

FibriCheck and the AI act

Keeping your finger on the pulse
of innovation



Who am I?



Glenn De Witte

glenn.dewitte@fibrichck.com

What is FibriCheck?



Atrial Fibrillation is a new millenium epidemic affecting millions



**Lifetime risk
1 out of 3
(50+)**

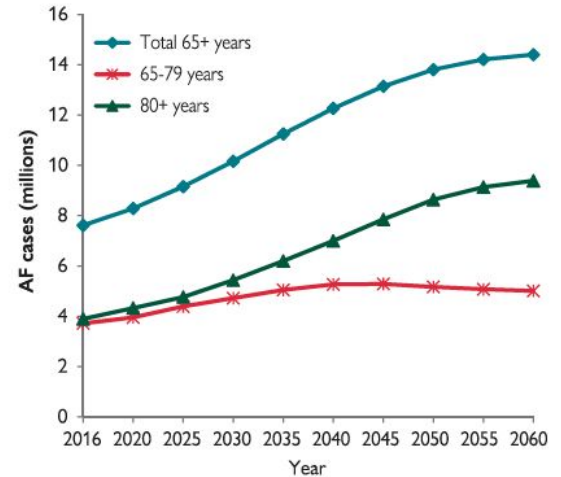


**40% remains undiagnosed
20% of all strokes**

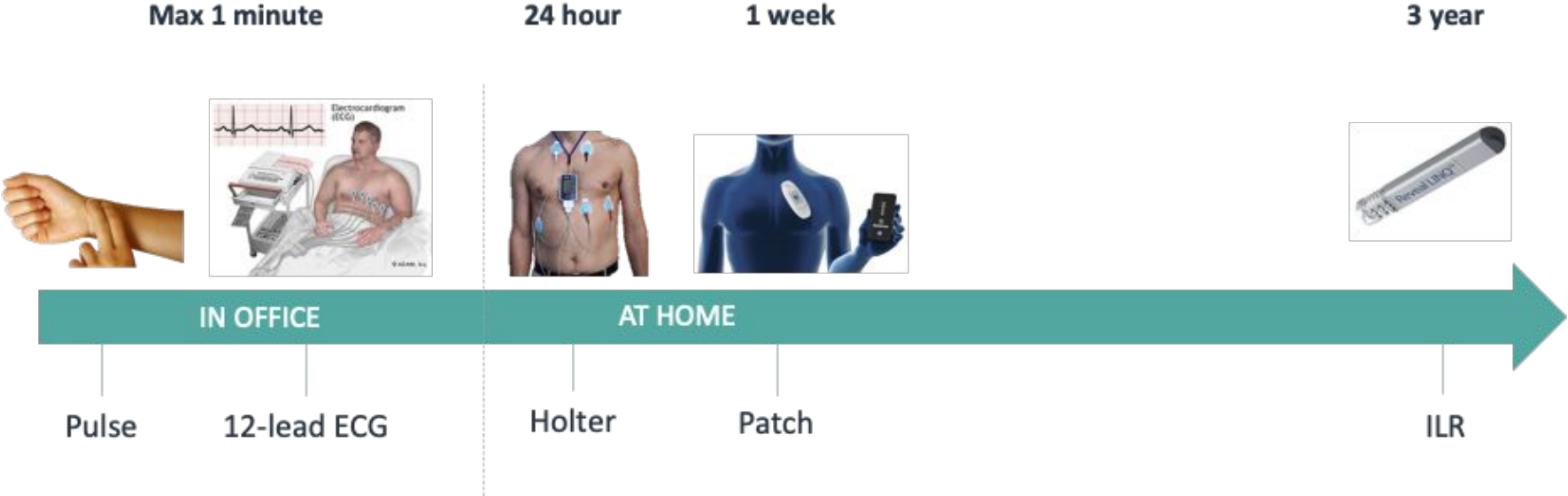


75% of strokes can be prevented

**Projected increase in AF prevalence
among elderly in EU 2016-2060**



