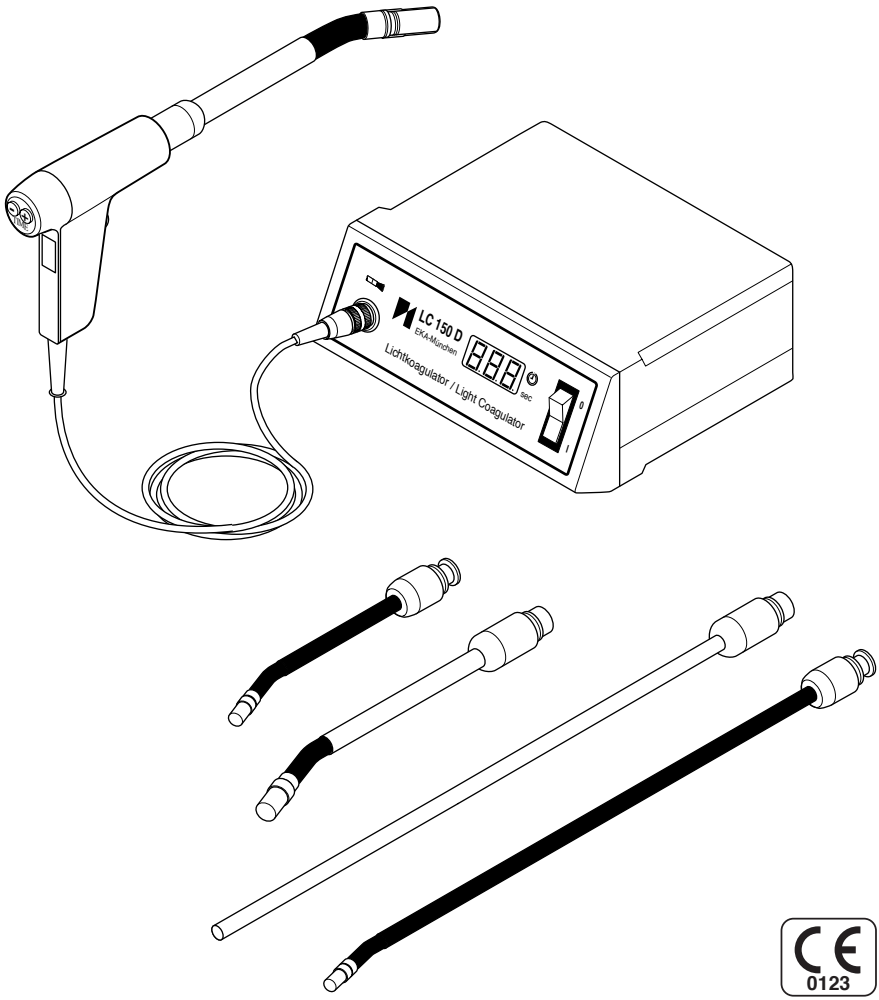
LC 150 D

Light Coagulator Digital
Instruction Manual



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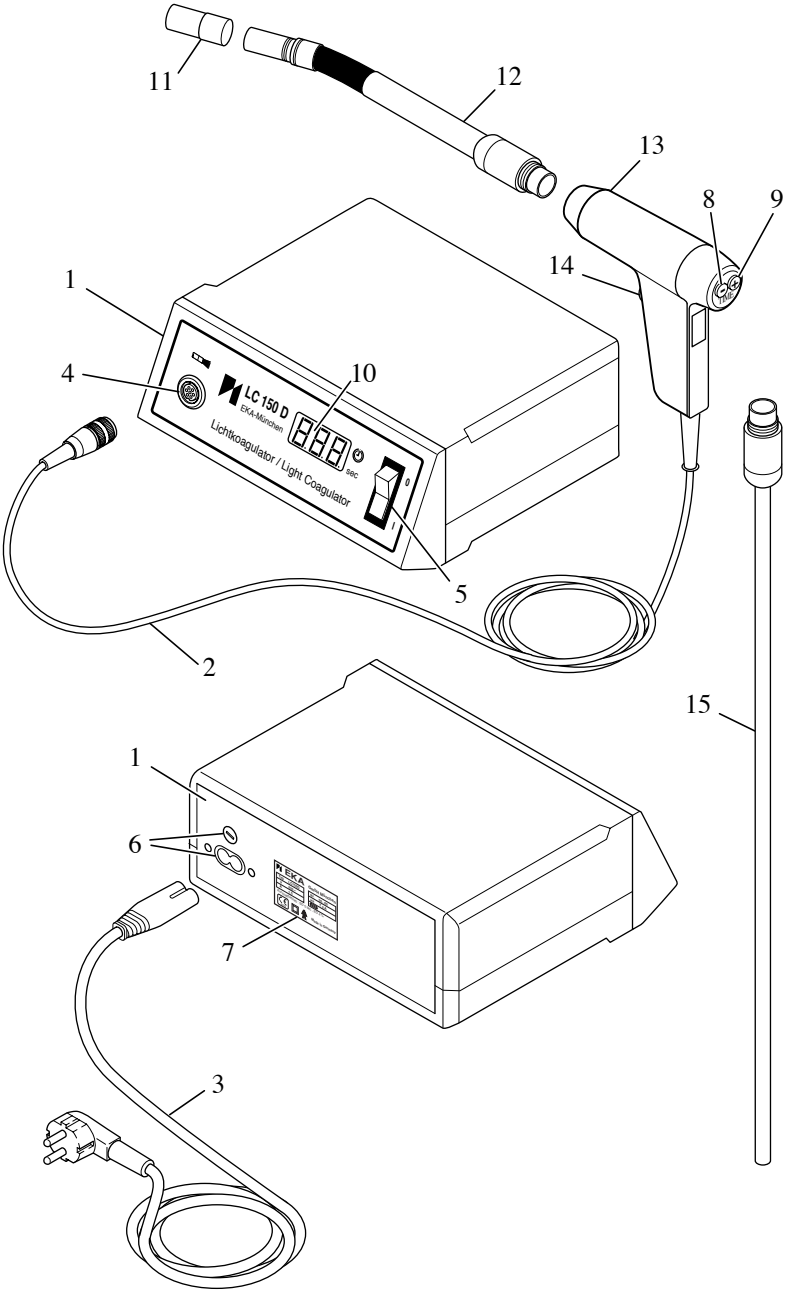
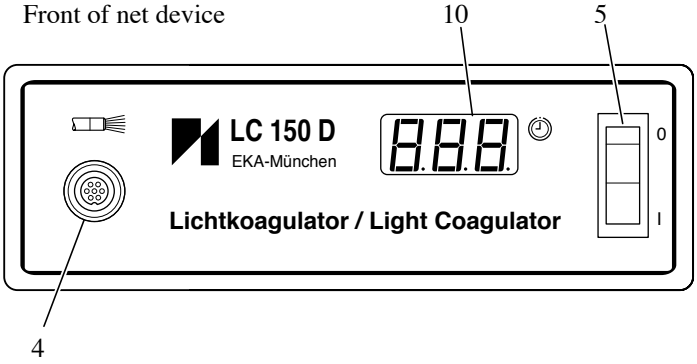
1 Technical Description



1 Technical Description

Initiation Process

Insert net cable (3) into socket (6) at rear of casing and probe cable (2) into socket (4) on front of casing.
Screw desired coagulation probe to probe adapter and adjust coagulation time.
The light coagulator LC 150 D is now ready for operation.
Please note chapter 4 ”Important Notes” and the directions in chapter 5 ”Use with Timer” or chapter 6 ”Practically noninterrupted operation”.



