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User Manual

Tap Water Iontophoresis Systems

HIDREX® GS *400*
HIDREX® PS *500*

CE 0197

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www.tuv.com TÜV TÜV Rheinland Group ID:9711307400

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Read Before Use

Your HIDREX iontophoresis device was designed to maximize functionality and usability. System setup is easy and the device is simple to operate. This manual is intended to guide you through the setup procedure, familiarize you with the system's features, and will offer hints on the use of your new therapy system.

Your safety is important - Contraindications

Important:

Under no circumstances should you use iontophoresis if any of the following conditions apply:

- ⓘ Patient with a cardiac pacemaker
- ⓘ Patient with an ICD (implantable cardioverter/defibrillator)
- ⓘ Pregnancy
- ⓘ Patient with a metal-containing intrauterine device (IUD)
- ⓘ Metallic implants within the current path (arm or leg)
- ⓘ Large skin defects / wounds that cannot be covered with petrolatum
- ⓘ Patients with impaired sensibility in their hands or feet (e.g. patients with polyneuropathies)

Warning:

- ⓘ The treatment system may only be powered by the HIDREX wall adapter (to recognize at HIDREX nameplate with Serial-No.). This power supply is especially designed for this device.
- ⓘ In order to prevent burns during treatment, make sure the supplied towels cover the treatment electrodes at all times. Avoid direct contact with the metallic surface.
- ⓘ Two devices may not be simultaneously used by one patient.
- ⓘ Prior to treatment, remove any metallic jewellery (wedding bands etc.) which would otherwise be immersed in the water bath. Keeping such accessories on would lead to localized minor (electrical) burns secondary to increased current densities.

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.
- ⌦ You may remove your hands or feet from the treatment water bath at any time, but it is advisable to lower the dose to zero before you do so. In rare cases, uncomfortable electric shocks[1] may result if the dose is not reduced.

[1] These electric shocks are definitely uncomfortable, but absolutely harmless.

- The system may not be operated in the vicinity of shortwave or microwave medical diathermy devices. A minimum distance of 2 meters should be kept at all times.
- Prior to using wall power, check that your outlet power meets the system's requirements of 110-230 V~ and 50-60 Hz.
- Unplug the wall power adapter if a thunderstorm approaches or if you do not intend to use the treatment system for an extended period of time.
- This treatment device may 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 any 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 the HIDREX Company.
- Never open the device; there are no control elements inside. The system may only be serviced by the HIDREX Company.
- Wash the supplied towels on a regular basis together with your regular laundry (make sure to comply with the laundry instructions on the tag).

Intended Use / Mechanism of Action

During HIDREX treatment, a current flows through the body regions under treatment. The water bath mediates this current flow. The skin areas inside the treatment 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.

Remark: In general, HIDREX treatment results do not depend on the direction of current flow. The anode (red), however, is slightly more effective than the cathode (black). Current direction should therefore be reversed on a regular basis – but not within one treatment session.

Important: The HIDREX iontophoresis units GS *400* and PS *500* are intended to treat hyperhidrosis affecting hands, feet, face, necks / back and arm pits. Any other use or usage beyond this scope is considered unintended use and may have dangerous consequences.

Treatment Fundamentals

HIDREX iontophoresis devices are primarily intended for treating hyperhidrosis[1] (excessive sweating) of hands and/or feet. Provided the optional axillary applicators are utilized, the system can also be used for treating axillary hyperhidrosis.

The HIDREX treatment concept comprises two treatment phases:

Phase 1: The initial phase (therapy initiation) is conducted under a doctor‘s supervision. During this stage, patients learn to administer treatments. For therapy initiation, 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 indicated because the HIDREX treatment effect is reversible. Patients should conduct maintenance therapy sessions by themselves at home and with their own unit. Depending on the severity of the condition, maintenance therapy involves one to three weekly sessions of approximately 15 minutes each.

[1] Additional indications include: Dyshidrotic dermatitis, palmoplantar pustolosis and acrocynosis.

System Components

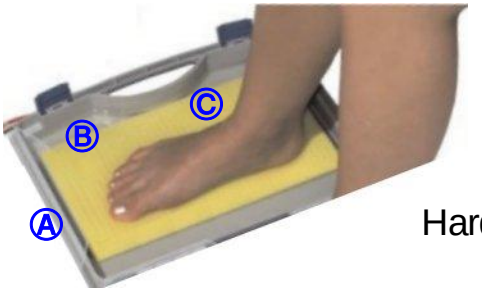
Your HIDREX therapy system comprises a control unit and the accessories explained in the following chapters.

Control Unit

Model
PS *500*

Model GS *400*

Standard Accessories



Ⓓ

Hard Shell Case
(Kofferschale Ⓐ)

Ⓑ Treatment electrode

Ⓒ Towel

Ⓓ Dual connecting cable set

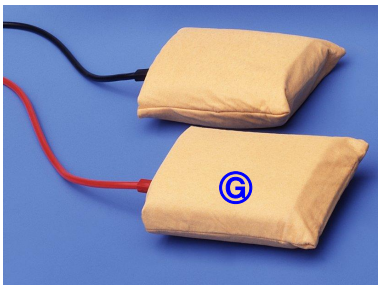
Ⓔ Safety wall adapter

Optional Accessories

Ⓕ

Ⓕ Ergonomic treatment tray

Ⓖ Axillary applicators
(Set AX I or AX II)



