

Double Roller Pump

User Manual

- Double Roller Pump for Laparoscopy (REF 16-2080)



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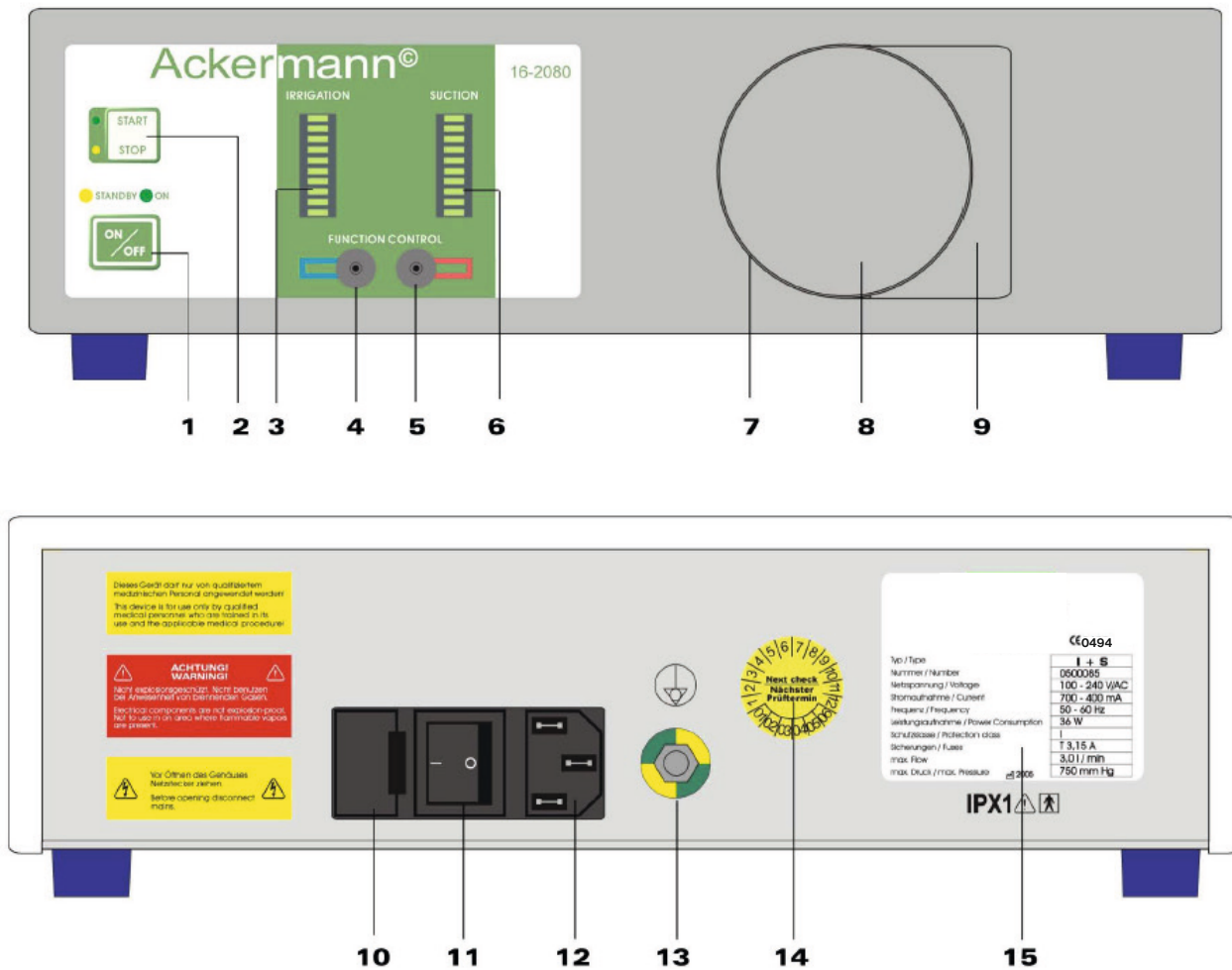
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1. Front and Real Panel



- | | |
|--|-------------------------------|
| 1 Push button ON/OFF | 8 Roller wheel SUCTION |
| 2 Push button START/STOP | 9 Tube holder |
| 3 Display bargraph IRRIGATION | 10 Fuse box |
| 4 Connector IRRIGATION for pneumatic manual control or double footswitch | 11 Mains power switch |
| 5 Connector SUCTION for pneumatic manual control or double footswitch | 12 Mains connection |
| 6 Display bargraph SUCTION | 13 Equipotentiality |
| 7 Roller wheel IRRIGATION | 14 Label next check |
| | 15 Model identification plate |