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**



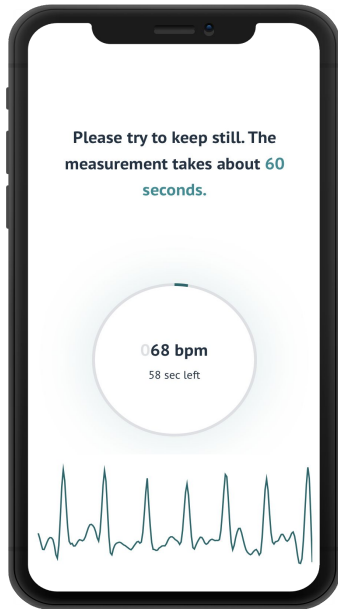
Expensive

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*

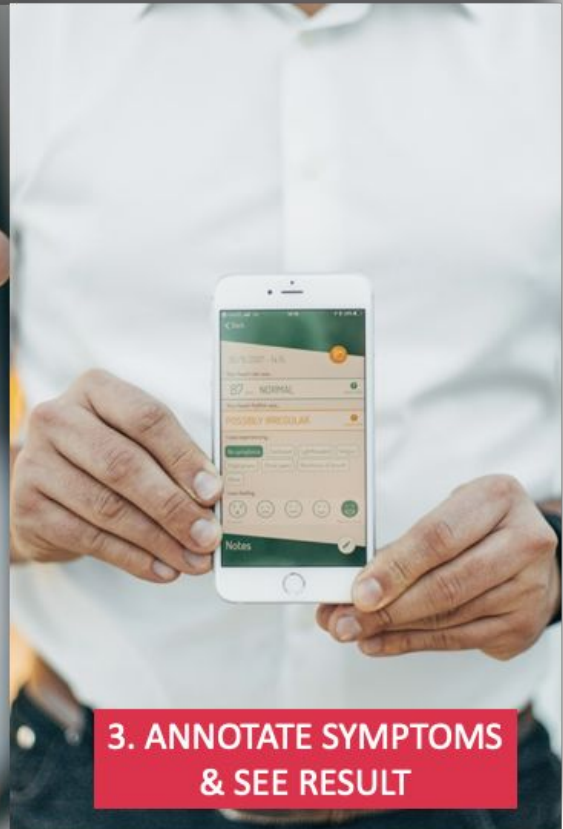


Mobile phones



Wearable Devices

FibriCheck on a smartphone

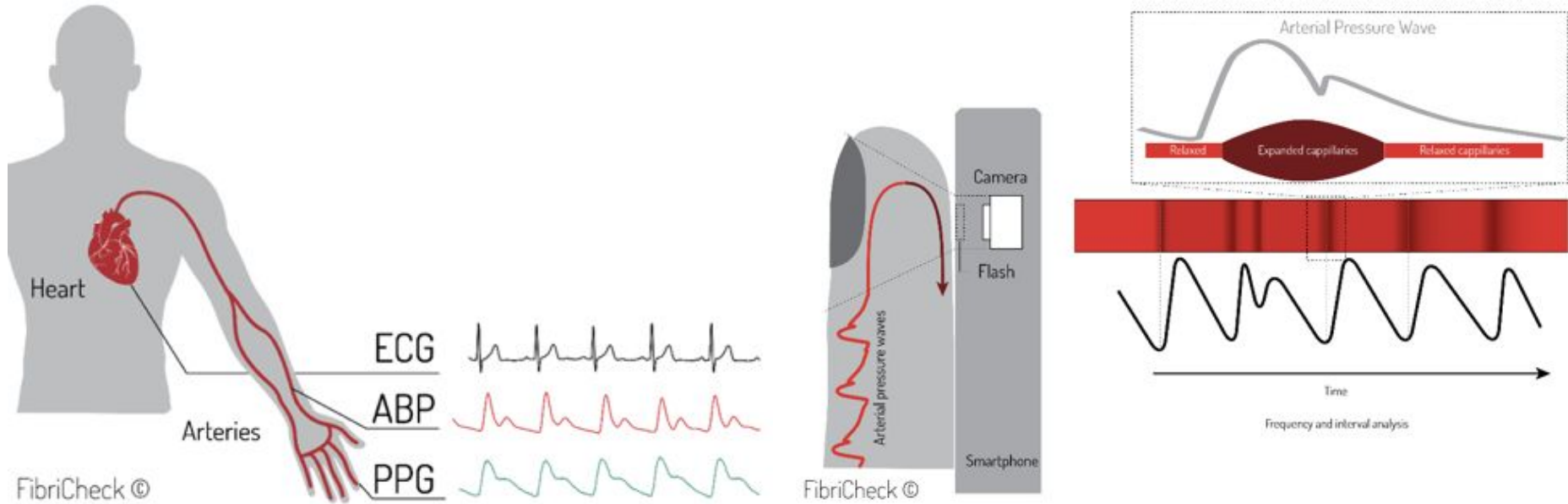


Which technology & the role of AI?



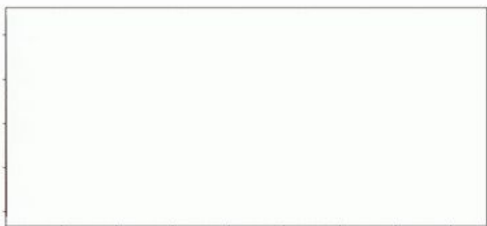
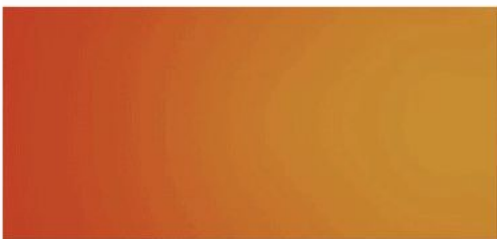
PhotoPlethysmoGraphy

