



**USER MANUAL**

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## Preface

(Manual last edited 180428 by Hidroxa consulting AB, retailer of the device.)

One should read the manual carefully before using the device. If any questions remain, don't hesitate to contact customer support. It is good to know that the most common reason for lack of effect from the treatment is due to non regular use. Studies have shown that a lot of patients seize using the device regularly after gaining effect from the treatment. One has to continue the treatments even after achieving wanted effect. If one is pregnant, has a pacemaker or a metal implant in ones body, it is advised not to use an iontophoresis device. Some individuals will experience discomfort towards the thought of using water and electricity combined. One should know should rest assured that the device runs on batteries and does not work when connected to the wall socket, as a mechanism of protection.

## Manufacturer

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Email:[info@aam-med.de](mailto:info@aam-med.de)

## General description

### Base equipment

A device with combined function of pulsed current (PC) and constant current (CC), 2 electrode cables, 4 rubber electrodes (2 of each size, the smaller one for treating the armpits), 4 electrode pouches (2 for each size of electrodes), 2 blue straps for treatment of the armpits, one battery charger.

### Accessories

2 plastic containers for water, during the iontophoresis treatment.

### Warranty

The period of warranty for machine malfunction is 24 months. The electrodes, electrode pouches, cables and batteries (expendables) are not included in the warranty. The warranty period for machine malfunction is 24 months.

### Warning

The values sent out from the device can differ when using the device next to (less than 1 meter) a short – or microwave device.

Portable devices such as can affect the device during treatment. Keep them a least 1 meter from the device during treatment. The best is to shut them off or keep them in another room.

Using accessories that are not approved by the manufacturer can cause harm and is not allowed. Doing this is at your own risk.

It is important that the electrode pouches are in full contact with the skin. If they are only partly in contact, irritation of the skin can occur.

### Service

The device requires no service. Any reparations shall be performed by the manufacture and their partners only.

### Classification "BF"

This electronic device runs on batteries. That means it is a device of the type BF according to DIN EN 60601-1.

### How to care for your iontophoresis device

1. The device and rubber electrodes can be cleaned with all products used for surface disinfection but no products that can lead to corrosion can be used. The device should not be put/lowered down into any fluid.
2. After use the electrode pockets as well as the rubber electrodes should be cleaned with lukewarm water. The electrode pockets can be cleaned in a washing machine.
3. When you disconnect the cables from the device, be gentle. The cables must not be bent and avoid knots on the cables.
4. If you do not use the device for a longer period of time, please remove the batteries and store them separately. Used batteries should be placed in container for battery recycling.

### Recycling of the device

The device should be left at a dump for electronic waste.

### MPC

The device fulfills the criteria for the electronic protection class II and the medical protection class II a according to MDD 93/42 EWG.

### Electromagnetic compatibility

The device is certified according to the rules of EN 60601-1-2:2001 and EN 60601-2-10:200.

### Technical specifications

Measurements: 172x116x41 mm

Weight: 270 g

Nominal voltage: 6,0 V

### Constant current (CC)

Type of current: Constant

Ampere: 0-20 mA. Can be adjusted infinitely from 1 to 20.

Voltage: Max 40 V depending on resistance.

### Pulsed current (PC)

Type of current: Pulsed

Ampere: 0-30 mA. Can be adjusted infinitely from 1 to 30.

Voltage: Max 60 V depending on resistance.

### The manufacturers responsibility

The manufacturer is only responsible for machine malfunction and not for errors due to inaccurate handling/use of the device and its accessories.

### Other

If you have any questions about your personal health and the use of our Hidroxa iontophoresis device, please speak with your doctor.

No technical skills are required to use the device. If you have any questions please contact customer support.

