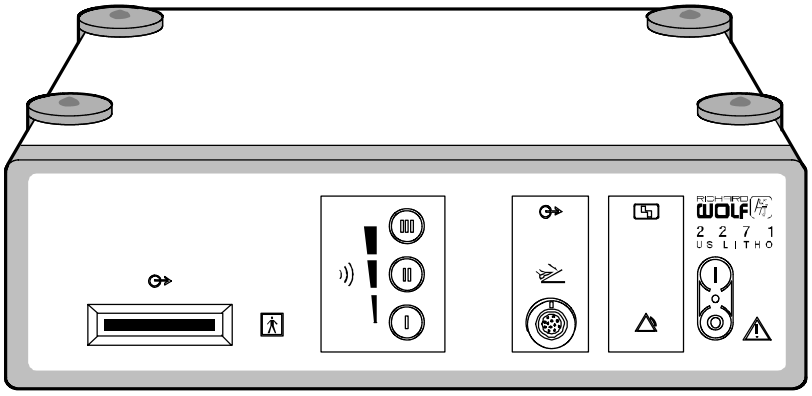
Instruction Manual



Ultrasound Generator

2271

GA-A 181 / en / Index: 09-05-5.0 / ÄM: KG 04-252

⚠ Important general instructions for use ⚠

Ensure that this product is only used as intended and described in the instruction manual, by adequately trained and qualified personnel, and that maintenance and repair is only carried out by authorized specialized technicians.

Operate this product only in the combinations and with the accessories and spare parts listed in the instruction manual. Use other combinations, accessories and wearing parts only if they are expressly intended for this use and if the performance and safety requirements are met.

Reprocess the products before every application and before returning them for repair as required by the instruction manual in order to protect the patient, user or third parties.

Subject to technical changes!
Due to continuous development of our products, illustrations and technical data may deviate slightly from the data in this manual.

CAUTION – USA only:
Federal law restricts this unit to be used or sold, except under the supervision of a medical doctor.

Safety instructions and levels of danger

Symbol	Level of danger
⚠	***WARNING!*** Failure to observe can result in death or severe injury.
⚠	***CAUTION!*** Failure to observe can result in slight injury or damage to the product.
☞	***IMPORTANT!*** Failure to observe can result in damage to the product or surrounding.
☞	***NOTE!*** Tips for optimum use and other useful information.

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Contents

1 General information

1.1 Symbols

Symbols	Meaning
	Attention, consult ACCOMPANYING DOCUMENTS
	Off (disconnection from mains/power)
	On (connection to mains/power)
	Equipotentality
	Fuse
	Alternating current (AC)
	TYPE BF APPLIED PART
	Intensity preselection, stage III
	Intensity preselection, stage II
	Intensity preselection, stage I
	Fault indicator “Generator malfunction” warning lamp
	Fault indicator ”Transducer malfunction” warning lamp
	Standby indicator, “Device output active” lamp (foot switch actuated)
	Socket for foot switch
	Interface symbol/device output (e.g. RIWO NET SYSTEM)
	Interface symbol/device input (e.g. RIWO NET SYSTEM)
	Socket, 4-pole, control output (Suction Pump)
REF	Order number
	A Registered Trademark of ETL, a Recognized Testing Laboratory, listing compliance as Medical Electrical Equipment to standard CAN/CSA C 22.2 No. 601.1 (**c**) and UL 60601-1 (**us**)
CE	Identification in conformity with Medical Devices Directive 93/42/EEC **only valid** if the **product and/or packagingis marked with this symbol**. Products of category IIa and above, as well as sterile products or products with measuring function of category I, are additionally marked with the code number of the notified body (0124).

1.2 Intended use

The ultrasound generator (US-LITHO) 2271 with transducer and sonotrode is used in intracorporeal ultrasound lithotripsy exclusively for desintegrating kidney stones, urinary bladder stones and ureter stones under direct endoscopic view. The use of this device for purposes other than the above is not admissible.

⚠ ***CAUTION!***
In therapeutic use an adequate backup unit must be available for the unlikely event that the device fails.

1.2.1 Contraindications

Contraindications directly related to the product are presently unknown. On the basis of the patient's general condition the doctor in charge must decide whether the planned use is possible or not. For further information please refer to the current medical literature.

☞ ***NOTE!***
Before the first use we recommend reading the relevant literature (see chapter 9 literature").

1.3 Combinations

⚠ ***WARNING!***
Danger of life-threatening embolism.
If used in combination with a peristaltic suction pump (e.g. Suction Pump 2207) no air or liquid must be discharged from the tip of the sonotrode. The sonotrode must be used exclusively for evacuating. Strictly follow the instruction manual of the roller suction pump.

☞ ***IMPORTANT***
In addition to this instruction manual follow the manuals of the products used in combination with this product.

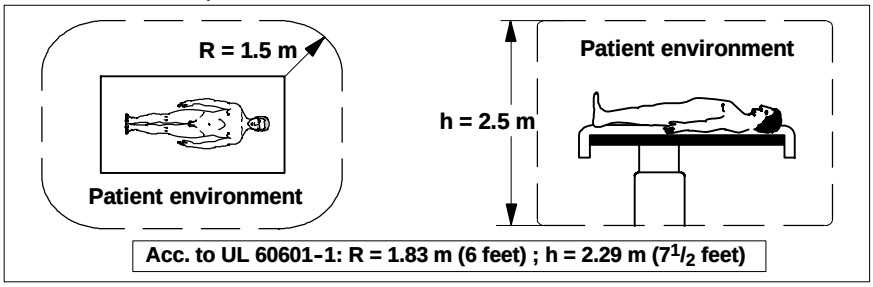
1.3.1 Device combinations

The Ultrasound Lithotriptor consisting of Ultrasound Generator 2271 with transducer and sonotrode may only be used in conjunction with a suitable suction device, e.g. a suction pump. The R.Wolf "Suction Pump 2207" is specially designed for use with the ultrasound generator and provides ideal conditions for the use of this device.

If a different suction pump or suction device (different manufacturer) is used, the operator/user must check whether the suction device features a controllable, adjustable vacuum, which meets the requirements.
To ensure sufficient cooling of the transducer and the sonotrode, make sure that the suction device can provide an adjustable vacuum of up to -0.6 bar on a continuous basis.

1.3.2 General requirements on products/components of a combination

The general requirements depend on whether the products/components are inside or outside the patient environment.



Medically used room: Inside the patient environment	Medically used room: outside the patient environment	Non-medically used room	Requirements / measures: Leakage currents to clause 19 IEC/EN 60601-1-1 *
MP – MP	–	–	–
MP – NMP MP – NMP ** MP NMP	–	–	a) additional protective earth connection (to be clarified with manufacturer), **or** b) with additional isolating transformer **
MP – - - - - - - - - - - - NMP		–	–
MP – - - - - - - - - - - - - - - - - - - - MP or NMP			a) common protective earth connection, **or** b) additional protective earth connection (to be clarified with manufacturer), **or** c) additional separating device (to avoid earth/ground loops in the case of a potential difference)

additional isolating transformer according to IEC/ EN 60601-1-1 **

additional separating device according to IEC/ EN 60601-1-1

- - - Functional connection

~ power supply grid

MP = **medical electrical device** according to IEC/ EN 60601-1, UL 60601-1, CSA C22.2 No. 601

NMP = **non-medical electrical** device in accordance with the relevant product-specific IEC/ EN/ UL/ IEC standards

* If connected via a joint mains/power cord under normal conditions the earth leakage current of the system must not exceed 500 µA (*300 µA* for systems in acc.with UL 60601-1).

** *e.g. Richard Wolf Video Trolley with "isolating transformer".*

1.3.3 Specific requirements on the products/components of a combination

☞ ***IMPORTANT!***

Persons combining products to form a system are responsible for not impairing the system's compliance with the performance and safety requirements, and that the technical data and the intended use are adequately fulfilled.

Electromagnetic interference or other types of interference occurring between this product and other products can cause failures or malfunctions.

When selecting the system components ensure that they meet the requirements for the medical environment they are used in, in particular IEC/ EN 60601-1-1. In case of doubt contact the manufacturer(s) of the system components.

Do not touch connecting devices for electrical connections between the different components (such as signal input and output connections for video signals, data exchange, control circuits, etc.) and the patient at the same time.

