delmont imaging

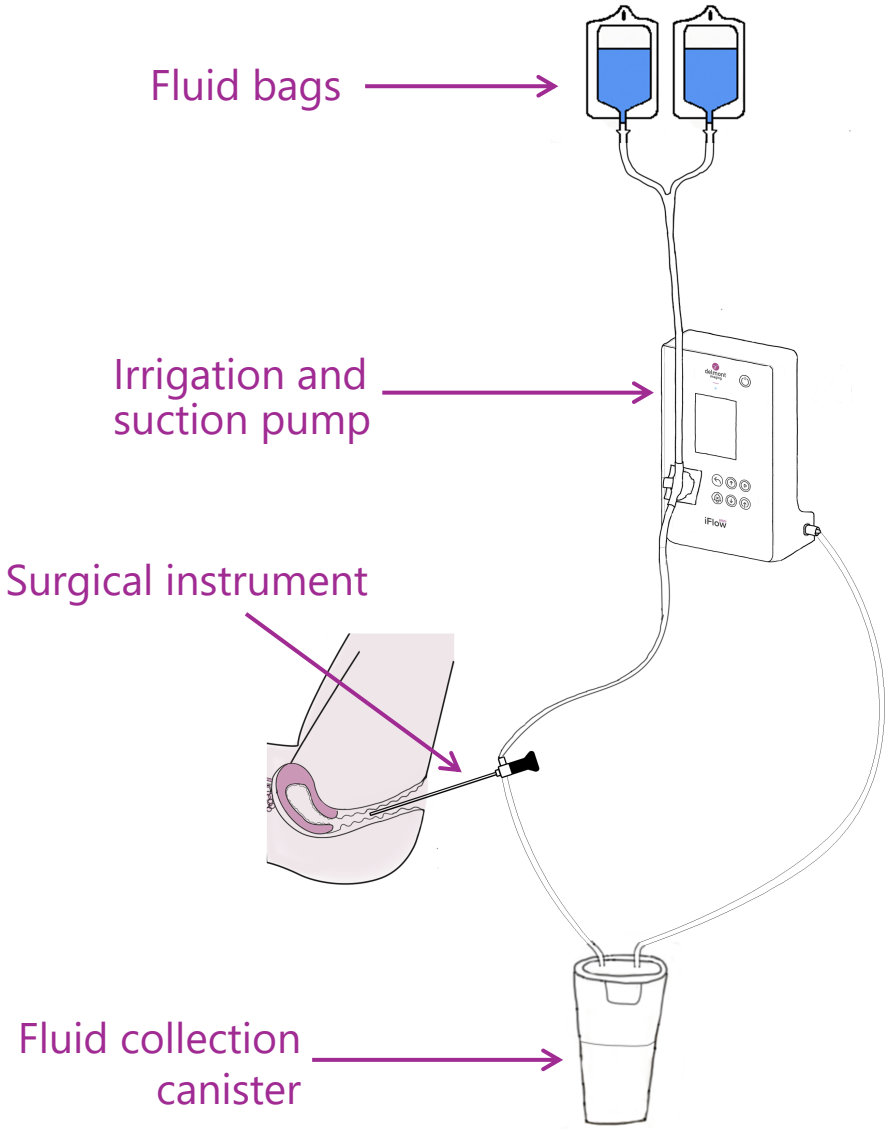
iFlow mini

Continuous flow, flawless care

1. THE PRINCIPLE

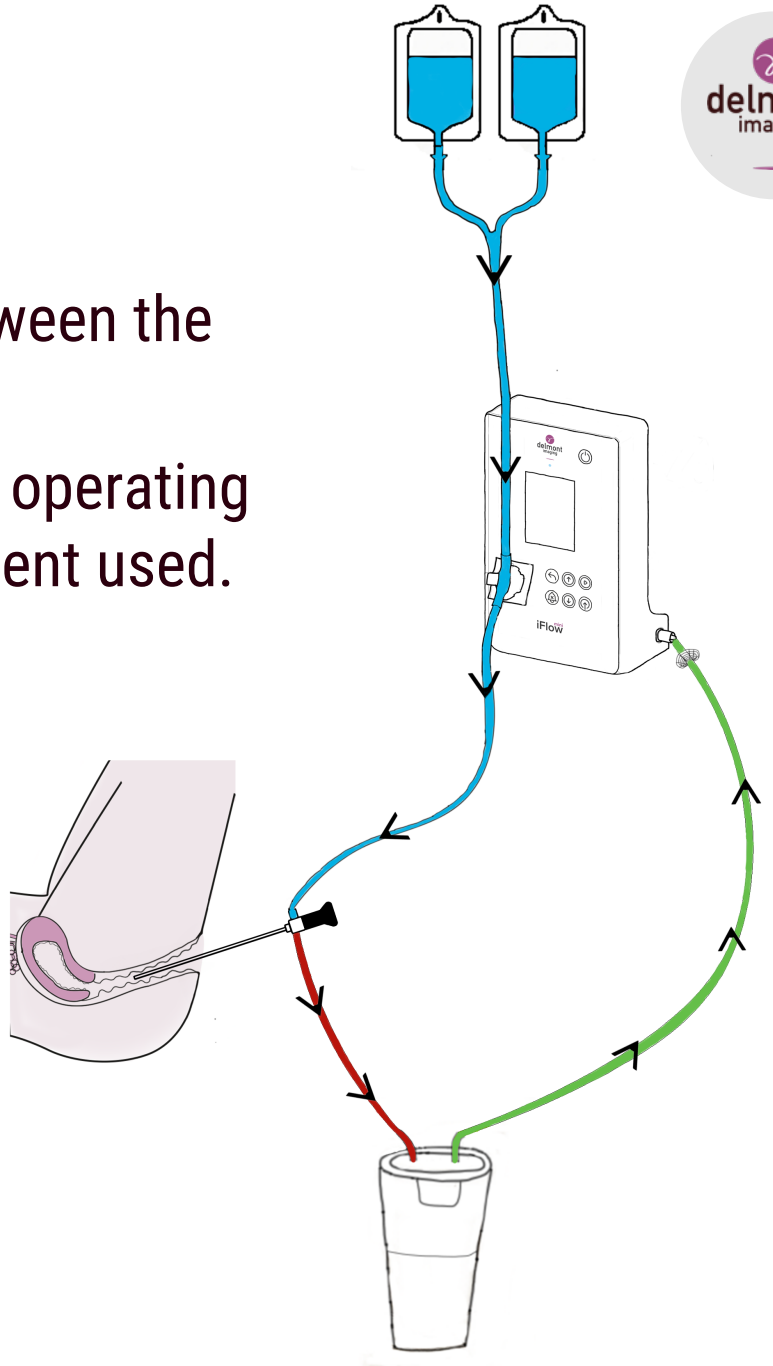
An **irrigation** and **suction** pump

- A medical fluid pump is designed to **deliver a fluid at a given pressure and/or flow rate** to the surgical field (irrigation) and sometime also **to evacuate this fluid** outside the surgical field (suction).
- To operate, an irrigation and suction pump requires several components:
  - **Fluid bags:** saline solution (NaCl) or glycocoll (also known as glycol or glycine solution).
  - A **surgical instrument** through which fluid is delivered to the organ being operated on/examined.
  - **Collection containers** for waste fluids.



The tubing configuration

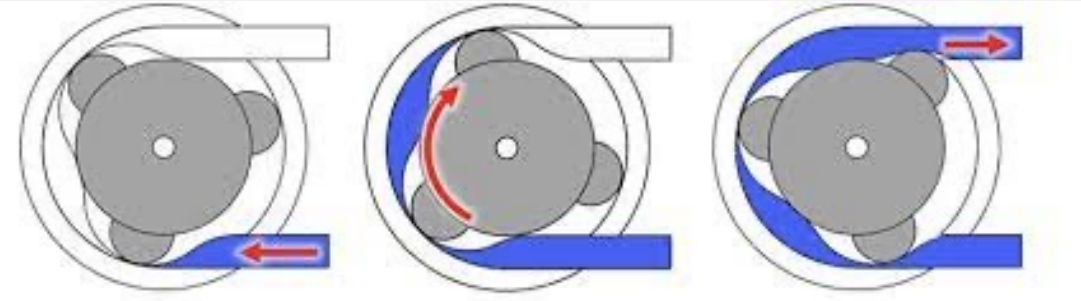
- A **circuit of tubing** is needed to allow the fluid to flow between the various elements described above.
- **Irrigation** allows "clean fluid" to flow from the bags to the operating field, passing through the irrigation channel of the instrument used.
- **Suction** is used to remove fluid and any impurities (e.g. blood) from the operating field. It consists of two parts:
  - **Suction of the liquid:** the "contaminated fluid" is collected in the containers, using the instrument's suction channel.
  - **Vacuum suction:** the pump (or thanks to a wall socket in the healthcare center) sucks the air from the collection containers, creating a vacuum. **No fluids may pass through this tubing.**



The different pump technologies

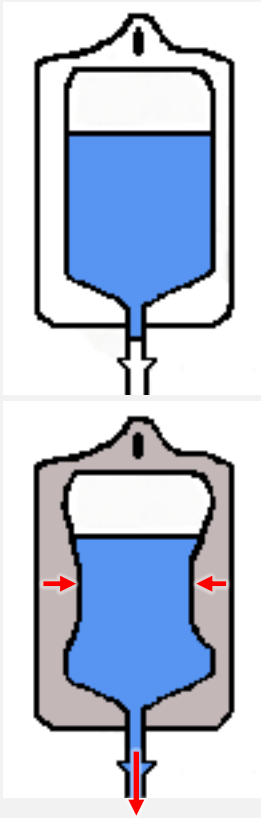
Peristaltic or roller pump

The irrigation tube is installed **around a roller** on the pump. This roller **squeezes** the tube at various points. Then, by its **rotation**, it pulls the fluid contained in the tube at a preset flow rate.



