

D-Heart Portable ECG Device Technical Description

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1. CONTENT OF THE PACKAGE	2
2. GENERAL DESCRIPTION	2
3. CLASSIFICATION	3
4. DEVICE OPERATION	3
a. POWER ON/OFF	3
b. DEVICE STATUS	3
5. ENVIRONMENTAL CONDITIONS	4
6. DECLARATION OF CONFORMITY	4
7. INTENDED USE, INTENDED USER, CONTRA-INDICATIONS AND PRECAUTIONS, RESIDUAL RISKS	4
8. MAINTENANCE AND CLEANING	6
a. CLEANING AND STERILIZING	6
b. MAINTENANCE	6
9. D-HEART PORTABLE ECG HARDWARE MATERIALS	6
10. D-HEART ECG TRACING CHARACTERISTICS	7
11. D-HEART APP	7
12. D-HEART DEVICE AND D-HEART APP COMPATIBILITY	12
13. DEVICE ELECTROMAGNETIC COMPATIBILITY	12
a. SPECIFICATIONS AND TECHNICAL INFORMATION: EMC (Electromagnetic Compatibility)	13
14. DISPOSAL OF THE DEVICE	14

1. CONTENT OF THE PACKAGE

- D-Heart Portable ECG Device with lanyard¹
- Disposable electrodes
- Charging cable
- Soft case with embedded Wireless charger
- Quick Guide

2. GENERAL DESCRIPTION

The D-Heart portable ECG (D-Heart ECG) is a 6 electrodes ECG device that records 8 or 12 Leads ECG (Fig.1) designed to be worn at the neck that records the electrical activity of the heart and transfers the collected data to a Smartphone via Bluetooth Low Energy (BLE). A dedicated App processes the data received from the ECG and plots an 8-12 leads electrocardiogram in real time (Fig.2). The App can connect to a dedicated Cloud application for the management of the users and for the connection to remote medical reporting services (Tele-cardiology).



Fig. 1 D-Heart Portable ECG Device on a patient

The D-Heart is battery operated. The battery is charged via wireless technology. A wireless charger is provided as an accessory of the D-Heart.

In order to operate, the D-Heart is connected to the human body by means of 6 sockets that are connected to disposable electrodes, glued to the skin of the body: four sockets are placed on retractable cables; two sockets are fixed in the chassis (back side). A power button is placed in the center of the chassis (front side) to switch on/off the device. The power button hosts a LED to signal the device status to the user.

When switched on, the D-Heart monitors the electrical activity of the heart by means of dedicated chipsets that convert the analog electrical signal generated by the heart into a digital bit stream; the correct connection to the human body and the presence of meaningful signals are automatically checked. The bit stream is then transferred - in real time - to a Smartphone via a BLE link. The D-Heart is battery (Li-Ion) operated. The battery charge level is transferred to the Smartphone in real time. The battery is recharged by wireless technology. The D-Heart hosts a wireless receiver connected to a coil. To enable the battery charging, the D-Heart is placed on an external wireless charger (provided as accessory).

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

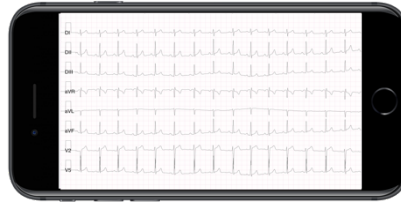


Fig. 2 D-Heart Portable ECG device ECG recording

The useful life of the device is estimated to be 5 years.

3. CLASSIFICATION

The D-Heart Portable ECG Device is classified as class IIa medical device according to rule 10 of Annex IX to Directive 93/42 / EEC For the purposes of the CE marking, the EC declaration of conformity for the product quality assurance system (Annex II.3 of Directive 93/42) was carried out relying on the following notified body: Notified Body no. 1370 Bureau Veritas Italia S.p.A. – Via Miramare, 15 - 20126 Milano – Italy.

4. 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 .

5. 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

6. DECLARATION OF CONFORMITY

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

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

(*) The conformity is limited to the applicable tests (as reported in the CE Technical File).

D-Heart Portable ECG Device has been qualified in accordance with SIG qualification rules:

- Declaration ID: D038825

7. 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 device is not suitable for direct cardiac application.
- An automatic check made by the D-Heart Portable ECG Device App advises 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.

