dr. hönle
medizintechnik

Instructions for use

idromed® 5 PS

Item no. 111001 – EU-plug / silver
Item no. 111501 – EU-plug / white
Item no. 111003 – UK-plug / silver
Item no. 111503 – UK-plug / white

Please read these instructions carefully before beginning treatment!

Rev. 06/2016

Part I – General Safety and Compliance Information

Dear Sir or Madam,

You have purchased an **idromed® 5 PS**, the iontophoresis device for treatment of excessive sweating (hyperhidrosis) of the hands, feet and armpits. We hope that you will be satisfied with the **idromed® 5 PS**. You will help assure your own satisfaction by carefully reading and observing all the following instructions before using the device.

Sincerely yours,

Dr. Hoenle Medizintechnik GmbH

1. Important notes for your safety

Please read these instructions before using the idromed® 5 PS and observe them carefully.

1.1 General safety instructions

	In case of contraindications as described in section 2.3, idromed® 5 PS should **not** be used or only in consultation with the attending physician.
	Using the device and another high frequency surgical device at the same time can cause burns under the electrodes.
	Operation in close proximity (less than 1m) to a medical device for short wave or microwave therapy can cause fluctuations in the output levels of idromed® 5 PS.
	Application of the electrodes on or near the chest may increase the risk of ventricular fibrillation.
	Use extra caution when operating with effective current densities of more than 2 mA/cm² on any electrode surfaces.

	The therapy should not be applied: on or through the head; directly to the eyes; inside the mouth; on the front of the neck (especially the carotid sinus); or with electrode surfaces attached on the chest and upper back or across the heart.
	During treatment, the circuit must always be closed, i.e. there must be at least one hand or foot in each tray.
	Conductive objects (e.g. metal, water conduits, etc.) must not be touched during treatment.
	All hand and foot jewellery, including wrist watches, must be removed before treatment.
	Damage to the stratum corneum (minor injuries, scratches, etc.) on the palms, soles of the feet, nail folds or armpits, as well as areas that are susceptible to eczema, must be covered with Vaseline or a fatty ointment, since conductivity is elevated in these areas. Please cover only these areas!
	Adjustment of the current should be performed individually for each user. The current is optimal when the treatment does not cause stitches or burning. The current levels specified are maximum permitted levels.
	Wet the sponge pockets very thoroughly inside and out, but not to the point that they drip water. Do not wring! If the sponge bags are too dry there is considerable **risk of burns!**
	Warning: direct skin contact with the metal electrodes can **cause burns!** During axillary treatment, the electrodes must be kept steady, with even pressure; otherwise there may be error messages or power fluctuations in the display.
	Never short metal electrodes!

The device may only be connected to a fixed wall socket with protective contact. The device may not be operated via extension cable or via splitters!

The device must not be used in conjunction with other household appliances.

Compliance to all important safety instructions is a prerequisite for safe and trouble-free operation of the **idromed® 5 PS**.

This manual contains all necessary instructions to operate the device properly. The manual, particularly the safety instructions, must be observed by anyone working with the device. Also, all applicable local rules and regulations for accident prevention must be obeyed.

1.2 Responsibility of staff

Individuals in clinical facilities or doctors' offices who are to work with idromed® 5 PS must, before they begin, agree to:

- observe the regulations on occupational safety and accident prevention.
- read the chapters on safety and the warnings in this manual and continually observe them during operation.

Apart from adhering to the instructions for use, no further technical requirements are needed for its operation.

1.3 Use in home treatment

This medical device was also developed for the treatment of patients in a home setting. The following minimum requirements apply to patients using the appliance independently:

- The user must be able to read these usage instructions independently and understand them. No further technical qualifications are necessary.
- The minimum age for use of **idromed® 5 PS** is 12 years. Children under 12 may use the medical device for therapeutic purposes only in consultation with the attending physician **and** under adult supervision.

1.4 Hazards when using this device

The **idromed® 5 PS** is built to a state-of-the-art standard incorporating the established safety regulations. The equipment may only be used

- as intended
- in a perfectly safe setting, and
- with the enclosed original accessories from the manufacturer.

Improper use can endanger the health of the user or other persons, or damage the equipment or other material.

Malfunctions that could affect safety must be corrected immediately.

1.5 Intended use

The **idromed® 5 PS** is an iontophoresis device for the treatment of hyperhidrosis of the hands, feet and armpits.

