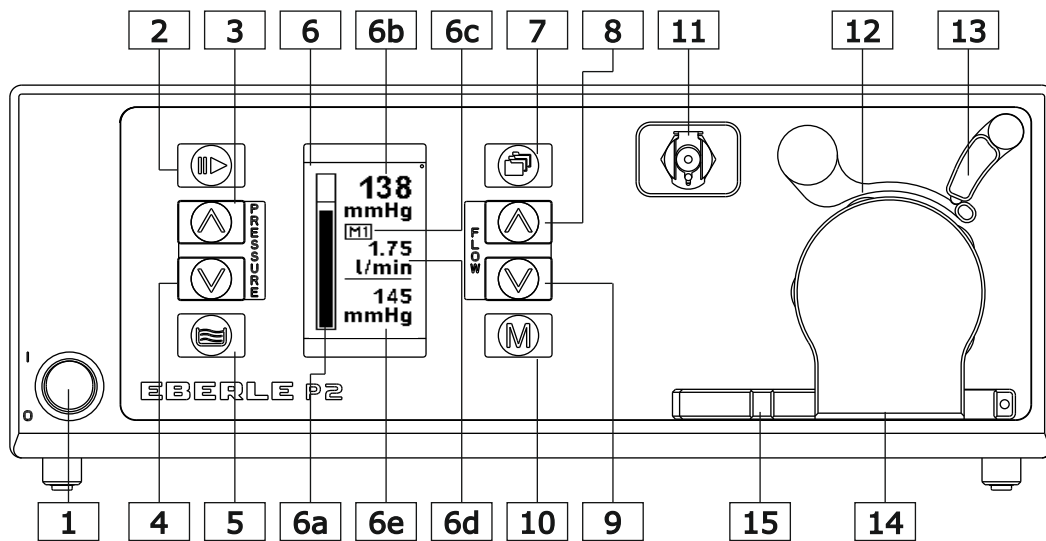
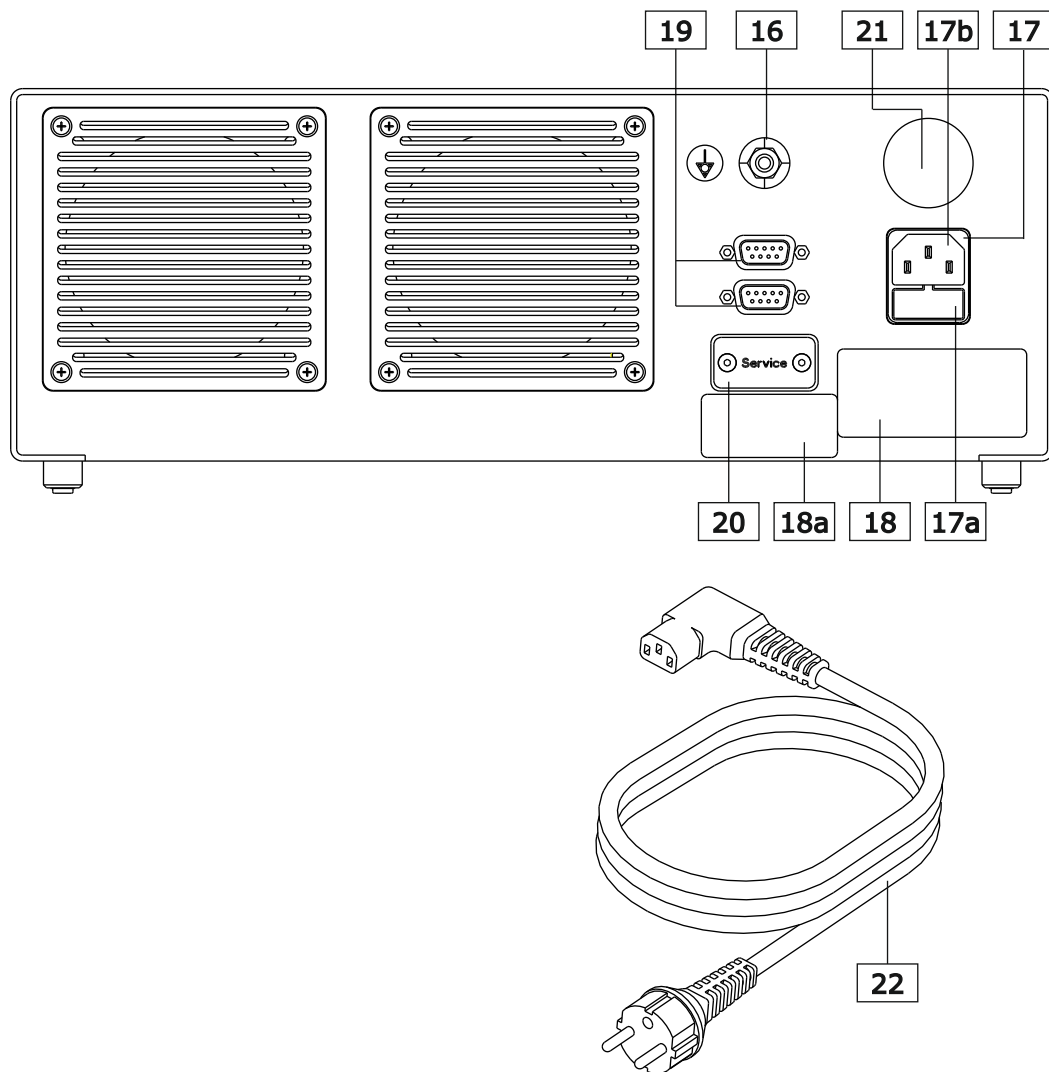






