terraplasma MEDICAL

Instructions for Use

plasma care®

plasma care® spacer

CE 0197

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1 Imprint

1.1 Imprint

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1.2 Disclaimer

The terraplasma medical GmbH is not liable for damage that results from the disregard of this instruction for use, in particular of the safety and warning notes herein. In such cases the warranty expires.

1.3 Information on the document

Type	manual plasma care®
Author	terraplasma medical GmbH
Version	7.0
Date	07.10.2022

2 Notes and symbols

2.1 Information for the user

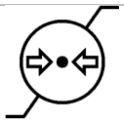
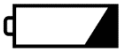
Report any difficulties, problems and safety issues to the manufacturer or the distributor. According to Regulation (EU) 2017/745 on medical devices, any serious inci-dents that occur in connection with the product must be reported to the manufacturer and the competent authorities of the Member State in which the user resides.

2.2 Read and abide by the manual

	**Before using the plasma care® the manual needs to be read carefully and completely. Reading and following the safety guidelines as well as the manual is compulsory for any use of the device. Non-comliance with the manueal and the safety instructions can lead to damage of the device, serious injuries and may even result in life-threatening situations**

2.3 Symbols

	Refer to instruction for use
	Read the instruction for use
	Warning! Please read the safety notes carefully. Disregard thereof can result in injury to persons or damage to property.
	Manufacturer's address
	Date of manufacture
	Serial number
	Lot number / batch code
	Order number / device reference of the manufacturer
	Attention! Presence of high voltage.
	Presence of high voltage.

	In the surroundings of devices that carry this label, disturbances may occur.
	Displays the limits of temperature to which the medical device may be exposed safely.
	Displays the limits of relative humidity to which the medical device may be exposed safely.
	Displays the limits of barometric pressure to which the medical device may be exposed safely.
	Fragile!
	Store dry.
	Protect the product form direct radiation by sun and light
	Check the battery, displays the current battery charge condition and indicates the charging process.
	CE-label with the code number of the notified body.
	Piece of equipment of type BF.
	Do not reuse.
	Do not sterilize again
	Use by
	Sterilisation procedure: ethylene oxide-(EO)-sterilisation.
	Do not use, when packaging is damaged.
	Electrical device, do not discard in domestic waste.

IP	Level of protection against intrusion (solid particles) and water.
Note	This symbol is used for information on installation, operation, service and repair of the medical device that is important, but not associated with any danger.

2.4 Warning and safety notes

2.4.1 Starting-up the medical device

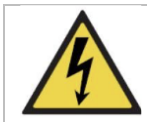
 ID001	Only use the plasma care®, after having read and understood the instructions for use in its entirety. Non-compliante usage of the devicedue to disregard of the manual can lead to personal injury or damage to property.
 ID002	Only use the plasma care® with the specified line voltage. Otherwise disturbances, outages, smoke emission and even fire can occur.
 ID003	Only use the plasma care® in dry rooms, which are not at any risk of explosion and only in rooms with sufficient ventilation and lighting.
 ID004	Do not use excessive force or remove the plug by pulling on the cable as the cable might be damaged thereby.
 ID004b	Only use the original power supply delivered by the manufacturer. The use of other power supplies is not admissible. **Warning:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
 ID005	Do not use excessive force to attach a country-specific adapter plug to the power supply. The electrical contacts might be damaged thereby.
 ID006	Only use the plasma care® in environmental conditions as defined in chapter 12. Excessive heat/cold or humidity can limit the functionality of the plasma care® or destroy it.
 ID007	Wait until the plasma care® has adjusted to the permissible environmental temperature, especially if the plasma care® has previously been transported or stored under environmental conditions outside of its defined operating conditions.

 ID008	Ensure that the plasma care® and in particular the plasma source is not contaminated, smutched or damaged.
 ID009	Before each use of a spacer, make sure that the sterile packaging is not damaged and has not already been opened prior to usage of the spacer.
 ID010	Only use the plasma care® with the original components and accessories from the manufacturer. The use of accessory part, in particular of power supplies other than determined and provided by the manufacturer. Inobservance may result in an increase of electromagnetic emitted interference, a decrease in electromagnetic interference resistance and nonconforming mode of operation.
 ID011	Do not perform any modifications on the plasma care®.
 ID012	Do not open the plasma care® under any circumstances. There is danger of high voltage!
 ID013	Before starting-up the plasma care® after it has been transported, the medical device needs to reach a temperature within the operating conditions (see chapter 12.1 Operating conditions).

2.4.2 Treatment and operation

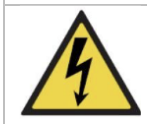
 ID014	The treatment with the plasma care® may only be performed by instructed healthcare professionals.
 ID015	Only use the plasma care® for its intended medical purpose (see chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**) taking into account its indications and contraindications (see chapter 5).
 ID016	Always use the plasma care® in combination with a plasma care® spacer. Using the plasma care® without a plasma care® spacer is not possible.
 ID017	Use a plasma care® spacer for a single patient only. Otherwise cross-contamination may occur.

 ID018	Gently place the plasma care® spacer onto the patient's skin to produce a closed volume, if possible.
 ID019	Prior to the treatment with the plasma care®, you need to remove all wound dressings and bandages. Furthermore, the wound bed needs to be prepared for example by debridement (see chapter 9).
 ID020	If non-vital tissue, necrotic tissue, fibrin layers or foreign particles are present in the wound, careful wound bed preparation (using wound rinsing solutions without active components) needs to be performed prior to plasma care® treatment. Otherwise the plasma treatment may not be effective.
 ID021	Wound rinsing solutions with active components may not be used immediately prior to the treatment with plasma care®. When plasma care® treatment is to be performed, wound bed preparation with a wound rinsing solution free of active components needs to be carried out right beforehand.
 ID022	The treatment of the wound of a patient with the plasma care® may only be performed once within a 12-hour window. The same section of a wound may only be treated for a maximum duration of 3 minutes.
 ID022b	The treatment can be interrupted at any time by exerting extended pressure on the on / off button. Removal of the plasma care® spacer also leads to immediate interruption of the treatment. If the treatment cannot be stopped by either of these two methods, the energy supply of the plasma source can be interrupted by removing the plasma source unit.
 ID023	The plasma care® can cause electronic disturbances during its normal operation for its intended purpose, which may interfere with the function of other electronic devices.
 ID024	Other electronic devices, especially high frequency devices such as mobile phones can impact electronic medical devices. The use of plasma care® in direct vicinity of such devices can therefore lead to an increased emission of or a strongly reduced immunity of the plasma care® against disturbances. Portable HF communication devices such as radio transceiver or mobile phones (including accessories such as aerial cable and complementary antenna) must not be used within a distance less than 30 cm to the plasma care®. Inobservance may lead to a performance decrease of the plasma care® .
 ID024a	The plasma care ® should not be used in direct proximity to ther devices or stapled with other devices as this can result in malefunction. In case the use of the device in a setting as just described cannot be avoided special attention has to be paid to the plasma care® as well as to all other devices to ensure proper functioning.