1.4 Electromagnetic compatibility (EMC)

NOTE: The device or system in the following called **product** always relates to the ultrasound generator 2271

Guidance and manufacturer's declaration – electromagnetic emissions

The product is intended for use in the environment specified below. The user should assure that the product is used in such an environment.		
Emissions measurement/test	**Compliance**	**Electromagnetic environment – Guidance**
HF emissions to CICPR 11	Group 1	The product uses HF energy for its internal function. The HF emission level is extremely low and it is not likely to cause any interference in nearby electronic equipment.
HF emissions to CISPR 11	Class B	The product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions to IEC 61000-3-2	Class A	
In conformity with IEC 61000-3-3 "Voltage fluctuations / flicker emissions"		

Guidance and manufacturer's declaration – electromagnetic immunity

The product is intended for use in the environment specified below. The user should assure that the product is used in such an environment.			
Immunity tests	**IEC 60601 test level**	**Compliance**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) to IEC 61000-4-2	± 6 KV contact ± 8 KV air	Yes	Floors should wood, concrete or ceramic tile. If the floors are covered with synthetic material, the releative humidity should be at least 30%.
Electrical fast transients, bursts to IEC 61000-4-4	± 2 KV for power supply lines ± 1 KV for input/output lines	Yes	Mains/line power quality should be that of a typical commercial or hospital environment.
Surge voltage (surges) to IEC 61000-4-5	± 1 KV differential mode ± 2 KV common mode	Yes	Mains/line power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines to IEC 61000-4-11	Voltage dip for 0.5 cycle > 95% U_T * Voltage dip for 5 cycles > 60% U_T * Voltage dip for 25 cycles > 30% U_T * Voltage dip for 5 sec > 95% U_T *	Yes	Mains/line power quality should be that of a typical commercial or hospital environment. If the user of the product requires continued operation during power mains/line interruptions it is recommended that the product be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field, to IEC 61000-4-8	3 A/m	Yes	Power frequency magnetic fields should be at levels characteristic of a typical location in a commercial or hospital environment.
* NOTE: U_T is the line/mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity for products that are not life-supporting

The product is intended for use in the environment specified below. The user should assure that the product is used in such an environment.

Immunity test	IEC 60601 test levels	Compliance level	Electromagnetic environment - guidance
Conducted HF interference to IEC 61000-4-6 Radiated HF interference to IEC 61000-4-3	3 V_{rms} 150kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Yes	Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ for 800 MHz to 2.5 GHz P = Nominal power output rating of the transmitter in watts (W) (according to the transmitter manufacturer) d = recommended separation distance in meters (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey**1**, should be less than the compliance level in each frequency range**2**. Interference may occur in the vicinity of devices with the following symbol:

REMARKS: At 80 MHz and 800 MHz the higher frequency range applies.

These guidelines may no apply in all situations, as the propagation of electromagnetic waves is affected by absorption and reflexion from buildings, objects and people.

1 = The field strength of fixed transmitters (e.g. base stations for radio telephones, land mobile radios, amateur radio, radio broadcast and TV broadcast, ...), cannot be predicted theoretically with accuracy. To assess the EMC environment due to fixed transmitters an electromagnetic site survey should be conducted. If the measured field strength in the location in which the product is used exceeds the applicable compliance level above, the product should be observed to verify normal operation.
If abnormal performance is observed, additional measures may be required, such as reorienting or relocating the product.

2 = Over the frequency range between 150 kHz and 80 MHz the field strength should be below 3 V/m.

The recommended separation distances between portable and mobile HF telecommunication devices and devices which are not life-supporting

The product is intended for use in an electromagnetic environment with HF disturbances are controlled.
The user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF telecommunications equipment and the product.

Rated nominal output power of the transmitter (Watts)	Separation distance as a function of transmitter frequency (m)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2 \sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

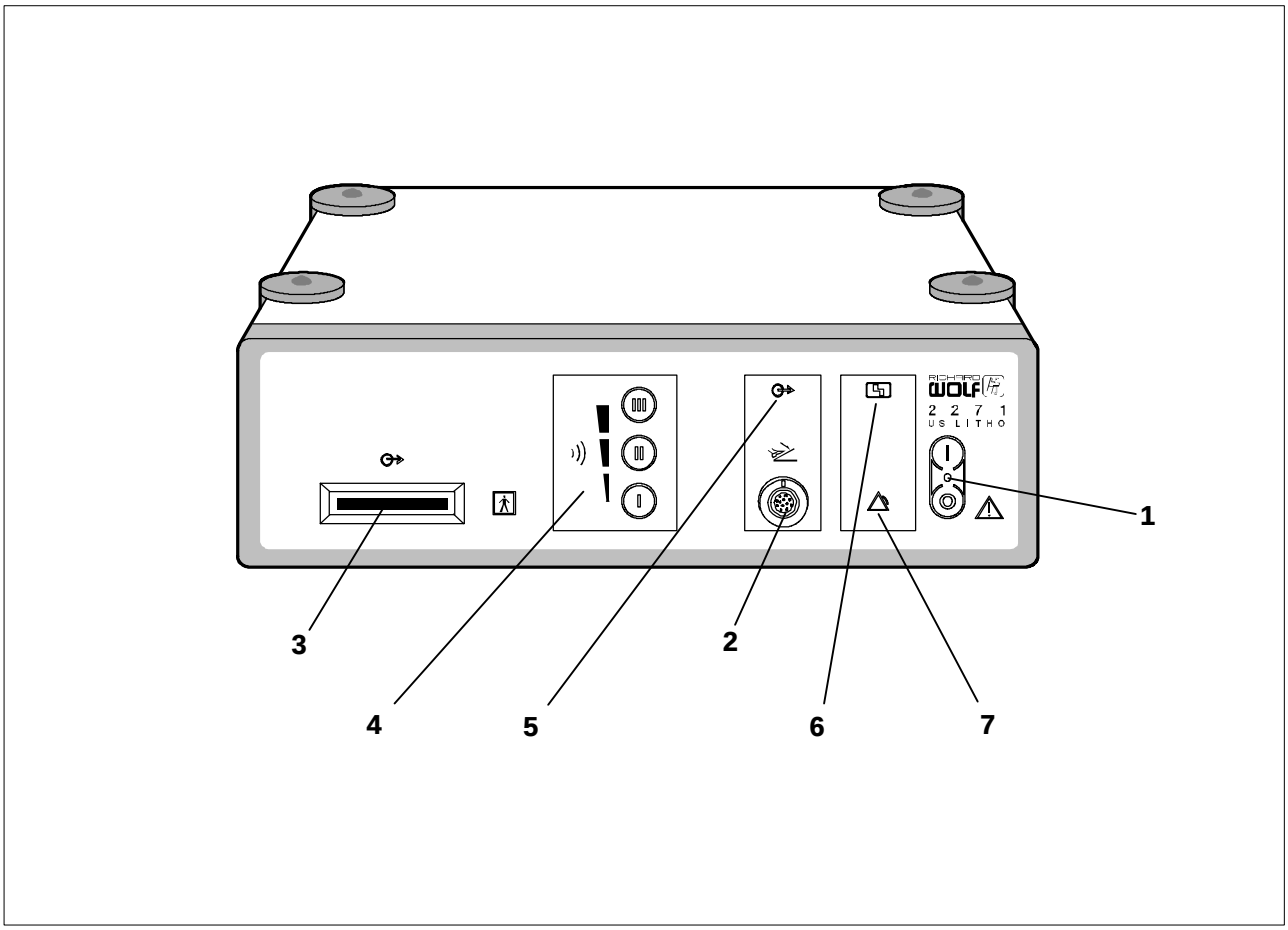
For transmitters rated at a nominal output power not listed in the table above, the recommended separation distance (d) in meters (m) can be determined using the applicable equation (observe frequency). P = nominal power of the transmitter in Watts (W).

REMARKS: At 80 MHz and 800 MHz the higher frequency range applies.

These guidelines may no apply in all situations. Electromagnetic propagation is affected by absorption and reflexion from buildings, objects and people.

2 Illustration

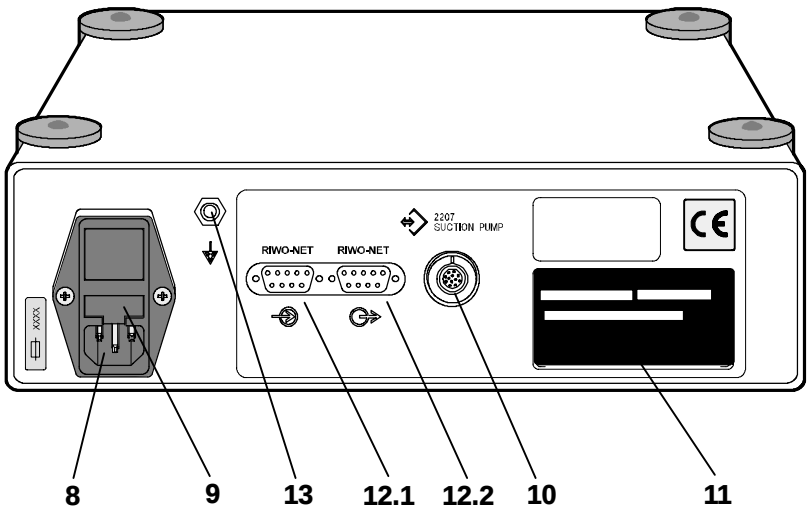
2.1 Front panel



2.1.1 Legend

1 Power switch with green LED
2 Socket for foot switch
3 Connection bar for transducer
4 Intensity button for power stage preselection
5 “Foot switch actuated” indicator lamp
6 “Transducer malfunction” warning lamp
7 “Generator malfunction” alarm lamp

2.2 Rear panel



2.2.1 Legend

8	Power input connector with fuse holder	**12.1**	CAN-BUS input connector (option)
9	Fuse holder with device fuses	**12.2**	CAN-BUS output connector (option)
10	Control output for suction pump (4-pole socket)	**13**	Equipotential connector
11	Identification plate		

3 Set up

⚠ ***WARNING!***
This device is not protected against explosions.
Explosion hazard.
Do not operate this device in areas where there is a danger of explosions.