1 net device, front and rear
2 probe cable
3 net cable
4 probe socket
5 net switch
6 net socket, fuse
7 name plate
8 minus key ⊖
9 plus key ⊕
10 time display
11 contact head
12 coagulation probe, screw-in
13 probe adapter for screw-in probes
14 trigger key
15 endoscopic probe, screw-in

2 Functional Methods

Physical Principles of the Light-Contact-Coagulation

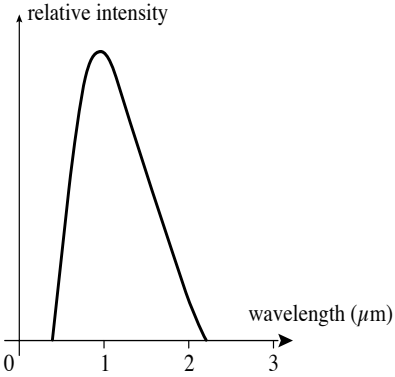
Intense light advances several millimeters into the bleeding tissue, where it is absorbed and converted to heat.

Dependent on the structure of the tissue and the application duration, sufficient temperature is obtained within seconds to achieve the following:

Effect	Temperature	Duration of Impulse	Coagulation Depth
Denaturalization	at approx. 50-60°C	approx. 0,5-2,0 s	approx. 1-2 mm
Evaporation of Cell Water	at approx. 100°C	approx. 2,0-3,5 s	approx. 2-3 mm
Collagen (Glue)	at approx. 170°C	approx. 3,5-5,0 s	approx. 3-5 mm
Carbonization	at approx. 300°C	over approx. 5,0 s	max. approx. 5-7 mm

Due to the consistency of blood, light waves achieve the greatest penetration depth at wavelengths of 0.7 - 1.2 μm. Consequently, it is desirable to employ radiation with a spectral distribution maximum of 1 μm, in order to achieve sufficient coagulation depth.

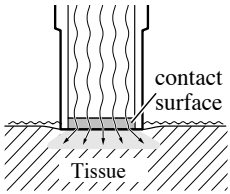
Spectral Distribution



2 Functional Methods

Application of the Light-Contact-Coagulation

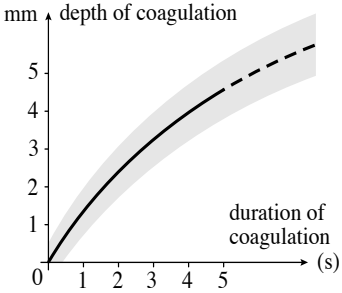
The tip of the probe is gently pressed onto the bleeding tissue surface (contact coagulation).



The duration of the impulse is controlled by a timer.

The hand switch is employed to trigger off the light impulse.

Due to the conversion of light to heat the light impulse generates a coagulation in the tissue. The depth in millimeters corresponds approximately to the duration of impulse in seconds.



After the light impulse extinguishes, the probe may be removed and immediately reapplied elsewhere. This is possible because of the absence of adherence to the probe, since only the tissue and not the tip of the probe (contact surface) absorbs radiation.

This results in a precisely definable coagulation area and depth.

Larger areas which require coagulation should be treated according to the ”mosaic-principle”.

3 Application

The LC 150 D with its selection of probes has been specially developed for outpatient treatment and for effective, locally confined coagulation in the following areas:

Hemostasis involving Rectoscopy Procedures

polypectomy
mucosa biopsy
diagnosis of chronic inflammatory intestinal diseases
tumor tissue biopsy
biopsy of anastomatic areas
biopsy of scar tissue
palliative therapy of heavily bleeding tumors or large polyps without tissue removal

Hemostasis in Gynecology

conization
resection of myometrial tumors
surgical therapy of endometriosis

Hemostasis in Proctology

analpolypectomy
removal of excessive tissue (skin tags) from healed hemorrhoids
hemorrhoidal bleeding
abscess and fistula surgery
• fissure coagulation
• condylomectomy