 ID025	Do not remove the plasma care® spacer or the plasma source unit under any circumstances during treatment.
 ID026	The plasma care® spacer protects the user and the patient from an unintended contact with the plasma source through the integrated protection mesh.
 ID027	Throughout treatment with the plasma care® ozone is generated at a low concentration. During the intended use of the plasma care® the legal limits for ozone are not exceeded; however, the ozone can be detected by its scent. The ozone is sufficiently diluted by the surrounding air. If the device is used in small rooms and/or if several plasma care® devices are used in the same room and/or upon extended treatment periods, a sufficient level of ventilation must be achieved (for example by opening windows or doors). The individual sensitivity towards ozone varies widely. If the plasma care® is used in the presence of people with a chronic respiratory disease/disorder or in the presence of infants and young children, special care needs to be taken regarding sufficient ventilation, as these groups of people are particularly sensitive.
 ID028	Upon treatment with the plasma care® ozone is generated at low concentrations. Treatments in the area of the head and particularly of the mouth should be avoided.
 ID028b	Upon treatment with the plasma care® UV radiation is generated at very low intensity. Avoid treatments at the eyes.
 ID029	The adjuvant (supportive) treatment with antiseptics, topic antibiotics, etc. needs to be carried out after the treatment with the plasma care®. Otherwise no statement regarding the effectiveness of the plasma treatment and/or the adjuvant treatment can be made. Nothing is known about possible interactions between the plasma and active components or drug substances.
 ID029b	Plasma treatment can lead to wound granulation stimulation (= therapy success). If wound pockets exist, professional supervision is required such that a superficial wound closure through mechanical measures can be prevented. Otherwise locked in wound micobes may not be accessible for antimicrobial treatment.

2.4.3 Cleaning, maintenance and servicing

 ID030	Clean the plasma care® after each treatment of a patient as described in chapter 10 to prevent cross-contamination.

 ID031	You may only use deteregents for cleaning of the plasma care® that are described in chapter 10.
 ID032	Perform the cleaning procedure for the plasma care® using wipe disinfection as described in chapter 10. Avoid a very humid cleaning procedure, for example by frequent use of spray disinfectant, because the electronic components can be damaged. Cleaning by submersion in a solution is prohibited.
 ID033	Do not use pointed objects to clean the plasma source. It can be damaged as a result, which may lead to faulty plasma generation and danger due to high voltage. Perform the cleaning procedure as described in chapter 10.
 ID034	Discard the plasma care® spacer safely in compliance with the applicable regulations for contaminated single-use items.
 ID035	If dirt remains on the plasma source after cleaning, the dirty plasma source needs to be replaced by a new clean plasma source unit.
 ID035a	Examine the device (both front and back) for residuals of body fluids, especially after the treatment of strongly exuding wounds
 ID036	When changing the plasma source unit, check the wired contacts between the plasma care® and the plasma source unit for corrosion. Also check whether the plasma source unit has been attached to the plasma care® carefully and flush.
 ID037	The plasma source unit needs to be cleaned as described at least once a month.
 ID038	If the plasma source unit is used beyond its expected service life the plasma care® will indicate this via a permanent red glow of the four segments of the plasma ring and the plasma source unit needs to be replaced.

2.4.4 Medical device malfunction

 ID039	When the four segments of the plasma ring glow red permanently, the plasma care® and particularly the plasma source unit need to be checked for dirt and damage. In case of dirt, the plasma source unit needs to be cleaned as described (see chapter 10.1.2) or replaced. In case of damage, the plasma source unit needs to be replaced.

	If the problem is not resolved subsequently, the plasma care® needs to be send to the manufacturer for servicing. It is not permitted to carry out any repairs independently or through third parties.
 ID040	Protect the plasma care® from mechanical damage, shocks and drops.

2.4.5 Unexpected events

 ID041	When you observe discomfort or an abnormal reaction in a patient, the treatment needs to be stopped immediately. If the adverse event is serious, this needs to be reported to the manufacturer and the responsible authority of the member state, in which user and/or patient live, immediately.
 ID042	When you notice that the environmental conditions change and that the plasma care® is used outside of its operating requirements and specifications, the treatment needs to be stopped.
 ID043	After the charging it is possible that the user interface (touchscreen) does not work due to electro-magnetic disturbances. In this case re-calibration of the touchscreen can be required.

2.4.6 Essential performances

The following performance characteristics might be limited to function in case the device is operated in presence of electromagnetic disturbances:

- The plasma source produces the required cold atmospheric plasma
- The duration of treatment does not exceed the specified time

3 Intended Use

The plasma care® in combination with the plasma care® spacer, a sterile single-use product, is a medical device for the painless treatment of wounds with cold atmospheric plasma. It requires minimal contact with the patient or rather with the patient's wound or intact skin and is operated by healthcare professionals.

3.1 Intended use

A sterile plasma care® spacer is unpacked and attached to the frame of the plasma care®. The device recognizes the valid spacer and the plasma treatment can be started after a brief period of preparation. For this purpose the operator (e.g. a nurse) places the sterile plasma care® spacer (attached to the plasma care®) gently onto the wound, starts plasma generation and keeps the medical device in position until the treatment is completed (a detailed description can be found in chapter 9).

The aim is to reduce bacterial or fungal infiltration of the wound with the plasma care® and thus to improve wound healing by modification of the microenvironment. When used as

prophylaxis, the aim of treating wounds with the plasma care® is to prevent an infection or rather to prevent or limit the outbreak of an infection.

