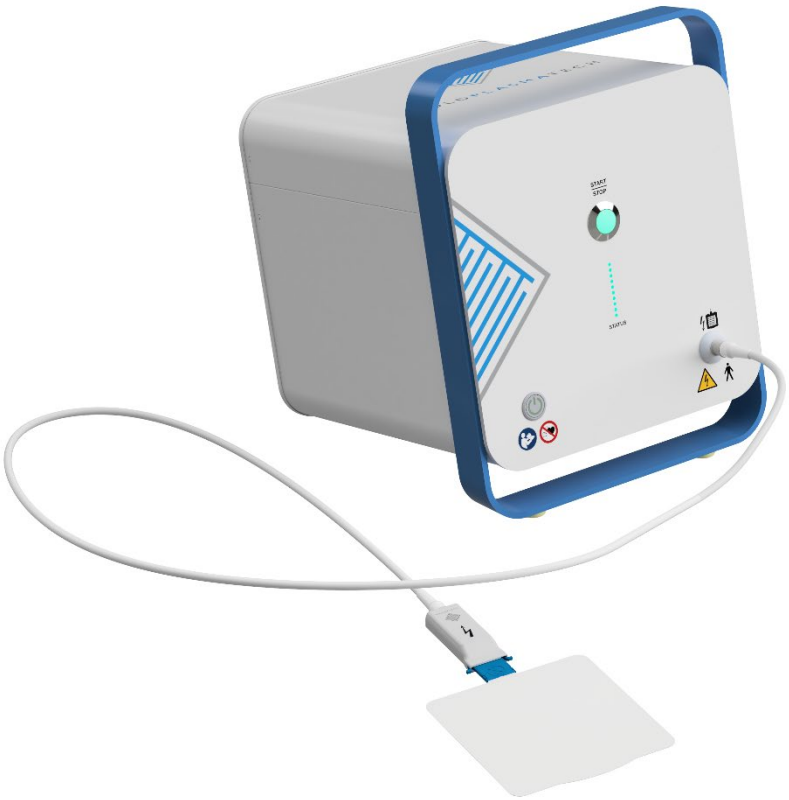
Instructions for use

CPTcube / CPTpatch



This device may only be used by trained medical specialists!

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CE 0482

Contents

1. General information

These instructions for use contain important information about the medical product and how it should be used. The use of technical medical equipment always poses a certain risk for patients, staff and the environment despite all design-related measures. Therefore, safety also depends on staff training and the correct operation of the device. The safety information in this document helps to protect you and your patients from injury and prevent damage to the device. Non-compliance with the safety information can lead to serious injuries or even life-threatening situations.

- » Anyone who works with the device must read, understand and apply the safety information.
- » Ensure that all persons who operate or perform preparatory, cleaning or disposal tasks have read the instructions for use carefully and in full, and make sure to keep them in a safe place.
- » Pass on the instructions for use with the device to any future owners.

1.1 Explanation of symbols

Symbols used in these instructions for use

Immediate danger that can lead to fatal, serious or irreversible injuries.

Dangerous situation that could lead to minor injuries or damage.

Information to help better understand the device and how it should be used correctly.


Comply with the instructions for use


Warning: electrical voltage


Connection socket for HV cable


Connection socket for supplementary equipotential bonding (POAG)


Name and address of manufacturer

Serial number

Production lot / batch number


Please follow the instructions for use.


Do not reuse! (Disposable product)

Sterile product, ethylene oxide (gas)


Do not use on persons with active implants (e.g. cardiac pacemakers)


Warning: non-ionising radiation


Type B applied part


Waste electrical and electronic equipment (WEEE) – Comply with all local regulations during disposal


Production date


Expiry date, do not use the product after this date

Article number (reference number)


Attention! Comply with all precautions and warnings in the instructions for use


Do not use if the package is damaged!


Keep dry; protect from moisture!

CE 0482 CE Certificate of conformity

Read the instructions for use before commissioning the CPTcube. Please contact the manufacturer if you have any questions.

- The CPTcube is a Protection Class I device with the Type B accessory CPTpatch.
- The CPTcube is not protected against moisture, splashwater or penetrating fluids.

2. Mode of action

The CPTpatch is a sterile, active wound dressing for single use and is only designed for use with the CPTcube. The CPTpatch has an atraumatic adhesive frame for simple application above the wound area that is to be treated. 'Physical plasma' is created in the shape of a glow skin between the wound and the underside of the CPTpatch during the treatment process.
Due to the plasma, the air within the defined volume between the CPTpatch and the wound surface is turned into an energised state. This also involves the generation of alternating electric fields, light in the UV and infrared range, the formation of ions and a slight increase in temperature. The combination of these physical effect mechanisms results in an antimicrobial / antimycotic effect of the physical plasma as well as stimulation of the body's own cells and tissue which, in combination, helps the wound to heal.

Improper use

- The CPTcube and CPTpatch may only be used by medical specialists (doctors or healthcare professionals).
- Only use the CPTcube and the CPTpatch for the intended purpose stated in these instructions for use.
- Always read the following indications and contraindications before using the medical product.

2.1 Purpose / indication

The purpose of the CPTpatch / CPTcube treatment system is to generate a flat, cold atmospheric pressure plasma to help the wound or any local infected tissue defects to heal. The parts of the body that can be treated with the medical device are the skin on the extremities and the trunk.

The medical product is only intended for use in professional healthcare facilities.