Ⓗ

Ⓗ Face mask

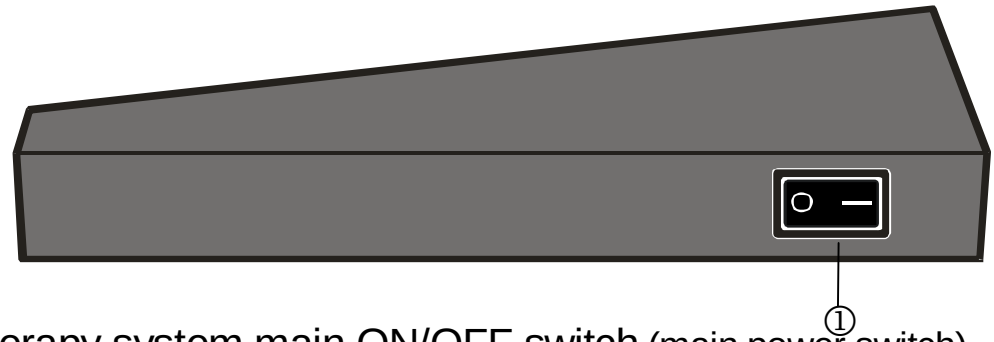
Ⓘ Nape or back applicator (not depicted)

Ⓙ Set DUO (not depicted)
includes 2 additional electrodes each, towels, and a dedicated cable set (allows simultaneous treatment of hands and feet)

Also refer to chapter "Treatment Setup und installation".

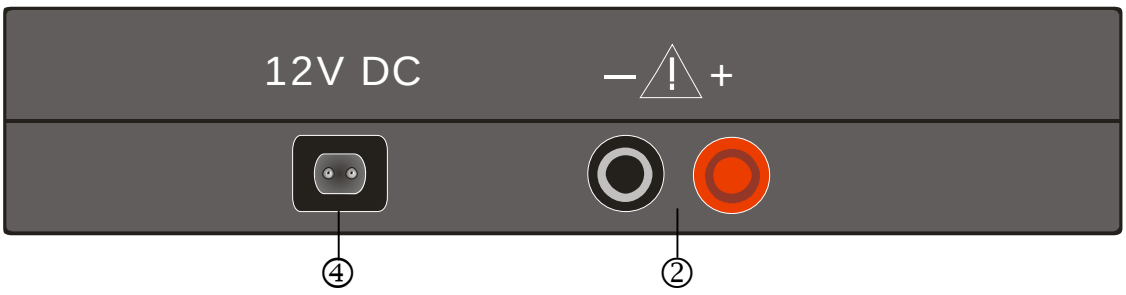
Two types of axillary applicators Ⓖ are available: a pair of sponge cushions with leather covers and a pair of sponge pouches with special small electrodes (AX electrodes).
The special applicators Ⓘ are made of foam and come equipped with hook and loop tapes. These applicators are also used with the AX electrodes.

Controls on the Side Panel



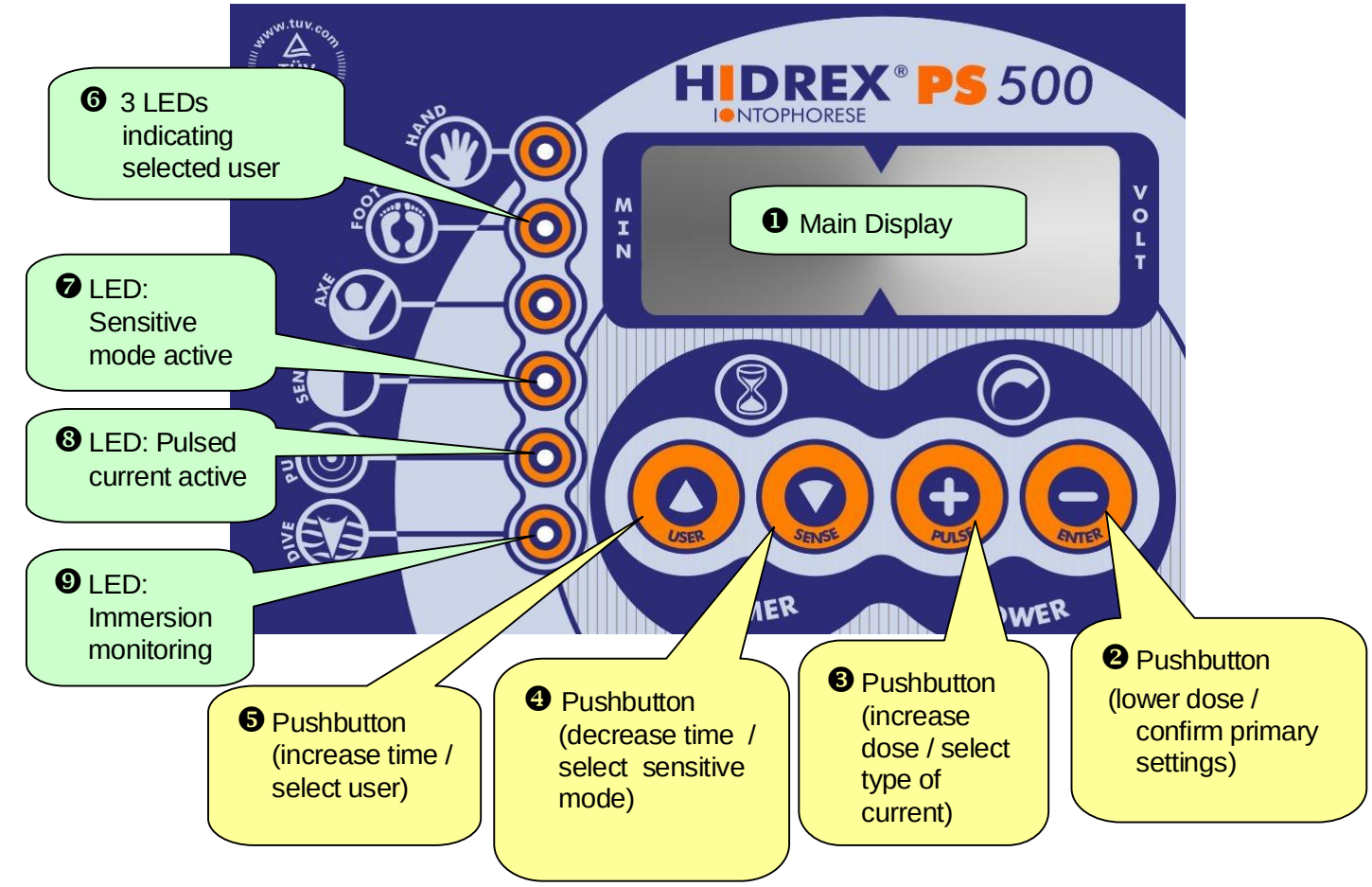
① Therapy system main ON/OFF switch (main power switch)

