idromed® 4 GS

Art.-No. 19160



Before putting the unit into operation and starting the treatment, read these operating instructions carefully.



Dear Sir or Madam,

With the <code>idromed® 4 GS</code> you have purchased a tried and tested iontophoresis unit for the treatment of excessive sweating (hyperhidrosis) on hands, feet and - with optional accessories - for armpits. We hope that you will be satisfied with the use of the <code>idromed® 4 GS</code>. In order to achieve good results, please follow these instructions exactly.

Kind regards,

Dr. K. Hönle Medizintechnik GmbH

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1. Important information on the idromed[®] 4 GS

1.1. Safety information

Please read these operation instructions carefully before starting the treatment with the idromed[®] 4 GS and follow our notes.



In case of the following contra-indications the idromed[®] 4 GS shall <u>not</u> be used or shall only be used after consulting your doctor:

- cardiac arrhythmia
- electronically controlled implanted devices (f. ex. pacemaker)
- metallic implanted devices in the area where the current flows
- metallic intrauterine implanted devices (loop)
- pregnancy
- bigger skin deseases
- insensibility for pain



For your own safety and for better control of the treatment time please use the digital timer enclosed with the unit.

During each tub



the treatment the electric circuit has to be closed constantly, i. e. in there has to stay at least one hand or one foot.

Conductive material (f. ex. metal, water pipes etc.) must not be touched during the treatment.

All jewellery on hands and feet must be removed before starting the treatment.

Any damages to the horny layer (minor injuries, scratches etc.) on the palms of the hands, soles of the feet, groove of the nailbed or at the armpits must be coated with vaseline or a fatty cream before treatment, as current permeability will be higher than normal on those spots. Please do only cover these spots!

Current intensity is set according to individual requirements of the user. The ideal current intensity evokes a pleasant, tingling sensation (not on the treatment of the armpits). The values listed in these instructions are the maximum values allowed. The current intensity chosen by the user, however, is normally much lower, otherwise there is a danger of burning the skin (f. ex. the usual range for the treatment of the armpits is about 1 - 2 mA).

Moisten the sponges from inside and outside, until they don't drop (do not wring them out)! If the sponges are too dry, there is a <u>danger of burns!</u>

Attention, there is a <u>danger of burns</u>, when the metallic electrodes are in direct contact with the skin! When treating the armpits, the sponge electrodes have to be kept quietly and with constant pressure under the armpits. Otherwise there will occur fluctuations of current at the display of the unit.

Never short-circuit the metallic electrodes!

The safe handling and smooth functioning of the idromed® 4 GS presuppose the careful observance of all relevant safety information.

The operation instructions contain all information necessary for the proper unit of the device. The operation instructions, especially the safety information, must be observed by all those who work with the unit. The accident-prevention rules and regulations prevailing at the place of use must also be observed.

Safety instructions for doctors / clinics:

Before commencing work, those people who are to work with the **idromed[®] 4 GS** have to:

- Observe the regulations governing safety and accident prevention,
- Read the chapter on safety and the warnings contained in these operating instructions and to observe these at all times during operation.

Hazards when operating this unit

The **idromed**[®] **4 GS** is built according to the state of the art and in compliance with recognized safety standards. The unit must be used

- only for that purpose for which it was intended,
- only when in perfect working order.

Improper use can endanger the health of the user and/or third parties as well as impairing the unit and other items of property.

Any faults which might impair the safety of the unit must be remedied immediately.

Proper use

The **idromed**[®] **4 GS** is an iontophoresis unit for the treatment of hyperhidrosis on the hands and feet and in the armoits.

Any other use of the unit going beyond this shall be deemed improper and may even be hazardous.

The operator may operate the unit only if all the user information contained in these operating instructions is observed at all times.

The company Dr. K. Hönle Medizintechnik GmbH shall not be liable for any damages caused by the improper use of the unit.

1.2. Symbols and warnings on the unit

+ Anode

Cathode

Normal operation (besides the green diode)

Attention! See operating instructions!

