delmont
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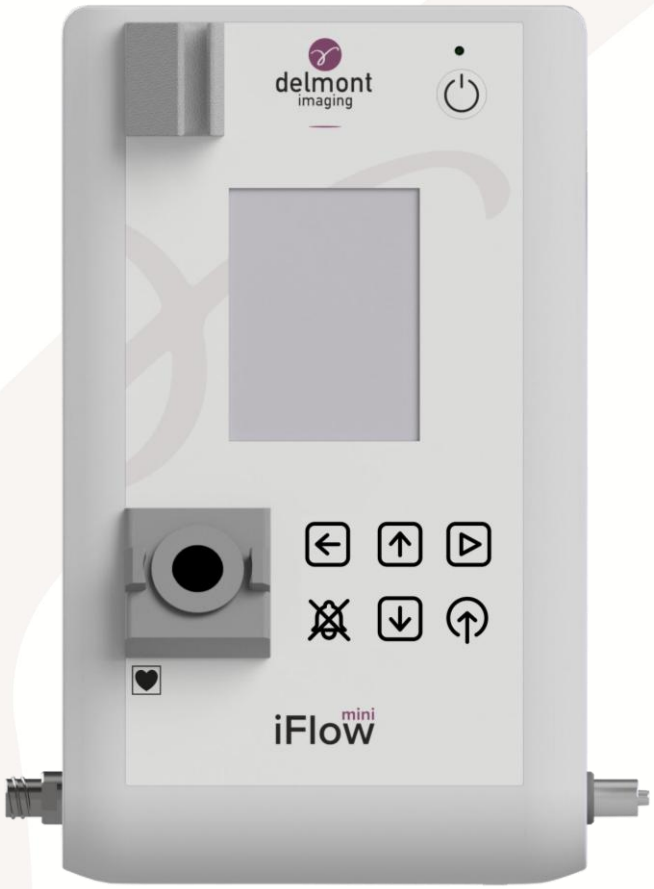

EN - Instructions for use
Irrigation fluid management system

D900 700 176 A EN

2024-11

Rx Only

This manual is addressed exclusively to trained and qualified personnel. Carefully read these instructions before using Delmont imaging devices. Keep them in a safe place for future reference.

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MD

This manual relates to the generic medical device group Irrigation fluid management system manufactured by Delmont imaging with basic UDI-DI 37012178IFLMHF. See declaration of conformity for the complete list of devices concerned.

Symbols used in this manual	
⚠	Safety information to prevent injury.
ⓘ	Special information requiring the user's attention.
☑	Prior information that the user must check.
→	Instruction information that the user must follow.

ⓘ ***This instruction for use can be supplied in hard copy on request from our customer within 6 days by contacting ifu@delmont-imaging.com or calling +33 9 51 51 30 30.***

ⓘ ***You can access instructional videos to help you use of our medical devices on: https://www.youtube.com/@delmontimaging***

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1. General device information

1.1. Intended use

This device and this manual are intended exclusively for trained and qualified personnel. This document describes the correct handling and function of the Irrigation fluid management system. This document may not be used to carry out endoscopic examinations or surgeries, nor may be used for training purposes.

For the benefit and safety of patients, physicians must select a method which they consider suitable based on their experience. If you as the user of this hysteroscopic system believe that you require more detailed information regarding the product's use and maintenance, please contact your representative.

The irrigation fluid management system is a non-invasive, active medical device intended for fluid management in endoscopic settings to provide distension, fluid irrigation and suction function.

1.2. Indication for use

The device is indicated for use by healthcare professional in diagnostic and operative endoscopic procedures for hysteroscopy and laparoscopy medical field in a healthcare centre equipped with an appropriate endoscopic configuration:

- Laparoscopy: Irrigation of body cavities and fluid aspiration during diagnostic and operative procedures.
- Hysteroscopy: Uterine distention and maintain of the dilation is achieved via a pressure control sensor and fluid aspiration during diagnostic and operative procedures.

The suction function is used to provide flushing flow and suck up secretions.

1.3. Target population

Population group	Hysteroscopy	Laparoscopy
Sex	Female	No restrictions
Age	The device should not be used for paediatric populations	
Weight	No restrictions	No restrictions
Health condition	Appropriate for treatment as assessed by the practitioner	

1.4. Device description

The irrigation fluid management system is constituted of :

REF	Description
D110 100 012	iFlow mini. Irrigation pump. Hysteroscopy and Laparoscopy.

It shall be used with a chosen set of accessories of the system : (see 1.5 for details on variants and accessories)
- One or two cuffs (see Figure 5),
- One irrigation tube (Figure 6),
- One vacuum suction tube (Figure 7).

And other accessories or consumables not part of the present device (see 1.5 for details on combination) :
- Fluid bags filled with electrolyte-free media such as glycine 1.5 % and sorbitol 3.0 % or with isotonic, electrolyte containing media such as saline 0.9 % and Lactated Ringer's.
- A surgical instrument through which fluid is delivered to the organ being operated on/examined and sucked down to the container directly or via a suction tube.
- A single or several connected collection containers for waste fluids.

The device is used to set a circuit of flows between the various elements described above:
- The irrigation flow is sterile liquid going from the fluid bags, pushed by the pressurised cuff, to the operating field, passing through the irrigation tube and the instrument used.
- The vacuum flow is air going from the collection containers to the pump, creating a void.
- The suction flow is contaminated fluid going from the operating field to the container, vacuumed by the void created by the vacuum flow, passing through an instrument and its suction tubing,

When used in hysteroscopy mode (see 3.5) :
- The irrigation flow enables the uterine cavity to be dilated to provide space and improve visibility.
- The user sets a nominal pressure, then the pressure control circuit continuously compares the measured pressure of the irrigation flow with the nominal pressure. The function of the device is to maintain the nominal pressure by adjusting the pressure in the cuff.
- The measurement of the pressure is done with a non-contact pressure measurement of the irrigation medium. The contact-free pressure measurement is taken by integrating the pressure chamber into the irrigation tube system. The pressure membrane transfers the tube pressure to the electronics of the device via a pressure sensor.

When used in laparoscopy (see 3.6)
- The irrigation flow is used as a means of cleaning the operating field: no nominal pressure is set, no measurement is necessary.

For both modes, the suction flow power is set by the user with the chosen vacuum modes (see 3.8).

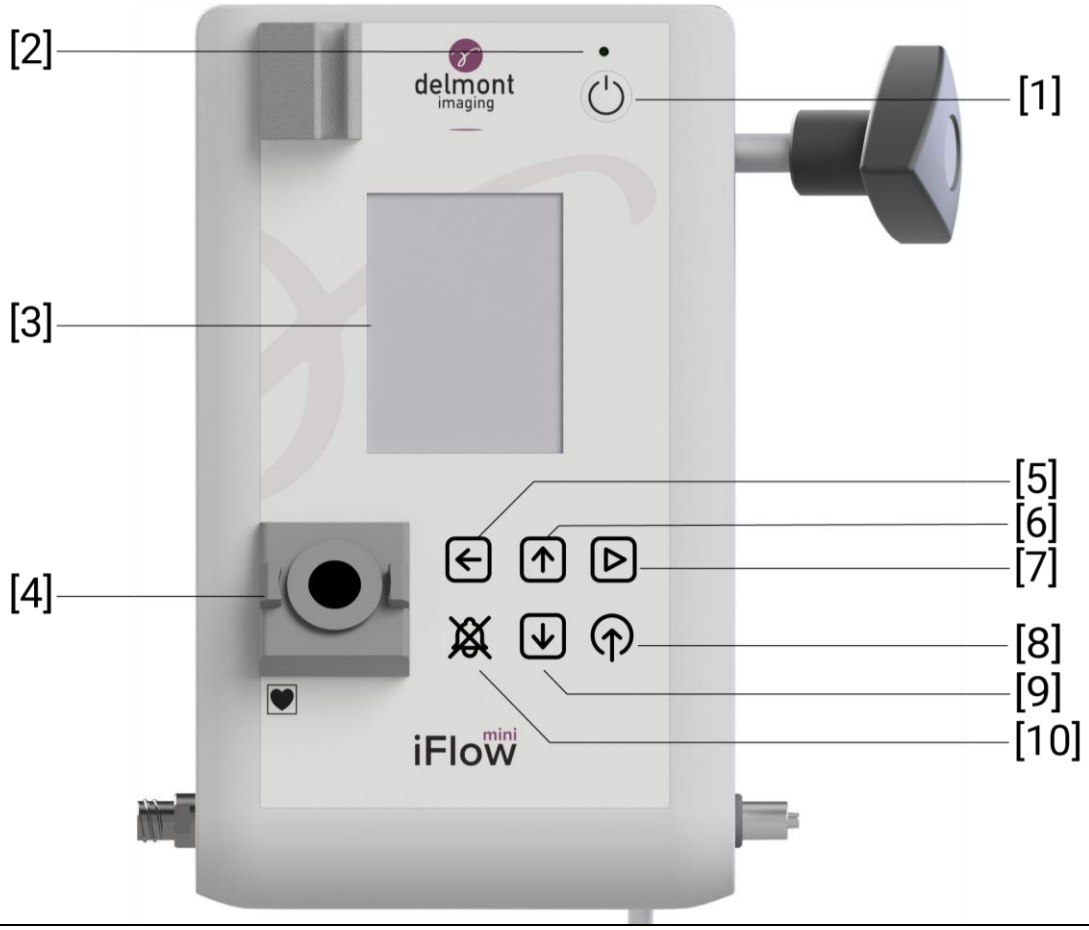


Figure 1 - Control unit, front side

Legend		Function
[1]	Standby ON/OFF button	Turns on or off the standby mode of the device.
[2]	Main power indicator	Indicates with a green light if the device is power or not.
[3]	Display screen	Shows the human machine interface.
[4]	Sensor housing	Interfaces with the pressure dome [22] to measure the pressure inside the tubing
[5]	Back button	Goes back to previous step in the interface menu.
[6]	Up arrow button	– In the menu: goes up in the menu. – In use in hysteroscopy mode: increases the target pressure.
[7]	Irrigation/Validation button	– In the menu: validates a choice. – In use: starts the irrigation function.
[8]	Vacuum button	In use : switches between the suction function mode (OFF/LOW/HIGH).
[9]	Down arrow button	– In the menu: goes down in the menu. – In use in hysteroscopy mode: decreases the target pressure.
[10]	Alarm silence button	Silences an alarm.

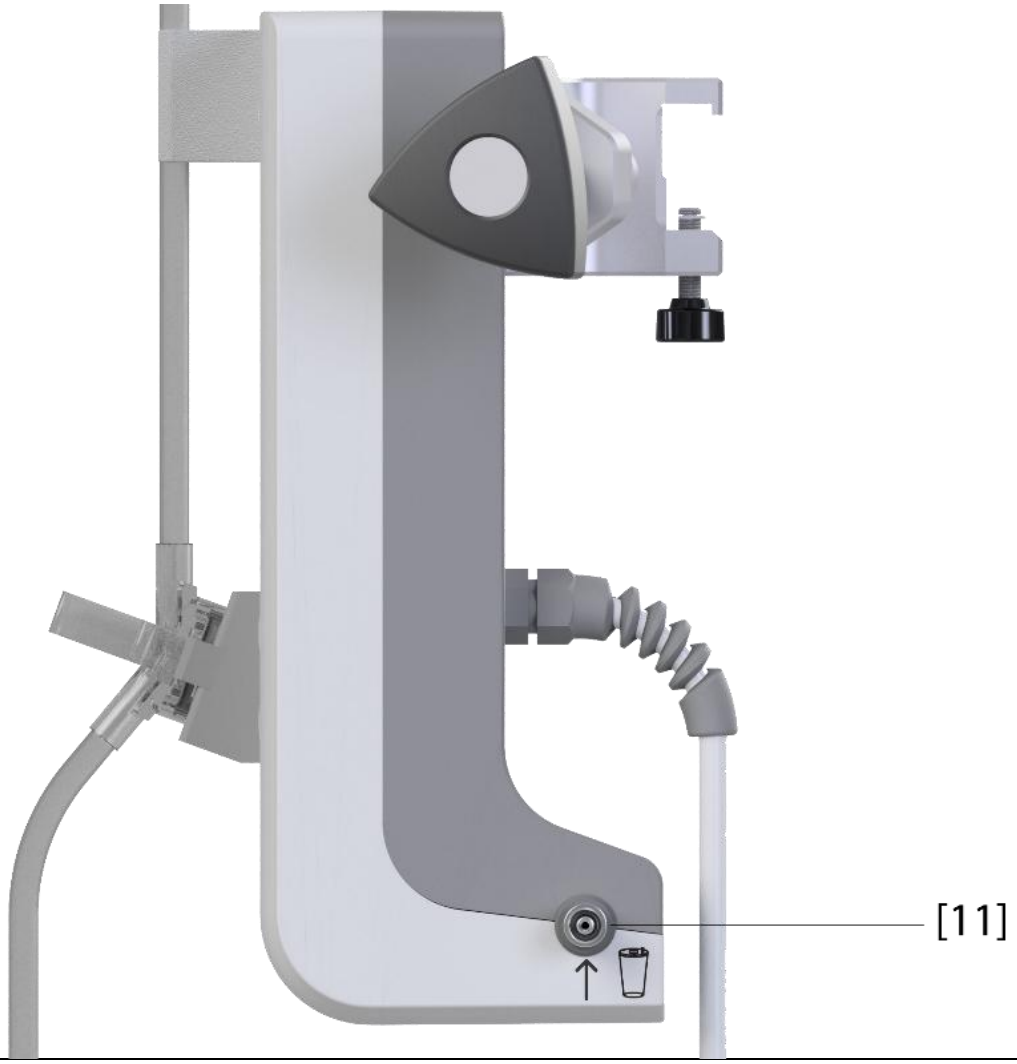


Figure 2 - Control unit right side

Legend		Function
[11]	Air vacuum in	Connects the control unit to the container with the vacuum tube set's luer lock [24].