Constant pressure pump

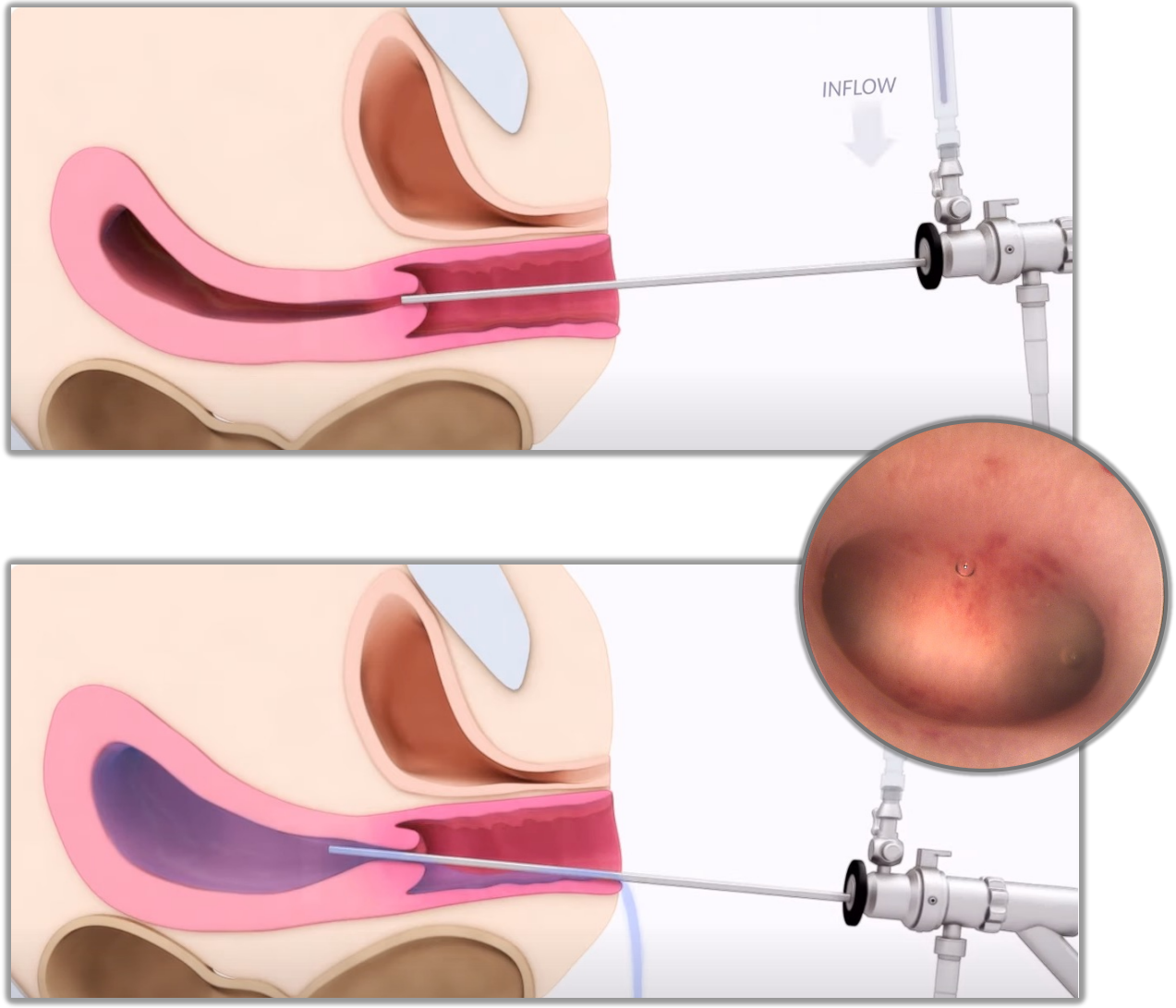
The fluid bag is placed in a container (for example, a cuff or a pressure chamber).
The pump **blows air** into the container to apply a **constant pressure to the bag**, driving the fluid out of the bag at a certain flow rate.



iFlow mini is a **constant pressure pump**. Most pumps on the market are peristaltic pumps.

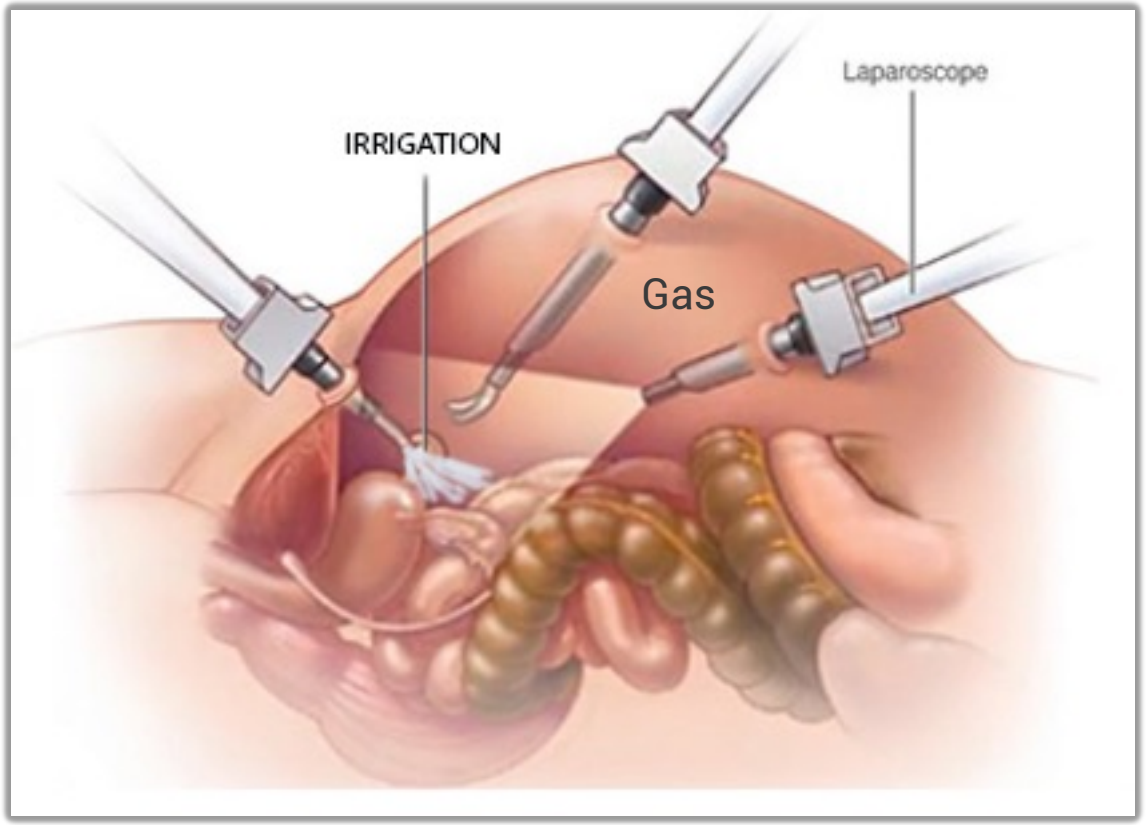
Use in hysteroscopy

- Hysteroscopy allows **direct visualization** of the uterine cavity for both diagnostic and operative purposes.
- The irrigation flow enables **the uterine cavity to be dilated** for better visualization.
- The suction flow is used to **renew the fluid in the cavity** when necessary to maintain a clear image.
- The main parameter is **the target pressure**. The higher it is set, the greater the dilation of the uterus.
- **The flow rate** can sometimes also be adjusted, but this is a secondary parameter.



Use in laparoscopy

- Laparoscopy is **the exploration of the interior of the abdominal cavity or pelvic cavity** and the intervention on the digestive (liver, colon, gall bladder, etc.), genital (uterus, ovaries, fallopian tubes) or urinary organs.
- In laparoscopy, to allow access to the organs and provide good visibility, **the abdominal cavity is also distended, but with the aid of a gas.**
- The liquid is not used as a means of distension, but mainly to **clean the operating field of impurities** thanks to the irrigation and suction flows, so that good visibility is always maintained.



Locations of use

- An irrigation pump is mainly used **for operating procedures**.
- Thanks to its compact size, iFlow mini is ideal for use in the ambulatory room but is also perfectly suited to use in the operating theatre.

OUTPATIENT ROOM

- In the outpatient room of a health center (private or public).
- iFlow mini is perfect for **hysteroscopic outpatient activities**, which includes diagnostic and minor operative procedures.
- No anesthetic is required for diagnosis. Surgery is performed under local anesthetic (paracervical block).

OPERATING THEATRE

- In the operating theatre of a health centre (private or public).
- For **hysteroscopic and laparoscopic operations**, from minor procedures to major surgeries.
- General anaesthesia is mainly used. Locoregional anaesthesia is also possible.

