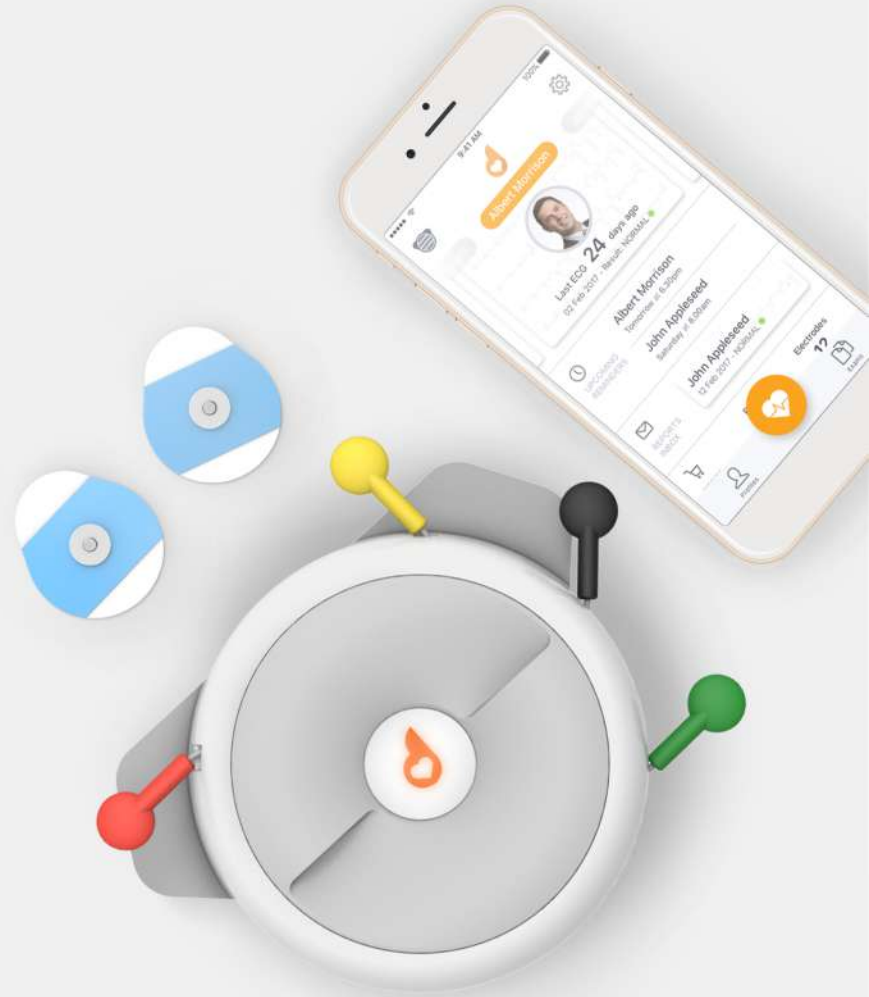


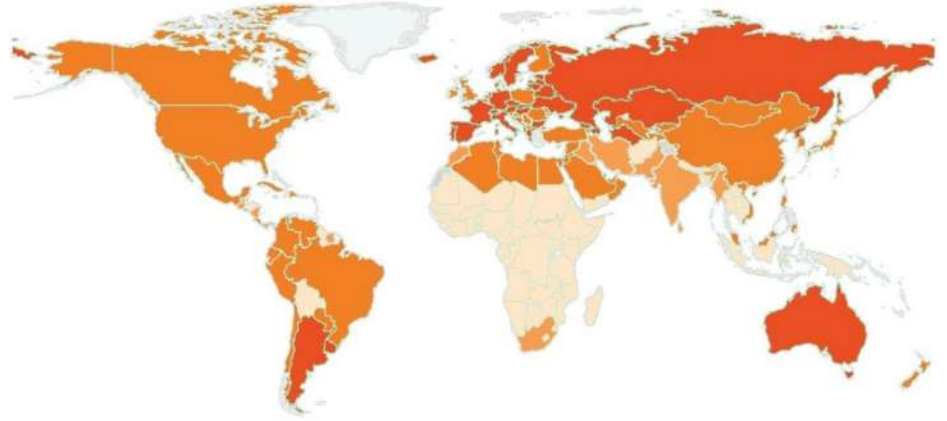
Medical Grade Smartphone/Tablet ECG Device