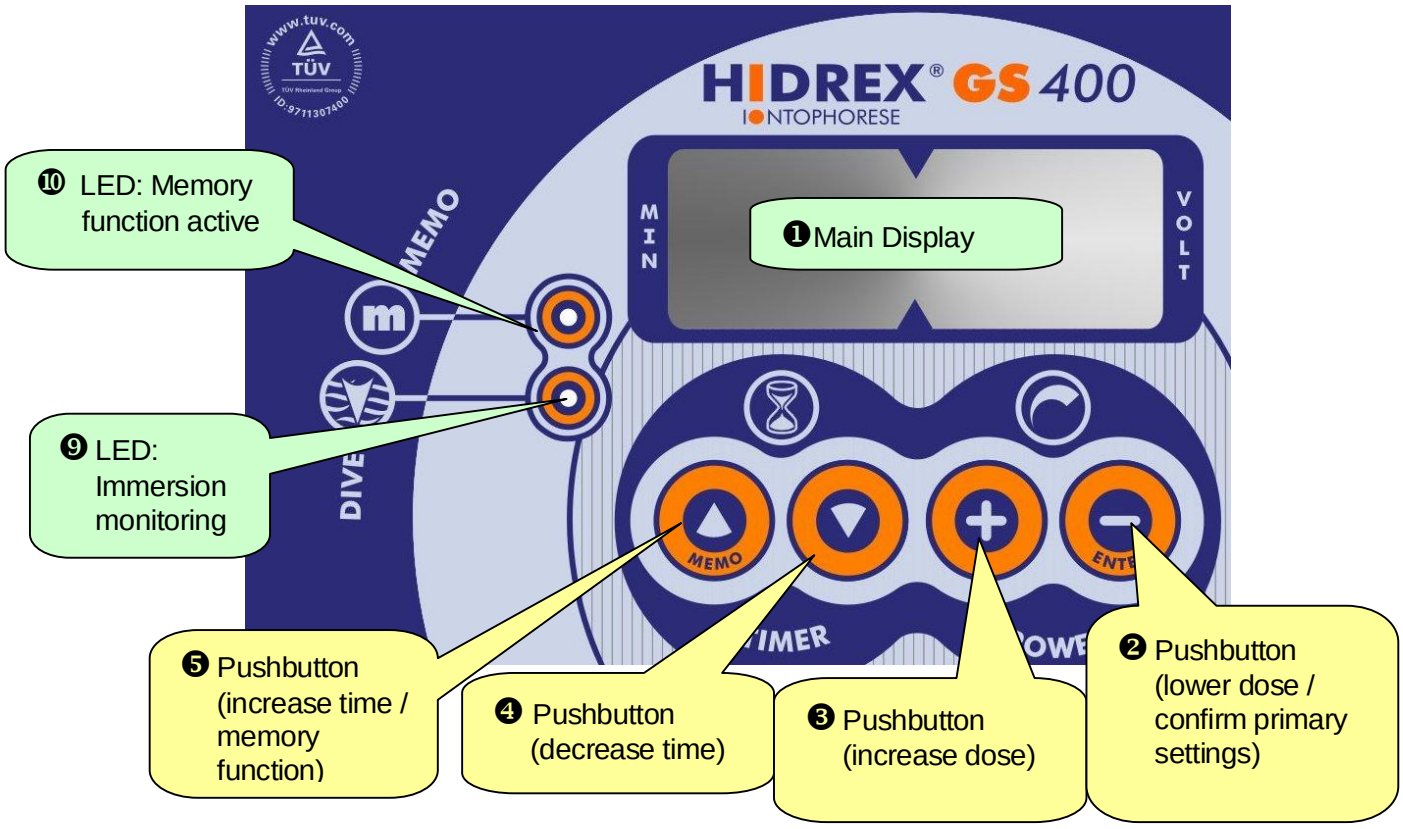
Controls on the Back Panel



② Jacks for connecting the dual connecting cable set (treatment electrodes)
④ Connector for safety wall adapter (12V DC)

Front Panel Controls





Installation / Treatment Setup

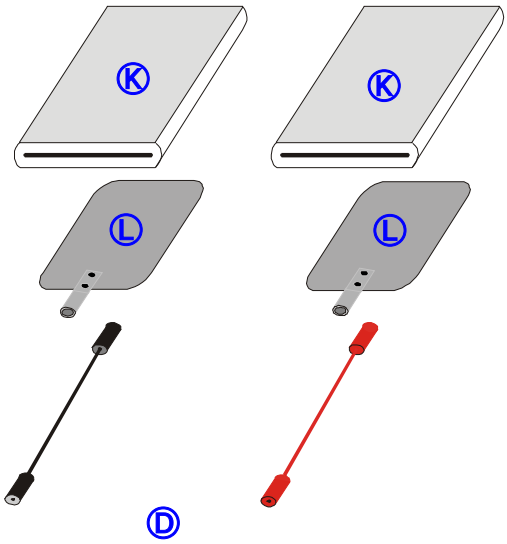
The following steps describe how you set up your therapy system for a treatment session. Please note that the setup for treating hands or feet is slightly different from the setup required for treating hands and feet simultaneously and for treating the armpits.