If the patient operates this medical device during its application completely and without assistance, then the patient becomes the operator.

The user may only operate the device in accordance with all the user and safety information in this manual.

Any other use, or use beyond its specifications, is regarded as improper and can be dangerous.

Dr. Hoenle Medizintechnik GmbH cannot be made liable for injury or damage caused by improper use of this device.

1.6 Symbols and warnings on the equipment

+	Anode	−	Cathode
	On/off switch (pressure switch)		Safety Class II devices
	Application part type BF	IP 21	Protection class against ingress of dirt and water
	Manufacturer's name and address		Observe instructions for use
CE 0123	CE mark with symbol of the designated authority		Do not dispose of with household waste! (See also Chapter 10)
	See warnings in instruction manual		

2. Areas of application, indications, contraindications, side effects and environment

2.1 Areas of application

With the idromed® 5 PS, depending on the indication, long-term iontophoresis therapy can be performed using tap water and a pulsed direct current (pulsed DC). Affected body parts, such as hands and feet, are placed in trays filled with tap water. During treatment, direct current flows through the extremities. During axillary treatment, the current flows through wet sponge bags. This current flow causes a normalization of perspiration. (See Part II - operating instructions, page 9).

2.2 Indication

According to the latest findings, treatment of the following indications is promising:

- Hyperhidrosis of the hands, feet and armpits
- Multiple therapy-resistant Verrucae-Vulgares on hands or foot soles
- Dyshidrotic hand or feet eczema
- Sudeck's syndrome
- Gramnegative infections of the interstitial spaces between the toes, the keratoma sulcatum and fungal infections (mycoses), possibly resulting from the hyperhidrosis.

2.3 Contraindications

In cases of the following contraindications, the **idromed® 5 PS** should **not** be used or only after consultation with the attending physician:

- Cardiac arrhythmia
- Electronically controlled implants (e.g. pacemakers)
- Metal implants in the area of the current flow
- Metal-containing (coil) intrauterine implants
- Pregnancy
- Large skin defects
- Insensitivity to pain stimuli

2.4 Side effects

In very rare cases, side effects can occur during treatment. Please see the following notes:

Side effect	Notes
Skin reaction (redness, very rarely blistering) especially along the waterline	➔ Reactions are temporary and normally resolve without additional treatment after 1 hour.
Dry, cracked skin	➔ Can be minimized by the use of cream.
Distressing pain in areas with injuries or rashes	➔ Cover injuries or inflamed areas of the skin with Vaseline.

2.5 Environmental conditions

The **idromed® 5 PS** is designed to be used in dry rooms with an ambient temperature of 15 °C to 30 °C (59 °F to 86 °F).

Do not operate in rooms with more than 85% humidity.

Always protect the device against chemical vapors and never operate it in potentially explosive areas.

Part II - Operating Instructions for the idromed® 5 PS

3. Scope of delivery, description and setup

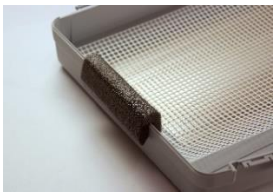
3.1 Scope of delivery

Basic treatment set:

1 x **idromed® 5 PS**
tap water iontophoresis device
(Basic unit) made from Terluran®.

1 x Power adapter
(24 V AC/DC ADAPTER, type: UE24WCP1-240030SPA)
or
(12 V AC/DC ADAPTER, type: KNW24U20A-120B0-I4410VL)

2 x aluminium plate electrodes (nickel-free)
2 x electrode cables
2 x plastic grids



2 x foam edge protectors

1 x shock-resistant PVC case
➔ whose two separable case shells also serve as treatment trays

1 x patient's diary

	1 x instructions for use

Optional accessories: (see Chapter 8 “Ordering spare parts”)

	2 x nickel-free armpit electrodes with sponge pockets for treating the armpits
	2 x large treatment trays, plus 2 x plastic cover mats for large treatment trays

3.2 Description

The basic treatment set consists of the components described in section 3.1 **“Scope of delivery"**.

The two halves of the supplied protective case serve as treatment trays. Mount the **idromed® 5 PS** following the steps described below.

Remove label and protective film from the electrodes prior to first use!

