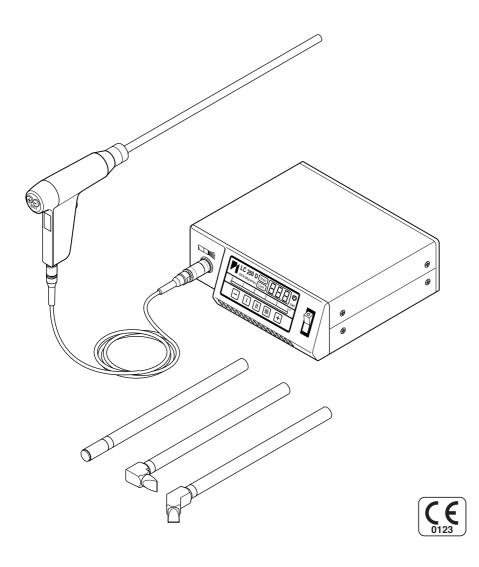
LC 250 D

Light Coagulator Digital Instruction Manual





As of 07/2011 Rev. Nr. 05



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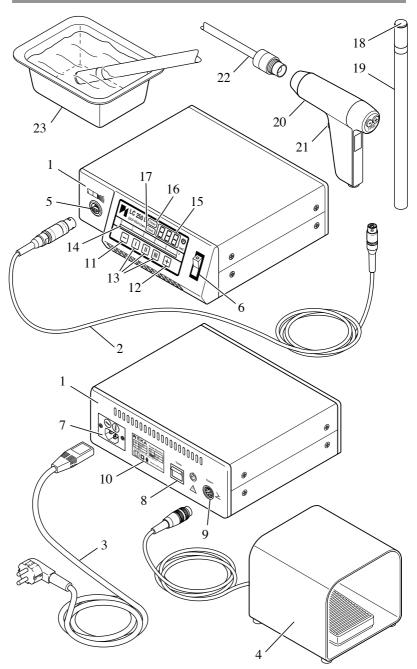


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1 Technical Description



1 Technical Description

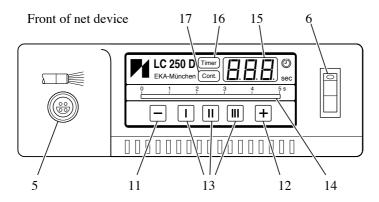
1 Technical Description

Initiation Process

Insert net cable (3) into socket (7) on rear of casing foot switch (4) (if applicable) into socket (9) on rear of casing and, probe cable (2) into socket (5) on front of casing.

Attach the desired coagulation probe to the probe cable and choose method of usage (with or without timer) by operating the timer switch (8) on rear of casing. For probe construction see chapter 12 "Technical Data", page 24. The light coagulator LC 250 D is now ready to be used.

Please note chapter 4 "Important Notes" and the directions chapter 5 "Use with Timer", or chapter 6 "Use without Timer".



- 1 net device, front and rear
- 2 probe cable
- 3 net cable
- 4 foot switch
- 5 probe socket
- 6 net switch
- 7 net socket
- 8 timer switch
- 9 foot switch socket
- 10 name plate
- 11 minus key \Box
- 12 plus key 🛨
- 13 key for pre-programmed coagulation time periods , , ,
- 14 luminous beam

- 15 time display
- 16 green luminous field for timer usage
- 17 yellow luminous field for continuous usage
- 18 contact area
- 19 coagulation probe
- 20 probe adapter for endoscopic probes
- 21 trigger key
- 22 endoscopic probe, screw in
- 23 container with approx. 1.5 l of salt solution



2 Functional Methods

Physical Principle of the Light-Contact-Coagulation

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

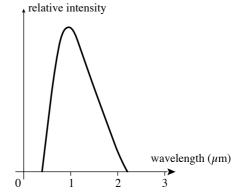
Dependent on the structure of the tissue and the application duration, sufficient temperature is obtained to achieve the following:

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 $0.7 - 1.2 \mu m$.

Consequently, it is desirable to employ radiation with a spectral distribution maximum of 1μ m, in order to achieve sufficient coagulation depth.

Spectral Distribution



2 Functional Methods

2 Functional Methods

Application of the Light-Contact-Coagulation

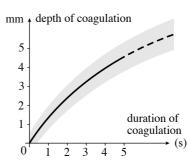
The tip of the probe is gently pressed onto the tissue surface (contact coagulation).



The duration of impulse is controlled by a timer.

The foot/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 with a depth in millimeters, which corresponds approximately to the duration of impulse in seconds.



