



Healy Wellness Instructions for Use



Frequencies for Life

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Disclaimer: While scientific research underlies Healy technology, its connection to health and wellness has not been extensively explored or demonstrated. The Healy is not intended to cure, treat, mitigate, diagnose or prevent disease, but rather to support energetic balance and enhance recovery, vitality and wellbeing.

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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. It aims to ensure safe handling and enables users to become familiar with the device.

2. Healy

2.1 Intended Use

Healy is a microcurrent device that uses specific frequencies to promote energetic balancing. It can be applied to different parts of the body.

2.2 Warnings

- 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.

2.3 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 output. The 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 smart-phone requirements in **section 4.1.1**.

2.3.1 Hardware Description



Figure 2.3.1.1: 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)

2.3.2 Software Description

The “Healy APP” is required for configuring and controlling the hardware. It allows sending application programs to the device.

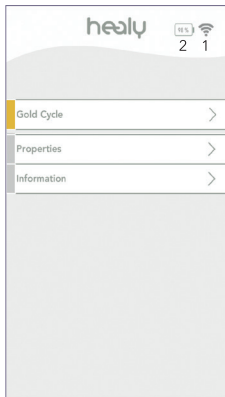


Figure 2.3.2.1

With the App you can start and stop the application. The “Healy APP” connects to your Healy hardware using Bluetooth. The “Healy APP” can connect only to one device at a time.

Figure 2.3.2.1: 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

2.4 General

- Intentional misuse can be harmful or reduce the effectiveness of the device.
- Carefully read the instructions for use before use.
- This product is intended only for the purpose described in these instructions for use.

- In this manual, the word DANGER warns of possible personal injury!
- In this manual, the word WARNING warns of possible damage caused to property!

2.5 Safety Notes

Danger/Warning:

- Keep this device out of the reach of children.
- Do 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 application.
- 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. Any attempt to repair the device will void the warranty.
- 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 application 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 device 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.
- The device should only be stored and transported under the conditions defined in these instructions.

- The device is designed for indoor use only.
- 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 must be operated only with supplied accessories and together with compatible smartphones.
- Not for use by those with a pacemaker or heart disease
- 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.
- The equipment and the connecting leads used with this device must all be in good condition.

- Do not use if recurrent episodes of skin irritation occur.
- 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.

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).

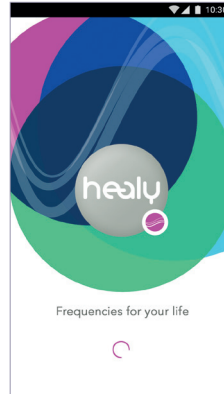


Figure 3.1.5.1: Starting screen

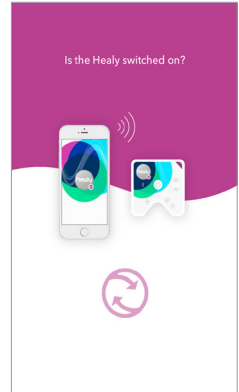


Figure 3.1.5.2: Scanning screen

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



Figure 3.1.5.3: Scan serial number screen



Figure 3.1.5.4: Connect screen

serial number of the device you can connect to the Healy by pressing the “Connect” button (see **figure 3.1.5.4**).

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. Place the electrodes onto the desired 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 application 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.

- Connect the electrode to the cable of the device.
- Check the functioning of the system before beginning the procedure.
- 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 device, 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 application if there is discomfort or a burning sensation.
- After the session, turn off the device, 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 im-

provement, replace with new electrode.

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

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 application (please refer to chapter 4.1)
- start application (please refer to chapter 4.1)
- connect the electrodes (please refer to chapter 3.1.6)

4.1 Starting the application using the smartphone

After the installation of the App, pairing and connection of the electrodes, the Healy is ready for operation. In the

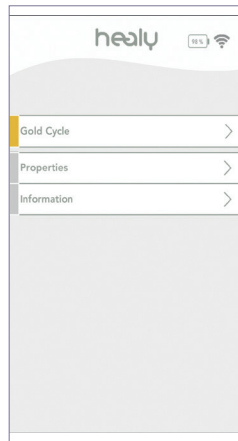


Figure 4.1.1: Overview interface

overview screen you can select which program category you want to use (see **figure 4.1.1**).

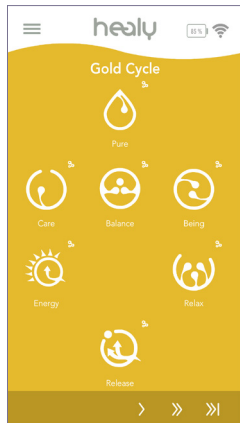


Figure 4.1.2: Program page

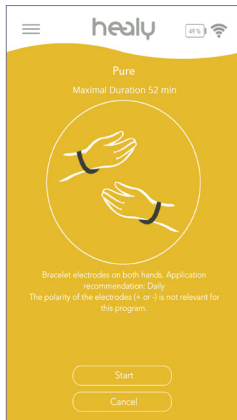


Figure 4.1.3: Information page for the placing the electrodes

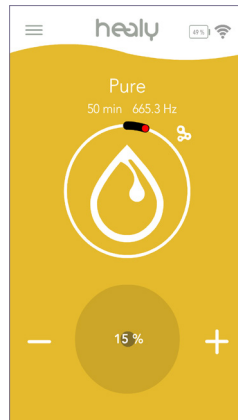


Figure 4.1.4: Application page

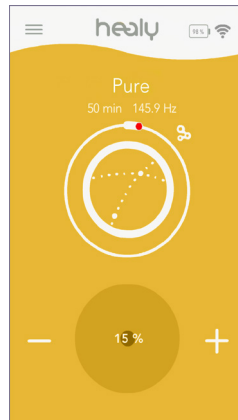


Figure 4.1.5: Application page with white time indicator – electrical circuit is closed

