ViroCAP med

Data Sheet

Manufacturer information

The manufacturer for the ViroCAP med is:

Tabelle 0-1 Contact Information

Manufacturer name	Viromed Medical AG
Manufacturer address	Hauptstraße 105, 25462 Rellingen
Manufacturer SRN	DE-MF-000047406
Manufacturer contact information	www.viromed.de Tel: 04101 8099622

Product trade name, device description

Product trade name and variants

The following table contains an overview of all product trade name and its variants and configurations.

Table 0-1 Device Overview

Product trade name	Variant / Configuration	Article number / REF	UDI-DI	Basic UDI-DI	GMDN	CND (EMDN)
ViroCAP med	N/A	140	4262518941404	426251894-ViroCAPmed-QF	tbd	Z12019003 WOUND TREATMENT UNITS

Device description

ViroCAP med is a mobile medical device that generates cold atmospheric plasma. The device has a piezoelectric plasma generator that enables to partly ionize surrounding ambient air due to its high electrical fields, thus providing cold atmospheric plasma in the discharge environment. The reactive oxygen and nitrogen species generated can now reach the wound or injured skin and develop their healing effect.

The appropriate spacer helps to focus the reactive species over the area to be treated and maintain a safe distance between the plasma generator and the patient. It also provides a hygienic interface to the treatment area. For treatment, the device is held with the spacer at a slight distance above the area to be treated. After 30 seconds an acoustic signal indicates that the device can be moved on.

Intended purpose and intended users

The device in combination with the appropriate spacer is a medical device to support the treatment of wounds or infected skin with cold atmospheric plasma by healthcare professionals to improve the healing process.

Indications

The following indications apply to the product:

Recovery/cause	Disease/condition	Symptoms and aspects
Chronic wounds arterial venous infectious diabetic neuropathic traumatic vasculitic	Ulcer, decubitus or pyoderma gangraenosum	Possible indication of bacterial contamination (prophylactic), colonisation and infection with bacteria
Acute, open wounds mechanically conditioned	Abrasions Lacerations Stab wounds Bruises Skinning wounds Bite wounds Gunshot wounds Impalement injuries Amputations of limbs Burns	
thermally induced	Burns Frostbite	
due to surgery	Surgical wounds Secondary healing surgical wounds Split skin extraction points	

ViroCAP med is intended for external use.

Contraindications

The following contraindications apply to the product:

- Wounds that bleed heavily
- Wounds on exposed organs (surgical site)
- Wounds on mucous membranes
- Wounds in the area of eyes, mouth and nose
- Children under the age of 12

Technical specifications

The following technical specifications describe ViroCAP med:

Electrical data

Supply voltage	12 V DC (device) / 100 – 240 V AC / 50 – 60 Hz (power supply unit TDK WMM30CN120-00E-502)
Charging voltage	12 V DC (power supply unit TDK WMM30CN120-00E-502)
Battery capacity	2 x 1100mAh
Battery Voltage	3.7 V
Power consumption	max. 10 VA
Protection class	II, if in charging station. Otherwise internally powered.
Device Type	Handheld unit with plug-in power supply or battery-powered handheld unit
Dimensions	
Weight	165g (handheld unit)
Length	215 mm
Width	38 mm
Depth	27 mm
Cable length	1800 mm
Typical application parameters	
Plasma temperature	< 50 °C
Skin temperature	< 40 °C
Operating conditions	
Air humidity	15 … 80 % rH (non-condensing)
Temperature	+10 - +30 °C; 41 - 86 °F
Pressure	800 hPa … 1060 hPa
Height	< 2000 m ASL
Ingress protection	IP 20 (handheld unit and charging tray), IP 22 (power supply unit)
Storage conditions	
Air humidity	15 … 80 % rH (non-condensing)
Temperature	0 - +40 °C; 32 - 104 °F
Pressure	700 hPa … 1060 hPa
	Keep dry, Keep away from sunlight
EMC conpliance	
Immunity	Test level in accordance with and corresponding to: EN 60601-1-2: 2015+A1:2021, IEC 60601-1-2:2014 + AMD: 2020, professional healthcare environment
Emission	Test level in accordance with and corresponding to: EN 60601-1-2: 2015+A1:2021, IEC 60601-1-2:2014 + AMD: 2020, professional healthcare environment
CISPR 11 group	1
CISPR 11 class	A

Operating conditions

The ViroCAP med can be operated under normal workplace lighting conditions and can be used in both inpatient and outpatient settings.

- The ViroCAP med and its associated components can be operated at temperatures between + 10°C and + 30°C
- The ViroCAP med and its associated components can be operated at a relative humidity between 15% and 80% rH non-condensing.
- The ViroCAP med and its associated components can be operated at air pressures between 800 hPa and 1060 hPa.
- The ViroCAP med and its associated components can be operated at hights of max. 2000 m ASL.
- Before operating the ViroCAP med after transport or storage, the device must reach operating conditions.
- At an ambient temperature of 20°C, the device requires at least 5 minutes to cool down from the highest storage or transport temperature to the highest operating temperature.
- At an ambient temperature of 20°C, the device requires at least 5 minutes to warm up from the lowest storage or transport temperature to the lowest operating temperature.

If you notice that the environmental conditions are changing and the ViroCAP med is being used outside the required specifications, the treatment must be stopped.

Transport and storage conditions

- The ViroCAP med and its associated components can be stored in the packaging at temperatures between 0 °C and +40 °C.
- The ViroCAP med and its associated components can be stored in the packaging at a relative humidity of between 15% and 80% rH.
- The ViroCAP med and its associated components can be stored in the packaging at an air pressure of 700 hPa to 1060 hPa.
- The ViroCAP med spacer can be transported and stored in its packaging until its expiry date. It must be kept dry and kept away from direct sunlight.

