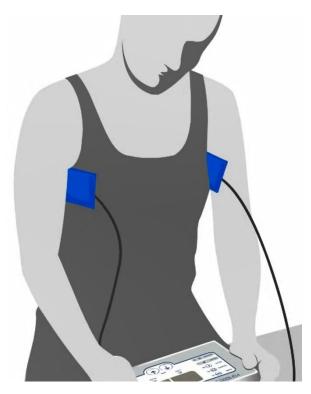
Please note that opened applicators cannot be exchanged or returned for hygienic reasons!



# Instruction Manual HIDREX Axillary Applicators

for tap water iontophoresis (TWI) against hyperhidrosis (excessive perspiration) under the armpits



This instruction manual contains supplementary information to the general user manual of the HIDREX devices.

Please read <u>both</u> operating instructions carefully!

# **Table of Contents**

Table of Contents	2
Read Before Use	
Contraindications	3
Side Effects	3
Additional Important Safety Considerations	3
Intended Use / Mechanism Of Action	4
Treatment concept - trial phase	4
Hints on conducting the axillary therapy	4
Types of current	
Efficacy of Treatment and Polarity Reversal	
Installation / Treatment Setup	6
Preparing the axillary applicators	7
Conduct Therapy	8
Primary Settings	8
Begin Treatment	
Important Advice for Conducting Treatments	
Care and Maintenance	10
Troubleshooting	11
Applicable Regulations and Legal Requirements	11
Lifespan	
Waste Management And Packaging Of Electronic Devices	
Technical Data	12

# **Read Before Use**



In addition to the instructions in the accompanying documents of the HIDREX control units and treatment sets, the following instructions, **safety instructions** and notes on **contraindications** as well as **side effects** must be observed.

# Contraindications



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

- ① neurological diseases in the head or neck area or diagnosed epilepsy
- (i) piercings in the contact area which cannot be removed

#### **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 in the areas of longer direct contact to an electrode



# **Additional Important Safety Considerations**

- These axillary applicators are only approved for use with a HIDREX control unit and original accessories!
- (i) To avoid burns, the treatment electrodes must always be completely within the applicator pocket and must not protrude from the cushion.

# Avoid direct contact between skin and the rubber or metal electrode!

- Always use sufficient water and always keep the cushions almost dripping wet!
- ① Do not turn the device off during the therapy. In most cases this causes a safe but uncomfortable electric shock<sup>1</sup>.
- (1) Before you start the actual treatment, conduct a trial phase to check your tolerance of the therapy (see chapter "Treatment concept")!
- ① Prior to the treatment, take off metallic jewellery (e.g. nipple piercings), which could be in the contact area during the treatment, as otherwise slight burns (current marks) can occur due to current concentrations in these places.
- ① In addition to these instructions, please observe all safety and maintenance instructions in the operating instructions for your control unit! Not all safety instructions for handling the device are repeated in these instructions.

\_

<sup>&</sup>lt;sup>1</sup> These electric shocks are definitely uncomfortable, but harmless.

#### **Intended Use / Mechanism Of Action**

#### **Intended Use:**

The HIDREX axillary applicators are designed for the treatment of focal hyperhidrosis under the armpits in conjunction with a HIDREX control unit. Any other or more extensive use is considered improper and can have dangerous effects.



#### **Mechanism of Action:**

The mode of action of tap water iontophoresis is basically identical to the treatment of the hands or feet and is described in detail in the accompanying documents of your control unit. During treatment with the axillary applicators, the treatment current is conducted through the contact surfaces into the underarms.

#### **Treatment concept - trial phase**

In addition to the initial and maintenance phase (see accompanying documents of your control unit), you should first conduct a trial phase when using the HIDREX axillary applicators. This is done by first treatments with shortened time at low doses, as follows:

- 1. Treatment: 5 minutes at 8 volts (level 1 for Connect variants)
- 2. Treatment: 10 minutes at 10 volts (Level 2 for Connect variants)

Depending on the equipment of your control unit, use a pulse width of 50% or pulse current (PC) for all axillary treatments. If the treatment is well tolerated, the maximum therapy duration can be extended and the dose increased so that it is neither painful nor unpleasant.

**Hint:** In general, we recommend not to exceed the maximum dose of 20 volts (Level 3 for Connect variants).

# Hints on conducting the axillary therapy

Since the skin in the armpit may be more sensitive to electricity, you should follow the instructions below:

- Wash your armpit with normal soap and water before each treatment to remove skin's own fat and talc. Even small films of fat can impair the flow of current and cause local irritation.
- Remove all deodorant or antiperspirant residues thoroughly before each treatment.
- Do not use cream soap.
- Do not perform the treatment under the armpits after shaving! Small skin defects lead to unpleasant pain sensations locally under current flow.

- 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 hand warm water to moisten the applicators. This is more pleasant for therapy than cold water.
- Do not carry out the treatment at the same time as applying antiperspirants containing aluminum chloride! Wait for at least 2 days.