8. 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.

9. D-HEART PORTABLE ECG HARDWARE MATERIALS

D-Heart dimensions are: 117 mm x 133 mm x 44 mm

D-Heart electrodes dimensions are: 31 mm x 43 mm electrodes

D-Heart weight is: 196 grams

D-Heart device is composed by:

Battery: 601663-PLC 600mAh.doc

Electrodes connection cables: Cavo Trangjan TD1701_001_ Cavo Trangjan TD1701_003_TD_1701_001

Disposable electrodes: CE007-608; CE1906

Plastic Materials: PA-757_RoHS; Properties for ABS757, PC110, TPR9870

Module BLE: STm SPBTLE-RF; Bluetooth Declaration ID: D028766

Wireless charger: CE - EMC Test Report; BCTC-151216097 Vetac-wireless charging pad - EMC report.

10. D-HEART ECG TRACING CHARACTERISTICS

ECG tracing data, transmitted by Bluetooth module, present the following characteristics:

1. Data recording frequency: sampling at 640 Hz with transmission (at 160Hz) of average values every 4 samples;
2. 4 Tracings:
 - a. Lead DI
 - b. Lead DII
 - c. Lead V2 (Unipolar precordial electrode placed behind and to the left of the device)
 - d. Lead V5 (Unipolar precordial electrode that can record signal from position V1, V2, V3, V4, V6)
3. Horizontal Resolution: 6,25ms;
4. Vertical Resolution: 0.0068mV;
5. AC Filter: 50/60 Hz digital filter;
6. Muscular Filter: digital filter 25/40 Hz;
7. Tracings recorded on calibrated paper.

Acquisition modality can be AUTOMATIC if D-Heart App is in the setting 'patient', MANUAL if D-Heart App is in the setting 'health professional'.

Standard Acquisition velocity is 25 mm/s. However, in D-Heart App settings acquisition velocity can be changed to 50 mm/s.

In case of 8 lead recording the final ECG, tracing would show DI, DII, DIII, aVR, aVL, aVF, V2, V5. ECG recording can last from 12 seconds to 60 seconds. Default configuration does set ECG recording time to 12 seconds.

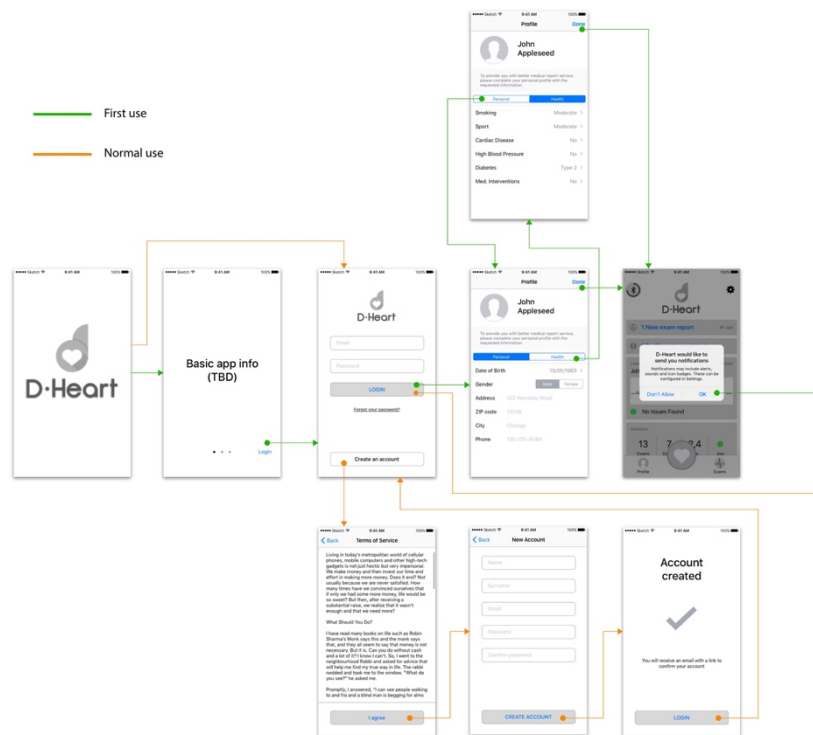
In case of 12 lead recordings (only for health professional users) the final ECG tracing would show DI, DII, DIII, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6. ECG recording is fixed to 12 seconds.