2.2 Contraindications

- Application on or close to patients with active implants or under physiological monitoring
- Application in concealed body cavities, in particular close to large, unprotected blood vessels If the CPTpatch is used near blood vessels, special care needs to be taken to prevent bleeding and damage to the blood vessels

- Acute infections around the wound and recurrent erysipelas due to the risk of spreading disease or impact on diagnostic parameters
- Known allergy to silicone

Due to insufficient data and lack of clinical studies:

- Pregnant or nursing patients
- Toddlers and infants
- Patients who are undergoing or have recently completed radiation therapy or chemotherapy in the affected treatment region
- Tumours in the treatment area due to the risk of cell transfer
- Diseases in the direct facial area (eyes, ears, nose) and on mucous membranes
- Known allergy to light / sun (photodermatitis)
- Heavily bleeding wounds

2.3 Side effects

There are no known side effects if used as intended.

2.4 Essentiell performance characteristics

There are several safety switches integrated into the CPTcube. These safety switches monitor safety-relevant parameters before, during and after the treatment. It is important here to detect when the patient leakage current is exceeded. If the safety switch fails during the first fault case, it may result in local burns and an electrical shock as a result of a short circuit in the CPTpatch.

3. Description of the device

Never open the CPTcube under any circumstances! Manipulating or tampering with the device is prohibited!

3.1 CPTcube

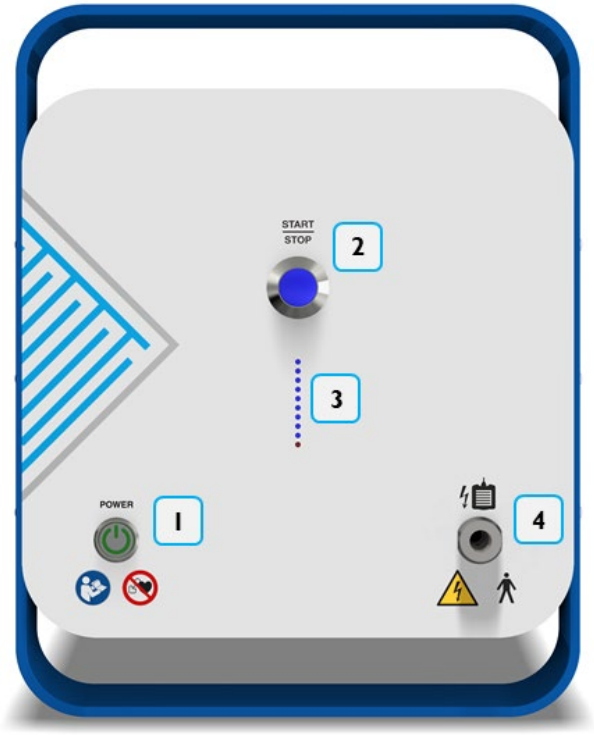


Fig. 1: Front view of the CPTcube with control elements

1 **Main power switch**

The CPTcube is switched on by pressing the green main power switch. This is followed by a self-test that takes about 10 s, after which the CPTcube is ready for operation. The main power switch lights up green; the lowest status LED flashes green.

2 **Start/stop button**

The treatment is started by pressing the start/stop button. The button lights up blue. After the specified treatment time, or after the start/stop button is pressed again, or in the event of an error or malfunction, the power supply is switched off and the button light turns off. The treatment can be ended at any time by pressing the start/stop button or the on/off button.

3 Status LEDs

There are several LEDs below the start/stop button that indicate the current operating status of the device. They serve to indicate normal operating modes (**Fig. 2**) and error messages (see also Section 7.2, page 25).

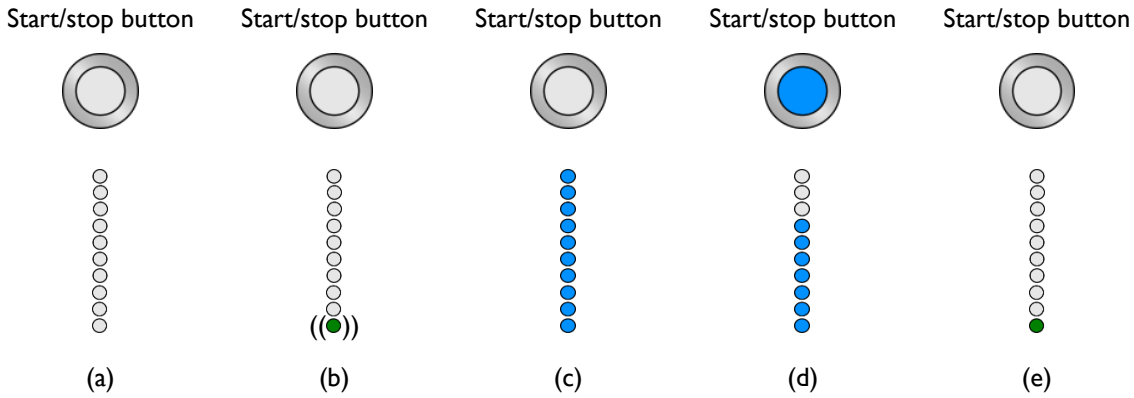


Fig. 2: Display of the status LEDs in normal operating modes.

(a) CPTcube switched off

(b) Self-test is completed successfully, device is in standby mode (no CPTpatch connected), the lowest LED flashes green.

(c) Device is in standby for treatment (error-free CPTpatch connected), all LEDs light up blue

(d) Treatment started, the start/stop button lights up blue, the blue status LEDs turn off from top to bottom as the treatment progresses; the status LEDs that are still lit up show the remaining treatment time (per LED 1/10 of the total duration)

(e) Successful completion of the treatment, the lowest LED lights up green

4 **Connection socket for connecting the CPTpatch to the CPTcube (high-voltage socket)**

The electrical connection between the CPTcube and the CPTpatch is realised via the HV socket. Therefore, the **h**igh-**v**oltage cable (HV cable) must be firmly inserted into the HV socket of the CPTcube. The plug makes an audible click when connected correctly.

Dangerous electrical voltage. Do not insert any objects into the HV socket (except for the HV plug of the HV cable).