2. RANGE OVERVIEW

Presentation of the range

iFlow mini pump

Pressure **cuffs**

Available in 1L or 3L versions

Y adapter for connecting 2 cuffs

A complete **fluid management trolley**

Single-use sterile **irrigation** tube

Single-use sterile **suction** tube

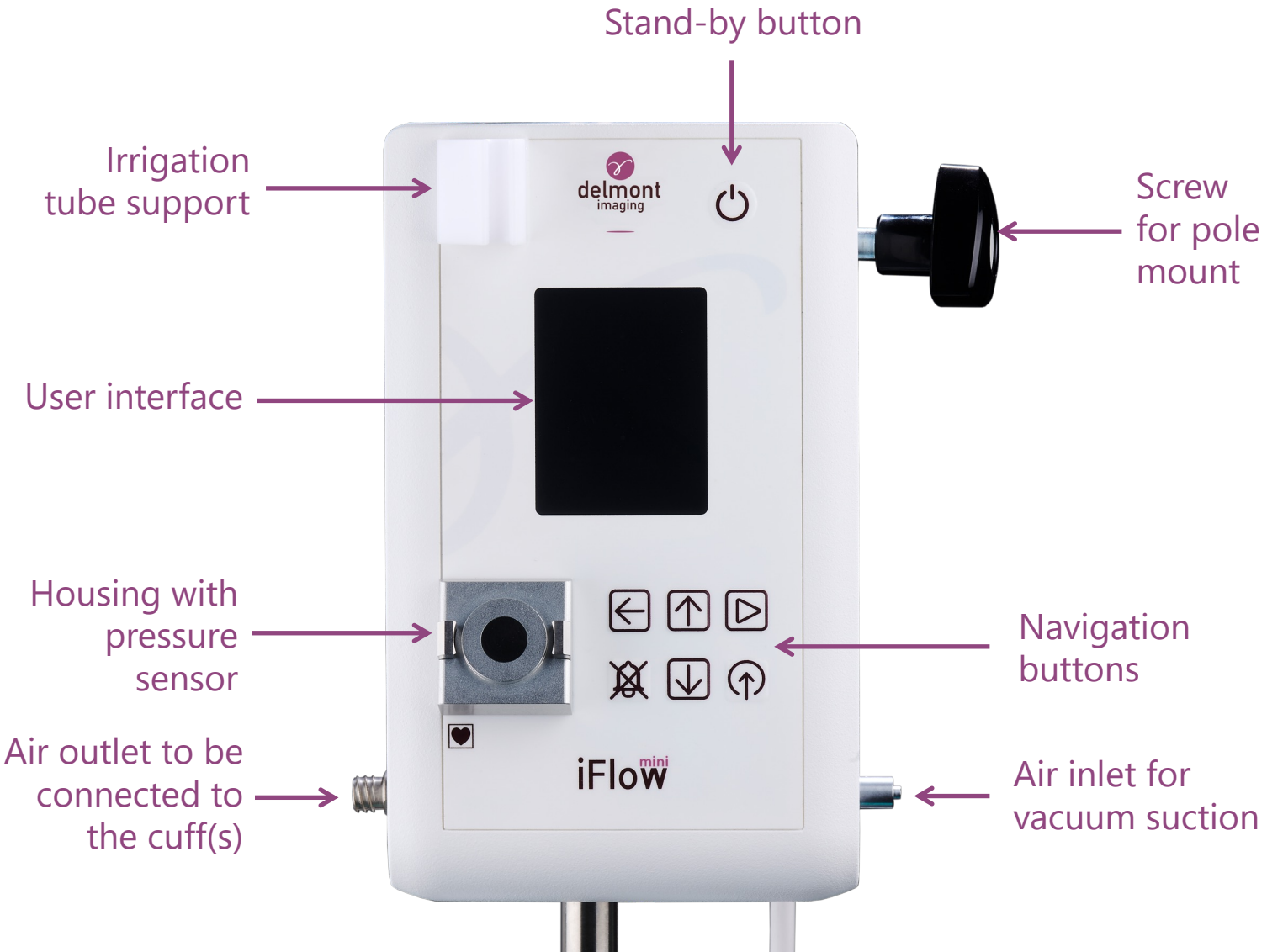
Reusable **vacuum suction** tube

With purchase, **iFlow mini** is delivered with:

- 2 pressure cuffs
- Y-adapter
- Self-test tube

iFlow mini pump

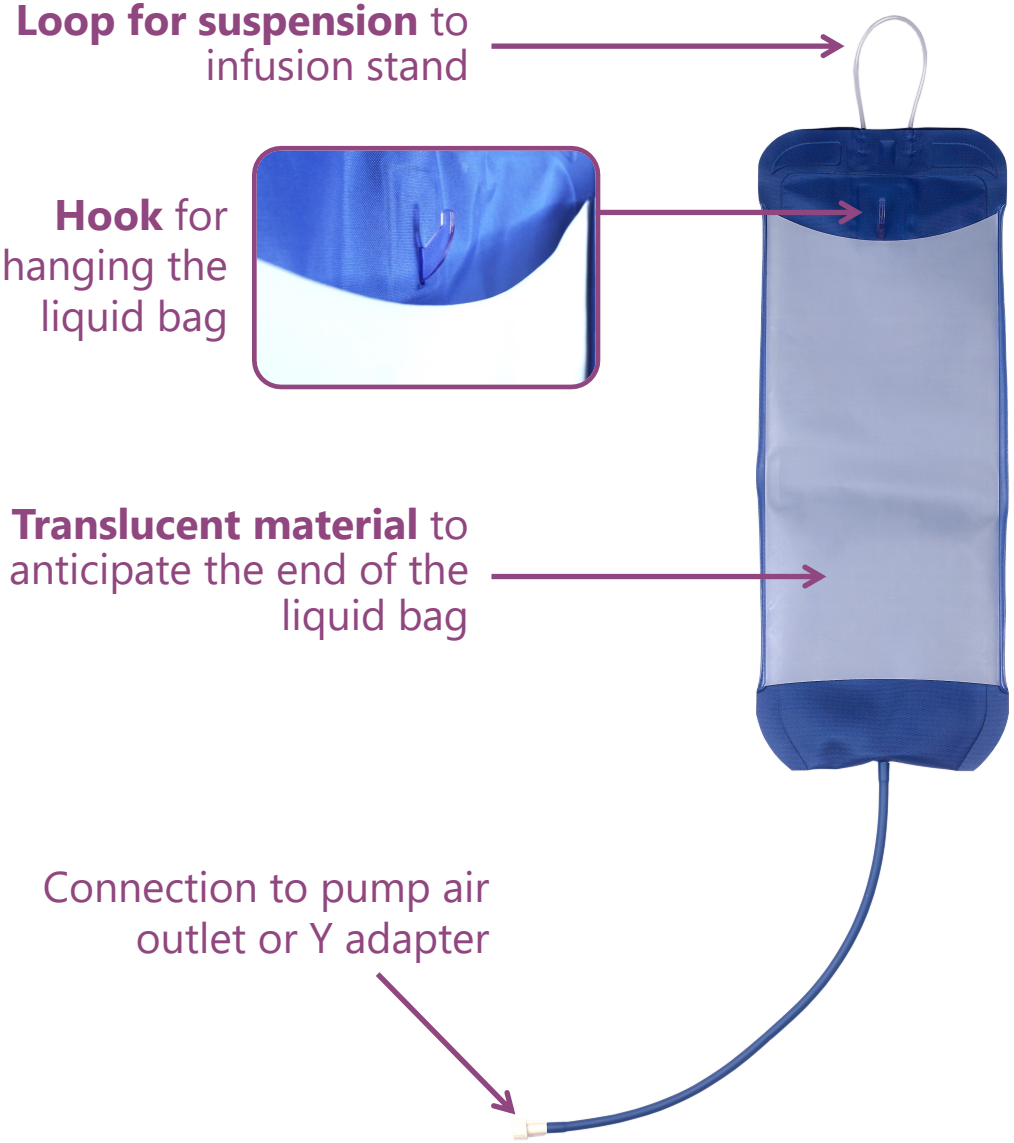
- The iFlow mini irrigation and suction pump can be used for both **hysteroscopy and laparoscopy**.
- The fluid bags are inserted into the cuffs. The pump **blows air into them so that the bags are compressed, and irrigation is performed**.
- There is a **pressure sensor** to regulate irrigation.



Pressure **cuffs**

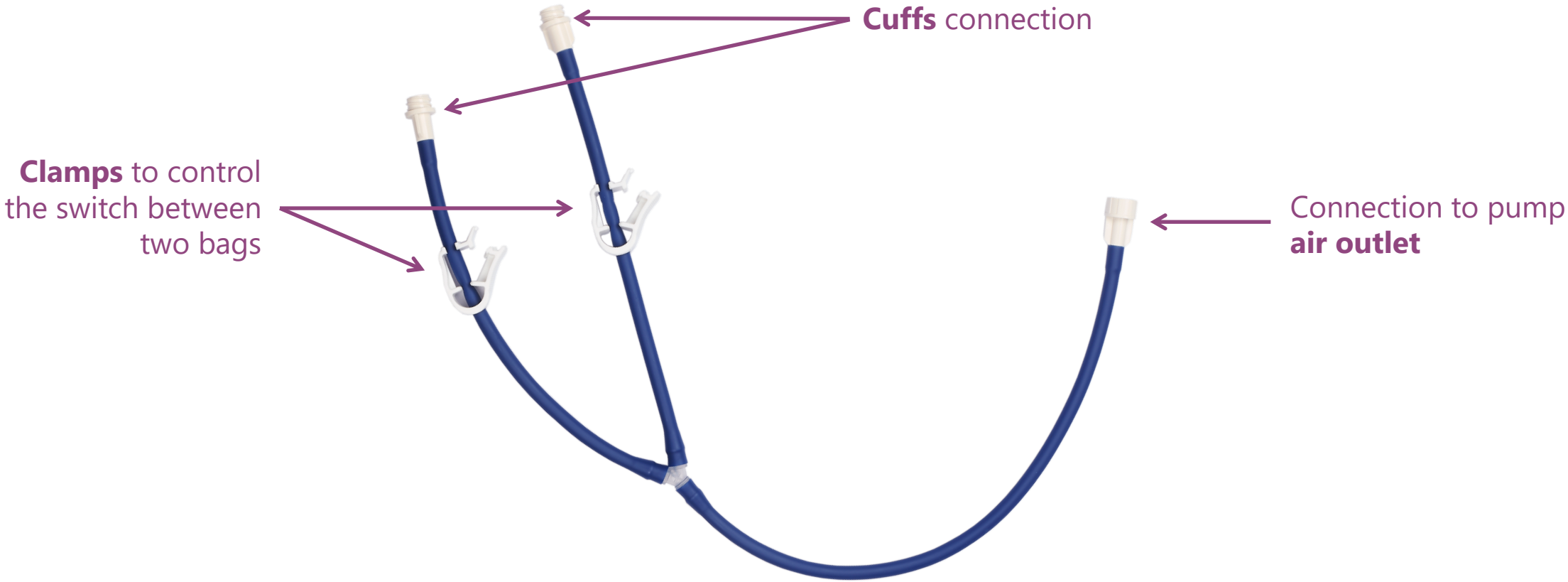
- **Three models** of pressure cuffs are available:
  - 3 liters for elongated fluid bags (Baxter or Fresenius)
  - 3 liters for square liquid bags (B.Braun)
  - 1 liter

