

# User Manual

## Double Roller Pump

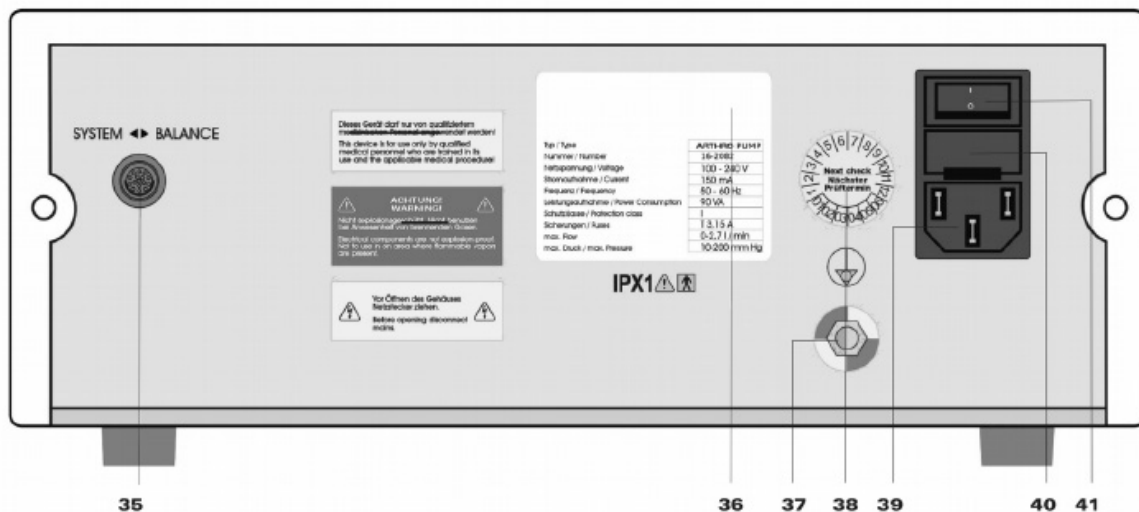
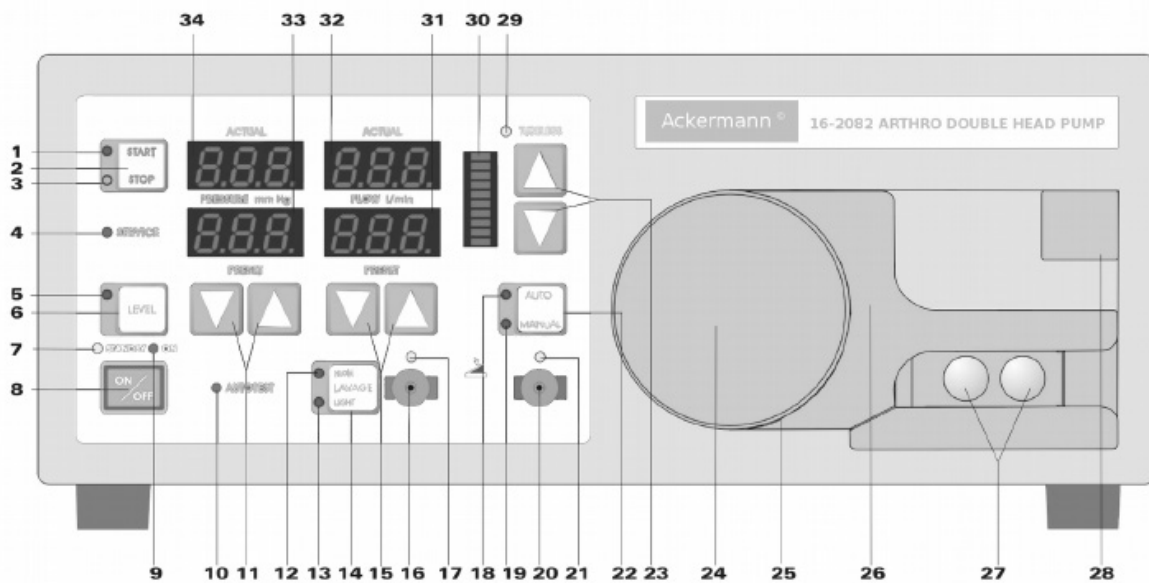
- **Double Roller Pump for Arthroscopy #16-2082**



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## 1. FRONT AND REAR PANEL



- |   |   |  |
|---|---|--|
| <p>1 LED green START<br/>2 Button START/STOP<br/>3 LED yellow STOP<br/>4 LED red SERVICE<br/>5 LED green LEVEL<br/>6 Button LEVEL<br/>7 LED yellow STANDBY<br/>8 Button ON/OFF<br/>9 LED green ON<br/>10 LED green AUTOTEST<br/>11 Buttons PRESSURE, UP/DOWN, LEVEL UP/DOWN<br/>12 LED green LAVAGE HIGH<br/>13 LED green LAVAGE LIGHT<br/>14 Button LAVAGE HIGH/LIGHT<br/>15 Buttons IRRIGATION FLOW UP/DOWN</p> | <p>16 Connector footswitch LAVAGE<br/>17 LED yellow LAVAGE active<br/>18 LED green SUCTION AUTO<br/>19 LED green SUCTION MANUAL<br/>20 Connector footswitch SUCTION<br/>21 LED yellow SUCTION active<br/>22 Button SUCTION AUTO/MANUAL<br/>23 Buttons SUCTION FLOW UP/DOWN<br/>24 Roller wheel SUCTION<br/>25 Roller wheel IRRIGATION<br/>26 Tubing holder with measuring chamber guide IRRIGATION<br/>27 Pressure sensors<br/>28. Tubing guide IRRIGATION<br/>29 LED yellow TUBELESS SUCTION<br/>30 Display SUCTION FLOW</p> | <p>31 Display preset IRRIGATION FLOW<br/>32 Display ACTUAL IRRIGATION FLOW<br/>33 Display preset PRESSURE<br/>34 Display ACTUAL PRESSURE<br/>35 RS232 interface<br/>36 Model identification plate<br/>37 Equipotential bonding pin<br/>38 Label next check<br/>39 Mains connection<br/>40 Fuse box<br/>41 Power switch</p> |
|---|---|--|

**2. TECHNICAL SPECIFICATIONS**

| <b>Parameter</b>                              | <b>Double roller pump for Arthroscopy</b>   |
|---|---|
| Power consumption                             | 80 VA   |
| Supply voltage                                | 100 - 230 V/AC - Power fuses T 3,15 A L 250 V                                       |
| 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 60601-1:2005   |
| EMC   | DIN EN 60601-1-2:2007   |
| Irrigation capacity                           | 0 -2.5 l/min  |
| Suction capacity                              | 0 - 1l/min  |
| Pressure range                                | 10 - 200 mm Hg  |
| Operating conditions                          | Temperature: +10°C to +40°C<br>Humidity: 30% to 70%                                 |
| Storage and transport conditions              | Temperature: -10°C to +70°C<br>Humidity: 10% to 90%                                 |
| Case protection                               | IPX1  |
| Tubing sets                                   | Silicone - autoclavable or<br>PVC - single use                                      |
| Dimensions                                    | 304 (W)x 125 (H)x 365 (D) mm  |
| Weight  | ca. 9 kg  |
| Optional                                      | Pneumatic double footswitch<br>Adapter duct with instrument connector, autoclavable |
| Certification                                 | CE0483  |

**3. INDENTED USE**

The Pump 16-2082 is a fluid pump featuring pressure surveillance and suction function which is integrated into control process. It is intended to be used in endoscopic operations in the fields of arthroscopy for diagnostic and therapeutic purposes. Hydrostatic pressure compensation procedure ensures correct pressure reading. The pump 16-2082 features the so-called LAVAGE function which provides fast and intense irrigation of the joint by increasing flow automatically for a short time.

