

Instruction Manual

SweatStop® Iontophoresis DE20

Direct current device with pulsating and constant current for tap water Iontophoresis for the treatment of hyperhidrosis at hands, feet and underarms (hyperhidrosis palmaris, plantaris and axillaris)



Made in Germany



Functional Cosmetics Company Inc., Nauenstrasse 67, CH-4052 Basel

Telephone: 0041 61 262 1000, contact@functional-cosmetics.com

www.functional-cosmetics.com

Table of Contents

- 1. Preface.....3**
 - 1.1. Introduction.....3
 - 1.1.1. Scope of Supply.....3
 - 1.2. Manufacturer Liability.....4
 - 1.3. Classification „BF“.....4
 - 1.4. Medical Protection Class.....4
 - 1.5. Electromagnetic Compatibility.....4
 - 1.6. Warranty.....4
 - 1.7. Maintenance.....4
 - 1.8. Cleaning.....4
 - 1.9. Disposal.....5
 - 1.10. Technical Data.....5
- 2. Starting up SweatStop® Iontophoresis DE20.....6**
- 3. Application.....7**
 - 3.1. Application at Hands OR Feet.....10
 - 3.2. Combined application at Hands AND Feet11
 - 3.3. Application Underarms12
 - 3.4. Facial Application.....12
 - 3.5. Potential application errors.....13
 - 3.6. Warning.....13
 - 3.7. Application Interval.....14
 - 3.8. Power Supply.....14
 - 3.9. Code Status15

1 Preface

1.1 Introduction

The manual should be read thoroughly before operating this device. If there should still be any questions, please contact us.

SweatStop® Iontophoresis DE20 should be used once a day over a period of 2-3 months, even if your medical condition should get better. A lasting abatement can only be achieved when using the device over a longer period of time.

A therapy with this device can also be a good way to add on to other therapies which have been conducted before.

Electric currents stimulate the nerves specifically. These currents are safe, comfortable, and according to medical knowledge to date, free from side effects. The current is adjustable very finely.

Due to the direct and indirect effect of the current very good treatment results can be achieved with hyperhidrosis of the hands, feet, underarms and facial hyperhidrosis.

If you have concerns for the application of the device, you should seek medical advice.

Application examples can be found in the appendix. You can use the device properly also without any technical understanding.

1.1.1 Scope of Supply

- SweatStop® Iontophoresis DE20 control unit
- Power supply unit
- Instruction manual
- Cable set & case (only needed and delivered for application hands/feet)

Depending on your needs the following accessories are also required:

- Application at hands and/or feet: Item No. 9034. Sponge Patches for Hands & Feet, with Electrodes
- Application underarms: Item No. 9035. Sponge Patches for underarms, with Electrodes
- Facial application Face: Item No. 9033. Facial Electrode against facial sweating

1.2 Manufacturer Liability

The manufacturer is only liable for failures, which can be ascribed to improper production or allowances which were not adhered to. The manufacturer is not liable for application errors and errors in treatment.

According to §5 of the Medical Devices Directive, version of 07.August 2002, the manufacturer is AAM GmbH, Tiefentalstrasse 2, 78 098 Triberg-Nussbach.

1.3 Classifikation „BF“

This electric-powered therapy device operates on batteries and therefore is free of earthing. According to DIN EN 60601-1 it is a device of type BF.

1.4 Medical Protection Class

The device complies with the electric protection class II and the medical protection class II a in accordance with MDD 93/42 EWG.

1.5 Electromagnetic Compatibility

The device is certified according to regulations of EN 60601-1-2:2001 and EN 60601-2-10:200. Tables of the guidelines of the manufacturer's declaration can be obtained through the manufacturer.

1.6 Warranty

The warranty period for manufacturing errors is 24 months. The electrodes, sponge pockets, cables and batteries (consumable supply) are not included in the warranty.

1.7 Maintenance

The device is free of maintenance.