2. Technical Specifications

Parameter	Suction-Irrigation pump
Power consumption	36 W
Supply voltage	100-240 V/AC - Mains fuse T 3,15 A
Power frequency	50/60 Hz
Classification acc. to EU directive 93/42/EEC	Class IIa
Type acc. to DIN EN 60601-1:2005	BF
Protection class acc. to DIN EN 60601-1:2005	I
Manufactured acc. to	DIN EN 60601-1 (03:1996)
EMC	DIN EN 60601-1-2 (199-05)
Irrigation capacity	0 - 3000 ml/min
Suction capacity	0 - 3000 ml/min
Pressure range	0 - 750 mmHg
Conditions	Temperature: +10°C to +40°C Humidity: 30% to 70%
Case protection	IPX1
Tubing sets	Silicone - autoclavable
Dimensions	300 (W) x 93 (H) x 260 (D) mm
Weight	ca. 5 kg
Optional	Pneumatic double footswitch Adapter duct with instrument connector, autoclavable
Certification	CE0494

3. Intended Use

The device is a suction-irrigation pump without pressure monitoring and is used in minimal invasive surgery. It can be utilized in all areas of endoscopic surgical operation procedures where the body cavities are not completely filled with fluid and where the volume of rinsing fluid is small in proportion to the volume of the anatomical cavity. The pump system is well suited for utilization in the abdomen, thorax and retroperitoneum.

The irrigation process of the pump system can, apart from the classic application, also act as a suction device for fumes which arise when laser and HF-devices are deployed. The use of special cannula (punction) also enhances the field of application for the pump system. The irrigation and the suction performance can be steadily set to requirement by the operating surgeon at the manual-control instrument by using two press buttons or with double footswitch.

The controlling concept for the pump system enables the operator to do without mechanically susceptible and, during cleaning, troublesome trumpet valves.

ATTENTION! The utilization in small and closed body cavities (arthroscopy and hysteroscopy), in which the irrigation process could lead to uncontrolled and dangerous increases of pressure, is strictly forbidden.

4. Delivery Range

The pump system and delivered accessories are to be immediately inspected on receipt for completeness and possible external damage. Claims for damage are only accepted if the supplier or authorised partners are immediately informed. If a return delivery of the pump system should be necessary, please use the original packaging.

Please enclose the following information:

- Name and address
- Model No. / Serial No.
- Failure description
- Error message

The unit consists of:

Pos.	Specification	Article no.	Qty.
1	Suction-Irrigation pump	16-2080	1
2	Test report	n/a	1
3	User manual	n/a	1
4	Silicone suction-irrigation tubing set, autoclavable	16-2080-100	1
5	Main cable Euro 2 m	15-1720-800	1
6	Fuses	15-1720-901	2
7	Suction-irrigation cannula, dia. 5 / 10 mm, autoclavable	16-2080-201/-202	1
8	Adapter duct, autoclavable	16-2080-203	1
9	Pneumat. manual control with double-lumen control tube, autoclavable	16-2080-200/-204	1

5. Safety Instructions, Disposal, Safety Signs and Symbols

Please make yourself familiar with this unit according to description in the user manual.

Please note:

- This device is for use only by qualified medical personnel which are trained in its use and the applicable medical procedure.
- The physician is responsible for the appropriate type of flushing liquid.
- Use only original accessories.
- Service and maintenance have to be carried out only by authorized persons.
- Do not use the device within demarcated hazard zones! (explosive gases).
- Liability may be voided by misuse, abuse, violation of instructions for use, omission of required maintenance, opening the equipment modifications, repairs by unauthorized persons! Use of other than original accessories shall void warranty and liability.

- Equipment has to be used at all times in accordance with the operating instructions!

This device complies with currently valid EMV standards. However tests of EMV standard DIN EN 60601-1-2:1993-05 are carried out. Nevertheless, EMV interference may lead to malfunctioning. If malfunctioning is observed, ensure that the device has been installed and is being operating in accordance with EMV guidelines for use supplied with the device. Note that portable and mobile high-frequency communication equipment may influence the operation of this device. If the device is used in the vicinity of or stacked together with other devices, the device or system must be monitored to ensure standard use in accordance with these guidelines. If necessary, notify the manufacturer of the corresponding details.

IMPORTANT! In case of failure switch off the device at its main power switch (1). Pull mains connection.

DANGER! Do not open the unit. No user-servicable parts inside.

