



Healy
Instructions for Use



To Order Healy Products Contact the Person Who sent
you this Information

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1. General

Thank you for choosing Healy. Please read this manual carefully and pay special attention to the warnings and cautions.

This manual is intended for the user. Intended users include adults at home, and medical professionals in the healthcare or professional environment. It aims to ensure safe handling and enables users to become familiar with the medical device.

2. Healy

2.1 Intended Use

Healy is a microcurrent stimulation device that supports the treatment of symptoms of diseases, using currents in the microampere range with different frequencies. It can be applied to different areas of the body.

2.2 Indications

The intended use of the Healy includes the following fields of application:

- in pain management (chronic pain, fibromyalgia, skeletal system pain, migraine)
- in case of mental illnesses such as depression, anxiety and associated sleep disturbances

2.3 Contraindications

Microcurrent treatment must not be performed when metallic foreign bodies are in the area of treatment, pacemakers or im-

planted defibrillators are present, bleeding, risk of bleeding or embolism are present. Treatments must not be performed on areas of the skin which have been treated radiotherapeutically or have a sensory disorder or if the user has a fever.

- Not for use by pregnant women
- Not for use by those with epilepsy
- Do not place the electrodes directly on the eyes, covering the mouth, on the front of the neck (especially the carotid sinus), or on the chest and the upper back or crossing through the heart.

Consult a medical professional before using if you have any of these contraindications.

2.4 Description

The Healy is a portable device, internally powered and controlled via Bluetooth by a software application that is installed on a Smartphone. It has one stimulation output. The stimulation output can be varied between -10 V and +10 V, 0 to 1 MHz, 0 – 4 mA. The charging of the internal battery is done through the Micro-USB-Port and the supplied power supply cable.

The software application “Healy APP” is necessary for configuration and control of the Healy. The “Healy App” is available in the Play Store or the App Store. Before installation verify the smartphone requirements in **section 4.1.1**.

2.4.1 Hardware Description



Figure 2.4.1.1: Healy top view: Pos. 1 Icon and LED for Bluetooth Connection; Pos. 2 On-Off Button; Pos. 3 Battery icon, Pos. 4 LED for generator action (if stimulator output is active, then the LED is blinking) and battery indicator; Pos. 5 Generator icon; Pos. 6 Icons for the positive and negative electrode plugs; Pos. 7 USB-Connector icon; Pos. 8 Socket for power supply

through micro-USB-connector (not visible in this figure); Pos. 9 Sockets for the electrodes (not visible in this figure)

2.4.2 Software Description

The “Healy APP” is required for configuring and controlling the hardware. It allows sending treatment programs to the device. With the App you can start and stop the treatment. The “Healy APP” connects to your Healy hardware using Bluetooth. The “Healy APP” can connect only to one device at a time.

Figure 2.4.2.1: Overview interface of the Healy APP. Pos. 1-Icon for the signal quality of the Bluetooth connection to the Healy; Pos. 2-Icon for the battery status of the Healy

2.5 General

The Healy is for use only to treat conditions described in these instructions. Intentional misuse can be harmful or reduce the effectiveness of the device.

- Carefully read the instructions for use before use.



Figure 2.4.2.1

- This product is intended only for the purpose described in the instructions for use.
- In this manual, the word DANGER warns of possible personal injury!
- In this manual, the word CAUTION warns of possible damage caused to property!

2.6 Safety Notes

Danger/Warning:

- Keep this device out of the reach of children.
- not immerse the device in liquids.
- Do not use while driving motor vehicles or operating heavy machinery. The ability to drive or to operate heavy machinery may be impaired immediately after treatment.

