

Instructions for Use

plasma care®

plasma care® spacer



Table of contents

1	Imprint.....	4
1.1	Imprint.....	4
1.2	Disclaimer.....	4
1.3	Information on the document.....	4
2	Notes and symbols.....	5
2.1	Read and abide by the manual.....	5
2.2	Symbols.....	5
2.3	Warning and safety notes.....	7
2.3.1	Starting-up the medical device.....	7
2.3.2	Treatment and operation.....	8
2.3.3	Cleaning, maintenance and servicing.....	10
2.3.4	Medical device malfunction.....	11
2.3.5	Unexpected events.....	12
2.3.6	Performance characteristics.....	12
3	Intended Use, Indications for Use, Side Effects, Complications, and Contraindications....	13
3.1	Intended use.....	13
3.2	plasma care® is adjunctive therapy.....	13
3.3	Indications for Use.....	13
3.4	Side effects / Contraindications.....	13
4	Operator and Patient Profiles.....	14
4.1	Operator.....	14
4.2	Patient Profile.....	14
5	Delivery contents.....	15
6	Description of the plasma care®.....	16
6.1	plasma care® components.....	16
6.2	plasma care® user interface.....	16
6.3	plasma care® spacer.....	16
6.4	User interface.....	17
7	Starting the plasma care®.....	19
8	Treatment.....	21
8.1	Performing a treatment with the plasma care®.....	21
8.2	Attaching and removing the spacer.....	23
8.2.1	Attaching the spacer.....	23
8.2.2	Removing the spacer.....	24
8.3	Treating wounds with the plasma care®.....	24
	Adjunctive use of the plasma care® for decontamination.....	24
8.3.1	24
8.3.2	Techniques for larger wounds.....	25

9	Cleaning, maintenance and servicing	25
9.1	Cleaning and maintenance	25
9.1.1	Cleaning of the plasma care® and docking station	25
9.1.2	Cleaning of the plasma source unit	26
9.1.3	Storage	28
9.2	Service	29
10	Orientation, training and support.....	30
10.1	Orientation	30
10.2	Training	30
10.3	Service and support.....	30
10.4	Troubleshooting	30
11	Environmental conditions	31
11.1	Operating conditions.....	31
11.2	Storage conditions	31
11.3	Transport conditions	32
12	Service life	32
13	Disposal.....	33
14	Device Labeling	34
15	Technical specification	34
16	Ordering replacements and single-use products	35
17	EMC.....	36
18	FCC Certification.....	37

1 Imprint

1.1 Imprint

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1.2 Disclaimer

The terrapiasma 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	terrapiasma medical GmbH
Version	0.1
Date	26.05.2020













Caution: U.S. Federal law restricts this device to sale by or on order of a physician.

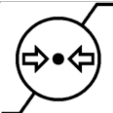






2 Notes and symbols

2.1 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-compliance with the manual and the safety instructions can lead to damage of the device, serious injuries and may even result in life-threatening situations
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2.2 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
	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 from 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.
	Level of protection against intrusion (solid particles) and water.
	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.







2.3 Warning and safety notes










2.3.1 Starting-up the medical device





 ID001	Only use the plasma care®, after having read and understood the instructions for use in its entirety. Non-compliance usage of the device due 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.
 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 11. 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.
 ID011	Do not perform any modifications on the plasma care® without permission of the manufacturer. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
 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 11.1 Operating conditions).





2.3.2 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 3) taking into account its indications and contraindications (see chapter 3).
 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 8).

 ID020	<p>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.</p>
 ID021	<p>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.</p>
 ID022	<p>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.</p>
 ID022b	<p>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.</p> <p>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.</p>
 ID023	<p>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.</p>
 ID024	<p>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.</p>
 ID024a	<p>The plasma care ® should not be used in direct proximity to other devices or combined with other devices as this can result in malfunction. 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.</p>
 ID025	<p>Do not remove the plasma care® spacer or the plasma source unit under any circumstances during treatment.</p>
 ID026	<p>The plasma care® spacer protects the user and the patient from an unintended contact with the plasma source through the integrated protection mesh.</p>



 ID027	<p>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.</p>
 ID028	<p>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.</p>
 ID028b	<p>Upon treatment with the plasma care® UV radiation is generated at very low intensity. Avoid treatments around the eyes.</p>
 ID029	<p>The application of antiseptics, topical antibiotics, etc. should occur after the treatment with the plasma care®. Otherwise no statement regarding the effectiveness of the plasma treatment and/or the antimicrobial treatment can be made.</p>

2.3.3 Cleaning, maintenance and servicing



 ID030	<p>Clean the plasma care® after each treatment of a patient as described in chapter 9 to prevent cross-contamination.</p>
 ID031	<p>You may only use detergents for cleaning of the plasma care® that are described in chapter 9.</p>
 ID032	<p>Perform the cleaning procedure for the plasma care® using wipe disinfection as described in chapter 9. Avoid excessive cleaning fluids, for example frequent use of spray disinfectant, because the electronic components can be damaged. Cleaning by submersion in a solution is prohibited.</p>
 ID033	<p>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 9.</p>

 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.