	For proper implementation of treatment and for your own safety, the device may **only** be operated with the enclosed original accessories from the manufacturer. Accessories from other manufacturers are **not** compatible with idromed® 5 PS!

3.3 Setting up the device

1

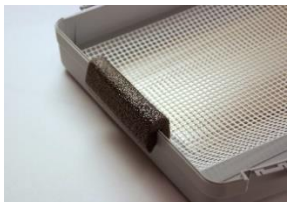
- ✓ The idromed® 5 PS should be used on a flat, stable base (table) close to a wall socket.
- ✓ Position the idromed® 5 PS so that it is easy to connect and/or disconnect the AC adapter.
- ✓ Open the case and take out all the supplied components.
- ✓ Place all parts on the table and set the packaging material aside.

2

The case halves serve as treatment trays.

- ✓ Before treatment the two case shells must be separated (for easy emptying after treatment).
- ✓ To do this, open the case completely, place it on a flat surface and pull the two halves gently apart in the direction indicated by the arrow.

3



The edge protection prevents uncomfortable pressure on the forearms.

- ✓ Attach the edge protection to the case edges.

4

The connectors for the electrode cable are on the outside left of the **idromed® 5 PS**.

- ✓ Connect the electrode cable marked (**+**) with the jack marked (**+**) on the device, and the electrode cable marked (**-**) with the jack marked (**-**).

5

- ✓ Cover each electrode with one of the supplied plastic grids.
- ✓ Now connect each electrode cable to the corresponding electrode tray.
- ✓ Place one electrode in each tray.

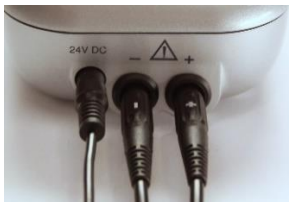
6

✓ Write down in your medical record with which polarity each hand or foot is treated. This will help you change the polarity for the next treatment.

7

✓ Fill the two treatment trays with tap water, high enough that the front finger joints or toe joints are barely covered.

8



✓ Now connect the power cord to the side of the **idromed® 5 PS** case and plug the AC adapter into a properly rated outlet (100 - 240V~ / 50 - 60Hz).
✓ The light on the power adapter will turn green.

The device is now ready for use.

4. Performing therapy

4.1 Preparing treatment

Remove all jewellery from around areas of treatment. Thoroughly clean the body parts to be treated, to remove any possible grease or cosmetic residue. If the body parts to be treated have any damage to the stratum corneum (minor injuries, scratches, eczema), cover these with Vaseline or a fatty ointment.

Observe all warnings and safety instructions listed in Chapter 1.1 "General safety instructions". Failure to comply may result in injury!

4.2 Types of treatment

The treatment should take place once a day to start. The therapy time is 15 minutes. A normal level of hidrosis is usually reached after 10-15 applications, meaning that moisture development of the skin is normalized.

Treatment example:

First week every day / **second** week every 2nd day / after the **third** week only **one – two times** per week.

The suppression of perspiration at the positive terminal (+ anode) is much more pronounced than at the negative terminal (- cathode). **In order to achieve an optimal therapeutic response, you should change the polarity after every 5 treatments.** Simply swap the connections of the electrodes (exchange the positive and negative connections).

The current level should be adjusted individually for each user. The following specified current levels are the maximum permitted levels. In general, however, the levels to be used are significantly lower.

The maximum allowable levels are as follows:

- For the treatment of hands: **15 mA**
- For the treatment of feet or hands and feet: **25 mA**
- For the treatment of armpits: **5 mA**

Too high a current can cause an unpleasant stinging or burning in the current-carrying extremities during treatment. If this occurs, the current level should be set lower; otherwise there is **risk of burns**!

4.3 Treatment of hyperhidrosis of the hands and/or feet

Do **not** turn off the device during treatment.

Direct skin contact with the metal electrodes can **cause burns!**

Position the treatment trays according to whether you want hands and feet treated at the same time or individual hand or foot treatments:

Fig (1):

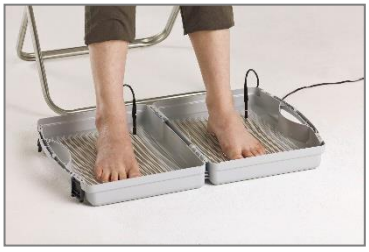
Fig (1) left
shows the positioning if simultaneous hand and foot treatment is to take place. For this situation, use one tray for the hands and one tray for the feet.