- Only charge with the supplied cable from an USB-Socket with 5V dc and max 2500 mA.
- In the case of a defect please contact the manufacturer. Don't open covers or try to repair the device.
- Use with care as the cables may cause a tripping or strangulation hazard.
- Don't use in presence of flammable gases or in an oxygen enriched environment.
- Stop treatment and remove the electrodes if any irritation, sensation, allergic reaction or burning occurs at the electrode contact points and contact us. Pay attention when using the stimulation and currents higher than 2 mA (ear-clip electrodes) or 4 mA (surface electrodes).
- Take care that the units output connectors are always pointed towards the floor. This way the device is protected against damage by water or liquids.
- Do not place electrodes on the chest; this can cause ventricular fibrillation.
- The device is designed for indoor use only.
- The device should only be stored and transported under the conditions defined in these instructions.
- Do not use the device in shielded locations, such as intensive care units in hospitals, airplanes or wherever the use of mobile phones is prohibited.
- The device has no life-sustaining functions.
- The device must be operated only with supplied accessories and together with compatible smartphones.
- Not for use by those with a pacemaker or heart disease.
- Portable and mobile HF-communication devices, e.g. mobile phones, may influence medical electrical devices. You should keep a safety distance of 30 cm (12 inches) from HF-communication devices of parts and cables of the Healy, when the device is in use. Don't stack it with such devices or put it next to other electrical equipment when used.
- Avoid damages to the electrode cables and the charging cables caused by sharp objects. If the cables are damaged do not use them and contact the manufacturer for a replacement. Don't use cables that are damaged.
- To protect the device and its accessories against contamination and damage keep it closed and away from children, dust, sunlight, moisture, pets and vermin.
- Only use cables and electrodes supplied with the equipment. Other accessories, cables or electrodes could result in higher electromagnetic field emissions or less electromagnetic immunity and may lead to loss of function.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.
- Do not use the adhesive electrode if the gel is dry or visible damage is present or the connecting cable is damaged.
- Do not use if recurrent episodes of skin irritation occur.

- The equipment and the connecting leads used with this device must all be in good condition.
- Do not apply electrodes on skin affected by abrasions, rash or wounds.
- Do not carry out maintenance while the equipment is in use.
- Operation in close proximity (i.e., less 3 feet) to a shortwave or microwave therapy ME equipment may produce instability in the stimulator output.
- Simultaneous use together with HF-surgical equipment is prohibited.

3. Preparations for using the Healy

3.1 Installation

Before putting the Healy into operation you need to prepare the hardware and install the “Healy APP”.

3.1.1 Smartphone requirements

Bluetooth	Bluetooth 4.0 or higher
Operating system	iOS ¹ version 9.0 or higher Android ² version 4.4 or higher

¹ iOS is a registered trademark of the operating system for smartphones and devices manufactured by Apple Inc.

² Android is a registered trademark of Google Inc. for the operating system for smartphones and other devices

3.1.2 Android operating system

- Open the Play Store³
- Search for the “Healy APP”
- Choose “Healy APP”
- Download and install on your smartphone

3.1.3 iOS Operating System

- Open the Apple Store⁴
- Search for the “Healy APP”
- Choose “Healy APP”
- Download and install on your smartphone

³Play Store is the trademark of Google Inc.

⁴App-Store is the trademark of Apple Inc.

3.1.4 Hardware

- Unpack the Healy and check for damage
- Charge the batteries for 1.5 hours before first use
- Switch on the Healy device by briefly pressing the on-switch and verify that the right LED is blinking

Note: The battery cannot be removed by the user.

3.1.5 Pairing via Bluetooth

After installation of the App, switch on the Healy by briefly pushing the on-switch (see **figure 2.4.1.1**) of the device.

After starting the App there is a short starting screen (see **figure 3.1.5.1**). After the App is loaded it is scanning for Bluetooth devices (see **figure 3.1.5.2**).

Within 20 seconds the App scans the environment and connects

to the Healy automatically. If your smartphone detects a Healy **figure 3.1.5.3** appears. After you scan the QR-Code on the back of the Healy or enter the serial number of the device you can connect to the Healy by pressing the "Connect" button (see **figure 3.1.5.4**).

