ActivCellpen®

User manual
English

developed and manufactured
in Switzerland

Table of Contents

1 Introduction

The ActivCellpen is a handheld, battery driven cold plasma therapy device intended to reduce microorganisms on the skin or in a wound and thus promote wound healing.

This user manual is intended for medical professionals who use the ActivCellpen for treatment of chronic, hard-to-heal wounds in healthcare and homecare environments. Users of the ActivCellpen should have a professional training that included the treatment of chronic wounds.

The ActivCellpen is developed and manufactured in Switzerland. ActivCellpen® is a registered trademark of ActivCell Group AG.

2 General Use Information

2.1 Mode of Action

The ActivCellpen induces micro-discharges between an electrode of the device and the human skin acting as counter electrode. These discharges partly ionize the air surrounding the surface of the electrode (which is acting as a dielectric barrier) and, as a consequence, cold atmospheric plasma is formed.

Through this mechanism, the ActivCellpen reduces microorganisms on the skin or in the wound and thus promotes wound healing.

2.2 Intended Use

The ActivCellpen is intended to reduce microorganisms on the skin or wound and thus promote wound healing.

2.3 Indication

The ActivCellpen can be used for:
Support of wound healing

2 General Use Information

2.4 Contraindications

The use of the ActivCellpen is contraindicated for:

- Craniofacial procedures, including eyes and ears
- Dental procedures
- Treatment in close proximity to the heart or carotid artery
- Patients with electric implants such as pacemakers, diagnostic devices, medical pumps
- Pregnant women

For patients with metallic implants, treatment of the extremity containing the implant should be avoided, while other extremities can be treated.

The device is not intended to be used in sterile body areas.

3 Warnings

3.1 Key to symbols

Warning

Failure to comply with the warning can result in death or serious injury.

Precaution

Indicates a low-risk hazard which, if not avoided, could result in minor or moderate injury.

Note

Indicates practical information and tips that facilitate optimal use of the product.

3.2 General warnings and precautions

The following warnings and precautions are general in nature. Other special warnings, precautions and notes related to specific instructions will appear in the respective paragraphs of the document.

General remarks

- In case of any serious incident in relation to the device, report to the manufacturer and to the competent authority of your state.
- The ActivCellpen is a medical device intended for use by qualified medical personnel; it is not intended for use by lay persons.
- Read these operating instructions carefully before using the ActivCellpen and keep them for future reference.

3 Warnings

- Follow the instructions contained in this manual when setting up and configuring the ActivCellpen.

- Risks associated with use of the device beyond the expected service life of 2 years mainly arise from ageing effects and can lead to delayed healing, skin burns and muscle stress.

- The LED of the pen will turn to permanent red in case of a deviation of the output power from the set power (see 5.4 LED codes) and plasma generation will be shut off. The device cannot be used any longer. Please contact your supplier.

Warning

- The ActivCellpen must not be used by healthcare professionals carrying a pacemaker or other electric implants.

- If the operating behaviour of the ActivCellpen changes in an unexpected way, if it generates unusual noise, if you handled the device or the charger improperly, stop using them and contact your supplier.

- Use the device only for the purposes described in this manual. Improper use of the device or any independent technical modifications of the device may result in health hazards.

Precautions

- The device must not be exposed to excessive force, dropped, or shaken and must only be stored in its case.

- If there is visible damage to the ActivCellpen, the charger, the connecting cable, the glass electrode or the power supply, do not use them under any circumstances and contact your supplier.

- If you dropped the device or the electrode, examine thoroughly for any damages and conduct a functional test before using the device again.

- If the device is not in use, switch it off and remove the battery. The device will automatically switch off after 20 minutes use time to prevent overheating.

- The power adapter is considered as disconnecting device when the battery is charging. To disconnect the power supply from the supply network, pull the power supply out of the mains.

- During the usage of the ActivCellpen ozone is generated. A higher local concentration of ozone can cause nausea and dizziness. To prevent such side effects, users must not use the device close to their own face and ensure good ventilation in the treatment room or area to prevent ozone concentrations from accumulating.

- The ActivCellpen may only be used in an environment with air humidity from 15 % to 80 % without condensation.

- The ActivCellpen must not be operated outside the temperature range of 5 – 25 °C.

- Repairs may only be performed by a specialist authorized by ActivCell Group. Contact your supplier for repair needs.