Identification of the HV socket for connecting the HV cable to the CPTcube.

The CPTpatch is a Type B applied part.

Fig. 3: Rear view of the CPTcube

5 Type plate

The type plate contains important information and details about the product, manufacturer and how to connect the power supply.

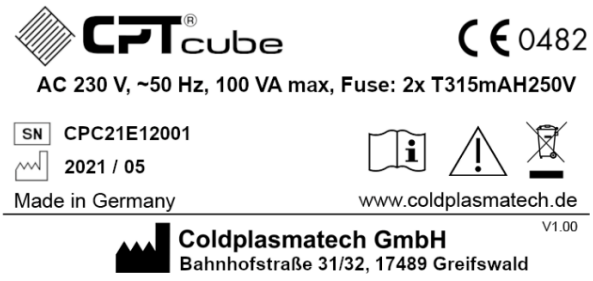


Fig. 4: Example of a type plate of the CPTcube.

6 **Connection socket for supplementary equipotential bonding (SEB socket)**

To ensure safe operation of the CPTcube, connect an equipotential bonding cable (SEB).

Identification of the SEB socket.

7 **Main power socket**

Connect the supplied power cable to this socket to connect the CPTcube to the main power supply (230 V, 50 Hz). Before connecting it to the main power supply, check the information on the type plate (see **Fig. 4**).

3.2 CPTpatch

The CPTpatch is a sterile, active wound dressing for single use.

Disposable product

- Only use each CPTpatch once.
- Only use CPTpatches from undamaged packages.
- Only use CPTpatches with a valid best-before date.

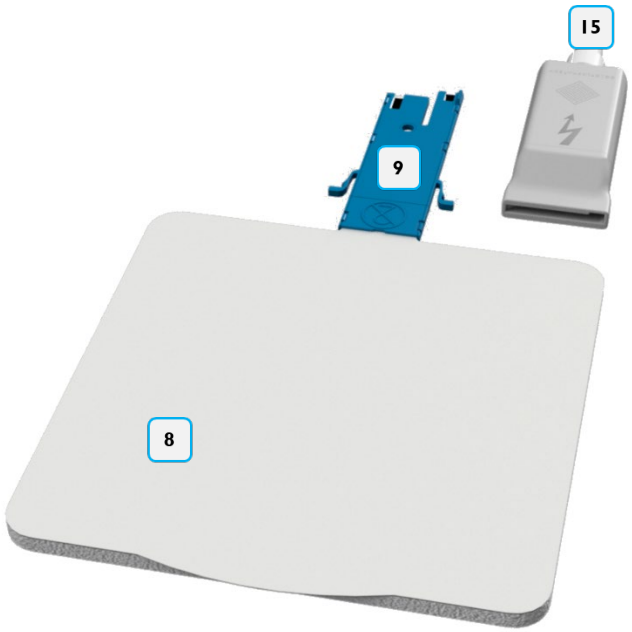


Fig. 5: Side of the CPTpatch facing away from the patient.

8 CPTpatch

The CPTpatch for the treatment of wounds.

9 CPTpatch connection

Connection of the CPTpatch with the HV cable using the HV socket located on the cable. The connector only fits one way into the HV socket.

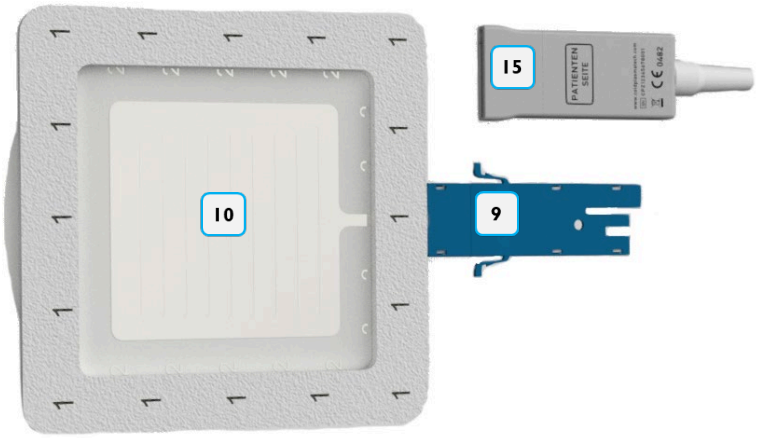


Fig. 6: Side of the CPTpatch, including the protective film, facing the patient.

10 **Active plasma surface**

Wound-facing surface on which the physical plasma is created.