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

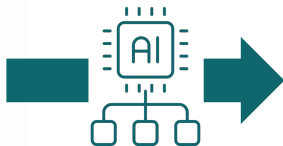


The role of AI

Camera image

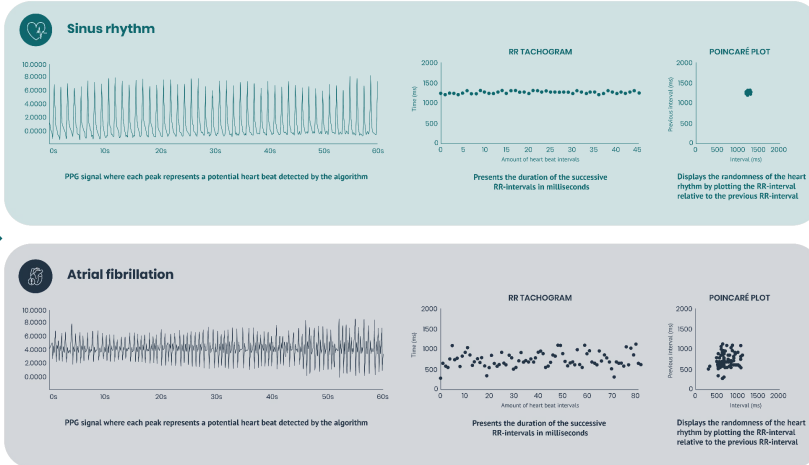


Raw PPG signal

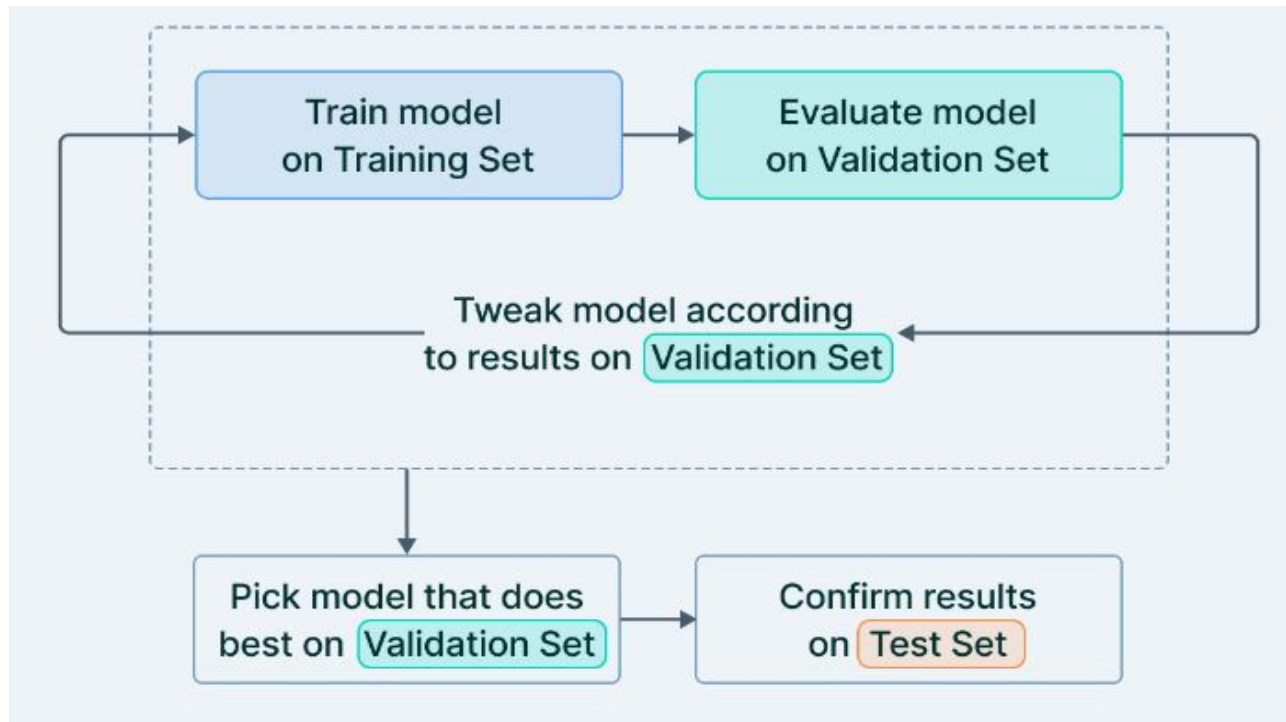


AI Classification of the PPG signal

PPG signals



How is the machine learning model trained?