4 The ActivCellpen

4.1 Components

Warning

The material of the electrode tip is glass. Caution needs to be taken as the electrode may break during handling or maintenance, or when the device falls to the ground. Damaged electrodes may cause injuries to patient and/or the user and must no longer be used.

Device Component	Article No.
1 ActivCellpen (housing with electronic components)	ACT-100.100
2 ActivCellpen Charger	ACT-100.310
3 ActivCellpen Battery (including its housing)	ACT-100.320
4 ActivCellpen Straight Electrode	CP-100.220
5 ActivCellpen Disc Electrode	CP-100.240

A suitable power supply (6) is provided together with the ActivCellpen, which is marked with a label «ActivCellpen® Power Supply».

4.2 User Interface

1. Glass electrode – two different types as described in 6.3.
2. Housing
3. Rotary switch to set the pulses per second
4. Rotary switch to switch the device on/off and set the output power
5. Control LED

5 Setting up Operation of the ActivCellpen

Precautions

- Check before first use that the set is complete, and that the product has not been damaged during transport. If the set is incomplete or transport damage is visible, do not use the product. Contact your supplier.
- The ActivCellpen must only be used with the components supplied as part of the set (refer to section 4.1), including the power supply, or with spare parts obtained through official distributors; the use of non-dedicated components is not allowed and can cause unwanted damage.
- The batteries must only be charged with the dedicated charger supplied as part of the set.
- Before using the charger, check that the voltage indicated on the charger matches the regional mains voltage.

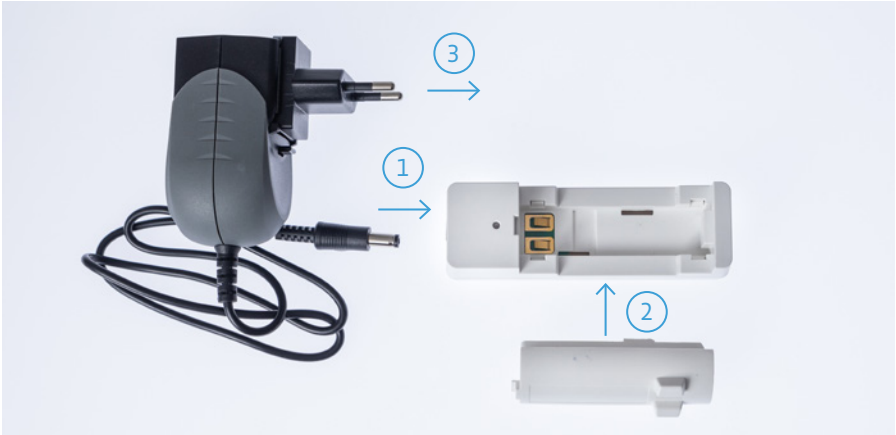
Before using the ActivCellpen for the first time, ActivCell Group recommends making sure the batteries are fully charged and to conduct a functional test before starting treatment as described in section 5.3. The functional test ensures that the device is functioning properly, and that treatment can be performed safely.

To conduct the functional test, the batteries must be charged and the ActivCellpen must be assembled properly.

5.1 Charging the batteries

The battery should be recharged when the LED on the ActivCellpen starts flashing green. Charging shall be performed as follows:

1. Connect the power cord to the battery charger.
2. Insert the battery into the charger.
3. Connect the power plug to a mains socket. A flashing green light on the charger indicates that charging of the battery is in progress.



4. An empty battery reaches around 80% of its maximum charge in approximately 90 minutes and is fully charged after approximately 165 minutes (2 h 45 min). A solid green light on the charger indicates that the battery is fully charged.
5. Disconnect the charger from the mains if you do not want to charge another battery.
6. Remove the battery from the charger.

5 Setting up Operation of the ActivCellpen

5.2 Assembly of the ActivCellpen

1. Check the device and all device components prior to assembly. Damaged components must not be used.

2. Make sure the ActivCellpen is switched off. You can do this by turning the amplitude control to the «OFF» position.

3. Insert the glass electrode into the ActivCellpen. A click indicates that the glass electrode is locked.

4. Before inserting the battery, always check that it is charged and the LED is green. Insert the battery. The battery can only be inserted one way and it is fixed magnetically. Do not use any pressure.

5.3 Functional Test

1. Assemble the ActivCellpen as described in paragraph 5.2.

2. Switch on the ActivCellpen by turning the amplitude control. The green light under the switch will light up, indicating that the device is powered on and ready for use.

