pump to determine the operating voltage of the system.

Grounding contact

The power connection must be equipped with a grounding contact. Use the Aquilex power cord to establish a connection between the wall outlet and the power cord connection located in the rear of the system.

Only for U.S. operators

Use only a certified (UL-listed), removable power cord, type SJT, minimal 18 AWG, 3 leads. The plug connectors must comply with NEMA 5-15 or IEC 320/CEE22. Grounding will only be reliable if the equipment is connected to a corresponding hospital grade outlet.

Potential equalization

Integrate the system into the potential equalization system as specified by local safety rules and 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.

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4.2 System Set-up

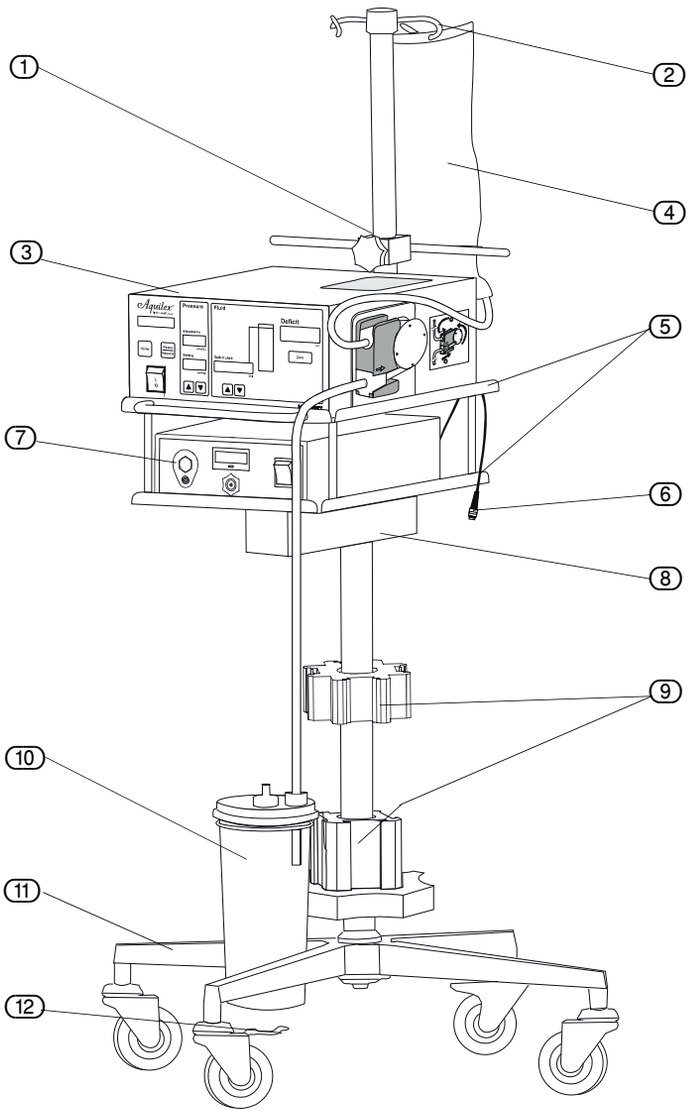

Figure 4-1 Set-up of Aquilex Fluid Control System

1. Cart
2. Bag holder
3. Pump
4. Fluid bag
5. Trays
6. Scale cable
7. MyoSure® Control Unit
8. Scale
9. Canister holders
10. Canister
11. Roller base
12. Locking foot brake

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

Box 1 contains:

- Pump
- Manual
- Wall power cord
- Aquilex vacuum tube set (low and high vacuum)
- MyoSure® Control Unit power cord

Box 2 contains:

- Cart/scale
- Canister rings

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5 System Operation

5.1 Front of Pump

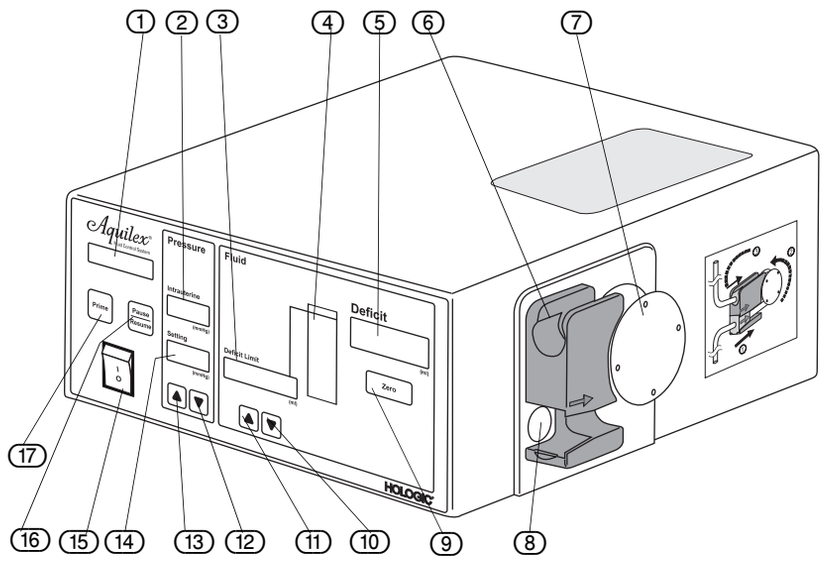

Fig. 5-1 Front of Pump

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 pump.

5.2 Rear of Pump

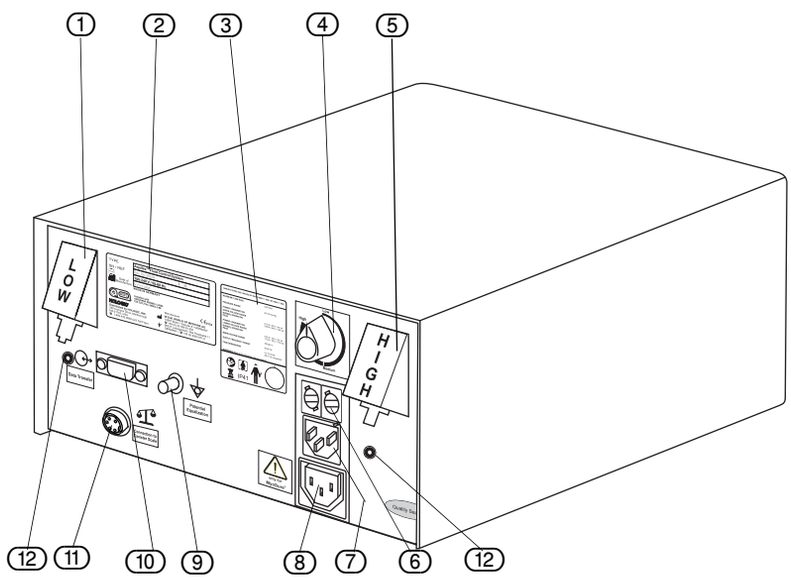

Figure 5-2 Rear of Pump

1. Low vacuum port (white)
2. Product ID label
3. Device performance data
4. Adjustment dial for high vacuum
5. High vacuum port (green)
6. Fuse holder(s)
7. Power cord connection
8. MyoSure® Control Unit Power Connection
9. Potential equalization connector
10. Service interface
11. Scale connection
12. Exhaust ports

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

CAUTION!
Any devices to be connected via the interface have to comply with EN 60950.

