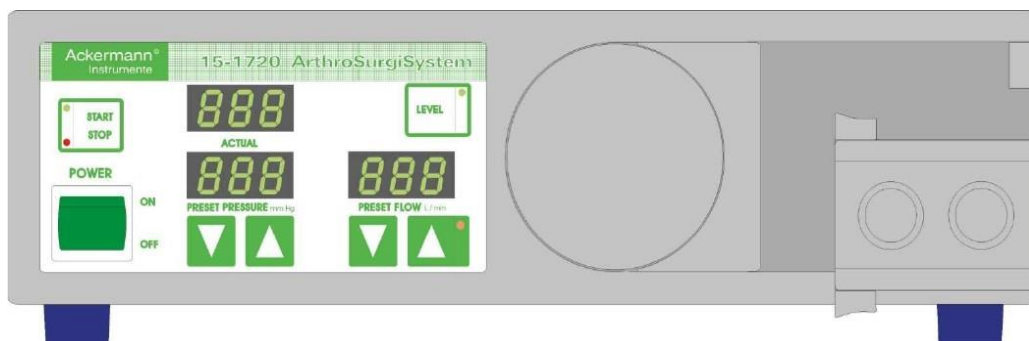


OPERATING INSTRUCTIONS

15-1720

ArthroSurgiSystem IRRIGATION PUMP for ARTHROSCOPY



Ackermann Instrumente GmbH
Eisenbahnstr. 65-67
78604 Rietheim-Weilheim - GERMANY
Tel.: +49 7461 966170 – Fax: +49 7461 9661770
e-mail: info@ackermanninstrumente.de

These operating instructions contain information that is subject to copyright.

All rights are reserved.

This manual should not be photo-copied, duplicated on microfilm or otherwise copied or distributed, completely or in part, without the approval of the manufacturer.

The manufacturer will appreciate any errors or anything unclear in this operating manual being pointed out to us by users of our products.

Due to the continuing progress and development of our products, we reserve all rights for technical alterations.

© by: **Ackermann** Instrumente May 2019.

SERVICE ADDRESS:

Ackermann Instrumente GmbH
Eisenbahnstr. 65-67
78604 Rietheim-Weilheim – GERMANY

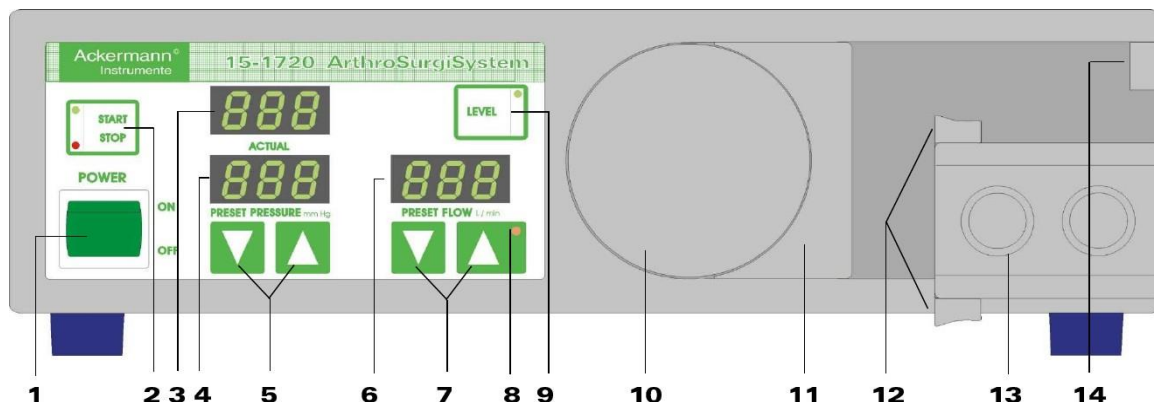
Tel.: 0049 7461 966170
Fax: 0049 7461 9661770