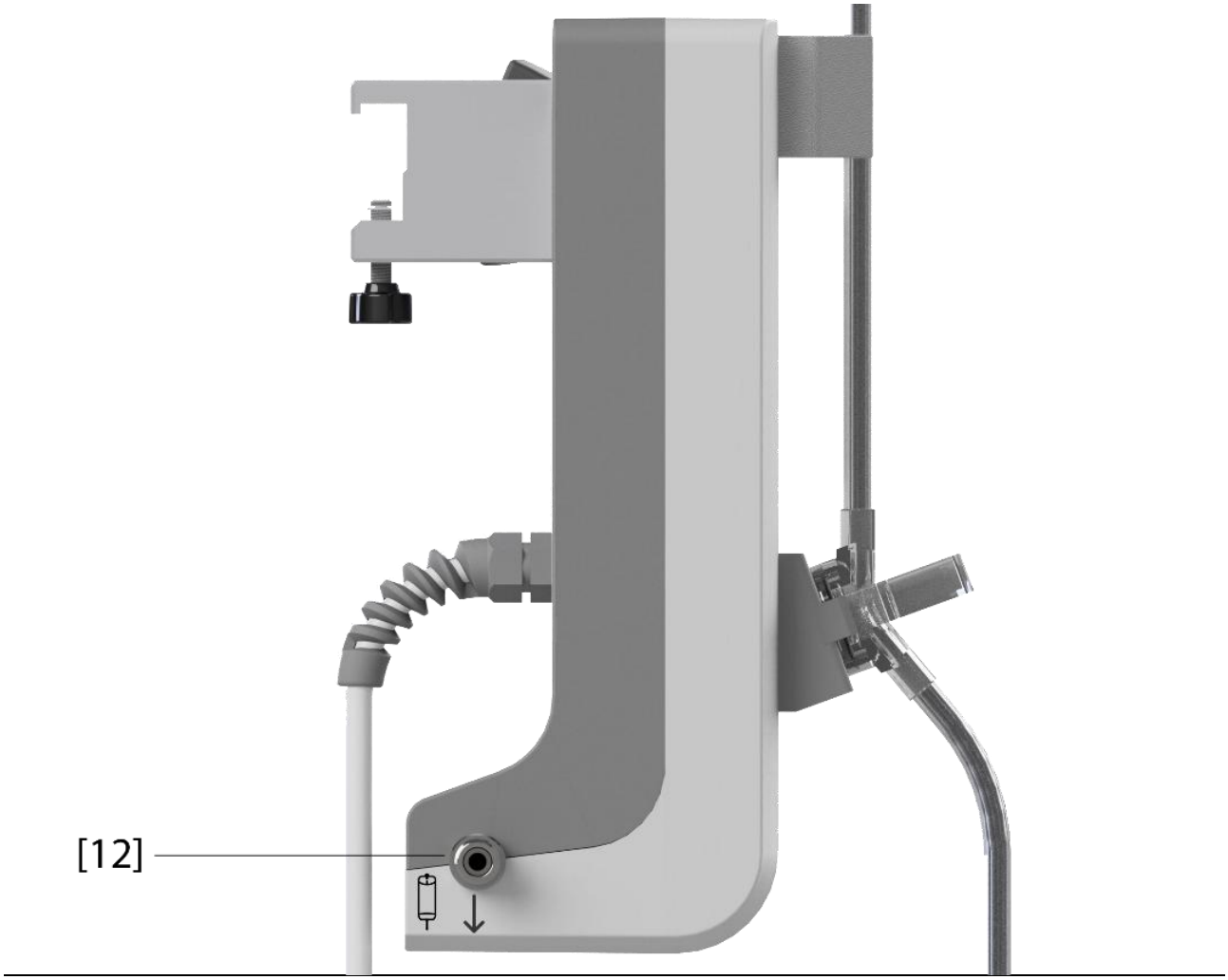


Figure 3 - Control unit left side

	Legend	Function
[12]	Air pressure out	Connects the control unit to the cuff [17].

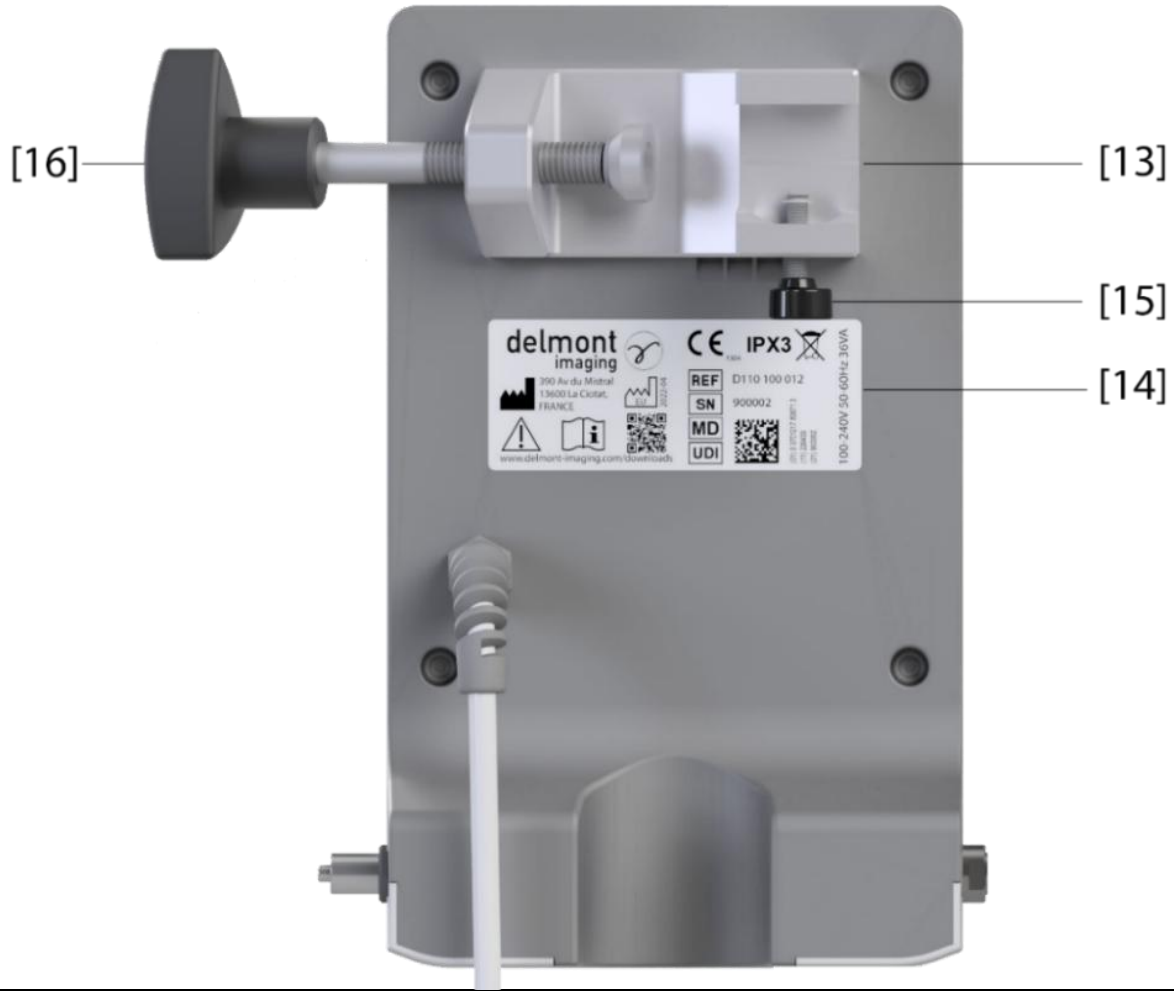


Figure 4 - Control unit rear side

	Legend	Function
[13]	Mounting bracket	Connects the control unit to a pole using [16] or a rail using [15].
[14]	Information label	Displays information on the device such as traceability.
[15]	Screw for rail	Screws the [13] on a rail.
[16]	Screw for pole	Screws the [13] on a pole.

Figure 5 – Pressure cuff

	Legend	Function
[17]	Connector to the control unit	Connects the cuff to the control unit [12].
[18]	Housing for the liquid bag	Holds and pressurizes the liquid bag.
[19]	Loop for the pole's hook	Hangs the cuff on a pole.

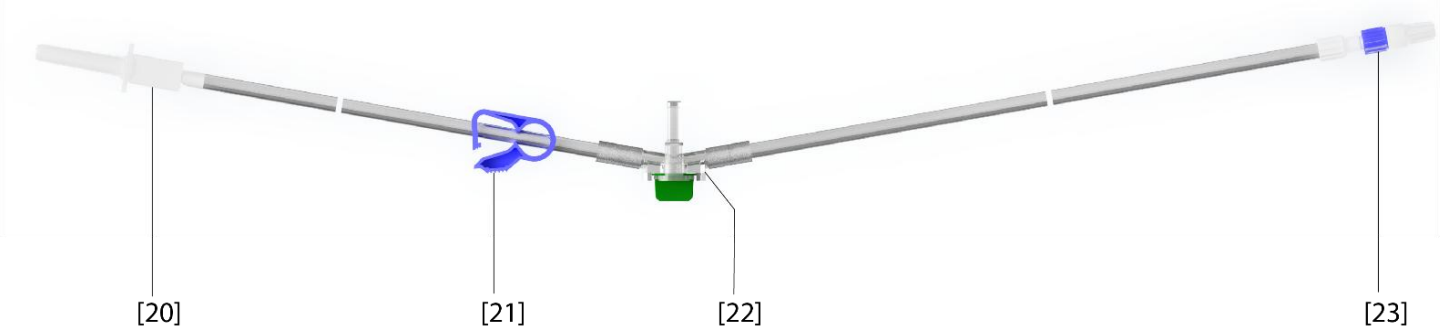


Figure 6 – Tube set for irrigation

	Legend	Function
[20]	Spike	Pierces and connects the tubing to the fluid bag.
[21]	Clamp	Opens or closes the liquid flow.
[22]	Pressure dome	Transfers the liquid pressure to the control unit when connected to [4].
[23]	Luer lock	Connects the tube set to the endoscopic instrument inflow.