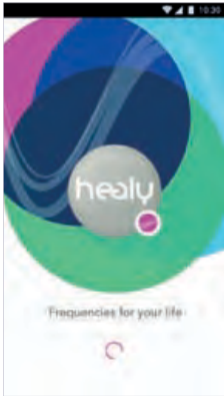


Figure 3.1.5.1: Starting screen

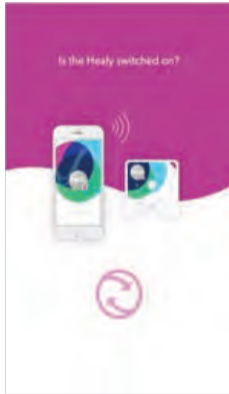


Figure 3.1.5.2: Scanning screen



Figure 3.1.5.3: Scan serial number screen



Figure 3.1.5.4: Connect screen

3.1.6 Connection of the electrodes

The electrodes have been tested and evaluated together with the Healy and are safe and effective for use, if the recommendations and advice in this manual are followed. Check the package containing the electrodes and make sure the gel is intact; if the package is visibly dented or damaged, do not use the product.

Put the plugs of the electrode cables into the sockets of the Healy. Be sure to have the correct polarity. Place the electrodes onto the desired treatment area.

Important note on using the adhesive electrodes:

- Never place electrodes in the region of the carotid artery
- Do not place the electrodes on open wounds
- Before use clean the treatment area and if necessary shave the area
- Choose an area free from hair, skin lesions or scars, folds in the skin, or bony protuberances and which is not in the vicinity of metallic implants.
- Clean and dry the application area before placing the electrode on it.
- Avoid the use of solvents as these could cause skin irritation and reduce the adherence of electrodes.
- If using alcohol to clean the area, make sure that it has completely dried before applying the electrodes.
- Check the functioning of the system before beginning the procedure.

- Connect the electrode to the cable of the electrostimulator.
- If the procedure is interrupted, check the functioning of the system again before recommencing the session.
- Remove the liner and apply the electrode to the skin surface.
- Before switching on the electrostimulator, check the adherence of the electrode to the skin surface.

WARNINGS:

- A reduced contact between the skin and the electrode may cause the electric current to concentrate in one point and cause burning.
- Interrupt the treatment if there is discomfort or a burning sensation.
- After the session, turn off the electrostimulator, disconnect the cable from the electrode and gently remove the electrode from the skin by lifting it up by one corner.
- Rapid removal of the electrode could cause skin traumas.
- Do not remove by pulling the connection part of the cable.
- After use, reposition the electrodes in the plastic liner and put them back in the pouch.
- Electrodes may be reused: Reuse only for the same person.
- Verify the adhesion of the electrode before use. When electrodes lose adhesion, gently rub one or two drops of water onto the gel surface. This may extend the usability. If there is no improvement, replace with new electrode.

- Do not reposition the electrode during use.
- Keep the packet closed in order to prevent the unused electrodes from becoming dehydrated.

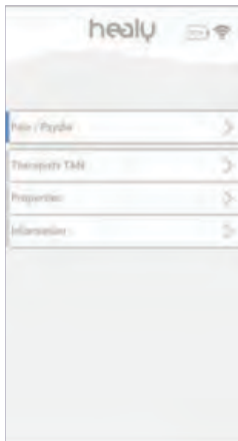


Figure 4.1.1: Overview interface

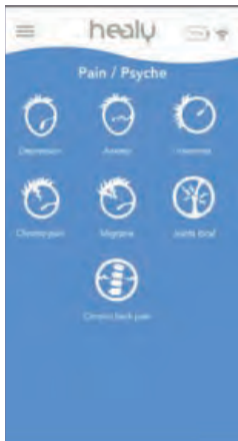


Figure 4.1.2: Program page

4. Operating the Healy

You should become familiar with these frequently used operations:

- switch On-Off (please refer to chapter 3.1.5 and 4.4)
- select treatment (please refer to chapter 4.1)
- start stimulation (please refer to chapter 4.1)
- connect the electrodes (please refer to chapter 3.1.6)

4.1 Starting the treatment using the smartphone

After the installation of the App, pairing and connection of the electrodes, the Healy is ready for operation. In the overview screen you can select which program category you want to use (see figure 4.1.1).