3.3 Adhesive frame

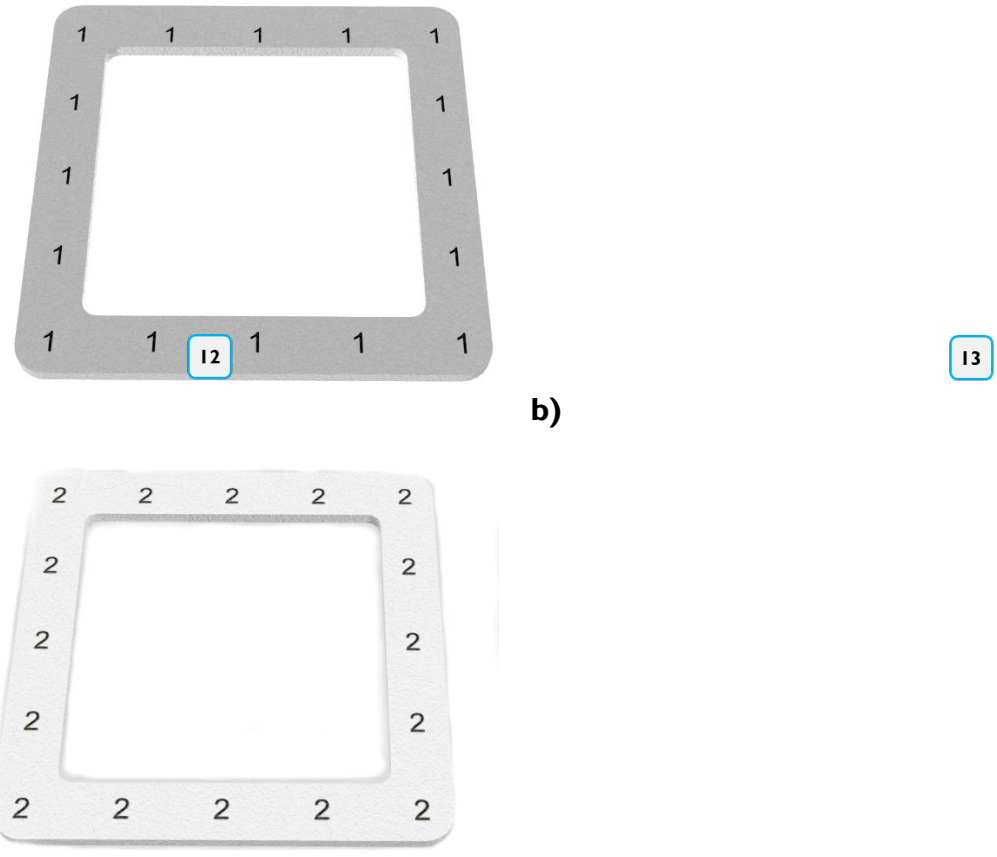


Fig. 7: Adhesive frame to affix the CPTpatch over the wound. a) Patient side, b) CPTpatch side

11 **Adhesive frame**

The frame is used to affix the CPTpatch over the wound.

12 **Protective film 1**

The film must be removed before the adhesive frame is affixed over the wound.

13 **Protective film 2**

The film must be removed before attaching the CPTpatch onto the adhesive frame.

3.4 High-voltage cable (HV cable)

Fig. 8: HV cable with HV plug and CPTpatch socket.

14 **HV plug**

The HV plug on the HV cable is inserted into the HV socket of the CPTcube.

15 **CPTpatch socket**

The CPTpatch connection is inserted into the CPTpatch socket. The connector only fits one way into the CPTpatch socket.

4. Installation

Initial installation by Coldplasmatech GmbH
The device may only be installed for the first time by a technician who has been trained and authorised by the manufacturer. During installation, the technician completes an installation log which is given to both the manufacturer and the purchaser.

Electric shock due to: ineffective protective conductor, faulty earthed socket, unsuitable power supply cable, extension cable, multi-socket power strip, incorrect mains voltage

- Ensure that the device is connected to the mains voltage specified on the type plate.
- Use the supplied main power supply cable for connection to the mains supply.
- Check the power supply cable for damage on a regular basis. A damaged cable may not be used.
- The power plug may only be inserted into a mains socket with a fully functional protective conductor.
- Do not use extension cables or multi-socket power strips.
- The device must be installed in such a way that the power plug can be disconnected at any time.

Please proceed as follows to install the CPTcube:

(1) Open the outer packaging and remove the CPTcube.
  » Keep the outer packaging in case there is a complaint in the future or if the CPTcube is relocated.

(2) The CPTcube must be installed in close vicinity to the treatment area (length of the CPTpatch power supply cable: 1.8 m).
  » The CPTcube must be installed so that the main power switch, mains socket and the SEB socket for the supplementary equipotential bonding are freely accessible.
  » Ensure that the CPTcube is always placed on a level, sturdy surface, and that it cannot fall down when the CPTpatch is used.
  » The installation surface must be dry and clean.

(3) Visual inspection of the CPTcube and supplied cable for damage.

Visible external damage
If there is any visible external damage, the CPTcube and CPTpatch may not be commissioned! Contact the manufacturer about inspecting the device.

(4) If it was stored or transported below +10 °C or above +40 °C, leave the CPTcube out for 3 hours at room temperature to acclimatise!

(5) Before every treatment, disinfect the entire CPTcube. For the disinfection process, use pre-saturated disinfection cloths with a low alcohol level (≤30% alcohol component) and good material compatibility (wipe disinfection is validated with Bacillol® 30 Tissues), and allow to work for 5 minutes. Please use a new disinfection cloth for every surface of the device, and then wipe the entire device again with a new disinfection cloth. To disinfect the buttons/switches, use Bacillol® 30 Foam as a spray disinfectant and allow to work for 1 min. To increase the effectiveness of the disinfection, press the button/switches several times after spraying. If necessary, dry the CPTcube on the end with a clean disposable cloth.

(6) If equipotential bonding is required for the connection of the electrical devices, connect the CPTcube using the SEB socket on the rear side of the device with the in-house equipotential bonding (length of equipotential bonding cable: 3 m).

(7) Connection of the CPTcube to the power supply network using the supplied power cable and, if possible, the equipotential bonding cable.

(8) Before switching on the CPTcube, ensure that the defined ambient/usage conditions are met.

- » Room temperature: 15 °C to 30 °C
- » Relative humidity: 30% to 75% rH
- » Air pressure: 800 – 1060 hPa

(9) Switch on the CPTcube by pressing the main power switch. The device starts a self-test (blue status LEDs light up in succession) and then goes automatically into standby mode (lowest status LED flashes green).

Once you have carefully carried out steps 1-9, as described in these instructions for use, and no error message is shown on the status LED, the CPTcube is **ready for operation**

Installation after relocation
Each time the CPTcube is moved to a new location, the installation routine needs to be completed in full by the specialised, qualified user.

5. Treatment process

Only trained specialists
Ensure that only trained specialists (doctors or healthcare professionals) perform the treatment! Ensure that the CPTcube is in **operational condition** and has been disinfected.