## Performing a treatment

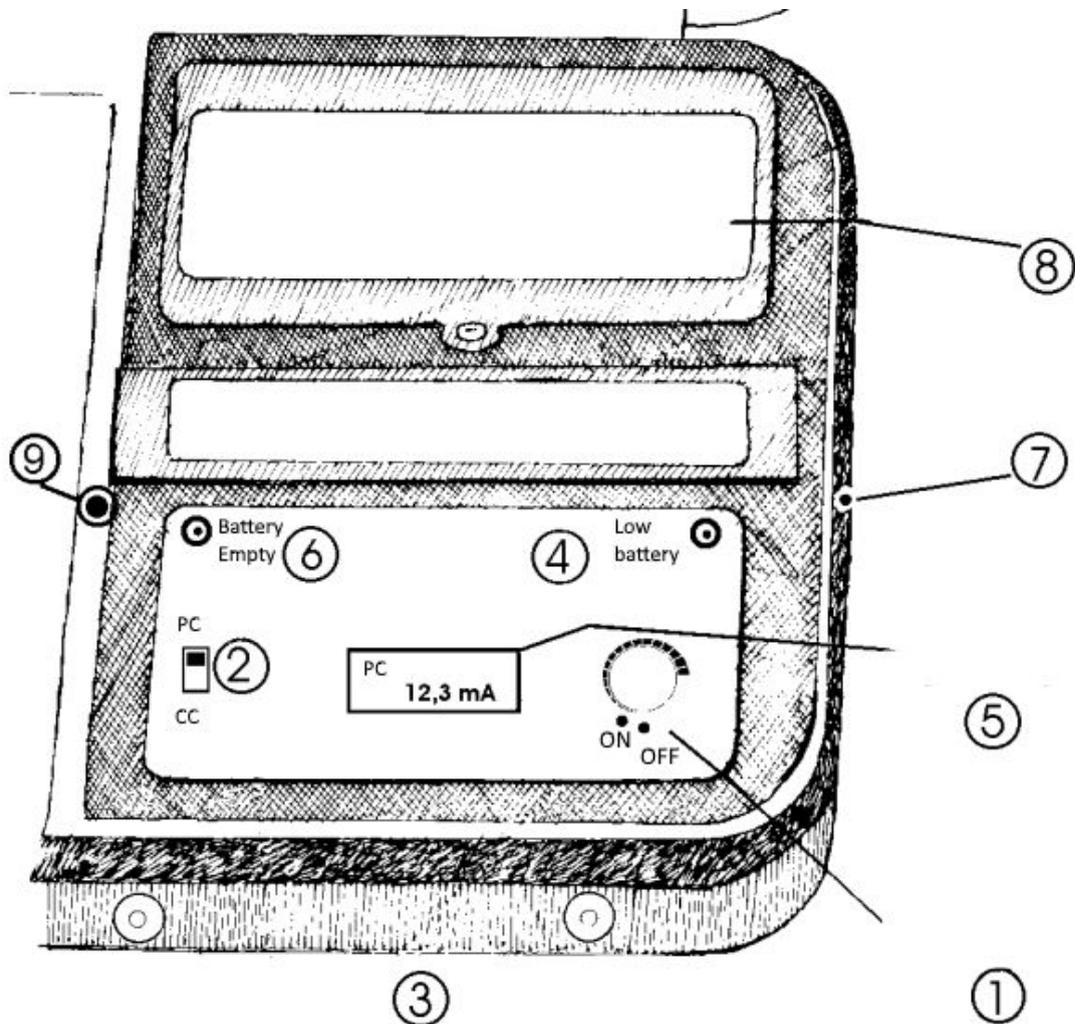


Figure 1: 1. Off/On switch. 2. Switch to choose type of current 3. Outlet 4. LED, low battery 5. Digital display 6. LED, empty battery 7. Charger outlet 8. Battery compartment

1. Before starting the treatment, remove all accessories made out of metal, eg jewelry.
2. Before turning on the device settings to choose type of current must be made: pulsed (PC) or constant (CC). Choice of current can only be made when the device is turned off. The first row on the display show if the device is set to constant current (CC) or pulsed current (PC). Choose between these on the switch intended for this (2).
3. To turn on the device: Turn the switch (1) to left. A text will appear on the screen for about 5 seconds: "AAM GmbH DE 20 v2.0" which indicates the device is about to start. Double check that the choice of current is correct. Check that the power supply is not plugged into the socket the charger (7). The device does not work if the device is plugged into the wall or the device. This is a mechanism of protection to make sure the power level never reached harmful levels.
4. Connect the red respective the black cable into the rubber electrodes. You can either place the electrodes (with the yellow electrode pouches) separately in the respective water

container or adhere the electrode (with the yellow pouch) directly on the hand or foot. The electrodes themselves should not touch the skin.

5. You can now plug the cables in the respective sockets (3) in the device. The red cable should be plugged in the red socket and the black cable in the black socket. Before every treatment, switch the socket for the cables, putting the red cable in the black socket and vice versa. You should do this to make sure the effect is even between the left and right hand/foot in the long run. There is a plus (+) on the electrode with the red cable and a minus (-) on the electrode with the black cable.
6. Wet the yellow electrode pouches, containing the electrodes, carefully and place one hand/foot on each electrode pouch.