# **Types of current**

When treating the armpits, the use of the pulse current (PC) or a setting of 50% of the variable pulse current (VPC) is recommended. Please inform yourself about the different types of current in the accompanying documents of your control unit.

Although the use of direct current (DC) is possible in principle, it should be used with great caution at low doses and is not recommended.

**Hint:** Please note that not all models have all types of current! Please refer to the user manual to find out which types of current your device has.

# **Efficacy of Treatment and Polarity Reversal**

In principle, the effect of HIDREX therapy does not depend on the direction of the current. However, clinical studies have shown that the anode is slightly more effective than the cathode at the beginning of the treatment series. However, this effect has no relevance for the treatment of the armpits. It is therefore ultimately irrelevant in which polarity the treatment is performed.

**Comment:** Any deviation from this procedure will not result in any hazard or side effects. In addition, the long-term success of the therapy does not depend on the direction of the current.

Please note the additional information on polarity changes in the accompanying documents of your control unit.

If your device is equipped with an automatic polarity reversal function<sup>1</sup> (PRF<sup>2</sup>), please activate<sup>3</sup> the function. If your device does not have a PRF, you do not need to pay any further attention here.

<sup>&</sup>lt;sup>1</sup> It is easy to recognize by the fact that your control unit is equipped with two connectors and cables of the same colour (not two-coloured red and black).

<sup>&</sup>lt;sup>2</sup> Devices equipped with a PRF will automatically change the polarity. This function is only advantageous for the treatment of hands or feet.

<sup>&</sup>lt;sup>3</sup> If PRF is active, your device will display it (please refer to the user manual).

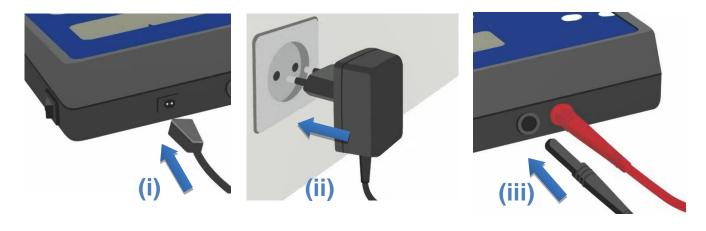
#### **Installation / Treatment Setup**

To prepare for treatment, set up your therapy device according to the instructions in the accompanying documents of your control device.

**Hint:** The handling of the respective control unit differs depending on the model, type and equipment of the unit. A detailed functional description and instructions for adjustment and therapy are described in the user manual of your control unit.

For detailed instructions on setting up and connecting the control unit and setting up a water bath (hand-foot treatment), please refer to the accompanying documents of your therapy system. Below you will find short instructions for connecting and setting up your therapy system.

- i) Insert the AC adapter cable into the jack on the rear panel.
- ii) Plug the AC adapter into an AC wall outlet.
- iii) Just plug a connection cable of the appropriate colour into the socket on the rear of the unit. It does not matter which cable you plug in.



**Hint:** Devices with polarity reversal function (PRF) are equipped with connectors and cables of the same colour, as there is no plug-in specification. It can therefore be plugged in as desired.

# Preparing the axillary applicators

The HIDREX axillary applicators are made of 3 components:

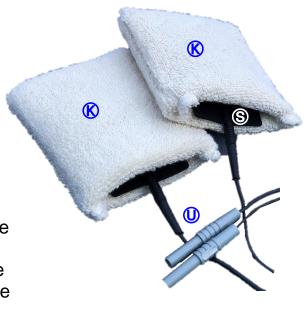
The cushions **®** form the contact surfaces with the underarms and store the required water.

The rubber electrodes **S** are permanently fixed in the cushion **S** so that they cannot slip out.

The two cables are connected with the small black plug to the electrodes. These plugs can remain in the electrodes for the lifetime<sup>1</sup> of the pads and do not have to be disconnected and plugged in all the time.

Before each use, make sure that the metal tips of the two black plugs of the cables ① are fully seated in the rubber electrodes ⑤. This is important for a good conductive connection. The metal pins should no longer be visible.

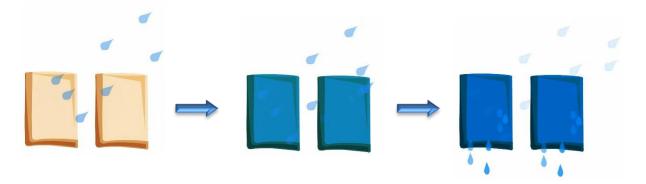
To insert, hold the rubber electrodes firmly at the upper end.







Now soak the cushions ® well with hand warm tap water. Make sure that the cushions are dripping wet and hardly wrung out.





The sponge cushions should store as much water as possible, as the water is needed for successful treatment and protects you from burns. Only damp is not enough!

<sup>&</sup>lt;sup>1</sup> In the event of wear, the cushions **®** are completely replaced, including the rubber electrode. The connecting cables are non-wearable parts and will continued to be used.

Now insert the plugs of the cables **(U)** into the grey couplings of the connecting cables as far

as they will go.

