D·Heart

D-Heart Portable ECG Device

Clinical Validations

Hospital Grade Multiple Leads Smartphone ECG

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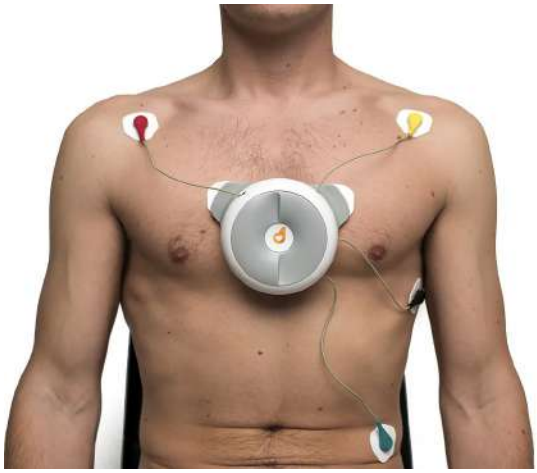

Medical grade ECG recording of 8-Leads ECG.

Accurate Morphologic evaluation of the ECG signal (DI, DII, DIII, aVR, aVL, aVR, V2, V5).

Innovative cable uncoiling mechanism designed to simplify and fasten the user experience.

Smartphone camera algorithm displays the electrodes position on the patient's chest with an accuracy of 0.5 cm*.

Personal medical folder with all medical data and exams history with the possibility to schedule exams.
24/7 telecardiology service that provides innovative triage report of the exam specifically designed for cardiac patients.

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WHEN D-HEART CAN BE IMPORTANT FOR MY PATIENT

Arrhythmias assessment
Evaluation of palpitations
Rule out cardiac conditions as a cause of palpitations

Managing patients with cardiac conditions
Pre and Post Atrial Fibrillation procedure
Post Myocardial Infarction surveillance
Titration of newly introduced medications

Diagnosing Arrhythmias early in high risk patients
Post cardiac surgery
30-days after Transient Ischemic Attack

Regular Screening of patients with cardiac risk factors
Hypertension
Atypical Chest Pain
Cardiomyopathy

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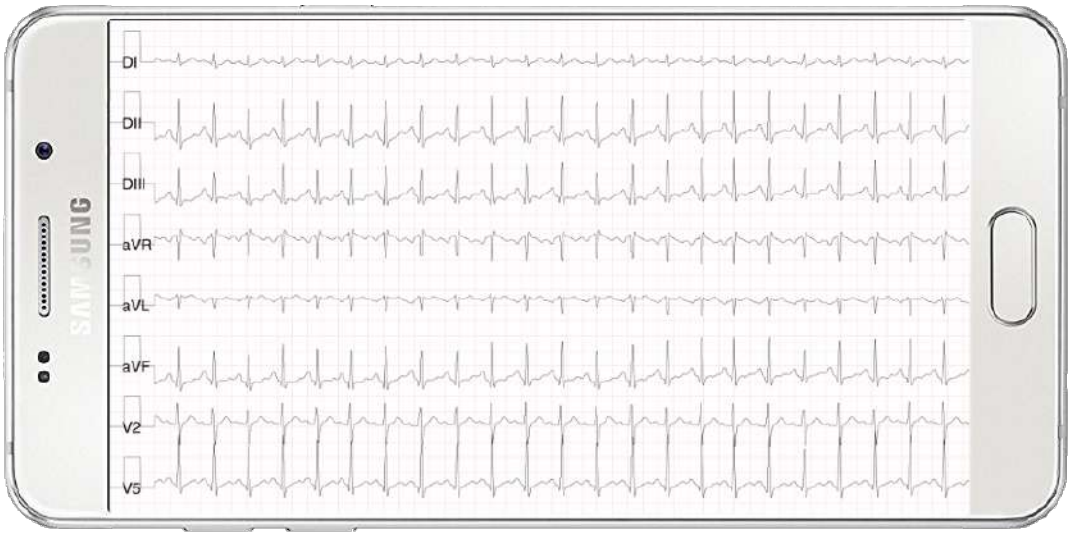
ECG Accuracy