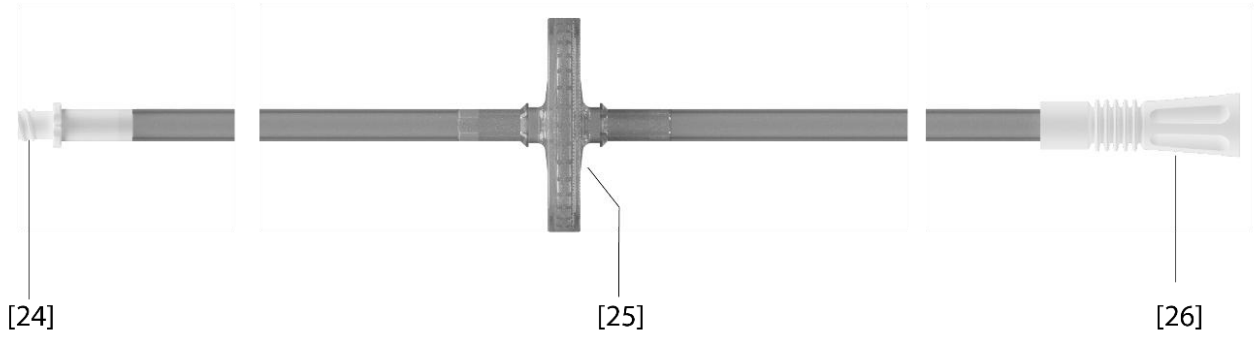


Figure 7 – Tube set for vacuum

Legend		Function
[24]	Luer lock	Connects the tube set to the control unit in [11] to get the vacuum power.
[25]	Hydrophobic filter	Prevents liquid to get in the control unit.
[26]	Container connector	Connects the tube set to the container.

For hysteroscopy indication, the device functions only with the tube sets described in the accessory list (see 1.5) for pressure measurement as a pressure dome is integrated in the tube set.

1.5. Combination and accessories

W.II

Use only recommended accessories with Delmont imaging devices. Using incompatible equipment may lead to:

- ***injury of the patient and/or the user,***
- ***damage to the device,***
- ***increase electromagnetic emissions or decreased electromagnetic immunity of this equipment and improper operation.***

W.III

Additional peripheral equipment connected to interfaces of the device must meet the requirements of the following specifications in the respective current valid version:

- ***IEC 60601-1 / EN 60601-1 for electrical medical devices,***
- ***IEC 60601-2-2 / EN 60601-2-2 for high frequency surgical equipment and high frequency surgical accessories,***
- ***IEC 60601-2-18 / EN 60601-2-18 for endoscopic devices.***

All configurations must comply with IEC 60601-1 / EN 60601-1 specifications. Whoever connects additional equipment to the present device is considered the system configurator and as such is responsible for complying with requirements of the standard IEC 60601-1 / EN 60601-1.

W.IV

The device is only intended for use with flexible fluid bags. Do not use rigid or glass containers as they might break.

The device is only intended for use with medical collection containers compliant with EN ISO 10079-3 that can withstand at least 550mmHg of vacuum level and has an overfill protection.

Contact your Delmont imaging representative if any doubt subsists on compatible equipment and for more details on accessories and details.

The following accessories and variants are available:

REF	Description
D110 100 013	3 liters pressure cuff for iFlow mini, long version
D110 100 020	3 liters pressure cuff for iFlow mini
D110 100 014	1 liter pressure cuff for iFlow mini
D110 100 015	Sterile. Single-use irrigation tube. 1 spike.
D110 100 016	Sterile. Single-use irrigation tube. 2 spikes.
D110 100 017	Vacuum suction tube with filter, non-sterile, for 30 days of use
D110 100 018	Y-adapter for double pressure cuff connection
D110 100 019	Self-test tube for iFlow mini pressure sensor
D110 100 022	Single-use suction tube. 2 connectors

The device can be used with flexible fluid bags of electrolyte-free media (e.g., glycine 1.5 % and sorbitol 3.0 %) and with isotonic, electrolyte containing media (e.g., saline 0.9 % and Lactated Ringer's).

2. Safety instructions


W.VI

Observe the safety instructions of the manufacturer. Non-observance of these safety instructions may lead to injuries, malfunctions, or other unexpected incidents.

2.1. Contraindications


W.VII

Do not use the device if, in the opinion of a qualified physician, the general condition of the patient is not adequate or if endoscopic methods are contraindicated, such as:

- ***Pregnancy,***
- ***Acute pelvic inflammatory disease (PID),***
- ***Arterial hypertension in agreement with the anaesthesiologist,***
- ***Blood coagulation disorders,***
- ***Severe anaemia,***
- ***General inoperability state or lack of willingness of the patient,***
- ***Ambiguous diagnosis.***

The responsible physician must decide on the basis of the patient's general condition, whether the intended application can be carried out. Country-specific regulations and laws must be observed. Further information can be found in the current literature.

2.2. Contraindications specific to hysteroscopy indication


W.VIII

Additionally, do not use the device if, in hysteroscopy indication, the following contraindications exist:

- ***Current pelvic/cervical/vaginal infection,***
- ***Inability to distend the uterus,***
- ***Invasive carcinoma of the cervix,***
- ***Recent uterine perforation,***
- ***Uterine leiomyoma.***

2.3. Side effects and residual risks


W.IX

Fluid overload: There is a risk of irrigation fluid reaching the circulatory system of the patient's soft tissue. This can be affected by distention pressure, flow rate, perforation of the distended body cavity and duration of the endoscopic surgery. The physician shall closely monitor the inflow and outflow of the distension liquid at all times as it is not supported by the system.


W.X

Serum sodium concentration: It is necessary to monitor the concentration of sodium in the blood of the patient to prevent electrolyte disturbances and hyponatremia. The physician shall monitor the concentration of sodium in the blood at all times as it is not supported by the system.


W.XI

Hypothermia (monitoring body temperature): Continuous flow of distention fluids can lead to a lowering of the patient's body temperature. Lower body temperatures can cause coronary and cardiovascular problems. Monitor the patient's body temperature during the entire surgery procedure must be performed by the physician and is not performed or supported by the system. Make especially sure that the following, hypothermia promoting, operation conditions are avoided as best as possible:

- ***longer operating times,***
- ***use of cold irrigation fluid.***


W.XII

Air embolism: An air embolism can be the result of air contained in the tube set, the connected instrument or generated during the operation, reaching the patient. Ensure to drain the device completely prior the surgery and make sure there is always fluid in the bag to prevent air from being injected into the patient.

2.4. Side effects specific to hysteroscopy indication


W.XIII

Pulmonary oedema: hysteroscopic surgery is associated with a risk of developing pulmonary oedema resulting from fluid overload with isotonic fluids. It is critical to closely monitor the inflow and outflow of the distension liquid at all times.


W.XIV

Cerebral oedema: hysteroscopic surgery is associated with a risk of developing cerebral oedema resulting from fluid overload and electrolyte disturbances with hyperosmolar (non-ionic) fluids such as glycine 1.5 % and sorbitol 3.0 %. It is critical to closely monitor the inflow and outflow deficit of the distension liquid at all times.


W.XV

Idiosyncratic reactions: In rare cases, idiosyncratic reactions including:

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

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


W.XVI

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 inflow and outflow of the distention liquid at all times.


W.XVII

Uterine perforation: hysteroscopic surgery is associated with a risk of perforation of the uterine cavity. The perforation could lead to irrigation fluid flowing into the patient's peritoneal cavity, resulting in a fluid overload. It is critical to closely monitor the inflow and outflow of the distention liquid at all times.

2.5. Warnings and precautions of use

 W.XVIII	***Make sure that the devices are used exclusively by trained and qualified personnel. Make sure that the surgeon is proficient, theoretically, and practically, in the approved surgical techniques. The surgeon is responsible for the correct execution of the operation.***
 W.XIX	***Never use the system if it has suspected or confirmed defects, especially if these involve the power plugs or the main power supply connection cable. In this case there is a risk of electric shock, unplug the device and stop using it.***
 W.XX	***Disconnection from the power supply is only guaranteed if the main plug is pulled from the mains wall socket. Make sure this wall socket is always accessible.***
 W.XXI	***Connect this device to a power supply equipped with a protective ground to avoid the risk of electric shock and do not connect this device or system to a multiple socket-outlets or an extension cord.***
 W.XXII	***Check the power supply to make sure the available main voltage matches the data listed on the label on the rear side of the device. Incorrect voltage can cause errors and malfunctions and may destroy the device.***
 W.XXIII	***Do not modify or open the device. A modification could cause electric chock or mechanical injuries. If the medical device is modified, a check and test must be carried out to ensure that the medical device complies with the safety instructions.***
 W.XXIV	***Do not insert metal objects into the unit to avoid electric shock, fire, short circuit or dangerous emission.***
 W.XXV	***Do not use this device in presence of a mix of flammable anaesthetics with air, oxygen, or nitrogen protoxyde. The device is not explosion-proof.***
 W.XXVI	***Tube sets are not applied parts and are not intended for patient contact.***
 W.XXVII	***The functional test described in 3.9 must be performed by the user prior to each surgery.***
 W.XXVIII	***Always work exclusively with sterile fluids, and sterile accessories.***
 W.XXIX	***In case the device or any of the accessories fail during surgery, a replacement device and replacement accessories should be kept within proximity to be able to finish the operation with the replacement components.***


W.XXX

Always work exclusively with sterile fluids, and, with sterile tubing sets for those going to the patient.

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

Additional information for safety is placed in this supplied information where appropriate.

2.6. Precautions of use specific to hysteroscopy indication


W.XXXI

Deficit surveillance: The physician is responsible to maintain strict fluid inflow and outflow surveillance. Try to collect all the fluid that runs out of the uterus during the procedure in order to achieve the most exact balancing possible. If a low viscosity liquid distention medium is used, intrauterine instillation exceeding 1 litre should be followed with great care due to the possibility of fluid overload. If a high viscosity fluid is used, the instillation of more than 500 mL should be followed with great care.


W.XXXII

The intrauterine pressure should be kept as low as possible to allow for a sufficient intracavitary distention and to reduce the forces that could allow fluid, ambient air, and/or gas into the circulatory system. Intrauterine distention is usually possible with pressure values between 60 to 80 mmHg to be inferior or equal to the mean arterial pressure. A pressure above 80 mmHg is required only in rare cases or if the patient has an excessively high blood pressure.

2.7. Vigilance

Definition of serious incident may depend on your local regulation. If any doubt exists, we encourage our users to proactively report any incidents. Contact your Delmont imaging representative for more information about reportability.

Medical information must be anonymized prior to be sent to us. Contact our data protection officer at dpo@delmont-imaging.com for more information related to confidentiality.

→ Notify without delay any serious incident or risk of serious incident occurring during the use of this device to:
- vigilance@delmont-imaging.com,
- Your Delmont imaging representative,
- Your competent authorities in accordance with your local regulation.

→ We encourage the users to gather and transfer all appropriate information regarding the incident which includes but is not limited to:
- Patient condition prior the incident and after the incident,
- Indications of the procedure,
- Date of incident,
- Reference number and serial/lot number of the device,

- Any pertinent information related to the incident,
- A preferred contact that Delmont imaging can reach in the best delay.

→ Send back the device following recommendation from 5.3, if required by your Delmont imaging representative.

3. Use of the device

3.1. Initial set up of the device

3.1.1. Location

W.XXXIII	***The device is only to be used in a professional healthcare facility.***
W.XXXIV	***The device should be set only on a medical pole, or a rail certified according to EN 60601-1 / IEC 60601-1 with a load capacity suitable for the control unit weight and associated irrigation liquid bags.***
W.XXXV	***Do not place any objects on the control unit. The device is not intended to support loads and could fall and be damaged otherwise.***
W.XXXVI	***When using a portable RF communication equipment, keep it 30 cm (12") or more away from any part, including cables, of the device. Otherwise, degradation of the performance of this equipment could result.***
W.XXXVII	***Do not expose the device to water splashes or in a place that is too humid. The device is only protected from limited water splash from above direction (IPX3).***
W.XXXVIII	***The location must be chosen to assure that cables and tubes can be laid safely between the device and the patient to not create any obstruction.***
W.XXXIX	***Do not position the device lower than the patient table and not higher than 60 cm and set the patient height in the settings of the control unit (see 3.3.1).***
W.XL	***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.***
	To verify the position of the device for monitoring the displayed values, the user shall be within a display viewing angle of ±50°, up to 1m/6.5ft from the device front.

→ Install the device either on a pole or on a rail using the mounting bracket [13] on the rear of the device (see Figure 4). Depending on the place of installation of the device:

☑ Check it is outside the sterile area,

☑ Check it can be easily switch off and on and disconnected from main power,

☑ Check from the user's position the displayed values can be read and the device's functions are accessible.

3.1.2. Unpack the device

W.XLI

Do not use the device if the integrity of the primary packaging is deteriorated and the device appear to be damaged.

