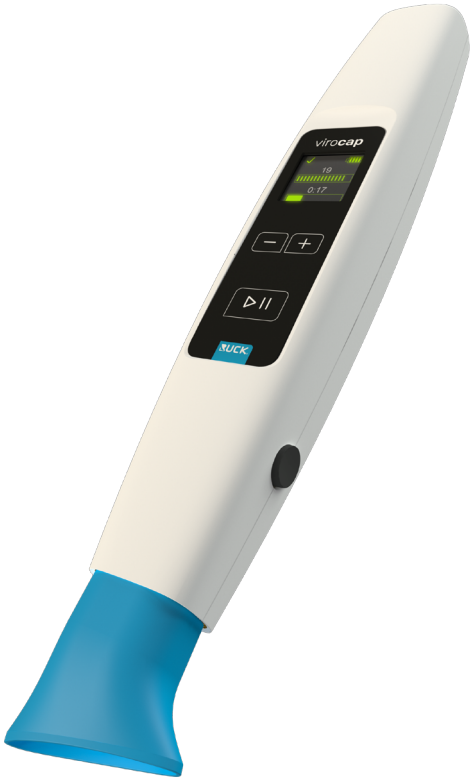
RUCK ViroCap Cold Plasma

Instructions for Use



EN | English

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CE

RUCK ViroCap Cold Plasma

Viromed Medical AG
Hauptstraße 105, 25462 Rellingen

HELLMUT RUCK GmbH | DE – 75305 Neuenbürg
hellmut-ruck.de

Dear Customer,

This instruction manual provides an introduction to the basic functions and operation of the device. It is designed to help you use the device safely and efficiently while preventing operating errors. Please read this manual carefully before using the device for the first time and keep it in a convenient location for future reference.

Our name stands for quality. We provide a one-year warranty for the device and a six-month warranty for the Plasma Module.

Thank you for the confidence you have placed in our products. We wish you every success and satisfaction in your daily work with this device.

Contents

1 General information 7
1.1 Manufacturer Information 7
1.2 Distributor Information 7
1.3 Product Information 7

2 Regarding this Instruction Manual 8
2.1 Symbols Used 8

3 Warnings and Precautions 11

4 Description of the Device 12
4.1 Components 12
4.1.1 Handheld Unit 13
4.1.2 Plasma Module 13
4.1.3 Spacer 13
4.1.4 Charging Cradle with Power Supply Unit 14
4.2 Main Components 15
4.3 Subcomponents 16
4.4 Intended Use 16
4.4.1 Indications for Use 16
4.5 Indication 17
4.6 Contraindication 17
4.7 Intended Users 17
4.8 Intended Patients 18
4.9 Principle of Operation 18

5 Instructions for Use 19
5.1 Preparation for Commissioning 19
5.2 Removal and Insertion of the Plasma Module 20
5.3 Attaching and Removing the Spacer 21

5.4 Display Contents 22
5.5 Start-Up/Treatment 26
5.6 Decommissioning 28

6 Maintenance 28
6.1 Cleaning and Disinfection 29
6.2 Replacement of the Plasma Module 30
6.3 Battery Replacement 31
6.4 Battery Replacement Procedure 32

7 Environmental Conditions 33
7.1 Operating Conditions 33
7.2 Transport and Storage Conditions 34

8 Errors, Alerts and Issues 34

9 Reporting of Serious Adverse Events 39

10 Disposal 40
10.1 Handheld Unit 40
10.2 Module 40
10.3 Spacer 40

11 Service Life 41

12 Ordering of Spare and Single-Use Items 41

13 Technical Specifications 42

Information Relevant to this Instructions for Use

Use the Ruck ViroCap Cold Plasma device only after you have read this instruction manual in its entirety. Failure to do so may result in personal injury or damage to property due to improper use.

This product is a medical device.

Abbreviations and Symbols

This symbol indicates a hazard to persons or to the product. It must be strictly observed.

This symbol indicates useful information. At this point, additional information regarding the product and its operation is provided.

Observe the disposal notice.

1 General information

1.1 Manufacturer Information

Name	Viromed Medical AG
Address	Hauptstraße 105, 25462 Rellingen, Germany
Contact	Tel.: 04101/809960, Mail: beratung@viromed.de

1.2 Distributor Information

Name	HELLMUT RUCK GmbH
Address	Daimlerstraße 23, 75305 Neuenbürg, Germany
Contact	Tel.: +49 (0)7082 944 20, Mail: kontakt@hellmut-ruck.de

1.3 Product Information

The RUCK ViroCap Cold Plasma is a portable handheld medical device that generates cold atmospheric plasma for the reduction of bacteria and fungi associated with dermatological skin conditions. Please read this instruction manual carefully before using the device to ensure safe and optimal operation.

Product name	**Article number/REF**
RUCK ViroCap Cold Plasma	1310001
Product name	**Article number/REF**
Spacer	1310101

2 Regarding this Instruction Manual

2.1 Symbols Used

These symbols are used in the instructions for use, on the packaging of the product or on the product itself:

Follow the instructions for use.

Attention! Please read the safety instructions. Failure to do so may result in personal injury or damage to property!

Manufacturer address

Date of manufacture

Distributor

Serial number

Lot number / Batch code

Order number / manufacturer's device reference

Interference may occur in the vicinity of devices bearing this symbol

Indicates the limits of the temperature to which the medical device can be safely exposed.

Indicates the range of ambient relative humidity to which the medical device can be safely exposed.

Indicates the range of ambient air pressure to which the medical device can be safely exposed.

Fragile, beware of breakage!

Keep dry

Protect against sun exposure

CE mark

Application Part of Type B

Protection class II

Alternating current

Direct current

Do not reuse.

Can be used until

Symbol Description

Do not use if packaging is damaged.

Electrical device, do not dispose of in household waste.

IP

Ingress protection class against contact (foreign bodies) and water.

Notice This symbol is used for information regarding installation, operation, maintenance or repair that is important but not associated with danger.

3 Warnings and Precautions

This device is a medical device designed in accordance with the applicable international standards. However, as with any technical product, improper or unintended use may present a risk.
This medical device has no essential performance as defined in IEC 60601-1. This means that a failure or malfunction of the device does not, by itself, result in an unacceptable risk to the patient or the operator.
All residual risks have been identified as part of the risk management process and have been addressed in this instruction manual.

Read the Instructions for Use
Do not use the RUCK ViroCap Cold Plasma device until you have read this instruction manual in its entirety. Failure to follow these instructions may result in personal injury or property damage due to improper use!