For a demonstration product, we recommend **to get all three versions**. In the case of a sale, please let us know **which cuff model you require**.



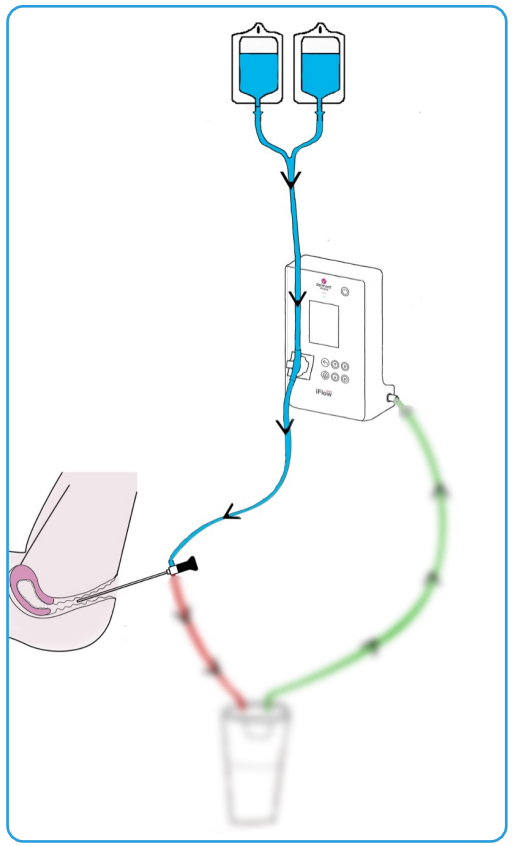
The Y-adapter

- The Y-adapter allows **two cuffs to be connected** to the pump simultaneously, so you can change fluid bags **without having to pause the pump**.

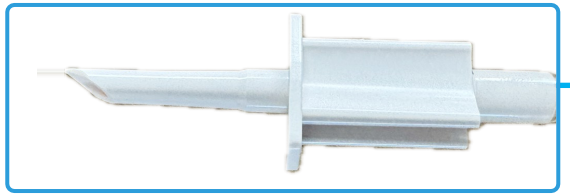


Irrigation tubes

- Our irrigation tubes are **sterile & single-use**, and are packaged in sets of 15.
- Two models are available, **with 1 or 2 spike(s),** to choose according to the number of liquid bags required for the examination. **Our irrigation tubes are captive.**



Spike(s) to perforate and connect the tubing to the liquid bag.



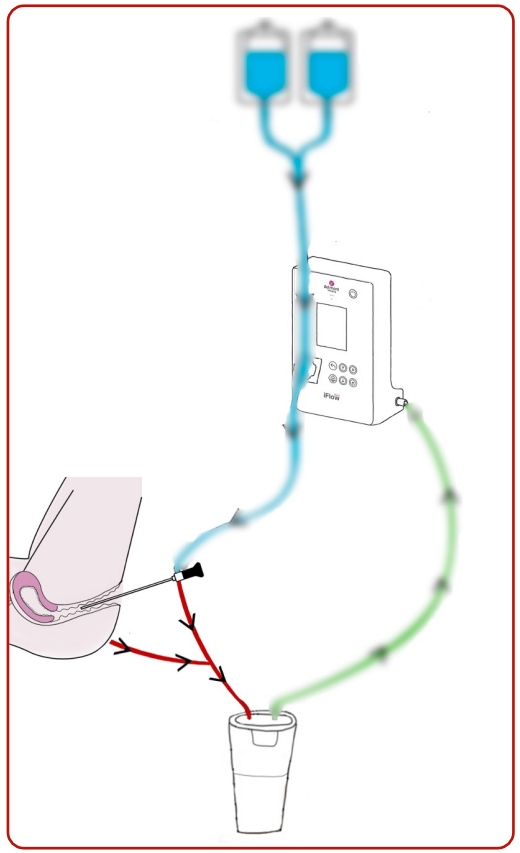
Clamp for opening or closing the liquid flow

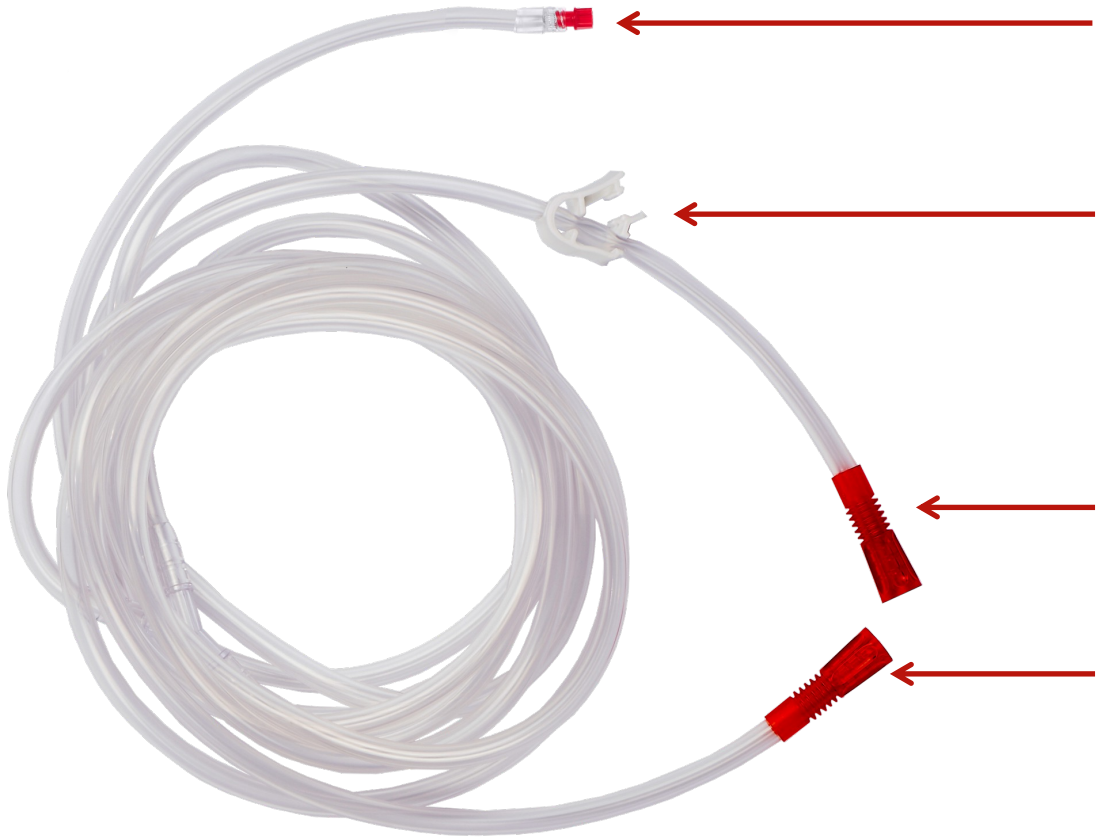
Pressure dome for the transfer of liquid pressure to the pump sensor

Luer Lock connection to instrument irrigation stopcock

The suction tube

- Our suction tube is **sterile & single-use**, and is packaged in sets of 15.
- It has **two connectors** for used fluid: the instrument's suction stopcock and the sterile surgical drape's collection bag.





