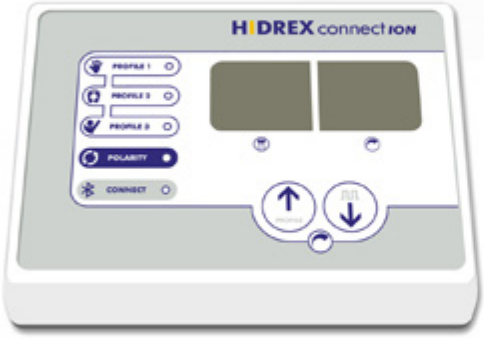
HIDREX® MED

USER GUIDE

ClassicION & ConnectION

TWI (Tap Water Iontophoresis) Treatment for Hyperhidrosis (excessive sweating)



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Read Before Use

Your HIDREX tap water iontophoresis device is designed to maximize functionality and usability. System setup is easy, and the device is simple to operate. However, the following safety instructions and legal regulations must be observed and strictly adhered to. To ensure the proper, safe and long-term functioning of your HIDREX iontophoresis device, the following maintenance, care and disinfection instructions must be performed regularly.
Please read this information carefully!

Your Safety Is Important

- This treatment system may only be powered by the HIDREX AC power adapter (which can be identified by a HIDREX nameplate with Serial-No.). This power supply is especially designed for this device.
- A change of the therapy device is not allowed. Do not open the device. This therapy device has no controls inside. All service work is only to be carried out by HIDREX GmbH.
- To prevent burns during treatment, make sure the supplied plastic nets 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 application of more current as can be safely and comfortably tolerated by the patient. Always treat carefully and observe patient reaction.
  (As a rule, avoid current intensity greater than 0,2mA/cm^2 of active electrode area.)
- Use only genuine accessories approved by HIDREX for use with your device. Other unapproved accessories may result in unforeseen and dangerous behavior of your device.
  Please follow the instructions for your accessories, as well.
- The long-term effects of chronic electrical stimulation have not been established.
- 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.
- Do not turn the device off during the therapy. In most cases this causes a safe but uncomfortable electric shock[1].

[1] These shocks are unpleasant, but absolute safe.

Who Is The Therapy Suitable For? - Contraindications

In principle, the therapy is suitable for all persons 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 having 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 electric current path
  - The electrical current path is considered as 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, or 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 treated skin areas:

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

Additional Important Safety Considerations

- ⓘ Place the treatment device on a firm level surface
- ⓘ Make sure that the treatment 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 cable and do not expose the cable to heat or chemicals. If the cable is damaged, unplug it from the device and have it checked by an authorized HIDREX repair center
- ⓘ Do not perform 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, face, back/ neck and underarms.

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

Mechanism of Action:

During the HIDREX treatment, a current flow 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 limits.

Treatment Fundamentals

The treatment concept of the HIDREX Tap-Water-Iontophoresis (TWI) comprises two treatment phases:

Phase 1: The initial phase (therapy initiation) is sometimes conducted under a doctor's supervision. During this stage, patients learn to administer treatments. For therapy initiation, 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 therapy) is necessary because the TWI treatment effect is reversible. Depending on the severity of the condition, maintenance therapy involves one to three weekly sessions of approximately 15 minutes each.

Hint: It is up to the doctor to decide whether the initial therapy should be partially or fully performed at the medical facility or at home with a loaner.

Hint: When using a special applicator, it is essential that you carry out a trial phase. Instructions for this trial phase are enclosed with your applicator.

Efficacy Of Treatment And Polarity Reversal

In theory, the efficacy of Tap-Water-Iontophoresis (TWI) does not depend on the direction of current flow. However, it has been clinically documented that the area being treated with the anode (connector ③A, see chapter Main System Components) will produce slightly better results initially than the area being treated with the cathode (connector ③B).

HIDREX connect *ION* - Automatically Change of Polarity:

For a balanced therapy result on both treatment sides from the beginning of the treatment, the polarity reversal function[1] (PWF) can be activated. Therefore, the voltage will be gently reduced to 0V at the first half of your treatment session, changes the polarity and rises back to your set voltage.

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

HIDREX classic *ION* - Manually Change of Polarity:

Despite this slight difference in efficacy in the current flow, it is recommended to conduct all treatments in the initial phase (Phase 1) without changing polarity until one side reaches an acceptable dryness level. Once normal or acceptable dryness has occurred in one side of the treatment area (for example, right hand), then it is advisable to reverse polarity and continue the initial phase without changing polarity up to normal or acceptable dryness has occurred in the other side of the treatment area (for example, left hand).