Nicolò Briante, CEO

Niccolò Maurizi, MD



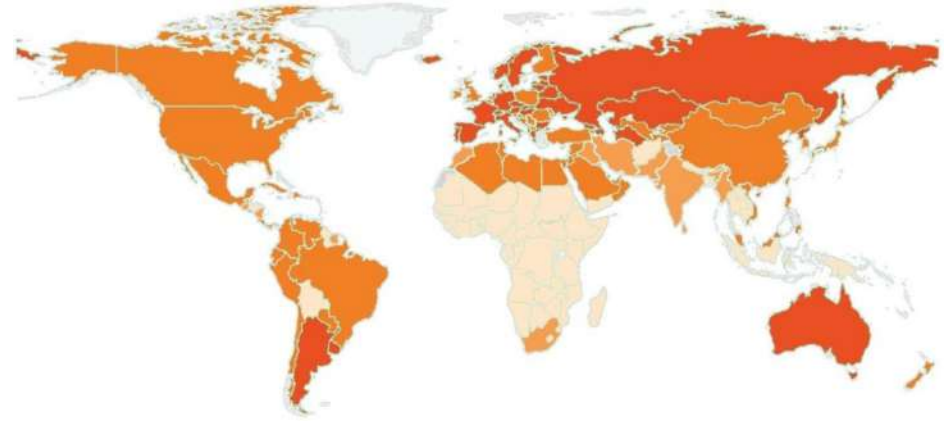
Today, Heart Diseases and Strokes are the **Leading Causes of Death in the World.**



Each year, **over 800,000 Americans** die from cardiovascular diseases, representing **1 of every 3 deaths** in the U.S.

Developing Countries:

- Lack of access to basic medical exams such as ECG.
- Lack of Risk Factors (RFs) control.



Developed Countries:

- Lack of timely Diagnosis.
- Lack of chronic patient management resulting in second events.

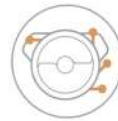


It's a heart test that tracks the electrical activity of your heart and records it on a moving screen.

It's the most simple, diffuse and cost-effective way to analyse the heart and detect irregularities that might lead to serious health problems such as a stroke or heart attack.

A multiple lead ECG allows a doctor to discern medically relevant information about the health of your heart muscle.

Only with hospital level multiple lead ECG such as D-Heart you can accurately recognize complex arrhythmias or heart attacks.



PREVENTION



DIAGNOSIS



MONITORING

The first portable hospital
grade 8 and 12-lead
Electrocardiograph:

Patented
Certified (CE & TGA)
Commercialized.



