ARTHROSKOPIE PUMPE
54-300.01

Operator`s Manual

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Intended use

The Arthroskopiepump has been designed especially for use in arthroscopy and shall be operated by trained personnel only.

Dear customer

Please read this manual carefully before putting the equipment to use for the first time. This will prevent damages that may otherwise occur due to faulty connections or incorrect operation.

Use this arthroscopy pump only for the purpose described in this Operating Manual. We assume no liability for damages resulting from any misuse of the instrument.

This Operating Manual provides no detailed description of endoscopic or any other special treatment procedures!

1. Introduction

The arthroscopy pump 54-300.01 is intended for producing a safe and continuing joint expansion by pumping a rinsing solution into the joint during arthroscopic procedures.
Thus the pump facilitates surgical procedures and guarantees clear visibility by continuous rinsing.

Unit components:
- Arthroscopy pump
- Tube set for pump section
- Tube set for patient section
- Pressure sensor

Pressure can be preset by the operator by means of pushbuttons and may be readjusted independently during the arthroscopic procedure, if necessary.
The speed is adjusted automatically.
The rinsing solution is supplied to the arthroscopy pump via the tube set from two reservoir bags attached to infusion stands.

CAUTION ***This device is to be used only under the supervision of a trained and licensed physician.***
This device should not be used be untrained personnel or used for indications other than those described in this Operating Manual.

2. Specifications

- Arthroscopy pump

Type:	54-300.01
Dimensions (W x D x H):	360 x 268 x 150 mm
Weight:	14 kg
Nominal input voltage:	230 VAC / 50 Hz
Primary fuses:	2 x 3A
Power consumption:	90 VA
Pressure:	0 - 280 mmHg
Speed:	200 - 450 rpm
Flow rate:	0-1500 ml/min
Pressure control:	electronic
Class of protection:	I
Applicator:	type BF
Type of protection:	IP X0
EN category:	2a
Cleaning:	Surface cleaning with mild detergent

- Tube set for patient section

- Tube set for pump section

- Pressure sensor

- Power cable

Type:	230 V, 10 A, three-pole

3. Safety notes

Please read this Operating Manual carefully before putting the arthroscopy pump to use.
These instructions provide you with information about the correct operation and handling of the arthroscopy pump.

The arthroscopy pump complies with all safety and health-related requirements, meets the state-of-the-art design guidelines and is safe to operate.
However, this unit may become a source of risk if these instructions for use and operation are not or not correctly followed or if the unit is operated by non-trained personnel and/or its application is not in accordance with the intended use.

No interference is known to occur between the arthroscopy pump and any other equipment used in the OP.

There are no known contra-indications for the arthroscopy pump if applied in accordance with the intended use.

Should there be indications of changes in the performance of the unit (e.g. pressure changes, noise, faulty displays, etc.) please inform the manufacturer without delay.

When applied in conformity with its intended use the arthroscopy pump causes no risk of explosion or fire under the influence of magnetic fields, interfering electric signals, electrostatic discharge, pressure and the like.

The following safety notifications are used in this Operating Manual:

CAUTION	***Pump damage may occur if directions shown under this heading are not or not correctly followed.***
NOTE	***More effective and easier application may be achieved if directions shown under this heading are followed.***

4. Inspection and maintenance

To ensure the fully functional condition of the arthroscopy pump it is essential to perform an inspection after receiving the unit.

Carefully unpack the unit and inspect the housing for scratches, indentations and other signs of physical damage.

If the pump is in perfect physical condition, perform a first functional test by following the sections *Startup* and *Operation.*

In case of an unit failure please contact the manufacturer.

Prior to each use of the pump check that the power cable is in good operating condition, i.e. that the cable is free of fissures, cracks or interrupted conductors.

The pump should be inspected for safe and proper operation by a qualified technician at least every six month.
Once a year the pup should be subjected to a complete check-up by the manufacturer.

5. Unit description

The ON/OFF main switch (1) is located in the lower left portion of the front panel.

Further right: the START/STOP button (2), the LED indicator SENSOR (3) and the TEST button (4) with the LED indicator ERROR (5).

Below are the PRESSURE display (6) with the related MIN (7) and MAX (8) pushbuttons for adjusting the pressure underneath.

Located on the mechanics protective cover (12) on the right side of the front panel are the sensor connector (9) and the hook for the sensor chamber (10).

On the rear panel are the fuses (13), power input connector (14), equipotential connector (15) with the equipotential label (16) and the nameplate (17).