⚠ ***CAUTION!***
Danger of faults and malfunctions.
To guarantee the safety of the user, the patient and others use only accessories and spare parts specified by the manufacturer of this product.
Other accessories or spare parts can cause the emission of increased electromagnetic radiation or reduced immunity against interference.

☞ ***IMPORTANT!***
*Medical devices are subject to special precautions with regard to electromagnetic compatibility (**EMC**).*
Make sure you observe the notes on EMC for installation and operation. Medical electrical devices can be influenced by mobile HF communication devices.
If it is necessary to stack the devices or place them next to each other and HF interference is observed, make sure you observe the intended use of the devices.

⚠ ***CAUTION!***
Danger of infection from unsterile accessories.
Sterilize reprocessed parts and accessory items before use.
Follow the sterilization instructions for the product in question!

☞ ***IMPORTANT!***
Make sure that the mains/grid voltage and the voltage indicated on the identification plate are the same. Connect the device only through the supplied power cord or a power cord meeting the same specifications.

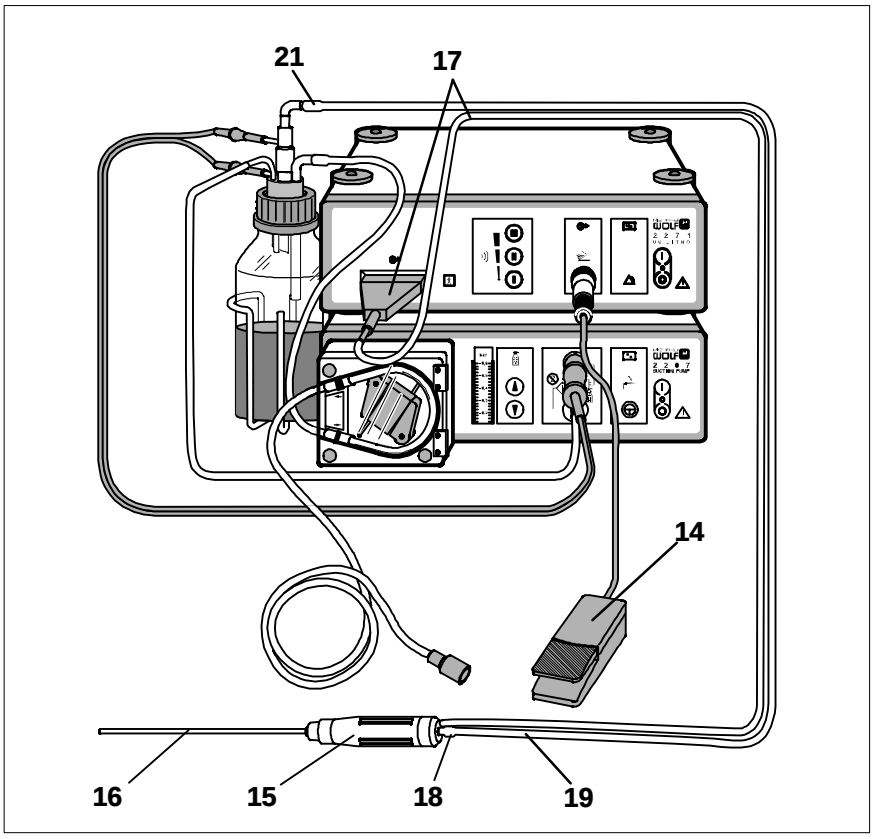
☞ ***NOTE!***
During operation place the device on an even, level, non-slippery surface.

3.1 Preparation when using Suction Pump 2207

WARNING!
Danger of life threatening embolism due to wrong connection of pump tubes.
When using a peristaltic suction pump (e.g. Suction Pump 2207) no air or liquid must be discharged from the sonotrode tip. The sonotrode tube only serves for evacuation purposes. Strictly follow the instruction manual of the suction pump used.

☞ ***IMPORTANT!***
The ultrasound generator is designed for use while the irrigation fluid is aspirated and pumped off. When setting up the Ultrasound Generator ***make*** *sure that a suitable suction device is available.*
The suction device should provide a continous adjustable vacuum of up to -0.6 bar. We recommend using a suction device adapted to the Ultrasound Generator (e.g. Suction Pump 2207).

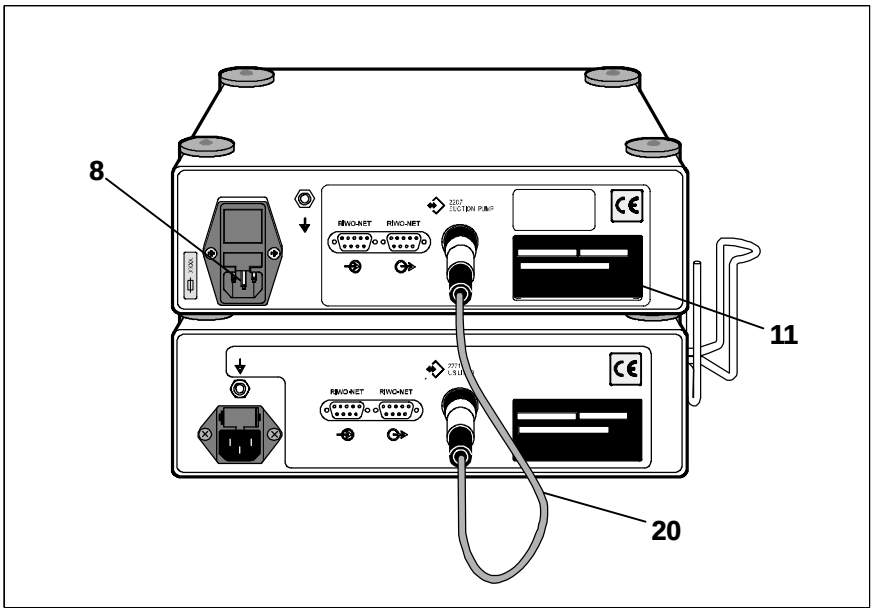
3.1.1 Ultrasound Generator with “Suction Pump 2207”



3.1.2 Legend

14 Footswitch with cable
15 Transducer
16 Sonotrode
17 Transducer cable with connection bar
18 Suction connector
19 Suction tube
21 Suction connector of fluid trap

3.1.3 Rear panel connectors

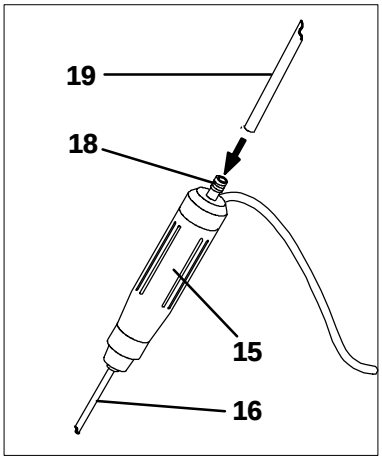


◇ The local mains/grid voltage and frequency must be the same as indicated on “identification plate” (**11**).

◇ Connect the supplied power cord to “power input connector” (**8**) of the Ultrasound Generator and the other end to the wall socket.

◇ Connect the control output of the Ultrasound Generator to the control input of the Suction Pump using connection cable 2207.991 (**20**). Connect the plugs to the corresponding sockets on the rear panels of the devices and secure by turning clockwise.

3.1.4 Front panel connectors



◇ Connect the plug of footswitch cable (**14**) to connection socket (**2**) of the Ultrasound Generator.

◇ Attach only approved sonotrode (**16**) to transducer (**15**). Ensure that the contact surfaces are clean and the connection tight.

◇ Plug the connector strip of transducer cable (**17**) into connection strip (**3**) of the Ultrasound Generator.

◇ Plug silicone suction tube (**19**) onto tube connector (**18**) of the transducer and connect the other end of suction tube (**19**) to the angle connector (i.e. suction connector) of fluid trap (**21**).

4 Checks

☞ ***IMPORTANT!***
Run through these checks before every use.

4.1 Visual check

◇ Check devices, connectors and cables for correct setup and assembly in accordance with the instruction manual(s).

◇ Check all device connections and plug–and–socket connectors for tightness, cleanliness and damage.

◇ Check all connection cables and tubes for damage, hygenic condition and completness.

◇ Check devices, instruments and accessories for damage, hygenic condition and completeness.

◇ Check condition of the device sonotrodes in accordance with section 5.4.

◇ Any lettering or labelling must be complete and easy to read.

4.2 Functional checks

⚠ ***CAUTION!***
Danger of overheating of transducer and sonotrode.
Activate the transducer only if irrigation fluid is evacuated (pumped off) through the transducer and sonotrode.