3. The frequency and the amplitude of the pulses can be adjusted using the rotary switches. The value set is indicated by a marking below the rotary switch.

4. Switch the ActivCellpen off if no immediate treatment is planned.

After a successful functional test, the ActivCellpen is ready to be used for treatment.

Precaution

If the functional test is not successful, refer to chapter 8, Troubleshooting, to determine which measures you can take, or get in touch with your supplier or a contact person authorized by ActivCell Group®.

5 Setting up Operation of the ActivCellpen

5.4 LED Codes

5.4.1 Charger

When a battery with low charging level is inserted, the control LED is flashing green.

A solid green control LED indicates that the battery is charged and ready for insertion into the ActivCellpen.

5.4.2 ActivCellpen

A solid green control LED close to the amplitude rotary switch indicates that the battery is charged and ready for use.

The control LED starts flashing green when the battery is running low. The battery should be exchanged and recharged as soon as possible.

When the control LED starts flashing red, the pen has reduced power and must no longer be used. The battery must be replaced by a fully charged battery.

A solid red LED indicates a potential problem with the device. Switch off the pen and then switch on again. If the LED turns back to green, the pen can be used further. If the LED remains red, contact your supplier.

6 Use of the ActivCellpen

6.1 Device Settings

The two rotary switches allow an adjustment of the energy at the tip of the electrodes that is converted into cold atmospheric plasma.

1. Rotary switch to switch on/off the device and set the amplitude.
   The amplitude (output voltage) can be regulated in intervals of 1 – 9. A setting of 5 and higher will be used during treatments. Do not use settings below 5, they are not relevant for current indications.

2. Rotary switch to set the number of pulses per second.
   Settings 50 – 100 correspond to 50 – 100 impulses/s. A setting of 50 and higher will be used during treatments. Do not use settings below 50, they are not relevant for current indications.

Note

To adjust the switches to the desired setting, turn anti-clockwise, in the direction of increasing numbers (refer to 6.4., use recommendations).

6 Use of the ActivCellpen

6.2 Application of the device

Precaution

Do not apply pressure to the wound. Too much pressure may cause pain for the patient and breaking of the electrode tip. Also, plasma ignition reaches its maximum at a slight distance.

If the pen or the electrode fall to the ground, examine the components carefully for any damage. Do not use if the glass is shattered or the housing is broken. If there is no damage, disinfect the electrode as described in section 7 before using it again.

Note

Single-use gloves are usually required to treat wounds under hygienic conditions. Therefore, gloves need to be worn when using the ActivCellpen to treat the wounds of patients.

Refer to chapter 7 for information on cleaning and disinfection before and after treatment.

1. Assemble and switch on the device as described in section 5.2.
2. Hold the ActivCellpen with the handle (with the two switches) in your fist as shown in the pictures below (both options are acceptable).

3. The plasma ignition will be visible as an orange light within the glass tip of the electrode and a crackling sound can be heard when coming close to or touching the skin or wound.
4. Move the tip of the pen slowly across the wound area to be treated and maintain a distance of roughly 1–2 mm, where the orange light and the crackling sound are at their maximum. This will maximize the formation of cold plasma, however plasma will also be generated when the wound is touched very slightly.
5. While moving the tip of the pen across the wound, cover an area of around 1 cm^2 in roughly 30–60 sec. Refer to 6.3 for the surface area of both electrodes.

6 Use of the ActivCellpen

6.3 Use of the two electrodes

6.3.1 The straight electrode

The straight electrode can be applied at a convenient 45° angle to the surface of the skin for focused treatment of small areas. The tip of the electrode covers approximately 0.5 cm^2.

The power per surface area of the cold atmospheric plasma generated at the tip of the electrode is approximately 160–186 mW/cm^2 at the highest setting combination and hence allows a very focused treatment.

6.3.2 The disc electrode

The disc electrode has a larger surface area than the straight electrode, therefore the plasma is distributed across a larger area. Hence, the electrode can be used to cover larger wound areas. The disc area of the electrode covers approximately 12 cm^2.

The power per surface area of the cold atmospheric plasma generated at the flat surface of the electrode is approximately 27–30 mW/cm^2 at the highest setting combination.

A power per surface area of 14 mW/cm^2 is sufficient to achieve the required antimicrobial efficacy to reduce microorganisms in the wound.

It is recommended to store the electrodes in the case between treatments .

