Aquex

Tap Water Iontophoresis

An effective solution for treating excessive sweating

Embrace Life with Confidence

Phothera

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Read before use

Your Aquex tap water iontophoresis device is designed to give you maximum efficiency and operability. It is easy to put into operation and simple to use. Nevertheless, the following safety instructions and legal regulations must be observed and strictly adhered to. The maintenance, care and disinfection instructions described below must be carried out regularly to ensure the proper, safe and long-term operation of your device.

Please read these instructions carefully!

Your safety is important

- The therapy device must only be operated with the Aquex AC power adapter specially selected for this medical device.
- Modifications to the therapy device are not allowed. Do not open the device. This therapy device has no operating parts inside. All service work must only be carried out by Phothera.
- To prevent burns during treatment, make sure the supplied towels, plastic grids or pads always cover the treatment electrodes. Avoid direct contact with the metallic surface.
- Several devices may not be simultaneously used by one patient.
- Prior to treatment, remove any metallic jewelry (wedding bands, etc.) which would otherwise be in touch with the water source (trays or pads). Keeping such accessories on would lead to **localized minor** (electrical) burns that are secondary to increased current densities.
- Avoid excessive treatment doses by ensuring that the patient does not experience any pain during treatment. Always treat carefully and observe the patient's reaction.
  (As a rule, avoid current intensity greater than 0.5-1.0 milliamperes per square inch of active electrode area.)
- Use only genuine accessories approved by Phothera for use with your device. Other unapproved accessories may result in unforeseen and dangerous behavior of your device.
- There are no known effects or side effects from long-term treatment with electrical stimulation currents.
- Keep the device out of the reach of children and do not leave children unattended during therapy! There is a risk of strangulation due to the enclosed cables.
- Never switch off the device while treatment is in progress. In most cases, this will result in a safe but unpleasant electric shock[1].
- Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.
- WARNING: Potential systemic adverse effects may result from the use of this device. Drugs or solutions delivered with this device have the potential to reach the blood stream and cause systemic effects. Carefully read all labeling of the drug or solution used with this device to understand all potential adverse effects and to ensure appropriate dosing information. If systemic manifestations occur, refer to the drug or solution labeling for appropriate action.

[1] Although these electric shocks are unpleasant, they are absolutely harmless.

Who is the therapy suitable for? - Contraindications

In principle, the therapy is suitable for all people from the age of 4 years. The prerequisite for this is that the therapy is carried out under the supervision of an adult.

From the age of 12, it is up to the legal guardians to decide whether the therapy can also be carried out without supervision.

Regardless of age, therapy must always be performed under the supervision of an adult if the patient is unable to understand the instruction manual and act according to the instructions contained therein (e.g. cognitive impairment).

Users with the following conditions are considered to have contraindications for iontophoresis, so treatment should not be administered unless otherwise directed by your physician:

- with a cardiac pacemaker or ICD (implantable cardioverter/ defibrillator)
- in pregnancy
- with a metal-containing intrauterine device (IUD)
- with any metal object within the electrical current path
  - The electrical current path is considered the shortest point through the body between the two electrodes. For example, the current path for a person treating hands would be from one hand in the tray with an electrode, up the arm, across the chest, down the other arm and hand to the other electrode.
  - This means that a user that has a metal screw in their leg or knee can do hand treatments, but not foot treatments
- with piercings in the contact area, which cannot be removed
- that have within the treatment area any large skin defects / wounds (too large to cover with petroleum jelly), potentially malignant lesions, acute localized infections, skin eruptions, swollen, broken, or inflamed areas
- that have within the treatment area any impaired or absent sensation (e.g. patients with polyneuropathies)
- Apply electrical current through or across the brain, or sinuses (increased risk of ventricular fibrillation)
- with suspected or diagnosed heart problems or epilepsy

Side effects

The following side effects or effects may occur for a short time after the therapy session on the skin treated:

- Mild dysesthesia (tingling or burning)
- Short-term skin irritation (reddening) after treatment
- Erythema (skin redness, transient vesicles or blisters)
- Skin irritation or burns in the areas of electrode contact have been reported with the use of electrical stimulators

Additional important safety considerations

- Place the device on a firm level surface
- Make sure that the device is at room temperature before you power it up
- The system should not be operated near shortwave or microwave devices. A minimum distance of 2 meters should always be kept
- Prior to using AC wall power, check that your outlet meets the system's requirements of 100-240 V~ and 50-60 Hz
- Unplug the AC power adapter if a thunderstorm approaches or if you do not intend to use the treatment system for a longer time
- This treatment device should only be used indoors. Do not expose the system to rain or excessive moisture
- Prior to cleaning the system, turn the device off and unplug all connectors. For cleaning, use a soft cloth moistened with a mild cleaning agent
- Do not use kerosene, thinner, alcohol, wax remover or other solvents
- Prevent kinking of the cables and do not expose them to heat or chemicals. Damaged cables must not be reused and must be replaced with new original Phothera cables
- Do not perform the iontophoresis therapy in parallel with aluminum-containing antiperspirants in the same treatment area
- Simultaneous connection of the patient to a ME unit for high-frequency surgery can result in burns under the electrode surfaces of the stimulation current unit and damage to the stimulation current unit.

Intended use / Mechanism of action

Intended Use:

This tap water iontophoresis device is intended to treat Hyperhidrosis (excessive sweating) affecting hands, feet and underarms.

Any other use or usage beyond this scope is considered unintended use and may have dangerous consequences.

Mechanism of action:

During the treatment, a current flows through the body regions that are being treated. The water in the trays or pads mediates this current flow. The skin areas in contact with the water will thereby secrete less sweat.

Although treatment success has been validated in numerous medical studies, there is still no completely satisfactory scientific explanation for the mechanism of action. Medical researchers believe that the electrical current irritates the synapses between sweat inducing nerves and sweat glands to such an extent that sweat glands can no longer be stimulated. In other words: the treatment does not affect the sweat glands directly; it only affects the nervous input to these glands.

This effect explains why the original condition returns relatively quickly when the treatment is discontinued.

The treatment current can be adjusted according to your individual sensitivity. There is no risk involved as the current cannot exceed certain maximum values.

Treatment fundamentals

The Aquex treatment concept comprises of two treatment phases:

Phase 1: In this stage (initial phase), patients learn to administer treatments. Daily or at least three weekly treatments of approximately 15 minutes each should be scheduled (not more than one treatment per day). Sweat secretion will normalize after approximately 10 treatments.