Subsequent to the light coagulation process, the probe may be removed and immediately reapplied elsewhere. Immediate re-application is possible due to the absence of adherence to the probe, since only the surrounding tissue and not the tip of the probe (crystal) is involved in the absorption of radiation.

Furthermore, it is perfectly possible to coagulate under a blood accumulation, as the probe head has direct contact with the bleeding tissue.

This results in a precisely definable coagulation area and depth.

Larger areas which require coagulation should be treated according to the "mosaic-principle". The choice of probe depends on the geometric location, as well as the type of hemorrhage involved.

The wedge-shaped probe head should only be used in case of ruptures, which guarantee complete contact with both wedged contact areas. In case of a tangential position of the hemorrhage the wedge may not be used, since it is impossible to obtain contact with both of the wedged contact areas, hence an undesirable light emmitance cannot be avoided. When coagulating ruptures with wegde-shaped, two-way light emitting contact areas, the coagulation period should be expected to be doubled.



3 Application

The LC 250 D and its specially designed probes are as well ideal for effective, locally confined endoscopic application as for conventional open surgery in the following areas:

Hemostasis in Abdominal Surgery-Tumor Surgery

atypical and anatomical partial hepatic resections resections of liver metastasis wedge-shaped excisions of liver biopsies Echinococcus cyst excisions liver transplantations

Hemostasis in Abdominal Surgery-Traumatology for both children and adult patients

superficial capsule lesions of liver and spleen deeper ruptures of the liver and spleen

Hemostasis in Urology

kidney tumor enucleation renal cyst resections heminephrectomy kidney ruptures diffuse bleeding of small retroperitoneal vessels

Hemostasis in Thoracic Surgery

parenchym sealing of wedge-shaped excisions parenchym sealing of segment resection and lobectomy coagulation of small emphysema blisters coagulation of open lung biopsy palliative operation for histology petechial thorax wall bleeding

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

3 Application



3 Application

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-Petient 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

Hemostasis in Minimal-Invasive Surgery

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

Further operational areas of the LC 250 D

hemostasis in the gall bed hemostasis in stomach wall surgery hemostasis in arthroscopic procedures hemostasis in tonsil operations

For application probes see appurtenance or parts list.

4 Important Notes

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.

Principally, during a coagulation pause the tip of the probe (the first 10-15 cm) should be kept in a salt solution (approx. 1.5 l).

Cooling phases are necessary in between each separate coagulation.

In the case of continuous power-output (coagulation period) of 15 s and longer the cooling phase must take place with the probe immersed in a salt solution.

The duration of the cooling phase must amount to a minimum of the duration of the coagulation.

The immersion of the probe in salt solution also alleviates the cleansing process of the crystal, since burnt tissue is soaked and can easily be wiped away. If tissue is burnt so deeply into the crystal that wiping is not sufficient, a scalpel can be used to scratch away residue.

4 Important Notes



Important Notes

4 Important Notes

Never coagulate without contact.

Never coagulate longer than 5 s in any given site.

Prior to each operation, set up a stable container with salt solution (approx. 1.5 l), to use for the cooling process.

Clean the crystal as often as possible using a wet sterile pad, so that the crystal constantly appears polished.

Non-adhesive caps see page 15.



5 Use with Timer

- Install the device according to the initiation process described on page 5.
- Switch the timer switch (8) on the rear of the device to the position . The green luminous field with the inscription "Timer" will now light up.
 - Adjust the time display (15), so that it indicates your chosen coagulation period (see page 13). Begin with a short period of coagulation (approx. 1.5 2.0 s) and then slowly increase the value.
- Immediately before the coagulation attempt to dab or vacuum the hemorrhage site. This reduction of the blood accumulation results in coagulation with a minimum of energy.
 - Apply the contact area (18) **wholly** to the tissue. Switch on the coagulator only if complete contact is ensured.
- Operate the foot/hand switch. The coagulation probe lights up and simultaneously an acoustic signal sounds. The time display, as well as the luminous beam, begin the countdown, indicating at any given moment the remaining coagulation time. The release of the foot/hand switch results in an immediate interruption of the coagulation process.
 - After the coagulation period lapses the radiation extinguishes and the time display, as well as the luminous beam, return to the original time. The coagulator is ready for the next impulse emmitance.
- After approx. 2.5 3.0 s, the tissue coagulation becomes noticeable, due to a hissing sound and the development of steam.
 - Do not remove the contact area before the radiation ceases. Using the timer ensures that a defined necroses depth for each coagulation is not exceeded, since the length of impulse is automatically limited.
- You have the possibility to pre-program frequently occurring coagulation times with the aid of the green keys (13) . I and I (see page 13).
- Please regard "Important Notes", chapter 4, pages 10-11.