Hemostasis in Colostomy (Anus Praeter Patients)

post polypectomy of chronic inflammatory intestinal diseases and granulation polyps

Hemostasis in Out-Patient Surgery

soft tissue tumors, ex: lipoma, fibroma, hemangioma or
lymph fistula formation
deeper lymph node resections (diffuse bleeding)
septic procedures, ex: abscesses, infected atheromas and furuncles, especially in patients with low clotting reaction values
varicose veins – but without skin contact

3 Application

Hemostasis in Minimal-Invasive Surgery

gall ectomy
hernias
biopsies
biopsies operation using trocar and rigid endoscopy
laparoscopy

Further operational areas of the LC 150 D

hemostasis in arthroscopic procedures
hemostasis in tonsil operations

For application probes see appurtenance or parts list.

Important Notes

The device is designed for short periods of operation. In the case of rapid, short interval impulse emmitance, the probe head may heat up due to the dissipated radiation. If this happens avoid skin contact with this area.

Cooling phases are necessary in between separate coagulations.

Important Notes

The duration of the cooling phase must be at least as long as the duration of the coagulation.

Never coagulate without contact.

Never coagulate longer that 5 s in any given place.

Clean the contact surface as often as possible using a wet sterile pad. The surface should always appear polished.

5 Use with Timer

- Install the device according to the initiation process described on page 5.
- Program the desired coagulation time (see page 13). Begin with a short coagulation duration (app. 1.5 to 2 s) which is then slowly increased.
- Try to dab or vacuum the hemorrhage site immediately before the coagulation. This reduces the blood accumulation and allows coagulation with a minimum of energy.

  Place the contact surface (11) **completely** onto the tissue. Do not switch on the coagulator before the contact is ensured.
- Operate the hand switch. The coagulation probe lights up and simultaneously an acoustic signal sounds. The time display begins the count down, indicating the remaining coagulation time. The coagulation process is immediately interrupted if the hand switch is released.

  After the coagulation period lapses the radiation extinguishes and the time display returns to the original time. The coagulator is ready for the next impulse emmitance.
- After app. 2.5 - 3 s the tissue coagulation becomes noticable through a hissing sound and steam development.

  Do not remove the contact surface before the radiation ceases. Using the timer ensures a defined necroses depth for each coagulation cannot be exceeded, since the length of coagulation is automatically limited.
- Please regard chapter 4, ”Important Notes”, pages 10-11.

5 Use with Timer

Adjusting the coagulation (timer usage)

The coagulation period is adjusted with the keys ⊕ and ⊖ on the rear of the adapter.

The plus-key (9) ⊕ increases the time in intervals of 0.25 s.

The minus-key (8) ⊖ decreases the time in intervals of 0.25 s.

The coagulation time appears on the time display (10).

6 Practically noninterrupted operation

- Install the device according to the initiation process described on page 5.
- Select the maximum coagulation on the time display (10) of 10 s.
- The duration of impulse and ie. the coagulation time corresponds to the operation time of the hand switch.

  The lamp extinguishes immediately with the release of the hand switch.

  After 10 s the device terminates the coagulation process automatically, due to safety considerations.
- Place the contact surface (11) **completely** onto the tissue. Do not switch on the coagulator before the contact is ensured.
- Do not coagulate too long. After 2.5 - 3 s a hissing sound and a small steam cloud are released. The coagulation process should be terminated at this point.
- Do not remove the contact surface before the radiation ceases.
- Please regard chapter 4, ”Important Notes”, pages 10-11.

7 Sterilization, Disinfection

The coagulation probe, probe adapter, endoscopic probes and probe cable are all autoclavable.

Admissible pressure: 3 bar

Admissible temperature: 135 °C

Admissible time: 20 min

The probe adapter, the screw-in probes and the contact head should be sterilized separately.

If non-adhesive caps are used, these must be sterilised seperately to the probes.