Only the manufacturer or companies authorised by the manufacturer are allowed to carry out repairs.

1.8 Cleaning

The device and the electrodes can be cleaned and disinfected with all detergents normally used in medical practices. The device should not be submerged in any form of liquids, furthermore no detergents which might cause corrosion should be applied to the device.

After having used the device the electrodes and the sponges are to be cleaned and disinfected in luke warm water. The sponges can also be washed in the washingmachine, along with your hot wash.

When disconnecting the cables from the device, make sure to pull the plug gently. The cables should not be bent too much and knots in the cables should be avoided.

Should you not be using the device over a longer period of time, please remove the batteries from the device and store them seperately. Used batteries are to be disposed in the hazardous waste.

1.9 Disposal

In the case of disposal, the device should be sent back to the manufacturer.

1.10 Technical Data

Dimensions:	172 x 116 x 41 mm
Weight:	270 g
Nominal voltage:	6,0 V

Constant Current (CC)

Strom:	Constant current
Current:	0 - 20 mA continuously adjustable from 1 to max. 2000 ohm load resistance
Output voltage:	maximum 40 V irrespective of measuring resistance

Pulsating Current (PC)

Current:	Pulsating current
Amperage:	0 - 30 mA continously adjustable from 1 to max. 2000 ohm load resistance
Output voltage:	maximum 60 V irrespective of measuring resistance

Accessories and replacement parts

Item	Item number
Control device	9030
Facial Electrode	9033
Sponge pockets hands / feet	9034

Sponge pockets underarms
Cables Set

9035
9036

Please refer to the delivery note for the exact configuration of your device. The aforementioned components are tested together with the device.

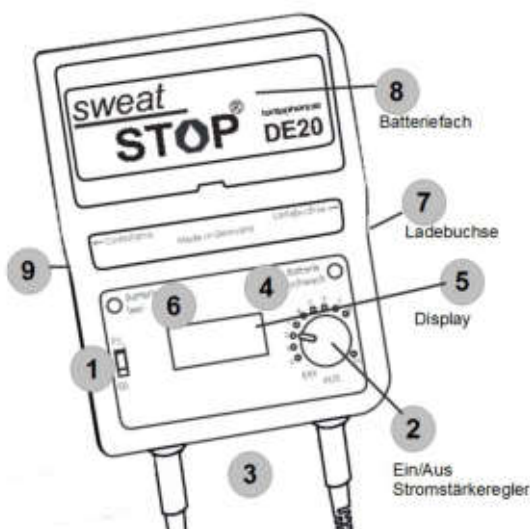
Maximum current density of electrodes when in full contact with skin

Sponge pockets hands / feet
Sponge pockets underarms

0,15 mA
0,83 mA

2 Starting up SweatStop® Iontophoresis DE20

1. On/Off switch with current controller
2. Diverter for type of current
3. Outlet sockets
4. LED, weak battery
5. Digitaly display
6. LED, flat battery
7. Charging socket
8. Compartment for batteries
9. Code-control



1. **Type of current CC or PC:** Use this switch you select the type of current CC (constant current) or PC (pulsating current)
2. **On/Off switch:** When turning this button (1) to the left until it has reached „0“ the device will be turned on. In order to switch the device off you need to turn the switch all the way back until it has reached its starting point. You will hear a click.
Amperage controller: After you have applied the electrodes, plugged in the cable plug into the output sockets (3) and have switched on the devices, slowly turn the amperage controller (1) clockwise until you have adjusted the amperage so that you can feel the current which is comfortable for you. When turning the amperage controller back into the other direction (contraclckwise) the amperage will be decreased.