Phase 2: Long-term treatment (maintenance phase) is necessary because the Aquex treatment effect is reversible. Depending on the severity of the condition, the maintenance phase involves one to three weekly sessions of approximately 15 minutes each.

Polarity reversal and the efficacy of treatment

In principle, the effect of Aquex therapy does not depend on the direction of the current. However, clinical studies have shown that the anode (connector E1, see chapter "main system components") is slightly more effective than the cathode (E2) at the start of the initial treatment.

Automatic Polarity Reversal

The automatic polarity reversal function[1] (APR) can be activated to ensure an even treatment result on both treatment sides right from the start. After the first half of the treatment, the voltage is gently reduced to 0V, the polarity is changed and then increased to the set voltage again.
The default setting for automatic polarity reversal is DISABLED. If you want to enable this function, please follow the instructions on page 23.

[1] The PRF can only be used if the therapy time is at least 10 minutes, as shorter times would lead to ineffective treatment.

Types of current

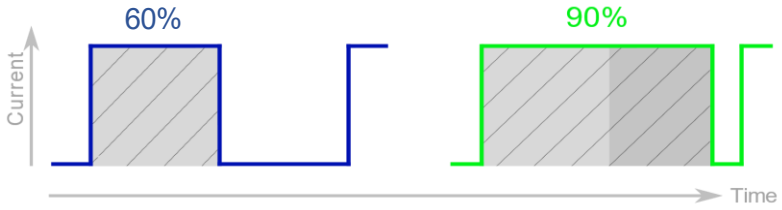
The Aquex iontophoresis therapy devices provide different types of current for optimal therapy of different areas:

- DC: Direct Current
- PC: Pulsed Current
- VPC: Variable Pulsed Current

The classic direct current (DC) has the highest efficiency. However, the current sensation of the DC is clearly distinct and sometimes unpleasant. Therefore, the use of PC or VPC is highly recommended for the treatment of sensitive skin areas (hands, armpits, face, etc.) and especially for children. Pulse current is significantly more sensitive and the "feeling" of the current is significantly reduced.

The term pulse width

The term "pulse width" used in this context describes the proportion of active current flow during the therapy in percent (for example, a pulse width of 90% means that the current flows in 90% of the time).



Direct Current (DC)

When using DC, the current flows continuously, which means 100 % of the time (corresponds to a pulse width of 100 %).

- highly effective / intense current sensation
- not recommended for children or for the treatment of sensitive skin areas (hands, armpits, face, etc.)

Pulsed Current (PC)

When using PC, the current flows alternately between ON (60% pulse) and OFF (40% pause) for intervals of equal length.

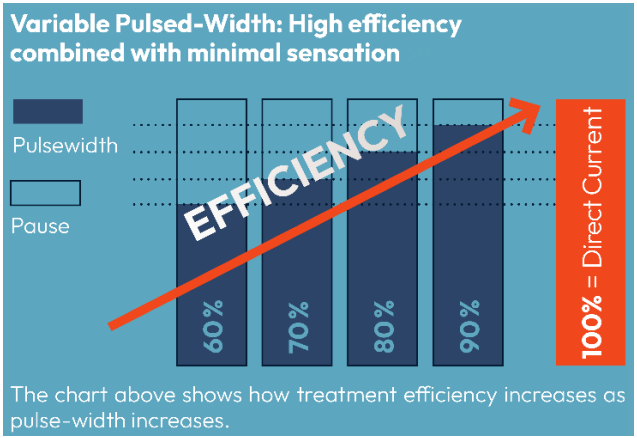
- very sensitive (little current sensation) / less effective
- not recommended for the therapy of feet or strong hyperhidrosis

Variable Pulsed Current (VPC)

The variable pulse current (VPC) can be described as a kind of combination of DC and PC. With VPC, it is possible to extend the ON phase compared to the OFF phase: e.g. 90 % pulse, 10 % pause (corresponds to a pulse width of 90 %).
The pulse width can be adjusted in 10% steps to suit individual requirements in order to achieve the greatest possible comfort with optimal efficiency.

- ⌦ very sensitive (little current sensation) / adjustable efficiency
- ⌦ recommended for all treatment areas

By increasing the percentage values of the pulse width, the length of the active current flow (pulse) is extended and the pause shortened accordingly. These shorter pause times allow more energy to be transferred than with conventional PC. The chart on the right shows how the efficiency of the therapy improves in relation to the increasing pulse width.
Extensive trials have shown that the efficiency of the pulsed current could be significantly improved in this way and is now finally also suitable for feet or particularly severe cases. The advantage of pulsed current - reduced sensitivity of the patient to the current - is not lost even with a pulse width of 90 %.



Installation / Treatment Setup

To prepare for treatment, set up your therapy device according to the following steps. Note that the set-up of the different treatment areas (hands / feet, armpits, face, neck / back) differs from each other.

Main system components and scope of delivery

I. Control Unit

① Control unit main ON/OFF switch (main power switch)
② Connector for AC adapter
(Type: HIPRO10, 12V DC)
③ Jacks for connecting the cable set to the treatment electrodes

(Anode) E1 E2 (Cathode)

II. AC Adapter

Your Aquex therapy system is equipped with a wide range AC adapter ④, which is suitable for different international mains electricity (please refer to technical data).
Depending on your region, various primary adapters ⑥ can be used for the different plug-in systems.
Your AC adapter is usually already equipped with an adapter that is suitable for your region. If required, other adapters can be plugged in, e.g. for stays abroad. Please refer to the instructions on the following page.

AC Adapter

DC Plug

Primary adapter

To change the primary adapter ⑥, press the lug Ⓐ on the bottom of the AC Adapter ④ firmly in and pull the adapter off toward the front. Plug on the required adapter from the front and press it on firmly until the lug Ⓐ snaps in.

Available primary adapters (power plugs):

Type-A (US) e.g. Japan, North and Central America
Part number: *ION19012*

Type-C (EU) e.g. Europe, South America, parts of Asia
Part number: *ION19010*

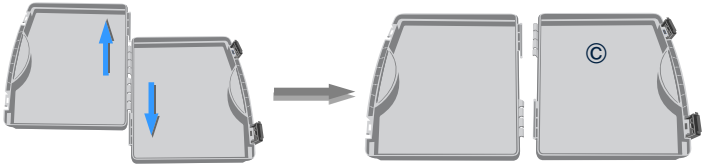
Type-G (UK) e.g. Great Britain, Malaysia, Singapore, Hong Kong
Part number: *ION19011*

III. Connecting cables

Connection cable Ⓑ for connecting the treatment electrodes to the control unit.