After selecting a program category the program page with the icons of the different programs is loaded (see figure 4.1.2).

After you select a program from the program page screen the information for placing the electrodes is displayed (see figure 4.1.3).

After selecting “Start” on the information page the treatment is started and the treatment page is loaded (see figure 4.1.4). In the treatment page you can set the intensity of the treatment by using the plus and minus buttons.

When the electrical circuit is closed the circle, which is an indicator for the time, will switch from black to white (see figure 4.1.5).



Figure 4.1.3: Information page for the placing the electrodes

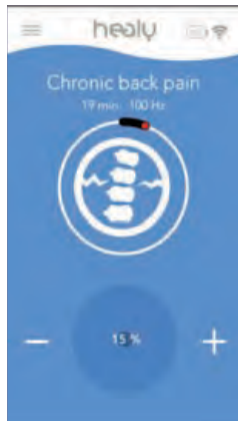


Figure 4.1.4: Treatment page

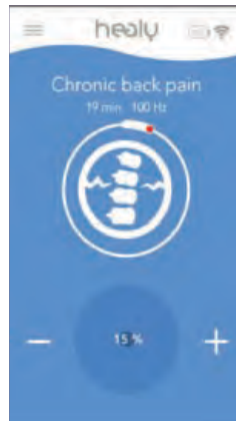


Figure 4.1.5: Treatment page with white time indicator – electrical circuit is closed

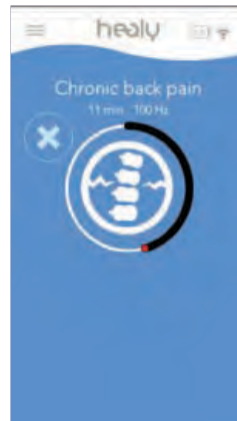


Figure 4.1.6: Treatment page with black time indicator – electrical circuit is open



Figure 4.4.1: Pause screen. By pressing the “X” in the pause screen you cancel the program and get back to the overview interface.

4.2 Handling of the Healy hardware

During the treatment you should use the clip on the back of the device to attach the Healy to your clothing. The electrodes should be affixed as shown in the App (please refer to chapter 10). Route the electrode cables to the Healy so that you feel comfortable.

4.3 Starting the treatment without the smartphone

The device always stores the last treatment program. By pressing the on-switch of the Healy hardware, the last program that was sent from the smartphone to the device will start with an intensity of 15%.

4.4 Stopping the treatment

You can see the current progress of the program running on the device by using the App.

To stop the treatment select one of the following:

- briefly press the on/off-switch (pause mode)
- tap the icon in the treatment mode in the app (see **figure 4.4.1**)
- hold the on/off-switch for about 10 seconds until device hardware resets
- in emergency situations it is possible to remove the electrodes or disconnect the electrode cables

5. Cleaning, disinfection and maintenance

5.1 General

Maintenance activities increase the lifespan and safety of the Healy. Cleaning and disinfection reduces the risks of cross contamination and infections. Please read this section carefully. Cleaning and disinfection should be performed once a week, or if used by different patients prior to use.

5.2 Cleaning

Switch off the Healy before cleaning. For cleaning, commercial cleaning products may be used. The surfaces can be wiped with a damp sponge or cloth. Do not use too much liquid and make sure that no liquid penetrates beneath the covers or enclosures.

Caution: Do not use cleaning agents with solvents (e.g. acetone, nail polish, cleaners) or abrasive cleaners as they will damage the surface.

