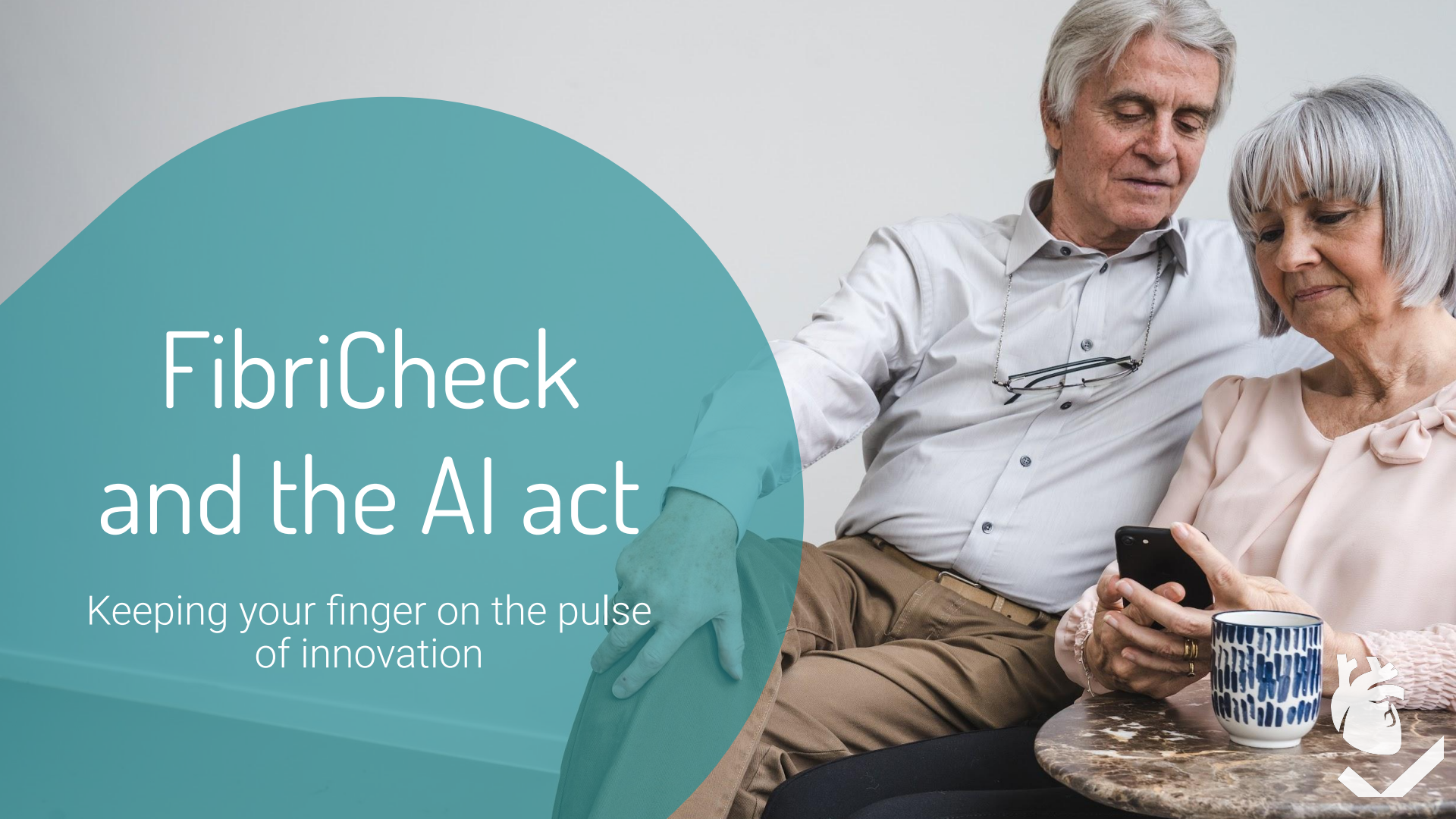
FibriCheck and the AI act

Keeping your finger on the pulse of innovation

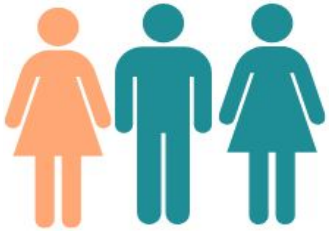


Who am I?

Glenn De Witte
glenn.dewitte@fibricheck.com

What is FibriCheck?

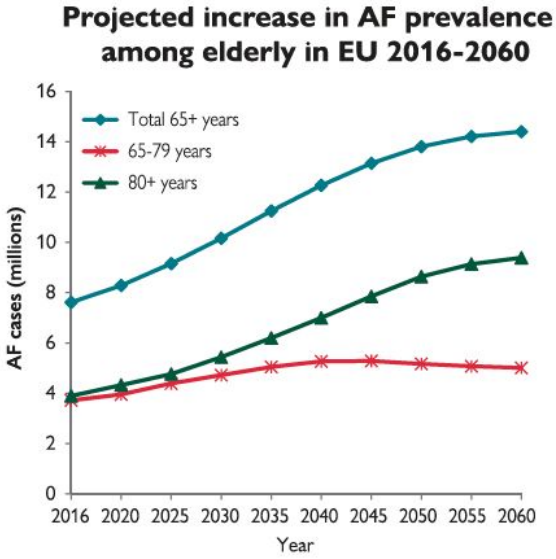
Atrial Fibrillation is a new millenium epidemic affecting millions



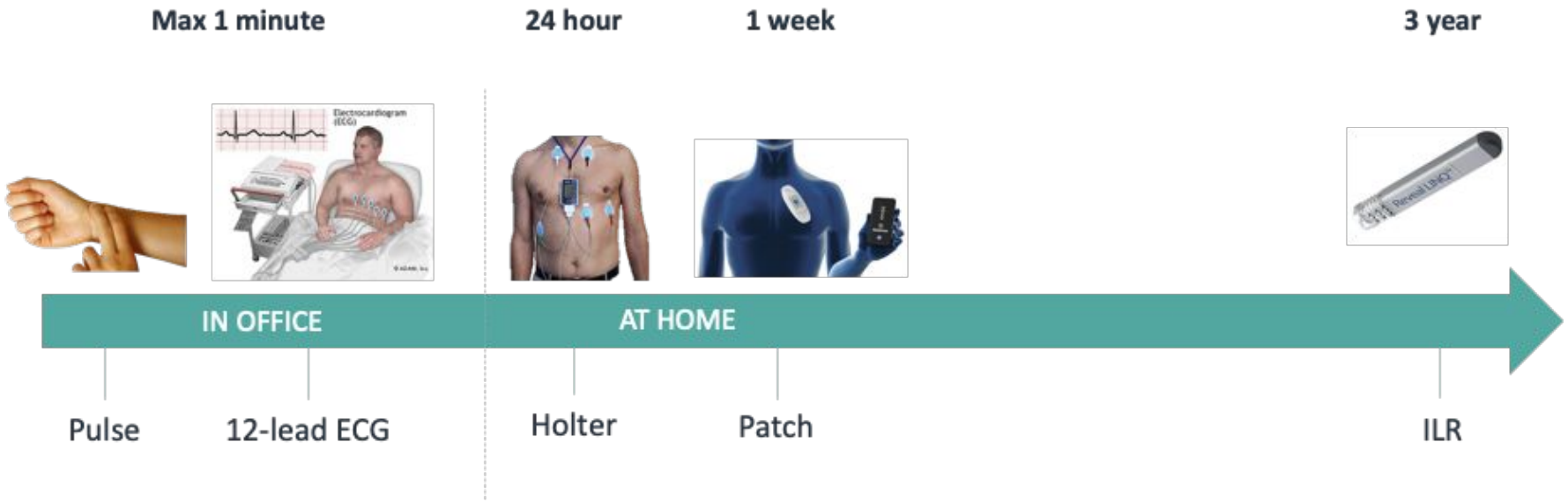
Lifetime risk
1 out of 3
(50+)

