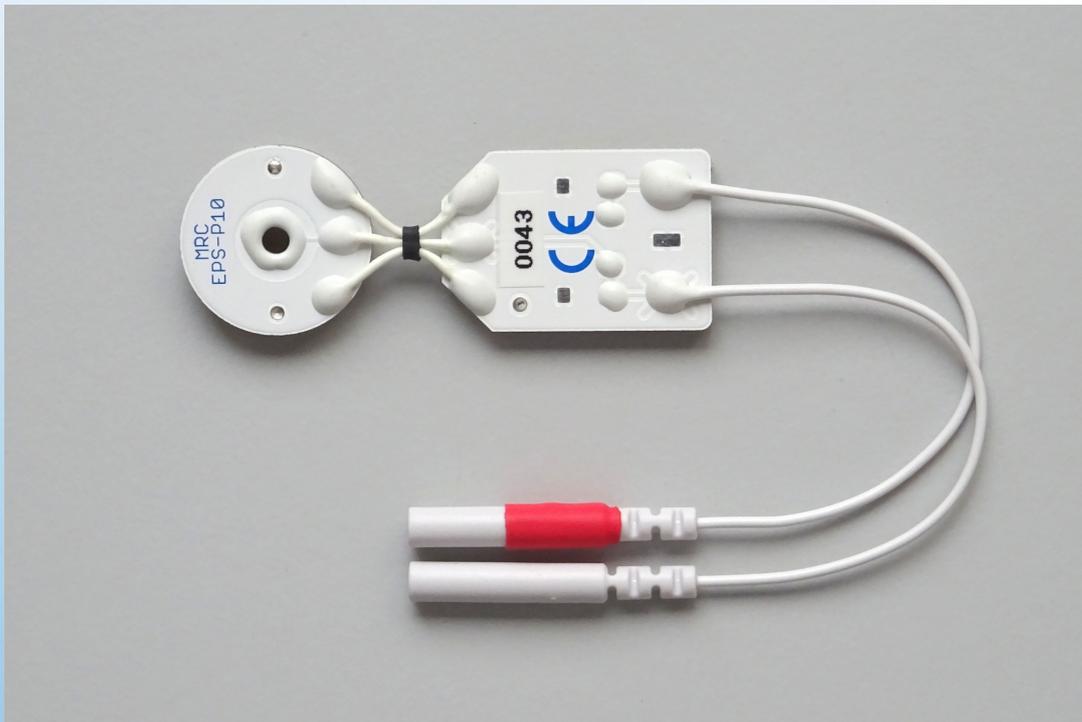


HFS Electrode “EPS-P10”

User Manual



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1. Intended use

The HFS electrode “EPS-P10” is intended to guide an electrical current for inducing secondary hyperalgesia and electrical pain in human subjects. It shall be applied in combination with the constant current stimulator Digitimer DS7A of Digitimer Ltd. or similar devices. The HFS electrode can be applied with low current. However, its design leads to high local current densities at the cathode pins so that unmyelinated free nerve endings can be activated.

“HFS” stands for high frequency stimulation. 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 use the electrode with bent or broken cathode pins.
- Do not apply currents of more than 10 mA or voltages higher than 400 V to the subject via the connected HFS electrode.
- 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 if there are any risks.

- Do not apply the electrode in the areas of breast, head and neck. In these areas you might evoke undesired effects.
- When placing the electrode please consider the anatomy and physiology of the subject. You should take special care in sensible areas (e.g. the genital area or areas above larger nerves or blood vessels).
- Avoid the contact of the electrode and the cables with injured skin.

3. Components of a set

Figure 1 shows the main components of the HFS electrode. The scope of delivery usually includes:

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

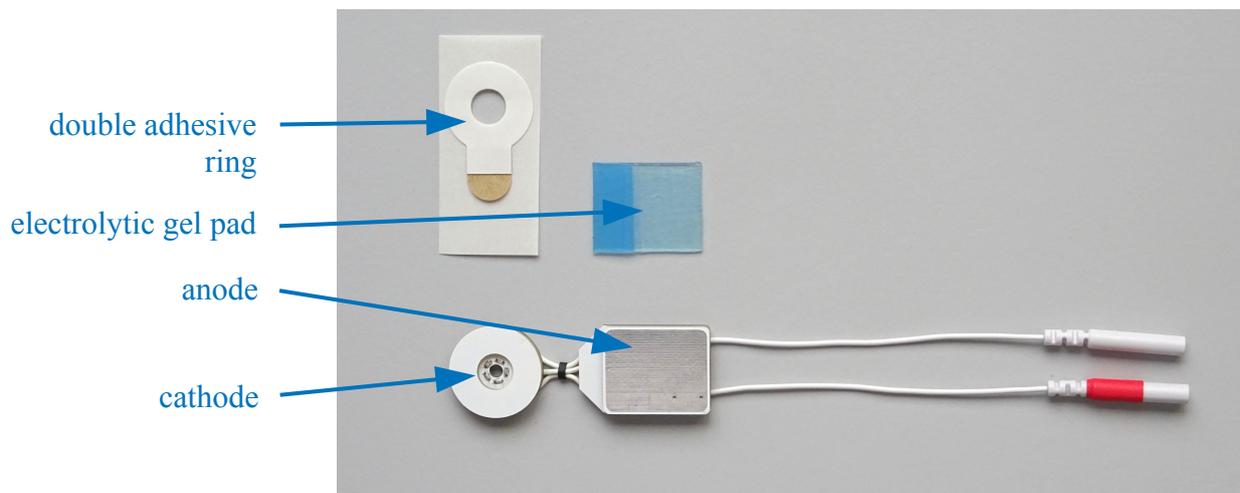


Figure 1: HFS electrode and its accessories

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 slight manual pressure lateral to these pins. If pins are missing or seem loose refrain from using the electrode.