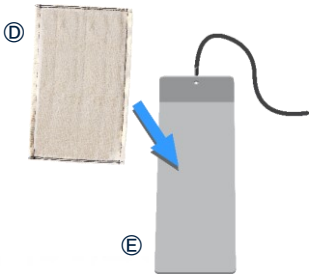
IV. Transport case and treatment tubs

The half-shells Ⓒ of the transport case are also used as treatment tubs and can be separated by simply sliding them apart[1] to ensure better handling. After treatment, the case can be easily reassembled in the same way.



V. Treatment electrodes and electrodes covers

The scope of delivery includes towels Ⓓ to cover the treatment electrodes.
Electrodes Ⓔ made of aluminum are included as standard, which are particularly suitable for patients with a chrome nickel allergy. Alternatively, you can choose electrodes made of stainless steel, which are significantly more scratch-resistant.



VI. Optional accessories

Axillary applicators Ⓘ (AX applicator) are required for therapy of the axillae.

[1] To do this, open the case completely and lay it flat on a flat surface!

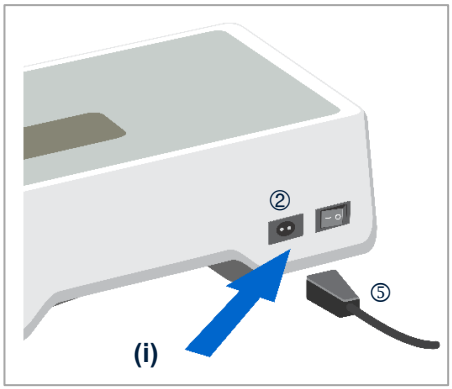
Therapy preparations (setup control unit)

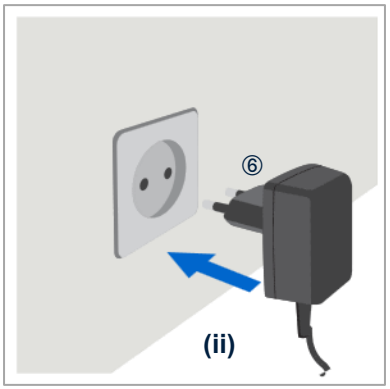
Place the therapy device in a well-lit room on a stable, level surface and make sure that you can easily disconnect it from the mains at any time. Make sure that a power outlet is accessible and do not perform therapy in excessively warm and humid rooms, e.g. a bathroom immediately after showering.

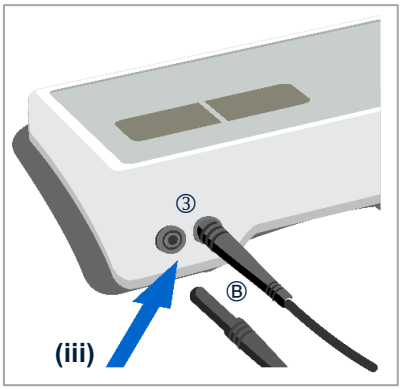
i) Connect the DC plug ⑤ of the AC adapter to the socket on the back ② of the unit.

ii) Connect the primary adapter ⑥ of the AC adapter to a wall socket.

iii) Insert the connection cables Ⓑ into the sockets on the back ③ of the unit.

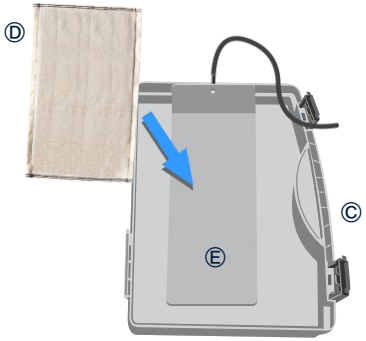






Setup for hands and feet treatment

Hands and feet are treated in a water bath. For this purpose, the two suitcase trays © are used.



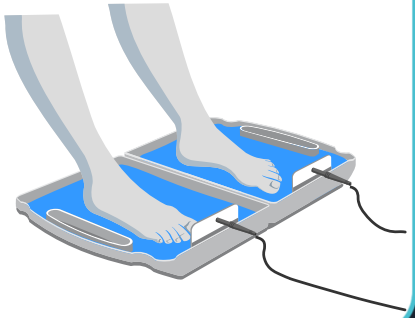
Place one treatment electrode Ⓔ in each of the two treatment trays.

Important: **Make sure to remove the protective film on both sides before using the electrodes!**

Cover the entire surface of both treatment electrodes Ⓔ with the towel Ⓓ and plug both connecting cables Ⓑ into the connectors of the treatment electrodes Ⓔ.

Important: **Plugs must be pushed firmly all the way onto the necks of the electrode connections!**

Prepare both case shells © by filling them with hand-warm tap water that allows you to immerse the skin areas to be treated well. The backs of the hands or feet should not be covered with water unless you want to treat them specifically.



Setup for axillary treatment

The Aquex axillary-applicators ① consist of 2 components:

- The pads that store the required water and form the contact surfaces to the armpit.
- The electrodes (metal or silicone, based on availability) that are used to transmit the current and are inserted into the pad.

Important: **Make sure that only one connection cable is connected to the control unit while setting up the AX-electrodes, otherwise the therapy will begin as soon as you touch both applicators!**

Metal electrodes

First plug the connection cable into the grey socket of the metal electrode. Make sure that the cable is fully inserted with a little force. This is important to ensure a good conductive connection.

Now push one metal electrode completely into each of the pads.

Important: **The plugs must be pushed firmly all the way onto the necks of the electrode connections!**

Conductive silicone electrodes

An adapter cable is used to connect the silicone electrodes. Insert the metal pin at the black end of the adapter cable into the opening on the silicone electrode. Connect the other side of the adapter cable to the treatment cables.