When sterilizing, store the separate pieces in such a way that they cannot be damaged. Special care must be taken with the endoscopic probes and the contact surfaces.

Important:

It is possible to exchange both the probes as well as the contact heads at any point during an operation, since these are sterilized separately from the probe adapter. However, it is not possible to exchange a bulb during an operation.

Caution:

Only autoclavable screw-in probes may be used. These are distinguished by a stainless steel shaft with the imprint ”autoclav”.

Non-autoclavable probes, distinguished by a black shaft, may be gas-sterilized (60°C) or disinfected with conventional antiseptics, always with the contact head screwed on.

7 Cleaning

All parts of the LC 150 D which are autoclavable can also be washed in conventional washing machines. During the washing process the components should be placed or fastened as to avoid be damage. Especially the endoscopic probes and the contact surfaces must be protected.

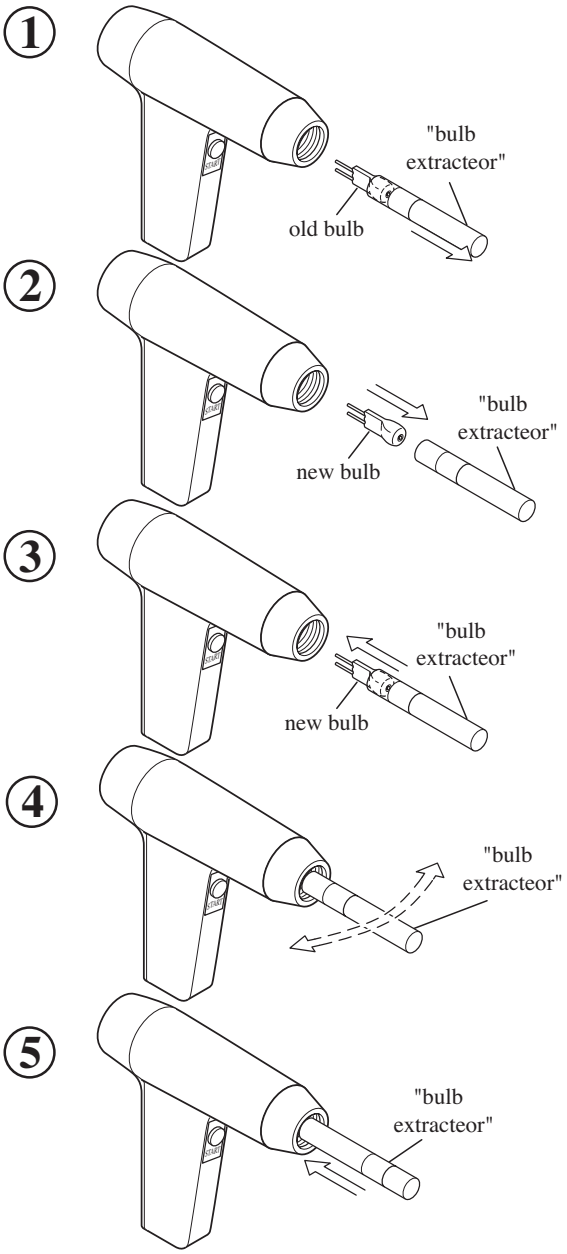
Probe adapter and endoscopic probe must always be cleaned separately. Non-adhesive caps must be removed off the probes before cleaning.

The parts can also be cleaned with water and alcohol. Under no circumstances may acetone be used to clean plastic parts. Burnt residue on the contact surfaces can be removed with a scalpel.

Prior to the use of the device all surfaces, especially the light permeable windows on the probe adapter and the endoscopic probes, should be checked for residue (water droplets, calcium carbonate etc.) and if necessary can be cleaned with a soft, fluff-free cloth.

In general: The cleaner the surfaces, the better the coagulation and the longer the life-time of the device.