The bacterial and fungal burden on the wound is reduced through the contact of the generated plasma species with the microorganisms. Eukaryotic (human) tissue is not damaged:

The effective components (reactive species) produced by the plasma can make the cell membrane "microporous" by different means. The effects that produce these micropores are either physical (e.g. local heating through recombination or decay of excited molecules/atoms on the cell surface) or chemical (e.g. hydrogen-denaturation through interactions of hydroxyl-radicals with the cell membrane). The micropores have a size of approximately 5 nanometers and remain open for a few microseconds only. In this short period of time the species generated by the plasma can enter the cell. In prokaryotic cells DNA is destroyed directly and the bacterium is deactivated. In eukaryotic cells the DNA is additionally protected in the nucleus – damage does not occur.

The plasma care® is designed for multiple use. The plasma source unit can be replaced, if necessary. The plasma care® spacer (one per patient – see chapter 7.2), which is required for operation, is a sterile single-use product.

3.2 plasma care® as stand-alone wound treatment / infection prophylaxis

If the plasma care® is to be used without any other topically applied medication, ointments or antiseptics, wound bed preparation with germfree water or a wound irrigation solution based on water (for example Ringer's solution) should be performed, especially in case of large amounts of exudate, fibrin layers ("escharing") or dirt. Alternatively, debridement can be performed.

The full effect of the plasma treatment can only be achieved, when the plasma species come into direct contact with the bacteria and fungi in the wound.

3.3 plasma care® as add-on therapy

The plasma care® can be used as an add-on to the regular wound therapy, i.e. in addition to the usual treatment methods. Depending on the respective standard procedure the order of the cleaning solutions / procedures, potential topically applied medications and ointments or antiseptics needs to be determined. In general, the plasma treatment must be carried out prior to the application of any other medications or active components which remain in the wound after treatment. If wound bed preparation is performed using wound irrigation or similar water-based solutions, this must be carried out prior to the plasma treatment.

Again, the full effect of the plasma treatment can only be achieved, if the plasma species come into direct contact with the bacteria and fungi in the wound.

4 Operator

The plasma care® is a medical device that is intended for use in a professional and home healthcare environment.

The operators are physicians and other healthcare professionals

- in hospitals (e.g. dermatology, surgery, angiology) and wound centers,
- in medical practices (e.g. GPs, dermatologists, diabetologists, surgeons, angiologists and podologists),
- in out-patient care,
- in retirement and nursing homes or
- in home care setting (e.g. travelling nurses)

The operators have undergone medical training and are experienced in the treatment of wounds in compliance with the current therapeutic guidelines.

Prior to use of the plasma care® with the plasma care® spacer all operators need to study the manual carefully and need to be instructed in the use of the plasma care®. The instruction can be given by the manufacturer or an expert. Further experience with the product is not necessary.

	Before using the plasma care® with the plasma care® spacer the operators need to read the manual carefully.

5 Patients

The patients are people with wounds of varying aetiology. The patients need to be at least 12 years of age. As wounds occure more frequently in elderly patients, a higher average age can be assumed. The patients often display co-morbidities or limitations such as the following:

- limited mobility
- sensory disorders
- metabolic disorders
- circulatory disorders
- venous insufficiency or veins damaged through thrombosis
- peripheral artery disease (PAD)
- Diabetes mellitus
- neoplasias

A gender-specific accumulation is not expected.

5.1 Indications

Therapeutic and diagnostic indications and specifications, which are the basis for plasma treatment with the plasma care®, are all skin wounds such as:

Aetiology/ Cause	Disease/ Condition	Symptoms and aspects
chronic wounds		
arterial	ulcers, decubitus or pyoderma gangrenosum	potential indication of a bacterial load (prophylactic), colonization and infection with bacteria
venous		
infectious		
diabetic		
neuropathic		
traumatic		
vasculitic		
acute, open wounds		
mechanical cause	abrasions	
	lacerations	
	stab wounds	
	contused wounds	
	degloving	
	fissures	
	bites	

	gunshot wounds	
	impalement injuries	
	amputation of extremities	
themal cause	burns	
	frostbite	
surgical	surgery wounds	
	secondary healing surgery	
	wounds	
	skin graft donor sites	

5.2 Contraindications

A treatment with the plasma care® must not be performed on:

- wounds that bleed strongly and acutely
- wounds at exposed inner organs (surgery)
- wounds at mucous membranes
- wounds in the head and neck area
- children under the age of 12 years

The plasma care® is intended for external use only. The plasma care® is allowed to come into contact with the following tissues and body fluids

plasma care®	**plasma care® spacer**
Operator: • intact skin	Operator: • intact skin
Patient: • no contact	Patient: • intact skin • damaged or infected skin or rather wound – wound margins – wound bed – exudate

6 Delivery contents

The plasma care® is delivered with the following components:

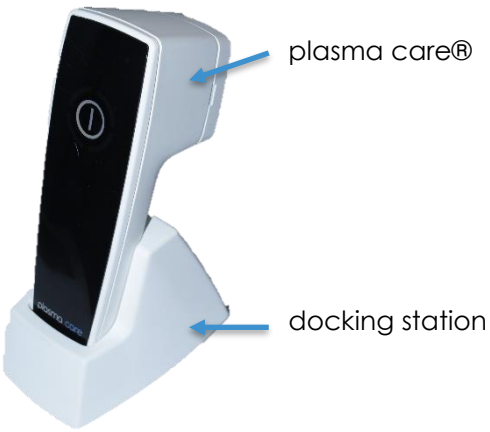
	plasma care® with removable plasma source unit

	
	docking station
	power supply for the docking station
	sterile, individually packaged plasma care® spacer (single use only)
	Instruction for Use

7 Description of the plasma care®

7.1 plasma care® components

The plasma care® is composed of the device, its docking station with the power supply and the plasma care® spacer.



The docking station has two functions:

- Safe placement and storage area for the plasma care®.
- Recharging of the plasma care® via contactless, inductive energy transfer as soon as the plasma care® is placed in the docking station.
- As soons as the plasma care® is placed into the docking station, the control-LED glows blue and the plasma care® re-charges.
- It takes about 3 hours to charge the plasma care® completely.

The removable plasma source unit contains the plasma source, which is composed out of a high voltage electrode, a dielectric barrier and a grounded electrode in the shape of a mesh at the front.

The user interface can be found on the upper side of the plasma care®. The interface allows the following commands by pressing the touch-button:

- Switching the plasma care® on / off by touching the button for 2 / 5 seconds
- Starting and stopping a treatment by exerting pressure briefly.