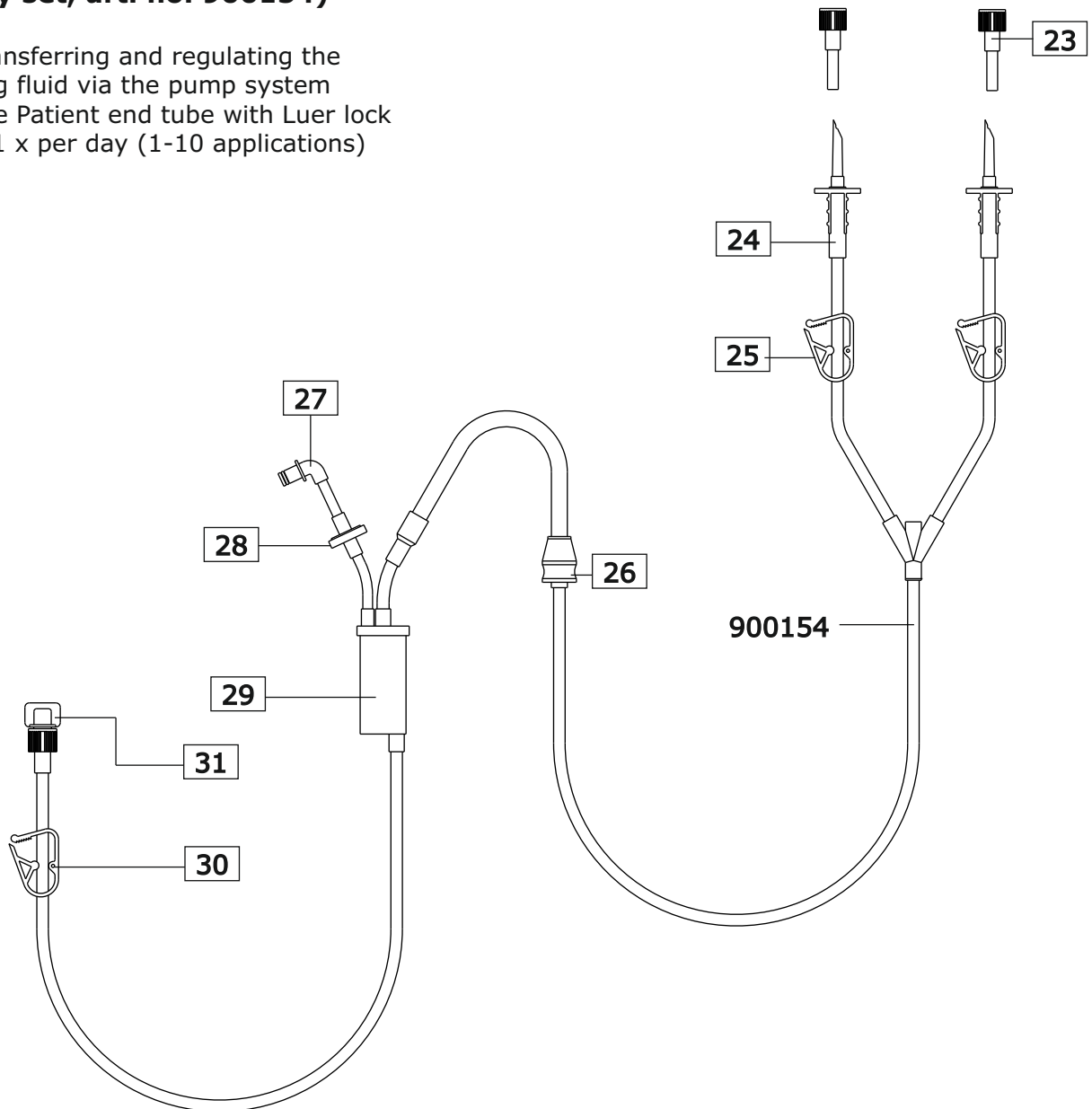
- |    |                                                                      |
|----|----------------------------------------------------------------------|
| 1  | Power switch                                                         |
| 2  | Start/stop key                                                       |
| 3  | Key for pressure increase (delivery volume / contrast)               |
| 4  | Key for pressure decrease (delivery volume / contrast)               |
| 5  | Key for filling (rinsing function)                                   |
| 6  | LCD display                                                          |
| 6a | Graphic pressure display                                             |
| 6b | Current pressure                                                     |
| 6c | Display of selected memory location                                  |
| 6d | Display of maximum delivery volume                                   |
| 6e | Display of set pressure                                              |
| 7  | Key for call of storage on memory location 1 to 3 (contrast setting) |
| 8  | Key to increase delivery volume                                      |
| 9  | Key to decrease delivery volume                                      |
| 10 | Memory key                                                           |
| 11 | Tube connector unit                                                  |
| 12 | Clamping bracket                                                     |
| 13 | Locking lever                                                        |
| 14 | Tube intake                                                          |
| 15 | Recess, patient end (tube set)                                       |



|     |                                 |
|-----|---------------------------------|
| 16  | Equipotential bonding           |
| 17  | Power connector                 |
| 17a | Mains fuse box with fuse holder |
| 17b | Connector for power plug        |
| 18  | Type plate                      |
| 18a | Type plate                      |
| 19  | ECB (external communication)    |
| 20  | Service port                    |
| 21  | Certification label             |
| 22  | Mains power cable               |

#### Tube set for arthroscopy (daily set, art. no. 900154)

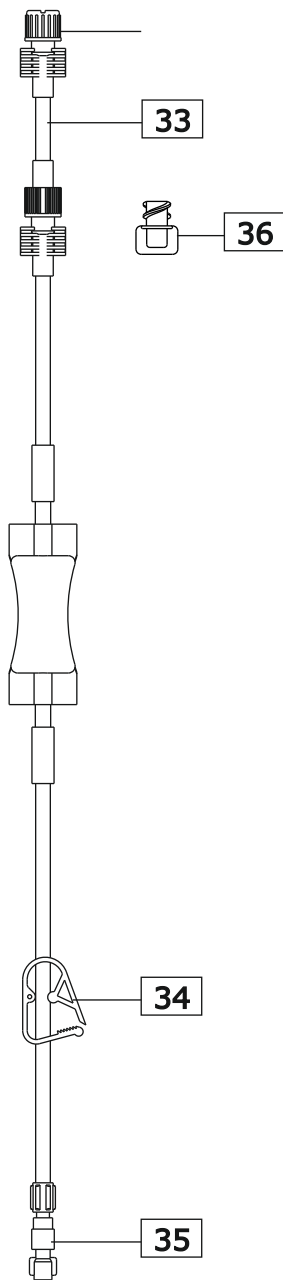
for transferring and regulating the  
rinsing fluid via the pump system  
for the Patient end tube with Luer lock  
Use: 1 x per day (1-10 applications)



|    |                                        |
|----|----------------------------------------|
| 23 | Luer lock adapter for piercing mandrel |
| 24 | Piercing mandrel                       |
| 25 | Tube clamp                             |
| 26 | White taper                            |
| 27 | Tube connector                         |
| 28 | Protective filter                      |
| 29 | Compensating reservoir                 |
| 30 | Tube clamp                             |
| 31 | White sealing cap                      |

#### Patient end tube with Luer Lock (art. no. 900153)

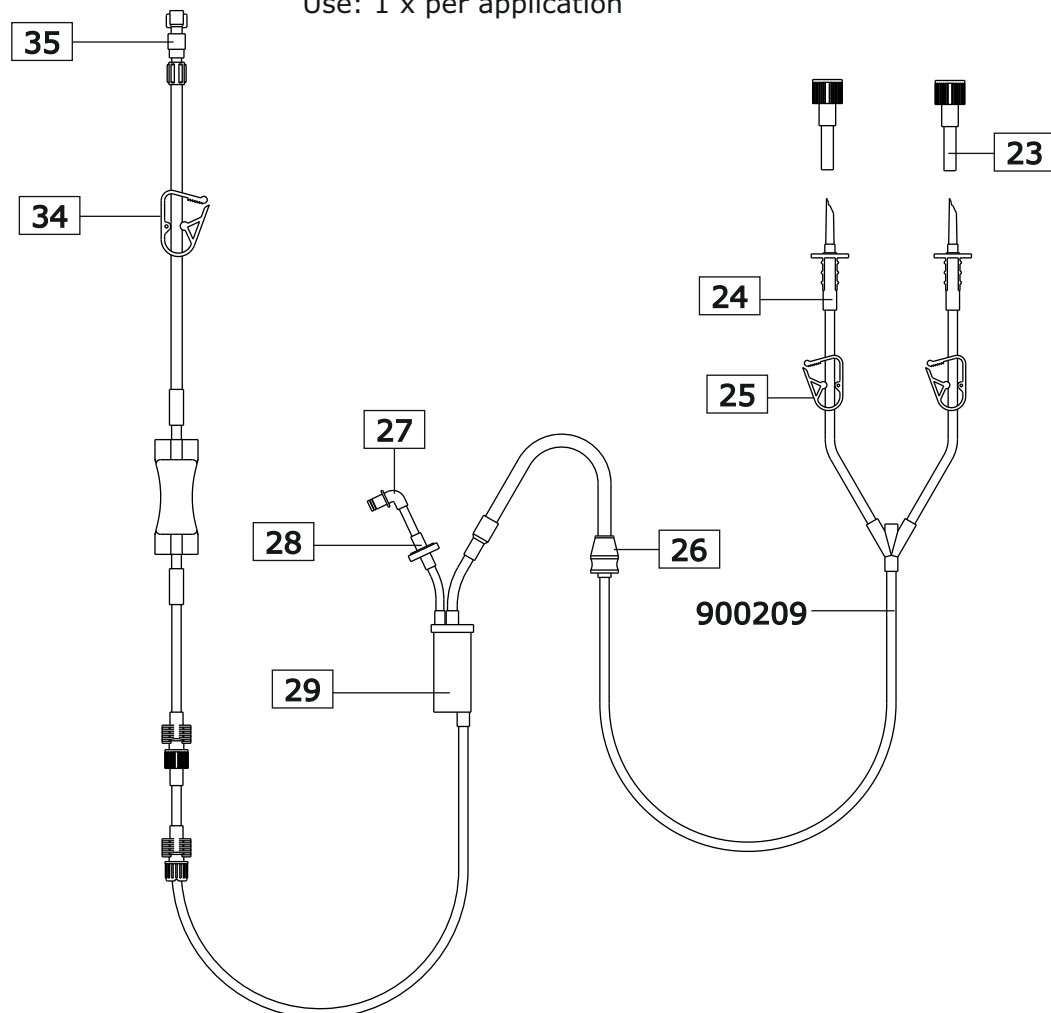
for transferring rinsing liquid between  
the daily tube set for arthroscopy and  
the arthroscopy shaft (for example,  
high-flow arthroscopy shaft; see  
compatibility list, page 23)  
Use: 1 x per application