3. **Commutator:** The pole change of the current flow can be carried out by replugging/changing the cables. The red cable needs to be plugged into the black socket. The black cable into the red socket.
4. **Light-emitting diode LED:** When the light-emitting diode (LED) lights up, it indicates that the accumulators are weak. You will be able to conduct 2 more treatments before having to recharge the accumulators.
5. **Digital display:** The digital display shows you the type of current and the milliamperere. Furthermore, it indicates if the battery voltage is low in this case you need to recharge the accumulators.
6. **Light emitting diode LED:** As soon as this LED lights up in red it indicates that the accumulators are flat. You will have to recharge the accumulators before being able to use the device again.
7. **Charge socket:** The charging device will be connected to this socket. The DC-plug of the charging device which is plugged into the charging socket disconnects the electronic circuit from the power supply.
8. **Batty compartment:** This device operates on 4 batteries or rather accumulators. Accumulators/batteries of type “baby” are to be used.
9. **Code-control:** The number of completed treatments will be saved and can be displayed when pressing this pushbutton and turning on the device.

3 Application

Basically, the treatment with constant current (CC) is to be recommended as therapeutically it gives better results. Only in a few cases, the pulsating current (PC) is more effective.

Constant current (CC): Turn the amperage on to the extent until you feel slightly the current. Then turn it back until you do not feel it anymore.

Pulsating current (PC): Turn the amperage on to the extent until you feel the power.

The amperage must be readjusted before each treatment.

The display shows you how much current is flowing.

- **Duration of treatment: about 20 minutes**
- **Treatments: 1 time daily until sweating decreases. Thereafter, the application interval can be adapted to every 1-3 days. This differs depending on the person and has to be adjusted individually.**

Reversal: Reverse the polarity of the current for each treatment

Before you start, take off all accessories made of metal (e.g. jewelry). Connect the 2 mm connector of the red and black cables to the electrodes and insert electrodes into sponge pockets. Either place electrodes (in sponge pockets) separately in water tubs or apply electrodes (in wet sponge pocket) directly to body part. The electrodes (black silicon part) should not touch the skin. Now plug cables into respective plug socket of the device (3). When the red cable is plugged into the red socket and the black cable plugged into the black socket, there is a “plus” (+) on the electrode with the red cable and a “minus” (-) on the black cable.

Before switching on the device, use the respective switch to choose a type of current; PC for pulsating current or CC for constant current. The type of current, PC or CC, can only be selected when the device is turned off.

You or your doctor will decide which type of current is best for you. Apparently constant current is more effective but most patients feel more comfortable when using pulsating current.

In order to switch on the device, turn the switch (1) to the left. A text will appear on the display for 5 seconds “AAM GmbH DE 20 V2.0”; this indicates that the device is switched on. Now check if the type of current is correct. The first line of the display shows if the device is set to “CC” constant current or “PC” pulsating current.

As soon as the electric circuit is closed the milliampere meter will jump to the “0,4 – 0,7 mA” setting. This measurement indicates that the electric circuit is closed correctly. It will stand still until the amperage regulator is turned up or rather it will slowly rise until it has reached the previously chosen amperage.

When turning the button (1) clockwise, the amperage will be increased. The second line of the display (5) will show how much electricity flows.

Switching off the device

The current flow will be disconnected automatically after 20 minutes. The text “treatment over” will appear on the display. To switch off the device turn the button (1) back until it is engaged again. You will hear a click.

Changing polarity

Change the polarity each time you start the therapy, unless otherwise recommended by your doctor. The pole reversal can be carried out when plugging the red cable into the black socket and the black cable into the red socket.

Maximum Amperage / Strength of current

The voltage of the constant current (CC) is limited to 40 V, the voltage of the pulsating current (PS) is limited to 60 V. Due to this, the maximum amperage cannot be reached when the electrical resistance of the skin is larger than 2000 ohm. In this case the word "max" will appear in the first line of the digital display. You should try decreasing the electrical resistance of your skin by wetting the sponges again or by taking a warm shower so that your skin is improved. Another possibility would be measuring the inherent resistance of the electrodes with the help of an ohmmeter. After a certain time the electrodes lose their conductivity and need to be exchanged by new ones.

