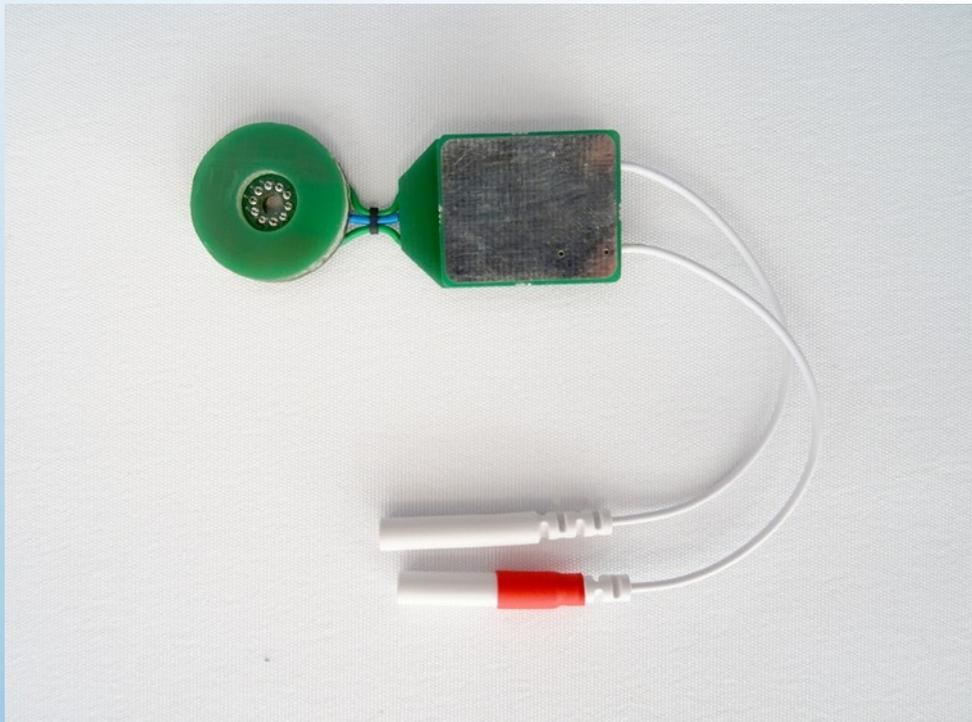


HFS Electrode “EPS-P10”

User Manual



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1. Intended use

The HFS electrode is intended to be used for inducing secondary hyperalgesia and electrical pain in human subjects by means of electrical current. The main purpose is to use it in combination with the constant current stimulator Digitimer DS7A of Digitimer Ltd. or similar devices. The product conducts low intensity current through the human skin, but reaches high local current densities to activate unmyelinated free nerve endings.

“HFS” stands for high frequency stimulation, but typical frequencies are in the range of 100 Hz.

2. Safety instructions



- Do not apply too much mechanical pressure onto the HFS electrode. Otherwise you may penetrate the skin of the subject and/or bend the cathode pins.
- Do not apply any current of more than 20mA to the subject via the connected HFS electrode.
- The cable between the electrode and the current stimulator is only specified up to 100 V by the vendor. If possible, you should not use voltages higher than 100V. Otherwise the cable may suffer.
- Do not use the HFS electrode in combination with other constant current stimulators than the Digitimer DS7A. If you want to use other devices please contact us so that we can check them for any risks.

3. Components

- HFS electrode (anode and cathode) with fixed connector cables
- connector cable for Digitimer DS7A
- double adhesive electrolytic gel pads
- double adhesive isolating rings
- user manual