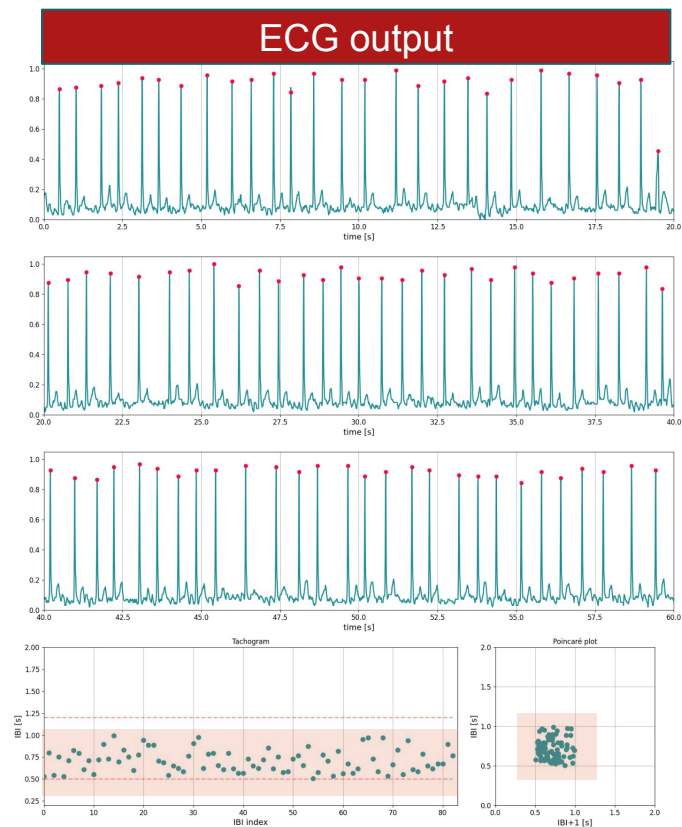
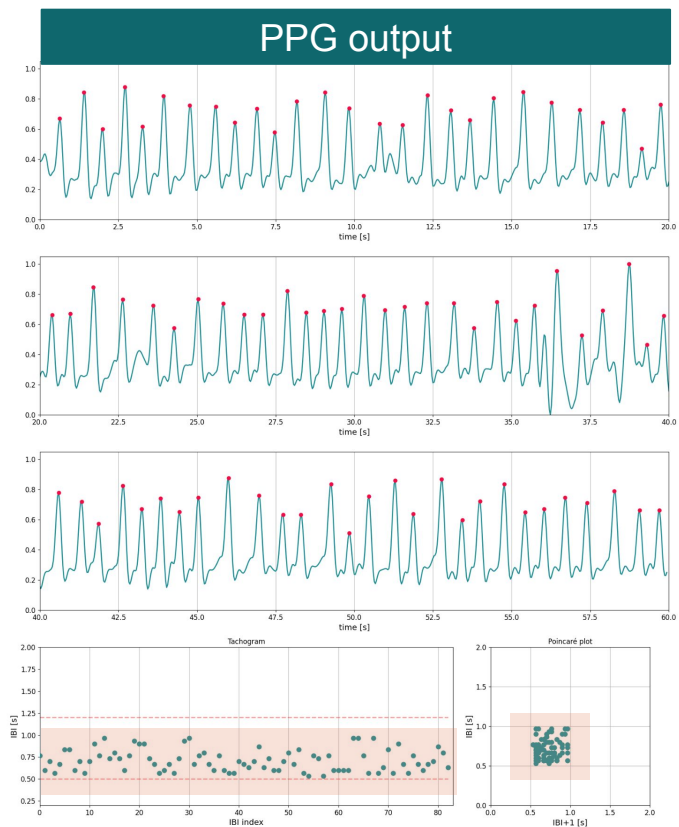
Train + validation set:

- 1M+ interpreted measurements
- data augmentation

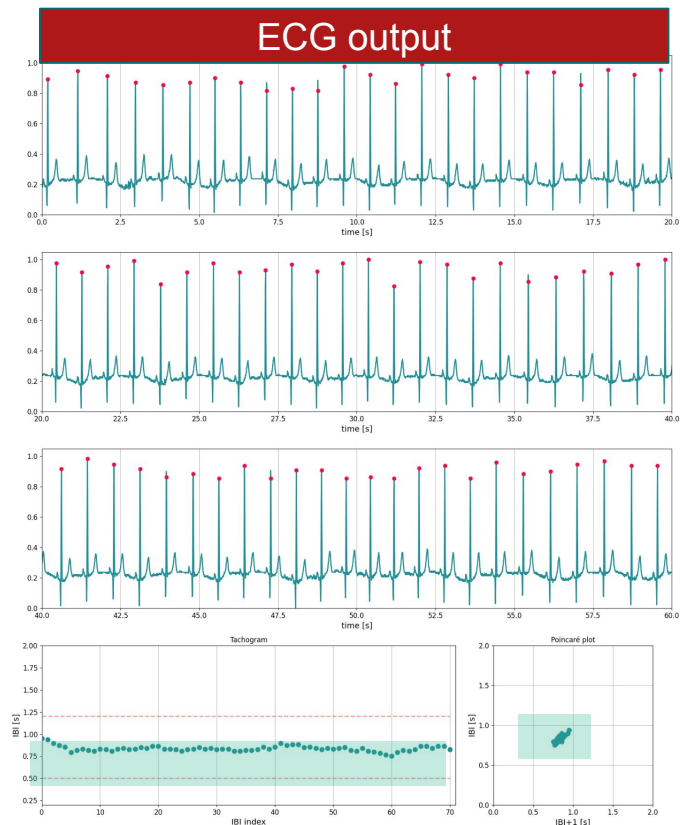
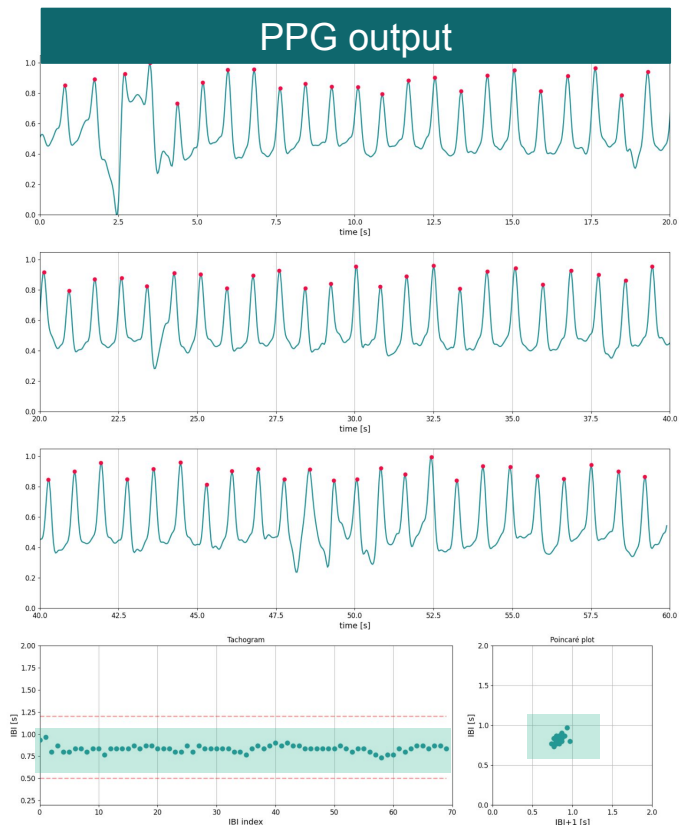
Test set:

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

Human interpretation - AF



Human interpretation - regular rhythm



Human interpretation beyond AF

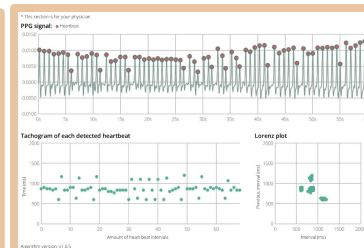
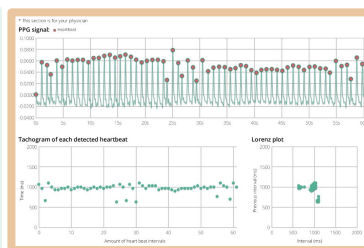
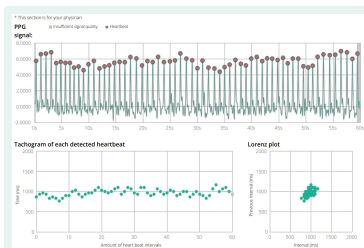
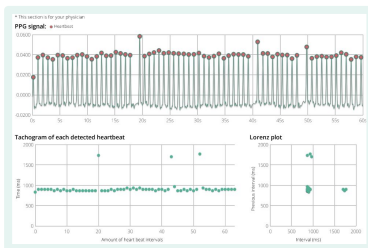
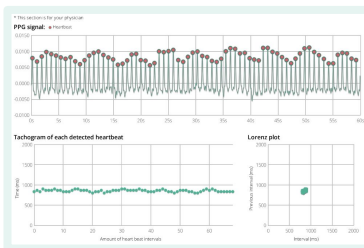
Regular

Isolated extrasystoles

Increased HRV

Frequent extrasystoles

Trigeminy episode



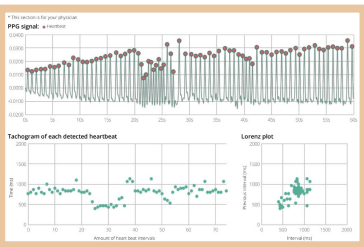
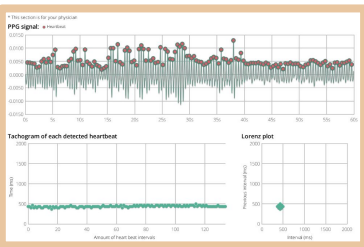
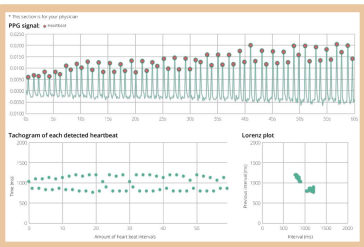
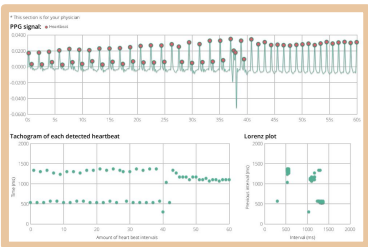
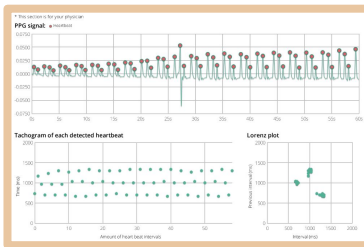
Trigeminy

Bigeminy episode

Bigeminy

Tachycardia

Tachycardia episode



Bradycardia

Bradycardia episode

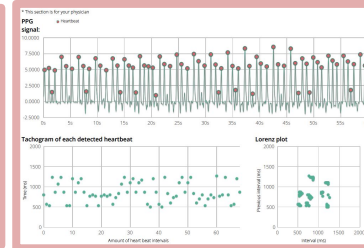
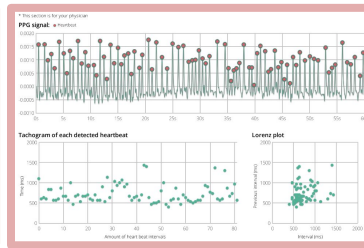
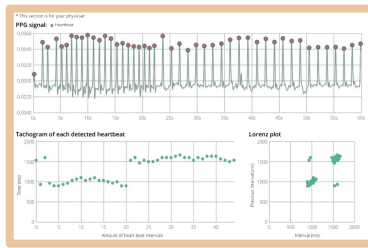
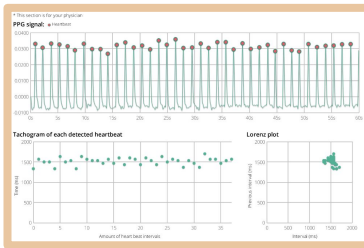
Atrial fibrillation

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?