Patients



Caregivers



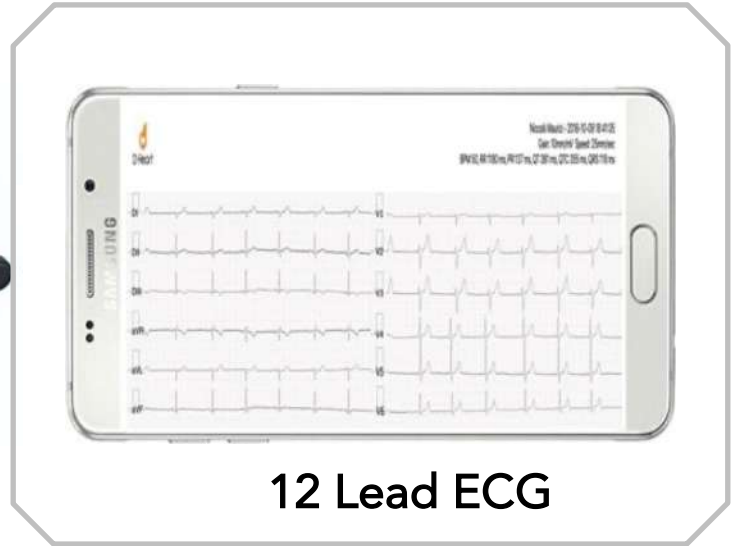
Doctors



1 device, 2 products



8 Lead ECG

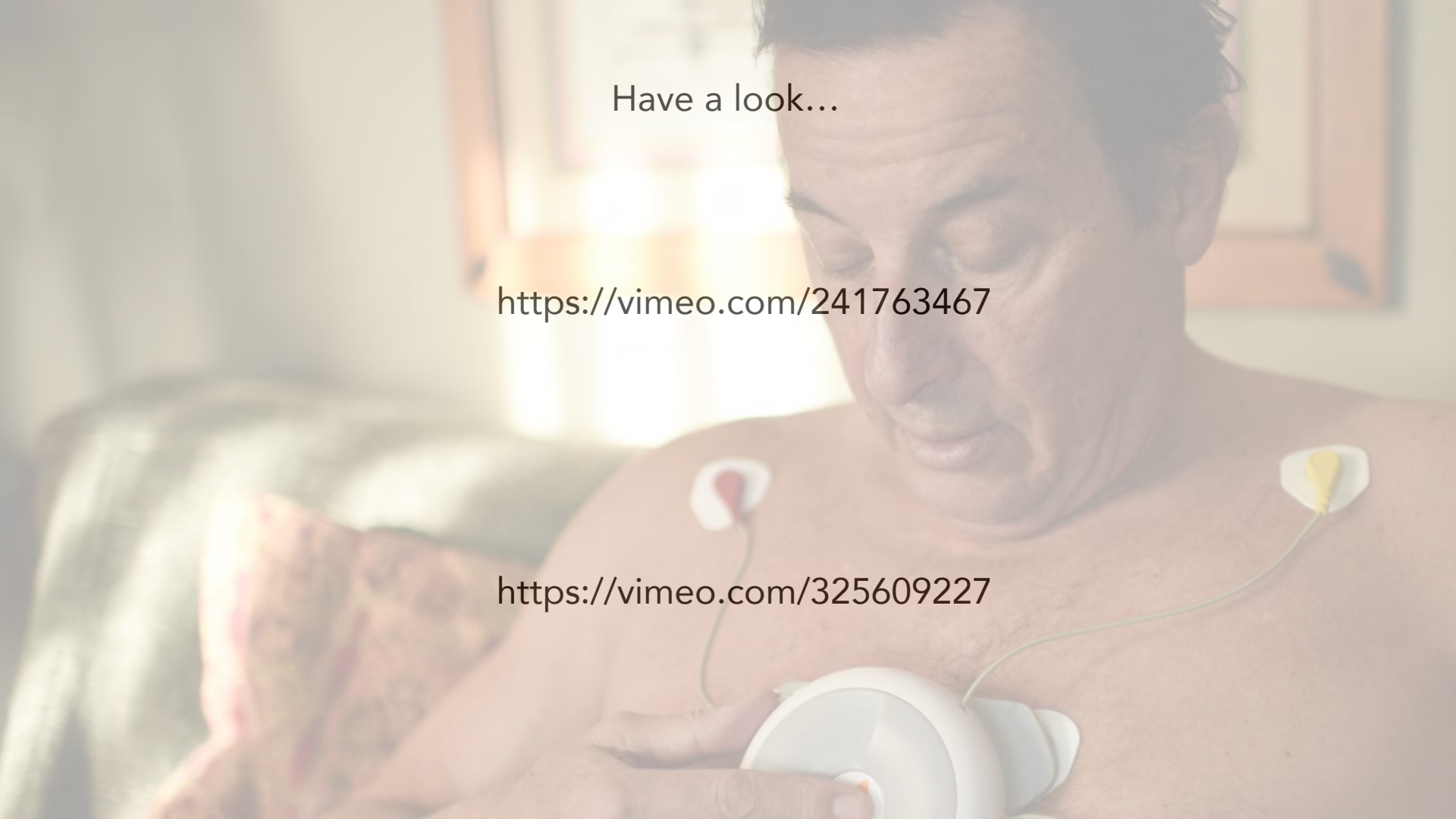


12 Lead ECG

Have a look...

<https://vimeo.com/241763467>

<https://vimeo.com/325609227>



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

Nicco Mauranti M.D. (1,2), Carlo Pumagli M.D. (1), Mattia Targetti M.D. (1), Silvia Pasantino M.D. (1), Anna Arzeroni M.D. (1), Alessia Tomberli (1), Katia Baldrini (1), Niccolò Marchionni M.D. (2), Franco Cecchi M.D. (3), Jacopo Olivetto M.D. (3)

(1) Unit Cardiopatie, Azienda Ospedaliera Universitaria di Careggi, Florence, Italy, (2) Department of Experimental and Clinical Medicine, University of Florence, Italy, (3) Fondazione ARCAD, Florence, Italy.

Background: **M-Health** technologies are revolutionizing cardiovascular (CV) medicine. However, a **low-cost, easy-to-use, multi-lead smartphone electrocardiogram (ECG) device, D-Heart®**, is a portable device that enables the acquisition of the ECG on multiple leads via electrodes (3 peripheral, 3 augmented and two preordial 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 ECG, in a cardiomyopathy outpatient clinic.

Methods: Consecutive patients (>18 years) with a diagnosis of Hypertrophic Cardiomyopathy (HCM; n=144, mean-age 56) 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

Demographics	Overall
Population - N (%)	144
Age	56(±12)
ECGM	16 (11%)
ECG Parameters	
LAD, mm	42(±6)
LVMWt, mm	21(±5)
Previous ACA	3 (1%)

revolutionizing cardiovascular (CV) medicine. However, in low-income settings, that are unable to take advantage of innovations for healthcare awareness and prevention.

Purpose: To assess the feasibility of a **simple CV screen campaign** with smartphone-based **M-Health devices: D-Heart®, a validated low-cost 8-lead electrocardiogram (ECG) device***, a validated low-cost 8-lead electrocardiogram (ECG) device* blood pressure (BP) recorder (770G)

Methods: A total of 213 patients were enrolled in a two-day screening at 4 rural dispensaries, 2 in Etoia (Bosnia Herzegovina) and 2 in Digulicher District (Serbia).

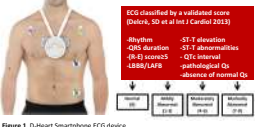


Figure 1. D-Heart Smartphone ECG device

Results: Results of ECG abnormality and interval 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 in D-Heart vs 12-lead ECG using a validated score.



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

Table 1. Baseline characteristics of the screened population

Parameter	Overall	Men	Women	p
Population - N (%)	231	125 (54)	106 (46)	<0.01
Age (years)	56(±12)	57(±11)	55(±13)	<0.01
ECGM (%)	23 (10)	12 (10)	11 (10)	0.93
ECG Parameters				
LAD, mm	39(±6)	40(±6)	38(±6)	0.63
LVMWt, mm	22(±5)	22(±5)	22(±5)	0.93
Previous MI	3 (1)	2 (2)	1 (1)	0.93

Methods: Methods are summarized in Figure 1 and 2.