Once normal or acceptable dryness has occurred in both sides of the treatment area (for example, both hands), then it is advisable to reverse polarity for each treatment during the maintenance phase (Phase 2).

Polarity is reversed simply by changing which side of the treatment area is treated by the anode or cathode.

For example, on the first treatment in the maintenance phase, if the right hand was treated with the anode and the left hand was treated with the cathode, then on the next treatment, the right hand would be treated with the cathode, and the left hand would be treated with the anode. This sequence would continue for every treatment.

Remark: Failure to do this does not cause any harm or side effects. Long-term treatment results do not depend on the direction of current flow.

Types Of Current

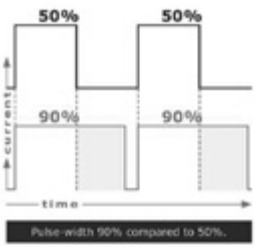
The HIDREX devices have several options for the type of current used during treatment of different areas:

- DC: Direct Current (Standard)
- PC: Pulsed Current
- VPC: Variable Pulsed Current

The classic direct current (GS) has the highest efficiency. However, the current sensation of the GS is clearly distinct and sometimes unpleasant. Therefore, the use of PS or VPS is highly recommended for the treatment of sensitive skin areas (armpits, face, etc.) or 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 defines a parameter of the proportion of active current flow during the therapy in percent (for example, a pulse width of 60% means that the current flows in 60% of the time)



Direct Current (DC):

In DC, the current (voltage) is being transmitted 100% of the time.

⊠ highly efficient / distinct feeling of current (sometimes painful)

Pulsed Current (PC):

In PC, the current alternates its transmission between ON (the pulse) and OFF (the pause) for equal lengths of time. The pulse and the pause are the same duration[1].

⊠ sensitive (less feeling of current) / typically slightly less effective

⊠ not recommended for treatment of feet or strong hyperhidrosis

Variable Pulsed Current (VPC):

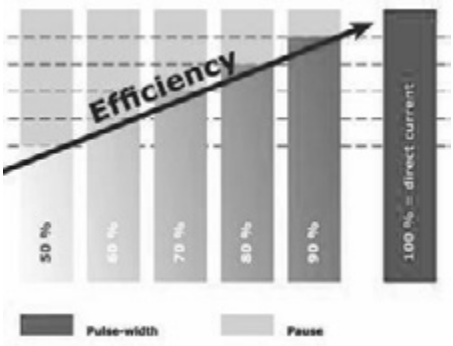
VPC is a type of hybrid current between DC and traditional PC and allows for the ON part of the cycle (the pulse) to run longer than the OFF part of the cycle (the pause).

This device allows you to change the pulse-width in 10% increments (for example, ON 60% and OFF 40% or ON 70% and OFF 30%, etc.). This allows for more effective treatment AND a better comfort level. It is customizable for your preferences and tolerance levels.

⊠ very sensitive (low current sense) / customizable effectiveness

⊠ recommended for all treatment areas

With increasing percentages of the pulse-width, the length of the pulse is increased, and the length of the pause is decreased accordingly. Due to the shorter pause, more current is applied than in PC. The chart to the right shows how treatment efficiency increases as pulse-width increases.



Extensive trials showed that the efficiency of pulsed current could be increased dramatically. The effectiveness is not reduced at all compared to direct current when the pulse-width is 90%.

[1] for example, 50 microseconds ON and then 50 microseconds OFF, and then the cycle repeats

The following overview shows you which types of current are available to you, depending on the variant of your control unit:

Control Unit	Type of current	Pulse-width
Hidrex classic *ION*	Direct current (DC) Pulsed current (PC)	100 50
Hidrex connect *ION*	Direct current (DC) Pulsed current (PC) Variable Pulsed current (VPC)	100 50 60, 70, 80, 90

Installation / Treatment Setup

To prepare for treatment, set up your therapy device according to the following steps. Please note that the different treatment areas (hands / feet, armpits, face, neck / back) have different set-ups. These instructions describe the structure for the hand / foot treatment. For the set-up for other areas, please refer to the instructions enclosed with the special applicators.

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 (12V DC)
③ Jacks for connecting the cable set to the treatment electrodes

II. AC Adapter

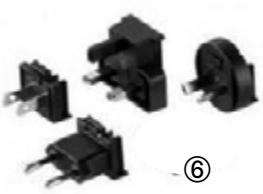
Your HIDREX therapy system is equipped with a wide range AC adapter, which is suitable for different international mains electricity (please refer to technical data).