Indication

If, after having placed hands or feet into the tubs, the milliampere meter does not exceed 0,0mA the cutaneous electrical resistance is too high and the electrical conductivity of the water too low. In this case, add one teaspoon of common salt to each tub of water and stir thoroughly. Always use large electrodes when applying therapy to hands.

The measurement of the cutaneous electrical resistance or rather electrical conductivity of the water was integrated in order to keep the stress ratio at a minimum.

- Set device to constant current (CC)
- Re-adjust the amperage before each treatment
- Duration of treatment: about 20 minutes
- Treatments: 1 time daily. Later, every 1-3 days.
- Remove all metal objects (such as jewelry)
- Reverse the polarity of the current for each treatment

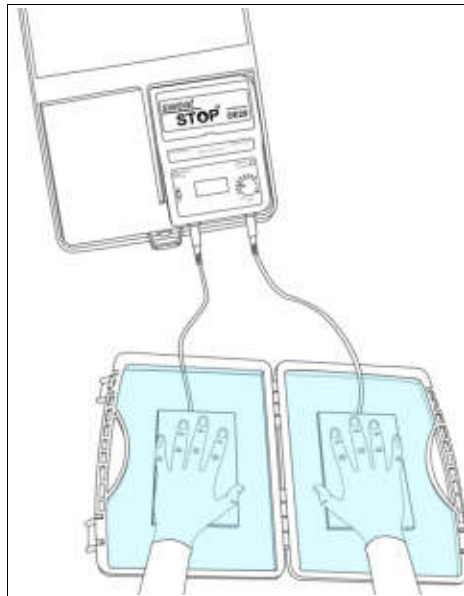
3.1 Application at Hands OR Feet

Place your feet and your hands in two electrically non-conductive tubs (eg plastic) filled with lukewarm water.

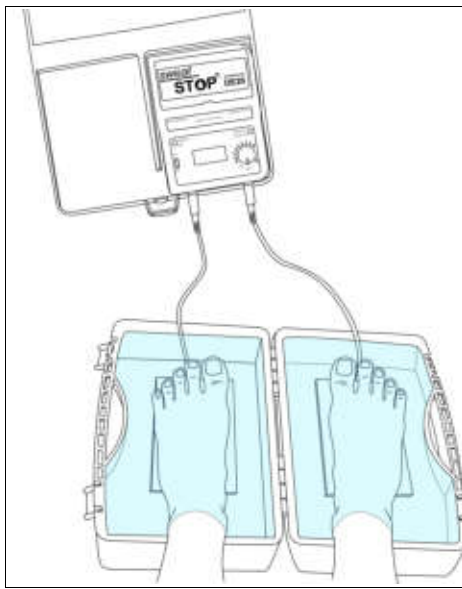
When doing the treatment for the first time you should ask another person to assist you with adjusting the amperage. Mark the spot with a permanent marker.

Starting from the second treatment switch on the device by turning the control knob up to the marked spot. Now put your hands or feet in the tubs filled with water. The current flow is activated as soon as you closed the circuit with your hands / feet. The voltage increases at a rate of 3 V per second until the preset current strength is reached.

You can take out your hands respectively feet at any time and re-adjust the current. Turn up the knob by not more than one score at a time.



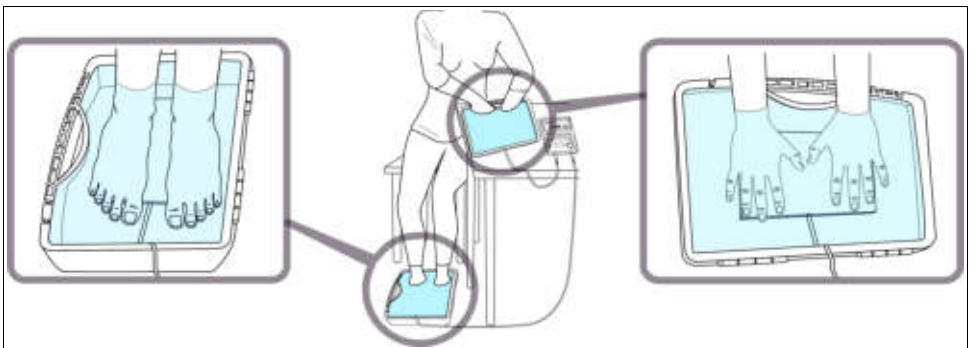
Application of SweatStop® Iontophoresis DE20 at hands