Tasks of 16-2082 are:

- applying and maintaining pressure within the treated joint to inflate it and thus to establish operation conditions
- flushing of blood, secretion and tissue particles from the organ during diagnostic and therapeutic processes
- providing maximum flow rate at low pressure by continuously aspirating fluid from the joint

## **4. DELIVERY RANGE**

Check device and accessories immediately on receipt for completeness and transport damage. In case of damages please inform your authorized dealer immediately.

If the unit has to be returned use only original box and attach the following information:

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

The unit consists of:

| Pos. | Specification  | Article no. | Qty. |
|------|--|-------------|------|
| 1    | Double roller pump for Arthroscopy                   | 16-2082     | 1    |
| 2    | User manual  | n/a         | 1    |
| 3    | Silicone suction-irrigation tubing set, autoclavable | 16-2082-100 | 1    |
| 4    | Footswitch   | 16-2082-500 | 1    |
| 5    | Main cable Euro 2 m                                  | 16-2082-600 | 1    |
| 6    | Fuses  | 16-2082-700 | 2    |

## **5. SAFETY INSTRUCTIONS, DISPOSAL, SAFETY SIGNS & SYMBOLS**

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

Please note:

- 16-2082 must only be used in endoscopic operations in the fields of arthroscopy. Use of pump for other than mentioned procedures is not allowed. Otherwise operator is responsible for any kind of risk.
- The type of irrigation fluid must be chosen in accordance with the selected surgical procedure.
- The device must only be used by trained specialists at medical institutions.
- For your and your patient's safety use only original accessories.
- Service and maintenance have to be carried out only by authorized persons.
- The device is not explosion-proof and must not be used in the vicinity of combustible gases.
- The manufacturer is responsible for the safety, reliability and performance of the system only if:
  - Assembly, expansions, new settings, changes and repairs are carried out by authorized persons.
  - Electrical installation of the operating room corresponds to the national standards for medical institutions.
  - The device is used in compliance with the operating instructions and with its associated accessories.
  - The device was switched on with all connecting elements fully connected and the system accessories were checked for operability before every use.

## DOUBLE ROLLER PUMP FOR ARTHROSCOPY




















- We accept no responsibility or liability for damage of any kind due to misuse, abuse, violation of operating instructions, omission of required maintenance, equipment modifications and service by unauthorized persons! Use of other than original accessories shall void warranty and liability!

- Equipotential bonding pin is to be used to get an additional potential equalization for the patient.

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.

**CAUTION!** To avoid risk of electric shock device must be connected to public mains with protective earth conductor only. **IMPORTANT!** In case of failure switch off the device by its main power switch (32). Defective device or parts are to dispose to the national standards. When operating lifetime has expired manufacturer will take back device for recycling.

This product should be used only by qualified medical professionals! Not explosion proof. Do not use the device within demarcated hazard zones (explosive gases)! Before opening the cover disconnect mains plug!

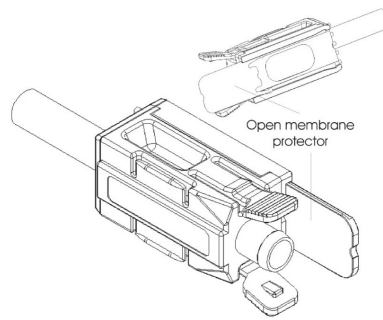
| Symbol and description  | Symbol and description  | Symbol and description   |
|---|---|--|
|  Follow the instructions for use |  Type BF applied part  |  Year of production   |
|  Legal manufacturer             |  mdc medical device certification GmbH,<br>Kriegerstraße 6,<br>70191 Stuttgart, Germany |  Equipotential<br>(equalising potential)                         |
|  Caution!<br>Hazardous voltage |  Batch number  |  Article number   |
|  Expiring date                 |  Non-sterile, reusable   |  Protective earthing  |
|  Product contains phthalate    |  Sterilized with ethylene oxide  |  Footswitch connector   |
|  Do not re-use                 |  Do not use if package is damaged  |  Spray protection (protection against vertically falling drops) |
|  Do not re-sterilize           |   |  |

## 6. HANDLING OF TUBING SET

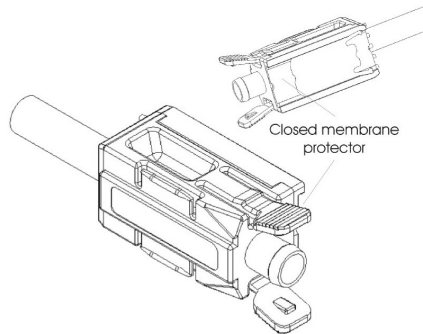
### 6.1. PRESSURE MEASURING CHAMBER WITH MEMBRANE PROTECTOR

Pressure measuring chamber is equipped with membrane protector in order to prevent damage to the membrane during transport, storage or handling.

The membrane protector opens and closes automatically when the pressure measuring chamber is inserted or removed (see image 1+2).



**FIG. 1** Open membrane protector - Membrane protector opens when the pressure measuring chamber is inserted into the measuring chamber guide



**FIG. 2** Closed membrane protector - Membrane protector before inserting and after removing of the pressure measuring chamber from the measuring chamber guide.

## 6.2. REPROCESSING OF REUSABLE TUBING SET

Read all instructions carefully before reprocessing the reusable tubing set. The entire user manual set consists of this product-specific user manual (delivered together with the pump) and the user manual of the tubing set to be used for 16-2082. Before reprocessing (see user manual of tubing set) tubing set is to disassemble into 4 segments (see Fig. in chapter 6.3). Refer to instruction manual of tubing set for details of cleaning and drying. Carefully check tube and membrane for cracks and brittle parts after each cleaning cycle. Therefore open and close membrane protector by hand. Tubing set is to sterilize by steam sterilisation (saturated vapour).

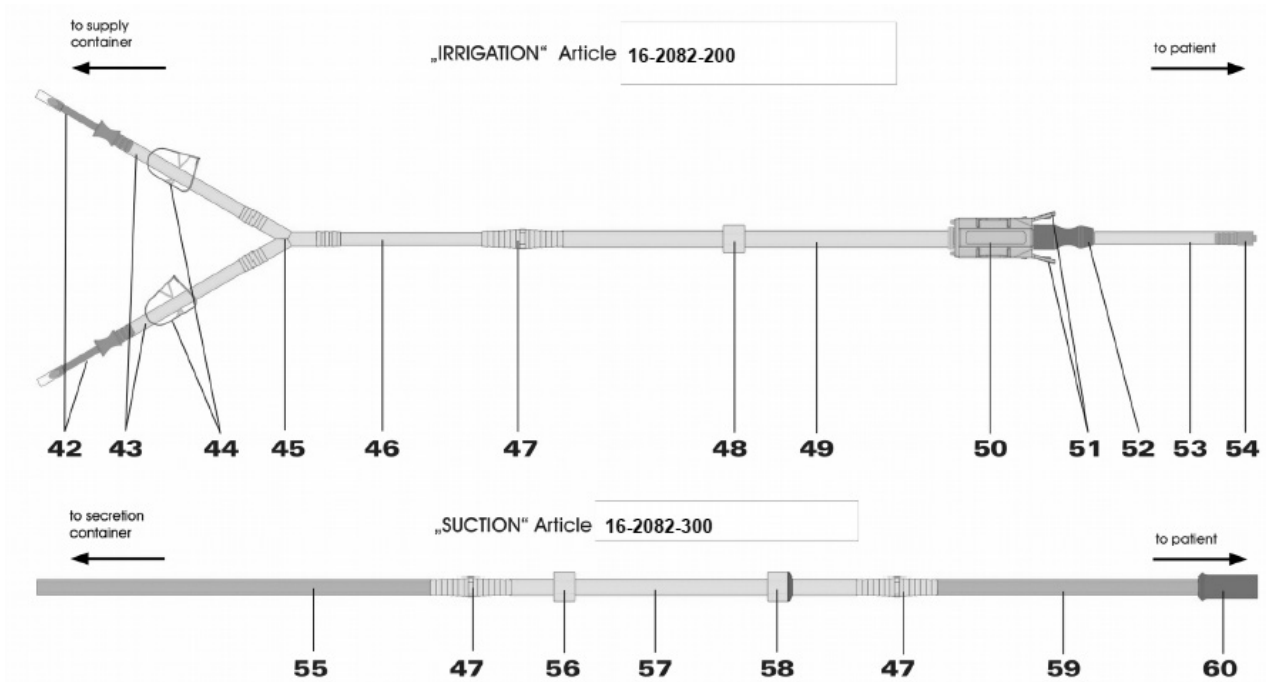
*Note: tubing segments IRRIGATION 2 and 3 / SUCTION 1 and 2 and pump segment SUCTION are to sterilize at least 20 min at a temperature of max. 134°C. Tubing segment IRRIGATION 1 and pressure measuring chamber are to sterilize at least 5 min at a temperature of max. 134°C.*