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5.3 Cart/scale

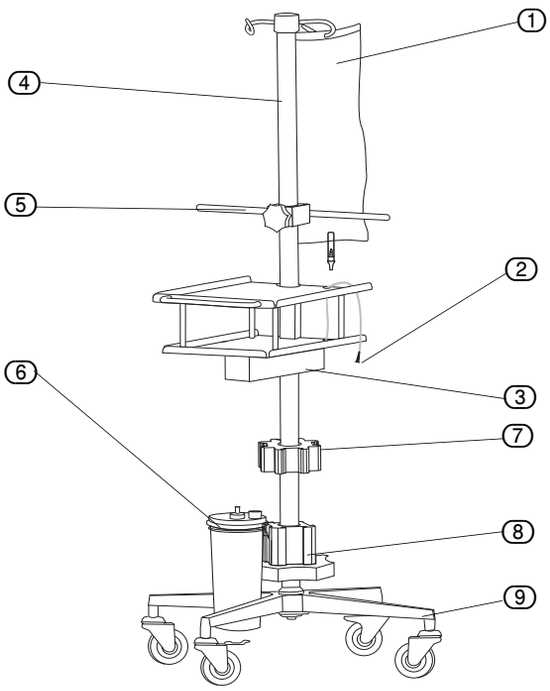


Figure 5-3 Cart/Scale

1. Fluid bag
2. Scale cable
3. Scale
4. Pole with bag hooks
5. Bag deflector
6. Canister
7. Upper canister holder (Serres, Medela, Baxter, Baxter flex)
8. Lower canister holder (Abbott, Bemis, Medi-Vac, DeRoyal)
9. Roller base

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

1. Remove the cart/scale from the cardboard shipper box.
2. Extend the pole to stop position.
3. Extend the bag deflector to stop position.
4. Remove the pump and the power cords from the first cardboard box.
5. Install canister rings (included in the second box) on upper (7) or lower (8) canister holders, in accordance with type of canister.
6. Connect the wall power cord to the male outlet at the rear of the pump ((7) Figure 5-2, Rear of Pump, page 13) and a grounded safety wall outlet.
7. Connect the scale to the pump by connecting the scale cable ((2) Figure 5-3, Cart/Scale) to the scale connection ((11) Figure 5-2, Rear of Pump).
8. Use the enclosed MyoSure Control Unit power cord to connect the pump ((8) Figure 5-2, Rear of Pump) with the MyoSure® Control Unit.

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

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 10, Technical Data). 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.

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

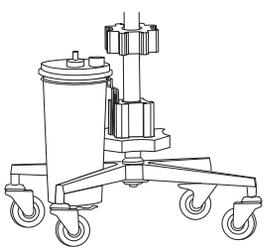
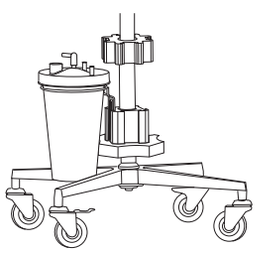
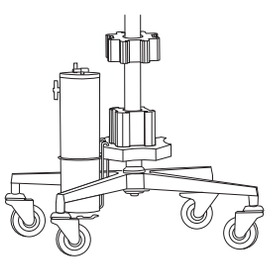
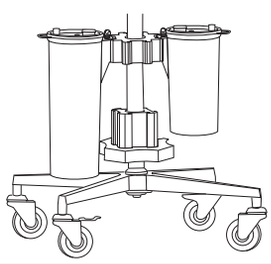
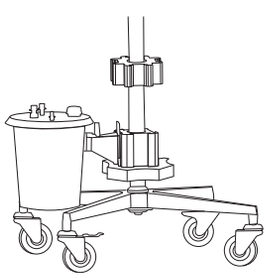
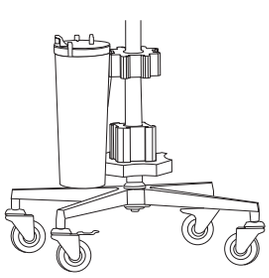
The scale can be loaded with a weight of up to 65 lbs (~30 kg). Weight above this value triggers the **Scale Overloaded/Check Scale** message. Three audible warning tones are emitted (See Chapter 9, Error and Warning Messages.)

CAUTION!
Ensure canisters hang freely and are not supported or in contact with anything; otherwise, the deficit calculated is inaccurate.

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

5.3.1 Scale Set-up

The scale can be equipped with different makes of canisters.

Bemis®3 liters		DeRoyal®	
Abbott 2 liters		Serres 2 & 3 liters	
Medi-Vac® 3 liters		Medela 3 liters	

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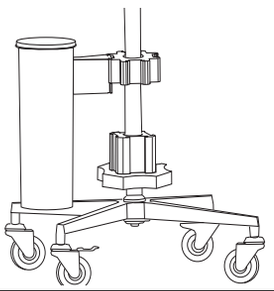
Medi-Vac Flex Advantage 3000 cc			

NOTE!
Ensure canisters are positioned properly in the respective holders.

NOTE!
Only use canisters with overflow protection.

5.3.2 Connecting the Vacuum Tubing

CAUTION!
When using the Aquilex System with MyoSure® or other morcellation systems, the combination of low set pressures and high 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 high distension pressures, the deactivation of the MyoSure® or other morcellator system can lead to pressure spikes that can exceed 150 mmHg. These situations may occur for a short time as the system automatically adjusts the flow rate to return to the set intrauterine pressure.

1. Connect vacuum to the suction containers (using vacuum tube with hygiene filter). This is done once during the initial set-up of the system, not prior to each procedure.
   - **Low Vacuum Side (White)**

   ▶ Connect vacuum tube with white connectors to low vacuum port ① Figure 5-4. This vacuum pump has a fixed vacuum pressure (~ 225 mmHg).

   ▶ Use tandem tube (⑤ Figure 5-4, Low vacuum tube) when two canisters are serially connected to the same vacuum port.

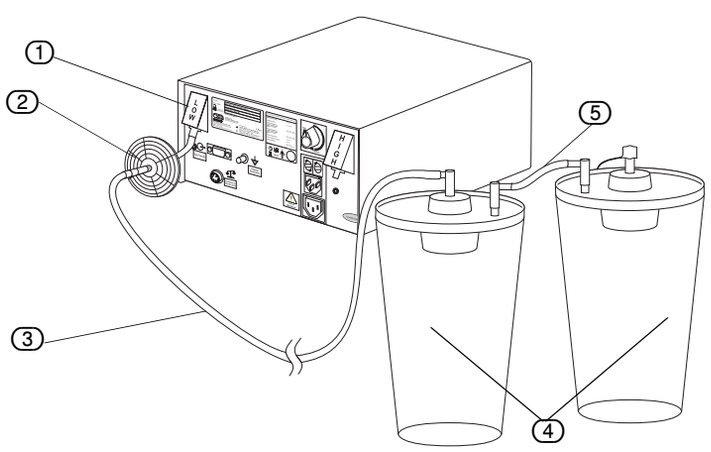


Figure 5-4 Low vacuum tube

① Low vacuum port (white)
② Hygiene filter
③ Vacuum tube
④ Canisters
⑤ Tandem tube

   - **High Vacuum Side (Green)**

   ▶ Connect vacuum tube set with the green connectors to the high vacuum port (green) ⑧ in Figure 5-5. This vacuum can be adjusted to a maximum

500 mmHg using adjustment dial.