☞ ***IMPORTANT!***
Before you perform functional checks, make sure that the devices are in perfect technical condition and are set up correctly, which is to be verified in a visual check.

4.2.1 Ultrasound generator and transducer

◇ Disconnect the connection bar of the transducer from the socket bar on the device.

◇ Switch on the Ultrasound Generator and preselect a power stage.

◇ Actuate the foot switch briefly,

➧ to test transducer fault monitoring, the “transducer malfunction” (**6**) warning lamp must light up.

◇ Repeat this test for all power stages, then switch off the device.

4.2.2 Ultrasound Generator and Suction Pump

◇ Connect the transducer to the Ultrasound Generator.

◇ Connect the suction tube of the pump to the transducer.

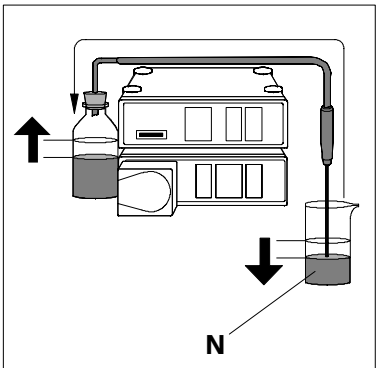
◇ Place the sonotrode of a transducer in a suitable container (N) filled with sterile liquid or irrigation fluid.

◇ Switch on the Ultrasound Generator and Suction Pump.

➧ Pump function test: the “Transducer malfunction” warning lamp (**6**) on the Suction Pump must not light up, the pump works at a low suction rate, i.e. speed.

◇ Briefly actuate the foot switch.

➧ Pump control activation test: the suction rate/speed of the pump must increase. If air or liquid is discharged from the sonotrode tip, the pump tubes are incorrectly connected. Connect the tubes as specified in the pump manual and follow the safety instructions. Repeat the test if required.

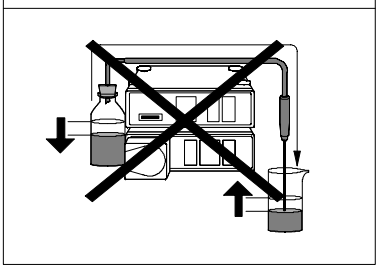


◇ Preselect the highest power stage (**4**) on the Ultrasound Generator.

◇ Actuate the foot switch.

➧ Transducer/sonotrode function test: the sonotrode must develop audible vibrations and noises. For this purpose hold the sonotrode by the transducer and remove it from the liquid just enough for the tip to be still immersed to ensure reliable suction. Oscillation amplitudes must be visible along the sonotrode tube.

➧ Suction test. The liquid level in liquid container (N) should have dropped visibly. If the liquid level has not decreased sufficiently, check the sonotrode tube for clogging and clean it as described in chapter 6 or replace it.



◇ With the footswitch actuated, switch from the highest to the next lower power stage.

➧ Generator malfunction monitoring test. During the switch–over the “Generator malfunction” warning lamp (**7**) must light up briefly.

◇ Repeat the switch–over test in all power stages including the lowest power stage.

5 Use

5.1 Operating principle of Ultrasound Generator

The Ultrasound Generator generates an output voltage at a frequency which corresponds to the resonance frequency of the oscillating system consisting of the transducer and a suitable sonotrode. The Ultrasound Generator 2271 automatically adapts to the resonance frequency of this oscillating system.

Actuating the footswitch supplies an output voltage to the transducer output of the device.

The ultrasound energy is generated outside the body and outside the device, in the transducer. The output voltage of the Ultrasound Generator excites two piezoceramic discs that transfer the ultrasound oscillations to the sonotrode.

The excitation of the sonotrode causes a stationary wave at the resonance frequency which has its maximum amplitude at the distal end of the sonotrode. Load–dependent changes in the oscillation behaviour are compensated by a control circuit in the generator. Selecting the required stage on the generator adapts the oscillation intensity to the requirements.

During operation, a safety circuit monitors the selected output power. If the output power exceeds the selected value, the “Generator malfunction” alarm lamp in the device lights up, at the same time an accustic alarm is sounded and the transducer output is switched off.

5.2 Operating principle of ultrasound lithotripsy

Ultrasound lithotripsy systems are used for minimally invasive desintegration of urinary bladder stones, kidney stones and ureter stones. Access to the stone is gained endoscopically via the urethra or percutaneously directly into the kidney. The stone is desintegrated under endoscopic view by contact with the sonotrode.

The stone fragments are pumped off through the sonotrode together with the irrigation fluid. Suction is achieved by a vacuum generated by a preadjustable suction pump via a fluid trap. The stone fragments and debris are collected in the fluid trap while the irrigation fluid is pumped via an overflow device into the drain.

5.3 Operation of Ultrasound Generator

⚠ ***CAUTION!***
Danger of overload and fracture of the sonotrode.
Using the sonotrode at a higher power setting than the maximum permissible power stage can lead to premature material fatigue and fracture of the sonotrode.
It is not permissible using the sonotrodes at higher power stages than the maximum permissible power stage indicated.

⚠ ***CAUTION!***
Danger from overheating of transducer and sonotrode.
During operation, cool the transducer and sonotrode by continous suction. Operating the device without or with insufficient suction and cooling can lead to overheating and damage due to quick and severe wear.
Never operate the device without adequate suction or cooling.

⚠ ***CAUTION!***
Danger of burns! Mind your fingers!
Do not hold the activated sonotrode between your fingers.

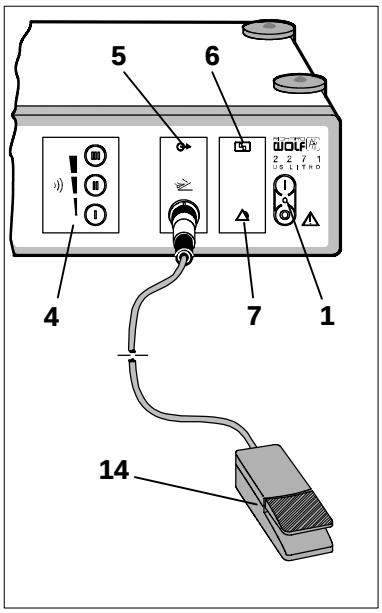
☞ ***IMPORTANT!***
The tip of the sonotrode must be visible at all times.
The sonotrode tip must be in contact with the stone while activated.
Avoid contact of tissue with the tip or sides of the sonotrode ; tissue damage could result.
Avoid pressing the probe against the endoscope during operation. This may stall the transducer and heat the sonotrode with in the working channel.

☞ ***IMPORTANT!***
Do not drop or struck the transducer against another object with may result in mechanical or electrical damage.

☞ ***IMPORTANT!***
During operation make sure that the transducer and the sonotrode are sufficiently cooled by fluid suction.
We recommend having a transducer and the required sonotrodes available as backup units.

☞ ***NOTE!***
When using the device we recommend wearing the supplied ear protection.

5.3.1 Controls and indicators of Ultrasound Generator 2271 (US-LITHO)



The Ultrasound Generator is switched on and off by means of mains/ power switch (**1**) with green LED.

To preselect the required power stage, actuate the corresponding intensity button (**4**).

Actuating the foot switch (**14**) triggers two functions:
- The transducer is activated.
- The suction rate increases to the preselected value.

When the footswitch is depressed, the " footswitch actuated" indicator lamp (**5**) lights up.

Malfunctions of the transducer are indicated by the "transducer malfunction" warning lamp (**6**).

Malfunctions of the generator are indicated by the "generator malfunction" alarm lamp (**7**).

5.3.2 Ultrasound Generator ON/OFF

◇ To switch the Ultrasound Generator on/off, use mains/power switch (**1**).

◗ The green LED (**1**) on the power switch and the background illumination of the warning/signal lamps as well as the intensity buttons light up.

☞ ***IMPORTANT!***

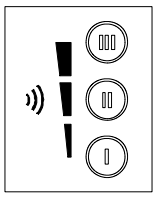
*If the LED and the background illumination remain dark after switching on or if the "transducer malfunction" warning lamp (**6**) or the "generator malfunction" alarm lamp (**7**) light up, follow the troubleshooting list under section 7.1.*

5.3.3 “Intensity” preselection (power stage)

CAUTION!
Danger of overload and fracture of the sonotrode.
Using the sonotrode at a higher power setting than the maximum permissable power stage can lead to premature material fatigue and fracture of the sonotrode.
It is not permissable using the sonotrodes at higher powers stages than the maximum permissable power stage indicated.

☞ ***IMPORTANT!***
Depending on the sonotrode diameter the following power stages are permissable:

Sonotrode ∅	maximum power stage
1.5 – 2.4 mm	II
3.5 – 4.0 mm	III



◇ After switching on the device, power stage I is set.
➧ Use the lowest power stage in which the stone can be effectively disintegrated.

◇ Preselect the required power stage by actuating the corresponding intensity button (I = low power, III = high power).
➧ The power stage selected is indicated by the intensity button lighting up.