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 equipped with D-Heart's, a multiple lead mobile ECG designed for users with no medical background.

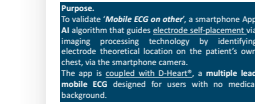


Figure 1. Validation study Enrollment and analysis

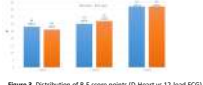


Figure 3. Distribution of R-R score points (D-Heart vs 12-lead ECG)



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

Figure 5. Comparison of P-R and QRS intervals (Bland-Altman method, non-parametric approach): showed excellent concordance for measurements (95% limit of agreement -20 to +20 ms for P-R and -10 to +10 ms for QRS).

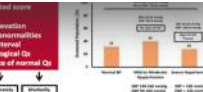


Figure 3. Blood Pressure measurement results



Figure 2. ECG Screening results

Cost-Effectiveness Analysis. Taking into account: -device price -consumables -user aware powered technology -short time (6-2 minutes) -ECG for community health worker -ECG for community health worker -ECG for community health worker

Conclusions: D-Heart® ECG screening combined with smartphone for measurement proved **efficient and cost-effective**. This should encourage development of low-cost/high-technology community-based CV screening programs in low-income settings.

References: Dr. Pumagli was awarded a research grant from D-Heart Srl in December 2017



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

Conclusions

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

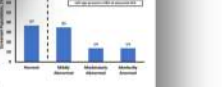


Figure 2. ECG Screening results



Figure 1. D-Heart mobile ECG for placement

CLINICAL RELIABILITY Scientifically Proven

5. Conclusions

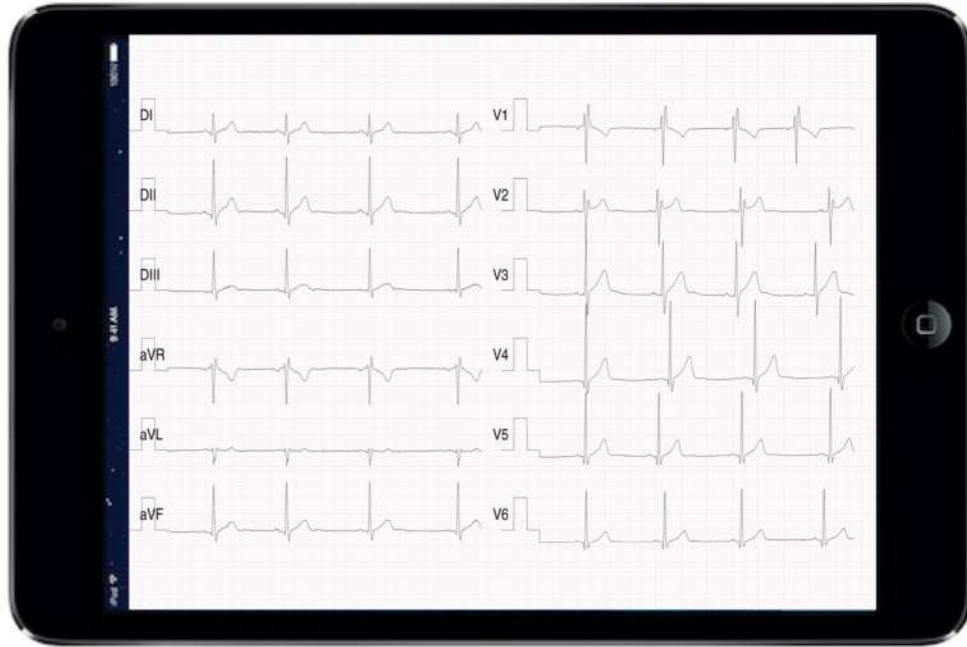
D-Heart® ECGs proved accurate, allowing a stratification of ECG abnormalities comparable to the standard 12-lead ECG in a low-income setting. Novel smartphone-based techniques open promising perspectives for low-cost cardiovascular screening programs. Further studies are clearly needed to assess if these theoretical advantages are supported by patient-centered outcomes and positive cost-benefit analysis.

The **only** solution for **Homecare** comparable with hospital ECG device and able to diagnose the **Myocardial ischemia**.