Application of SweatStop® Iontophoresis DE20 at feet

3.2 Combined application at Hands AND Feet

Hands and feet can be treated simultaneously. Place your feet and your hands in a tub. If you wish to adjust the amperage, simply use one of your hands (already placed in tub) and turn the button (1) until you have reached the desired amperage. After having adjusted the amperage, place your hand back into the tub. This way all four extremities will be treated at the same time. We have had several of patients who confirmed that this way of the treatment is as successful as the others.

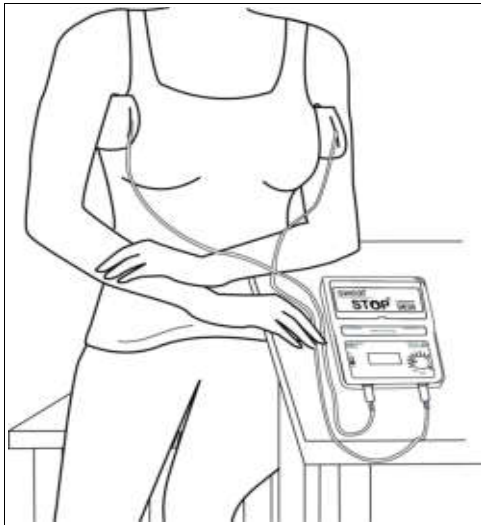


Application of SweatStop® Iontophoresis DE20 at hands and feet

3.3 Application Underarms

The easiest way to attach the axillary electrodes is to put on a close-fitting t-shirt and to place the electrodes with the sponges underneath the t-shirt. The sponges need to be wetted thoroughly.

Place the electrodes directly onto the respective skin area. Before applying the sponge pockets please make sure that they are thoroughly moistened (to the extent that they do not drip). Please ensure that there is no punctual application of the electrodes.



Application of SweatStop® Iontophoresis DE20 underarms

3.4 Facial Application

Before putting on the facial electrode, moisten it strongly, to the extent that it barely does not drip. Then, connect the cable to the three electrodes (black pads) and place the electrode onto the face. Tighten all straps snugly.

It is important to ensure that the facial electrode seats solidly on the whole face and does not only have punctual contact with the skin. If necessary, tighten the straps.

After the facial electrode is applied and the cables are connected to the device, turn on the device. For the next steps please read “3 Application”.

The current for the facial treatment should not be set higher than 2 mA. The ideal intensity of current for the facial treatment lies in between 1 to 2 mA.

If it should medically be necessary to set the current higher than 2 mA, this must be done under the supervision of a doctor and possible skin irritations are to be carefully monitored.

Indication

If the current cannot be activated and remains between 0.2 and 0.5 mA, the resistance between the three electrodes is too high. In this case you need to remove the facial electrode again. Fill a tub with lukewarm water and add a teaspoon of table salt to it. Stir the water until the salt is completely dissolved. Moisten the facial electrode in this tub and apply it anew.

Start the treatment again as described above.

3.5 Potential application errors

If you should perceive the current to be biting or unequally strong you should wet the electrodes again or by adjusting the electrodes more precisely onto the area of your body which you wish to treat.

Overly high adjusted amperage does not lead to a more successful treatment, but can in contrast lead to skin irritations. This is considered to be an error in treatment. Constant current (CC) - treatments should be conducted subliminally (not noticeable) and pulsating current (PC) - treatments should be conducted slightly noticeable.