5.3.4 Activation of transducer

◇ Activate transducer by actuating the footswitch.
➧ Via the “Suction Pump control output” (**10**) the suction rate (power) of the suction pump increases to the preselected value by send in/out a signal.
➧ The “Foot switch actuated” indicator lamp (5) lights up.

☞ ***NOTE!***
If the transducer is activated for some time and if the temperature of the grip becomes excessively high we recommend changing the transducer.

5.3.5 ”Transducer malfunction” warning lamp

◇ Lights up in case of a transducer malfunction.

5.3.6 ”Generator malfunction” alarm lamp

◇ Lights up if the preselected output power/rate is exceeded or if the Ultrasound Generator is defective.
➧ The device switches off, accompanied by an accustic alarm.

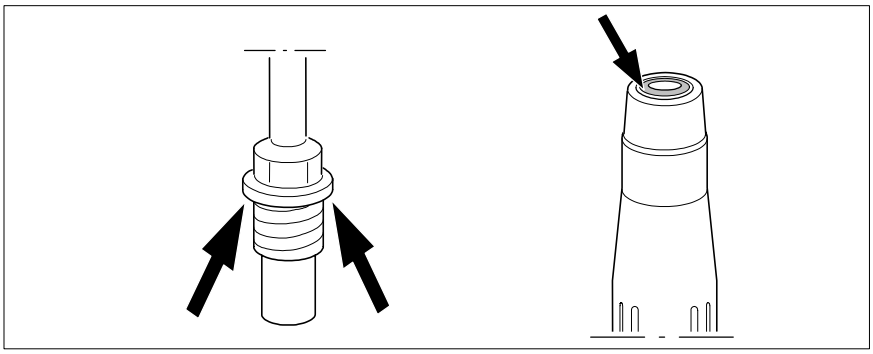
5.4 Changing the sonotrode

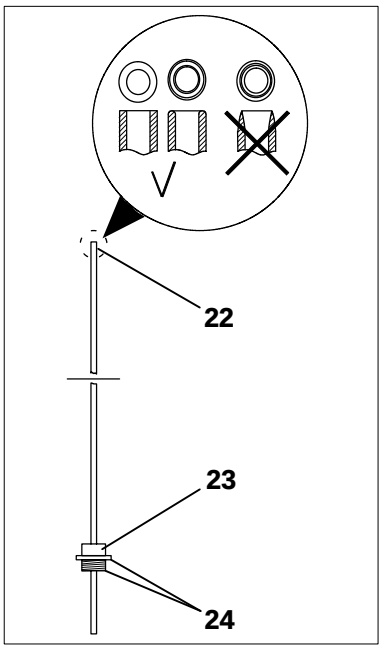
CAUTION!
Danger if a damaged or non-approved sonotrode is used.
Using the device with damaged sonotrodes or sonotrodes which are not approved for this device is not permissible.
Replace sonotrodes immediately, use only sonotrode models approved for this device by R.Wolf and which are sterilized and in perfect technical condition.

☞ ***IMPORTANT!***
Bent or damaged sonotrodes may damage the instruments.
Before use make sure that only sonotrodes in perfect technical condition and of the type and model approved for this device and this transducer are used.
When attaching the sonotrode ensure firm connection.

5.4.1 Checking the sonotrodes

☞ ***IMPORTANT!***
*After each use clean the sonotrode **and** transducer flange surfaces with a brush, as residues on these surfaces will cause malfunctions.*





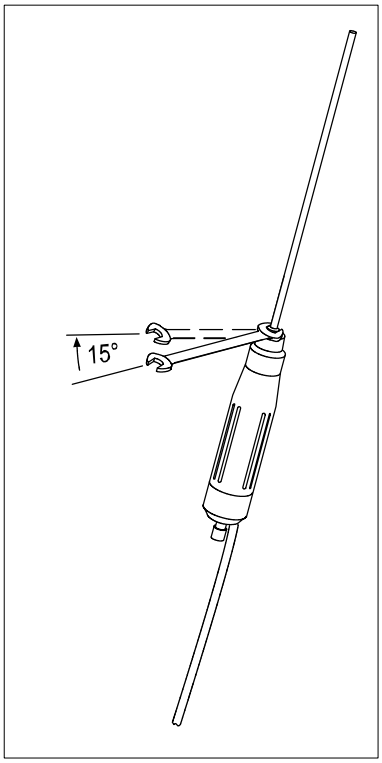
◇ Check the sonotrode for cleanliness and wear.
- The sonotrode must be clean and free of residues inside (sonotrode channel) and out.
- The sonotrode must neither be scratched nor cracked or bent, as this may cause a fracture of the sonotrode.
  The tip (**22**) must not be flared towards the inside or have sharp edges, and must not be worn in any way.

◇ Check the connector (**23**) for firm connection, the flange surface and threaded portion (**24**) of the adapter portion for cleanliness and damage.
- The adapter must be firmly connected to the sonotrode tube.
- The thread and flange surface must not have any residues on them nor be damaged in any way.

Replace sonotrodes which are worn, bent or damaged.

The sonotrodes approved by R.Wolf for use with this device are listed in section 7.4.

5.4.2 Changing the sonotrodes



The sonotrodes are connected to the transducer through the fine thread on the adapter flange. To ensure a reliable transmission of the sound energy generated in the transducer to the sonotrode, neither the thread nor the flange surfaces of the sonotrode or transducer must have any residues or damage on them, and the threaded connection must be sufficiently tight.

Disassembly:

◇ Use the supplied quarter inch open–ended wrench on the sqare of the adapter and loosen the sonotrode by turning counter clockwise (CCW). Then unscrew the sonotrode by hand.

Assembly:

◇ Screw the new sonotrode into the transducer thread by hand, by turning clockwise (CW) as far as it will go. Then apply the quarter inch open–ended wrench to the square of the adapter flange and carefully tighten the connection by approx. 15°.

➧ The connection must be tight but the thread should not be tightened with excessive force.

☞ ***NOTE!***
If the sonotrode makes a rattling noise or if the sonotrode has insufficient drilling power, check that the screw connections are tight and the flange surfaces of the sonotrode and the transducer are clean.

6 Operation in the RIWO NET SYSTEM

6.1 Combination with RIWO NET SYSTEM

Via the integrated CAN–BUS interface the ultrasound generator 2271can be integrated into the R.Wolf RIWO NET SYSTEM.

Only the components approved for use with the RIWO–NET–SYSTEM must be connected to the “CAN–BUS” interface.
The components must meet the requirements of the latest instruction manual for the RIWO–NET–SYSTEM, section on “Combinations”.

The control computer complies with IEC / EN 60601–1 and can be operated in the patient environment.

☞ ***IMPORTANT!***
In addition to this manual make sure you follow the latest manual for the RIWO–NET–SYSTEM.

6.2 Operation

The instruction set used in the interface software is suitable for operating this device within the RIWO NET SYSTEM.

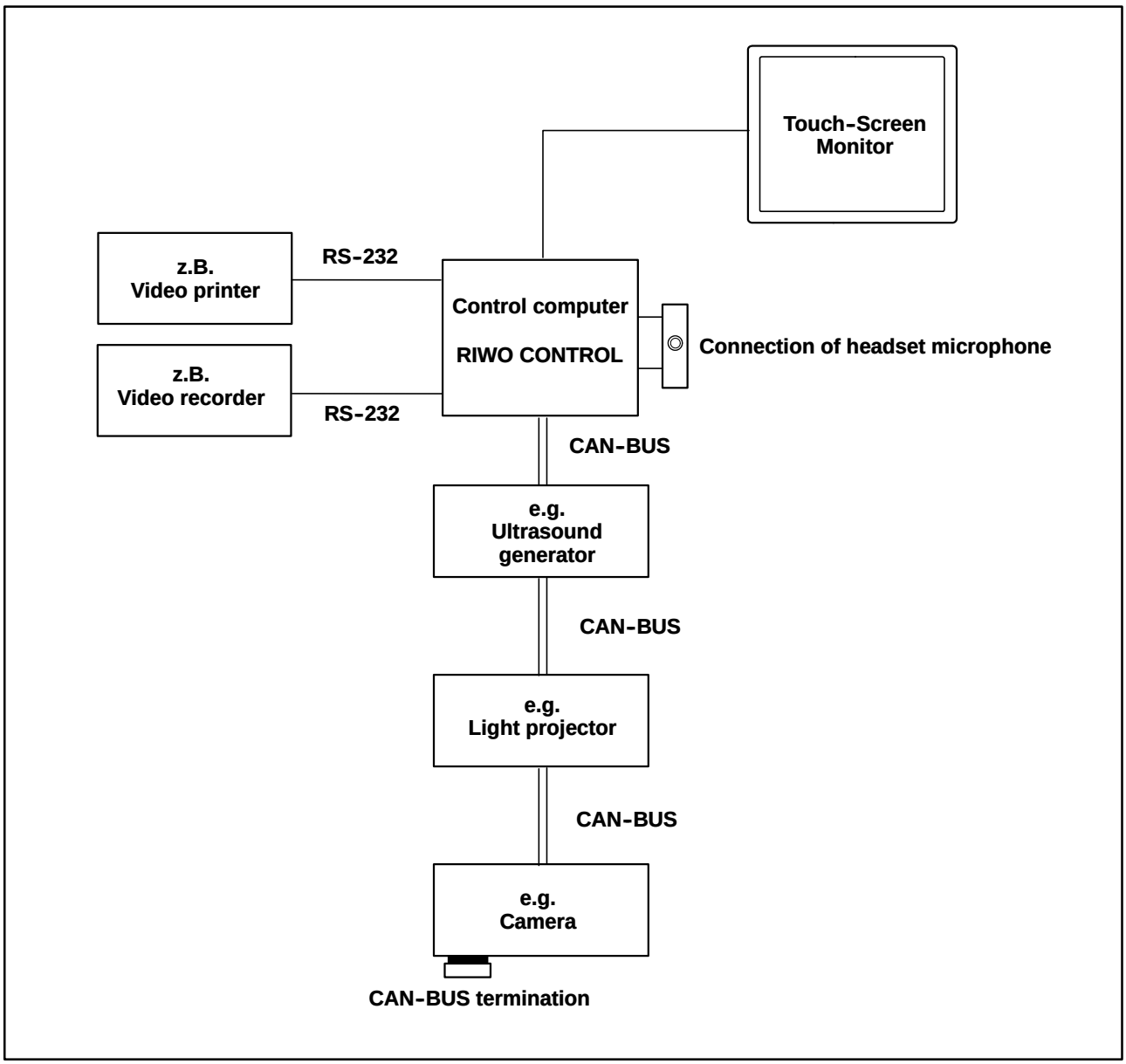
The ultrasound generator unit can be controlled via the RIWO NET SYSTEM with remote control, speech control, touch–screen monitor or manually via the buttons on the device front panel.