The treatment can be repeated until the desired therapeutic success is achieved. Please note that there should be at least 24 hours without plasma treatment between the treatments. At the discretion of the attending doctor, the treatment can and should be applied adjuvant to other types of treatments, e.g. topical medication therapy. In this case, the plasma treatment should be completed in advance of the topical therapy.

Please note the following safety information before every treatment:

Malfunction of life-support systems or monitoring devices
Treatment on or in close vicinity to patients with active implants or under physiological monitoring is prohibited! Use on monitoring or intensive care units is only allowed after a rigorous risk-benefit assessment.

Ignitable/flammable gases and fluids
The CPTcube creates an electrical gas discharge on the CPTpatch and is therefore an ignition source.

- Please take special precautions when using the CPTcube and CPTpatch in areas where there is a higher risk of fire and explosion (e.g. when using anaesthetic gases, pure oxygen, nitrous oxide).

5.1 Patient preparation

Note the contraindications
Before using the system, please always note the contraindications stated in Section 2.2!

(1) Remove any existing wound dressings.
(2) Remove any body jewellery from an area of at least 20 cm around the wound.
(3) Clean the wound bed. Any barriers in the form of expanded biofilms and/or residues of ointments, salves or creams can diminish the effect of the treatment.
(4) To guarantee that the adhesive frame adheres well, ensure that the area around the wound is dry, clean and free of oils and grease.

Check the size of the wound
The wound area that is being treated may not exceed a size of 10 cm x 10 cm.

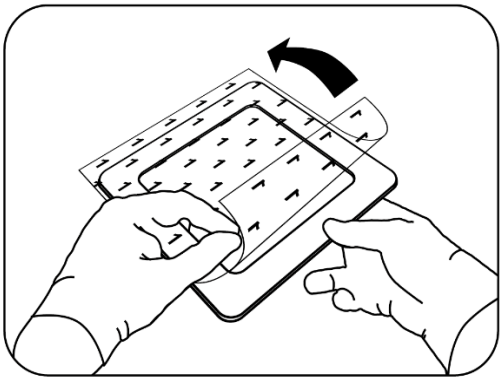
5.2 Treatment preparation

Do not use a damaged CPTpatch!
- Any tampering or manipulation of the CPTpatch (e.g. cutting, bending) or the connection cable is prohibited!
- If damage occurs during operation, the treatment must be terminated immediately, the CPTcube must be disconnected from the main power supply, and the CPTpatch must be disposed of correctly.

(5) Ensure that the CPTcube / HV cable is in an **operational condition** and has been disinfected.

(6) Take a sterile bag with a CPTpatch from an undamaged shipping carton. Open the sterile pouch at the indicated place.

(7) First, remove the adhesive frame from the sterile pouch.



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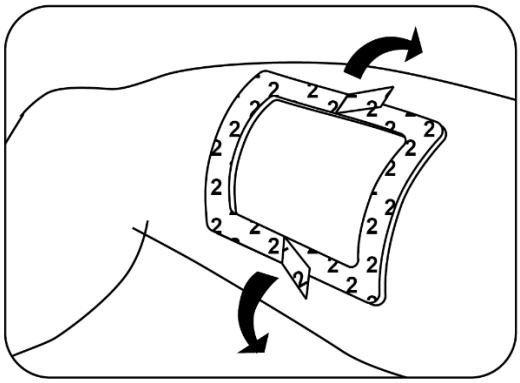

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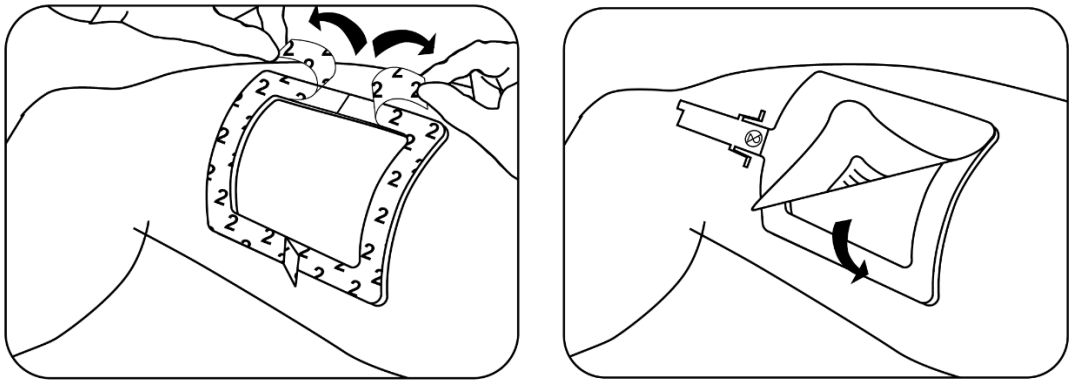

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Fig. 9: Position the adhesive frame and the CPTpatch over the wound.

(8) Remove the protective film 1 (marked with many '1s') from the adhesive frame.

(9) Adhere the adhesive frame around the wound with the side from which you have just peeled off the protective film. Ensure that the adhesive frame keeps its square shape as far as possible and that the wound is in the middle of the adhesive frame.

(10) Remove the protective film 2 (marked with many '2s') from the adhesive frame.

(11) Place the CPTpatch with the patient side (marked with many '2s') onto the adhesive frame and press the CPTpatch onto the adhesive frame. Ensure that the CPTpatch completely covers the adhesive frame.

(12) If necessary, remove the HV cable from the packaging, and remove the cable ties and the pink safety cap.

(13) Visually inspect the HV cable for any damage.

(14) Then insert the HV plug of the HV cable into the HV socket of the CPTcube. A new self-test is performed. If all status LEDs light up blue, the self-test has been completed successfully and the CPTcube is completely operational. The flashing start/stop button indicates that the CPTcube is ready to operate.

