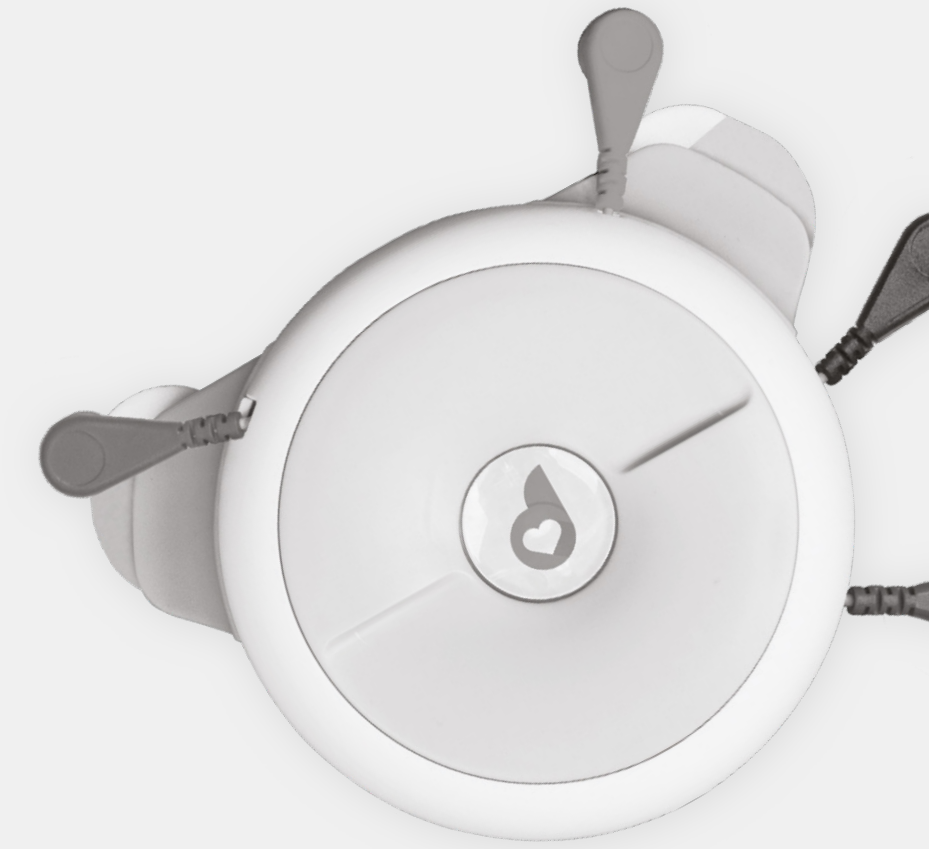
D-Heart
Portable ECG Device

User Manual / Manuale Utente



D·Heart®

Rev. 3.0.0 2019/07/08

CONTENT

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D-HEART PORTABLE EGC DEVICE USER MANUAL

ATTENTION: Read this manual carefully before using the instrument.
Please keep it in a safe place for future reference.

1. CONTENT OF THE PACKAGE

- D-Heart Portable ECG Device with lanyard [1]
- Disposable electrodes
- Charging cable
- Soft case with embedded Wireless charger
- Quick Guide

2. DEVICE OPERATION

a. POWER ON/OFF

- When the device is OFF (Led off), press the central button to switch the device ON.
- When the device is ON (Led blinking), press the central button to switch the device OFF.

b. DEVICE STATUS

- OFF (Led off)
- ON / NOT PAIRED
  Led single blinking; timing: 1s
- ON / CONNECTED
  Led ON (fixed)
- ON / MEASURING
  Led double blinking; timing: 1s
- ON / BATTERY DISCHARGED
  Led blinking 3 times; then OFF
- ON / FIRMWARE UPDATE
  Led fast blinking; timing: 0,3s
- OFF / CHARGING
  Led single blinking; timing: 5s
- OFF / CHARGED
  Led single blinking; timing: 1,5s

How to operate the device is described in the *Quick Guide for D-Heart Portable ECG Device* included in the package and in the Video Tutorial available at www.d-heartcare.com.

[1] In case of need, the holder of the lanyard can be detached from the D-Heart Portable ECG Device.