2.3.4 Medical device malfunction

 ID039	<p>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.</p> <p>In case of dirt, the plasma source unit needs to be cleaned as described (see chapter 9.1.2) or replaced.</p> <p>In case of damage, the plasma source unit needs to be replaced.</p> <p>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.</p>
 ID040	Protect the plasma care® from mechanical damage, shocks and drops.

2.3.5 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.

2.3.6 Performance characteristics

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

- The plasma source produces the required cold atmospheric plasma
- A malfunctioning plasma source is recognized via the monitoring system
- The duration of treatment does not exceed the specified time
- The terrapiasma spacer can only be used once
- The internal power supply supplies the device with the required voltage and frequency

3 Intended Use, Indications for Use, Side Effects, Complications, and Contraindications

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

3.1 Intended use

The aim is to reduce the bacterial and fungal infiltration of a skin wound with the plasma care®. For this purpose the operator (e.g. a nurse) places the plasma care® with the spacer attached 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 8).

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

3.2 plasma care® is adjunctive therapy

The plasma care® can be used as an add-on to regular wound therapy, (i.e. in addition to the usual community standard treatment methods). Standard procedures using cleaning solutions / debridement, topically applied medications or antiseptics, and wound dressings should be continued.

In general, wound bed preparation using any form of debridement and wound irrigation or similar water-based solutions should be performed prior to the plasma treatment. However, the plasma treatment should be carried out prior to the application of any other medications that remain in the wound.

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.

3.3 Indications for Use

The plasma care® device decreases the microbial flora of skin wounds. The plasma care® device is an adjunct to standard therapies including wound debridement and topical antimicrobial solutions.

The plasma care® device has been shown *in vitro* to reduce the following bacteria by greater than 5 log: *Staphylococcus aureus*, *Staphylococcus epidermidis*, methicillin resistant *Staphylococcus aureus* (MRSA), *Pseudomonas aeruginosa*, *Escherichia coli*, *Enterococcus faecalis*, *Streptococcus agalactiae*, *Streptococcus constellatus*, and *Corynebacterium propinquum*.

The plasma care® device has been shown *in vitro* to reduce *Candida albicans* by greater than 4.6 log.

3.4 Side effects / Contraindications

There are no known side effects or complications associated with a treatment using the plasma care® device.

A treatment with plasma care® is contraindicated for:

- Wounds without hemostasis
- Wounds with exposed inner organs (e.g., during surgery)
- Wounds at mucous membranes
- Wounds of head and neck area
- Children under the age of 12 years

4 Operator and Patient Profiles

4.1 Operator

The plasma care® is a medical device that is intended for use in a professional 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.



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

4.2 Patient Profile

The patients are people with wounds of varying aetiology. The patients need to be at least 12 years of age. As wounds occur 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
- peripheral artery disease
- Diabetes mellitus
- neoplasias

The treated wounds are not gender-specific.

5 Delivery contents

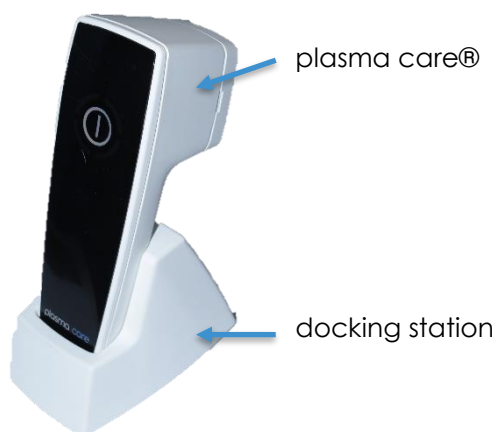
The plasma care® is delivered with the following components:

	<p>plasma care® with removable plasma source unit</p>
	<p>docking station</p>
	<p>power supply for the docking station</p>
	<p>sterile, individually packaged plasma care® spacer (single use only)</p>
	<p>Instruction for Use</p>

6 Description of the plasma care®

6.1 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 soon as the docking station is plugged in, the control-LED glows blue and the plasma care® can be recharged. It takes about 3 hours to charge the plasma care® completely. During the charging process the battery symbol of the plasma care® flashes red, yellow and green.