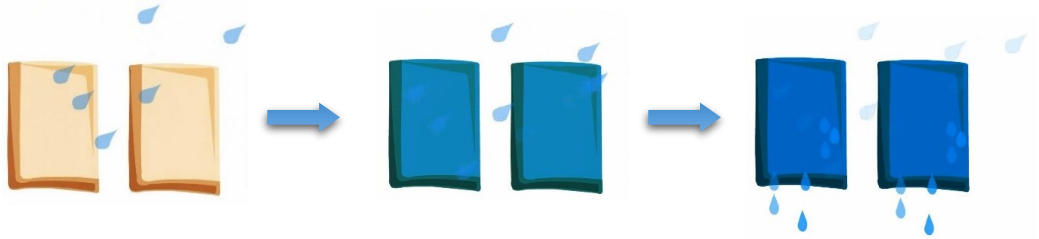
Important: **The plugs must be pushed firmly all the way onto the necks of the electrode connections!**

Important: **To avoid wear, leave the adapter cable connected to the silicone electrode even after therapy.**

Preparing the AX applicators for the therapy

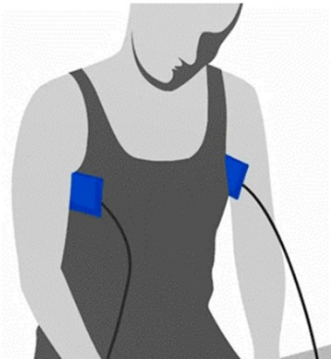
Important: **The steps described below must be carried out in the same way for both types of electrodes.**

Soak the cushions well with lukewarm tap water. Make sure that the pockets are dripping wet and barely wrung out.



Clamp the well-soaked pads under your armpits. Ensure a good fit for the largest possible contact area with the skin.

Attention: The sponge pads should store as much water as possible, as the water is needed for successful treatment and protect against burns. Just moist is not enough!



Advice: Start the treatment as soon as possible after applying the axillary-applicators to prevent them from drying out. If necessary, have a towel ready to catch dripping water.

When you have completed the setup, connect the therapy cable to the control unit to start the treatment.

Conduct therapy

Hints on conducting therapy

- Thoroughly remove residues of oil-based care products from the skin before starting treatment.
- Before each treatment, wash the therapy area with normal soap and water to remove grease and sebum from the skin. Even small films of grease can impair the current flow and cause local irritation.
- Do not use cream soap.
- Use hand-warm water, which is both more comfortable initially and slightly reduces the sensation of electricity compared to cold water.

Attention: Cover small injuries and any painful areas with petroleum jelly (e.g. Vaseline). The applied localized layer of petroleum jelly prevents the flow of current in the affected area and thus reduces tingling, burning or pain in the injured areas.

The treatment is much more pleasant this way!

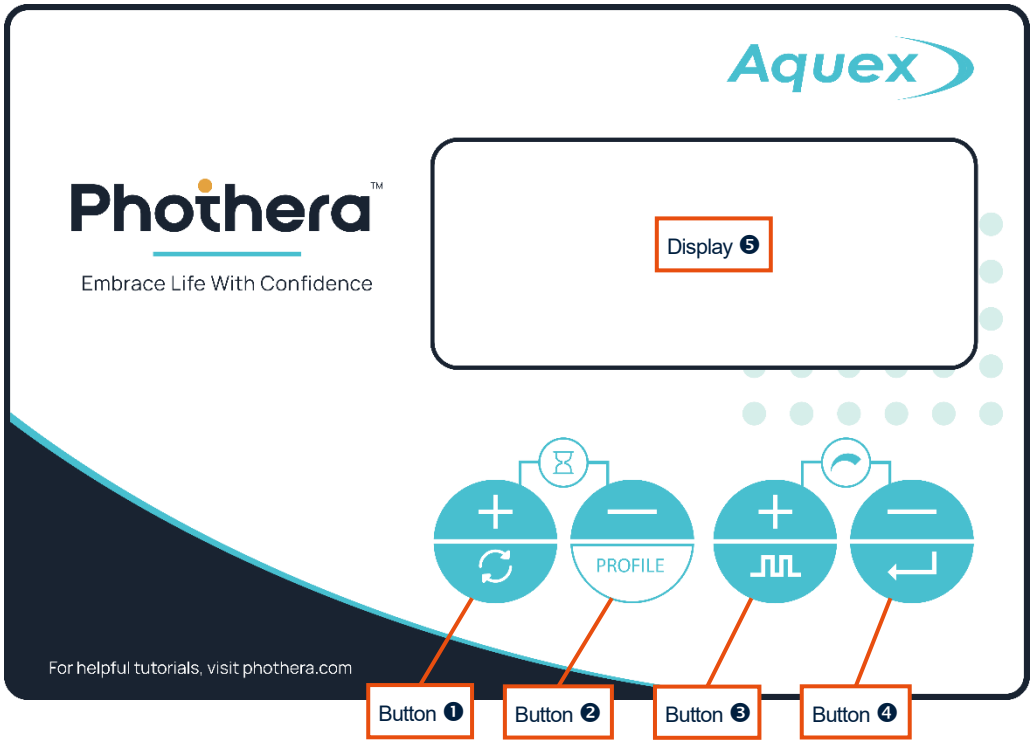
- Tap water iontophoresis leads to superficially dry skin when used frequently and especially at the beginning of the therapy. Therefore, treat your skin with a moisturizing care product immediately after each treatment.

Attention: Switch the device on at the main switch ① before closing the therapy circuit with your armpits, hands or feet.

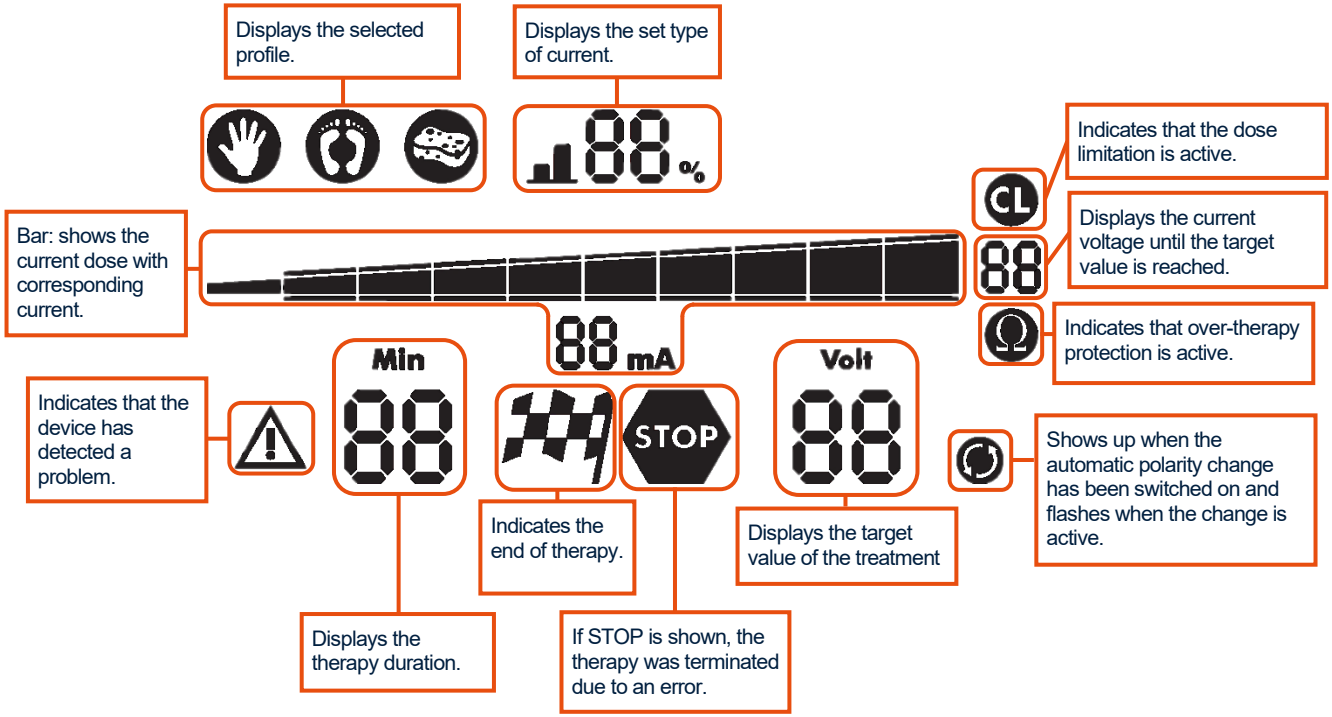
In the reverse order, a safe but unpleasant electric shock could occur despite the appropriate protective circuit.