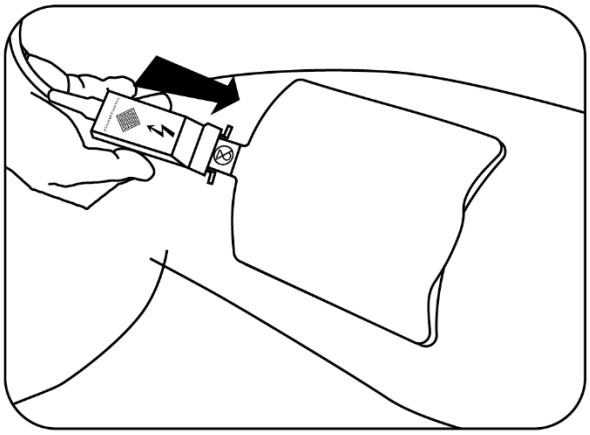

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Fig. 10: Connection of the CPTpatch to the CPTpatch socket.

(15) Insert the CPTpatch connection into the CPTpatch socket. A clicking sound indicates that the CPTpatch has locked firmly into place.

(16) In some cases, it may be necessary to affix the cable to the patient with an additional adhesive plaster.

5.3 Treatment process

If pressure is applied to the surface of the CPTpatch during the treatment, the CPTpatch may come off the wound. Also, if the distance between the wound and the CPTpatch is too small, the treatment will be automatically terminated and trigger an error message on the device (4th LED from above flashes blue).

Do not apply any pressure on the CPTpatch

- During the treatment, no pressure may be put on the CPTpatch.
- During the treatment, position the patient so that they are not lying or sitting on the CPTpatch.

When the CPTpatch is commissioned, a small quantity of ozone is created between the CPTpatch and the wound; this is then released into the ambient air when the CPTpatch is removed and dissipates very quickly. If the CPTpatch is not completely attached to the adhesive frame, gas can escape continuously during the treatment. This may affect the success of the treatment and cause discomfort (unpleasant odour).

Only use in vented rooms

- Only treat patients in well-ventilated rooms.
- If several treatments are administered in quick succession, adequate ventilation is advised.

The duration of a single plasma application is optimised to achieve the best possible treatment effect. Skin irritation may occur if the treatment duration is exceeded.

Skin irritation after excessively long treatment

- There should be at least day one between the individual treatment sessions.
- If the treatment is terminated prematurely, remove the CPTpatch from the wound. Do **not** restart the application!

(17) Start the treatment by pressing the start/stop button on the CPTcube for 1 s. As soon as the treatment starts, you will hear a noise in the CPTcube and the start/stop

button stays continuously lit up in blue. The status LEDs turn off from top to bottom according to the progress of the treatment. After the application time (2 minutes) that is defined in the device, the power supply is automatically interrupted. Once the treatment has been completed successfully, the lowest status LED lights up green.

In case of emergency
The treatment can be terminated at any time by pressing the start/stop button or on/off button again. The treatment can also be terminated by disconnecting the HV cable from the CPTcube. In an emergency, disconnect the power plug of the CPTcube.

(18) Then remove the HV plug of the HV cable from the HV socket of the CPTcube. The lowest status LED flashes green again.

(19) Then disconnect the CPTpatch from the HV cable.

(20) Remove the CPTpatch and the adhesive frame carefully from the wound and dispose of both as described in Section 6.

(21) Then carry out the normal wound preparation and dressing steps.

(22) Switch off the CPTcube.

(23) Disconnect the CPTcube from the main power supply by removing the power plug.

(24) Disinfect the smooth surfaces of the CPTcube using a disinfectant wipe. Use Bacillol® 30 Tissues to disinfect the surfaces of the housing (note the manufacturer's instructions about the application and exposure time). The buttons should be disinfected using Bacillol® 30 Foam in a spray form. Pressing the switch again after spraying the area can increase the disinfection effect (note the manufacturer's instructions about the application and exposure time).

(25) After every treatment, disinfect the entire HV cable by spraying the entire cable with Incidin Oxyfoam S. To avoid long drying times, please hang up the cable with the CPTpatch socket facing down. Please clean the transitions between the cable and the CPTpatch socket and the grooves in the CPTpatch socket thoroughly with a soft brush. Then wipe the entire cable thoroughly with a cloth soaked in Incidin Oxyfoam S. It needs to be left on to work for 5 minutes. Ensure that the surface remains damp during this time.

Penetrating fluids

The device can be penetrated by fluids.

- Do not pour liquid cleaning agents or disinfectants directly onto the device.
- Instead, pour the agent onto a cloth and use it to disinfect the device.
- Do not allow fluids to penetrate the CPTpatch socket on the HV cable! To disinfect, please hang up the cable up with the CPTpatch socket facing down.

6. Transport, storage, disposal

6.1 Transport

The CPTcube is supplied in an outer packaging. This offers protection against environmental influences during transportation. We recommend keeping the original packaging in case the device needs to be returned to the manufacturer or transported or stored in-house.

6.2 Storage

The storage conditions for the CPTpatch and CPTcube are stated on the secondary packaging of the products.

6.3 Disposal

The CPTpatch and the adhesive frame are for single use only. Reusing them poses the risk of transferring pathogens from one patient to another or between different areas of skin. Neither the CPTpatch nor the adhesive frame are suitable for reuse. Uncontrolled material damage can occur unnoticed if they are used several times. There is a risk of electrical shock.

Reuse and reprocessing are prohibited

- Only use each CPTpatch and adhesive frame once.
- It is prohibited to recycle the CPTpatch and the adhesive frame!

Used CPTpatches may not be disposed of in the regular waste bin (household waste).