**ATTENTION!** Obey sterilization condition! Higher temperatures may lead to deformations of pressure measuring chamber. Such deformations are not obvious in any case but may induce failure of pressure measurement.

**IMPORTANT!** Make sure to re-assemble all parts of tubing set correctly and tight after reprocessing.

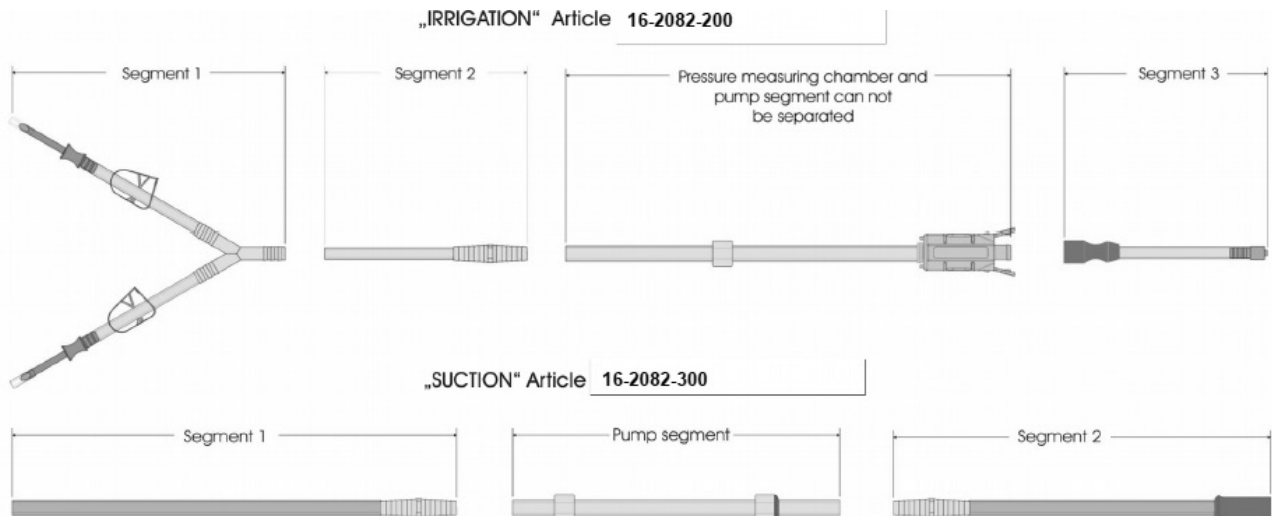
**6.3. ILLUSTRATION OF REUSABLE TUBING SET**

Assembled:



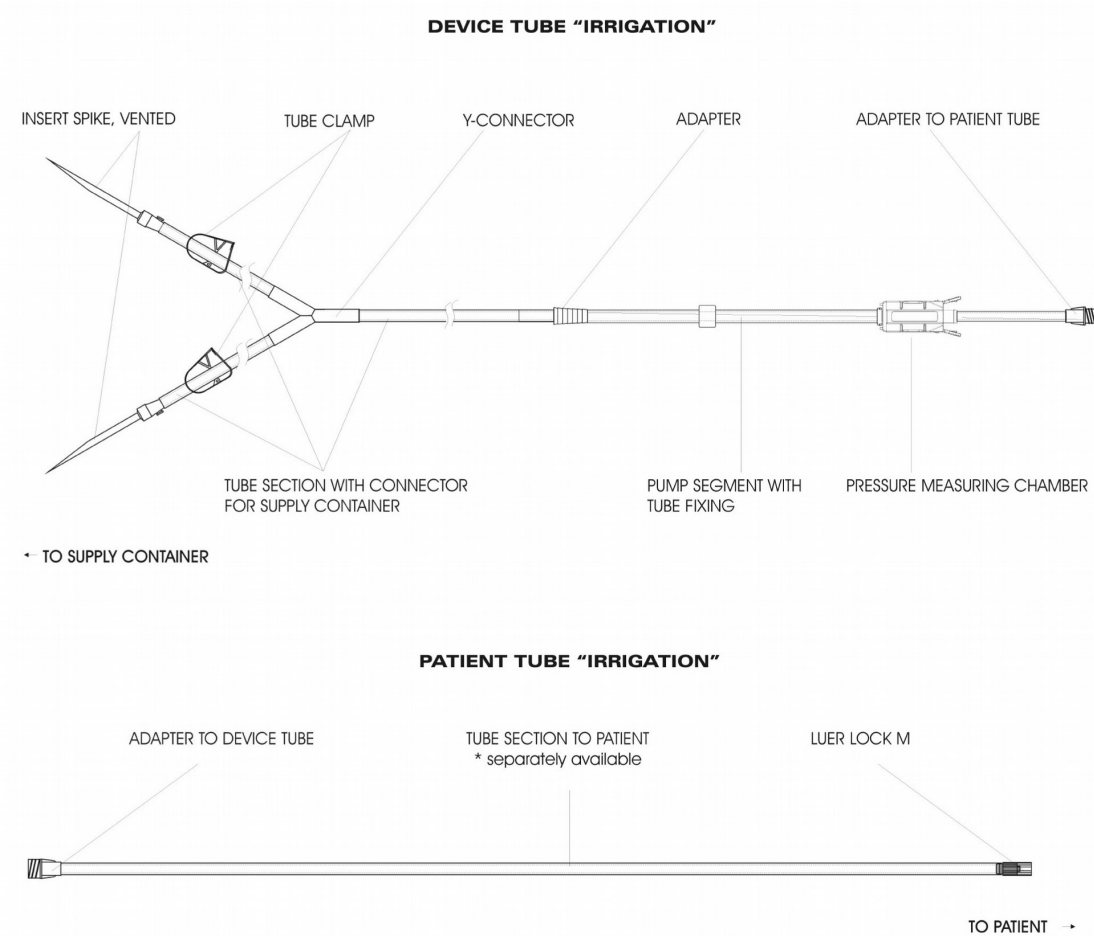
- |  |   |
|--|---|
| <b>42</b> Insert spike - connector for supply container          | <b>53</b> Tube section to patient - segment 3                     |
| <b>43</b> Tube section to supply container - segment 1           | <b>54</b> Luer Lock M connector for instrument                    |
| <b>44</b> Tube clamp   | <b>55</b> Tube section to secretion container - segment SUCTION 1 |
| <b>45</b> Y-connector  | <b>56</b> Tube fixing SUCTION                                     |
| <b>46</b> Tube section to supply container - segment 2           | <b>57</b> Pump segment SUCTION                                    |
| <b>47</b> Adapter  | <b>58</b> Tube fixing with red marking SUCTION                    |
| <b>48</b> Tube fixing IRRIGATION                                 | <b>59</b> Tube section to patient - segment SUCTION 2             |
| <b>50</b> Pressure measuring chamber                             | <b>60</b> Adapter red - connector for instrument SUCTION          |
| <b>51</b> Release clips  |   |
| <b>52</b> Adapter blue - Connector to pressure measuring chamber |   |

Disassembled:





## 6.4. ILLUSTRATION OF PVC-TUBING SET



**IMPORTANT!** Insert tubing set with pressure measuring chamber only when device is switched-on and self test is passed successfully. Otherwise errors may be reported.