40% remains undiagnosed
20% of all strokes

75% of strokes can be prevented

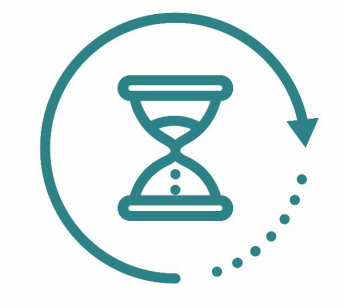


How to detect atrial fibrillation?



Limitations of traditional technologies

Limited to a
location
-
doctor's office



Limited in **time**
-
spotcheck or
maximum
24 hours

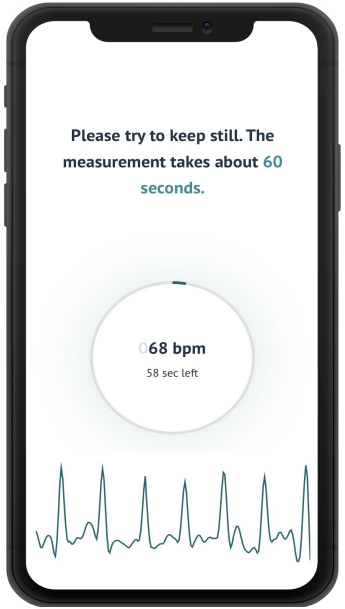
Lacking **user friendliness**

Expensive

FibriCheck fills the gap

Say 👋 to FibriCheck

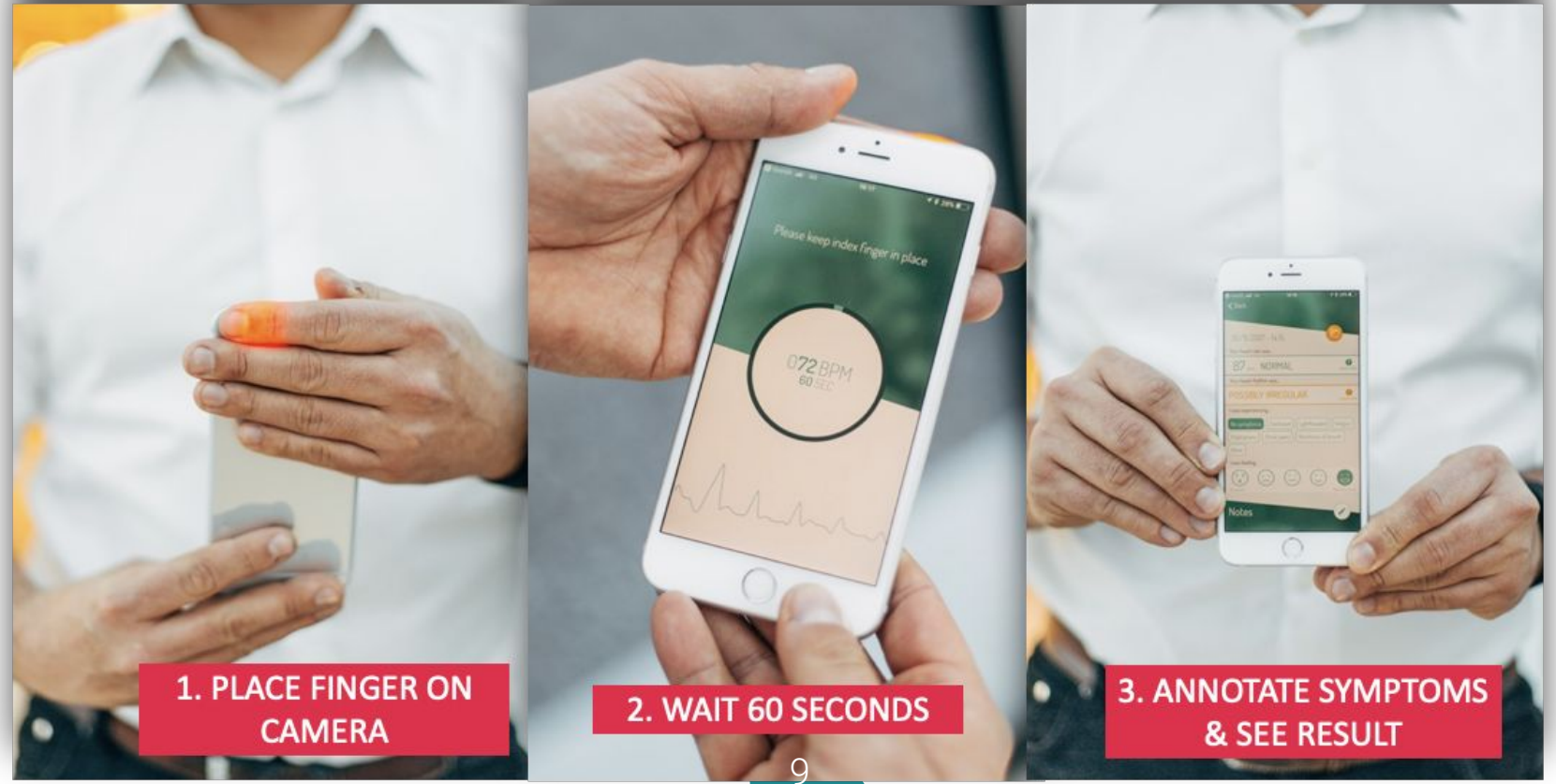
"FibriCheck is a device agnostic software solution **that is capable to detect and identify heart rhythm disorders based on optical signals***". People can use it anywhere, anytime*