Functional error (near the orange diode)
In the event of a functional error, please switch off the unit and then switch it on again.

Application device of type BF

Units of protection class II

•

Alternating current

Unit contains electronic parts and may not be disposed in the household rubbish.

(see also chapter 10.)

2. Scope of delivery

The **idromed**[®] **4 GS** treatment set for the treatment of the hands and feet consists of the following parts (accessories for the treatment of the armpits are optional):



1 x **idromed**[®] **4 GS** iontophoresis unit



1 x Power supply with foot switch (with the foot switch, the unit can be switched on or off without taking out the hand of the tub)



2 x stainless steel plate electrodes (nickel-free)

2 x electrode cables

2 x distance grids



1 x shock-proof suitcase; the 2 parts of the suitcase are used as treatment tubs.

without picture



Digital timer (art.-no. 0466)

2x nickel-free electrodes with sponges for the treatment of the armpits.

Optional accessories, have to be ordered separately, if necessary. Art.-no. 19484

3. Application of the idromed[®] 4 GS

3.1. Fields of application

With the **idromed**[®] **4 GS** a tap-water iontophoresis therapy with direct current can be carried out.

Indications: Acc. to the actual state of knowledge the treatment of the following indications is promising:

Hyperhidrosis

3.2. Preparation of the treatment

The **idromed**[®] **4 GS** is used with a power pack. After the following preparations your unit is ready for use:

- a) For the treatment you should separate the two parts of the suitcase. To do this, open the suitcase completely, put it on a plain surface and separate the 2 parts carefully in opposite directions (see arrows on the hinges on the suitcase).
- b) Fill the 2 treatment tubs with tap water to a depth of approx. 3-4 cm. (the finger and toe joints should be just covered).
 - Please see also the warings on page 13, point 7.4.!
- c) Connect one of the cables to one of the plate electrodes and to the **(+)**-connection on the front of the **idromed**[®] **4 GS**.
- d) Connect the 2nd cable of the electrode with the other electrode and with the (-)-connection on the front of the idromed[®] 4 GS.
- e) Place the electrodes 1 in each tub and cover the electrodes with the distance grids.
- f) Take care, that the black control knob for the regulation of the current intensity is pointing to [1] and that the foot switch is pointing to [0].
- g) Connect the plug of the power supply to the rear of the **idromed**[®] **4 GS** and plug the power supply to a mains socket (220-230 V / 50 Hz). The green control lamp on the power pack is now alight.
- h) Switch on the unit via the foot switch.
- i) Adjust the treatment time on the digital timer delivered with the unit and start the timer when beginning the treatment. (Treatment time: 10–15 minutes, acc. to doctor's prescription)

The **idromed**[®] **4 GS** is now ready for the treatment!



The LCD-display of the **idromed**[®] **4 GS** indicates a positive value only when the current flow is closed via the body. Only then the really flowing therapy current is indicated on the display.

When the 2 electrodes have no contact to the body and the foot switch is switched to [1], the LCD-display always indicates the value [0]! (see also Chapter 7)

3.3. Treatment

If possible, the treatment should be performed once a day in the beginning. Treatment should last 10-15 minutes, depending on the doctor's prescription. Normally, after 10 treatments, a normal hydrosis level is reached and the skin moisture is normalized. After this, treatment is normally carried out once a week.

The inhibition of sweating is much more pronounced at the plus pole than at the minus pole. In order to optimize the therapeutic effect, you should therefore switch polarities before every 5th treatment session. To do this, you have only to swap the electrode leads.

Current intensity is set according to individual requirements of the user. The ideal current intensity evokes a pleasant, tingling sensation. The values listed in these instructions are the maximum values allowed. The current intensity chosen by the user, however, is normally much lower.

The **maximum values** permissible are:

For the treatment of the hands:
For the treatment of the feet or of hands and feet:
For the treatment of the armpits:
5 mA

If the current intensity selected is too high, you may experience an unpleasant tingling sensation in the extremities treated during the session. If this occurs, a lower current intensity has to be selected otherwise there is a <u>danger of burns!</u>

After each session, please empty the tubs and dry the tubs, the electrodes and the cable with a towel.