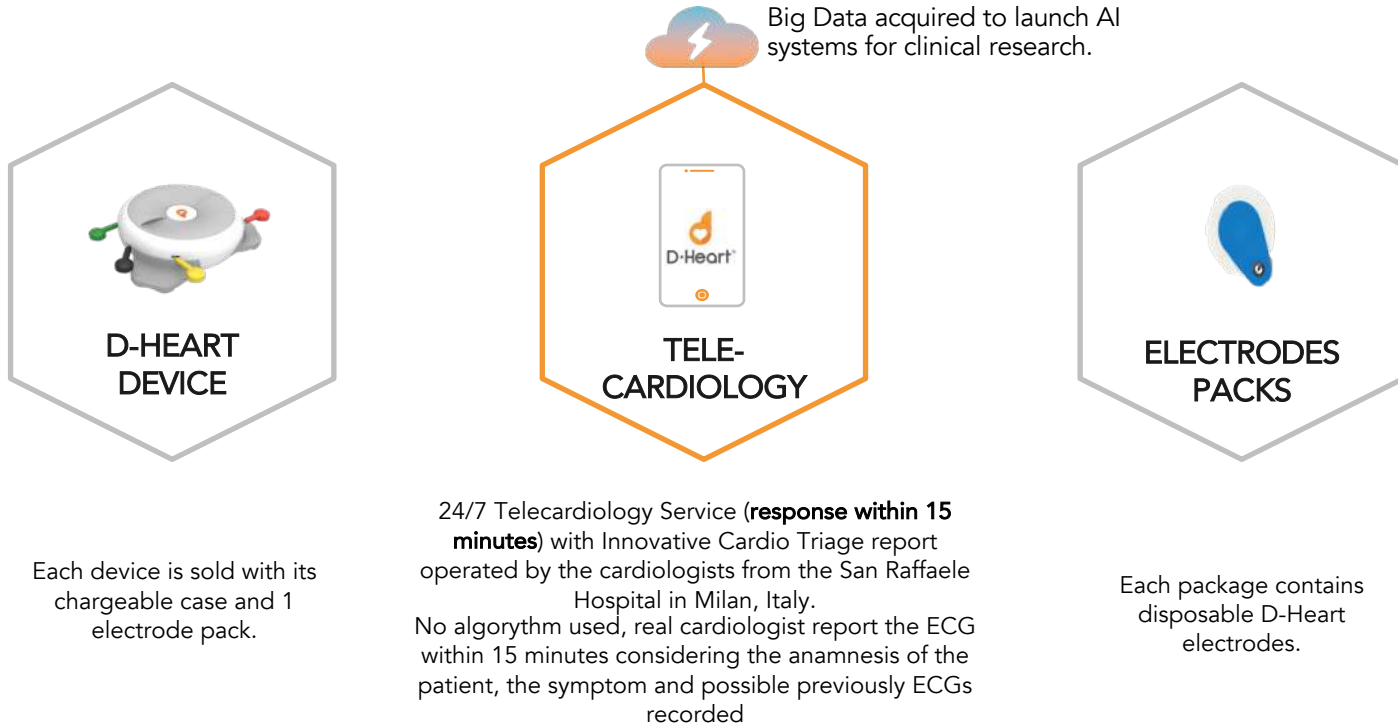
For more informations: <https://www.d-heartcare.com/health-professionals.html>

Maurizi et al. EHJ 2018
Maurizi et al. Int J card 2017

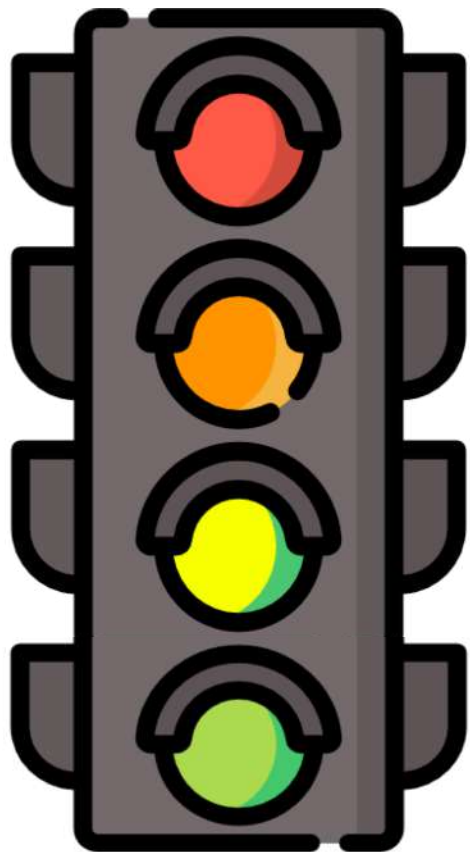
MEDICAL GRADE 8/12 LEADS – FOR CHEST PAIN?



ENABLE MYOCARDIAL INFARCTION DIAGNOSIS



D-Heart Cardio Triage Service



Red – Urgent Help Required

You need to seek immediate medical attention with the help of 911 to properly manage your problem – remember to show them your D-Heart ECG



Orange – Seek Medical Attention

You need to perform other cardiac tests within 2-3 hours in order to better define your problem – 911 can help you, remember to show them your ECG