Mobile phones

Wearable Devices

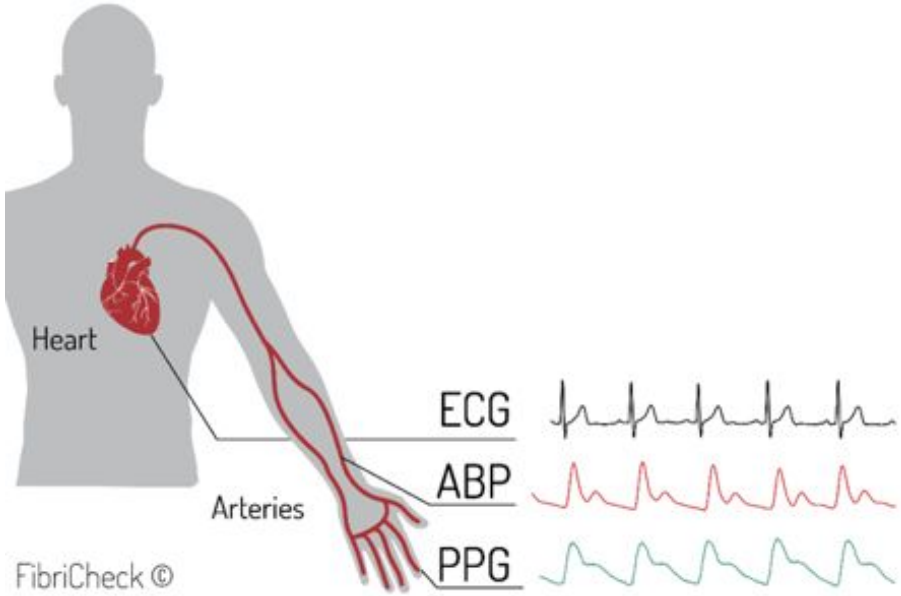
FibriCheck on a smartphone

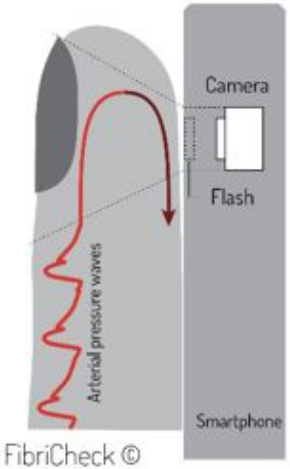


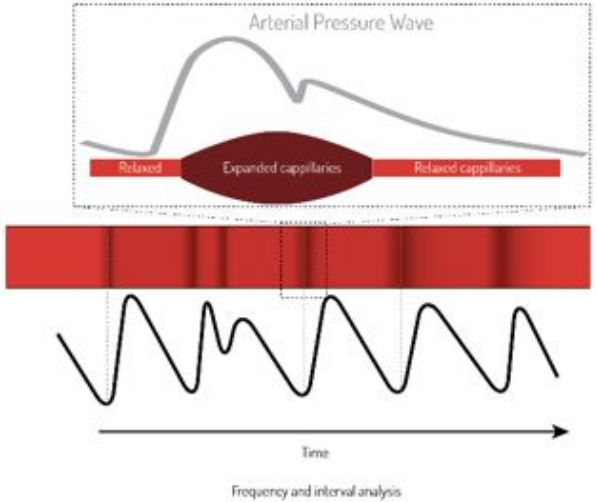
Which technology & the role of AI?

PhotoPlethysmoGraphy

Measures changes in light absorption in the microvascular bed of tissue caused by blood volume changes