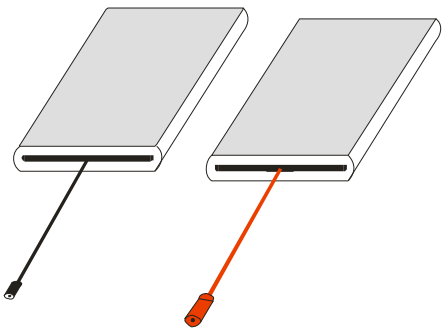
Setup for Treating Hands and Feet

1) Place the therapy device on a firm, level surface. Make sure an electric outlet is within reach.
2) Insert the safety wall adapter cable Ⓔ into jack ④ on the rear panel and plug the adapter into a wall outlet.
3) Plug the color-coded connectors of the dual cable set Ⓓ into the jacks ② on the back panel, matching colors.
4) Push the red and black terminals of the dual connecting cable set Ⓓ firmly onto the respective connectors on the treatment electrodes Ⓑ. **Make absolutely sure to forcefully push the connectors all the way onto the necks of the treatment electrodes.**
5) For simultaneous treatment of hands and feet, use the optional DUO accessory set and the hard shell cases Ⓐ for your feet and the ergonomic blue treatment trays Ⓕfor your hands. Connect the two electrodes in the hard shell cases and the electrodes in the treatment trays each to the respective cables from the DUO set. Now connect the black and red connecting cable Ⓓ with one electrode of the hard shell case and one electrode of the treatment tray.
6) Place one treatment electrode Ⓑ in each hard shell caseⒶ, or in each treatment tray Ⓕ, respectively. When using the ergonomic treatment trays Ⓕ, make sure the sloping rims point toward yourself (drainage groove away from you) – this will facilitate hand immersion.
7) Completely cover all treatment electrodes Ⓑ with a towel Ⓒ each.
8) Now fill both hard shell cases and/or treatment trays with hand warm tap water so that the skin areas to be treated can be easily immersed (the backs of the hands and backs of the feet should not be covered with water!).

Setup for Axillary Treatment (Armpits)

The setup for axillary treatment is mostly identical to the setup for hand or feet treatment, although axillary treatment requires special axillary applicators Ⓖ instead of water baths (trays).





Ⓖ Axillary applicators

1) Proceed with steps 1 to 3 of the instructions on the previous page.
2) Firmly push both plugs of the dual connecting cable Ⓓ onto the jacks of the AX electrodes Ⓛ.
3) Thoroughly soak the sponge cushions (AX I) equipped with integral leather pouches or the sponge pouches (AX II) Ⓚ with hand warm tap water. At this time, insert the AX electrodes Ⓛ **(Do not squeeze any water from the sponge cushions or sponge pouches.)**.

Treatment Setup for Special Applicators

The AX electrodes Ⓛ are also used for conducting treatments with the face mask Ⓗ or the nape or back applicator Ⓘ. Treatment setup is identical to the setup for axillary treatments except for the requirement to insert the AX electrodes Ⓛ into the pouches sewn onto the respective applicators.

Please ascertain that the sponge material is completely soaked (do not squeeze). Now secure the applicator with the hook and loop fasteners.

Conducting Treatments

Please observe the following two items before you begin a treatment session:

1) When conducting a treatment, avoid removing your hands or feet from the water bath or removing the axillary applicators from your armpits. If you ignore this advice, you run a slight risk of feeling a completely harmless – yet quite uncomfortable – electric shock. This shock may occur although the HIDREX system comes equipped with a protection circuit designed to permit current flow interruption.

2) Before you start a treatment session and close the current path with your armpits, hands, or feet, 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 – yet quite uncomfortable – electric shock!

Primary Parameter Setup (Setup Mode)

Depending on the specific HIDREX system you own, you can choose between various options before you initiate a treatment. How you select and store these parameters is described in the following paragraphs.

1) After setting up your HIDREX therapy system in accordance with the instructions in the “Installation” chapter, turn on the control unit by pushing the main power switch ①. First, the main display ❶ will briefly show three moving bars. Next, the following text is shown for about 8 seconds:

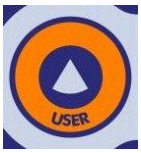
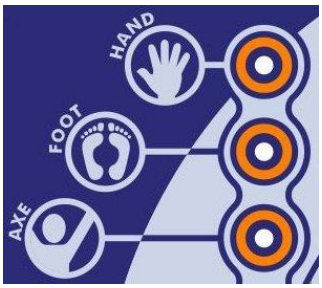
Setup Mode indication

Various treatment options can be selected as long as this text remains visible.

Important: If no button is pressed within approximately 8 seconds, the device will automatically switch from setup to treatment mode.

Hint: By pressing the ENTER key ❷, you can directly switch to treatment mode without having to wait.