- Dispose of used CPTpatches and adhesive frames in a special container for contaminated items.
- Comply with the valid national regulations for the disposal of potentially infectious materials.

The CPTcube is packaged in environmentally compatible and therefore recyclable packaging materials. Returning the packaging to the materials cycle saves raw materials and reduces waste. We recommend keeping the original packaging in case the device needs to be returned to the manufacturer or transported or stored in-house.

Used CPTcubes may not be disposed of in the regular waste bin (household waste).

This product may not be disposed of in the regular waste bin (household waste). If this device needs to be disposed of, please send it to the manufacturer for professional disposal (for address, please see page 27).

7. In case of a fault, malfunction or power failure

Service, maintenance, and repairs only by the manufacturer

- Any intervention into the treatment system by the user is prohibited!
- In case of a malfunction, please first refer to the instructions in Section 7.2 Error messages. If this does not remedy the problem, please contact the manufacturer directly.

Power failure

- After the end of a power failure, the CPTcube will remain off.
- Please pull off the used patch, remove the adhesive frame and dispose of both correctly.
- It is not recommended to treat the patient again on the same day.

7.1 Maintenance CPTcube

Annual maintenance must be performed to maintain the device properties and ensure that the device functions correctly. Maintenance work may only be carried out by a technician authorised by the manufacturer. Please contact the manufacturer for an appointment. Apart from the annual maintenance of the CPTcube by the manufacturer, the user does not need to perform any further maintenance.

Lack of maintenance

- The manufacturer needs to perform annual maintenance to ensure that the device functions correctly.
- A faulty device or a device that has not been serviced may not be used!

7.2 Error messages

In the event of an error, the status LEDs below the start/stop button indicate the type of error by means of various colour and flashing combinations. An error message can be acknowledged by switching off the CPTcube or by removing the HV cable from the CPTcube. Once the HV cable has been disconnected from the (active) CPTcube, it automatically goes into standby mode (the lowest status LED flashes green).

Visualisation	Description of the error

This error may occur during the treatment process.

Cause:
The CPTpatch is faulty.

How to deal with this error:
Please take a new CPTpatch.
Please note that the treatment time of 2 minutes may not be exceeded.

This error may occur during the treatment process.

Cause:
The patient leakage current is too high.

How to deal with this error:
If the CPTpatch is too close to the patient's skin or has direct contact with the skin, the permitted patient leakage current can be exceeded. The CPTcube detects this and stops the treatment. Please take a new CPTpatch and ensure that the total treatment time of 2 minutes is not exceeded.

This error may occur when the treatment process starts.

Cause:
You pressed the start/stop button for longer than 4 s.

How to deal with this error:
Pull the CPTpatch out of the CPTcube and then reinsert it. After the CPTcube has performed a self-test, the treatment can be restarted.

Additional safety functions have been integrated into the CPTcube to guarantee the safety of the patient and the user at all times. **If an error occurs that is not described in more detail here, you can acknowledge it either by disconnecting and then reconnecting the HV cable to the CPTcube or by restarting the CPTcube**. If the error persists, please contact the manufacturer.

8. Technical data

Table 1:Technical data

Security requirements	
Protection against electrical shock	Class I
Type	B
Mains fuse	T315mAH250 V
Power supply CPTcube	
Mains voltage	230 V AC
Power frequency	50 Hz
Maximum power consumption	100 VA
Operating mode	Continuous operation
Dimensions L x W x H	375 mm x 315 mm x 395 mm
Weight	13 kg
CPTpatch	
Dimensions L x W x H	244 mm x 150 mm x 3 mm (without adhesive frame, with clip)
Weight	30 g
Length HV cable for connecting CPTpatch/CPTcube	2 m
Plasma	
Sine-wave voltage	6 KHz
Pulse frequency	5 Hz
UV emission UV-A (315-380 nm)	95%
UV emission UV-B (280-315 nm)	5%
UV emission UV-C (100-280 nm)	0%
Ozone concentration	Below the limit
Nitrogen oxide concentration	Below the limit
Transport and storage conditions	
Specified on the secondary packaging of the CPTpatch or CPTcube.	
Operating conditions	
Ambient temperature	+15 °C to +30 °C
Relative humidity	30% to 75% rH, non-condensing
Air pressure	800 hPa to 1,060 hPa
Acclimatisation	
If the device is stored or transported at temperatures below +10 °C and over +40 °C, the device requires about 3 hours at room temperature to acclimatise.	

8.1 Delivery scope

Designation	Quantity	Article number
CPTcube with HV cable	1	E 100.112
Main supply power cable [2.35 m]	1	Z 100.102
Equipotential bonding cable [3 m]	1	Z 100.101
Instructions for use	1 (this document)	M 100.102

8.2 Consumables and spare parts

The CPTcube provides high voltage for generating plasma on the CPTpatch. The system is designed so that the high voltage can be fed safely to the CPTpatch. There is a risk of electrical shock if accessories other than the original CPTpatch are connected.

Only use with original accessories
Using devices, power supply units, mains adapters, connection cables, adapters or other accessories that are **not** approved by the manufacturer for use with the CPTcube/CPTpatch can pose a risk to the user and/or patient, limit performance, impair operational security, damage or destroy the system, or lead to higher electromagnetic radiation or reduced electromagnetic immunity of the device.

Please only use the following CPTpatch with an adhesive frame (packaging label, see **Fig. 11**): Art. No. A 100.T41.
If the HV cable is faulty or you require an additional spare part, please contact the manufacturer. The spare part number for the HV cable is: Z 100.103.