W.XLII

Do not unpack the device prematurely and do not switch it on until enough time has passed and the device has adapted to the room climate. If the device did not adapt to the room climate after transport or storage, the device may be damaged.

→ Unpack the control unit and accessories from the packaging.
→ Always check all items immediately after receiving the shipment.
→ Save the original packaging in a safe place, to eventually return the device in proper conditions.

3.1.3. Installation on a pole

To install the device on a pole, perform the following actions (see Figure 4):

Step 1	Step 2
	
→ Unscrew [16]. → Position the device at the desired height.	→ Screw [16] to secure the device on the pole. ☑ Check the control unit is at least 10cm (4”) lower from the liquid bag. ☑ Check the control unit is no higher than 60cm (24”) from the patient.

3.1.4. Installation on a rail

To install the device on a rail, perform the following actions (see Figure 4):

→ Unscrew [15].
→ Position as desired the device on the rail,
→ Screw [15] to secure the device on the rail.

☑ Check the control unit is at least 10cm (4”) lower from the liquid bag.
☑ Check the control unit is no higher than 60 cm (24”) from the patient table.

3.2. Operating the device

3.2.1. Transport the device

When placed on a pole, the device is transportable, the wheels of the pole are used for positioning at the usage site. To transport the device safely:

☑ Check power cord is unplugged and does not lie on the floor.

☑ Check all fluid bags from the cuffs are removed.

☑ Check there are no containers or only completely emptied containers on the stand.

☑ Check inflow and outflow tubing are removed.

☑ Check there are no other objects located on the device.

3.2.2. Powering on the device

To power on the device:

→ Plug the power cord.

The front main power indicator [2] should light up green.

→ Press the standby button [1] on the front panel of the unit to start.
→ Wait the end of the booting sequence.

☑ Check the monitor displays a boot screen with Delmont imaging logo.

☑ Check the booting sequence ends after 5 seconds.

☑ Check the welcome menu appears on the monitor (see Figure 8).

3.2.3. Navigating in the interface

W.XLIII

The user must not touch the device and the patient at the same time.

→ Press [6] or [9] to navigate in the menu.
→ Validate your choice by pressing [7].
→ You can in the welcome menu:
– Choose the hysteroscopy indication, (see 3.5),
– Choose the laparoscopy indication (see 3.6),
– Go to the settings menu (see 3.2).

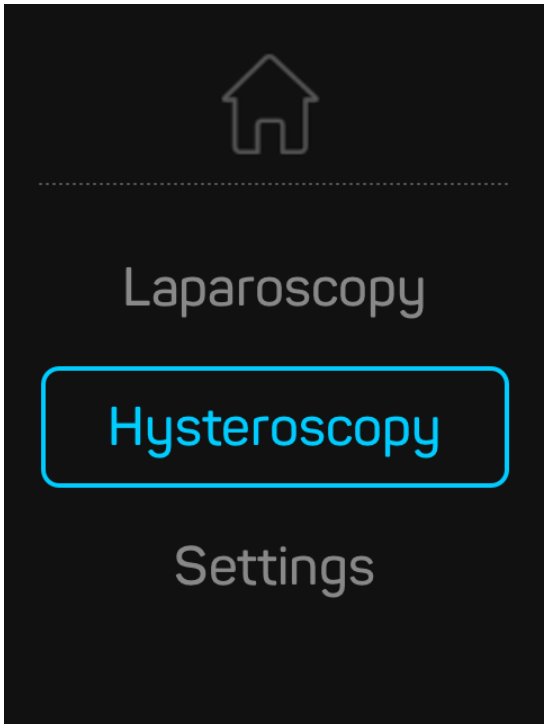


Figure 8 - Welcome menu

3.2.4. Powering off the device

W.XLIV

Unplug the device to cut completely the connection to main power. Always grasp the plug of the power cable when unplugging; never pull on the cable itself.

→ Press the standby button [1].
→ Unplug the device.

3.3. Device configuration

→ To configurate the device, in the welcome menu, select *Settings*.
→ You arrive in the Settings menu (see Figure 9).

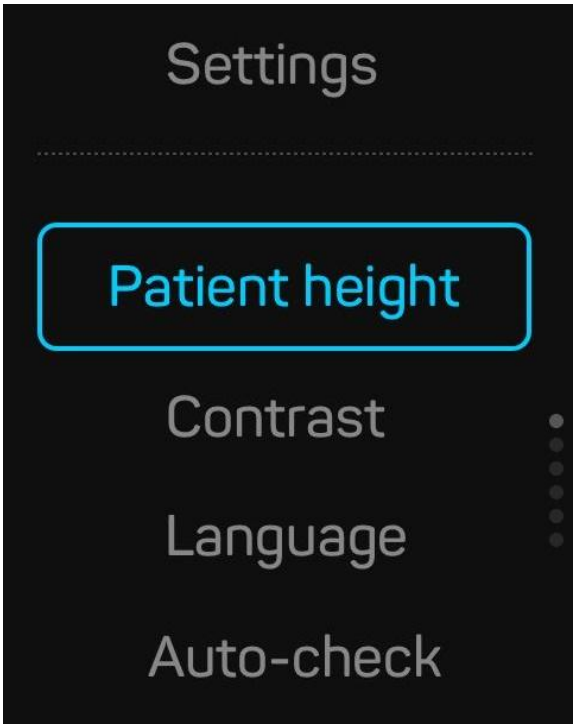


Figure 9 - Settings menu

3.3.1. Patient height

W.XLV

The patient height must be correctly set to ensure accurate pressure measurement and achieve appropriate uterine distension. Do not measure the distance between the patient table and the floor nor the distance between the control unit and the floor.

This setting is only used in the hysteroscopy indication, it has no impact for laparoscopy indication.

- → Measure the distance between the sensor housing [4] of the control unit and the patient table from 0 to -60 cm
- → Go in the settings and in the patient height setting screen (see Figure 10).
- → Set the distance using the buttons [6] and [9].
- → Confirm by pressing [5].

3.3.2. Contrast

You can set the appropriate contrast from 10 to 100% to have the best visibility for the user depending on your surrounding lighting conditions.

3.3.3. Language configuration

You can choose the appropriate language for you from the available list.

Figure 10 – Patient height settings

3.3.4. Maximum target pressure

You can set the maximum target pressure for hysteroscopy indication at 150 or 200mmHg.

Figure 11 – Maximum target pressure settings

3.3.5. Device information

In the device information menu, you can see information related to the device.

Figure 12 - About screen

3.3.6. Factory settings

You can reset all configuration to factory settings using this module:

Setting	Factory value
Patient height	-50 cm
Language	English
Contrast	80 %
Max set pressure	150 mmHg

3.4. Set up of the fluid configuration

3.4.1. Setting up the irrigation system

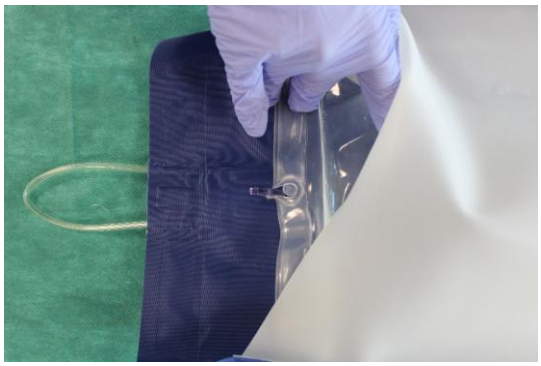
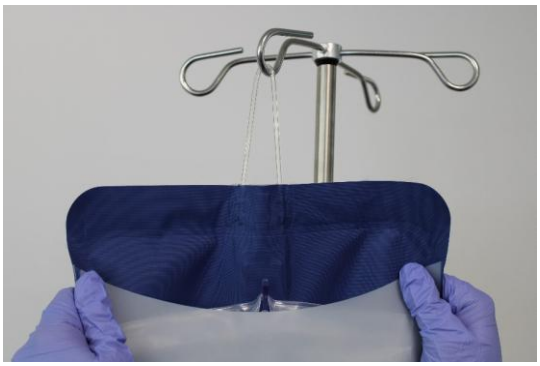
W.XLVI ***The physician must determine the distension fluid suitable for the application and medical procedure.***

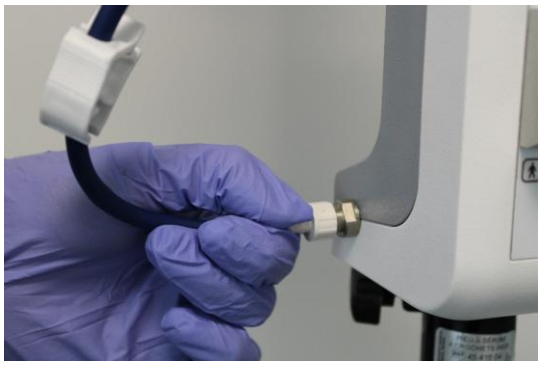
W.XLVII ***Do not use sterile tubing set for which the date of use has expired, or it is not readable anymore. There is a risk of infection. Dispose the expired tubing set in compliance with the rules of hygiene of your facility.***

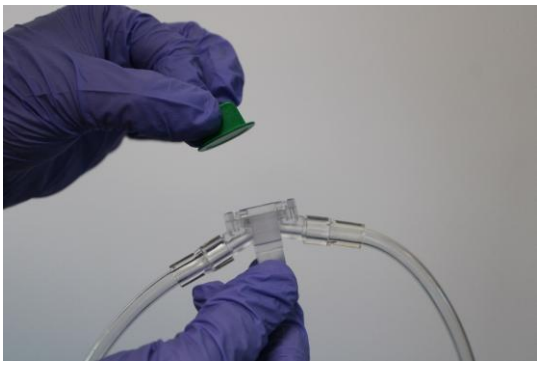
W.XLVIII ***Connect the pressure dome only if the chamber is empty and not pressurized with water, otherwise the pressure measurement may be impacted.***

The irrigation system consists of:

- A fluid bag (not included with the present device),
- The spike [20], in the tube set for irrigation, is used to connect the tube section with the irrigation fluid bag.
- The clamp [21], in the tube set for irrigation are used to stop irrigation fluid to leave the fluid bag,
- The pressure dome [22] in the tube set for irrigation helps to measure the liquid pressure,
- The luer lock [23] connector in the irrigation tube is used to an endoscopic instrument inflow stopcock

Step 1	Step 2
	
To be carried out by non-sterile technician: → Slide the fluid bag(s) in the cuff(s). → Hang the bag on the hook in the housing of the cuff(s) [18].	To be carried out by non-sterile technician: → Hang the cuff(s) on a pole's hook above the control unit using the loop [19].

Step 3

To be carried out by non-sterile technician: → Connect the cuff(s) [17] to the control unit [12]. ☑ Use a Y-adaptor when using two pressure cuffs.

Step 4

To be carried out by non-sterile technician: → Open outer packaging of the irrigation tubing set. To be carried out by a sterile technician: → Remove the inner tubing set package, open it. → Keep the Luer lock connector [23] in the sterile area and hand the tube end with the spike(s) to the non-sterile technician To be carried out by non-sterile technician: → Press the ears of the pressure dome [22] and take away the protective cap. Make sure to not damage the membrane.

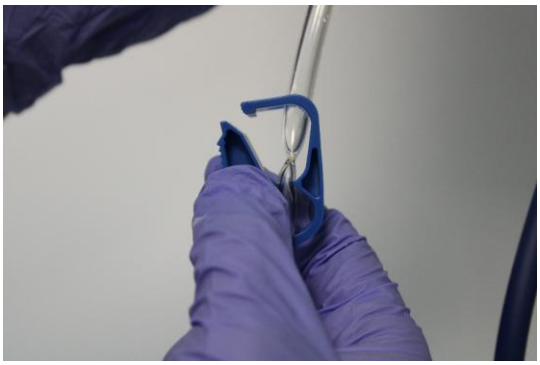
Step 5

To be carried out by non-sterile technician: → Keep the ears of the pressure dome open and place it on the sensor housing [4]. When placing it make sure there is no space between the sensor and the housing.