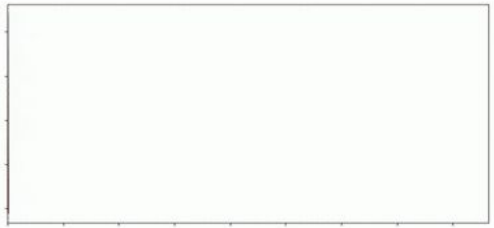




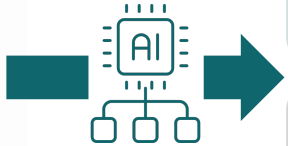


The role of AI

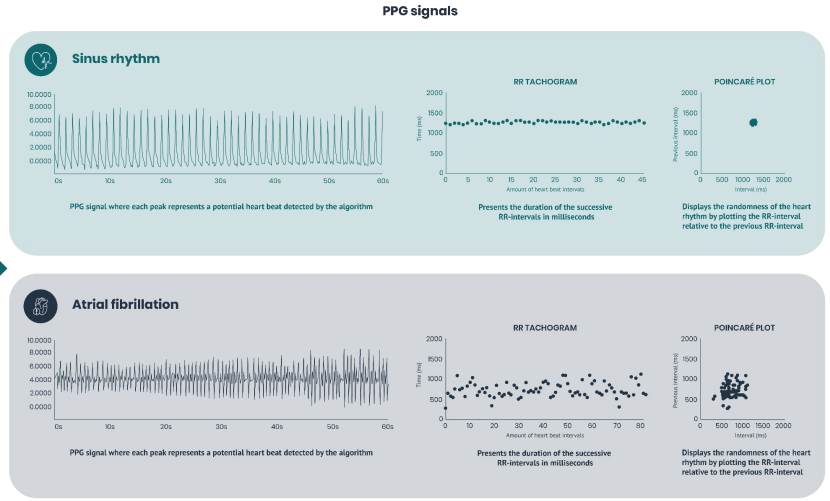
Camera image



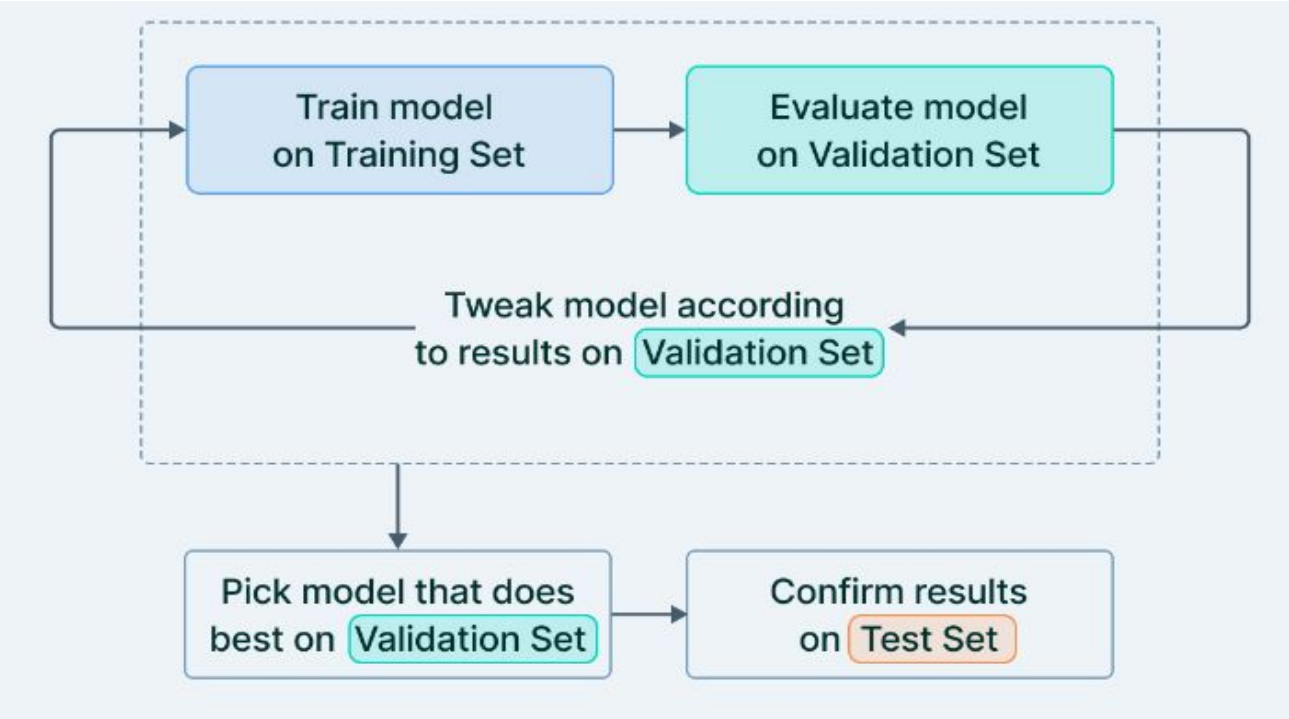
Raw PPG signal



AI Classification of the PPG signal



How is the machine learning model trained?



Train + validation set:

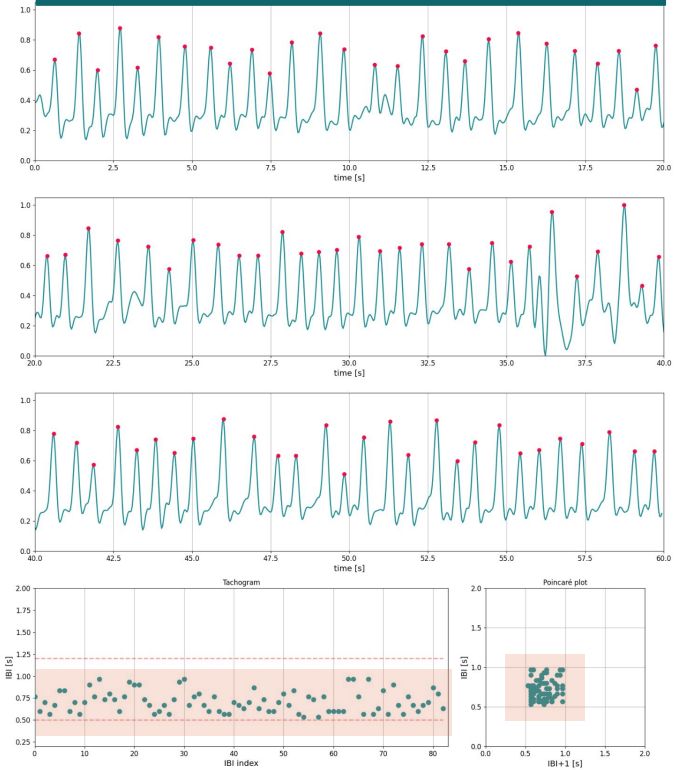
- 1M+ interpreted meaurements
- data augmentation

Test set:

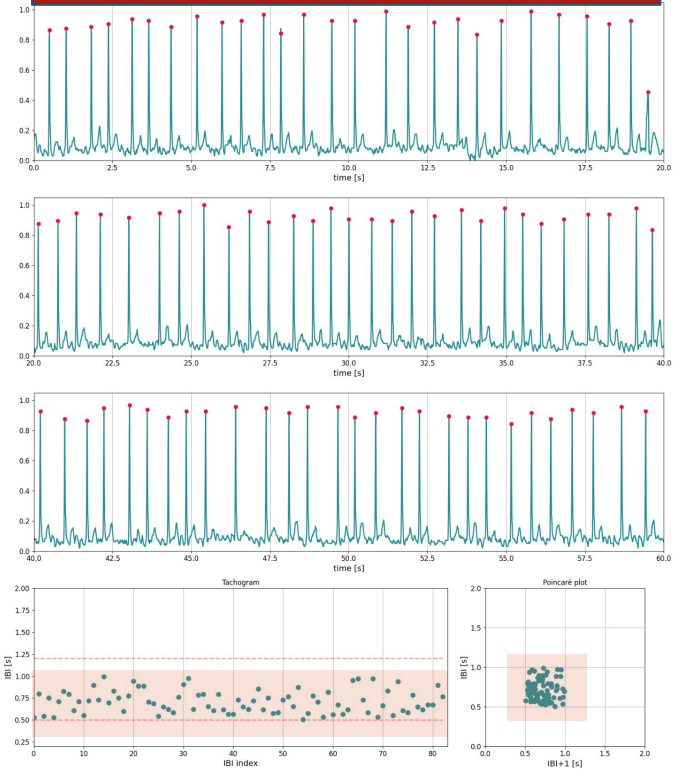
- Not used during training !
- Regulatory instances look at performance on test set