Notice **Electronic Interference**
When used as intended, the RUCK ViroCap Cold Plasma device may generate electromagnetic interference (EMI) that could impair the operation of nearby electronic equipment.

Notice **Notice – Interference Emission**
The emission characteristics of this device make it suitable for use in industrial environments and hospitals (CISPR 11, Class A). If used in a residential environment, where CISPR 11 Class B is normally required, this device may not provide adequate protection for radio services. In such cases, it may be necessary to relocate or reorient the device.

Caution – Distance
Other electronic devices, in particular those equipped with high-frequency (HF) equipment such as mobile phones, may interfere with medical electrical devices.
The use of the RUCK ViroCap Cold Plasma device in close proximity to such equipment may result in increased emissions or reduced immunity of the RUCK ViroCap Cold Plasma device.
Portable RF communication equipment, such as radios or mobile phones (including accessories such as antenna cables and external antennas), should not be used closer than 11.8 inches to the RUCK ViroCap Cold Plasma device. Failure to observe this requirement may result in reduced performance of the RUCK ViroCap Cold Plasma device.

Caution – Device Integrity and EMC Compliance
This device has been designed in compliance with IEC 60601-1-2 for operation in a typical professional healthcare environment.

The user is responsible for ensuring that the device is installed and operated in an environment that complies with the electromagnetic compatibility (EMC) conditions specified in Section 7.9.3 of IEC 60601-1 and Table 1 of IEC 60601-1-2.

Before each use, the device and all associated components, in particular the handheld unit, Plasma Module, charging station, and power supply, must be inspected for physical integrity.

Any signs of housing damage, cable defects, or damaged shielding shall be regarded as a potential safety risk, as they may impair both electromagnetic compatibility and electrical safety. In case of damage or irregularities, please contact technical support before further use.

4 Description of the Device

The RUCK ViroCap Cold Plasma device is a portable medical device that generates cold atmospheric plasma. The device features a piezoelectric plasma generator which, due to its high electric fields, enables partial ionization of ambient air, thereby generating cold atmospheric plasma within the discharge area.

The resulting reactive oxygen and nitrogen species (RONS) can reach the affected skin or wound area and exert their therapeutic effect. The corresponding Spacer helps to focus the reactive species on the treatment area while maintaining a safe distance between the plasma generator and the patient. In addition, it provides a hygienic interface to the treatment site.

For treatment, the device is held with the Spacer at a short distance above the area to be treated. After 30 seconds, an acoustic signal indicates that the device can be moved to the next area.

4.1 Components

The RUCK ViroCap Cold Plasma system comprises the handheld unit, the Plasma Module, the charging station with power supply unit, and the Spacer. All components can be safely stored and transported in the supplied case.

4.1.1 Handheld Unit

The handheld unit is equipped with a display, two arrow buttons (up and down), and a start/stop button for controlling the device.

The Handheld Unit May Be in One of the Following Operating States:

- Ready
- Application
- Notification
- Energy Saving
- Loading
- Screensaver
- Error

To exit power-saving mode, press the start/stop button or attach a new Spacer. The display is used to check the battery charge status and provides information on the device's current settings.

4.1.2 Plasma Module

The Plasma Module contains a ceramic element. The discharges responsible for generating the cold atmospheric plasma occur at the tip of this ceramic element.
A grip area for safe handling and replacement of the module is located at the front of the Plasma Module. The contact PCB is located at the rear.

4.1.3 Spacer

The Spacer is a single-use consumable that is inserted into the front of the housing of the portable device to ensure a safe distance between the Plasma Module and the treatment area. It must be used only once and on a single treatment site to prevent cross-contamination.
After use, the Spacer must be disposed of.
The Spacer also protects the user by preventing direct contact with the plasma source via a protective grid.

4.1.4 Charging Cradle with Power Supply Unit

The charging station is used for safe storage of the handheld unit and for charging the battery. The charging station is connected to the mains supply via the power supply unit. The handheld unit and the charging station are equipped with charging contacts that automatically connect when the RUCK ViroCap Cold Plasma device is placed into the charging station. Magnets additionally ensure secure and correct positioning.
The portable handheld unit may only be placed in the charging station without the Spacer installed, while the Plasma Module may remain in the device. Only the specified power supply unit TDK WMM30CN120-00E-502 shall be used.

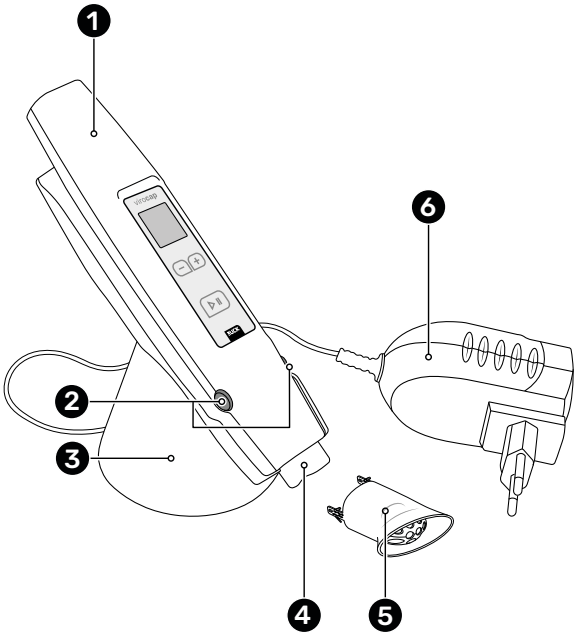
Warning
Operate the RUCK ViroCap Cold Plasma device only with the specified mains voltage. Otherwise, malfunctions, device failure, smoke generation, or even fire may occur.

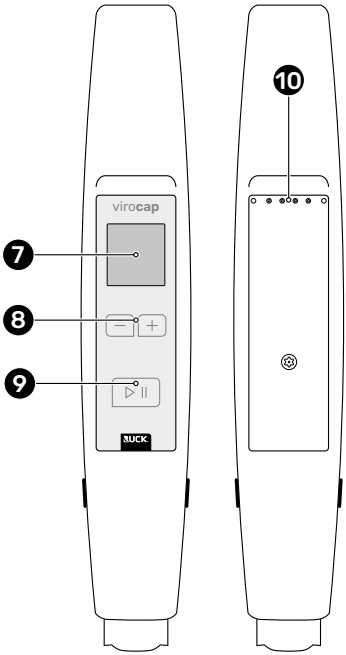
Warning – Only Use Original Components
Use the RUCK ViroCap Cold Plasma device only with original manufacturer parts and accessories. The use of accessories other than those specified or supplied by the manufacturer may result in increased electromagnetic emissions or reduced electromagnetic immunity of the device and may cause malfunctions.