2) Once in Setup Mode, activate or deactivate the options as desired[1]:

Option	Model	Function	Symbol
Memory  Key ❺	GS *400*	If *Memory* is activated, the unit will always save the most recent "time" and "dose" treatment settings; otherwise the system runs in manual mode.	Active if LED ❿ is lit 
USER  Key ❺	PS *500*	In addition to the primary settings (pulse and sense), the unit saves the "time" and "dose" treatment parameters for 3 users. If no LED is lit, the unit is in manual mode. (User change by pressing the button several times.)	Active if LED ❻ is lit 
SENSE  Key ❹	PS *500*	When SENSE is active, decreased setting apply to power output, maximum current, and current slope. This function was designed for sensitve patients, children, and for treating armpits and face.	Active if LED ❼ is lit 
PULSE  Key ❸	PS *500*	When *PULSE* is active, a pulsatile treatment current is used. *PULSE* minimizes the uncomfortable tingling sensation when current is flowing.	Active if LED ❽ is lit 

Important: The Setup Mode is generally activated only direct after switching on the device. If you left the Setup mode, you must turn off the device shortly and then again, must switch on in order to alter the above treatment options.

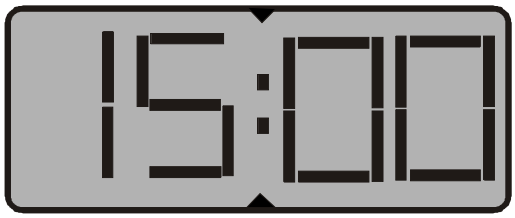
[1] Adjust the system in accordance with your doctor's instructions.

Begin Treatment (Treatment Mode)

After completion of the initial setup, the unit will automatically switch to treatment mode after about 8 seconds or when the ENTER button ❷ is pressed. Depending on user selection or memory function, the intended treatment time and dose will be displayed. Before you start the actual treatment session, you need to check and/or set the “time” and “dose” treatment parameters.

1) Setting treatment parameters:

If you have deactivated the memory function (LED ❿ is not lit) or if no user has been selected (none of the three LEDs ❻ is lit), the main display will show the following:



On the left, the display indicates the scheduled treatment duration in minutes, and on the right, the pre-selected treatment dose in Volts.

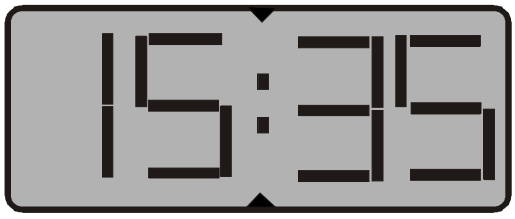
The colon blinks during this phase!

Select the desired treatment dose[1] with buttons ❷ and ❸, and the desired treatment duration with buttons ❹ and ❺. Each time you push one of these buttons, the corresponding treatment parameter is increased or decreased by one Volt or one minute, respectively.

Hint: By holding one of the push buttons down, you can continuously in- or decrease the corresponding treatment parameter.

Special functions MEMO, respectively HAND, FOOT, AXE

If the memory function is active or when a user has been selected, the device proposes the corresponding saved treatment parameters (time and dose). You can adjust these to your needs by pushing the respective buttons.



The system saves these settings. When another treatment session is started, the device will automatically suggest the latest settings.

If you adjust treatment parameters during a treatment session, the system will automatically save these changes as well.

[1] Select the dose in accordance with your doctor’s orders or use the table of factory-preset treatment parameters for guidance (see page 14 in this manual).

Hint: In addition to storing HAND, FOOT, and AXE for each user, model PS 500 also saves the respective treatment dose and time plus the selected primary settings SENSE and PULSE. These are the settings the device will propose when a new treatment session begins.

In the factory, your HIDREX system is preset as follows:

Option	Gerät	Behandlungsparameter
Memory 	GS *400*	SENSE: not available PULSE: not available DOSIS: 0 Volt ZEIT: 15 minutes
HAND 	PS *500*	SENSE: deactivated PULSE: activated DOSIS: 20 Volt ZEIT: 15 minutes
FOOT 	PS *500*	SENSE: deactivated PULSE: deactivated DOSIS: 30 Volt ZEIT: 15 minutes
Axe 	PS *500*	SENSE: activated PULSE: activated DOSIS: 18 Volt ZEIT: 15 minutes

The settings provided in the table above are also the recommended initial values for treating in manual mode.

In order to avoid skin irritation by excessive dose settings in pulsed mode (where current flow is nearly completely imperceptible), we recommend that you assess your individual direct current thresholds for hands, feet, or armpits before you start the first treatment session. To conduct axillary treatments, the dose should not be raised above 15, not even in SENSE mode, because the sensitive skin may otherwise get burnt.

2) Treatment start:

When treating hands or feet, place only one hand or foot onto the towels Ⓒ laying in the tap water filled hard shell cases (KofferschalenⒶ) or treatment trays Ⓕ. Make sure that your skin does not touch the electrodes directly. **Do not forget to remove any jewellery!**

To conduct an axillary treatment, pack the soaked axillary applicators Ⓖ into your armpits. Make sure the applicators fit well and apply even pressure to maximize the contact area in your armpit. The well soaked face mask and special applicators are secured with hook and loop fasteners.

When the integral “immersion monitoring” system recognizes that the circuit is closed, the Dive-LED ❾ lights up to indicate that treatment has started.

The colon expires during the Treatment!

On the display, the dose setting changes from the desired setting to zero, before it slowly increases to the desired value.