Step 6

To be carried out by non-sterile technician: → Rotate the pressure dome to lock it in place

Step 7	Step 8
	
To be carried out by non-sterile technician: → Hang the tube into the holder.	To be carried out by non-sterile technician: → Remove the protection from the spike(s) [20] to connect the tube end of the irrigation tubing set to the fluid bag. → Keep the clamp(s) [21] closed for now

Step 9	Step 10
	
To be carried out by sterile technician → Connect the Luer lock [23] connector with the instrument inflow stopcock. → Open the inflow valve of the instrument	To be carried out by non-sterile technician: → Open the clamp [21] of the first fluid bag and of the Y adapter if necessary. To be carried out by sterile technician: → When all the air is out of the tube set, close the inflow valve of the instrument.

3.4.2. Setting up the vacuum system

W.XLIX ***Do not plug the suction tube set connected to the instrument directly to the control unit, the outflow must go in the container.***

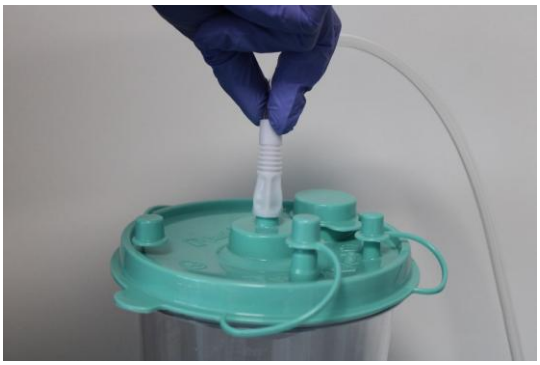
W.L ***Use only the vacuum tube set provided by the manufacturer with a hydrophobic filter to avoid any liquid to enter the device.***

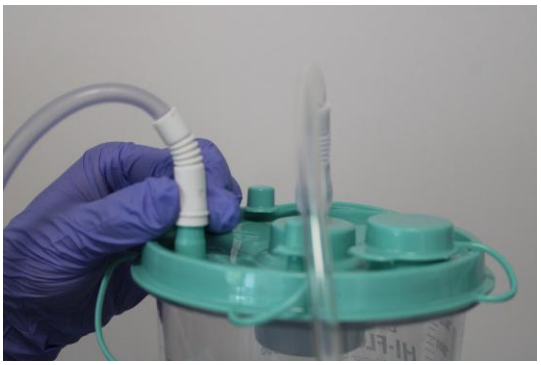
The suction system consists of the following:
- Vacuum tube set with filter (see Figure 7),

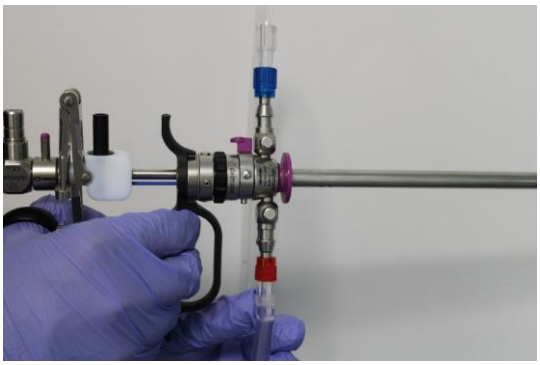
– Secretion container,
– Suction instrument with its suction tubing set.

Step 1

To be carried out by non-sterile technician: → Open the vacuum tube set packaging. → Connect the luer lock of the vacuum tube set [24] to the control unit [11].

Step 2

To be carried out by non-sterile technician: → Connect the vacuum tube set [26] to the container.

Step 3

To be carried out by non-sterile technician: → Open outer packaging of the suction tube set. To be carried out by a sterile technician: → Remove the inner package of the suction tube set and open it. → Keep the patient side in the sterile area and hand the other tube end to the non-sterile technician. To be carried out by non-sterile technician: → Connect the tube to the container. ☑ Check the container cover is sealed, correctly placed and all openings are closed.

Step 4

To be carried out by sterile technician: → If applicable, connect the suction tube connector with the instrument outflow. → Open the outflow valve of the instrument

3.4.3. Changing a fluid bag

The fill level of the irrigation fluid bags must be monitored by the medical personnel and always keep a full fluid bag on hand to replace an empty one. This avoid having to interrupt surgery due to a lack of distention fluid.

If your surgery will require more than one fluid bag, always prepare two fluid bags with a tube set for irrigation with two spikes and two cuffs.

If more than two bags are necessary, proceed the following way when the first bag gets empty:

Steps	Instructions
1. Open the full fluid bag line	To be carried out by non-sterile technician: → Unclamp the Y-adaptor of the cuff with the full bag. → Unclamp [21] the tube set for irrigation of the full bag.
2. Close the empty fluid bag line	To be carried out by non-sterile technician: → Clamp the tube set [21] for irrigation of the empty fluid bag. → Clamp the Y-adaptor of the empty fluid bag's pressure cuff.
3. Replace the empty fluid bag	To be carried out by non-sterile technician: → Unscrew the cuff to deflate it from the Y adaptor. → Unhang the cuff from the pole and remove the empty fluid bag. → Replace it with a new one as explained in 3.4.1. → Hand the cuff again to the pole and screw the cuff again to the Y adaptor.

3.4.4. Replacing the secretion container

The fill level of the containers must be monitored by the medical personnel and always keep an empty container on hand to replace a full one. This avoid having to interrupt surgery due to a full container.

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

Steps	Instructions
1. Stop the suction	To be carried out by sterile technician: → Close the suction valve from the instrument. → Clamp any second suction line. To be carried out by non-sterile technician: → Pause the suction function [8].

Steps	Instructions
2. Replace the container	To be carried out by non-sterile technician: → Open a valve on the container to vent the system. → Disconnect the suction tubing and the vacuum tubing from the container. → Connect them to a new container.
3. Start the suction again	To be carried out by non-sterile technician: → Launch the suction function [8]. To be carried out by sterile technician: → Open the suction valve from the instrument. → Unclamp any second suction line.

3.4.5. Disassemble the irrigation system

Steps	Instructions
1. Disconnect the instrument	To be carried out by non-sterile technician: → Close the clamp(s) of the irrigation tube set. To be carried out by sterile technician: → Close the inflow valve from the instrument. → Disconnect the Luer lock connector from the instrument. → Hand the Luer lock connector to the non-sterile technician.
2. Disconnect from the device	To be carried out by non-sterile technician: → Make sure the irrigation function is off. → Disconnect the cuff(s) from the device. → Disconnect the spikes from the fluid bags. → Rotate the pressure dome and press its ears to release it from the sensor housing. → Discard the tube set.

3.4.6. Disassemble the suction system

Steps	Instructions
1. Disconnect the instrument	To be carried out by sterile technician: → Close the outflow valve from the instrument. → Disconnect the luer lock connector from the instrument. → Hand the Luer lock connector to the non-sterile technician.
2. Disconnect from the device	To be carried out by non-sterile technician: → Make sure the vacuum function is off. → Disconnect the suction tube set from the container. → Disconnect the vacuum tube set from the container.

3.5. Use in hysteroscopy indication

3.5.1. Hysteroscopy indication screen displays

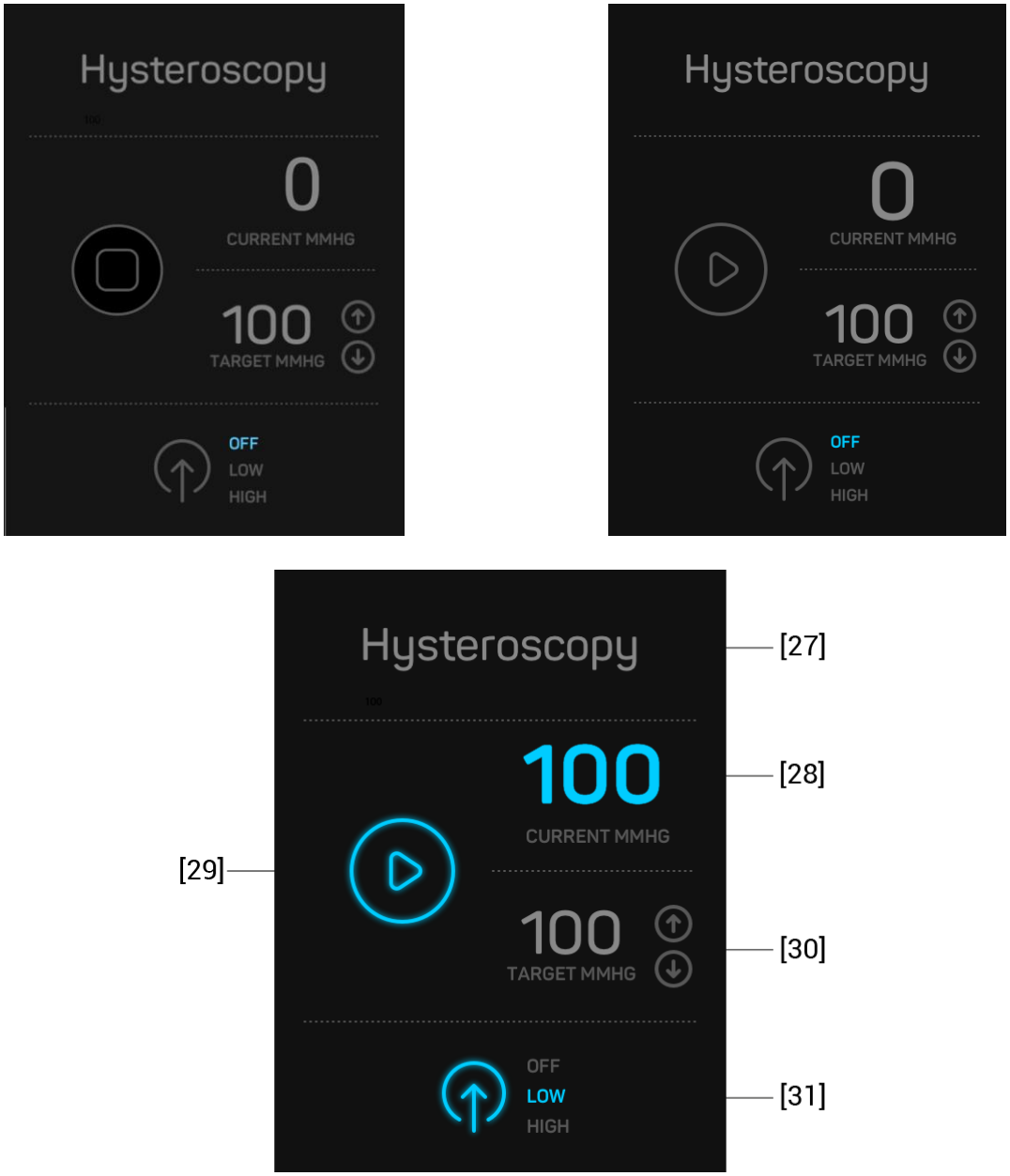


Figure 10 - Hysteroscopy indication screen: device not ready (top left), device ready and irrigation and suction turned off (top right) and turned on (down).

Legend		Function
[27]	Hysteroscopy Indication	Indicates the device is in hysteroscopy mode
[28]	Current intrauterine pressure	Indicates the current estimated intrauterine pressure in mmHg
[29]	Irrigation function status	Indicates the irrigation status mode (NOT READY/READY/ON)

Legend		Function
[30]	Target intrauterine pressure	Indicates the chosen target pressure in mmHg
[31]	Vacuum function status	Indicates the vacuum status mode (OFF/LOW/HIGH)

3.5.2. Set the target pressure

W.LIV

If the current pressure cannot reach the target pressure, a perforation of the uterine cavity might be the cause. This result is an increased risk for bacteria entering the body. Examine the uterus for injuries.

W.LV

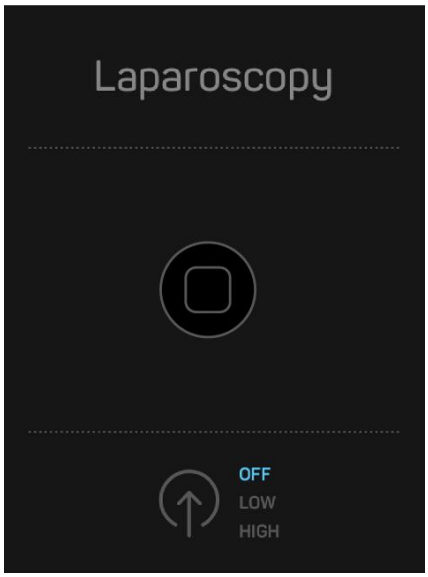
Select the optimum pressure based on the patient profile, including but not limited to: blood pressure, height, weight and age and the indication of the operation.

