EN

Instruction Manual

SweatStop®
Tap Water
Iontophoresis Device

Trust the Specialist
www.sweat-stop.com

Index

Before operation

The manual should be read thoroughly before operating this device. Home treatment should be conducted only after consulting a doctor/dermatologist. This iontophoresis device was designed for optimal functionality and usability. Its operation is simple and ergonomic. This manual is intended to familiarize you with the system and its proper usage. Should there still be any questions after reading the manual, please don't hesitate to contact us.
The treatment with this device may also be a positive influence on the therapeutic effects of any other adjunct therapy.

Intended use

The device is intended to use tap water for the temporary reduction of excessive perspiration. Specialised electrodes for different body parts are made available. The patient is the intended operator of the iontophoresis device under the instruction or guidance of the clinician. The device is intended to be used in medical facilities and in private homes by healthcare professionals as well as non-professionals. The operation must be exclusively conducted in closed rooms. Any other use is considered "unintended use" at the risk of the user.

Contraindications

1. Do not use if you have any electronic implant, such as a cardiac pacemaker or ICD (implanted cardioverter defibrillator).
2. Do not use if you have a suspected or diagnosed cardiac condition.
3. Do not use if you are or have recently been pregnant.
4. Do not use if you wear any metallic implant such as a metal-containing IUD (intrauterine device), screws, plates or wires within the possible current path. Take off all metal jewellery before the treatment.
5. Do not use if the body parts you wish to treat suffer from malign tumours, thrombosis, diabetes, impaired sensitivity, inflammation, uncovered skin defects, fresh wounds or vascular disorders.

Warning

1. The patient is the responsible user of this device and should only operate it under the instruction or guidance of a medical professional.
2. The target population is over 18 years old and was given a medical prescription to use the device.
3. Do not disassemble the device. If needed, return it for examination or repair.
4. CAUTION: All modifications of this equipment or its accessories are forbidden.
5. The medical device should not be used close to or on top of other electric equipment. Should such a usage be strictly necessary, the medical device must be verified to conduct normal operation in the configuration in which it will be used.
6. CAUTION: The usage of accessories, chargers or cables other than those specified or provided by the manufacturer of this equipment may negatively influence the electromagnetic emissions or electromagnetic immunity of this equipment and result in a faulty operation.
7. CAUTION: Portable RF communications equipment (including peripherals such as antenna cables and external antennae) should be used no closer than 30 cm (12 inches) to any part of the medical equipment, including the cables specified by the manufacturer. Otherwise, the function of the equipment might deteriorate.
8. Do not use the iontophoresis device near the active high frequency equipment and the RF-shielded room of an MRI scanner, where the intensity of disturbances is extraordinarily high.
9. Use only with tap water. Liquids other than tap water are not allowed.

Safety measures

1. Keep away from children.
2. This device should only be used with the leads and cables provided by the manufacturer to ensure the maximum clinical effectiveness. Using accessories which are not approved by the manufacturer may cause damage or an unauthorised interference emission and loss of operating license.
3. To prevent burns during the treatment, make sure the electrodes are covered at all times. Direct contact with the surface of the electrodes must be avoided at all times.
4. Any damage to the skin (minor injuries, scratches etc.) in the treatment area must be coated with Vaseline or a fatty lotion before treatment to avoid further damages.
5. Two devices may not be used simultaneously on one patient.
6. Make sure that the device is at room temperature before operating it. If the device has been stored in low temperatures, a condensation of the air humidity may lead to malfunctions or damage of the device.
7. All jewellery worn in the treatment areas must be removed before starting the therapy. Due to their increased current density, metal objects can cause local skin injuries.

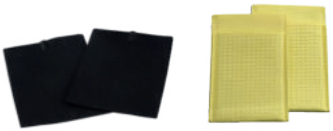
8. This device is designed for indoor use only. Do not expose it to rain or humidity.
9. Caution should be used when treating areas of the skin that lack normal sensation (e.g. diabetic patients). Note: watch out for skin irritations. Pause the treatment if necessary.
10. High currents do not lead to a more successful treatment, but can lead to skin irritation instead. The current strength should be adjusted to the comfort of the patient. In cases of skin irritation, stop the treatment and seek advice from your doctor.
11. If the treatment feels uncomfortable, reduce the current strength to a comfortable level or stop the session.
12. If the treatment is ineffective or unpleasant, discontinue the sessions and seek advice from your doctor.
13. Before operation, the patient must sit still and all cables must be plugged in firmly.
14. The mains plug is specified as a part of this medical equipment. Only use the adaptor supplied by the manufacturer.
15. Do not submerge the device in water.
16. Dropping the device may cause damage.

