CAUTION!
Use of other accessories, other transducers and cables
The use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM (see Chapter 22 "Glossary") as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the ME EQUIPMENT or ME SYSTEM.

CAUTION!
ME Device in Rack
The ME device may not be used when stacked or stored directly adjacent to or with other devices. If it should be necessary to operate the device close to stacked with other devices, the ME device or ME system should be monitored to ensure it works properly as configured.

CAUTION!
ME systems (Medical Electrical System)
The medical electrical device is suitable for integration in ME equipment systems (see Chapter 22 Glossary). Operation of the ME device in vicinity of non-ME devices may result in voiding the intended use of the ME device.

CAUTION!
The device may not be used in conjunction with a defibrillator since it is not equipped with corresponding safety elements. The manufacturer accepts no liability in this case for ensuing damage.

CAUTION!
Do not reach into the area of the roller wheel during operation. There is a risk of jamming.

3 General Information

Intended use

The devices PG130/PG145 are multi-indication pumps with irrigation functions for 4 indications:

- Laparoscopy
- Arthroscopy
- Hysteroscopy
- Urology

Each indication must be activated individually. Only activated indications can be enabled. Activation is done with a special transponder (see Chapter 6.2 "Activating Indication on New Factory Devices").

The device PG145 is equipped with an additional vacuum function.

The devices themselves are non-invasive and designed for use in multi-unit racks (non-sterile area). They pump medically sterile irrigation fluids (saline solution or sorbitol/mannitol solution) through a sterile tube. These fluids are used to distend and irrigate corresponding body cavities to provide space or improve visibility for the attending physician. The optional suction function can be used to siphon off secretions. The devices function only with the tube sets described in the accessory list (see Chapter 20 "Article/Accessory List PG130/PG145"). The transponder technology ensures safe and reliable use in the operating room and the user is protected from accidental operating errors.

The devices may not be used to inject medication.

The devices are not designed or suitable for use with gas.

Essential performance

The essential performance of the devices in the indication modes hysteroscopy, urology, and arthroscopy is to dilate and maintain the dilation of a body cavity with fluid. The dilation is here achieved via a pressure control.

The essential performance of the devices in laparoscopy mode is to provide an irrigation flow.

Another essential performance of the device PG145 in all indication modes is to provide suction pressure to suction the fluid from the patient.

WARNING!
Only physicians and surgical personnel with the required prior training in surgical applications may operate the devices PG130/PG145. Before the first use of the device, they must be trained in how to use the equipment and must have read the corresponding manual carefully and thoroughly.

3.1 Using the Laparoscopy Indication

Intended use: Laparoscopy

The devices PG130/PG145 may serve as irrigation pump for use in minimally invasive laparoscopic surgery (keyhole surgery). The optional suction function can be used to siphon off secretions. The optional suction function can be used to extract and remove waste gas when using laser or RF surgical devices.

Contraindications

The devices may not be used in the laparoscopy indication for surgical procedures where a specific pressure must be preset and reached as required such as during hysteroscopy, urology, and arthroscopy procedures, for example.

Technical application scope: Laparoscopy

The following characteristics apply to the laparoscopy indication:

- The devices PG130/PG145 work with a permanently preset pressure of 500 mmHg when used in the laparoscopy indication.

3.2 Using the Arthroscopy Indication

Intended use: Arthroscopy

The devices PG130/PG145 may be used for the distention and irrigation of knee, shoulder, hip, elbow, ankle and wrist joint cavities during diagnostic and surgical procedures such as:

- Ligament injuries
- Meniscus injuries
- Cartilage injuries
- Surgical plans and follow-up exams

The user can preset the desired joint pressure.

The pump attempts to reach and maintain the preset pressure in the joint by supplying irrigation fluid. If the joint cannot be drained (e.g., because closed valve at instrument), and if the preset pressure has been reached, the pump reduces the influx of fluid and attempts to maintain the preset pressure. If the intra-articular pressure falls below the selected value, fluid automatically continues to be supplied.

Contraindications

Use of these devices to inject fluid into a joint is prohibited whenever arthroscopy is contraindicated.

Arthroscopy is contraindicated in the following cases:

- Ankylosis (anchylosis)
- Inflammation or bacterial contamination

The devices may not be used to inject medication.

The devices are not designed or suitable for use with gas.

Recommended pressure

The preset pressure should be based on the average blood pressure of the patient to prevent bleeding in the joint. The manufacturer recommends the following pressure settings for the following application areas:

Knee joint	**70 mmHg**
Shoulder joint	**60 mmHg**
Hip joint	**60 mmHg**
Elbow joint	**50 mmHg**
Ankle joint	**70 mmHg**
Wrist joint	**60 mmHg**

Each surgery and each patient require different parameters. The values indicated by the manufacturer are therefore only recommendations and are not intended to substitute or replace the expertise of the surgeon.

Technical application scope: Arthroscopy

The following characteristics apply to the arthroscopy indication:

- The nominal pressure can be preset to a range of 15 to 200 mmHg.
- The nominal flow can be preset to a range of 0.1 to 2.5 l/min.
- The devices feature an instrument recognition function.
- To improve visibility within a joint, the devices are equipped with a "Wash" function.
- The devices have an optional suction function with 2 settings for shavers.
- The pump reacts to pressures greater than the set nominal pressure by emitting warnings. The devices have safety thresholds.

Clinical use

When performing monopolar electrosurgery, only non-conductive irrigation fluids may be used. Examples include glycine, sorbitol, mannitol, sorbitol plus mannitol, and dextran.

3.3 Using the Hysteroscopy Indication

Intended use: Hysteroscopy

The devices PG130/PG145 may be used for intrauterine distension, aspiration of secretory fluids, and monitoring of fluid deficit during endoscopic procedures. It is used to irrigate the cavum uteri with fluid to prepare for diagnostic and surgical hysteroscopies. The devices also offer the option of monitoring the volume difference between the fluid injected into the uterus and the fluid draining from the uterus (balancing).

The devices PG130/PG145 without fluid balancing may only be used for diagnostic purposes.

Contraindications

The devices may not be used to introduce fluids into the cavum uteri when a hysteroscopy is contraindicated.

Relative contraindications to endometrial ablation: Surgical skills ("Acute Technical").

Technical application scope: Hysteroscopy

The following characteristics apply to the hysteroscopy indication:

- The nominal pressure can be preset to a range of 15 to 150 mmHg.
- The nominal flow has 2 settings, LO and HI. The nominal flow levels can be preset to the following ranges in the user menu:
  - LO = 50-200 ml/min
  - HI = 200-500 ml/min
- The pump reacts to pressures greater than the set nominal pressure by emitting warnings. The devices have safety thresholds.
- The pump reacts to reaching and exceeding the deficit threshold by emitting warnings.
- The pump reacts to perforation (exceeding the deficit threshold) by emitting warnings.
- The pump reacts to a scale defect by emitting warnings.

3.4 Using the Urology Indication

Intended use: Urology

The devices PG130/PG145 may be used for the distention and/or irrigation of the lower and upper urinary tract, fluid aspiration and monitoring of fluid deficit during diagnostic and surgical procedures. The optional suction function can be used to siphon off secretions. It serves to introduce fluid into the ureter and upper urinary tract during diagnostic and therapeutic urological procedures such as, for example:

- urethroscopy, urethrotomy interna
- Transurethral resections of the prostata
- Dystoscopy, transurethral resection of bladder tumors
- Nephroscopy, nephro litholapaxy
- Intubated antegrade urethrotomies
- Resection of renal cavity system tumors

The devices PG130/PG145 are used for the controlled distention of the urogenital and upper urinary tract by infusing a sterile irrigation fluid using a trocar to improve the visibility of the surgical field during minimally invasive urological procedures. Please comply with the specific indications and instructions provided in the manual of your endoscope.

Contraindications

The devices PG130/PG145 should not be used on patients with traumatic damage to the ureter, bladder, or kidney. The use on patients with narrowing or obstruction of the urethra (e.g. due to large prostata adenoma) is contraindicated as well.

The devices may not be used for delivering fluids into the upper and lower urinary tract if this procedure is contraindicated.

Technical application scope: Urology

The following characteristics apply to the urology indication (only PG130/PG145):

- The nominal pressure can be preset to a range of 15 to 90 mmHg.
- The nominal flow can be preset to a range of 0.025 to 0.5 l/min.
- The devices feature an instrument recognition function.
- The pump reacts to pressures greater than the set nominal pressure by emitting warnings. The devices have safety thresholds.

3.5 Pressure Measuring and Regulating

Contact-free pressure measurement

The devices operate with a completely non-contact pressure measurement of the irrigation medium. The contact-free pressure measurement is taken by integrating the pressure chamber into the tube system. The pressure membrane transfers the tube pressure to the electronics of the device via a pressure sensor. The pressure control circuit continuously compares the actual pressure with the nominal pressure. The function of the device is to maintain the nominal pressure. The nominal pressure cannot be reached if the nominal flow is set too low. Check for possible leaks.

3.6 General Distention Warnings

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

WARNING!
In order to allow proper dilation of the body cavity and to reduce forces that could introduce irrigation fluid, room air, and gas into the bloodstream, the intracavitary pressure should be kept as low as possible.

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

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

WARNING!
Hypothermia (monitoring body temperature)
The continuous flow of the distension liquid may lower the body temperature of the patient. Lower body temperatures can cause coronary and cardiovascular problems. Always monitor the patient's body temperature during the entire surgical procedure. Make especially sure that the following, hypothermia promoting, operation conditions are avoided as best as possible:
- **longer operating times**
- **use of cold irrigation fluid.**

WARNING!
Air Embolisms
An air embolism can be the result of air contained in the tube set or connected instrument reaching the patient. Make sure that there is always fluid in the bag to prevent air from being aspirated into the patient.

3.7 General Laparoscopy Warnings

WARNING!
Connecting the tube
The tube outlet may only be connected to instruments which are intended for intra-abdominal fluid suction and irrigation.

3.8 Arthroscopy Warnings

WARNING!
The height difference between the device and the patient must be adjusted correctly in order to ensure exact pressure measurement.

WARNING!
Fluid irrigation pumps used in Arthroscopy may cause fluid extravasation into the surrounding tissue. In severe cases, the resulting pulmonary edema may result in a serious adverse patient event which may include compartment syndrome, neuropraxia, tachycardia, pneumothorax, tissue tearing or nerve compromise. Should extravasation be observed, it is recommended to reduce pressure settings and closely observe the excess fluid build up.

WARNING!
The nominal pressure of the described device can be preset to values described in this manual. Select the optimum pressure based on the patient profile, including but not limited to blood pressure, height, weight and age. The manufacturer recommends pressure settings for different areas of application; however these are suggestions only and are not intended to substitute or replace the expertise of the surgeon.

3.9 Hysteroscopy Warnings

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

WARNING!
The deficit and inflow values are lost in case of a power loss or "brownout".

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

WARNING!
Fluid intake and output surveillance
Strict fluid intake and output surveillance should be maintained. If a low viscosity liquid distention medium is used, intrauterine instillation exceeding 2 liters should be followed with great care due to the possibility of fluid overload. If a high viscosity fluid is used, the use of more than 500 ml should be followed with great care.

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

WARNING!
Pulmonary edema
A surgical procedure has the risk of pulmonary edema, which is formed due a "fluid overload" with isotonic fluids. It is critical to closely monitor the input and outflow of the distending liquid at all times.

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

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

may occur during a surgical procedure if a liquid distention medium is used.

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

WARNING!
Instrument replacement
Stop the device using the START/STOP switch if replacing the instrument during surgery.

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

WARNING!
Fluid volume/sodium concentration
The fluid left in the patient and the concentration of sodium in the blood serum must both be monitored. The deficit amount is the entire amount of fluid lost by or to the system. Take note of the measurement tolerance of the system. Estimating the fluid volume remaining in the patient is the doctor's responsibility.

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

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

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

3.10 Urology Warnings

WARNING!
Instrument replacement
Stop the device using the START/STOP switch if replacing the instrument during surgery.

WARNING!
The inflow value is lost in the event of a power failure.

WARNING!
Fluid volume/sodium concentration
The fluid left in the patient and the concentration of sodium in the blood serum must both be monitored. The deficit amount is the entire amount of fluid lost by or to the system. Take note of the measurement tolerance of the system. Estimating the fluid volume remaining in the patient is the physician's responsibility.

WARNING!
If a stone is in the surgical field, it can be moved by the flow of irrigation fluid settable via the pressure and flow rate values and possibly flushed into the kidneys.

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

may occur during a surgical procedure if a liquid distention medium is used.

WARNING!
Pulmonary edema
A surgical procedure has the risk of pulmonary edema, which is formed due a "fluid overload" with isotonic fluids. It is critical to closely monitor the input and outflow of the distending liquid at all times.

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

WARNING!
Fluid intake and output surveillance
Strict fluid intake and output surveillance should be maintained. If a low viscosity liquid is used, a transurethral instillation exceeding 2 liters must be monitored with great care due to the possibility of fluid overload.

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

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

4 Initial Device Startup

Operation of the devices PG130/PG145 is reserved for persons with the relevant professional qualifications and trained to use the device.

4.1 Delivery Scope

- Device PG130/PG145
- Instruction for use
- Power cable

Delivery inspection

Always check all parts and optional accessories of the device immediately after receiving the shipment. The manufacturer considers only replacement claims that have been immediately submitted or reported to a sales representative or an authorized service company.

Returning the device

Use the original packaging material if the device has to be returned. The manufacturer is not responsible for transport damages due to insufficient or unsuitable packaging.

Please make sure that all required information has been supplied:

- Name of owner
- Address of owner
- Device type and model
- Serial number of the equipment (see identification plate)
- Detailed description of defect

4.2 Setting up and Connecting the Device

NOTE!
Locations
The device may be used only in the hospital or operating rooms.

Setting up

Place the device on a flat surface free of vibration located in a dry environment. The ambient temperature and humidity must meet the requirements mentioned in Chapter 19 "Technical Data".

WARNING!
ME System (Medical Electrical System)
Use only parts and/or devices from ME systems (see Chapter 22 Glossary) in patient environments in compliance with the standard IEC60601-1 in the respective currently valid version.

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

CAUTION!
ME systems (Medical Electrical System)
The medical electrical device is suitable for integration in ME equipment systems (see Chapter 22 Glossary). Operation of the ME device in vicinity of non-ME devices may result in voiding the intended use of the ME device.

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

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

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

CAUTION!
Place the device outside the sterile field.

CAUTION!
Position of the user
To avoid a malfunction, the user must be positioned correctly
- **within a display viewing angle of ±50° to operate the device**
- **up to 2 m/6.5 ft from the device front for monitoring the actual values**

Mains connection

CAUTION!
Check to make sure the available mains voltage matches the data listed on the type label attached to the back of the device. Incorrect voltage can cause errors and malfunctions and may destroy the device.

Make sure the connection data and technical specifications of the power supply comply with DIN VDE or national requirements. The mains connection cable may be plugged only into a properly installed, grounded safety wall socket (shockproof socket) (see DIN VDE 0100-710). Read the device label located in rear of device (type plate) to determine the operating voltage of the device.

Grounding contact

The power connection must be equipped with a grounding contact. Use the original power cable (if included in scope of delivery) to establish a connection between the mains wall socket and the non-heating device plug located in the rear of the device.

Only for U.S. operators

Only use a certified (UL-listed), removable mains connection cable, type SJT, minimal 18 AWG, 3 leads. The plug connectors must comply with NEMA 5-15 and IEC 16320-C13. Grounding will only be reliable if the equipment is connected to a corresponding hospital grade socket.

Potential equalization

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

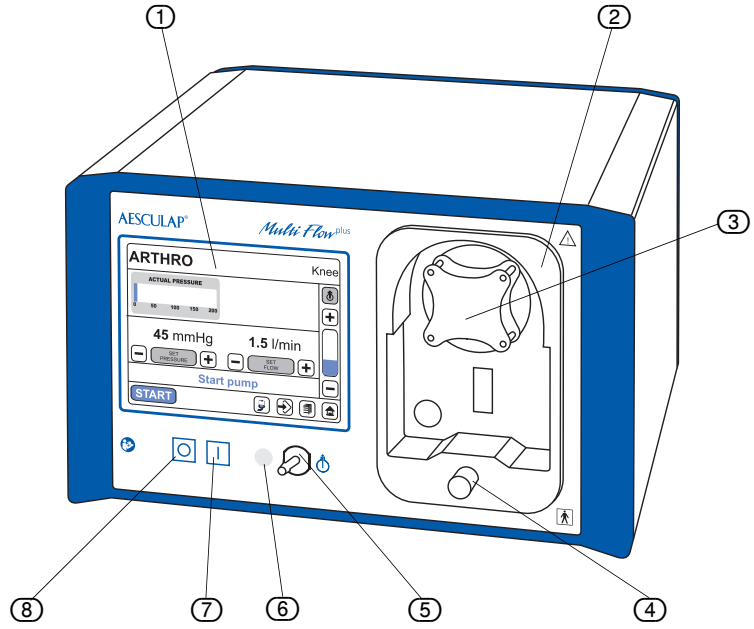
5 Description of Device

5.1 Front of Device

Familiarize yourself with the control and display elements of the PG130/PG145.

en

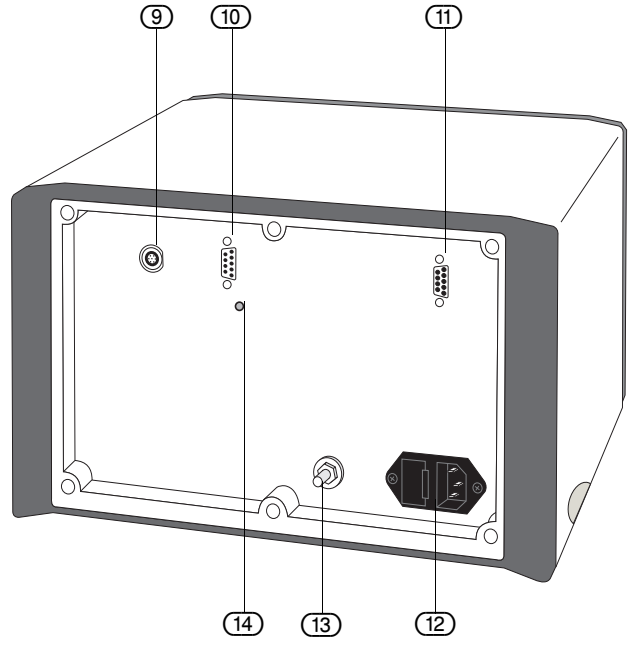
Fig. 5-1 Device front



① Touchscreen
② Tube retainer
③ Roller wheel
④ Mechanical tube set trigger
⑤ Vacuum pump connection (only PG145)
⑥ IR interface
⑦ ON switch
⑧ OFF switch

5.2 Rear of the Device

Fig. 5-2 Rear of the device



⑨ Foot pedal connection
⑩ Scale connection
⑪ Service interface RS232, 9-pin
⑫ Mains power connection with fuse holder
⑬ Potential equalization plug
⑭ Air outlet

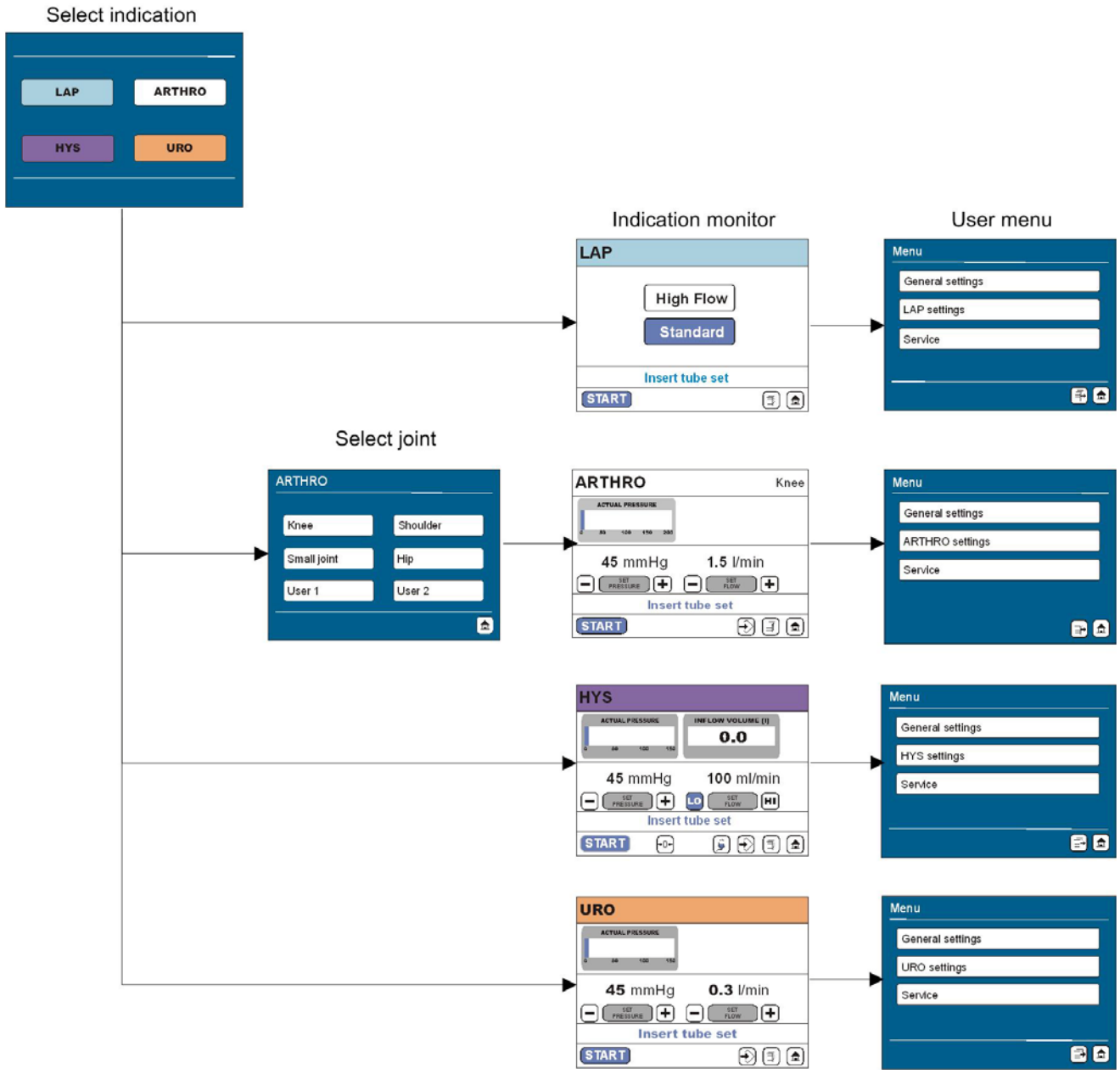
5.3 Touchscreen

The touchscreen connects display and control elements and offers intuitive ease of use. Function fields or symbols are used to control the unit. An acoustic signal (beep) is emitted when pressing a function field or symbol. This beep confirms your input. The following different screen displays are depicted when operating the device:

- Indication selection
- Indication screen
- User menu
- Joint selection (only arthroscopy)

The following is an overview of the screen displays of the indications.

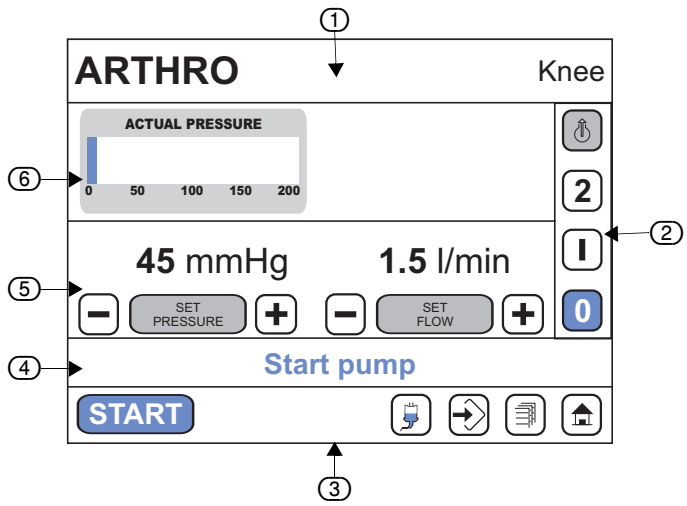
Fig. 5-3 Screen displays overview



Indication screen

Fig. 5-4 "Indication screen overview" depicts the 6 areas with display and control elements.

Fig. 5-4 Indication screen overview



① Header
② Suction level (only PG145)
③ Footer
④ Status line
⑤ Nominal values
⑥ Actual values

The indication screen is divided into the following 6 areas:

1. **Header**: Depicts the indication type. For arthroscopic procedures, the joint type is depicted in the upper right. For hysteroscopies, a connected scale is depicted.
2. **Suction level (only PG145):** Used to select one of two available suction pump levels. The respective suction level is depicted in blue.
3. **Footer**: Only control elements are depicted here: Function fields and symbols.
4. **Status line**: Depicts messages, warnings, and error messages.
5. **Nominal values**: Set the nominal pressure on the left and the nominal flow on the right side (not for laparoscopy!).
6. **Actual values**: Indicates the measured actual pressure on the left side. In Hysteroscopy, the right side depicts the pumped volume or the difference volume if a scale is connected.

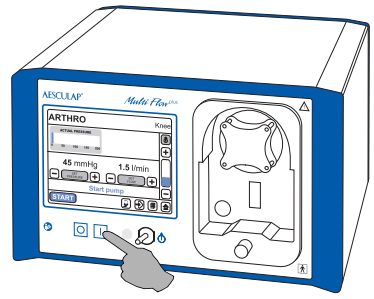
The 4 specific indication screens are described in details in the following Chapters:

- 8.3 "Screen Displays of the Laparoscopy Indication"
- 9.5.1 "Screen Displays of the Arthroscopy Indication"
- 10.3 "Screen Displays of the Hysteroscopy Indication"
- 11.3 "Screen Displays of the Urology Indication"

6 Operating the Device

6.1 Turning the Device On

1. Connect the device with the mains power.
2. Make sure **no** tube set is inserted into the tube retainer (exception: day set during arthroscopy! See 9.4 "Switching Device on When Using Day Patient Set", item b). Press the ON switch. An acoustic warning signal is emitted.



3. The device performs a device check after being switched on. The touchscreen first displays the **Company logo/Device check**. After approx. 2 seconds, **Company logo/Device OK** is displayed on screen. A beep is emitted 3 times. After the successful device check, the screen depicts all activated indications in the form of function fields. A maximum of 4 indication types are available:
   - **LAP** for laparoscopy
   - **ARTHRO** for arthroscopy
   - **HYS** for hysteroscopy
   - **URO** for urology

4. If a tube set is in the tube retainer before the device is being switched on, the screen depicts the following message: **Remove tube set** (exception: day set during arthroscopy! See 9.4 "Switching Device on When Using Day Patient Set", item b). Remove tube set. The device conducts a device check (see item 3).

   If the device check is unsuccessful, the corresponding error messages are displayed (see Chapter 6.1.1 "Device Displays after Unsuccessful Completion of Device Check").

6.1.1 Device Displays after Unsuccessful Completion of Device Check

If the device check was **not** successful, the touchscreen depicts the respective device error. The following errors may be depicted:

***Device error*:**

Motor error

Sensor error

Electronic error

Calibration error

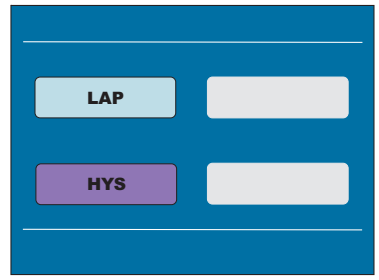
Please read Chapter 18 "Error and Warning Messages" for additional information.

6.2 Activating Indication on New Factory Devices

Devices new from the factory are shipped without any activated indications. The desired indication must be activated before first use. Activation is done individually for each indication using a special transponder (see Chapter 20 "Article/Accessory List PG130/PG145").

The activated indications are depicted on the touchscreen in color. Not activated indications are depicted as gray areas.

Activate indication with transponder



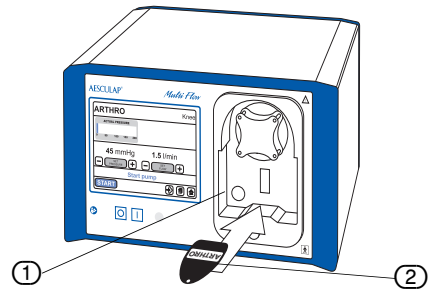
Once an indication has been activated with a transponder, that transponder is automatically invalidated and can not be used a second time. Each transponder can be used only **once**.

Invalidating a transponder

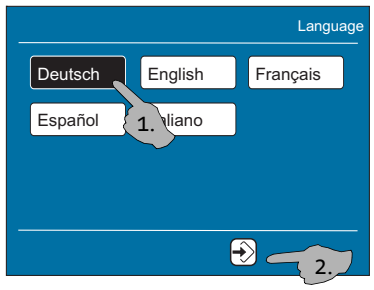
Fig. 6-1 Inserting transponder into tube retainer

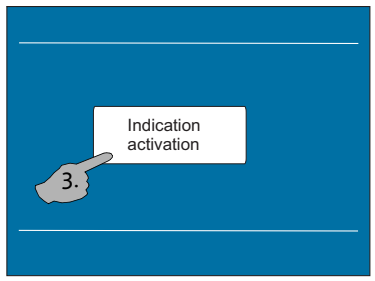
① Tube retainer

② Transponder



1. Switch device on. The touchscreen of the device depicts the language selection if an indication has not yet been activated. Press the desired language.
2. Press **[Save]** to save the language.
3. The touchscreen depicts the following in the selected language: **[Indication activation]**. Press **[Indication activation]**. Please follow the instructions on the touchscreen.





4. Hold the desired transponder onto the center of the horizontal area underneath the roller wheel (see Fig. 6-1 "Inserting transponder into tube retainer").
5. The device checks the reliability and validity of the transponder. With a successful check, the indication screen depicts the activated indication. All other indications can now be activated as described in Chapter 6.3 "Activating a New Indication".

   If the transponder is invalid, the screen depicts the following: **Activation transponder invalid**. If this is the case, repeat the process with a new and valid transponder.

6.3 Activating a New Indication

Activate new indication with transponder

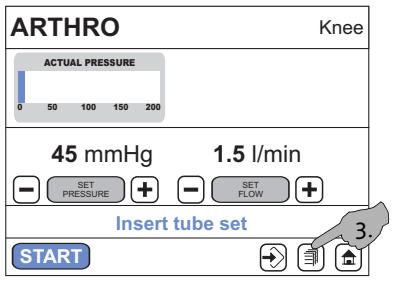
A device with already one or several activated indications, can be enabled for one additional indication (max. of 4 indications per device!). Activation is done individually for each indication using a special transponder (see Chapter 20 "Article/ Accessory List PG130/PG145").

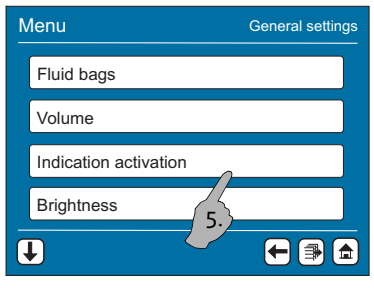
Invalidating a transponder

Once an indication has been activated with a transponder, that transponder is automatically invalidated and can not be used a second time. Each transponder can be used only **once**.