6. Startup

- Take the arthroscopy pump out of its package and place it on the equipment cart or a solid surface. Prevent it from dropping.
- Plug the power cable into the power input connector (14) on the rear panel of the pump.
- Connect the power cable to a suitable wall outlet.
- Have the sterile tube set and pressure sensor handy.

CAUTION ***The arthroscopic pump must only be operated with the origina tube sets***

- Close the tube clamps (18, 19, 20).
- Slide the pressure sensor over the short end of the tube (25) at the sensor chamber (21) and screw it on.
- Connect the end of the patient section to the free end of the pump section and screw it on. The system is now closed and can be handed over to the assistant for connection to the unit.
- Insert the puncturing needles (22) of the tube sets into the liquid reservoir bags (23) suspended from the stand.

HINWEIS ***When connecting only one bag the free tube must be closed with an additional clamp.***

- Place the silicon portion of the pump tube into the machine section (in direction of the arrow) and secure it.
- Attach the sensor chamber (21) to the sensor chamber hook (10).
- Connect the pressure sensor to the connector (9) (the SENSOR indicator lights up when the sensor is not connected).

7. Operation

- Put the main switch (1) to position “ON”.
- Use the pushbuttons (7, 8) to preset the desired pressure.
- The speed is adjusted automatically
- Open tube clamp (18).
- Press the START button (2) and vent the tube set (a liquid level forms in the sensor chamber (21).
- Close the tube clamp (20).

NOTE ***The pump stops as soon as the preset pressure level is reached in the sensor chamber (21). At the same time, this feature serves as a pressure sensor test. If the pump continues to run after closing tube clamp (20) the pressure sensor must be replaced; make sure to maintain sterile conditions.***

- After connecting the patient tube to a separate supply cannula or to the arthroscopic shaft open tube clamp (20). Now the pump fills the joint and maintains the preset pressure during the arthroscopic procedure.

CAUTION ***Always turn the pump off before manipulating the machine section.***

- When the connected reservoir bag is empty, close tube clamp (18) and open the other tube clamp (19).
- Insert the puncturing needle (22) of the tube set into the other reservoir bag (23).
- At the end of the arthroscopic procedure press the STOP button (2).
- Close tube clamp (20).

NOTE ***For each subsequent arthroscopy the patient section must be reconnected. The pump tube may be used for several arthroscopies.***

NOTE ***Prior to connecting a new pump tube to the arthroscopy pump you must set switch (1) to “OFF” and press the STOP button (2).***

8. Replacing the pressure sensor or the tube set

Exchanging the sensor

CAUTION ***Press the STOP button (2) before replacing the pressure sensor.***

- Briefly open tube clamp (20) so that the pressure of the sensor chamber (21) is relieved.
- Remove the old pressure sensor.
- Place the new pressure sensor on the short tube end of the sensor chamber and screw it on.
- Connect the pressure sensor to a wall outlet (the SENSOR (3) indicator lights up when the sensor is not connected).

Exchanging the pump tube

CAUTION ***Turn the pump off (OFF) before replacing the pump tube***

- The pump tube may be used for several arthroscopies.
- Remove the old tube.
- Place the silicon portion of the pump tube into the machine section (in direction of the arrow) and secure it.
- Attach the sensor chamber (21) to the sensor chamber hook (10).
- Slip the pressure sensor over the short tube end of the sensor chamber and screw it on.
- Slip the patient section over the free end of the pump section and screw it on.
- Insert the puncturing needle (22) of the tube set in the reservoir bag.

Replacing the patient tube

CAUTION ***Turn the pump off (OFF) before replacing the pump tube***

- Always reconnect the patient section for every subsequent arthroscopic procedure.
- Remove the tube from its package while keeping it sterile.
- Close the tube clamps (18, 19, 20).
- Slide the blue end of the patient section over the free end of the pump section and screw it on.
- After connecting the other end of the patient tube to a separate inflow cannula or the arthroscopic shaft open the tube clamp (20). Now the pump fills the joint and maintains the preset pressure during the arthroscopic procedure.

Replacing the reservoir bag

- When the connected reservoir bag is empty, close tube clamp (18) and open the other tube clamp (19).
- Insert the puncturing needle (22) of the tube set into the new full reservoir bag.

9. Cleaning and disinfection

For cleaning or disinfection only use a soft moist cloth together with a mild cleaning and/or disinfecting solution.