3) Adjusting treatment parameters:

At any time throughout the treatment session, you can change treatment time and dose settings by pressing the respective push buttons.

Important: If you perceive very localized pain during a treatment, you need to interrupt the session and cover the painful area with petrolatum. By pressing an arbitrary button, the automatic rising of the treatment dose can be interrupted.

If you interrupt the treatment by removing your hands or feet from the bath, the Dive-LED ❾ goes off and the treatment timer is halted. The display shows the remaining treatment time and the selected dose. When you continue the treatment, the Dive-LED ❾ will light up again and the dose display changes to zero, before it slowly increases to the desired value.

Hint: You can use your fingers to operate the controls even if your hands are inside the hard shell cases. To accomplish this, the device needs to be positioned directly in front of one of the hard shell cases. Make sure that the palm of the hand you intend to operate the controls with stays under water and on the towel, so that the current path remains closed. After dose adjustment, pull the entire hand into the water bath, making sure palm and towel remain in contact at all times.

4) Ending a treatment session:

When the treatment time is up, the treatment dose is automatically lowered to zero. Please keep your hands and feet in the water bath (or the axillary applicators in place, respectively) until the dose display reads “End“. Switch the device off.

Important Advise for Conducting Treatments

For your safety, your HIDREX treatment system comes equipped with several protective circuits.

Immersion monitoring

Until the treatment current path is closed (immersion monitoring) by immersion of the palms, the dose cannot be increased to any value above zero. The Dive-LED ❾ will light up when immersion is complete.

Over-treatment protection

If your skin is dryer than normal[1], the dose cannot be increased (protection against over-treatment). Your HIDREX system automatically checks your specific skin conductance. If your skin conductance is beyond the preset threshold, the protection circuit is activated and locks the system. The Dive-LED ❾ does not light up, even when the treatment current path is closed.

Hint: To double-check if over-treatment protection has been activated for you, simply ask another person to close the current path (this can be done without starting an actual treatment). If the Dive-LED ❾ lights up when the other person closes the current path, the system is in good working order.

If over-treatment protection is activated, you should interrupt your treatment course for at least one week until excessive perspiration returns.

Please contact us if the over-treatment circuit triggers although you still have excessive perspiration, a situation that may arise in rare circumstances. In that case, we would readjust the sensitivity settings to your needs.

Side Effects

Mild dysesthesia (tingling or burning) can occur under therapy, as well as short-term skin irritation (reddening) after treatment.

Important: Make absolutely sure to pay attention to the list of contraindications! Excessive dose settings can lead to burns!

[1] This does not relate to the water bath, but to the moisture content of the deeper skin layers, an indicator of the extent of hyperhidrosis.

General Information

This chapter contains important instructions about your HIDREX system.

Special Remark

Our responsibility for system safety, functionality, and reliability applies only if any maintenance and servicing is exclusively performed by ourselves or by personnel authorized by us. Our warrantee ceases and we assume no liability if any manipulation or service is performed by unauthorized personnel.

Care and Maintenance

HIDREX iontophoresis systems are basically maintenance-free. To prevent calcium deposits on the sheet metal, please make absolutely sure to remove any moisture from the treatment electrodes after each treatment.

The control unit, treatment trays, and electrodes should be cleaned with a moistened cloth or with a common detergent. Surface disinfectants may also be used.

The AX sponge cushions can be washed at 90°C; alternatively, they may be steam-sterilized or immersed in a disinfectant solution. If disinfectant is used, the sponges should be thoroughly rinsed with water before they are reused. The towels can be washed in the washer with your regular laundry -- follow the specific instructions. Common disinfectant supplements for laundry detergents may be used.

Calcium deposits on the electrodes can impair current flow. Use a household calcium deposit remover or immerse the electrodes in vinegar. Expect discoloration of the electrode metal after the first therapy sessions.

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

* Henkel: Incidin Extra (1%), Incidin Plus (0.5%), Incidur (0.5%), Minutil (0.5%)
Dr. Trippen (desomed): Biguamed
B. Braun: Melesept SF (0.5%/5%), Hexaquart S (1.5%/5%), Meliseptol (undiluted)

Symbol Legend

Connector for treatment electrodes
+ = Anode (red cable)
− = Cathode (black cable)

CE 0197

Type BF[1] device

Device identification: Serial-No.: yy-x.x zzz

yy: Year of manufacture
x.x: internal product type ID
zzz: consecutive number

Error Checklist

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 before you send the device for repair. Working through the checklist as the first step can save you considerable cost and inconvenience. Thank you.

- Verify that the safety wall adapter is properly connected to the control unit and to the wall outlet.
- Verify that the connectors on the dual connector cables are pushed far enough onto the receptacles of the treatment electrodes for establishing a reliable connection.
- The dose will only be increased to the selected setting after the time display shows a value of greater than 1 minute **and** the skin has closed the treatment current path (Dive-LED ❾ is lit).
- Verify that the device works properly on another person (over-treatment protection).
- Complete the operational check described below.

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

[1] Device leakage currents comply with standards -- the system provides protection against electrical shock (Type B); device is insulated (floating) (Type F).

Operational Check

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

1) Set up the therapy system as you would for a treatment.
2) Activate the main power switch ① to turn the control unit ON. Dose and treatment time settings should appear on the main display ❶.
3) Now close the treatment current path by placing one electrode onto the towel that covers the other electrode, but do not let the electrodes touch. Both electrodes a now immersed in a water-filled tray and lie on top of each other, remaining separated by a towel. When testing the system with AX electrodes, directly press both water-soaked sponge cushions together.
4) The unit's Dive-LED ❾ should now be lit and the dose should rise to the preset value.

