

# D-Heart Portable ECG Essential Technical File

Rev. 2.2.0 2021-05-11



CONTENT OF THE PACKAGE		
	Measures	Weight
D-Heart Portable ECG with lanyard, BT module and incorporated battery	117 mm x 133 mm x 44 mm	196 grams
Disposable electrodes	31 mm x 43 mm	2 grams
Soft case with incorporated wireless charger (CE - EMC Test Report)		
Recharge Cable		
Rapid Guide		
ECG	Acquisition	Transmission
Leads	8/12	8/12
Recording Frequency	640 Hz / ch	640 at 4 intervals on average (160 Hz / ch)
A/D Resolution	24 bit	
Mesaurment Range	> $\pm 5$ mV	
Frequency Response	0,05 Hz ~ 130 Hz (-3db)	
Recording velocity	25 mm/s (std) / 50 mm/s	
Acquisition lenght	From 12 s to 60 s	
Filters:	AC: not present	
	Muscolar: not present	
CLASSIFICATION / DECLARATION OF CONFORMITY		
93/42 / EEC Directive	Class II A	In accordance with rule 10 of the attachment IX
CISPR 11:2009 (Radio-frequency disturbance characteristics)	Class B	
IEC62304:2006 (Software Safety)	B	
IEC60601-1-2 (Electromagnetic Compatibilty)	Class B	

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	The conformity is limited to the applicable tests (as reported in the CE Technical File)
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	Issued by Eurotest Lab	
<b>COMPATIBILITY OF D-HEART DEVICE AND D-HEART APP</b>	D-Heart is compatible with both the iOS and ANDROID environment. Compatible devices are listed on our website <a href="http://www.d-heartcare.com">www.d-heartcare.com</a> . Please visit it for more information.	
<b>ENVIRONMENTAL CONDITIONS</b>		
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%	
Atmospheric pressure range	700 hPa to 1060 hPa	
Minimal Length of the battery	24 hours	With newly charged battery
Charging time in normal condition (from 0 to 90% charge)	2 hours	In normal conditions

D-Heart lifetime as a device is estimated as being around 5 years.

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

- Declaration ID: D038825

## 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 update our compatibility list. Check below if your device is comprised within the list (Last update on February 15th, 2021).

### iOS 12 to 14 (not compatible iOS 13.4)

- iPhone SE, 6, 6s, 6s plus, 7, 7 plus, 8, 8 plus, X, XS, XR, 11, 11Pro, 12, 12 Pro

iPad:

- iPad Mini
- iPad Pro

## Android 5.0 to 10.0

### Smartphone:

- Lenovo Moto G5
- Samsung A21s
- 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, K41s
- Google Nexus 5X, Pixel, Pixel XL, Pixel 2, Pixel 2XL
- Honor 8
- Xiaomi Mi 9T
- Redmi Note8T, Note9S
- Oppo A53s

### Tablet:

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