Fig (2) on the top right
shows the positioning if only the hands are being treated.

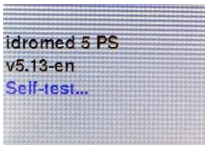
Fig (3) on the bottom right
shows the positioning if only the feet are being treated.

Fig (2):

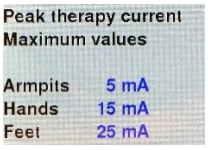
Fig (3):



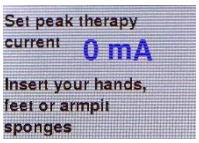
- ✓ Set the rotary switch so that the indentation is level with the dot (●) on the case before switching on the device.
- ✓ Turn on the device by pressing down the dark gray knob that regulates the current.
- ✓ Experience has shown that the desired therapeutic levels can best be adjusted to comfort from this setting.



After switching on, the device will perform a self-test automatically. This process takes a few seconds.



In the display you can read the maximum levels of the current selected for therapy.

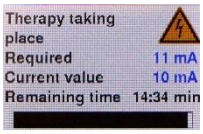


- ✓ Set amperage by rotating the knob to a minimum level (for hand treatment approx. 4 mA and for feet approx. 9 mA).
- ✓ This level can be increased by turning the knob to the right and decreased by turning to the left.
- ✓ Connect the circuit by putting a hand or a foot in each of the water-filled trays.

If you experience a stitching or burning sensation, the current is set too high and must be decreased until the feeling ceases.
If no stitching or burning occurs at maximum amperage, the treatment should be carried out with the maximum allowable amperage for each area.

To set the amperage, hands or feet can safely be taken from the treatment trays even with the power on.

Please dry off your hands before you adjust the amperage on the device!



The therapy time is 15 minutes. The remaining session time can be seen on the display.

If therapy is interrupted, the device stores the remaining treatment session time.

- ✓ If the therapy was interrupted, hands and/or feet may be put back into the trays.
- ✓ The therapy will continue automatically.

- ✓ After the treatment period, remove hands and/or feet from the treatment trays.
- ✓ Dry your hands thoroughly.
- ✓ Turn off the device by pressing the knob downwards.

After each treatment, disconnect all cables. Drain the water from the trays and dry the trays, electrodes and cable with a cloth.

4.4 Treatment of hyperhidrosis in the armpits

✓ For treatment of the armpits please use the two optional electrodes together with the sponge pockets (See Chapter 8 “Ordering spare parts”).

Do **not** turn off the device during treatment.

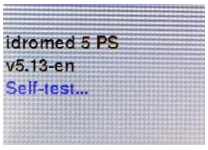
✓ Soak the sponge pockets in a water bath through dipping in, pressing and again dipping in. Press some water from the sponge bags, just enough that they no longer drip (do not wring!).
✓ The more water stays in the sponge pockets, the better the current will transfer to the areas undergoing treatment.

If the sponge bags are too dry there is considerable **risk of burns!**

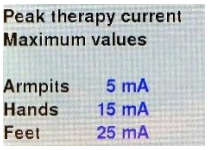
Attention! Direct skin contact with the metal electrodes **can cause burns!**

✓ Put the electrodes **completely** into the wet sponges.
✓ Use the two electrode cables to connect the electrodes to the positive and negative poles of the device.

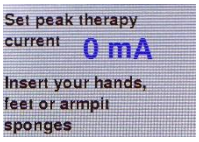
✓ Set the rotary switch so that the indentation is level with the dot (●) on the case before switching on the device.
✓ Turn on the device by pressing down the dark grey knob that regulates the current.
✓ Experience has shown that the desired therapeutic levels can best be adjusted to comfort from this setting.



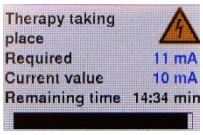
After switching on, the device will perform a self-test automatically. This process takes a few seconds.



In the display you can read the maximum levels of the current selected for therapy.



- ✓ Set amperage by rotating the knob to a minimum level of the maximum permissible current intensity (approx. 3 mA).
  - This level can be increased by turning the knob to the right
  - and decreased by turning to the left.
- ✓ Connect the circuit by squeezing a sponge electrode under each armpit.
- ✓ Throughout the entire treatment period keep the sponge electrodes under your armpits steadily and with even pressure; otherwise error messages or power fluctuations may occur in the display.