Human interpretation - AF

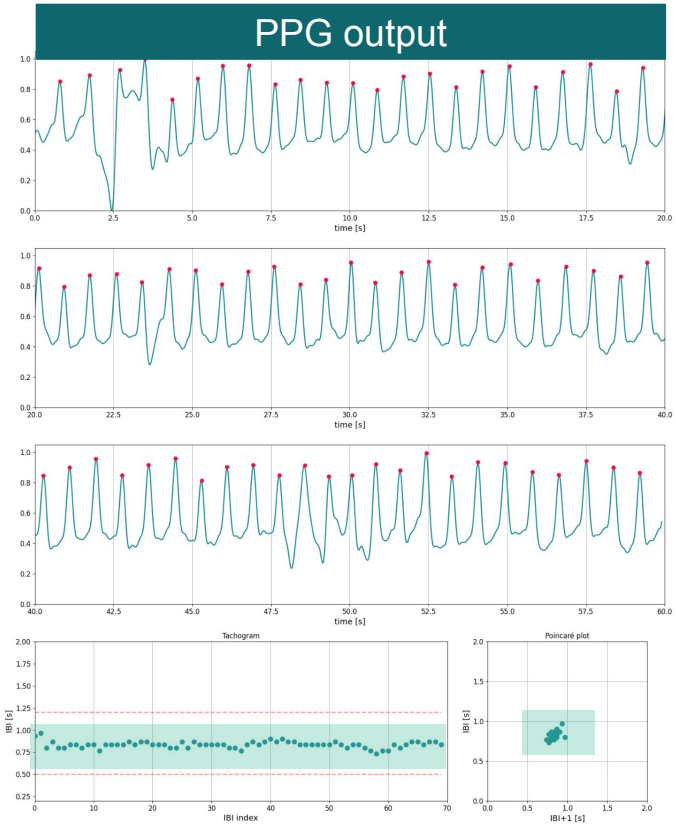
PPG output

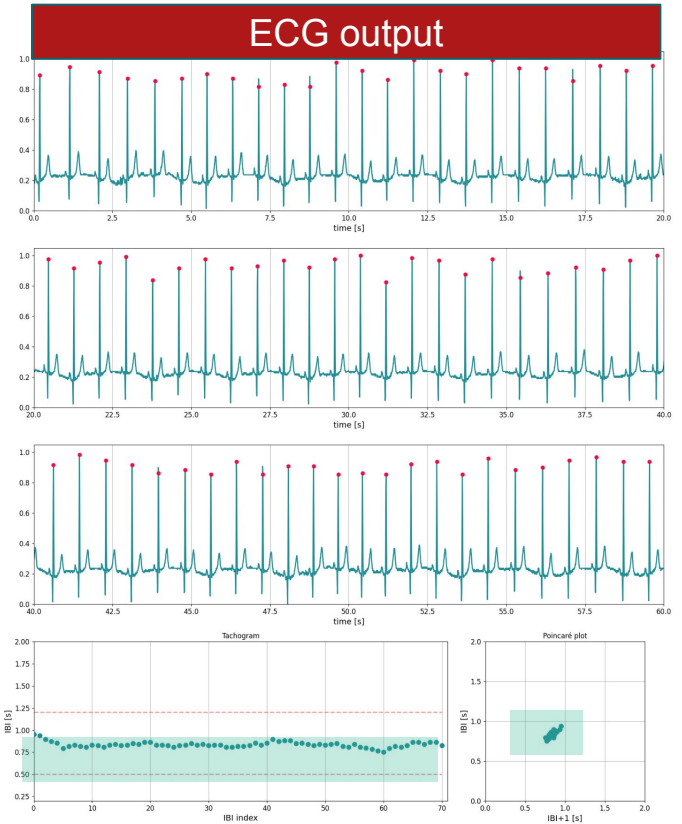


ECG output



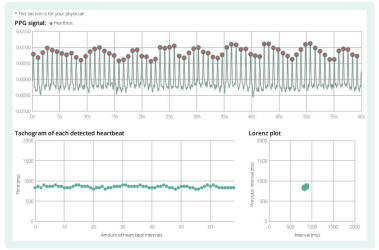
Human interpretation – regular rhythm



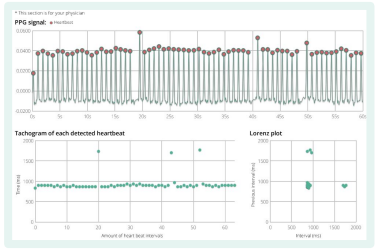


Human interpretation beyond AF

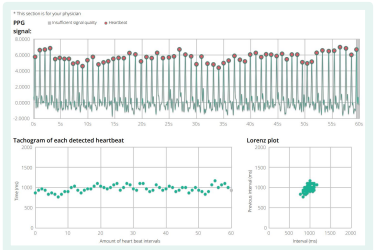
Regular



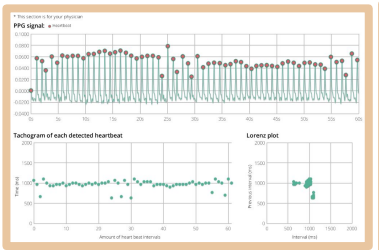
Isolated extrasystoles



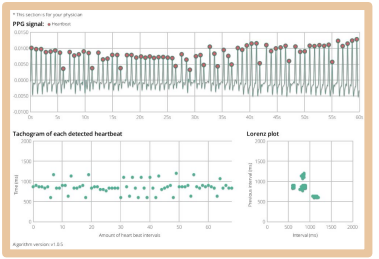
Increased HRV



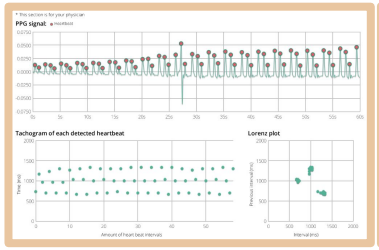
Frequent extrasystoles



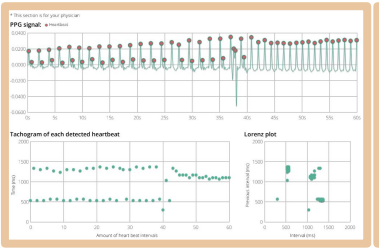
Trigeminy episode



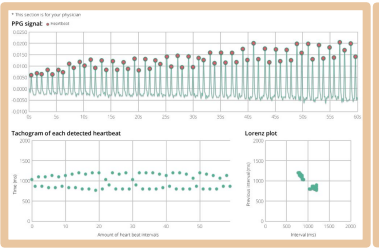
Trigeminy



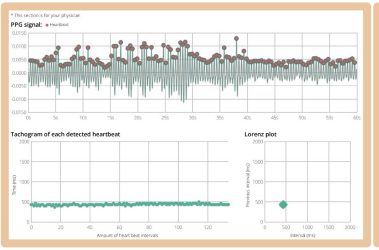
Bigeminy episode



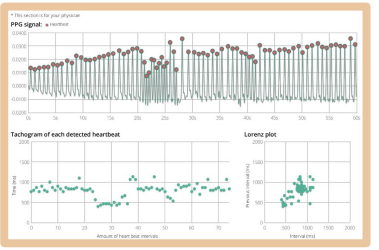
Bigeminy



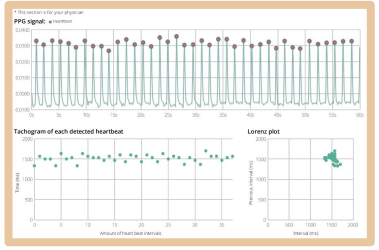