Side effects / accompanying symptoms

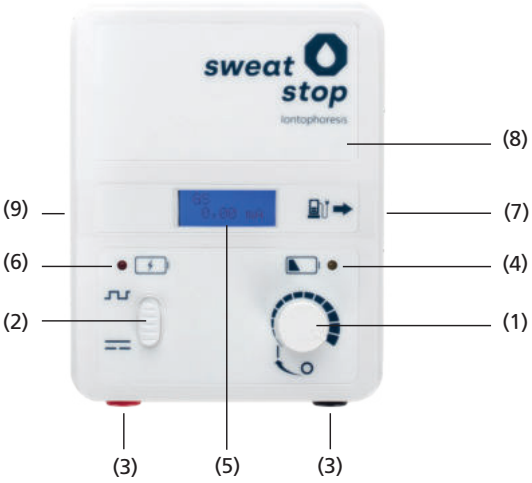
- Skin irritations are one possible side effect of the intended usage. The treatment should be stopped until the cause of the irritation can be determined.
- You will perceive every treatment differently. For this reason, the milliampere value should only be used as a rough guidance. The current strength should be adjusted according to your personal comfort level.
- Iontophoresis treatment stimulates the circulation, so a harmless reddening of the skin after the treatment may occur.
- During the treatment you may experience tingling or stinging sensations. In this case, you should reduce the current strength to a comfortable value.
- As a consequence of the treatment, the skin will become increasingly drier.
- If the treatment leads to skin that is too dry, chapped or cracked, stop the treatment and consult your doctor.

Scope of delivery

Depending on your prescription, the scope of delivery may differ or include other accessories.

Description and number	Image
Device in case Item number: 9030	
Accumulator (rechargeable battery) (4x Baby NiMH 1,2 V 2500 mAh)	
Charger Charger for series of 4 NiMH accumulators	
Cables for electrodes Item number: 9036	
Case / tubs for tap water	
Electrodes in sponges for the treatment of hands and feet Item number: 9034	
User manual	

Structure of the device and basic functions



(1) On/Off switch with current controller
(2) Diverter for type of current
(3) Outlet sockets for electrodes
(4) LED, indicator "weak battery"
(5) Digital display
(6) LED, indicator "empty battery"
(7) Charging socket
(8) Battery compartment
(9) Code control

(3) Sockets to connect cables to electrodes

(7) Charging socket for charger

1. On / Off switch with current controller

To start the device, switch on clockwise until you hear a click.

Continue turning to control the amperage: turn clockwise to increase the value, anti-clockwise to lower it.

This function is only available when the electric circuit is closed. When the circuit is interrupted, the display will show "0,00" until the circuit is closed. Then, the current will slowly be raised until it reaches the selected value.

The values 1-10 denote 10-100 % of the maximum value: in direct current mode, the maximum value is 20 mA; 30 mA for pulsed current mode.

Stufe	1	2	3	4	5	6	7	8	9	10
GS [mA]	2	4	6	8	10	12	14	16	18	20
PS [mA]	3	6	9	12	15	18	21	24	27	30

After the predefined treatment time of 20 minutes, the current flow will be interrupted automatically. The text „treatment over" will appear on the display. To switch off the device, turn the button (1) back until it locks into place with a click.

The treatment time of 20 minutes begins once the circuit is first closed (displayed value > 0,00) and will not be started anew if the circuit is momentarily interrupted to make adjustments.

2. Diverter for type of current

You may either choose direct current (DC) or pulsed current (PC). In "pulsed current" mode, the ratio between pulse and pause is 1:1. This means that the efficient PC value is nearly half of the displayed current value. Due to its decreased percentage of direct current, the pulsed current allows more precise increments (5 mA PC is equivalent to 2,5 mA DC). Due to the interruptions in the current, pulsed currents feel more comfortable for some patients.

3. Outlet sockets for electrodes

Two outlets: "Red" - Anode (+) and "Black" - cathode (-). Plug in the cables according to their colours to connect the device with the electrodes. Change the polarity each time you start the therapy, unless otherwise recommended by your doctor. The pole reversal can be carried out by plugging the red cable into the black socket and the black cable into the red socket.

4. LED indicator "weak battery"

When this yellow LED lights up, it indicates that the accumulators are weak and must be recharged soon. You will be able to conduct 2 more treatment sessions before needing to recharge the accumulators.