The therapy time is 15 minutes. The remaining time is readable on the display.

If therapy is interrupted, the device stores the remaining treatment session time.

- ✓ If the therapy was interrupted, the sponges with the electrodes may be put back under the armpits.
- ✓ The therapy will continue automatically.

If you experience a stitching or burning sensation, the current is set too high and must be decreased until the feeling ceases.
If no stitching or burning occurs at maximum amperage, the treatment should be carried out with the maximum allowable amperage for each area.

- ✓ After the treatment period, remove the sponge electrodes from under your armpits.
- ✓ Dry your hands thoroughly!
- ✓ Turn off the device by pressing the knob downwards.

After each treatment, disconnect all cables. Rinse the sponge bag thoroughly and let it dry. Clean the electrodes and cable with a cloth.

4.5 Tips and information

To simplify the treatment, use the same treatment amperage in mA once it is determined. Maximum current and maximum voltage adhere to safety standards that are defined by the DIN EN 60601-1 code. Keep the circuit closed during treatment and follow the treatment instructions. Make sure that the device is not turned off during ongoing treatment.

For optimal treatment results, please switch the polarity after 5 treatments. Simply swap the electrode terminals (plus ↔ minus).

Make sure that the water you are using has not been treated by a water softener. This reduces the conductivity of the water, which means the treatment can only be partially effected or not at all. If only softened tap water is available, use mineral water or soda water to perform the treatment instead.

Service required #1234	✓ If you see this message in the display, please call our customer service. ✓ Note the number that follows the hash sign (#) in the message and inform our staff. ✓ You will find our customer service contact information in Chapter 6 “Service”.

4.6 Cleaning and Maintenance

Drain the water from the trays after every treatment and dry the trays, electrodes and cable with a cloth.

Disinfect the treatment set (case, plate electrodes and cover mats) with a commercial disinfectant if needed. Discoloration of the electrode surfaces may occur after the first therapy sessions and is normal.

Wipe the device with a damp cloth only when needed.

Make sure no water gets into the device.

Never use abrasives or solvents such as alcohol, acetone or benzene.

The plate electrodes and plastic grids need to be cleaned regularly with a usual vinegar based solution.

Rinse the sponge bag thoroughly, clean them with water and let them not dry in the sun or on a radiator.

Note for doctors’ offices:

Dr. Hoenle Medizintechnik recommends the disinfectant Sani-Cloth Active® cleaning cloths by Ecolab. This product was tested in a long-term trial and can be recommended.

Part III - Maintenance and Service

5. Maintenance

The manufacturer recommends a safety inspection by our customer service at regular intervals (every 2 years). All accessories must be included in maintenance and safety inspections.

Maintenance on this device may not be carried out while the medical device is being used. A maintenance check may only be carried out by Dr. Hoenle Medizintechnik GmbH, or a person or institution authorized by Dr. Hoenle Medizintechnik.
Maintenance on this device may not be performed by the operator or user.

6. Service

If you notice a problem with your **idromed® 5 PS**, please start by reading Chapter 7 "***Troubleshooting***". If you cannot resolve the fault this way, please call the following contacts for assistance.

- For **questions** about **operation**, **service**, and **spare parts orders**, please contact us at:

Main Office:

Dr. Hoenle Medizintechnik GmbH
Dornierstrasse 4
D-82205 Gilching, Germany

Phone: 0049-(0)8105-73029-0
Fax: 0049-(0)8105-73029-50
Email: medizin@drhoenle.de
Website: www.drhoenle.de

- If the **medical device is defective** or if customer service recommends that you **return the device**, please send it to the following address:

Branch (production site):