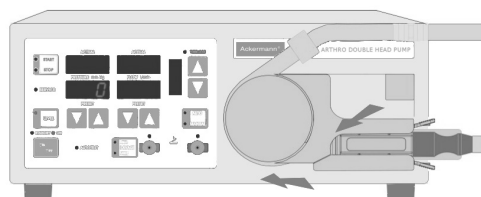
**ATTENTION!** Do not touch surface of pressure sensors! Do not use pointed or sharp objects in the vicinity of pressure sensors!

## 6.5. INSERTING THE TUBING SET

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

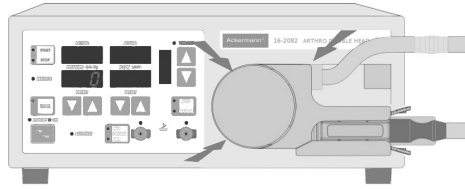
### Step 1 - Irrigation tube:

Insert pressure measuring chamber (50) into measuring chamber guide (26). Pull the pump segment (49) in direction of roller wheel (25) until pressure measuring chamber (50) snaps audibly into position.

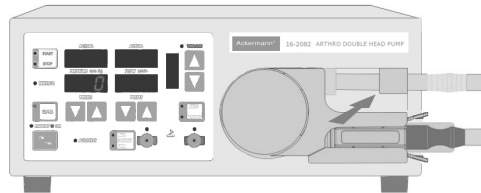


### Step 2 - Irrigation tube:

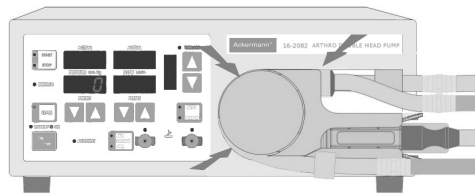
Place the pump segment (49) around the roller wheel (25) and fix it in the upper tubing holder (26). Check for correct position of tube fixing (48).

**Step 3 - Suction tube:**

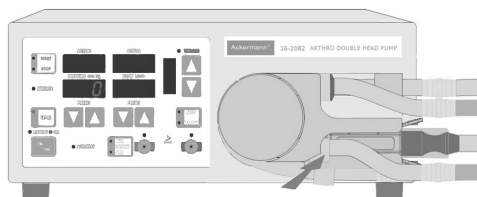
Insert the tube section - segment 2 (46) into the tubing guide (28). Now connect the tube section - segment 1 (43) to supply container, and the tube section - segment 3 (53) to the instrument.

**Step 4 - Suction tube:**

Insert the tube fixing with red marking (58) into the upper tubing holder (26) and place the pump segment (57) around the roller wheel (24).

**Step 5 - Suction tube:**

Guide the pump segment (57) through the lower tubing holder (26) and fix it with tube fixing (56). Check for correct positions of tube fixings (56, 58). Now connect the tube section - segment SUCTION 2 (55) to secretion container, and the tube section - segment 1 (59) to the instrument.



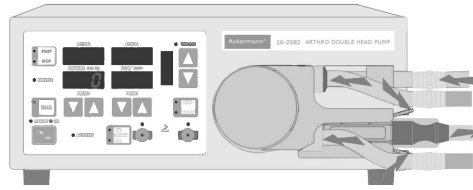
**IMPORTANT!** The pump 16-2082 can also be operated without suction tube. System will detect the absence of suction tube and will work as Arthro irrigation pump without suction.

**6.6. REMOVING THE TUBING SET**

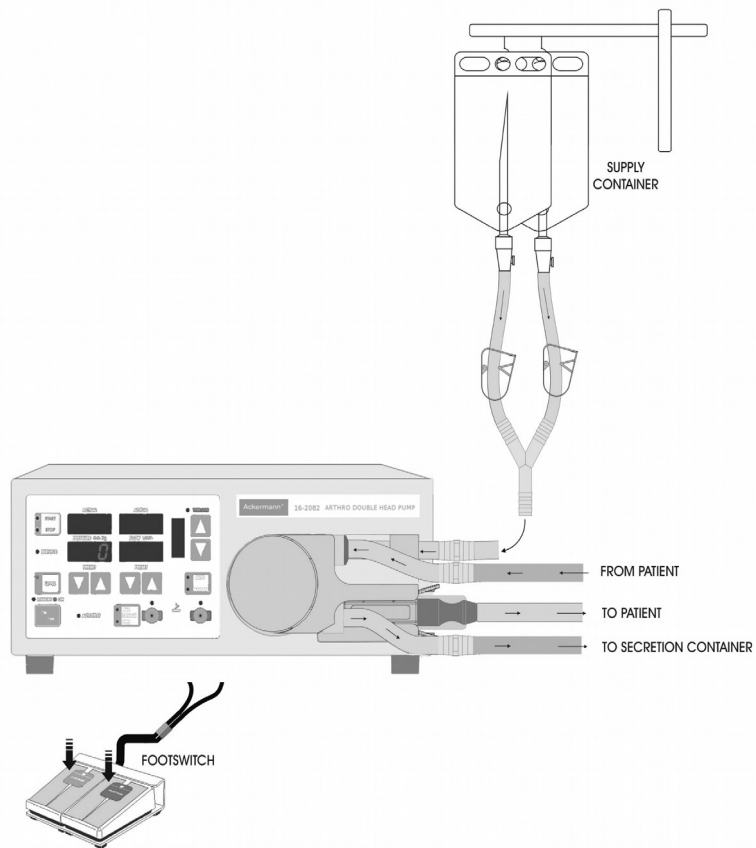
Separate connection to instrument and to supply container before tubing set is removed.

First of all tube section - segment 1 (43) is to disconnect from the supply container. Proceed as in chapter 6.5, however in reverse order. Remove suction tube completely. Now remove irrigation tube. Release the pump segment (49) from the tubing guide (28) and the tubing holder (26). Press both release clips (51) and slowly pull the pressure measuring chamber (50) out of the measuring chamber guide (26). PVC-tubing set is a disposable product and not suitable for reprocessing. The manufacturer is released from any product liability if products intended for single use are processed and re-sterilized contrary to these instructions.

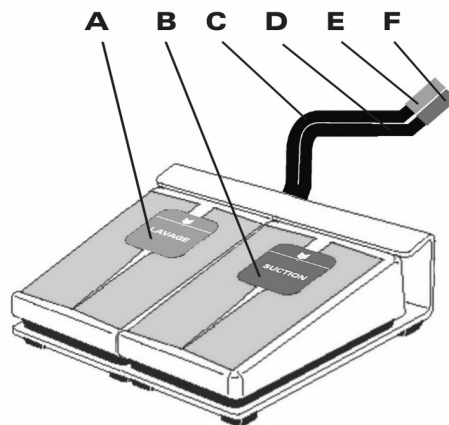
Reprocessing of reusable tubing set see chapter 6.2.