Comparative analysis of multiple leads smartphone electrocardiograph (D-Heart®) versus standard 12-leads electrocardiograph in patients with Hypertrophic Cardiomyopathy

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Background. **M-Heath** technologies are revolutionizing cardiovascular (CV) medicine. However, a low-cost, user-friendly multi-lead smartphone electrocardiograph is still lacking.
D-Heart® is a portable device that enables the acquisition of the ECG on multiple leads via 6 electrodes (3 peripheral, 3 augmented and two precordial leads -V2 and V5) which streams via Bluetooth to any smartphone.
Both **high and low-income** settings may benefit from a low-cost/high-technology device.

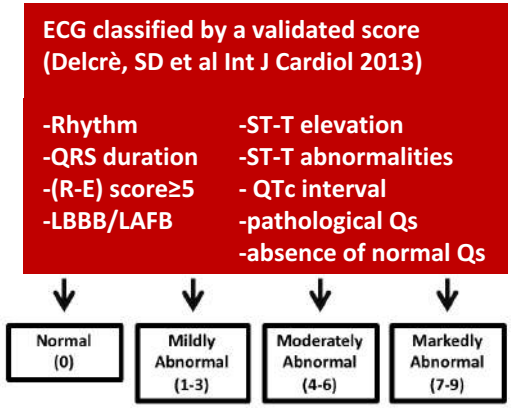
Purpose. To assess the accuracy of D-Heart® recordings in the stratification of ECG morphological abnormalities, compared with 12-lead ECGs, in a cardiomyopathies outpatient clinic.

Methods. Consecutive patients (>18 years) with a diagnosis of Hypertrophic Cardiomyopathy (HCM, N=144, men=96) referred for outpatient control at a referral national institution for cardiomyopathies were enrolled from May to August 2017 (**Table 1**)

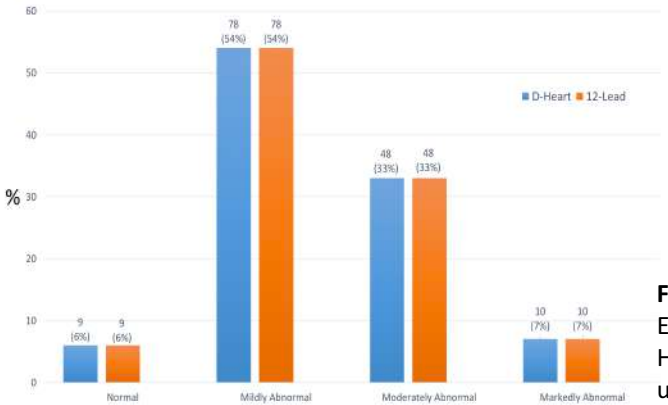
Table 1. Baseline Clinical characteristics

	Overall
Demographics	
Population – N, (%)	144
Age	35±21
ICD/PM	16 (12%)
Echo Parameters	
LAD, mm	42±6
LVMWT, mm	21±5
Previous ACA	3 (1%)

Figure 1. D-Heart Smartphone ECG device



Results. Results of ECG abnormality and intervals measurement are summarized in **Figures 2, 3, and 4**. Agreement was obtained in 143/144 (99%) cases with D-Heart tracings and in 142/144 cases with 12-lead ECGs.



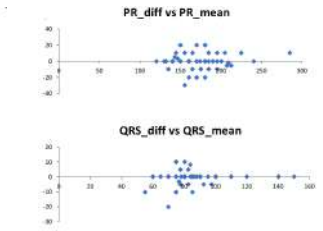


Figure 2. Agreement of ECG abnormalities (D-Heart vs 12-lead ECG) using a validated score

Figure 5. Comparison of **PR** and **QRS** intervals (Bland-Altman method, non-parametric approach) showed excellent concordance for D-Heart® measurements (95% limit of agreement −20 to +20 ms for PR and −10 to +10 ms for QRS).

