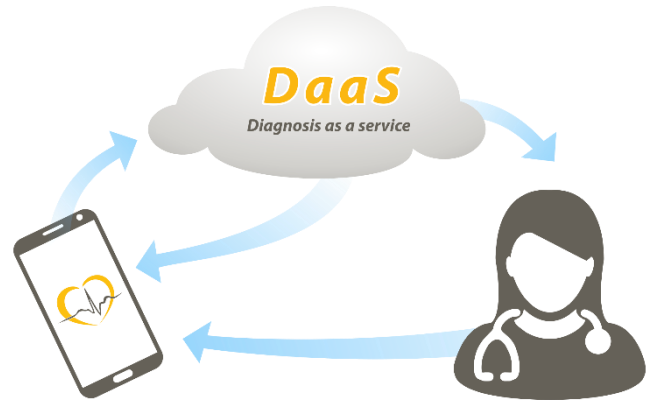
Heart2SaVe

Save a Life - Prevent a Stroke



The problem we are solving

World Stroke Campaign | World Stroke Organization

1 in 5 women

and

1 in 6 men

will have stroke by the age of 75

Hidden arrhythmia causes 25% of strokes

Early diagnosis and treatment decreases the risk of stroke by 65%

How to find (hidden) arrhytmia before stroke?

2016 ESC Guidelines for the management of atrial fibrillation

European Heart Journal - doi:10.1093/eurheartj/ehw210

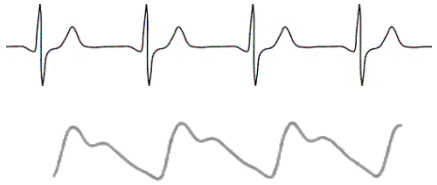
EUROPEAN SOCIETY OF CARDIOLOGY®

Screening for atrial fibrillation

Recommendations	Class	Level
Opportunistic screening for AF is recommended by pulse taking or ECG rhythm strip in patients >65 years of age.	I	B
In patients with TIA or ischaemic stroke, screening for AF is recommended by short-term ECG recording followed by continuous ECG monitoring for at least 72 hours.	I	B
It is recommended to interrogate pacemakers and ICDs on a regular basis for atrial high rate episodes (AHRE). Patients with AHRE should undergo further ECG monitoring to document AF before initiating AF therapy.	I	B
In stroke patients, additional ECG monitoring by long-term non-invasive ECG monitors or implanted loop recorders should be considered to document silent atrial fibrillation.	IIa	B
Systematic ECG screening may be considered to detect AF in patients aged >75 years, or those at high stroke risk.	IIb	B

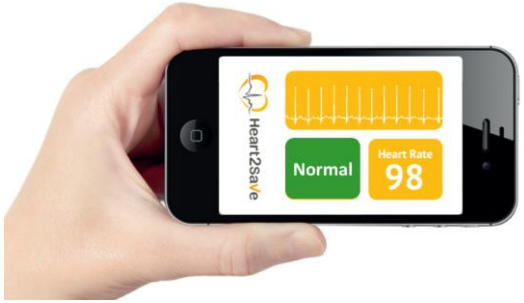
European Heart Journal - doi:10.1093/eurheartj/ehw210

Our solution: health care

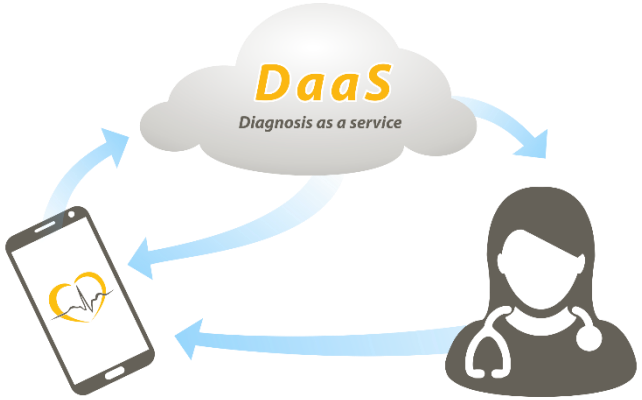


ECG, PPG, HR
Signals from 3rd party devices

SUUNTO

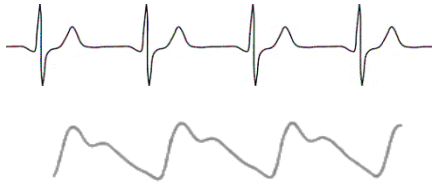


Mobile Application
Data integration, User Interface, signal quality detection & data transmission