6.4 Use recommendations

Warning

Take note of the contraindications in paragraph 2.4.

Precaution

- For patients with metallic implants, treatment of the extremity containing the implant should be avoided, while other extremities can be treated.
- The maximum contact time should not be exceeded, as exceeding the contact time can potentially lead to burns.

The effectiveness of the treatment is defined by the amplitude and the frequency of the pulses. In addition, the effectiveness is influenced by the following parameters:

- The contact time.
- The duration of a therapy session and the frequency of sessions per week.
- The shape of the electrode.
- The straight electrode generates a more focused plasma and is suitable for a smaller treatment area; the disc electrode generates a more dispersed plasma and enables treatment of larger wounds.

6 Use of the ActivCellpen

The following settings are generally recommended:

- Typically, the highest setting combination with amplitude 9 and 100 impulses/s shall be used.
- The recommended treatment time is 30 – 60 seconds per cm^2. A maximum contact time of 90 seconds per area should never be exceeded.
- A setting combination of 7/70 and higher will be effective with both electrodes at the maximum treatment time of 90 sec.
- To enable a comfortable adjustment of the patient to the treatment, a slow increase of the respective settings of amplitude and impulses is advisable, starting from a medium setting combination of 5/50 (which will not yet be efficacious).
- If no improvement is noticed, a different wound treatment scheme should be applied.
- If the clinical or subjective symptoms worsen, additional or alternative treatment schemes should be applied.
- If the symptoms improve, the set values and the treatment time should be maintained until slow-down of progress.

An in-depth description of all possible procedures associated with wound care or eczema treatment is beyond the scope of these instructions. Medical professionals who use the ActivCellpen must take each patient's clinical state and medical status into consideration and familiarize themselves with the general procedures involving the use of cold atmospheric plasma.

7 Cleaning and Storage

Precaution

- The device must be assembled (electrode and battery inserted) and switched off before disinfection.
- The ActivCellpen is not waterproof. Do not immerse the device in water or clean under running water.
- Do not spray the disinfectant directly on the device. Disinfection must be carried out by wiping the electrode down with a (pre)impregnated wipe.
- Disinfection must be carried out before every first use of the device on a patient and after each patient use.

7 Cleaning and Storage

Note

- No separate cleaning step is required. To ensure efficient disinfection, the electrode of the device has to be wiped twice, using a fresh wipe each time.
- Regular disinfectants in combination with dry wipes or ready-to-use, pre-impregnated disinfectant wipes can be used for cleaning and disinfection.
- When using the ActivCellpen to treat patients in a home environment, a disinfectant and dry wipes or pre-impregnated wipes must be included in the equipment brought along for the patient visit.

The ActivCellpen generates cold atmospheric plasma in and around the electrode. Therefore, the electrode has some self-disinfecting properties.

Disinfection must be carried out:

- Before first use and each time after a use break (e.g. at the beginning of a working day): the electrode must be disinfected twice, each time with a fresh wipe, after the device has been assembled, i.e. after the electrode and the battery have been inserted.
- After each use: the electrode must be disinfected twice, each time with a fresh wipe, before the device is disassembled.
- The housing does not come into contact with the patient and the user wears gloves during patient treatments, hence the risk of any contamination is minimal and disinfection is not mandatory at the same intervals.

Disinfection of the electrode before and after use on a patient:

- Make sure that the device is assembled and turned off.
- Use a pre-impregnated wipe or use a dry wipe and spray the disinfectant on the wipe until saturation.
- Wipe the electrode with the moist wipe and make sure the wound-contacting glass part of the electrode has been fully covered. Special attention is recommended to ensure full wetting of the wound contact surface of the disc electrode.
- Maintain contact time as per the use instructions of the disinfectant manufacturer.
- Repeat the disinfection step once, with another fresh wipe.
- The pen can be re-used or disassembled and put back into the case when the electrode is dry.

Suitable disinfectant products comprise alcoholic formulations with an efficacy spectrum covering bactericidal, mycobactericidal or at least tuberculocidal, fungicidal and virucidal efficacy and with material compatibility against ABS and PU polymers.

The validation of the disinfection process has been conducted using Bacillol AF Tissues. Bacillol AF together with suitable dry wipes can be used in the same way.

The same disinfectant can be used to clean the whole device from time to time as appropriate, or as defined by internal standard operating procedures used in the respective healthcare facility.