FibriCheck®

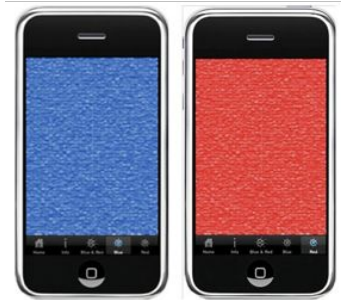
Different types of apps

“(C)rapps

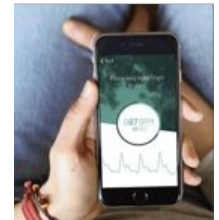
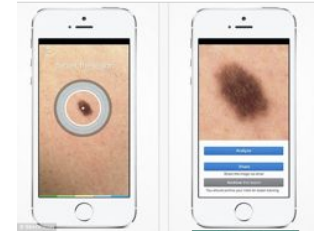
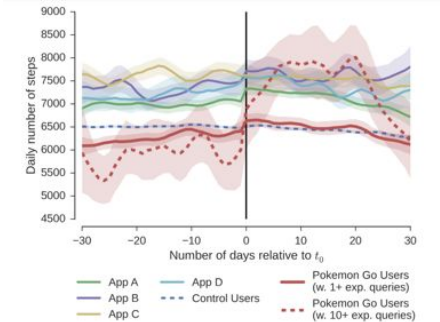
Fitness & Wellness

Medicalised wellness

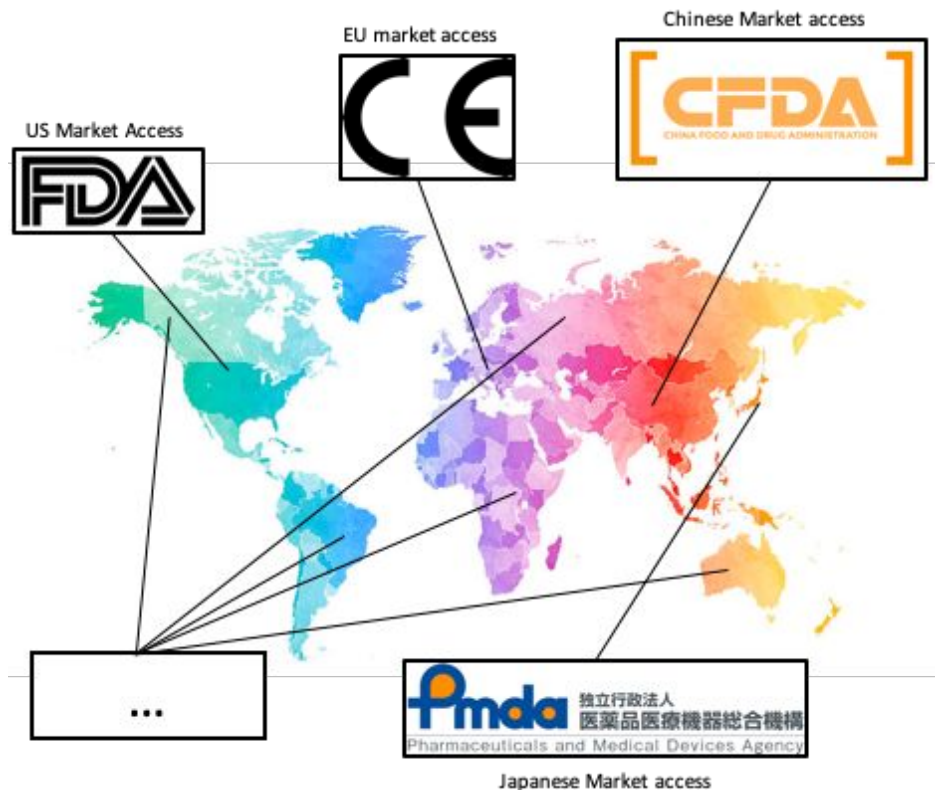
Medical apps



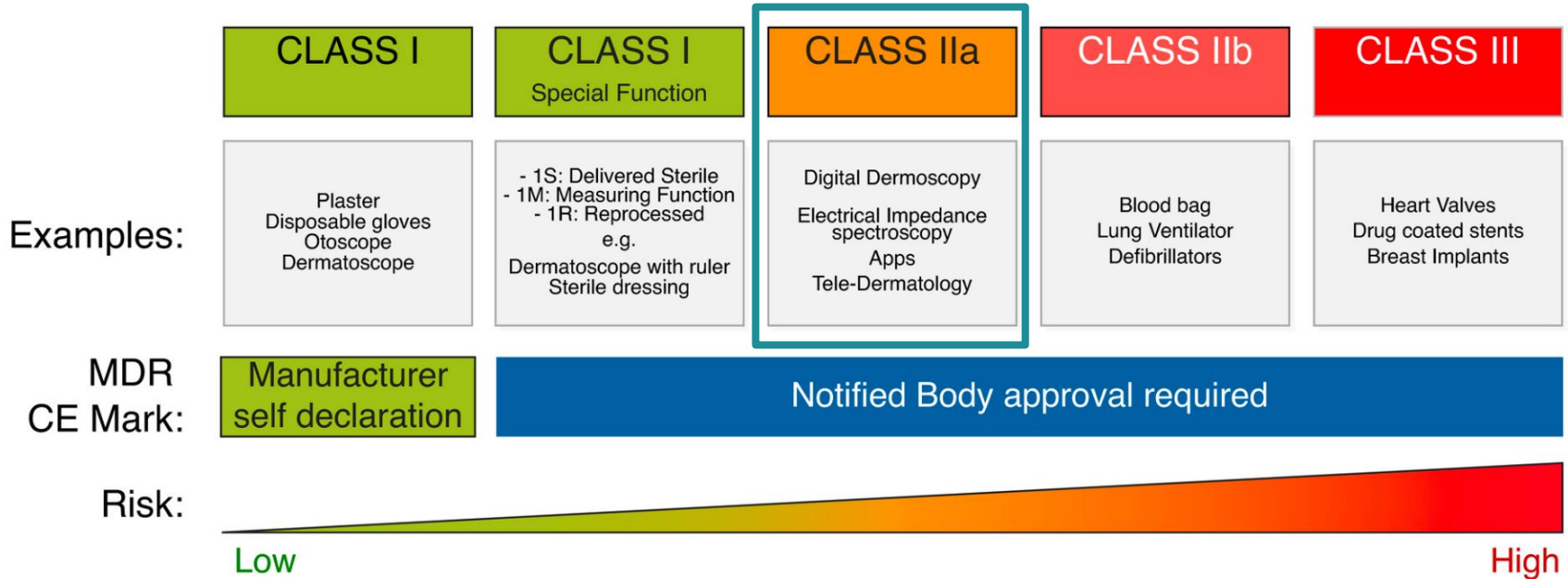
The AcneApp claims to 'zap wrinkles and acne' using 420 nanometer blue light and 550 nanometer red light