5.3 Disinfection

Disinfection should be performed in the same manner as cleaning. Disinfectants and methods recommended by the Robert Koch Institute or other societies should be used (RKI recommendations).

Caution: Spray disinfection can cause a security risk. Only use disinfectant wipes.

5.4 Storage between applications

After the treatment unplug all cables and electrodes and put them into the storage case and store in a cool dry location. Refer to the safety notes for environmental storage conditions.

5.5 Maintenance

There are no serviceable parts by the users. In a case of damage please contact the manufacturer. The following maintenance activities are recommended and should be considered for safe working.

Frequency	By whom	Maintenance activity
Prior to each use	User	Check housing, cables and electrodes for damages. In case of damages contact the manufacturer or an authorized dealer

5.6 Troubleshooting

In the following you find typical warnings or messages that are related to the app or hardware of the device. If you face an event that is not listed here or a problem still exists, please contact the manufacturer.

Event or message	Cause	Actions required
No connection from the smartphone to the device	Device is switched off	Switch on the device and restart the App
No connection from the smartphone to the device	Bluetooth in your smartphone is deactivated.	Open connectivity settings and activate Bluetooth
Repeated short blinking of right LED	Batteries are low	Charge the device
Device is not responding	Undefined error/EM disturbance	Hold the on-switch for 10 seconds. This triggers a hardware reset.
No Stimulation output	Undefined error/EM disturbance	Contact your authorized dealer or the manufacturer Healy GmbH

6. System Components

The Healy is delivered with a set of electrodes and a charging cable.

Reference number	Description	Quantity
0006	Healy hardware device	1
108-4063	Press button adhesive electrodes round Ø 32 mm	4
108-4062	Connection cable for electrodes 96 cm – press button on 2 mm	2
108-4061	Bracelet electrode (black, carbon)	2
108-4004	Ear electrodes (pair)	1
108-4096	Felts	20
108-4068	Charging cable USB 0.15 m	1

7. Technical Data

7.1 General

Protection against ingress of water and particulate matters	IP 42, Protected against particulate matter, larger than 1mm. Protection against dripping water at an angle of 15°.
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7.2 Electrical parameters

7.2.1 Power source requirements

The Healy can be connected to any power source with the supplied USB-charging cable and the following specifications:

Supply voltage range	4.4 V – 5.5 V DC
Output current	Max. 2500 mA
Frequency	DC
Socket type	USB- Type A
Power type	High powered 500 mA or higher
Insulation type	Double or reinforced insulation
Compliance	To IEC60950 or IEC60601-1

7.2.2 Healy

Input voltage	See 8.2.2
Input Current	20 mA
Protection class	Internally powered
Applied type	BF, the electrodes are in contact to the patient's body
Compliance	IEC60601-1:2012; IEC60601-1-2
Battery capacity	145 mAh
Battery charging time	60 min – 90 min
Charging cycles Life expectancy	500 times, more than 80% of initial capacity at 20°C
Output voltage – Stimulation	-10 V to +10 V
Output current	Max. 4 mA (voltage control) / $\pm 2,6$ mA (current control)
Accuracy voltage	± 0.1 V with ± 10 %
Accuracy current	± 20 μ A with ± 10 %
Output frequency – Stimulation	DC up to 1 MHz
Signal form	Rectangular biphasic, rectangular monophasic or DC

7.2.3 Electromagnetic compatibility

CISPR 11 – emissions EN55022	Group 2, 30 MHz – 1 GHz and 1 GHz – 6 GHz, classe B, The Healy is suitable for use in all establishments, including the domestic area and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions	Class A acc. to IEC61000-3-2
Flicker	Complies IEC61000-3-3
Immunity	Complies IEC60611-2:2014 and EN61000-4-3, 80 MHz – 2,7 GHz, 10 V/m; Immunity against wireless communication equipment, 28 V/m for MHz: 450, 810, 870, 930, 1720, 1845, 1970, 2450, 27 V/m for MHz: 385, 9 V/m for MHz: 710, 745, 780, 5240, 5500, 5785
ESD protection	Complies IEC61000-4-2 8kV contact – 15 kV air
Power frequency magnetic fields	Complies IEC61000-4-8 Test level 30 A/m for 50 Hz and 60 Hz