3. ENVIRONMENTAL CONDITIONS

- Operating Temp (battery discharging): -10°C to 40°C
- Operating Temp (battery charging): +5°C to +35°C
- Storage Temp: -20°C to +30°C
- Storage Humidity: 45% ~ 75% (relative)
- Atmospheric pressure range: 700 hPa to 1060 hPa

4. DECLARATION OF CONFORMITY

The D-Heart Portable ECG Device is compliant with the following standards:

- ETSI EN 301 489-1 V2.1.1 (2017-02)
- ETSI EN 301 489-17 V2.2.1 (2012-09)
- CEI EN 60601-1-2:2016-04
- CEI EN 60601-2-25:2016-04 (*)
- ETSI EN 300 328: v2.1.1 (2016-11)
- CEI EN 60601-1-11:2015
- IEC 60601-1:2005+A1:2012

5. INTENDED USE, INTENDED USER, CONTRA-INDICATIONS AND PRECAUTIONS, RESIDUAL RISKS

- The device is intended for supporting or providing useful information regarding the process of diagnosis or care of users at risk for or with heart diseases.
- The device is intended to be operated in hospital, general physician's office, out-of-hospital locations such as homecare environment.
- The device is intended for adults. Keep the device away from young children up high, out of sight, and out of reach to prevent potential ingestion hazards of small parts (e.g. disposable electrodes).
- The conductive parts of electrodes should not contact any other conductive parts including earth.
- Use ONLY disposable electrodes provided with the device or other electrodes of the same model. Contact info@d-heartcare.com to be informed on how purchasing the disposable electrodes.
- The device shall not be operated in combination with a cardiac defibrillator.
- The device shall not be operated in combination with high frequency surgical equipment.
- The device shall not be operated in combination with flammables.
- The device shall not be operated in combination with flammable anaesthetics.
- The device shall not be operated in environments saturated by oxygen.
- The device is classified as Class B according to CISPR 11:2009 (Radio-frequency disturbance characteristics).

(*) The conformity is limited to the applicable tests (as reported in the relevant Test Reports).

- The device is not suitable for direct cardiac application.
- An automatic check made by the D-Heart Portable ECG Device App advices and prevents the operator from situations when the device is inoperable (e.g. not all the electrodes are connected properly to the patient's body).
- The ECG measurement precision could be affected by cardiac pacemaker or other electrical stimulators.
- The minimum operating time is 24 hours provided that the battery is new and fully charged.
- The battery charge time from depletion to 90 % charge in normal use and battery conditions is 2 hours.
- In order to charge the battery the user must place the device on the wireless charger included in the package. Battery charging is made by wireless technology.
- Don't connect the device to the body while the battery is being charged (please note that the device is not operative while the battery is being charged).
- After the charging has completed leave the device getting cool before putting it in contact with the patient's body.
- The battery charging level must be checked by the user before operating the device by using the proper indication in the App.
- The isoelectric segments within the QRS complex are excluded from the Q-, R- or S-waves.
- The device is built in with specific filter settings to remove low-frequency components such as motion artefact, respiratory variation, and baseline wander.
- Before executing any measurement, check the device to make sure that there is no visible damage that may affect user's safety and measurement performance. Stop using the unit when there is obvious damage.
- At least on monthly basis check the availability of App and Firmware updates and make the required upgrades accordingly.

6. MAINTENANCE AND CLEANING

a. CLEANING AND STERILIZING

- Turn off the device before cleaning. Wipe the device with a dry and clean cloth for cleaning. Do not allow any liquid to get in the device.
- NEVER re-use the disposable electrodes.

b. MAINTENANCE

- Do not open the device case to avoid damages to internal components.
- Prevent any liquid from getting in the device as it would affect the safety and performance of the device.
- Software and firmware upgrade are notified to the user and automatically performed via the Smartphone App.

c. TROUBLESHOOTING

c.1 TROUBLE: The device doesn't switch on	
Possible reason	Solution
The battery is drained or almost drained.	Charge the battery.
The device is damaged.	Consult the following web site: https://www.d-heartcare.com/contact.
c.2 TROUBLE: The device doesn't connect to the Smartphone	
Possible reason	Solution
The Bluetooth function of the Smartphone is switched off.	Switch the Bluetooth function of the Smartphone ON.
The Smartphone is connected to another D-Heart device.	Switch the other D-Heart OFF.
The device is damaged.	Consult the following web site: https://www.d-heartcare.com/contact.
c.3 TROUBLE: The automatic check in the App shows one or more disconnected electrodes	
Possible reason	Solution
Disposable electrodes don't contact body well.	Place the disposable electrodes correctly.
The plugs are not connected to the disposable electrodes.	Connect the plugs to the disposable electrodes.
The device is damaged.	Consult the following web site: https://www.d-heartcare.com/contact.
c.4 TROUBLE: the device fails measuring the heart rate or the trace shows strong irrelevant waveforms	
Possible reason	Solution
Disposable electrodes don't not contact body well.	Place the disposable electrodes correctly.
The plugs are not connected to the disposable electrodes.	Connect the plugs to the disposable electrodes.
Movement when measuring.	When measuring, please keep quiet and avoid moving.

Electromagnetic interference.	Keep away from interference source.
The device is damaged.	Consult the following web site: https://www.d-heartcare.com/contact.

c.5 TROUBLE: the battery doesn't charge

Possible reason	Solution
Wrong position on the wireless charger.	Place the device correctly on the wireless charger (the LED blinks slowly).
The device is damaged.	Consult the following web site: https://www.d-heartcare.com/contact.