## 6.7. USING THE DEVICE IN OPERATING ROOM - ILLUSTRATION



## 7. FOOTSWITCH



## DOUBLE ROLLER PUMP FOR ARTHROSCOPY

- A Pedal LAVAGE - to activate LAVAGE
- B Pedal SUCTION - to switch suction on/off
- C Control line (tube) - LAVAGE
- D Control line (tube) - SUCTION
- E Adapter control line (blue) LAVAGE
- F Adapter control line (red) SUCTION

### 7.1. LAVAGE FUNCTION

LAVAGE function provides increased flow for a short time (3 sec) to irrigate the joint fast and intensely. The pump generally activates suction (see chapter 7.2) while Lavage function. Lavage function renders pressure control inoperative. To activate Lavage function press pedal LAVAGE during irrigation or suction/irrigation process. LED LAVAGE (17) is on as long as LAVAGE is running. Actual flow and actual pressure values can be read from displays 32 and 34. When Lavage time is expired pressure will decrease to preset values automatically while LED LAVAGE (17) is blinking. After that period LAVAGE can be activated again.

When 16-2082 is operated without suction tube, Lavage function is also available but without suction.



**CAUTION!** In case of malfunction please remove adapter (E) from connector footswitch LAVAGE (16) on front panel for a short time and connect it again.

LAVAGE causes overpressure while running.

*Note: As long as LED LAVAGE (17) is on or blinking, next activation of LAVAGE is disabled.*

### 7.2. SUCTION FUNCTION

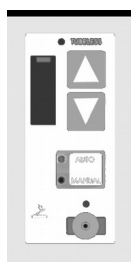
Suction function is used to aspire blood, tissue particles and irrigation liquid from the joint. Due to continuous aspiration maximum flow rate at low pressure is provided. Suction is active only in combination with irrigation and is fully integrated into control process. The pump 16-2082 automatically adjusts suction flow according to preset irrigation flow and actual pressure to prevent the joint from collapsing.

Choose one of both suction modes:

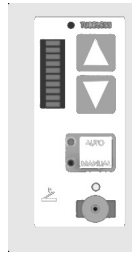
#### 1. Suction auto

Suction AUTO always provides maximum available suction flow. Preset of suction flow is disabled. Please note increased consumption of irrigation liquid in AUTO mode!

Before activating suction: maximum available suction flow is displayed



During suction: actual suction flow is displayed



## 2. Suction manual

Suction MANUAL is intended to reduce maximum available suction flow to an appropriate value. Preset of suction flow is enabled at any time. Suction is activated automatically while LAVAGE is running (see chapter 7.1).

Before activating suction: maximum available suction flow is displayed



During suction: actual suction flow is displayed

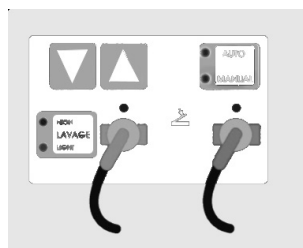


**ATTENTION!** In case of malfunction please remove adapter (F) from connector footswitch SUCTION (20) on front panel for a short time and connect it again.

## 7.3. SETUP FOOTSWITCH

Choose a convenient position for the footswitch. Connect footswitch to connectors (16, 20) on frontpanel of 16-2082.

*Please note: adapters of footswitch and connectors on frontpanel are color-coded: blue - LAVAGE, red - SUCTION. Ensure correct and tight connection. The control line must not be kinked or twisted.*


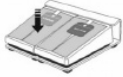

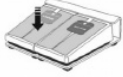


**ATTENTION!** Footswitch must not be pressed during self test!





**IMPORTANT!** Footswitch shall be disconnected when the pump is switched off.

**7.4. COMBINING SUCTION AND LAVAGE**


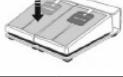


**SUCTION - active**

|   |   |   |              |   |
|---|---|---|--------------|---|
|  | + |  | LAVAGE START | LAVAGE activates suction, suction flow is reduced to preset valve |
|  | + |  | LAVAGE START | LAVAGE activates suction, max. suction flow is provided           |

**SUCTION tube inserted, SUCTION - inactive**

|   |   |   |              |   |
|---|---|---|--------------|---|
|  | + |  | LAVAGE START | LAVAGE activates suction, suction flow is reduced to preset valve |
|  | + |  | LAVAGE START | LAVAGE activates suction, max. suction flow is provided           |

**SUCTION tube not inserted**

|  |   |  |              |                        |
|--|---|--|--------------|------------------------|
|   | + |   | LAVAGE START | LAVAGE without suction |
|  | + |  | LAVAGE START | LAVAGE without suction |

When Lavage time is expired pump returns automatically to previous operating mode (irrigation or suction/irrigation).

**8. FUNCTIONAL BUTTONS, START-UP, FUNCTIONAL TEST & OPERATION**

**8.1. FUNCTIONAL BUTTONS**

**8.1.1. POWER SWITCH**

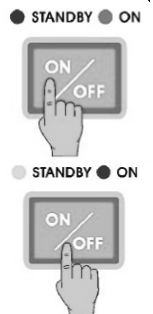
The power switch (41) is used to switch the device on and off.

**8.1.2. ON/OFF**

The push button ON/OFF (8) activates/ deactivates the device.

To activate device: Press the button ON/OFF. The ON LED (9) lights up.

To deactivate device: Press the button ON/OFF. The STANDBY LED (7) lights up.  
(For safety reasons button ON/OFF is to press at least for 3 sec).



**8.1.3. START/STOP**

The push button START/STOP (2) puts the pump into operation and stops it.

To start pump:

Press the button START/STOP. The START LED (1) lights up and the roller wheel IRRIGATION (25) starts moving.

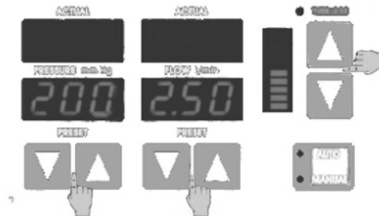
## To stop pump:

Press the button START/STOP. The STOP LED(3)lights up and the roller wheel IRRIGATION(25)stops.

## **8.1.4. UP / DOWN PRESET PRESSURE / PRESET FLOW IRRIGATION / PRESET FLOW SUCTION / LEVEL**

The push buttons(11, 15, 23)are to adjust preset values of pressure, irrigation flow and suction flow. When LEVEL function is activated the push buttons(11)are used to adjust LEVEL value(see chapter 8.1.7).

Preset values are internally stored at each pump start.



## **8.1.5. LAVAGE HIGH / LIGHT – IRRIGATION**

The button LAVAGE HIGH / LIGHT (14) toggles LAVAGE parameters from HIGH to LIGHT and reverse. Press the button LAVAGE HIGH / LIGHT until LED HIGH (12) is on.

Press the button LAVAGE HIGH / LIGHT until LED LIGHT (13) is on.

Selected Lavage option is internally stored at each pump start.

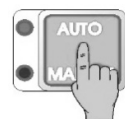


## **8.1.6. AUTO / MANUAL - SUCTION**

The button AUTO / MANUAL (22) toggles suction mode from AUTO to MANUAL and reverse

### AUTO:

Press the button AUTO / MANUAL until LED AUTO (18) is on. Maximum available suction flow is provided.



### MANUAL:

Press the button AUTO / MANUAL until LED MANUAL (19) is on. The push buttons(23)are to reduce maximum available suction flow, see chapter 8.1.4.



Selected suction mode is internally stored at each pump start.

## **8.1.7. LEVEL / HYDROSTATIC PRESSURE COMPENSATION**

The pressure sensors(27)are installed at the front of device. When the treated joint is placed above or below the pressure sensors, static pressure of liquid in tube is to be considered. The pump 16-2082 automatically compensates for that hydrostatic pressure. Thus displayed pressure value is always the pressure within the joint. Function LEVEL is to enter the difference in height between pressure sensors and treated joint. The pump will prompt to set and/or confirm LEVEL as height difference in cm before operation could be started. Access to LEVEL adjustment is always enabled during operation. Press button LEVEL (6) to activate LEVEL adjustment, LED LEVEL (5) is blinking. Press button LEVEL (6) again to confirm LEVEL value and quit LEVEL function.