Clamp the well-soaked cushions (6) in your underarms. Make sure you position them for the largest possible contact surface with the skin



Make sure that only one cable is connected to the control unit!

**Hint:** Start the treatment as soon as possible after applying the axillary applicators to avoid drying out. If necessary, prepare a towel to collect dripping water.

# **Conduct Therapy**

Switch on the device at the main switch.



Make sure that only one cable is connected to the control unit, otherwise a safe but unpleasant electric shock could occur.

# **Primary Settings**

After you have switched on your HIDREX therapy system with the main switch, select the desired basic settings (setup mode) and treatment parameters<sup>1</sup>.

**Hint:** The handling of the respective control unit differs depending on the model, type and equipment of the unit. Please refer to your device manual for a detailed functional description and instructions for adjustment and therapy.

<sup>&</sup>lt;sup>1</sup> Adjust the device according to the instructions in the chapter "Treatment concept" (e.g. for the first treatment: 5 Volt or Level 1, 50% pulse width or PS).

# **Begin Treatment**

After you have selected the basic setting, the device is in the treatment mode.

Now close the therapy circuit by plugging the cable into the free socket on the back of the device.

Make sure that your skin is not in direct contact with the rubber electrode.

#### Do not forget to remove jewelery!

The device detects the closing of the circuit via the "immersion monitoring" feature and signals the start of the treatment.

Attention: If punctual pain stimuli occur during therapy, the therapy



must be interrupted and the painful areas covered with Vaseline. However, never switch off the device during treatment! Simply remove the cushions from your underarms or pull a connecting cable out of the device to interrupt.

The treatment dose can be changed at any time during therapy using the buttons. If the treatment is interrupted, the timer is stopped.

**Hint:** Please refer to your device manual for detailed instructions on how to operate your control unit before or during treatment and which displays are available.

At the end of the therapy time, the device automatically lowers the treatment dose to zero and signals the end of treatment.

**Tip:** If necessary, interrupt the treatment after approx. 7 minutes in order to soak the cushions **(8)** again!

# **Important Advice for Conducting Treatments**

Your HIDREX therapy device is equipped with several protection features for your safety.

- Immersion monitoring
- Over-treatment Protection
- Current Limitation
- Protection function against short circuit

You will find a detailed explanation of the function and effect of the above-mentioned protective mechanisms in the accompanying documents of your control unit.

**Hint:** Avoid direct contact between the two sponge cushions when both cables are connected to the device, as this is equivalent to a short circuit. Since your control unit is protected against short-circuits, it will not be damaged, but preset treatment values could be automatically set to zero to protect the unit and must be reset.

#### **Care and Maintenance**

Please observe the instructions for cleaning, care, maintenance, disinfection and preparation in the accompanying documents of your control unit. In addition, the following special features must be observed when using the axillary applicators:

- In the case of changing patients, each patient is assigned a separate pair of cushions (§), which can be used for the subsequent sessions of the treatment of this patient.
- Thoroughly rinse the cushions ® with warm tap water (without detergent or detergent additives) and let them dry in the air.
- Replace the cushions in case of heavy dirt or wear.
- Disinfection of the cushions (6) is not required!
- Preparation of the axillary applicators is not required.
- Do not expose the applicators to direct sunlight.

Attention: Calcium deposits on the permanently fixed rubber electrodes in the cushion can impair the flow of current. In this case it is advisable to replace the cushions.

**Important:** The axillary applicators have to be stored completely dry!

Once the cushions have dried, they should no longer be deformed, as inner sponges become brittle and could break.

# **Troubleshooting**

If your HIDREX iontophoresis device does not work as described in the accompanying documents and this manual, please proceed as described in the device's manual. Go through the checklist described in the manual and perform the function test before sending the device in for repair. If you still need to return your device, please also follow the instructions in the device manual.

# **Applicable Regulations and Legal Requirements**

Please note all information regarding electromagnetic compatibility (EMC), applicable regulations and rules as well as the symbol explanation in the device manual of your control unit!

Please note that the operator is solely responsible for compliance!

# Lifespan

For legal reasons, the lifetime of the cables ① is set to 2 years. The cushions ⑥ must be replaced if necessary for hygienic and technical reasons.

The HIDREX axillary applicators are <u>not</u> independent medical devices, but are accessory electrodes and <u>may only</u> be used in conjunction with an original HIDREX set!

# **Warranty / Manufacturer**

The HIDREX axillary applicators are wearable parts and are excluded from warranty claims. If material or manufacturing defects are discovered before first use, please contact us.

***	Manufacturer	HIDREX GmbH, Otto-Hahn-Str.12 , 42579 Heiligenhaus, Germany, info@hidrex.de www.hidrex.com
-----	--------------	--

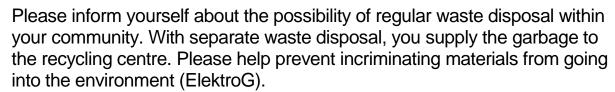
# Waste Management And Packaging Of Electronic Devices



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.



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

# Technical Data

(See accompanying documents of your control unit)