Symbol and description	Symbol and description	Symbol and description
 Follow the instructions for use	 Type BF applied part	 Year of production
 Legal manufacturer	 CE-Mark and notified body number	 Equipotential (equalising potential)
 Caution! Hazardous voltage	 Batch number	 Article number
 Expiring date	 Non-sterile, reusable	 Protective earthing
 Product contains phthalate	 Sterilized with ethylene oxide	 Do not re-sterilize
 Do not re-use	 Do not use if package is damaged	IPX1 Spray protection (protection against vertically falling drops)
 Medical device distributor		

6. Handling of Tubing Set

6.1. Components of tubing set

The tube set comprises two separate, color-coded tubes.

The blue tube is used for irrigation and the red one for suction. Both tubes are fitted with colored rings (blue and red). You will find a colored ring at tube stopper of pump segment, see section 6.3.

To insert the correct tubes you will find corresponding color-coding on the device's tube holder in blue and red.

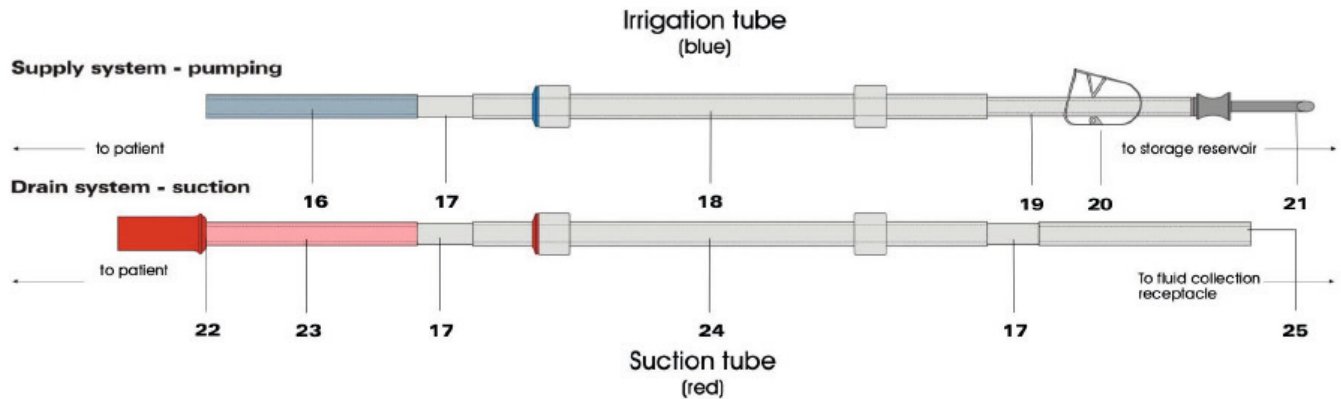
6.2. Reprocessing of reusable Tubing Set

All components of the reusable tube set can be autoclaved at a maximum temperature of 134°C and pressure of 2 bar.

The tube set can be dismantled (see section 6.3.), but must be completely reassembled and dried before sterilization.

IMPORTANT! When fitting together the tube set, please ensure that there is a tight, leak-proof connection between the adapter and the tube sections.

Assembled:



16 Patient-side tube section - IRRIGATION - for instrument

17 Adapter

18 Pump segment - Irrigation

19 Supply tube with connector for reservoir

20 Tube clamp

21 Spike connector

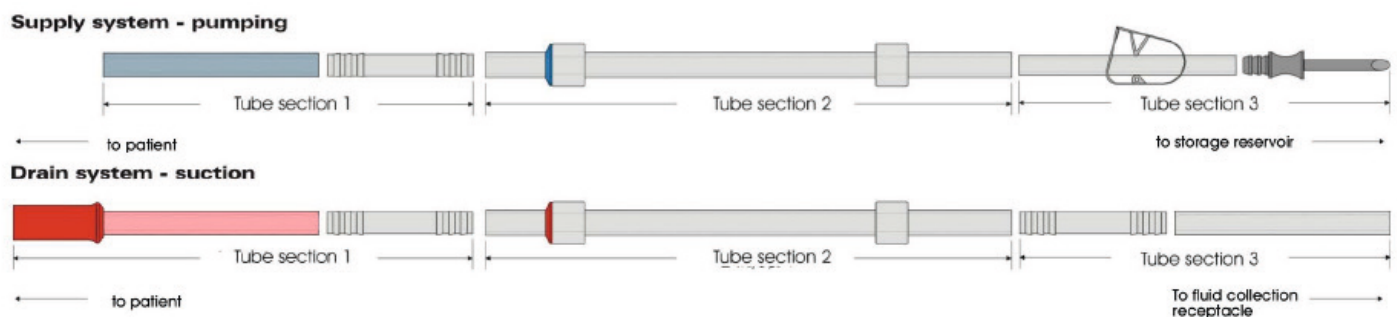
22 Adapter for instrument

23 Patient-side tube section- SUCTION- for instrument

24 Pump segment - SUCTION

25 Tube section for fluid collection receptacle

Disassembled:



IMPORTANT! The tube set may only be installed after the device has successfully performed a self test!