▶ Use tandem tube (⑫ Figure 5-5, High vacuum tube) when two canisters are serially connected to the same vacuum port.

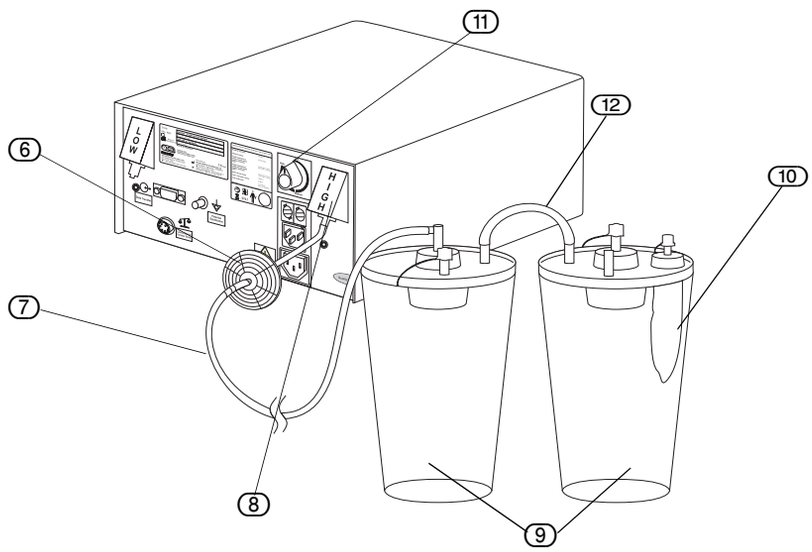
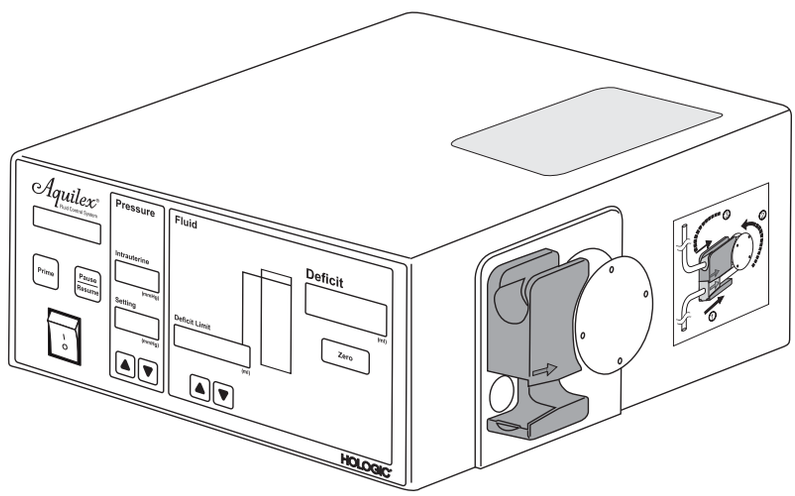


Figure 5-5 High vacuum tube

⑥ Hygiene filter
⑦ Vacuum tube (green connectors)
⑧ High vacuum port (green)
⑨ Canisters
⑩ Tissue trap (MyoSure® procedures)
⑪ Adjustment dial
⑫ Tandem tube

5.4 Turning On the Aquilex System



1. Press the ON/OFF switch. The displays and indicators light up and system turns on.
2. The system now performs a self-diagnostic test.
3. If a tube set is in the inflow tube holder when the pump switches on, the **pump display** (Fig. 5-1, Front of Pump ①) shows **Remove Tube Set**. The self-test resumes once the tube set is removed from the roller wheel.

   If the system self-test is unsuccessful, the corresponding error messages are displayed. (See Chapter 9, Error and Warning Messages).

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

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

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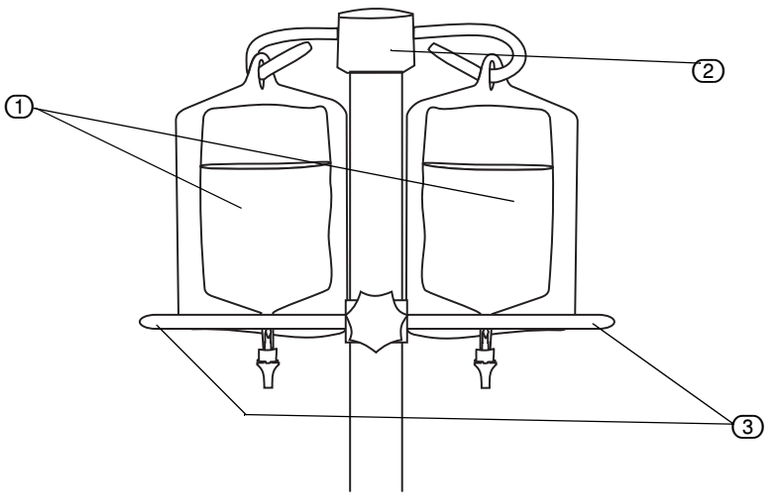
5.5 Hanging the Fluid Bags

Figure 5-6 Fluid bag suspension

① Fluid bags
② Pole with bag hooks
③ Bag deflector



WARNING!
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!
The system is only intended for use with flexible fluid containers. 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 disposable inflow and outflow tube sets.

Tube set recognition technology

Each inflow tube set is equipped with tube set recognition technology. An RFID transponder detects the type of tubing, whether it has been used, and its reliability automatically. The pump display indicates this information. This eliminates accidental reuse of tubing on more than one patient (see Chapter 5.7, Tubing Overview).

WARNING!
Reprocessing of sterile disposable products
Reuse of inflow or outflow tubing 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 single-use inflow or outflow tubing.

NOTE!
Comply with hygiene rules when disposing of tubing, fluid collected, and the canisters.

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5.7 Tubing Overview

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

Part Number	Description
AQL-110	Aquilex Fluid Control System Inflow Tube Set
AQL-111	Aquilex Fluid Control System Outflow Tube Set
AQL-112	Complete tube set (Inflow and Outflow) disposable, sterile
AQL-114	Aquilex Fluid Control System High and Low Vacuum Tube Set: re-usable, non-sterile

Table 5-1

5.8 Connecting the Outflow Tubing

CAUTION!
When using the Aquilex System with MyoSure® or other morcellation systems, the combination of low set pressures and high 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 high distension pressures, the deactivation of the MyoSure® or other morcellator system can lead to pressure spikes that can exceed 150 mmHg. These situations may occur for a short time as the system automatically adjusts the flow rate to return to the set intrauterine pressure.