You should be able to feel the current, but it must NOT be uncomfortable. You will perceive every treatment differently. This is why the miliampere gauge should only be referred to a benchmark. You should adjust the amperage according to your comfort.

If cases of skin irritations should come up, stop the treatment and seek advice from your doctor. The doctor will then decide how the treatment can be continued.

When turning off the device it can come to electrostatic discharge. These can be unpleasant but they are totally harmless. This effect was only observed when the floor, on which the patient stood, was electroconductive e.g. carpet with plastic fibre. These electrostatic discharges have nothing to do with the wellknown electric fence effect (effect of pasture fence).

3.6 Warning

When using the device next to (less than ca. 1m) a short wave or microwave device, fluctuations of the output value can occur.

Portable and mobile high-frequency devices (e.g. mobile phone) can affect the device.

Using accessories, which are not approved by the manufacturer can cause damage and can lead to an increased emission of electromagnetic waves or to a reduced inference resistancy of the device.

An effective current density on the electrodes exceeding 2 mA/cm² requires a great deal of attention. It is important that the electrodes are applied correctly, so that the sponge-covered electrode is in full contact with the skin. If only applied partially the current density can cause skin irritations.

The provided electrode cables are used to connect the electrodes to the device.

Indication for diabetics

Since diabetics are very insensitive to current, they should – in order to avoid skin irritations - turn up the current strength at the start of treatment in no case higher than 5 mA and monitor the course of the therapy exactly. If the skin reddens, the therapy should be aborted immediately and a dermatologist should be consulted. If it is medically necessary to adjust the amperage to a higher level, this should be done under the supervision of a doctor so that changes of the skin may be closely monitored.

3.7 Application Interval

The iontophoresis treatment should initially be carried out once a day, until the perspiration decreased. Thereafter, the application interval can be adapted to every 1-3 days. This differs depending on the person and has to be adjusted individually.

The perspiration usually reduces after only a few treatments. In exceptional cases, it may happen that the effect only occurs after a few weeks or even months. Thus a continuous treatment is recommended even if there is no initial effect.

The therapy must be continued, even if the desired treatment outcome has already taken place.

3.8 Power Supply

The device has a built in battery compartment (8) for four batteries (Baby – cell type LR 14) or rather accumulators (Baby – cell type C).

Monitoring battery capacity

As soon as the battery voltage drops below 4,9 Volt the yellow LED (4) will light up. The display will alternatively show the message “battery low”, the type of current and the miliampere. You will be able to conduct max. 2 more treatments. When the battery voltage drops under 4,7 volt the red LED (6) will light up. The display will show the message “batteries empty”. You will have to either charge the accumulators or replace them for dry batteries before you can continue your treatment.

Charging of accumulators

Located on the right side of the device is a charging socket (7). Only the charging device delivered by our company should be connected, since it is synchronized with the built in accumulators.

Indication

When the DC plug of the charging device is plugged into the charging socket the treatment cannot be conducted. The DC plug of the charging device disconnects the electrical circuit of the power supply. Before using the device again the DC plug from the charging device must be unplugged from the charging socket.

If there is no possibility of recharging the accumulators (e.g. when you are in a country where the power supply is 110 V) you can also use dry batteries (baby cell, typ LR14) to ensure the power supply of the device.

In any case it is prohibited to use accumulators and batteries at the same time.

When replacing empty batteries, all four batteries are to be replaced. We recommend using alkaline batteries.

The duration of recharging of the accumulators is ca. 14 hours.

3.9 Code Status

The code status indicates the number of treatments you have already conducted. In order to read the code status off the digital display you need to insert a pointy device e.g. pencil (max. 4 mm diameter) into the hole on the left side of the nameplate to switch on the code status. A four letter-figure combination will appear on the display. If you wish to know how many treatments you have conducted so far you can call us. With the help of this letter-figure combination we will be able to inform you on the number of treatments already conducted.