Activate new indication

Up to 4 indications can be activated for the devices PG130/PG145.

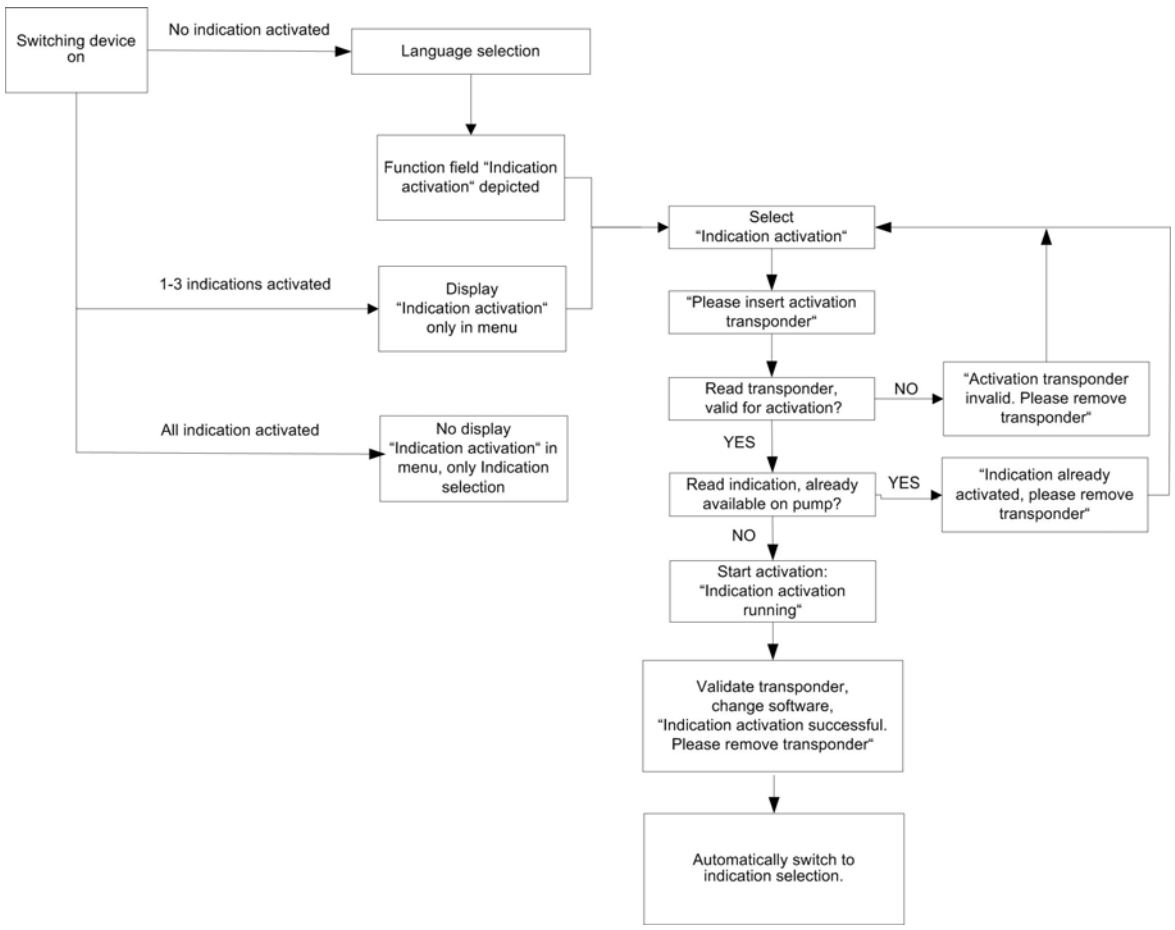




1. Switch device on.
2. All of the already activated indications are depicted on the touchscreen. Press the function field of one of the depicted indications (e.g., **[ARTHRO]**). The indication screen opens. If you have selected the indication ARTHRO, then you must press one of the displayed function fields (e.g., **[Knee]**) before being able to press the **[User menu]** symbol.
3. Press the **[User menu]** symbol. The corresponding user menu opens.
4. Press **[General settings]**. The following function field opens, among others: **[Indication activation]**.
5. Press the **[Indication activation]** function field. Please follow the instructions on the touchscreen. The device checks the reliability and validity of the transponder. With a successful check, the indication screen depicts the new activated indication and all previously activated indications.

If the transponder is invalid, the screen depicts the following: **Transponder invalid**. If this is the case, repeat the process with a new and valid transponder.

6.4 Indication Activation Overview



6.5 Using the Tube Sets

RFID technology (transponder technology)

The transponder technology detects the tube type, the validity and reliability of a tube set automatically and a corresponding message is output in the status line of the touchscreen. This eliminates virtually all "operating errors" since non fitting, invalid, and not allowed tube sets are reliably detected. The corresponding transponder is located underneath the tube retainer in each allowed tube set (see Chapter 20 Article/Accessory List PG130/PG145).

Invalidating a tube set

If a allowed tube set is located in the device, the transponder technology automatically invalidates this tube set when the device is started. Depending on the tube set, this has the following consequences:

- **Disposable tube set**: After inserting the tube set and starting the irrigation cycle, the tube set is invalidated. If the irrigation cycle is stopped, the device can be restarted within 60 minutes. If the device is switched off or in case of a power failure, the tube set is invalidated. The irrigation cycle can no longer be started. If this is the case, you must insert a new, valid, and allowed tube set.
- **Reusable tube set**: The reusable tube set can be used about 20 times. The status line of the touchscreen depicts the following: **Remaining cycles: X**. After inserting and starting irrigation, one use cycle is invalidated. If irrigating is stopped during the use cycle, irrigation can be restarted within 60 minutes. If the device is switched off or in case of a power failure, the current use cycle is invalidated.

  Before the last cycle the status line of the touch screen depicts **Last cycle!**. Once the last use cycle has been invalidated, irrigation can no longer be started. If this is the case, you must insert a new, valid, and allowed tube set.
- **Day patient set** (in short **day set)**: Checks and outputs messages only for the day tube! The status line of the touchscreen depicts the following: **Day set inserted:** After inserting and starting irrigation, one use cycle is invalidated. If the

device is switched off or in case of a power failure, the current use cycle is invalidated. Once the last use cycle has been invalidated, irrigation can no longer be started. If this is the case, you must insert a new, valid, and allowed day tube.

Transponder signal loss

The device stops and cannot be restarted if the transponder loses its signal during current operation (e.g. defective electronic component). If the signal is restored with 60 seconds, it is possible to continue using the tube set.

6.6 Usable Tube Sets Overview

NOTE!
Tubes must be stored at room temperature. The shelf life for all tubes is 5 years.

NOTE!
Observe applicable hygiene regulations when disposing of the tube set.

A total of 9 different tube sets can be inserted into the tube retainer on the front of the device. The following table lists the function of each type of tube set depending on the selected indication. Explanation: [x] = usable, [-] = not usable.

Tube type	Art. No.	Tube category	LAP	ARTHRO	HYS	URO
Reusable	PG131	Reusable tube set, luer lock connector, and tap spikes	x	x	x	x
Disposable (one-time use)	PG132SU	Disposable tube set, luer lock connector, and tap spikes	x	x	x	x
	PG133SU	Disposable tube set, luer lock connector, and Care lock	x	x	x	x
LAP tube set	PG122SU	Disposable tube set with suction/ irrigation grip, luer lock connector, and tap spikes	x	-	-	-
	PG123SU	Disposable tube set with suction/ irrigation grip, luer lock connector and Care lock	x	-	-	-
Day patient set	PG134SU	Day patient set with luer lock connector and tap spikes, consisting of day tube and patient tube	-	x	-	-
	PG135SU	Day patient set with luer lock connector and Care lock, consisting of day tube and patient tube	-	x	-	-
Day tube	PG136	Day tube with luer lock connector and tap spikes	-	x	-	-
	PG137	Day tube with luer lock connector and Care lock	-	x	-	-

WARNING!
Disposable tube sets contain Diethylhexylphthalate (DEHP), which is classified as toxic to reproduction according to the EU Directive 67/548/EEC on Classification and Labelling of Dangerous Substances. DEHP may impair fertility, may cause harm to unborn child, may excrete in breast milk. Therefore, this product must not be used for unauthorized applications. When applied within the intended use, the potential risk to pregnant or breastfeeding women as well as to children resulting from the DEHP contained in this product is not critical. In regard to the short exposure time and the physical characteristics the eventuality of critical quantities of DEHP being dissolved from the tube sets is neglectable.

WARNING!
Reprocessing of sterile disposable products
Infection hazard for patients and/or users and impairment of product functionality due to reuse. Risk of injury, illness or death due to contamination and/or impaired functionality of the product! Do not reprocess the product.

6.7 Inserting a Standard Tube Set

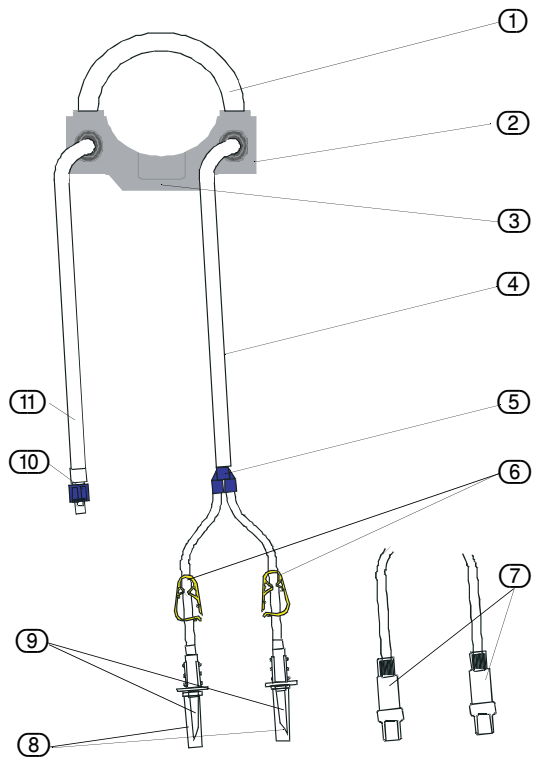


Fig. 6-2 Tube set elements

1. Pump segment
2. Tube holder with pressure membrane
3. Transponder
4. Inflow tube
5. Y-connector
6. Tube clamps
7. Care lock connectors
8. Protective caps
9. Tap spikes
10. Luer lock connector
11. Instrument tube

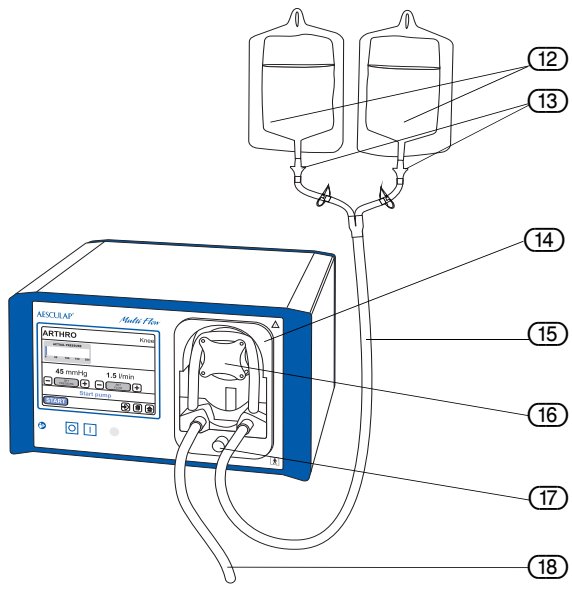
The **tube set** is available as a disposable or reusable tube set (autoclavable) (see Chapter 20 Article/Accessory List PG130/PG145).

The tube set consists of 3 tube components (inflow tube (4), pump segment (1), and instrument tube (11)), a Y-connector (5), and 2 tap spikes (9) or Care lock connectors (7). The tube components are connected to the irrigation fluid bags with the help of the tap spikes (9) or the Care lock connectors (7).

The Luer lock connector (10) connects the instrument tube with the instrument.

Fig. 6-3 Inserting the tube set

(12) Irrigation fluid bags
(13) Tap spikes/Care lock
(14) Tube retainer
(15) Inflow tube/irrigation tube
(16) Roller wheel
(17) Mechanical tube release
(18) Instrument tube



In order to separate sterile from non-sterile areas, assign the following tasks to the "sterile" or "non-sterile" nurse or medical technician. The indicated numbers refer to Fig. 6-2 "Tube set elements" and Fig. 6-3 "Inserting the tube set".

Open outer packaging

1a. Disposable tube set - To be carried out by non-sterile technician:

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

Open sterile autoclavable container

1b. Reusable tube set - To be carried out by non-sterile technician:

- ▶ Open the sterile autoclavable container of the tube set.
- ▶ A sterile technician then removes the tube set from the inside of the package.

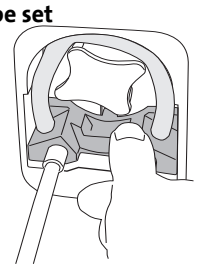
Connect instrument

2. To be carried out by sterile technician:

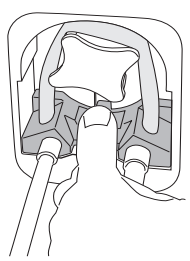
- ▶ Keep the Luer lock connector (10) in the sterile area and hand the tube end with the tap spikes (9)/Care lock (7) to the non-sterile technician.
- ▶ Connect the Luer lock connector (10) with the instrument (e.g. inflow cannula). Open inflow valve at instrument.

Insert tube set

A.



B.



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

- ▶ Turn the device on and select the desired indication. The indication screen shows the following: **Insert tube set**.
- ▶ **A**. Place the pump segment (1) loosely over the roller wheel (16) and press the tube holder (2) towards the rear and into the tube retainer (14) of the device.
- ▶ **B**. Press on tube holder (2) center using your thumb and push holder down vertically until it snaps into the tube retainer. This can be heard and felt. The pump segment (1) is now tensioned firmly over the roller wheel (16).
- ▶ The validity of the tube set is now checked. In case of an invalid tube set, the status line alternately shows the following: **Tube set not valid** and **Please replace**. An acoustic alarm is emitted 3x. The entire procedure must be repeated with a valid tube set if an invalid tube set has been inserted.
- ▶ Connect the tube end with the tap spikes (9)/Care lock (7) and the full irrigation fluid bags (12).
- ▶ If the **Fluid bag warning** function is enabled (see "Setting the Fluid Bag Warning"), press the **[Fluid bag]** symbol to reset the device to a full fluid bag. Make sure the bag volume is set correctly.
- ▶ Press the **[START]** function field and wait until the tube set is completely filled with irrigation fluid.
- ▶ The device is now ready for use.

6.8 Inserting the Day Patient Tube Set

The **day patient set** consists of two tube sections comprised of the **day tube** and the **patient tube**. The day tube establishes the tube connection between the irrigation fluid bags and the patient tube. The day tube is inserted into the tube retainer of the device and not replaced for the duration of one day between surgeries and/or surgical procedures. Only the patient tube (tube connection between day tube and the instrument) must be replaced between surgical procedures. Efficiency is increased with a day set if several surgeries are to be performed on one day. The patient tube has to be replaced after each surgical procedure. Make sure to connect tubes as indicated by the matching connectors.

CAUTION!
Use only original day patient sets by the manufacturer. Other day patient set systems are not compatible with the pump!

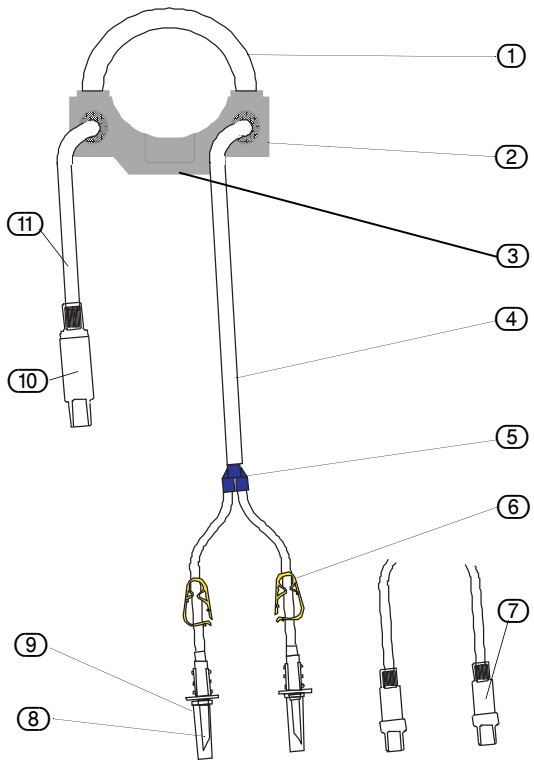


Fig. 6-4 Day tube set elements

(1) Pump segment
(2) Tube holder with pressure membrane
(3) Transponder
(4) Inflow tube
(5) Y-connector
(6) Tube clamps
(7) Care lock connectors
(8) Tap spikes
(9) Protective caps
(10) Patient connection (Care lock)
(11) Instrument tube, 15 cm

The day tube

The day tube includes the connectors to the fluid bags and to the hygiene connector (Fig. 6-5 "Patient tube elements" see (15)) of the patient tube.

The day tube may be used the entire day of surgery. However, it is designed for a maximum of **10 uses**. After 10 uses, the day tube must be **replaced with a new one**.

WARNING!
The day tube must be replaced at the end of the day of surgery but not later than after 24 hrs.

A new sterile cap (included with the patient tube in the delivery) must be screwed onto the patient connector (Fig. 6-4 (10)) of the day set immediately after the surgical procedure to prevent contamination. This sterile protector remains connected to the day tube until the next surgery.

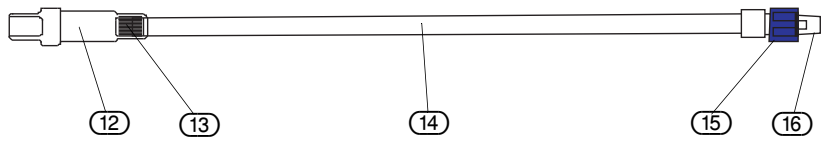
The patient tube

The patient tube has a connector on one side to connect with the day tube (hygiene connector (13)). A luer lock connector (15) to connect to an instrument

such as a trocar, for example, is fitted to the other side. Connect the hygiene connector (13) of the patient tube with the matching piece on the day tube (Fig. 6-4 (10)).

Fig. 6-5 Patient tube elements

(12) Protective cap for hygiene connector
(13) Hygiene connector (Care lock)
(14) PVC tube, 285 cm
(15) Luer lock connector with screw cap
(16) Protective cap for luer lock

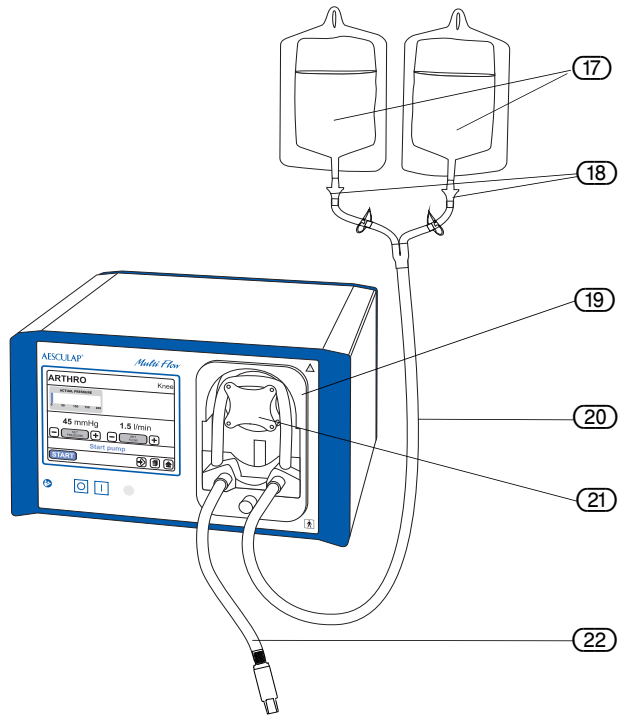


The patient tube set has to be replaced for every patient to prevent cross-contamination. The day tube remains connected to the device after each surgery. The used patient tube must be disposed of after each surgery.

WARNING!
Make sure to connect tubes as indicated by the matching connectors.

Fig. 6-6 Inserting the day patient tube set

(17) Irrigation fluid bags
(18) Tap spikes/Care lock
(19) Tube retainer
(20) Inflow tube/irrigation tube
(21) Roller wheel
(22) Instrument tube with patient connector (Care lock)



In order to separate sterile from non-sterile areas, assign the following tasks to the "sterile" or "non-sterile" nurse or medical technician. The indicated numbers refer to Fig. 6-4 "Day tube set elements", Fig. 6-5 "Patient tube elements" and Fig. 6-6 "Inserting the day patient tube set".

Remove day patient set

1. To be carried out by non-sterile technician:

- Open the packaging of the day tube and keep it with you.
- Open the packaging of the patient tube and have a sterile technician remove it for you.

Connect patient tube

2. To be carried out by sterile technician:

- Keep the luer lock connector (15) in the sterile area and hand the tube end with the hygiene connector (13) to the non-sterile technician.

- ▶ Connect the luer lock connector (15) with the instrument (e.g., inflow cannula). Open inflow valve at instrument.

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

Insert new day tube

- ▶ Connect the hygiene connector (13) with the patient connector (10).
- ▶ Switch the device on and select the arthroscopy indication (see Chapter 9.4 "Switching Device on When Using Day Patient Set").
- ▶ Select the desired joint type. The indication screen shows the following: **Insert tube set**.
- ▶ Place the pump segment (1) loosely over the roller wheel (21) and press the tube holder (2) towards the rear and into the tube retainer (19) of the device.
- ▶ Press on tube holder (2) center using your thumb and push holder down vertically until it snaps into the tube retainer. This can be heard and felt. The pump segment (1) is now clamped in place firmly over the roller wheel (21).
- ▶ The validity of the tube set is now checked. In case of an invalid tube set, the status line alternately shows the following: **Tube set not valid** and **Please replace**. A short acoustic alarm is emitted 3x. The entire procedure must be repeated with a valid tube set if an invalid tube set has been inserted.
- ▶ Connect the tube end with the tap spikes (8)/Care lock (7) and the full irrigation fluid bags.
- ▶ If the **Fluid bag warning** function is in the **General settings -> Fluid bags** menu is set to **ON**, press the **[Fluid bag]** symbol to reset the counter to **0**.
- ▶ Press the **[START]** function field and wait until the day patient set is completely filled with irrigation fluid.
- ▶ The device is now ready for use.

WARNING!
The physician must determine an irrigation fluid suitable for the application and medical procedure!

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

Inserted day tube

- ▶ Connect the hygiene connector (13) with the patient connector (10).
- ▶ Switch the device on and select the arthroscopy indication (see Chapter 9.4 "Switching Device on When Using Day Patient Set").
- ▶ Select the desired joint type. The indication screen shows the following: **Day tube inserted**.
- ▶ The validity of the tube set is now checked. In case of an invalid tube set, the status line alternately shows the following: **Tube set not valid** and **Please replace**. A short acoustic alarm is emitted 3x. The entire procedure must be repeated with a valid tube set if an invalid tube set has been inserted.
- ▶ Connect the tube end with the tap spikes (8)/Care lock (7) and the full irrigation fluid bags.
- ▶ Press the **[Fluid bag]** symbol to reset the counter to **0**.
- ▶ Press the **[START]** function field and wait until the day patient set is completely filled with irrigation fluid.
- ▶ The device is now ready for use.

WARNING!
The physician must determine an irrigation fluid suitable for the application and medical procedure!

6.8.1 Replacing the Patient Tube After Surgery

WARNING!
The day tube remains connected to the device after each surgery. The patient tube must be disposed of immediately after surgery. A new sterile cap (included with the patient tube) must be screwed onto the hygiene connector at the day tube after each surgery. This sterile protector remains connected to the day tube until the next surgery.

1. To be carried out by non-sterile technician:

- ▶ Open packaging of the patient tube.
- ▶ A sterile technician then removes the patient tube from the inside of the package.

2. To be carried out by sterile technician:

- ▶ Keep the luer lock connector (15) and hand the other end of the patient tube to the non-sterile technician.
- ▶ Connect the luer lock connector (15) of the patient tube with the instrument (e.g., inflow cannula).

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

- ▶ Remove the sterile protector of the day tube and connect the new patient tube to the day set without delay.

6.9 Removing a Tube Set

Remove tube set

In order to separate sterile from non-sterile areas, assign the following tasks to the "sterile" or "non-sterile" nurse or medical technician. The indicated numbers refer to Fig. 6-2 Tube set elements and Fig. 6-3 Inserting the tube set.

1. To be carried out by sterile technician:

- ▶ Disconnect the Luer lock connector (10) of the instrument (e.g. inflow cannula).
- ▶ Hand the Luer lock connector (10) to the non-sterile technician.

2. To be carried out by non-sterile technician:

- ▶ Disconnect the end with the tap spikes (9) from the irrigation fluid bags (12).
- ▶ Press the mechanical tube release (17) and keep depressed.
- ▶ Remove the tube holder (2) with the pump segment (1) from the tube retainer (14).

6.10 Attaching and Connecting the Fluid Bags

WARNING!
Fluid bags
The device is only intended for use with flexible fluid containers. Do not use glass containers as they might break. Fluid cannot flow quickly enough due to the vacuum being generated inside of the bottle. Risk of implosion.

WARNING!
The physician must determine an irrigation fluid suitable for the application and medical procedure!

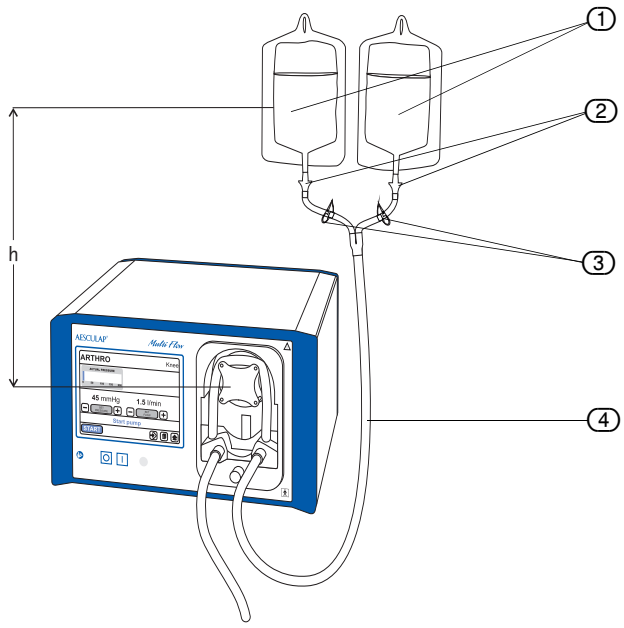


Fig. 6-7 Hanging the irrigation fluid bags

① Irrigation fluid bags
② Tap spikes
③ Tube clamps
④ Inflow tube

To be carried out by non-sterile technician:

- ▶ The inflow tube ④ can take irrigation fluid from 2 fluid bags ①. Connect both tube clamps ③ to the branches of the inflow tube.
- ▶ Connect the tube ends of the tube set with the irrigation fluid bags using the tap spikes ② (or Care lock connector). When doing this, grasp the tap spike ② at the provided handle when connecting.
- ▶ Insert the tap spike ② (or Care lock connector) into the fluid bags ① while ensuring sterile conditions (safety measure).
- ▶ Hang the fluid bags ① at a height of **h** (between 0 to 1.5 m) on a provided stand (see Fig. 6-7 "Hanging the irrigation fluid bags").
- ▶ Open **one** of the two tube clamps ③ of the irrigation tube.

6.11 Replacing an Irrigation Fluid Bag

If the function **Fluid bag warning** in the **General settings -> Fluid bag** menu is set to **ON** (see "Setting the Fluid Bag Warning"), an alarm is issued as soon as the fluid bag is almost empty (volume ≤ 15%). A short warning beep is emitted 3 times and the status line depicts the following: **Replace fluid bag**. If the fluid bag warning is not enabled, the fill level of the irrigation fluid bags must be monitored by the medical personnel.

Enabling the fluid bag warning is only practical if:

- the height between roller wheel and fluid bag remains constant,
- the same bag size is used each time, and
- only **one** of the two tube clamps of the irrigation tube is opened at any time.

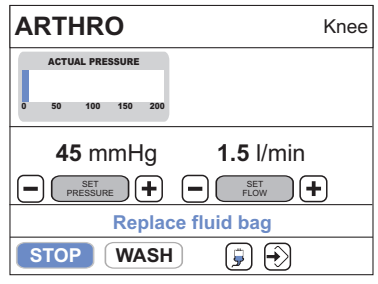
If the fluid bag warning is indicated visually or acoustically, the empty bag must be replaced with a full one.

CAUTION!
Make sure the bag volume of the used fluid bags is set correctly in the user menu (see "Setting the Fluid Bag Warning").

To be carried out by non-sterile technician:

- ▶ Open tube clamp of the full fluid bag.
- ▶ Close tube clamp of almost empty fluid bag.
- ▶ Press the **[Fluid bag]** symbol on the touchscreen to reset the device to a full fluid bag. The status line depicts the following: **Fluid bag replaced**.

Bag warning



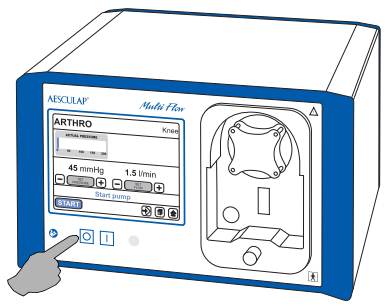
Replacing the fluid bag

- ▶ Replace the almost empty fluid bag with a full one.
- ▶ Keep the tube clamp of the new, full fluid bag closed until this bag is also in need of replacement.

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

6.12 Switching Device Off

- Press the OFF switch. The device shuts off.

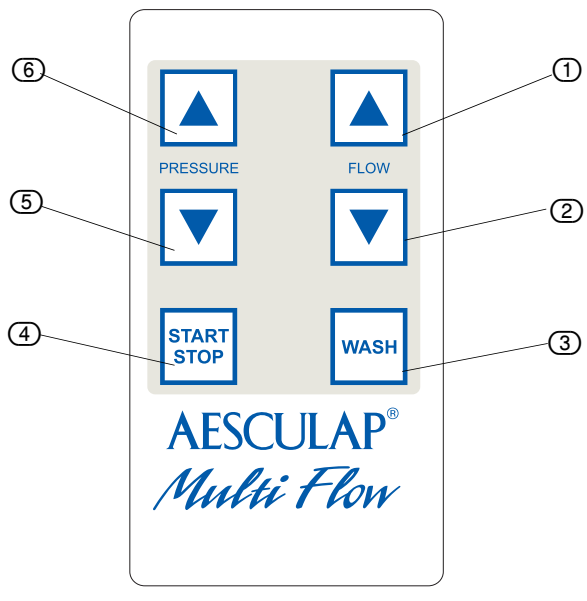


6.13 Using the Remote Control (Optional)

WARNING!
Before surgery, check if the remote control influences other devices or if other existing remote controls influence the device.

WARNING!
Do not use the remote control without sterile cover within the sterile area.