Yellow – Visit your trusted doctor

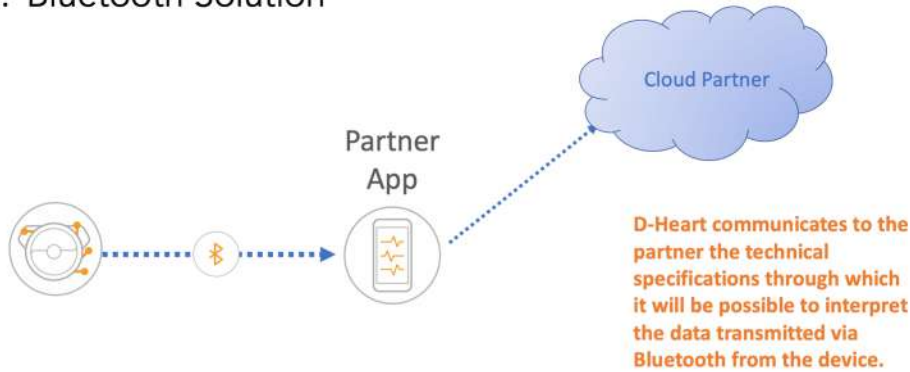
Visit your trusted physician tomorrow. Evaluate with him the possibility of performing further testing if judged to be appropriate – Remember to show him your D-Heart ECG



Green – In the absence of symptoms everything is normal

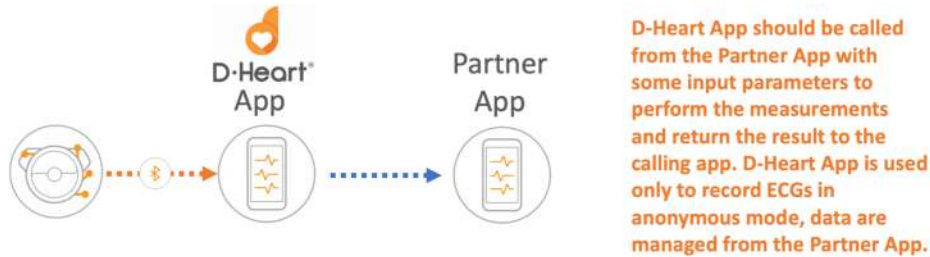
Keep calm and reassure yourself. An expert cardiologist has evaluated your tracing and judged it to be normal – remember to show your trusted physician your D-Heart ECG

1. Bluetooth Solution



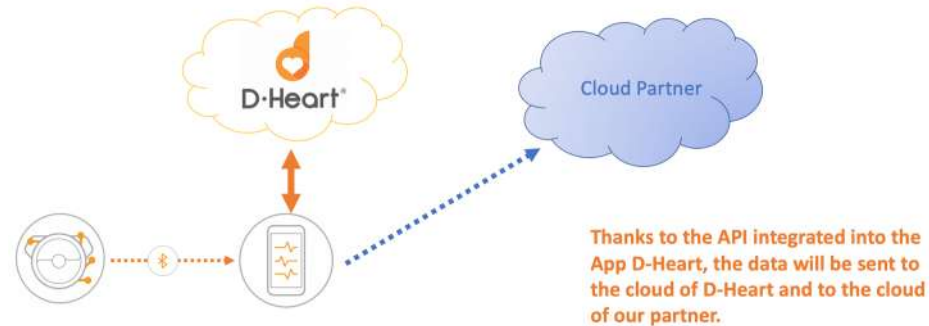
Integrate D-Heart in a System ?
Choose what best suits the client

2. App to App Solution



Android: the Partner App will receive the 8/12 lead ECG in PDF format.
Apple: the Partner App will receive the 8/12 lead ECG in JSON format.

3. App to Cloud Solution



B2B

General Practitioner



"Thanks to D-Heart I can offer ECG service to my patients: I can work as the hub for cardiac care for patients with known heart conditions or at risk for cardiac problems".

Pharmacist



"I have a pharmacy 100 km far from the first medical facility. D-Heart allows us to be a reference for chronic heart patients and those under drugs treatment".

Paramedic



"D-Heart allows us to diagnose anywhere and remotely ST elevation for myocardial infarction with the possibility to dramatically reduce time to balloon".

Caregiver



"Thanks to D-Heart I can offer home ECG service to my patients: I can provide it to all my clients that are old or with disabilities".

B2BC

Patient with already more than one heart risk factors



"Thanks to D-Heart now I can finally discover what is going on, when I am feeling a possible heart symptoms".

Chronic Heart Patient



"Thanks to D-Heart now I feel reassured, because I can go anywhere and I have always my cardiologist just a click away from me".

B2B

General Practitioner



“Thanks to D-Heart I can offer ECG service to my patients: I can work as the hub for cardiac care for patients with known heart conditions or at risk for cardiac problems”.

