

User Manual for Facemask with HIDREX Iontophoresis Devices

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

Please read both operating instructions carefully!



Table of Content

Table of Content	1
Read Before Use	2
Contraindications	2
Side Effects	2
Additional Important Safety Considerations	2
Intended Use / Mechanism of Action	3
Trail Treatment	3
Hints On Conducting The Therapy For The Face	4
Types of Current	4
Efficacy Of Treatment And Polarity Reversal	4
Installation / Treatment Setup	5
Device-Setup (Quick Guide)	5
Putting On The Facemask	6
Conduct Treatments	8
Primary Settings	8
Begin Treatment	9
Important Advice for Conducting Treatments	10
Care and Maintenance	10
Troubleshooting	11
Applicable Regulations and Legal Requirements	11
Lifespan	11
Warranty / Manufacturer	11
Waste Management and Packaging of Electronic Devices	11
Technical Data	12

Read Before Use



Additionally, 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 face, so treatment should not be administered unless otherwise directed by a physician:

- ① Neurological diseases in the head or neck area or diagnosed epilepsy
- ① Piercings in the contact area which cannot be removed
- ① Fixed braces, metal implants and other current-conducting objects in the area of the electrical current flow (in or on the head)
- ① Potentially malignant lesions, acute localized infections, skin eruptions, or swollen, broken, or inflamed skin in the facial area

Side Effects



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

- ① Mild dysesthesia (tingling or burning)
- ① Short-term skin irritation (reddening) after treatment
- ① Erythema (skin redness, transient vesicles or blisters)
- ① Skin irritation or burns at the areas of longer direct contact to an electrode



Additional Important Safety Considerations

- ① This face mask is only approved for use with a HIDREX control unit and original accessories!
- ① To avoid burns, the treatment electrode must always be completely covered by the sponge cloth.
- ① Avoid direct contact with the rubber electrode!
- ① Always use sufficient water and always keep the sponge almost dripping wet!
- ① Before you start the actual treatment, carry out 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. earrings), which could be in the contact area during the treatment, as otherwise slight burns (current marks) can occur due to current concentrations at these places.

- ① In addition to these instructions, please observe all safety and maintenance
- ① instructions in the operating instructions for your control unit! Not all safety
- ① instructions for handling the device are repeated in these instructions.
- ① Several devices may not be simultaneously used by one patient.

Intended Use / Mechanism of Action

Intended Use:

The HIDREX face mask is designed for the treatment of focal hyperhidrosis in the face 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 a face mask, the treatment current is conducted through the contact surface on the face to the second contact surface on one hand or foot in a water bath.

Trial Treatment

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

1. Treatment: 2 Minutes at 5 volts (Level 1 for Connect-Version)
2. Treatment: 5 Minutes at 8 volts (Level 2 for Connect-Version)
3. Treatment: 10 Minutes at 10 volts (Level 2 for Connect-Version)

Depending on the equipment of your control unit, use a pulse width of 50% or pulsed current (PC) for all face treatments.

If the treatment is well tolerated, the maximum therapy parameters can be extended to

- the maximum duration of 15 minutes and
- the dose should be increased so that it is neither painful nor uncomfortable.

Hint: In general, we recommend not to exceed the maximum dose of 15 volts

Hints On Conducting The Therapy For The Face

Since the face or facial skin may be more sensitive to electricity, you should consider the following:

- Thoroughly remove all cosmetics and care products containing fat before each treatment.
- Wash your face 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.
- Do not use cream soap.
- Do not perform the treatment in the face 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.

Types of Current

When treating the face, the use of pulsed current (PC) or a pulse-width of 50% of 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 power! Please refer to the user manual to find out which types of current your device has.

Efficacy Of Treatment And Polarity Reversal

It is recommended to connect the face mask to the anode (red cable) and to connect the cathode (black cable) to the electrode of the second contact surface (hand or foot in water bath).

When treating the face, it is not necessary to change the polarity.

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

If your control unit¹ is equipped with an automatic polarity change function (PWF), you should deactivate this function as described in the user manual and select the anode marked + to connect the mask.

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

Installation / Treatment Setup

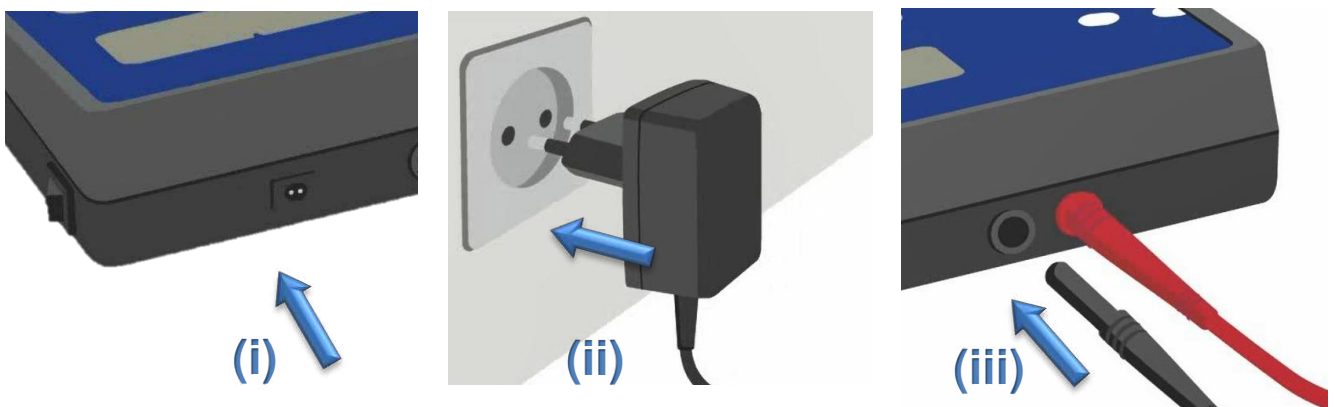
To prepare for treatment, set up your therapy device according to the instructions in the accompanying documents of your control device.