Do not use the electrode with bent or broken cathode pins.

4.2. Preparation of the HFS electrode

After making sure that the electrode is safe to use, you can prepare it for use at a subject.

Therefore you need to attach an adhesive 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 remains 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).

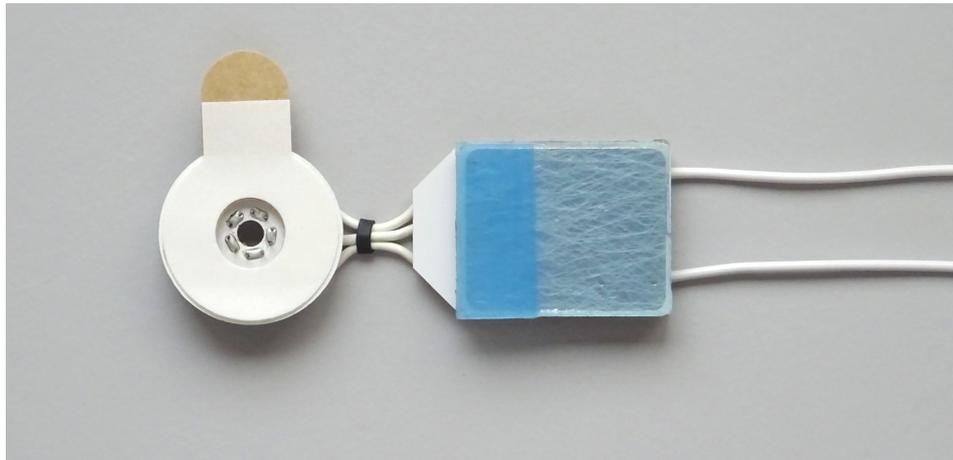


Figure 2: HFS electrode with adhesive electrolytic gel pad and double adhesive ring attached, protective foils still in place



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 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 of the skin where the cathode is going to be attached to should be disinfected before the application. It should be completely dry for a good cohesion of the adhesive ring.
3. Remove 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. Start with the cathode. Press it carefully down to the skin while still holding up the anode.

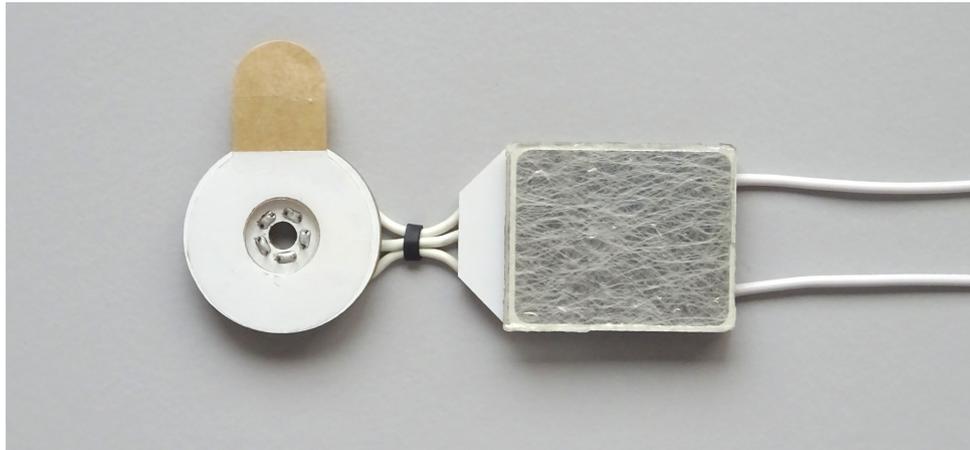


Figure 3: HFS electrode with electrolytic gel pad and double adhesive ring attached, protective foils removed



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 remains 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.