Warning – Only Use the Original Power Supply Unit
Only use the original manufacturer power supply unit (TDK WMM30CN120-00E-502). The use of any other power supply units is not permitted.

Warning: The use of this device adjacent to or stacked with other equipment should be avoided, as it may result in improper operation. If such use is necessary, this device and the other equipment should be monitored to verify that they are operating properly

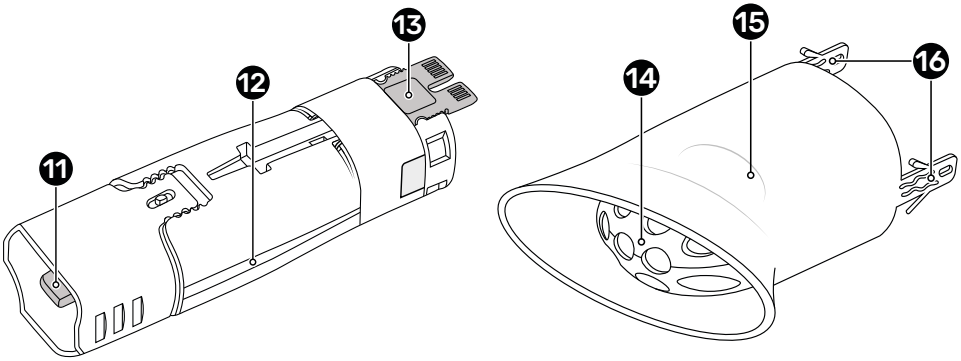
4.2 Main Components





1 Handheld unit
2 Plasma Module release button (on both sides)
3 Charging station
4 Plasma Module
5 Spacer
6 Power supply unit
7 Display
8 Arrow keys
9 Start/Stop button
10 Charging contacts

4.3 Subcomponents



11 Ceramic element
12 Handle area
13 Contact circuit board
14 Protective grille
15 Grip recesses
16 Snap hooks

4.4 Intended Use

The RUCK ViroCap Cold Plasma device, when used in combination with the corresponding Spacer, is an active non-therapeutic medical device intended for the reduction of bacteria and fungi associated with dermatological skin conditions using cold atmospheric plasma, for use by healthcare professionals.

4.4.1 Indications for Use

The RUCK ViroCap Cold Plasma device may be used, within the scope of its intended purpose, on dermatologically relevant skin areas.
In the podiatric setting, the area of application includes in particular the foot, toes, interdigital spaces, the surface of the toenails, the nail folds, and the nail bed.

Caution – Use in Accordance with Intended Purpose
Use the RUCK ViroCap Cold Plasma device only for its intended medical purpose and in accordance with the indications and contraindications.

4.5 Indication

Skin conditions caused or aggravated by bacteria or fungi, as well as atopic dermatitis and viral skin diseases with bacterial superinfection:

- Bacterial infections
- (bacterioses)
- Acne vulgaris
- Perioral dermatitis
- Soft tissue infections (folliculitis, furuncles, abscesses)
- Impetigo contagiosa
- Fungal infections (mycoses) Pityriasis versicolor (tinea versicolor)
- Dermatophytosis (tinea)
- Other skin diseases Atopic dermatitis (neurodermatitis)
- Actinic keratosis
- Viral skin diseases with bacterial superinfection
- (e.g. herpes labialis)

4.6 Contraindication

The treatment area with the RUCK ViroCap Cold Plasma device must not overlap with openings of the mouth, nose, or eyes.
Children under 12 years of age must not be treated.

4.7 Intended Users

The RUCK ViroCap Cold Plasma device is intended for professional use by physicians and healthcare professionals.

The device is to be used by users with professional qualifications and experience in the treatment of dermatological skin conditions. It must be used in accordance with current therapeutic standards and in compliance with this instruction manual.

Before use, all users must read the instruction manual in its entirety and become familiar with the safe use of the RUCK ViroCap Cold Plasma device and the RUCK ViroCap Cold Plasma Spacer.

Read the Instruction Manual
Use the RUCK ViroCap Cold Plasma device only after you have read the instruction manual in its entirety.
Failure to do so may result in personal injury or property damage due to improper use.

4.8 Intended Patients

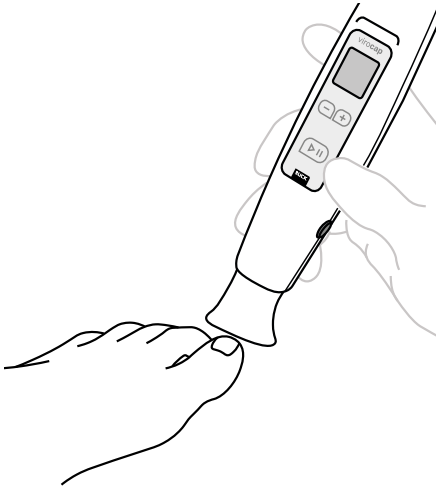
The intended patients are individuals aged 12 years and older with dermatological skin conditions in a dermatological or podiatric application context, insofar as these indications are covered by this instruction manual.

4.9 Principle of Operation

The device uses a piezoelectric plasma generator that enables partial ionization of the surrounding air, thereby generating cold atmospheric plasma in the vicinity of the discharge.
This process produces reactive oxygen and nitrogen species, including ions (RONS). These ions can reach the treatment area and exert their bacteria- and fungi-reducing effect there.
A Spacer helps to concentrate the reactive species over the treatment area and to maintain a safe distance between the plasma generator and the patient.

An example application is shown in the figure on the right.
The Spacer also provides a hygienic interface to the treatment area.
For treatment, the device is held with the Spacer at a short distance above the area to be treated.

After 30 seconds, an acoustic signal is emitted. This informs the user that the device can be moved to the next treatment area and that treatment can be continued. The remaining application time is shown on the display.



5 Instructions for Use

Warning – Wear Gloves During Operation and Cleaning
It is recommended to always wear gloves when using or cleaning the device.