6.4. Inserting the Tubing Set

Tubing set has to be completely assembled and sterile, see chapter 6.3.

Step 1:

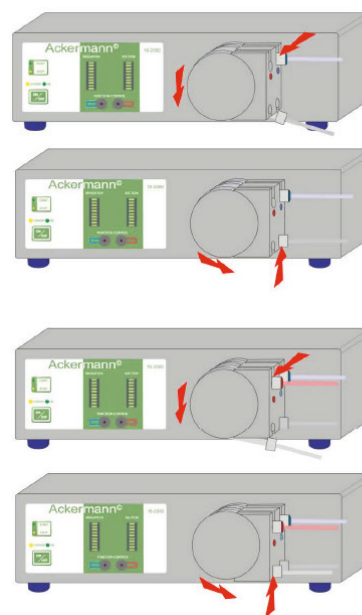
Take the blue irrigation tube. Place the tube stopper (blue) in the upper tube holder (marked blue). Pull the pump segment taught around the roller wheel and route it through the lower tube holder until the second tube stopper (colorless) locks firmly into place. Ensure the tube stoppers are correctly seated.

Step 2:

Take the red suction tube. Place the tube stopper (red) into the upper tube holder (marked red). Proceed as described in step 1.

Step 3:

Next, connect all connectors on the suction and irrigation tubes to the instrument, to the reservoir and to the fluid collection receptacle.



STEP 1

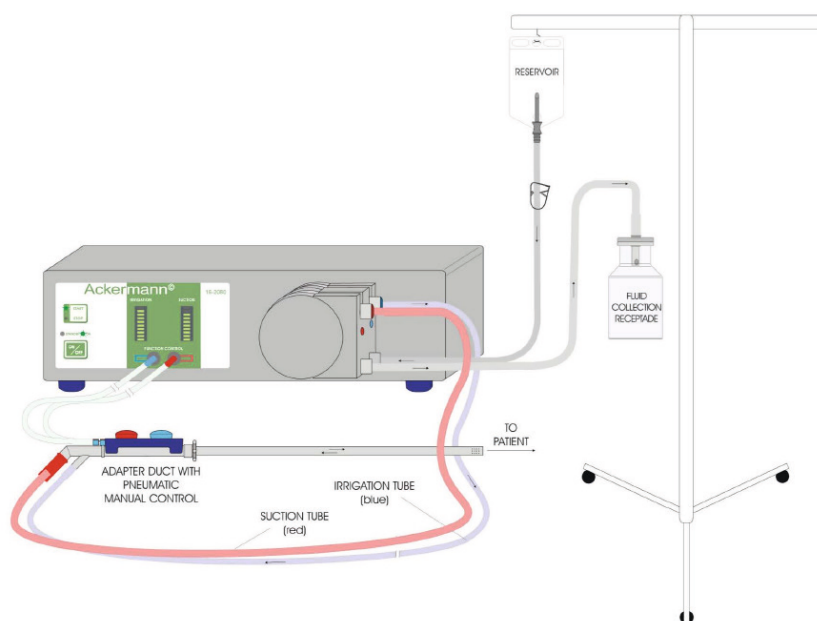
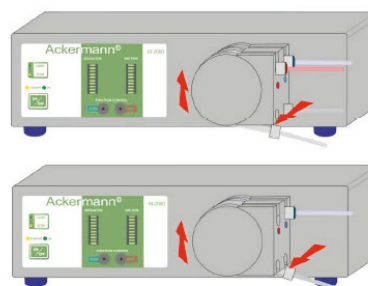
STEP 2

6.5. Removing the Tubing Set

Detach all connectors between the instrument and reservoir before detaching the tube from the roller wheels.

Take the pump segment of the red suction tube out of the tube holder first, and then the pump segment of the blue irrigation tube.

Recondition reusable tube sets for later use (see section 6.2.)



7. Adapter Duct - Pneumatic Control

The pneumatic control controls the pump's suction and flow rate.

The adapter duct is optionally supplied with two cannulas which are attached to the handgrip by a threaded fitting. If necessary, the cannula can even be changed during the operation.