5 Use with Timer

5 Use with Timer

Adjusting the coagulation period (timer usage)

The coagulation period is adjusted by operating the keys ±/-.

The plus-key (12) \pm increases the time in intervals of 0.25 s.

The minus-key (11) \square reduces the time in intervals of 0.25 s.

The display (15) indicates the chosen time period, while the luminous beam assumes the corresponding length.

Programming chosen coagulation periods (timer usage)

Keep the green luminous key (13) \square , \square or \square pressed down while adjusting the time with the key (12) \square or (11) \square .

When releasing the key (13) \square , \square or \square , the chosen value is stored.

This process may be repeated indefinitely.

When pressing one of the pre-program keys (13), the programmed value will appear on the display.

Probe Adapter

The plus and minus keys \bigcirc on the rear of the probe adapter correspond in all functions to the \bigcirc (12) and \bigcirc (11) keys on the front of the net device.

Similarly, the trigger key (21) on the probe adapter handle is functionally identical to the foot switch.

Endoscopic probes with lateral radiation of light energy are equipped with angle indications on the tip of the probe.

In each case the direction lies diametrically (180°) opposite the indication (\blacktriangleright) on the tip of the probe, as well as diametrically opposite the palpable elevation on the rotating ring, located at the screw-in end of the endoscopic probe (see chapter 12 "Technical Data", page 24).

6 Use without Timer

- Install the device according to the initiation process described on page 5.
- Switch the timer switch (8) on the rear of the device to the position △. The yellow luminous field with the inscription "CONT." will now light up. The display reading drops to "0" and the luminous beam extinguishes.
- The impulse duration and hence the period of coagulation correspond to the operation duration of the foot/hand switch.

During the coagulation process an acoustic signal sounds, while the time display, as well as the luminous beam measure, the time and continue indicating the actual coagulation time for 2 s after the termination of the coagulation.

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

Due to safety considerations the device independently terminates the coagulation process after 5 s.

- Apply the whole contact area (18) to the tissue. Switch on the coagulator only if complete contact is ensured.
- Do not coagulate for too long. A small steam cloud, accompanied by a hissing sound is generated approx. 2.5-3.0 s into the coagulation. At this point the coagulation process should be terminated.
- Do not remove the contact area before the extinction of the radiation.
- Please regard chapter 4 "Important Notes", pages 10-11.

Probe Adapter

For useing without a timer the plus and minus keys ① on the rear of the probe adapter are without function.

As with the foot switch, the coagulation can be initiated at any time, by operating the trigger switch (21) on the probe adapter handle.

Endoscopic probes with lateral radiation of light energy are equipped with angle indications on the tip of the probe.

In each case, the direction lies diametrically (180°) opposite the indication (►) on the tip of the probe, as well as diametrically opposite the palpable elevation on the rotating ring located at the screw-in end of the endoscopic probe (see chapter 12 "Technical Data", page 24).

7 Non-adhesive Caps

The light coagulator LC 250 D can principally be used with or without non-adhesive cap. When using the non-adhesive cap, please note the following:

- The non-adhesive caps are delivered in **non-sterile** condition and may be sterilized in any way desired. The preferred way, however, is sterilization through autoclaving. If non-adhesive capes are used, these must be sterilised seperate to the probes.
- The non-adhesive caps are made of pure PTFE (Teflon) and are thus protected against any adhesion to the tissue surface. If, however, there is no tissue contact during radiation, isolated tissue or blood remains can burn into the surface of the cap.

Important:

- When using the non-adhesive caps, never coagulate without contact to the tissue.
- Never interrupt contact with the tissue before the radiation has expired.
- Always conduct the lift-off of the non-adhesive cap with a sideways wiping motion. This ensures that no isolated tissue or blood remains are left on the facesurface of the non-adhesive cap.
- Ensure that no tissue fluid seeps over the rim of the non-adhesive cap and enters between the crystal surface and the cap. If this does occur, pull off the cap and clean together with the surface of the crystal. Proceed in the same way if saline solution gets in between the surfaces during cooling. Attaching the non-adhesive caps.
- Non-adhesive caps for contact units with diameters from 16mm to 25mm and for wedges are snapped onto the contact unit. To do this, tilt the non-adhesive cap sideways when applying and push it onto the tip of the probe until it clicks.
- Non-adhesive caps for endoscopic application are screwed on. To do this, set the non-adhesive cap on the top of the endoscopic probe and screw it in until the stop.