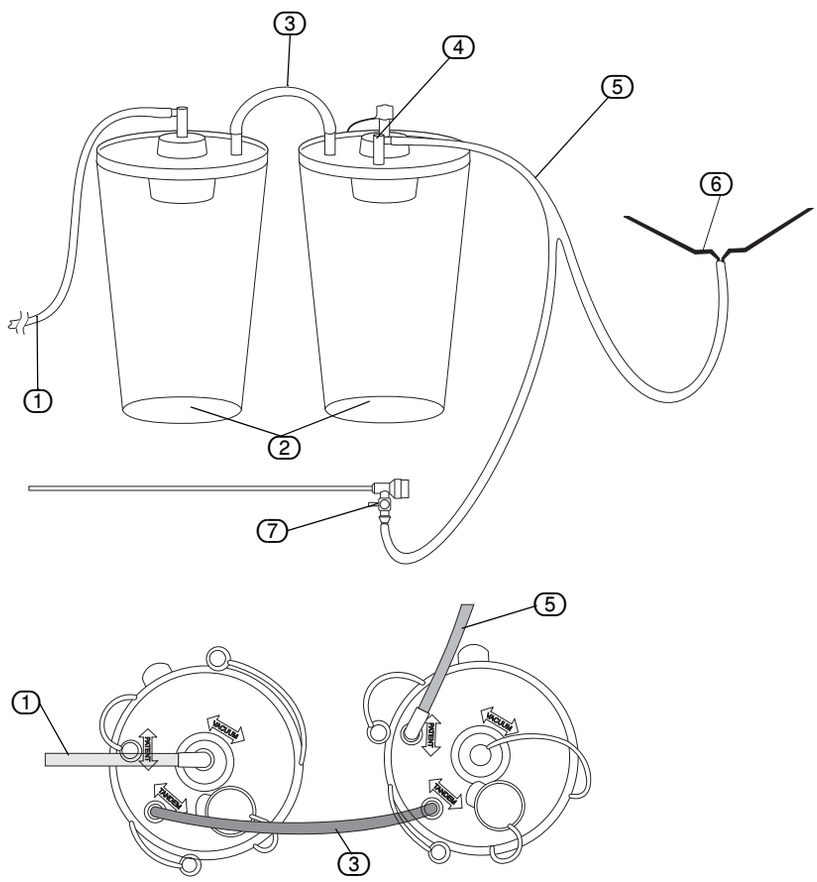

Figure 5-7 Outflow Tubing

① To low vacuum port (white)
② Canisters
③ Tandem tube
④ Patient port
⑤ Outflow tube set
⑥ Drape
⑦ Removable Outflow Channel (MyoSure®) or hysteroscope outflow sheath stopcock

Using Low Vacuum configuration of Figure 5-4, connect outflow tubing (Y-tube) to patient port ④ of second canister. Yellow flexible connector attaches to drape ⑥. Yellow luer fitting connects to stopcock ⑦ of Removable Outflow

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Channel (MyoSure®) or hysteroscope outflow sheath.

5.8.1 MyoSure® Outflow Connection

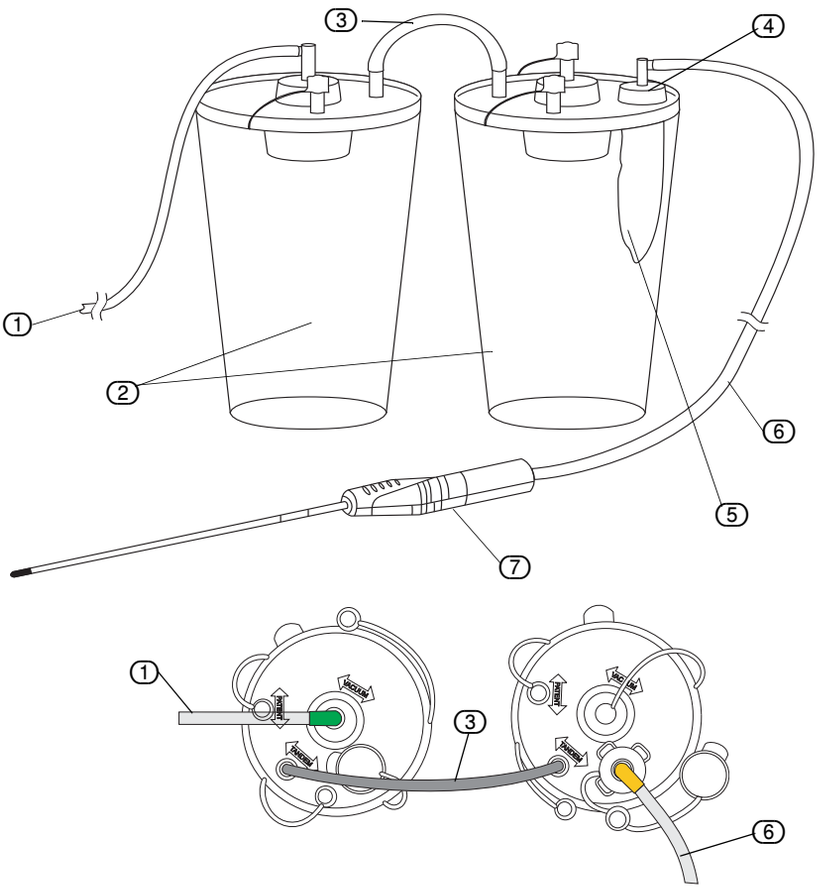

Figure 5-8 MyoSure®Connection

① To High Vacuum port (green)
② Canisters
③ Tandem tube
④ Specimen tissue port
⑤ Tissue trap
⑥ MyoSure® vacuum tube
⑦ MyoSure® Tissue Removal Device (TRD)

If intrauterine pathology is identified, the MyoSure® TRD can be connected to the Aquilex System as shown in Figure 5-8. The MyoSure® vacuum tube ⑥ is connected to the tissue trap ⑤ located in the second canister.

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5.9 Inserting the Inflow Tube Set

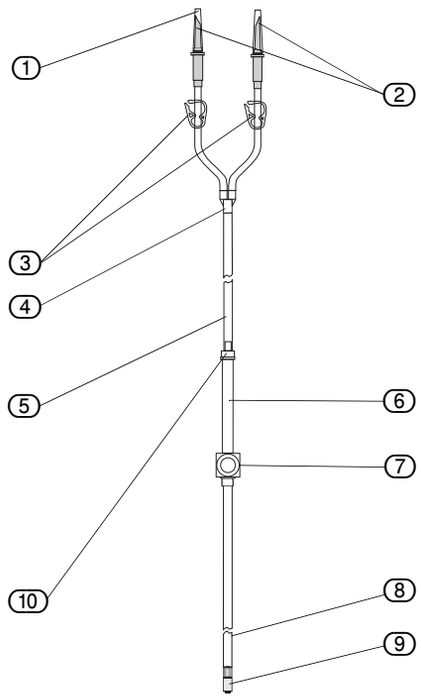

Figure 5-9 Tube set elements

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

(See Figure 5-9, Tube set elements) The inflow tube set consists of three tube sections, a Y-connector (4) and two bag spikes (2). The three tube sections are: roller wheel section (6), inflow section (5), and hysteroscope section (8).The bag spikes (2) are used to connect the tube sections to the bags.