ECG tracings can be visualized and stored on the App in PDF format or exported in SCP format.

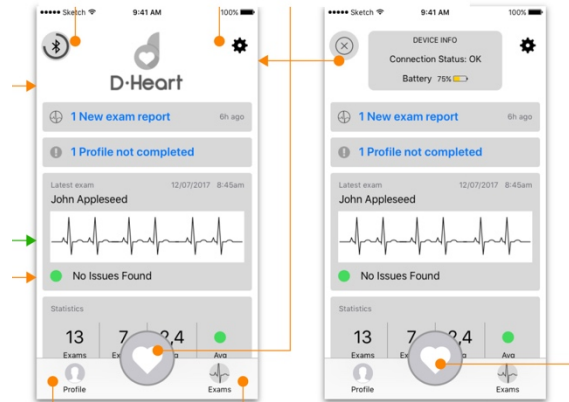
Moreover, ECG can be sent as PDF via mobile connection or printed via Bluetooth with a connected printer.

11.D-HEART APP

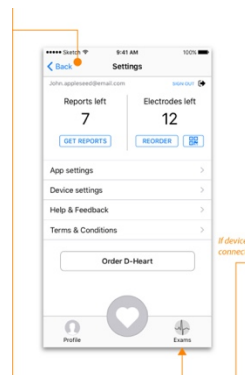
D-Heart App offers to the user of D-Heart Portable ECG Device a full set of graphical functions described as follows. The App is available both for Android and iOS operating systems.



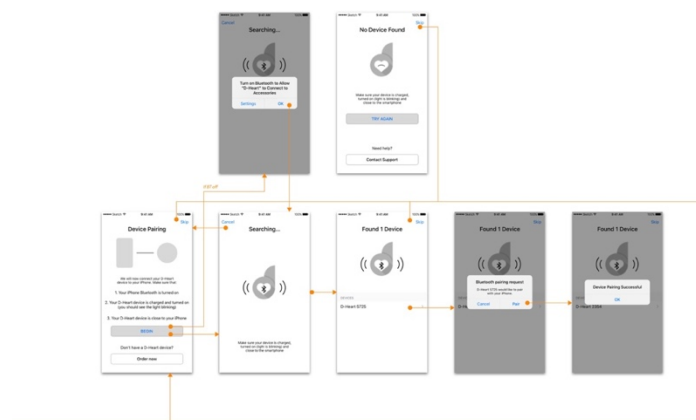
The authentication controllers group is the first one that user access when the application has been launched. After a 3 seconds splash screen, D-Heart opens an infographic that explain what D-Heart is and how to use It, with a checkbox to avoid to show this controller in future. After the infographic, D-Heart opens the main controller of the authentication group. From this controller, user can authenticate, enable Touch ID login or create new account (after the acknowledge of Terms and Conditions). After the authentication, if the account is not yet completed the application will prompt the controller to complete the profile. The completion of the user account is useful for D-Heart to have more outlined analytics data and it's mandatory to send ECGs to the Telecardiology system. If the user account results complete, user will be prompted to the main screen of D-Heart application.



The main controller of D-Heart allows access to the main features of the application. With the tab-bar navigation menu user can register new ECG, open his personal profile and patient's profiles or open the already completed ECG's archive. In the top part of the controller, there are the settings icon and Bluetooth connection state icon. This controller has a bunch of dynamic information to simplify User experience, as link to the last user exam, statistics about exams, notification about user data completion, Telecardiology results.

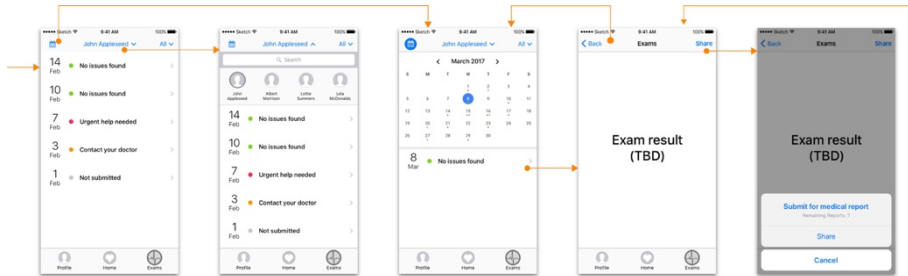


The settings controller has buttons to navigate to specific application settings, device settings, last accepted Terms and Conditions and a link to the Feedback and Help system. If the user hasn't a D-Heart device connected, there will be a button to order it. On the top part of the controller there are the number of reports available (already paid by the user) and the number of electrodes that user might have, based on the number of electrodes ordered and on the number of exams already done. Both of these counters have the button to buy other reports and electrodes, plus the QR code icon to scan new electrode box to add electrodes.