5.1 Preparation for Commissioning

The RUCK ViroCap Cold Plasma device must be fully charged before first use. To do so, follow the steps below:

1. Connect the power supply unit to the charging station of the RUCK ViroCap Cold Plasma device. The connection for the power supply unit is located at the rear of the base of the charging station.
2. Plug the power supply unit of the charger into a wall socket.
3. Place the RUCK ViroCap Cold Plasma device into the charging station. The handheld unit fits securely into the charging station, and the charging contacts on the underside of the device automatically connect with those in the charging station. Ensure that no Spacer is attached to the handheld unit before placing it into the charging station.
4. While the RUCK ViroCap Cold Plasma device is charging, the display shows the charging progress (see section 5.4).
5. The RUCK ViroCap Cold Plasma device should be fully charged before first use. This process may take up to three hours.
6. The handheld unit can be charged with or without the Plasma Module inserted in the charging cradle. Before use, a Plasma Module must be inserted into the handheld unit. Charging with an attached Spacer is not possible.
7. Before use, also ensure that the components of the RUCK ViroCap Cold Plasma device have reached a temperature within the permissible limits as specified in section 7.1. These limits may be exceeded or not reached during transport, which may affect device function.

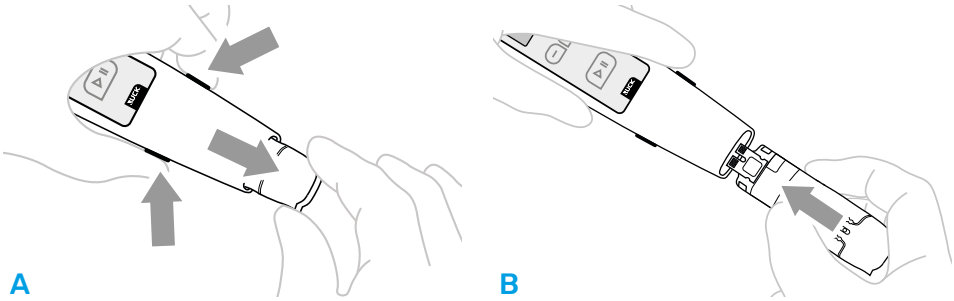
Warning – Operating Conditions
Wait until the RUCK ViroCap Cold Plasma device has adapted to the permissible ambient temperature. This is especially important if the device has previously been transported or stored outside the permitted temperature limits (see section 7.1).

Warning – Wear Gloves During Operation and Cleaning
It is recommended to always wear gloves when using and cleaning the device for self-protection and to prevent cross-contamination.

5.2 Removal and Insertion of the Plasma Module

In the event of a defect or for cleaning purposes, the Plasma Module can be removed and replaced with a new Plasma Module.

1. To remove a Plasma Module, first wait until it has cooled down. Operation of the RUCK ViroCap Cold Plasma device may cause the Plasma Module to become warm.
2. Hold the handheld unit in one hand, press both release buttons on the Plasma Module simultaneously, and keep them pressed.
3. Grasp the Plasma Module with one hand at the ribbed grip areas, avoiding contact with the piezo element and carefully pull the replaceable Plasma Module out of the device (Picture 3: Plasma Module Replacement (A: Removal / B: Insertion).
4. To insert a new Plasma Module, remove it from the packaging and hold it by the grip area, avoiding contact with the piezo element (Picture 3).
5. Ensure that the contact board of the replacement module and the label marking are on the same side as the device's display and buttons to guarantee correct installation.
6. Carefully insert the new Plasma Module into the device (without applying excessive force) (Picture 3) until the module clicks into place.
7. When the device is switched on, the detected Plasma Module will be displayed on the screen.
8. The display contents are described in Section 5.4.



Picture 3: Replacing the Plasma Module (A: Removal / B: Insertion)

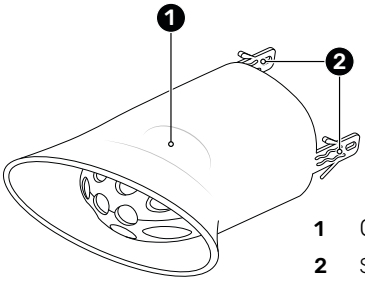
Notice – Keep a Spare Module Ready
It is recommended to always keep a spare module available to ensure uninterrupted operation in the event of a module failure.

Caution – Hot Surface!
The Plasma Module may become hot during operation. Do not touch it until it has cooled down. Allow the device to cool before replacing the module.

5.3 Attaching and Removing the Spacer

Check the Spacer for damage before use. Only use the Spacer if it is undamaged.
Open the Spacer packaging in such a way that the Spacer is supported within the packaging and the snap hooks point freely upwards.
Hold the Spacer by the designated grip recesses to ensure a secure hold.

The Spacer can now be inserted into the front of the handheld unit and fitted over the Plasma Module, as shown in the figure on the right.
Carefully press the Spacer into the handheld unit without applying excessive force until the retaining clips engage.

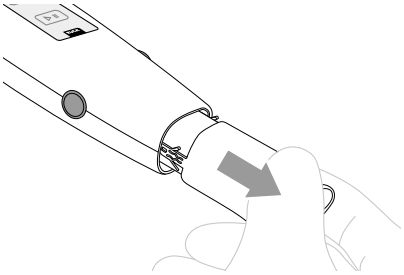


1 Grip recesses
2 Snap hooks

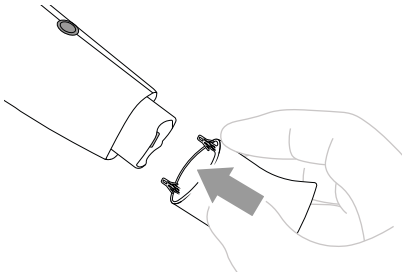
After treatment, the Spacer can be simply removed from the device (Picture 1) and disposed of in accordance with Section 10.3.
To remove it, hold the Spacer securely by the recessed grip areas (1) and pull evenly and straight until the Spacer disengages from the handheld unit.

Do not press the release buttons of the Plasma Module when removing the Spacer!

When removing a Spacer from the handheld unit, ensure that it has been completely removed and that no parts remain inside the device housing.



Picture 1: Removing the Spacer



Picture 2: Attaching the Spacer

Warning
The Spacer protects both the user and the patient from unintentional contact with the Plasma Module thanks to its integrated protective grid. The Spacer may become contaminated through contact with the skin.

Warning – Cross-Contamination
Use the Spacer for only one patient and one treatment area. Otherwise, cross-contamination may occur.

Caution
Contact of the Spacer with the skin may cause injury if used improperly.