5. Digital display
During normal usage, the display shows the current value measured in mA (milliampere), as well as the chosen current type (PC or DC). Additionally, it shows messages such as “treatment over”.

6. LED indicator “empty battery”
When this red LED lights up, it indicates that the accumulators are empty. You will have to re-charge the accumulators before being able to use the device again.

7. Charging socket
The charging socket is located on the right side of the device (7). You may only use the supplied charger, since it is adjusted to the accumulators built into the device. Connecting the device to the wrong charger may lead to severe damage.
If the DC plug of the charger is inserted, the circuit will be interrupted and the device will be deactivated.

8. Battery compartment
The device has a battery compartment (8) for four rechargeable batteries/accumulators of the cell type LR (Baby/C). 4 NiMH accumulators are part of the delivery scope. The charging duration depends on the capacity of the batteries and the charger – new cells (standard equipment, 4x 2500 mAh) take approximately 11-12 hours to charge.

9. Code control
The number of all completed treatments will be saved. This code status has replaced the “therapy diary” in order to offer an alternative proof for a regular trial phase to health insurances.

Trial phase under prescription by health insurance
Code status

Many health insurances want to make sure that the device is actually needed before they take over the costs. Often, a therapy diary or the questionnaire provided by AAM (including code) is used as proof of the therapy sessions. The code status indicates the number of treatments you conducted. By demand of certain health insurances, the number of completed sessions was coded to impede a possible deception. In order to read the code status on the display, insert a pointy object, e.g. a screwdriver (2-3 mm in diameter) into the hole on the left side (9)* to press the code switch. Keep it pressed down and switch on the device – after a few moments, a four-letter figure will appear on the display. The code switch can now be released.

*Insert horizontally if you own the version in the etui; insert slantwise from above if you own the version in the plastic case.

Safety features

• Anti-overtreatment

As a result of a successful treatment, the electric resistance of the skin rises up. To avoid an over-treatment, the system monitors the conductivity of the skin. The displayed message "max" signals that the predefined resistance has been met. If a second, higher limit is reached, the system will be locked and won't even start. Since these limits have been adjusted to the "average patient", they may not fit your individual situation.

If the hyperhidrosis is not relieved and the device won't start due to the protective function, please don't hesitate to contact us so that we can find an individual solution for your situation.

• Maximum current strength

The current strength is controlled by the device and cannot be increased above the maximum values of 20 mA (direct current - DC) and 30mA (pulsed current – PC). To give you the best possible feedback, the display always shows the real current value.

• Disconnecting the device from the current supply (240V / 110V)

When the DC plug of the charger is plugged into the charging socket of the device, the treatment cannot be conducted. The DC plug disconnects the electric circuit. For this reason, the treatment is only possible when the charger is disconnected.

• Protection against accidental change of current type

Switching between pulsed current and direct current is impossible during the operation of the device. An accidental change between the current types cannot occur during the treatment. When the device is started, the position of the button is saved and will be upheld until the end of the treatment session even if the current type is changed.

• Anti pasture fence effect

To avoid electric shocks by the adjusted voltage when submerging the hands or feet, the controls will only be started once the current is closed (= hands or feet are submerged). The current will now rise gradually. If the circuit is interrupted during the treatment, the value will be reset to zero. Once the treatment is continued, the current will gradually rise to the chosen value.

Application

Basics

Tap water iontophoresis is used for the temporary relief of the hyperhidrosis affecting the palms of hands and feet and the underarms. The chances to reduce the perspiration to a normal level without damaging the perspiratory glands are very high. This effect is achieved by running an electric current (constant or pulsed) through the affected body parts to accustom the cells to electric stimulation. As a result, the sweat glands will be slower to react to their own stimulation. Since the glands are "only" familiarised with electric stimulation, their original condition will return relatively fast once the treatment is discontinued!

As a rule of thumb, conduct a daily initial therapy until you observe a significant effect (without skin irritations). Once positive results are registered, you can start to pause the daily treatment. Since the causes of hyperhidrosis differ between patients, you will have to adjust the therapy to your individual needs and lifestyle. These factors may vary according to yearly seasons and everyday occurrences.

Before you commence the session, take off all metal accessories (e.g. jewellery). Clean the skin in the treatment areas. Remove all ointments, lotions and cosmetics.