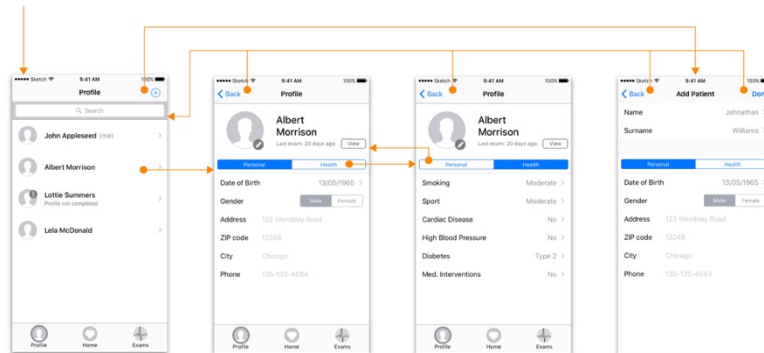
The application flow for the connection of the Bluetooth device is represented in this image. In the first controller, there will be some basic information about the procedure to connect a D-Heart device. After the

power on of the Bluetooth on the device, the iOS system asks for the permission for using Bluetooth with D-Heart application. In the second controller, there will be the list of D-Heart devices found with Bluetooth. After the user selects a device, D-Heart will connect to the device and save the device ID to the user on cloud. The saved device will be automatically connected every time the application starts and the user accesses it. If the device search doesn't find any D-Heart available, the controller shows a button to contact D-Heart support team.

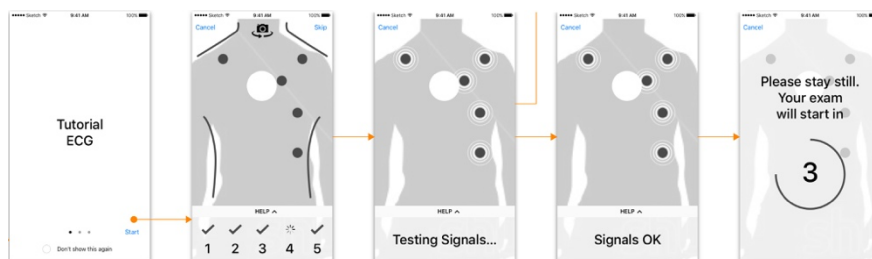


The archive flow starts with the list of the last exams done. Every exam will be shown with the date, the exam result (if it has been sent to Tele cardiology system) and the patient's name.

On the navigation bar there will be the calendar button and the Patient filter button. With the calendar button, a calendar will be shown in the controller, and user can select a date to see exam done in the selected day. If user select the patient filter button, a search bar with the last patient shortcut will be shown and exam can be filtered by patient's name. If user select an ECG, the ECG Result controller will be shown.