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.

6.2 plasma care® user interface

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:

- The system status, i.e. on / off, plasma source active
- The battery charge condition
- Warning and error notices

6.3 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.

- The integrated safety grid prevents contact of the patient or the operator with the plasma source integrated into the plasma source unit, while it produces plasma.
- An unambiguous identification of the attached spacer is enabled via an integrated RFID-transponder. 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.



6.4 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 10.4 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 continuously.



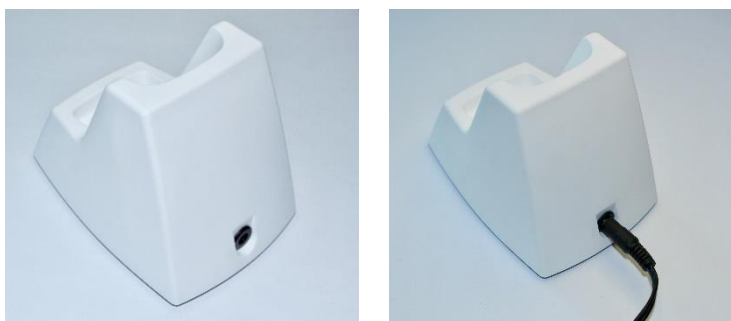
Docking station on / off glow

The blue control-LED will glow as long as the docking station is plugged-in.

7 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:

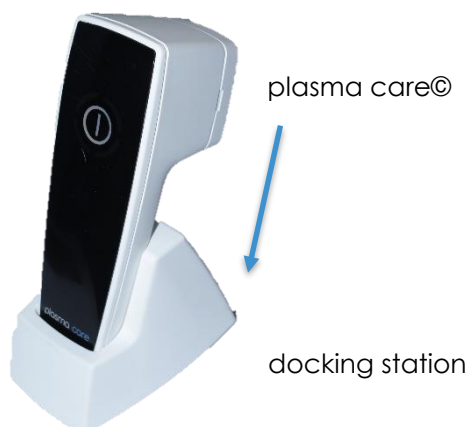
1. Attach the power supply of the docking station to the docking station of the plasma care®. The connector for the power supply is inside the black indentation at the back of the docking station.







2. Attach a country-specific adapter plug to the power supply if necessary.
3. Plug the power supply of the docking station into the power socket. The blue control-LED of the docking station will start to glow.



4. Place the plasma care® into the docking station.



5. When the plasma care® is placed into the docking station and charges, the battery-LED will flash from red, yellow and green. When the plasma care® is fully charged the battery symbol will only flash green.
6. For the very first use, 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.





8 Treatment


The treatment with the plasma care® is carried out in treatments of **one minute** each. The complete treatment of a single area must not exceed **three sequential treatments** and thus **three minutes**. A treatment-free interval of at least 12 hours should elapse before another plasma treatment is performed. The decision regarding the overall duration and frequency of the treatment is at the discretion of the responsible physician and is based on the infection and colonization status of the wound.




8.1 Performing a treatment with the plasma care®

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

<p>1.</p> 	<p>The plasma care® is switched off, all displays are inactive.</p> <p>The grey symbol in the middle of the user interface indicates the button for switching the medical device on and off.</p>
<p>2.</p> 	<p>By exerting pressure for about 2 seconds on the on / off button, the plasma care® is switched on and the symbol in the middle of the user interface glows white.</p> <p>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.</p> <p>Note: When the red battery symbol flashes, the plasma care® needs to be charged immediately to avoid an automatic shutdown of the medical device.</p>
<p>3.</p> 	<p>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 continuously (this might take several seconds).</p> <p>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.</p> <p>During this period of preparation be careful not to contaminate the spacer.</p>