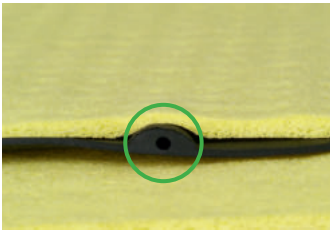
Exception: All damages to the skin (minor injuries, scratches etc.) must be coated with vaseline or a fatty lotion before the treatment to avoid further injuries. Damaged skin parts have an especially high current permeability and offer a greater risk of injury. The "entirety" of the current will run "only" through the damaged skin. Please only cover the spots affected by injury – caution is advised, since vaseline and other fatty lotions block the current flow and impede the therapeutic effect.

The device monitors the skin resistance and the electric conductivity of the water in order to reduce the strain (anti-overtreatment protection).

If your tap water is very hard, an addition of cooking salt may help increase the conductivity.

Preparation

Connect the red and the black cables with the electrodes.



Now, plug the cables into the corresponding outlet socket located on the device: plug the red cable into the red socket and the black cable into the black socket.

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

Treatment of the hands and/or feet

Place the tubs on a firm, level surface. For the treatment of the hands, place both trays side by side on a table; for the treatment of the feet, place both trays side by side on the floor. If you treat hands and feet simultaneously*, position one tray on the table and one on the floor.

* Since the conductivity of hands and feet varies, this is only recommended for experienced users.

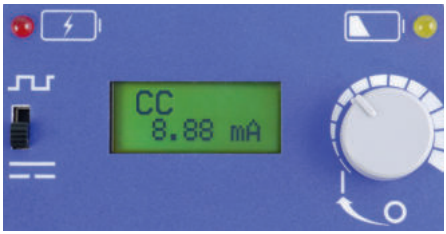
The electrodes must never directly touch the skin. Otherwise you will risk burns! Please pour a small amount of tap water (hand treatment: ~ 0.5 l, foot treatment: ~ 0.75 l) into each tub. The water temperature should be according to your personal comfort and has no effect on the therapy. The water should cover only the body parts affected by the hyperhidrosis – not the whole hand or the whole foot.

Treatment of the underarms or other body parts
Place a tub on a firm, level surface and fill it with tap water (~ 1 l). Put the connected sponge electrodes into the tub and soak them completely.

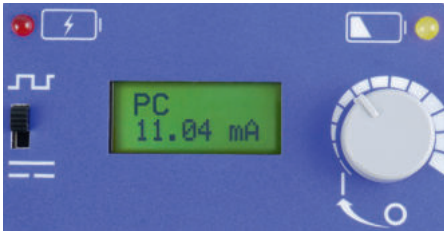
Hand treatment
Please read the chapter "Basics" first before you go on!

When conducting the hand treatment for the first time, ask another person to assist you with the adjustment of the amperage.
When conducting the second treatment, simply start the device by turning the button and adjust the amperage according to the value you used during your first treatment. Place both of your hands into the water-filled tubs – one tub per hand. The current flow will be activated as soon as the electric circuit is closed. The current strength will increase until the desired value has been reached. You can take your hands out of the tub at any time to readjust the amperage. Please note that you should only increase the amperage slowly. The increase of the current strength is restricted, which means that turning the button quickly won't lead to an equally quick increase!
Choose the current type according to your prescription or doctor's recommendation – direct current is more effective, but most patients prefer the comfortable treatment feeling of the pulsed current.
The current type, PC or DC, can only be selected when the device is turned off. Otherwise the original choice will be kept.
To turn on the device, turn the switch (1) to the left. A text will appear on the display for 5 seconds; this indicates that the device is running.
Now, check whether you have selected the correct current type. The first line on the display shows if the device is set to „DC" direct current or „PC" pulsed current. Put your hands into the treatment tubs – the water should cover only the areas affected by the hyperhidrosis – not the entire hand. If necessary, adjust the water level.

When turning the button (1) clockwise, the amperage will be increased. The second line on the display (5) shows the current flow.

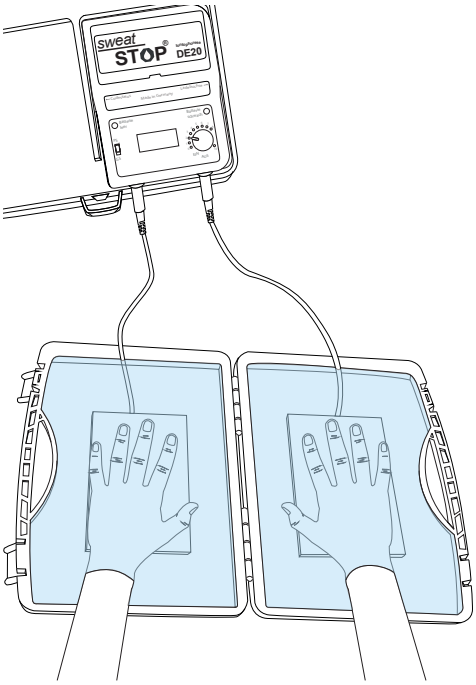


Direct current:
Turn up the amperage until the current is noticeable, then turn it down again until you can no longer feel it.