5.4 Display Contents

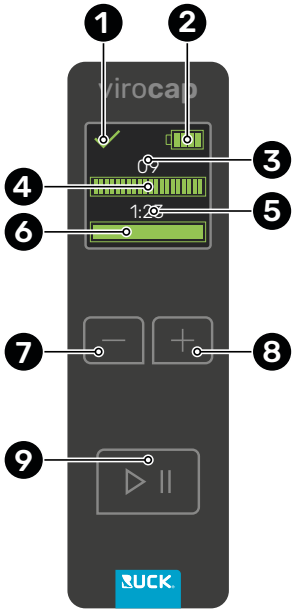
The device status is indicated by the symbol in the upper left corner (1) of the display:

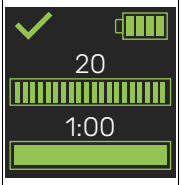
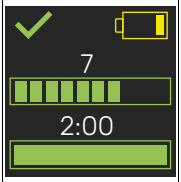
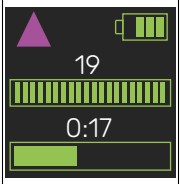
Ready

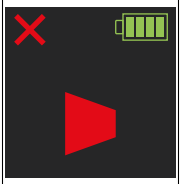
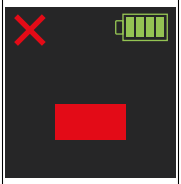
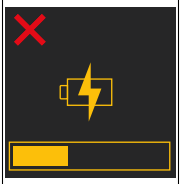
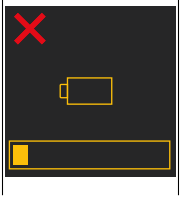
Active Plasma Generation

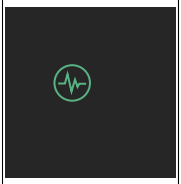
Not Ready For Use

The battery charge level is indicated by a four-segment bar graph within the battery icon (2).
The remaining total application time for the currently attached Spacer is displayed both numerically (3) and as a segmented bar graph (4), in minutes, with each segment representing one minute.
The selected or remaining application time (count-down during active treatment) is displayed in minutes and seconds (5).
A progress bar (6) graphically indicates the remaining application time.
The preset maximum application time (1 or 2 minutes) can be changed using the [−]-button (7) and the [+]-button (8).
The treatment, i.e. active plasma generation, can be started and stopped using the start/stop button (9).



Mode	Display	Explanation / Display Contents
Start		
		Startup Welcome Display
Ready		
		The device is ready for use. The Plasma Module is ready, and a valid Spacer is attached. The battery is fully charged. For the current Spacer, 20 treatments of 1 minute each are still available. A treatment duration of 1 minute has been selected.
		The device is ready for use. The Plasma Module is ready, and a valid Spacer is attached. The battery charge level is low. For the current Spacer, 7 treatments of 2 minutes each are still available. A treatment duration of 2 minutes has been selected.
Treatment		
		Active plasma generation is in progress. The battery is nearly fully charged. For the current Spacer, 19 treatments of 1 minute each are still available. The current treatment (active plasma generation) has 17 seconds remaining.
		Active plasma generation is in progress. The battery is nearly empty and should be recharged soon. For the current Spacer, 2 treatments of 2 minutes each are still available. The current treatment (active plasma generation) has 1 minute and 45 seconds remaining.

Notifications		
		Active plasma generation is currently not possible. The battery is fully charged. No Spacer is attached, or the attached Spacer is invalid. Please attach a new Spacer.
		Active plasma generation is currently not possible. The battery is fully charged. Either no Plasma Module is inserted, or the inserted module is invalid or defective. Please insert a valid Plasma Module.
		Active plasma generation is currently not possible. The battery is empty. Please recharge the battery.
Charging		
		Active plasma generation is currently not possible. The device is in the charging station, and the battery is being charged. The charge level is approximately 33%, as indicated by the charging bar.
		Active plasma generation is currently not possible. The device is in the charging station, but the battery is not being charged. The charge level is approximately 10%, as indicated by the charging bar.

Charging		
		Active plasma generation is currently not possible. The device is in the charging station, but the battery is not being charged. The battery is fully charged.
Error		
		Active plasma generation is currently not possible. The device is in error mode. Error codes E1100 and E2001 are displayed. The meaning of the error codes and instructions for resolving the respective errors can be found in Section 6.
Screensaver		
		When the device is placed in the charging station, a screensaver is activated after 2 minutes. The device continues to charge. To reactivate the display without interrupting the charging process, press any button. To stop charging and reactivate the display, remove the device from the charging station.

5.5 Start-Up/Treatment

Ensure that the working area is adequately ventilated. Remove the RUCK ViroCap Cold Plasma device from the charging station and ensure that it is sufficiently charged.
Ensure that a valid Plasma Module is inserted into the device.
Ensure that a new Spacer is attached to the device.

Select the desired maximum application time (1 or 2 minutes) using the arrow buttons. The selected maximum application time is shown above the time bar.
Press the start/stop button to start or stop the treatment (active plasma generation). The device automatically stops plasma generation once the set maximum application time (1 or 2 minutes) has elapsed.

After plasma generation has stopped, the next interval can be started by pressing the start/stop button. The treatment can be interrupted at any time by pressing the start/stop button, which stops active plasma generation. Hold the RUCK ViroCap Cold Plasma handheld unit steady and at a short distance above the area to be treated.

After 30 seconds, the RUCK ViroCap Cold Plasma device emits a short acoustic signal indicating that it can be moved to an adjacent treatment area. This rhythm helps ensure even treatment of larger areas.
The display also shows the application time as a countdown.

After treatment, remove and dispose of the Spacer in accordance with sections 5.3 and 10.3. Ensure that the RUCK ViroCap Cold Plasma handheld unit is cleaned in accordance with section 6.1. Only use the specified cleaning/disinfection agents for this purpose.

After use or when not in use, store the RUCK ViroCap Cold Plasma handheld unit in the charging station.

Notice

Notice – Disposal
Contaminated parts of the device must be disposed of in accordance with the applicable regulations, e.g., LAGA AS 180103.

Caution – Do Not Use a Defective Device!
Do not use the device if it is defective (e.g., if the display is damaged or frozen). Patient and user safety can no longer be guaranteed under such conditions.

Warning – Emissions
During treatment with the RUCK ViroCap Cold Plasma device, ozone is generated in low concentrations. When used as intended, the legal limit values are not exceeded; however, the olfactory threshold ("smell threshold") may be exceeded.
The ozone is sufficiently diluted by the ambient air. When used in small rooms and/or with multiple devices and/or during prolonged treatment times, adequate ventilation must be ensured (e.g. by opening windows or doors). Individual sensitivity to ozone varies considerably. When using the RUCK ViroCap Cold Plasma device in the presence of individuals with chronic respiratory diseases, infants, and young children, special attention must be paid to ensuring adequate ventilation due to their increased sensitivity.

Caution – Hot Surface!
The surface of the Spacer can reach temperatures of up to 55 °C.
Maintain a slight distance between the Spacer and the skin. Limit contact times as much as possible, ideally to less than 1 minute. In particular, avoid contact with contraindicated areas.