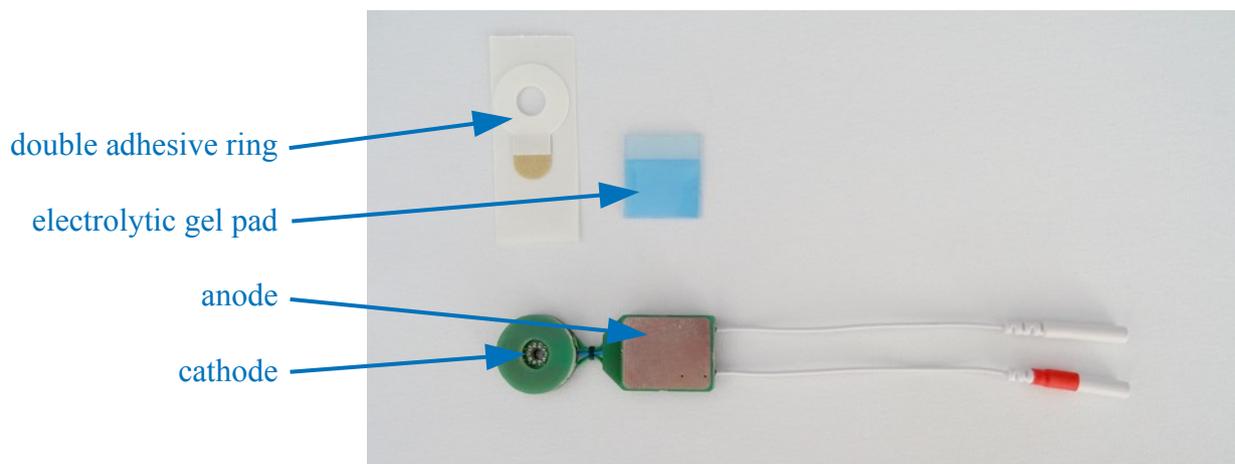


Figure 1: HFS electrode and its accessories

4. Instructions for use

4.1. Before each use

Before you use the HFS electrode, please make sure that it was disinfected.

Inspect the bottom of the cathode. If there are bent pins, please try to straighten them by applying manual pressure lateral to the affected pins. If pins are missing, dismantled or seem loose please refrain from using the electrode.

4.2. Preparation of the HFS electrode

After making sure that the product is safe to use, you can prepare the HFS electrode for use.

Therefore you need to attach an electrolytic gel pad to the anode surface of the HFS electrode. Start with peeling of the pad from its substrate (clear colour). Then press it with the now unprotected side right onto the anode surface until it stays in place.

Take a double adhesive ring, strip it off its support material, and attach it with the exposed side facing towards the electrode onto the cathode. Try to place it concentrically to the ring of cathode pins (see figure 2).

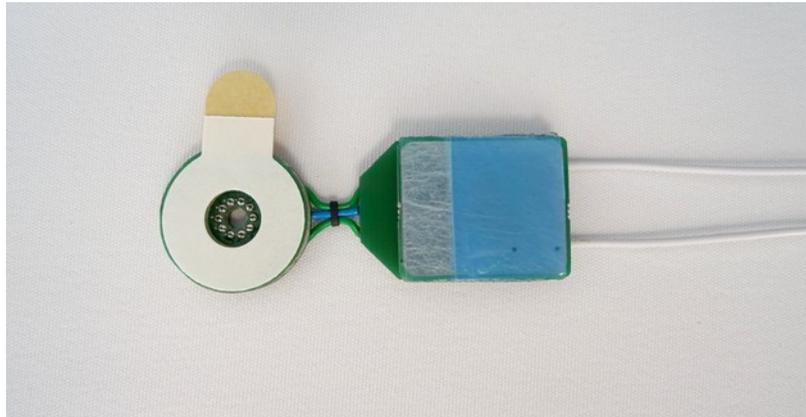


Figure 2: HFS electrode with electrolytic gel pad and double adhesive ring attached, protective foils still in place



The metallic area of the anode must be completely covered by the gel pad. Bare areas can cause a burning of the skin.

4.3. Correct application of the HFS electrode

Before you begin please make sure that both, the electrolytic gel pad and the double adhesive ring are correctly attached to the HFS electrode.

The following steps have to be performed directly before using the HFS electrode to avoid contamination of the adhesive surfaces.

1. Prepare the part of the skin where the anode is going to be attached to. Wet the skin and wipe away any residual drops. This improves the stickiness of the electrolytic gel pad. The skin should be semi-moist, not wet.
2. The part where the cathode is going to be attached to should be disinfected before the application. This area should be completely dry for a good cohesion of the adhesive ring.

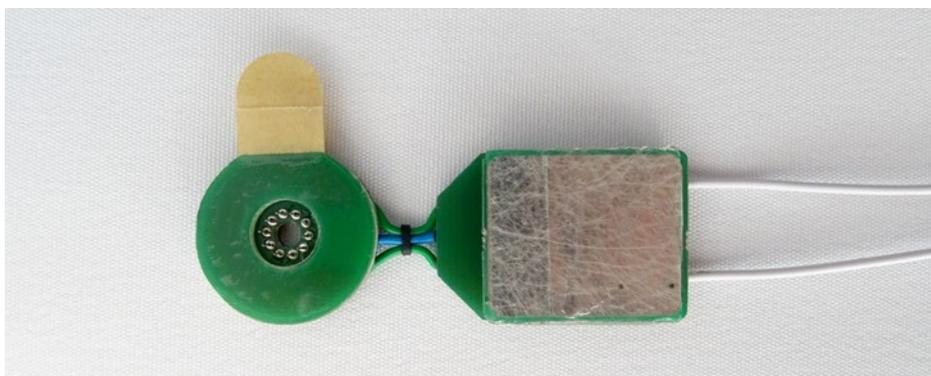


Figure 3: HFS electrode with electrolytic gel pad and double adhesive ring attached, protective foils removed