Appropriate storage conditions are as defined on the ActivCellpen case label:

Temperature range -20 °C – +50 °C

Humidity range 15 % – 80 %

Atmospheric pressure range 75 kPa – 106 kPa

8 Troubleshooting

The following problems can be addressed by the user:

If the LED does not light up when the device is switched on (turn the amplitude rotary switch from the «OFF» position), do the following:

1. Switch off the device (turn the amplitude switch clockwise to the «OFF» position).
2. Check whether the electrode is properly inserted in the pen, remove it if necessary and insert again. Check if the pen is working.
3. If necessary, check if the battery is inserted properly and re-insert if necessary.
4. If the control LED does not light up, replace the battery with a fresh, fully charged battery and charge the one you removed.
5. After inserting a charged battery, turn the amplitude switch anticlockwise from the «OFF» position and check whether the control LED lights up green. If the LED is solid green, then the ActivCellpen is fully functional.

If these measures do not solve the problem, contact your supplier.

9 Technical Data

ActivCellpen
- Max. output voltage 25 kVAC
- Primary frequency 20 Hz – 100 Hz
- Operating voltage 3.7 VDC

Battery
- Lithium-Ion battery
- LND Li-ion14500C
- Typical Capacity 800mAh @ 0.2C Discharge
- Nominal voltage 3.7 VDC

Operational environment (for ActivCellpen and power supply)
- Temperature 5 °C – 25 °C The maximum temperature at the glass tip (applied part) can be 43 °C
- Air pressure 75 kPa – 106 kPa
- Air humidity 15 % – 80 %

Charger
- Input voltage 12 VDC
- Max output 4.2 VDC

Power supply for charger
- Cincon Electronics TR15RAM120
- Address: No. 8-1 Fu Kung RD. Fu Hsing Park, Fu Hsing Hsiang, Chang Hua Hsien, Taiwan, R.O.C
- Input: 100 VAC -240 VAC; 50 Hz – 60 Hz (not to be exceeded)
- Output: 12 VDC; 1A

Protection against electric shock
- Type BF applied part (60601-1), internally powered ME device with two exchangeable electrodes (straight and disc electrode), their glass tips are also type BF applied parts.

List of BF applied parts (60601-1)
- Straight electrode
- Disc electrode

The ActivCellpen has been tested according to DIN SPEC 91315: Allgemeine Anforderungen an medizinische Plasmaquellen, Juni 2014.

10 Detailed Safety Information

10.1 Electromagnetic emission and immunity

This ActivCellpen is intended for use in the electromagnetic environment specified below. The user of the device must ensure that the device is used in the specified environment.

Electromagnetic Emission

Emission test	Conformity	Electromagnetic environment – clues
RF emissions CISPR 11	Group 2	The device applies RF energy to the patient.
RF emissions CISPR 11	Class A	The device is intended for use by healthcare professionals and that is not intended for sale to the general public.
Emission of harmonics IEC 61000-3-2 with or without specified accessories	n/a	Not tested (Professional Equipment)
Voltage fluctuations / flicker IEC 61000-3-3 with or without specified accessories	n/a	Not tested (Professional Equipment)

Note

The emissions characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the device.

Warning

- The device should not be operated on, under or next to other devices.
- The use of components other than those specified for the device is not allowed. These can lead to increased emissions or reduced immunity to interference from the device.
- Additional equipment connected to medical electrical equipment must comply with the relevant IEC or ISO standards. In addition, all configurations must meet the requirements for medical electrical systems (see IEC 60601-1-1 or sentence 16 of the 3rd edition of IEC 60601-1). Any person who connects additional equipment to medical electrical equipment configures a medical system and is therefore responsible for ensuring that the system meets the requirements for medical electrical systems. Note that the laws in force at the site take precedence over the above requirements. In case of doubt, contact your local representative or technical support.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ActivCellpen, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