Never switch off the device while treatment is in progress. This is highly likely to result in a safe but unpleasant electric shock ("electric fence effect").

User interface



Display elements



Basic settings and saving profiles

Your Aquex device offers you several treatment options that you must set before starting treatment. The following paragraph explains how you can carry out these basic settings and save them if necessary.

1) Switch the device on:

Once you have set up your therapy system as described in the chapter 'Installation', switch on the control unit using the main switch ①. As soon as the device has started, you will see the selected profile, the type of current, the therapy duration and dose on the display ❺.

2) Select and customize profiles :

Profiles are to be understood as memory slots. The device is shipped with factory preset parameters (see p. 24), but you can adjust the profiles at any time. To do this, select the desired profile and change the parameters. As soon as you start therapy, the values are saved automatically.

Select the profile as follows:

Description
Press and hold the ❷ button for about 5 seconds. All available profiles are now shown on the display, with the currently selected profile flashing. Briefly press the same button again until the desired profile is reached. Wait approx. 8 seconds or press the ❹ button to confirm your selection.

3) Set therapy duration

Description
Press the button ❶ to increase the therapy duration by one minute at a time (maximum 60 minutes). Press the button ❷ to reduce the therapy duration by one minute at a time (minimum 1 minute).

4) Set the treatment dose

Description
Press the button ❸ to increase the dose by one volt at a time (maximum 60 volts). Press the button ❹ to reduce the dose by one volt at a time (minimum 6 volts).

Important: For safety reasons, the treatment settings for time and dose can only be made by pressing the buttons one time for each minute or voltage change (no automatic change by holding the buttons for a longer period).

Please note that holding the buttons for longer may trigger additional functions, depending on the device version and situation.

5) Set the current type and pulse width

Type of current	Description
PC: 60% VPC: 70 – 90% DC: dc (100%)	Press and hold the button ❸ for about 5 seconds. The pulse width now flashes on the display. Briefly press the same button again until the desired setting is reached. Wait approx. 8 seconds or press ❹ to confirm your selection.

6) Activate automatic polarity reversal function (APR):

Description
Press and hold the button ❶ for about 5 seconds to switch the automatic polarity change function (APR) on or off.

Begin Treatment

If you do not know or have not been given any other treatment parameters, the following values are recommended **as starting values only** for the therapy. It is strongly recommended that you start the therapy for children with reduced voltage and pulse width. If possible, increase the value slowly and pay attention to how the patient feels!

The therapy should never be unpleasant or painful.

Profile		Adult	Child
Hand	Pulse width: Dose: Time:	90% 20 Volt 15 Minutes	80% 10 Volt 15 Minutes
Foot	Pulse width: Dose: Time:	100% 30 Volt 15 Minutes	90% 15 Volt 15 Minutes
Axillary applicator	Pulse width: Dose: Time:	60% 8 Volt 15 Minutes	60% 6 Volt 15 Minutes

When treating with special applicators (e.g. armpits or face), the dose should not exceed 15 volts, otherwise there is a risk of burning the sensitive skin.

Important: In order to avoid skin irritation due to excessive dose settings during therapy with pulsed current (the "feeling" of the current flow is almost completely prevented), it is advisable to determine the individual "limit values" for hand and foot treatment with direct current (pulse width = 100%) once before the first therapy session.

Conducting therapy

Dip your hands or feet into a tub filled with water © and place them on the towels Ⓓ.

Attention: Always remove any jewelry that would be in the water bath beforehand and make sure that your skin does not touch the electrodes directly for a long period of time!

The device detects when the circuit is closed ("immersion monitoring") and signals the start of treatment by stopping the flashing of the setting values and showing the bar graph on the display ❺. At the same time, the momentary treatment current is displayed in the middle below the bar display and the momentary dose[1] is displayed to the right of it, which slowly increases to the previously set value together with the bar display.

The treatment dose can be changed at any time using the buttons ❸ and ❹ or stopped when it increases.

Attention: If punctual pain occurs during therapy, the therapy must be interrupted immediately. Painful areas (minor skin injuries) should be covered with Vaseline.

The remaining treatment time is shown in minutes on the display ❺.

[1] If the target dose is reached, this display disappears. If the dose setting value is not reached, the display remains on (see also the note on "Dose limitation" on the following pages).

Stopping the treatment

The treatment can be interrupted at any time by lifting out the hands or feet, this stops the treatment time, the bar display turns off and the active treatment parameters (remaining time and target dose value) flash.

Attention: Never switch the device off at the main switch ① during therapy! Despite the integrated protective circuits, this often leads to a safe but unpleasant electric shock (electric fence effect).

Important: If therapy is interrupted, both the target dose and the current type and/or pulse width can be changed. The profile, APR and therapy time can no longer be changed once treatment has been started.

Continuation of treatment and end of therapy

The treatment is automatically continued by immersing the hands or feet (closing the circuit). The setting values stop flashing, the therapy time continues to run and the bar graph is shown again on the display ❺.