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.

Device-Setup (Quick Guide)

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.

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

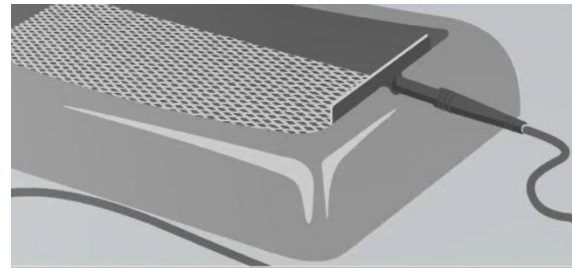


Hint: Devices with polarity change function (PWF) are equipped with connectors and cables of the same colour, as there is no plug-in specification. It can therefore be plugged in at will.

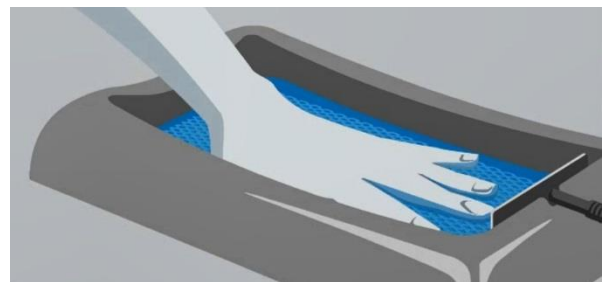
¹ It is easy to recognize by the fact that your control unit is equipped with two connectors and cables of the same colour (not two-coloured red and black).

For treatment with the face electrode, a second contact surface (hand or foot in a water bath) is required as counter electrode to the current flow. A case shell¹ or a single ergonomic tray is used for this purpose.

Place one treatment electrode in a case tray or ergonomic tray. Cover the entire surface of the treatment electrode with a treatment cloth or net grid and connect the connecting cable completely with force to the connection of the treatment electrode.



Now fill the case shell or ergonomic tray with hand warm tap water. The back of the hand or foot should not be covered with water.



Hint: If you use a foot as counter electrode, then you have both hands free during the therapy and can correct the position of the mask if necessary or operate the control unit easily.

Putting On The Facemask

The HIDREX face mask consists of 3 parts,

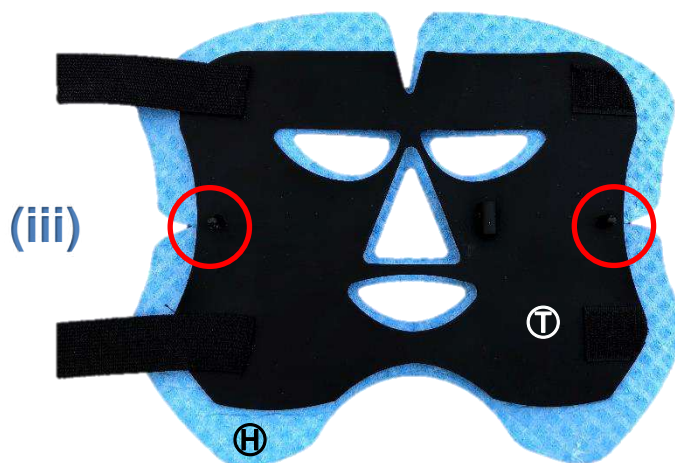
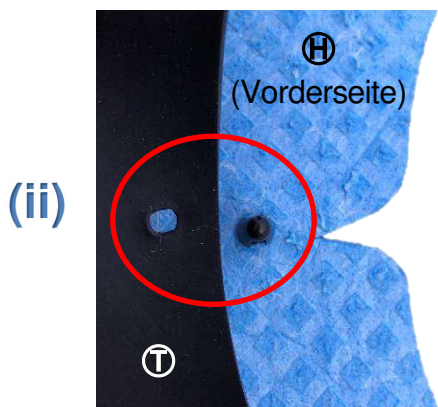
- the sponge plate  with holding pins as contact surface to the face,
- the rubber electrode  with connector and head strap,
- the connection cable .

The rubber electrode  with the two straps is intended for more frequent use, whereas the sponge plate  must generally be replaced after about 10 – 15 treatment sessions or when used by different people.