Dr. Hoenle Medizintechnik GmbH
Thura Mark 8+10
D-06780 Zoerbig, Germany

7. Troubleshooting

Problem	Solution
The Display shows nothing	✓ Please check if the green LED on the power supply (AC/DC adapter) lights up. ✓ Please check the function outlet. ✓ Repeatedly press the on/off switch (push knob). ✓ If the unit still does not operate properly, return it to the manufacturer for repair (see Chapter 6). ✓ Please check the connection of the power cord to the device and the cable connections to the electrodes. ✓ Make sure that the water you are using has not been treated by a water softener. This would reduce conductivity. ✓ If necessary, untreated tap water or non-carbonated mineral or bottled water may be used. ✓ For axillary treatment, check whether the sponge pockets are wet enough. ✓ A depilation of hair under the armpits is recommended.
The green LED on the power supply (AC/DC) does not light up	It may be that the brightness of the room is making the LED light hard to see. ✓ Please shade the LED light with a hand and check to see if it is visible this way. The **outlet** may be **faulty**. ✓ Please connect the device to a different outlet or check the integrity of the outlet.
The device display screen shows "Error"	✓ If the device has malfunctioned, output current is automatically interrupted and the instrument gives an error message. ✓ Repeatedly press the on/off switch (push knob). ✓ If the error message persists, please contact our customer service (see Chapter 6)

Problem	Solution
The therapy session does not start (the display does not show "Therapy taking place...").	Let the device perform a self-test to determine whether the device is defective, or whether there is an application error: ✓ connect all cables (electrode cable & power supply) correctly; ✓ connect an electrode cable to each electrode plate; ✓ pour approx. 1 cm of water in one of the trays; ✓ place the first plate electrode in the tray, a white plastic grid over the electrode, and the second plate electrode on top of the grid; ✓ turn the current up; ✓ if the therapy session starts, i.e. the time countdown starts in the display, the device is now working. If the **self-test is positive**, the source of error is often ✓ the user **drinks too** little, i.e. the amount of fluid in the body is not sufficient to pass the current. Please drink 1.5 - 2 liters daily. ✓ the **horny layer** - especially for foot treatment - is too thick. **Solution:** take a 10-minute foot bath in clear water (without additives) to soften the horny layer and to allow the current to flow. ✓ while axillary treatment, the **sponge bags are not sufficiently soaked** (they should be soaked in water for about 5 minutes, so that they can absorb it properly). ✓ during the application, make sure that the electrodes are gripped under the arms neither too tightly (since too much water is then squeezed out of the sponge) nor too loosely (since without sufficient contact the current cannot flow). ✓ a common problem is the **areas of treatment not having been cleaned**, so that residues of deodorant, creams or lotions hinder the flow of the current. **Solution:** Please thoroughly clean the areas to be treated and rinse with clean water to remove any soap or cream residues completely.

8. Warranty and liability

Primarily, the general terms and conditions of Dr. Hoenle Medizintechnik GmbH apply. These shall be available to the user after finalization of the contract at the latest. The warranty on the device is 4 years. Warranty and liability claims for personal injury and property damage are excluded if they can be attributed to one or more of the following causes:

- Improper use of the **idromed® 5 PS**;
- Improper installation, commissioning or operation of the **idromed® 5 PS**;
- Operation of the **idromed® 5 PS** with defective and/or non-functioning safety and protection devices;
- Ignoring the instructions in this manual concerning the commissioning, maintenance and operation of the device;
- Unauthorized modifications to the **idromed® 5 PS**;
- Repairs carried out by staff that is not authorized by Dr. Hoenle Medizintechnik;
- Accidents caused by foreign bodies or force majeure.

9. Ordering spare parts

The following spare parts/optional accessories are available for purchase. For contact details, see Chapter 6, "**Service**".

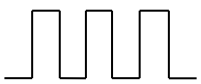
Item	Item no.
Nickel-free armpit electrodes with sponge pockets for treatment of the armpits	995100
Nickel-free armpit electrodes	995110
Sponge pockets	995120
Nickel-free tray electrodes	995140
Large treatment trays	995130
Plastic grids for large treatment trays	995131
Suitcase (trays)	995050
Plastic grids for tray electrodes	995150

Connecting cables + (anode) - (cathode)	 995170 995171
Power adapter	995160
UK power adapter	995162

Part IV - Technical Data, EMC, Disposal

10. Specifications of the idromed® 5 PS

Type:	idromed® 5 PS
Item number:	111001 – silver 111003 – silver UK plug 111501 – white 111503 – white UK plug
Device dimensions: (L x W x H)	210 mm x 120 mm x 70 mm
Case dimensions (L x W x H)	290 mm x 390 mm x 110 mm
Total weight (Base unit, case and accessories)	2.5 kg
Power supply	Power Supply (100 - 240V~ / 50 - 60Hz), Type: UE24WCP1-240030SPA or Power Supply (100 - 240V~ / 50 - 60Hz), Type: KNW24U20A-120B0-I4410VL 12 V