This AC adapter gives the user the option to change different primary adapters (also referred to as mains or wall plugs) as alternatives. The AC adapter of

your system is usually connected with the fitting plug for your region. To change the mains plug, please refer to the following instructions:

AC Adapter

DC Plug

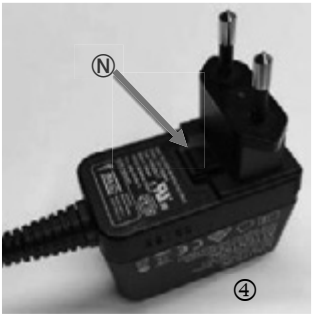


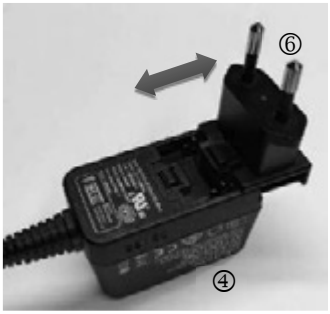
Mains plug adapters

Available Mains Plug Adapters (optional accessory):

Type-A	(US)	i.e. Japan, North and Central America
Type-C	(EU)	i.e. Europe, South America, parts of Asia
Type-G	(UK)	i.e. Great Britain, Malaysia, Singapore, Hong Kong
Type-I	(AUS)	i.e. Australia, China

Remove mains plug adapter by pressing the catch Ⓝ at the bottom side powerful and pull the adapter towards the front.
Insert the desired mains plug adapter at the front of the AC adapter and push it firmly until the catch Ⓝ locks.



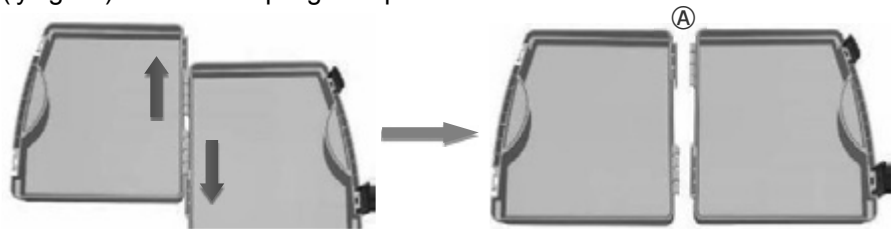


III. Cable Set

To connect the treatment electrodes to the control unit, use the two connection cables Ⓓ.

IV. Carrying Case and Treatment Case

The case shells are also used for treatment. For better handling, the two sides of the case Ⓐ can easily be separated by pushing the left side away from you while pulling the right side toward you. The case must be completely open (lying flat) before attempting to separate the sides.



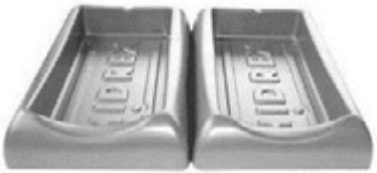
V. Treatment Electrodes and Electrode Cover

You will receive plastic nets to cover the treatment electrodes. As standard, the electrodes are made of stainless steel, but patients with a chrome-nickel allergy also have the option of having electrodes made of aluminum.

VI. Optional Accessories

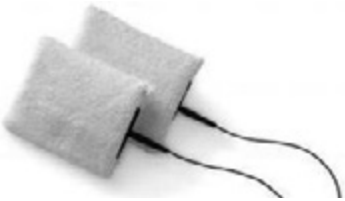
The optional accessories are not included and can be ordered separately if required.

Ⓕ The ergonomic trays can be used for treatment instead of the carrying case. The rounded and extended edge provides a much more comfortable surface for the forearms, especially when treating the hands.

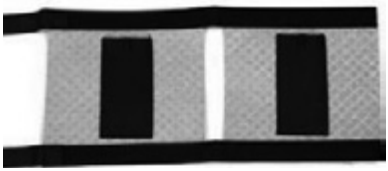


Ⓗ The face mask is needed for the therapy of the face and consists of 2 components. On the one hand the black rubber electrode and on the other hand the sponge material.

Ⓖ The axillary applicators are needed for the therapy of the armpits.



① The neck and back applicators are needed for the therapy of the neck and back.