Fig. 6-8 Infrared remote control



① **[▲]** button to increase nominal flow

② **[▼]** button to decrease nominal flow

③ **[WASH]** button

④ **[START]**/**[STOP]** button

⑤ **[▼]** button to decrease nominal pressure

⑥ **[▲]** button to increase nominal pressure

Using the remote control

With the infrared remote control (see Chapter 20 "Article/Accessory List PG130/PG145"), the physician is able to control the device from the sterile surgical station. The infrared remote control can be used with all 4 indications. The devices PG130/PG145 are controlled with the following control elements of the infrared remote control.

Explanation: [x] = Function available [-] = Function not available

Buttons	Function	LAP	ARTHRO	HYS	URO
[START]/[STOP]	Starting and stopping irrigation	x	x	x	x
[▲]/[▼] for the nominal pressure	Increase and decrease nominal pressure	-	x	x	x
[▲]/[▼] for the nominal flow	Increase and decrease of nominal flow	x	x	x	x
[WASH]	Starting and stopping the Wash function	-	x	-	-

The infrared opening for the infrared remote control is located on the front of the device. Point the remote control in the direction of the front of the device and start using the switched on device by pressing the desired function buttons on the remote control.

6.14 Replacing the Battery

NOTE!
Commercially available batteries can be used.

CAUTION!
The batteries must only be replaced by authorized specialists. Before changing the batteries, check the data of the batteries to be used. Use only batteries type AA (LR6)1.5 V with the remote control.

Do not use rechargeable batteries. Use the remote control/battery regularly.

Remove the used battery from the remote control and dispose of it in accordance with national regulations.

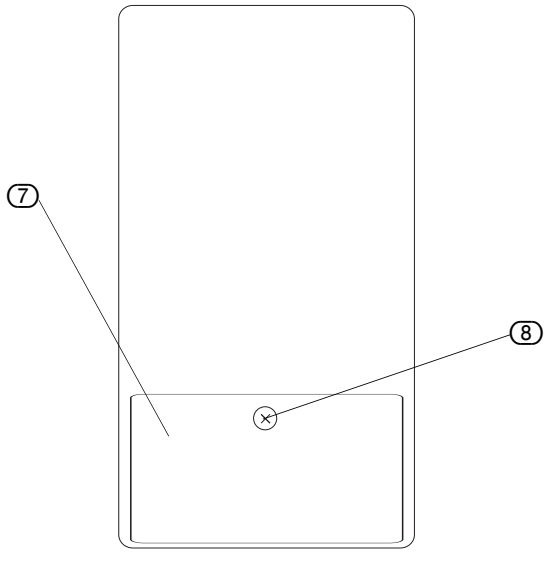


Fig. 6-9 Back of remote control

⑦ Battery tray

⑧ Screw

1. Using a screwdriver, open the cover on the back of the remote control.
2. Remove the old batteries and insert the new batteries in the orientation indicated by the symbols on the remote control housing.
3. Replace the cover and tighten with screw.

WARNING!
Never switch polarity and make sure that the plus (+) and minus (-) poles are aligned correctly to prevent short circuits.

NOTE!
Keep batteries in their original packaging until needed.

NOTE!
Remove the battery from the remote control if the unit will not be used for a long period of time, the remote control may be damaged by leaking batteries.

Disposal

The product must be prepared by the operator for disposal. When disposing or recycling the product or its components, make sure to comply with national rules and regulations at all times! A product labeled with this symbol must be disposed separately according to local rules about the waste collection of electrical and electronic devices. The disposal is carried out free by the manufacturer if within the European Union. Please contact your local B. Braun/Aesculap representative or distributor for additional information about the disposal of your product; see Chapter 15 Care and Maintenance.

6.15 Using a Foot Pedal (Optional)

CAUTION!
The foot pedal can be disinfected by wiping off and must not be sterilized.

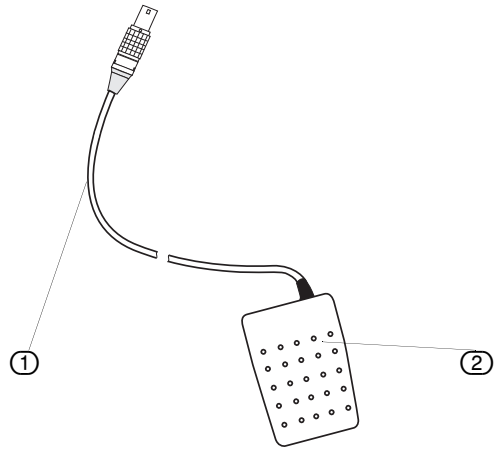


Fig. 6-10 Foot pedal elements

① Connection cable

② Foot pedal

Using the foot pedal

In the arthroscopy indication, the physician can operate the device with an optionally connectable foot pedal (see Chapter 20 Article/Accessory List PG130/ PG145) and thus activate and deactivate the Wash function. The device can be controlled with the following control elements on the foot pedal:

Explanation: [x] = Function available [-] = Function not available

Buttons	Function	LAPAROSCOPY	ARTHROS-COPY	HYSTEROS-COPY	UROLOGY
[WASH] Pedal	Starting and stopping the Wash function	-	x	-	-

Starting and stopping the WASH function via foot pedal

1. The foot pedal must be connected and the device must have recognized the foot pedal after being switched on.
2. Press the foot pedal to start the Wash function. Please note that the Wash function stops automatically after 10, 20 or 30 seconds and the device returns to the previously specified nominal values. The remaining time of the WASH function is depicted on the upper right of the screen in the form of a countdown. After stopping the Wash function, it can be restarted again.
3. Press the foot pedal to stop the WASH function before the 10, 20, or 30 seconds expire. After stopping the Wash function, it can be restarted again.

7 Using Suction Function (Only Pg145)

The device PG145 is equipped with a vacuum pump. The vacuum pump is used to suction off secretions of a patient by using a suction tube and a secretion container. A suction tube can be used with all 4 indications.

The vacuum pump generates 2 different vacuum levels:

Suction level	Vacuum
Level 1	300 mbar
Level 2	700 mbar

Table 7-1

The suction state indicator is also depicted on the right edge of the indication screen. The following depicts the difference between the two screen displays.

Fig. 7-1 PG130 without suction level indication

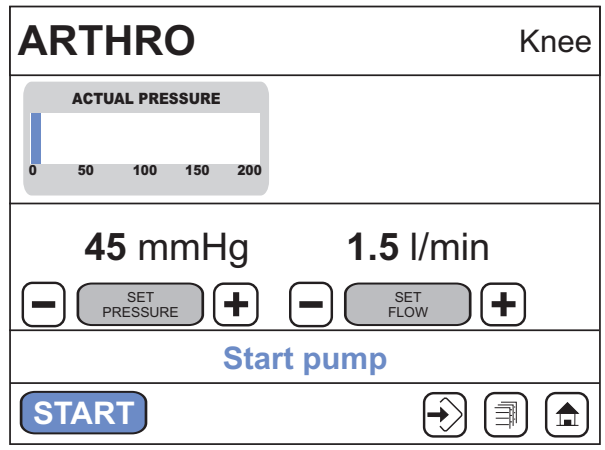
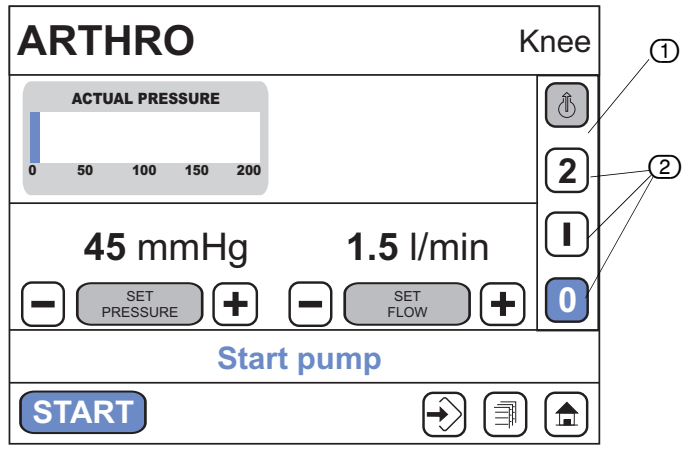


Fig. 7-2 PG145 with suction level indication

① Suction level indication range

② Suction levels 0, 1, 2



7.1 Connecting a Suction Tube

The suction system consists of the following:

- Secretion container tube with filter
- Secretion container
- Suction instrument tube
- Suction instrument

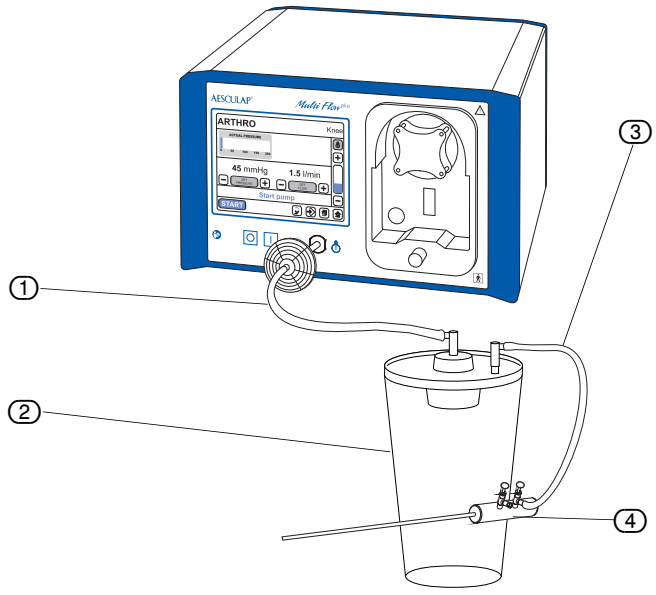


Fig. 7-3 Connecting the suction system

① Secretion container tube with filter (vacuum tube)
② Secretion container
③ Suction instrument tube
④ Suction instrument

WARNING!
Filter
The vacuum tube with integrated filter PG139 is designed for max. 28 days. In case the PG139 is not used, please use a new/sterile filter for each patient. Please insert a hydrophobic 2-way, 0.2 µm filter (filtering rate of 99.99%) between patient and device. The filter prevents bodily fluids from entering the inside of the device and possible contaminants from the device reaching the patient. Please note that the filter may reduce the suction capacity.

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

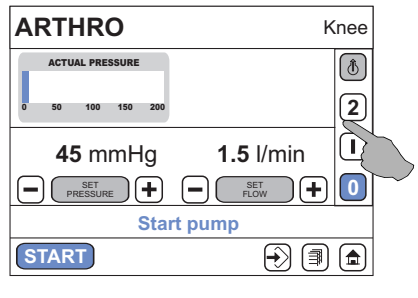
CAUTION!
Only use secretion containers with overflow protection.

1. Connect the device with the secretion container tube with filter ①.
2. Connect the secretion container tube ① with the secretion container ②.
3. Connect the secretion container ② with the suction instrument tube ③
4. Connect the suction instrument tube ③ with the suction instrument ④.
5. Close the inflow valve of the suction instrument.

7.2 Starting Suction

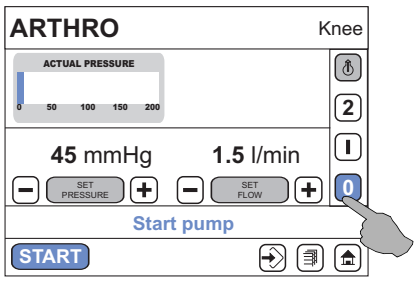
On the touchscreen, press the symbols **[1]** or **[2]** to activate suction level 1 or 2. The vacuum pump generates a negative pressure. Once a negative pressure matching the respective suction level has been reached, the vacuum pump stops. As soon as the negative pressure falls below the respective suction level setting, the vacuum pump restarts within 3 seconds.

Start suction



7.3 Stopping Suction

Stop suction



Close the inflow valve of the instrument. On the indication screen, press the **[0]** symbol to deactivate suction level 1 or 2.

7.4 Replacing the Secretion Container

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

Container change during surgery

The full secretion container can be replaced with an empty one during surgery.

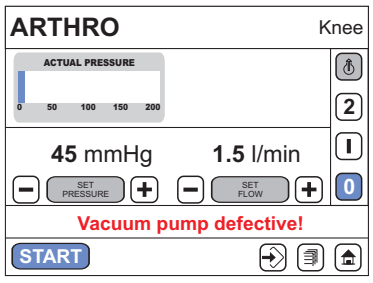
1. Stop the suction (see Chapter 7.3 "Stopping Suction").
2. Replace the full secretion container with an empty one.
3. Start the suction (see Chapter 7.2 "Starting Suction").

7.5 Removing a Suction Tube

1. Remove the suction instrument tube (3) from the instrument (4).
2. Remove the secretion container (2) with the suction instrument tube (3).
3. Remove the secretion container tube (1) with the secretion container (2).
4. Remove the secretion container tube (1) from the device.

7.6 Safety Functions

Defective vacuum pump



If the suction function or vacuum pump is malfunctioning, the status line depicts the following warning message in red: **Vacuum pump defective!** A long warning beep is emitted 3 times. Surgery can be continued. After surgery, safeguard the device until checked by an authorized service technician (see Chapter 15.4 "Aesculap Technical Service").

8 Using the Laparoscopy Indication

Intended use: Laparoscopy

The devices PG130/PG145 may serve as irrigation pump for use in minimally invasive laparoscopic surgery (keyhole surgery). The optional suction function can be used to siphon off secretions. The optional suction function can be used to extract and remove waste gas when using laser or RF surgical devices.

Contraindications

The devices may not be used in the laparoscopy indication for surgical procedures where a specific pressure must be preset and reached as required such as during hysteroscopy, urology, and arthroscopy procedures, for example.

Technical application scope: Laparoscopy

The following characteristics apply to the laparoscopy indication:

- The devices PG130/PG145 work with a permanently preset pressure of 500 mmHg when used in the laparoscopy indication.

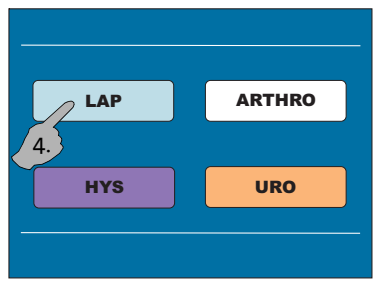
8.1 Device-Inherent Dangers: Laparoscopy Indication

WARNING!
Connecting the tube
The tube outlet may only be connected to instruments which are intended for intra-abdominal fluid suction and irrigation.

8.2 Switching Device On

Switch device on

1. Make sure **no** tube set is inserted into the tube retainer before switching the device on.
2. Press the ON switch. The device turns on. The touchscreen displays the following in succession: **Company logo/Device check** and **Company logo/Device OK.**
3. After the successful device check, the available indications are displayed for selection (see Chapter 6.3 Activating a New Indication). If the device check is unsuccessful, please read Chapter 6.1.1 Device Displays after Unsuccessful Completion of Device Check).
4. Press the **[--]** function field. The indication screen Laparoscopy is displayed.



8.3 Screen Displays of the Laparoscopy Indication

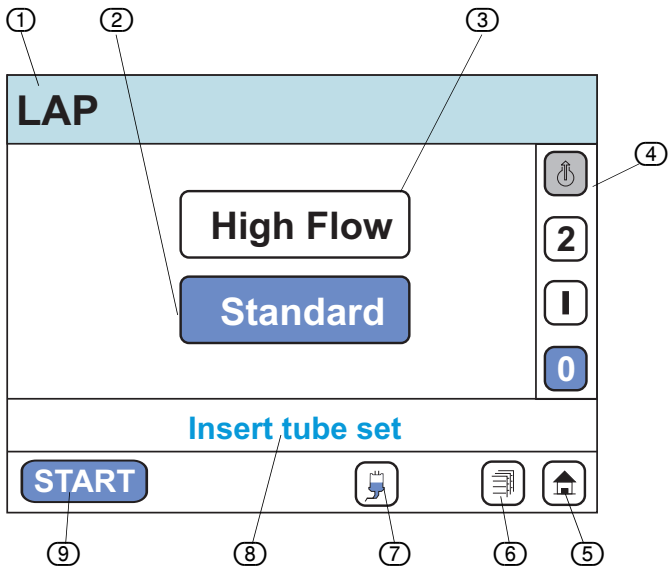


Fig. 8-1 Laparoscopy indication screen

① Indication
② **[Standard]** function field
③ **[High Flow]** function field
④ Suction function indicator (only PG145)
⑤ **[Indication selection]** symbol
⑥ **[User menu]** symbol
⑦ **[Fluid bag]** symbol (optional)
⑧ Status line for messages
⑨ **[START]/[STOP]** function field

The **[STANDARD]** flow level (factory setting) is set when activating the laparoscopy indication. The **[STANDARD]** flow level can be set in the user menu to a value

between 1.0 and 2.5 l/min. The user can switch between the **[STANDARD]** flow level and the higher **[HIGH FLOW]** level (up to 3.5 l/min).

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

8.4 Inserting a Tube Set

The following tube sets can be used with the laparoscopy indication (ordering information can be found in Chapter 20 "Article/Accessory List PG130/PG145"):

Tube type	Tube category
LAP tube set	Disposable tube set with suction/irrigation grip, luer lock connector, and tap spikes
	Disposable tube set with suction/irrigation grip, luer lock connector, and Care lock
Disposable (one-time use)	Disposable tube set, luer lock connector, and tap spikes
	Disposable tube set, luer lock connector, and Care lock
Reusable	Reusable tube set, luer lock connector, and tap spikes

Table 8-1

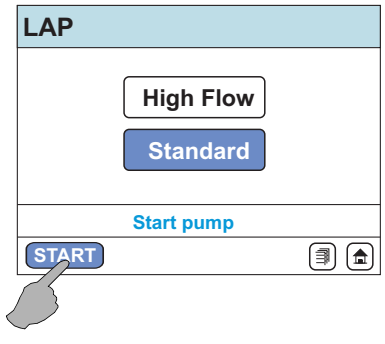
CAUTION!
When inserting a tube set already filled with irrigation fluid into the tube retainer, it is possible to damage the membranes. Only insert unfilled tube sets to avoid such damage.

For additional information, see 6.5 "Using the Tube Sets", 6.7 "Inserting a Standard Tube Set" and 6.9 "Removing a Tube Set".

8.5 Starting Irrigation

While in the laparoscopy indication, the pump works with a permanently preset pressure of **500 mmHg**. This value **cannot** be changed. The nominal flow depends on the nominal pressure and may reach a max. value of **3.5 l/min.**

Starting irrigation



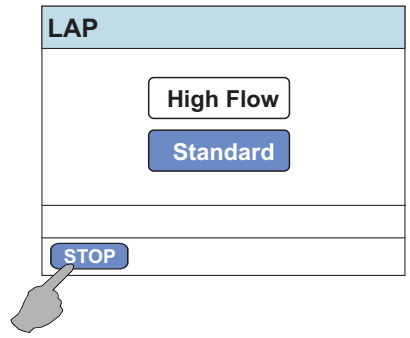
1. Insert the tube set (see Chapter 8.4 "Inserting a Tube Set").
2. Open tube clamps at irrigation tube.
3. Open inflow valve at instrument.
4. Press the **[START]** function field to start the irrigation process. The roller wheel starts to turn.

   Irrigation can also be started with the remote control (see Chapter 6.13 "Using the Remote Control (Optional)").
5. Wait until the tube set is completely filled with fluid.

8.6 Stopping Irrigation

1. Press the **[STOP]**. unction field. The roller wheel stops. The irrigation process is canceled or ended.
2. Irrigation can also be stopped with the remote control (see Chapter 6.13 "Using the Remote Control (Optional)").

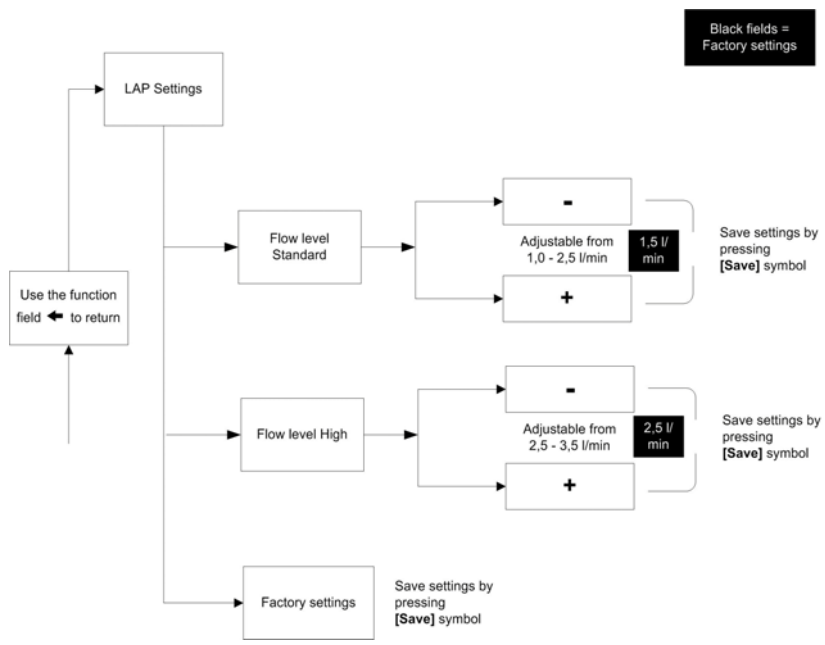
Stop the irrigation process



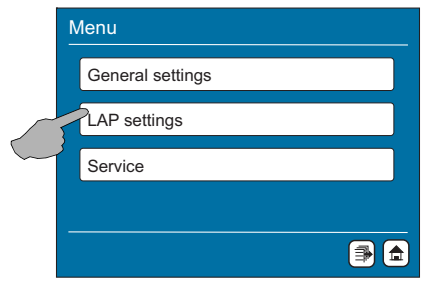
8.7 Opening and Configuring the User Menu for the Laparoscopy Indication

Device parameters are displayed and changed in the **[LAP settings]** menu. The following chart provides an overview over the possible settings.

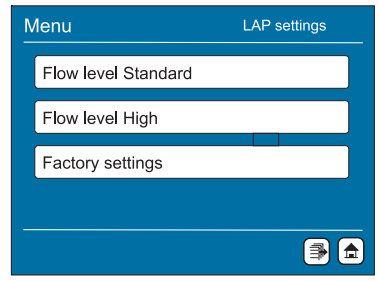
User menu overview



1. In the user menu, press the **[LAP settings]** function field. This opens the laparoscopy user menu.

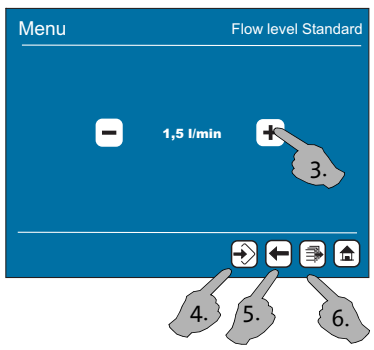


2. Press one of the following function fields: **[Flow level Standard], [Flow level High]** or **[Factory settings]**.



The following is a detailed description of how to change the indication-specific device parameters.

Set the flow level Standard/flow level High



8.7.1 Setting the Flow Level Standard/Flow Level High

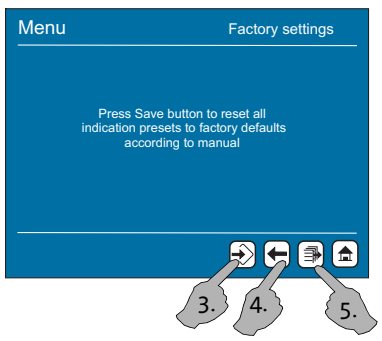
1. In the user menu, press the **[LAP settings]** function field. This opens the laparoscopy user menu.
2. Press the **[Flow level Standard]/[Flow level High]** function field. You can set values between 1.0 and 2.5 l/min for the Standard flow level and a value between 2.5 and 3.5 l/min for the High flow level.
3. Press the **[-]** or **[+]** symbol to increase or decrease the nominal flow.

   You can now do the following:
4. Press **[Save]** to save the setting. After saving, the previous menu level is automatically opened.
5. Press **[←]** to return to the previous menu level without saving.
6. Press **[Exit user menu]** to return to the screen display of the laparoscopy indication without saving.

Factory setting flow level Standard: 1.5 l/min

Factory setting flow level High: 2.5 l/min

Reset to factory settings



8.7.2 Resetting to Factory Settings

1. In the user menu, press the **[LAP settings]** function field. This opens the laparoscopy user menu.
2. Press the **[Factory settings]** function field to reset the LAP device parameters to the factory settings.

   You can now do the following:
3. Press **[Save]** to reset to the factory settings. After saving, the previous menu level is automatically opened.
4. Press **[←]** to return to the previous menu level without saving.
5. Press **[Exit user menu]** to return to the screen display of the laparoscopy indication without saving.

9 Using the Arthroscopy Indication

Intended use: Arthroscopy

The devices PG130/PG145 may be used for the distention and irrigation of knee, shoulder, hip, elbow, ankle and wrist joint cavities during diagnostic and surgical procedures such as:

- Ligament injuries
- Meniscus injuries
- Cartilage injuries
- Surgical plans and follow-up exams

The user can preset the desired joint pressure.

The pump attempts to reach and maintain the preset pressure in the joint by supplying irrigation fluid. If the joint cannot be drained (e.g., because closed valve at instrument), and if the preset pressure has been reached, the pump reduces the influx of fluid and attempts to maintain the preset pressure. If the intra-articular pressure falls below the selected value, fluid automatically continues to be supplied.

Contraindications

Use of these devices to inject fluid into a joint is prohibited whenever arthroscopy is contraindicated.

Arthroscopy is contraindicated in the following cases:

- Ankylosis (anchylosis)
- Inflammation or bacterial contamination

The devices may not be used to inject medication.

The devices are not designed or suitable for use with gas.

Technical application scope: Arthroscopy

The following characteristics apply to the arthroscopy indication:

- The nominal pressure can be preset to a range of 15 to 200 mmHg.
- The nominal flow can be preset to a range of 0.1 to 2.5 l/min.
- The devices feature an instrument recognition function.
- To improve visibility within a joint, the devices are equipped with a "Wash" function.
- The devices have an optional suction function with 2 settings for shavers.
- The pump reacts to pressures greater than the set nominal pressure by emitting warnings. The devices have safety thresholds.

Recommended pressure

The preset pressure should be based on the average blood pressure of the patient to prevent bleeding in the joint. The manufacturer recommends the following pressure settings for the following application areas:

Knee joint	**70 mmHg**
Shoulder joint	**60 mmHg**
Hip joint	**60 mmHg**
Elbow joint	**50 mmHg**
Ankle joint	**70 mmHg**
Wrist joint	**60 mmHg**

Each surgery and each patient require different parameters. The values indicated by the manufacturer are therefore only recommendations and are not intended to substitute or replace the expertise of the surgeon.

Clinical use

When performing monopolar electrosurgery, only non-conductive irrigation fluids may be used. Examples include glycine, sorbitol, mannitol, sorbitol plus mannitol, and dextran.

9.1 Device-inherent Dangers: Arthroscopy Indication

WARNING!
The height difference between the device and the patient must be adjusted correctly in order to ensure exact pressure measurement.

WARNING!
Fluid irrigation pumps used in Arthroscopy may cause fluid extravasation into the surrounding tissue. In severe cases, the resulting pulmonary edema may result in a serious adverse patient event which may include compartment syndrome, neuropraxia, tachycardia, pneumothorax, tissue tearing or nerve compromise. Should extravasation be observed, it is recommended to reduce pressure settings and closely observe the excess fluid build up.

WARNING!
The nominal pressure of the described device can be preset to values described in this manual. Select the optimum pressure based on the patient profile, including but not limited to blood pressure, height, weight and age. The manufacturer recommends pressure settings for different areas of application; however these are suggestions only and are not intended to substitute or replace the expertise of the surgeon.

9.2 Inserting a Tube Set

Tube types Arthroscopy

One of the following two tube sets can be specified in the indication Arthroscopy:

- **Standard tube set** (disposable and reusable)
- **Day patient set** (in short: **Day set**)

A standard tube set is not inserted into the tube retainer until the device has been switched on and the device check has been completed. The day set, however, remains in the tube retainer after surgery (unless it must be replaced).

The following tube sets can be used for the indication Arthroscopy (see also Chapter 20 Article/Accessory List PG130/PG145):

Tube type	Tube category
Disposable (one-time use)	Disposable tube set, Luer lock connector, and tap spikes
	Disposable tube set, Luer lock connector, and Care lock
Reusable	Reusable tube set, Luer lock connector, and tap spikes
Day patient set	Day patient set with Luer lock connector and tap spikes, consisting of day tube and patient tube
	Day patient set with Luer lock connector and Care lock, consisting of day tube and patient tube
Day tube	Day tube with Luer lock connector and tap spikes
	Day tube with Luer lock connector and Care lock

Table 9-1

CAUTION!
When inserting a tube set already filled with irrigation fluid into the tube retainer, it is possible to damage the membranes. Only insert unfilled tube sets to avoid such damage.

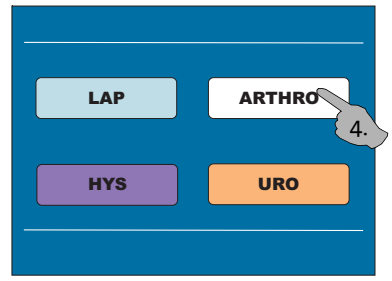
For additional information see 6.5 "Using the Tube Sets", 6.7 "Inserting a Standard Tube Set", 6.8 "Inserting the Day Patient Tube Set" and 6.9 "Removing a Tube Set".

9.3 Switching Device on When Using Standard Tube Set

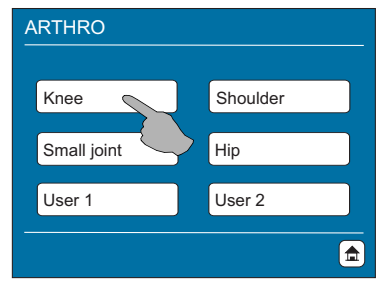
1. Make sure **no** tube set is inserted into the tube retainer before switching the device on.
2. Press the ON switch. The device turns on. The touchscreen displays the following in succession: **Company logo/Device check** and **Company logo/Device OK**.
3. After the successful device check, the available indications are displayed for selection (see also Chapter 6.3 "Activating a New Indication"). If the device check is unsuccessful, please read Chapter 6.1.1 "Device Displays after Unsuccessful Completion of Device Check").

Switching device on without standard tube set

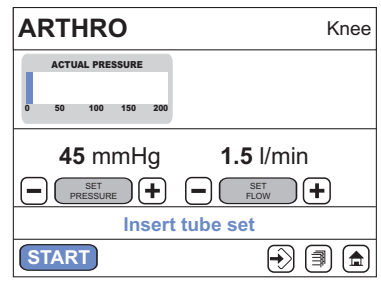
4. Press the **[ARTHRO]** function field. The joint selection is displayed (see Chapter 9.5 "Selecting Joint Type").