Tachycardia



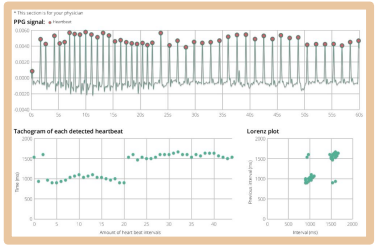
Tachycardia episode



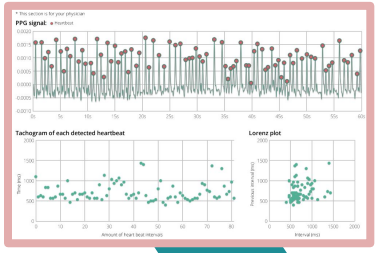
Bradycardia



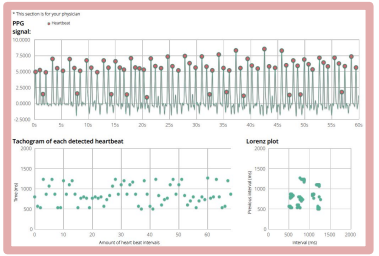
Bradycardia episode



Atrial fibrillation



Atrial flutter



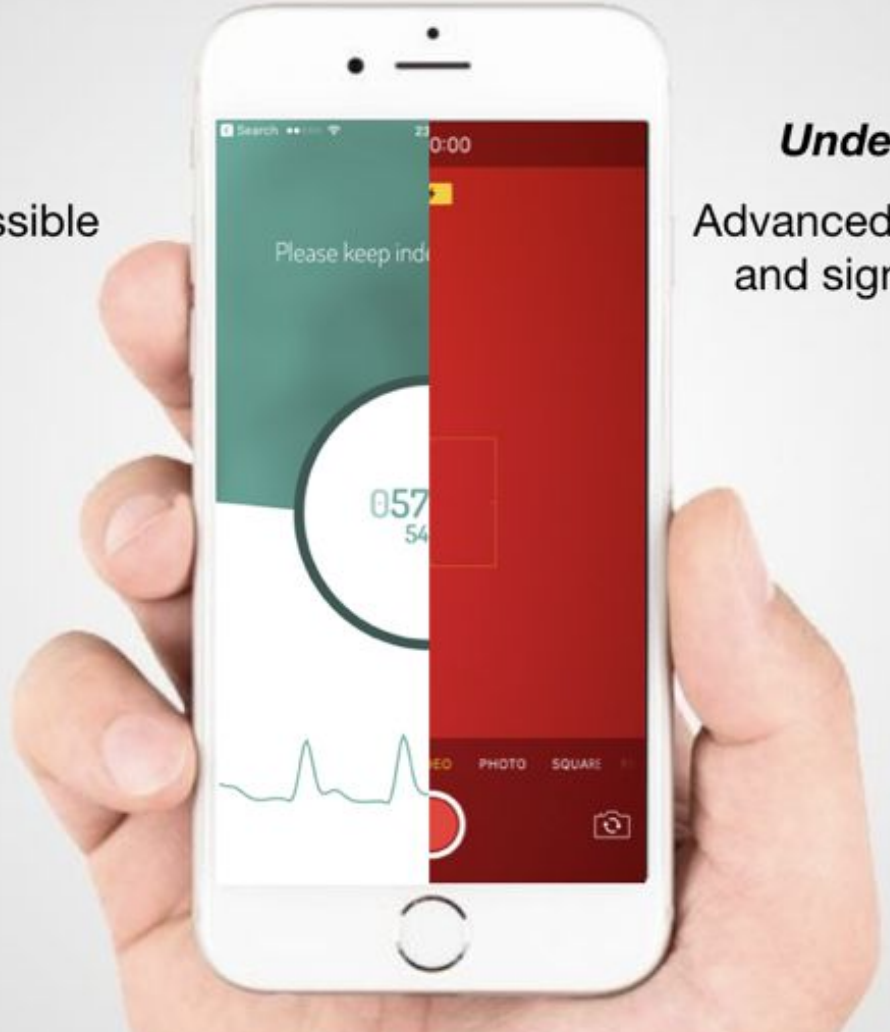
Regular rhythm

Non-AF arrhythmia

Possible AF

The look & feel

Made as simple as possible for the patient



Under the hood

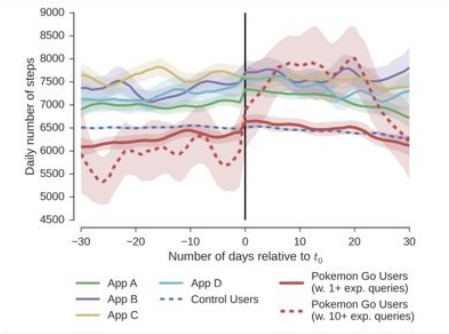
Advanced image analysis and signal processing

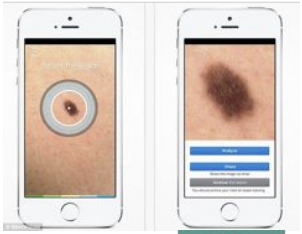
Innovation and compliance?

Different types of apps

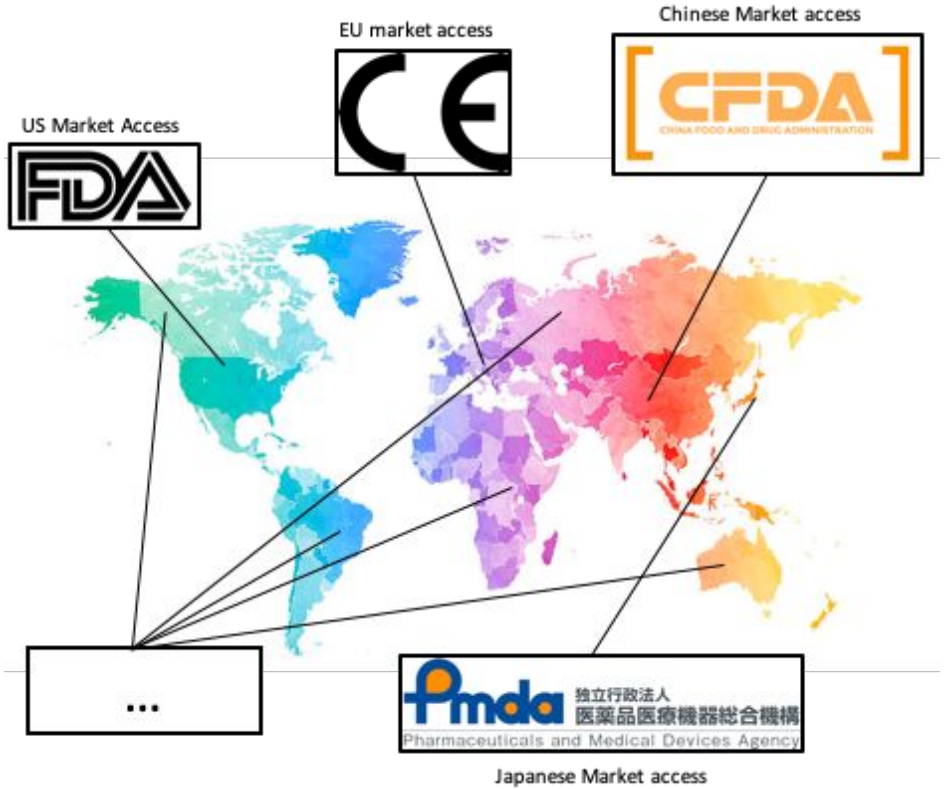
"(C)rapps | Fitness & Wellness | Medicalised wellness | Medical apps

The AcneApp claims to 'zap wrinkles and acne' using 420 nonometer blue light and 550 nanometer red light