### Hydrostatic pressure compensation:

Hydrostatic pressure compensation is defined as follows:

#### „LEVEL Positive“, Fig.3

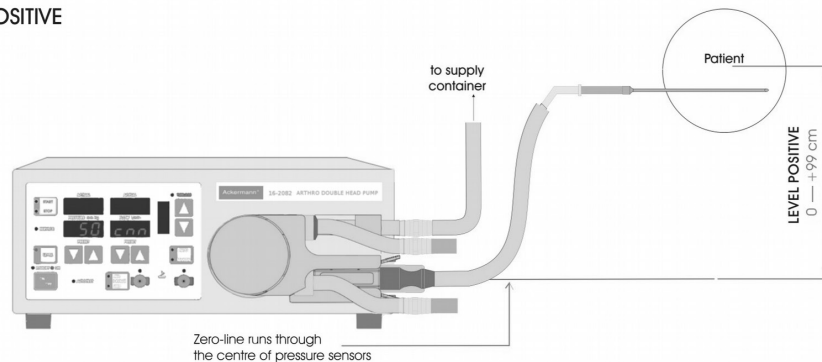
- treated joint of patient is placed above pressure sensors
- range 0 to +99 cm

#### „LEVEL Negative“, Fig.4

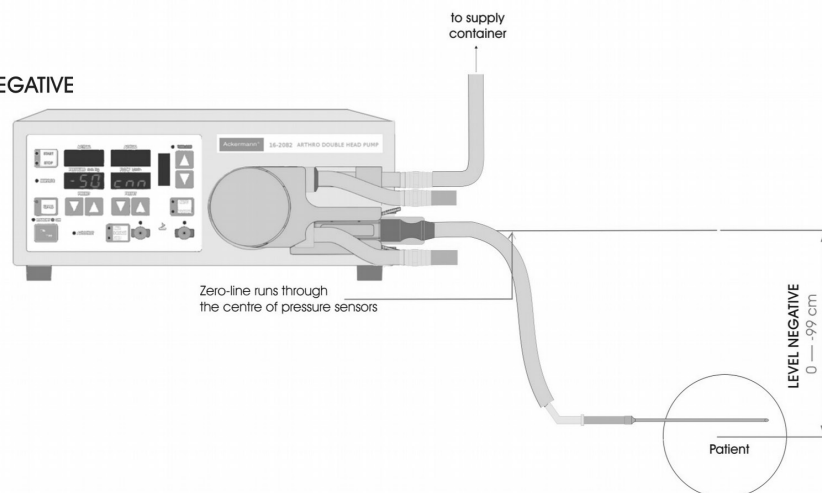
- treated joint of patient is placed below pressure sensors
- range 0 to -99 cm

### Hydrostatic pressure compensation - Illustration:

LEVEL POSITIVE



LEVEL NEGATIVE



## 8.2. START-UP/SELF TEST

**ATTENTION!** Place the device on a level surface in a dry environment.

Temperature +10 - +40°C

Relative Humidity 30-70%

**CAUTION!** EXPLOSION HAZARD

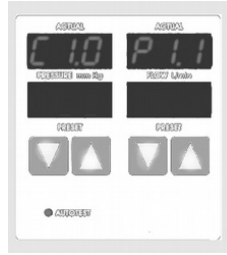
The electrical components are not explosion proof.

Do not use in an area where flammable gases are present!

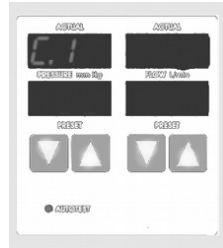
1. Connect the pump 16-2082 to mains (39). Switch on device with power switch (41). LED STANDBY (7) will be on. Do not insert tubing set yet!
2. Activate the device by pressing button ON / OFF (8). A short beep sounds.
3. The device enters self test. Self test:
  - a. All LEDs and displays are turned on for 2 sec.



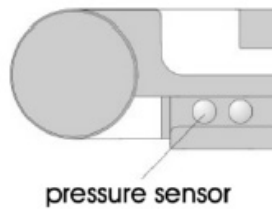
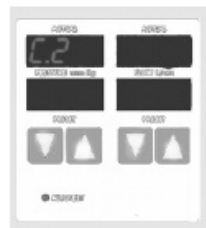
b. ACTUAL displays (23, 25) show program versions of control board (Px.x) and display board (Cx.x) for 1 sec.



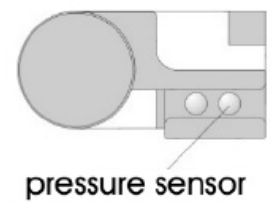
c. CHECK 1(C.1) - test of internal connections, test of chamber detection. Self test will not continue when tubing set is inserted.



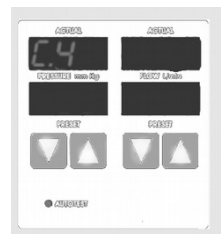
d. CHECK 2(C.2) - test of pressure sensor 1



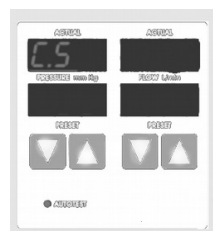
e. CHECK f. CHECK 4(C.4) - test of footswitch sensors



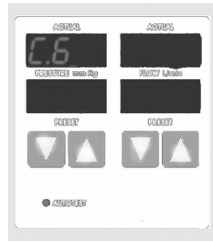
f. CHECK 4(C.4) - test of footswitch sensors



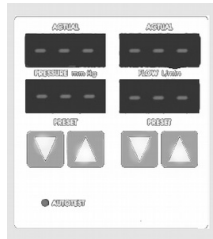
g. CHECK 5(C.5) - test of irrigation motor



h. CHECK 6 (C.6) - test of suction motor

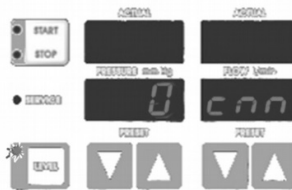


4. When self test is passed correctly a triple beep sounds. All displays (31, 32, 33, 34) show „—“. Now tubing set shall be inserted, see chapter 6.5.

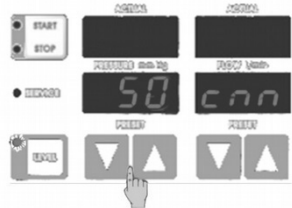


**ATTENTION!** 16-2082 can also be operated without suction tube. System will detect the absence of suction tube and will work as Arthro irrigation pump without suction.

5. When tubing set is inserted the pump enters LEVEL function. LED LEVEL (5) is blinking. PRESET display (33) shows LEVEL value at last pump start. PRESET display (31) shows unit „cm“.

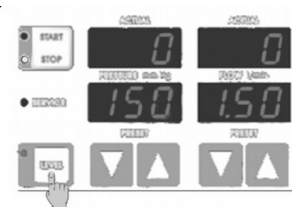


Adjust LEVEL value using UP/DOWN buttons (11), see chapters 8.1.4 and 8.1.6.

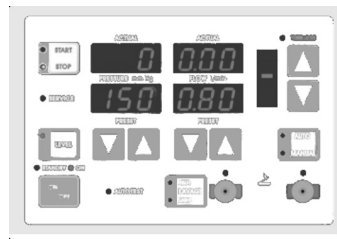


Press LEVEL button (6) to confirm LEVEL value. LED LEVEL (5) will be off.

Note: LEVEL value must be confirmed. Otherwise pump can not be started.