Warning – Emissions
During treatment with the RUCK ViroCap Cold Plasma device, low levels of UV radiation are produced.
Avoid treating areas near the eyes.
Low concentrations of ozone are also generated during treatment.
Avoid treating areas near the mouth and nose.

Caution
Before using the RUCK ViroCap Cold Plasma device after transport, ensure that the device has reached a temperature within the operating range (see Section 7.1).

Caution
Under no circumstances should the Spacer or Plasma Module be removed during treatment.

5.6 Decommissioning

During normal operation, the handheld unit may be stored in the charging station during and between uses. When the handheld unit is placed in the charging station and connected to the mains power supply, it remains switched on (the display may switch off or a screensaver may be activated).
If no mains power is connected, the device automatically switches to power-saving mode.

In the event of a battery replacement, device return, or a malfunction, the device must be taken out of service.

Proceed as follows:

- Press and hold both arrow buttons simultaneously for seven seconds. The device will then be reset and restarted.
- While the startup logo is displayed on the screen, release the buttons and press the down arrow button. This interrupts most of the internal power supply and switches the device off.
- The device is now decommissioned.

6 Maintenance

The RUCK ViroCap Cold Plasma device, including the handheld unit, Plasma Module, charging station, and power supply unit, operates reliably provided that the specified maintenance measures are observed.
The Spacer is intended for single use only.

6.1 Cleaning and Disinfection

After each use, the RUCK ViroCap Cold Plasma device must be thoroughly cleaned and disinfected in accordance with applicable hygiene regulations before returning the hand-held unit to the charging station. Only clean the external, touchable surfaces. Remove the Spacer before cleaning and dispose of it in accordance with Section 10.3.
If the device is heavily soiled, the module can also be removed to allow more thorough cleaning of the surfaces.

Step	Description	Specifications/ Recommendations
1. Preparation for Cleaning	Remove the Spacer Remove the Spacer and dispose of it in accordance with Section 10.3. Immediately remove any coarse contamination after use using a suitable disposable cloth.	Use disposable gloves and wipes.
2. Manual Cleaning	Clean the accessible surfaces of the handheld device with a damp disposable cloth.	Ensure that the cloth is only damp and that no excessive liquid enters the handheld device.
3. Drying	Thoroughly dry all cleaned parts.	Use a lint-free cloth and ensure complete drying.
4. Desinfection	Disinfect the accessible surfaces of the handheld device using a suitable disinfectant wipe.	Compliance with Contact Time, Concentration, and Temperature According to Manufacturer Instructions Recommendation: e.g., Bacillo AF. Use only disinfectants approved by the Robert Koch-Institute.

Caution – Wear Gloves During Operation and Cleaning!
It is recommended to always wear gloves when using and cleaning the device.

Notice

Notice
- Do not clean the piezo element.
- Do not rinse the handheld device or Plasma Module with liquids.
- Do not immerse the handheld device or Plasma Module in liquids.

Clean the RUCK ViroCap Cold Plasma device after each patient treatment to prevent cross-contamination.
For cleaning, use only the cleaning/disinfecting agents specified in Section 6.1.

For cleaning the RUCK ViroCap Cold Plasma device, use only the cleaning agents specified in Section 6.1. Clean the RUCK ViroCap Cold Plasma by wipe disinfection.
Avoid excessive wet cleaning, such as frequent spray disinfection, as this may damage electronic components. In particular, immersion cleaning is prohibited.

6.2 Replacement of the Plasma Module

The Plasma Module may be damaged due to improper use (e.g. operation outside the specified operating conditions or dropping the device). To ensure proper function, a defective Plasma Module can be replaced.

Proceed as follows:
- Wear fresh gloves or disinfect your hands before replacing the module to prevent contamination.
- If necessary, switch off active plasma generation or remove the device from the charging station.
- Remove the attached Spacer if applicable (see Section 5.3).
- Ensure that the Spacer is disposed of in accordance with Section 10.3.
- Press both Plasma Module release buttons on the side of the device and carefully pull the module out by the designated grip area.
- Carefully insert a new Plasma Module into the device. Ensure that the contact board faces the display. The module will lightly click into place. Do not use excessive force (see Section 5.2).

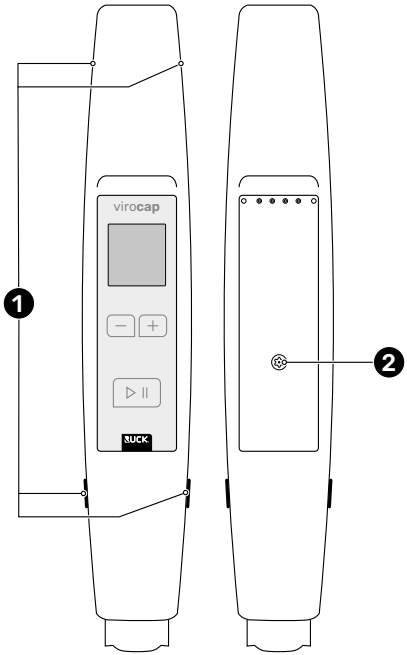
6.3 Battery Replacement

When fully charged, the battery provides at least 35 minutes of active plasma generation. If this duration is noticeably reduced, the battery should be replaced.

If replacement is required, proceed as follows:

- At first, put the device into the appropriate operating state (see Section 5.6). To do this, press and hold both arrow buttons simultaneously for seven seconds. The device will reset and restart.
- When the startup logo is displayed, release the buttons and press the down arrow button. This interrupts most of the internal power supply.
- Only use original replacement parts.
- Suitable replacement parts are available from the manufacturer (see Section 12).
- A T10 Torx screwdriver is required to open and close the device.

Caution – Electrical Voltage
Never use electrically conductive tools to remove the battery.



Have the handheld device, the tool, and the replacement batteries (2 units) ready.

The nameplate on the back of the device has a marking in the centre (circle, approx. 0.0787 inch in diameter).

The housing screw is located beneath this marking.