5. Press the desired function field, e.g., **[Knee]**.

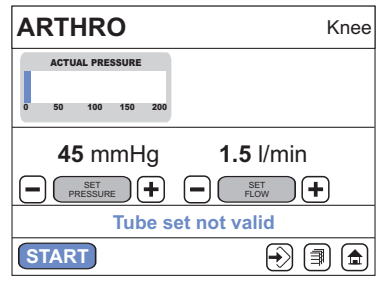


6. The arthroscopy indication screen is displayed. The displayed parameters correspond with the factory settings or the last saved nominal values. The status line depicts the following: **Insert tube set.**



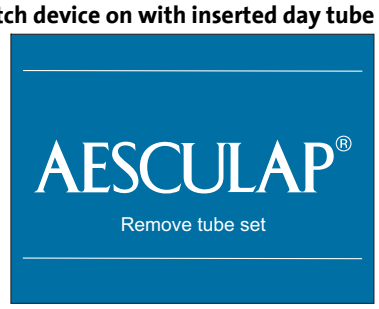
In case an invalid tube set has been inserted, the status line alternately shows the following: **Tube set not valid** and **Please replace**. A short acoustic alarm is emitted 3x.

Tube set not valid



9.4 Switching Device on When Using Day Patient Set

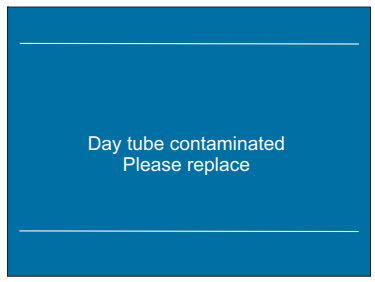
Switch device on with inserted day tube



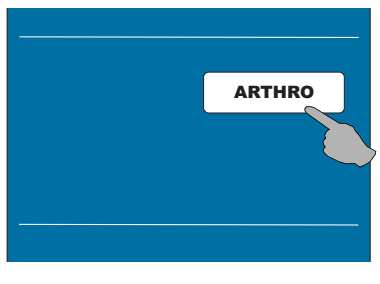
a. If the device is switched on and a new day set is inserted, the status field of the display depicts the following: **Remove tube set.** The day tube must be removed.

b. If the device is switched on and a day set used during the previous surgery is inserted, the status field of the display depicts the following consecutive messages: **Company logo/Device check** and **Company logo/Device OK**. The day tube may remain in place.

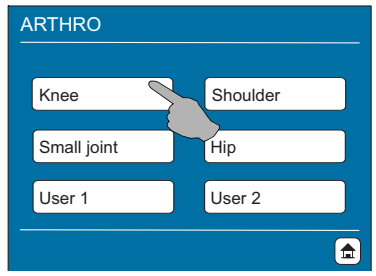
c. If the day set has become contaminated during the previous surgery, the day set must be replaced. The start screen opens and depicts the following: **Day tube contaminated**, **Please replace**.



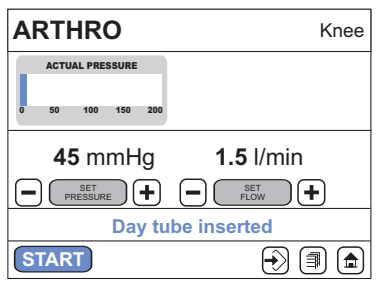
1. After the successful device check, the available indications are displayed for selection (see also Chapter 6.3 "Activating a New Indication"). If the device check is unsuccessful, please follow the instructions in Chapter 6.1.1 "Device Displays after Unsuccessful Completion of Device Check").



2. Press the **[ARTHRO]** function field. The joint selection is displayed (see Chapter 9.5 "Selecting Joint Type").

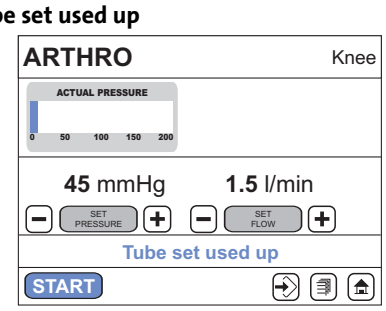


3. Press the desired function field, e.g., **[Knee]**.



4. The arthroscopy indication screen is displayed. The displayed parameters correspond with the factory settings or the last saved nominal values. A newly inserted day tube is validated (see 9.3 "Switching Device on When Using Standard Tube Set", item 6). The status line depicts the following: **Day tube inserted**.

Tube set used up



In case a used up tube set has been inserted, a warning beep is emitted 3 times and the status line alternately shows the following: **Tube set used up** and **Please replace**.

9.5 Selecting Joint Type

After pressing the **[ARTHRO]** function field, the following joint selection function fields are displayed on the touchscreen:

- Knee
- Shoulder
- Small joint
- Hip
- User 1
- User 2

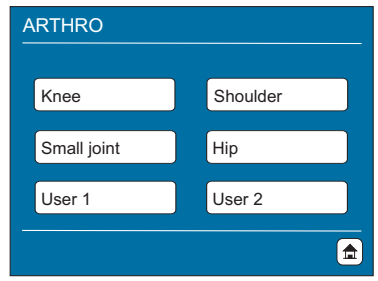
Enter and save your own user profiles into the function fields **[User 1]** and **[User 2]**.

1. Press the corresponding function field on the touchscreen to select the joint type.
2. The display depicts the selected joint type, the set values, and the function fields used to control the device. The factory default settings are as follows:

Joint type	Nominal pressure factory setting	Nominal flow factory setting
Small joints	35 mmHg	0.7 l/min
Knee joint	45 mmHg	1.0 l/min
Shoulder joint	50 mmHg	1.5 l/min
Hip joint	60 mmHg	1.0 l/min
User 1	50 mmHg	1.5 l/min
User 2	50 mmHg	1.5 l/min

Table 9-2

Select a joint



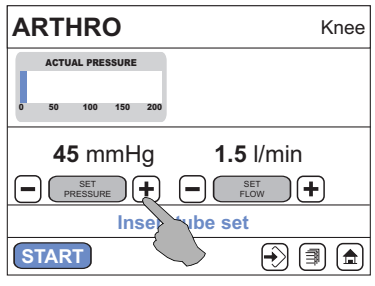
en

Fig. 9-1 Arthroscopy indication screen displays

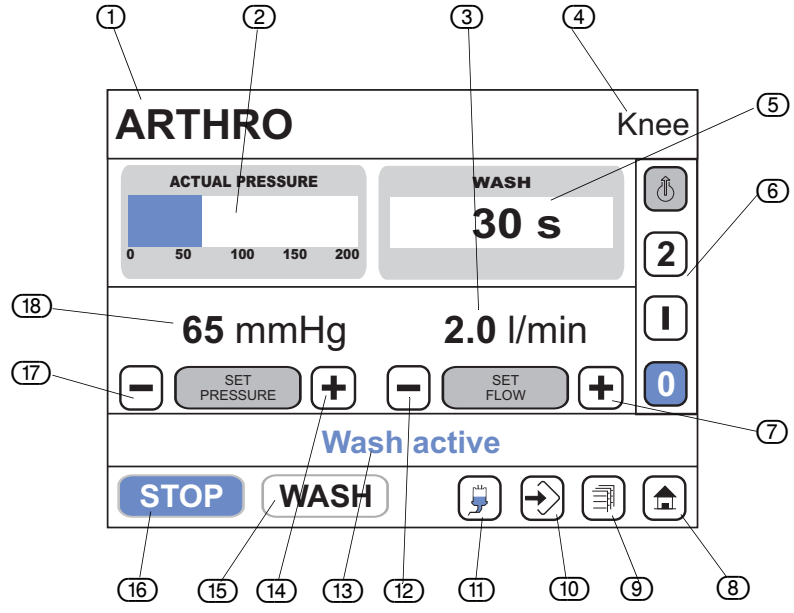
(1) Indication
(2) Actual pressure display
(3) Nominal flow display
(4) Joint type
(5) WASH time display
(6) Suction function display (only PG145)
(7) **[+]** symbol to increase nominal flow
(8) **[Indication selection]** symbol
(9) **[User menu]** symbol
(10) **[Save]** symbol
(11) **[Fluid bag]** symbol (optional)
(12) **[-]** symbol to decrease nominal flow
(13) Status line for messages
(14) **[+]** symbol to increase nominal pressure
(15) **[WASH]** function field
(16) **[START]/[STOP]** function field
(17) **[-]** symbol to decrease nominal pressure
(18) Nominal pressure display

Improved pressure measuring due to the instrument detection function

Increasing nominal pressure



9.5.1 Screen Displays of the Arthroscopy Indication



Follow these steps to select a different joint type.

1. Press the **[Indication selection]** (8) symbol. The indication selection opens.
2. Press the **[ARTHRO]** function field. The joint selection opens.
3. Select the desired joint type.

9.5.2 Automatic Instrument Recognition

The device features the automatic instrument detection function when using the Arthroscopy. The automatic instrument detection function runs in the back after each start of the irrigation process and serves to compensate pressure losses due to the flow through the narrow working channel. The pressure drop at the instrument is here included in the measured value of the actual pressure.

9.5.3 Preselecting the Nominal Pressure

The nominal pressure can be increased or decreased while the device is being used or not used. Values may be in the range from 15 to -200 mmHg.

- Briefly press the **[+]** symbol to increase the nominal pressure in increments of 5 mmHg. Pressing the **[+]** symbol longer than 1.5 seconds activates scrolling of the values in increments of 10 mmHg.

  The nominal pressure can also be raised with the help of the remote control (see Chapter 6.13 "Using the Remote Control (Optional)").

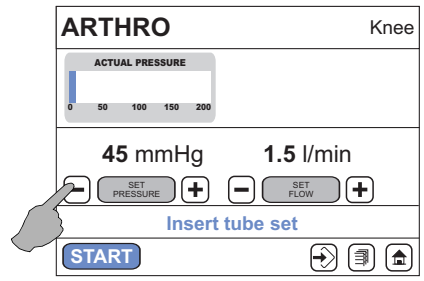
  Factory setting: See Table 9-2

- Briefly press the **[-]** symbol to decrease the nominal pressure in increments of 5 mmHg. Pressing the **[-]** symbol longer than 1.5 seconds activates scrolling of the values in increments of 10 mmHg.

  The nominal pressure can also be reduced with the help of the remote control (see Chapter 6.13 "Using the Remote Control (Optional)").

  Factory setting: See Table 9-2

Decreasing nominal pressure



9.5.4 Preselecting the Nominal Flow

CAUTION!
The nominal pressure cannot be reached if the nominal flow is set too low.

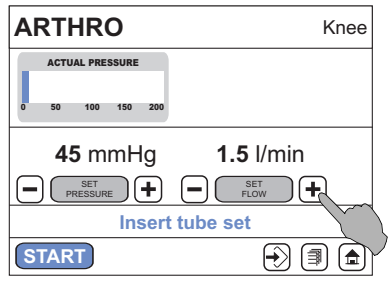
The nominal flow can be increased or decreased while the device is being used or not used. Values may be in the range of 0.1 to 2.5 l/min.

- Press the **[+]** symbol to increase the nominal flow in increments of 0.1 l/min.

  The nominal flow can also be raised with the help of the remote control (see Chapter 6.13 "Using the Remote Control (Optional)").

  Factory setting: See Table 9-2

Increasing nominal flow

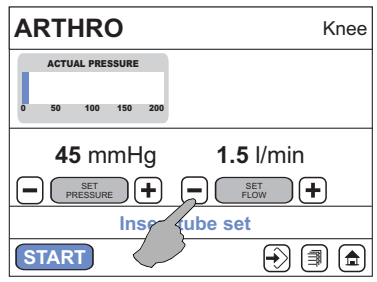


- Press the **[-]** symbol to decrease the nominal flow in increments of 0.1 l/min.

  The nominal flow can also be reduced with the help of the remote control (see Chapter 6.13 "Using the Remote Control (Optional)").

  Factory setting: See Table 9-2

Decreasing nominal flow

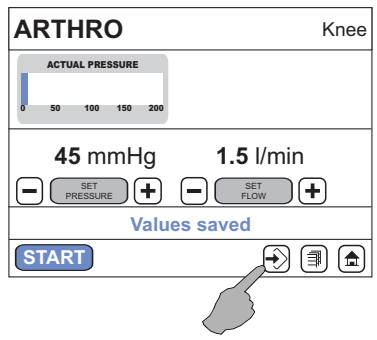


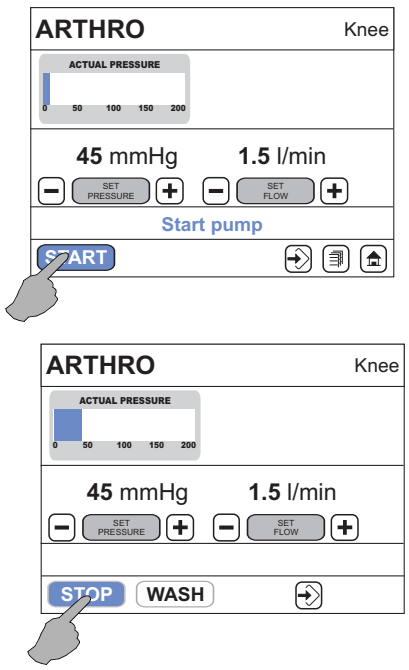
9.5.5 Saving the Nominal Values

The values set for nominal pressure and nominal flow can be saved for the already selected joint. Next time the arthroscopy indication is opened, the last saved values are applied to the selected joint.

- Press **[Save]** to save the entered nominal values. The status line depicts the following: **Values saved**. A short acoustic alarm is emitted (3 beeps).

Save nominal values





Better visibility with the Wash function

9.6 Starting Irrigation

1. Insert the tube set/day set as described in Chapter 9.2 "Inserting a Tube Set".
2. The status line depicts the following: **Start pump** or **Day tube inserted**.
3. Open a tube clamp at irrigation tube.
4. Open inflow valve at instrument completely.
5. If present, completely close the instrument outflow valve.
6. Press the **[START]** function field to start the irrigation process. The actual pressure display shows the current measured value. The roller wheel starts to turn. The device now carries out an **instrument recognition**.

   The **[START]** function field can also be controlled with the help of the remote control (see Chapter 6.13 "Using the Remote Control (Optional)").
7. Wait until the tube set/day set is completely filled with fluid (expels all air in the tubes).

9.7 Stopping Irrigation

1. Press the **[STOP]** function field.

   The **[STOP]** function field can also be controlled with the help of the remote control (see Chapter 6.13 Using the Remote Control (Optional)).
2. The touchscreen then depicts the following values:
   - Actual pressure display: Current measured value
   - Nominal flow display: Last set value
   - Nominal pressure display: Last set value

9.8 Wash Function

The Wash function helps the physician performing the surgery to see better inside of the joint. The WASH function is activated either with the touchscreen, the foot pedal (optional), or the remote control (optional). This activates a **WASH time** of 10, 20, or 30 seconds (see Chapter 8.7.1 "Setting the Flow Level Standard/ Flow Level High"). This also increases the nominal flow rate by 0.5 l/min up to a max. value of 2.5 l/min *(example: previously: 0.7 l/min, Wash: 1.2 l/min)*. The nominal pressure simultaneously increases by 50 % (rounded off in increments of 5) up to a max.value of 200 mmHg *(example: previously: 60 mmHg, Wash: 90 mmHg)*. Starting and stopping the Wash function is only possible while the device is in operation.

The Table 9-3 depicts the parameters of the Wash function:

WASH time	10 s	20 s	30 s **(factory setting)**
Nominal pressure	+50 % (max. 200 mmHg)		
Nominal flow	+0.5 l/min (max. 2.5 l/min)		

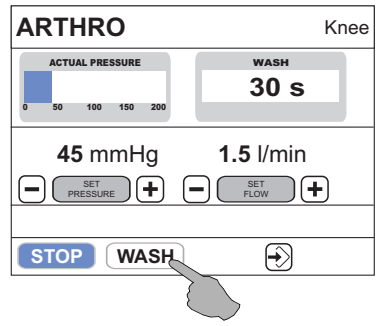
Table 9-3

9.8.1 Using WASH Function via Touchscreen

Follow these steps to activate the WASH function via touchscreen while operating the device:

1. Press the **[WASH]** function field to start the Wash function. Please note that the Wash function stops automatically after 10, 20, or 30 seconds and the device returns to the previously specified nominal values. The remaining time of the WASH function is depicted on the upper right of the screen in the form of a countdown.
2. Press the **[WASH]** function field to stop the WASH function before the 10, 20, or 30 seconds expire. After stopping the WASH function, it can be restarted. The device automatically returns to the previously specified nominal values and the screen display after stopping the Wash function. After stopping the Wash function, it can be restarted again.

Starting and stopping the WASH function via touchscreen



9.8.2 Using WASH Function via Foot Pedal (Optional)

The WASH function can also be activated with a connected foot pedal (see Chapter 20 "Article/Accessory List PG130/PG145").

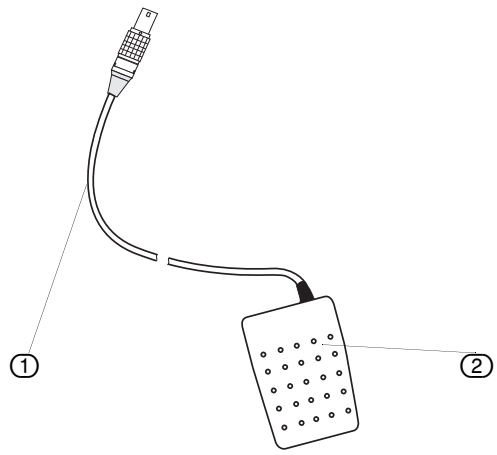


Fig. 9-2 Foot pedal elements

① Connection cable

② Foot pedal

1. The foot pedal must be connected and the device must have recognized the foot pedal after being switched on.
2. Press the foot pedal to start the Wash function. Please note that the Wash function stops automatically after 10, 20 or 30 seconds and the device returns to the previously specified nominal values. The remaining time of the WASH function is depicted on the upper right of the screen in the form of a countdown. After stopping the Wash function, it can be restarted again.
3. Press the foot pedal to stop the WASH function before the 10, 20, or 30 seconds expire. After stopping the Wash function, it can be restarted again.

Starting and stopping the WASH function via foot pedal

9.8.3 Using WASH Function via Remote Control (Optional)

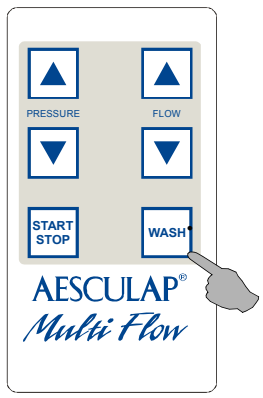
The WASH function can also be activated with the help of the infrared remote control (see Chapter 20 "Article/Accessory List PG130/PG145").

Place remote control into sterile bag before use (see Chapter 20 "Article/Accessory List PG130/PG145").

CAUTION!
The remote control can be disinfected by wiping off (do not immerse in liquid). Do not sterilize the remote control.

WARNING!
Before every surgery, make sure the remote control does not affect other devices within the surgical field.

Starting and stopping the WASH function via infrared remote control

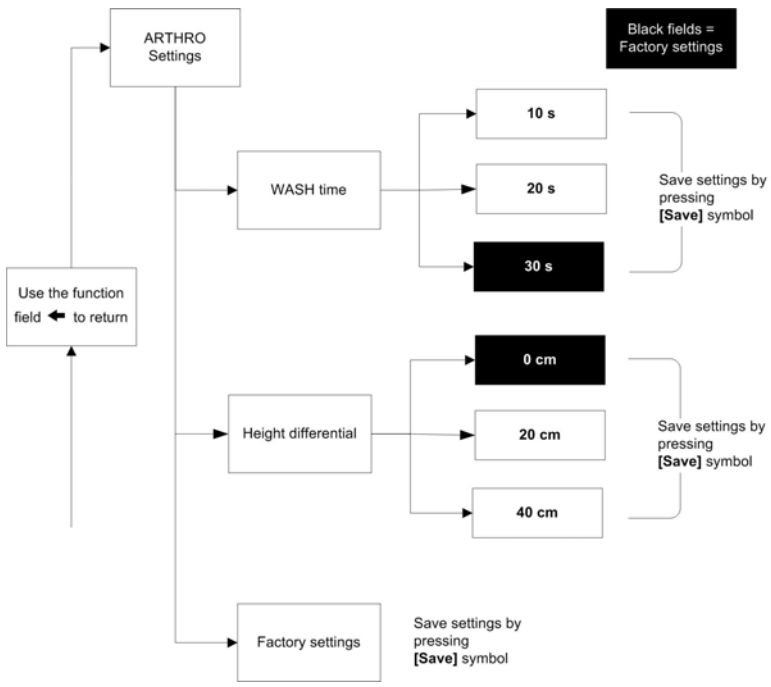


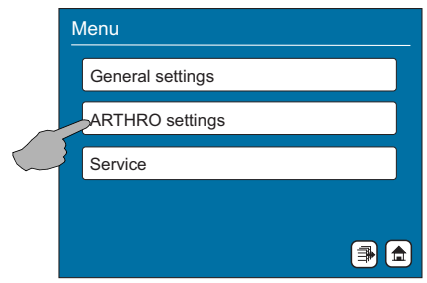
1. The infrared remote control is operational and points towards the front of the device.
2. Press the **[WASH]** function field to start the Wash function. Please note that the Wash function stops automatically after 10, 20, or 30 seconds and the device returns to the previously specified nominal values. The remaining time of the WASH function is depicted on the upper right of the screen in the form of a countdown.
3. Press the **[WASH]** function field to stop the WASH function before the 10, 20, or 30 seconds expire. The device automatically returns to the previously specified nominal values and the screen display after stopping the Wash function. After stopping the Wash function, it can be restarted again.

9.9 Opening and Configuring the User Menu for the Arthroscopy Indication

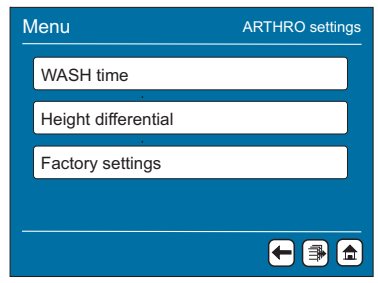
Device parameters are displayed and changed in the **[ARTHRO settings]** menu. The following chart provides an overview over the possible settings.

User menu overview





1. In the user menu, press the **[ARTHRO settings]** function field. This opens the arthroscopy user menu.
2. Press one of the following function fields: **[WASH time]**, **[Height differential],** or **[Factory settings]**.



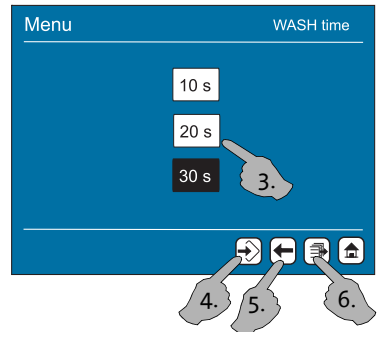
The following is a detailed description of how to change the indication-specific device parameters.

9.9.1 Setting the WASH Time

Set Wash time

1. In the user menu, press the **[ARTHRO settings]** function field. This opens the arthroscopy user menu.
2. Press the **[WASH time]** function field. Select 10, 20, or 30 seconds as the Wash time.
3. Press the **[10]**, **[20]**, or **[30]** symbol to increase or decrease the Wash time.

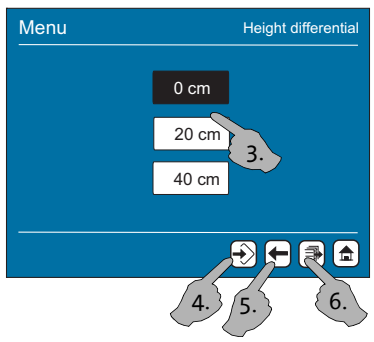
   You can now do the following:
4. Press **[Save]** to save the setting. After saving, the previous menu level is automatically opened.
5. Press **[←]** to return to the previous menu level without saving.
6. Press **[Exit user menu]** to return to the screen display of the laparoscopy indication without saving.



Factory setting: 30 s

9.9.2 Setting the Height Difference

Set the height differential



1. In the user menu, press the **[ARTHRO settings]** function field to open the Arthroscopy user menu.
2. Press the **[Height differential]** function field. Select 0, 20, or 40 cm.
3. Press the **[0 cm]**, **[20 cm]**, or **[40 cm]** symbol to compensate for a pressure loss created by the positioning of the pump in the device tower or rack at a height **below** the body cavity. For example: If the pump is positioned 20 cm below the body cavity, press **[20 cm]** to compensate for the pressure loss.

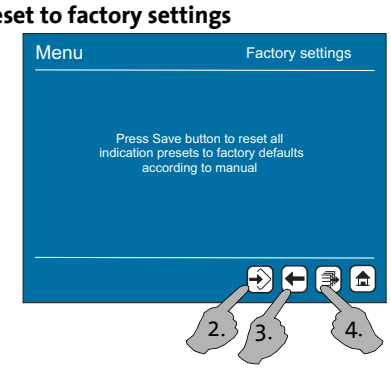
   You can now do the following:
4. Press **[Save]** to save the setting. After saving, the previous menu level is automatically opened.
5. Press **[←]** to return to the previous menu level without saving.
6. Press **[Exit user menu]** to return to the screen display of the Arthroscopy indication without saving.

Factory setting: 0 cm

9.9.3 Resetting to Factory Settings

Use the arthroscopy user menu to reset the arthroscopy device parameters to the factory settings. Please consult Table 9-4 for the device parameters and the corresponding values.

Reset to factory settings



1. Press the [Factory settings] function field to reset the ARTHRO device parameters to the factory settings.

   You can now do the following:
2. Press **[Save]** to save the setting. After saving, the previous menu level is automatically opened.
3. Press **[←]** to return to the previous menu level without saving.
4. Press **[Exit user menu]** to return to the screen display of the laparoscopy indication without saving.

Joint type	Nominal pressure factory setting	Nominal flow factory setting
Small joints	35 mmHg	0.7 l/min
Knee joint	45 mmHg	1.0 l/min
Shoulder joint	50 mmHg	1.5 l/min
Hip joint	60 mmHg	1.0 l/min
User 1	50 mmHg	1.5 l/min
User 2	50 mmHg	1.5 l/min
Wash time	30 s **(Factory setting)**	
Height difference	0 cm **(Factory setting)**	

Table 9-4

9.10 Safety Functions

9.10.1 General Safety Functions

During device operation, the function display depicts safety and warning messages. These messages refer to the handling and safety of the device during use. Please read Chapter 13 Safety Functions for additional information concerning the general safety functions.

9.10.2 Exceeding Nominal Pressures When Using Standard Tube Set

Overpressures may occur during device operation. The device features corresponding safety mechanisms that support the physician performing the surgery in deciding on appropriate responses.

If the actual pressure exceeds the nominal pressure by more than 30 mmHg *(example: nominal pressure = 45 mmHg, actual pressure = 76 mmHg)*, the following safety mechanisms are automatically triggered by the device:

Actual pressure > nominal pressure +30 mmHg

- After a few second: a pressure relief function is activated consisting of turning the roller wheel backwards. A low acoustic alarm (beep) is emitted 4x.
- If the actual pressure falls below the nominal pressure, the roller wheel starts turning forward again and irrigation is continued.

If the actual pressure exceeds a value of 200 mmHg, the following safety mechanisms are automatically triggered by the device:

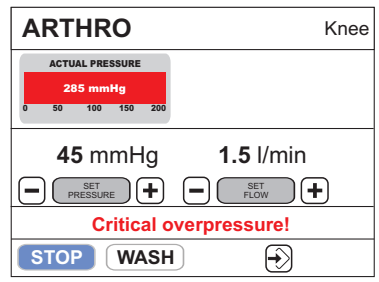
Actual pressure > 200 mmHg

- Immediately: The color of the actual pressure display bar changes from blue to **red**. The center of the bar depicts the actual pressure.
- A loud warning beep is emitted 1 time after a few seconds have passed.

If the actual pressure exceeds a value of 250 mmHg, the following safety mechanisms are automatically triggered by the device:

Actual pressure > 250 mmHg

- After a few seconds: The status line depicts **Critical overpressure!** in red letters.
- A pressure relief function is activated that consist of turning the roller wheel backwards.
- After a few seconds: A continuous acoustic signal (beep) is emitted and the roller wheel stops.
- If the actual pressure falls below the nominal pressure, the roller wheel starts turning forward again and irrigation is continued. The warning message in the status line is no longer displayed.



CAUTION!
The message "Critical Overpressure!" overwrites all other possible messages. Overpressure warnings serve as information for the attending physician to respond appropriately to the existing excess pressure. The intra-articular joint pressure can be reduced by opening the outflow cannula, for example. If possible, the attending physician should perform this task.

9.10.3 Exceeding the Nominal Pressure When Using a Day Patient Tube Set

Overpressures may occur during device operation. The device features corresponding safety mechanisms that support the physician performing the surgery in deciding on appropriate responses.

If the actual pressure exceeds the nominal pressure by more than 30 mmHg *(example: nominal pressure = 45 mmHg, actual pressure = 76 mmHg)*, the following safety mechanisms are automatically triggered by the device:

Actual pressure > nominal pressure +30 mmHg

- The roller wheel stops.
- After a few seconds: A low acoustic alarm (beep) is emitted max. 4x.
- If the actual pressure falls below the nominal pressure, the roller wheel starts turning forward again and irrigation continues.

If the actual pressure exceeds a value of 200 mmHg, the following safety mechanisms are automatically triggered by the device:

Actual pressure > 200 mmHg

- Immediately: The color of the actual pressure display bar changes from blue to **red**. The center of the bar depicts the actual pressure.

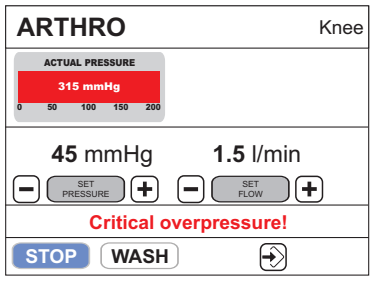
If the actual pressure exceeds a value of 250 mmHg, the following safety mechanisms are automatically triggered by the device:

Actual pressure > 250 mmHg

- Immediately: The roller wheel stops.
  The status line depicts **Critical overpressure!** in red letters if the overpressure actually occurs inside of the joint.
- A continuous acoustic signal is emitted if the overpressure actually occurs in-

side of the joint.

Actual pressure > 300 mmHg



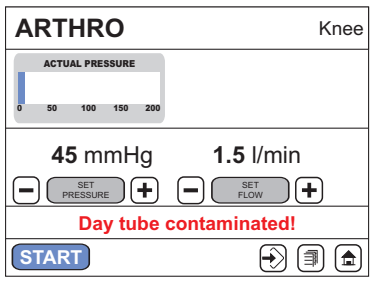
If the actual pressure exceeds a value of 300 mmHg, the following safety mechanisms are automatically triggered by the device:

- Immediately: The roller wheel stops.
- A continuous acoustic signal is emitted. The status line depicts **Critical overpressure!** in red letters.
- If the overpressure actually occurs inside of the joint, the pump triggers a pressure relief function consisting of turning the roller wheel backwards. The day set is identified as being contaminated (see Chapter 9.10.4 "Contamination of the Day Patient Set").
- The roller wheel stops after 5 additional seconds.
- If the actual pressure falls below the nominal pressure, the roller wheel starts turning forward again and irrigation continues. The warning message in the status line is no longer displayed.