6. PRESET displays (30, 31, 33) show preset pressure, preset irrigation flow and preset suction flow at last pump start, LEDs LAVAGE (12, 13) and LEDs AUTO / MANUAL (18, 19) correspond to conditions at last pump start.



7. Perform functional test.

### 8.3. FUNCTIONAL TEST

The functional check must be carried out prior to each operation.

1. Start the pump.



2. Liquid is transported.

3. Fill the tubing set and the instrument completely with liquid until liquid emerges from the instrument.

4. The functional check is complete. Now the device is tested and ready to be used in the operating room.



**ATTENTION!** Prior to each operation the function „hydrostatic pressure compensation“ is to perform. For your patient’s safety you are prompted to confirm LEVEL. Otherwise the pump will not start. Confirm with the LEVEL button. Press LEVEL button again to enter the setting mode at any stage during operation.

It is recommended to repeat function if:

- the device’s installation position was modified by more than  $\pm 10$  cm height
- the surgical table was lifted or lowered by more than 10 cm

Function LEVEL is to enter the difference in height between pressure sensors and treated joint. The pump 16-2082 compensates for referring hydrostatic pressure automatically.

### 8.4. OPERATION OF THE DEVICE

1. After performing the functional check the pump can be started.

2. The pump is activated.

3. The roller wheel IRRIGATION(25) rotates and liquid is transported.

4. Flow and pressure values can be adjusted during operation (see chapter 8.1.4)

5. Lavage function can be activated while pump is running (see chapters 7.1, 7.4 and 8.1.5). To toggle LAVAGE parameters from HIGH to LIGHT and reverse press button LAVAGE HIGH / LIGHT (14) at any time (see chapter 8.1.5).

6. Suction can be activated while pump is running (see chapters 7.2, 7.4 and 8.1.6). To toggle suction mode from AUTO to MANUAL and reverse press button (22) at any time (see chapter 8.1.6).

7. Access to LEVEL adjustment is always enabled during operation. Keep the button LEVEL (6) pressed until pump will stop. LED LEVEL (5) is blinking and LEVEL value can be adjusted (see chapters 8.1.4 and 8.1.7). Press button LEVEL (6) again

## DOUBLE ROLLER PUMP FOR ARTHROSCOPY

to confirm. Start pump to proceed with operation.

8. If preset pressure is not obtained, a pulsating beep will sound and display (31) will be blinking. In that case increase flow by pressing button UP FLOW (15) and / or reduce leakage. Pulsating beep can be switched off by pressing button LEVEL (6). Display (31) will remain blinking.

9. During operation overpressure can occur for a short time. It will be reduced to preset pressure automatically.

10. Stop irrigation process by pressing the button START/STOP (2).

11. Deactivate device by pressing the button ON/OFF (8) for 3 sec.

12. Switch off the device with power switch (41).

## 9. WARNING SIGNALS, FAILURE- & FAULT DESCRIPTION

Signals during self test and operation:

### # triple beep

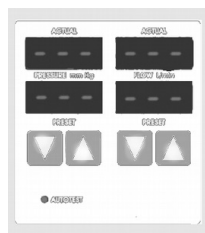
- signal for self test is passed correctly

### # pulsating beep

- overpressure warning
- preset flow too low or leakage too high action: increase preset flow and / or reduce leakage.

**\*ALL DISPLAYS (31, 32, 33, 34) SHOW „--“.**

- Tubing set shall be inserted.
- If tubing set is inserted but display remains, measuring chamber might be damaged or not correctly snapped into position.



Error messages:

### # Error display: E1.1 CHb

- Tubing set inserted during self test
- Action: remove tubing set; press button ON/OFF (8) to deactivate device and activate again after 15s. Should the error message still occur refer to qualified technical service.



### # Error display: E5.3 Itb

- Pump segment IRRIGATION (49) is not or wrongly fixed
- Action: check tube fixing (48) and pump segment IRRIGATION (49) to be in correct positions and start pump again. Should the error message still occur remove tubing set, press button ON/OFF (8) to deactivate device and activate again after 15s. Should the error message still occur refer to qualified technical service.



## # Error display: E5.4 Itb

- The roller wheel IRRIGATION (25) is blocked
- Action: check tube fixing (48) and pump segment IRRIGATION (49) to be in correct positions and start pump again. Should the error message still occur remove tubing set, press button ON/OFF (8) to deactivate device and activate again after 15s. Should the error message still occur refer to qualified technical service.



## # Error display: E6.3 Stb

- Pump segment SUCTION (57) is not or false clamped
- Action: check tube fixings (56, 58) and pump segment SUCTION (57) to be in correct positions and start pump again. Should the error message still occur remove tubing set, press button ON/OFF (8) to deactivate device and activate again after 15s. Should the error message still occur refer to qualified technical service.



## # Error display: E6.4 Stb

- The roller wheel SUCTION (24) is blocked
- Action: check tube fixings (56, 58) and pump segment SUCTION (57) to be in correct positions and start pump again. Should the error message still occur remove tubing set, press button ON/OFF (8) to deactivate device and activate again after 15s. Should the error message still occur refer to qualified technical service.

## LED Autotest (10):

- LED AUTOTEST (10) is on as long as self test is running.

## LED Service (4):

- LED SERVICE (4) is on when a technical defect was detected during self test or operation. Pump is stopped immediately. All buttons except for button ON/OFF (8) are disabled and pump can not be started.
- Action: remove tubing set, press button ON/OFF (8) to deactivate device and activate again after 15s. Should LED SERVICE (4) still be on refer to qualified technical service.

**ATTENTION!** In case of further error messages please refer to qualified technical service.

**10. CLEANING & MAINTENANCE**

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

Cleaning of the device:

Switch off the device with power switch (41). Disconnect device from mains. Remove power cable from mains connection (39) at the rear of device. Use mild disinfecting solution to clean the exterior of the device. For fluid concentration follow instructions from disinfectant manufacturer. Strictly prevent the ingress of liquid into the device!

**ATTENTION!** The device must not be sterilized!

---

**11. SERVICE**

The unit must be checked by an authorized service partner once a year. Repair, calibration and further services are to be carried out by authorized service only. Unauthorized services release manufacturer from any liability for the operating safety of the pump. Inspection shall be marked with a label „next check“ on the rear panel of device. Opening of casing, service and any other modifications of device and accessories by unauthorized persons releases manufacturer from any liability for the operating safety of the pump.

Depending on respective country-specific regulations, a function and safety inspection must be performed by the user. Manufacturer recommends quarterly inspections, see chapter 12. Each device is carefully tested with regard to function and safety by the manufacturer.

Information regarding schematics, component lists, descriptions and/ or calibration instructions can be provided by the manufacturer on demand.

---

**12. QUARTERLY INSPECTIONS****12.1. CHECKING THE PRESSURE MEASUREMENT**For this test you will need:

- Pump 16-2082
- New original tubing set (irrigation)
- Manometer with tube and matching Luer Lock connector

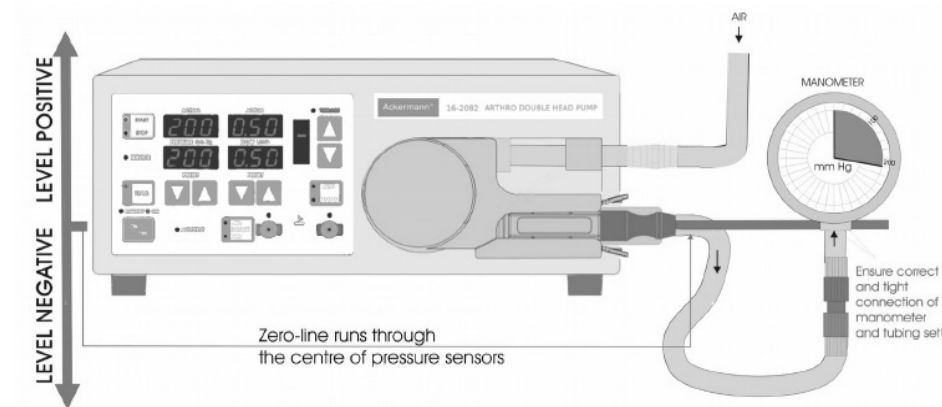
This test will be carried out without liquid.