☞ ***IMPORTANT!***
The ultrasound generator unit can still be operated via the front panel buttons, should the RIWO NET SYSTEM fail.

☞ ***IMPORTANT!***
To fully understand the system please read the latest manual for the RIWO–NET–SYSTEM.

☞ ***IMPORTANT!***
*For control via the touch–screen monitor it is sufficient to touch the monitor surface **only slightly**.*

6.3 Connection to the RIWO NET SYSTEM



☞ ***IMPORTANT!***
The device system must be operated via a "Separating transformer with DC coupling".

☞ ***IMPORTANT!***
The last device in the CAN-BUS chain requires a termination using the supplied terminating resistor.

6.4 Controlling the devices using the RIWO-NET menu

6.4.1 Controlling the devices via the different input media

Via Touch-Screen Monitor:

- The function is selected and executed by gently touching the desired menu function (button) directly on the Touch-Screen Monitor.

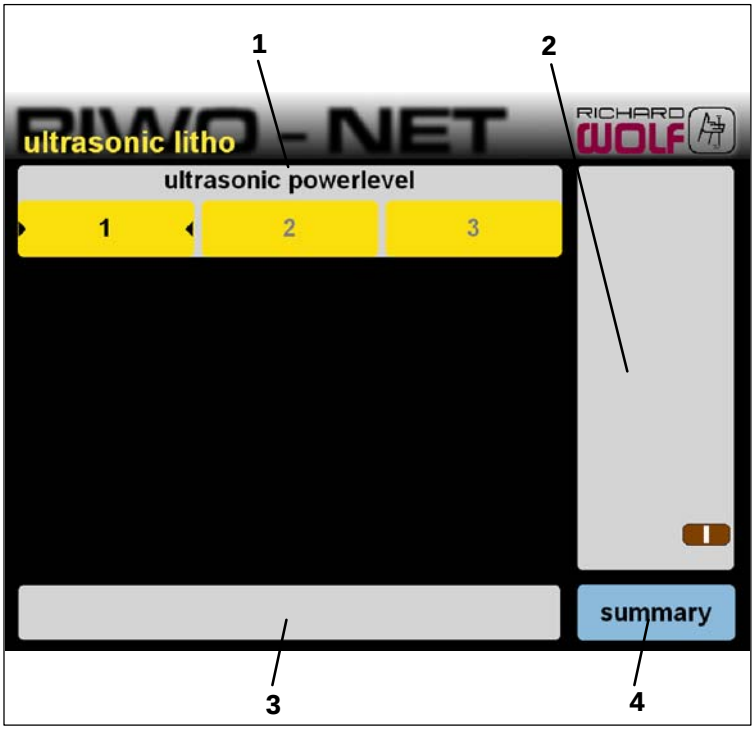
Via voice control:

- The same instructions/commands must be used as displayed on the Touch-Screen Monitor.
- If an instruction/command consists of a “Function” and an “Action”, both terms must be pronounced one after the other without pausing. Example: “SUCTION RATE” – “MINUS” or “SUCTION RATE” – “PLUS”
- Before and after each instruction/command, a short pause of approx. 0.5 seconds is required.

Via remote control unit:

- The arrow buttons serve to select the corresponding device in the main menu and the corresponding function in the submenu.
- The yellow buttons serve to execute the corresponding action.
- The blue buttons serves to return to the main menu.
  From the main menu, the RIWO NET SYSTEM can be exited, in which case the computer is shut down automatically.

6.4.2 Illustration of menu



Legend

1	Control menu	**3**	System messages
2	Status display	**4**	Back to main menu

6.4.3 Main menu

The main menu lists all devices connected to the RIWO NET SYSTEM. Selecting a device calls up and displays the corresponding device menu.

6.4.4 Ultrasound output function

◇ The “Ultrasound output” menu item serves to preselect the output power stage 1, 2 or 3 of the ultrasound transducer.

6.5 System messages

☞ ***IMPORTANT!***
If you cannot eliminate the fault or error with the help of this table, please contact the service department or return the device for repair.
◗ *Do not attempt to do any repairs yourself!*

★ Depending on the status or error state the POWER CONTROL displays the following messages on the RIWO–NET menu monitor:

6.5.1 Operating instructions

Message type	Message text	Possible cause	Remedy
Operating instruction 1	Maximum output selected	Stage 3 is selected, although this stage has already been selected.	◗ ----

“**+ Voice output**” = In the case of the system messages marked with this symbol an additional acoustic warning is sounded (only if the “ Voice output” option is available).

6.5.2 Warnings

Message type	Message text	Possible cause	Remedy
Warning 1	Malfunction of transducer or sonotrode	Sonotrode is not in resonnance because the sonotrode is not firmly bolted down, the flange surfaces of the sonotrode or transducer are soiled or the wrong power setting has been preselected.	◗Firmly bolt down the sonotrode ◗Clean the flange surfaces of the sonotrode or transducer ◗Select a different power stage.

6.5.3 Error messages

Message type	Message text	Possible cause	Remedy
Fault 1	Ultrasound output power too high	When actuating the footswitch, for 1 second the current ultrasound output power is higher than the preselected power.	◗Contact the service dpt.

7 Reprocessing and maintenance

7.1 Reprocessing of device

WARNING!
Danger if moisture enters in the device.
Danger of electric shock.
Before reprocessing, the device must be switched off and disconnected from the mains/power supply.

The device can be cleaned with a soft cloth soaked with surface disinfectant, alcohol or spirit.
Follow the disinfectant manufacturer's instructions.

IMPORTANT!
Make sure that no humidity enters in the device. Do not use any cleaning agents, scouring agents or solvents on the device!

7.2 Reprocessing of accessories

⚠ ***CAUTION!***
Danger of infection due to unsterile parts and accessories. Sterilize reprocessible parts and accessories before use. Follow the regulations on sterilization valid in your country.

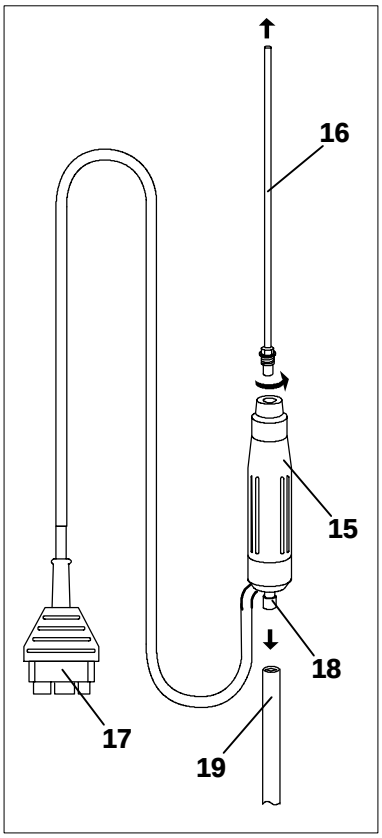
☞ ***IMPORTANT!***
Follow the procedures described in the ***"General instructions and notes on the reprocessing of R. Wolf products, accessories and devices"*** *(order no.: GA-J 020) .*

7.2.1 Wet preparation at the point of use

After use immerse used accessory items such as transducer, sonotrodes and suction tube in a disinfectant solution for wet preparation at the point of use.
For this pupose follow the disinfectant manufacturer's instructions!