3.3.1. Treatment of hyperhidrosis on the hands



Don't switch off the unit via the foot switch during the treatment.

The hands can be removed from the tubs without any danger during treatment in order to choose the current value.

- a) Separate the 2 parts of the suitcase as described in Point 3.2.a) and place them in front of the idromed[®] 4 GS on the table. Connect the electrodes as described in Point 3.2.b).
- b) Switch the control knob to the value [1] and the foot switch to [1].
- c) **Quickly** put each hand in one of the water-filled treatment tubs.
- d) There are 2 possibilities to choose the current intensity:
 - Switch on the unit by the foot switch. The person helping you now chooses the current intensity by turning the control knob to a value, at which you experience a pleasant tingling sensation.
 - Switch on the unit via the foot switch and put one hand in one tub. Turn the control knob by approx. ½ of a value indicated on the scale with the other hand and then put the second hand **<u>quickly</u>** in the other tub, in order to close the circuit. If you don't experience a tingling sensation in the hands, take one hand out of the tub and turn the knob by another ½ of the value, then **<u>quickly</u>** put your hand again in the tub. Repeat this procedure, until you experience a pleasant tingling sensation on your hands.



In order to choose the correct current value, the hands can both be taken out of the tubs whitout any danger, even when the unit is switched on.

- e) The actual value of the current intensity is indicated on the LCD-display. Note this value and the position of the control knob for the next treatment session.
- f) At the next treatment session leave the control knob on the position determined before. Make sure that the unit is **switched on** via the foot switch.
- g) Put the hands **quickly** in the treatment tubs.
- h) At the end of the session, after 10-15 minutes, take the hand **<u>quickly</u>** out of the tubs and switch off the unit via the foot switch.

Turn the control knob to the value [1].

3.3.2. Treatment of hyperhidrosis on the feet



The patient must not remove the feet from the tubs during treatment!

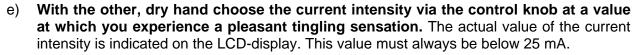
- a) Separate the 2 parts of the suitcase as described in Point 3.2.a) and place them on the floor. Connect the electrodes as described in Point 3.2.b).
- b) Switch the control knob to the value [1] and the foot switch to [1]
- c) **Quickly** put each foot in one of the water-filled treatment tubs.
- d) Choose the current intensity with the control knob at a value, at witch you experience a pleasant tingling sensation. The actual value of the current intensity is indicated on the LCDdisplay. This value must always be below 25 mA.
- e) At the end of the treatment, after 10-15 minutes, **quickly** remove your feet from the tubs and switch off the unit via the foot switch.
- f) Turn the control knob to the value [1].



3.3.3. Treatment of hyperhidrosis on hands and feet

For the simultaneous treatment of hands and feet you should separate the two parts of the suitcase. To do this, open the suitcase completely, put it on a plain surface and separate the 2 parts carefully in opposite directions (see arrows on the hinges on the suitcase).

- a) Put one tub (suitcase) for the hands on the table in front of the **idromed**[®] **4 GS** and connect the electrode with the connection cable to the negative pole of the unit. Put the second tub (suitcase) for the feet on the floor and connect the electrode with the connection cable to the positive pole of the unit. Cover the electrodes with the grids.
- b) Switch the control knob to the value [1] and the foot switch to [1].
- c) Put **both** feet in the water-filled tub on the floor. During treatment you shouldn't remove the feet from the treatment tub.
- d) Put one hand in the second tub.



- f) Put this second, dry hand in the treatment tub to the other hand.
- g) In order to regulate the current intensity, only one hand is taken out of the tub.
- h) At the end of the treatment, after 10-15 minutes, remove the hands and feet **quickly** from the tubs. Switch off the unit via the foot switch.
- i) Turn the control knob to the value [1].