The suction-irrigation duct is able to rotate in relation to the manual control. Once the cannula/instrument has been inserted, the suction-irrigation duct automatically finds a position that avoids kinking the tube. This ensures constant availability of the full suction-irrigation capacity.

The manual control can be separated from the adapter duct, which enables the pump system to be controlled by an assistant.

The double-lumen control tube must be connected between the device and the manual control.

There are blue and red color-coded control connectors on the manual control and on the front of the device.

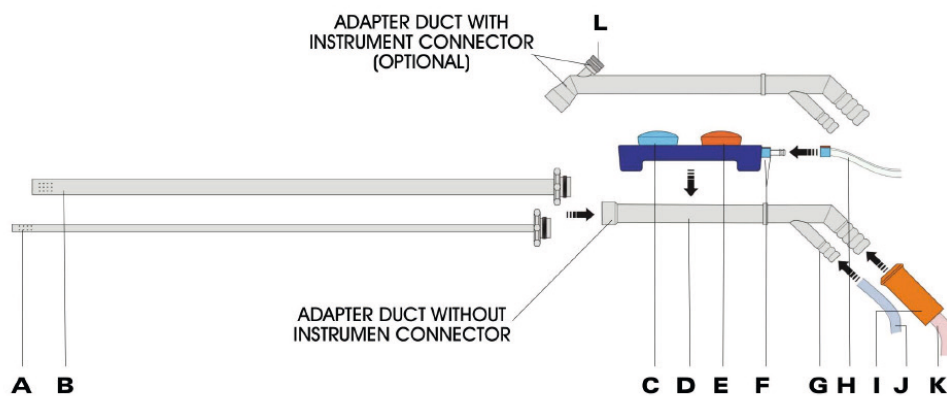
Connect the blue-coded control tube to the blue-coded control connector and the red-coded tube to the red-coded connector.

The manual control is fitted with two buttons. The blue button activates the irrigation function, the red button the suction function.

The irrigation and suction rates are proportional to the pressure applied to the buttons, enabling a fine degree of control.

Pressing both buttons simultaneously has no effect.

Manual control with adapter duct:



A Suction-irrigation cannula dia. 5 mm
B Suction-irrigation cannula dia. 10 mm

C Blue button - IRRIGATION

D Suction-irrigation duct

E Red button - SUCTION

F Control connector (IRRIGATION (blue) | SUCTION (red))

G Small adapter for tubing set - IRRIGATION

H Double-lumen control tube

I Big adapter for tube set - SUCTION

J Tubing set - IRRIGATION (blue)

K Tubing set - SUCTION (red)

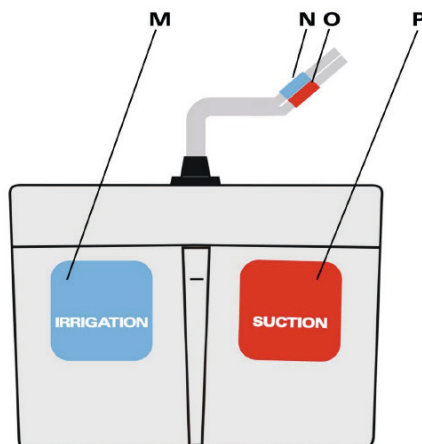
L Instrument connector

As an alternative to the pneumatic manual control, it is also possible to operate the pump using the pneumatic double footswitch.

The two control lines must be connected between the device and the pneumatic double footswitch. There are blue and red color-coded control connectors on the rear of the double footswitch and on the front of the device. Connect the blue-coded control line to the blue-coded control connector and the red-coded line to the red-coded connector.

The double footswitch is equipped with a left and a right footswitch. The left switch activates the irrigation function, the red switch the suction function. The irrigation and suction rates are proportional to the pressure applied to the footswitches, enabling a fine degree of control. Pressing both footswitches simultaneously has no effect.

Pneumatic double footswitch:



M Left footswitch- IRRIGATION

N Control connector - IRRIGATION (blue)

O Control connector - SUCTION (red)

P Right footswitch - IRRIGATION

8. Functional Buttons, Start-Up, Functional Test & Operation

8.1. Setting Up

1. Plug the AC plug into an AC outlet and switch on the device using the AC power switch. The STANDBY LED light yellow.
2. Find a suitable location for the double footswitch if required, and connect it to the device. Ensure that the tube is not kinked or compressed. If you do not require the double footswitch and wish to use the manual control, then connect this. The tube set must not be in place before the self test or be installed while the self test is in progress!
3. Activate the device by pressing the push button ON/OFF .
4. The device performs a self test.