◇ Disconnect connection bar (**17**) of the transducer (**15**) from the device. Disconnect suction tube (**19**) from the tube connector on the device. Immerse accessories in the solution for wet preparation at the point of use.

7.2.2 Disassembly before cleaning



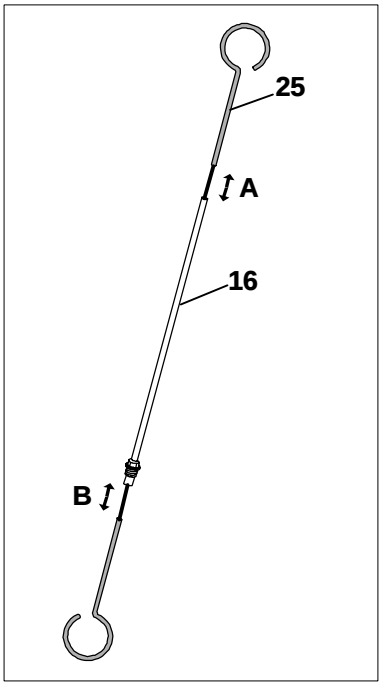
Remove accessories items before cleaning.

◇ Unscrew the sonotrode (**16**) with the supplied open-ended wrench (size: quarter inch) by turning counter clockwise (right hand thread). Disconnect suction tube (**19**) from tube connector (**18**) of the transducer.

7.2.3 Manual cleaning

Prior to disinfection, clean and dry disassembled accessory items manually as follows:

◇ **Transducer:**
Clean transducer (**15**) and rinse transducer channel with a cleaning gun.
Clean the transducer with a suitable cleaning rod (2167.508) first from the distal end, then from the proximal end (tube connector). Ensure that the transducer channel is clean and free of residues through its entire length.
Clean the flange surface of the transducer with a brush.
Clean the transducer channel with a cleaning gun, and dry the channel with compressed air, the transducer surface with a cloth.



◇ **Sonotrodes:**
Clean sonotrodes (**16**) and rinse sonotrode channel with a cleaning gun.
Clean sonotrodes with a suitable cleaning rod (**25**) first distally (**A**), then proximally (**B** adapter flange) from both ends. Ensure that the sonotrode channel is clean and free of residues over its entire length.
Clean the flange surface of the sonotrode with a brush.
Clean the sonotrode channel with a cleaning gun, and dry the channel with compressed air, and the sonotrode surface with a cloth.
Check the sonotrodes for wear and damage as described in section 5.4.1, dispose of damaged or worn sonotrodes as required by the regulations.

◇ **Suction tube:**
Clean the suction tube (**19**) and rinse with a cleaning gun from both ends. Make sure that the tube is free of residues inside and out throughout its entire length.
Then dry the tube channel with compressed air and the outside with a cloth.

7.2.4 Machine cleaning

◇ **Sonotrodes:**
Due to the length and the small internal dimensions of the sonotrode,machine cleaning is not recommended.

◇ **Transducer:**
The transducer can be reprocessed manually. To prevent any damage to the transducer, we recommend using the transducer reprocessing basket (38011.501). See instruction manual GA–J 040.

7.2.5 Disinfection

For disinfection, immerse accessories in disinfectant solution. Before you immerse the parts fill the channels of the transducer, sonotrode and suction tube completly with disinfectant using a syringe.
Follow the disinfectant manufacturer's instructions!
After disinfection dry the channels of the accessory items with compressed air and the surfaces with a sterile cloth.

☞ ***NOTE!***
Do not use disinfectants containing chlorine or phenole derivate for the disinfection of R. Wolf products.
Avoid immersion/soaking times of more than two hours!

7.2.6 Steam sterilization

Never steam–sterilize the tranducer and the sonotrodes in assembled condition!
To sterilize the transducer, we recommend the transducer reprocessing-basket (38011.501). See instruction manual GA–J 040.

◇ Steam sterilization at 134°C (272°F) using the fractional method.

7.2.7 Assembly

Assemble accessories only immediately before use and in reverse order as described under 'Disassembly'.
Follow assembly instructions for sonotrodes under section 5.
Perform the neccessary checks before each use in accordance with section 4.

7.2.8 Reprocessing of foot switch

The device can be cleaned with a soft cloth moistened with surface disinfectant, alcohol or spirit.
Follow the disinfectant manufacturer's instructions!

7.3 Maintenance of device and accessories

7.4 Maintenance

☞ ***NOTE!***
In your correspondence please always specify the model/type and series number indicated on the identification plate. If required further documentation is available from the manufacturer.

7.4.1 Maintenance intervals

☞ ***IMPORTANT!***
To prevent damage that results from ageing and wear of the device and the accessories maintenance must be carried out at adequate intervals. Depending on the frequency of use, however every twelve months at the latest, have an expert check the functional and operational safety.

7.5 Quarterly check

☞ ***IMPORTANT!***
The check may only be performed by qualified and adequately trained personnel of the user.
Do not use the devices if the specified values are not displayed or the functions are not fulfilled.
If the specified values and tolerances are not adhered to, the system must be checked by an authorized service technician.

☞ ***NOTE!***
The quarterly check must comprise a visual check as described in section 4.1.

7.5.1 Measuring devices and auxiliary means for checking

◇ Transducer with sonotrode and suction tube.
Suction device or suction pump with accessories.
Transparent container (e.g. measuring vessel with a contents of approx. 2–4 litres)

☞ ***IMPORTANT!***
When testing the function of the Ultrasound Generator, make sure that liquid is pumped off through the sonotrode.

7.5.2 Visual check

◇ Check the device setup, connection and connection cable for correctness in accordance with section 3 of this manual.

7.5.3 Functional checks

⚠ ***CAUTION!***
Danger of transducer or sonotrode overheating.
The transducer must only be activated if irrigation fluid is pumped off through the sonotrode at the same time.

☞ ***IMPORTANT!***
Before you carry out a function check, make sure that the devices and accessories are in perfect technical state and have been set up correctly. To ensure this, carry out a visual check.

Function test of Ultrasound Generator and transducer:

◇ Connect the transducer to the Ultrasound Generator and the suction tube to the suction connector of the transducer.

◇ Place the transducer together with the sonotrode in a suitable container filled with sterile liquid or irrigation fluid.

◇ Switch on the Ultrasound Generator and the suction function, and adjust the suction rate.

◇ Select the highest power stage on the Ultrasound Generator, hold the transducer and briefly actuate the footswitch.

➧ The sonotrode should start vibrating and generate noise. For this purpose lift the transducer with the sonotrode out of the liquid to the extent that the tip remains immersed far enough to ensure reliable suction. Oscillation amplitudes must be visible along the sonotrode tube.
If the noise is only low or if the sonotrode clanks audibly, check the screw connection of the sonotrode. When assembling the sonotrode and the transducer, make sure that the flange surfaces are clean and the screw connection is tight. Then repeat the test.
If neither oscillations nor a noise is generated or the “transducer malfunction” (**6**) warning lamp lights up, repeat the test with a spare transducer.

Test generator fault monitoring:

◇ With the footswitch actuated, switch from the highest to the next lower power stage.

➧ During switch–over, the “ generator malfunction” alarm lamp (**7**) should light up briefly.

◇ Repeat switch–over test until the lowest stage is reached.

☞ ***NOTE!***
The drilling performance of the sonotrode can be tested with the help of a test item (surgically removed kidney stone or comparable material). For the test, use the same setup and procedure as described under "transducer/sonotrode function check" as well as the following test routine:

◇ *Prepare the Ultrasound Generator and Suction Pump as for the function tests of the transducer and sonotrode.*

◇ *Place the test item in a container filled with irrigation fluid.*

◇ *Hold the transducer in such a way that the sonotrode tip touches the test item (do not press, use suction effect of pump).*

◇ *Actuate the foot switch.*

➧ *Within a matter of a few seconds the sonotrode should drill into the stone. The drilling effect will depend on the sonotrode contact as well as the hardness of the test item. Switch to the different power stages to check the drilling behaviour at different intensity settings.*

7.6 Technical safety check

☞ ***IMPORTANT!***
Technical safety checks may only be carried out by the manufacturer or persons with special technical knowledge.
The test results must be documented and included in the device accompanying book.
Do not use the device if the specified values are not shown or measured, or functions are not fulfilled.

Test interval:
Every 12 months, perform a technical safety check with the following scope:

◇ Visual check for completness, contamination, aging and wear.

➧ Check lettering and labelling for proper condition and legibility.

➧ Check electrical lines and connectors for condition, possible damage and correct connection.

➧ Check liquid delivery systems for leakage.

◇ Electrical safety check to IEC/EN 60601–1.

➧ Check protective ground/earth connection.

➧ Check leakage current.

◇ Check function in accordance with this manual.