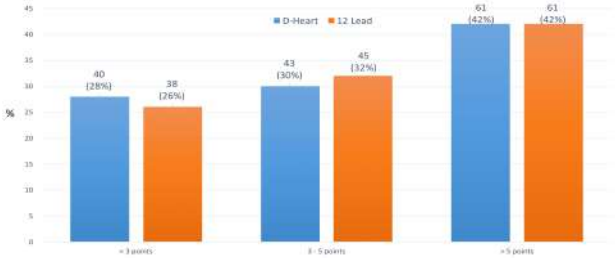


Figure 3. Distribution of R-E score points (D-Heart vs 12-lead ECG)

Figure 4. Examples of D-Heart ECGs recorded from HCM patients during the study

Conclusions. **D-Heart®** proved effective and accurate, allowing stratification of ECG abnormalities **comparable** to the 12-lead electrocardiographs. These results open new perspectives for low-cost community cardiovascular screening programs in low-income settings or homecare delivery in high income countries.

D·Heart

Electrodes Placement Algorithm

Validation of a smartphone-camera based software for the identification of electrodes location on human chest

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Background.

- Smartphone are producing profound changes in diagnostics.
- Clinically **actionable** data could now be generated locally by the patient.
- Multiple-lead **ECG** is a cost-effective, valuable and non-invasive test, but its use requires trained healthcare workers to correctly record the exam (due to specific position that electrodes).

Purpose.
To validate '***Mobile ECG on other***', a smartphone App **AI** algorithm that guides electrode self-placement via imaging processing technology by identifying electrode theoretical location on the patient's own chest, via the smartphone camera.
The app is coupled with D-Heart®, a **multiple lead mobile ECG** designed for users with no medical background.

Methods. Methods are summarized in Figure 1 and 2.

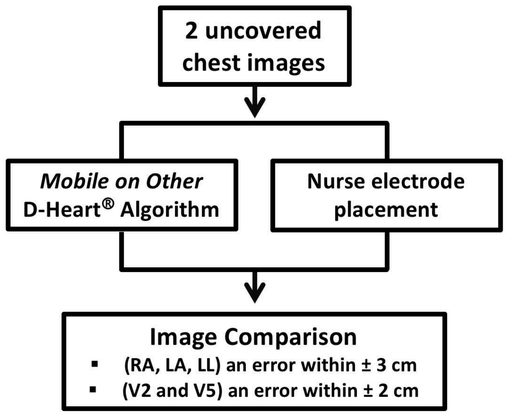

Figure 1. Validation study Enrollment and analysis

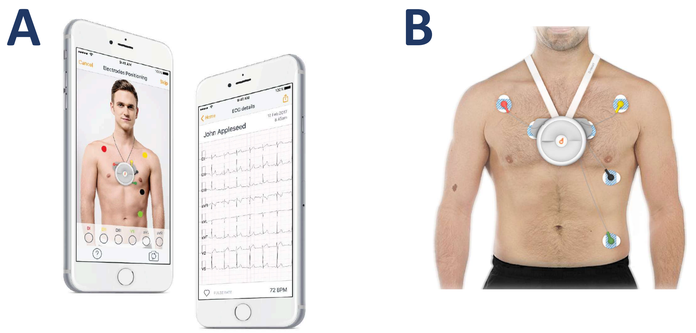

Figure 2. A. Mobile on other AI electrode placement algorithm with D-Heart. **B. D-Heart mobile ECG** final placement

Results. Consecutive healthy volunteers (n=40, men=30) were enrolled from June to July 2017. Results are presented in Table 1, Table 2 and Figure 3.