Self test sequence:

- a. All lights come on for 1 sec and then go out again.
 - b. The left and right bargraph show the software version for 1 sec.
 - c. 1st segment of the left bargraph display lights: checking the pressure sensor for pneumatic control
 - d. 2nd-5th segments of the left bargraph light up: checking the irrigation function of the motor
 - e. 6th-8th segments of the left bargraph light up: checking the suction function of the motor
 - f. All segments are unlit again. The device signals that it is ready for operation with a triple beep signal and the ON and STOP LEDs light.
5. Now install the tube set as described in section 6.4.
 6. Carry out a functional test.

8.2. Functional test

Each time the device is used, a functional test must be carried out first.

1. Start the pump by pressing the push button START/STOP. The START LED light green.
2. Pressing the IRRIGATION button on the pneumatic control causes fluid to be pumped. Bleed the tube set until fluid exits from the end of the instrument.
3. Pressing the SUCTION button on the pneumatic control causes the suction roller to rotate.
4. The functional test is complete. Stop the pump by pressing the push button START/ STOP. The STOP LED light yellow. The device is now ready for operation.

8.3. Control buttons

8.3.1. Power switch

The AC power switch is used to switch the device on and off.

8.3.2. On/off

The push button ON/OFF activates/deactivates the device.

To activate device:

Press the push button ON/OFF. The ON LED light green and the STANDBY LED goes out.



To deactivate device:

Press the push button ON/OFF. The STANDBY LED light yellow and the ON LED goes out.



8.3.2. Start/stop

The push button START/STOP puts the device into operation and stops it.

To start device:

Press the push button START/STOP. The START LED light green and the roller wheels can be set in motion using the pneumatic control.



To stop device:

Press the push button START/STOP. The STOP LED light yellow and the START LED goes out.

The pneumatic control is inactive.



8.1. Operation of the device

1. You can start the device after carrying out a functional check.
2. The pump is activated, the ON LED light green, the STOP LED light yellow.
3. Start the pump by pressing the push button START/STOP. The START LED light green.
4. Pressing the red button on the manual control I right footswitch on the double footswitch starts the SUCTION roller wheel moving and pressing the blue button left footswitch the IRRIGATION roller wheel. The stronger the pressure exerted, the greater the flow rate (can be seen on the the bargraph displays). If pressure on the button is released, the pump stops. The suction and irrigation processes cannot both take place at the same time. After every irrigation process lasting longer than 1.5 sec, the roller wheel (IRRIGATION) turns 1 revolution in the reverse direction in order to prevent the irrigation fluid from dripping.
5. Stop the device by pressing the push button START/STOP. The STOP LED light yellow.
6. Deactivate the device by pressing the push button ON/OFF. The STANDBY LED light yellow.
7. Switch off the device at the AC power switch.

9. Warning Signals, Failure- & Fault Description

- If a beep signal lasting for three seconds sounds and all the LEDs are flashing, there is a fault with the device.
 - a. The pump stops immediately and cannot be restarted. Deactivate the device by pressing the ON/OFF button. Remove the tube set and reactivate the device after 15 seconds. The device then performs a self test.
 - b. If the roller wheel cannot be moved using the pneumatic controller, the control line is leaking or the connections have become detached. To check for leaks, first deactivate the device by pressing the ON/OFF button. Pull the end of the control line away from the device and then reinsert it in the device shortly afterwards. Remove the tube set and reactivate the device after 15 seconds. The device then performs a self test.
- Further possible reports
 - a. Selftest stops at first segment of left bargraph display. Result of pressure sensor check of pneumatic control is negative. Deactivate the device by pressing the ON/OFF button. Pull the end of the control line away from the device and then reinsert it in the device shortly afterwards. Remove the tube set and reactivate the device after 15 seconds. The device then performs a self test. The device signals that it is ready for operation with a triple beep signal and the ON and STOP LEDs light up. Now proceed as described in section 8. If the self test fails again, please notify the relevant service partner.

10. Cleaning and Maintenance

To preserve the device and ensure its proper function please note as follows:

Cleaning of the device:

Please switch off the device after use. Remove the power cable from the AC outlet. Then remove the power cable from the AC connector on the rear of the device. A disinfectant solution may be used to clean the exterior of the device. Please consult the manufacturer's instructions for the concentration of the solution.

ATTENTION! The device must not be sterilized under any circumstances!