1 Snap hooks

2 Screw

6.4 Battery Replacement Procedure

1. Carefully pierce the rating label with a pointed object, e.g. a screwdriver.
2. Now fully loosen the housing screw using a screwdriver (turn counterclockwise). The housing consists of an upper and a lower half-shell. The two half-shells are additionally connected by snap-fit hooks at the front and rear.
3. Now gently press the lower half-shell together at the level of the front snap-fit hooks and release the connection by lifting the upper half-shell off the lower half-shell.
4. Proceed in the same way with the rear snap-fit hooks.
5. Carefully open the housing. Please note that the two housing parts are still connected by cables. Ensure that no electrically conductive tools are used inside the device.
6. Now carefully disconnect the battery terminals.
7. The batteries are glued into the housing. Pull tabs are attached to the batteries to facilitate removal.
8. Now gently pull the tab to release the battery from the housing.
9. Take the replacement battery and remove the protective film from the adhesive surface.
10. Place the battery with the adhesive side facing down into the designated compartment in the lower half of the housing.
11. Repeat this procedure with the second battery.
12. Connect the battery to the designated connector on the device's PCB. Both batteries can be connected to either of the two sockets on the PCB. The connectors are marked with polarity indicators. Ensure correct orientation when connecting.
13. Then close the housing by placing the upper and lower half-shells together and gently pressing them until the four snap-fit hooks engage.
14. Ensure that no cables are trapped.
15. Then retighten the screw connection on the back of the device using a screwdriver. Light tightening is sufficient.
16. Reseal the cover using the supplied rating label.
17. To reactivate the device after battery replacement, place it in the charging station and fully charge the battery.
18. The device is ready for use again.

7 Environmental Conditions

Operation of the device after storage or transport is only permitted if the specified operating conditions are met:

7.1 Operating Conditions

The RUCK ViroCap Cold Plasma device can be operated under normal working lighting conditions and is suitable for both stationary and mobile use.

- The RUCK ViroCap Cold Plasma device and its associated components may be operated at temperatures between +10 °C to +30 °C.
- The RUCK ViroCap Cold Plasma device and its associated components may be operated at a relative humidity between 15% and 80% RH, non-condensing.
- The RUCK ViroCap Cold Plasma device and its associated components may be operated at atmospheric pressures between 800 hPa and 1060 hPa.
- The RUCK ViroCap Cold Plasma device and its associated components may be operated at altitudes of up to 2000m above sea level.
- Before use after transport or storage, the RUCK ViroCap Cold Plasma device must reach the specified operating conditions.
- At an ambient temperature of 20 °C the device requires at least 5 minutes to cool down from the maximum storage or transport temperature to the maximum operating temperature.
- At an ambient temperature of 20 °C the device requires at least 5 minutes to warm up from the minimum storage or transport temperature to the minimum operating temperature.

If you observe that the environmental conditions have changed and the RUCK ViroCap Cold Plasma device is being used outside the specified limits, the treatment must be discontinued.

Warning
Use the RUCK ViroCap Cold Plasma device only under the specified environmental conditions. Excessive heat, cold, or humidity may impair or damage the functionality of the device.

Warning
If you observe that the environmental conditions have changed and the RUCK ViroCap Cold Plasma device is being used outside the specified limits, the treatment must be discontinued.

7.2 Transport and Storage Conditions

- The RUCK ViroCap Cold Plasma device and its associated components may be stored in their packaging at temperatures between 0 °C and +40 °C.
- The RUCK ViroCap Cold Plasma device and its associated components may be stored in their packaging at a relative humidity between 15% RH and 80% RH.
- The RUCK ViroCap Cold Plasma device and its associated components may be stored in their packaging at atmospheric pressures between 700 hPa and 1060 hPa.
- The Spacer must be kept dry and protected from direct sunlight.

8 Errors, Alerts and Issues

Malfunction/Errors	Possible Cause	Remedy
The device shows visible external damage.	Mechanical damage.	Discontinue use of the device and contact customer service.
The Plasma Module cannot be inserted.	Damage of the device.	Discontinue use of the device and contact customer service.
	Damage of the Plasma Module.	Use a new Plasma Module.
	Foreign object inside the device.	Discontinue use of the device and contact customer service.
	Foreign (invalid) Plasma Module.	Use only a suitable Plasma Module.
The Plasma Module cannot be removed.	Damage of the device.	Discontinue use of the device and contact customer service.
	Damage of the Plasma Module.	Discontinue use of the device and contact customer service.

Malfunction/Errors	Possible Cause	Remedy
The Spacer cannot be attached.	Damage of the device.	Discontinue use of the device and contact customer service.
	Damage of the Spacer.	Use a new Spacer.
	Foreign object inside the device.	Discontinue use of the device and contact customer service.
	Spacer incorrectly installed.	Attach the Spacer according to the instructions.
	Incorrect/invalid Spacer.	Use only a suitable Spacer.
	Spacer already in use.	Use a new Spacer.
The Spacer detaches again.	Incorrect/invalid Spacer.	Use only a suitable Spacer.
	Spacer already in use.	Use a new Spacer.
The Spacer cannot be removed.	Damage of the device.	Discontinue use of the device and contact customer service.
	Damage of the Spacer.	Discontinue use of the device and contact customer service.
The device does not respond to inputs, and the display shows nothing.	Empty battery.	Charge the Battery.
	Button defective.	Discontinue use of the device and contact customer service.
	Loose electrical contacts inside the device.	Discontinue use of the device and contact customer service.

Errors, Alerts and Issues

Malfunction/Errors	Possible Cause	Remedy
The device does not respond to inputs, although something is displayed on the screen.	Defective button.	Discontinue use of the device and contact customer service.
	Loose electrical contacts inside the device.	Discontinue use of the device and contact customer service.
The display is "frozen".	Software error.	Hold down both arrow buttons. The device will restart.
The device does not enter standby mode (although the module and Spacer are correctly installed and the battery is fully charged).	Software error.	Hold down both arrow buttons. The device will restart.
	The Plasma Module is not recognized.	Remove the Plasma Module and reinsert it.
	Incorrect/invalid Plasma Module.	Use only a suitable Plasma Module.
	The Spacer is not recognized.	Use only a suitable Spacer.
	Incorrect/invalid Spacer.	Use only a suitable Spacer.
	Spacer already in use.	Use a new Spacer.
The device is not charging in the charging station.	The charging station is not connected to the mains power supply.	Connect the plug-in power supply to the charging station. Connect the plug-in power supply to the mains power supply.
	The Spacer is attached.	Remove the Spacer.
	Charging contacts are contaminated.	Carefully remove any visible contamination from the charging contacts.
	The device is not properly seated in the charging station.	Place the device correctly into the charging station.