8 Exchanging bulps



8 Exchanging bulps

- Remove probe adapter from power supply unit.
- Unscrew probe.
- Probe adapter needs to cool down.
- Pull the end of the rubber tubing of the enclosed ”bulb extractor” over bulb and gently remove it (dia. 1).

  The reflector area must not be contaminated.
- Slightly push the new bulb into the ”bulb extractor” (dia. 2). **Carefully** – touching only the pegs – remove the bulb out of its packaging.
- Important: Never touch the bulb with bare finger, otherwise fingerprints will burn into the surface. If this does accidently happen, the bulb must be cleaned with isopropanol before the next use.
- With the aid of the ”bulb extractor”, insert the bulb into the reflector (dia. 3).

  Release the ”bulb extractor” through gentle back and forth movement if it is too tightly attached to the bulb (dia. 4).
- With the rear of the ”bulb extractor”, push in the bulb until it clicks.

9 Technical Safety Checks

Technical Safety Checks

The device, along with all probes and cables, is subject to an annual safety check.

If approved by us, circuit diagrams, parts lists and examining instructions may be forwarded.

9 Servicing and Maintenance

Servicing

Prior to every operation, the following steps must be completed:

- All probes, especially the contact surfaces, are to be visually examined for mechanical defects.

  Splintered contact surfaces are not to be used. Carbonized or damaged non-adhesive caps are to be exchanged.
- The probe cable is to be checked for mechanical faults (bends, squashes, fatigue etc.).
- The functioning of the bulps should be tested, (the helix of the bulp can break or be fractured due to mechanical impacts). Connect the adapter to the net device and light it up for a short time (2 s). Direct the probe down and away from the body.

  Caution: Do not look into the beam, do not direct the contact surface towards any body part, do not direct the contact surface towards any flammable material.

The o-rings of the probes are to be exchanged regularly, at least after every 20th applications.

Do not leave the probe adapter open, i.e. always store it with a screw-in probe or black safety cap attached to avoid contamination.

Maintenance

Maintenace of the device and all appurtenances may only be conducted by us or someone of our approval, (exceptions are the exchanging of bulps and o-rings).

No parts except for original parts may be used. The use of components from other sources is not permitted. This is especially true for extra bulps and o-rings.

10 Transport and Storage

Transport and Storage

For transport and storage periods of up to 6 months the following storage conditions apply:

Temperature:	0°C to +70°C
Relative Humidity:	10% to 75%
Air Pressure:	500hPa to 1060hPa

Subsequently, values corresponding to conditions of use must be obeyed:

Temperature:	+10°C to +40°C
Relative Humidity:	30% to 75%
Air Pressure:	700hPa to 1060hPa

Storage should take place in closed off areas.

The device should not be subject to extreme jolts or impacts.

10 Disposal

Disposal of the Device, Appurtenances and Packaging

1. Device

At first, all detachable plastic parts (front and rear plates and isolation plates) should be removed. The four components of the casing can now be disposed of as metal waste (aluminium). The two PC-boards, along with the previously detached plastic parts, can now be discarded as the electronic waste.

2. Appurtenances

All appurtenances are to be disposed of as the electronic waste. Products which may be soiled due to contact with body tissue (probes), are to be cleaned according to instructions in the instruction manual.

3. Packaging

The box, as well as all foil, can be recycled (cardboard, polyethyl).

The carrier case (if present) should be kept for future transport.