3. Start with removing the protective foil of the electrolytic gel pad (blue colour) and the cover foil of the double adhesive ring (white colour). Move the HFS electrode close to the designated area of skin, which you want to stimulate. Press down the cathode while still holding up the anode. Do not press down harder than necessary for fixation. Otherwise the cathode pins may penetrate the skin of the subject. Make sure that the cathode is firmly attached to the skin.
4. Place the anode on the skin. Press onto the anode and check if it stays in place. Please avoid tensions in the junction of anode and cathode. Do not change the position of the anode while the cathode is fixed. This could lead to an injury if the cathode pins rotate or move when they are pressed onto the skin.

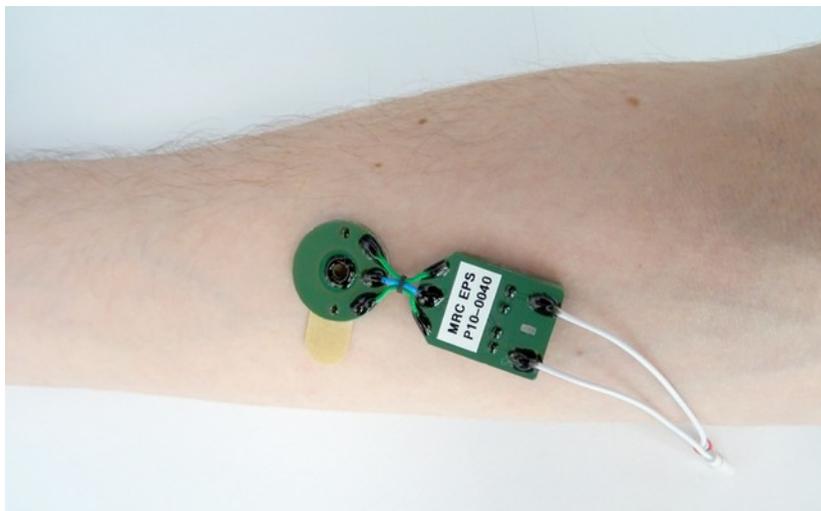


Figure 4: HFS electrode placed on the skin

5. Before connecting the HFS electrode to the Digitimer DS7A, examine again whether or not both, anode and cathode are firmly attached to and have full contact with the skin. It is important that all cathode pins have a good contact to the skin.



It's important that in the application all cathode pins have contact with the skin. If this is not the case, the current will flow only via the pins which have contact. Here, the current density will be respectively increased which can cause local burns.

If necessary, you can detach the HFS electrode and reposition it. For multiple repositioning it is recommended to exchange the double adhesive ring and the electrolytic gel pad. At least you should clean the gel pad with a wet tissue and exchange the double adhesive ring.

4.4. Connecting the HFS electrode to the Digitimer DS7A

Please use the rotary controls on the Digitimer DS7A to set the maximum voltage to just under 100V and the applied current to 20mA at the maximum. Connect the connector cable to the Digitimer DS7A by injecting the big red connector into the red socket and the big black connector into the black socket.

After that connect the connectors attached to the electrode to the sockets of the connector cable.

Insert the connector with the red mark into the red socket and the connector without any mark into the black socket.

By doing so you connect the cathode pins to the cathode output and the anode to the anode output of the Digitimer DS7A.