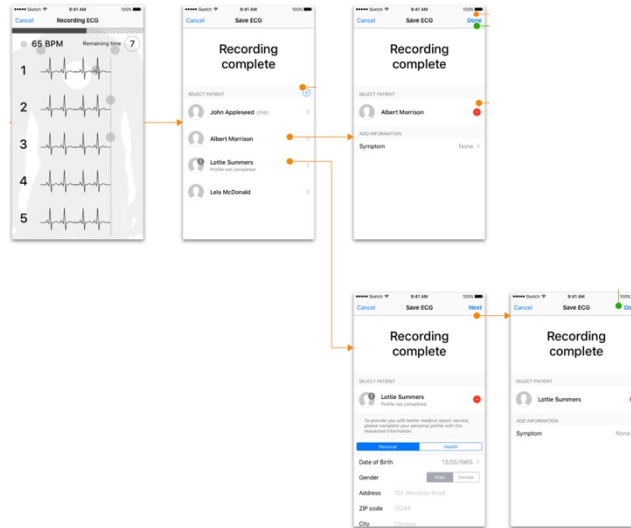


The profile flow starts with the list of all patients found on the device with a search bar. If the user searches for a cloud patient or a cloud exam, the patient will be automatically downloaded and added to this list. The patient list has a "+" button to create a new patient. If the patient will be completed by the user, the patient will be saved in the D-Heart cloud system. If the user taps on a patient, the patient's detail controller will be prompted. The opened patient will be editable if it hasn't been completed yet. If the patient has several exams linked, there will be a last exam button to open it faster.



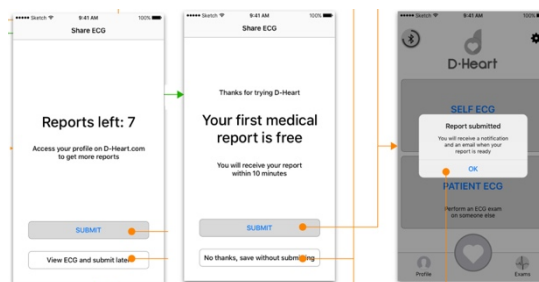
When the user will register a new ECG, D-Heart application shows a tutorial about the positioning of the D-Heart electrodes on patient's body. There will be a checkbox to avoid the opening of this infographics on the next ECGs.

After the infographics, a skippable real time help to position electrodes will be opened. This realtime help uses the phone camera to show on patient's body the area where the electrodes might be attached. When user taps the button to start the exam, a signal test will be done to avoid bad positioning before the ECG starts. If the signals are correct, a countdown to the registration will be prompted.



During the registration user can see the ECGs on the screen. There will be a countdown that shows the remaining registration time and the real time heart rate (BPM). Should any error occur with the communications (e.g. Packet loss with the Bluetooth device) the registration restarts (the count down as well). If the sensor disconnects during the exam, the complete ECG flow will be restarted from the real time help for the electrodes. The minimum set of ECG data that the application needs to complete the exam is 12 seconds (to fill a landscape A4 ECG report).

If the registration is completed with success, the application will prompt the recording complete controller. In this controller, user can select the patient of the recorded ECG and the symptoms that the patient has. Should the user data be incomplete, application will prompt a popup asking user if she/he wants to complete the user data input before saving the exam (because patient data must be completed to use tele cardiology system).



After the completion of the first exam by the user, a free Telecardiology report can be obtained by the user. If the user has already used his free report, the controller will show the paid reports left or the link to buy reports if the user hasn't already paid reports available. User can skip the Telecardiology service and go to the ECG results. If the user sends the ECG to the Telecardiology system, a cloud notification or email will inform about the results.

Software Safety Classification

According to the IEC62304:2006 International Standard section 4.3 "Software safety classification" and considering the Technical File 03 Risk Analysis and Evaluation, the software and firmware contained in the device have been classified as:

Class B

According to FDA “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” and applying the following decision route, the level of concern of the software and firmware contained in the device composing the D-Heart system have been classified as:

Moderate

12. D-HEART DEVICE AND D-HEART APP COMPATIBILITY

D-Heart is a medical device that is regulated by international laws; we rigorously test and validate devices with smartphones and tablets to meet or exceed these regulations before we claim compatibility. We routinely add support for new phones and tablets. Check back if your device is not listed below. (Last update on August 5th, 2019)

iOS 11.1

- iPhone 5, 5c, SE, 6, 6s, 6s plus, 7, 7plus, 8, X
- iPad Mini

Android 5.0 to 8.0

Smartphone

- Lenovo Moto G5
- Samsung Galaxy J5, J6, J7, J8
- Samsung Galaxy S5, S6, S7, S8, S9
- Huawei P9, P9 Plus, P10, P10 Plus, P20, P20 Plus
- LG G6, G7
- Google Nexus 5X, Pixel, Pixel XL, Pixel 2, Pixel 2XL
- Honor 8

Tablet

- Samsung Tab A 2019
- Huawei Mediapad T3 10'
- Mediacom Smartpad 10'

13. DEVICE 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 are 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)	All requirements are met

Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU	
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14. DISPOSAL OF THE DEVICE

According to Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic 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.