NOTE	***To prevent equipment malfunction always protect the sensor plug and the sensor connector as well as the arthroscopy pump from moisture and liquids of any kind.***
	It is essential to keep the area around the sensor connector dry when cleaning the arthroscopy pump.
CAUTION	***Moisture at the sensor plug or the sensor connector may cause the arthroscopy pump to stop or to run continuously.***
	In such a case use compressed air or a hair dryer to blow dry the plug and/or the connector or replace the entire pressure sensor unit.
CAUTION	***The pump is provided <u>non-sterile</u> and cannot be sterilized.*** ***The tubs (patient und pump) and the pressure sensor are supplied pre-packaged <u>sterile</u> .*** ***Do not resterilize.***

10. Malfunctions

In case of any functional problem with the unit immediately contact the responsible technical department or the supplier.

The producer assumes a warranty to the first purchaser for a twelve month Period with regard to defects or failure of its medical devices. All defective products covered by the warranty are repaired or replaced free of charge by the producer.

Warranty claims will not be accepted if:

- the unit is damaged as a result of force majeure or negative environmental influences (like moisture, electrical interferences, etc.);
- the unit has been opened or repaired by non-authorized service stations or other personnel;
- sterilization regulations have not been complied with.
- when the unit is changed in any way or repairs are performed by any party other than the producer.

11. Shipping and storage

In transport the unit it should be protected by the original packing material.

Therefore, we recommend saving the packing material for such purposes. Should the packaging is no longer be available, please contact the manufacturer to obtain instructions for proper shipping.

Incorrect packaging renders the warranty invalid.

Operating conditions

- Temperature: +10 to +50 °C (50 to 122 °F)
- Relative humidity: 30% to 75%

Storage conditions

- Temperature: -10 to +50 °C (14 to 122 °F)

12. Disposal

The final disposal of the arthroscopy pump 54-300.01 creates no problem since the unit does not contain any material harmful to the environment.

At the end of its service life the pump can be disposed of as electronic waste in public scrap yards.

Explanation of symbols

Caution, refer to accompanying documents

Equipotential bonding

Alternating current

Application element complies with the regulations for type BF

CE 0483

European certification label with reference number

Panel description

Arthroscopy pump – front panel:

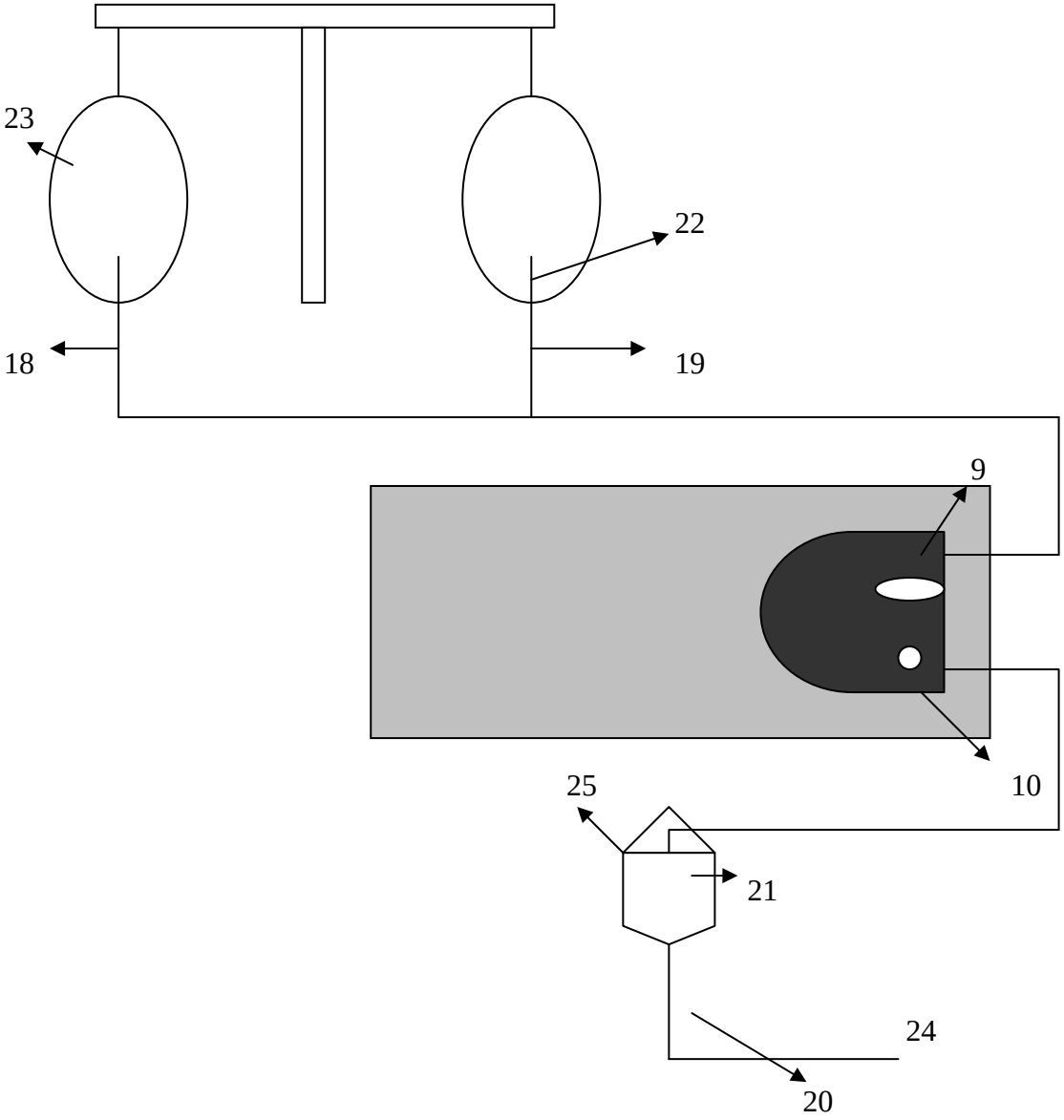
1. ON/OFF main switch
2. START/STOP button
3. SENSOR indicator
4. TEST button
5. ERROR indicator
6. PRESSURE display
7. MIN control button for pressure adjustment
8. MAX control button for pressure adjustment
9. Pressure sensor connector
10. Hook for sensor chamber
11. Pump disk
12. Mechanical protection device