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

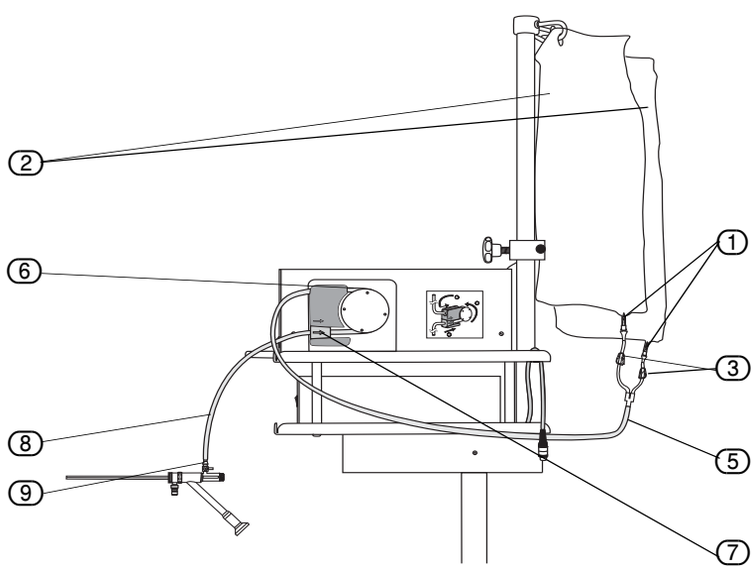

Figure 5-10 Inserting the tube set

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

1. Inflow tube set - To be carried out by non-sterile nurse:

Open outer packaging

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

2. To be carried out by sterile nurse:

Connect to hysteroscope

- ▶ Keep the blue Luer lock connector (9) in the sterile area and hand the tube end with the bag spikes (1) to the non-sterile nurse.

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▶ Connect the blue Luer lock connector (9) with the hysteroscope inflow stopcock. Open stopcock.

Insert tube set

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

▶ Ensure system is turned on.

▶ Close the clamps (3) on the inflow tubing below the bag spikes (1).

▶ Insert the inflow tube set into the inflow tube holder.
Insertion of the roller wheel tube is depicted in Figure 5-11, Positioning the roller wheel tube.

▶ Carefully insert the pressure chamber (7) into the lower notch of the inflow tube holder (12) until you feel resistance. Align pressure chamber and inflow tube holder using arrows (see Figure 5-11, Positioning the roller wheel tube).

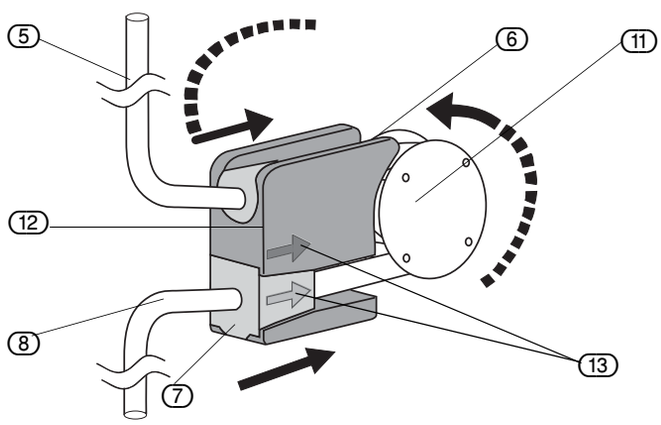
▶ When inserting the roller wheel tube, ensure not to damage the membrane of the pressure chamber. Insert the pressure chamber (7) only if chamber is not pressurized.

▶ Place the roller wheel tube (6) around the roller wheel (11).

Connect the fluid bags

▶ When connecting or removing the tube to or from the irrigation fluid bags, grasp the bag 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.

Figure 5-11 Positioning the roller wheel tube



(5) Irrigation tube
(6) Roller wheel tube
(7) Pressure chamber
(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. Use the ▲ and ▼ buttons (Fig. 5-1, Front of Pump). The pressure setting can be adjusted to between 40 to 150 mmHg in steps of 5 mmHg. The intrauterine pressure is shown on the intrauterine pressure display (2).

Safety threshold

When scrolling with the ▲ button (Fig. 5-1, Front of Pump) if the safety threshold of 100 mmHg is reached, an audible tone is emitted. Release the ▲ button for one second and scroll again to set higher values up to 150 mmHg.

CAUTION!
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 Setting the Deficit Limit

Deficit limit setting

The deficit limit can be adjusted while the system is in operation. Use the ▲ and ▼ buttons (Fig. 5-1, Front of Pump). The deficit limit can be adjusted to between 600 to 2500 ml in increments of 100 ml. The deficit limit is shown on the deficit limit display (3). The deficit meter is designed to help the user track the deficit volume. The color of the deficit meter changes as the deficit limit is approached. The user set deficit limit is marked with a red LED on the top of the deficit meter.

During the operation as the actual deficit climbs, the LEDs will light up sequentially representing the actual deficit volume until the deficit limit is reached. (See Section **Deficit Limit** in Chapter 6, Safety functions).

5.12 Using the Pump during Operation

- ▶ Open bag clamps (③ Figure 5-10).
- ▶ Fully open hysteroscope inflow stopcock.
- ▶ Press the **Prime** button (⑰ Fig. 5-1).
- ▶ Pump will run for approximately 20 seconds to purge air from tubing and run the Automatic Lumen Calibration.
- ▶ Pump will display **Calibration Running.**

Automatic lumen calibration

The pump is equipped with an automatic lumen calibration functionality. 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. In order to overcome this resistance the pump allows pressure of up to 80 mmHg during calibration. This is indicated in the Intrauterine Pressure display. In case calibration fails due to high resistance it will be repeated allowing pressure of up to 150 mmHg. If it still cannot be completed the pump will show **Prime Fail -Open Stopcock, Clamps**.

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

- ▶ Once Automatic Lumen Calibration is completed, pump will beep three times. The pump display will show **Prime Successful Close Stopcock** for 5 secs followed by **System Operating.**
- ▶ Close hysteroscope inflow stopcock to stop fluid flow. Once all fluid has been removed from the drape, zero the deficit display.

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

NOTE!
Automatic lumen calibration has to be performed each time a different hysteroscope is used during the procedure by pressing the Prime button.

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 system operation is complete, close the hysteroscope inflow stopcock.
- ▶ Wait until the entire fluid volume in the under-buttock drape and the tube set has been has been collected into the canisters.
- ▶ Press the **Pause/Resume** button.
- ▶ Record the deficit volume on the deficit display. This is the total fluid volume that was absorbed by the patient.

WARNING!
Device error: Do not use the Aquilex System if a defect is suspected or detected during the function check. This also applies to obvious and visible defects, especially defects and damage of the power plug and power cord.

5.13 Changing Canisters during Procedure

Changing canisters during the procedure

- ▶ Pause the pump by pressing **Pause/Resume** button. This locks the fluid deficit display number.
- ▶ Remove desired canisters and install new canisters.

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- ▶ Reconnect canister tubing.
- ▶ Press **Pause/Resume** button to resume procedure.

CAUTION!

If a filled canister is removed from scale without activating the " Pause/Resume" button, the message "Container Change, Press Resume" will appear, the pump will stop immediately and the deficit display locked to insure an accurate deficit count is maintained. Once the canister exchange is completed, the System is re-started by pressing "Pause/Resume" button.

5.14 Total Volume Displayed

Total volume displayed

If a manual check of fluid deficit is desired, the total fluid volume can be obtained by simultaneously pressing and holding both the up and down arrows (⑩ & ⑪ in Fig. 5-1, Front of Pump) underneath the Fluid Deficit Limit display (③ in Fig. 5-1, Front of Pump). The number in the Deficit Display is the total fluid volume in ml. Once one or both of these buttons is released, the Deficit Display will return to the Fluid Deficit value.

5.15 Turning System Off

Shut down

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

WARNING!

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.

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6 Safety functions

The electronic components continuously monitor the proper function of the system. System malfunctions are indicated with audible warning tones, error messages, and/or the blocking of system functions. A table listing a summary of possible error and warning messages is provided in Chapter 9, Error and Warning Messages.