If the dose does not increase under this test although the items on the error checklist have been followed, or if dose selection fails, please contact us so that we can coordinate the required steps.

Shipping the Device for Repair or Maintenance

The device should only be shipped in the supplied carrying case. If at all 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, sponge cushions, or the facial mask.

Please send all electrical accessories (safety wall adapter, treatment and AX electrodes, and dual connecting cable set) together with the HIDREX control unit.

Applicable Regulations and Legal Requirements

In accordance with addendum I and II of the MPBetreibV [Medical Device Vigilance System] , the operator of a medical device is required to maintain a Medical Device Log and to document completion of the safety inspections listed below.

Important: Private persons who use the device only privately do not have to comply with these requirements. Nevertheless, we recommend periodic safety inspections in accordance with the regulations.

Technical Safety Inspection

Only competent technicians trained by the HIDREX GmbH may be contracted for technical safety inspections. Suitable measuring and test equipment is mandatory. The medical device may only be operated with the accessories listed in the instruction manual.

In accordance with “MPBetreibV”, HIDREX iontophoresis units require technical safety inspections every 2 years in addition to inspections after each repair or reconditioning. Technical safety inspections have to cover at least the following items:

- Visual check of medical device and accessories
- Protective conductor test in accordance with DIN EN 60601-1:1990
- Leakage current test in accordance with EN 60601-1:1990
- Operational check of the medical device in accordance with the instruction manual

The operator is responsible to rectify any faults detected during the technical safety inspections (i.e. the user has to make arrangements for repair).

Waste disposal of package and Electro Garbage

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 appliance can become use no more, you please dispose expertly of it. In the remainder, the national ordinances are to be heeded.

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 the regular waste disposal with your commune. With the separate waste disposal, you supply the garbage to the recycling. You help to avoid with it that incriminating materials reach into the environment (ElektroG).

Reconditioning and Disinfection

HIDREX iontophoresis systems are reusable medical devices; reconditioning is classified as “non-critical”. The applicable joint recommendations of the “Kommission für Krankenhaushygiene und Infektionsprävention am Robert-Koch-Institut (RKI) [Robert-Koch Institute Division of Applied Infection and Hospital Hygiene]” and the “Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) [Federal Institute for Drugs and Medical Devices]” on “Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten [Reconditioning of Medical Devices: Hygiene Requirements]”, published on August 25, 2001, need to be complied with.

For reconditioning, the device has to be cleaned and disinfected in accordance with the instructions provided in the chapter on “Care and Maintenance”. The accessories towels, treatment electrodes, and treatment trays (carrying case) need to be disposed of and have to be replaced by new ones. In addition, a technical safety inspection has to be completed and documented. The medical device may be reconditioned up to 10 times.

Lifespan

Legal reasons limit the lifespan of this medical device to 4 years. The manufacturer has to recondition the medical device not later than by the end of this term. 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.

Electric-Magnetic Compatibility

Of course, the HIDREX Devices are developed after the stipulated guidelines for electromagnetic compatibility (EMV) and been manufactured.

Caution: Medical-Electric-Appliances are subject to medical-electric-appliances. The EMV particular precautions and must install in accordance with the EMV-Hints contained in the accompanying-papers and in operation is taken. Wearable and mobile HF-Communication facilities, as portable phones or Pager, can influence medical-electric-appliances!

Broadputlines and Manufacturer-Declaration

The following tables include the broad outlines and manufacturer-explanations after DIN EN 60601-1-2:2001 of all magnet-field-therapy-appliances of the company Hidrex GmbH, Otto-Hahn-Str. 12, D-42579 Heiligenhaus.

<table>
<tr><td colspan="3">ELECTROMAGNETIC RADIATIONS DIN EN 60601-1-2, 6.8.3.201, Table 201</td></tr>
<tr><td colspan="3">The Therapy-Appliances of the company Hidrex GmbH is certain for the business in the below stated electromagnetic surroundings. The user of the respective appliance should guarantee that it is used in such a surrounding.</td></tr>
<tr><td>Emission- measurement</td><td>Conformity</td><td>Electromagnetic environment - broad outlines</td></tr>
<tr><td>HF- Emission
after CISPR 11</td><td>Group 1</td><td>The appliance uses high frequency-energy exclusively for his/its internal function. His/its HF therefore is - end-program very low, and it is unlikely that neighbouring electronic appliances are disturbed.</td></tr>
<tr><td>HF- Emission after CISPR 11</td><td>Class B</td><td rowspan="3">The appliance is for the use in all facilities including residential-areas and such certain that is connected directly at a public supply-net, which looks after also buildings that are used for residential-purposes.</td></tr>
<tr><td>Overtone after
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage swing/ patcher after IEC 61000-3-3</td><td>Comply</td></tr>
</table>

RECOMMEND DEFENCE DISTANCE BETWEEN ACCEPTABLE AND MOBILE HF- TELE COMMUNICATION DEVICE AND THERAPY DEVICE OF THE COMPANY HIDREX GMBH DIN EN 60601-1-2, 6.8.3.201, Table 206

The device is meant for the business in a electromagnetic surrounding, where are HF- sturgeon sizes are controlled. The user of the device can help due the fact, to avoid electric magnetic disturbulece, by keeping the minimum distance between acceptable and mobile HF- Tele communication device (transmitter) and the device – dependent on the power output of the Communication device, like specified below.