10 Detailed Safety Information

Electromagnetic Immunity

Immunity Test	Test level according to IEC 60601-1-2	Compliance Level	Electromagnetic Environment – Clues
Electrostatic discharge (ESD) **IEC 61000-4-2**	±8kV contact ±2, ±4, ±8, ±15kV air	±8kV contact ±2, ±4, ±8, ±15kV air	The floor should be made of wood, concrete, or ceramic tiles. Relative humidity should be at least 30% on floors with synthetic flooring.
Fast transient electrical disturbances/burst **IEC 61000-4-4**	±2 kV for power supply lines	±2 kV for power supply lines	The quality of the network supply should correspond to a typical professional health care environment.
Voltage surges **IEC 61000-4-5**	±1 kV differential mode	±1 kV differential mode	The quality of the network supply should correspond to a typical professional health care environment.
Voltage dips, short interruptions and voltage fluctuations in the power supply lines **IEC 61000-4-11**	<5% Ut (>95% dip in Ut) over 0.5 cycles 100% Ut 1 cycle 70% Ut (30% dip in Ut) over 25 cycles <5% Ut (>95% dip in Ut) for 5s	<5% Ut (>95% dip in Ut) over 0.5 cycles 100% Ut 1 cycle 70% Ut (30% dip in Ut) over 25 cycles <5% Ut (>95% dip in Ut) for 5s	The quality of the network supply should correspond to a typical professional health care environment.
Magnetic field due to the mains frequency (50/60 Hz) **IEC 61000-4-8**	30A/m	30A/m	Not applicable, device does not contain magnetically sensitive components or circuitry.
Conducted HF **IEC 61000-4-6**	3Vrms 150kHz to 80MHz 6Vrms ISM	10Vrms 150kHz to 80MHz 10Vrms ISM	Portable and mobile RF communications equipment should not be used closer to any part of the equipment, including cables, than the recommended separation distance, which is calculated based on the equation applicable to the frequency of the transmitter.

10 Detailed Safety Information

Electromagnetic Immunity

Immunity Test	Test level according to IEC 60601-1-2	Compliance Level	Electromagnetic Environment – Clues
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.7GHz	10 V/m 80MHz to 6.0Hz	N/A
Proximity fields from RF wireless communications equipment IEC 61000-4-3	385MHz: 27V/m @ 18 Hz pulse modulation 450MHz: 28V/m @ 18Hz pulse modulation 710MHz, 745MHz, 780MHz: 9V/m @ 217Hz pulse modulation 810MHz, 870MHz, 930MHz: 28V/m @ 18Hz pulse modulation 1720MHz, 1845MHz, 1970MHz: 28V/m @ 217Hz pulse modulation 2450MHz: 28V/m @ 217Hz pulse modulation 5240MHz, 5500MHz, 5785MHz: 9V/m @ 217Hz pulse modulation	385MHz: 27V/m @ 18 Hz pulse modulation 450MHz: 28V/m @ FM modulation 710MHz, 745MHz, 780MHz: 9V/m @ 217Hz pulse modulation 810MHz, 870MHz, 930MHz: 28V/m @ 18Hz pulse modulation 1720MHz, 1845MHz, 1970MHz: 28V/m @ 217Hz pulse modulation 2450MHz: 28V/m @ 217Hz pulse modulation 5240MHz, 5500MHz, 5785MHz: 9V/m @ 217Hz pulse modulation	N/A

The field strength of fixed transmitters, for example base stations for radio telephones (mobile telephones, cordless telephones) and of fixed radio stations, amateur radio stations, AM and FM radio transmitters and television transmitters cannot be predicted theoretically with accuracy. To assess the electromagnetic environment in the vicinity of fixed RF transmitters, an electromagnetic site survey should be carried out. If the measured field strength at the location where the device is used exceeds the RF compliance level mentioned above, the normal functioning of the device should be checked. If abnormal behaviour is detected, additional measures may be required, such as realigning or repositioning the device.

Hints

- Ut is the mains voltage (alternating current) before the test level is applied.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and people.

10 Detailed Safety Information

10.2 Emission of Radiation

The ActivCellpen emits low levels of UV radiation in the UV-A, -B and -C range. The risks derived from UV radiation to the patient or user have been determined as low. The information below shall enable the user to assess their personal risks individually.

According to EU Directive 2006/25/EC, «Minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation)», exposure limits of 30 J/m² apply to the wavelength range of 180–400 nm (UV). In order not to exceed the limit, the irradiance of the UV source must not exceed 1 mW/m² (or 0,1 µW/cm²) for 8 hours of uniform exposure.

UV emission data of the ActivCellpen (which is used for much less than 8 hours) are shown below:
UV irradiance of the straight electrode at a distance of 1,5 mm: 0,14 µW/cm²
UV irradiance of the disc electrode at a distance of 1,5 mm: 0,86 µW/cm² (i.e. worst case)

The risk assessment for a patient has been conducted as follows:
The exposure time of the patient to UV light with the irradiance described above is therefore considerably shorter than the acceptable limit of 8 hours defined in the EU Directive.