The user interface displays the following information via differently colored LED-elements:

- Depiction of the system status, i.e. on / off, plasma source active
- Depiction of the battery charge condition
- Depiction of warning and error notices

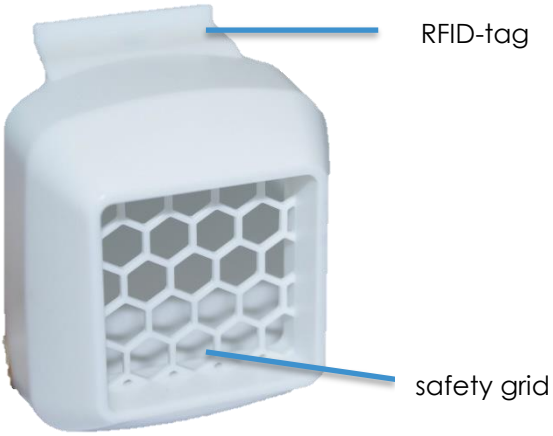
After charging it is possible that the user interface (touchscreen) does not work due to electro-magnetic disturbances. In this case re-calibration of the touchscreen can be required.

7.2 plasma care® spacer

The spacer (sterile single-use product) is attached to the plasma care® onto the plasma source unit and has the following functions:

- Designed as a sterile, single-use product to prevent cross-contamination.
- Integration of a safety grid in order to prevent contact of the patient or the operator with the plasma source integrated into the plasma source unit.

- An unambiguous identification of the attached spacer is enabled via an RFID-transponder that is integrated into the clip. After using the spacer, it is marked as "invalid" and cannot be used for any further treatments. In case of an invalid spacer the plasma care® device cannot be activated.
- With one spacer a maximum of 6 plasma treatments can be performed on a single patient. The use of a spacer on more than one patient is not permitted due to the cross-contamination risk.



7.3 User interface

The user interface indicates the system status and is used for controlling the device. The following status displays are possible:

On / Off (white):
By exerting extended pressure, the plasma care® is switched on or off. If the plasma care® is switched on the On / Off button will glow white.

Plasma ring (blue):

Blue flashes: Indicates that a valid spacer is clipped onto the plasma care® and that the preparation period is running.

Blue glow: When the preparation period is completed all four plasma ring segments glow steadily and the plasma treatment can be started by exerting pressure on the On / Off button briefly.

When the plasma treatment is started, the individual plasma ring segments will flash one after the other and will each switch off after a quarter of the treatment time.

Plasma ring (red):

Red flashes: Indicates that the spacer was already used and is invalid. A new spacer must be used.

Red glow: Indicates a malfunction of the device. Please proceed according to chapter 11.4 Troubleshooting.

Battery symbol (green, yellow, red):

The battery symbol indicates the battery charge condition:

If it glows green, the battery is fully charged. If it glows yellow, the battery is semi-charged. If it glows red, the plasma care® needs to be re-charged.

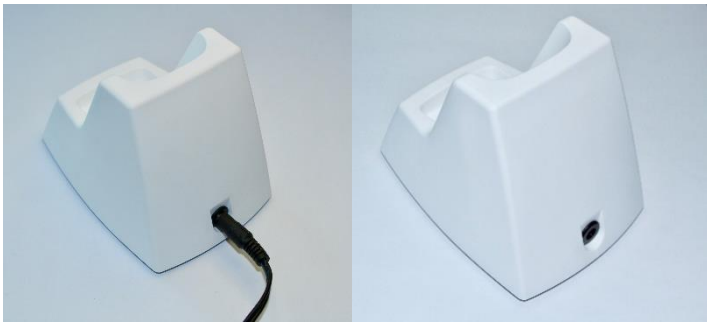
When the plasma care® is placed into the docking station, the battery symbol will alternate between the green, yellow and red glow for as long as the plasma care® is being re-charged. When the plasma care® is fully charged the battery symbol will glow green permanently.

Docking station on / off glow
When the plasma care® is placed into the docking station the control-LED will glow as long as the plasma care® is being charged.

8 Starting the plasma care®

Prior to its first use, the plasma care® needs to be fully charged. For this purpose, carry out the following steps:

1. Attach the power supply of the docking station to the docking station of the plasma care®. The connector for the power supply is inside the black indentation at the back of the docking station.



2. Attach a country-specific adapter plug to the power supply if neccessary.
3. Plug the power supply of the docking station into the power socket.
4. Place the plasma care® into the docking station.

docking station

5. When the plasma care® is placed into the docking station, the control-LED glows while the plasma care® is charged.
6. For the very first use, the the plasma care® should be fully charged. This can take up to 3 hours.

 ID004	Do not use excessive force or remove the plug by pulling on the cable as the cable might be damaged thereby.
 ID005	Do not use excessive force to attach a country-specific adapter plug to the power supply. The electrical contacts might be damaged thereby.
 ID007	Wait until the plasma care® has adjusted to the permissible environmental temperature, especially if the plasma care® has previously been transported or stored under environmental conditions outside of its defined operation values.
 ID004b	Only use the original power supply delivered by the manufacturer. The use of other power supplies is not admissible. **Warning:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

9 Treatment

The treatment with the plasma care® can be carried out in partial treatments of one minute each. **The complete treatment of a single area must not exceed three partial treatments and thus three minutes.** The decision regarding the overall duration of the treatment is at the discretion of the responsible physician and is based on the infection and colonization status of the wound. The physiscian can delegate the treatment procedure.

9.1 Performing a treatment with the plasma care®

In general, the following steps need to be carried out for the treatment:

1.	The plasma care® is switched off, all displays are inactive. The grey symbol in the middle of the user interface indicates the button for switching the medical device on and off.