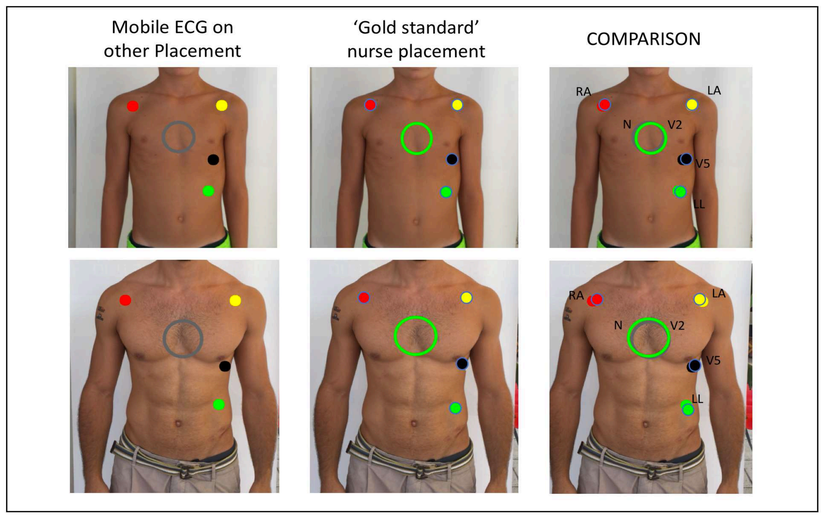

Figure 3. Mobile on Other vs Nurse placement comparison

Table 1. Median displacement in the horizontal and vertical axis for each electrode in the modality D-Heart 'Mobile ECG on other'

	Δ Height	Δ Width
RA (cm)	0.3 [0.1-1] (0-3)	0.5 [0.3-1] (0-2)
LA (cm)	0.5 [0.2-1] (0-3)	0.3 [0.2-1] (0-3)
LL (cm)	1 [0.5-1] (0-2)	0.6 [0.5-1] (0-2)
V2 (cm)	0.5 [0.1-1] (0-3)	0.5 [0.1-0.9] (0-3)
V5 (cm)	0.5 [0.1-1] (0-3)	0.5 [0.2-1] (0-1.5)

Table 2. Number of electrodes misplaced by the algorithm in the modality D-Heart 'Mobile on other ECG'.

	Misplacement (N)
RA	1
LA	1
LL	0
V2	5
V5	4

Six (15%) patients had >1 electrode misplaced.

Mean **time for ECG placement and recording** (defined as the time needed for the user to open the D-Heart soft case until the beginning of the ECG streaming from the D-Heart device to the smartphone) was **58 ± 12 seconds.**

Conclusions. 'Mobile ECG on other' software proved reliable and accurate for correct electrode self-placement, thereby opening new perspectives for accurate patient generated remote diagnostic tests.

D·Heart

Clinical Applications

ESPECIALLY VALUABLE FOR

Feasibility of cardiovascular screening in low-income settings using smartphone-based technologies

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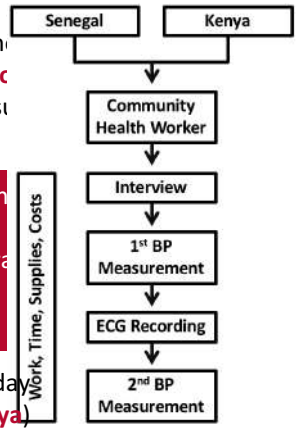
Introduction. Mobile health (**m-Health**) technologies revolutionizing cardiovascular (CV) medicine. However, m than 80% of heart disease related deaths occur in **lo income settings**, that are unable to take advantage of su innovations for healthcare awareness and prevention.

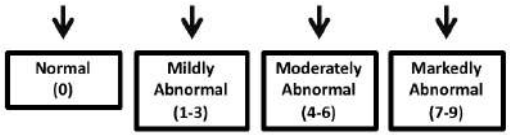
Purpose. To assess the feasibility of a pilot CV screen campaign with smartphone based m-health devices:
-D-Heart®, a validated low-cost 8-lead electrocardiogra (199€)
-iHealth® blood pressure (BP) recorder (~70€)

Methods. A total of 231 patients were enrolled in a two-day screening at 4 rural dispensaries, 2 in Kitui District (**Kenya**) and 2 in Ziguinchor District (**Senegal**).