e-mail: info@ackermanninstrumente.de

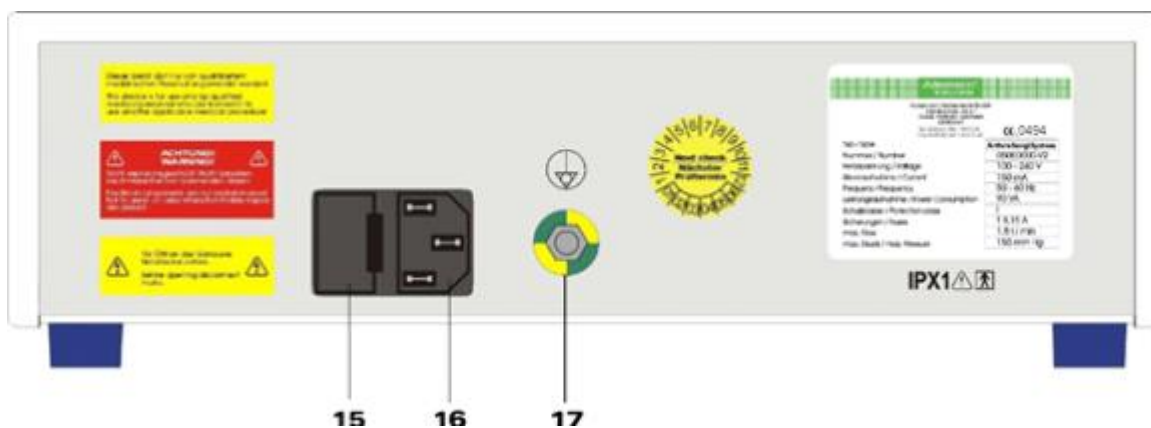
Chapter	Page
1. FRONT AND REAR PANEL	4
2. TECHNICAL DATA	5
3. DELIVERY	6
4. SAFETY INSTRUCTIONS	7
5. TUBING SETS INSTRUCTIONS	8
5.1. ASSEMBLING THE TUBING SET	8
5.2. INSERTING THE TUBING SET	9
5.3. TAKING OUT THE TUBING SET	10
6. CLEANING AND STERILIZATION	11
7. OPERATING INSTRUCTIONS	12
7.1. OPERATING THE UNIT	11
7.2. HYDROSTATIC PRESSURE COMPENSATION	12
7.3. SEQUENCE OF OPERATIONS	13
8. CLEANING AND CARE	14
9. SERVICE AND MAINTENANCE / WARRANTY	15
10. INSPECTIONS	16
10.1. CHECKING THE PRESSURE SENSORS	16
10.2. CHECKING THE FLOW RATE	16
11. ACCESSORIES	18
12. SYMBOLS USED ON LABEL	19

1. FRONT AND REAR PANEL

Ackermann®
Instrumente



- | | |
|--|--|
| <ul style="list-style-type: none"> 1. Mains Power Switch 2. Push Button START/STOP 3. Display ACTUAL PRESSURE 4. Display PRESET PRESSURE 5. Push Button for PRESET PRESSURE SETTING 6. Display PRESET FLOW 7. Push Button for FLOW SETTING 8. Indicator FLOW LIMIT 9. Push Button Level (to set Hydrostatic Pressure Compensation) | <ul style="list-style-type: none"> 10. Roller Wheel 11. Tube Holder 12. Clamping Jaw 13. Pressure Measuring Chamber Adaptor 14. Tubing Guideway 15. Fuse Box 16. Mains Connection 17. Equipotentiality |
|--|--|



VOLTAGE 100-240 V/AC - Mains fuse T 3,15 A

FREQUENCY 50-60 Hz

POWER CONSUMPTION Max. 90 VA

DEVICE TYP BF

SAFETY CLASS IIa

CONSTRUCTION DIN EN 60601-1 (03.96)

RADIO INTERFERENCE SUPPRESSION DIN EN 60601-1-2 (1993-05)

IRRIGATION CAPACITY 0-1.500ml/min

PRESSURE RANGE 10-150 mm Hg

TEMPERATURE RANGE +10 - +40°C

HUMIDITY 30-70%

PROTECTION AGAINST WATER ENTRY IPX1

CERTIFICATES CE 0494

DIMENSIONS 300 x 93 x 260 mm
W x H x D

WEIGHT approx. 6 kg

OPTIONAL Computer interface

TUBING SETS Silicon – autoclavable or PVC -
disposable

Please check the device for external damage and control the unit and the accessories after receipt of device.