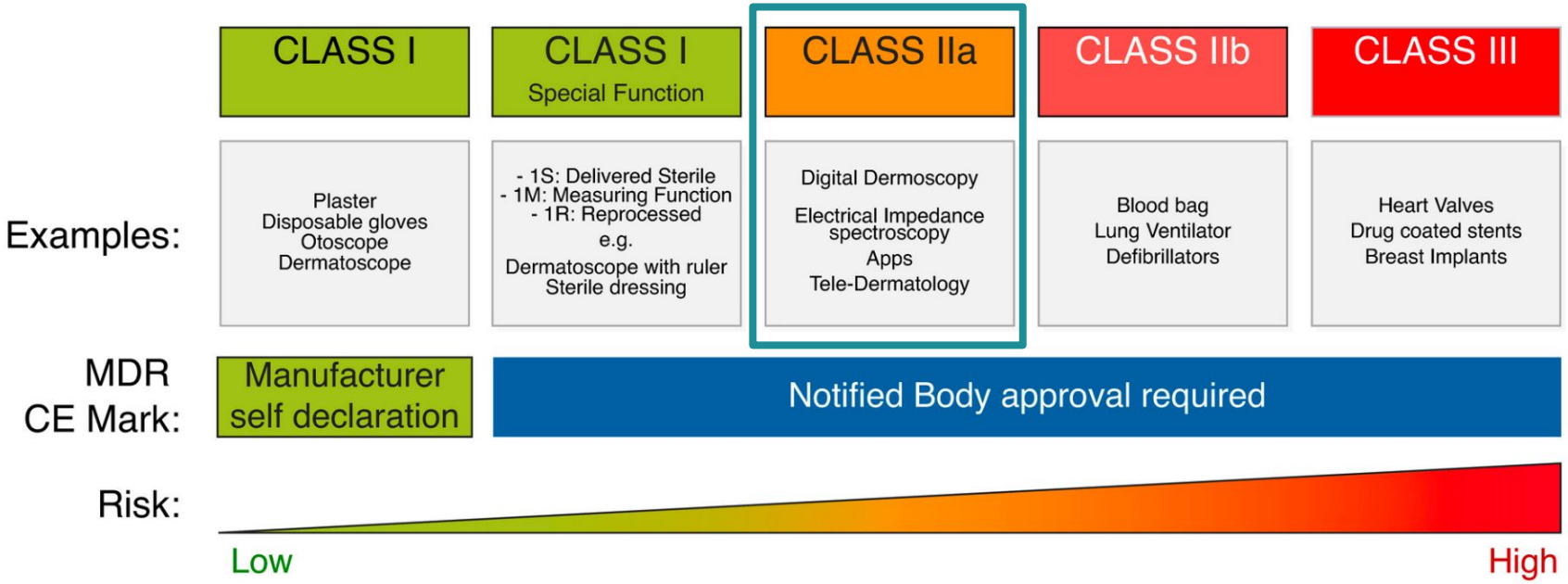




You cannot access the market without approvals as medical app



European regulation: Medical Device Regulation



Source: https://onlinelibrary.wiley.com/doi/full/10.1111/jdv.17830

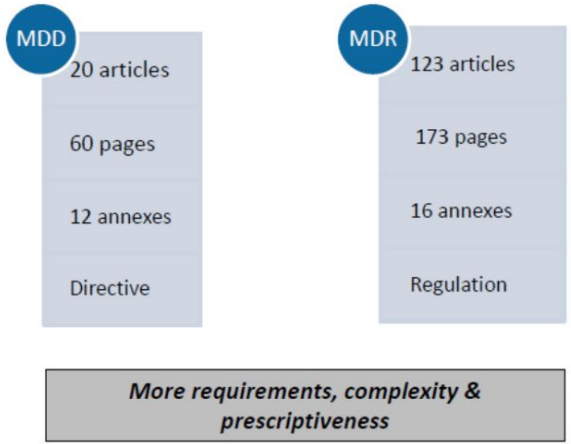
MDR: successor of the MDD

SGS

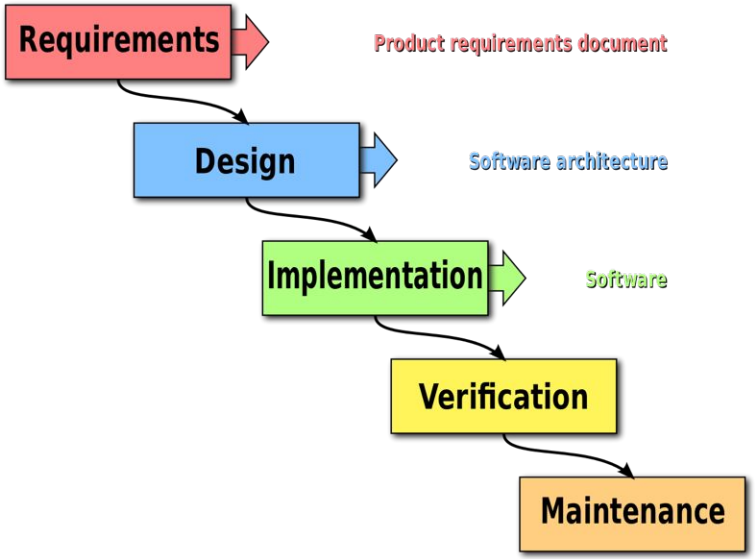
New Medical Device Regulations (MDR)

- 5 May 2017: **Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 78/2002 and Regulation (EC) No 1223/2009 and **repealing Council Directives 90/385/EEC and 93/42/EEC**

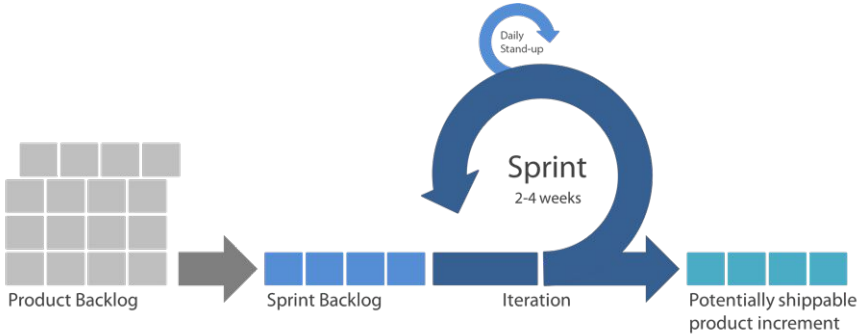
=> also called: MDR



Software development for medical apps



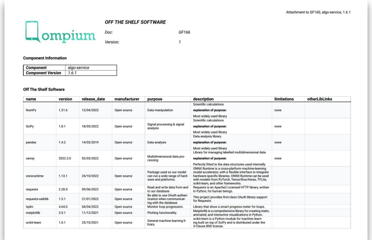
V.S.



Our algorithm is version controlled software...

For every version, we deliver the following documentation:

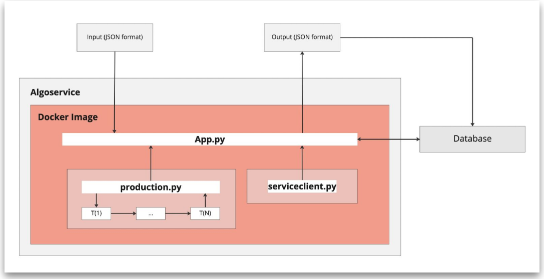
- Clinical validation
- Software requirements
- Off the shelf software
- Architectural design
- Detailed design
- Verification evidence
- ...