3.3.4. Treatment of hyperhidrosis at the armpits

Before the treatment clean the armpits with clear water, in order to remove any cosmetics and so to avoid any irritations of the skin.

For the treatment of the armpits use the 2 optional sponge electrodes with the sponges.



2x nickel-free electrodes with sponges for the treatment of the armpits.

Optional accessories, have to be ordered separately, if necessary. Art.-no. 19484

- a) Use the 2 electrode cables to connect the electrodes with the positive and the negative pole of the unit.
- b) Moisten the sponges <u>from inside and outside</u> until they don't drop (do not wring them out)! During this the electrodes can stay in the sponges. **Attention, there is a danger of burns, if the sponges are too dry and if the metallic electrodes are in direct contact with the skin!**
- c) Switch the control knob to the value [1] and the foot switch to [1].
- d) Put one sponge electrode under each armpit.
- e) Choose the current intensity via the control knob at a value at which you experience a pleasant tingling sensation, then turn back the knob, until the tingling sensation stops. The actual value of the current intensity is indicated on the LCD-display. This value must always be below 5 mA. (the optimum value is 1 2 mA).
- f) When treating the armpits, the sponge electrodes have to be kept quietly and with constant pressure under the armpits. Otherwise there will occur fluctuations of current at the display of the unit.
- g) At the end of the treatment, after 10-15 minutes, turn down the current intensity to the value [1], remove the sponge electrodes from the armpits and switch off the unit via the foot switch.

4. Important tips and information

- To simplify the therapy, the current intensity at which you experience a pleasant tingling sensation can be set again by using the LCD-display before the treatment.
- The maximum current and voltage are limited by safety limits prescribed for electrical medical equipment. Nevertheless, do not remove your hand and/or feet from the treatment tubs during the session (keep the current circuit closed). Take care, that the unit is not switched off via the foot switch during the treatment.
- The inhibition of sweating is much more pronounced at the positive pole than at the negative pole. In order to optimize the therapeutic effect, you should therefore switch polarities before every 5th treatment session. To do this, you have only to swap the electrode leads.
- If you suffer from hyperhidrosis on certain parts of the body more than on others (f. ex. on the feet more that on the hands), you will achieve the desired results faster, if you treat your hands and feet simultaneously and if you use the plus pole to treat your feet.
- Please take care, that the water you are using is normal tap water and <u>has not been treated</u> with a water softener before.

5. Cleaning and Care

After each treatment session, empty the treatment tubs and dry the tubs, the electrodes and the cable with a towel. Disinfect the treatment set regularly with a usual commercial disinfectant.

6. Maintenance

Acc. to the Medical Device Directive (MDD) and the regulations for operators the safety of the unit has to be checked regularly by our Customer Service or by a technician authorized by the company Dr. K. Hönle GmbH. This applies only to commercial users. Nevertheless we generally recommend the same procedure also for private users.

7. Problems and how to solve them

PROBLEM	SOLUTION			
7.1. The lamp on the mains plug does not work.	In brightly lit rooms, it can be difficult to see whether the lamp is on or not. Shade the lamp with your hand to check, whether it is working properly.			
	The socket may be defect. Please connect the unit to another socket or check whether the socket in question is working properly.			
7.2. The green control lamp (I) does not work.	In brightly lit rooms, it can be difficult to see whether the lamp is on or not. Shade the lamp with your hand to check, whether it is working properly.			
	The unit is not connected properly. Check the connection between the mains cable and the unit.			
	The unit is not switched on. Turn the control knob to the value 1 and switch on the unit via the foot switch.			
7.3. The orange error lamp is on.				
7.4. The LCD- display shows	The LCD-display shows a positive value only when the electric circuit is closed.			
unalteredly 0 mA.	If no current flow is indicated during the treatment, check the connection between the mains cable and the unit as well as the electrode connections.			
	Please check, if the water you are using has been treated with a water softener before. By using softened water, the conductivity is reduced. In this case please use untreated tap water or use non-carbonated (still) mineral or table water.			
	If there isn't a positive value, if all connections are correct, please contact the Customer Service.			
7.5. Current intensity is not sensible.	Check the connections and the function of the unit (see above).			

