Healy
Electrostimulation device

Instructions for Use

Frequencies for Life

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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 used for pain management, using currents in the microampere range with different frequencies. It can be applied to different areas of the body.

2.2 Indications

The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arms and legs due to strain from exercise or normal household work activities and for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

2.3 Contraindications

Microcurrent treatment must not be performed when metallic foreign bodies are in the area of treatment, pacemakers or implanted 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 on the head or neck.

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.

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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.

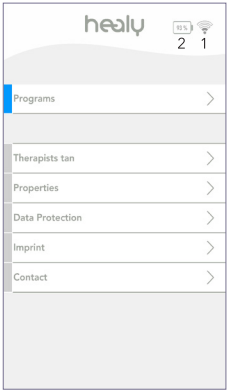

Figure 2.4.2.1: Overview interface of the Healy APP. Pos. 1-Icon for the signal quality of the Bluetooth connection to the Healy; Pos. 2-Icon for the battery status of the Healy

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.
- 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.
- 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 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. 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 treatment and remove the electrodes if any irritation, sensation, allergic reaction or burning occurs at the electrode contact points and contact us.
- 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.
- Fixed, portable, mobile HF-communication devices and RF-emitters, e.g. mobile phones, RFID, diathermy and security systems (e.g. electromagnetic anti-theft systems, metal detectors), may influence medical electrical devices. You should keep a safety distance of 30 cm (12 inchs) from HF-communication devices and RF-emitters 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.
- 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 diathermy, shortwave or microwave therapy ME equipment may produce instability in the stimulator output.
- Simultaneous use together with RF-surgical equipment, electrocautery or a defibrillator 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 Store[1]
- Search for the "Healy APP"
- Choose "Healy APP"
- Download and install on your smartphone

3.1.3 iOS Operating System

- Open the Apple Store[2]
- Search for the "Healy APP"
- Choose "Healy APP"
- Download and install on your smartphone

[1] Play Store is a registered trademark of Google Inc.

[2] App-Store is a registered 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**).

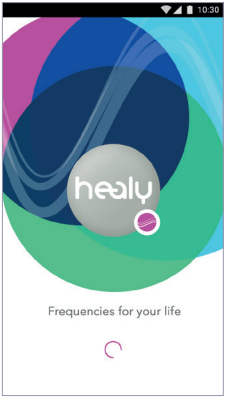

Figure 3.1.5.1:
Starting screen

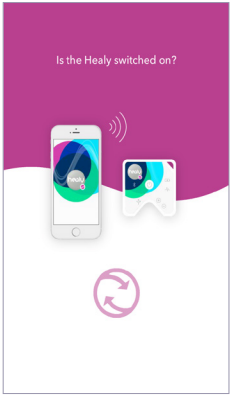

Figure 3.1.5.2:
Scanning screen

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.

Figure 3.1.5.3:
Scan serial number screen

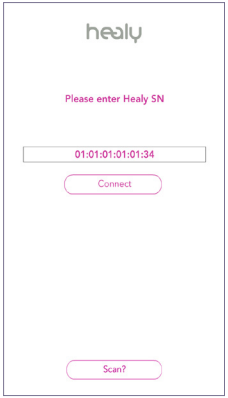

Figure 3.1.5.4:
Connect screen

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.
- Connect the electrode to the cable of the electrostimulator.
- 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 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.
- 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 Device

You should become familiar with these frequently used operations:

- switch On-Off (please refer to chapter 4.1.5 and 5.4)
- select treatment (please refer to chapter 5.1)
- start stimulation (please refer to chapter 5.1)
- connect the electrodes (please refer to chapter 4.1.6)

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 displayed (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**).

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.