Malfunction/Errors	Possible Cause	Remedy
The device is not charging in the charging station.	Battery already fully charged.	–
	Charging station defective.	Carefully remove any visible contamination from the charging contacts.
	Power supply defective.	Discontinue use of the device and contact customer service.
The device does not fully charge, the charging process is terminated prematurely.	The charging station is not permanently connected to the mains power supply.	Check the connection of the power supply.
	Charging contacts are contaminated.	Carefully remove any visible contamination from the charging contacts.
	The device is not correctly seated in the charging station.	Place the device correctly in the charging station.
The application duration cannot be changed.	Battery charge level too low.	Charge the battery.
	Buttons defective.	Discontinue use of the device and contact customer service.
Although the device is fully charged, only a few applications (<10) are possible.	Battery significantly aged.	Discontinue use of the device and contact customer service.
The plasma generation does not start.	Spacer already in use.	Insert a new Spacer.
	The Spacer is not recognized.	Insert a new Spacer.
	Plasma Module defective.	Replace the Plasma Module.

Errors, Alerts and Issues

Malfunction/Errors	Possible Cause	Remedy
The plasma generation does not start.	Plasma Module too cold.	Wait until the device has reached a suitable operating temperature.
	Plasma Module not correctly installed.	Remove the Plasma Module and reinstall it correctly.
The plasma generation stops.	Battery significantly aged.	Discontinue use of the device and contact customer service.
	Plasma Module not correctly installed.	Insert the Plasma Module according to the instructions.
	Spacer is not correctly recognized.	Insert a new Spacer.
	Spacer already in use.	Insert a new Spacer.
The application is interrupted prematurely.	Battery significantly aged.	Discontinue use of the device and contact customer service.
	Plasma Module not correctly installed.	Insert the Plasma Module according to the instructions.
	Spacer is not correctly recognized.	Insert a new Spacer.
	Spacer already in use.	Insert a new Spacer.
Error code E1xxx is displayed (except E1004).	Internal errors.	Discontinue use of the device and contact customer service.
Error code E1xxx is displayed (except E1004).	Internal errors.	Discontinue use of the device and contact customer service.

Malfunction/Errors	Possible Cause	Remedy
Error code E5001 is displayed.	Plasma error.	Confirm ** and restart the application. Please follow this user manual.
Error code E5004/E5005 is displayed.	Device too hot.	Wait until the device as cooled down to an acceptable temperature. Confirm** and continue the treatment.
Error code E5006 is displayed.	The device was not used as intended.	Please return to use in accordance with this user manual. Confirm** and follow this user manual.

** Confirmation after resolving a fault is performed by pressing and holding the start/stop button.
If the problem cannot be resolved using these measures, please contact:

HELLMUT RUCK GmbH
after-sales@hellmut-ruck.de

9 Reporting of Serious Adverse Events

If a serious incident occurs in connection with the use of this product, it must be reported immediately to the manufacturer and to the competent authority of the Member State in which the user and/or patient is located.

When reporting, please provide the following information:

- Description of the incident and the circumstances of use
- Device identification (name, model, serial/batch number, UDI, if available)
- Contact details of the reporting healthcare professional or reporting facility

Manufacturer contact details: Viromed Medical AG
Mail: beratung@viromed.de
Tel.: +49 4101 80996-0

10 Disposal

10.1 Handheld Unit

The device contains valuable raw materials that can be recycled. Please dispose of the device at an appropriate collection point.

Protect the environment.
Waste electrical and electronic equipment must not be disposed of with household waste. Applicable national disposal regulations and legislation must be observed.

10.2 Module

Please return defective or replaced spare modules to the manufacturer for analysis. Please contact us in advance.

10.3 Spacer

Dispose of the Spacer safely in accordance with applicable regulations.
After use, the Spacer falls under the following waste code (AS 18 01 03): Other waste requiring special collection and disposal procedures to prevent infection (AS 18 01 03).
The Spacer must therefore be disposed of in accordance with the current implementation guidance for the disposal of waste from healthcare facilities issued by the German Working Group on Waste (LAGA 18).

Notice **Notice – Disposal of Contaminated Waste**
Dispose of the Spacer safely in accordance with applicable regulations for contaminated waste.

11 Service Life

The RUCK ViroCap Cold Plasma system is designed for long-term professional use. The service life of the handheld device and Plasma Module is at least two years from first use, provided the device is used and maintained in accordance with the instruction manual.

This specified service life corresponds to the period for which safety and performance have been formally validated. The device may continue to function beyond this period; however, continued use requires regular maintenance as described in Section 6. The Plasma Module is replaceable and can be reordered separately.

When fully charged, the battery supports at least 35 minutes of active plasma generation. If the operating time falls significantly below this value, the battery has reached the end of its service life and must be replaced.

12 Ordering of Spare and Single-Use Items

For spare parts, please contact:

HELLMUT RUCK GmbH
Daimlerstraße 23
75305 Neuenbürg
Germany

after-sales@hellmut-ruck.de

DIY spare parts can be ordered via:

www.hellmut-ruck.uk

13 Technical Specifications

Electrical Data	
Supply Voltage	12 V DC (Device) / 100 – 240 V AC / 50 – 60 Hz (Power Supply TDK WMM30CN120-00E-502)
Charging Voltage	12 V DC (Power Supply TDK WMM30CN120-00E-502)
Battery Capacity	2 x 1100mAh
Battery Voltage	3.7 V
Power Consumption	max. 10 VA
Protection Class	II, when in the charging station. Otherwise powered internally.
Device Type	Hand-held device with mains power supply or battery-operated hand-held unit.

Measurements	
Weight	5.82 oz (Handpiece)
Length	8.46 inch
Width	1.50 inch
Depth	1.06 inch
Cable Length	59.06 inch

Typical Application Parameters	
Plasma Temperature	< 50 °C
Skin Temperature	< 40 °C

Operating Conditions	
Humidity	15 … 80 % rH (non-condensing)
Temperature	+5 - +30 °C; 41 - 86 °F
Air Pressure	800 hPa … 1060 hPa
Height	< 6561.7 ft (=2000 m) ASL
Ingress Protection	IP 20 (Handpiece and Charging Cradle, IP 22 (Power Plug)

Storage Condition	
Humidity	15 … 80 % rH (non-condensing)
Temperature	0 - +40 °C; 32 - 104 °F
Air Pressure	700 hPa … 1060 hPa
	Keep dry and protect from direct sunlight

Technical Specifications

EMC Conformity	
Immunity to interference	Test level in accordance with and compliant with: EN 60601-1-2: 2015+A1:2021, IEC 60601-1-2:2014 + AMD: 2020, Professional healthcare
Emissions	Test level in accordance with and compliant with: EN 60601-1-2: 2015+A1:2021, IEC 60601-1-2:2014 + AMD: 2020, Professional healthcare
CISPR 11 Group	1
CISPR 11 Class	A

Notes

Hersteller

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25462 Rellingen | Germany
Tel.: +49 4101 80996-0
e-Mail: beratung@viromed.de

Vertrieb

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4144 Arlesheim | CH