8 Technical description

8.1 Trouble shooting

☞ ***IMPORTANT!***
If you cannot eliminate the faults with the help of this table, please contact the service department or return the device for repair.
➧ *Do not attempt to do any repairs yourself!*

8.1.1 Device faults

Fault/error	Possible cause	Remedy
Device without function	– Mains/power switch not on	➧Actuate mains/power switch
	– Power cord not connected	➧Connect power cord
	– Device fuse defective	➧Replace fuse
	– No mains/line voltage	➧Check in–house power supply
“Generator fault” alarm lamp (**7**) lights up when the device is switched on	– Device defective	➧Contact service department or return the device for repair
Transducer without function	– Foot switch incorrectly connected	➧Connect foot switch/ check plug for correct connection
	– Transducer improperly connected	➧Connect transducer/ check plug for correct connection
	– Preset power stage button is not lit	➧Contact service department or return device for repair
	– “Footswitch actuated” signal lamp (**5**) does not light up when actuating the footswitch	➧Contact service department or return device for repair.
“Transducer malfunction” warning lamp (**6**) lights up when the footswitch is actuated	– Transducer defective	➧Replace transducer
	– Sonotrode improperly connected	➧Check screw connection of sonotrode for correct and tight connection.
No sonotrode oscillation/ improper oscillation	– Sonotrode improperly connected	➧Check screw connection of sonotrode for correct and tight connection.
	– Sonotrode damaged	➧Check sonotrode for proper operation or replace
	– Transducer defective	➧Replace transducer
	– Flange surface of sonotrode or transducer soiled	➧Clean flange surfaces
	– Device defective	➧Contact service department or return device for repair

8.2 Technical data

8.2.1 Electrical connection

Model/type	Voltage V ~	Frequency Hz	Power consumption VA	Current rating A	Fuse A
2271.001	230	50 / 60	200	0.9	T 1.25 L
2271.002	100	50 / 60	200	2.0	T 2.50 L
2271.003	110 / 115	50 / 60	200	1.8	T 2.50 L
2271.004	120 / 127	50 / 60	200	1.7	T 2.50 L
2271.101	230	50 / 60	200	0.9	T 1.25 L
2271.102	100	50 / 60	200	2.0	T 2.50 L
2271.103	110 / 115	50 / 60	200	1.8	T 2.50 L
2271.104	120 / 127	50 / 60	200	1.7	T 2.50 L

8.2.2 Technical data of ultrasound generator

Electromagnetic compatibility (EMC) to	IEC / EN 60601-1-2
Medical Devices Directive 93/42/EEC	Class II b
Protection against electric shock	see transducer
Protection class to IEC / EN 60601-1; (UL 2601-1 / CSA C22.2 No.601.1 - for USA)	I
Degree of protection against the ingression of liquid	IP 20 (Not protected)
Duty factor	Continous operation with load interval (INT. 20 sec / 20 sec)
Noise level	75 dB(A)
Degree of protection in the presence of flammable gasses	This device is not protected against explosions (Do not operate this device in flammable environments)
Weight	8.5 kg (18.7 lbs)
Dimensions WxHxD	320 mm x 105 mm x 360 mm

8.2.3 Interfaces of ultrasound generator

Transducer output	1 x connector strip, 2 x 9-pole
Footswitch output connector	1 x socket, 3-pole
Suction device output socket (Suction Pump)	1 x socket, 4-pole
Connectors for RIWO NET SYSTEM (option)	2 x socket, 9-pole

8.2.4 Technical data of transducer (2271.501)

Protection against electric shock	BF type applied part
Degree of protection against the ingression of liquids	IP 67
Degree of protection in the presence of flammable gasses	This device is not protected against explosions. (Do not operate this device in flammable environments)
Weight	0.300 kg (0.7 lbs)
Dimensions (dia. x length)	30 mm x 143 mm

8.2.5 Technical data of footswitch (2030.12)

Degree of protection against the ingression of liquid:	IP 68
Degree of protection in the presence of flammable gasses	This device is not protected against explosions. (Do not operate this device in flammable environments)
Weight	0.730 kg (1.61 lbs)
Dimensions (Width x height x length)	70 mm x 61 mm x 220 mm

8.3 Operating, storage, transport and shipping conditions

Operating conditions	ambient temperature + 10°C to + 40°C, 30% to 75% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa
Storage, transport and shipping conditions	ambient temperature – 20°C to + 60°C, 10% to 90% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa

☞ ***NOTE!***

To avoid damage to the products during transport or shipment we recommend using the original packaging material.

8.4 Spare parts and accessories

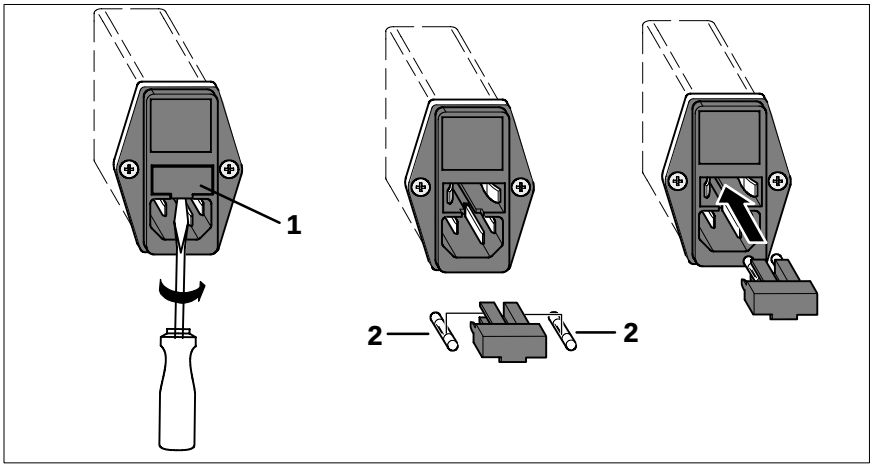
Ultrasound generator		
Units	**Model/type**	**Designation**
1	64268.003	Device fuse T 1.25 L (pack of 10St.)
1	72315.008	Device fuse T 2.5 L (pack of 10)
1	2440.03	Power courd (Europe), 3.0 m
1	64221.093	Suction tube, dia. 5.0 mm , length 2.0 m, 60 shore
1	2167.951	Ear plugs (Ear protection, pack of 10)
1	2030.12	Foot switch
1	2271.501	Transducer
1	74003.009	Open end wrench (size $^1/_4$ inch)
		In addition for 2271.10x:
1	103.701	CAN BUS connection cable, length 0.6 m
Probes for Nephroscopy		
Units	**Model/type**	**Designation**
1	8962.519	Sonotrode (dia. 1.9 mm, working length 361 mm, straight)
1	8962.524	Sonotrode (dia. 2.4 mm, working length 359 mm, straight)
1	8963.535	Sonotrode (dia. 3.5 mm, working length 358 mm, straight)
1	8962.541	Sonotrode (dia. 4.0 mm, working length 358 mm, straight)
1	8963.635	Sonotrode with core drill bit (dia. 3.5 mm, working length 370 mm, straight)
1	8962.641	Sonotrode with core drill bit (dia. 4.0 mm, working length 360 mm, straight)
Probes Uretero-renoscopy		
Units	**Model/type**	**Designation**
1	8954.515	Sonotrode (dia. 1.5 mm, working length 564 mm, straight)
1	8954.519	Sonotrode (dia. 1.9 mm, working length 562 mm, straight)
1	8959.515	Sonotrode (dia. 1.5 mm, working length 444 mm, straight)
1	8959.519	Sonotrode (dia. 1.9 mm, working length 458 mm, straight)
Others		
Units	**Model/type**	**Designation**
1	2167.508	Cleaning rod for transducer and sonotrodes, dia. 3.5 – 4.0 mm
1	2167.509	Cleaning rod for sonotrodes, dia. 1.5 – 2.4 mm
1	38011.501	Reprocessing basket for transducer
1	2207.991	Device connection cable (4 pole)
		➧ further accessories on request

8.5 Replacing parts

8.5.1 Device fuses

CAUTION!
The specification of the fuses in the device must correspond with the fuse ratings on the identification plate.
Use only the fuses specified in the spare parts list.

★ ***Device power connector with fuse holder***



◇ Switch off the device and disconnect the power cable from both the wall socket and the device connector.

◇ Use a screwdriver to remove the fuse holder (**1**).

◇ Then remove the fuses (**2**) from the fuse holder (**1**) and replace.

◇ Reinsert the fuse holder and push until it snaps into place.

8.5.2 Disposal of the product, packing material and accessories

For the disposal make sure you adhere to the regulations and laws valid in your country.

➧ For further information please contact the manufacturer.

9 Literature

☞ ***IMPORTANT!***
As we cannot provide a comprehensive bibliography we would ask users to keep themselves informed of all new developments in this field.

◇ **Atlas der urologischen Endoskopie**
Band 2: Diagnostik und operative Endoskopie
Hans Joachim Reuter
1984, Georg Thieme Verlag Stuttgart, New York

◇ **Extra- und Intrakorporale Lithotripsie**
Ch. Ell, M. Marberger, P.Berlien
1990, Georg Thieme Verlag Stuttgart, New York