|    |                     |
|----|---------------------|
| 32 | Blue sealing cap    |
| 33 | Sterile buffer zone |
| 34 | Tube clamp          |
| 35 | Luer-connector      |
| 36 | Sealing cap         |

#### Complete set for arthroscopy (art. no. 900209)

for the transferring and regulating the rinsing fluid  
via the pump system to the arthroscopy shaft  
(for example, high-flow arthroscopy shaft, see  
compatibility list, page 23)  
Use: 1 x per application



|    |                                                            |
|----|------------------------------------------------------------|
| 23 | Luer lock adapter for piercing mandrel, set art no. 900209 |
| 24 | Piercing mandrel                                           |
| 25 | Tube clamp                                                 |
| 26 | Fleima connector                                           |
| 27 | Tube connector                                             |
| 28 | Protective filter                                          |
| 29 | Compensating reservoir                                     |
| 34 | Tube clamp                                                 |
| 35 | Luer connection                                            |

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## **1. General Information, description and field of application**

The EBERLE arthroscopy pump P2 is for the expansion of joint spaces by filling the joint with fluid, e.g. NaCl or Ringer's solution, and is for building up a consequential positive overpressure, which, depending on the amount of pressure, works against the blood pressure of the patient, thereby suppressing bleeding into the endoscopic viewing area. At the same time, thanks to the built-up pressure in the joint, detached particles (such as bone or tissue fragments) can be flushed out of the patient by means of a surgical endoscopic procedure.



The arthroscopy pump P2 shall only be used by skilled and trained expert staff, while permanently monitoring the user's application, in the designated medical facilities!

The EBERLE arthroscopy pump P2 is intended for use in arthroscopic joint surgery of knee, shoulder, elbow, wrist or ankle. Use in other areas is prohibited!

The period of use of the pump corresponds to the usual arthroscopic procedures and is ø 10 min. – 45 min. for 1-10 applications per day.

The average period of use of a tube set (disposable product) is, in the case of the complete set as well as the patient set, between 10 min. and 45 min. The daily tube set for arthroscopy can remain at the device after the operation and be used for 1 – 10 uses per day (disposable product, 1 x per day), see: Brief description

Before operating the pump, please read these instructions carefully. They contain all necessary information to ensure an appropriate connection and operation of the device. Additionally, important safety and cleaning information is explained.

Keep these operating instructions in a safe and easily accessible place for future reference.



Utilizing or operating the device in non-conformance to these operating instructions can injure the patient and /or the operating personnel and damage the pump!

We thank you for your confidence and wish you much success with the EBERLE arthroscopy-pump P2!

## **2. Scope of Delivery**

After delivery of the arthroscopy-pump, at first the packaging should be checked for external damage.

The delivery of the arthroscopy-pump (art. no. 913031) includes the following items:

- |   |                             |                    |
|---|-----------------------------|--------------------|
| 1 | Arthroscopy pump P2         | article no. 913031 |
| 1 | Mains power cable 1,8m [23] | article no. 913035 |
|   | Operating instructions P2   |                    |

Should one or several components be damaged or found to be missing, please immediately contact an EBERLE representative or an authorized service or distribution center.

### 3. Symbols, symbol explanation

|                                                                                     |                                                                                                                                                                                                                       |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | Triangular icons advise the user to important information that must be observed.                                                                                                                                      |
|    | Circular icons with a diagonal bar indicate actions that are prohibited.                                                                                                                                              |
|    | This symbol alerts the user to an information that must be observed. Failure to observe this information can result in patient or user injury and / or damage the unit.                                               |
|    | This symbol alerts the user that the instructions for use must be followed.                                                                                                                                           |
|    | This symbol alerts the user to follow the operating instructions.                                                                                                                                                     |
|    | This symbol on the packaging, instruction manuals, and / or the device indicates that this product shall not be treated as consumer waste. The correct disposal will help to prevent health or environmental impacts. |
|   | This symbol indicates a device with one or more applied parts of Type BF                                                                                                                                              |
|  | This symbol on the packaging indicates the upper and lower storage temperature for the device.                                                                                                                        |
|  | This symbol on the packaging indicates the upper and lower humidity limits for the device.                                                                                                                            |
|  | This circular symbol indicates that products with damaged packaging must not be used.                                                                                                                                 |
|  | This symbol in conjunction with a date e.g. 2007-06, shows the usability of the product until the specified date.                                                                                                     |
|  | This symbol identifies products that have been sterilized in the final packaging and additional the sterilization process, in the illustrated case, the sterilization with ethylene oxide.                            |
|  | This circular symbol identifies products that are approved for single use only and may not be reused.                                                                                                                 |
|  | This circular symbol identifies products which may not be resterilized.                                                                                                                                               |
|  | This symbol identifies products that contain phthalates in the form of di-2-ethylhexyl phthalate.                                                                                                                     |

### 3.1 Safety Instructions and Warnings

|                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                       | Applying or operating the pump not in accordance with these operating instructions can result in the patient and / or the operator being injured and in components of the pump being damaged!                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <br> | The tube sets of the pump system (complete, daily and patient sets) are meant for single use and may not be reused or resterilized! Damaged or defective tube systems must no longer be used and must be exchanged immediately.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|                                                                                       | <p>Electrical medical devices and appliances underlie special requirements, need special measures pertaining to the electrical safety and electromagnetic interferences / environment. The installation of premises and devices must correspond to the requirements of the applying standards and to the applicable national regulations (also refer to chapter 10)! The pump is only reliably grounded, if the control unit is connected to a CEE 7/4 Schuko socket. Routinely check the plug and the cable and do not use in case of damage!</p> <p>The pump may only be switched on, once all connecting cables are completely connected. Prior to every application check the device with regard to possible damages and operational capability!</p> <p>If HF surgery is used, the “applied part” of the shaver system is to be removed from the patient. Mobile HF communication devices such as GSM telephones can also influence electrical medical devices! Do not operate these devices near electrical medical devices and keep them a distance of at least 30cm away!</p> <p>Position the pump out of the reach of the patient on a secure support.</p> <p>For exact pressure measurement, the pump is to be set up at the level of the operation area.</p> <p>Pay attention to the permissible environmental conditions!</p> |
|                                                                                     | Do not operate the device in hazardous areas. Using ignitable anesthetic gas in the near vicinity of the pump increases the risk of explosion.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|                                                                                     | The device must be disconnected from the mains for all maintenance, cleaning and disinfection work. The outer surfaces of the pump can be cleaned and disinfected with a disinfectant or cleaning agent. Make sure that no fluid penetrates into the device!                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|                                                                                     | Do not open the device! Risk of electric shock! Arbitrary opening, repairing or modifying of the device absolves us from any liability regarding the operational safety of the device and results in expiry of any claims whatsoever during the period of warranty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|                                                                                     | Using incompatible third-party components and cables may result in the patient and/or the operator being endangered or injured and may influence the service capability of the pump pertaining to electromagnetic interferences!                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | Ensure sufficient aeration at the vents on the rear of the device. Insufficient aeration results in damage or malfunction!                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|                                                                                   | The pump serves to regulate pressure and quantity of rinsing fluids in joint areas. Immediately switch off the device in case of malfunction or fault. The device does not have any significant performance features as defined by the standard aside from the clinical functions described. In case of faults, operate the pump separated from possibly disturbing sources. In the event the pump malfunctions (e.g. due to excess voltage), please have a replacement unit or an alternative in store (e.g. to take care of the patient using the gravity method)! |
|                                                                                   | Avoid contact with moving parts.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                                                                                   | Avoid using the pump in the immediate vicinity of other devices or stacked together with other devices, this may result in malfunctioning. If no other type of assembly is possible, the devices need to be monitored and proper functioning must be checked.                                                                                                                                                                                                                                                                                                        |
|                                                                                   | The respective service life of the pump should correspond to the ordinary application cycle.                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