Pulsed current:
Turn up the amperage until the current is barely noticeable.

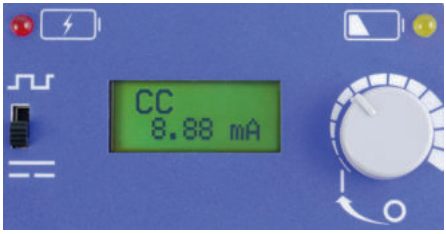
Iontophoresis treatment of the hands



Foot treatment
Please read the chapter "Basics" first before you go on!

Choose the current type according to your prescription or doctor's recommendation – direct current is more effective, but most patients prefer the comfortable treatment feeling of the pulsed current.
The current type, PC or DC, can only be selected when the device is turned off. Otherwise the original choice will be kept.
To turn on the device, turn the switch (1) to the left. A text will appear on the display for 5 seconds; this indicates that the device is running.
Now, check whether you have selected the correct current type. The first line on the display shows if the device is set to „DC" direct current or „PC" pulsed current. Put your feet into the treatment tubs – the water should cover only the areas affected by the hyperhidrosis – not the entire foot. If necessary, adjust the water level.

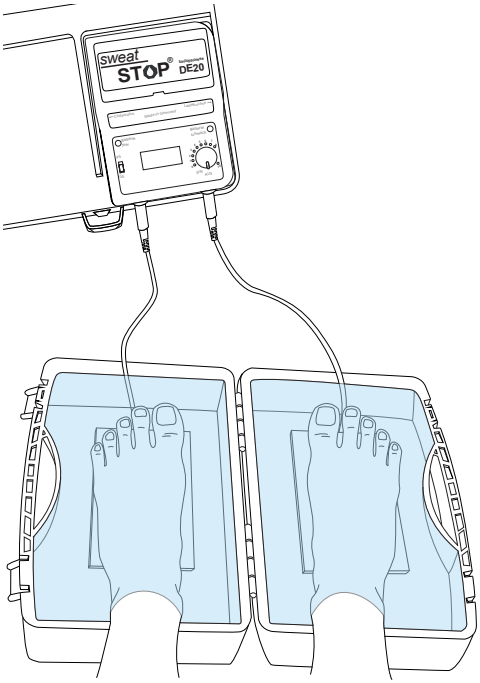
When turning the button (1) clockwise, the amperage will be increased. The second line on the display (5) shows the current flow



Direct current:
Turn up the amperage until the current is noticeable, then turn it down again until you can no longer feel it.

Pulsed current:
Turn up the amperage until the current is barely noticeable.

Iontophoresis treatment of the feet

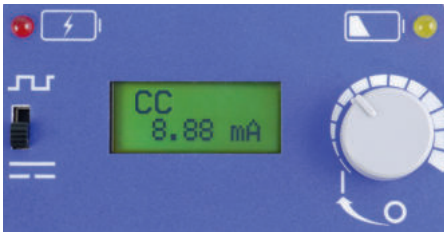


Combined treatment of hand and feet
Please read the chapter "Basics" first before you go on!

When conducting the hand treatment for the first time, ask another person to assist you with the adjustment of the amperage.
When conducting the second treatment, simply start the device by turning the button and adjust the amperage according to the value you used during your first treatment.
Put your hands into one treatment tub and your feet into the other tub – the water should cover only the areas affected by the hyperhidrosis – not the entire hands or feet. If necessary, adjust the water level.
The current flow will be activated as soon as the electric circuit is closed. The current strength will increase until the desired value has been reached. You can take your hands out of the tub at any time to readjust the amperage. Please note that you should only increase the amperage slowly. The increase of the current strength is restricted, which means that turning the button quickly won't lead to an equally quick increase!
Choose the current type according to your prescription or doctor's recommendation – direct current is more effective, but most patients prefer the comfortable treatment feeling of the pulsed current.

To turn on the device, turn the switch (1) to the left. A text will appear on the display for 5 seconds; this indicates that the device is running.
Now, check whether you have selected the correct current type. The first line on the display shows if the device is set to „DC" direct current or „PC" pulsed current.