Removal of the non-adhesive caps

- Non-adhesive caps for contact units with diameters from 16mm to 25mm and for wedges are slightly lifted from the side and are pulled of with a light tilting motion.
- Non-adhesive caps for endoscopic applications are unscrewed.

Important:

• The non-adhesive caps are reusable items. They can be autoclaved or sterilized repeatedly. However, they should to definitely be replaced if burnt areas appear on the surface or if the non-adhesive caps are worn out, that is if the non-adhesive caps no longer sit fully and tightly on the contact area.



6 Use without Timer

7 Non-adhesive Caps



8 Sterilization

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

Admissible pressure: 3 bar

Admissible temperature: 135°C

Admissible time: 20 min

The probe adapter and the screw-in endoscopic probe should be sterilized separately.

Standard probes may only be sterilized when closed, i.e. the probe head is completely screwed onto the probe.

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

When sterilizing, the separate parts – especially the endoscopic probes and the contact areas – must be protected from damage.

Important:

It is possible to exchange the endoscopic probe at any time during an operation (since these are sterilized separately from the probe adapter). However, the probe heads accommodating the contact areas are not interchangeable (since these must be sterilized together).

Similarly, the exchanging of a bulp during an operation is not possible.

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8 Cleaning

All parts of the LC 250 D that are autoclavable can be cleaned in normal, conventional washing machines. During the washing process the components should be placed or fastened so that they cannot be damage. Especially the endoscopic probes and the contact areas must be protected.

Standard probes may only be washed when they are closed, i.e.: the head is completely screwed onto the probe. Probe adapter and endoscopic probes must always be cleaned separately. Non-adhesive caps must be removed off the probes before cleaning.

The parts can otherwise be cleaned with water and alcohol. Under no circumstances may acetone be used on the plastic parts. Burnt residue on the contact areas can be removed using a scalpel.

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

In general: The quality of the coagulation and the life-time of the probe increases, with increasing cleanliness of the glass surfaces.



8 Cleaning Sterilization

8 Technical Safety Checks

8 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 examing instructions may be forwarded.



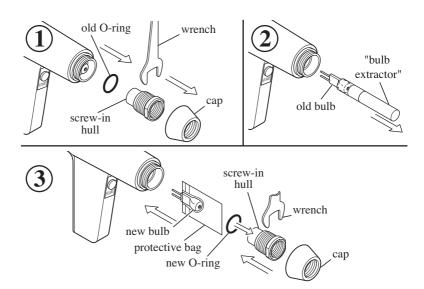
9 Exchanging bulbs

Probe Adapter

- Separate hand device from probe cable.
- Unscrew endoscopic probe.
- Allow the probe adapter to cool, if necessary.
- · Unscrew cap.
- Remove screw-in hull with wrench (22).
- Place the end of the rubber tubing of the included "bulb extractor" over the bulb and gently remove the bulb.

No defilement of the reflector area is permitted.

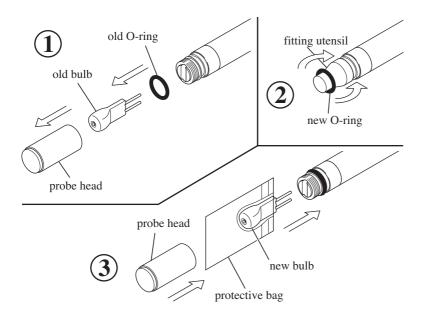
- Remove 0-ring.
- Insert new bulb (do not take the bulb out of the protective bag. Open the bag and push the bulb forward until the pegs are outside the bag. Touch the bulb, still inside the bag, and push the bulb into the socket. Now remove the bag).
- Important: Never touch the bulb with bare fingers, or the finger prints will burn into the surface. If this does accidentally happen, be sure to clean the bulb with isopropanol before the next use.
- Pull the new O-ring (LCD.303) onto the screw-in hull. Caution, no defilement of the interior area is permitted.
- Screw in the hull with the wrench (22).
- · Screw on cap.



9 Exchanging bulbs

Standard Probes

- Separate probe from probe cable.
- Unscrew probe head with contact areas. The infra-red bulb is now openly accessible (caution, it may still be hot).
- Remove and discard the bulb (electronic disposal).
- With each bulb exchange, the O-ring should also be repalced. Remove old O-ring and pull on new O-ring (LCD.304), using the included fitting utensil (O-ring is included with every bulb).
- Insert new bulb (do not take the bulb out of the protective bag. Open the bag and push the bulb forward until the pegs are outside the bag. Touch the bulb, still inside the bag, and push the bulb into the socket. Now remove the bag).
- Important: Never touch the bulb with bare fingers, or the finger prints will burn into the surface (if this does accidentally happen, be sure to clean the bulb with isopropanol before the next impulse).
- · Screw in probe head.