Remember to stress

- **Hospital grade 12 lead ECGs** which ensure **reliability level**;
- **24/7 telecardiology service** would provide an innovative triage report of the exam;
- **Easy to use** thanks to the step by step guidance of the App;
- **Only 4 cables**, with a special coiling/uncoiling system, no more tangled cables;
- Possibility to **create a folder** for each patient with her/his exams history;
- Possibility to exclude a heart condition from an another type of problem.
- Connection via Bluetooth with smartphones & tablets (Android and Apple)

B2B



Pharmacist

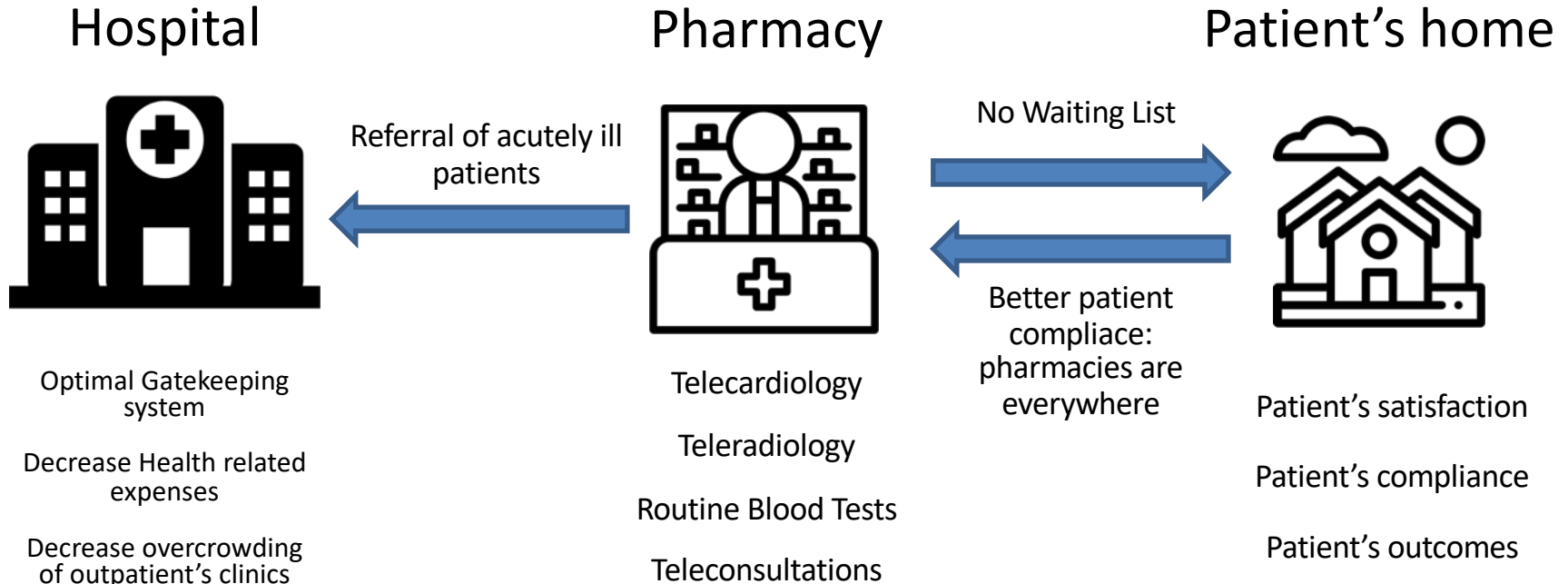
"I have a pharmacy 100 km far from the first medical facility. D-Heart allows us to be a reference for chronic heart patients and those under drugs treatment".

Remember to stress

- Hospital grade 12 lead ECGs which ensure reliability level;
- No need of bed, patient can just sit on a chair;
- Telereport from 24/7 Telecardiology Service within max 15 minutes;
- Extreme portability, no need of socket;
- Easy to use thanks to the step by step guidance of the App;
- Only 4 cables, with a special coiling/uncoiling system, no more tangled cables;

The Opportunity for the Pharmacist

The Pharmacy of the near future should be the hub for the execution of the primary level exam.



Why Choose D-Heart in your Pharmacy

Characteristics

Portable Hospital Grade ECG

Bluetooth Connection with
Smartphones & Tablets

Guide to correct electrode
placement

Anti-entanglement cables

24/7 Telecardiology Service

Report within 15 minutes

Less than 3 minutes to record an
ECG

The Plus for the Pharmacist

No bed needed, recording while
seated

Approved for use by non-medical
users

No need for Power Outlet

Hospital Quality at half of the
market price thanks to its
innovative technology

Updated to the EU Privacy Law

Patient Retention

Up to date design for better
patient comfort

B2B

Remember to stress

- It can be extremely important to reduce time treatment especially in case of myocardial ischemia;
- With AED only a single channel ECG can be done, it means that doesn't detect ischemia; with our solution (12 channels) also ischemia can be detected;
- It is portable, only 196 grams and very small, perfect for little places like ambulances;
- The ECG can be transmitted immediately to the hospital, in order to prepare the operating room in case of need;



Paramedic

"D-Heart allows us to diagnose anywhere and remotely ST elevation for myocardial infarction with the possibility to dramatically reduce time to balloon".

B2B

Remember to stress

- **Hospital grade 12 lead ECGs** which ensure **reliability level**;
- **Telereport from 24/7 Telecardiology Service** within max 15 minutes;
- **Portable**, only 196 grams;
- **Only 4 cables**, with a special coiling/uncoiling system, no more tangled cables;



Caregiver

"Thanks to D-Heart I can offer home ECG service to my patients: I can provide to all my clients that are old or with disabilities".