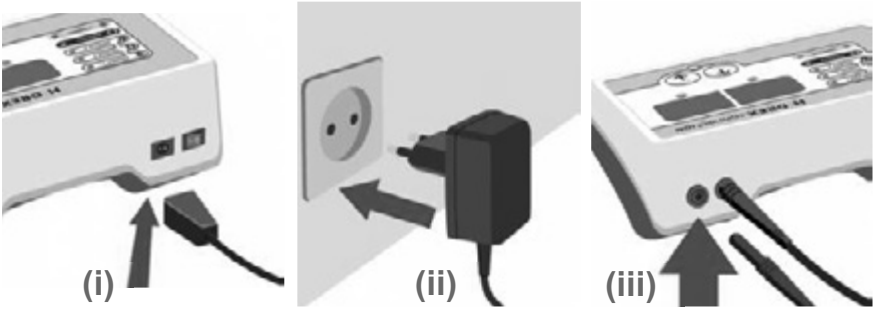
Ⓙ The DUO set for simultaneous treatment of hands and feet consists of a pair of adapter cables, a pair of treatment electrodes and a pair of ergonomic trays.

Therapy Preparations (Setup Control Unit)

Place the device in a well-lit room on a firm, level surface and make sure you can easily disconnect it from the power supply at any time. Ensure a wall outlet is within reach and do not carry out the therapy in excessively warm and humid rooms, e.g. a bathroom immediately after a shower.

i) Insert the AC adapter cable ⑤ into the jack ② on the rear panel.
ii) Plug the AC adapter ④ into an AC wall outlet.
iii) Plug the color-coded connectors of the cable set Ⓓ into the jacks ③ on the back panel to their matching colors

Make sure that the plugs are pushed firmly onto the electrodes!



Setup for Hands and Feet Treatment

Place one electrode[1] Ⓑ into each side of the carrying case or ergonomic tray as pictured at right.
When using the ergonomic trays Ⓕ, make sure that the pulled-down side of the tray (palm rest) is on the side facing you.
Cover each electrode Ⓑ with one treatment cloth Ⓒ over the entire surface and insert the two connection cables Ⓓ according to the colors on the connections of the treatment electrodes Ⓑ.

Make sure to forcefully push the connectors all the way onto the necks of the treatment electrodes.

Fill both case sides Ⓐ or ergonomic trays Ⓕ with warm tap water so that the skin surfaces to be treated are well submerged. The tops of the hand or feet should not be covered with water, **unless those areas need to be treated.**

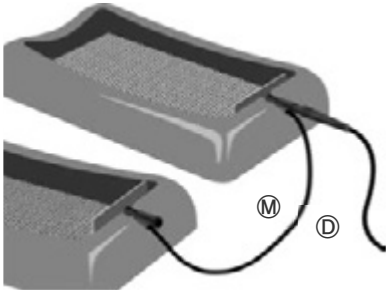
Simultaneously Treatment of hands and feet:

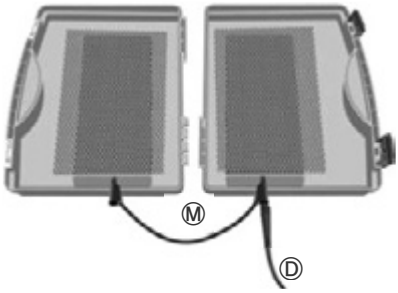
For the simultaneous treatment of hands and feet, you need additional accessories to work with the included components for hand-foot treatment. The following items are required: 1) a set of ergonomic trays Ⓕ 2) the accessory set DUO Ⓙ (consisting of a pair of treatment electrodes Ⓑ, plastic nets Ⓒ and DUO connection cables).

The carrying case can be used for foot treatment, and the ergonomic trays can be used for the hands. One plastic net and one electrode should be placed into each case side and tray, and then the sides and trays should be filled with hand-warm tap water.

[1] Please remove the protective foils from the electrodes before using them!

The DUO cables Ⓜ are utilized to connect two electrodes each to one of the grey cables as pictured below:





Now start the treatment in accordance with the instructions in the chapter “Conduct Therapy”.