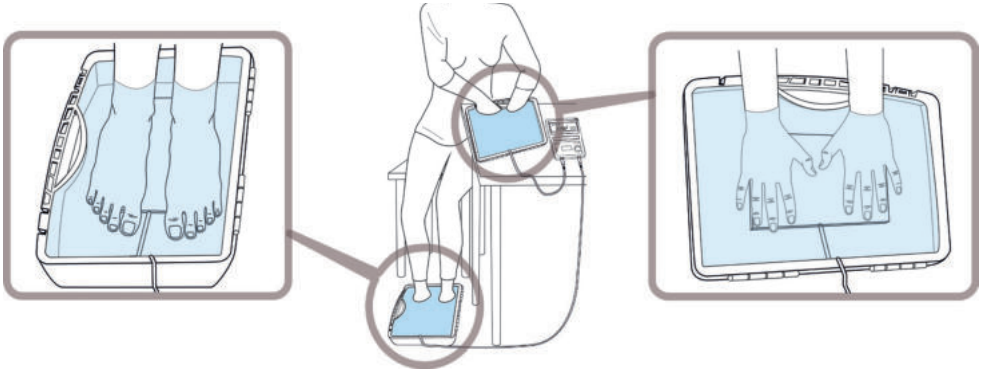
When turning the button (1) clockwise, the amperage will be increased. The second line on the display (5) shows the current flow.



Direct current:
Turn up the amperage until the current is noticeable, then turn it down again until you can no longer feel it.

Pulsed current:
Turn up the amperage until the current is barely noticeable.

Iontophoresis treatment of the hands and feet



Underarm treatment
Please read the chapter "Basics" first before you go on!

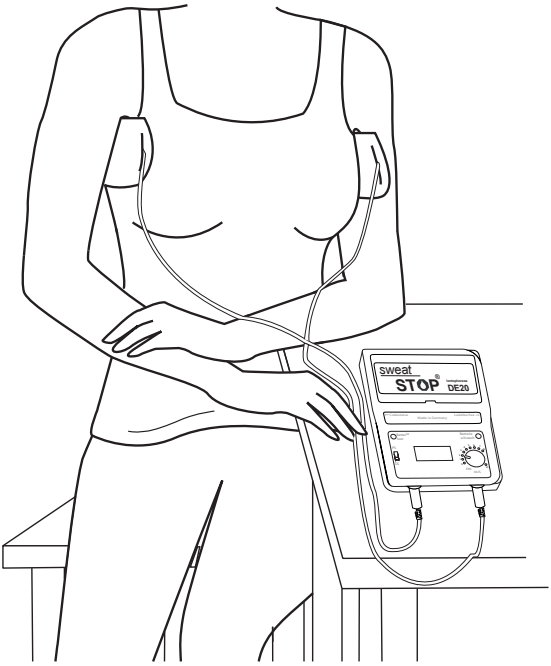
Soak the underarm electrodes thoroughly and squeeze them lightly until they are no longer dripping wet. Put them under your arms. Position them high up, directly in your armpit.
We recommend wrapping a towel around your body – during this treatment, water drops will occur.
Choose the current type according to your prescription or doctor's recommendation – direct current is more effective, but most patients prefer the comfortable treatment feeling of the pulsed current.
To turn on the device, turn the switch (1) to the left. A text will appear on the display for 5 seconds; this indicates that the device is running.
Now, check whether you have selected the correct current type. The first line on the display shows if the device is set to „DC" direct current or „PC" pulsed current.

When turning the button (1) clockwise, the amperage will be increased. The second line on the display (5) shows the current flow.

Direct current:
Turn up the amperage until the current is noticeable, then turn it down again until you can no longer feel it.

Pulsed current:
Turn up the amperage until the current is barely noticeable.

Iontophoresis treatment of the underarms



Treatment interval

The iontophoresis treatment should initially be carried out once a day, until the perspiration has decreased. Afterwards, the application interval can be adjusted to one treatment every 1-3 days, or alternatively to whatever setting is best for your body.

The perspiration is usually reduced after only a few treatments. In exceptional cases, it is possible that the effect occurs only after a few weeks or even months. For this reason, a continuous treatment is recommended even when there is no initial effect.

The therapy must be continued even if the desired result has already been achieved.

Rough guideline:

Alternate treatment and pause – every second day; three times a week with a minimum pause of one day.

Paused treatment – every third day; two times a week with a minimum pause of two days.