As the last minute of therapy elapses, the treatment dose is automatically reduced to "zero". Please do not remove your hands or feet from the water bath until the "target flag" appears on the display, signaling the end of treatment. You should only switch off the device afterwards.

Attention: Only switch the device on or off at the main switch ① when all treatment areas are disconnected from the device (e.g. hands and feet outside the water bath). Failure to do so will often result in a safe but unpleasant electric shock for the user (electric fence effect), despite the appropriate protective circuit.

Important remarks on therapy safety (protective functions and information)

Your Aquex therapy device is equipped with several protective circuits for your safety.

Immersion and switch-on monitoring

As long as you have not closed the circuit through the skin areas to be treated, the device will not deliver a therapy dose. All settings that you make when the therapy circuit is open are saved in the active profile.

If the circuit is already closed when the device is switched on, this error is detected and ⚠ E0 flashes on the display ❺. The error is cleared by opening the treatment circuit (e.g. eliminating the short circuit or removing the hands or feet) and the device is ready for operation.

Over-Treatment-Protection and therapy monitoring (OTP)

The device permanently monitors the therapy circuit and the patient's individual body values (including skin conductance). In this way, possible problems with the setup and accessories or excessively dry skin of the patient (protection against excessive therapy) can be detected at an early stage.

- If the skin conductance is too high during immersion, the treatment will not start.
- If the device detects an increased value during the ongoing treatment, the Ω symbol is displayed. In this case, you can continue the treatment for the time being, although the success of the treatment is likely to be significantly impaired if the cause is not rectified.
- If the maximum value is exceeded for longer than 5 seconds, the dose is reduced completely; the symbols ⚠ E2 and Ω are displayed and treatment is aborted[1] STOP.

Hint: If the device displays one of the warning messages for a longer period or repeatedly at the start or during treatment, check the basic therapy setup and the electrodes for calcification[2] after the treatment session. In particular, check that all cable connections are fully plugged in or disconnect them briefly and reconnect the cables. If necessary, carry out the function check described in the chapter Function test or ask any other person to use the device for a short time and observe whether the warning no longer appears.

If a warning message is still displayed in both cases or the device does not start, please contact us.

Important: If your device starts properly in the function test and does not issue any errors or warnings, the over therapy protection function is most likely active. In this case, please suspend therapy until the excessive sweating is clearly noticeable again or for at least 2 to 3 weeks.
If this does not help, please contact us.

[1] You must restart the device to start a new treatment.
[2] Further information on dealing with calcification on the electrodes can be found in the Cleaning, care and maintenance chapter.

Dose limitation CL[1]

For your safety, the device permanently monitors the maximum permitted treatment current. This may mean that the dose you have set cannot be reached. In this case, the protection circuit of the current limitation intervenes and stops any further increase of the dose.

This protects you from burns and has no negative influence on the success of the treatment!

The symbol CL is displayed as long as the dose limitation is active. The number below also shows you the dose at which it was stopped. The device will continue to attempt to reach the original target value at regular intervals.

During the following treatment sessions, higher doses can be achieved successively as the sweating subsides.

Hint: Due to the reduced sensation of the current, this protective circuit appears to start more quickly in pulsed current mode. In this case, increase the set pulse width if necessary (and if tolerated) in order to achieve a higher treatment efficiency. The highest dose values and best efficiency are achieved with 90 % pulse width or with direct current (dc = 100 % pulse width).

Protection function against a short circuit

Your device has a function that protects it against short circuits. If a short circuit is detected, the symbols ⚠E1 and CL are displayed and the device is locked[2] STOP.

If you have any questions or problems regarding the setup of the treatment system or the implementation of the therapy, please visit www.phothera.com

[1] CL = Current-Limitation
[2] To start a new treatment, the device must be restarted.

Care and maintenance

This chapter contains information that you should observe when using your Aquex system.

Special remarks

Our responsibility for system safety, functionality, and reliability applies only if any maintenance and service is exclusively performed by an authorized Phothera repair center. Our warranty ceases, and we assume no liability if any manipulation or service is performed by unauthorized personnel.

Multi Patient use

The Aquex iontophoresis therapy devices are suitable to be used by multiple patients in medical facilities to perform initial and / or maintenance therapy under the supervision of an attending physician.

As a multi-patient use device, the following protocols should be obeyed:

- Each patient will be provided with **their own** consumables for iontophoresis treatment (towels Ⓓ or sponge applicators)[1], which can be re-used for every session.
- Between treatments, the electrodes Ⓔ and tubs (case shells Ⓒ) must always be cleaned, dried and disinfected, as described in the following section.

Hint: It is at the physician's discretion whether to issue (sell) either the actual device used during in-office treatments or a brand-new device to any given patient.

[1] It is suggested that the consumables are given to the patient to take home and clean themselves and then bring them back to subsequent sessions.

Care and purification

For a flawless and long-lasting function of your Aquex system, we recommend the following steps after each use:

Attention: Before cleaning, make sure that the device is switched off and disconnected from the power supply. Do not use petroleum, thinner or other solvents.

Care after each treatment:

- Dry the electrodes Ⓔ with a soft cloth to prevent calcium deposits on the metal.
- Dry the treatment tubs (case shells Ⓒ) with a soft cloth and let them air-dry (do not close the hard case tray due to humidity).
- Rinse the towels Ⓓ thoroughly with hot water. Then remove any residual liquid by letting them air-dry.

Purification / Cleaning (every 5 sessions or whenever necessary):

- The control unit, the treatment tubs Ⓒ and electrodes Ⓔ should be cleaned with moistened cloth or with a common detergent.

Attention: Calcifications on the electrodes Ⓔ can hinder the current and efficacy of the treatment. This mineral build-up can be removed with a common descaler, or even vinegar or citric acid.
A discoloration of the electrode metal after the first couple of therapy sessions is normal, does not affect efficacy, and does not indicate mineral build-up.

Maintenance

Aquex tap water iontophoresis devices are basically maintenance-free.
Nevertheless, maintenance-free does not mean that cleaning as described in the previous section on Care and Purification does not have to be carried out regularly to ensure the longevity of the system.

Disinfection

Because only unscathed skin will be treated, the Aquex iontophoresis therapy devices are classified as "non-critical"[1] concerning disinfection.

As a multi-patient use device, the following protocol should be obeyed:

- Spray the electrodes Ⓔ, connecting cables Ⓑ and the treatment tubs (case shells Ⓒ) with a surface disinfectant, so that all areas are covered.
- Let the disinfectant[2] remain on the surface as directed by its instructions and then wipe it dry with a clean cloth.
- Consumables (towels Ⓓ and sponge applicators) must be replaced with new / patient's own.