Cleaning of the manual control, adapter duct and instruments:

The manual control, adapter duct, instruments and the tube system are cleaned in the same way as is usual for surgical instruments. Cleaning in washers is also permissible. For cleaning, the suction/irrigation cannulas and the tubes should be detached from the handgrip. Please ensure that no fluid remains in the control tube or in the handgrip. The disinfection process prior to sterilization should not exceed one hour in duration. All methods of sterilization are permissible.

ATTENTION! The maximum values if steam sterilization is used should not exceed a temperature of 134°C and a pressure of 2 bar.

11. Service

The device must be inspected by authorized service personnel once a year.

The entire repair work, calibrations and other servicing may only be carried out by authorized service personnel.

The manufacturer is relieved of any liability for the operational safety of the device if these points are not observed. For the annual inspection or repair work, the owner of the machine must receive a certificate from the service personnel in view of the type and extent of services performed.

Make sure that this certificate is handed over and that a label is attached to the rear side of the device stating the date of the next inspection.

The manufacturer is relieved of any liability for the operational safety of the device if it is opened, repaired and/or modified by anyone other than the authorized service personnel.

Medical devices regulations request the user of the device to carry out regular function and safety checks. As manufacturers, we recommend quarterly inspections which are to be carried out by hospital technicians or other authorized personnel. You will find a description of the user inspection in the next chapter of these operating instructions.

Before delivery, a complex function and safety test is conducted by the manufacturer for every device. The results of this quality control are documented in the inspection protocol, which is supplied with the device. The values of the suction and irrigation performance are valid as guidelines for the user inspection.

12. Quarterly Inspections

12.1. Checking the pneumatic control (manual control/double footswitch)

For this test you will need:

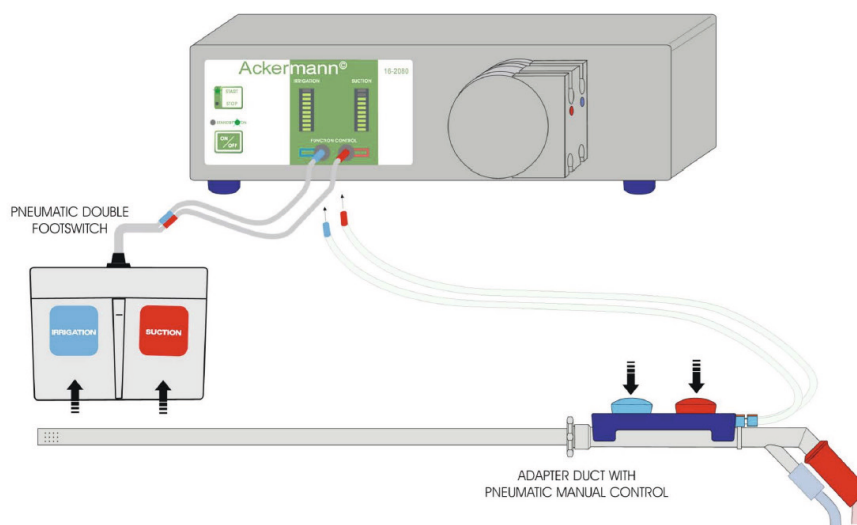
- The device
- Pneumatic control (manual control/double footswitch)

The pneumatic controller test procedure is carried out in the following steps:

1. Plug the AC plug into an AC outlet and switch on the device using the AC power switch. The STANDBY LED light yellow.
2. Connect the pneumatic control (manual control/double footswitch) to the device. Ensure that the connection is tight and there are no leaks.
3. Activate the device by pressing the push button ON/OFF.
4. The device performs a self test.
5. Start the device by pressing the push button START/STOP. The START LED light green.
6. Pressing the manual control (blue or red button) / double footswitch (left or right footswitch) sets the associated roller wheel (SUCTION/IRRIGATION) in motion.

If this does not happen, repeat the procedure. If the second attempt also fails, please contact the relevant authorized service partner.

Setup of functional test of pneumatic control:



12.2. Checking the Flow Rate

For this test you will need:

- The device
- New tube set
- 3,5 liter measuring beaker with scale (A)
- Water reservoir with 3,0 liters of water (B)
- Manual control/double footswitch
- Adapter duct with cannula connected
- A watch that displays seconds, or a stopwatch