The unit consists of:

1.	The main device	1
2.	Protocol	1
3.	Operating instructions	1
4.	Silicon tubing set	1
5.	Mains cable	1
6.	Fuses	1
7.	Pressure measuring chamber	1
8.	Membrane protection	1

In case of damages please inform immediately your authorized dealer.
If the unit has to be returned use only original box and the following information:

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

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

Please note:

1. The physician is responsible for the appropriate type of flushing liquid.
2. The intended use of this device is to maintain hysteroscopic procedures. The use of this device is contraindicated whenever hysteroscopy is contraindicated. This device is for use only by qualified medical personnel which are trained in its use and the applicable medical procedure.
3. Use only original accessories.

4. Service and maintenance have to be carried out only by authorized persons.
5. Do not use the device within demarcated hazard zones! (explosive gases).
6. Liability may be voided by misuse, abuse, violation of instructions for use, omission of required maintenance, opening the equipment modifications, repairs by unauthorized persons! Use of other than original accessories shall void warranty and liability.
7. Equipment has to be used at all times in accordance with the operating instructions!



IMPORTANT!

In case of failure switch off the device at its main power switch (1).



IMPORTANT!

Pressure measuring chamber (21) is auto-clavable (max. temperature 134° C).

Higher temperature will cause damages!



IMPORTANT!

All tubings and connections have to be connected accurately.

5.1. ASSEMBLING THE TUBING SET

Tubing set consists of:
2 autoclavable tubings and 1 measuring chamber (21) (see illustration)

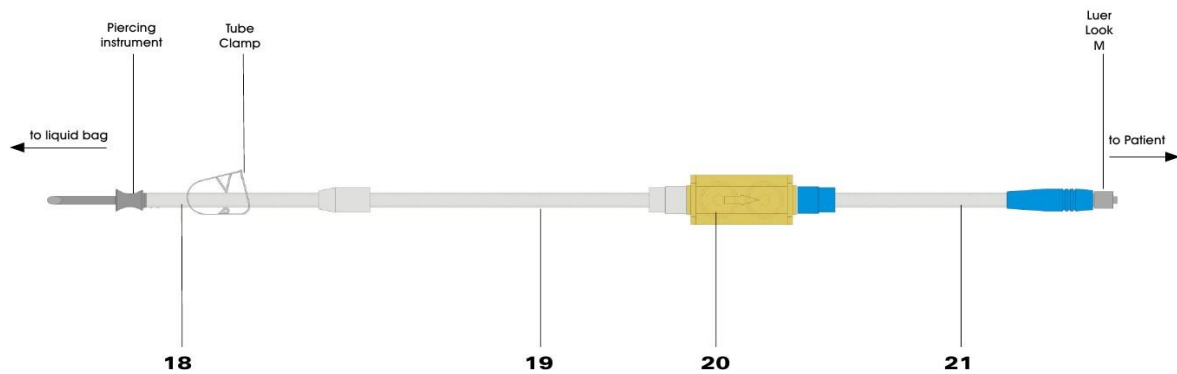
(For cleaning purposes the tubing set can be disconnected).

Connection: To Patient (22)
Connection: To Liquid Bag (18)

Please note:

All tubes and connections have to be assembled acc. the illustration !

ILLUSTRATION OF THE TUBING SET

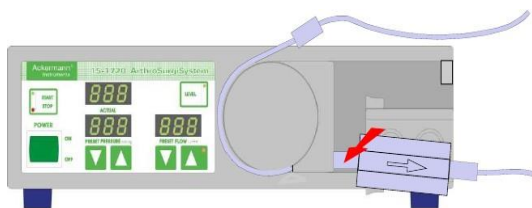


- 18. Tube with piercing instrument for liquid bag
- 19. Pumpsegment
- 20. Tube stopper
- 21. Pressure measuring chamber (arrow indicates flow-direction)
- 22. Tube section to patient with LL-connector for instrument

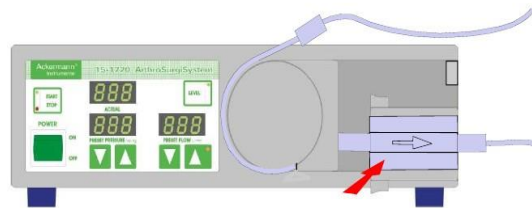


IMPORTANT!