<p>4.</p> 	<p>As soon as the blue plasma ring glows permanently, the plasma care® is ready for treatment.</p> <p>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.</p> <p>By pressing the on / off button briefly the plasma treatment is started.</p> <p>Note: By briefly pressing the on / off button again the plasma treatment can be stopped early.</p>
<p>5.</p> 	<p>The four blue plasma ring segments represent a treatment duration of one minute; each segment flashes for 15 seconds before being switched off.</p> <p>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. Alternatively, a second treatment of one minute can be performed on the same area or on an adjacent area.</p> <p>Note: If the plasma treatment is to be extended, the used spacer must remain attached to the medical device. After a few seconds, the blue plasma ring reappears. To continue the treatment, press the on / off button briefly to restart plasma generation. Three sequential one minute treatments may be given to a wound area at any one time, however, a time interval of 12 hours must elapse between two separate treatments. In total, 6 one minute treatments of the same patient are possible using one spacer. The treatment of e.g. large wounds is possible by placing the spacer on six different, neighbouring areas of a large wound and treating each area for one minute.</p>
<p>6.</p> 	<p>By pressing the on / off button for an extended period of time (at least 5 seconds), the plasma care® is switched off and the symbol in the middle of the user interface turns grey.</p>
	<p>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.</p> <p>Note: In order to treat a new patient it is mandatory to exchange the spacer.</p>

	<p>If the plasma ring glows red permanently, a device malfunction has occurred.</p> <p>Note: Perform the steps described in chapter 10.4 Troubleshooting. If the plasma ring continues to glow red permanently, please contact the customer service.</p>
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 ID008	<p>Ensure that the plasma care® and in particular the plasma source is not contaminated, smutched or damaged.</p>
 ID022	<p>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.</p>
 ID022b	<p>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.</p> <p>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.</p>
ID028	<p>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.</p>

8.2 Attaching and removing the spacer

8.2.1 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.



8.2.2 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.

8.3 Treating wounds with the plasma care®

In general the treatment of wounds with the plasma care® is performed within the scope of the current therapeutic standards for wound treatment. The use of the plasma care® is in addition to the current recommendations for wound treatment.

8.3.1 Adjunctive use of the plasma care® for decontamination



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.



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.

Generally a wound is treated with a wet-to-dry dressing. First, the wound bed is irrigated and topical antiseptics are applied. A wet dressing is applied which is destined to dry in the wound bed. At the next dressing change, removal of the dry dressing debrides the wound base.

Treatment with the plasma care® should occur after a dressing is removed and the wound bed is irrigated with sterile NaCl or Ringer's solution. Surgical or ultrasonic debridement, if used, should also occur before use of the plasma care®. The wound should no longer bleed, and excessive blood should be removed.

Topically applied antiseptics should be applied only **after** 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
- Topically applied antibiotics e.g. fusidic acid, sulfonamide, gentamycin
- All other substances and reagents that remain in the wound after application.



ID029

The application of antiseptics, topical antibiotics, etc. should occur after the treatment with the plasma care®. Otherwise no statement regarding the effectiveness of the plasma treatment and the antimicrobial treatment can be made.

8.3.2 Techniques for larger wounds

Treating large wounds with the plasma care®

If the wound area is larger than the area that can be covered by the spacer, the plasma care® should be 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.

9 Cleaning, maintenance and servicing

9.1 Cleaning and maintenance

9.1.1 Cleaning of the plasma care® and docking station

Cleaning of the plasma care® is carried out in two steps:

1. Pre-cleaning:

If necessary, 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:
 - 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.

Generally, disinfection wipes are recommended. Validated disinfection wipes are:

- Bacillol® AF Tissues (BODE Chemie GmbH)
- Pursept® A Xpress wipes (Schülke & Mayr GmbH)



ID032

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

9.1.2 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®.