#### **4. Connection and Start-Up of Device**

All components should again be checked visually for any signs of damage before connecting the device and starting it up.



A damaged packaging can lead to unsterile or damaged parts. Damaged parts and parts from damaged sterile packaging must not be used and replaced immediately!



The sequence shown below must always be observed for connection and start-up.

Please follow the steps described below:

- Switch off power switch [1] at the front panel of the pump (position **0**)
- Insert the mains power cable [22] into the connector [17] at the back of the device, now connect to mains.
- Establish equipotential bonding [16] (where required, by skilled personnel)  
Optional Potential equalization line, see compatibility list, page 16
- Switch on power switch [1] at the front of the pump (position **I**) and check the operational controls for correct functioning.

##### **4.1. Insertion of the tube set and the complete set for arthroscopy (art no. 900154 and art no. 900209)**

- If necessary, open the tube connector unit [11] by pressing the slide downwards.
- If necessary, open the locking lever [13] by turning clockwise and fold the clamping bracket [12] down counterclockwise.
- Remove the tube set from its sterile packaging.
- Insert the tube connector [27] into the tube connector unit [11] until it audibly engages.
- Position the compensating reservoir with the pump segment at the right below the tube intake (upper side of the compensating reservoir [29] [14] [29] covered completely by the tube intake [14])
- Center the pump segment around the pump rollers and then pull it downwards through the white marked recess
- Let the tube relax and slide the white tapper [26] from below into the therefore provided opening
- Position check of the pump segment (tube must be centered in the clamping roller). If necessary, correct the position of the pump segment in the area of the pump rollers
- Fold in the clamping bracket [12] clockwise
- Turn the locking lever [13] anticlockwise until it clicks into place in the clamping bracket [12]
- Press the patient end of the daily tube set into the recess [15]

**4.1.1. Check for leaks in the daily tube set and the complete set for arthroscopy**

- Seal the daily tube set or complete set for arthroscopy on the patient side (open in its delivered condition)
- Switch the pump on by means of the power switch [1], set a pressure greater 100 mmHg / 53 in H<sub>2</sub>O band then press the start/stop key [2]
- End control mode by pressing the Start/Stop button [2] again and check the set value. If this value remains unchanged for approx. 1 minute or if it goes up, the leak test has been passed.
- If this value drops within this minute, check to see if the tube connector [27] has been installed correctly or check the tube closure on the patient side. Now check the set value again. If the value then does not drop for one minute, the leak test has been passed.
- If these measures are not effective, check the centered position of the tube in the area around the pump rollers. Then begin the leak test again. If these measures are not successful, exchange the set for a new set.

**4.2. Connecting of Patient End-Tube with Luer-Lock (art. no. 900153)**

- The sterile person removes the patient end-tube with Luer-lock from the sterile packaging (leaving the sterile-packed sealing cap [36] in the packaging), checks the screw fittings and hands over the end with blue sealing cap [32] (sterile buffer zone [33]) to the non-sterile person.
- The unsterile person removes the blue sealing cap [32] at the patient end tube with Luer lock as well as the white sealing cap [31] at the daily tube set for arthroscopy and immediately connects both tubes together.
- The sterile person connects the remaining end to the Luer-connector of the arthroscopy shaft.
- The sterile person hands over the sterile packing, with the sealing cap [36] still inside, to the non-sterile person. **Store the sealing cap [36] in a safe place since it will be needed at the end of the surgery!**



The complete set, art. no. 900209, is meant for one-time use and is already delivered with a permanently connected end tube. It is not possible to change the patient end tube with this set.

### **4.3. Filling the daily tube set and the complete set for arthroscopy**



A complete filling of the compensating reservoir [29] can lead to damage of the pump. To reduce this risk, the reservoir must always be fixed below the tube intake [14].

- Connect at least one bag of infusion solution to the supply (Y port) of the tube set or complete set for arthroscopy and completely open all tube clamps. If only one bag is used, do not close the tube clamp [26] at the unused inlet.
- Now press the "Fill" key  [5] (key is flashing) until there are no more air bubbles visible in the rinsing medium at the patient end.
- Close the patient-side outflow of your instrument.

**The pump is now ready for operation!**

### **4.4. After the operation (daily / patient set)**

- Close the tube clamp [30] between the reservoir [28] and the sterile buffer zone [33].
- Stop the pump by pressing the start/stop key  [2]
- Open the sterile packaging of the sealing cap [36] (from the sterile packaging of the patient end tube set)
- Disconnect the tube connection on the second blue Luer lock connector and seal it immediately with the sealing cap [36]. The short tube section remains on the daily tube set until the next operation.

### **4.5. Preparing for the next operation ( daily / patient set)**

- The sterile person removes the patient end-tube with Luer-lock (art. no. 900153) from the sterile packaging, leaving the sterile-packed sealing cap [36] in the packaging, checks the screw fittings and hands over the end of the sterile buffer zone [33] with the blue sealing cap [32] to the non-sterile person.
- The unsterile person removes the blue sealing cap [32] at the patient end tube with Luer lock as well as the short tube section (sterile buffer zone [33]) with the blue Luer lock at the daily tube set for arthroscopy and immediately connects both tubes together.