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)

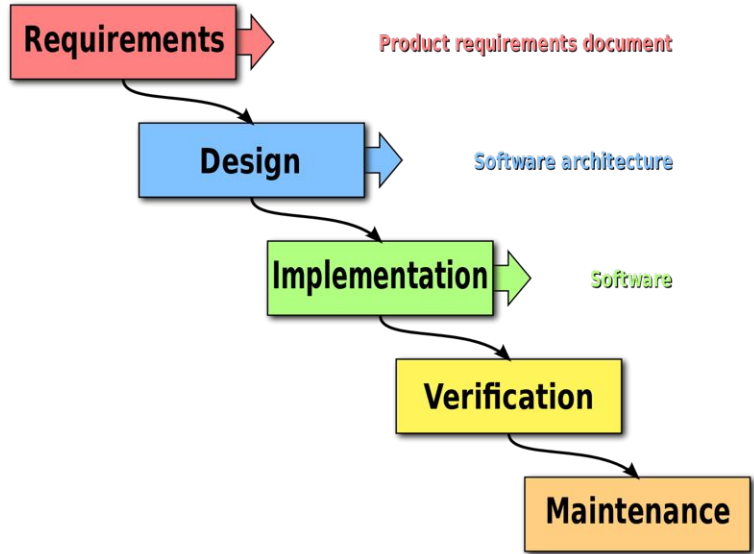
- 5 May 2017: **Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 78/2002 and Regulation (EC) No 1223/2009 and **repealing Council Directives 90/385/EEC and 93/42/EEC**

=> also called: MDR

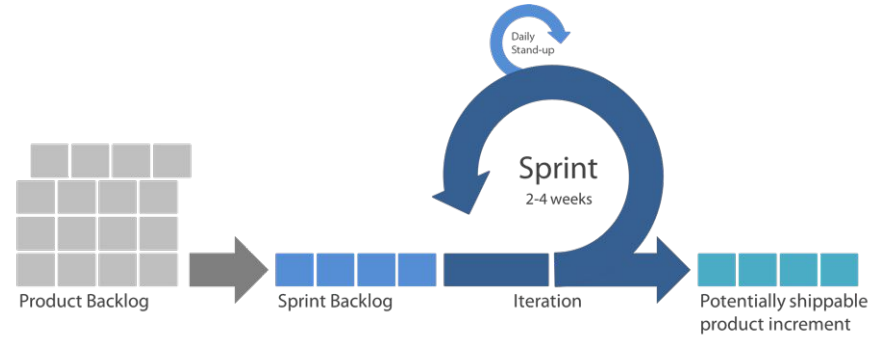
MDD	MDR
20 articles	123 articles
60 pages	173 pages
12 annexes	16 annexes
Directive	Regulation

More requirements, complexity & prescriptiveness

Software development for medical apps



V.S.



Our algorithm is version controlled software...

For every version, we deliver the following documentation:

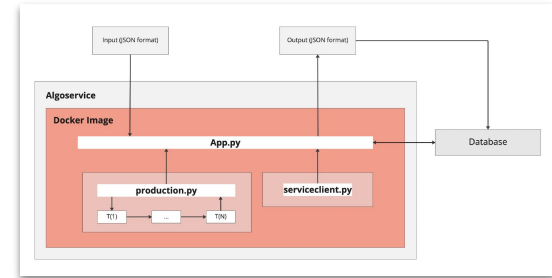
- Clinical validation
- Software requirements
- Off the shelf software
- Architectural design
- Detailed design
- Verification evidence
- ...