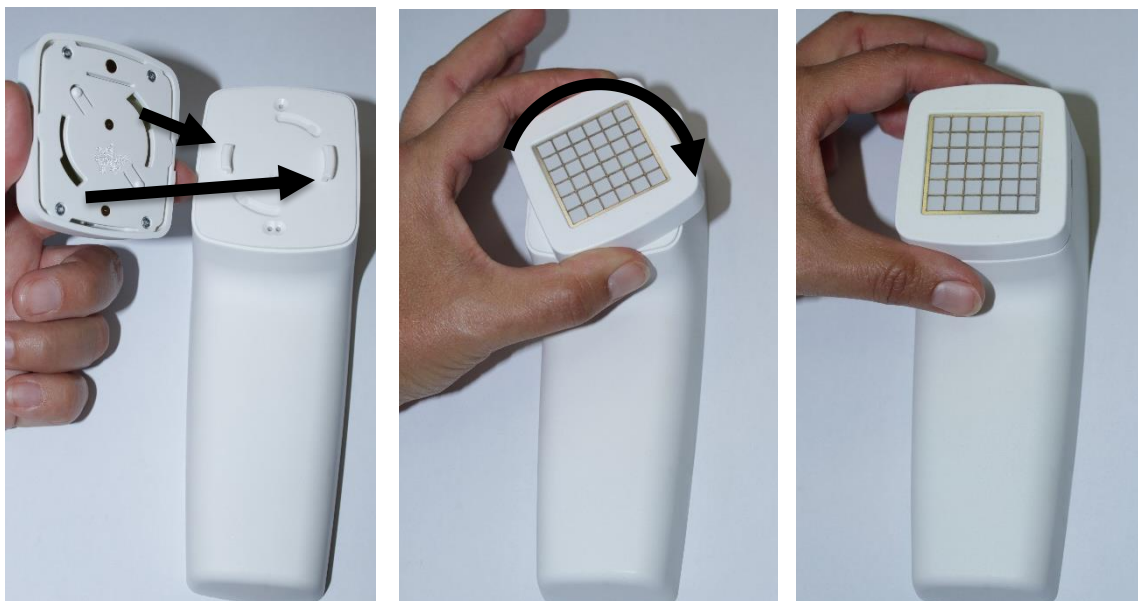


Cleaning the plasma source unit:

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; Bacillo® AF Tissues (BODE Chemie GmbH) or Pursept® A Xpress wipes (Schülke & Mayr GmbH).
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)
- Pursept® A Xpress wipes (Schülke & Mayr GmbH)

 ID035	<p>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.</p>
 ID035a	<p>Examine the device (both front and back) for residuals of body fluids, especially after the treatment of strongly exuding wounds</p>
 ID036	<p>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.</p>
 ID037	<p>The plasma source unit needs to be cleaned as described at least once a month.</p>

9.1.3 Storage

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

9.2 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@terrapiasma-medical.com). Please supply the serial number for 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 9.1 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.

10 Orientation, training and support

10.1 Orientation

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

10.2 Training

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

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

10.3 Service and support

In case of questions employees of terrapiasma 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 0

Fax: +49 89 588 0 553 99

E-Mail: support@terrapiasma-medical.com

10.4 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 is **flush** to the plasma care® device:

- 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 9.1.2 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 the 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.

11 Environmental conditions

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






11.1 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	<p>Before starting-up the plasma care® after it has been transported, the medical device needs to reach a temperature within the operating conditions.</p> <p>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.</p> <p>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.</p>

11.2 Storage conditions

	The plasma care® can be stored at temperatures between +5°C and +45°C.
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	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.

11.3 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.

12 Service life

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

	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.
ID038	


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.

13 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.
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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.

14 Device Labeling



terraplasma medical GmbH
Parking 32
85748 Garching b. München



		(01) 4260644540010 (11) 2019 (21) 55000001A	Manufacturing date
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Caution: U.S. Federal law restricts this device to sale by or on order of a physician

Note: The manufacturing date can be found on the backside of the plasma care® next to the DataMatrixCode after the indicator number (11).

15 Technical specification

REF	1000
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Name	plasma care®
Medical device class	II
Software Version	2.0
Plasma generation	SMD
Operating time	3 minutes
User interface	LED-Touchpanel
Supply voltage range	100 V - 240 V
Supply frequency range	50 Hz / 60 Hz
Isolation from mains voltage	Sicherheitsnetzteil 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.
FCC	Certification according to Federal Communications Commission (FCC)

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/ TV technician for help.

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 0

Fax: +49 89 588 0 553 99

E-Mail: support@terraplasma-medical.com

Or by regular mail to:

terraplasma medical GmbH
Support
Parking 32
85748 Garching b. München

17 EMC

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

Phenomenon	EMC-Basic standard	Immunity testing levels	
		Professional healthcare facilities	Home healthcare facilities
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Luft	
High frequency electromagnetic fields	IEC 61000-4-3	3 V/m 80 MHz up to 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz up to 2,7 GHz 80 % AM at 1 kHz
Power frequency magnetic field	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	
Electrical fast transient/burst	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	
Surge voltages Wire against wire	IEC 61000-4-5	± 0,5 kV, ± 1 kV	
Conducted Interference induced by High-Frequency Fields	IEC 61000-4-6	3 V 0,15 MHz up to 80 MHz 6 V at ISM-Frequencybands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	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
Voltage drops	IEC 61000-4-11	0 % UT; 1/2 Periods at 0, 45, 90, 135, 180, 225, 270 and 315 degrees	
		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	



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.

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

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

18 FCC Certification

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.



www.terraplasma-medical.com