Output current	25 mA to 2 kOhm continuously adjustable control 0 - 25 mA
Measurement accuracy	± 3%
Accuracy of controls	± 10%
Nominal input voltage	12-24 V DC
Fuse	The device has an electronic current limiter. In case of malfunction of the device, output current is automatically interrupted and an error message is displayed. After turning off and on again the device is ready for use.
Protection class	II, protective insulation
Medical Device Class	II a
Protection class against ingress of liquids	IP21
Labeling	CE 0123
Current path	Output pulse power, peak current treatment max. 25mA, treatment voltage max. 59V Output waveform: rectangle, 10kHz, PWM ratio 50:50 All technical data are given with an accuracy of ± 3%.
Output waveform	 ton = 50µs ±5µs / toff = 50µs ±5µs Pulse repetiton frequency: 9-11 kHz Max peak output current: 30mA Max peak output voltage: 80V Load resistance range: 1kΩ ... 2kΩ

Manufacturer (The company is certified according to DIN EN ISO 13485) 	**Dr. Hoenle Medizintechnik GmbH** **Main Office:** Dornierstrasse 4 D-82205 Gilching, Germany **Branch (production site):** Thura Mark 8+10 D-06780 Zoerbig, Germany Tel.: 0049-(0)8105-73029-0 Fax: 0049-(0)8105-73029-50 E-Mail: medizin@drhoenle.de http://www.drhoenle.de
Environmental conditions	Temperature range: +15 ... +30 degrees (operation) -10 ... +55 Degrees (storage and transport) Humidity: max. 85% (not condensing) Atmospheric pressure: 500-1200 hPa This device must not be operated at an altitude of over 2000m.
Environmental protection	The medical device idromed® 5 PS meets the requirements of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of use of certain hazardous substances in electrical and electronic equipment. The device was tested for biocompatibility and classified as harmless.
Standards and tests	The idromed® 5 PS has been tested to the following standards in accredited testing laboratories: DIN EN 60601-1:2013-12; DIN EN 60601-1-2:2007-12; DIN EN 60601-1-6:2016-02; DIN EN ISO 60601-1-11:2008; DIN EN 62366; VDE 0750-241:2008-09; DIN EN ISO 60601-2-10:2003; DIN EN ISO 10993-5:2009-10
Schematics and other technical information	Schematics, component lists, descriptions, and other required technical information can be made available on request for authorized repairs by authorized personnel.

11. Electromagnetic Compatibility

Table 1 according to EN 60601-1-2: 2007

Guidelines and MANUFACTURER Declaration - ELECTROMAGNETIC EMISSIONS		
The idromed® 5 PS is intended for use in the ELECTROMAGNETIC ENVIRONMENT specified below. The customer or user of the idromed® 5 PS should ensure that it is used in such an environment.		
Emission measurement data	**Compliance**	**Electromagnetic environment - Guidelines**
RF emissions CISPR 11	Group 1	idromed® 5 PS uses RF energy only for its internal function. RF emissions are therefore very low, and it is unlikely that any nearby electronic equipment will be affected.
RF emissions CISPR 11	Class B	Idromed® 5 PS is intended for use in all facilities, including residential areas and such that are directly connected to a PUBLIC POWER SUPPLY that also supplies buildings used for domestic purposes.
Harmonics according to IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker acc. to IEC 61000-3-3	Not applicable	