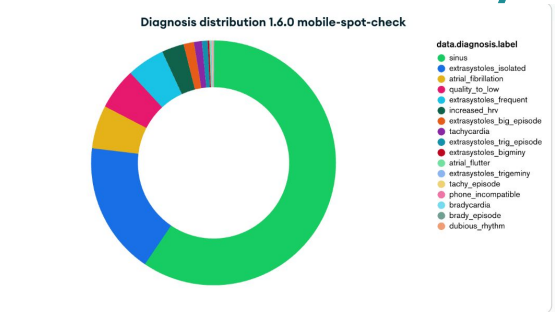
Clinical Performance Testing - Premium
Smartphone
Measurement-level
We first treat each measurement separately.

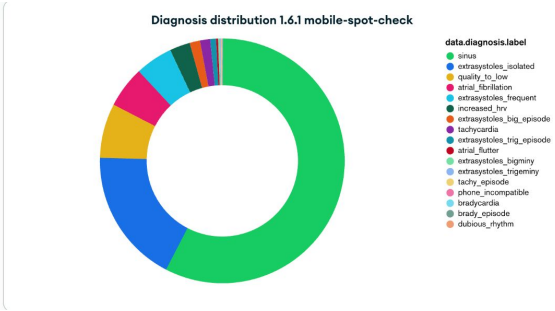
Previous version		**Prediction**			
		A - Quality	B - Normal	C - Urgent	D - Warning
Ground truth	1 - Normal	2	405	2	62
	2 - Urgent	7	0	372	6
	3 - Warning	4	63	2	460

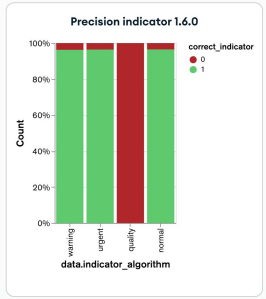
New version		**Prediction**			
		A - Quality	B - Normal	C - Urgent	D - Warning
Ground truth	1 - Normal	2	405	2	62
	2 - Urgent	7	0	373	5
	3 - Warning	4	63	2	460

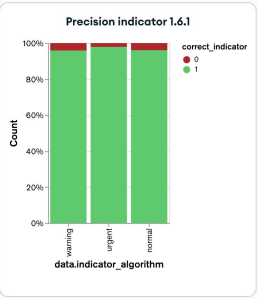


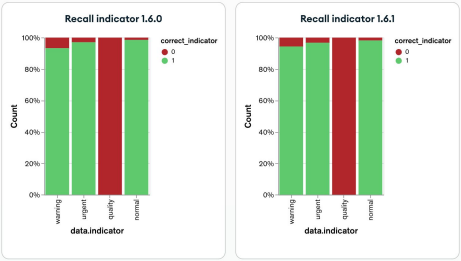
… that is closely monitored after launch

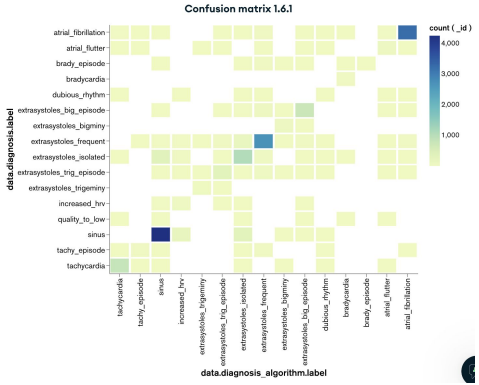












Compliance & regulatory approvals

Compliance

ISO 13485:2016
Certified for medical device quality management systems.

ISO 27001:2022
Certified for managing information security risks.

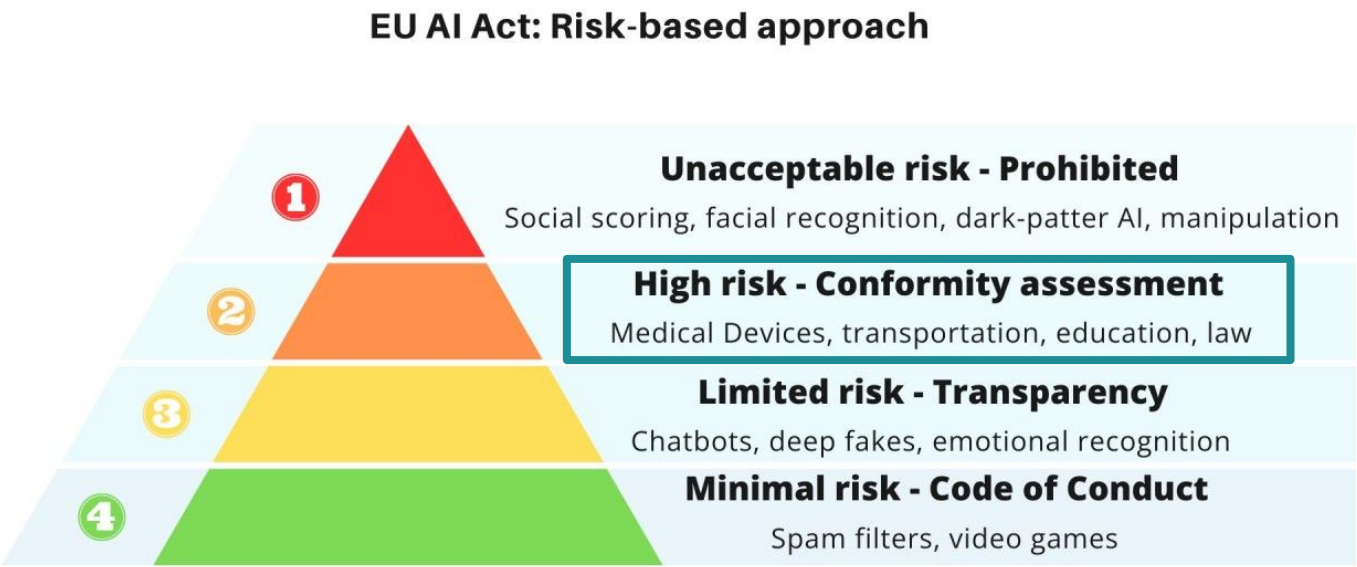
GDPR
Qompium is GDPR compliant.

HIPAA
Protecting health information.

Current Regulatory approvals

Australia - TGA	Smartphone/Smartwatch	B2B/B2C
Europe - CE Class IIa	Smartphone/Smartwatch	B2B/B2C
Singapore	Smartphone/Smartwatch	B2B/B2C
UAE	Smartphone/Smartwatch	B2B/B2C
UK	Smartphone/Smartwatch	B2B/B2C
US - FDA (510k)	Smartphone / (extension in Q1 2024)	B2B
Saudi Arabia	Smartphone	B2B/B2C

How does the EU AI Act fit into this?



Source: https://www.linkedin.com/pulse/ai-regulatory-frameworks-medical-devices-us-vs-eu-alona-lazarenko/

Compliant with MDR will mean in practice also compliant with the EU AI Act

Thank you!
Happy to answer your questions

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