10 Servicing and Maintenance

Servicing

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

- All probes, especially the contact areas, are to be visually examined for mechanical defects. Splintered crystals are not be used.
- The probe cable is to be checked for mechanical faults (bends, squashes, fatigue, etc.)
- The functioning of the bulbs for all probes is to be tested (the helix of the bulb can break or be fractured, due to mechanical impacts). In turn, attach every probe, via the probe cable, to the net device and allow an impulse phase of approx. 2 s. Direct the probe, slanted downwards, away from the body.

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

The O-rings of the probes/probe adapter are to be exchanged regularly, at least after every tenth application, as well as with every bulb exchange (see chapter 9 "Exchanging of bulb", pages 18-19).

Maintenance

Maintenance of the device and all appurtenances is to be conducted solely by us or someone of our approval (exceptions are the exchange of the chapter 8 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 bulbs and O-rings.

11 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 $+70^{\circ}\text{C}$ 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 Servicing Maintenance

11 Transport Storage



11 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	Aluminium, varnished
	front and rear plates - polystyrol, isolation plate - poly carbonate
Keyboard covering	Polyester foil
PC board	Epoxide resin
Foot switch	Bow - aluminium, varnished
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
Probe adapter	Gold, plastic parts - polysulphone, aluminium
	Casting substance
Non-adhesive Caps	PTFE (teflon), FEP

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

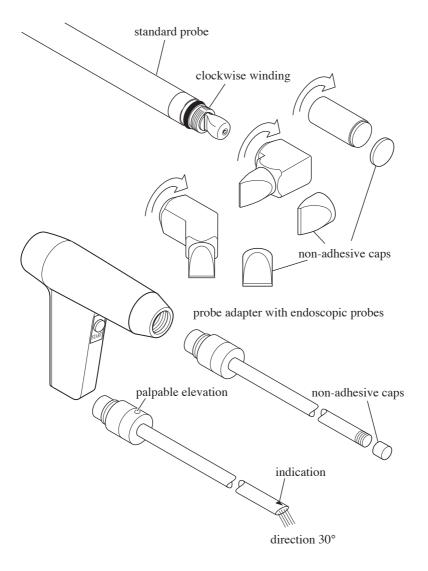
All components (net device, probes and all appurtenances) may be returned to the manufacturer for disposal purposes.

12 Technical Data

Probe Construction

11 Disposal

12 Technical Data





LC 250 D

12 Technical Data

Net Device:

Rated Input Voltage: 230 V a.c.
Rated Frequency: 50 / 60 Hz
Rated Input Power: 1.5 Amp
Protective Class: II
Class: B
Weight: approx. 6 kg
Dimensions (width, depth, height): 260 x 240 x 90 mm

Foot Switch:

Protective type: IP 68

Non-engageable, with protective bow

Switch output: 0,5A/12V

Standard Probes:

Input Voltage: 24V Power: 250 W max.

Contact areas: diameter 16 mm, in various exportations

Output lighting power at tip of probe: approx. 40 W/cm² contact area approx. 20-25 W/cm² Weight: approx. 250 g

Probe Adapter:

Input Voltage: 24 V

Power: 250 W max. Exchangeable, screw-in in various exportations

endoscopic probe contact areas: diameter 5 - 16 mm

Output lighting power

at tip of probe: approx. 40 W/cm² contact area For wedged contact areas: approx. 20-25 W/cm² weight including and assenie probe:

Weight, including endoscopic probe: approx. 500 g

The device is designed for short periods of operation (max. impulse duration 5 s, operational period may be 4% of time.

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

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

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

13 Key

\sim	Alternating Current	12 Technical Data
	Fuse	13 Key
	Timer-controlled use	J
<u>></u>	Footswitch contact	
\triangle	Attention, regard accompanying papers	
†	Application part, Type B	
	Device of protective class II	
\bigcirc	Off (Supply, Separation from Net)	
	Probe socket	
+	Plus key, increases time adjustment	
	Minus key, decreases time adjustment	
	Time preset key, Stage I	
	Time preset key, Stage II	
	Time preset key, Stage III	
SD	Duration of impulse	
ED %	Duration of operation in %	
(C) (123)	CE marking with Notified Body TÜV SÜD Product Service GmbH, München	



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