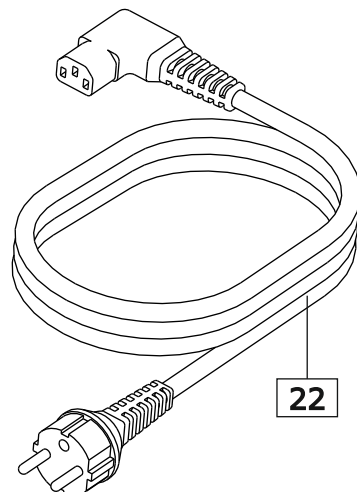
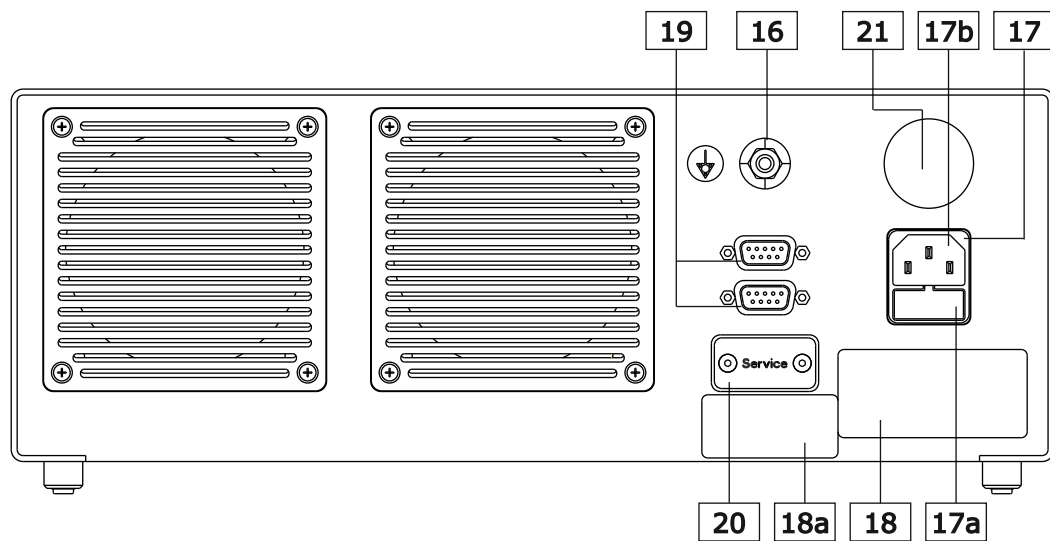
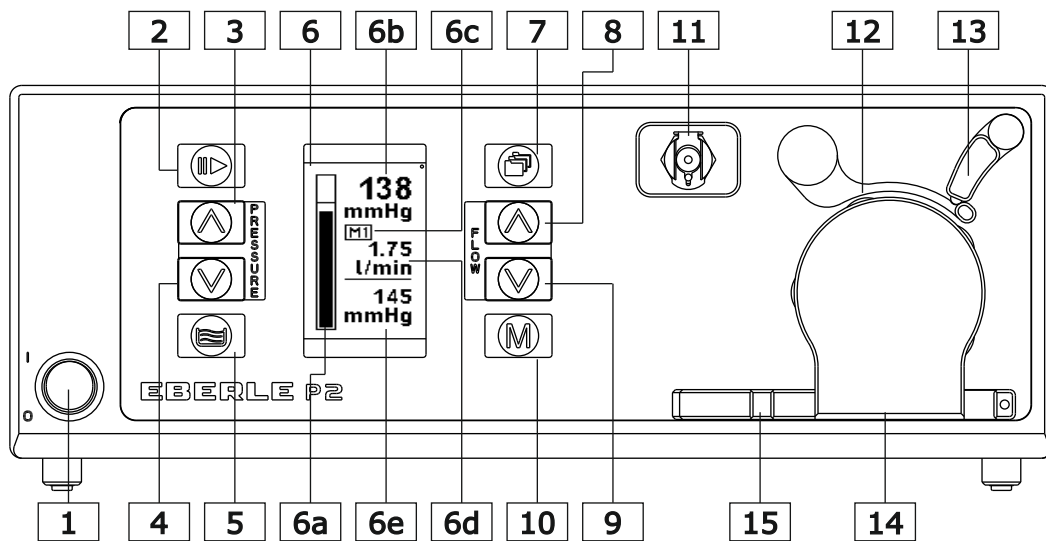
Two sterile buffer zones may never be connected to one another

- The sterile person connects the remaining end to the Luer-connector of the arthroscopy shaft.
- The sterile person hands over the sterile packing, with the sealing cap [36] still inside, to the non-sterile person. **Store the sealing cap [36] in a safe place since it will be needed at the end of the surgery!**
- Now fill the patient tube-set as described in [Filling of Patient End-Tube with Luer-Lock](#)

#### **4.6. After Last Surgery of the Day**

- Close all tube clamps
- Switch off pump with the power switch [1]
- Open the tube connector unit [11] by pressing the slide downwards. Pull off the tube connector [27] from the pump.
- Open the clamping bracket [12] in the counter-clockwise direction.
- Release the white taper [26] by pulling it down and remove the tube.
- Dispose of all tubes

## 5. Operating



|     |                                                                      |
|-----|----------------------------------------------------------------------|
| 1   | Power switch                                                         |
| 2   | Start/stop key                                                       |
| 3   | Key for pressure increase (delivery volume / contrast)               |
| 4   | Key for pressure decrease (delivery volume / contrast)               |
| 5   | Key for filling (rinsing function)                                   |
| 6   | LCD display                                                          |
| 6a  | Graphic pressure display                                             |
| 6b  | Current pressure                                                     |
| 6c  | Display of selected memory location                                  |
| 6d  | Display of maximum delivery volume                                   |
| 6e  | Display of set pressure                                              |
| 7   | Key for call of storage on memory location 1 to 3 (contrast setting) |
| 8   | Key to increase delivery volume                                      |
| 9   | Key to decrease delivery volume                                      |
| 10  | Memory key                                                           |
| 11  | Tube connector unit                                                  |
| 12  | Clamping bracket                                                     |
| 13  | Locking lever                                                        |
| 14  | Tube intake                                                          |
| 15  | Recess, patient end (tube set)                                       |
| 16  | Equipotential bonding                                                |
| 17  | Power connector                                                      |
| 17a | Mains fuse box with fuse holder                                      |
| 17b | Connector for power plug                                             |
| 18  | Type plate                                                           |
| 18a | Type plate                                                           |
| 19  | ECB (external communication)                                         |
| 20  | Service port                                                         |
| 21  | Certification label                                                  |
| 22  | Mains power cable                                                    |

## 5.1 Key assignment

### Power switch [1]

Switch on the device by pressing the power button.

The power switch has two positions:

|   |     |          |
|---|-----|----------|
| I | ON  | switched |
| O | OFF | off      |

If the device is switched on a green indicator light illuminated in the switch.

### Start/Stop key [2]

Use this key to start (acoustic signal 1x) or stop (acoustic signal 2x) the pumping process. During operation, the illumination of the key flashes to indicate an activated pump function.

### Key for pressure increase/decrease [3-4]

Use these key to change pressure.

To adjust the pressure, press the keys  [3] and  [4] until the required pressure is reached.

For safety reasons, the pressure increase from 120 mmHg/64 inH<sub>2</sub>O is interrupted every 5 mmHg/in H<sub>2</sub>O. A further increase in pressure is only possible after releasing the button  [3].

### Key: Filling/rinsing function [5]

This button is used to fill the tube set as described in "Filling the tube set and complete set for arthroscopy".

In normal operation, this button can be used to briefly increase the pressure. When this is done, the button  [5] flashes and the pressure increase can be changed by using the  [3] and  [4] buttons. Pressing it again ends the rinsing function.



When the rinsing function is performed, the set pressure of the normal operation is increased by 50%, but no more than 200 mmHg/107 inH<sub>2</sub>O, for a period of 45 seconds.

### Key: Memory [10], memory location [7]

These keys can be used to retrieve and store the application data such as flow and pressure settings.

The saved values can be recalled using the key  [7]. Up to 3 memory locations can be preset depending on the specific application (e.g. knee with tourniquet, hip, shoulder). For safety reasons, it is not possible to change between memory locations during standard operation.

To save the values, press key  [10] for approx. 1 second until the memory location [6c] flashes in the display. The confirmation of the saved value flashes until the key is released. The values are saved to the set memory area.

For safety reasons, saving values greater than 120 mmHg / 64 inH<sub>2</sub>O is not possible.

### Key: Increase or decrease of maximum delivery volume [8-9]

The maximum delivery volume is changed using these keys.

Press the keys  [8] or  [9] until the desired maximum delivery volume is set.

## 5.2 Contrast Setting

To set the contrast of the display press key  [7] and keep it pressed while adjusting the desired contrast value by means of the keys  [3] and  [4].