Luer-lock connection to instrument suction stopcock

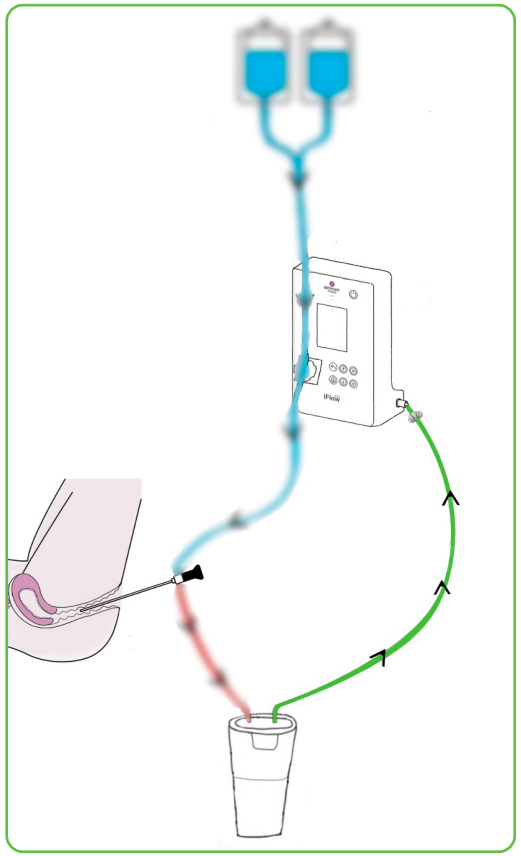
Clamp to close the passage if there is no collection bag on the surgical drape

Connection to the surgical drape collection bag under the patient

Connection to the collection canister

The vacuum suction tube

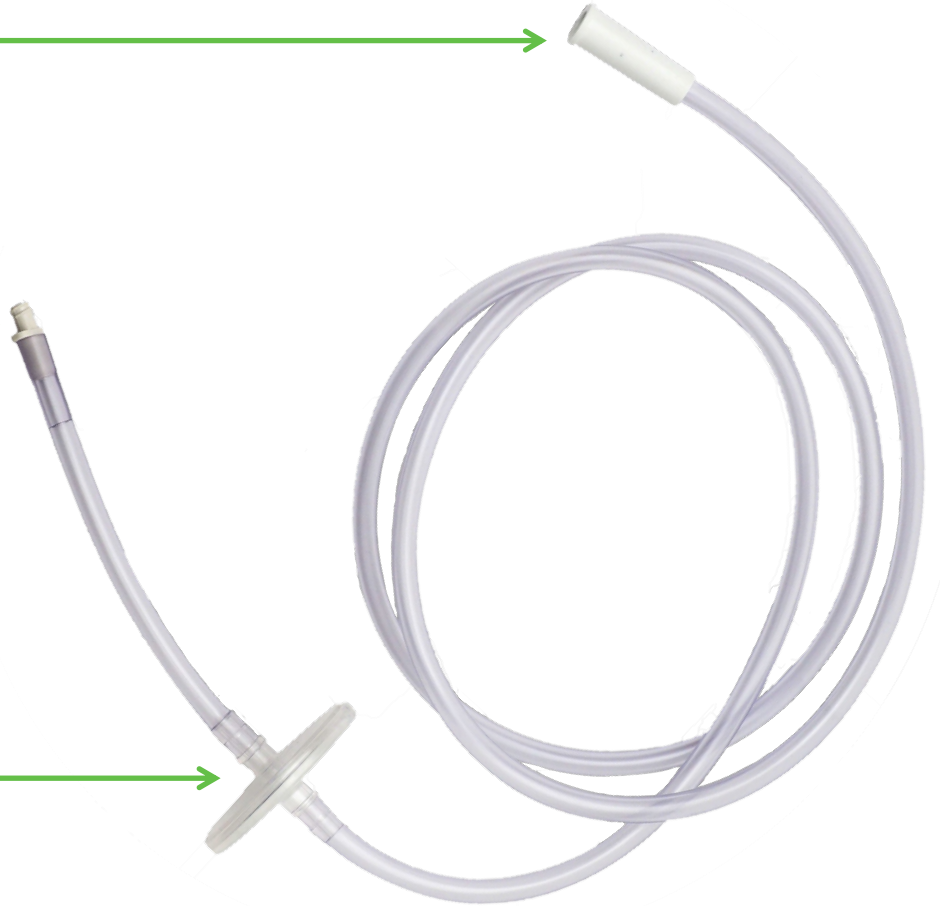
- Our vacuum suction tube is **non-sterile & reusable**.
- It is sold individually, and can be used for **up to 30 days**.



Connection to the collection canister

Luer-lock connection to the pump vacuum suction

Hydrophobic filter preventing the passage of liquid through the pump in the event of misuse



The fluid management cart

Height-adjustable stand with two hooks

Pole for mounting iFlow mini pump

Integrated handle for easy handling and movement of the cart

Rail included for positioning **up to 4** fluid collection canisters
(by default, 2 are supplied with the cart)

5-wheel base, **2 with brakes**

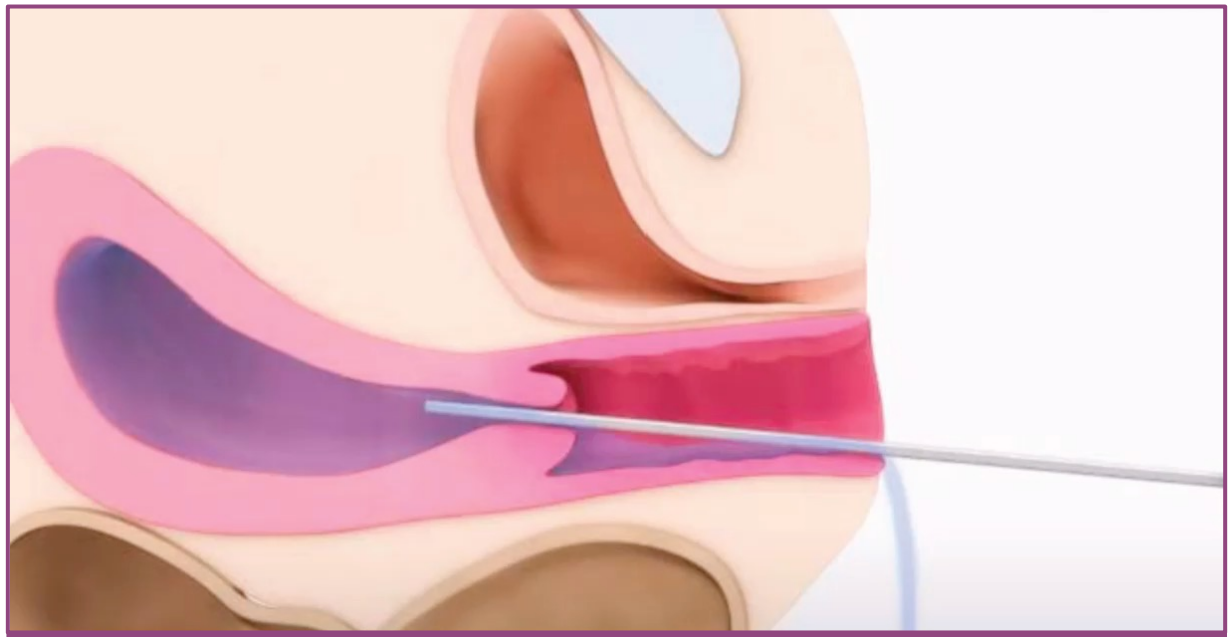
Tandem tubes for vacuum and fluid suction
(1 of each supplied with the cart)

Serres fluid collection canisters with **lids and disposable plastic bags**

3. STRENGTHS

A **constant-pressure** pump

- iFlow mini is a **constant-pressure pump** using cuffs that inflate with air and compress the fluid bags.
- The fluid flows **linearly, rather than pulsating** as with a roller pump.
- This technique increases the precision and stability of fluid pressure in the uterus for **optimal visualization**.



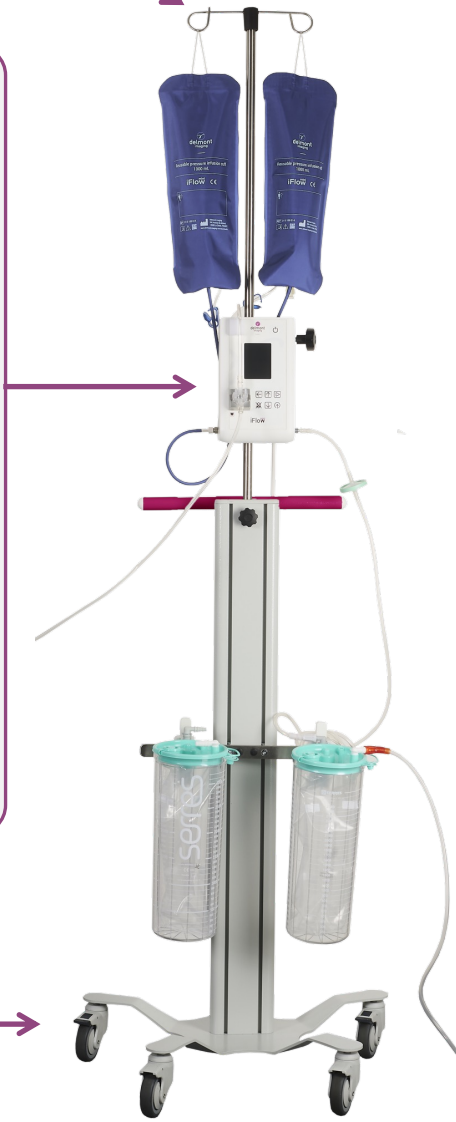
Representation of the **pulsating movements** of the uterine walls with a **roller pump**

Extremely **easy to use**

- iFlow mini features an **ergonomic user interface and simplified operation** for smooth and efficient use:
  - **« Plug and play » operation in just 3 steps**, as shown opposite.
  - Displays only **key information** (actual pressure, target pressure and status of irrigation and suction).
  - **Six action buttons** for easy navigation and operation.