7. LEGENDA OF SYMBOLS

The D-Heart Portable ECG Device is certified according to the relevant recommendations set by the European Community for electromedical devices (93/42/CEE). The number "1370" identifies the notified body that verifies the compliance of the device to the applicable essential requirements.

The D-Heart Portable ECG Device is protected against water and dust with the level of protection IP22 as defined by the IEC standard 60529:

- The enclosure provides protection to access to hazardous parts for Fingers or similar objects
- The enclosure provides protection to Dripping water when tilted at 15°

Separate collection for Waste of Electric and Electronic Equipment (WEEE).

Manufacturer.

The D-Heart Portable ECG Device supports the Bluetooth® technology.

The D-Heart Portable ECG Device is classified as TYPE CF regarding the protection against electrical shock according to standard CEI EN 60601-2-25.

Range of temperature.

Range of atmospheric pressure.

Range of humidity.

Keep dry: store and use the device in a dry environment.

8. SUPPORT IN CASE OF NEED AND ADVERSE EVENT REPORTING

Please consult the following web site: **https://www.d-heartcare.com/contact** for assistance, if needed, in setting up, using or maintaining the D-Heart Portable ECG Device or to report unexpected operation or events.
Adverse event should be reported. Reporting form and information can be found at http://www.salute.gov.it. Adverse events related to D-Heart Portable ECG device should also be reported to D-Heart Srl on 0039 010 3017000

9. ELECTROMAGNETIC COMPATIBILITY

This device is classified in class B according to IEC60601-1-2.
This instrument has been tested and found to comply with the limits for medical devices to the IEC60601-1-2 and Medical Device Directive 93/42/EEC. These limits are intended to provide reasonable protection against harmful interference in a typical medical environment. This instrument generates, uses and can radiate radio frequency energies and, if not put in service and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular location.

If the system does cause harmful interference to other devices, which can be determined by turning the system off and on, try to eliminate the interference by adopting one or more of the following measures:

- reorient and/or relocate the receiving device;
- increase the distance between the devices;
- connect the system to an outlet on a different circuit than that to which the other devices is connected;
- consult the manufacturer or field service technician for help.

Essential performance: continuous operation (measurement status).

a. SPECIFICATIONS AND TECHNICAL INFORMATION: EMC (ELECTROMAGNETIC COMPATIBILITY)

Guidance and manufacturer's declaration - electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Guidance and manufacturer's declaration - electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	Compliance level
ETSI EN 301 489-1 V1.9.2 (2011-09) Electromagnetic compatibility and Radio spectrum Matters (ERM) Electromagnetic Compatibility (EMC) standard for radio equipment and services Part 1: Common technical requirements ETSI EN 301 489-17 V2.2.1 (2012-09) Electromagnetic compatibility and Radio spectrum Matters (ERM) Electromagnetic Compatibility (EMC) standard for radio equipment Part 17: Specific conditions for Broadband Data Transmission Systems CEI EN 60601-1-2:2016-04 EN 60601-1-2:2015-09 IEC 60601-1-2:2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	10 V/m 80 MHz to 2.7 GHz
ETSI EN 301 489-1 (V2.2.0) ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements ETSI EN 301 489-17 (V2.2.1) ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems	3 V/m 2.7 GHz to 6.0 GHz
CEI EN 60601-1-2:2016-04 EN 60601-1-2:2015-09 IEC 60601-1-2:2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	
Electrostatic Discharge	According to IEC 61000-4-2 ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air

Proximity fields from RF wireless communications equipment	According to IEC 61400-4-3 CEI EN 60601-1-2:2016-04 Table 9 test level applied
Rated Power magnetic fields	According to IEC 61000-4-8 30 A/m 50 Hz and 60 Hz

Guidance and manufacturer's declaration – electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Emission test	Compliance Criteria
ETSI EN 300 328: v2.1.1 (2016-11) Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU	All requirements are met

10. DISPOSAL OF THE DEVICE

According to Directive 2012/19/EU of the European Parliament and of the Council.4 July 2012 on waste electrical and electrical equipment (WEEE):

The crossed-out wheeled bin symbol printed either on the equipment or on the package indicates that the product shall be disposed separately from other waste at the end of its life cycle and that the user shall deliver the old equipment to collection centers authorized for electrical waste, alternatively the old equipment shall be sent back at the time of the purchasing of a new equipment of the same model in one-to-one proportion. The old equipment can be delivered either to the reseller or to the manufacturer D-HEART srl at the time of the delivery of the new equipment.

The correct disposal of waste according to the instructions above helps in preventing potential drawbacks for the environment and the public health and helps the recycling of the materials the equipment is made of. The incorrect disposal of the equipment is subject to administrative sanctions according to the existing law.

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CE 1370

Made in Italy

reddot design award
winner 2018