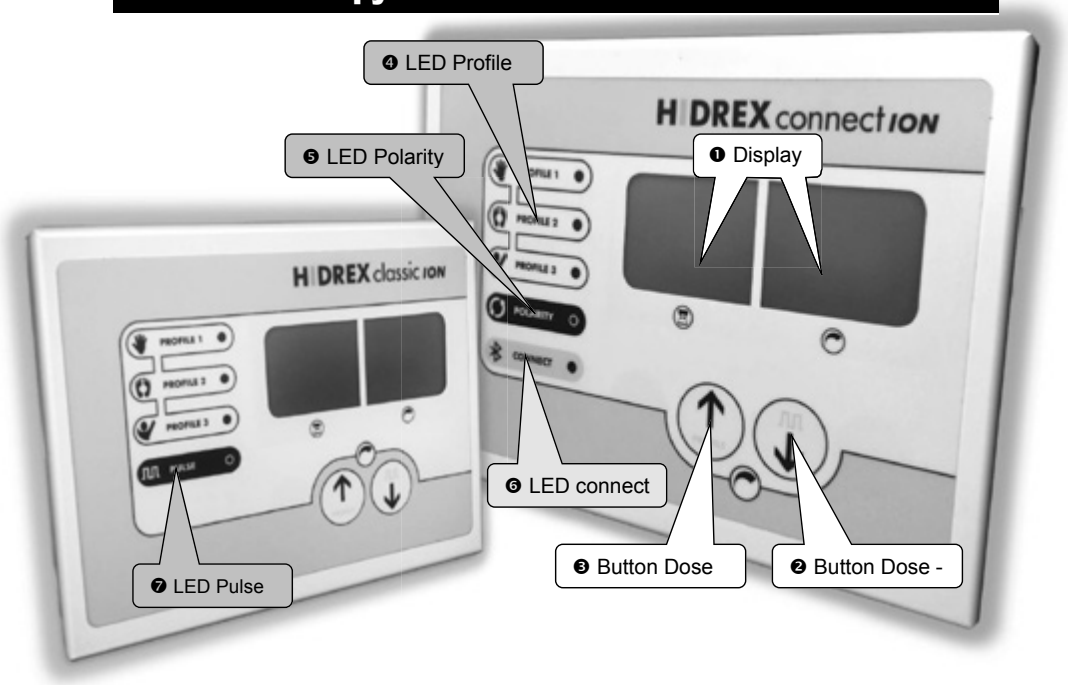
Please note that the simultaneous therapy of hands and feet does not always achieve the optimal result. This is due to the probable different voltage requirements and recommended pulse-width for each area. (Due to thicker skin and less sensitivity, the feet are usually treated with higher doses than the hands, and a higher pulse-width can usually be tolerated).

If the therapy does not have the expected effect on the feet, you should treat the hands and feet separately.

Hints On Conducting Therapy

- Before starting treatment, thoroughly remove residues of fat-containing care products from the skin.
- Wash the therapy area (e.g. hands) before each treatment with normal soap and water to remove the skin's own fat and talc. Even small films of fat can impair the flow of current and lead to local irritations.
- Do not use cream soap.
- Tap water iontophoresis leads to dry skin with frequent use and especially at the beginning of therapy. Therefore, treat your skin immediately after each treatment with a moisturizing care product.
- Use warm water, which is more absorbent and reduces the sensation of electricity compared to cold water.

Conduct Therapy



❷	**Reduction of dosage** before and during treatment and choice of current type (DC, PC or VPC) [VPC only for **Hidrex connect *ION***]
❸	**Increase of dosage** before and during treatment and selection of profiles before therapy start
❹	**LED Profile -** shows if memory for own settings is active
❺	**LED Polarity** – indicates that the polarity has been changed [only for **Hidrex connect *ION***]
❻	**Connect – i**ndicates that the Bluetooth connection is active. [only for **Hidrex connect *ION***]
❼	**LED Pulse** – indicates that pulse current (PC) is active [only for **Hidrex classic *ION***]

Attention: BEFORE you start the treatment and close the electrical current circuit with your hands, feet or underarms, make sure to FIRST turn ON the main power switch ①. If this sequence is reversed, there is also a chance that you receive a completely harmless, but uncomfortable, electric shock!

Do not turn the device off during the therapy. In most cases this causes a safe but uncomfortable electric shock (electric fence effect).

Primary Settings And Saving Of Profiles

Your HIDREX 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) Turn the device on:

After setting up your HIDREX therapy system as described in the chapter "Installation/Treatment Setup", switch on the control unit with the main switch ①.

First, the main display ❶ will briefly show three moving bars for about 5 seconds (self-test of the device).

Next, the currently set therapy duration is shown in minutes on the left and the set dose in volts is shown flashing on the right.

2) Select desired profile:

If a profile is selected (one of the LED ❹ lights up), the device will automatically suggest the respective stored treatment parameters (time, dose and pulse width). In the delivery state, recommended default values are stored for each profile. However, you can also create your own profiles.

If no profile is selected (none of the LEDs ❹ are lit), the device always starts in manual mode with the settings 15 minutes and 4 volts.

Select the profile as follows:

Button	Function	Symbol / Display
	Press ❸ and hold the button to activate the profile selection. Press the button ❸ again to select the profile. After 8 seconds without pressing the button ❸ you leave the submenu.	LED ❹ on = respective profile active LED ❹ off = manual mode 

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Begin Treatment

If you have no other treatment parameters known or given to you, the following values are recommended as initial values for the therapy.

It is strongly recommended that you start treatment of children with reduced parameters as indicated in the following table. If necessary, increase the values slowly and pay attention to the patient's sensation! The treatment should never be unpleasant or painful.