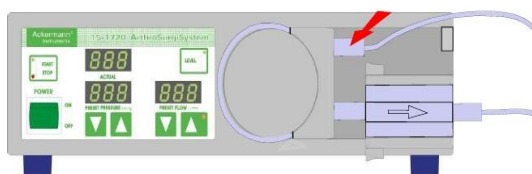
Before inserting the tubing set, the Pump must be switched on at the power switch (1)!
Otherwise a warning message could be issued (see Chapter 5.1).



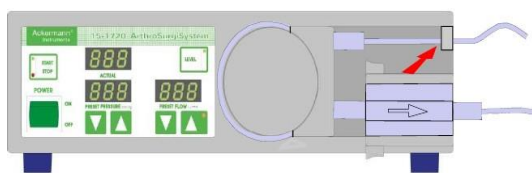
STEP 1



STEP 2



STEP 3



STEP 4

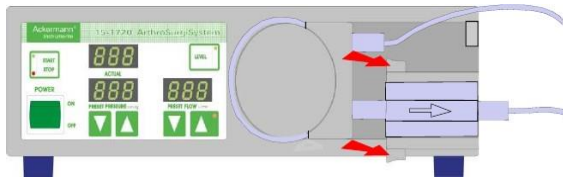
5.2. INSERTING THE TUBING SET

Please take the pump segment (41) of the tubing set (already fitted together) with the left hand and the pressure measuring chamber (44) with the right one. Now tighten the pump segment (41) lightly and push it into the lower slot on the tube holder (22). The tube stopper (43, at the bottom) should now be slipped into the lower borehole input for the tube holder (22) and closely fitted.

Stretch the pump segment (41) around the roller wheel (25) and guide it through the upper slot of the tube holder (22). The tube stopper (43, at the top) should now sit in the upper borehole of the tube holder (22).

Now pressed the pressure measuring chamber (44) into its holder (20). In doing so, please observe that both clamping levers (21) are completely engaged. Please make sure that the pressure measuring chamber (44) is sitting tightly. The arrow for the pressure measuring chamber (44) should now point to the right from the tube holder (22).

The feed tube with connector for supply container (42) is to be inserted into the tube guide (18). Finally, this feed tube (42) is connected to the supply container and the patient-applied tube section (45) to the instrument.



5.3. WITHDRAWING THE TUBING SET

Proceed as in paragraph 3.2., however in the reverse order. Please observe, in particular, that the feed tube with connector for supply container (42) is separated from the supply container before the pump segment (41) is released from the roller wheel (23).

To withdraw the pressure measuring chamber (44), please press the clamping levers (21) together.

Tubing set is autoclavable
max. temperature = 134°C / 2 bar pressure.

We do recommend 121°C due to the durability.

Please handle with care!

- Pressure measuring chamber
- Use of the membrane

Protection is necessary to avoid damages at the delicate membranes!

Please attach the protection to the pressure measuring chamber and during cleaning you have to keep it tight with your hand!

This will avoid damages at the membranes!

Please note:

The nubs from the membrane protection have to be positioned into the pressure measuring chamber to protect the delicate membranes against bursting during rinsing and drying.

Never use a damaged pressure measuring chamber!

The complete tubing set can be disassembled for cleaning purposes (see page 7) .