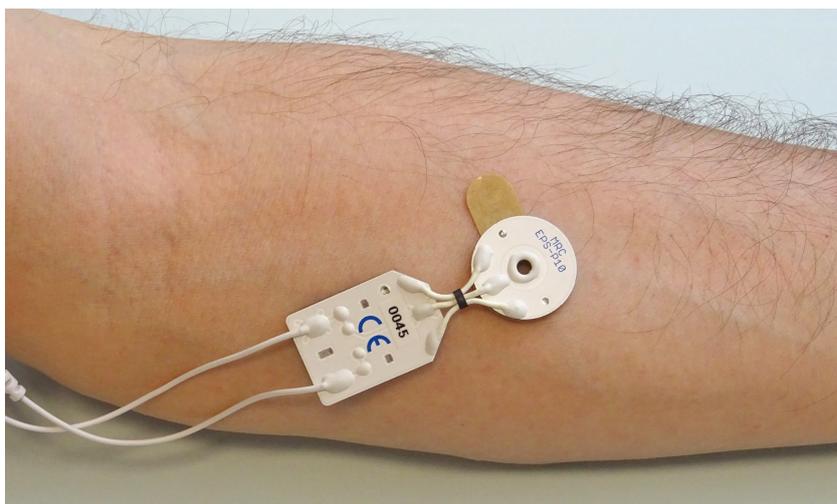


Figure 4: HFS electrode placed on the skin

5. Before connecting the HFS electrode to the Digitimer DS7A, check 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 is important that during 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. At these pins 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 cloth and exchange the double adhesive ring.

4.4. Connecting the HFS electrode to the Digitimer DS7A

The Digitimer DS7A has an “Output” lever. In its lower position the subject is isolated from the electronics. Please make sure that the lever is in the lower position so that the output is inactive and an undesired stimulation is prevented. Please further consider that the voltage is set below 400 V and the applied current is below 10mA. Then connect the connector cable to the Digitimer DS7A by inserting the big red connector into the red socket and the big black connector into the black socket. The different colors shall prevent a permutation.

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.

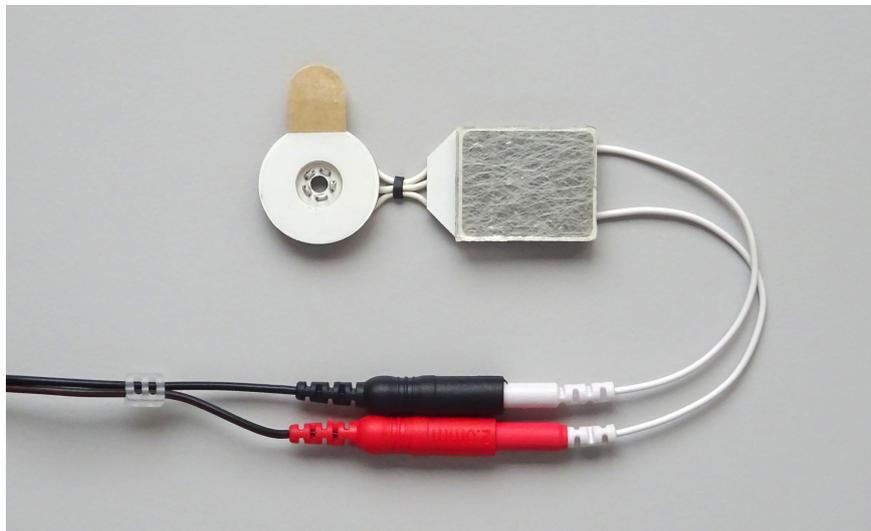


Figure 5: HFS electrode connected to connecting cable

If you followed the described steps, you can release the output of the Digitimer DS7A (“Output” lever in upper position) and it is safe to use the HFS electrode.

4.5. Disconnecting the HFS electrode from the Digitimer DS7A

After applying stimuli to the subject please turn off the Digitimer DS7A and switch the “Output” lever back to the lower position in order to isolate the output. Wait for some seconds. Disconnect

the connector cable from the electrode by pulling the connector while holding the socket in your other hand.



Do not pull 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 the cathode until it releases 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 the anode until it releases 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 24 hours on the same subject, you can leave the 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 gel pad with a wet cloth.

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

For further instructions on cleaning and maintenance please refer to chapter 6.

5. Specification

5.1. Dimensions

Cathode's diameter: $\varnothing = 21$ 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 from the electronic layer (0.65 mm from the adhesive ring).

Anode's area: 24x20 mm²

Distance between centre of pins and anode: 20 mm

5.2. Materials

The cathode 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 a residual risk of penetrating the skin.



That is why, as an additional safety measure for minimizing the risk of infection, you should clean the cathode needles and the anode before each application. Please use an appropriate disinfection spray. Never plunge the electrode entirely into a disinfectant.

To disinfect these parts 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. If you are unsure whether or not your disinfectant is suitable you can contact us.

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

To avoid the transfer of germs you should change the disposables (gel pads, adhesive rings) for each application with a new subject.

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 in 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.



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

- For intermediate storage where the gel pad remains on the anode surface, it is essential that the protective foil is attached to the gel pad.
- Roll up the connecting cable and place it into the left tray. Please avoid the build-up of knots.

There is no strictly defined maintenance interval for the electrode since the interval depends on the frequency of its use. In case of a rather rare use you should nevertheless ask for a check after 2 years.

7. Labelling



The product is a medical device of class 1 according to the Medical Device Regulation. It is manufactured and tested according to the requirements of our ISO 13485 compliant quality management system.

8. Information to manufacturer and competent authority

If a serious incident has occurred with the electrode, you have to inform the manufacturer and the competent authority of your region.

9. Contact

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The product “EPS-P10” is continuously developed further. Changes compared to this user manual can occur.

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