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 pressure reduction function is activated. The roller wheel will move forward or backward a few times during the pressure reduction process. If the pressure cannot be reduced, the message **Overpressure/ Open Stopcock** is displayed and three audible tones are emitted.

Intrauterine pressure > 150 mmHg

The message **Maximum Pressure** is displayed and the pump will emit 3 audible tones once the intrauterine pressure exceeds 150 mmHg. The maximum permissible pressure has now been reached.

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. Three short continuous audible warning tones are continuously emitted until the pressure is reduced. Once the intrauterine pressure falls below 200 mmHg, the audible alarm stops and the pump wheel resumes turning automatically.

Check Tube Set Installation

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

Errors of the pressure measuring system

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

Scale overload

If the maximum permissible weight of the scale is exceeded (65 lbs/30 kg), a continuous audible tone is 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

If a container is removed from the scale while the pump is being operated, three short continuous warning tones are emitted and **Container Change, Press Resume** is displayed. The audible warning tone stops once the initial status is restored or the **Pause/Resume** button is pressed

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

Each additional deficit increase by 100 ml above the selected deficit threshold triggers 3 audible warning tones that are repeated while the pump continues to operate. The message **Deficit Limit Exceeded** is displayed.

Deficit rate >300 ml/min

When the deficit rate exceeds 300 ml/min, three audible warning tones 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

Five short audible tones are emitted and **Motor Error** is displayed. It is possible that errors can occur in the start up sequence prior to the enabling of the Pump Display. In this situation, the Pump Display will remain blank.

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7 Care and Maintenance

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.

7.1 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.

NOTE!
Do not sterilize the system.

7.2 Authorized Service Technician Maintenance

Two-year maintenance interval

It is recommended that an authorized service technician inspects and services the system at appropriate intervals to ensure safety and functionality. The **minimum** service interval is two years, depending on frequency and duration of use. If this interval is not maintained, the manufacturer does not assume any liability for the functional safety of the system. A sticker located on the rear panel of the system contains the latest date for the next service or maintenance check.

Certification

Ask the service technician for a certificate after he or she has inspected the system or performed any service tasks. This certificate must list:

- type and scope of service,
- date of service,
- name of company performing service
- as well as signature.

7.3 Replacing the Fuse

CAUTION!
Before replacing the fuse, check the values of the fuse to be inserted according to Chapter 10, Technical Data.

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

- one or more of the pump displays does not light up,
- the system does not function.

Check whether

- the power cord is properly connected to the power cord connection (Figure 5.2) 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 Figure 7-1, 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 Chapter 10, Technical Data).
8. Insert the fuse holders.
9. Reconnect the power cord and connect the pump to the wall outlet.

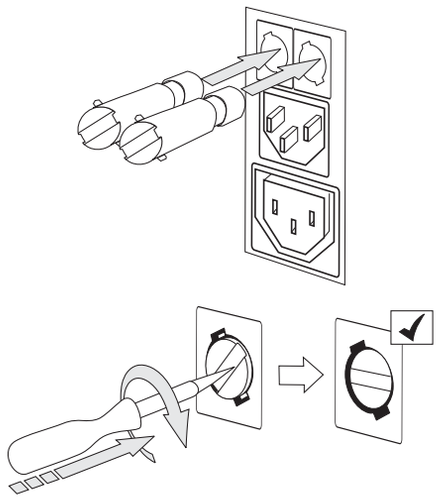

Figure 7-1 Opening the fuse holder

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8 Annual Inspection

Manufacturer's specification

The manufacturer stipulates that qualified personnel or biomedical technicians must regularly test the system to assess its functionality and technical safety. These inspections must be carried out annually. Regular inspections will assist in early detection of possible malfunctions. This helps maintain the system and increases its safety and service life.

Inspection tests

The following tests are designed specifically for trained personnel or a biomedical technicians. System operation, functionality, and serviceability are easily checked. Each test conducted must be documented by signing and dating the test log.

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

8.1 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.

8.2 Basic Function Tests

The basic function tests check displays, buttons, and general performance of the system. For this test, you will need:

- Aquilex inflow tube set
- Fluid bags
- Measuring container with marked scale (1 Liter)
- Stop-watch
- Precision weight (e.g., Ohaus 1 kg 49016-11 or 41000-00 or equivalent).

8.3 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. **Scale Test** is shown on the pump display.
4. ~~Place a precision weight on the scale (500 g - 2000 g)~~
5. The fluid deficit limit display will display the weight.
6. The acceptable tolerance is ±20 g.
7. If a greater difference is detected, a service technician has to re-calibrate the scale.
8. Remove weight from scale.
9. Press the **Pause/Resume** button to conclude this test.

Record results in the test log in Section 15.1. Test is successful if results fall within acceptable tolerance limits.

8.4 Flow Rate Test

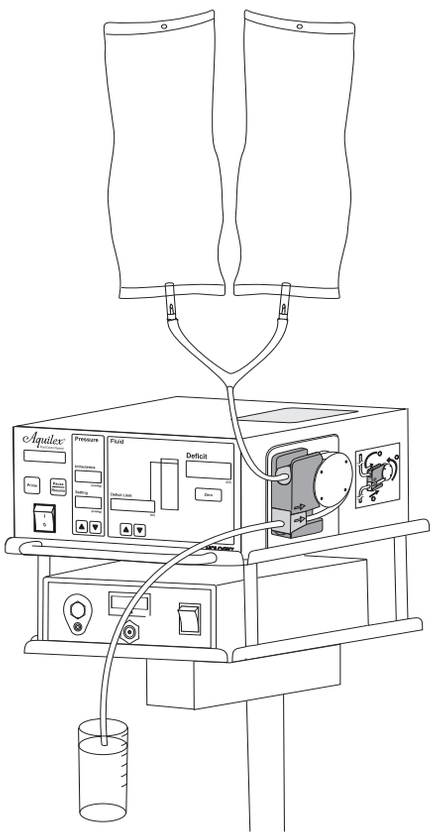

Figure 8-1 Flow rate test

The test set-up is depicted in Figure 8-1, Flow rate test.

Performing flow rate test

1. Turn the system on. (See 5.4, Turning On the Aquilex System)
2. Insert the tube set into pump and close bag clamps.
3. Hang the fluid bags onto the hooks of the bag holder.
4. Spike bags and open bag clamps.
5. Insert hysteroscope tube into measuring container.
6. Set intrauterine pump pressure to 150 mmHg.
7. Press the **Prime** button.
8. The roller wheel starts to turn to purge air from tubing and complete automatic lumen calibration.
9. Once automatic lumen calibration finishes (~20 sec), press **Pause/Resume** button.
10. Empty measuring container.
11. Re-Insert hysteroscope tube into measuring container.
12. Press the **Pause/Resume** button.
13. After one minute, press the **Pause/Resume** button. The measuring container should contain approximately 800 ml of fluid.
14. The acceptable tolerance is ±25 ml/min.

Record results in the test log in Section 15.1. Test is successful if results fall within acceptable tolerance limits.

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8.5 Pressure Measuring Test

The test set-up is depicted in Figure 8-2, Set-up of pressure measuring test.