*The surface of the electrode pouch (containing the rubber electrode) should be in full contact with the skin. Uneven contact with the electrode can create discomfort.*

7. Place each electrode separately in to a non conductive container (eg the plastic containers that come with the device). Pour luke warm water into the container. The water should only cover the area that is to be treated, eg the palm of the hand or the sole of the foot. The circuit is not closed and no voltage level is shown on the screen before the hands/feet are lowered into the water.
8. The level of voltage needed for treatment is individual. Turn up the current to a level where you start to feel discomfort and then turn it down just below that level. It should not hurt to perform the treatment but some people can experience that the treatment is slightly uncomfortable, especially in the beginning.
9. When putting your hand/foot in the respective water container, the circuit is closed.

*As soon as the electrical circuit is closed, the milliampere meter will show a number over 0, often 0,4-0,7 mA, but it can vary a lot. That the number rises above 0 indicates that the circuit is closed in a correct way. The value will remain at that level until one starts to turn up the voltage. Or rather it will slowly increase to the chosen level of voltage. When the button (1) is switched clockwise, the voltage will increase. The second line on the display (5) will show how much electricity that is flowing.*

10. Turn up the voltage to desired level.
11. The device does not work if the battery charger is plugged in the device, as a safety precaution.

*If the milliampere meter does not exceed 0,0 mA when you have put your hands/feet in the water containers, this means that the resistance of the skin is too high and the conducting level of the water is too low. In this case, try adding a teaspoon of salt to each water container and stir firmly. Always use the large electrodes when treating your hands or feet.*

*TIP! If the resistance of the skin is too high or the conducting level of the water is too low try adding a teaspoon of salt to each container and make sure that the water covers only the area to be treated, eg the palms of the hands or soles of the feet.*

## Treatment schedule

We recommend that you start your treatment with 20 minutes each day the first 1-3 months. There are different options on how to best perform iontophoresis treatments and this is known to be very individual. Some think that 3 treatments á 20 minutes the first weeks is a good start. When one has reached desired effect (usually after 1-3 months), one can try to sparse out the treatments and aim

on 1 treatment per week. Some report that 1 treatment each 3-4 week is enough but this is more uncommon.

### Changing the level of voltage during ongoing treatment and how to finish a treatment

If you wish to change the level of voltage during an ongoing treatment you can remove one hand from the water to adjust the level. PLEASE NOTE! that if one does this one can experience some discomfort but this is NOT harmful in any way. We therefore recommend asking someone to assist you the first few treatments to help you find the correct level of voltage. This is only a recommendation. It is perfectly ok to use the device on your own. The current is turned off automatically after 20 minutes and the treatment is then finished. The text "treatment over" will show on the display. To turn off the device, turn the switch (1) back to its original position until you hear a click.

### Changing direction of the current (4)

You should change the direction of the current each time you start the device, if your doctor does not recommend anything else. To do this, put the **red** cable in the **black** socket and the **black** cable in the **red** socket. The time, do the other way around. This is to make sure you receive an even effect on both hands/feet over time.

### Maximal level of current

The voltage for the constant current (CC) is limited to 40 V and to 60 V for the pulsed current (PC). Because of this, the maximal current that can be achieved cannot be reached when the resistance of the skin is higher than 2000 ohm. In this case, the word "max" will show on the first row on the digital display. You should try to increase the resistance by wetting the electrode pouches again or by taking a hot shower. Another possibility is to measure the resistance of the electrodes with an ohm-meter. Eventually the electrodes will lose their conductivity and need to be changed.

### Area of use for iontophoresis

Iontophoresis can be used to treat hyperhidrosis of the hands and feet, even all 4 extremities at a time. Some say that you also can treat your armpits and face with iontophoresis but there is no scientific evidence to support this. There are resellers that say you can treat arthritis of the knees with iontophoresis but this is not something our device is meant to be used for.

### Combined treatment of hands and feet

This is possible but we recommend that they are treated separately because combined treatment requires higher level of voltage which can increase any discomfort. Place your hands in one container and your feet in the other. If you wish to adjust the voltage level turn the switch (1) to desired level. After this, put your hand back in the water. In this way, you can treat all 4 extremities at the same time.