Option		Adult	Child
HAND 	Pulse-width: Dose: Time:	90% 20 volts 15 minutes	80% 10 volts 15 minutes
FOOT 	Pulse-width: Dose: Time:	100 % = DC 30 volts 15 minutes	90% 15 volts 15 minutes
AXE[1] 	Pulse-width: Dose: Time:	50% 8 volts 15 minutes	50% 5 volts 15 minutes

Attention:  In order to avoid skin irritation by excessive dose settings in pulsed mode (where current flow is practically imperceptible), we recommend that you assess your individual direct current (pulse width = 100%) thresholds for hands, feet, or armpits before you start the first treatment session. To conduct axillary treatments, as a rule the dose should not be raised above 15 volts, because the sensitive skin may otherwise get burnt.

1) <u>Starting:</u>

Put your hands or feet in each water-filled tray and place them on the plastic nets ©.

Attention: Avoid direct contact between skin and the metal electrode! Do not forget to remove any jewelry! 

[1] Beachten Sie, dass die Verwendung der Sonderapplikatoren jeweils in einer eigenen Anleitung beschrieben wird. Diese Anleitungen müssen unbedingt beachtet werden.

2) Conduct treatment:

The device detects the closing of the circuit ("immersion monitoring") and signals the start of the treatment. The dose in the display stops flashing and slowly rises, starting at 4V, to the previously set value[1].

Attention: If you experience any localized pain during treatment, interrupt the session and cover the painful area with petroleum jelly. Pressing button ❷ or ❸ will stop the automatic increase of the dose.

3) Adjusting treatment parameters:

The treatment dosage may be increased or decreased at any time throughout the treatment session by pressing buttons ❷ or ❸.

The remaining therapy time cannot be changed once the treatment has started.

4) Stop the treatment:

The treatment can be paused at any time by removing the hands or feet easy. The treatment time is stopped (dose flashes again and shows the selected value).

With stopped therapy, the treatment time and profile can no longer be changed. The dose can then be changed with the ❷ or ❸ keys and the pulse with by holding key ❸.

The treatment is continued by diving in the hands or feet in the water bath again. As at the start of treatment, the dose value jumps to 4, stops flashing and slowly rises again to the desired value.

5) Ending a treatment session:

The remaining treatment time is shown in minutes in the display, with the last minute in seconds (flashing).

When the treatment time is up, the treatment dose is automatically lowered to zero. Please keep your hands or feet in the trays until the dose display reads "End".

Only switch off the device afterwards.

Attention: Do not turn off the device at main switch ①, as long as the user is connected to the device. Otherwise this can cause a safe but uncomfortable electric shock, even if there are protection features (electric fence effect).

[1] See also the note on "Dose Limitation" on the following pages.

Important Advice for Conducting Treatments

For your safety, your HIDREX therapy device is equipped with several protective circuits.

Immersion monitoring

As long as you haven't closed the circuit through the skin surfaces to be treated, the device won't deliver a therapy dose. All settings you make when the therapy circuit is open are default settings. When the therapy circuit is closed, the dose indicator stops flashing. Only then will the dose rise to the previously set value and the therapy time expires.

Over-Treatment-Protection and therapy monitoring (OTP[1])

The device permanently monitors the therapy circuit and the individual body resistance of the patient. By this, problems in set-up and with the accessories can be early recognized.

If a value that is too high is detected right at the start of therapy, the device prevents the start of therapy.

If the device detects an increased value during the current treatment, the display will alternate showing the voltage and "ot". In this case you can continue the therapy without danger.

If the value exceeds the limit for a longer period of time, the device first reduces the dose briefly and then slowly returns to the preset value.

If the resistance remains above the limit, the device will stop the treatment, for your safety, lock[2] the device and the display show "StoP".

Hint: If treatment does not start, "ot" or "StoP" is displayed, check the connections and ensure that they are pushed completely. Also inspect the electrodes for calcifications[3] and cleans as necessary. If you do not notice any errors in the connections and the electrodes have been adequately cleaned, the OTP feature is very likely to be active. In this case, please pause the treatments for at least 2 to 3 weeks and at least until the excessive sweating is clearly noticeable again. If this does not help, please contact us.

[1] OTP = Over-Treatment-Protection

[2] To be able to start a new treatment a restart of the device is necessary.

[3] Further information on handling calcifications on the electrodes can be found in the chapter care and purification.

Dose limitation

For your safety, the device permanently monitors the maximum permitted treatment parameters. This may result in the dose you have set not being reached. In this case, a protective circuit intervenes and stops the dose from increasing.