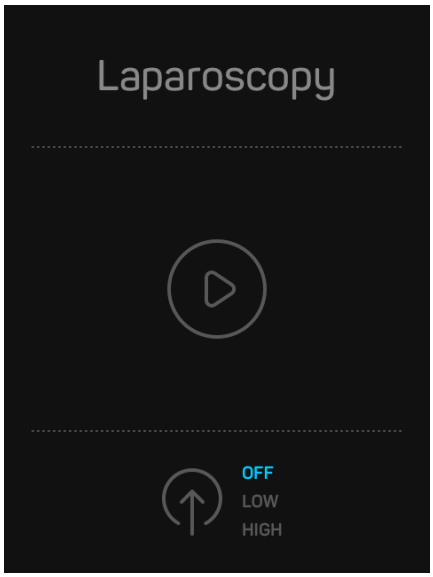
The estimate of intrauterine pressure is based on the measurement taken and the height of the patient, to take account of the effect of gravity.

The nominal pressure can be increased or decreased while the device is being used or not used. Values vary between 60 and 150mmHg. The default value is 80mmHg. You can set the maximum to 200mmHg in the settings (see 3.3.4).

→ When in hysteroscopy indication, briefly press [6] to increase or [9] to decrease the target pressure by increments of 10 mmHg.

3.6. Use in laparoscopy indication





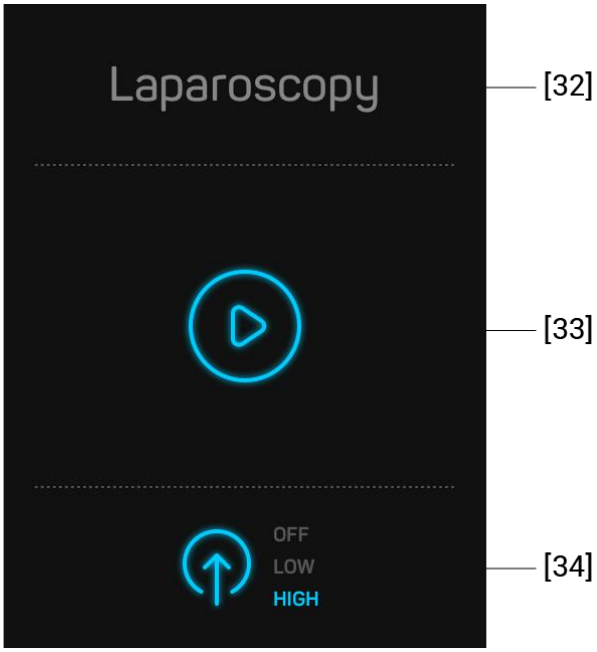


Figure 13 - Laparoscopy indication screen: device not ready (top left); device ready irrigation and suction turned off (top right), and turned on (down)

	Legend	Function
[32]	Laparoscopy indication	Indicates the device is in laparoscopy mode
[33]	Irrigation function status	Indicates the irrigation status mode (NOT READY/READY/ON)
[34]	Vacuum function status	Indicates the vacuum status mode (OFF/LOW/HIGH)

When in laparoscopy indication, no settings are necessary. The device will display the current state of the vacuum and irrigation function only.

3.7. Use of the irrigation function

W.LVI ***Clamp the irrigation tube set if replacing the instrument inflow during surgery, otherwise you may lose distension liquid and impact accurate deficit balance.***

W.LVII ***Even if the device is off, irrigation may still occur with gravity. Make sure the instrument inflow valve is closed or clamp the irrigation tube set to completely stop the irrigation flow.***

W.LVIII ***Always keep the instrument outflow valve slightly open to diminish overpressure risk.***

The full irrigation capacity is only available if the cuff is pre-pressured. Pre-pressurization takes about 60 seconds depending on the volume of the cuff.

☑ Check you drained the entire tube set before starting the surgery.

→ Close the inflow valve on the instrument.
→ Start the irrigation by pressing [7]. The cuff will start to inflate.

You may now start the surgical procedure and open the inflow valve. When the surgical procedure is over:
→ Stop the irrigation by closing the inflow valve or clamping the irrigation tube set.
→ Stop the control unit by pressing [7]. The cuff will be deflated.

3.8. Use of the suction function

W.LIX

If liquid goes into the vacuum tubing, you need to discard it immediately and replace it by a new one, otherwise the suction may not function as intended.

The full suction capacity is only available if the tube system is completely pre-evacuated. Pre-evacuation takes about 30 to 60 seconds depending on the volume of the container.

The suction device has three suction levels:

Suction level	Suction
OFF	0 kPa
LOW	30 kPa
HIGH	50 kPa

→ Start the suction function by pressing [8].
→ Press [8] again to switch from the three levels.
☑ Check the current suction level displayed in the lower part of the indication view.

After using the device, even in OFF level, remaining vacuum may exist in the container, open the container to completely stop the vacuum.

3.9. Visual and functional inspection

W.LX

Do not use a damaged device or a device with improper functioning. The use of a damaged device or of a device with improper functioning may cause an electric shock, mechanical injury, infection, and/or thermal injury. Replace a damaged device or a device with improper functioning.

Always have a spare device and tubing set ready to avoid postponing a surgery in case of a defective device.

3.9.1. Inspection prior to set up the device

The user must perform this functional checklist after first installation and prior to each use of the device:

- ☑ Check the control unit for no visible wear and damage.
- ☑ Check power cord for no visible wear and damage.
- ☑ Check the pressure sensor housing membrane surface for no visible wear and damage.
- ☑ Check each sterile tubing packaging for no visible wear and damage.
- ☑ Check the cuff(s) for no visible wear and damage.

3.9.2. Inspection prior to use the device

The user must perform this checklist after setting up the device prior to its use:

- ☑ Check the control unit is safely secured on the pole or rail with the screw is tight.
- ☑ Check the welcome menu appears on the screen with no error message (see Figure 8).
- ☑ Check for adequacy the patient height setting should be (see 3.3.1).
- ☑ Check the irrigation bag is correctly hanged to the cuff.
- ☑ Check the cuff is correctly hanged to the pole.
- ☑ Check the cuff is correctly plugged to the control unit.
- ☑ Check the pressure dome is correctly secured on the sensor housing without gap.
- ☑ Check the vacuum tubing set is correctly plugged to the control unit and to the container.
- ☑ Check the tubing lines have no leak nor air bubbles.

3.10. Device safety functions

W.LXI

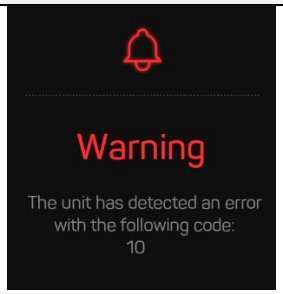
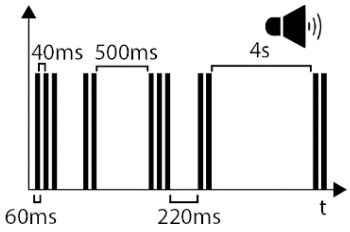
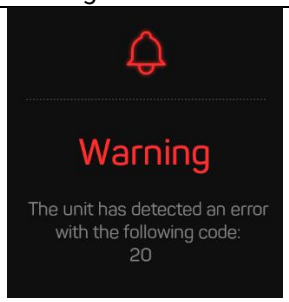
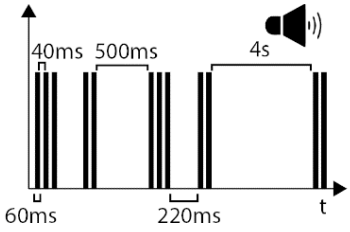
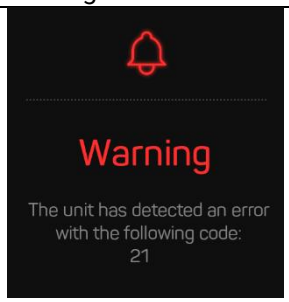
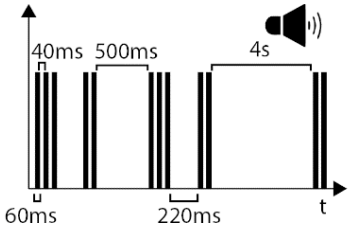
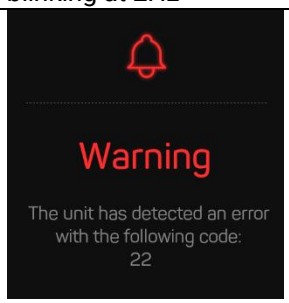
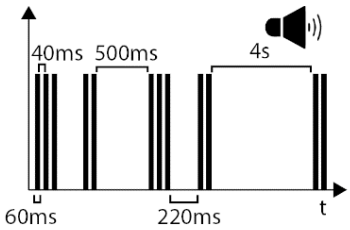
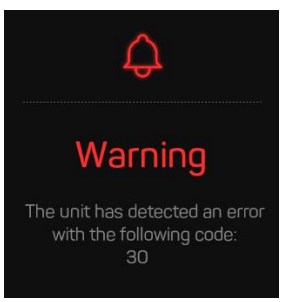
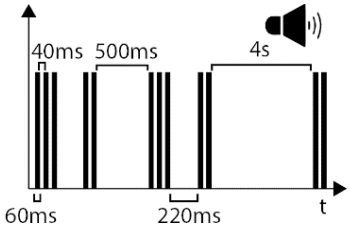
To be correctly informed by the alarm system of the device, at least one user must be situated at a distance of 1m from the device, the screen in view.

3.10.1. Device self-test and technical alarm

Technical alarm overwrites all other possible messages. The device is in safe mode and cannot proceed.

When a technical alarm is on, the device is in default mode until the condition of the alarm is resolved. In default mode, the device main functions are stopped.

After being switched on, the device performs continuous self-test of the sensors, and electronic components. The following describes the error messages for defects of the individual modules.

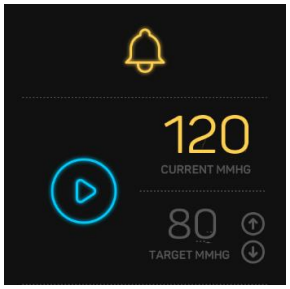
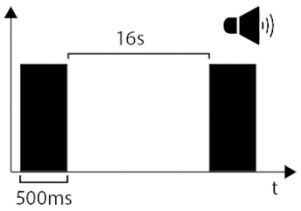
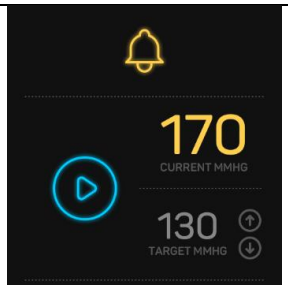
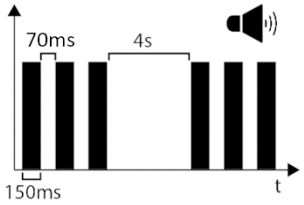
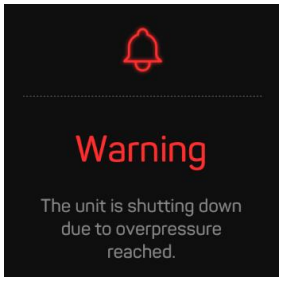
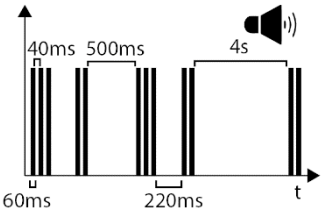
Condition	Sign	Sound	Solution
Error 10 Internal system error	 Note: The bell signal is blinking at 2Hz		→ Open the instrument outflow valve completely. → Stop the surgery. → Contact your Delmont imaging representative.
Error 20 Measurement sensor error	 Note: The bell signal is blinking at 2Hz		→ Open the instrument outflow valve completely. → Stop the surgery. → Contact your Delmont imaging representative.
Error 21 Pressure sensor error	 Note: The bell signal is blinking at 2Hz		→ Open the instrument outflow valve completely. → Stop the surgery. → Contact your Delmont imaging representative.
Error 22 Suction sensor error	 Note: The bell signal is blinking at 2Hz		→ Open the instrument outflow valve completely. → Stop the surgery. → Contact your Delmont imaging representative.
Error 30 Display system error			→ Open the instrument outflow valve completely. → Stop the surgery. → Contact your Delmont imaging representative.