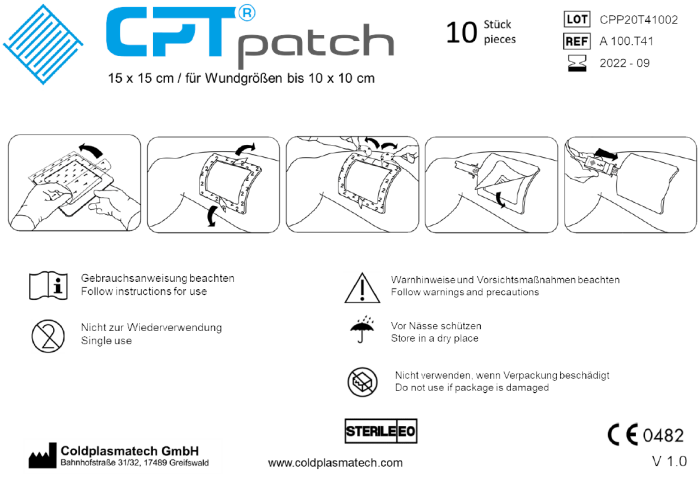

Fig. 11: Packaging labelling on the CPTpatch.

9. Information on electromagnetic compatibility (EMC)

With regard to EMC, electrical medical devices are subject to special precautions and need to be installed and then commissioned according to the EMC information stated here.

The emission-specific properties of this device mean that it can be used in industrial environments and in hospitals (CISPR 11, Class A). This device may not provide adequate protection against radio (communication) services if used in residential spaces/rooms (which usually requires Class B pursuant to CISPR 11).

Portable HF communication devices (radio devices, including their accessories such as antennas or antenna cables) may not be used closer than 30 cm (12 inches) to the CPTcube/CPTpatch. Non-compliance with this can lead to a reduction in the device performance.

Avoid using this device directly next to other devices or stacked onto other devices because this may cause it to operate incorrectly.

Electromagnetic emissions		
The device is designed for operation in the electromagnetic environment stated below. The user of the device should ensure that it is used in this kind of environment.		
Measurement	Result	Description
HF emissions pursuant to CISPR 11	Group I	It is highly unlikely that the CPTcube or the CPTpatch will interfere with adjacent devices. Nevertheless, there should be a safety clearance of at least 30 cm to other devices.
HF emissions pursuant to CISPR 11	Class A	The CPTcube and CPTpatch may only be operated in industrial sectors and in professional healthcare environments.
Voltage fluctuations and flicker according to IEC 61000-3-3	Met	The CPTcube and CPTpatch may only be operated in industrial sectors and in professional healthcare environments.
Harmonics according to IEC 61000-3-2	Class A	The CPTcube and CPTpatch may only be operated in industrial sectors and in professional healthcare environments.

Electromagnetic immunity			
Immunity test	Test level	Result	Impact
Electrostatic discharges (ESD) according to IEC 61000-4-2	2 kV, 4 kV, 8 kV, 15 kV on buttons, cables and CPTpatch; 2 kV, 4 kV, 6 kV, 8 kV on the housing	Met, interruption of the plasma operation is accepted.	Floors should be made of wood or concrete or be covered with ceramic tiles. If floor is covered with non-conductive synthetic material, the relative humidity should be at least 30%.
Electrical fast transient disturbances/bursts according to IEC 61000-4-4	0.5 kV, 1 kV, 2 kV	Met, interruption of the plasma operation is accepted.	The quality of the supply voltage should correspond that of a typical hospital environment.
Surge voltages according to IEC 61000-4-5	0.5 kV, 1 kV, 2 kV	Met	The quality of the supply voltage should correspond to that of a typical hospital environment.
Power frequency magnetic fields according to IEC61000-4-8	30 A/m, 50 Hz, 6 0Hz	Met	Power frequency magnetic fields should correspond to the values that are typical in hospital environments.

Voltage dips, short interruptions and voltage fluctuations according to IEC 61000-4-11	100%, 10 ms 100%, 20 ms 60%, 200 ms 30%, 500 ms 100%, 5 s	Met, interruption of the plasma operation is accepted.	The quality of the supply voltage should correspond to that of a typical hospital environment. If the user of the device wants the function to continue even though the power supply is interrupted, the device must be connected to an uninterrupted power supply or a battery.

Electromagnetic immunity

When portable and mobile HF communication equipment is used, the recommended safety distance from the device (including the cables) may not be exceeded. The safety distance is calculated using various equations depending on the transmission frequency of the portable and mobile HF communication equipment:

1) $d = 1.2 * P^{1/2}$
2) $d = 1.2 * P^{1/2}$
3) $d = 2.3 * P^{1/2}$

'P' stands for the rated output of the transmitter in watts (W) according to the information provided by the manufacturer of the transmitter. 'd' stands for the recommended safety distance in metres (m).

Theoretically, the field strength of stationary transmitters, e.g. base stations of mobile phones and land mobile services, amateur stations, AM and FM radio and TV stations, cannot be precisely determined in advance. We recommend examining the site to determine the electromagnetic environment caused by stationary HF transmitters. If the field strength determined at the site of the device exceeds the test level stated below, the device needs to be observed when in normal mode at every application location. If unusual performance features are noticed, it may be necessary to take additional action, e.g. reorientation or relocation of the device.

Immunity test	Test level	Result	Impact
Conducted disturbances induced by high-frequency fields according to IEC 61000-4-6	150 kHz to 80 MHz, 6 V	Met	Equation 1
High-frequency EM fields according to IEC 61000-4-3	80 to 800 MHz	Met, interruption of the plasma operation is accepted.	Equation 2

High-frequency EM fields according to IEC 61000-4-3	800 MHz to 2.7 GHz	Met	Equation 3

10. Manufacturer

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11. Disclaimer

The CPTcube and the CPTpatches may only be used under the specified conditions and for the intended purposes, and must be maintained as stated in these instructions for use. The manufacturer is not liable for any damage caused by incorrect or improper use of the CPTcube and CPTpatches.

12. List of figures

13. List of tables