## 5.3 Setting of the specified unit of measure for pressure

To change the unit of measure for pressure, switch the device off at the power switch [1] (position ). Now simultaneously press the buttons  [10] and  [9]. Now select the desired unit of measurement with the  [3]  [4] buttons and confirm the selection with the  button.

## 5.4 Connectors/Ports



Never touch the patient and the connections on the control unit at the same time!

### Tube connector unit [11], Tube connector unit [12/13/14]

Connector to mount and control the Tube-Set and the Complete-Set for Arthroscopy.

### Equipotential bonding [16]

Generally, the control unit is earthed by the 3-pin safety plug, if it is connected – as stipulated - to an earthed power cable. When this device is operated in rooms of application group 2 according to DIN VDE 0107 it is indispensable that the device is connected to the stationary equipotential bonding of the room or of the medical device cart by a corresponding cable. The device has an according plug connector for this (according to DIN 42801).

### Power connector [17]

The plug of the power cable is connected to this inlet connector for non-heating apparatus [17]. Only use the delivered mains power cable [22]. The fuses of the device are located in the fuse holder [17a]. Please only use the fuse types that are mentioned on the type plate [18]! How to exchange the fuses is explained in the service chapter of these operating instructions.

### ECB [20]

Coded connection (Eberle Communication BUS)



The ECB port is used for the mutual control of Eberle devices. Only use EBERLE approved equipment and connecting cables for connection to the ECB.

### Service Port [21]

Service and diagnostic port



The service port is for diagnostics, and may be used only by authorized personnel and for service purposes only.

## 6. Device-specific Symbols

|                                                                                   |                                   |
|-----------------------------------------------------------------------------------|-----------------------------------|
|  | Start/Stop [2]                    |
|  | Pressure increase [3]             |
|  | Pressure decrease [4]             |
|  | Filling [5]                       |
|  | Memory location [7]               |
|  | Increase delivery volume [8]      |
|  | Decrease delivery volume [9]      |
|  | Memory key [10]                   |
|  | Power switch on [1]               |
|  | Power switch off [1]              |
|  | Potential equalization connection |

## 7. Preparation of Device and Accessories

Prior to the first use the device must be cleaned in accordance with the procedure described under point 7.1. It cannot be sterilized.

The cleaning, disinfection, and sterilization methods apply that are listed in these or in other instructions that may possibly be included in the delivery of the device or of the accessories. This does not apply to accordingly designated, disposable articles that come in sterile packing

Insufficient cleaning, disinfection, and/or sterilization can result in the patient and/or the operator being infected. The operator is responsible for the validation of these processes.

### 7.1. Cleaning of Device

The outer surfaces of the device can be cleaned and disinfected with a disinfectant or cleaning agent for spray/wipe disinfection. Here, always observe the specifications of the disinfectant manufacturer, DGHM / VAH as well as RKI with regard to concentration and reaction times.

Cleaning agents and application:

Bacillol® AF, Bode Chemie GmbH, Hamburg  
Spray and wipe disinfection  
Undiluted, 5 min.

|                                                                                     |                                                                                                           |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|
|  | The device must be disconnected from the mains prior to any kind of cleaning and disinfecting procedures! |
|  | Attention must be paid that no liquid enters the device during cleaning!                                  |

## 8. Service, Maintenance, Inspection and Disposal



Defective devices may only be repaired by authorized experts and only by using original parts.

Replacing of the mains fuse can be performed as described below by local qualified personnel:

- Switch off power switch [1] at the front of the device (position **O**)
- Disconnect power plug [22] and equipotential bonding [16] from the device
- With a flathead screwdriver or any other suitable tool lift the fuse holder out of the mains-fuse box [17a]
- Take out defective fuses and insert new fuses according to type plate [18]
- Insert fuse holder into mains-fuse box [17a]
- Connect power plug [22] and equipotential bonding [16]
- Switch on power switch [1] (position **I**)

Regular servicing can help to detect defects and malfunctions at an early stage and thereby possibly extend the service life of the device. Nevertheless, servicing is not mandatory.

Independent of the country-specific safety regulations (e.g. accident prevention regulation, inspection interval regulation), we recommend yearly function and safety checks according to VDE 751 by an authorized service center. This check should be displayed on the device by means of a sticker.

National regulations must be observed, should disposal of the device become necessary.

## 9. Trouble Shooting

| Symptom                                                                                                                                                        | Possible Cause                                                                                          | Remedy                                                                                                                                                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Complete failure of device <ul style="list-style-type: none"> <li>- out of operation</li> <li>- power switch on</li> <li>- power switch lamp is off</li> </ul> | <ul style="list-style-type: none"> <li>- power supply failed</li> <li>- mains fuse defective</li> </ul> | <ul style="list-style-type: none"> <li>- check power supply</li> <li>- replace fuse on device</li> </ul>                                                     |
| Pump causes irregular pressure fluctuations                                                                                                                    | <ul style="list-style-type: none"> <li>- protective filter wet [28]</li> </ul>                          | <ul style="list-style-type: none"> <li>- replace day's tube-set</li> </ul>                                                                                   |
| Level in the compensating reservoir [29] is too high                                                                                                           | <ul style="list-style-type: none"> <li>- leakage</li> </ul>                                             | <ul style="list-style-type: none"> <li>- Check whether the tube connector [27] is correctly mounted. If required, replace the entire tube system.</li> </ul> |
| Pump does not reach the set pressure                                                                                                                           | <ul style="list-style-type: none"> <li>- set flow rate too low</li> </ul>                               | <ul style="list-style-type: none"> <li>- increase max. flow rate</li> </ul>                                                                                  |

|                                               |                                                                                                     |                                                                                                                                                                                                    |
|-----------------------------------------------|-----------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Display can hardly be read or not at all      | - set contrast too high/lo                                                                          | - adjust contrast as described in the chapter contrast setting 5.2<br>- restart the device                                                                                                         |
| Pump does not reach the pressure in patients. | - Arthroscopy shaft does not permit the required pressure flow.<br><br>- Pump below operative field | - Cleaning of the rinsing openings of the arthroscopy shaft or replacement by high-flow arthroscopy shaft art. no. 900235<br><br>- Set the pump at the level of the operation field pressure flow. |

Device failures or disturbances resulting due to the presence of electromagnetic disturbances are not to be expected (also refer chapter 3.1 / chapter 10).

### 9.1. Software Version

After switching on the device, the software version (for example, 2.00), motor controller, APP and hardware are shown for about two seconds.

### 9.2. Factory Settings

To delete the custom settings you can activate the factory default settings with a software reset. Turn the power switch [1] off (position **0**). Now press simultaneously  [3] and the  [4] key, keep it pressed and switch on the device. Hold the keys down until the message "**Settings loaded**" appears.

Did the first factory reset fail, rerun the software reset. Should this not be successful, please contact the service.