Cloud Service
Arrhythmia detection, data storage, integration with healthcare solutions & PHR

Our solution: self-monitoring



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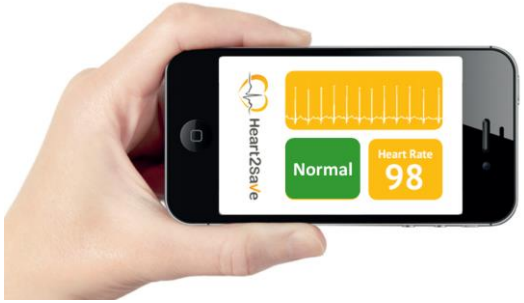

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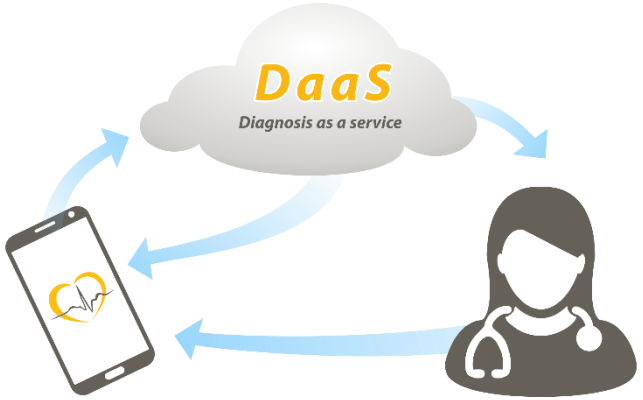

Cloud Service
Arrhythmia detection, data storage, integration with healthcare solutions & PHR

Team

Medical Experts

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Medical signal analysis

Medical Device Experts

Pekka Kola
Proven track record in development of high quality medical graded products
CTO

Hannele Toroi
Director of regulatory and quality

Susanna Martikainen, PhD
SW usability expert

What one should check out when planning a health related product

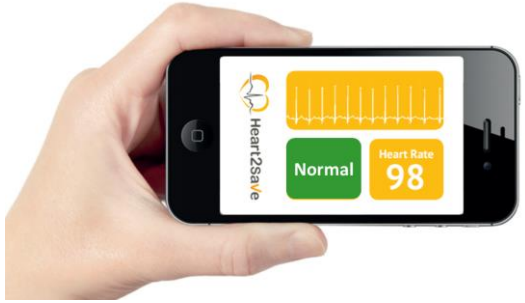
Medical Device Regulation (MDR)

Will my product be a medical device?

By Medical Device Regulation ‘Medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.






Does it apply to some of you?

- Many of us are building products that are intended to monitor body functions for some specific purpose
- Those of us who do it for medical purposes (criteria in previous slide) are producing a medical device, and oblidged to follow the Medical Device Regulation whether we like it or not
- The authorities (Valvira in Finland) are interested in what you say about the your product in your marketing communication. If you really want to keep out of the medical device market, it's better to carefully read your message against the MDR in case there are any doubt that it may apply.
- It should be noted that the the regulation does not say whether the target user is a consumer or a healthcare professional or whether you provide physical product or software; only the intended use of your product determines your destiny

Medical device

Heart2Save

How does the MDR affect to business?

- You will need ISO 13485 quality system to manage your business
  - Gives a set of rules for product development, testing, manufacturing and post-marketing
  - Depending the class your product belongs, you may need to sertify your quality system and your product
- You have to provide clinical evidence proving your device do what you say (intended use) before releasing the product
  - This can take time!
- You have to organize the post-marketing surveillance and means to manage possible serious adverse events
  - Such events shall be reported to authority and fixed in control of the authority
  - Can cause a product recall
- You have to take responsibility of your products lifetime from the point you make a development decision until 10 years of the day the last device was placed on the market has gone.
  - This is everyday business for device manufacturers but not always undestood in software companies (”We are in project business” --- No, you are not, if you do MDR requlated software)

Can startup do it?

- Yes it can (we are a one)
- You just have to take care of it when you organize your startup and apply the requirements in ISO 13485 from very beginning of your development project – all what it requires is to follow good design and manufacturing practices
- There will be costs caused by
  - hiring a quality manager (we have an outsourced one),
  - building and sertifying your quality system and the product too if it belongs to class II or higher and
  - organising clinical studies (prove your device do what you say),
  - securing your business with insurances.
- Those are not extra costs by any means and will pay back by lower risk level when you are in the market
- The challenge just now: After May 2020 you only can go into market with devices sertified according to MDR. You will need a notified body (E.g. SGS) but there are no accrediated bodies until 2019.

Contact

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