ECG classified by a validated score

-Rhythm
-QRS duration
-(R-E) score≥5
-LBBB/LAFB
-ST-T elevation
-ST-T abnormalities
- QTc interval
-pathological Qs
-absence of normal Qs



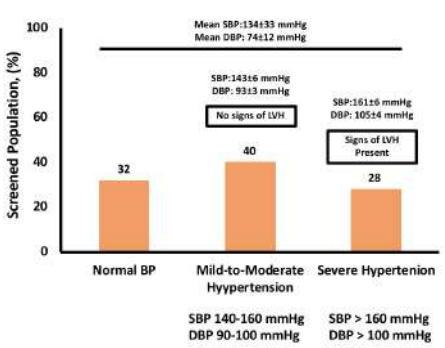


Figure 1. Blood Pressure mesaurment results

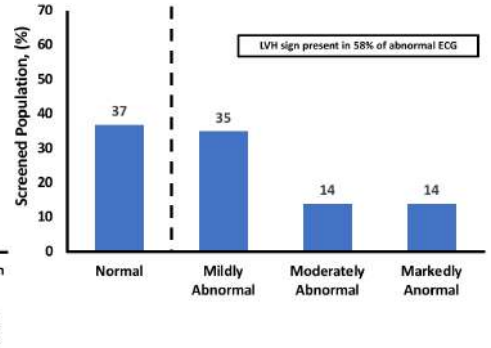


Figure 2. ECG Screening results

Results. Clinical characteristics of the 231 patients are summarized in **Table 1, Figure 1 and Figure 2.**

Table 1. Baseline characteristics of the screened population

	Overall	Men	Women	p
Demographics				
Population – N, (%)	231	121 (52)	110 (48)	
Age	36±21	41±17	32±12	<0.01
BMI	24±2.9	22.3±1.5	27.2±1.1	<0.01
CV risk Factors				
Smoking Hx – N, (%)	78 (34)	60 (50)	18 (16)	<0.01
Alcohol (>2.5 U/day) – N, (%)	92 (40%)	67 (55)	37 (33)	<0.01
HTN Hx – N, (%)	11(5)	5 (4)	6 (5)	ns
Diabetes Mellitus	15	7 (6)	8 (7)	ns
Previous AMI	3 (1)	2 (2)	1 (1)	ns

71% never had BP measured before

91% never had ECG recording before

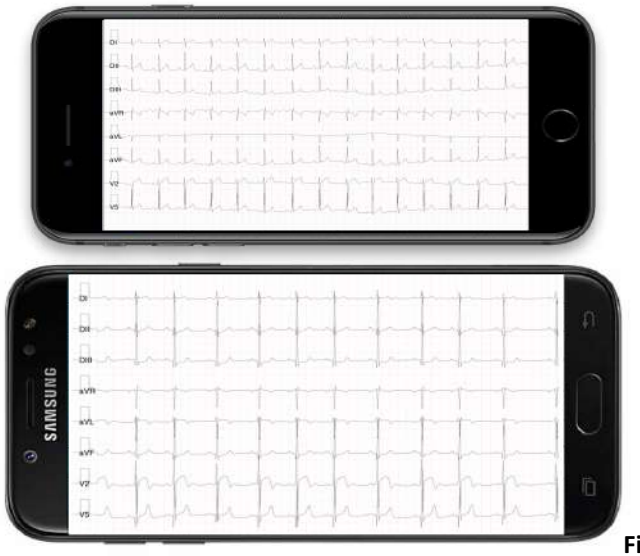


Figure 3. Samples of D-Heart ECGs recorded

Cost-Effectiveness Analysis. Taking into account:
-device price
-consumables
-salaries
-USB solar powered technology
-visit time (6±2 minutes).

€1.10/patient
- **€0.80 for community health worker**
- **€0.30 for consumables**

Conclusions. D-Heart® ECG screening combined with smartphone BP measurement proved **efficient** and **cost-effective**. This should encourage to develop low-cost/high-technology community-based CV screening programmes in low-income settings.

Disclosures. Dr. Fumagalli was awarded a research grant from D-Heart Srl in December 2017