CAUTION!
The message "Critical Overpressure!" overwrites all other possible messages. Overpressure warnings serve as information for the attending physician to respond appropriately to the existing excess pressure. The intra-articular joint pressure can be reduced by opening the outflow cannula, for example. If possible, the attending physician should perform this task.

9.10.4 Contamination of the Day Patient Set

If the day patient set is contaminated, the pump reacts with acoustic (beeps) and visual warning signals.



If the day tube has become contaminated during the carried out surgical procedure, the status line depicts in red letters: **Day tube contaminated**. A short acoustic alarm (beep) is emitted 3x. Surgery can still be finished until the **[STOP]** key has been pressed. After the surgical procedure is finished, the pump cannot be started any longer. The status line depicts the following alternating messages: **Day tube contaminated** and **Please replace**.

10 Using the Hysteroscopy Indication

Intended use: Hysteroscopy

The devices PG130/PG145 may be used for intrauterine distension, aspiration of secretory fluids, and monitoring of fluid deficit during endoscopic procedures. It is used to irrigate the cavum uteri with fluid to prepare for diagnostic and surgical hysteroscopies. The devices also offer the option of monitoring the volume difference between the fluid injected into the uterus and the fluid draining from the uterus (balancing).

The devices PG130/PG145 without fluid balancing may only be used for diagnostic purposes.

Contraindications

The devices may not be used to introduce fluids into the cavum uteri when a hysteroscopy is contraindicated.

Relative contraindications to endometrial ablation: Surgical skills ("Acute Technical").

Technical application scope: Hysteroscopy

The following characteristics apply to the hysteroscopy indication:

- The nominal pressure can be preset to a range of 15 to 150 mmHg.
- The nominal flow has 2 settings, LO and HI. The nominal flow levels can be preset to the following ranges in the user menu:
  - LO = 50-200 ml/min
  - HI = 200-500 ml/min
- The pump reacts to pressures greater than the set nominal pressure by emitting warnings. The devices have safety thresholds.
- The pump reacts to reaching and exceeding the deficit threshold by emitting warnings.
- The pump reacts to perforation (exceeding the deficit threshold) by emitting warnings.
- The pump reacts to a scale defect by emitting warnings.

10.1 Device-inherent Dangers: Hysteroscopy Indication

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

WARNING!
The deficit and inflow values are lost in case of a power loss or "brownout".

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

WARNING!
Fluid intake and output surveillance
Strict fluid intake and output surveillance should be maintained. If a low viscosity liquid distention medium is used, intrauterine instillation exceeding 2 liters should be followed with great care due to the possibility of fluid overload. If a high viscosity fluid is used, the use of more than 500 ml should be followed with great care.

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

WARNING!
Pulmonary edema
A surgical procedure has the risk of pulmonary edema, which is formed due a "fluid overload" with isotonic fluids. It is critical to closely monitor the input and outflow of the distending liquid at all times.

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

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

may occur during a surgical procedure if a liquid distention medium is used.

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

WARNING!
Instrument replacement
Stop the device using the START/STOP switch if replacing the instrument during surgery.

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

WARNING!
Fluid volume/sodium concentration
The fluid left in the patient and the concentration of sodium in the blood serum must both be monitored. The deficit amount is the entire amount of fluid lost by or to the system. Take note of the measurement tolerance of the system. Estimating the fluid volume remaining in the patient is the doctor’s responsibility.

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

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

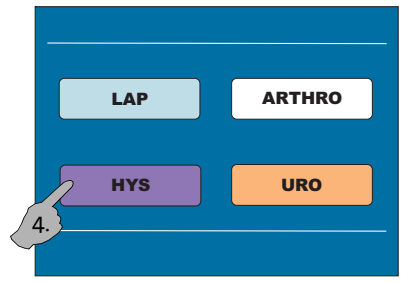
WARNING!
Filling the tubing with irrigation fluid and resetting the deficit display to zero are to be done at the physician's discretion.

WARNING!
The height difference between the device and the patient must be adjusted correctly in order to ensure exact pressure measurement.

10.2 Switching Device On

1. Make sure **no** tube set is inserted into the tube retainer before switching the device on.
2. Press the ON switch. The device turns on. The touchscreen displays the following in succession: **Company logo/Device check** and **Company logo/Device OK.**
3. After the successful device check, the available indications are displayed for selection (see Chapter 6.3 Activating a New Indication). If the device check is unsuccessful, please read Chapter 6.1.1 Device Displays after Unsuccessful Completion of Device Check).
4. Press the **[--]** function field. The indication screen Hysteroscopy is displayed.

Switch device on



10.3 Screen Displays of the Hysteroscopy Indication

The hysteroscopy indication should always be used with a connected scale to measure the differential volume. In case a scale is not connected, the screen display changes as depicted below.

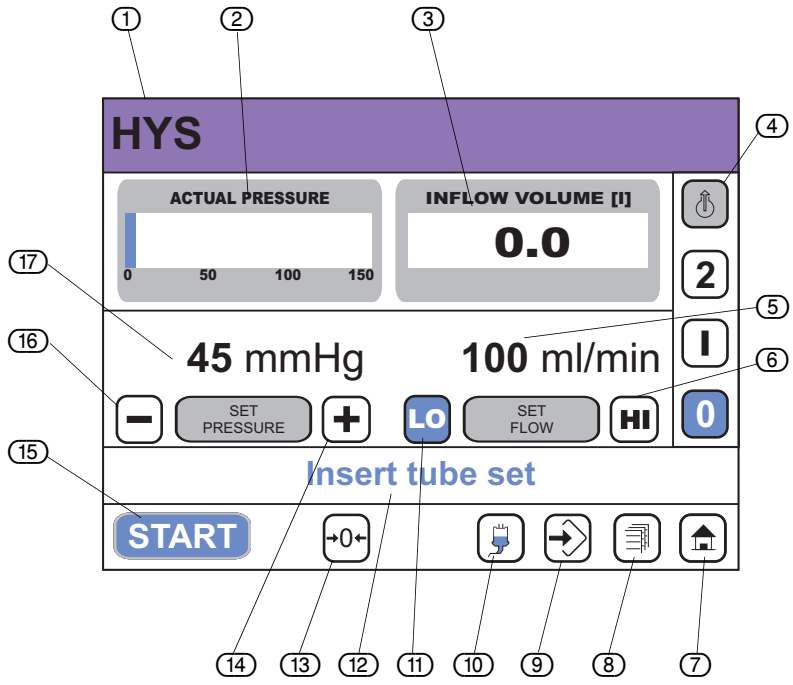


Fig. 10-1 Hysteroscopy indication screen displays without connected scale

(1) Indication
(2) Actual pressure display
(3) Volume display
(4) Suction function display (only PG145)
(5) Nominal flow display
(6) **[HI]** symbol to increase nominal flow
(7) **[Indication selection]** symbol
(8) **[User menu]** symbol
(9) **[Save]** symbol
(10) **[Fluid bag]** symbol
(11) **[LO]** symbol to decrease nominal flow
(12) Status line for messages
(13) **[->0<-]** symbol for deficit reset
(14) **[+]** symbol to increase nominal pressure
(15) **[START]**/**[STOP]** function field
(16) **[-]** symbol to decrease nominal pressure
(17) Nominal pressure display

Once the scale is connected to the device, the differential volume (deficit volume) is displayed by the device instead of the consumed amount of fluid (volume display ③).

The deficit volume is displayed when the scale is connected

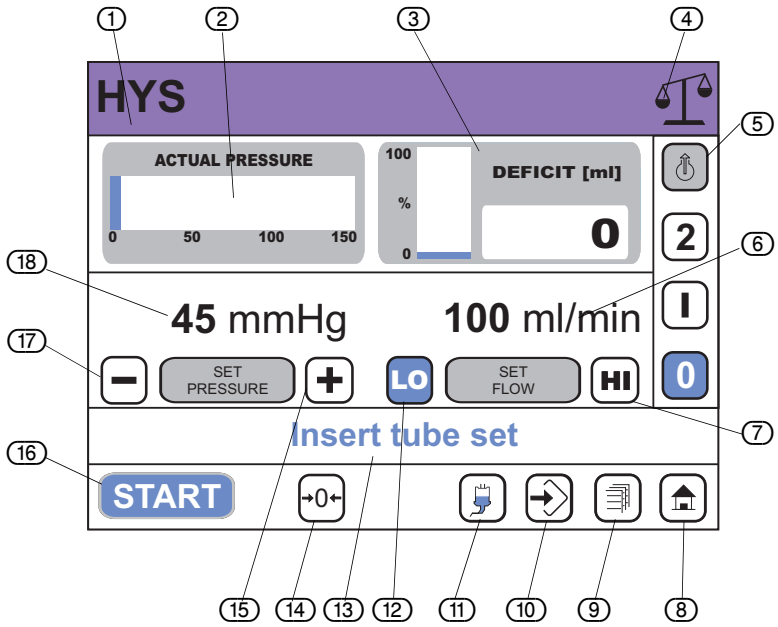


Fig. 10-2 Hysteroscopy indication screen displays with connected scale

① Indication
② Actual pressure display
③ Differential volume display
④ Scale connected
⑤ Suction function display (only PG145)
⑥ Nominal flow display
⑦ **[HI]** symbol to increase nominal flow
⑧ **[Indication selection]** symbol
⑨ **[User menu]** symbol
⑩ **[Save]** symbol
⑪ **[Fluid bag]** symbol
⑫ **[LO]** symbol to decrease nominal flow
⑬ Status line for messages
⑭ **[->0<-]** symbol for deficit reset
⑮ **[+]** symbol to increase nominal pressure
⑯ **[START]/[STOP]** function field
⑰ **[-]** symbol to decrease nominal pressure
⑱ Nominal pressure display

10.4 Inserting a Tube Set

The following tube sets can be used for the indication Hysteroscopy (see also Chapter 20 Article/Accessory List PG130/PG145):

Tube types Hysteroscopy

Tube type	Tube category
Disposable (one-time use)	Disposable tube set, Luer lock connector, and tap spikes
	Disposable tube set, Luer lock connector, and Care lock
Reusable	Reusable tube set, Luer lock connector, and tap spikes

Table 10-1

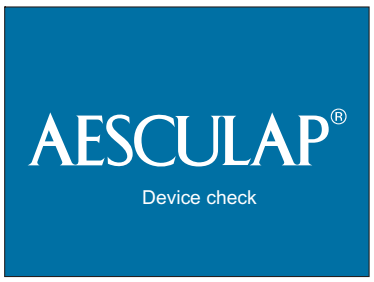
A standard tube set is not inserted into the tube retainer until the device has been switched on and the device check has been completed.

CAUTION!
When inserting a tube set already filled with irrigation fluid into the tube retainer, it is possible to damage the membranes. Only insert unfilled tube sets to avoid such damage.

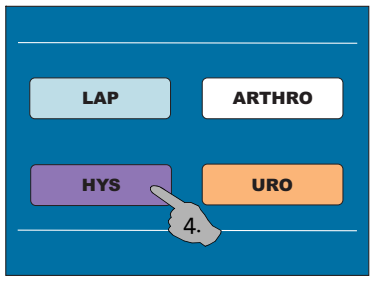
For additional information, see 6.5 "Using the Tube Sets", 6.7 "Inserting a Standard Tube Set" and 6.9 "Removing a Tube Set".

10.5 Switching Device on When Using Standard Tube Set

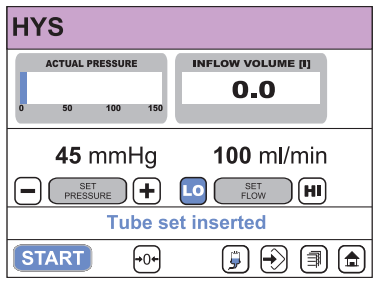
Switching device on without standard tube set



1. Make sure **no** tube set is inserted into the tube retainer before switching the device on.
2. Press the ON switch. The device turns on. The touchscreen displays the following in succession:
   Company logo/Device check/Device OK
3. After the successful device check, the available indications are displayed for selection (see also Chapter 6.3 "Activating a New Indication"). If the device check is unsuccessful, please read Chapter 6.1.1 "Device Displays after Unsuccessful Completion of Device Check").

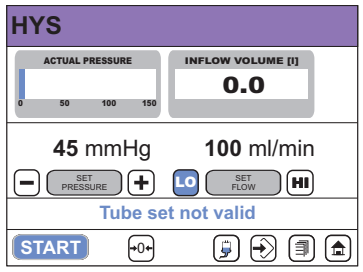


4. Press the **[HYS]** function field.



5. The hysteroscopy indication screen is displayed. The displayed parameters correspond with the factory settings or the last saved nominal values. The status line depicts the following: **Insert tube set.**

Tube set not valid



In case an invalid tube set has been inserted, the status line alternately shows the following: **Tube set not valid** and **Please replace**. A short acoustic alarm is emitted 3x.

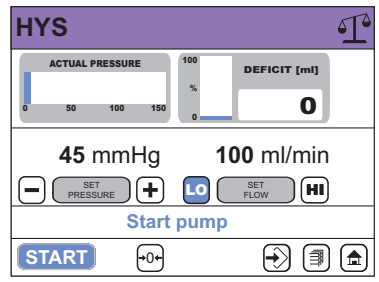
10.6 Using a Scale

WARNING!
In accordance with its design purpose, the pump may be used without balancing system only for diagnostic purposes.

en

When using a scale, the fluid volume remaining in the patient during the procedure and not drained and collected is depicted in the volume display of the device. To determine this value, the fluid irrigation consumption and the volume of the collected irrigation fluid are measured. The difference between both values yield the fluid volume remaining in the patient or lost during surgery. This differential (deficit) volume is depicted on the screen: see Volume display/Differential volume display (3) in Fig. 10-2 "Hysteroscopy indication screen displays with connected scale".

The differential (deficit) volume is displayed if a scale is connected



NOTE!
The differential volume (deficit volume) is not calculated until the end of the tube filling phase (see section 8.5 "Starting Irrigation").

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

WARNING!
Volume overload (hypotonic hyperhydration)
By passing through the uterus, irrigation fluid could reach the blood system or the patient's tissue. This could happen in the cases of overpressure, a lengthy operation, or a perforation of the cavum uteri. The resulting interference with the electrolyte levels of the patient can cause TUR syndrome. Monitoring and estimating these factors is the responsibility of the physician.

10.6.1 Installing and Connecting the Scale

CAUTION!
The scale to be connected must be attached to the device before the device is switched on or the device does not detect the scale.

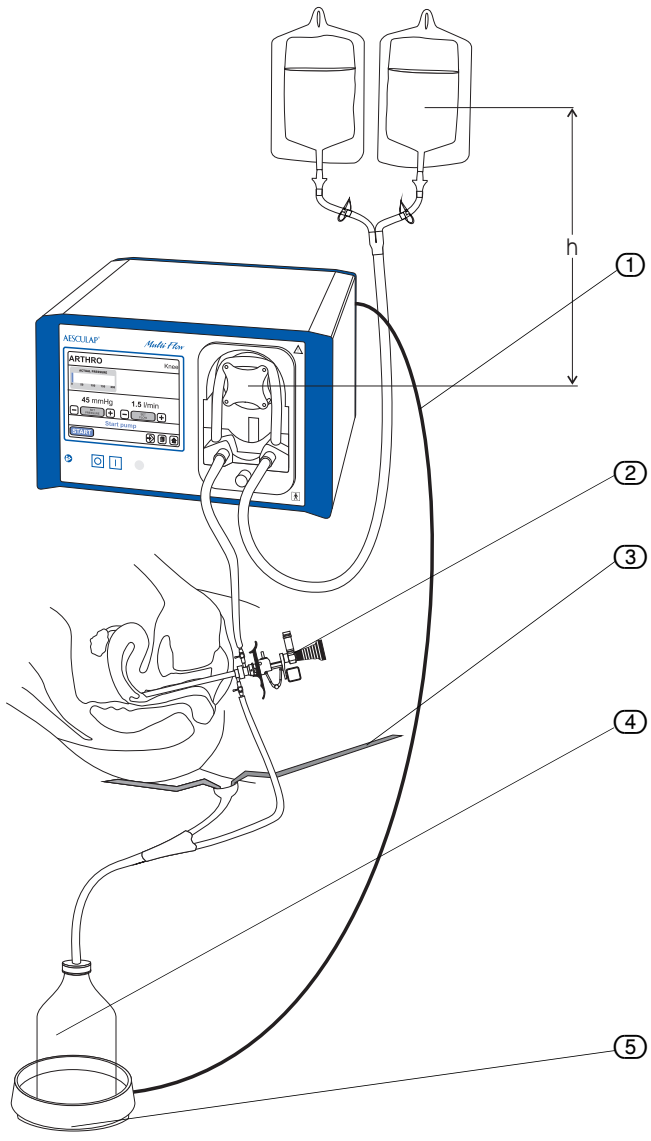


Fig. 10-3 Connecting the scale

① Connection cable
② Instrument
③ Apron
④ Secretion container
⑤ Scale

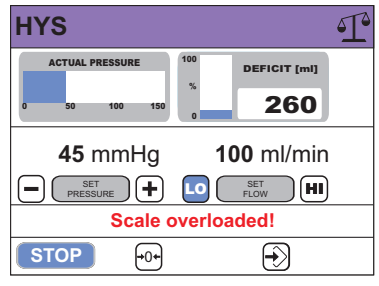
Connect scale

1. Set scale with secretion container ④ in a stable and secure area, on a level surface, below the device.
2. Attach the connection cable ① of the scale to the correspondingly marked connection socket at the rear of the device (see Fig. 5-2 "Rear of the device").
3. Turn the device on and select the **HYS** indication.
4. If the scale was detected, the scale symbol (an icon representing a scale) is depicted on the upper right of the screen.

If the weight of the connected scale exceeds the value of 7 kg, the status line depicts **Scale overloaded!** in red letters and a continuous acoustic signal is emitted.

Stop the pump and remove the weight.

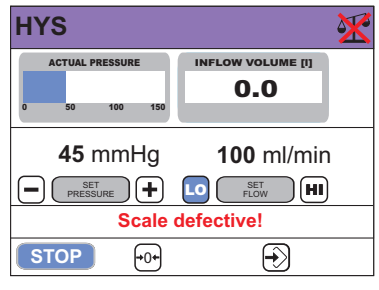
Weight > 7 kg



If the connected scale is detected as being defective during operation of the device, the status line depicts the following error message in red: **Scale defective!** A short warning beep is emitted 3 times and the symbol is depicted. Safeguard the device until checked by an authorized service technician (see Chapter 15.4 "Aesculap Technical Service").

Surgery can be finished but without the scale.

Scales defective!



10.7 Preselecting the Nominal Pressure

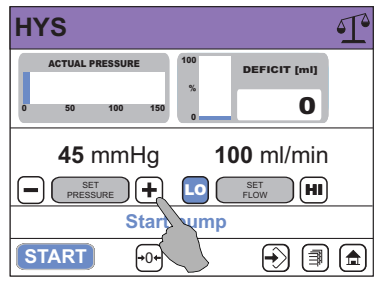
WARNING!
If the current pressure does not react to an increase of the flow value during surgery, a perforation of the cavum uteri might be the cause. This results in an increased risk for bacteria entering the body. Examine the uterus for injuries.

The nominal pressure can be increased or decreased while the device is being used or not used. Values may be in the range of 15 to 150 mmHg.

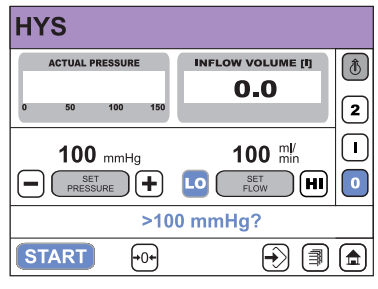
- Briefly press the **[+]** symbol to increase the nominal pressure in increments of 5 mmHg. Pressing the **[+]** symbol longer than 1.5 seconds activates scrolling of the values in increments of 10 mmHg.
  The nominal pressure can also be raised with the help of the remote control (see Chapter 6.13 "Using the Remote Control (Optional)").

  Factory setting: 45 mmHg

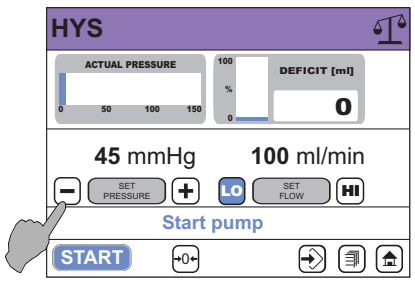
Increasing nominal pressure



When setting a nominal pressure value higher than 100 mmHg, a warning beep is emitted 1 time and the status line depicts. **>100 mmHg?**.



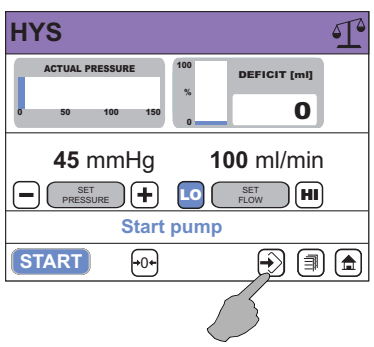
Decreasing nominal pressure



- Briefly press the **[-]** symbol to decrease the nominal pressure in increments of 5 mmHg. Pressing the **[-]** symbol longer than 1.5 seconds activates scrolling of the values in increments of 10 mmHg.

  The nominal pressure can also be reduced with the help of the remote control (see Chapter 6.13 "Using the Remote Control (Optional)").

Save nominal pressure value



The set nominal pressure value can be saved. Next time the hysteroscopy indication is opened, the last saved value for the nominal pressure (for values 15 to 80 mmHg) is used automatically. If the nominal pressure value to be saved exceeds 80 mmHg, the nominal pressure value is reset automatically to 80 mmHg next time the hysteroscopy indication is opened.

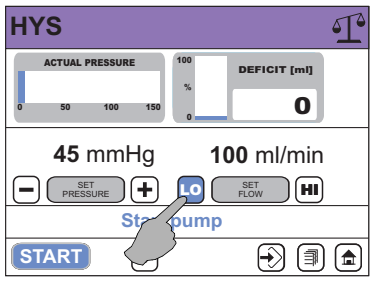
- Press **[Save]** to save the entered nominal pressure value.

10.8 Preselecting the Nominal Flow

CAUTION!
The nominal pressure cannot be reached if the nominal flow is set too low.

The nominal flow can be increased or decreased while the device is being used or not used. The nominal flow has 2 settings, **LO** and **HI**. The hysteroscopy user menu is used to set the values for both nominal flow levels (see Chapter 10.13 "Opening and Configuring the User Menu for the Hysteroscopy Indication").

Setting nominal flow level LO

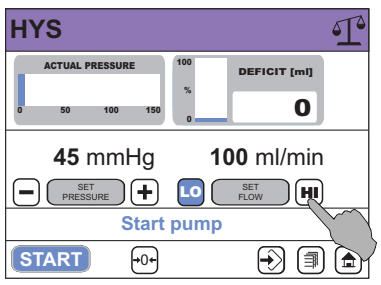


- Press the **[LO]** symbol to enable the nominal flow level **LO**. The active function field is depicted in blue. The set nominal flow level **cannot** be saved.

  The nominal flow level **LO** can also be controlled with the help of the remote control (see Chapter 6.13 "Using the Remote Control (Optional)").

  Factory setting: Nominal flow level **LO**=100 ml/min

Setting nominal flow level HI



- Press the **[HI]** symbol to enable the nominal flow level **HI**. The active function field is depicted in blue. The set nominal flow level **cannot** be saved.

  The nominal flow level **HI** can also be controlled with the help of the remote control (see Chapter 6.13 "Using the Remote Control (Optional)").

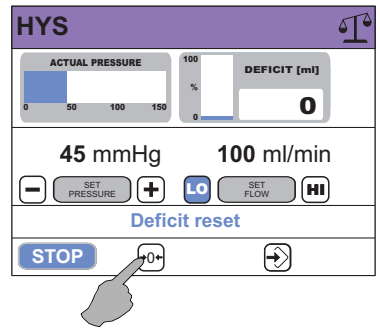
  Factory setting: Nominal flow level **HI**=300 ml/min

10.9 Resetting the Differential Volume

You can reset the differential (deficit) volume to the value **0**.

- Press the **[->0<-]** symbol (reset) to reset the differential (deficit) volume to the value **0**. The status line depicts the following: **Deficit reset**.

Reset differential volume



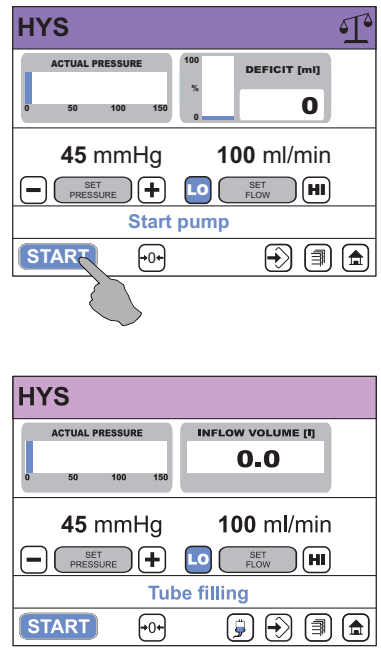
10.10 Starting Irrigation

1. Insert the tube set as described in Chapter 8.4 "Inserting a Tube Set".
2. Open tube clamps at irrigation tube.
3. Open inflow valve at instrument.
4. If present, completely close the instrument outflow valve.
5. Press the **[START]** function field to start the irrigation process. The actual pressure display shows the current measured value. The roller wheel starts to turn.

   The **[START]** function field can also be controlled with the help of the remote control (see Chapter 6.13 "Using the Remote Control (Optional)").
6. The status line depicts **Tube filling.** Wait until the tube set is completely filled with fluid.
7. Once the tube filling phase is finished, the status line depicts **Tube filling completed** and three beeps are emitted.
8. Close the inflow valve of the instrument.
9. You may now start the surgical procedure.

The tube filling phase is restarted and the indicated in the status line after

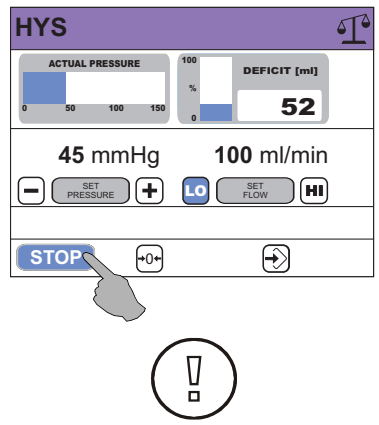
- each ON/Off of the pump
- each removal of the tube during surgical mode
- each tube change
- each indication change



10.11 Stopping Irrigation

1. Press the **[STOP]** function field.

   The **[STOP]** function field can also be controlled with the help of the remote control (see Chapter 6.13 Using the Remote Control (Optional)).
2. The touchscreen then depicts the following values:
   - Actual pressure display: Current measured value
   - Nominal flow display: Last set value
   - Nominal pressure display: Last set value



10.12 Replacing the Secretion Container

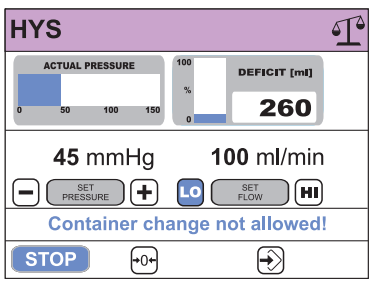
CAUTION!
Full secretion containers must be replaced immediately without stopping surgery. If the overflow protection of the secretion containers is triggered, suction is stopped to prevent the ingress of fluids.

The full secretion collection container can be replaced with an empty one during surgery without losing the current measured value of the deficit volume.

Container change during surgery

1. Press the **[STOP]** function field.
2. Open inflow valve at instrument to vent the system.

Container change not allowed



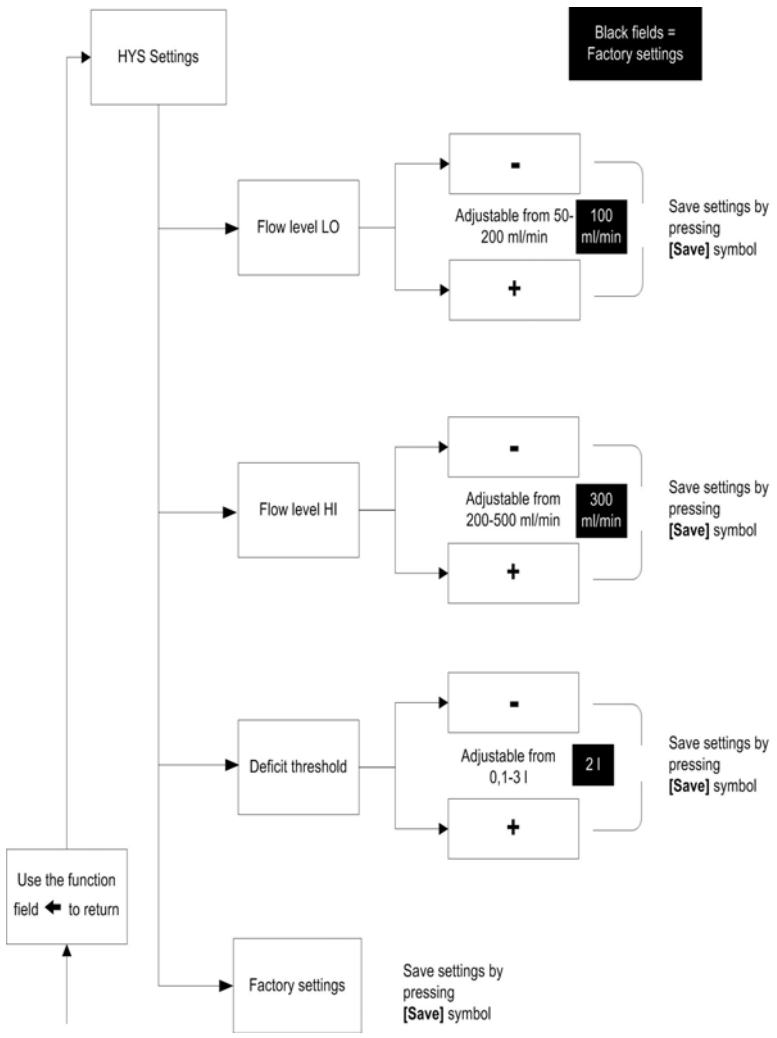
3. Replace the full secretion container with an empty one.
4. Close the inflow valve of the instrument.
5. Press the **[START]** function field.
6. Measurement of the differential (deficit) volume is continued.

If the secretion container on the scale is accidentally replaced during the irrigation cycle, the status line depicts the following error message in blue: **Container change not allowed!** A long warning beep is emitted 3 times. The secretion container must be put back on the scale or the pump must be stopped.

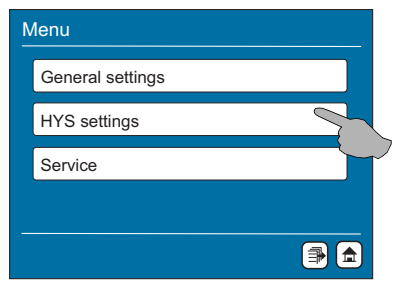
10.13 Opening and Configuring the User Menu for the Hysteroscopy Indication

Device parameters are displayed and changed in the **[HYS settings]** menu. The following chart provides an overview over the possible settings.