If you have further problems, please contact our **Service-Hotline**:

Telephone **+49-8191-30555-0** or by e-mail to medizin@drhoenle.de.

For orders of spare parts please contact:

Dr. K. Hönle Medizintechnik GmbH Viktor-Frankl-Str. 20 D–86916 Kaufering Tel.: 0049-8191-305 55-0
Fax: 0049-8191-305 55-50
E-Mail: medizin@drhoenle.de
Internet: www.idromed.de

8. Technical Data

Type idromed[®] 4 GS

Art.-No. 19160

Dimensions of the unit 200 mm x 170 mm x 87 mm (L x W x D)

Dimensions of the suitcase 290 mm x 390 mm x 110 mm (L x W x D)

Total weight (unit, suitcase and

accessories)

2,5 kg

Current supply Power pack, 230 V~ / 50 Hz

Fan-Out current $25 \text{ mA} / 2.0 \text{ k}\Omega$

infinitely variable from 0 - 25 mA

Accuracy $\pm 0.5\%$

Nominal input voltage 24 V ~

Fuse protection The unit has an electronic current limiting. In case of a

functional error the output current is automatically cut off and the orange lamp will be alight. Once the unit has been

switched off, the lamp will be out.

Protection class II, all insulated

MDD-classification lla

CE-Mark **(€**0123

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(Subject to technical alterations!)



8.1. Electromagnetical compatibility

idromed[®] **4 GS** uses high frequency energy exclusively for its internal function. Therefore its HF-emission is very low and it is unlikely that surrounding electronic devices are disturbed. (HF-emissions acc. to CISPR 11, group 1)

idromed® 4 GS is determined for the use in an environment as described below. The user should take care that the unit is used in such an environment.

idromed® 4 GS is determined for the use in all facilities, including residential areas and such facilities connected directly to an official supply network, which also supplies buildings and residential buildings. (HF-emissions acc. to CISPR 11, class B)

Magnetic fields at the supply frequency should correspond to the typical values for business and hospital environments.

Portable and mobile radios should not be used at a lower distance to the **idromed**[®] **4 GS** including cables than the recommended security distance acc. To the table below:

Nominal capacity of	Security distance depending on the transmitter frequency m			
the transmitter	150 kHz - 80 MHz	80 MHz - 800 MHz	800 MHz - 2,5 GHz	
0,01	0,12 m	0,12 m	0,23 m	
0,1	0,37 m	0,37 m	0,74 m	
1	1,17 m	1,17m	2,33 m	
10	3,70 m	3,70 m	7,37 m	
100	11,7 m	11,7 m	23,3 m	

9. Warranty and liability

Generally, the general Terms of Sales and Delivery of the company Dr. K. Hönle Medizintechnik GmbH shall apply. These shall be submitted to the operator upon the signing of the contract at the very latest. The warranty for the **idromed® 4 GS** is 24 months. Warranty and liability claims are excluded in case of personal injury or damage of property if these are attributable to one or more of the following causes:

- The use of the **idromed**[®] **4 GS** for a purpose other than that for which it is intended
- Improper assembly, commissioning and operation of the idromed[®] 4 GS
- Operation of the idromed[®] 4 GS with defective and/or malfunctional safety and protective equipment
- Failure to observe the information contained in the Operating instructions on the commissioning, maintenance and operation of the unit
- Unauthorized structural modifications on the idromed[®] 4 GS
- Repair work performed by persons not authorized by the company Dr. K. Hönle Medizintechnik GmbH
- Catastrophes caused by foreign bodies or acts of God.

10. Environmental protection

idromed[®] **4 GS** has been constructed for a long-time reliable operation. If the **idromed**[®] **4 GS** has to be disposed, please take care, that the unit must not be disposed with the household rubbish. Please return the unit to your dealer, in order to grant an environmentally suitable disposal.