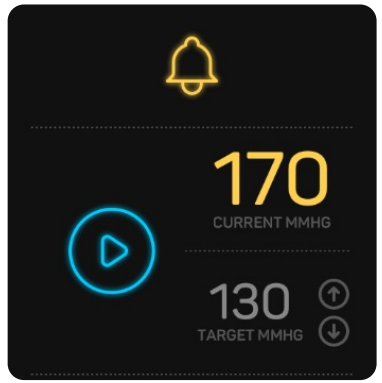
A small-sized pump

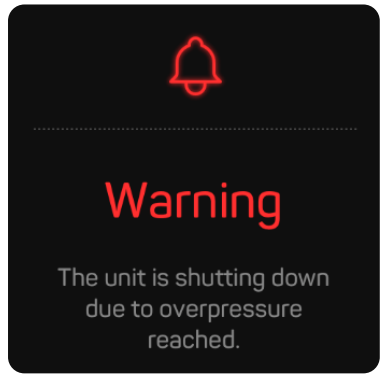
- iFlow mini is a **compact** pump. Its reduced size and performance make it suitable for use in **all types of environments**:
  - iFlow mini is the ideal size for your **outpatient hysteroscopy rooms**. Combined with iCare+, you get an all-in-one solution.
  - iFlow mini has the hysteroscopy and laparoscopy programs required for use in **the gynecological room of an operating theater**.
- With its fluid management cart, you benefit from a **complete solution, with an optimized footprint.**



Safe to use

- Pressure measurements are made using the pump's sensor. **Sensor accuracy is 5mmHg.**
- **Three alarm levels** are present in hysteroscopy mode to indicate overpressure and **guarantee patient safety:**
  - Level 1: overpressure > 20mmHg of set pressure for more than 4 seconds.
  - Level 2: overpressure > 20mmHg of maximum pressure for more than 4 seconds.
  - Level 3: overpressure > 40mmHg for more than 2 seconds or > 20mmHg for more than 20 seconds relative to maximum pressure.
- The pump features an **automatic shutdown** in the event of severe overpressure (alarm level 3).





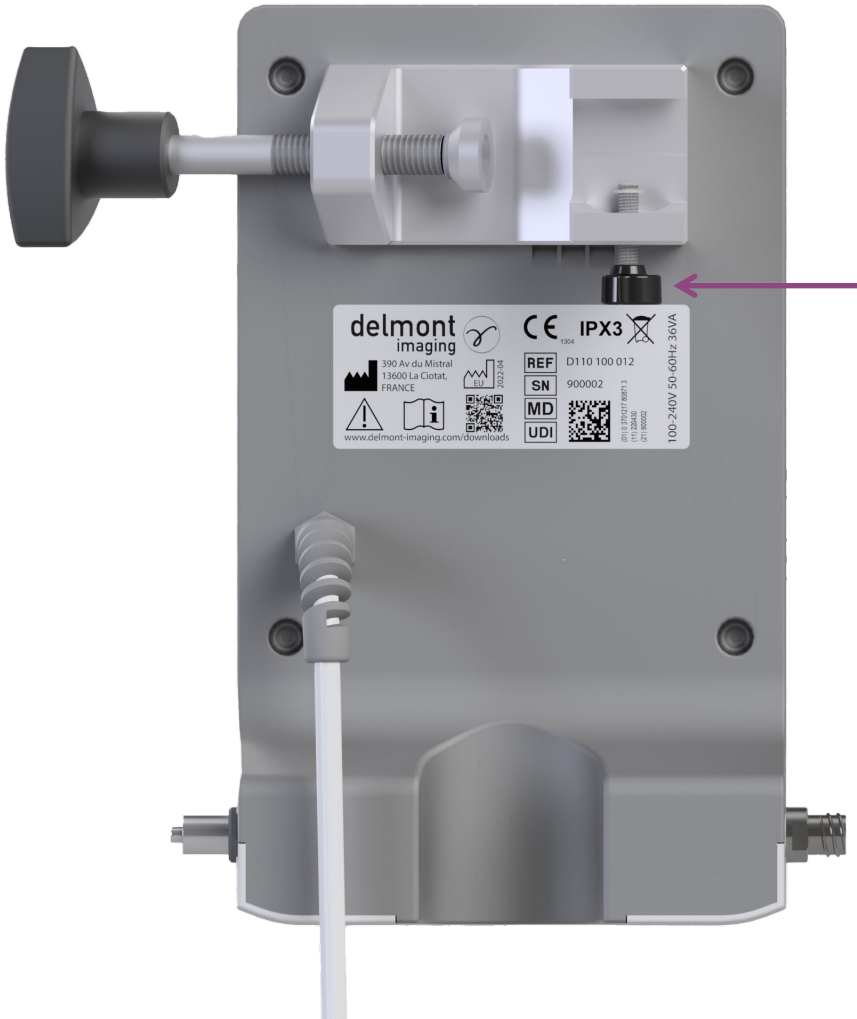
This button stops the sound of the current alarm.

4. THE USE

Pump installation

- iFlow mini has **two mounting options**, available on the rear panel:

Screws for mounting the pump to **a pole**



Screws for mounting the pump to **a rail**

Pump interfaces

Tubing holder

Home screen

Pressure sensor housing

Standby ON/OFF button

Back button

Up navigation button

Enter button or irrigation start button

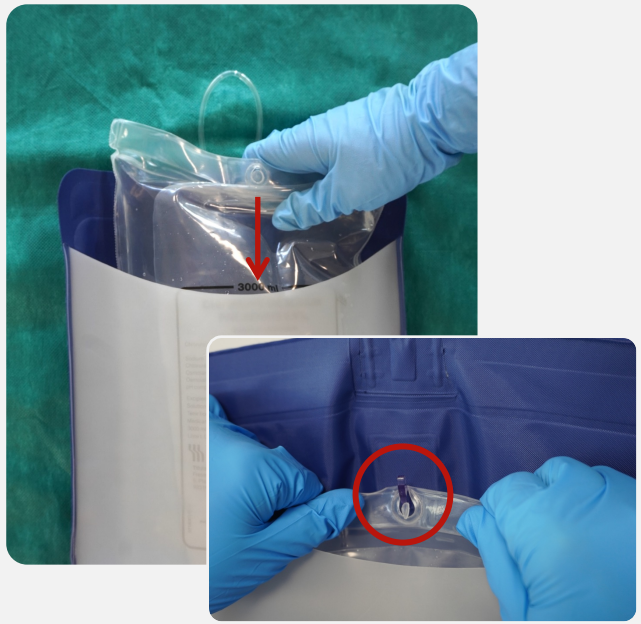
Vacuum start/stop button

Down navigation button

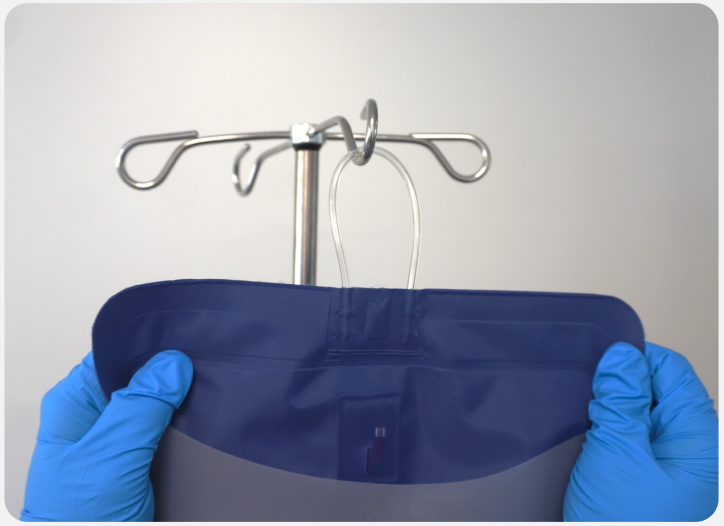
Stop button for current alarm sound

Cuff installation

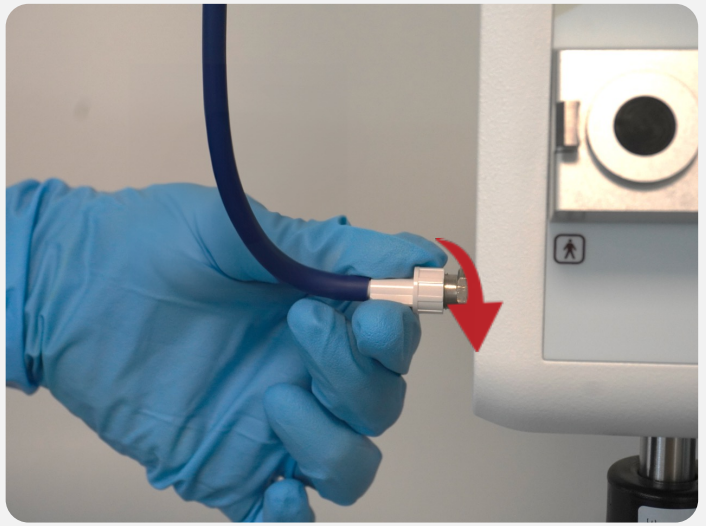
Steps performed by a non-sterile hand



1. Slide the fluid bag(s) into the cuff(s) through the **top opening**. Hang each fluid bag from the **hook** in the cuff.



2. Place the cuff(s) on the **infusion stand hooks** using the suspension loop..



3. **Connect the cuff to the pump's air outlet** if you're using just one. Otherwise, connect both cuffs to the Y-adapter, then connect the Y-adapter to the pump's air outlet.