	
2. 	By exerting pressure for about 3 seconds on the on / off button, the plasma care® is switched on and the symbol in the middle of the user interface glows white. In the upper right corner, the battery charge condition is indicated via the battery symbol. Green means that the device is fully charged, yellow indicates a semi-charged level and red indicates a critically low battery charge condition. Note: When the red battery symbol flashes, the plasma care® needs to be charged immediately to avoid an automatic shutdown of the medical device.
3. 	Attach the spacer to the plasma care®. Be careful not to contaminate the spacer by physical contact. As soon as the spacer is attached the plasma ring flashes blue. The medical device has now entered the preparation period. One needs to wait until the blue plasma ring glows permanently (this might take several seconds). During this preparation period the plasma source is prepared for the subsequent treatment. A high frequency sound can be heard, and a slight scent of ozone can be smelled. During this period of preparation be careful not to contaminate the spacer.
4. 	As soon as the blue plasma ring glows permanently, the plasma care® is ready for treatment. Place the plasma care® gently onto the wound to be treated with the open side of the spacer. The frame of the spacer should lie flat on the wound or the skin such that a closed volume is created. By pressing the on / off button briefly the plasma treatment is started. Note: By briefly pressing the on / off button again the plasma treatment can be stopped early.
5. 	The four blue plasma ring segments represent an overall treatment duration of one minute; each segment blinks for 15 seconds before being switched off. As soon as the last plasma ring segment has been switched off, the plasma source is also automatically switched off. The spacer can now be removed from the device and be discarded. Note: If the plasma treatment is meant to be extended, the used spacer must remain attached to the medical device. After a few seconds, the blue plasma ring re-appears. To continue the treatment, press the on / off button briefly to restart plasma generation. Thereby the treatment of e.g. large wounds is possible. In total, 6 treatments of the same patient are possible within 10 minutes.

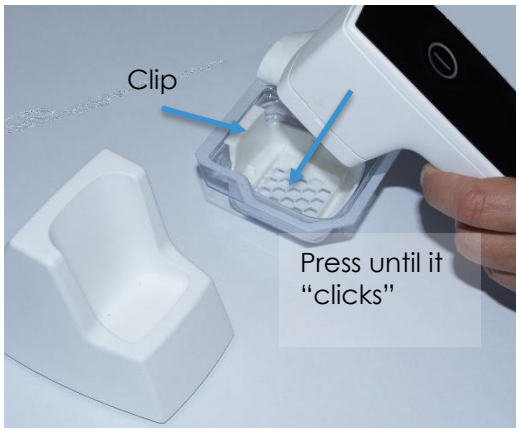
6. 	By pressing the on / off button for an extended period of time (at least 3 seconds), the plasma care® is switched off and the symbol in the middle of the user interface turns grey.
	When the plasma ring flashes red, this indicates that an invalid spacer is attached to the plasma care®. The spacer must be exchanged, otherwise treatment is not possible. Note: In order to treat a new patient it is **mandatory** to exchange the spacer.
	If the plasma ring glows red permanently, a device malfunction has occurred. Note: Perform the steps described in chapter 11.4 Troubleshooting. If the plasma ring continues to glow red permanently, please contact the customer service.

 ID008	Ensure that the plasma care® and in particular the plasma source is not contaminated, smutched or damaged.
 ID022	The treatment of the wound of a patient with the plasma care® may only be performed once within a 12-hour window. The same section of a wound may only be treated for a maximum duration of 3 minutes.
 ID022b	The treatment can be interrupted at any time by exerting extended pressure onto the on / off button. Removal of the plasma care® spacer also leads to immediate interruption of the treatment. If the treatment cannot be stopped by either of these two options, the energy supply of the plasma source can be interrupted by removal of the plasma source.
ID028	Upon treatment with the plasma care® ozone is generated at low concentrations. Treatments in the area of the head and particularly of the mouth should be avoided.

9.2 Attaching and removing the spacer

9.2.1 Attaching the spacer

1. Open the sterile packaging of the spacer and place it on a solid surface such as a table with the spacer still inside its sterile packaging.
2. Hold the plasma care® directly over the spacer as depicted. The clip of the spacer needs to point towards the front of the medical device.
3. Now press the plasma care® onto the spacer until you hear a clicking sound. This indicates that the spacer is securely attached to the plasma care®.
4. Lift the plasma care® with the attached spacer out of the packaging.



9.2.2 Removing the spacer

1. Remove the spacer as depicted. This works best using the thumb and middle finger.
2. Remove or rather push off the spacer at the clip with the thumb and stabilize it with the middle finger to not let it fall.

 ID009	Before each use of a spacer, make sure that the sterile packaging is not damaged or has not already been opened prior to usage of the spacer.

9.3 The plasma care® in the context of wound treatment

In general the treatment of wounds with the plasma care® is performed within the scope of the current therapeutic standard for wound treatment – in the case of chronic wounds outlined in the S3-guideline „Lokaltherapie chronischer Wunden bei Patienten mit den Risiken periphere arterielle Verschlusskrankheit, Diabetes mellitus, chronische venöse Insuffizienz“ for example.

9.3.1 Independent use of the plasma care® for decontamination

Generally, the following steps take place during wound treatment with the plasma care®:

1. **Wound bed preparation in case of non-vital tissue, necrotic tissue, fibrin layers and / or foreign particles**

The active, periodic wound bed preparation serves the targeted, repeated mechanic wound bed preparation in the course of wound dressing replacement. Here, the detachment, removal and flushing out of non-vital tissue, fibrin layers and / or foreign particles are achieved, while in parallel intact anatomic structures remain, and the granulation tissue is maintained.
For wound bed preparation, wound rinsing solutions without active components (e.g. NaCl 0,9% or Ringer's solution) are used, if neccessary in combination with e.g. sterile compresses, instruments or ultrasound-assisted debridement.
If neccessary, surgical debridement can be performed additionally.

 ID021	Wound rinsing solutions with active components may not be used immediately prior to the treatment with plasma care®. When plasma care® treatment is to be performed, wound bed preparation with a wound rinsing solution free of active components needs to be carried out immediately beforehand.

2. **Decontamination of the wound with the plasma care®**

If a pathogen-dependent infection is expected to occur, a decontamination of the wound through plasma treatment according to chapter 9.1 is carried out after wound bed preparation.

 ID020	If non-vital tissue, necrotic tissue, fibrin layers or foreign particles are present in the wound, careful wound bed preparation (using wound rinsing solutions without active components) needs to be performed prior to plasma care® treatment. Otherwise the plasma treatment may not be effective.

9.3.2 Using the plasma care® for decontamination as add-on therapy

Topically applied antiseptics (pharmaceuticals) or other reagents (e.g. ointments) that are used for the anti-microbial treatment of wounds remain in the treatment site post application.

In case such agents are used during the decontamination of a wound, they can only be applied after the treatment with the plasma care®.
The following substances must be applied after the treatment with the plasma care®:

- Antiseptics, e.g. iodopovidone-solution, polyhexanide, octenidine
- Topicalley applied antibiotics e.g. fusidic acid, sulfonamide, gentamycin
- All other substances and reagents that remain in the wound after application.