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

If the dose limitation is active, the display will alternate showing the voltage and "CL". The device "remembers" the dose you have set in the background and continues to try to reach this target value at regular intervals.

During subsequent treatment sessions, as decreased sweating is reached (and body resistance increases), higher voltage values can be achieved, if necessary.

Hint: The lower the pulse width settings, the more sensitive the protective circuit is, and therefore a higher chance of dose limitation activation.

If possible, increase the pulse width to achieve higher dose values.

The highest dose values and best treatment efficiency can be achieved with 90% pulse width or 100% pulse width.

Protection function against short circuit

The device has a function that protects it against short circuits. If a short-circuit or other internal fault is detected in the device, "Err 1" appears on the display and locks the device[1].

If you have any questions or problems with the therapy, please feel free to contact our customer service at any time. You will find our contact details at the end of these instructions.

[1] To be able to start a new treatment a restart of the device is necessary.

Care And Maintenance

This section contains important instructions about your HIDREX system.

Special Remarks

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

Multi-Patient Use

The device is suitable for the use by several patients at the prescribing physician's office or hospital, to conduct the initial or maintenance phases of the treatment under a doctor's supervision.

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

- Each patient will be provided with **own** consumables for iontophoresis treatment (plastic nets or sponge applicators)[1], which can be re-used to every session.
- Between treatments, the electrodes Ⓑ and trays Ⓐ (hard case trays or ergonomic trays Ⓕ) 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. In either case, if the device issued (sold) is ever in need of repair or replacement parts or additional accessories are needed, the patient can contact customer service at +49 7641 959376-0 or info@iontophorese.de.

Care and Purification

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

Attention: Before cleaning, make sure the device is turned off and separated from the power line. Never use kerosene, thinner, or any other solvents.

[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 after each treatment:

- Dry electrodes with a soft cloth to prevent calcium deposits on the metal.
- Dry the treatment trays (case trays or ergonomic trays) with a soft cloth and let them air-dry (do not close the hard case tray due to humidity).
- Rinse the plastic nets thoroughly with hot water. Then remove any residual liquid by shaking the plastic nets rigorously and letting them air-dry.

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

- The control unit, the treatment trays and electrodes should be cleaned with a 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:

HIDREX tap water iontophoresis devices are basically maintenance-free.

Nevertheless, for safety reasons we recommend a technical check and safety inspection by an authorized HIDREX repair every 2 years. Suitable measuring and test equipment are mandatory for the technical safety inspection (STK)[1] which cover at least the following:

- Visual inspection of medical device and accessories
- Leakage current and insulation resistance test according to EN 60601-1
- Operational check of the medical device

[1] "MPBetriebV": every 2 years and after each repair or reconditioning. The operator is responsible for rectifying (causing the rectification) the deficiencies identified at STK.

Disinfection

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

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

- Spray a surface disinfectant[2] on the electrodes and treatment trays so that the entire surfaces are completely moistened.
- Let the disinfectant remain on the surface as directed by its instructions and then wipe it dry with a clean cloth.
- The consumables (plastic nets) should be replaced by new or patient owned ones.

Reconditioning

HIDREX iontophoresis devices are reusable medical devices and can be reconditioned after use of a customer. The reconditioning of the devices is classified as “non-critical”[3]. The reconditioning should be done only by an authorized HIDREX repair center. If a device is to be reconditioned, the following actions will also be taken:

- The consumables (plastic nets, electrodes and ergonomic tubs) need to be disposed of and replaced by new ones.
- The control unit and accessories (hard case trays, cables) must be purified and disinfected.
- A functional check and safety inspection must be completed and documented.

The medical device may be reconditioned up to 10 times.

Troubleshooting

If prior to, during, or after a treatment session, the device does not operate in accordance with this manual, please go through the following checklist and perform the operational check before you send the device for repair.

This can save you considerable cost and inconvenience.

[1] For single-patient use in home therapy the care and purification according to the preceding chapter is sufficiently. In this case a regular disinfection is not strictly necessary.

[2] Henkel: Incidin Extra (1%), Incidin Plus (0,5%), Minutil (0,5%), Dr. Trippen (desomed): Biguamed, Bbraun: Melesept SF (0,5%/5%), Hexaquart S (1,5%/5%), Meliseptol (undeluted)

[3] Observe the 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 "Requirements for Hygiene in the Processing of Medical Devices" of 25.08.2001.

Error Checklist

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

- ⌦ Verify that the AC power adapter 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.