The duration is fixed to 20 minutes to allow an evaluation of the effectiveness of the treatment; this leads to a reduction of application errors. This time value has been deducted by scientifically significant clinical studies (15 or 30 minutes).

Should you perceive the current as biting or unevenly intense, please reduce the current strength. If you are conducting a treatment outside of the tubs, please soak the electrodes in the sponge pockets anew or adjust their position on your body to make sure they are in full skin contact.

High currents do not lead to a more successful treatment, but can lead to skin irritations and injuries instead. This is viewed as an application error. Direct current (DC) treatments should be conducted subliminally (not noticeable). Pulsed current (PC) treatments should be conducted slightly noticeably.

You should be able to feel the current, but it must NOT be uncomfortable. You will perceive every treatment differently. This is why your last current settings should only be viewed as a benchmark. You should adjust the current strength according to your comfort.
In cases of skin irritation, stop the treatment and seek advice from your doctor. Your doctor will then decide whether the treatment can be continued.

Summary:
- Adjust the device to the direct current setting (DC). Use pulsed current (PC) for more sensitive body parts. Due to its pauses, the pulsed current offers a finer dosage.
- Readjust the current strength before every new treatment.
- Duration of the treatment: 20 minutes.
- Sessions: once a day. Later, every 1-3 days or according to your personal needs.
- Remove all metal objects (jewellery).
- Change polarity before every treatment.
- Consult a doctor in cases of skin irritation.

Power supply

The device comes with a built-in battery compartment (8) for four standard rechargeable NiMH batteries (= accumulators) connected in series, type HR14 (= Baby = C). In delivery condition, their capacity is 2500 mAh. Due to this, the device can be operated independently from a power connection.

Monitored battery / accumulator capacity
As soon as the battery voltage drops below a defined value, the yellow LED (4) will light up. The display will alternatively show the message "battery low", the current type, and the current strength. You will be able to conduct a minimum of 2 more treatment sessions before the accumulators need to be recharged. When the battery voltage drops further, the red LED (6) will light up. The display will show the message "batteries empty". You will have to recharge the accumulators before you will be able to continue your treatment.

Charging the accumulators
The charging socket is located on the right side of the device (7). You may only use the supplied charger, since it is adjusted to the accumulators built into the device. Connecting the device to the wrong charger or power supply may lead to severe damage.
If the DC plug of the charger is inserted, the circuit will be interrupted and the device will be deactivated.
Caution: Never try to recharge primary battery cells with the recharging unit – only rechargeable NiMH batteries ("accumulators") are allowed.
When replacing batteries, all four batteries must be replaced. The charging duration of the rechargeable batteries is 11 to 12 hours (delivery condition).

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

Technical specifications

Dimensions:	172 x 116 x 41 mm
Weight:	270 g
Power source:	4 standard rechargeable NiMH batteries (= accumulators) size LR/Baby/C connected in series Capacity: min. 2500 mAh (delivery condition) Note: Mixing different types of batteries is prohibited. Do not mix new and old batteries, charge all batteries at the same time. Caution: Only use chargers for NiMH accumulator packs!
Operating conditions:	Temperature: from 5 °C to +40 °C. Max. relative humidity: 15 - 93 % humidity. Atmospheric pressure rage of 700 to 1060 hPa-
Output:	**Direct current (DC)** Ampere: 0 - 20 mA Voltage: 0 - 40 V **Pulsed current (PC)** Ampere: 0 - 30 mA (peak) Voltage: 0 - 60 V (peak)

Cleaning and maintenance

- The device is free of maintenance.
- Disconnect the cables carefully. Do not bend or tie the cables.
- The device must be cleaned damp (not wet!).
- The device and the electrodes can be cleaned with all non-corrosive detergents normally used in medical practices. The device must not be submerged in any kind of liquid.
- It is imperative that the sponge pouches are cleaned and laid out to dry after every treatment. Take the electrodes out of the pouches for drying.
- After usage, the electrodes and the sponges are to be cleaned and disinfected in lukewarm water.

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

Important!

Accessories such as electrodes,sponge pouches and cables are subjected to a certain amount of wear and may require replacement after prolonged use. Check all parts for damage before each application, especially the cables. If damaged, they must be replaced. Should the outlet sockets of the device be damaged, send the device for inspection.