Reconditioning

Aquex iontophoresis devices are reusable medical devices and can be reconditioned after use from a customer. The reconditioning of the devices is classified as “non-critical”[3].

The reconditioning should be done only by an authorized Phothera repair center. If a device is to be re-conditioned, the following actions will also be taken:

- Disposal of consumables (towels Ⓓ, sponge applicators, treatment electrodes Ⓔ) and replacement with new ones.
- Cleaning and disinfection of the control unit, the AC adapter ④ and the accessories (transport case Ⓒ, connection cable Ⓑ)
- A functional check and safety inspection must be completed and documented.

The medical device may be reconditioned up to 10 times.

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[1] Regular disinfection is not mandatory for home therapy for non-changing patients.

[2] Henkel: Sagrotan Hygienespray (EAN: 4053700260218 · PZN: 01181239),
ECOLAB: Incidin Liquid (EAN: 4028163033396 · PZN: 07503098)

[3] Observe the joint recommendation of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene requirements for the reprocessing of medical devices" [Bundesgesundheitsblatt 55 (2012):1244-1310 with supplement Epidemiological Bulletin No. 68 (February 2018)]

Troubleshooting

If your Aquex iontophoresis therapy device does not function as described in the accompanying documents and these instructions, please first go through the following checklist and carry out the function test described below before sending the device in for repair. You may save yourself and us time, effort and avoid costs for an inspection by us.

Error checklist

Please go through this checklist as the first step in troubleshooting:

- ☒ Verify that the AC power adapter ④ is properly connected to the control unit and to the wall outlet.
- ☒ Verify that the connectors on the cable set Ⓑ are pushed far enough onto the receptacles of the treatment electrodes Ⓔ for establishing a reliable connection.
- ☒ Verify that the device works properly on another person. If it does, the OTP or other monitoring functions may be active.

Hint: In rare cases, tap water conductance may be inadequate (e. g. when tap water deionizing equipment is in use). In that case, try non-carbonated mineral or table water instead to raise the current.

Error codes

⚠ E0	The switch-on monitoring prevents the device from starting (see pp. 27, section Immersion and switch-on monitoring)
⚠ E1	Short circuit between the treatment electrodes (see pp. 27, section Protective function against short circuit)
⚠ E2	The overtreatment protection function is active (see pp. 27, section Overtreatment protection and therapy monitoring)

Operational check

Proceed with the following steps for an operational check of your system:

1) Set up the therapy system as you would for treatment.
2) Switch on the device at the main switch ①. The display ❶ should show values for dose and treatment duration.
3) Now close the therapy circuit by placing one electrode Ⓔ on the towel Ⓓ of the second electrode without the electrodes touching each other directly. Both electrodes are now lying on top of each other in a tub filled with water (separated by a cover).
4) The setting values on the device should now stop flashing, the bar graph should appear, and the dose should slowly increase. In addition, no warning or error messages should appear on the display.

If, even taking the error checklist into account, the treatment does not start without errors, please contact us to discuss the next steps.

Shipping the device for repair or maintenance

The device should only be shipped in the supplied carrying case Ⓒ. If possible, use the original packaging material for shipping. Make sure the device is protected against impact inside the case and that packaging is suitable for shipping.

Prior to shipping, do not forget to clean and dry the system and the accessories. Please do not ship towels Ⓓ or sponge applicators.

Please send all electrical accessories (AC power adapter ④, electrodes Ⓔ, and cable set Ⓑ) together with the control unit.

Applicable regulations and legal requirements

All applicable rules and regulations of the country in which the device is operated must be complied with in relation to the operator location (e. g. medical facility) under the sole responsibility of the operator.

Hint: Individuals who only use the device privately usually do not have to comply with special requirements.

Lifespan

Legal reasons limit the lifespan of this medical device to 4 years. The manufacturer must recondition the medical device not later than the end of this period. Each successful reconditioning by the manufacturer extends the lifespan of the medical device by 2 years. If the Aquex iontophoresis system is reconditioned for the same patient, the treatment trays or carrying case (depending on their condition) do not necessarily have to be replaced.

Symbol Legend / Manufacturer / Device Identification

	Caution, Power Output	Connector for electrodes, E1 = Anode, E2 = Cathode
	Application part Type BF	Device leakage currents comply with standards – the system provides protection against electrical shock (Type B); device is insulated (floating) (Type F).
	Prescription Use Only (USA)	Federal law restricts this device to sale by or on the order of a physician.
	Indoor Use Only	Do not expose the device to moisture and use it only in closed rooms.
	Consult Instructions for Use	Read and understand the instruction manual before you start treatment or using the device.
	Not for General Waste (EU States) (ElektroG, WEEE)	The device is reusable and not contaminated at end of life (complies with WEEE-Directive).
	Manufacturer	HIDREX GmbH, Otto-Hahn-Str.12, 42579 Heiligenhaus, Germany, info@hidrex.de, www.hidrex.com
FDA cleared		The device has been cleared through a 510(k)-pre-market submission process.
	GTIN	Device Identification: 14-digit unique DI# (Gtin)
SN	Serial Number (part of UDI)	
IP41	Degree of protection of the housing	1st digit = protection against contact / foreign bodies 2nd digit = protection against water

Electromagnetic Compatibility (EMC)

Aquex devices are developed and manufactured after the stipulated guidelines for electromagnetic compatibility (EMC).

Attention: Medical-Electric-Appliances are subject to particular EMC precautions and must be installed and be put into operation according to the following EMC-Hints.
Wearable and mobile HF-Communication facilities, like portable phones or pagers can influence medical-electric-appliances!

Please note the guidelines and manufacturer's declarations according to **DIN EN 60601-1-2**, which you can request from us.

EMI-WARNING:

RADIO WAVE SOURCES MAY AFFECT DEVICE CONTROL
Radio wave source, such as radio stations, TV stations, amateur radio (HAM) transmitters, two-way radios, and cellular phones, can affect powered devices.
Following the warning listed below should reduce the chance of incidents, which could result in serious injury.