Warnings

The following warnings and restrictions apply to the product:

Keep distance to communication devices

Other electronic devices, especially those with high-frequency equipment such as mobile phones, can interfere with medical electrical equipment. Using the ViroCAP med in close proximity to such devices may result in increased emissions or reduced immunity of the ViroCAP med.

Portable HF communication devices such as radio devices or mobile phones (including accessories such as antenna cables and external antennas) should not be used at a distance of less than 30 cm from the ViroCAP med. Failure to comply may result in a reduction in the performance characteristics of the ViroCAP med.

Caution - Device integrity and EMC compliance
This device has been designed in accordance 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 conditions specified in clause 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 tray and power supply unit – must be inspected for physical integrity. Any signs of housing damage, cable defects, or compromised shielding enclosures must be considered potential safety risks, as they may impair both electromagnetic compatibility and electrical safety. In case of any damage or irregularity, please contact technical support before further use.

Warning – Only use original components
Only use the ViroCAP med with the manufacturer‘s original components and accessories.
The use of accessories other than those specified or supplied by the manufacturer may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and lead to incorrect operation.

Warning
Operate the ViroCAP med only with the specified mains voltage. Failure to do so may result in malfunctions, failure, smoke development or even fire.

Warning - Only use the original power supply unit
Only use the original power supply unit from the manufacturer (TDK WMM30CN120-00E-502). The use of other power supply units is not permitted. Warning: Use of this device adjacent to or in combination with other devices should be avoided as this may result in improper operation. If such use is necessary, this device and the other devices should be observed to ensure that they operate normally.

Caution – Use according to Intended use
Only use the ViroCAP med for its intended medical purpose in compliance with the indications and contraindications.

Caution - Wear gloves for operating and cleaning!
We recommend to always wear gloves when using and cleaning the device.

Warning – Operating Conditions
Wait until the ViroCAP med has adjusted to the permitted ambient temperature. Especially, if the ViroCAP med was previously transported or stored outside the allowed values (see section 7.1).

Caution - Wear gloves for operating and cleaning!
We recommend to always wear gloves when using and cleaning the device for your own protection and to avoid cross-contamination.

Caution - Have a spare module ready!
It is recommended that you always have a spare plasma module in stock so that smooth operation even can be guaranteed if a module fails.

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 down before replacing it.

Warning
The spacer protects the user and patient from unintended contact with the plasma module thanks to the integrated protective screen. The spacer may become contaminated through contact with the skin.

Warning – Cross-contamination
Use the ViroCAP med spacer only for one patient and one treatment area at a time. Otherwise cross-contamination may occur.

Caution
Contact of the spacer with the skin can lead to injuries if used improperly.

Caution - Do not use a defective device!
Do not use the device if it is defective (e.g. broken or frozen display). The safety of the patient and the user can no longer be guaranteed.

Warning – Emissions
Treatment with ViroCAP med produces ozone in low concentrations. When used as intended, the legal limits are not exceeded, but the 'odour threshold' may be exceeded. The ozone is sufficiently diluted by the ambient air. When used in small rooms and/or with several devices and/or for longer treatment times, ensure adequate ventilation (e.g. by opening windows or doors). Individual sensitivity to ozone varies greatly. When using ViroCAP med in the presence of people with chronic respiratory diseases, infants and

small children, particular attention must be paid to adequate ventilation due to their special sensitivity.

Caution – Hot surface!
The Spacer surface may reach temperatures of 55°C. Ensure a slight distance between the spacer and skin. Reduce contact times as much as possible and below 1 minute to ensure safe contact. Avoid contact especially with areas that are contraindicated.

Warning – Emissions
Treatment with ViroCAP med generates very low levels of UV radiation. Avoid treatment around the eyes. During treatment with ViroCAP med, ozone is produced in low concentrations. Avoid treatment in the area, of mouth and nose.

Caution
Before operating the ViroCAP med after transport, the device must reach a temperature within the operating values (see section 7.1).

Caution
Under no circumstances remove the ViroCAP med spacer or the plasma module during treatment.

Caution - Wear gloves for operating and cleaning!
We recommend to always wear gloves when using and cleaning the device.

Clean the ViroCAP med after each patient treatment to avoid cross-contamination. Only use the cleaning agents described in section 6.1 to clean the ViroCAP med.

Clean the ViroCAP med by wipe disinfection. Avoid very wet cleaning, e.g. by frequent spray disinfection, as this can damage electronic components. In particular, cleaning in an immersion bath is prohibited.

Caution - Electrical voltage
Never use electrically conductive tools to take out the battery.

Warning
Only use the ViroCAP med within the specified ambient conditions. Excessive heat/cold or humidity can compromise the function of the ViroCAP med or destroy it.

Warning
If you notice that the environmental conditions are changing and the ViroCAP med is being used outside the required specifications, the treatment must be stopped.

Think about protecting the environment.
Used electrical and electronic devices must not be disposed of with household waste. The applicable national disposal regulations and laws must be observed.

Principles of operation

The device consists of a piezoelectric plasma generator that enables to partly ionize surrounding ambient air due to its high electrical fields, thus providing cold atmospheric plasma in the vicinity of the discharge.

The produced reactive oxygen and nitrogen species can reach the injured skin and develop their healing effect.

To prevent a direct discharge towards the patient, a sterile spacer is attached to the device, which provides the necessary distance between the plasma generator and the patient and ensures that the reactive species are retained and made available locally. For treatment, the device is moved with the spacer at a slight distance over the area to be treated. After 30 seconds, a beep indicates that the device can continue.