	Defence distance, dependent on the transmit frequency in m		
Wattage rating of the transmitter W	150 kHz to 80 MHz $d=\{ 3,5/V_1 \}\sqrt{P}$	80 MHz to 800 MHz $d=\{ 3,5/E_1 \}\sqrt{P}$	800 MHz to 2,5 GHz $d=\{ 7/E_1 \}\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,70	3,70	7,37
100	11,70	11,70	23,33

For transmitters, that maximum wattage rating is not specified in table above, the advice defence distance d can be ascertained in meters (m) under disposition of the equation, that belongs to the respectively chasm, which according the specification of the transmitter producer, the maximum wattage rating of the Transmitter in watt (W) is P.

NOTE 1: The higher frequency-area near 80 MHz and 800 MHz is valid .

NOTE 2: These broad outlines may not be applicable in all cases. The spread of electromagnetic sizes is influenced by absorptions and reflections of the buildings, objects and people.

ELECTROMAGNETIC STABILITY
DIN EN 60601-1-2, 6.8.3.201, table 202

Stability verification	**IEC 60601-Verification gauge**	**Conformity gauge**	**Electromagnetic environment-broad outlines**
Discharge static Electricity-(ESD) after IEC 61000-4-2	± 6 kV Contact-discharge ± 8 kV Air discharge	± 6 kV ± 8 kV	Floors should consist of wood or concrete or with ceramics-flow is equipped. If the floor with synthetic material is equipped, the relative humidity must amount at least 30 percent.
Fast transient electric sturgeon-sizes / Bursts of IEC 61000-4-4	± 2 kV for main connection ± 1 kV für in and out connection	Not applicable --- ± 1 kV	The quality of the supply-tension should correspond to that of a typical business or hospital-surroundings.
Withstanding (Surges) after IEC 6100-4-5	± 1 kV scanning-tension ± 2 kV common mode tension	± 1 kV ± 2 kV	The quality of the supply-tension should correspond to that of a typical business or hospital-surroundings.
Tension-break-ins, shortly, in the time of-interruptions and with fluctuations of the supply voltage after IEC 61000-4-11	There was been by the power adapter the test. The power adapter has an independent decrease.		
Magnetic field at the supply frequency (50/60 Hz) after IEC 61000-4-8	The device engendered a magnetic therapy field. Cancelled the measuring.		

ELECTROMAGNETIC STURGEON-SOLIDITY DIN EN 60601-1-2, 6.8.3.201, table 204			
Sturgeon-strength test	IEC 60601- test gauge	Accordance-levels	Elektromagnetic surroundings - broad outlines
HF led - sturgeon-sizes after IEC 61000-4-6 Beamed HF - sturgeon-sizes of IEC 61000-4-3	$3\ V_{eff}$ 150 KHz to 80 Mhz 3 V/m 80 MHz to 2,5 GHz	$V_1 = 3\ V$ $E_1 = 3\ V/m$	Wearable and mobile radio equipments should be used in no more inferior distance between the appliances including the managements as the recommended protection-distance that is calculated after the equation applying to the transmitting frequency. recommended protection distance: $d=\{3,5/V_1\}\sqrt{P}$ $d=\{3,5/E_1\}\sqrt{P}$ for 80 MHz to 800 MHz $d=\{7/E_1\}\sqrt{P}$ for 800 MHz to 2,5 GHz with P as nominal-performance of the station in watt (W) in accordance with statements of the station-manufacturer and d as recommended protection-distance in meters (m). The field-strength of stationary radio-stations should be more inferior than the accordance-level with all frequencies in accordance with an examination on the spot. In the surroundings of appliances, that carries the following picture-sign, disturbances are possible: 

NOTE 1: The higher frequency-area near 80 MHz and 800 MHz is valid .

NOTE 2: These broad outlines may not be applicable in all cases. The spread of electromagnetic sizes is influenced by absorptions and reflections of the buildings, objects and people.

a. The field-strength of stationary stations, like Z.B. Basis-stations of radio-telephones and mobile country-radio equipments, amateur-radio-stations, AT THE, and FM, radio and TV stations cannot be predetermined exactly theoretically. In order to determine the electromagnetic surroundings regarding the stationary stations, a study of the location should be considered. If the measured field-strength in the location, at which the appliance is used, exceeds the above accordance-levels, the appliance should be observed in order to prove the due functions. If uncommon features are observed, additional measures can be necessary, like i.e. a changed alignment or another location of the appliance.

b. Over the frequency-area of 150 kHz of 80 MHz, the field-strength should be more inferior than 3 V/m.

Technical Data

Control Unit GS *400* and PS *500*

Display-Tolerance	Treatment Voltage (Dose)	± 2 V
	Treatment Time	± 1 %
Dimensions	190 x 49 x 137 mm	(W x H x D)
Mass	0.5 kg	
Power input	Input voltage:	12 V
	Max. input current:	500 mA
	Input power:	max. 6 VA
Environmental temperature	+10°C to +30°C	
Direct current output	Treatment voltage	60 V= max.
	Treatment current	35 mA max.(into a 1 kΩ load)
	Max. output power	225 mW
Pulsed current output	Treatment voltage	60 V= max.
	Treatment current	35 mA max (into a 1 kΩ load)
	Pulse repetition frequency	9.9 kHz

See supplementary sheet for guidelines and factory declarations in accordance with DIN EN 60601-1-2:2001 (EMC).

Safety Wall Adapter (Typ: Egston P2xFMW3 6W)

Input	Input voltage	100-240 V~ / 50-60 Hz
	Max. current	400 mA
Output	Nominal output voltage	12 V=
	Output current	max. 0,5 A
	Max. output power	6 VA

Manufacturing and Distribution

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