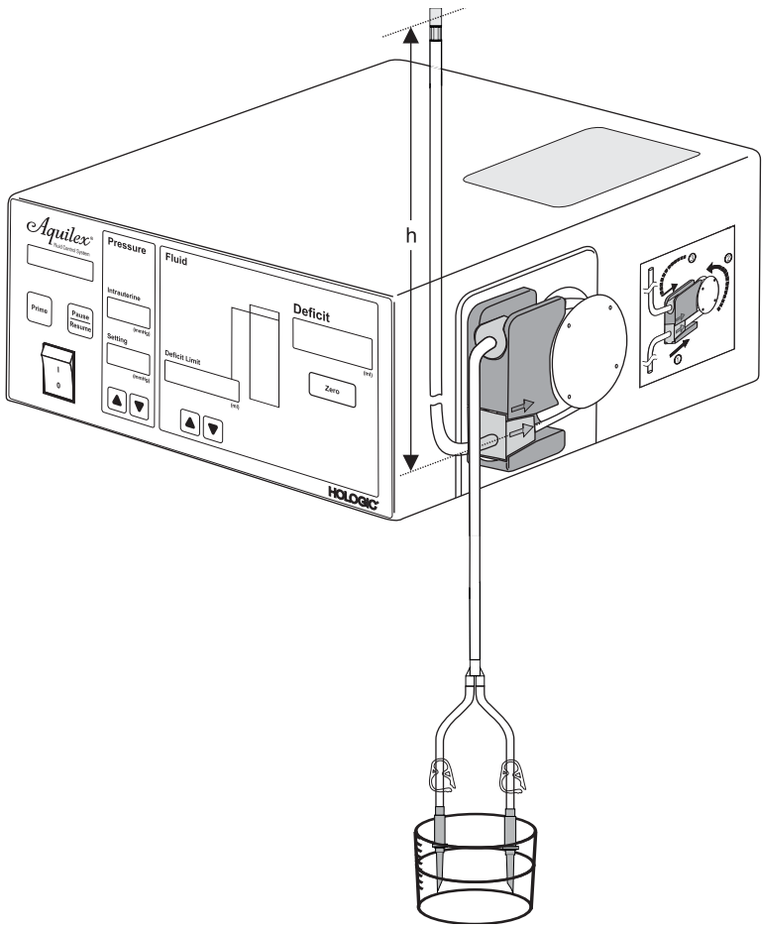

Figure 8-2 Set-up of pressure measuring test

h Height of the water line

The pressure test checks the pressure chamber, pressure sensor, and accurate measurement of pressure to ensure all elements are functioning properly. This test requires an inflow tube set and a canister filled with **water**. The height of the water column (hydrostatic pressure) is used to test the pressure transducer.

1. Place the inflow tube end with the bag spikes into a canister filled with water.
2. Fill the end of the tube set completely with water by starting the pump using the **Prime** button. Let the pump run until the calibration sequence is completed. Press the **Pause/Resume** button to stop the roller wheel. The Intrauterine Pressure display displays 0 mmHg.
3. Close the hysteroscope end of the tube (use finger on luer connector tip).
4. Hold the water level of the end of the hysteroscope tube (h) 12 in [30 cm] above the pressure chamber. The water column provides a hydrostatic pressure load onto the pressure transducer.
5. Release the finger covering the luer connector end of the hysteroscope tube.
6. The intrauterine pressure display should be 20 mmHg (±5 mmHg).
7. Change the water column height. The value of the intrauterine pressure display should change accordingly.

Record results in the test log in Section 15.1. Test is successful if results fall within acceptable tolerance limits.

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8.6 Fluid Deficit Measurement Test

The test setup is depicted in Fig. 8-3, page 31. It is critical that the collection canister be placed **on** the scale as shown in Fig. 8-3.

1. If Basic Function Tests 8.3 to 8.5 have been conducted, skip to step 2. If not, see Basic Function Tests 8.4 steps 1 to 11.
2. "Zero" the fluid deficit display by pressing the **Zero** button (see Fig. 5-1 Item ⑨).
3. Press the **Pause/Resume** button.
4. Let system run for 1 minute. The canister should have ~800 ml of fluid but the fluid deficit display should stay at ~0.
5. The acceptable tolerance is ±50.

Record results in the test log in Section 15.1. Test is successful if results fall within acceptable tolerance limits.

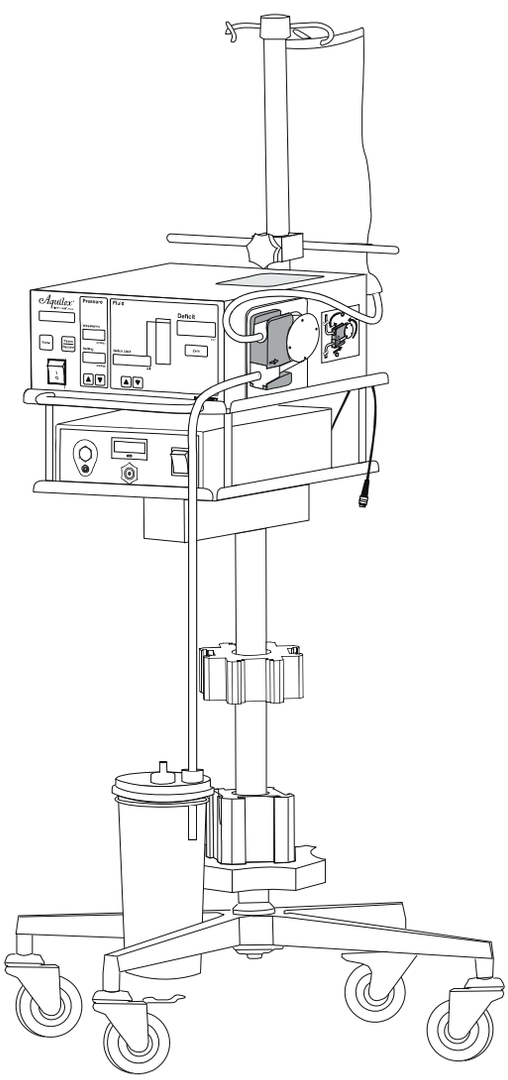

Fig. 8-3 Fluid deficit measurement test setup

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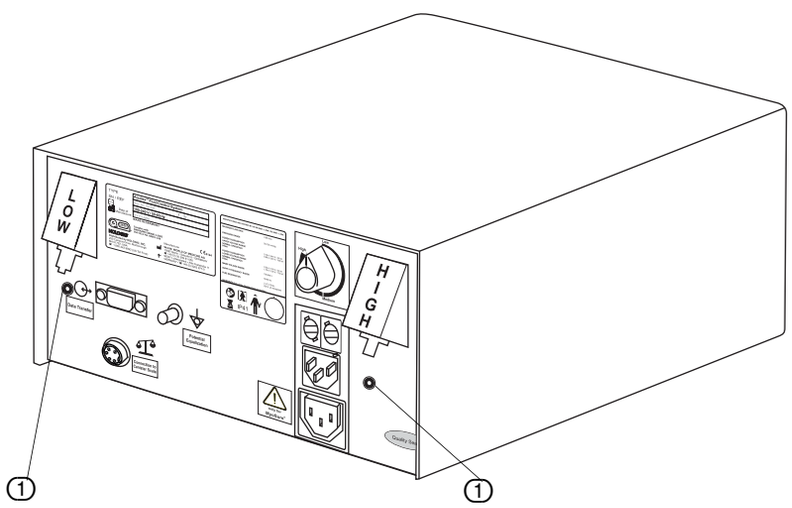
8.7 Vacuum Pump Operational Test

This test is not designed as a performance test to measure the vacuum pressure but only to assess if vacuum pumps are operational.