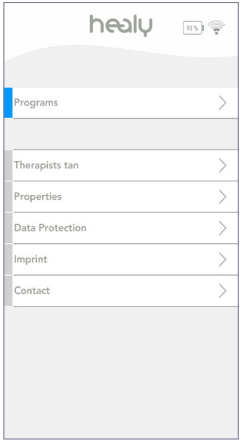

Figure 4.1.1:
Overview interface

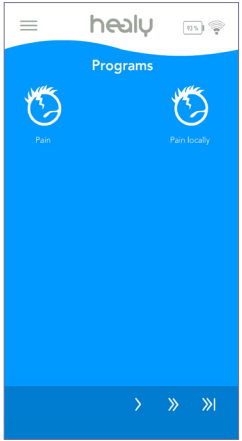

Figure 4.1.2:
Program page

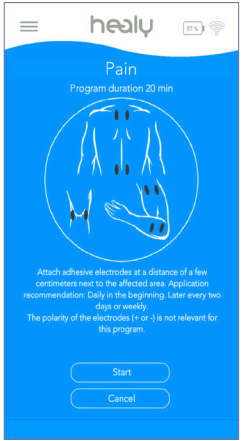

Figure 4.1.3: Information page for the placing the electrodes

Figure. 4.1.4:
Treatment page

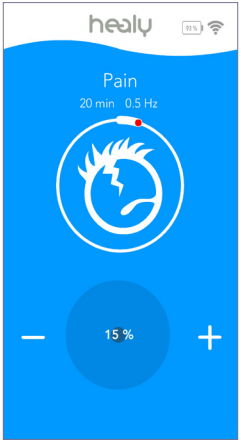

Figure 4.1.5: Treatment page with white time indicator – electrical circuit is closed

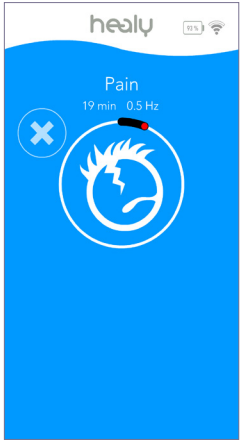

Figure 4.1.6: Treatment page with black time indicator – electrical circuit is open

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.

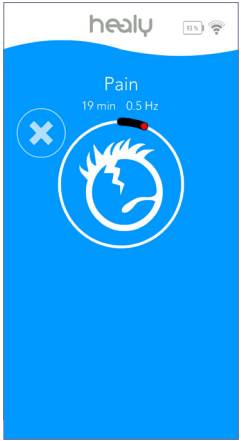

Figure 4.4.1: Pause screen
By pressing the "X" in the pause screen you cancel the program and get back to the overview interface.

5.2 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. Use only chemical disinfectants in liquid state cleared by the FDA. Use a sponge or a cloth to wipe the disinfectant over the device.

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 and 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 damage, 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 or	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
108-4068	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
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) / ±2,6 mA (current control)
Accuracy voltage	±0.1 V with ±10 %
Accuracy current	±20 µA 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 IEC6061-1-2:2014 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

7.2.4 Radio Frequency Wireless Technology

Description	Bluetooth Low Energy RF – Bluetooth V4
Compliance	SIG TCRL Core - 2015-12-22; Core and Host Version 2.0-4.2 (SIG = Bluetooth Special Interest Group) ETSI EN301 489-1; ETSI EN301 489-17
Compatibility	Smartphones with Bluetooth Wireless technology and Bluetooth 4.0 or higher
Operating frequency	2.4GHz
Configuration	The Healy device starts the Bluetooth wireless technology automatically when it is switched on. Switch on the Bluetooth wireless technology on your smartphone and start the Healy App. During the first scan, the app scans and connects to the Healy device, see Section 3.1.5. The first connection is called pairing.

Notes on usage	After pairing, the Healy device is permanently connected to the Healy App. The Healy App can only control one Healy device at a time. The wireless Bluetooth technology has a limited range, therefore the smartphone should be close to the Healy during use (distances not more than 10 m [32 feet]). If the connection is interrupted, the last configured or started application will be resumed. The pairing is not lost, only the connection can be lost. It is not necessary to perform the pairing again after each shutdown or loss of connection with the Healy device. If you want to pair with another Healy device, turn off the paired one or go to the settings and select "Connect to another Healy". Then it is possible to pair again with another Healy device, see section 3.1.5.

7.2.5 FCC Statement

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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	30 % to 80 %
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
Pain	+/- 600 µA	0.5 Hz	1 s	0 s	1 s	0 s
Pain locally	+/- 600 µA	100 Hz	2.5 ms	2.5 ms	2.5 ms	2.5 ms

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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:

	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
40°C 5°C	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	92 %	Battery status of the Healy hardware
	Symbol for generator operation – stimulation output		Icon for overview interface	healy	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 adhesive electrodes. Appears after selection of the stimulation 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 “Pain, Pain locally” therapy program.
15 %	Symbol with information about actual intensity of the stimulation		Symbol for scanning and connecting with the Hea-ly hardware, appears after starting the app and during establishing the Bluetooth connection		Button for jumping two pages backwards
	Button for scrolling to the first page with programs		Button for moving one page back		Button for jumping two pages forward
	Button for scrolling to the last page with programs		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
1	22th October 2017	Minor corrections
2	14th November 2018	Changes for FDA
3	27th October 2019	Changes for FDA

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