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	450

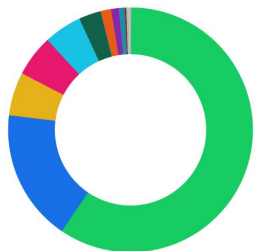
New version		Prediction			
		A - Quality	B - Normal	C - Urgent	D - Warning
Ground truth	1 - Normal	2	405	2	62
	2 - Urgent	7	0	372	6
	3 - Warning	4	63	2	450

Name	Version	Release Date	Manufacturer	Product	Description	Status	Risk Rating
Smartphone	1.0.0	2020-01-01	Smartphone	Smartphone	Smartphone	OK	Low
Smartphone Premium	1.0.0	2020-01-01	Smartphone	Smartphone Premium	Smartphone Premium	OK	Low
Smartphone	1.0.1	2020-01-01	Smartphone	Smartphone	Smartphone	OK	Low
Smartphone Premium	1.0.1	2020-01-01	Smartphone	Smartphone Premium	Smartphone Premium	OK	Low



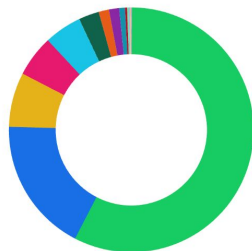
... that is closely monitored after launch

Diagnosis distribution 1.6.0 mobile-spot-check



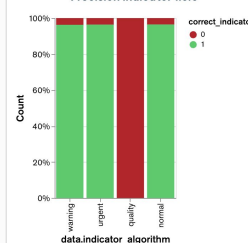
- data.diagnosis.label
- sinus
 - extrasystoles_isolated
 - atrial_fibrillation
 - quality_to_low
 - extrasystoles_frequent
 - increased_hrv
 - extrasystoles_big_episode
 - tachycardia
 - extrasystoles_big_episode
 - extrasystoles_big_episode
 - atrial_flutter
 - extrasystoles_big_episode
 - tachy_episode
 - phone_incompatible
 - bradycardia
 - brady_episode
 - dubious_rhythm

Diagnosis distribution 1.6.1 mobile-spot-check

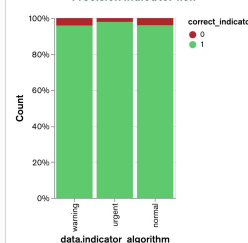


- data.diagnosis.label
- sinus
 - extrasystoles_isolated
 - quality_to_low
 - atrial_fibrillation
 - extrasystoles_frequent
 - increased_hrv
 - extrasystoles_big_episode
 - tachycardia
 - extrasystoles_big_episode
 - atrial_flutter
 - extrasystoles_big_episode
 - atrial_flutter
 - extrasystoles_big_episode
 - tachy_episode
 - phone_incompatible
 - bradycardia
 - brady_episode
 - dubious_rhythm

Precision indicator 1.6.0



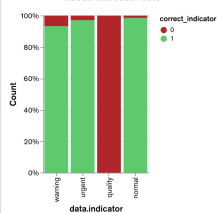
Precision indicator 1.6.1



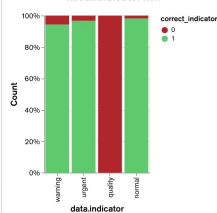
Quality throughout the years



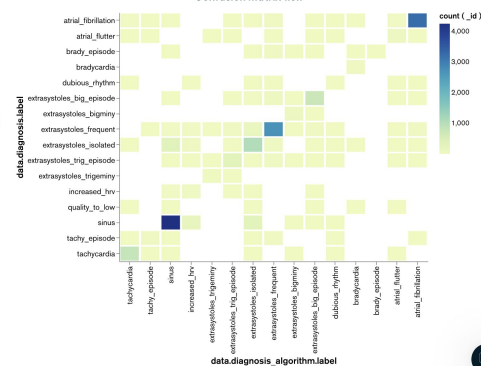
Recall indicator 1.6.0



Recall indicator 1.6.1



Confusion matrix 1.6.1



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

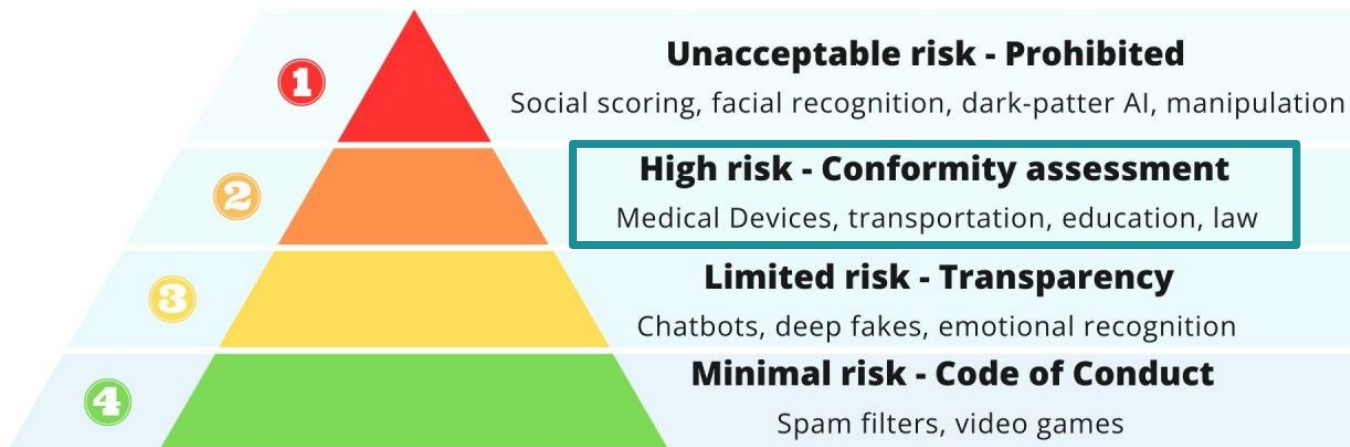
Protecting health information.

Current Regulatory approvals

Australia - TGA	Smartphone/Smartwatch	B2B/B2C
Europe - CE Class Ila	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?

EU AI Act: Risk-based approach



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



FibriCheck®