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

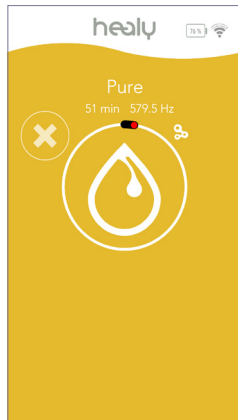


Figure 4.1.6: Application page with black time indicator – electrical circuit is open

After selecting “Start” on the information page the application is started and the application page is loaded (see **figure 4.1.4**). In the application page you can set the intensity of the application 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**).

4.2 Handling of the Healy hardware

During the application 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 application without the smartphone

The device always stores the last application 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 application

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

- To stop the application select one of the following:
- briefly press the on/off-switch (pause mode)
- tap the icon in the application 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

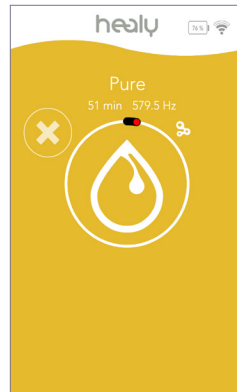


Figure 4.4.1: Pause screen. By pressing the “X” in the pause screen you cancel the program and get back to the overview interface.

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.

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 Storage between applications

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

5.4 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 damage, contact the manufacturer or an authorized dealer

5.5 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

Event or message	Cause	Actions required
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 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

Reference number	Description	Quantity
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 7.2.1
Input Current	20 mA
Protection class	Internally powered
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	-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	DC up to 1 MHz
Accuracy current	± 20 μ A with ± 10 %
Output frequency – Stimulation	DC up to 1 MHz

7.3 EC-Declaration of Conformity Under the Directive 2004/108/EC of the council regarding electromagnetic compatibility

This is an electrical device for application on humans.

Type: Healy **Year of manufacture:** 01-2019 – 12-2019

The product is designed and manufactured in accordance with the following directives:

2014/30/EU Electromagnetic compatibility

2014/35/EU Low Voltage Directive

2011/65/EU ROHS - Directive

under the sole responsibility of:

Company: Healy GmbH | Darritzer Str. 6 | 16818 Kränzlin – Germany

The device complies with the following harmonized norms:

EN 61000-3-ff

EN 55014 ff

EN 61558 ff

EN 60335 ff

The technical documentation with risk analysis is completely available.

The instructions for use accompanying the product are available in the respective national language.

Kränzlin/13.03.2019

Place/date



A handwritten signature in blue ink, appearing to be 'J. Healy', is written over a horizontal line.

Signature CEO

7.4 Mechanical parameters

Dimensions	55 x 57 x 13 mm
Weight	32 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

7.5 Environmental conditions

7.5.1 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

8. Disposal

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





9. Used Symbols and Icons


The following icons are used on the device, the packaging and the labelling:







	Use only inside		Electronic waste – do not dispose. Recycle acc. to local regulations or contact your authorized dealer or the manufacturer.		Recycling symbol
	SGS US CAN certification Mark		In conformity with European legislation		Keep away from heat
	Bluetooth		Read instructions for use before use		Symbol for Bluetooth Wireless connection
	Caution: Read instructions for use before use. Follow safety advices in this manual.		Temperature limitations		Symbol for Battery
	Follow the instructions for use		Best before		Symbol for on- and off-switch
	Keep dry	REF	Hardware reference number		Symbol for USB-Connection
	One patient use		Plus icon for positive electrode socket		Minus icon for negative electrode socket






	Symbol for generator operation – stimulation output
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The following symbols are used in the Healy – App

	Icon for over-view interface		Icon for the trademark Healy		Battery status of the Healy hardware		Icon for the blue-tooth signal strength between the Healy App and Healy hardware
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	Pictograph for the placement of bracelet electrodes. Appears after selection of the program	Note: the background colour may vary, depending on the selected and configured program parameter
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	Button for increasing the intensity in percentage (current or voltage)		Button for decreasing the intensity in percentage (current or voltage)		Icon for “Meridians” program.
	Symbol with information about actual intensity of the application		Symbol for scanning and connecting with the Healy hardware, appears after starting the app and during establishing the Bluetooth connection		Button for scrolling to the first page with programs

	Button for jumping two pages backwards		Button for jumping two pages forward		Button for scrolling to the last page with programs
	Button for moving one page back		Button for moving one page forwards	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

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

11.1 Description

The bracelets are made of conductive fabric and hydratable material or conductive elastic 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 apply the bracelet onto the skin in the presence of abrasions, erythema or wounds.

11.4 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

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 application 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 application for a few minutes until you feel normal again.

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.

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

- Prior to the application, the electrodes must be equipped with the supplied self-adhesive felts!
- The felts must be well-moistened throughout the entire application.
- In case of any kind of discomfort, such as stinging, burning, or pain stop the application or reduce the intensity immediately until no unpleasant symptoms remain. If necessary, check the contacts and improve the conductivity by remoistening the felts..



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Frequencies for Life



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