CE-Mark approved, just in time for the 2nd wave

Couple of years ago my friend suddenly died of a heart attack in his 60’s. Nothing new you might say, a lot of people leave this world like that. But what I found out later on is that he had an ECG test and was sent home saying everything is okay. Just a couple of weeks after he was gone. I feel there is a lot of people that can relate to this. So that’s how this story began. I wanted to develop a device that will show to patient their real heart state. It took alot of work but here we are finally. And I strongly believe it can help people across the world.

Fifteen years in the making, breakthrough heart diagnostic device is CE Cleared, just in time to address Europe’s Pandemic consequences of COVID-19 caused heart conditions?

Europe’s vaunted medical systems strained to breaking point as a result of COVID-19, Healthcare systems, slow to move to telemedicine before the pandemic, have dropped all pretence of caution as social distancing through telemedicine makes healthcare workers safer, without being any less effective for the patient.

With the immediate threat of COVID-19 mitigated, the pandemic legacy of COVID-19 induced heart disease will ravage symptomatic COVID-19 patients leading to increased heart disease related morbidity, and this for years to come. As if not enough, many COVID-19 asymptomatic and mild-symptomatic, patients could have also been exposed to its legacy of heart disease, which could yet manifest itself in a widespread epidemic of COVID-19 induced heart disease.

As telemedicine becomes the new front-line of Primary Care, so Telemedicine Primary Care is the new front-line of heartcare, for all Europeans.

Abstract

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Post-Pandemic Cardiac-Telemedicine™

The divide between Primary Care and Cardiology Care, the next level of care, was always a major unmet medical need, tolerated only because of a lack of an effective, easy to use, medical device that could help bridge the gap. At 44%, the traditional ECG/EKG devices were simply never sufficiently effective pre-pandemic, and will be virtually useless in a post-pandemic telemedicine environment.

Effective Cardiac-Telemedicine™ has two main conditions: First, it must support Telemedicine, allowing the physician to easily access a patient’s heart diagnostic test online, and understand it; and, second, it has to be highly effective, providing comprehensive diagnostic information on the patient’s condition, far beyond that of the traditional Pre-Pandemic ECG/EKG devices.

The strategy for Europe is really simple. First, an effective Cardiac-Telemedicine™ device able to detect 95% of all common heart diseases, by prevalence. Second, it must be able to be administered by a medical assistant. Lastly, it must support Primary Care telemedicine access.

Cardio-HART™ (a.k.a. “CHART”) is Cardiac-Telemedicine™

CHART, short for Cardio-HART™, is now a CE Mark approved system that combines a device for capturing the heart’s physiological bio-signals and a cloud-based AI-Powered diagnostic analysis engine, to ensure high levels of cardiac diagnostic effectiveness, and transforming Primary Care into the new front line of heart care.

CHART can detect and diagnose 95% of all significant and common heart diseases, by prevalence. Compared to ECG’s 44%, it is a magnitude of difference in effectiveness.

CHART’s breakthrough technology can detect cardiac conditions normally diagnosed only by a cardiologist using echocardiography including: 14 critical HART HART findings reflect the same diseases as ECHO findings, but because they not derived from images created by Echocardiography, but rather by novel bio-signals captured by the Cardio-TriTest™ device, much like ECG. Because of this, FDA suggested a change of name, not to confuse the two diagnostic sources. The main benefit, of using bio-signals instead of images, the CTT device can be used within the existing standard of care in Primary Care. (ECHO) findings including:

LVH, LVE, LVDF, RVEF, RVE, LAE, AS, MS, RVS, DDH, MR, AR,TR w/o Pulm. Hypertension & TR w/ Pulm. Hypertension.

... and diagnoses 22 common and significant ECG findings, including:

ML, LVH, RVH, AE, ST-Deviation, AF, AFl, Rhythms, Long PR,QR,RS intervals, Bundle Branch Block (3), LAFb, and more...

...and diagnose many serious PCG and MCG findings, including:

Murmurs, Systolic and diastolic, S1, S2, & S4 (4th heart sound),EMAT, PEP, SPI, LVE, ST-Wide, and more...

An essential element of CHART is the role it plays in helping HCPs understand when to refer their patients to the cardiologist, and

...to provide the cardiologist with relevant information about the patient’s condition to guide clinical decisions about testing and treatment.

To this end, CHART enables a collaborative triage between cardiologist and the HCP.

This collaboration is based on a decision support system that helps the cardiologist determine if they “need to see this patient”, and on what priority, whether urgent, intermediate, or routine, or “not need to see the patient”, and either set a “control” at 2, 3, 6, or 8 months, or finding the patient in good heart health.

CHART’s wide range of disease findings, creates a “better patient” based on acceptable medical justification that supports the referral to the cardiologist.

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In a recent clinical study, conducted on over 560 patients, GP’s increased their diagnostic effectiveness by some 250% over the most advanced State-of-The-Art ECG/EKG systems. This resulted in a 24% reduction in FN and a 14% reduction of FP.

These are numbers that GP’s in Telemedicine need, to fight the legacy of COVID-19 induced heart disease, and reduce the burden on a re-building healthcare system. CHART will help ensure that affected patients are not be left behind, forgotten and neglected, in the shadow of COVID-19, or its second wave. It is a very cost-efficient technology that will ensure greater access by more patients to best-in-class cardiovascular diagnostic services.

With the much dreaded second wave of COVID-19, heart disease needs to be detected earlier and faster to help mitigate the long-term morbidity potential and ongoing healthcare system costs that could threaten to undermine the effectiveness and access of Europe’s health-care systems.

CHART is effective Cardiac-Telemedicine that is CE Mark cleared just in time to help Europe prepare for the second wave, and the long recovery from COVID-19’s legacy of associated heart disease that will follow.

We are in talks to do a pilot study in Italy, Spain, UK and Mexico.

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