## Treatment of hands/feet separately

When you treat your hands or feet for the first time, you can ask someone to help you adjust the voltage to the level that suits you. When using the device in the future, turn the voltage to the level you have found to be correct for you, before you start the treatment. Then place one hand/foot in each water container. This will close the circuit and the current will be activated. The voltage will increase with 3 V per second until chosen level is reached

*You can remove your hands/feet from the water containers to adjust the voltage level any time during the treatment but this can cause a slight electric shock that is NOT dangerous but that can be uncomfortable to some. You should only adjust the level of voltage on step at a time.*

## Power supply

The device has an inbuilt battery compartment for 4 rechargeable batteries of the type R14.

## Battery capacity

As soon as the voltage of the batteries drops below 4,9 V, the yellow LED-lamp (4) will be turned on. The display will show “batterie schwach” which means battery low, type of current and milliampere level. You can then perform 2 more treatments before the batteries are empty. Then the red LED-lamp (6) will be turned on and the screen will say either “batterie leer” which means battery empty or simply “batterie laden” which means charge the battery. You will either have to charge or change the batteries before continuing the treatments.

## Charging the batteries

On the right side of the device there is a socket (7) for charging the batteries. Only the charger that comes with the device is to be plugged in. Only **rechargeable** R14-batteries are to be used. It takes about 14 hours to charge the batteries. To use the non rechargeable batteries and charge the device at the same time can harm the device and even cause fire.

**Please note!** *When the cable for the charger is plugged in, no treatments can be performed. The cable must therefore be unplugged before starting the treatment.*

If you cannot charge the batteries for any reason (you forgot the charger etc) you can use non rechargeable batteries (baby cell, type LR14). But if you do so YOU MUST NOT under any circumstances plug in the charger at the same time.

**Please note!** *It is always forbidden to use the charger with non rechargeable batteries. When changing the batteries, please change all 4 at the same time. We recommend that you use alkaline batteries*

## Potential problems when using the device

If you feel that the current is uneven or uncomfortable, try wetting the electrodes and electrode pouches again or adjusting them so that they adhere to the whole hand/foot. To high voltage level can lead to local skin irritation but does not lead to better treatment effect. You should feel the current but it should NOT be painful. If you experience pain, seize the treatments and contact customer support. Different people can experience different voltage differently from treatment to

treatment. The voltage level used at the last treatment is just a benchmark but you should adjust the level to your own convenience each time. If skin irritation occurs, cease using the device and speak with your doctor. If you have a larger wound on the body part that is to be treated, wait until it has healed. If you have smaller wounds, cover them with a thick layer of vaseline. When you turn off the device, and electrostatic discharge can occur. This can be unpleasant but is not dangerous. This has only been observed when the patient was standing on a conducting floor or carpet.

## Description of the device (short version)

**Before you start: Cell phones and other electronic equipment should be at least 1 meter from the device during the treatment because they can interfere with the device. Remove all metal objects such as jewelry before starting the treatment. Remember that if you are pregnant or have a pacemaker or a metal implant in your body, you should not use the device.**

- 1. Choice of current.** With this switch (2) you can choose what type of current you would like, constant (CC) or pulsed (PC)
- 2. ON/OFF-switch.** When turning the switch (1) until it has reached "0" (ampere), the device is turned on. To turn it off, turn it all the way back to the original position until you hear a click. The device does not work if the battery charger is plugged in the device, as a safety precaution.
- 3. Digital display (5).** Shows what type of current you have chosen and the milliampere level. It also shows the battery level, when it is low and when they are empty.
- 4. Controlling the level of voltage.** When you have adhered the electrodes in the pouches, plugged in the cables in the sockets (3) and turned on the device, slowly turn the power switch clockwise until desired voltage level. This means a level that you can feel but that is not painful. If you feel discomfort, lower the voltage just under this level.
- 5. Please note! Switching direction of the current.** **Should be switched before each treatment.** Read more about this earlier in the manual.
- 6. Light emitting diode, LED (5).** When the LED-lamp (5) lights up in yellow, this shows that the battery level is low. You can now perform 2 more treatments.
- 7. Light emitting diode 2, LED (6).** When the LED-lamp (6) lights up in red, this shows that the batteries are empty and need to be charged.
- 8. Power supply.** The cable is plugged in this socket. When the cable is plugged in, the device cannot be used, as a safety precaution. In kopplas in i detta uttag. Therefore, you cannot perform any treatments while charging the batteries.
- 9. Battery compartment.** The device has room for 4 batteries. Batteries of the type R14 should be used.