Table 2 acc. to EN 60601-1-2:2007

Guidelines and MANUFACTURER Declaration - ELECTROMAGNETIC IMMUNITY			
The idromed® 5 PS is intended for use in the ELECTROMAGNETIC ENVIRONMENT specified below. The customer or user of the idromed® 5 PS should ensure that it is used in such an environment.			
IMMUNITY TESTS	**IEC 60601-TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDELINES**
Electrostatic Discharge (ESD) acc. to IEC 61000-4-2	± 6 kV Contact discharge ± 8 kV Air discharge	± 6 kV Contact discharge ± 8 kV Air discharge	Floors should be wood, concrete or ceramic tile. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst immunity test acc. to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines	± 2 kV for power lines ± 1 kV for input and output lines	The quality of the supply voltages should be that of a typical commercial or hospital environment.
Electrical surges/burst acc. to IEC 61000-4-5	± 1 kV Diff. mode voltage ± 2 kV Common mode voltage	± 1 kV Diff. mode voltage ± 2 kV Common mode voltage	The quality of the supply voltages should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and fluctuations in supply voltage acc. to IEC 61000-4-11	< 5 % U_T for ½ period (> 95 % dip) 40 % U_T for 5 periods (60 % dip) 70 % U_T for 25 periods (30 % dip) < 5 % U_T for 5 secs (>95% dip)	< 5 % U_T for ½ period (> 95 % dip) 40 % U_T for 5 periods (60 % dip) 70 % U_T for 25 periods (30 % dip) < 5 % U_T for 5 secs (>95% dip)	The quality of the supply voltages should be that of a typical commercial or hospital environment.
Magnetic field at supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	If faults occur, it may be necessary to place idromed® 5 PS further away from the sources of mains frequency magnetic fields.
NOTE: U_T is the mains AC voltage prior to application of test level			

Table 3 acc. to EN 60601-1-2:2007

Guidelines and MANUFACTURER Declaration - ELECTROMAGNETIC IMMUNITY			
The idromed® 5 PS is intended for use in the ELECTROMAGNETIC ENVIRONMENT specified below. The customer or user of the idromed® 5 PS should ensure that it is used in such an environment.			
IMMUNITYtests	**IEC 60601-TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - Guidelines**
Conducted HF disturbances acc. IEC 61000-4-6 Radiated HF disturbances acc. IEC 61000-4-3	3 V rms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V rms 3 V/m	Portable and mobile radio equipment may not be used closer to any idromed® 5 PS, including the lines, as the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the nominal power of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). According to a test in situ[a] the field strength of stationary radio transmitters at all frequencies is lower than the COMPLIANCE LEVEL.[b] Interference is possible in the vicinity of equipment marked with the following symbol. 
NOTE 1: At 80 MHz and 800 MHz the higher value applies. NOTE 2: These guidelines may not apply in all situations. The propagation of electromagnetic waves is influenced by absorptions and reflections from structures, objects and people.			
[a] The field strength of stationary transmitters, such as base stations of cordless telephones and land mobile services, amateur radio stations, AM and FM radio and TV transmitters can theoretically not be predicted with accuracy. To determine the ELECTROMAGNETIC ENVIRONMENT from fixed RF transmitters, an electromagnetic site survey is recommended. If the measured field strength in the location of the idromed® 5 PS exceeds the above compliance level, the idromed® PS must be observed for its normal operation at each place of application. If abnormal performance is observed, it may be necessary to take additional measures, such as re-orienting or relocating the idromed® 5 PS. [b] Throughout the frequency range of 150 kHz to 80 MHz, the field strength is lower than 3 V/m.			

Table 4 acc. to EN 60601-1-2:2007

Recommended separation distances between portable and mobile RF communications devices and idromed® 5 PS	
The idromed® 5 PS is designed for operation in an ELECTROMAGNETIC ENVIRONMENT in which radiated HF disturbances are controlled. The client or user of idromed® 5 PS can help prevent electromagnetic interference by maintaining minimum distances between portable and mobile HF communications equipment (transmitters) and the idromed® 5 PS as recommended below, in accordance with the maximum output power of the communications equipment.	
Nominal power of transmitter	**Separation distance acc. to transmission frequency** m

W	**150 kHz to 80 MHz** $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters whose nominal power is not specified in the above table, the distance can be determined using the equation for the respective column, where *P* is the nominal power of the transmitter in watts (W) according to the data of the manufacturer.

NOTE 1: To calculate the recommended separation distance of transmitters in the frequency range of 80 MHz, an additional factor of 10/3 was used to reduce the probability that a mobile/portable communication device that is unintentionally carried into the PATIENT area could lead to disturbance.

NOTE 2: These guidelines may not apply in all situations. The propagation of electromagnetic waves is influenced by absorptions and reflections from structures, objects and people.

12. Disposal

The **idromed® 5 PS** is designed for durable and reliable operation. Should the **idromed® 5 PS** no longer be used and have to be disposed of, please note that electronic components do not belong in household waste. Please contact us regarding its disposal.

Part V – Product and user video

YouTube-Link:

https://www.youtube.com/watch?v=xDLpH0SRLFc

Homepage:

http://drhoenle.de/