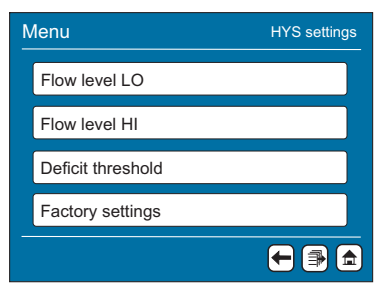
User menu overview



1. Switch device on.
2. Press the **[HYS]** function field. This opens the screen display of the hysteroscopy indication.
3. Press the **[User menu]** (8) symbol (see Fig. 10-1 "Hysteroscopy indication screen displays without connected scale"). The user menu opens.
4. Press the **[HYS settings]** function field.

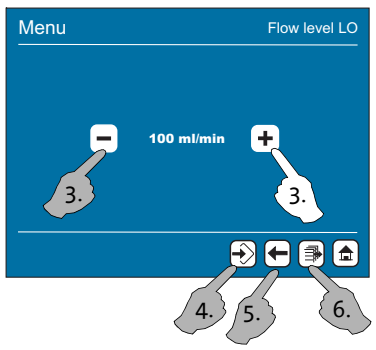


5. Press one of the 4 function fields: **[Flow level LO]**, **[Flow level HI]**, **[Deficit threshold],** or **[Factory settings]**.



The following is a detailed description of how to change the indication-specific device parameters.

Set nominal flow level LO



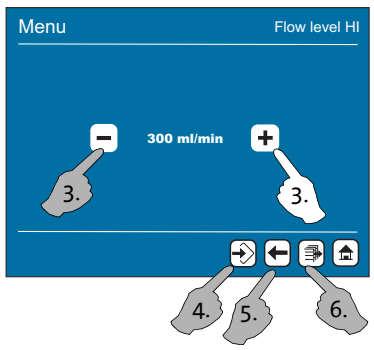
10.13.1 Setting the Nominal Flow Level LO

1. In the user menu, press the **[HYS settings]** function field. This opens the hysteroscopy user menu.
2. Press the **[Flow level LO]** function field. The nominal flow level **LO** can be set in a range of 50-200 ml/min.
3. Press the **[+]** or **[-]** symbol to increase or decrease the nominal flow level **LO**. Pressing this symbol briefly increases or decreases the flow in increments of 5 ml/min, pressing it longer in increments of 20 ml/min.

   You can now do the following:
4. Press [Save] to save the setting. After saving, the previous menu level is automatically opened.
5. Press [←] to return to the previous menu level without saving.
6. Press **[Exit user menu]** to return to the screen display of the hysteroscopy indication without saving.

Factory setting: 100 ml/min

Set nominal flow level HI



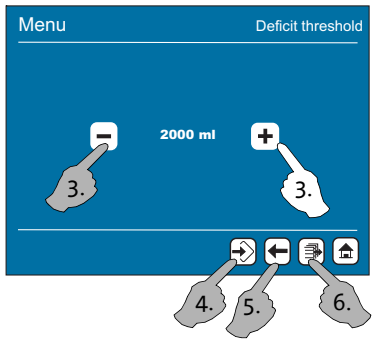
10.13.2 Setting the Nominal Flow Level HI

1. In the user menu, press the **[HYS settings]** function field. This opens the hysteroscopy user menu.
2. Press the **[Flow level HI]** function field. The nominal flow level **HI** can be set in a range of 200-500 ml/min.
3. Press the **[+]** or **[-]** symbol to increase or decrease the nominal flow level **HI**. Pressing this symbol briefly increases or decreases the flow in increments of 10 ml/min, pressing it longer in increments of 20 ml/min.

   You can now do the following:
4. Press **[Save]** to save the setting. After saving, the previous menu level is automatically opened.
5. Press [←] to return to the previous menu level without saving.
6. Press **[Exit user menu]** to return to the screen display of the hysteroscopy indication without saving.

Factory setting: 300 ml/min

Set deficit threshold



10.13.3 Setting the Deficit Threshold

The deficit threshold defines the threshold valve for triggering the warning messages.

1. In the user menu, press the **[HYS settings]** function field. This opens the hysteroscopy user menu.
2. Press the **[Deficit threshold]** function field. The deficit threshold can be set within a range of 100<a>3000 ml/min.
3. Press the **[-]** or **[+]** symbol to increase or decrease the deficit threshold. Pressing this symbol briefly increases or decreases the flow in increments of 10 ml/min, pressing it longer in increments of 100 ml/min.

   You can now do the following:
4. Press **[Save]** to save the setting. After saving, the previous menu level is automatically opened.
5. Press [←] to return to the previous menu level without saving.
6. Press **[Exit user menu]** to return to the screen display of the hysteroscopy indication without saving.

Factory setting: 2000 ml

10.13.4 Resetting to Factory Settings

Use the hysteroscopy user menu to reset the hysteroscopy device parameters to the factory settings. Please consult the following table for the device parameters and the corresponding values:

Hysteroscopy device parameters	Hysteroscopy factory settings
Nominal pressure	45 mmHg
Flow level LO	100 ml/min
Flow level HI	300 ml/min
Deficit threshold	2000 ml

Table 10-2

1. Press the **[Factory settings]** function field to reset the HYS device parameters to the factory settings.

Reset to factory settings

You can now do the following:

2. Press **[Save]** to save the setting. After saving, the previous menu level is automatically opened.
3. Press [←] to return to the previous menu level without resetting to the factory settings.
4. Press **[Exit user menu]** to return to the screen display of the hysteroscopy indication without saving.

10.14 Safety Functions

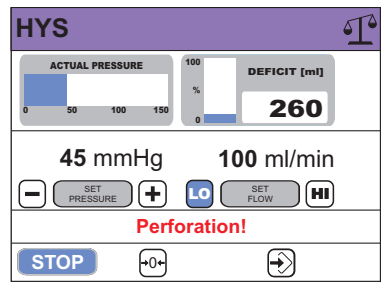
10.14.1 General Safety Functions

During device operation, the function display depicts safety and warning messages. These messages refer to the handling and safety of the device during use. Please read Chapter 13 Safety Functions for additional information concerning the general safety functions.

10.14.2 Exceeding the Deficit Rate

If the deficit rate of 300 ml/min is being exceeded, a continuous warning beep is emitted and the screen displays the following in red letters: **Perforation!**.

Deficit rate exceeded

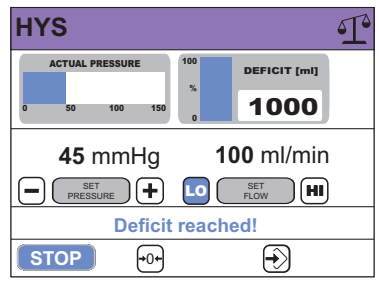


10.14.3 Reaching and Exceeding the Deficit Threshold

The deficit threshold defines the threshold value of the scale for triggering the warning messages (see Chapter 10.13.3 "Setting the Deficit Threshold").

If the differential (deficit) volume reaches the set threshold (100-3000 ml), a long warning beep is emitted 3 times and the screen depicts the following: **Deficit reached!**.

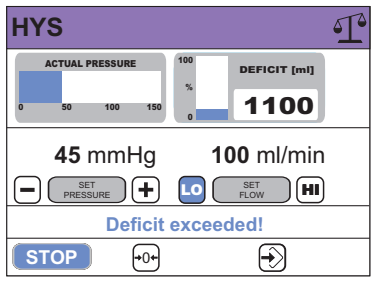
Differential volume = threshold value



Differential volume > threshold value

If the differential (deficit) volume exceeds the set threshold value, a short warning beep is emitted 3 times and the screen depicts the following: **Deficit exceeded!**.

Every additional 100 ml the value exceeds the threshold value is indicated with the same warning signal.



10.14.4 Exceeding Nominal Pressures When Using Standard Tube Set

Overpressures may occur during device operation. The device features corresponding safety mechanisms that support the physician performing the surgery in deciding on appropriate responses.

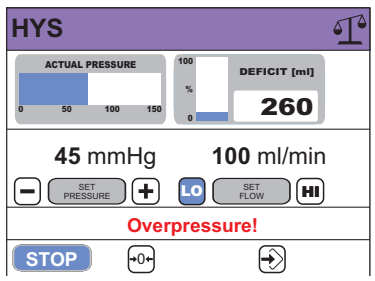
Actual pressure > nominal pressure

If the actual pressure exceeds the nominal pressure,the following safety mechanisms are automatically triggered by the device:

- Immediately: A pressure relief function is activated that consist of turning the roller wheel backwards.
- If the actual pressure falls below the nominal pressure, the roller wheel starts turning forward again and irrigation continues.

Actual pressure > nominal pressure + 10 mmHg

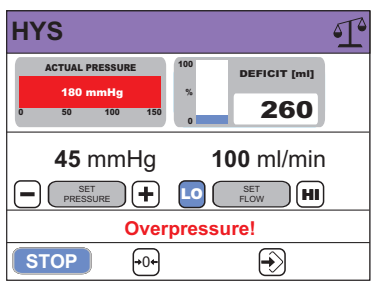
If the actual pressure exceeds the nominal pressure by more than 10 mmHg *(example: nominal pressure = 45 mmHg, actual pressure = 56 mmHg),* the following safety mechanisms are automatically triggered by the device:



- Immediately: A continuous acoustic signal is emitted. The status line depicts **Overpressure!** in red letters.
- A pressure relief function is activated that consist of turning the roller wheel backwards.
- If the actual pressure falls below the nominal pressure, the roller wheel starts turning forward again and irrigation is continued. The warning message in the status line is no longer displayed.

Actual pressure > 150 mmHg

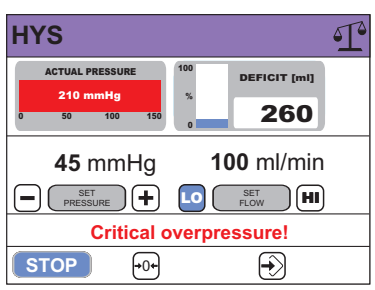
If the actual pressure exceeds a value of 150 mmHg, the following safety mechanisms are automatically triggered by the device:



- Immediately: The color of the actual pressure display bar changes from **blue** to **red**. The center of the bar depicts the actual pressure.
- A pressure relief function is activated that consist of turning the roller wheel backwards.
- If the actual pressure falls below the nominal pressure, the roller wheel starts turning forward again and irrigation is continued.. The warning message in the status line is no longer displayed.

Actual pressure > 200 mmHg

If the actual pressure exceeds a value of 200 mmHg, the following safety mechanisms are automatically triggered by the device:



- Immediately: A continuous acoustic signal is emitted. The status line depicts **Critical overpressure!** in red letters.
- A pressure relief function is activated that consist of turning the roller wheel backwards.
- The roller wheel stops after 5 additional seconds.
- If the actual pressure falls below the nominal pressure, the roller wheel starts turning forward again and irrigation continues. The warning message in the status line is no longer displayed.

CAUTION!
The message "Critical Overpressure!" overwrites all other possible messages. Overpressure warnings serve as information for the attending physician to respond appropriately to the existing excess pressure. The intrauterine pressure can be reduced by opening the outflow cannula, for example. If possible, the attending physician should perform this task.

11 Using the Urology Indication

Intended use: Urology

The devices PG130/PG145 may be used for the distention and/or irrigation of the lower and upper urinary tract, fluid aspiration and monitoring of fluid deficit during diagnostic and surgical procedures. The optional suction function can be used to siphon off secretions. It serves to introduce fluid into the ureter and upper urinary tract during diagnostic and therapeutic urological procedures such as, for example:

- urethroscopy, urethrotomy interna
- Transurethral resections of the prostata
- Dystoscopy, transurethral resection of bladder tumors
- Nephroscopy, nephro litholapaxy
- Intubated antegrade urethrotomies
- Resection of renal cavity system tumors

The devices PG130/PG145 are used for the controlled distention of the urogenital and upper urinary tract by infusing a sterile irrigation fluid using a trocar to improve the visibility of the surgical field during minimally invasive urological procedures. Please comply with the specific indications and instructions provided in the manual of your endoscope.

Contraindications

The devices PG130/PG145 should not be used on patients with traumatic damage to the ureter, bladder, or kidney. The use on patients with narrowing or obstruction of the urethra (e.g. due to large prostata adenoma) is contraindicated as well.

The devices may not be used for delivering fluids into the upper and lower urinary tract if this procedure is contraindicated.

Technical application scope: Urology

The following characteristics apply to the urology indication (only PG130/PG145):

- The nominal pressure can be preset to a range of 15 to 90 mmHg.
- The nominal flow can be preset to a range of 0.025 to 0.5 l/min.
- The devices feature an instrument recognition function.
- The pump reacts to pressures greater than the set nominal pressure by emitting warnings. The devices have safety thresholds.

Recommended pressure and flow settings

The manufacturer recommends the following pressure and flow settings for the following application areas:

Urethroscopy, cystoscopy	25 mmHg	250 ml/min
TURP, TURB	25 mmHg	500 ml/min
URS	25 mmHg	25 ml/min
PCNL	25 mmHg	500 ml/min

Each surgery and each patient requires different parameters. The values indicated by the manufacturer are therefore only recommendations and are not intended to substitute or replace the expertise of the surgeon.

Clinical use

When performing monopolar electrosurgery, only non-conductive irrigation fluids may be used. Examples include glycine, sorbitol, mannitol, sorbitol plus mannitol, and dextran.

11.1 Device-inherent Dangers: Urology Indication

WARNING!
Instrument replacement
Stop the device using the START/STOP switch if replacing the instrument during surgery.

WARNING!
Fluid volume/sodium concentration
The fluid left in the patient and the concentration of sodium in the blood serum must both be monitored. The deficit amount is the entire amount of fluid lost by or to the system. Take note of the measurement tolerance of the system. Estimating the fluid volume remaining in the patient is the physician's responsibility.

WARNING!
If a stone is in the surgical field, it can be moved by the flow of irrigation fluid settable via the pressure and flow rate values and possibly flushed into the kidneys.

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

may occur during a surgical procedure if a liquid distention medium is used.

WARNING!
Pulmonary edema
A surgical procedure has the risk of pulmonary edema, which is formed due a "fluid overload" with isotonic fluids. It is critical to closely monitor the input and outflow of the distending liquid at all times.

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

WARNING!
Fluid intake and output surveillance
Strict fluid intake and output surveillance should be maintained. If a low viscosity liquid is used, a transurethral instillation exceeding 2 liters must be monitored with great care due to the possibility of fluid overload.

WARNING!
Hyponatremia
Some distension fluids may lead to fluid overload and, consequently, hyponatremia with its attending sequelae. This can be affected by the distending pressure, flow rate, and duration of hysteroscopic procedure. It is critical to closely moni-

tor the input and outflow of the distending liquid at all times.

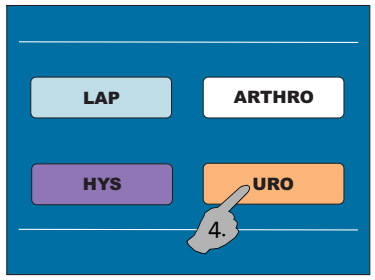
WARNING!
Fluid Overload
There is a risk of irrigation fluid reaching the circulatory system of the patient's soft tissue. This can be affected by distention pressure, flow rate, perforation of the distended body cavity and duration of the endoscopic surgery. It is critical to closely monitor the input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

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

WARNING!
The height difference between the device and the patient must be adjusted correctly in order to ensure exact pressure measurement.

11.2 Switching Device On

Switch device on



1. Make sure **no** tube set is inserted into the tube retainer before switching the device on.
2. Press the ON switch. The device turns on. The touchscreen displays the following in succession: **Company logo/Device check** and **Company logo/Device OK.**
3. After the successful device check, the available indications are displayed for selection (see Chapter 6.3 Activating a New Indication). If the device check is unsuccessful, please read Chapter 6.1.1 Device Displays after Unsuccessful Completion of Device Check).
4. Press the **[--]** function field. The indication screen Urology is displayed.

11.3 Screen Displays of the Urology Indication

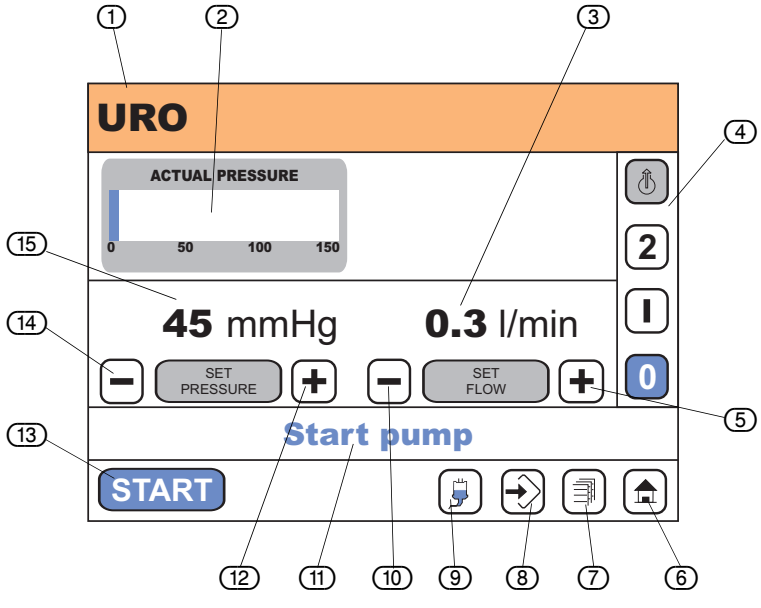


Fig. 11-1 Screen displays of the urology indication

① Indication
② Actual pressure display
③ Nominal flow display
④ Suction function display (only PG145)
⑤ **[+]** symbol to increase nominal flow
⑥ **[Indication selection]** symbol
⑦ **[User menu]** symbol
⑧ **[Save]** symbol
⑨ **[Fluid bag]** symbol
⑩ **[-]** symbol to decrease nominal flow
⑪ Status line for messages
⑫ **[+]** symbol to increase nominal pressure
⑬ **[START]/[STOP]** function field
⑭ **[-]** symbol to decrease nominal pressure
⑮ Nominal pressure display

11.4 Inserting a Tube Set

The following tube sets can be used for the indication Urology (see also Chapter 20 Article/Accessory List PG130/PG145):

Tube types Urology

Tube type	Tube category
Disposable (one-time use)	Disposable tube set, Luer lock connector, and tap spikes
	Disposable tube set, Luer lock connector, and Care lock
Reusable	Reusable tube set, Luer lock connector, and tap spikes

Table 11-1

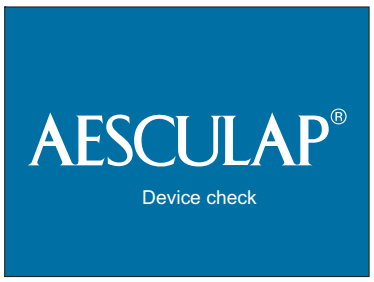
A standard tube set is not inserted into the tube retainer until the device has been switched on and the device check has been completed.

CAUTION!
When inserting a tube set already filled with irrigation fluid into the tube retainer, it is possible to damage the membranes. Only insert unfilled tube sets to avoid such damage.

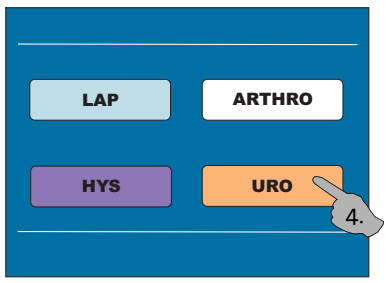
For additional information, see 6.5 "Using the Tube Sets", 6.7 "Inserting a Standard Tube Set" and 6.9 "Removing a Tube Set".

11.5 Switching Device on When Using Standard Tube Set

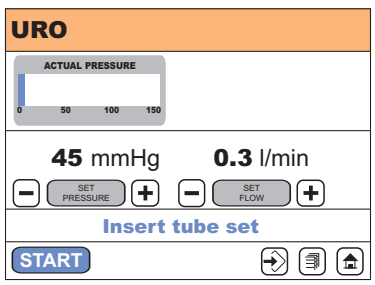
Switching device on without standard tube set



1. Make sure **no** tube set is inserted into the tube retainer before switching the device on.
2. Press the ON switch. The device turns on. The touchscreen displays the following in succession:
   Company logo/Device check/Device OK
3. After the successful device check, the available indications are displayed for selection (see also Chapter 6.3 "Activating a New Indication"). If the device check is unsuccessful, please read Chapter 6.1.1 "Device Displays after Unsuccessful Completion of Device Check").

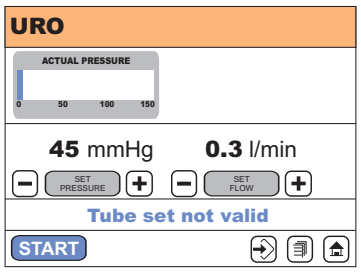


4. Press the **[URO]** function field.



5. The Urology indication screen is displayed. The displayed parameters correspond with the factory settings or the last saved nominal values. The status line depicts the following: **Insert tube set.**

Tube set not valid

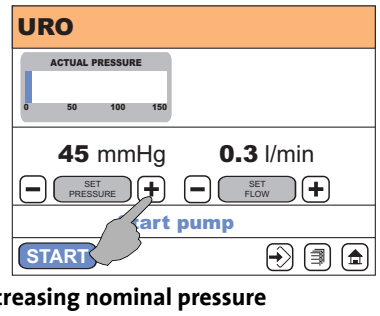


In case an invalid tube set has been inserted, the status line alternately shows the following: **Tube set not valid** and **Please replace**. A short acoustic alarm is emitted 3x.

11.6 Preselecting the Nominal Pressure

The nominal pressure can be increased or decreased while the device is being used or not used. Values may be in the range of 15 to 90 mmHg.

Increasing nominal pressure



- Briefly press the **[+]** symbol to increase the nominal pressure in increments of 5 mmHg. Pressing the **[+]** symbol longer than 1.5 seconds activates scrolling of the values in increments of 10 mmHg.

  The nominal pressure can also be raised with the help of the remote control (see Chapter 6.13 "Using the Remote Control (Optional)").

  Factory setting: 30 mmHg

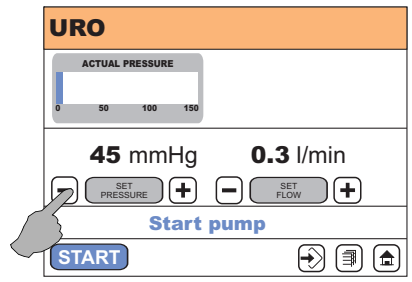
  When setting a nominal pressure value higher than 45 mmHg, a warning beep is emitted 1 time and the status line depicts. **>45 mmHg?**.

Decreasing nominal pressure

- Briefly press the **[-]** symbol to decrease the nominal pressure in increments of 5 mmHg. Pressing the **[-]** symbol longer than 1.5 seconds activates scrolling of

the values in increments of 10 mmHg.

The nominal pressure can also be reduced with the help of the remote control (see Chapter 6.13 "Using the Remote Control (Optional)").



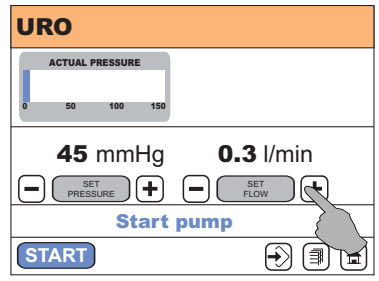
11.7 Preselecting the Nominal Flow

CAUTION!
The nominal pressure cannot be reached if the nominal flow is set too low.

The nominal flow can be increased or decreased while the device is being used or not used. Values may be in the range of 0.025 to 0.5 l/min.

- Press the **[+]** symbol briefly to increase the nominal flow in increments of 0.025 l/min. Pressing the **[+]** symbol longer than 1.5 seconds activates scrolling of the values in increments of 0.050 l/min.

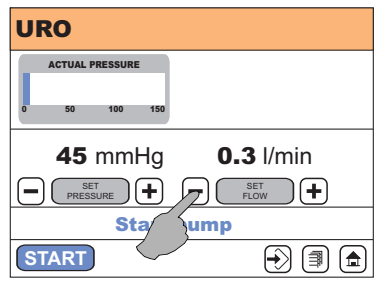
The nominal flow can also be raised with the help of the remote control (see Chapter 6.13 "Using the Remote Control (Optional)").



Factory setting: 0.25 l/min

- Briefly press the **[-]** symbol to decrease the nominal pressure in increments of 0.025 l/min. Pressing the **[-]** symbol longer than 1.5 seconds activates scrolling of the values in increments of 0.050 l/min.

The nominal flow can also be reduced with the help of the remote control (see Chapter 6.13 "Using the Remote Control (Optional)").

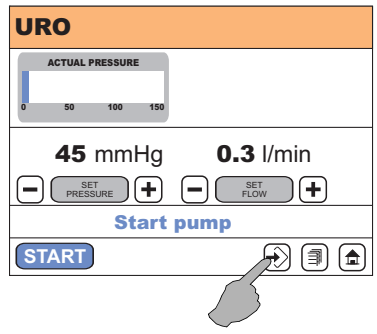


11.8 Saving Nominal Values

The two set nominal values can now be saved. Next time the urethroscopy indication is opened, the last saved values for the nominal pressure and the nominal flow are used automatically. If the nominal pressure value to be saved exceeds 45 mmHg, the nominal pressure value is reset automatically to 45 mmHg next time the URO indication is opened.

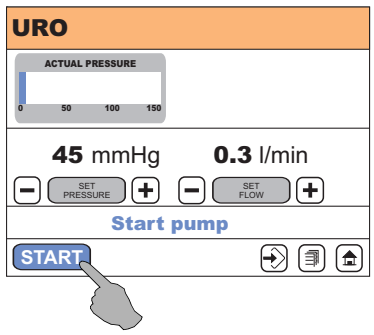
- Press **[Save]** to save the entered nominal values.

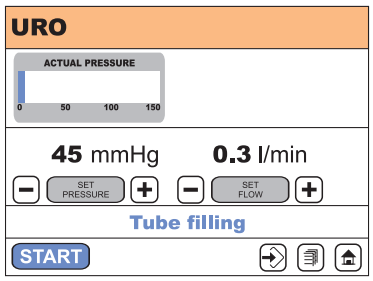
Save nominal values

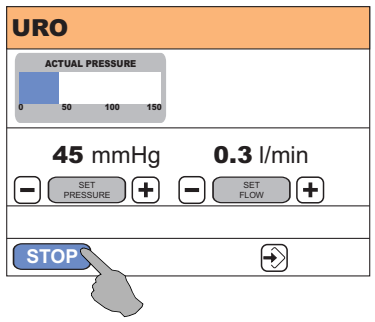


11.9 Starting Irrigation

1. Insert the tube set as described in Chapter 8.4 "Inserting a Tube Set".
2. Open tube clamps at irrigation tube.
3. Open inflow valve at instrument completely.
4. If present, completely close the instrument outflow valve.
5. Press the **[START]** function field to start the irrigation process. The actual







pressure display shows the current measured value. The roller wheel starts to turn and the device begins to run the instrument detection function.

The **[START]** function field can also be controlled with the help of the remote control (see Chapter 6.13 "Using the Remote Control (Optional)").

6. The status line depicts **Tube filling.** Wait until the tube set is completely filled with fluid.
7. Once the tube filling phase is finished, the status line depicts **Tube filling completed** and three beeps are emitted.
8. Close the inflow valve of the instrument.
9. You may now start the surgical procedure.

The tube filling phase is restarted and the indicated in the status line after

- each pump start

11.10 Stopping Irrigation

1. Press the **[STOP]** function field.

   The **[STOP]** function field can also be controlled with the help of the remote control (see Chapter 6.13 Using the Remote Control (Optional)).
2. The touchscreen then depicts the following values:
   - Actual pressure display: Current measured value
   - Nominal flow display: Last set value
   - Nominal pressure display: Last set value

11.11 Automatic Instrument Recognition

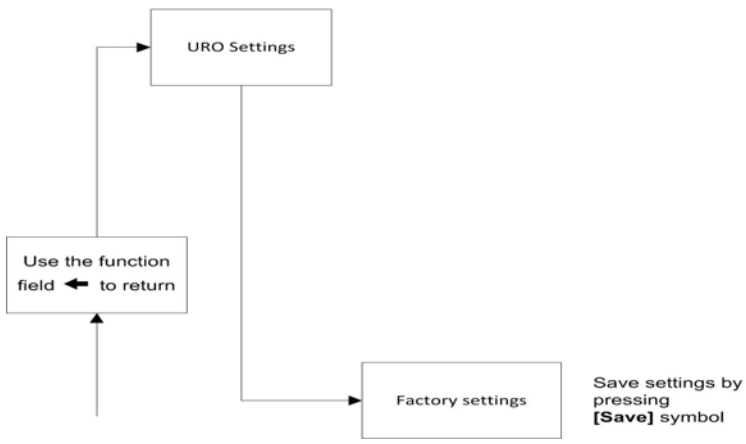
Improved pressure measuring due to the instrument detection function

The device features the automatic instrument detection function when using the Urology. The automatic instrument detection function runs in the back after each start of the irrigation process and serves to compensate pressure losses due to the flow through the narrow working channel. The pressure drop at the instrument is here included in the measured value of the actual pressure.

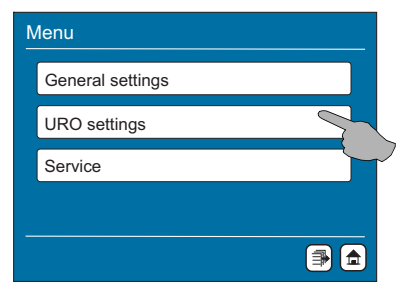
11.12 Opening and Configuring the User Menu for the Urology Indication

Device parameters are displayed and changed in the **[URO settings]** menu. The following chart provides an overview over the possible settings.

User menu overview



1. Switch device on.
2. Press the **[URO]** function field. This opens the screen display of the urology indication.
3. Press the **[User menu]** symbol (see Fig. 10-1 "Hysteroscopy indication screen displays without connected scale"). The user menu opens.
4. Press the **[URO settings]** function field.



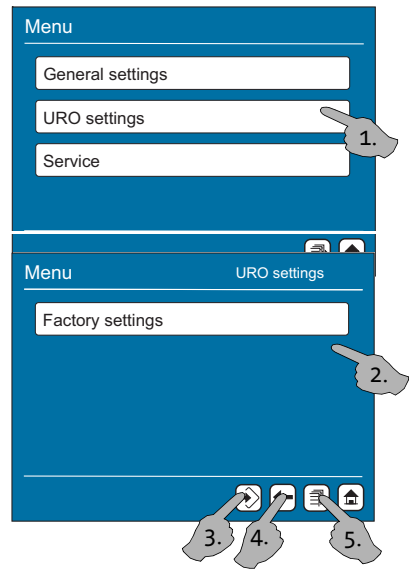
5. Press the **[Factory settings]** function field.

11.12.1 Resetting to Factory Settings

Use the **[URO settings]** menu to reset the nominal pressure and the nominal flow to factory settings.

Urology device parameters	Urology factory settings
Nominal pressure	30 mmHg
Nominal flow	0.25 l/min

Table 11-2



1. In the user menu, press the **[URO settings]** function field. This opens the Urology user menu.
2. Press the **[Factory settings]** function field. The device resets the urology device parameters to the factory settings (see Table 11-2).