Vacuum tube installation

Steps performed by a non-sterile hand

1. Screw the vacuum suction tube to the pump air inlet.

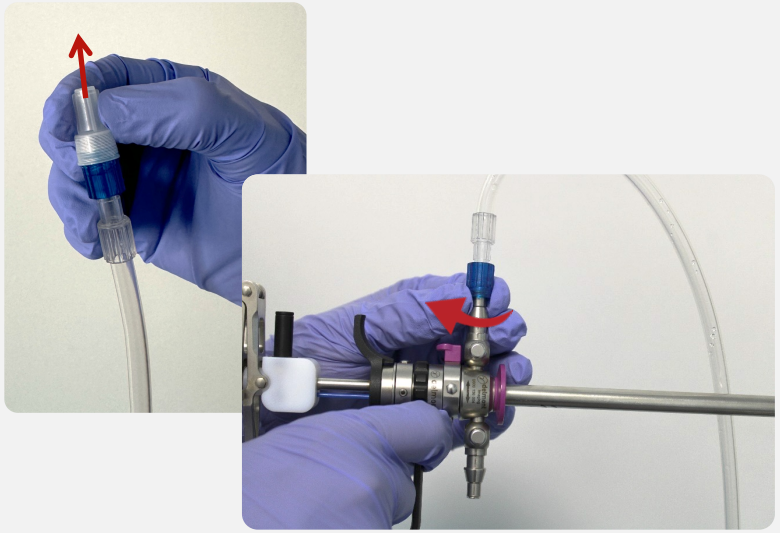
2. Connect the second tip of the vacuum tube to the collection canister.

3. If you're using more than one canister, make sure there is a tandem connection for the vacuum suction.

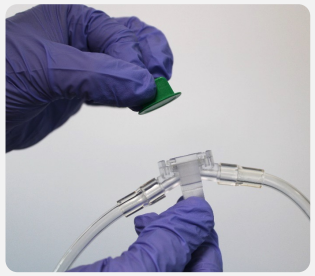
Irrigation tube installation

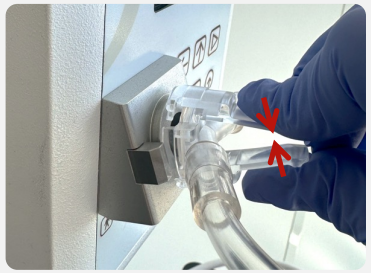
Steps performed by a sterile hand

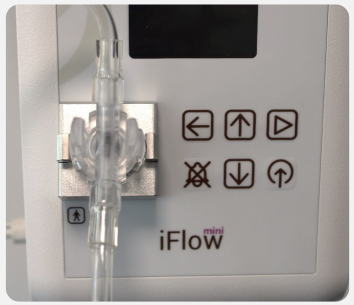
1. Disconnect the transparent plastic protective cap.
2. Connect the irrigation tube to the corresponding stopcock on the surgical instrument.
3. Give the other side of the tubing to the non-sterile hand.

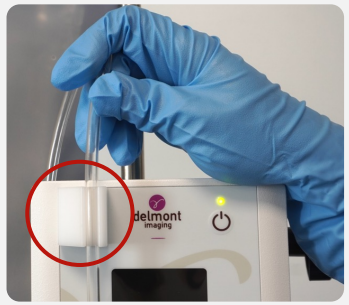


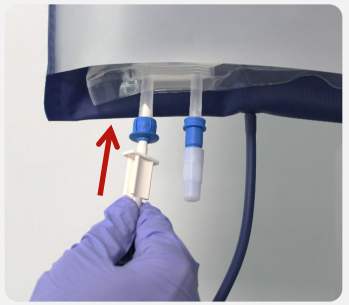
Steps performed by a non-sterile hand







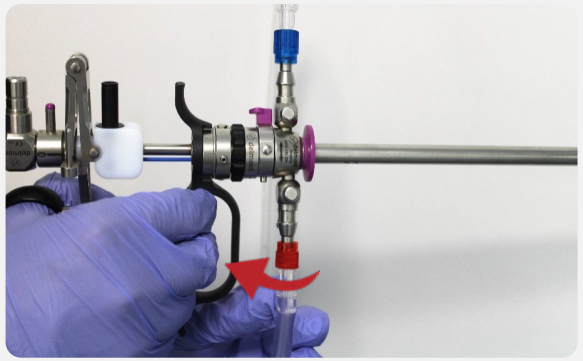




1. Take the irrigation tube from the sterile hand.
2. Press the two tabs on the dome to remove the green protective cap.
3. Maintain pressure on the dome tabs and position it on the sensor housing. Make sure there is no gap between the tubing dome and the pump sensor.
4. Rotate the pressure dome by the tubes (not the tabs) to lock it in place.
5. Position the tube in its holder.
6. Connect one or two spikes to the fluid bags.

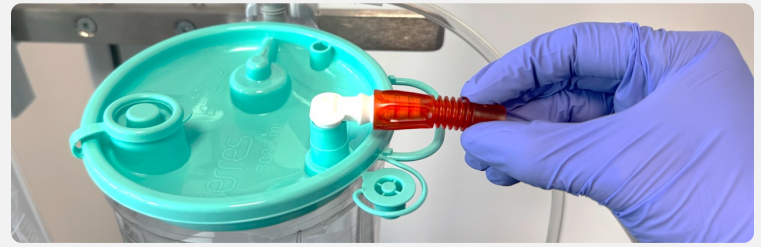
Suction tube installation

Steps performed by a sterile hand



1. Disconnect the transparent plastic protective cap.
2. Connect the suction tube to the corresponding stopcock on the surgical instrument.
3. If present, connect the second end of the suction tube to the collection bag on the surgical drape. If not, close the clamp on this tube end.
4. Give the other side of the tubing to the non-sterile hand.

Steps performed by a non-sterile hand

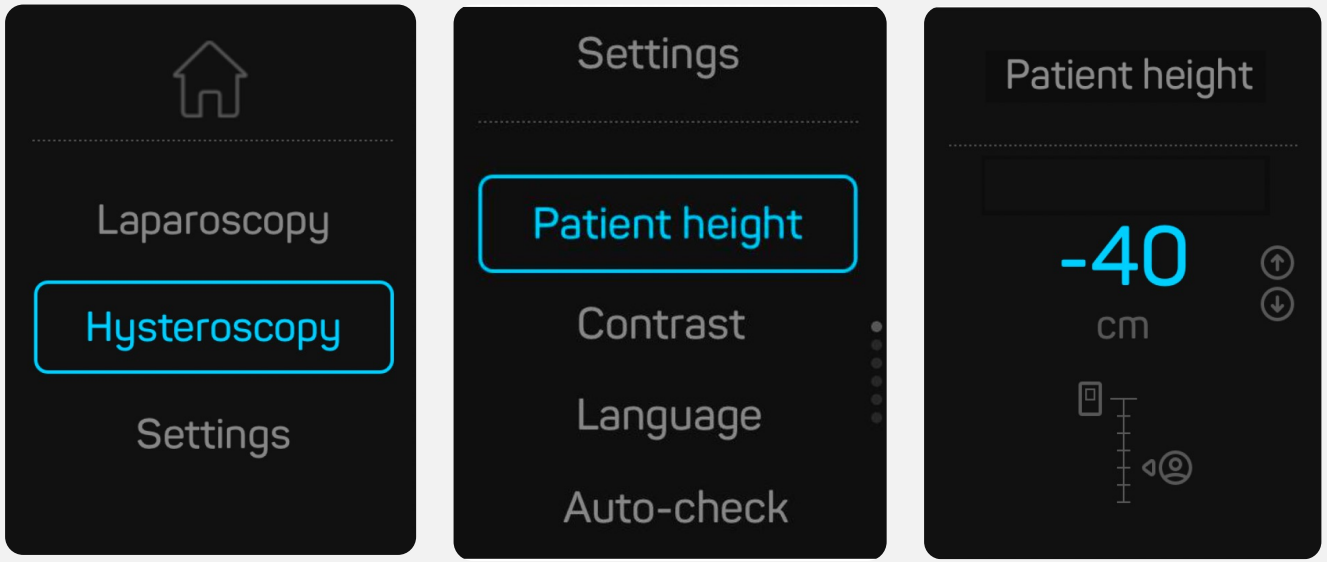


1. Take the suction tube from the sterile hand and connect it to the canister.
2. Check for the presence of tandem tube for liquid flow in the case of several collection canisters.

Patient height setting

- During installation, the **distance of the patient from the pressure sensor** must be recorded in order to obtain an **accurate display of the current intra-uterine pressure**.
- Due to the height difference between the patient and the pump, the pressure measurement at the sensor may not be equivalent to the one in the uterine cavity.