Storage and transportation

- The storage and transportation conditions must not exceed the following values: Temperature: from -25 °C to +70 °C.
  Max. relative humidity: Less than 93 % humidity.
  Atmospheric pressure rage of 700 to 1060 hPa.
- For long time storage, please take the batteries out. For short-term storage, please check or renew the batteries periodically to keep the equipment in a fully usable condition.

Disposal

The model iontophoresis device contains electronic components. At the end of its service life, the device has to be sent to an appropriate waste disposal site in accordance with local regulations* or returned to the manufacturer.

* Within the European Union, the deciding regulations are 2006/66/EG and 2012/19/EU.

Warranty, guarantee and lifetime

Warranty

The guidelines 1999/44/EG and 2011/83EU of the European Union apply.
They specify a warranty period of twelve months from the delivery of the goods.
All claims are to be directed at the seller (issuer of your invoice).
The warranty includes material flaws and production errors. Electrodes, sponges, cables and batteries must be viewed separately as consumable supplies and are subjected to an individual assessment.
Ignoring the chapters “warning” and “safety measures” will lead to a loss of the warranty claim and producer’s liability.

Guarantee
Extended services can be covered by an additional guarantee.
If applicable, please refer to your guarantee card.

Lifetime
The service life of the device is 10 years, if it is used appropriately and cleaned regularly.

Signs and symbols

Sign or symbol	Description
	Type BF. Patient part type – Body Floating
	Caution
	Read operator manual
	Consult instruction for use
	Manufacturer
	Manufacture date
	Batch code
IP21	Protected against solid objects over 12.5 mm. Protected against vertically falling drops of water.
CE 2460	CE marking with identification number of the modified body: Complies with MDD 93/42/EEC requirements.
	European Authorized Representative/Authorized Representative.
	Disposal: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary: Waste Electrical Electronic Equipment (WEEE).
	GRS: Common collection system batteries.

Contact

Functional Cosmetics Company AG
Nauenstr. 67
4052 Basel
Switzerland

Distribution Center EU
Schwarzwaldstr. 31
79539 Lörrach
Germany

Tel: +41 61 262 10 00
Fax: +41 61 303 80 09
contact@functional-cosmetics.com
www.sweat-stop.com

Emissions test	**Compliance**	**Electromagnetic environment – guidance**
Conducted Disturbance CISPR 11	Class B Group 1	RF energy is used only to maintain device's operation. Therefore, its RF emissions are so low that it's not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B Group 1	The device is suitable for use in all establishments, including domestic establishments, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic emissions

The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50 or 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 or 60 Hz	30 A/m 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Resistance against electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 2 kV Power lines	± 2 kV Power lines	Mains power quality should be that of a typical commercial or hospital environment.

Interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle 70 % UT; 25/30 cycles 0 % UT; 250/300 cycles	0 % UT; 0.5 cycle At0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle 70 % UT; 25 cycles 0 % UT; 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.

Recommended separation distances between portable and mobile RF communication equipment and the device

The device is intended for use in an electromagnetic environment where radiated RF disturbances are under control. The user can help prevent electromagnetic interference by keeping the device at a minimum distance from portable and mobile RF communications equipment (transmitters). The following table details the maximum output power of the communication device:

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration – electromagnetic emissions

The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3V rms At 0.15-80 MHz 6V rms At ISM & Radio Amateur Freq.	3V rms bei 0.15-80 MHz 6V rms bei ISM & Radio Amateur-Freq.	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m at 80-2700 MHz (AM Modulation)	10 V/m bei 80-2700 MHz (AM-Modulation)	**Recommended separation distance** d = 1.2 $\sqrt{P}$ d = 1.2 $\sqrt{P}$ 80 MHz zu 800 MHz d = 2.3 $\sqrt{P}$ 800 MHz zu 2.5 GHzz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed,

Distribution
Functional Cosmetics Company AG
St. Jakob-Str. 84
4132 Muttenz
Schweiz

Distribution Center EU
Schwarzwaldstr. 31
79539 Lörrach
Deutschland

Tel: +41 61 262 10 00
Fax: +41 61 303 80 09
contact@functional-cosmetics.com
www.sweat-stop.de

Manufacturer
Durtech System Corp.
3F, No. 27, Lane 381, Fude 1ST Rd.
Xizhi Dist.Taipei 221, Taiwan, R.O.C.
Tel: +886 2 26946022
Fax: +886 2 26935668

EU Representative
AAM GmbH
Wolfsmatten 1, Bau 160
77955 Ettenheim
Deutschland
Tel: +49 7822 4039 500
Fax: +49 7822 4039 499
www.aam-med.de

functional
cosmetics