1. If Basic Function Tests 8.3 to 8.5 have been conducted, skip to step 2. If not, see Basic Function Tests 8.4 steps 1 to 9.
2. Check canisters to be sure at least one port is open.
3. Press the **Pause/Resume** button.
4. Place a finger adjacent to one or both of the gold exhaust ports (Fig. 8-4, ①) on the back of the pump and feel for air flow.

Record results in the test log in Section 15.1. Test is successful if air flow is observed.

Fig. 8-4 Vacuum pump exhaust ports



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9 Error and Warning Messages

Display messages are indicated visually on the pump display, as well as audibly. Audible tones to indicate warnings or operation updates (audible tones) are emitted a certain number of times.

Pump Display Message	Pump Audible Tone	Instructions
Check Tube Set Installation	1 audible tone	Remove and re-insert tube set. If message recurs, switch to a new tube set.
Tube Set Over Usage Limits	1 audible tone	Tube set recognition function indicates tube set has been used already. Insert new tube set.
Check Flow Path, Stopcock, Clamps	3 audible tones	Flow path is blocked. Check that bag clamps & hysteroscope stopcock are open. Check that tube set is free of obstructions.
Incorrect Tube Set	1 audible tone	Replace tube set. Tube set does not match type necessary for Aquilex System.
Pump Paused, Press Resume	1 audible tone	"Pause/Resume" button was activated. Hit "Pause/Resume" button again to continue operation.
Container Change, Press Resume	3 audible tones	Removal of canister without activating. Pause button. Insert empty canister and hit "Pause/Resume" button.
Overpressure Open Stopcock	3 audible tones	Most commonly triggered when hysteroscope stopcock is closed while pump is operating at peak flow rate. Open hysteroscope stopcock or other occlusion to relieve pressure.
Overpressure Check Stopcock	5 tones repeatedly continuously until pressure reduced	Pressure has exceeded 200 mmHg safety limit and must be reduced. Most probable cause is hysteroscope being closed while pump was operating at peak flow rate. Open inflow stopcock on hysteroscope or obstruction that is pinching inflow tube set.
Maximum Pressure	No audible tone	The message Maximum pressure is displayed if the intrauterine pressure exceeds 150 mmHg.
Deficit Limit Reached	3 audible tones	Physician must respond appropriately.
Deficit Limit Exceeded	3 audible tones	Physician must respond appropriately. Conduct manual deficit assessment, if necessary.
Pressure Threshold	1 audible tone	Pressures exceeding 100 mmHg are not usually required for hysteroscopy. Diligent monitoring of fluid deficit is recommended.
Connect Scale Restart System	3 audible tones	Check scale connection. Reconnect scale and restart device. If message recurs, contact Hologic.
Remove Tube Set for System Check	1 audible tone	System check must be performed with tube set removed from the roller wheel assembly. Remove tube set and wait for audible tone and display to indicate "Insert Tube Set."
Prime Fail -Open Stopcock, Clamps	3 audible tones	Check bag clamp(s) and hysteroscope inflow stopcock are open. Hit "Prime" button to restart.
High Fluid Loss Check Leakage	3 audible tones	Physician must respond appropriately. Conduct manual deficit assessment, if necessary.

Pump Display Message	Pump Audible Tone	Instructions
Scale Overloaded Check scale	3 audible tones	Scale weight exceeds 65 lbs. Weight on scale must be reduced. System function will resume once excess weight is removed.
Communication Error	5 audible tones	Contact Hologic Technical Support.
Calibration Error	5 audible tones	Contact Hologic Technical Support.
Sensor Error	5 audible tones	Contact Hologic Technical Support.
Motor Error	5 audible tones	Contact Hologic Technical Support.
Low Vac Failed Use Alternative	3 audible tones	A substitute low pressure vacuum source is necessary to continue procedure. Contact Hologic Technical Support.
High Vac Failed Use Alternative	3 audible tones	A substitute high pressure vacuum source is necessary to continue procedure. Contact Hologic Technical Support.
Vac Systems Out Use Alternative	3 audible tones	Substitute vacuum sources are necessary to continue the procedure. Contact Hologic Technical Support.

10 Technical Data

Model or type designation		AQL-100		
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		
Power consumption		Current [A]	Voltage [V]	Power consumption [VA/W]
Upper voltage range				
	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)		Designed to work within a BF isolated system		
Defibrillator protected (yes/no)		No		
Protection type (IP code)		IP41 (Pump unit), IP21 (Scale)		
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 and transportation conditions		-20 to +70 °C / -4 to +158 °F 10 to 90 % rel. humidity 70 to 106 kPa air pressure		
Max. sound level:		<80 dB(A)		
Maximum load		65 lbs/30 kg		
Adjustable values				
	Pressure range [mmHg]	40-150 mmHg		
Measurement range				
	Flow [ml/min]	0-800 ml/min		
	Pressure [mmHg]	0-500 mmHg		
	Deficit [ml]	-995/+9995		
Accuracy repeatability				
	Flow [ml/min]	± 5 ml/min		
	Pressure [mmHg]	±2 mmHg		
	Deficit [ml]	±10 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]	±7 %
	Pressure [mmHg]	±7.5 mmHg
	Deficit [% measured value]äöälölll	±10 %
Interfaces:		
	Signal IN/OUT components	1x scale port (flanged socket/5-pin round connector socket/ RS232) 1x service port (RS232 socket DSUB9/RS232)
	Mains connection	IEC-60320-1 C14

11 Guidelines and manufacturer's statement - electromagnetic compatibility

11.1 Impact of Mobile and Portable HF Communication Devices

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

11.2 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.

11.3 Guidelines and Manufacturer’s Statement – Electromagnetic Emissions

The Aquilex Fluid Control System is intended for use in the electromagnetic environment specified 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 functions. Therefore, the camera's HF emission is very low and it is unlikely that devices in close proximity will experience interference.
HF emission according to CISPR 11	Class B	The 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	

11.4 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 should 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 AC 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 normal mode voltage, ± 2 kV common mode voltage	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 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 s		
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.

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

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11.5 Guidelines and Manufacturer's Statement - Electromagnetic Interference Immunity

Electromagnetic interference immunity tests	Test level	Compliance	Electromagnetic environment guidelines
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 Aquilex Fluid Control System (including cables/ lines) than the recommended safety distance calculated based on the transmitting frequency and the applicable formula. Recommended safety distance: $d = 1.2\sqrt{P}$ for 150 KHz to 80 MHz $d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 800 MHz to 2.5 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. 
Radiated HF interference quantities according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	In compliance	

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

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

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

11.6 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 based on the transmitting frequency [m]		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
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 max. 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 differs depending on the absorption and reflection of buildings, objects, and people.

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12 Accessory List

The following accessories are available:

Item	Order No.
Aquilex Fluid Control System Complete Tube Set (Inflow and Outflow)	AQL-112
Aquilex Fluid Control System Vacuum Tube Set (high and low)	AQL-114
Aquilex Fluid Control System Canister 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

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13 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 System according to the instructions provided by Technical Support. Be sure to clean the Aquilex 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 (2002/96/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 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

14 Glossary

Term	Statement
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
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)
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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15 Appendix

15.1 Test Log

Date	Tests Performed	Results	Comment	Signature

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