7.1. OPERATING THE UNIT

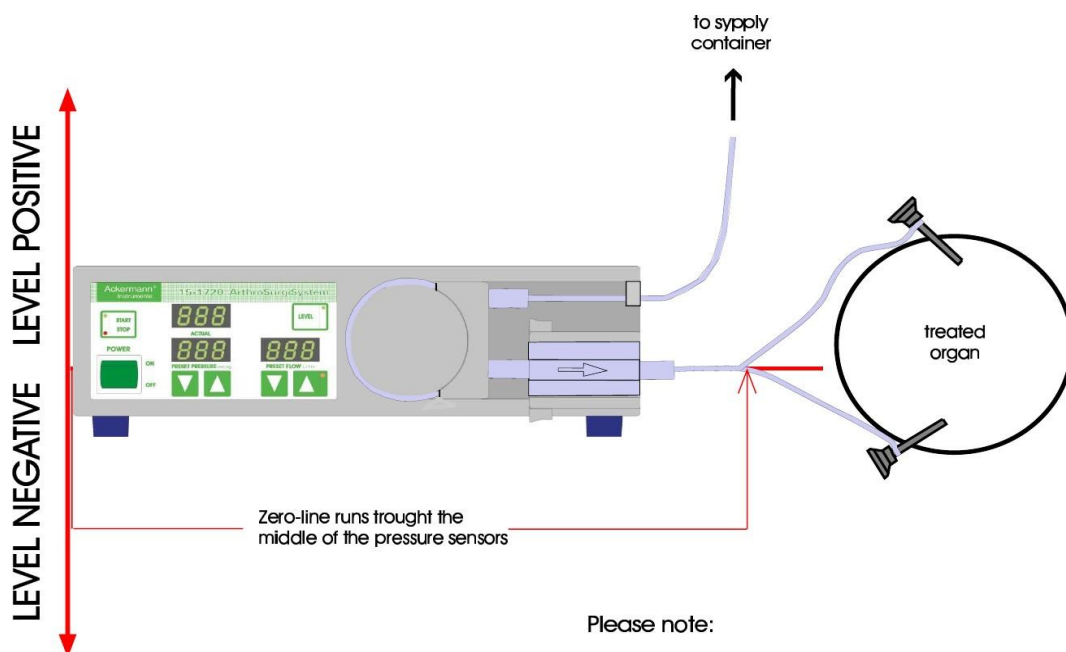
Switch on the unit (power switch (1))
Automatic safety test is performed. If a peep (3 x) is audible the unit is ready. In case of problems switch off the unit and start again (after 5 sec.). If you can not hear the 3 peeps please consult your authorized distributor.

7.2. HYDROSTATIC PRESSURE COMPENSATION

After the safety test you have to check the high difference between pressure sensors and the organ (cm).

If necessary please adjust the measured value with the buttons ((5) pressure preset).
Adjustable values: - 99 cm - + 99 cm
Example: Level negative = - 10 cm
Level positive = +10 cm

To store the value press button LEVEL (9).
In case of changing the level of OP-table during operation (more than e.g. +10 cm/ -10 cm) please adjust once more the new values by pressing the LEVEL button (9) for min. 3 seconds and you are in the LEVEL modus. Please proceed as described!



Please note:

ORGAN above 0 - LINE = LEVEL Positive
ORGAN below 0 - LINE = LEVEL Negative



IMPORTANT!

The unit is not ready and cannot be started before LEVEL adjustment confirmation.

Push button (9) to set the value.

For user safety and accurate measurements it is necessary to observe strictly this advice!

7.3. SEQUENCE OF OPERATIONS

1. Switch on the device (mains switch (1)) automatic self-test is carried out.
Connect the tubing set with pressure measuring chamber only after switching the unit on and after the self-test has been successfully completed.
2. Store LEVEL value for accurate LEVEL compensation.
3. Insert the tubing set (see 5.2.)
4. Choose desired values for flow and pressure.
5. Connect tubing (21) to instrument (Patent).
6. Start device by pressing button Start/Stop (2) and flush the complete tubing set (ventilate the tubing).
7. If necessary change the pre-settings (flow rate/pressure) by pressing the buttons (5/7).
8. In case of low flow rate the flow limit indicator flashes and a signal is audible. To reach the preset pressure increase the flow rate.
9. Overpressure - Warning signal is audible, display (3) flashes, overpressure compensation = automatically maintained.
10. End of OP-Press Stop.
11. Take out the tubing set.

CLEANING

- Switch off the device (1)
- Disconnect power cord

Outer surface:

- use mild detergents or disinfectants
- no fluids should enter the interior of the device!
- unit cannot be sterilized!