 ID029	The adjuvant (supportive) treatment with antiseptics, topic antibiotics, etc. needs to be carried out after the treatment with the plasma care®. Otherwise no statement regarding the effectiveness of the plasma treatment and/or the adjuvant treatment can be made. Nothing is known about possible interactions between the plasma and active components or drug substances.

9.4 Special features for notable wounds

Treating large wounds with the plasma care®

If the wound area is larger than the area that can be covered by the opening of the spacer, the plasma care® is carefully relocated (i.e. lifted off and put down again gently) to the adjacent untreated area and the plasma treatment is restarted.

This procedure is repeated until the entire wound has been treated.

Pay attention to creating a slight overlap between the areas covered by the spacer, when relocating the plasma care®.

Exchanging the spacer

If more than 6 plasma treatments are required to cover the entire wound area, the spacer needs to be exchanged as a single spacer can only be used for 6 consecutive plasma discharges.

Application at the entry points of drainages and catheters or at strongly curved locations

When treating entry points of drainages and catheters or strongly curved wound locations try to place the opening of the spacer as planar as possible to create a closed volume.

Wounds with wound pockets

Cold plasma therapy can stimulate wound healing (= therapy success), resulting in development of granulate. However the effect of cold plasma is located at the wound surface. The operator must pay attention in regards of deep wounds with pokets that no granulation and thereby a closure of the wound evolves during the treatment. A closure would catalyst the nucleus production and subsequently make the antimicrobial effect inaccessible in the complete wound area. Wound pokets must be kept open mechanically by all means (e.g. by tamponade).

 ID029b	Plasma treatment can lead to wound granulation stimulation (= therapy success). If wound pockets exist, professional supervision is required such that a superficial wound closure through mechanical measures can be prevented. Otherwise locked in wound micobes may not be accessible for antimicrobial treatment.

10 Cleaning, maintenance and servicing

10.1 Cleaning and maintenance

10.1.1 Cleaning of the plasma care® and docking station

Cleaning oft he plasma care® is carried out in two steps:

1. Pre-cleaning:

   If neccessary, remove rough dirt and deposits thoroughly. For this purpose, use a lint-free cloth, warm water and a common detergent and wipe down the surface without touching the plasma source or its mesh. Do not use scouring agents or aggressive detergents. Allow the device to dry completely.

2. Disinfection:
   - The disinfection of the plasma care® must be performed using wipe disinfection.
   - Use a lint-free cloth or paper cloth for disinfection that is moistened with disinfectant.
   - Wipe down the plasma care® with this cloth as follows:
     - For at least 30 seconds from each side
     - Take particular care of the edge between the top and the body of the device.
   - Allow the disinfection agent to take effect according to the manufacturer's instructions, but at least 5 minutes.

Disinfection agents recommended for wipe disinfection:

- generally, disinfection wipes are recommended for disinfection
- Bacillol® AF Tissues (BODE Chemie GmbH)

Only use disinfection agents that are approved by the Robert Koch Institute for the disinfection of equipment.

 ID032	Avoid a very humid cleaning procedure, for example by frequent use of spray disinfectant, because the electronic components can be damaged. Cleaning by submersion in a solution is prohibited.

10.1.2 Cleaning of the plasma source unit

If wound exudate or any other contaminant has deposited on the plasma source, the plasma source unit needs to be cleaned as follows:

Detach the plasma source unit from the device:

1. Hold the plasma care® at the handle with one hand.
2. Grab the plasma source unit with the other hand at the edges on the side of the mesh.
3. Twist the plasma source unit a quarter of a turn counter-clockwise.
4. The plasma source unit can now be lifted off the plasma care®.

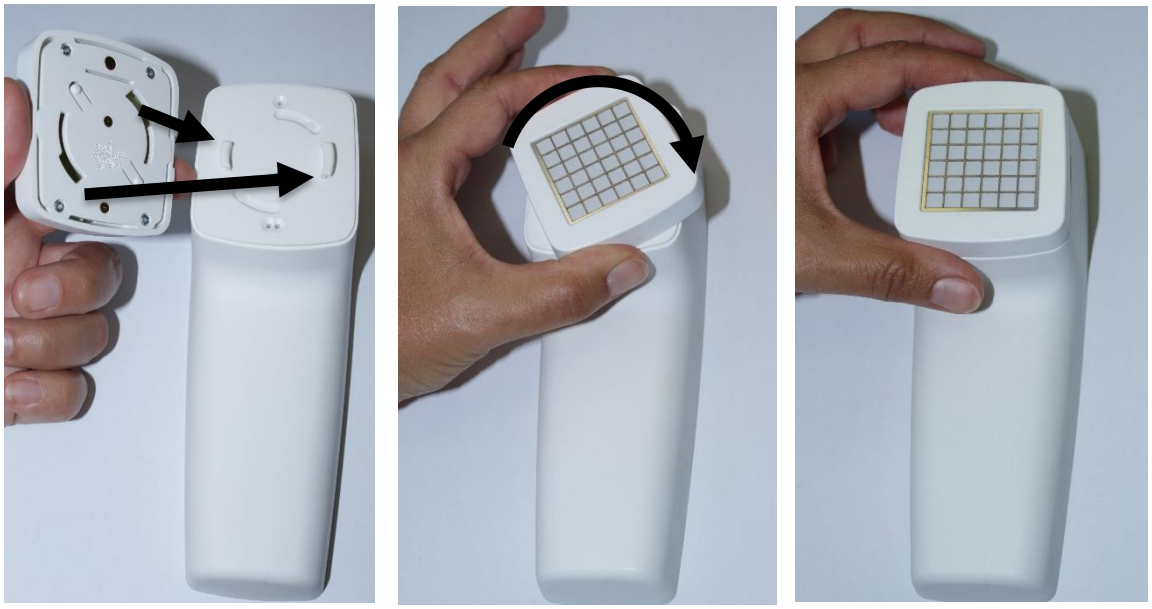


Cleaning the plasma source unit:

1. The disinfection of the plasma care® must be performed using wipe disinfection.
2. Use a lintless cloth or paper cloth for disinfection that is moistened very well with disinfectant. Bacillol® AF Tissues (BODE Chemie GmbH) are recommended.
3. Dab the plasma source unit on the surface. Take care to not leave paper or cloth particles behind on the mesh of the plasma source. Avoid strong rubbing of the mesh.
4. Allow the disinfectant to take effect according to the manufacturer's instructions.
5. Allow the plasma source unit to dry over night.