1. Do not turn ON hand-held personal communication devices, such as citizens band (CB) radios and cellular phones that are not at least 2 meters away, while the device is turned ON;
2. Be aware of nearby transmitters, such as radio or TV stations, and try to avoid coming close to them; We recommend a minimum distance of 2 meters.
3. If unexpected events occur, remove treated area from the water and turn the powered device OFF;
4. Be aware that adding accessories or components, or modifying the powered device may take it more susceptible to interference from radio wave sources
   (**Note**: There is no easy way to evaluate their effect on the overall immunity to powered device)
5. Report all incidents of unexpected events to the powered device manufacturer and note whether there is a radio wave source nearby.
6. Portable and mobile radio-frequency communication devices, such as mobile phones and pagers, can affect medical devices.

Important Information

1. 20 volts per meter (V/m) is a generally achievable and useful immunity level against interference from radio wave sources (as of May 1994) (the higher the level; the greater the protection).
2. This device has an immunity level of 20V/m with no accessories connected to the device.

Aquex iontophoresis devices should be used in an electromagnetic environment as listed below.

Table 1 Electromagnetic Emissions

Emission tests	Conformity	EMC environment - Guide
RF emission following CISPR 11	Group 1	The test unit generates RF energy only for internal use. Radiation thus is low, and it seems unlikely that adjacent medical apparatus is perturbed
RF emission following CISPR 11	Class B	Aquex iontophoresis devices are suitable for use in all establishments, including domestic establishments and those directly connected to a public low-voltage power supply network that supplies buildings used for domestic purposes.
Mains harmonics following IEC61000-3-2	Class A	
Emission of voltage dips/ flicker following IEC61000-3-3	Complaint	

Table 2 Electromagnetic Immunity

Susceptibility	IEC 60601-1-test level	Compliance level
ESD IEC 61000-4-2	+/-8 kV cd +/-15 kV ad	+/-8 kV cd +/-15 kV ad
Bursts IEC 61000-4-4	+/-2 kV mains +/-1 kV I/O	+/-2 kV mains +/-1 kV I/O
Surges IEC 61000-4-5	+/-1 kV dm +/-2 kV cm	+/-1 kV dm n/a
Voltage drops etc IEC 61000-4-11	Reduction to	Reduction to
	5 % for 10 ms / positive amplitude	5 % for 10 ms / positive Amplitude
	5 % for 10 ms / negative Amplitude	5 % for 10 ms / negative Amplitude
	40 % for 100 ms	40 % for 100 ms
	30 % for 500 ms	30 % for 500 ms
	0 % for 5000 ms	0 % for 5000 ms
H-field at 50/60 Hz IEC 61000-4-8	3 A/m	3 A/m

Table 4 Electromagnetic Immunity – None Life Support Equipment

Susceptibility	IEC 60601-1-test level	Compliance level
Conducted RF IEC 61000-4-6	3 Veff 150 kHz to 80 MHz	3 V
Radiated RF IEC 61000-4-3	3 Veff 80 MHz to 2.5 GHz	3 V/m

Table 6 Recommended Separation Distances

Output power of transmitter W	SAFETY DISTANCE DEPENDING ON FREQUENCY / M		
	150 kHz to 80 MHz	80 MHz to 800MHz	800 MHz to 2.5 GHz
0.01	0.12 m	0.12 m	0.24 m
0.1	0.37 m	0.37 m	0.74 m
1	1.17 m	1.17 m	2.34 m
10	3.69 m	3.69 m	7.38 m
100	11.67 m	11.67 m	23.34 m

Waste management and packaging of electronic and devices

Our packages and the transportation-protection-parts were produced out of non-polluting, salvageable materials. The form parts are from PS (foamed, Polystyrol free of FCKW), foils and bags are from PE (Polyethylene) and outside package are of cardboard. Dispose all package parts in an environmentally acceptable way.

If the device can no longer be used, please dispose of it properly. The national ordinances are to be heeded regarding any other parts.

Appliances that are marked with the marginal symbol cannot be disposed of with the house-garbage. You are indebted to dispose of such electro and electronics garbage separately.

Please inform yourself about the possibility of regular waste disposal within your community. With separate waste disposal, you supply the garbage to the recycling center. Please help prevent incriminating materials from going into the environment (ElektroG).

WEEE-Reg.-#.: DE 42510094
Manufacturer-#. Duales System Interseroh: 134502 (VerpackV)

Technical Data

Control Unit

Display-Tolerance	**Treatment Voltage (Dose)**	**Treatment Current**	**Treatment Time**
	± 2 V	± 1 mA	± 1 %
Dimensions	**W x H x D**		
	190 x 49 x 137 mm		
Mass	**Net Weight**		
	0,5 kg		
Power Input	**Input Voltage**	**Max. Input Current**	**Input Power**
	12 V	500 mA (Fuse)	max. 6 VA
Environment – Storage and Transport	**Temperature**	**Rel. Humidity**	**Air Pressure**
	-25°C bis +70°C	30% bis 70%	700 hPa bis 1060 hPa
Environment – Usage	**Temperature**	**Rel. Humidity**	**Air Pressure**
	10°C bis 40°C[1]	30% bis 70%	700 hPa bis 1060 hPa
Output	**Treatment Voltage**	**max. Current**	**Treatment Current**
	6 - 60 VDC	35 mA (Fuse)	0 - 30 mA
	max. Output Power	**Pulse Repetition Frequency[2]**	
	2 W	9.9 kHz (for PC or VPC only)	

[1] The maximum temperature of touchable parts determined in the laboratory under the most unfavorable conditions was 46.2°C.
[2] Only applies to devices that have the current type pulse current (PC) or variable pulse current (VPC).

AC Power Adapter Type: Friwo FW8002M12 (Use genuine parts only!)

Input	Input Voltage	100-240 V~ / 50-60 Hz
	max. Current	400 mA
Output	Output Voltage	12 V_{DC}
	max. Output Current	0,6 A
	max. Output Power	7,2 VA

Current densities of the applicators and electrodes

Applicator / Surface	Contact Area [cm^2]	Current density at 30 mA [mA/cm^2]	short-term peaks at 35 mA [mA/cm^2]
Hand-Feet, Hard Shell Case Water Surface	818	0,037	0,043
Hand-Feet, HF-Electrode	397	0,075	0,088
AX-Applicator	180	0,17	0,19

Electrodes

	Material	Dimensions (H x B)
HF-Electrodes	1.4301-2b (Stainless Steel) or AlMg3 (Aluminium)	34,5 x 11,5 cm
AX-Electrodes	AlMg3 (Aluminium)	4.5 x 4 cm
AX-Electrodes	Conductive silicone rubber	9.8 x 5 cm
pH-Puffer	none	

Tap Water Iontophoresis

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