Silicon Tubing Set:

- autoclavable (acc. the respective manufacturers operating instructions)
- sterilize the tubing set after cleaning and rinsing/drying process

Service and repair may be performed only by authorized persons.

The unit must be checked once a year by the manufacturer or by an authorized service engineer.

Unauthorized opening of the device or repairs, use of other than original spare parts and accessories, performed by the user may compromise performance of the device and will void all warranties!

The system is warranted against defects in material and workmanship to the original purchase for a period of one year from date of sale.

This warranty may be voided by misuse, abuse, violation of instructions for use, omission of required maintenance, failure to adhere to suggested protocols or any other action on the part of the user which constitutes negligence or failure to exercise due caution in the care, use and maintenance of the product.

In case of returning the unit please note:

Return in original package or similar package affording an equal degree of protection.

Freight has to be prepaid. Products has not been altered, repaired or serviced by anyone other than authorized persons.

Serial no. and warranty label has not been altered in any way.

Product has not been subjected to accident, misuse, abuse or operated contrary to instructions.

We assume no responsibility or liability other than as described.

RECOMMENED QUARTERLY INSPECTIONS

Measurement check:

Necessary items:

- Tubing set
- Measuring cup (2l) scaled
- Container (min. 2l)
- Stop watch

10.1. CHECKING THE PRESSURE SENSORS

- Insert the tubing set
- Flush tubing set completely
- Lift tubing set (22) above the 0 – line

$$1 \text{ cm H}_2\text{O} = 0,74 \text{ mm Hg}$$

$$1 \text{ mm Hg} = 133,32 \text{ Pa}$$

- The value depends to the height of the water pillar above the pressure measuring chamber (13).
- A value is displayed on the actual pressure display (3).
- You have to measure the height of the water pillar (cm) from measuring chamber (13) up to the height of the tube.
- If value differs more than 10% from calculated value consult your authorized service engineer.

10.2. CHECKING THE FLOW RATE

- Switch on the device.
- Wait for the self-test.
- Insert the tubing set.
- Connect tubing set to instrument.
- Fill the container with approx. 2 l of water.
- Dip the tubing for the liquid bag (incl. piercing instrument) into the container (bottom).
- Preset a pressure of 70 mm Hg.
- Guide the other end from the tubing set into the scaled measuring cup (2 l) and start the device. Flush approx. 300 ml liquid and push the stop button. The tubing set is completely flushed.
- Pour out the measuring cup and be prepared with the stop watch.
- Start again the unit with maximum flow rate for exactly 1 minute. Stop the unit.
- Result;




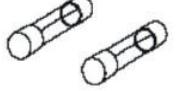
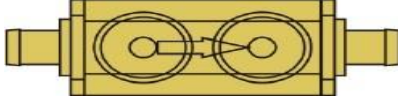

1,35 l liquid should be in the measuring cup.



PLEASE NOTE:

All checks have to be listed in the service table!

The following accessories are available:

<p>1.</p>	<p>Silicon tubing set, not sterile, autoclavable Article 15-1720-100</p>		<p>PU 1</p>
<p>2.</p>	<p>PVC-tube set, sterile, disposable Article 15-1720-300</p>		<p>PU 10</p>
<p>3.</p>	<p>Mains cable Euro 2m Article 15-1720-800</p>		<p>PU 1</p>
<p>4.</p>	<p>Fuses Article 15-1720-900</p>		<p>PU 10</p>
<p>5.</p>	<p>Pressure measuring chamber, not sterile, autoclavable Article 15-1720-500</p>		<p>PU 10</p>
<p>6.</p>	<p>Membrane protector, not sterile, autoclavable Article 15-1720-700</p>		<p>PU 1</p>



Legal manufacturer:

MISS Medizintechnik GmbH
Neuendorfstr. 16A
167461 Henningsdorf
Germany



Manufacturing date



Batch code



Product number



Caution, consult accompanying documents



Non-sterile



Keep out of direct sunlight



Prescription use only



Do not use if package is opened or damaged



Protect against moisture



Consult instructions for use



CE-Number