**10. Technical Data**

|                                                                                |                                                                                         |                                                                                                                             |
|--------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| <b>Safety classification, IEC 601-1</b>                                        | Protective class<br>Application part                                                    | I<br>Typ BF                                                                                                                 |
| <b>Classification MDD 93/42/EEC</b>                                            | Risk class                                                                              | IIa                                                                                                                         |
| <b>Electrical data</b>                                                         | Supply voltage<br>Mains frequency<br>Mains fuse<br>Max. power input                     | 100-240 V/AC<br>50/60 Hz<br>2xT1AH250V<br>100 VA                                                                            |
| <b>Possible EM- or other disturbances</b><br>Interference<br>emission/immunity | IEC 60601-1-2<br>Group/Class<br>IEC 60601-1-2<br>Classification<br><br>IEC 61000-3-2    | I / B<br><br>Environment: professional med.<br>care institutions<br><br>A                                                   |
| <b>IP-Code</b>                                                                 | solid particle protection<br>liquid ingress protection                                  | IP30                                                                                                                        |
| <b>Pressure ranges</b>                                                         | Pressure                                                                                | 0-200 mmHg/0-107 inH <sub>2</sub> O                                                                                         |
| <b>Setting ranges</b>                                                          | Setting range<br>Working range<br>Memory range                                          | 10-200 mmHg or 5-107 inH <sub>2</sub> O<br>0-200 mmhH or 0-107 inH <sub>2</sub> O<br>10-120 mmHg or 5-64 inH <sub>2</sub> O |
| <b>Pressure flow</b>                                                           | Flow rate                                                                               | 0-1500 ml/min                                                                                                               |
| <b>Environmental conditions</b>                                                | Temperature<br>Relative humidity<br>maximum altitude<br>minimum atmospheric<br>pressure | 15 to 35°C<br>30-75% not condensed<br>2000m<br>795hPa                                                                       |
| <b>Storage and transportation conditions</b>                                   | Temperature<br>Relative humidity<br>Shelf life                                          | -10 to 70°C<br>30-75% not condensed<br>Storage time without use<br>max. 2 years                                             |
| <b>Mechanical data</b>                                                         | Dimensions: L/W/H in mm<br>Weight                                                       | 300x350x125mm<br>7800g                                                                                                      |
| <b>Packaging</b><br>(collapsible box with inlay)                               | dimensions: l/w/h in mm<br>weight corrugated cardboard<br>weight PE insert              | 470x470x365mm<br>1200 g<br>1100 g                                                                                           |
| <b>Application cycle</b>                                                       | 1-10 uses of the pump per day for a usage time of 10-45 min                             |                                                                                                                             |
| <b>Accessories</b>                                                             | see compatibility list (page 23)                                                        |                                                                                                                             |

#### Guidelines and Manufacturer's Declaration – Electromagnetic Emissions

The Arthroscopy Pump P2 is destined for operation in the electromagnetic environment mentioned below. The customer or the user of the Arthroscopy Pump P2 should ensure that it is used in such an environment.

| Emission measurements                                       | Conformity | Electromagnetic environment – guidelines                                                                                                                                                                                                                                                                                                                                                                                                    |
|-------------------------------------------------------------|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| HF emissions<br>pursuant to CISPR 11                        | group 1    | The Arthroscopy Pump P2 uses HF energy only and exclusively for its internal function. Therefore, the HF emission is extremely low, and it is very unlikely that neighbouring electronic devices will be disturbed.<br><br>The Arthroscopy Pump P2 is suitable for use in all establishments, including domestic establishments and those directly connected to the PUBLIC MAINS SUPPLY that supplies buildings used for domestic purposes. |
| HF emissions<br>pursuant to CISPR 11                        | class B    |                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Harmonic components<br>pursuant to IEC 61000-3-2            | class A    |                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Voltage fluctuations / flicker<br>pursuant to IEC 61000-3-3 | conforms   |                                                                                                                                                                                                                                                                                                                                                                                                                                             |

#### Guidelines and Manufacturer's Declaration – Electromagnetic Emissions

The Arthroscopy Pump P2 is intended for operation in environments as stated below. The customer or user of the Arthroscopy Pump P2 shall ensure that it is operated in such an environment.

| Immunity test                                                                                       | IEC 60601 test level                                                                                                                                                                                                              | Compliance level                                                                                                                                                                                                                  | Electromagnetic environment - guidance                                                                                                                                                                                                                                                                                                 |
|-----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ESD IEC 61000-4-2<br>IEC 61000-4-2                                                                  | ± <b>8 kV</b> contact<br>± <b>15 kV</b> air                                                                                                                                                                                       | ± <b>8 kV</b> contact<br>± <b>15 kV</b> air                                                                                                                                                                                       | Floors shall be made out of wood or concrete or shall be covered with ceramic tiles. If the floor is covered with synthetic material the relative humidity must amount to at least 30 %.                                                                                                                                               |
| Bursts<br>IEC 61000-4-4                                                                             | ± <b>2 kV</b> power supply lines<br>100kHz repetition frequency<br>± <b>1 kV</b> input/output                                                                                                                                     | ± <b>2 kV</b> power supply lines<br>100kHz repetition frequency<br>± <b>1 kV</b> input/output                                                                                                                                     | The quality of the supply voltage shall correspond to a typical environment as is found in commercial or hospital locations.                                                                                                                                                                                                           |
| Surges<br>IEC 61000-4-5                                                                             | ± <b>1 kV</b> differential mode<br>± <b>2 kV</b> common mode                                                                                                                                                                      | ± <b>1 kV</b> differential mode<br>± <b>2 kV</b> common mode                                                                                                                                                                      | The quality of the supply voltage shall correspond to a typical environment as is found in commercial or hospital locations.                                                                                                                                                                                                           |
| Voltage drops,<br>short interruption and<br>fluctuations of the<br>supply voltage<br>IEC 61000-4-11 | <b>0 %</b> UT; 0,5 Periode<br>dip in UT; 0,5 cycle<br><b>0 %</b> UT; 1 Periode<br>dip in UT; 1 cycle<br><b>70 %</b> UT; 25/30 Perioden<br>dip in UT; 25/30 cycles<br><b>0 %</b> UT; 250/300 Perioden<br>dip in UT; 250/300 cycles | <b>0 %</b> UT; 0,5 Periode<br>dip in UT; 0,5 cycle<br><b>0 %</b> UT; 1 Periode<br>dip in UT; 1 cycle<br><b>70 %</b> UT; 25/30 Perioden<br>dip in UT; 25/30 cycles<br><b>0 %</b> UT; 250/300 Perioden<br>dip in UT; 250/300 cycles | The quality of the supply voltage shall correspond to a typical environment as is found in commercial or hospital locations. If the user of the Arthroscopy Pump P2 requires continued functioning also in the event the power supplies are interrupted, it is advisable to energize the Arthroscopy Pump P2 with an USV or a battery. |
| Supply frequency magnetic fields<br>at (50/60) Hz<br>IEC 61000-4-8                                  | <b>30 A/m</b>                                                                                                                                                                                                                     | <b>30 A/m</b>                                                                                                                                                                                                                     | Power frequency magnetic fields shall correspond to a typical environment as is found in commercial or hospital locations.                                                                                                                                                                                                             |