3.10.2. Physiological alarm for hysteroscopy indication

Alarm of higher level overwrites alarm of lower level. When the alarm of higher level is raised, the alarm of lower level may still be active if its condition exists.

When a physiological alarm of level high is raised, the device goes in default mode until the condition of the alarm is resolved. In default mode, the device main functions are stopped.

When using the device in hysteroscopy indication, the following alarm messages may appear:

	Condition	Sign	Sound	Solution
LOW	Overpressure of 20mmHg above the target value for more than 4 seconds.	 Note: The bell signal is not blinking.		→ Open the instrument outflow valve completely. The alarm will stop after 4 seconds the intrauterine pressure is back to normal.
MEDIUM	Overpressure of 20mmHg above the maximum pressure (150 or 200mmHg) for more than 4 seconds.	 Note: The bell signal is blinking at 0.5Hz		→ Open the instrument outflow valve completely. The alarm will stop after 4 seconds the intrauterine pressure is back to normal.
HIGH	Overpressure of 20mmHg above the maximum pressure (150 or 200mmHg) for more than 20 seconds or 40mmHg above the maximum pressure (150 or 200mmHg) for more than 2 seconds	 Note: The bell signal is blinking at 2Hz		→ Close the instrument inflow → Open the instrument outflow valve completely. The alarm will stop after 4 seconds the intrauterine pressure is back to normal.

3.10.3. Bell cancel

The Bell cancel button [10] stops only the current individual alarm sound and does not affect other alarm signal that may occur. The alarm sound is cancelled until the alarm condition is cleared or a new alarm condition occurs.

→ To silence the alarm, press the bell button [10] to deactivate the sound signal.

3.11. Troubleshooting

Issue type	Solution
The device does not turn on when we press the ON/OFF button	☑ Check the power cord is correctly plugged. ☑ Check the power matches the necessary power for the device.
The irrigation function does not start when press start and the following icon appears. 	☑ Check the irrigation bag is at least 10cm (4”) above the control unit. ☑ Check the tube set is correctly placed as indicated in 3.4.1. ☑ Check the clamps are open.
The cuff is not inflating	☑ Check the connection between the control unit and the cuff. ☑ Check, when using a Y- adaptor, the connection between the Y and the cuffs, and the clamps are opened. ☑ Check for possible leaks in the system. → Replace the cuff if it has a leak.
In hysteroscopy indication, the target pressure cannot be reached	☑ Check the fluid bag level, replace the bag if necessary (see 3.4.3). ☑ Check the clamp of the irrigation tubing line is open. ☑ Check the valve of the instrument is opened. ☑ Check for possible leaks in the system. ☑ Check the condition of the uterine cavity for injuries and/or perforation.

Issue type	Solution
The vacuum is not reached in the container	☑ Check the vacuum function is on (LOW or High). ☑ Check the vacuum tube connection between the control unit and the container on both ends. ☑ Check the container's cover for openings and that it is correctly closed. ☑ Check the connection between the container and the instrument. ☑ Check for possible leaks. → Replace the tubing if it is leaking.
An error message appears	☑ Stop using the device, turn it off. ☑ Use a replacement device if available.
The displayed pressure in hysteroscopy mode seems not accurate	☑ Stop using the device and dispose the tube set. ☑ Launch an auto check (see 5.1.1). If the test is correct, relaunch the device with a new tube set, if not stop using the device and turn it off.
The pressure flow in laparoscopy is low	☑ Check the fluid bag level, replace the bag if necessary (see 3.4.3). ☑ Check the clamp of the irrigation tubing line is open. ☑ Check the inflow valve of the instrument is completely opened. ☑ Check for possible leaks in the system.

→ Contact your Delmont imaging representative if the issue persists.

4. Reprocessing

W.LXII	***Do not reprocess the single use tube sets. There is risk of infection and illness due to contamination.***
W.LXIII	***If necessary, repeat the reprocessing process until the device is optically clean.***
W.LXIV	***The instructions of the cleaning agents' manufacturers must be observed. The cleaning and disinfection results must be confirmed by the corresponding manufacturers.***
W.LXV	***Neither the device nor the cuff is intended to come into contact with the patient. No sterilization is necessary for these devices.***
W.LXVI	***If the cuff has been contaminated with blood or other fluid, it should be discarded.***

The instructions provided have been validated by the manufacturer of the medical device as being capable of preparing the medical device for reuse. This requires verification and/or validation and routine monitoring of the process.

4.1. Reprocessing of the control unit and the cuff

Always use cleaners with a neutral pH value to prevent damage to the surface of the devices

Steps	Instructions
1. Preparation before cleaning	→ Turn off and disconnect the control unit from the power grid, → Make sure the cuff is disconnected from the control unit
2. Manual Cleaning	→ Use single use cleaning drapes or soaked cloth with cleaning disinfectant to clean the surface of the control unit and the cuff for at least one minute. Comply with the manufacturer's cleaning instructions. → Dry the equipment with a lint-free soft cloth. ☑ After cleaning, inspect the control unit for cleanliness and damage as instructed in 3.8.

4.2. Service life and reprocessing limitation

W.LXVII

The claimed service life can be reduced due to wear and wrong use and shall be verified before each use following instruction in section 3.8.

The irrigation fluid management system is composed of different items with different service life:

Item	Service life	Details
Irrigation and suction tube set	1 use	All tubing sets intended to be used with the device are single use and shall be discarded after its use.
Vacuum tube set	30 days	The vacuum tube set is intended to be used for 30 days prior to be replaced, with respect to the following instruction: → Discard it if liquid goes into the tube set.
Control unit	5 years	The control unit has an estimated service life of 5 years with respect to the following instruction: → You can verify the proper functioning of device following instruction in section 3.8. → You must follow the maintenance instruction in section 5.1.
Cuff	300 uses	The cuff is intended to be used 300 times prior to be replaced, with respect to the following instruction: → You can verify the proper functioning of device following instruction in section 3.8.

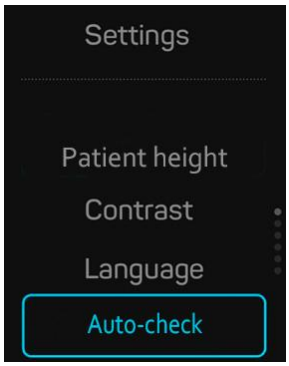
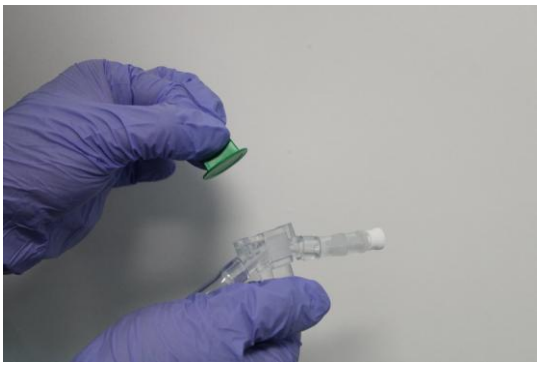
5. After-Sales service and maintenance

5.1. Maintenance

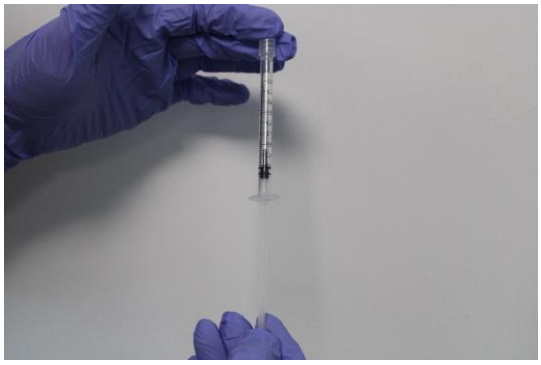
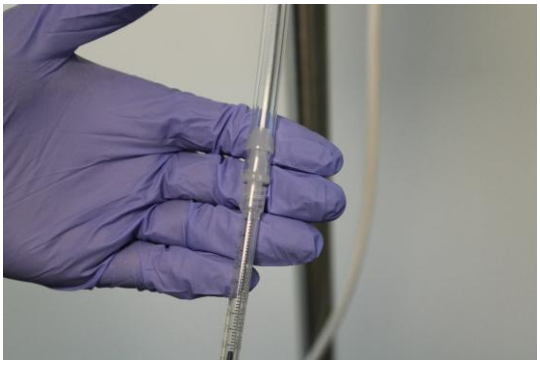
5.1.1. Periodic self-check of the pressure sensor

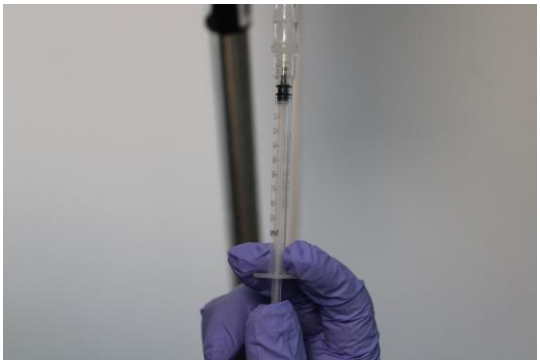
For the periodic self-check, it is necessary to use self-test set (REF D110 100 019) containing a tube and a syringe, this set is supplied with the device or can be ordered.

→ Perform the auto check every six months or if you have any doubt on the correct functioning of the pressure sensor of the device.
→ Make sure you have the self-test tube set (D110 100 019) available.
→ Launch the auto check from the settings menu.

Step 1	Step 2
	
→ Go to settings menu and launch Auto-check. → Follow the instructions from the display screen.	→ Press the ears of the pressure dome of the self-check tube and remove the protective cap.

Step 3	Step 4
	
→ Place the pressure dome on the pressure sensor.	→ Turn it clockwise to lock it.

Step 5	Step 6
	
→ Pre-fill the syringe from the self-check set with air by pulling the syringe.	→ Screw on the syringe pre-filled with air to the test tube.

Step 7	Step 8
	
→ Click on the play button [7]. ☑ The screen shall display the current pressure.	→ Press the syringe until you completely empty it ☑ Check the pressure displayed is correct : 100 +/- 10 mmHg. → Confirm the test is completed by pressing the play button [7]. → Remove the self-tube set.

→ If the self-check test fails, contact your Delmont imaging representative.

5.1.2. Periodic electrical safety check

At a minimum of every 12 months perform the following maintenance according to IEC/EN 60601-1 for test methods:

→ Ensure the earth leakage current is 500µA, ground protective earth impedance is <0.1 ohms, power consumption is less than or equal to the rated power,

→ The unit passes a dielectric withstand test of 1500V without breakdown.

→ If the unit fails these tests, contact your Delmont imaging representative.

5.2. Repair


W.LXVIII

Do not perform repairs or maintenance operations other than the ones specified in these instructions. There is a risk of injury to the patient and/or the user caused by unauthorized repairs and device modification. Possible injuries include mechanical injuries, electric shock, burns and intoxication.

Delmont imaging does not accept warranty claims for damage caused by inadequate packaging.

Delmont imaging does not supply original parts to independent workshops or other similar devices manufacturers. Repairs may only be performed by qualified servicing personnel that have been authorized by Delmont imaging. Thus, only Delmont imaging is in a position to carry out repairs using original parts. The original technical specifications and the operational safety of the device can only be guaranteed by using original parts. Delmont imaging does not accept responsibility for devices that have been modified from the original device.

→ Contact your Delmont imaging representative for repair information and process.

5.3. Return of the device


W.LXIX

Do not return a device without prior reprocessing (see 4). There is risk of infection when returning a used medical device. Returning used medical devices is exclusively permitted when cleaned and disinfected, and with written verification thereof. If reprocessing could damage the device completely, clean the device as thoroughly as possible and mark it accordingly.

Contact your Delmont imaging representative to get the appropriate shipping instruction based on your location.

If you need to return the device:

→ Reprocess the device according to 4.

→ Use the original cardboard packaging for the transport of the device. If this is not possible, wrap each component individually in sufficient paper or sheets of foamed material and place them in a cardboard box.

5.4. Warranty

Contact your Delmont imaging representative for more details on your warranty according to your country of use.

This device is guaranteed against defects in workmanship and material. In the event of defects, the device will be repaired or replaced at the manufacturer's discretion.

The warranty for Delmont imaging devices shall become void if repairs, attempted repairs, alterations, or other tampering of this device is carried out by unauthorized personnel. Delmont Imaging exclusively provides its customers with tested and impeccable devices. All devices are designed and manufactured to meet the highest quality requirements.