Arthroscopy pump – rear panel:

13. Fuses
14. Power input connector
15. Equipotential pin
16. Equipotential label
17. Nameplate

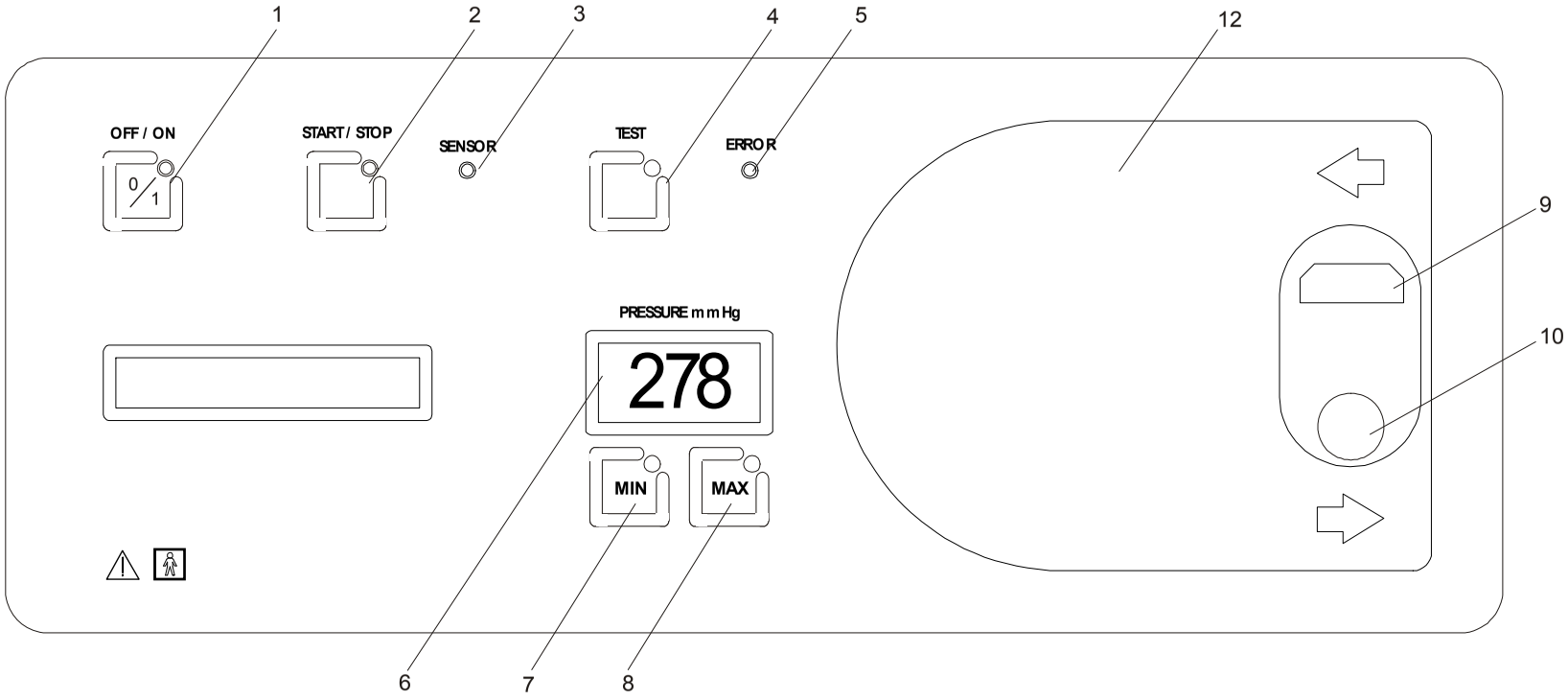
Tube set – pump section:

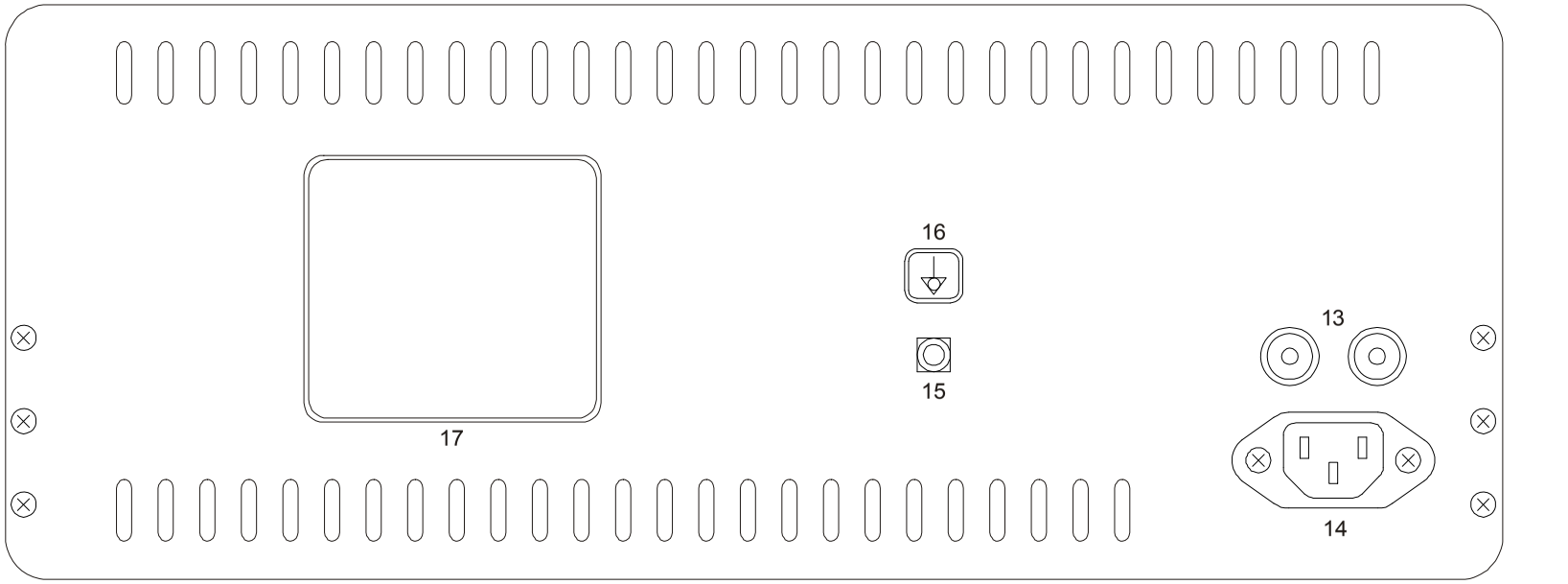
18. Tube clamp
19. Tube clamp
20. Tube clamp
21. Sensor chamber
22. Puncturing needles for tube set
23. Liquid reservoir bag
24. Connector for patient section
25. Connector for pressure sensor



9 - Pressure sensor connector
10 - Hook for sensor chamber
18, 19, 20 - Tube clamp
21 - Sensor chamber
22 - Puncturing needles for tube set
23 - Liquid reservoir bag
24 - Connector for patient section
25 - Connector for pressure sensor

Assembling the tube set and connecting the pressure sensor


1
2
3
4
5
12
OFF / ON
0
1
START / STOP
SENSOR
TEST
ERROR
9
PRESSURE mm Hg
278
10
MIN
MAX
6
7
8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