   You can now do the following:
3. Press **[Save]** to save the setting. After saving, the previous menu level is automatically opened.
4. Press [←] to return to the previous menu level without saving.
5. Press **[Exit user menu]** to return to the screen display of the urology indication without saving.

11.13 Safety Functions

11.13.1 General Safety Functions

During device operation, the function display depicts safety and warning messages. These messages refer to the handling and safety of the device during use. Please read Chapter 13 Safety Functions for additional information concerning the general safety functions.

11.13.2 Exceeding Nominal Pressures When Using Standard Tube Set

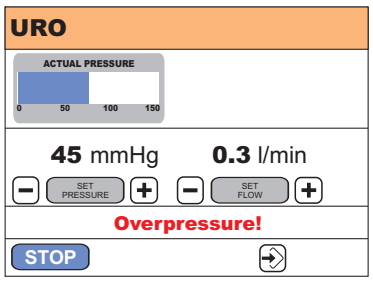
Overpressures may occur during device operation. The device features corresponding safety mechanisms that support the physician performing the surgery in deciding on appropriate responses.

Actual pressure > nominal pressure

If the actual pressure exceeds the nominal pressure, the following safety mechanisms are automatically triggered by the device:

- Immediately: A pressure relief function is activated that consist of turning the roller wheel backwards.
- If the actual pressure falls below the nominal pressure, the roller wheel starts turning forward again and irrigation continues.

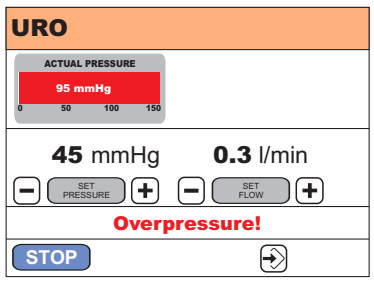
Actual pressure > nominal pressure +10mmHg



If the actual pressure exceeds the nominal pressure by more than 10 mmHg *(example: nominal pressure = 45 mmHg, actual pressure = 56 mmHg)*, the following safety mechanisms are automatically triggered by the device:

- Immediately: A continuous acoustic signal is emitted. The status line depicts **Overpressure!** in red letters.
- A pressure relief function is activated that consist of turning the roller wheel backwards.
- If the actual pressure falls below the nominal pressure, the roller wheel starts turning forward again and irrigation is continued. The warning message in the status line is no longer displayed.

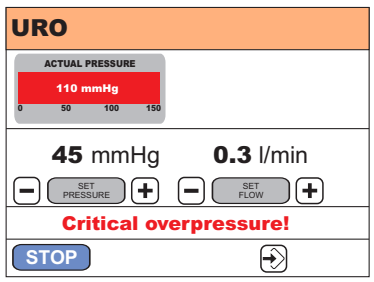
Actual pressure > 90 mmHg



If the actual pressure exceeds a value of 90 mmHg, the following safety mechanisms are automatically triggered by the device:

- Immediately: The color of the actual pressure display bar changes from blue to **red**. The center of the bar depicts the actual pressure.
- A pressure relief function is activated that consist of turning the roller wheel backwards.
- If the actual pressure falls below the nominal pressure, the roller wheel starts turning forward again and irrigation is continued. The warning message in the status line is no longer displayed.

Actual pressure > 100 mmHg



If the actual pressure exceeds a value of 100 mmHg, the following safety mechanisms are automatically triggered by the device:

- Immediately: A continuous acoustic signal is emitted. The status line depicts **Critical overpressure!** in red letters.
- A pressure relief function is activated that consist of turning the roller wheel backwards.
- After 5 additional seconds: The roller wheel stops.
- If the actual pressure falls below the nominal pressure, the roller wheel starts turning forward again and irrigation continues. The warning message in the status line is no longer displayed.

CAUTION!

The message "Critical Overpressure!" overwrites all other possible messages. Overpressure warnings serve as information for the attending physician to respond appropriately to the existing excess pressure. The intravesical and intraureteral joint pressure can be reduced by opening the outflow cannula, for example. If possible, the attending physician should perform this task.

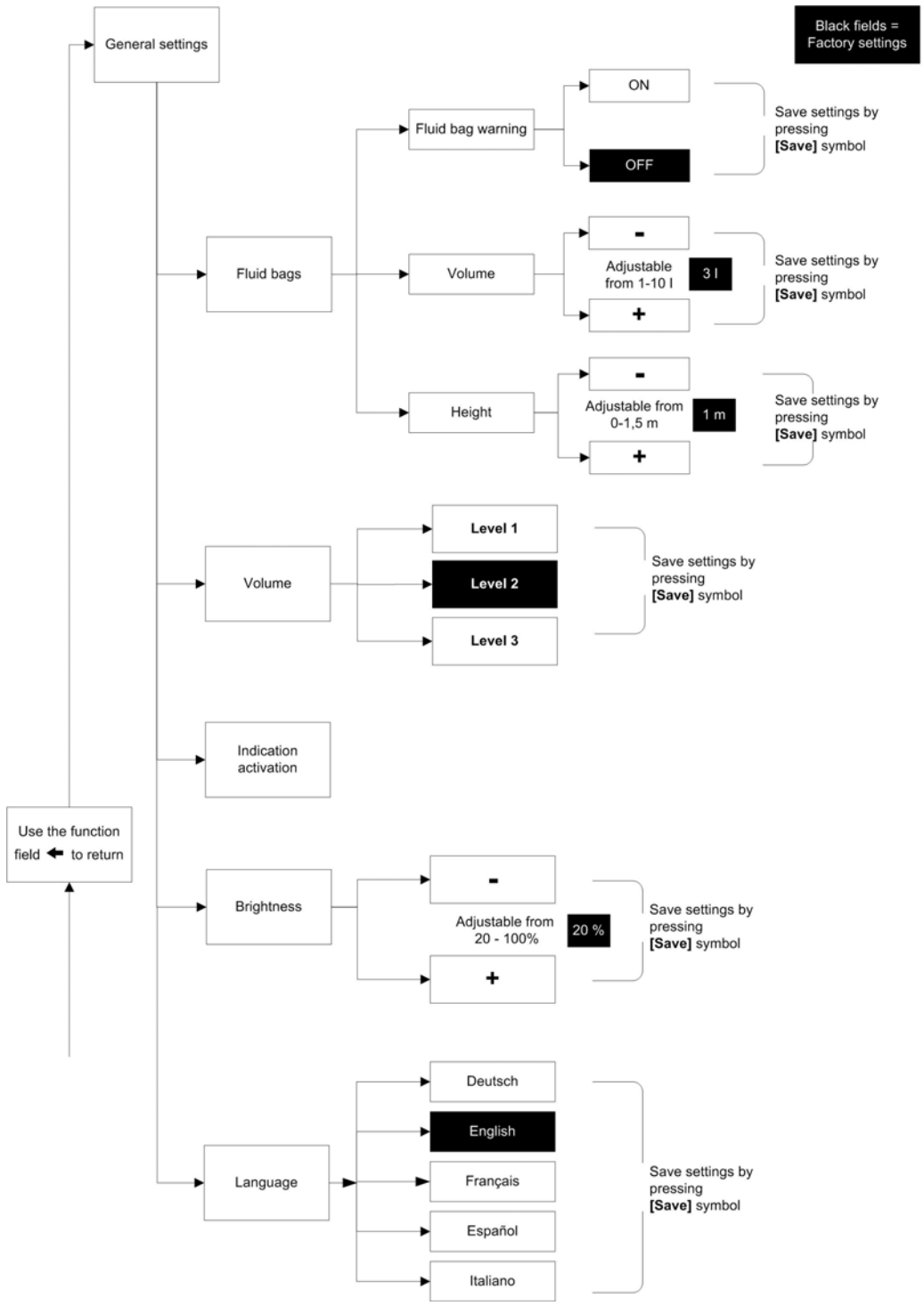
12 User Menu

The following is possible in the user menu:

- Change the general device parameters
- Change the indication-specific parameters
- Activate new indicators
- Call the service menu (only for authorized service personnel!)

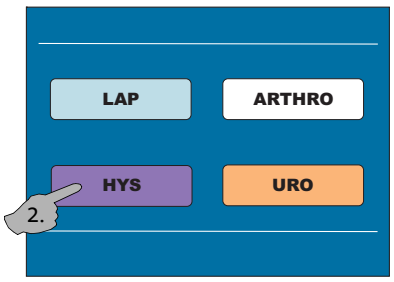
The following chart provides an overview over the possible settings.

12.1 Overview: User menu - General settings

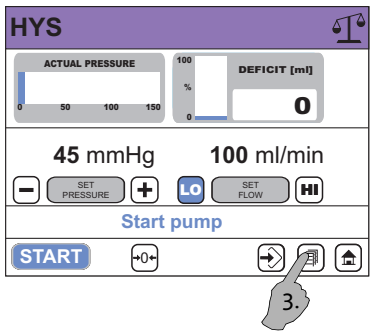


12.2 General Settings

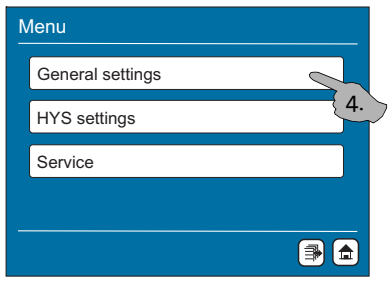
Open General settings menu



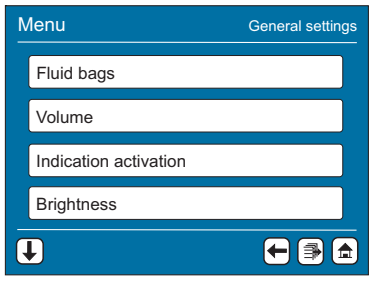
1. Switch device on.
2. Press the function field of an indication (e.g., **[HYS]**). This opens the screen display of the indication. If you have selected the indication ARTHRO, then press one of the displayed function fields (e.g., **[Knee]**) to then access the arthroscopy screen display.



3. Press the **[User menu]** symbol. The user menu opens.



4. Press the **[General settings]** function field.



5. Press one of the 5 function fields: **[Fluid bags]**, **[Volume]**, **[Indication activation]**, **[Brightness],** or **[Language]**.

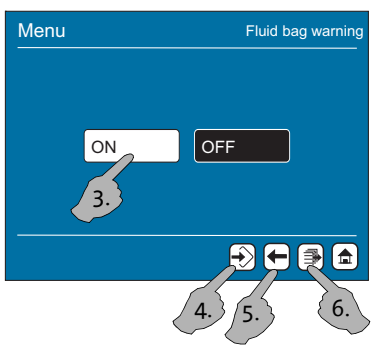
   To access the **[Language]** function field, press the [**Down Arrow]** symbol in the user menu.

The following is a detailed description of the general device parameters.

12.2.1 Fluid Bag Settings

Setting the Fluid Bag Warning

Setting the fluid bag warning



1. In the user menu, press the **[Fluid bags]** function field.
2. In the user menu, press the **[Fluid bag warning]** function field.
3. Press the **[ON]** function field to enable or the **[OFF]** function field to disable the fluid bag warning function. The enabled function field is depicted in black.

   You can now do the following:
4. Press **[Save]** to save the setting. After saving, the previous menu level is automatically opened.
5. Press [←] to return to the previous menu level without saving.
6. Press **[Exit]** to return to the screen display of the selected indication without saving.

   Factory setting: Off

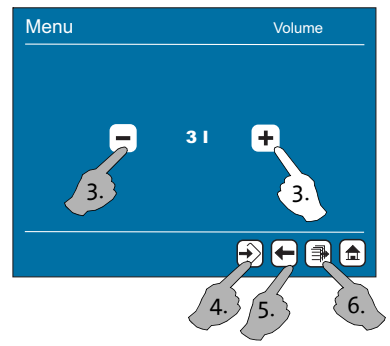
Setting the Bag Volume

1. In the user menu, press the **[Fluid bags]** function field.
2. In the user menu, press the **[Volume]** function field.
3. Press the **[+]** or **[-]** symbol to set the volume of the irrigation fluid bags to a value between 1 and 10 l.

   You can now do the following:
4. Press **[Save]** to save the setting. After saving, the previous menu level is automatically opened.
5. Press [←] to return to the previous menu level without saving.
6. Press **[Exit]** to return to the screen display of the selected indication without saving.

   Factory setting: 3 l

Set volume



Set the Height

(see Fig. 6-7 "Hanging the irrigation fluid bags")

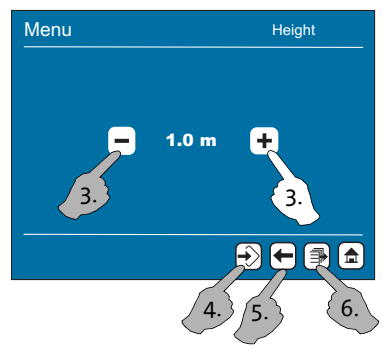
1. In the user menu, press the **[Fluid bags]** function field.
2. In the user menu, press the **[Height]** function field.
3. Press the **[+]** or **[-]** symbol to set the height of the irrigation fluid bags to a value between 0 and 1.5 m.

   Pressing the **[+]** or **[-]** symbol longer than 1.5 seconds activates scrolling of the values in increments of 0.5 m.

   You can now do the following:
4. Press **[Save]** to save the setting. After saving, the previous menu level is automatically opened.
5. Press [←] to return to the previous menu level without saving.
6. Press **[Exit]** to return to the screen display of the selected indication without saving.

   Factory setting: 1.00 m

Set height



12.2.2 Activating an Indication

Chapter 6.3 "Activating a New Indication" describes how to activate additional indications.

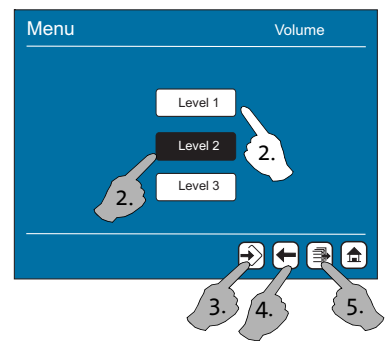
12.2.3 Setting the Volume of the Acoustic Signals and Audio Warnings

1. In the user menu, press the **[Volume]** function field.
2. Press the **[Level 1]**, **[Level 2]**, or **[Level 3]** to set the desired volume level 1, 2, or 3.

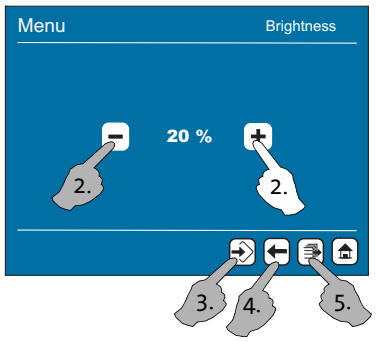
   You can now do the following:
3. Press **[Save]** to save the setting. After saving, the previous menu level is automatically opened.
4. Press [←] to return to the previous menu level without saving.
5. Press **[Exit]** to return to the screen display of the selected indication without saving.

   Factory setting: 2

Setting the volume



Setting the brightness



12.2.4 Setting the (Display) Brightness

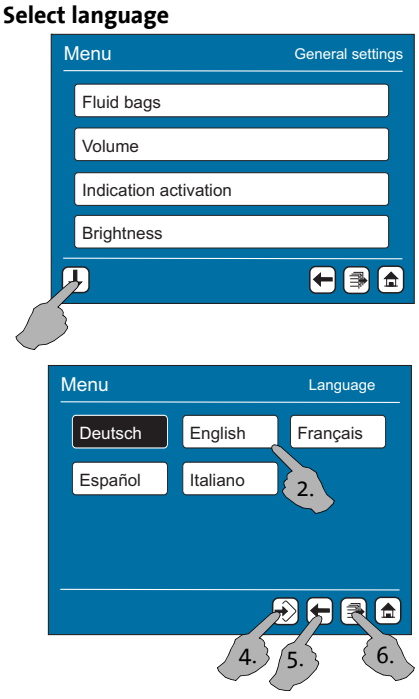
1. In the user menu, press the **[Brightness]** function field.
2. Press the **[+]** symbol or **[-]** symbol to set the desired brightness to a value between 20 and 100 %.

   Pressing the **[+]** or **[-]** symbol longer than 1.5 seconds activates scrolling of the values in increments of 10 %.

   You can now do the following:
3. Press **[Save]** to save the setting. After saving, the previous menu level is automatically opened.
4. Press [←] to return to the previous menu level without saving.
5. Press **[Exit]** to return to the screen display of the selected indication without saving.

   Factory setting: 20 %

Select language



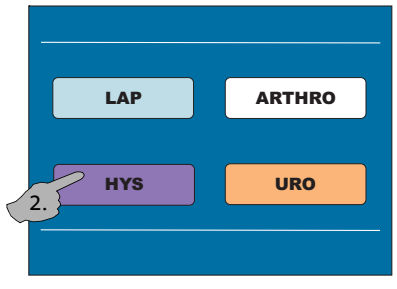
12.2.5 Selecting a Language

1. In the user menu, press the **[arrow down]** symbol to open the **[Language]** function field.
2. In the user menu, press the **[Language]** function field.
3. Press the function field of the desired language (e.g., **[English]**). The enabled function field is depicted in black.

   You can now do the following:
4. Press **[Save]** to save the setting. After saving, the previous menu level is automatically opened.
5. Press [←] to return to the previous menu level without saving.
6. Press **[Exit]** to return to the screen display of the selected indication without saving.

   Factory setting: English

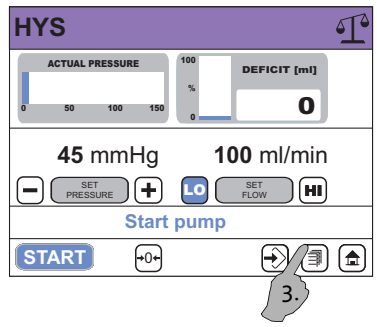
Opening the service menu



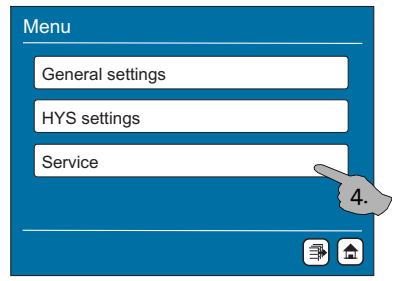
12.3 Service

1. Switch device on.
2. Press the function field of an indication (e.g., **[HYS]**). This opens the screen display of the indication. If you have selected the indication ARTHRO, then press one of the displayed function fields (e.g., **[Knee]**) to then access the arthroscopy screen display.

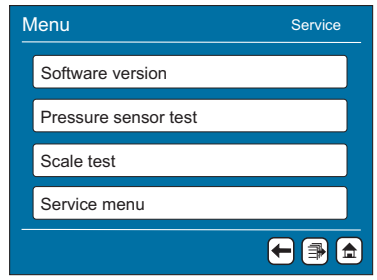
3. Press the **[User menu]** symbol. The user menu opens.



4. Press the **[Service]** function field.

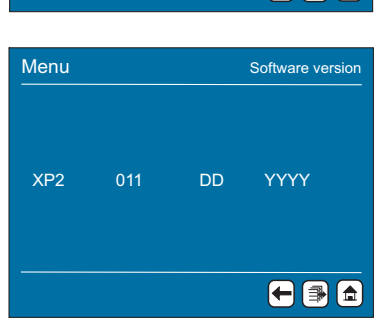


5. Press one of the 4 function fields: **[Software version]**, **[Pressure sensor test]**, **[Scale test]**, or **[Service menu]**.



12.3.1 Software Version

1. In the user menu, press the **[Service]** function field.
2. Press the **[Software version]** function field to open the corresponding display.



12.3.2 Performing a Pressure Sensor Test

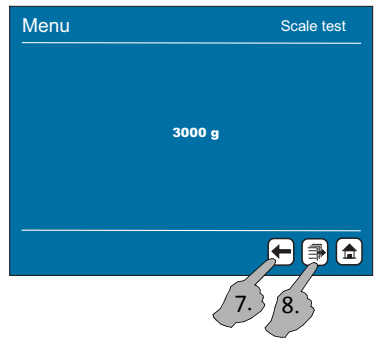
The pressure sensor test is part of the annual inspection, see Chapter 16.3 "Pressure Measuring Test".

12.3.3 Performing a Scale Test

1. A scale without weight is connected to the switched on device (see Chapter 10.6.1 "Installing and Connecting the Scale").
2. In the user menu, press the **[Service]** function field.
3. Press the **[Scales test]** function field.
4. The weight display depicts **0 g**.
5. Place a defined weight between 1 to 5 kg (e.g., 3 kg) on the scale.
6. The weight display of the device must depict the applied weight in grams (e.g., 3000 g). The permissible tolerance is ≤ 100 g. If a greater difference is detected, a service technician must re-calibrate the scale (see Chapter 15.4 "Aesculap Technical Service").

   You can now do the following:
7. Press [←] to return to the previous menu level.
8. Press **[Exit]** to return to the screen display of the hysteroscopy indication.

Test connected scale



The test of the scale is successfully completed when the permissible tolerance of ≤ 100 g is maintained.

12.3.4 Service Menu

Access to the service menu is restricted to trained and authorized service personnel. Please consult the service manual for further information.

13 Safety Functions

The electronic components continuously monitor the proper function of the device. Device malfunctions are indicated with audible warning signals (beeps), error messages, and/or by blocking device functions. A table listing a summery of possible error and warning messages is provided in Chapter 18 "Error and Warning Messages".

13.1 Device Self-Test

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

13.2 Sensor Errors

Sensor error

The offset values are verified as part of the device check process that is executed when the device is switched on. If an impermissible deviation or error in the pressure measurement electronic system is detected, the display shows consecutively **Device error**, **Call service** and **Sensor error** and 3 warning beeps are emitted.

A **Sensor error** may also occur due to pressure on the sensor while a tube set is not inserted.

Turn the device off and back on after approx. 10 seconds. If the error message is displayed again, the device may not be used any longer. Make sure the device can no longer be operated until a qualified service technician conducts the appropriate tests and repairs.

13.3 Motor Error

Motor error

If the motor drive is defective, the display shows consecutively **Device error, call service** and **Motor error** and 5 warning beeps are emitted.

Turn the device off and back on after approx. 10 seconds. If the error message is displayed again, the device may not be used any longer. Make sure the device can no longer be operated until a qualified service technician conducts the appropriate tests and repairs.

13.4 Electronics Error

Electronics error

In case of an electronic component malfunction, the display shows consecutively **Device error, call service** and **Electronics error** and 2 warning beeps are emitted.

Turn the device off and back on after approx. 10 seconds. If the error message is displayed again, the device may not be used any longer. Make sure the device can no longer be operated until a qualified service technician conducts the appropriate tests and repairs.

13.5 Calibration Error

Calibration error

If a calibration error occurs, the display shows consecutively **Device error, call service** and **Calibration error** and 10 warning beeps are emitted.

Turn the device off and back on after approx. 10 seconds have expired. If the error message is displayed again, the device cannot be used any longer. Make sure the device can no longer be operated until an authorized service technician conducts the appropriate tests and repairs.

14 Functional Test

WARNING!
Functional test
The functional test must be performed prior to each surgery.

WARNING!
Checking the warning signals
The warning signals must be checked prior to each operation. The system is to be set up so that all warning signals can be perceived.

WARNING!
Sterilize the reusable instruments and tubes before surgery to prevent infections. Check all the single-use/disposable items before removing them from the package to ensure that the packaging is intact and that the expiration date is still valid. Check instruments and tubes for damage. Replace them if necessary.

WARNING!
Check for damage
Check all products used for the operation for damage before surgery. Replace them if necessary.

WARNING!
Original accessories
For your own safety and that of your patient, use only original accessories.

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

14.1 Preparing the Function Test of the Device

Prepare device as outlined by the following function test instructions.

Prepare functional test

- ▶ Connect the equipotential line to the device.
- ▶ Use your hand to control the roller wheel and slightly turn it to check for ease of movement.
- ▶ Hang the fluid bags as described in Chapter 6.10 "Attaching and Connecting the Fluid Bags".
- ▶ Check to make sure all tube connections are free of mechanical stresses and are routed without snagging.

Switch device on

- ▶ Switch device on.
- ▶ Press the desired function field on the touchscreen (e.g., **LAP**) to select an indication type. If you have selected the indication ARTHRO, then press the **[Knee]** function field.
- ▶ Insert a tube set into the tube retainer.
- ▶ Connect an instrument.

- ▶ Open the tube clamp and the inflow valve.
- ▶ Press the **[START]** function field.
- ▶ The roller wheel starts to turn. Wait until tube set and instrument are completely filled with water.
- ▶ Press the **[STOP]** function field. The roller wheel stops.

Check user menu

- ▶ Check the settings in the user menu (see Chapter 12.2 "General Settings").

14.2 Performing the Device Function Test (Only for Laparoscopy Indication)

1. Set the "Standard" flow rate.
2. Press the **[START]** function field.
3. Open inflow valve at instrument. The roller wheel is turning forward and delivers irrigation fluid.
4. Close the inflow valve of the instrument. The roller wheel stops.
5. Press the **[STOP]** function field. The roller wheel turns approx. one rotation backwards.

The function test of the device is successfully completed when the roller wheel behaves as described in item 3., 4., and 5.

14.3 Performing Device Function Test (Only for Arthroscopy, Hysteroscopy, and Urology Indication)

1. Set the nominal pressure to 50 mmHg and the nominal flow to 0.5 l/min.
2. Press the **[START]** function field.
3. Close the inflow valve of the instrument about halfway so that device can still deliver fluid through the instrument.

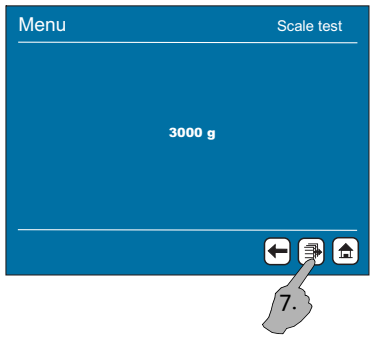
The function test of the device is successfully completed when the progress bar of the actual pressure depicts a value of approx. 50 mmHg.

14.4 Performing Function Test of the Wash Function (Only for Arthroscopy Indication)

1. Switch device on.
2. Press the **[ARTHRO]** function field. The joint selection is displayed (see Chapter 9.5 "Selecting Joint Type").
3. Press the desired function field, e.g., **[Knee]**.
4. Press the **[START]** function field.
5. Open inflow valve at instrument.
6. Press the **[WASH]** function field to enable the Wash function.
7. The Wash function is running.
8. The nominal values of the Wash function are displayed.
9. Press the **[WASH]** function field to end the Wash function early. The previously set nominal values are displayed.

14.5 Performing Scale Function Test (Only for Hysteroscopy Indication)

Test connected scale



1. A scale without weight is connected to the switched on device (see Chapter 10.6.1 "Installing and Connecting the Scale").
2. In the menu, press the **[HYSTEROSCOPY]** function field. This opens the hysteroscopy settings.
3. Press the **[Scales test]** function field.
4. The weight display depicts **0 g**.
5. Place a defined weight between 1 to 5 kg (e.g., 3 kg) on the scale.
6. The weight display of the device must depict the applied weight in grams (e.g., 3000 g). The permissible tolerance is ≤ 100 g. If a greater difference is detected, a service technician must re-calibrate the scale (see Chapter 15.4

"Aesculap Technical Service").
7. Exit the user menu by pressing **[Exit]**.
8. Remove weight from scale.

The function test of the scale is successfully completed when the permissible tolerance of ≤ 100 g is maintained.

14.6 Function Control of Foot Pedal (Only for Indication Arthroscopy)

1. A foot pedal is connected to the switched-on device.
2. Press the foot pedal to test the functions described in Chapter 6.15 Using a Foot Pedal (Optional).

14.7 Function Check of the Remote Control

1. An optional remote control is connected to the switched-on device.
2. Press the remote control to test the functions described in Chapter 6.13 Using the Remote Control (Optional).

14.8 Ending the Function Test

The device is ready for surgical use after the function test has concluded successfully. Position the device as needed for surgery.

WARNING!
The physician must determine an irrigation fluid suitable for the application and medical procedure!

Please read Chapter 13 "Safety Functions" thoroughly before using the device. This Chapter describes all safety features. The function test must be completed successfully before each surgery.

1. Before surgery:
- ▶ Select the desired nominal pressure and the nominal flow at the device.
- ▶ Press the **[START]** function field. The roller wheel starts to turn.
- ▶ Insert the instrument filled completely with irrigation fluid into the patient.

2. After surgery:
- ▶ Close the inflow valve of the working shaft.
- ▶ Press the **[STOP]** function field. The roller wheel stops.
- ▶ Switch device off.
- ▶ Remove the tube set and the fluid bags.

NOTE!
Observe applicable hygiene regulations when disposing of the tube set.

15 Care and Maintenance

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

15.1 Cleaning the Device

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

NOTE!
Do not sterilize the device.

15.2 Maintenance Intervals

Manufacturer's specifications

The manufacturer stipulates that qualified personnel or hospital technicians must regularly test the device to assess its functionality and technical safety. The device needs to be serviced at least every two years. The tests are described in Chapter 16 "Annual Inspection".

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

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

15.3 Maintenance Carried out by Authorized Service Technician

Two-year maintenance interval

An authorized service technician must inspect and service the device at appropriate intervals to ensure the safety and functionality of the device. The minimum service interval is two years, depending on frequency and duration of use. If the service interval is not maintained, the manufacturer does not assume any liability for the functional safety of the device.

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

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

Authorized trained personnel

All services, such as modifications, repairs, calibrations, replacement of the remote control battery, etc., may only be performed by the manufacturer or by specialists authorized by the manufacturer.

Unauthorized personnel

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

Liability

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

Technical documents

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

Certification

Ask the service technician for a certificate after he or she has inspected the unit or performed any service tasks. This certificate lists the type and scope of the service as well as the date and name of the servicing company together with the signature of the service technician.

15.4 Aesculap Technical Service

Technical service address

Aesculap Technical Service
Am Aesculap-Platz
78532 Tuttlingen/Germany
Phone: +49 7461 95-1601
Fax: +49 7461 14-939
Email: ats@aesculap.de

Please contact the address above for additional service addresses.

15.5 Replacing the Fuse

CAUTION!
Before replacing the fuse, check the values of the fuse to be inserted acc. to Chapter 19 Technical Data.

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

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

Check to make sure

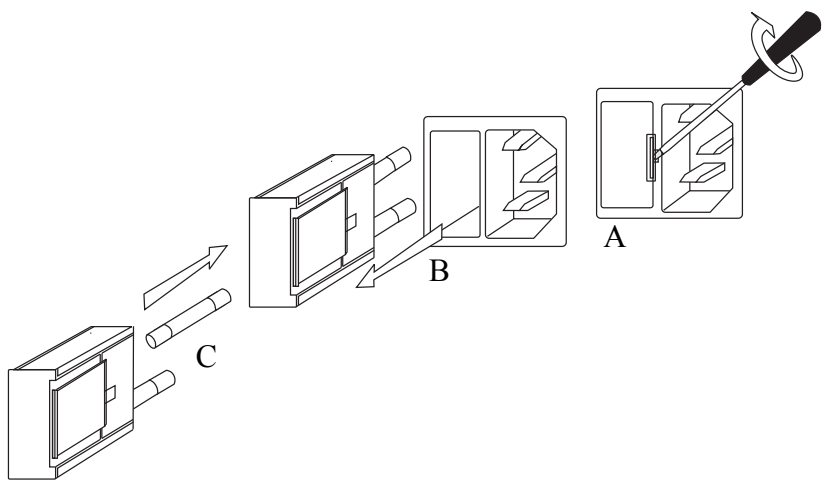
- the main power supply cable is properly connected to the power supply input and to a safety socket,
- the house power supply fuse is functioning.