7.3 Mechanical parameters

Dimensions	55 x 55 x 7 mm
Weight	34 g
Cable length charging cables	0.15 m
Cable length electrode cables	96 cm (REF: 108-4062)
Output socket	2 x 2 mm pin
Input socket	USB-Type B micro

7.4 Environmental conditions

7.4.1 Operation and storage

Temperature Range	5°C to 40°C / 41°F to 104°F
Relative humidity	15 % to 93 %
Atmospheric pressure	700 hPa to 1060 hPa

7.5 Stimulation settings (standard programs)

The waveform is always a biphasic rectangle. One phase is defined through one positive peak and one negative peak. By the nature of the rectangle signal each current peak is considered as a DC level. There is no offset (DC or AC) to the signal. The parameters are valid for a load resistance of 1 kOhm.

Name of the program	Intensity current or voltage (amplitude for 100% setting)	Frequency 1 Phase	Impulse width high	Impulse delay/ rest	Impulse width low	Impulse delay/rest
Chronic pain	+/- 500 μ A	0.5 Hz	500 ms	500 ms	500 ms	500 ms
Chronic back pain	+/- 500 μ A	71.5 Hz	3.5 ms	3.5 ms	3.5 ms	3.5 ms
Migraine	+/- 400 μ A	0.5 Hz	1 s	0 s	1 s	0 s
Joints local	+/- 600 μ A	0.3 Hz	1.65 s	0 s	1.65 s	0 s
Depression	+/- 600 μ A	0.5 Hz	1 s	0 s	1 s	0 s
Anxiety	+/- 400 μ A	0.5 Hz	1 s	0 s	1 s	0 s
Insomnia	+/- 400 μ A	0.5 Hz	1 s	0 s	1 s	0 s










8. Disposal

The expected service life is 5 years. Ask your local authority for recycling advice.




9. Used Symbols and Icons

Following icons are used on the device, the packaging and the labelling:


















	Symbol for manufacturer		Electronic waste – do not dispose. Recycle acc. to local regulations or contact your authorized dealer or the manufacturer.		Recycling symbol
	Use only inside		In conformity with European legislation		Keep away from heat
	Applied part type BF		Read instructions for use before use		Symbol for Bluetooth Wireless connection
	Caution: Read instructions for use before use. Follow safety advices in this manual.		SGS US CAN certification Mark		Symbol for Battery
	Temperature limitations		Bluetooth		Symbol for on- and off-switch
	Follow the instructions for use		Best before		Symbol for USB-Connection

	Keep dry		Plus icon for positive electrode socket		Icon for the bluetooth signal strength between the Healy App and Healy hardware
REF	Hardware reference number		One patient use		Battery status of the Healy hardware
	Symbol for generator operation – stimulation output		Icon for overview interface		Icon for the trademark Healy
	Minus icon for negative electrode socket				

The following symbols are used in the Healy – App

	Pictograph for the placement of ear clip electrodes. Appears after selection of the stimulation program		Pictograph for the placement of adhesive electrodes. Appears after selection of the stimulation program		Pictograph for the placement of bracelet electrodes. Appears after selection of the stimulation program
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Note: the background colour may vary, depending on the selected and configured program parameter

	Button for increasing the intensity in percentage (current or voltage)		Button for decreasing the intensity in percentage (current or voltage)		Icon for "Depression" therapy program.
	Symbol with information about actual intensity of the stimulation		Symbol for scanning and connecting with the Healy hardware, appears after starting the app and during establishing the Bluetooth connection		Icon for "Insomnia" therapy program.
	Icon for "Chronic pain" therapy program.		Icon for "Anxiety" therapy program.		Icon for "Migraine" therapy program.
	Icon for "Joints local" therapy program.		Icon for "Chronic back pain" therapy program.		Button for jumping two pages forward
	Button for scrolling to the first page with programs		Button for moving one page forwards		Button for jumping two pages backwards
	Button for scrolling to the last page with programs		Button for moving one page back	Note: The background colour may vary, depending on the selected and configured program parameter	