Operational Check

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

1) Set up the therapy system as you would for a treatment.
2) Activate the main power switch to turn the control unit ON. Dose and treatment time settings should appear on the main display ❶.
3) Place one electrode onto the plastic net that covers the other electrode in a water-filled tray, but don't let the electrodes touch directly.
4) The device should now display the dose indication constantly and the voltage should rise to the set value starting from 4V.

If the treatment does not start with this setup, even taking the error checklist into account, please contact us in order to coordinate the further procedure.

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 plastic nets or sponge applicators.

Please send all electrical accessories (AC power adapter, electrodes, and cable set) together with the control unit as well as an detailed error description.

Applicable Regulations And Legal Requirements

The regulations valid in the respective operator's country (e.g., infection prevention, technical servicing or registration and documentation regulations) are to be kept in connection with the location of use (e.g., medical institution), in any case, by 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 HIDREX 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 + = Anode, - = Cathode
	Shock protection 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 instructions manual / booklet 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
CE 0633	CE-Mark, ID# of Notified Body	Conformity with health and safety requirements set out in European Directive (93/42/EU).
	UDI (Device Identification)	Device Identification: 14-digit unique DI# (Gtin)
SN	Serial Number (part of UDI)	Serial #: yy-x.xxxx (yy: year of manufacture)
IP41	Degree of protection of the housing	1st digit = protection against contact / foreign bodies 2nd digit = protection against water

Electromagnetic Compatibility (EMC)

HIDREX 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, as portable phones or pagers can influence medical-electric-appliances!

Please note the guidelines and manufacturer's declarations according to **DIN EN 60601-1-2: 2016**, 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); and
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 EMI 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.

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

The client or user should ensure that it is used in an appropriate environment.

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	HIDREX 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	Actual level
ESD IEC 61000-4-2	+/-6kV cd +/-8kV ad	+/-6kV cd +/-8kV ad
Bursts IEC 61000-4-4	+/-2kV mains +/-1kV I/O	+/-2kV mains +/-1kV I/O
Surges IEC 61000-4-5	+/-1kV dm +/-2kV cm	+/-1kV dm +/-2kV cm
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 / negativee 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	Actual level
Conducted RF IEC 61000-4-6	3Veff 150 kHz to 80 MHz	3 V
Radiated RF IEC 61000-4-3	3Veff 80 MHz to 2,5 GHz	3 V/m

Table 6 Recomended 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 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 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 centre. Please help prevent incriminating materials from going into the environment (ElektroG).

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

Technical Data

Controller

Display-Tolerance	Treatment Voltage (Dose)	± 2 V
	Treatment Current	± 1 mA
	Treatment Time	± 1 %
Dimensions	W x H x D	190 x 49 x 137 mm
Mass		0,5 kg
Power input	Input Voltage	12 V
	Max. input Current	500 mA (Fuse)
	Input Power	Max. 6 VA
Environment – Storage and Transport	Temperature	-10°C to +50°C
	Rel. humidity	30% to 70%
	Air pressure	700 hPa to 1060 hPa
Environment – Usage	Temperature	10°C to 30°C
	Rel. humidity	30% to 70%
	Air pressure	700 hPa to 1060 hPa
Output	Treatment Voltage	4 - 60 V_{DC}
	Max. Current	35 mA
	Treatment Current	0 - 30 mA (5 mA reserved for the device)
	Max. output Power	225 mW
	Pulse repetition frequency[1]	9.9 kHz (pulsed Current only)

AC Power Adapter: Friwo FW8002M12 (Use genuine parts only!)
Disconnects the device from the mains voltage!

Input	Input Voltage	100-240 V~ / 50-60 Hz
	Max. Current	400 mA
Output	Nominal output Voltage	12 V_{DC}
	Max. output current	0,6 A
	Max. output Power	8 VA

[1] Applies only to devices which have the current type pulse current (PC) or variable pulse current (VPC).

Electrodes

	Material	Dimensions
AX-Electrodes	1.4301-2b (Stainless steel)	5,5 x 4,8 cm
HF-Electrodes	1.4301-2b (Stainless steel) or EN AW 5754 (Aluminum)	34,5 x 11,5 cm
pH-Buffer	None	

Current Density of Applicators and Electrodes

Applicator / Surface	Conductive Area [cm^2]	Max. Density at 30 mA [mA/cm^2]	Peak Density at 35 mA [mA/cm^2]
Hand-Feet, Hard Shell Case Individual Water Surface	818	0,037	0,043
Hand-Feet, Ergonomic tube individual Water Surface	595	0,05	0,059
Hand-Feet, HF-Electrode	328	0,091	0,11
Armpit, Sponge Cushions	128	0,23	0,27
Armpit, AX-Electrode	52	0,58	0,67

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