User Applications

Why D-Heart?

Remember to stress:

- Cardiologist might recommend it for patient with chronic angina, following the results of ISCHEMIA trial (control every angina attack to spot STEMI);



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
- Early diagnosis of Acute Heart failure re-acutezation
- Early diagnosis of acute myocardial infarction



Management of patients with cardiac risk factors

Regularly screen patient with:

- Hypertension
- Atypical Chest Pain
- Cardiomyopathy
- Post cardiac Surgery
- 30-days after TIA
- Sport Certificate

B2B2C



Patient with already more than one heart risk factors

“Thanks to D-Heart now I can finally discover what is going on, when I am feeling a possible heart symptoms”.



Chronic Heart Patient

“Thanks to D-Heart now I feel reassured, because I can go anywhere and I have always my cardiologist just a click away from me”.

Don't forget...

Small and Medium Sized Clinics

Rural Clinics

Rest homes

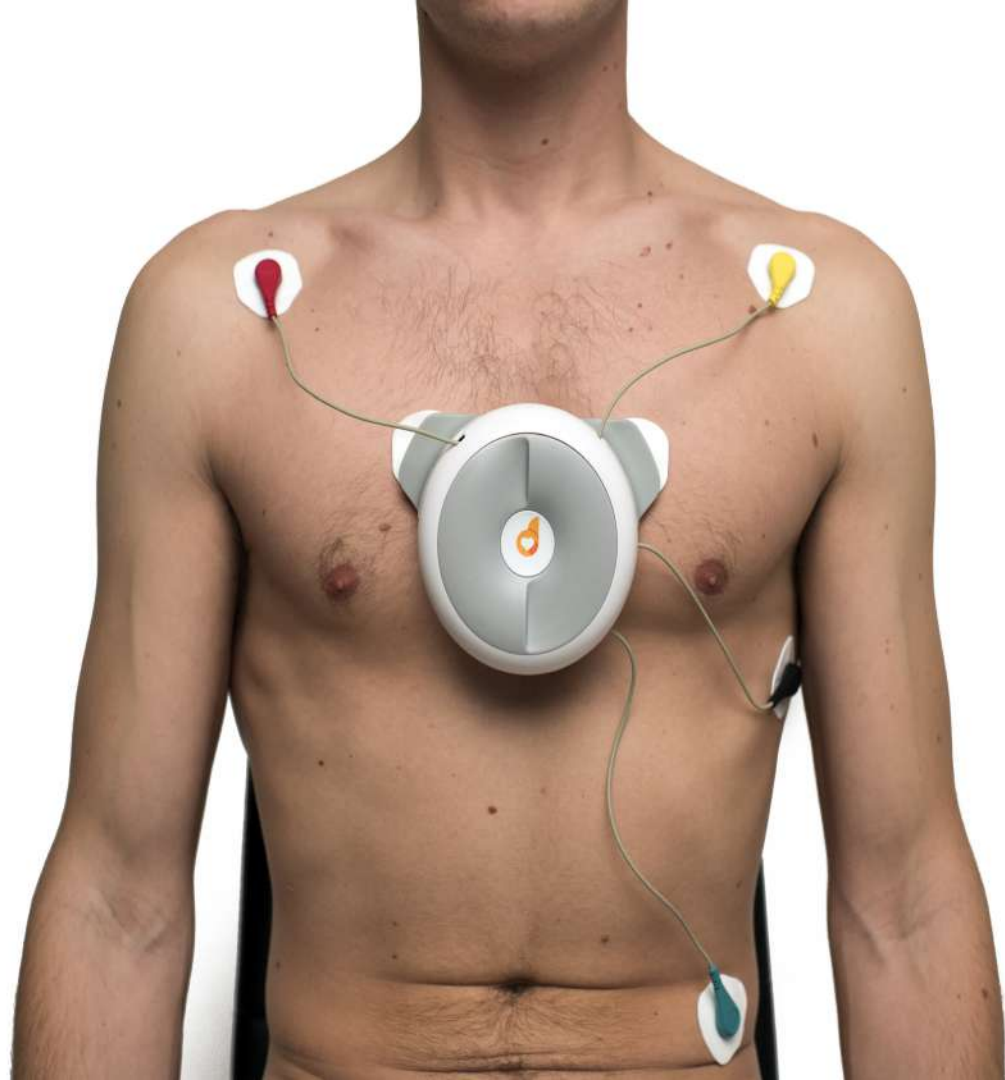
Oil and Gas Platforms

Gyms

Occupational Medicine

Ambulances

Insurance Companies



Remember, we are always at your service as it
is our website www.d-heartcare.com

Useful Links:

Why ECG is important – the Expert - <https://vimeo.com/283295449>

What's in the Box - <https://vimeo.com/307279120>

Turn on and off - <https://vimeo.com/262981645>

Our Story - <https://vimeo.com/246419397>



D-Heart

To Check Everyone's heart..
...everywhere in the world

THANK YOU

info@d-heartcare.com
www.d-heartcare.com