Reattach the plasma source unit to the device:

1. Hold the plasma care® at the handle with one hand again.
2. Grab the cleaned plasma source unit with the other hand at the edges on the side of the mesh.
3. Position the plasma source unit in such a manner on the socket, that the large attachment bolt fits into the large pocket and that the small attachment bolt fits into the small pocket.
4. Twist the plasma source unit a quarter of a turn clockwise until it clicks into place. The plasma source unit must then be flush with the body of the plasma care®.
5. The medical device is ready-for-use.



Recommended disinfection agents:

- Bacillol® AF Tissues (BODE Chemie GmbH)

Only use disinfection agents that are approved by the Robert Koch Institute for the disinfection of equipment.

ID035	If dirt remains on the plasma source after cleaning, the dirty plasma source unit needs to be replaced by a new clean plasma source unit.
ID035a	Examine the device (both front and back) for residuals of body fluids, especially after the treatment of strongly exuding wounds
ID036	When changing the plasma source unit, check the wired contacts between the plasma care® and the plasma source unit for corrosion. Also check whether the plasma source unit has been placed onto the plasma care® carefully and flush.
ID037	The plasma source unit needs to be cleaned as described at least once a month.

10.1.3 Storage

When the plasma care® is not in use, it should be placed in the docking station for safe storage.

10.2 Service

The plasma care® needs to be returned to the manufacturer once a year for servicing. Please inform the manufacturer in writing prior to each return (e.g. via *support@terraplasma-medical.com*). Please state the device reference of the plasma care® and request a return number (RMA-number).

Please clean and disinfect the plasma care® prior to each return as described in chapter 10.1 cleaning and maintenance. Please use the original packaging for returning the plasma care®.

 ID038	If the plasma source unit is used beyond its expected service life the plasma care® will indicate this via a permanent red glow of the four segments of the plasma ring and the plasma source unit needs to be replaced.

11 Introduction, training and support

11.1 Introduction

Orientation regarding the intended use is provided upon delivery of the plasma care®. It can be provided in person or by telephone.

11.2 Training

Training in how to use the plasma care® that extends beyond usual orientation is offered by terraplasma medical GmbH in the form of:

- Personal training on site by an employee of terraplasma medical GmbH.
- Personal training by telephone or video/web conference by an employee of the terraplasma medical GmbH.
- Training video on the website of terraplasma medical GmbH *www.terraplasma-medical.com*

11.3 Service and support

In case of questions employees of terraplasma medical GmbH can be contacted during the regular office hours (Monday to Thursday from 09:00h to 17:00h, Friday from 09:00h to 15:00h) via:

Telephone: +49 89 588 0 553 77

Fax: +49 89 588 0 553 99

E-Mail: *support@terraplasma-medical.com*

11.4 Troubleshooting

Error: Plasma ring glows red permanently:

Remove the spacer and re-attach it again.

Check whether the plasma source unit is attached properly and flush to the plasma care®:

- If this is not the case, re-attach the plasma source unit carefully and flush to the plasma care®.

Check the plasma source unit and the plasma source for humidity and wetness, for example due to disinfectant residues:

- If this is the case, the plasma source unit and the plasma source need to be dried. For this purpose, allow the plasma source unit to dry over night.
- Alternatively, you can employ a new plasma source unit.

Check the plasma source unit for contamination:

- If this is the case, clean the plasma source unit according to chapter 10.1.2 Cleaning of the plasma source unit.
- If cleaning in due form is insufficient, exchange the plasma source unit and use a new plasma source unit.

Check the plasma care®, especially plasma source unit and the plasma source for damage such as cracks or fissures:

- In case of damage, the plasma care® needs to be returned to the manufacturer for servicing and repair.

Check the wired contacts between the plasma care® and the plasma source unit for corrosion:

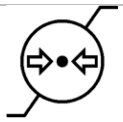
- In case of corrosion of the wired contacts between the plasma care® and the plasma source unit the plasma care® needs to be returned to the manufacturer for servicing.

12 Environmental conditions

Start-up of the plasma care® after storage or transport must only take place if the operating conditions are met:

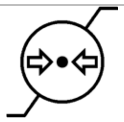
12.1 Operating conditions

The plasma care® can be operated under regular lighting conditions at the work place.
The plasma care® can be used for inpatient as well as outpatient care.

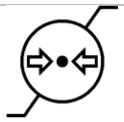
	The plasma care® and the spacer can be used at temperatures between +10°C and +35°C.
	The plasma care® and the spacer can be used at a relative humidity between 25% and 70% RH.
	The plasma care® and the spacer can be used at atmospheric pressure between 800 hPa and 1060 hPa.

 ID013	Before starting-up the plasma care® after it has been transported, the medical device needs to reach a temperature within the operating conditions. At 20°C the medical device needs at least 5 minutes to cool down from the highest permissible storage or transport temperature to the highest admissible operating temperature. At 20°C the medical device needs at least 5 minutes to warm up from the lowest permissible storage or transport temperature to the lowest admissible operating temperature.

12.2 Storage conditions

	The plasma care® can be stored at temperatures between +5°C and +45°C.
	The plasma care® can be stored at a relative humidity between 15% and 90% RH.
	The plasma care® spacer can be stored at temperatures between -20°C and +55°C until the end of its use-by date.
	The plasma care® spacer must not be used after its use-by date is passed.
	The plasma care® spacer can be stored at a relative humidity of 20% and 75% RH.
	The plasma care® and the plasma care® spacer can be stored at atmospheric pressure between 700 hPa and 1060 hPa.

12.3 Transport conditions

	The plasma care® can be transported inside its packaging at temperatures between +5°C and +45°C.
	The plasma care® can be transported inside its packaging at a relative humidity between 15% and 90% RH.
	The plasma care® spacer can be transported inside its packaging at temperatures between -20°C and +55°C.
	The plasma care® spacer can be transported inside its packaging at a relative humidity between 20% and 75% RH.
	The plasma care® and the plasma care® spacer can be transported inside their packaging at atmospheric pressure between 700 hPa and 1060 hPa.

13 Service life

The expected minimal service life of the plasma care® is 1 year from first use, if the required servicing cycles are observed.

 ID038	If the plasma source unit is used beyond its expected service life the plasma care® will indicate this via a permanent red glow of the four segments of the plasma ring and the plasma source unit needs to be replaced.

The exchangeable plasma care® spacer is intended for single-use. The plasma care® spacers have a separate use-by date that is indicated on the primary sterile packaging.