|                                                                                                      |                                                                                                                     |                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Conducted RF disturbances<br/>IEC 61000-4-6</p> <p>Radiated RF disturbances<br/>IEC 61000-4-3</p> | <p><b>3 V eff. *</b><br/>150 kHz – 80 Mhz<br/>(*6 V eff. in ISM bands)</p> <p><b>3 V/m</b><br/>80 MHz – 2,7 GHz</p> | <p><b>3 V eff. *</b><br/>150 kHz – 80 Mhz<br/>(*6 V eff. in ISM Bändern)</p> <p><b>3 V/m</b><br/>80 MHz – 2,7 GHz</p> | <p>Portable and mobile communication devices shall not be used in closer proximity to the Arthroscopy Pump P2 or its cables than the recommended safety distance:</p> <p><b>d = 1,17/√P</b> 150 kHz – 80 Mhz<br/><b>d = 1,2 √P</b> 80 MHz - 800 Mhz</p> <p><b>d = 2,3/√P</b> 800 MHz - 2,7 Ghz</p> <p>The field strength of stationary transmitters, as determined by a field survey, shall be less than the compliance level for all frequencies. Disturbances are possible in the close proximity of devices showing the following symbol.</p>  |
|------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| Test determinations for INTERFERENCE IMMUNITY of ENCASEMENTS<br>against high-frequency wireless communication devices |                                    |                                                                                |                                                     |                        |               |                                               |
|-----------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------------------------------------------------------------------------|-----------------------------------------------------|------------------------|---------------|-----------------------------------------------|
| Test frequency<br>Mhz                                                                                                 | Frequency band <sup>a</sup><br>Mhz | Radio service <sup>a</sup>                                                     | Modulation <sup>b</sup>                             | Maximum<br>Output<br>W | Distance<br>m | INTERFERENCE<br>IMMUNITY TEST<br>LEVEL<br>V/m |
| 385                                                                                                                   | 380 to 390                         | TETRA 400                                                                      | Pulse modulation <sup>b</sup><br>18 Hz              | 1,8                    | 0,3           | 27                                            |
| 450                                                                                                                   | 430 to 470                         | GMRS 460,<br>FRS 460                                                           | FM <sup>c</sup><br>± 5 kHz deviation<br>1 kHz sinus | 2                      | 0,3           | 28                                            |
| 710                                                                                                                   | 704 to 787                         | LTE band 13, 17                                                                | Pulse modulation <sup>b</sup><br>217 Hz             | 0,2                    | 0,3           | 9                                             |
| 745                                                                                                                   |                                    |                                                                                |                                                     |                        |               |                                               |
| 780                                                                                                                   |                                    |                                                                                |                                                     |                        |               |                                               |
| 810                                                                                                                   | 800 to 960                         | GSM 800/900,<br>TETRA 800,<br>iDEN 820,<br>CDMA 850,<br>LTE band 5             | Pulse modulation <sup>b</sup><br>18 Hz              | 2                      | 0,3           | 28                                            |
| 870                                                                                                                   |                                    |                                                                                |                                                     |                        |               |                                               |
| 930                                                                                                                   |                                    |                                                                                |                                                     |                        |               |                                               |
| 1 720                                                                                                                 | 1 700 to 1 990                     | GSM 1800;<br>CDMA 1900;<br>GSM 1900;<br>DECT;<br>LTE band 1, 3,<br>4, 25; UMTS | Pulse modulation <sup>b</sup><br>217 Hz             | 2                      | 0,3           | 28                                            |
| 1 845                                                                                                                 |                                    |                                                                                |                                                     |                        |               |                                               |
| 1 970                                                                                                                 |                                    |                                                                                |                                                     |                        |               |                                               |

| Test frequency<br>Mhz | Frequency band <sup>a</sup><br>Mhz | Radio service <sup>a</sup>                                      | Modulation <sup>b</sup>                 | Maximum<br>Output<br>W | Distance<br>m | INTERFERENCE<br>IMMUNITY TEST<br>LEVEL<br>V/m |
|-----------------------|------------------------------------|-----------------------------------------------------------------|-----------------------------------------|------------------------|---------------|-----------------------------------------------|
| 2 450                 | 2 400 to 2 570                     | Bluetooth,<br>WLAN 802.11<br>b/g/n,<br>RFID 2450,<br>LTE band 7 | Pulse modulation <sup>b</sup><br>217 Hz | 2                      | 0,3           | 28                                            |
| 5 240                 | 5 100 to 5 800                     | WLAN 802.11 a/n                                                 | Pulse modulation <sup>b</sup><br>217 Hz | 0,2                    | 0,3           | 9                                             |
| 5 500                 |                                    |                                                                 |                                         |                        |               |                                               |
| 5 785                 |                                    |                                                                 |                                         |                        |               |                                               |

NOTE: If necessary, the distance between the transmitting antenna and the ME DEVICE or ME SYSTEM may be reduced to 1 m in order to reach the INTERFERENCE IMMUNITY TEST LEVEL. The 1 m test distance is allowed according to IEC 61000-4-3

<sup>a</sup> For some radio services, only the frequencies for the radio connection from the mobile communication device to the base station (uplink) were included in the table.

<sup>b</sup> The carrier must be modulated with a square wave signal with a 50% duty cycle.

<sup>c</sup> As an alternative to frequency modulation (FM), a pulse modulation with 50 % duty cycle with 18 Hz may be used since this, if not the actual modulation as well, would constitute the worst case.

#### Recommended safety distances between portable and mobile RF telecommunication devices and the Arthroscopy Pump P2

The Arthroscopy Pump P2 is intended for use in an electromagnetic environment, in which RF disturbances are controlled. The user (customer) of the Arthroscopy Pump P2 may help to prevent electromagnetic disturbances by observing the minimum distance between portable and mobile RF telecommunication devices (transmitters) and the Arthroscopy Pump P2 – dependent on the output power of the communication device as stated below.

| Nominal power of transmitter<br>W | Safety distance dependent on transmitter frequency<br>m |                                       |                                        |
|-----------------------------------|---------------------------------------------------------|---------------------------------------|----------------------------------------|
|                                   | 150 kHz – 80 MHz<br>$d = 1,17\sqrt{P}$                  | 80 MHz - 800 MHz<br>$d = 1,2\sqrt{P}$ | 800 MHz - 2,7 GHz<br>$d = 2,3\sqrt{P}$ |
| 0,01                              | 0,12                                                    | 0,12                                  | 0,23                                   |
| 0,1                               | 0,37                                                    | 0,38                                  | 0,73                                   |
| 1                                 | 1,17                                                    | 1,2                                   | 2,3                                    |
| 10                                | 3,70                                                    | 3,8                                   | 7,3                                    |
| 100                               | 11,7                                                    | 12                                    | 23                                     |

If the nominal power of certain transmitters is not stated in above table, the protective distance d in meters (m) can be determined using the equation given in the respective column. Here, P is the maximum nominal power of the transmitter in watt (W) according to the details given by the manufacturer of the transmitter.

Note 1: For 80 MHz and 800 MHz the higher frequency range applies.

Note 2: These guidelines may not be applicable for all cases. The propagation of electromagnetic factors is influenced by the absorption and reflection of buildings, objects, and humans.

## 11. Compatibility

When operating the EBERLE pump P2 only use the EBERLE components listed in the table below!

| Article no.                                                                                                                          | Description                                                             |
|--------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|
| 900153                                                                                                                               | Patient end-tube with Luer-lock                                         |
| 900154                                                                                                                               | Daily tube set for arthroscopy                                          |
| 900209                                                                                                                               | Complete set for arthroscopy                                            |
| 900235                                                                                                                               | High-flow arthroscopy shaft for optics Ø 4.0 mm, 2x stopcock, rotatable |
| 900241                                                                                                                               | Potential equalization line POAG 1 meter                                |
| 900252                                                                                                                               | High-flow arthroscopy shaft, quick-lock for optics Ø 4.0 mm             |
| 900305                                                                                                                               | High-flow arthroscopy shaft 30°, 2x stopcock rotatable, Ø 4,0 mm        |
| 913035                                                                                                                               | Mains power cable 1,8m                                                  |
| 913036                                                                                                                               | ECB connecting cable 1,0m                                               |
| Future EBERLE products can also be compatible. Detailed information regarding this can be obtained from every EBERLE representative. |                                                                         |



Using non-compatible foreign auxiliaries can result in the patient and/or the operator being endangered or injured!

## 12. Warranty

The warranty period for the EBERLE arthroscopy pump P2 is 12 months. Faults resulting from faulty material and/or workmanship will be rectified free of charge by the manufacturer during this warranty period.

Transportation costs and shipping risks cannot be assumed by the manufacturer. Over and above, the details apply that are stated in our General Terms and Conditions of Business.



Do not open device! Unauthorized opening, repairing and modifying the device results in immediate expiry of the warranty obligation and discharges us of any liability regarding the operational safety!

**13. Addresses****Development, Production  
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