5.5. Disposal

 W.LXX	***Keep the used device out of reach of unauthorized person.***
 W.LXXI	***Disposing the tube set: comply with the rules of hygiene when disposing of the tube set, collected fluid, and the secretion container.***
 W.LXXII	***Disposing the control unit: do not trash the device with unsorted municipal waste. The control unit contains electrical waste, it must be collected separately in accordance with applicable national or institutional related policies relating to obsolete electronic equipment.***
	***Contact your Delmont imaging representative for more details on disposal of the device according to your local rules and recycling opportunity.***

We encourage our customers to recycle the control unit whenever possible or to return the device to Delmont imaging who will then take the appropriate steps to recycle the device.

6. Technical data

6.1. General specifications of the control unit

Mains voltage range [V]	100 - 230
Supply frequency range [Hz]	50 / 60
Power consumption [VA] at 100 V/60 Hz	36
Power consumption [VA] at 240 V/50 Hz	36
Fuses	2x T0.63A - 250V UL/CSA 5 x 20 mm
Protection class (I, II)	I
Application part type (B, BF, CF)	CF
Defibrillator protection (yes/no)	No
Equipotential plug (yes/no)	No
Batteries	None
Protection class (IP code)	IPX3
Suitability for use in an oxygen rich environment (yes/no)	No
Mode of operation	Continuous
Software version	The version is given in the Device information setting (see 3.3.5).
Maximum size of the control unit [mm]	185 x 230 x 130
Weight of the control unit [kg]	2
Setting target pressure range [mmHg] in hysteroscopy	60 – 200
Measurement range [mmHg] in hysteroscopy	60 – 250 ± 15
Maximum negative suction pressure [kPa]	50
Maximum negative suction pressure [mmHg]	375
Suction power [l/min]	2.0 (depending on instrument outflow)

6.2. Conditions of use

6.2.1. Transport conditions

Ambient temperature	-30°C to 50°C
Relative humidity	10% to 90%, non-condensing
Atmospheric pressure	20.0 kPa to 106.0 kPa

6.2.2. Storage conditions

Ambient temperature	10°C to 35°C
Relative humidity	10% to 85%, non-condensing
Atmospheric pressure	70.0 kPa to 106.0 kPa

6.2.3. Operating conditions

Ambient temperature	10°C to 30°C
Relative humidity	30% to 75%, non-condensing
Atmospheric pressure	70.0 kPa to 106.0 kPa

6.3. Guidance on electromagnetic compatibility

6.3.1. Electromagnetic emissions

This device is intended for use in the electromagnetic environment specified below. The user must ensure that it is used in this environment.

Emissions test	Compliance	Electromagnetic environment-Guidance
RF emissions CISPR 11	Group 1	The product uses HF energy for its own operation. The HF emissions are very low and are unlikely to affect nearby electronic devices.
RF emissions CISPR 11	Class A	The device is suitable for use in all installations, other than residential installations and premises directly connected to the public low voltage power distribution network intended to supply residential buildings.
Harmonic emissions IEC 61000-3-2	Compliant	
Voltage fluctuations/Flicker IEC 61000-3-3	Compliant	

6.3.2. Electromagnetic immunity

This device has been designed for use in the electromagnetic environment specified below. The user must ensure that it is actually used in this environment.

Immunity test	IEC 60601 Severity Level	Compliance Level	Electromagnetic environment-Guidance
Electrostatic discharges (ESD) IEC 61000-4-2	± 8 kV via contact ± 15 kV via air	± 8 kV ± 15 kV	The floor must be made of wood, concrete or tiles. If the floor is covered with a synthetic material, the relative humidity must be at least 30%.
Rapid transient peaks IEC 61000-4-4	± 2 kV power lines ± 1 kV for input and output lines	± 2 kV ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Electric shocks IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV ± 2 kV	
Power outages, short power outages and voltage fluctuations IEC 61000-4-11	<5% UT for 10 ms 40% UT for 100 ms 70% UT for 500 ms <5% UT for 5 s	<5% UT 10 ms <40% UT 100 ms <70% UT 500 ms <5% UT 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of this device must be able to continue working during power outages, it is recommended that this device be powered from an uninterruptible power supply or a battery.
Magnetic field at mains frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	The magnetic field at the mains frequency must be at a characteristic level of a location (50/60 Hz) in a typical commercial or hospital environment. The device should be kept at least 15 cm away from the source of power frequency magnetic fields during use.

6.3.3. Electromagnetic emissions

This device is intended for use in the electromagnetic environment specified below. The user must ensure that it is actually used in this environment.

Safety test	IEC 60601 Severity Level	Compliance Level	Electromagnetic environment- Guidance
Conducted disturbances induced by RF fields IEC 61000-4-6	3 Veff 150 kHz to 80 MHz	3Veff	Portable and mobile RF communication devices should not be used at a distance, including cables, from this device that is less than the recommended distance, calculated by applying the formula that corresponds to the transmitter frequency. d = 1,16 P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	d = 1,16 P 80 MHz to 800 MHz d = 2,33 P 800 MHz to 2,7 GHz Where "P" is the maximum output power of the transmitter, in Watts (W), assigned by its manufacturer and "d" is the recommended separation distance in meters (m). Field strength levels emitted by fixed RF transmitters - which must be established by in situ electromagnetic measurement must be below the compliance level in each frequency band. Interference may occur with de- vices marked with the following symbol: 

Note 1: U_T is the a.c. mains voltage prior to application of the test level.
Note 2: At 80 MHz and 800 MHz, the highest frequency band should be used.
Note 3: Guidelines regarding conducted disturbances induced by RF fields or radiated RF fields may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
Note 4: The ISM bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz, 13.553 MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz, and 40.66 MHz to 40.70 MHz
Note 5: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
Note 6: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

6.3.4. Recommended distances between portable and mobile RF communication systems for this device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device.

Immunity to proximity fields from following RF wireless communication equipment has been confirmed:

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Minimum separation distance (m)	EC / EN60601 test level (V/m)	Compliance level (V/m)
385	380-390	TETRA 400	Pulse modulation: 18Hz	1.8	0.3	27	27
450	430-470	GMRS 460, FRS 460	FM - ± 5 kHz deviation 1 kHz sinus	2	0.3	28	28
710	704-787	LTE Band 13, 17	Pulse modulation: 217 Hz	0,2	0.3	9	9
745							
780							
810	800-960	GSM 800 / 900, TETRA 800, iDEN 820 CDMA 850, LTE Band 5	Pulse modulation: 18Hz	2	0.3	28	28
870							
930							
1720	1700-1990	GSM 1800. CDMA 1900. GSM 1900. DECT. LTE Band 1, 3, 4, 25. UMTS	Pulse modulation: 217 Hz	2	0.3	28	28
1845							
1970							
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation: 217 Hz	2	0.3	28	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation: 217 Hz	0.2	0.3	9	9
5500							
5785							

Note 1: For some services, only the uplink frequencies are included.

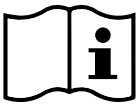
Note 2: Carrier waves are modulated using a 50 % duty cycle square wave signal.

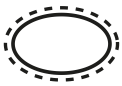
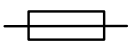
For other portable and mobile RF communication equipment (transmitters), minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

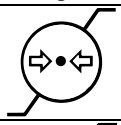
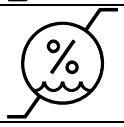
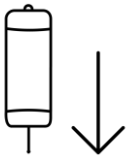
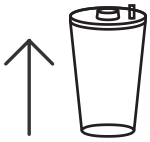
Maximum assigned transmitter output power in W	Separation distance as a function of transmitter frequency (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1{,}16 \sqrt{P}$	$d = 1{,}16 \sqrt{P}$	$d = 2{,}33 \sqrt{P}$
0.01	0.116	0.116	0.233
0.1	0.366	0.366	0.736
1	1.16	1.16	2.33
10	3.66	3.66	7.36
100	11.6	11.6	23.3

Note 1: At 80 MHz and 800 MHz, the separation distance given in the upper frequency band applies.
Note 2: These recommendations may not be applicable in all situations. The propagation of electromagnetic waves is altered by absorption and reflection from structures, objects and people. For transmitters whose maximum output power is not listed in the table above, the recommended separation distance d, in meters (m) can be established using the equation applicable to the transmitter frequency, where P is the maximum output power of the transmitter in Watts (W) assigned by the transmitter manufacturer.

7. Used symbols

Symbol	Description
	Symbol for “Caution”. Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Symbol for “Refer to operating instructions”. Indicates to the user that it is necessary to consult the operating instructions.
	Symbol for “Refer to user manual/brochure”. Indicates mandatory action to read the instructions for use.
	Symbol for “Manufacturer”. Indicates the manufacturer of the medical device.
	Symbol for “Date of manufacture”. Indicates the date the medical device was manufactured
	Symbol for “Country of manufacture”. Identifies the country in which the products were manufactured.
	Symbol for “CE marking”. Indicates that a device has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements.
	Symbol as an alternative to the prescription device labeling statement. Indicates that U.S.A. Federal law restricts this device to sale by or on the order.
	Symbol for “RoHS compliant”. Indicates that a device has been assessed by the manufacturer and deemed to meet European Union’s restrictions of certain dangerous substances used in electronic and electrical equipment
	Symbol for “Medical device”. Indicates that the item is a medical device.
	Symbol for “Serial Number”. Indicates the manufacturer's serial number in order to formally identify a specific medical device.
	Symbol for “Lot code”. Indicates the manufacturer's lot code so that the lot can be formally identified.

Symbol	Description
	Symbol for “Catalogue number”. Indicates the manufacturer's catalog number so that the medical device can be positively identified.
	Symbol for “Unique Device Identifier”. Denotes a medium that contains information about a unique device identifier.
	Symbol for "Quantity". Indicates the number of devices included in the package.
	Symbol for “Not made with natural rubber latex”. Indicates, that product is not made with natural rubber latex.
	Symbol for “Non-sterile”. Denotes a medical device that has not been subjected to a sterilization process.
	Symbol for “Sterilized with Ethylene Oxide”. Denotes a medical device that has been sterilized with ethylene oxide.
	Symbol for “Expiry Date”. Indicates the date after which the medical device should no longer be used.
	Symbol for “Do not reuse”. Indicates a medical device intended for single use.
	Symbol for “Single sterile barrier system with protective outer packaging”. Denotes a single sterile barrier system with protective packaging on the outside.
	Symbol for “Do not use if package is damaged”. Indicates a medical device that should not be used if the packaging has been damaged or opened and the user should consult the instructions for use for further information.
	Symbol for “Type CF applied part”. To identify a type CF applied part complying with IEC 60601-1. Classification of protection against electrical shock.
	Symbol for “Standby” Indicates the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand-by condition.
	Symbol for “UL/CSA tied fuses” Indicates the fuses boxes or their location marked with type and rating.
	Symbol for “Bell cancel” To identify the control whereby a bell may be switched off or to indicate the operating status of the bell

Symbol	Description
	Symbol for “Temperature limit”. Indicates the minimum and maximum temperatures to which the medical device may be safely exposed.
	Symbol for “Atmospheric pressure limit”. Indicates the range of atmospheric pressure to which the medical device may be safely exposed.
	Symbol for “Humidity limit”. Indicates the minimum and maximum humidity to which the medical device may be safely exposed.
	Symbol for “Protect from heat and radioactive sources”. Indicates a medical device that is sensitive to heat and radioactive sources.
	Symbol for “Moisture Sensitive”. Indicates a medical device that is moisture sensitive.
	Symbol for “Fragile, handle with care”. Indicates a medical device that may be broken or damaged if not handled with care
	Symbol for “Transport conditions”. Indicates the transport conditions that should be respected.
	Symbol for “Storage conditions”. Indicates the storage conditions that should be respected.
	Symbol for “Handle with care”. Indicates the package should be handled with precaution
	Symbol for “This way up”. To indicate correct upright position of the transport package.
	Symbol for “WEEE; waste electrical and electronic equipment; crossed-out wheeled bin”. Indicates that separate collection for waste electric and electronic equipment (WEEE) is required.
	Symbol for “Cuff plug” Indicates that the tube going to the pressure cuff should be plugged here.
	Symbol for “Container plug” Indicates that the tube going to the secretion container should be plugged here

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