An exemplary comparison of the irradiance × exposure time (assuming a wound size of 100 cm² treated using the disc electrode with a surface area of 12 cm², i.e. for 10 mins) is shown below:
Irradiance × exposure time for the disc electrode: 0,86 µW/cm² × 0,16 h = 0.14 µWh/cm²
Irradiance × exposure time allowable by 2006/25/EC: 0,1 µW/cm² × 8 h = 0,8 µWh/cm²

Ratio (safety margin): 0,8 / 0,14 = 5,7

The worst-case UV emission onto the patient's wound by the disc electrode is more than 5 times lower than the limits defined by Directive 2006/25/EC.

The risk assessment for a user depends on the frequency with which the ActivCellpen is used.

In case a user treats 10 patients per day, the resulting exposure time is 10 × 10 min or 1,6 h, higher than for a patient, but still much lower than the 8 h exposure time of Directive 2006/25/EC.

The irradiation dose that a user is exposed to is considerably lower than for a patient. As the user wears gloves during treatment, the closest potentially exposed area is the skin of wrist and forearm, at a distance of at least 10 cm. With that, the exposure distance is about 100× higher for the user as compared to the patient (1 mm vs. 10 cm). Consequently, due to the square law of radiation intensity the user's skin is exposed to a dose that is 100 × 100 = 10 000 times lower. The user may further minimize any potential risk of irradiation by wearing long sleeves to cover wrist and arms.

Note

- It has to be noted, that measurements below 200 nm are not possible due to the fact that air and any liquid absorbs this short-wavelength radiation immediately. Measurements would have to be conducted in a vacuum or a noble gas and do not represent a real-world situation. Therefore, the exact risk cannot be quantified. General principles of physics suggest that VUV exposure should not be higher than the UV exposure described above. Computer simulations suggest that the integrated intensity below 200 nm is much lower than above 200 nm.
- Because air absorbs radiation below 200 nm the risk for the user is low due to the distance between electrode and user.
- The exact amount of radiation below 200 nm that the patient is exposed to cannot be determined, however as mentioned above simulations suggest low radiation intensity.

11 Compliance

11.1 IEC 60601

IEC 60601-1: Medical electrical equipment – General requirements for safety including the essential performance features

IEC 60601-1-2: Medical electrical equipment – Part 1–2: General requirements for safety including the essential performance characteristics – supplementary standard: electromagnetic compatibility – requirements and tests

11.2 Regulation (EU) 2017/745 (MDR)

Regulation (EU) 2017/745 of the European Parliament and of the EU Council of 5 April 2017 on Medical Devices

CE
0297

12 Contacts

12.1 Legal Manufacturer

Effectum Medical AG
Kirchgasse 11
CH-4600 Olten

www.effectummedical.com
E-Mail: info@effectummedical.com
Telefon: +41 77 493 72 72

12.2 European Authorized Representative

MED-RAS GmbH
Eichenallee 8H
D-21512 Wohltorf

www.medras.de
E-Mail: info@medras.de
Telefon: +49 4104 99 44 44-0

12.3 Product-Related Questions

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Telefon: +41 41 924 11 88

12.4 Support and Distribution

Refer to the ActivCell Group website (www.activcellgroup.com)

13 Warranty

The General Terms and Conditions of ActivCell Group AG apply at the time of purchase.

- Pen: 2 years, covering material, functional and manufacturing defects
- Electrode: 2 years from the date of purchase
- Batteries: 1 year

In the event of improper use or broken glass of the electrodes, a guarantee will be refused.

The expected service life of the batteries is around 1 year and will ultimately depend on the number of recharge cycles (typically 500 cycles). The batteries should, however, be replaced as soon as a noticeably shorter running time after full charging is found.

During storage it must be ensured that the battery is charged once every six months.

For reordering of components, refer to the article numbers in section 4.1.

14 Symbols on Labels


Manufacturer


Conformité Européenne

Medical Device

Catalogue Number

Serial Number

European Authorised Representative

IP21 Protected against solid objects over 12.5 mm e.g. hands, large tools.
Protected against vertically falling drops of water or condensation


Refer to user manual/booklet


Type BF applied part


Direct current


Not to be placed in general waste; dispose through a maintenance centre or specialized dealer


Fragile, handle with care


Temperature limit for storage


Humidity limitation


Atmospheric pressure limitation


Indoor use


Double insulation

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