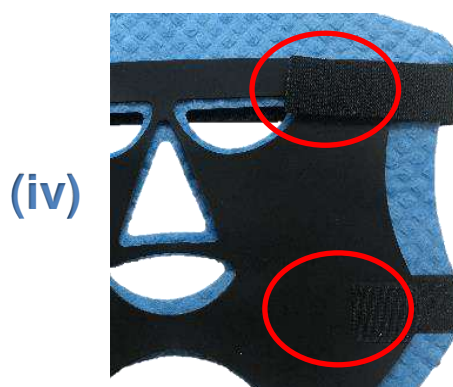
¹ The half shells of the transport case can be separated by pushing them apart.



First soak the sponge plate ④ thoroughly. Wring out the sponge material only slightly so that it remains dripping wet and fix the rubber electrode ⑤ with the two fixing pins on the sponge plate ④.



Before putting on the mask, first close the upper headgear on the right side with the Velcro fastener on the electrode. Try to estimate the appropriate length for your head.

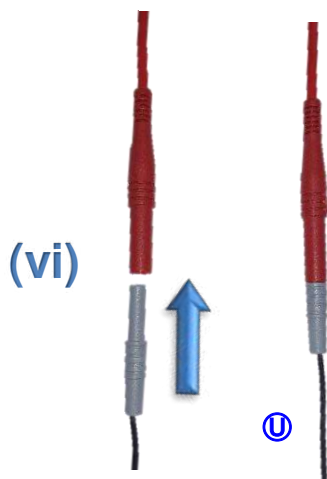


Now carefully pull the mask onto your head from above.

Then fix the lower neck strap.

Make sure that the mask lies as close as possible to the face, but does not sit so tightly that the water is pressed out of the sponge plate.





Now insert the plug of the connecting cable into the grey coupling of the connecting cable ① as far as it will go.

Before each use, make sure that the metal tip of the black plug of the connecting cable ① is fully seated in the small tab of the rubber electrode ①. This is important for a good conductive connection. The metal pin should no longer be visible.



Hint:

- If there is no second person who can help you, use a mirror to check the correct position of the electrode.
- Start the treatment as soon as possible after putting on the face mask to avoid drying-out.

If necessary, place a towel around the neck and chest area or place the second, remaining, case bowl or ergonomic tray directly in front of your body to collect dripping water.

Conduct Treatments

Switch on the device at the main switch ①.

Make sure that you do not close the therapy circuit at this point with one hand or one foot (do not dip into the water bath yet!), as this could result in a safe but unpleasant electric shock.



Primary Settings

After you have switched on your HIDREX therapy system with the main switch, select the desired basic settings (setup mode) and treatment parameters¹.

¹ Adjust the device according to the instructions in the chapter "Treatment concept" (e.g. for the first treatment: 5 Volt. 50% pulse width or PC).

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.

Begin Treatment

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

Now close the therapy circuit by placing one foot or one hand on the towel in the hand warm water filled case or ergonomic tray. Make sure that your skin does not come into direct contact with the electrode.

Do not forget to remove jewelry!

The device detects the closing of the circuit via the "immersion monitoring" 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 your hand or foot from the tray to stop the treatment.



The treatment dose can be changed at any time during therapy using the buttons.

The treatment is interrupted by removing the foot or hand. The device indicates the interruption of the power circuit and the timer stops.

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 sponge plate  again!

Tip: It is the best to carry out the treatment in the early evening. Skin redness in the face, which is caused by increased blood circulation and usually subsides quickly, can be tolerated better in the evening. In addition, the skin can recover for a long time after shaving in the morning.

Important Advice for Conducting Treatments

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

- Immersion monitoring
- Over-treatment Protection
- Dose 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.

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 face mask:

- In the case of changing patients, each patient is assigned a separate sponge plate , which can be used for the subsequent sessions of the treatment of this patient.
- Thoroughly rinse the sponge plate  with warm tap water (without detergent or detergent additives) and let them dry in the air.
- In general, replace the sponge plate after about 10-15 treatment sessions.
- Disinfection of the sponge plate  is not intended!
- Wipe the rubber electrode  with a dry cloth and let it dry in the air. If necessary, the rubber electrode can be treated with surface disinfectant.
- Preparation of the face mask is not intended.
- Do not expose the face mask to direct sunlight.
- Dry and wash the accessories for the second contact surface (foot or water bath) according to the instructions in the equipment manual.

Attention:  Calcium deposits on the electrodes can impede the flow of current. These deposits can be removed with commercially available calcium carbonate solvents or with vinegar or citric acid.

Important: The whole face mask has to be stored completely dry! Once the sponge plate  has 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 rubber electrode ⓘ is set to 2 years. The sponge plate ⓘ must be renewed regularly after 10-15 treatment sessions.

The HIDREX face mask is no independent medical device, but an accessory electrode and may only be used in conjunction with an original HIDREX set!

Warranty / Manufacturer

The HIDREX face mask is a wear part and is 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 (Polyäthylen) 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 ca not 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 center. Please help prevent incriminating materials from going into the environment (ElektroG).

WEEE-Reg.-Nr.: DE 42510094

Manufacturer-# Duales System Interseroh: 134502 (VerpackV)

Technical Data

(See accompanying documents of your control unit)