10. Revision status

Revision	Date	Remark
0	21th October 2016	First edition
1	22th October 2017	Minor corrections
2	14th November 2018	Changes for FDA

11. Attachment instruction for use “Electrodes” REF: 108-4061 bracelet electrode (black, carbon)

11.1 Description

The reusable conductive electrical stimulation bracelets are made of conductive fabric.

11.2 Instructions for use

- Check that the packaging is not damaged. If it is damaged or has visible defects, do not use the product.
- Connect the bracelet of the equipment selected, with the connection cable.
- When the session is complete, switch off the equipment and disconnect the cable.

11.3 Warnings

- Do not use products on patients with progressive episodes of skin irritation or contact allergies.

- The product supplied is not sterile.
- Do not apply the bracelet onto the skin in the presence of abrasions, erythema or wounds.

11.4 Cleaning

To clean the bracelets, use detergents (non ionic surfaceactive agents) and disinfectant solutions (components with quaternary ammonium of 0.1 – 0.2%) must be used. For the use of these products follow the relative instructions. After cleaning rinse under running water.

11.5 Product life

The life of the product is a direct result of the amount of use and the conditions of maintenance and storage of the product itself. As soon as any signs of material deterioration appear the product must be eliminated.

12. Attachment instruction for use “Electrodes” REF: 108-4004 ear electrodes (pair)

12.1 Description

The cranial electro stimulation (CES) is usually performed through the ears using ear electrodes.

Only use the ear electrodes in combination with the supplied adhesive felts. In people with very dry skin, problems may occur due to insufficient electrical contact in individual cases. Therefore, always ensure that the felts are soaked with physiological saline.

In the treatment with ear electrodes the intensity should be set that the current is slightly perceptible. A too high current intensity can cause dizziness and nausea. During the application mood changes can occur, such as a feeling of heaviness or lightness. In such cases, you should continue the treatment for a few minutes until you feel normal again. If the disturbing symptoms persist even after a few minutes, you should discontinue the treatment. In this case, contact a therapist.

12.2 Care and storage of the electrodes

Add one to two splashes of a mild detergent to warm water. Clean the electrode with this water and a soft cloth (or sponge) thoroughly and rinse off after that. Do not immerse the electrode in the liquid. For storage put the electrode back into the packaging until next use and store it in a dry, clean place.

Disinfection should be performed with a soft cloth or wipe.

Clean weekly. Disinfection should be performed if needed or every two weeks.

12.3 Service life of the product

The service life of the product depends on the functionality which is in turn dependent on the number of applications, the state of maintenance and the condition.

Upon recognition of any damages, the product shall not be used anymore and shall be disposed.

12.4 Specifications

Connectors: 2 mm connector

12.5 Important note on using the ear electrodes

- Do not use in case of any known metal allergies!
- Prior to the application, the electrodes must be equipped with the supplied self-adhesive felts!
- The felts must be well-moistened throughout the entire treatment.
- In case of any kind of discomfort, such as stinging, burning, or pain stop the treatment or reduce the intensity immediately until no unpleasant symptoms remain. If necessary, check the contacts and improve the conductivity by remoistening the felts.
- For hygienic reasons, the electrodes may only be used for one individual patient. This means that every patient requires his/her own pair of ear electrodes.



Healy GmbH
Darritzer Str. 6
16818 Kränzlin, Germany



Healy GmbH | Schloss Kränzlin | Darritzer Str. 6 | 16818 Kränzlin - Germany
T. +49 30 54905949-1 | www.healy.eu | info@healy.de