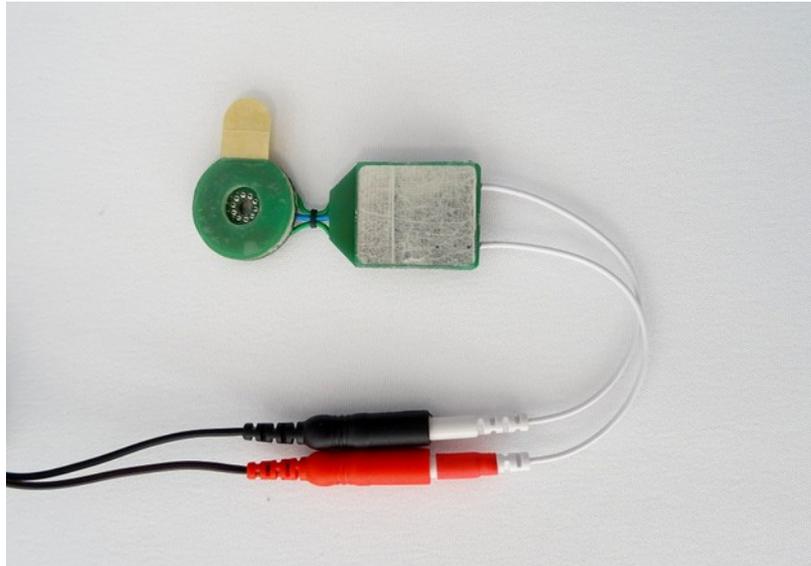


Figure 5: HFS electrode connected to connecting cable

If you followed the described steps, it is safe to use the HFS electrode with the Digitimer DS7A.

4.5. Disconnecting the HFS electrode from the Digitimer DS7A

After applying current to the subject please turn off the Digitimer DS7A. Wait some seconds. Disconnect the connector cable from the electrode by pulling on the connector while holding the socket in your other hand.



Do not pull on the cable itself! Otherwise the cable may break or you may hurt the subject.

Then you can remove the HFS electrode from the subject. Pull on the cathode until it disengages from the skin. Please only pull the cathode upwards and do not apply any force lateral to the cathode. Otherwise you may bend the cathode pins or hurt the subject. While holding the cathode in the air you can now pull on the anode until it disengages from the skin. Do not bend or twist the anode more than 30° against the cathode. Lay down the HFS electrode on a clean surface with the cathode pins and anode surface facing upwards.

Now you can unplug the connector cable from the Digitimer DS7A.

4.6. After use

If you want to use the HFS electrode in the next 12 hours on the same subject, you can keep the electrolytic gel pad on the anode surface. Just attach the protective foil (blue colour) to its top again. Before reattaching it is recommended to clean the adhesive surface of the electrolytic gel pad with a wet tissue.

Either way you should remove the double adhesive ring because it is not intended to be used twice.

For further instructions please refer to chapter 6.

5. Specification

5.1. Dimensions

Cathode: $\varnothing = 21$ mm

The cathode is equipped with 10 needle pins which are arranged on a circle with a diameter of 5 mm. Each pin has a diameter of 250 μ m and protrudes by 0.8 mm from the electronic layer (0.65 mm from the adhesive ring).

Anode: 24x20 mm²

Distance between centre of pins and anode: 20 mm

5.2. Materials

The contact pins are made of tungsten.

6. Disinfection and maintenance instructions

6.1. Disinfection, sterilisation

The application of the HFS electrode is a non-invasive procedure. But there is an improbable residual risk of penetration through the skin. Therefore, as an additional safety measure for minimizing the risk of infection, you should clean the needles and the anode before each application. Please use an appropriate disinfection spray.



Do not sterilise the HFS electrode or the connection cable. We can not guarantee that the HFS electrode will still be working afterwards.

To disinfect it properly you can use a disinfectant for medical devices. Please only use disinfectants that are characterized by a good disinfection power, but most notably they should be not corrosive and should not affect the thin needles. The pH value of the solution should be in the range of pH 6-8

6.2. Maintenance and storage

Please take care for a generally clean status of the electrode.



If you notice loose or missing pins or any other damage on the electrode or the cables, refrain from using the electrode and contact us for further support.

It is recommended to store the HFS electrode and its accessories between uses in the way it was delivered to you:

- Place the electrode in the recess provided in the blue insert in the transport box. The cathode pins and the anode surface should face down and only come into contact with the insert. Please take special care that the cathode pins are placed in the recess provided for them.
- For intermediate storage where the gel pad remains on the anode surface, it is essential that the protective foile is attached to the gel pad.
- Wind up the connecting cable and place it into the left tray. Please avoid the build-up of knots.



Figure 6: HFS electrode and accessories placed in the storage box

7. Contact

MRC Systems GmbH
Hans-Bunte-Str. 10
D-69123 Heidelberg
Germany

Phone: +49-(0)221/13803-00
Fax: +49-(0)6221/13803-01
Website: www.mrc-systems.de
E-mail: info@mrc-systems.de

The product “MRC HFS electrode” is continuously developed further. Changes compared to this user manual can occur.

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