WARNING!
Unplug the power cable from the device before checking the fuse.

The device does **not** have to be opened to replace the fuse.

1. Switch device off.
2. Disconnect device from power supply.
3. Remove power connection cable from mains socket.
4. The fuse holder is located to the left of the mains socket. Remove fuse holder as depicted in Fig. 15-1.

Fig. 15-1 Opening the fuse holder



5. **A** Undo the latch of the fuse holder with a small screwdriver.
6. **B** Remove the fuse holder.
7. **C** Check fuses.
8. Insert a new fuse. Use only the specified type of fuse (see Chapter 19 Technical Data).
9. Insert the fuse holder until it can be heard snapping into place.
10. Use the power cable to reconnect the shockproof safety socket with the rear mains socket.

15.6 Cleaning the Accessories

1. Switch device off.
2. Disconnect device from power supply.
3. Disconnect the accessories (foot pedal and scale) from the device.

The concentration of the used disinfectant depends on the information provided by the manufacturer of the disinfectant. Wipe with a soft cloth moistened with the disinfectant. The ingress of liquid into the accessories such as foot pedal, scale, and remote control must be prevented at all costs.

The manufacturer recommends **Meliseptol rapid** from B. Braun as a disinfectant for the foot pedal and scale. The manufacturer recommends **Incidin Extra N** from ECOLAB Healthcare as disinfectant for the remote control.

CAUTION!
Do not use any alcohol-based desinfectants on the remote control.

WARNING!
Cleaning the Accessories
The accessories (foot pedal, scale, remote control) may not be sterilized.

15.7 Care of the Reusable Tube Set

WARNING!
Please check the reusable tube for signs of damage after sterilization and before use. Never use a tube showing signs of damage, especially brittleness and perforation.

CAUTION!
The reusable tube system consists primarily of silicone, polysulfone (PSU), and stainless steel. For cleaning and disinfection, use pH-neutral or slightly alkaline cleaners and disinfectants approved for the utilized materials. If using unsuitable cleaners or disinfectants, the tube system and especially the PSU connectors may become damaged.

CAUTION!
Recycling limitations
The manufacturer has inspected the reusable tube system for a limited number of recycling cycles. Always comply with the instructions on the label. Never exceed the number of uses indicated by the manufacturer.

Application site

Use a soft cloth immediately after surgery to remove tissue, blood, etc. completely. This cloth may be moistened with a slightly alkaline cleaner.

Sticky coagulates can be removed carefully using a brush.

Storage and transport

No special requirements.

It is recommended to recondition the tube set as soon as possible after use.

15.8 Cleaning the Reusable Tube Set

Preparing for cleaning

Dismantle the tube set into its individual parts.

It is recommended to recondition the tube set as soon as possible after use.

Automatic cleaning and disinfecting

Machine cleaning and disinfecting with the Miele disinfector. The vario program can be used for disinfection.

Manual cleaning

Carefully wash the individual parts under running water. Clean and flush the individual parts with demineralized water. Sticky coagulates can be removed carefully using a soft brush.

Let all individual parts drip off and then dry them with a sterilized soft cloth.

15.9 Disinfecting the Reusable Tube Set

WARNING!
Do not leave tube set or other silicone parts in the solution for more than 30 minutes. Silicon absorbs various disinfectants and thus can be damaged when sterilized with steam.

Disinfection

1. Only disinfect a thoroughly cleaned tube set.
2. Place the individual parts of the tube set into the disinfectant (e.g., neodisher MediClean). Do not stack parts on top of each other. The concentration and application duration of the disinfectant depends on the information provided by the manufacturer of the disinfectant. The tube set can be damaged if the concentration is too high.
3. Remove the parts from the solution using forceps with a soft edge.
4. Remaining disinfection solution should be rinsed off with sterile water under sterile conditions.
5. Dry all parts with a sterile cloth and wrap each part in a separate sterile cloth.
6. Assemble all parts before sterilization.

Drying

Allow the tube system to dry completely at 80°C.

Maintenance

Maintenance is not required.

Packaging

Individually: A standardized packaging material can be used. The bag must be large enough for the tube set to prevent the seal from being stressed.

15.10 Sterilization of Reusable Tube Set

Autoclave sterilization

Only clean, dry, disinfected, and assembled tube sets should be sterilized in an autoclave. Please comply with the instructions of the operating manual included with your autoclave. The manufacturer recommends autoclaving under the following conditions:

134°C / 3 bar / 5 min

Storage

Place the tube set in a sterile container if stored for a longer period of time.

Additional information

When sterilizing several tube systems, instruments, etc. at once using one sterilization cycle, make sure not to exceed the max. load of the sterilizer.

Inspection and function test

Please check the reusable tube set for signs of damage after sterilization and before use. Never use a tube set that shows signs of damage, especially brittleness and perforation.

16 Annual Inspection

Manufacturer's instructions

The manufacturer stipulates that a specialist or a hospital technician must regularly inspect the device and its accessories with regard to function and safety. These inspections have to be carried out on an annual basis. Regular inspections will assist in early detection of possible malfunctions. This helps preserve the device and increases its safety and service life.

Inspection tests

The tests described in this Chapter are designed specifically for trained personnel or a hospital technician. The operation of the device as well as its functionality and serviceability are easily checked. Each test conducted must be documented with date and signature in Chapter 21.2 "Service and Checklist".

Measured values and tolerances

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

- Original tube set
- Fluid bags
- Graduated measuring cup with 1l scaling
- Stopwatch

WARNING!
If the specified parameters and tolerances are not maintained or adhered to, an authorized service technician must check the device.

16.1 Electrical Safety Test

1. Perform a visual inspection. Make sure that
   - the fuse corresponds with the specifications indicated by the manufacturer,
   - labels and stickers on device are legible,
   - the mechanical condition of the device allows for its safe use,
   - the device is clean to ensure proper and safe functionality.
2. Carry out the measurements for the ground leakage current, short-circuit current/housing leakage current, and the protective conductor resistance as per IEC 62353 in the current version or according to the applicable national standard.

16.2 Basic Function Test

A basic function test checks the displays, buttons, and performance of the device. For this test, you will need the following:

- One disposable tube set
- One fluid bag (3 l)
- One stopwatch
- One 1-liter measuring cup (100 ml scaling)

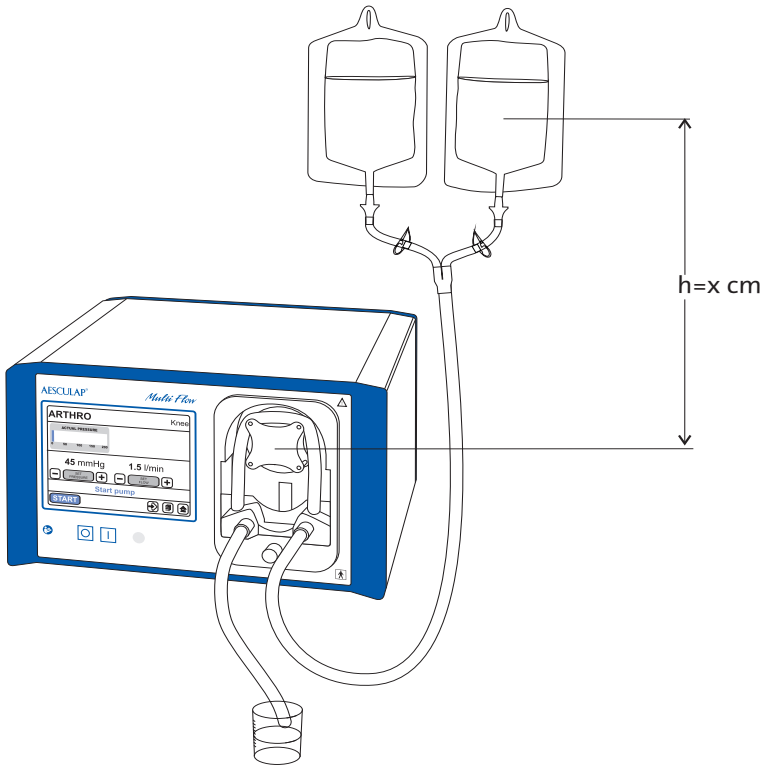


Fig. 16-1 Setup of basic function test

The layout of the test and its setup are depicted in Fig. 16-1 "Setup of basic function test".

1. Switch device on. Wait until the device check has finished.
2. Select one of the possible indications. If you have selected the Arthroscopy indication, then press the **[Knee]** function field.
3. Insert a disposable tube set into the tube retainer.
4. Suspend fluid bag at a height illustrated in Fig. 16-1 "Setup of basic function test" and connect bag with irrigation tube.
5. Place the end with the luer lock into the measuring cup.
6. Set the following nominal values:

   Arthroscopy, hysteroscopy, and urology indications:
   - **Nominal pressure = 90 mmHg**
   - **Nominal flow = 500 ml/min**

   Laparoscopy indication:
   - **Flow standard = 1 l/min**
7. Press the **[START]** function field.
8. Wait until the tube set is completely filled with irrigation fluid.

   Arthroscopy and Urology Indications

   Allow the device to pump fluid for at least 1 minute (instrument recognition function).
9. Clamp off the instrument tube end in the measuring cup without stopping the pump.
10. Empty the measuring cup and place the end of the tube back into the measuring cup.
11. Release the tube end. The irrigation process runs. Press the start button of the stopwatch.
12. ***Arthroscopy, hysteroscopy, and urology indications***

    After 2 minutes, press the **[STOP]** function field and the stop key of the stopwatch at the same time. The measuring cup then contains approx. 1 l (±10 %)

of fluid.

Laparoscopy indication

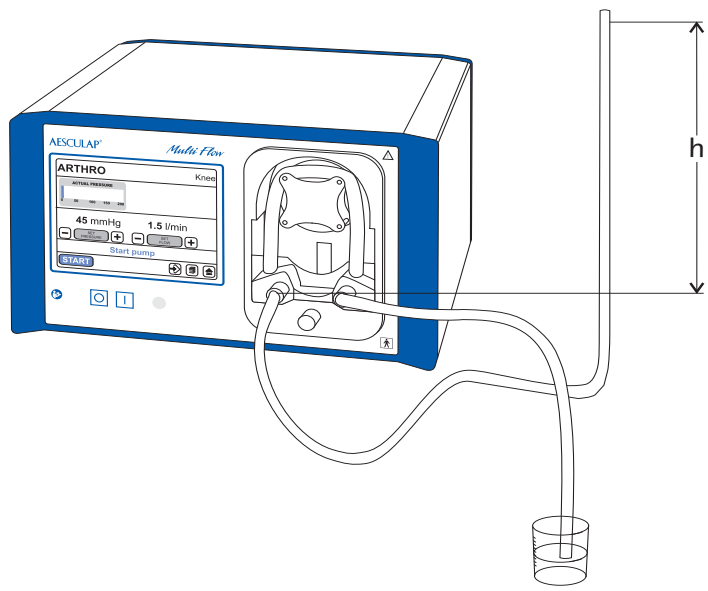
After 1 minute, press the **[STOP]** function field and the stop key of the stopwatch at the same time. The measuring cup then contains approx. 1 l (±10 %) of fluid.

The basic function test has been successfully completed once these values have been reached.

16.3 Pressure Measuring Test

The layout of the test and its setup are depicted in Fig. 16-2 "Setup of pressure measuring test".

Fig. 16-2 Setup of pressure measuring test



The pressure measurement test checks the proper functioning of the pressure measurement. This test requires a complete tube set and a container filled with **water**. The height of the water column (hydrostatic pressure) is used for measuring and is then converted to mm mercury column (mmHg). The height of the water column above the pressure chamber has to match the value of the actual pressure display after conversion.

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

1. Switch device on. Wait until the device check has finished.
2. Select one of the possible indications. If you have selected the arthroscopy indication, then press the **[Knee]** function field to access the arthroscopy screen display.
3. Press the **[START]** function field. Wait until the tube set is completely filled and bubble-free.

   Important: The tube set behind the roller wheel must be filled completely with fluid.
4. Press the **[STOP]** function field.
5. Press the **[User menu]** symbol. The user menu opens.
6. Press the **[Service]** function field.
7. Press the **[Pressure sensor test]** function field.
8. Hold the end of the completely filled instrument tube at the height of the

sensor.

9. The actual pressure display should depict approx. 5 mmHg.
10. Hold the instrument tube at a level of approx. 67.5 cm above the roller wheel. Make sure the tube segment between this point and the cartridge is completely filled with fluid. Also make sure that no point of the tube is higher than the indicated value.
11. The height of the water column is used to calculate the generated hydrostatic (water) pressure according to 67.5 cm H_2O x 0.74 = 50 mmHg.
12. The actual pressure display now should depict approx. 50 mmHg (±10 mmHg).
13. When varying the height of the tube set above the roller wheel, the actual pressure display also varies accordingly.

The test of the pressure measurement is successfully completed when the values of the actual pressure display correspond to those of the converted water column height. Please enter each completed test into the test log (see Chapter 21.1 "Test Log").

16.4 Scale Function Test (Only for Hysteroscopy Indication)

Chapter 12.3.3 "Performing a Scale Test" describes the scale function test.

17 Electromagnetic Compatibility

Precautionary measures

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

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

CAUTION!
Accessories
To ensure compliance with the requirements of IEC 60601-1-2 in the current version, the device PG130/PG145 must be used only with the accessories listed in Chapter 20 Article/Accessory List PG130/PG145.

To ensure the basic safety and essential functionality concerning electromagnetic interference over the life of the device, the device must be restarted no later than after 24 hours so that a diagnostic self-test can be performed. In addition, the specified maintenance intervals must be observed (see Chapter 15.2 "Maintenance Intervals").

17.1 Electrical Connections

ESD (Electrostatic Discharge) precautionary measures

The following are ESD precautionary measures:

- Apply potential equalization (PE), if available on your equipment, to all devices to be connected.
- Use only the listed equipment and accessories.

Hospital employees should be informed about and trained in ESD precautionary measures.

17.2 Guidelines and Manufacturer's Statement – Electromagnetic Emissions

The PG130/PG145 is intended for use in an environment as described below. The user/operator of the PG130/PG145 should make sure the device is operated within such an environment.

Emitted interference measurements	Compliance	Electromagnetic environment guidelines
HF emission according to CISPR 11	Group 1	The PG130/PG145 uses HF energy solely for its internal functions. Therefore, the camera's HF emission is very low and it is unlikely that devices in close proximity will experience interference.
HF emission according to CISPR 11	Class B	The PG130/PG145 is suitable for use in all facilities including those in residential areas and those directly connected to a public utility network supplying buildings used for residential purposes as well.
Emission of harmonic oscillations according to IEC 61000-3-2	Class A	
Emission of voltage fluctuations / flickers according to IEC 61000-3-3	In compliance	

17.3 Guidelines and Manufacturer's Statement/Electromagnetic Interference Immunity

The PG130/PG145 is intended for use in an electromagnetic environment as described below. The user/operator of the PG130/PG145 must make sure the device is operated within such an environment.

Electromagnetic interference immunity tests	**IEC 60601-1-2 test level**	**Compliance Level**	**Electromagnetic environment/guidelines**
Discharge of static electricity (ESD) according to IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be made from wood or concrete or covered with ceramic tiles. If the floor covering consists of synthetic material, the relative humidity should be at least 30 %.
Electrical fast transients/ bursts according to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines Modulation 100 KHz	± 2 kV for power lines ± 1 kV for input and output lines Modulation 100 KHz	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment.
Voltage surges according to IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment.
Blackouts, brownouts, and fluctuations of the power supply according to IEC 61000-4-11	< 5 % U_T* (> 95 % dip in the U_T) for ½ cycle	< 5 % U_T * (> 95 % dip in the UT) for 1/2 cycle	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment. If the user/operator of the system requires the continuation of functionality after power interruptions/disruptions, it is recommended to supply the device with power from an uninterruptible power supply.
	< 40 % U_T (> 60 % dip in the U_T) for 5 cycles	40 % U_T (60 % dip in the U_T) for 5 cycles	
	< 70 % U_T (> 30 % dip in the U_T) for 25 cycles	70 % U_T (30 % dip in the U_T) for 25 cycles	
	< 5 % U_T (> 95 % dip in the U_T) for 5 cycles	< 5 % U_T (> 95 % dip in the U_T) for 5 seconds 0 % U_T; 1/2 cycle at 0°, 45°, 90°, 135°, 180°, 225°,270°, and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0° 0 % U_T; 250/300 cycles	
Supply frequency magnetic field (50/60 Hz) according to IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields of the mains power frequency should comply with the typical values of business and hospital environments.

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

17.4 Guidelines and Manufacturer's Statement/Electromagnetic Interference Immunity

The device PG130/PG145 is intended for operation in an electromagnetic environment as described below. The user of the device PG130/PG145 should make sure the device is operated within such an environment.

Electromagnetic interference immunity tests	IEC 60601-1-2 test level	Compliance levels	Electromagnetic environment/guidelines
Conducted HF interference quantities according to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff} 80 MHz to 800 MHz	Portable and mobile wireless devices should not be used in closer proximity to the device PG130/PG145 (including cables/lines) than the recommended safety distance calculated based on the transmitting frequency and the applicable formula. Recommended safety distances:
Radiated HF interference quantities according to IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	$d = 1.2\sqrt{P}$ for 150 KHz to 80 MHz $d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 800 MHz to 2.7 GHz P is the max. rated output of the transmitter in watt (W) according to the information provided by the manufacturer of the transmitter. The recommended separation distance in meters (m) is d. The field strength of stationary transmitters for all frequencies tested on site [a] should be lower than the concordance level. [b] Interference is possible in the proximity of devices featuring the following pictograph. 

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

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

[a] The field strength of stationary transmitters, such as base stations of wireless phones and cell phones, ham radio operators, AM and FM radio and TV stations theoretically cannot always be determined in advance. A study of the installation site should be considered to determine the electromagnetic environment concerning the stationary transmitter. If the field strength measured at the usage site of the device PG130/PG145 exceeds the compliance levels listed above, the device PG130/PG145 should be monitored for proper function. If unusual performance characteristics are observed, additional measures may be required such as changing orientation or the location of the device PG130/PG145.

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

IMMUNITY TESTS

Transients HF IEC 61000-4-3

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

WARNING!
Portable HF communication devices can have an effect on the performance characteristics of the device PG130/PG145. Therefore, such devices must be kept at a minimum distance of 30 cm (independent of any calculation) from the device PG130/PG145, its accessories, and the cables.

17.5 Recommended safety distances between portable and mobile HF telecommunications devices and the PG130/PG145

The PG130/PG145 is intended for use in an electromagnetic environment where HF interferences are controlled. The user/operator of the PG130/PG145 can contribute to lowering electromagnetic emissions by complying with the minimum distance between portable and mobile HF telecommunications devices (transmitters) and the PG130/PG145 - depending on the output power of the communication device listed below.

Rated output of the transmitter [W]	Safety distance based on the transmitting frequency [m]		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

18 Error and Warning Messages

Error and warning messages are indicated by the device acoustically and visually. The visual indication is usually a message in the status line of the touchscreen or a full screen display. Acoustic messages are usually warning signals emitted a certain number of times (beeps).

NOTE!
Each warning signal is to be assigned one of the corresponding priorities. If multiple signals of equal priority are called at the same time, they are processed according to an internal priority ranking.

Error/error messages, full screen display

Error/error message	Troubleshooting
Device error <-> Call service <-> Electronics error 2 warning beeps	Turn the device off and back on after approx. 10 seconds. If the malfunction or error message is displayed again, the device may not be used any longer. Make sure the device can no longer be operated until an **authorized service technician** conducts the appropriate tests and repairs.
Touchscreen stays black	
Device error <-> Call service <-> Sensor error 3 warning beeps	
Device error <-> Call service <-> Motor error 5 warning beeps	
Device error <-> Call service <-> Calibration error 10 warning beeps	

Warning messages depicted in status line

Warning message	Remedy
Overpressure! Continuous acoustic signal (beep)	Physician must reduce pressure
Critical overpressure! Continuous acoustic signal (beep)	
Day tube contaminated 3 short warning beeps	Replace day tube
Vacuum pump defective! 3 long warning beeps	The suction function can no longer be used. Make sure the device can no longer be operated until an **authorized service technician** conducts the appropriate tests and repairs.
Deficit limit reached! 3 long warning beeps	Physician must respond appropriately
Deficit limit exceeded! 3 short warning beeps	Physician must respond appropriately
Perforation! Continuous acoustic signal (beep)	

Warning message	Remedy
Scales overloaded! Continuous acoustic signal (beep)	Stop currently active irrigation process Reduce or remove weight
Container change not allowed! 3 long warning beeps	• Stop the irrigation process • Empty or replace secretion container • Starting the irrigation process
LAP tube set not allowed 3 short warning beeps	A LAP tube set is not allowed for the currently running indication. Replace tube set
Day patient set not allowed 3 short warning beeps	A day patient set is not allowed for the currently running indication. Replace tube set

19 Technical Data

Type designation:	PG130/PG145
Production date:	AESCULAP AG Am Aesculap-Platz D-78532 Tuttlingen Germany
Software version:	See instructions for use to determine software version (Chapter 12.3.1 "Software Version").
Mains voltage range:	100-240 V~
Supply frequency range:	50/60 Hz
Fuse designation:	2 x T 3,15 AH, 250 V, UL-recognized, slow blow
Internal voltage supply:	No
Max. power consumption:	125 VA
Max. current consumption:	100 V: 1150 mA 240 V: 510 mA
Protection class (I, II, III)	I
Application part type [B, BF, CF]:	BF
Defibrillator protected application part:	No
Type of protection (IP code):	IP41
Classification according to Medical Device Directive 93/42/EEC, (I, IIa, IIb:)	IIb
Tested to the following standards (in the respectively valid version):	EN 60601-1/IEC 60601-1 EN 60601-1-2/IEC 60601-1-2
Operating conditions:	10-40° C / 50-104° F 30 to 75% rel. humidity 70-106 kPa air pressure 3000 m max. above sea level for device use
Possible use with explosive anesthetic gases	This system is not designed for use with flammable anesthetic gases (Class AP) or flammable anesthetic gases with oxygen (Class APG).
Storage conditions:	5-40° C / 41-104° F 5 to 85 % rel. humidity 70-106 kPa air pressure
Transport conditions:	-20 to +60° C / -4 to 140 °F 10-90 % rel. humidity at 30 °C/86 °F 70-106 kPa air pressure
Max. sound level:	65 dB(A) 80 dB(A) (with acoustic signals)
Max. scale capacity:	7 kg
Maximum output pressure:	500 mmHg ± 10 %
Negative suction pressure, vacuum pump:	Max. 700 mbar

Adjustable values/ranges	Nominal flow range:	Arthroscopy: 0.1-2.5 l/min (max. flow) Hysteroscopy: 50-500 ml/min (max. flow) Urology: 25-500 ml/min (max. flow) Laparoscopy: 1.0-3.5 l/min (max. flow)
	Suction power:	Max. 2.0 l/min (depending on outflow cannula)
	Starting nominal pressure range:	Arthroscopy: 15-200 mmHg Hysteroscopy: 15-150 mmHg Urology: 15-90 mmHg Laparoscopy: not adjustable
	Deficit threshold:	Hysteroscopy: 100-3000 ml
Measurement range	Flow:	0-3.5 l/min
	Pressure:	0 to 750 mmHg
	Deficit/inflow volume:	9995 ml
Precision (repeatability)	Flow:	± 10 %
	Pressure:	± 10 %
	Deficit:	±10 % (relative to pumped inflow volume)
Accuracy	Flow:	± 10 %
	Pressure:	± 5 % (of final value)
	Deficit/inflow volume:	±10 % (relative to pumped inflow volume)
Dimensions	Width x Height x Depth:	305 x 183 x 305 [mm] 12.0 x 7.2 x 12.0 [inch]
Mass:	8.4 kg	
Interfaces/ports	IN/OUT signal for components:	1 scale connection (RS232 socket, DSUB9/RS232) 1 service port (USB port, USB 2.0) 1 foot pedal (acc. to IEC 60601-1)
	Mains power socket:	IEC 60320-1 C14
	RFID Transponder Technology	Transmit/Receive Frequency Range: 13.56 MHz ± 0.424 MHz Transceiver class: Class I RF Output Power: -10.83 dBµA/m at 10 m/ 32.8 ft Type of Antenna: Inductive Loop Antenna Antenna loop area: 0.00032 m² Modulation: Amplitude-shift keying (ASK) Mode of Operation (Simplex / Duplex): Duplex
	for use with remote control	PG125 - Infrared interface

Essential Performance	Hysteroscopy:	Pressure build-up in the body cavity, control and measurement, limit value: max. 150 mmHg (normal state) First error: 200 mmHg for max. 5 seconds
	Urology:	Pressure build-up in the body cavity, control and measurement, limit value: max. 90 mmHg (normal state) First error: 100 mmHg for max. 5 seconds
	Arthroscopy:	Pressure build-up in the body cavity, control and measurement, limit value: max. 200 mmHg (normal state) First error: 250 mmHg for max. 5 seconds *
	Laparoscopy:	Generate irrigation flow, 1.0 l/min, 1.4 l/min, ± 10 % (normal state) First error: 0 l/min (no function) or 3.5 l/min (limit due to design constraints)

* When using the day patient set and a pressure of 300 mmHg for max. 16 seconds, the day patient set is identified as contaminated.

20 Article/Accessory List PG130/PG145

Item No.	Description
PG130	***Multi Flow*** Without vacuum pump
PG145	***Multi Flow plus*** With vacuum pump

Table 1: Tube sets

Article No.	*Packing units	Description
PG122SU	10	Tube set with suction/irrigation grip, disposable, for PG130/PG145/PG210
PG123SU	10	Tube set with suction/irrigation grip, disposable, for PG130/PG145/PG210
PG131	1	Tube set, reusable, for PG130/PG145/PG210
PG132SU	10	Tube set for irrigation, disposable, for PG130/PG145/PG210
PG133SU	10	Tube set for irrigation, disposable, for PG130/PG145/PG210
PG134SU	10+1	Day patient set ARTHRO, for PG130/PG145/PG210
PG135SU	10+1	Day patient set ARTHRO, for PG130/PG145/PG210
PG136	10	Day patient set ARTHRO, disposable, for PG130/PG145/PG210
PG137	10	Day patient set ARTHRO, disposable, for PG130/PG145/PG210
PG138SU	10	Y-tube, one-time use
PG139	10	Vacuum tube with filter for PG130/PG145/ PG210

Table 2: Transponder

Article No.	*Packing units	Description
PG140	1	Transponder set for LAP for PG130/ PG130/PG145, incl. 3x PG132SU
PG141	1	Transponder set for ARTHRO for PG130/ PG130/PG145, incl. 3x PG132SU
PG142	1	Transponder set for HYS for PG130/ PG130/PG145, incl. 3x PG132SU
PG143	1	Transponder set for URO for PG130/ PG130/PG145, incl. 3x PG132SU

Table 3: Additional accessories

Article No.	*Packing units	Description
PG124	1	Footswitch for PG130/PG145/PG210/PG150
PG125	1	Remote control for PG130/PG145/PG210
PG126SU	10	Disposable sterile cover for PG125
PG144	1	Differential volume scale for PG130/PG145/PG210
TE780	1	Power cable for Europe, length 1.5 m
TE730	1	Power cable for Europe, length 5 m
TE734	1	Power cable for Great Britain and Ireland, length 5 m
TE735	1	Power cable for USA, Canada and Japan, length 4 m
TE676	1	Mains socket extension cable 1 m**
TE736	1	Isolating transformer mains socket plug** length 2.5 m

*Packing units

**The mains connection cables T676 and T736 are only intended for direct connection to the device towers PV880/PV881/PV890/PV891,PV800/PV810 and not for extension of other mains connection cables.

21 Appendix

21.1 Test Log

Date	Results	Comment	Signature

21.2 Service and Checklist

en

Date of service: _____

Device type: _____ Serial number: _____

Location of use: _____ Software version: _____

Tester: _____ Company: _____

I: Safety test

Mechanical condition	☐	Front panel and case:	☐	Labels/identifications:	☐
Boards:	☐	Cleanness:	☐		
Mains fuse:	☐	Cabling:	☐		

II. Function test (see service manual)

_____	☐	_____	☐
_____	☐	_____	☐

III. Notes

Date: _____ Signature: _____

22 Glossary

Term	Explanation
Transponder	A RFID transponder is a wireless communication and monitoring device that receives and automatically responds to signals. The term transponder is a mixture of "transmitter" and "responder." Transponders can be active or passive.
RFID	RFID (Radio Frequency Identification) is an automated identification process that makes it possible to detect objects without touching them and to log or acquire and save data automatically. A RFID system usually consists of a transponder and a reading device. While the transponder marks objects, the reading device makes it possible to read out data, which are then further processed.
Wash function	The Wash function briefly increases the pressure and the nominal flow during the irrigation process. The physician performing the surgery is thus provided with a better field of sight and improved visibility within the joint, for example.
Actual value	The actual value is the measured value of a parameter or unit.
Nominal value	The nominal value is the specified or target value to be reached or maintained.
Pressure sensor	The pressure sensor measures the pressure applied to the pressure membrane.
Pressure membrane	The pressure membrane is located in the tube retainer of a tube set and transfers the pressure to the pressure sensor.
Day patient set	The day patient set is a tube set for arthroscopy, hysteroscopy, and urology and consists of a day and patient tube. While the patient tube must be replaced for each surgery, the day tube can remain in the device for up to 24 hours.
EMC	The electromagnetic compatibility describes the ability of a device to function satisfactorily within an electromagnetic environment without adding unacceptable electromagnetic interferences/disturbances to the environment that may cause problems for other devices or equipment located nearby.
ME device	Medical electrical device used for therapy, monitoring or diagnosis of patients, equipped with no more than one connection to a supply network and which necessarily comes into physical or electrical contact with the patient or which transfers energy to or from the patient or which records or captures such energy transfer to or from the patient.
ME system	Medical electrical system consisting of a combination of devices, of which at least one is classified as a medical electrical device and specified by the manufacturer as such and which are joined together by a functional connection or by using a power strip.
Touchscreen	A touchscreen (sometimes also spelled touch screen) makes it possible to control a device directly by touching its screen or display.
HF surgery	High-frequency surgery uses high-frequency alternating current conducted through the human body to cut tissue or achieve coagulation.
Function test	The function test must be carried out before each surgery to ensure the respective device is fully functional.

Term	Explanation
Safety test	The device safety test is part of the annual inspection.
Basic function test	The basic function test checks the fundamental operation of the device and is part of the annual inspection.
Urethroscopy	Endoscopic view of the urethra
TURB	Transurethral resection of the bladder
TURP	Transurethral resection of the prostate
URS	Ureterorenoscopies include endoscopic interventions in the ureter and renal pelvis
PCNL	A percutaneous nephrolithotomy (PCNL) is characterized by the endoscopic removal of kidney stones through a direct puncture through the skin and into the affected kidney.

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