	The plasma care® spacer must not be used after its use-by date is passed.
	Do not sterilize again

At full charge the capacity of the battery allows at least 120 treatments to be carried out.

The re-chargeable battery has a residual capacity of at least 65% after 300 complete charging cycles.

14 Disposal

	The plasma care® needs to be discarded via a separate collection of electric and electronic appliances. The effective country-specific disposal regulations and laws must be complied.

The plasma care® needs to be discarded via a separate collection of electric and electronic appliances. The effective country-specific disposal regulations and laws must be complied.

Discard the plasma care® spacer safely in accordance with the effective regulations:

After its use the plasma care® spacer is subject to the following disposal key: (AS 18 01 03)

Other wastes, whose collection and disposal are subject to special demands in view of preventing infections (AS 18 01 03)

Accordingly, the plasma care® spacer needs to be discarded in compliance with the „*Vollzugshilfe zur Entsorgung von Abfällen aus Einrichtungen des Gesundheitsdienstes* der Bund/Länderarbeitsgemeinschaft Abfall (LAGA) 18“.

15 Technical specification

CE 0197	CE-Icon with number of notified body
	terraplasma medical GmbH Parkring 32 85748 Garching
	**e.g. 2022 – 09** (Manufacturing date can be found on the plasma care® label nearby this icon)
REF	**1000**

Trade Name	**plasma care®**
Medical device class	IIa
Software Version	2.0
Plasma technology	SMD (Surface micro discharge)
Therapy time	1 minute
Maximum number of therapy sessions per area	3 sessions (equals 3 minutes)
Maximum number of therapy sessions per spacer	6 sessions within 10 minutes
User interface	LED-Touchpanel
Control	Semi-automatic
Supply voltage range	100 V - 240 V
Supply frequency range	50 Hz / 60 Hz
Isolation from mains voltage	Safety power supply XP Power VEP24US12
Battery	FEY ELEKTRONIK GMBH PA-IEC-LNB76.R001
Outer dimensions	16cm x 5,5cm x 6cm (L x W x D)
Weight	320g

	Applied part of type BF
IP22	**plasma care:** Protected against access with a finger to dangerous parts and protected against dripping water, when the body of the device is bent up to 15°.

IP21	**plasma care power supply and docking station:** Protected against access with a finger to dangerous parts and protected against dripping water.

16 Ordering replacements and single-use products

Replacements and single-use products can be ordered from the manufacturer via:

Telephone: +49 89 588 0 553 77

Fax: +49 89 588 0 553 99

E-Mail: *support@terraplasma-medical.com*

Or by regular mail to:

terraplasma medical GmbH
Support
Parkring 32
85748 Garching

17 EMC and UV

The following table shows the compliance with the respective standards regarding electromagnetic emission and immunity.

Phenomenon	EMC-Basic standard	Immunity testing levels	
		Professionel and home healthcare facilities	Electromagnetic environment - Guidance
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Luft	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
High frequency electromagnetic fields	IEC 61000-4-3	10 V/m 80 MHz up to 2,7 GHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance 30 cm.
Power frequency magnetic fiel	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Electrical fast transient/burst	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	Mains power quality should be that of a typical environment.
Surge voltages Wire against wire	IEC 61000-4-5	± 0,5 kV, ± 1 kV	Mains power quality should be that of a typical environment.
Conducted Interference induced by High-Frequency Fields	IEC 61000-4-6	3 V 0,15 MHz up to 80 MHz 6 V at ISM- and amateur radio frequency bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance 30 cm.
Voltage drops	IEC 61000-4-11	0 % UT; 1/2 Periods at 0, 45, 90, 135, 180, 225, 270 and 315 degrees	Mains power quality should be that of a typical environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device is powered from an uninterruptible power supply or battery.
		0 % UT; 1 Periode And 70 % UT; 25/30 Periods Single-phase: at 0 degrees	
Voltage interruptions	IEC 61000-4-11	0 % UT; 250/300 Periods	

The plasma care® is intended for professional and home healthcare environment.

ID028b

Upon treatment with the plasma care® UV radiation is generated at very low intensity. Avoid treatments at the eyes.

The following table shows the compliance with the respective standards regarding immunity against high frequency wireless communication devices.

Testfrequency MHz	Frequency-band MHz	Radio service	Modulation	Maximal power W	Distance m	Immunity testing levels V/m
385	380 bis 390	TETRA 400	Puls modulation 18 Hz	1,8	0,3	27
450	430 bis 470	GMRS 460 FRS 460	FM ± 5 kHz Hub 1 kHz Sinus	2	0,3	28
710 745 780	704 bis 787	LTE Band 13, 17	Puls modulation 217 Hz	0,2	0,3	9
810 870 930	800 bis 960	GSM 800/900 TETRA 800 IDEN 820 CDMA 850 LTE Band 5	Puls modulation 18 Hz	2	0,3	28
1720 1845 1970	1700 bis 1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1,2,4,25 UMTS	Puls modulation 217 Hz	2	0,3	28
2450	2400 bis 2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Puls modulation 217 Hz	2	0,3	28
5240 5500 5785	5100 bis 5800	WLAN 802.11 a/n	Puls modulation 217 Hz	0,2	0,3	9

Emission

Test	Limit	Electromagnetic environment - guidance
Conducted emission	CISPR 11, Group 1, Class B	Device uses RF energy only for its internal function and charging the device. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated emission	CISPR 11, Group 1, Class B	
Harmonic current emissions	/	Device is directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. Only for Home healthcare environment.
Voltage fluctuations and flicker	IEC 61000-3-3	

The following table shows the transmission- and receiving frequencies of the plasma care®

Receiving frequency	13,56 MHz
Preffered frequency	13,56 MHz
Receiver bandwidth	14 kHz
Transmission frequency	13,56 MHz
Transmitter bandwidth	14 kHz
Modulation of frequency	Amplitude modulation (ASK)
Effective radiated power	200 mW

The following table shows the characteristics of the plasma care® wireless charging module

Input Voltage	4,75 – 13 V
Output Voltage	15W
Frequenzy	110 – 148 KHz
Min Load	0,1A
Max Load	1,25A
Peak Load	1,5A
Storage High Temp	16h @ 60 °C
Storage Low Temp	16h @ -20 °C
Operation High Temp	8h @ 40 °C
Operation Low Temp	8h @ -20 °C

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