Patient height setting



1. After selecting the **"Settings" tab** on the home screen, go to the **"Patient height"** setting.
2. **Evaluate the distance** between the operating table and the iFlow mini pump sensor.
3. Enter the estimated value in this "Patient height" settings. The available range is from **0 to -60cm.**

Tubing detection function

- To ensure **patient safety**, iFlow mini features a **tubing detection function**. The pump cannot be launched if an irrigation tube is not connected.
- This function is available in both hysteroscopy and laparoscopy programs.
- Detection takes place when the sensor measures **at least 10mmHg for 5sec**. To achieve this:
  - The irrigation tube must be fully connected (from the instrument to the fluid bag).
  - The irrgation tube clamp must be open.
  - **The distance between the bottom of the cuff and the sensor must be at least 10cm.**

The different states of the tubing detection function

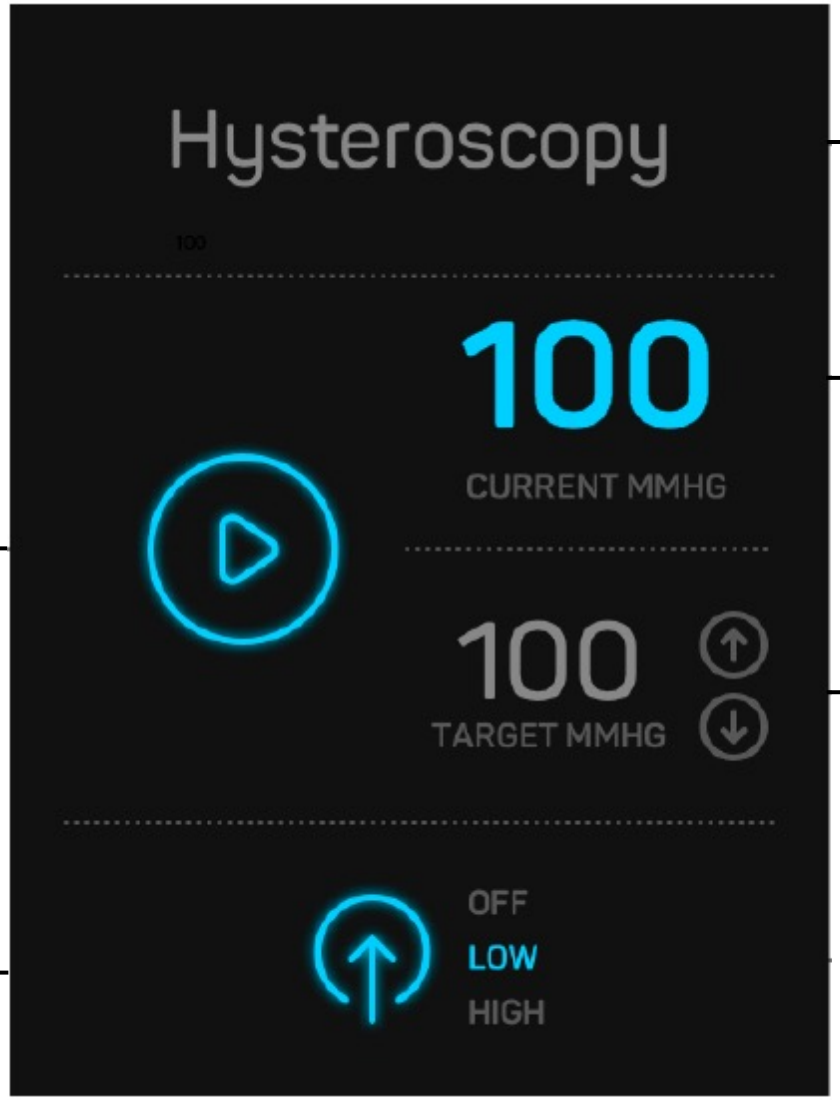
No tubing detected.
Pump cannot be started.

Error signal when the user tries to start the pump while no tubing is yet detected.

Irrigation tube detected.
Pump can be started, but is not currently running.

Irrigation tube detected.
Pump in operation..

Hysteroscopy program interface



Display of program in use

Current pressure measured.
Display in increments of 5

Status of irrigation function and tubing detection function

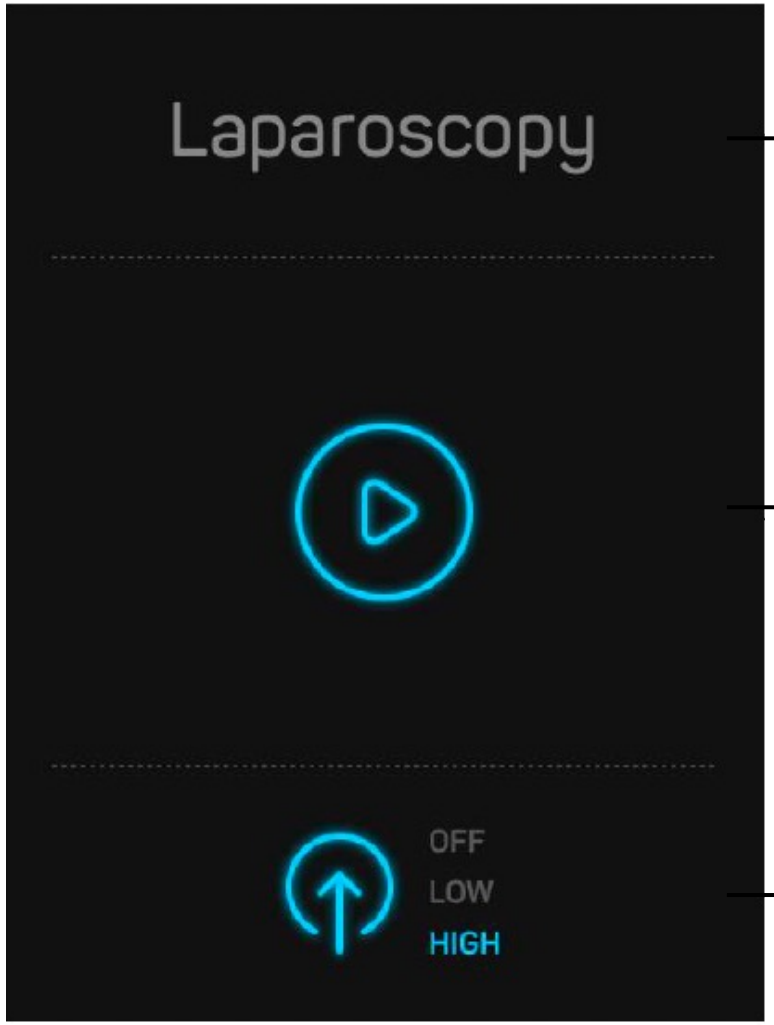
Intra-uterine **target pressure adjustable between 60 and 150mmHg** in increments of 10

(factory setting of 80mmHg)

(Maximum value adjustable to 200mmHg in settings)

Vacuum suction status:
Off / Low (30kPa) / High (50kPa)

Laparoscopy program interface



Display of program in use

Status of irrigation function and tubing detection function.

Using the pump in laparoscopic mode doesn't require any specific settings, and the **fluid flow is constant at over 1L/min**.

Vacuum suction status: Off / Low (30kPa) / High (50kPa)

Switch between two bags

- When more than one bag is required, the **Y-adapter should be used**. It allows you to switch between two fluid bags **without having to pause irrigation**.
- Two different switching techniques are available:

Pre-inflation of both bags

1. Open **both** Y-adapter clamps.
2. Start the pump.
3. Wait for both cuffs to fill with air until target pressure is reached.
4. Clamp one of the two cuffs.
5. Start surgery.
6. When the first bag is empty, clamp the first cuff and open the second.
7. Unscrew the cuff with the empty fluid bag and replace it with a full one. Screw the cuff back on.

Two **pre-inflated** cuffs.

Using air from the first cuff

1. Open **only one** of the two clamps on the Y-adapter.
2. Start the pump.
3. Wait for the first cuff to fill with air until the target pressure is reached.
4. Start surgery.
5. When the first bag is empty, open the clamp on the second cuff. Wait for some of the air in the first cuff to transfer to the second.
6. Clamp the first cuff.
7. Unscrew the cuff with the empty fluid bag and replace it with a full one. Screw the cuff back on.

Only one inflated cuff. Switching air to 2nd cuff when 1st. cuff is empty.

« Auto-check » function

- iFlow mini features an **Auto-check function**, enabling the user to quickly and easily check that the **pressure sensor is working properly**.
- This check should be carried out **every 6 months**, using the self-test tubing supplied:

Performing the Auto-check

1. Select **Settings** from the Home screen, then **Auto-control**.

2. **Connect the self-test tubing** supplied with the pump to the sensor housing.

3. Fill the supplied syringe **completely with air.**

4. **Connect it to the tubing.** Press Start to proceed.

5. **Empty the syringe** entirely. Check that the value displayed is **between 90 and 110mmHg.**

5. THE COMPETITION

KARL STORZ — ENDOSKOPE

Endomat Select

- **Multi-disciplinary** (7 different software programs) and user-selectable.

- **Peristaltic** pump.
- **No suction module integrated** into the pump (cannot be used for irrigation and suction at the same time).
- No complete solution (fluid management cart).
- **Large size**.

ROCAMED

EndoFlow II Double Chamber

EndoFlow II Single Chamber

- **Constant-pressure** pump (pressure chamber).
- Fluid bag temperature heated to 38°C.

- **Large size**.
- 4 built-in programs **by default**. Higher purchase price.
- **Mandatory irrigation flow stop** when changing fluid bag *(single chamber model).*
- **No suction module integrated** into the pump *(single chamber model).*
- No complete solution (fluid management cart).
- Various **operating difficulties** (door jamming, tubing getting stuck, etc.).

Fluid Control 2225

- **Complete solution** available (ergonomic fluid management cart).
- **Optimized programs available** for their instruments.
- Weighing module for **deficit measurement**.

- **Large size**.
- **Peristaltic** pump.
- 3 built-in programs **by default**. Higher purchase price.

OLYMPUS®

HysteroFlow

- **Complete solution** available (ergonomic fluid management cart).
- Weighing module for **deficit measurement**.

- **Large size**.
- **Peristaltic** pump.
- **One unique program:** Hysteroscopy**.**
- **No suction module integrated** into the pump.
- User interface **not ergonomic and difficult to use**.

Medtronic

HysteroLux

- **Complete solution** available (ergonomic fluid management cart).
- Weighing module for **deficit measurement**.

- **Large size**.
- **Peristaltic** pump.
- **One unique program:** Hysteroscopy**.**

HOLOGIC®
The Science of Sure

Aquilex

- **Complete solution** available (ergonomic fluid management cart).
- Weighing module for **deficit measurement**.

- **Large size**.
- **Peristaltic** pump.
- **One unique program:** Hysteroscopy**.**
- User interface **not ergonomic and unmodern** (small, scattered screens and action buttons only).