Proceed as follows:

1. Connect the pump 16-2082 to mains (39). Switch on device with power switch (41).
2. Activate the device by pressing button ON / OFF (8).
3. The device enters self test.
4. Insert tubing set.
5. Adjust LEVEL value to „0cm“ using UP/DOWN buttons (11). Press LEVEL button (6) to confirm it.
6. Connect manometer to Luer Lock for instrument on tubing set (54). Ensure correct and tight connection.
7. Adjust irrigation pressure to 200 mmHg and irrigation flow to 2.0 l/min.
8. Start the pump. The pressure increases. After a short time the roller wheel will stop and the manometer shall display 200 mmHg +/- 5%. Carefully detach the Luer Lock connection to cause a pressure drop. The roller wheel shall start moving. Tighten the Luer Lock connection. Again, the roller wheel will stop and manometer shall display 200 mmHg +/- 5%.

In case of deviations check connections and repeat the test. If deviation is observed again refer to qualified technical service.

Setup of pressure measuring test:



## 12.2. CHECKING THE FLOW RATE

For this test you will need:

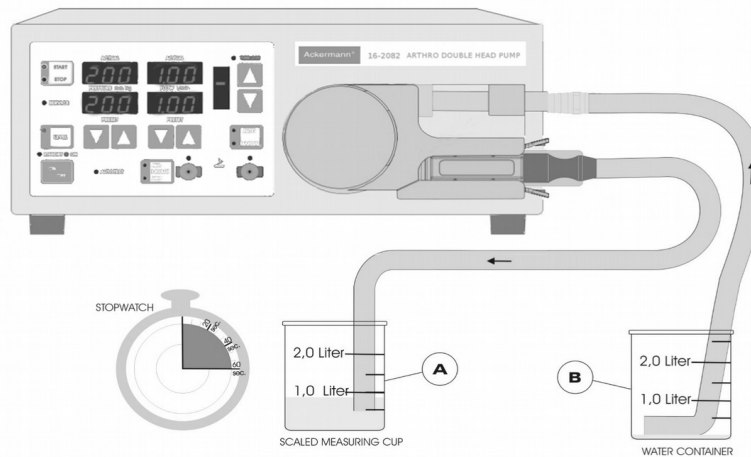
- Pump 16-2082
- New original tubing set (irrigation)
- Scaled measuring cup 2,0 l (A)
- Water container filled with 2,0 l of water (B)
- Stopwatch

This test will be carried out without Luer Lock (54) and without insert spikes, remove Luer Lock (54) and supply tube, segment 1 (43) from original tubing set.

Proceed as follows:

1. Connect the pump to mains (39). Switch on device with power switch (41).
2. Activate the device by pressing button ON / OFF (8).
3. The device enters self test.
4. Insert tubing set.
5. Adjust LEVEL value using UP/DOWN buttons (11). Press LEVEL button (6) to confirm it.
6. Place the end of supply tube, segment 2 (46) on the bottom of water container (B).
7. Place the end of patient tube, segment 3 (53) into the measuring cup (A).
8. Adjust irrigation pressure to 200 mmHg and irrigation flow to 2.0 l/min.
9. Start the pump. Prevent tube from sucking itself to the wall of water container (B).
10. Fill the tubing set completely with liquid until liquid emerges from tube into measuring cup (A). When ca. 300ml of water were transported stop pump.
11. Return the water from measuring cup (A) to water container (B). Have the stopwatch ready.
12. Run the pump for exactly 30 seconds. Subsequently the measuring cup (A) shall contain 1,0 l (-15% to +5 %) of water. In case of deviations check setup and repeat the test. If deviation is observed again refer to qualified technical service.

Setup of flow rate test:



## 12.3. CHECKING THE FOOTSWITCH

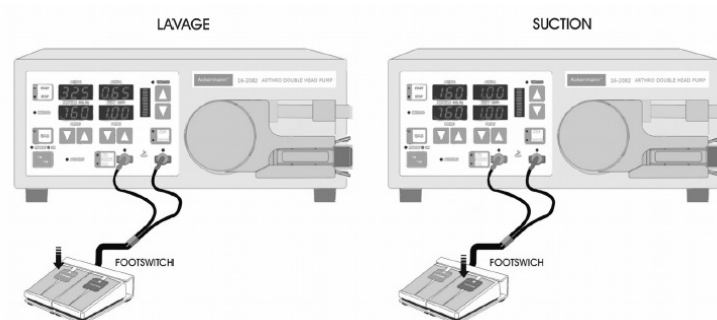
For this test you will need:

- Pump 16-2082
- New original tubing set (irrigation and suction)
- Footswitch

This test will be carried out without liquid.

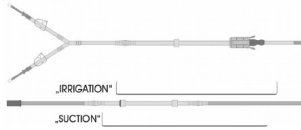
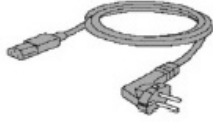
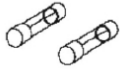
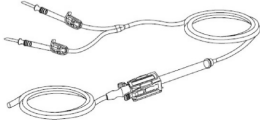


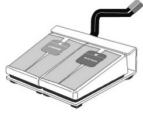
Proceed as follows:

1. Connect the pump 16-2082 to mains (39). Switch on device with power switch (41).
2. Activate the device by pressing button ON / OFF (8).
3. The device enters self test.
4. Insert tubing set (irrigation and suction).
5. Adjust LEVEL value to „0cm“ using UP/DOWN buttons (11). Press LEVEL button (6) to confirm it.
6. Connect footswitch to connectors (16, 20) on frontpanel of the pump 16-2082. Ensure correct and tight connection. The control lines must not be kinked or twisted.
7. Start the pump. The roller wheel IRRIGATION (25) rotates.
8. Press pedal LAVAGE to activate Lavage function. LED LAVAGE (17) is on as long as LAVAGE is running. Roller wheel IRRIGATION (25) speeds up significantly. Note: Suction is activated automatically while LAVAGE is running (see chapter 7.1).
9. Press pedal SUCTION to activate suction. LED SUCTION (21) is on as long as suction is active. Roller wheel SUCTION (24) starts moving.
10. Press pedal SUCTION again to deactivate suction. LED SUCTION (21) is off and roller wheel SUCTION (24) stops. In case of deviations check setup and repeat the test. If deviation is observed again refer to qualified technical service.





## 13. ACCESSORIES

| Item #                                    | Description   | Illustration   | Quantity |
|---|---|--|----------|
| 16-2082-100<br>(=16-2082-200+16-2082-300) | Silicone irrigation tubing set, autoclavable          |    | 1 pc.    |
| 16-2082-600                               | Main cable Euro 2m                                    |    | 1 pc.    |
| 16-2082-700                               | Fuses   |    | 10 pcs.  |
| 16-2082-200                               | PVC irrigation tubing set, sterile pack, disposable   |    | 10 pcs.  |
| 16-2082-300                               | PVC patient tube, 2.5 m, sterile pack, disposable     |    | 20 pcs.  |
| 16-2082-400                               | Pressure measuring chamber with pump segment, autocl. |  | 1 pc.    |
| 16-2082-500                               | Footswitch  |  | 1 pc.    |

## 14. APPENDIX

All product codes covered by these instructions are listed below:

- Double Roller Pump for Arthroscopy **#16-2082**

## 15. CONTACT DETAILS



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