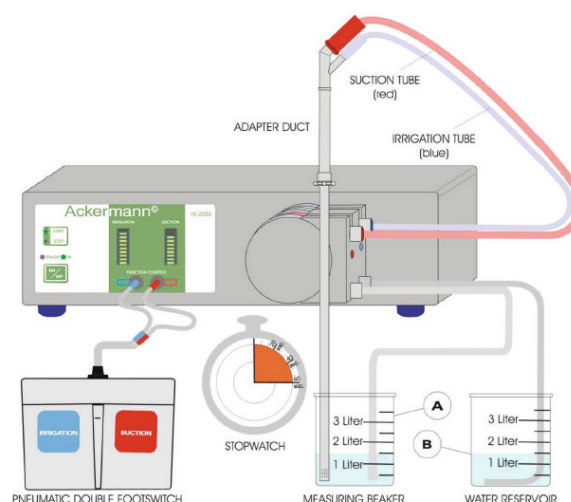
The suction and irrigation flow rate test procedure is carried out in the following steps:

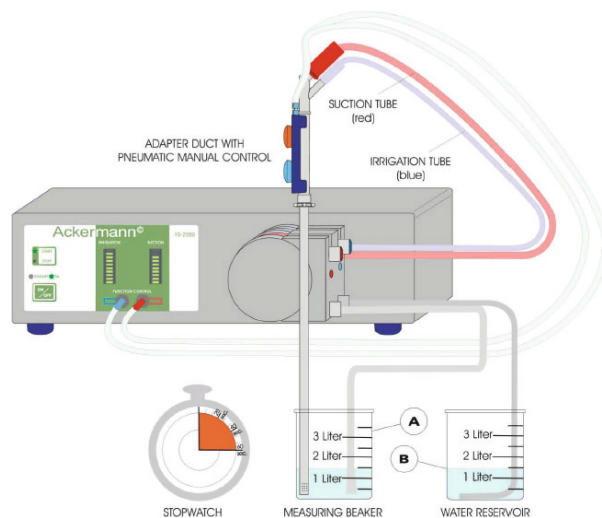
1. Plug the AC plug into an AC outlet and switch on the device using the AC power switch. The STANDBY LED light yellow.
2. Connect the pneumatic control (manual control I double footswitch) to the device. Ensure that the connection is tight and there are no leaks.
3. Activate the device by pressing the push button ON/OFF.
4. The device performs a self test.
5. Now install the tube set.
6. Immerse the end of the supply tube in the water reservoir (B) and the end of the tube section for the fluid collection receptacle in the measuring beaker (A). The ends must be positioned to lie on the bottom of the receptacle.
7. Start the device by pressing the push button START/STOP. The START LED light green.
8. Point the cannula of the adapter duct into the measuring beaker (A) and press the blue button on the manual control / the left footswitch on the double footswitch. The irrigation procedure is activated.
9. Pump fluid until fluid exits from the end of the tube in the measuring beaker (A). Continue to pump until there is approx. 300 ml water in the measuring beaker. Stop the irrigation procedure by pressing the push button START/STOP. The STOP LED light yellow.
10. Immerse the distal end of the cannula in the collected water in the measuring beaker (A). Press the red button on the manual control / the right footswitch on the double footswitch to suck back up approx. threequarters of the contents. The entire tube system is now filled with water.
11. Return the water collected in the measuring beaker (A) back to the water reservoir (B). Then have the watch ready for measuring the exact time that elapses.
12. Start the irrigation process by pressing and holding down the blue button on the manual control / left footswitch on the double footswitch for exactly 1 minute at maximum flow. At the end of this time, there must be 3,0 liters of water (-15 % to +5 %) in the measuring beaker (A).
13. Now start the suction process by pressing the red button on the manual control / the left footswitch on the double footswitch. Now, also at maximum power, pump (suction) the water out of the container again. At the end of this time, the measuring beaker must be pumped practically empty.

If the amount of liquid pumped is outside (greater or less than) the tolerances, repeat the procedures. If the second attempt also fails, please contact your authorized service partner.

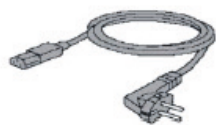
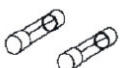
Setup of flow rate test:

PNEUMATIC DOUBLE
FOOTSWITCH





13. Accessories

Item #	Description	Illustration	Quantity
16-2080-100	Silicone irrigation tubing set, autoclavable		1pc.
15-1720-800	Main cable Euro 2m		1pc.
15-17209-00	Fuses		10pcs.
16-2080-201	Suction-Irrigation cannula dia. 5 mm, autoclavable		1pc.
16-2080-202	Suction-Irrigation cannula dia. 10 mm, autoclavable		1pc.
16-2080-203	Adapter duct, autoclavable		1pc.
16-2080-200	Pneumatic manual control, autoclavable		1pc.
16-2080-204	Double-lumen control tube, autoclavable		1pc.
16-2080-1000	Pneumatic double footswitch		1pc.



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