Environmentally Relevant Materials

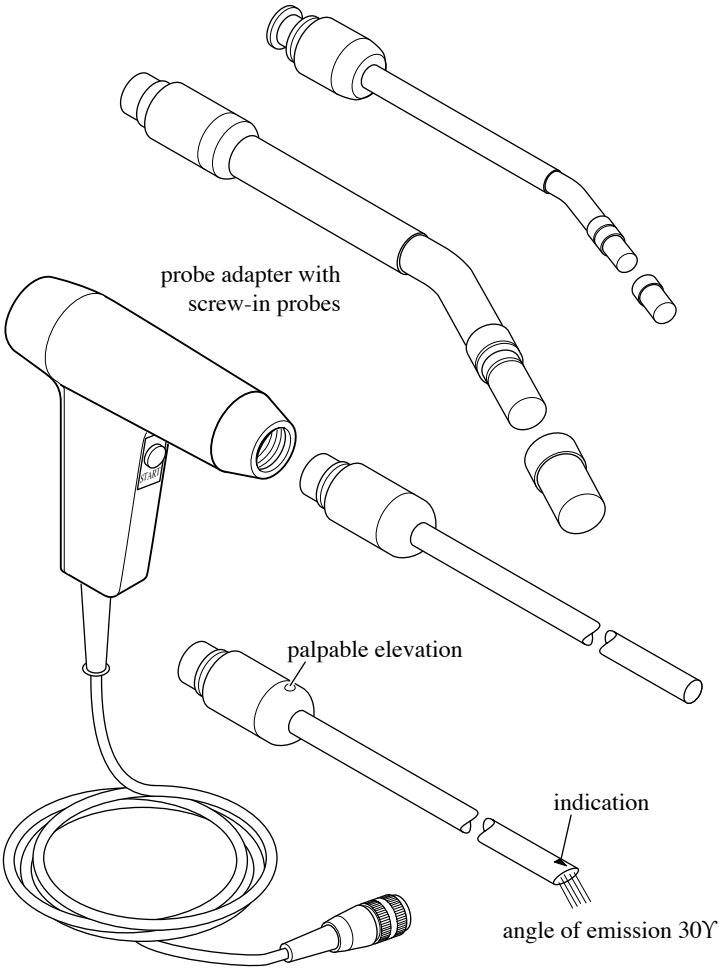
Part	Material
Casing	PS
Keyboard covering	Polyester foil
PC board	Epoxide resin
Transformer	Casing and spools - polyamide 6.6 glass-fibre reinforced plastic
	Wire isolation - polyurethane
	Layer isolation - nornex foil
Probes	Gold, stainless steel, aluminium, casting substance
	heat-strinkable tubing, PTFE, FEP
Probe adapter	Gold, plastic parts - polysulphone, aluminium
	Casting substance

Disposal should be carried out according to the national regulations. Relevant disposal companies may need to be contacted.

All components (net device, probes and all appurtenances) may be returned to the manufacturer for disposal purposes.

11 Technical Data

Probe Construction



11 Technical Data

Power Supply Unit:

Rated Input Voltage;	230 V AC
Rated Frequency:	50 / 60 Hz
Rated Input Power:	0,95 A
Protective Class:	II
Class:	BF
Weight:	app. 3 kg
Dimensions (w, d, h):	205 x 175 x 80 mm

Probe Adapter for Screw-in Probes:

Input Voltage:	15 V
Power:	150 W max
Exchangable, screw-in probes:	various models with contact surfaces of 5 - 16 mm
Output power at tip of probe:	app. 40 W / cm^2 contact surface (for wedged contact surfaces): app. 20 - 25 W / cm^2
Weight, including endoscopic probe:	app. 500 g

The device is designed for short periods of operation (max. impulse duration is 10 s, 4 % of activated time).

The device is tested and certified according to DIN EN 60601-1-2 electromagnetic compatibility (EMV).

It is the responsibility of the user to ensure that none of the above values is exceeded.

Technical data, as well as further development, is subject to change.

12 Key

	Alternating Current
	Fuse
	Timer-controlled use
	Application part, Type BF
	Device of protective class II
	Off (Supply, Separation from Net)
	On (Supply, Connection with Net)
	Probe socket
	Plus key, increases time
	Minus key, decreases time
SD	Duration of impulse
ED %	Duration of activity
	CE marking with Notified Body TÜV SÜD Product Service GmbH, München