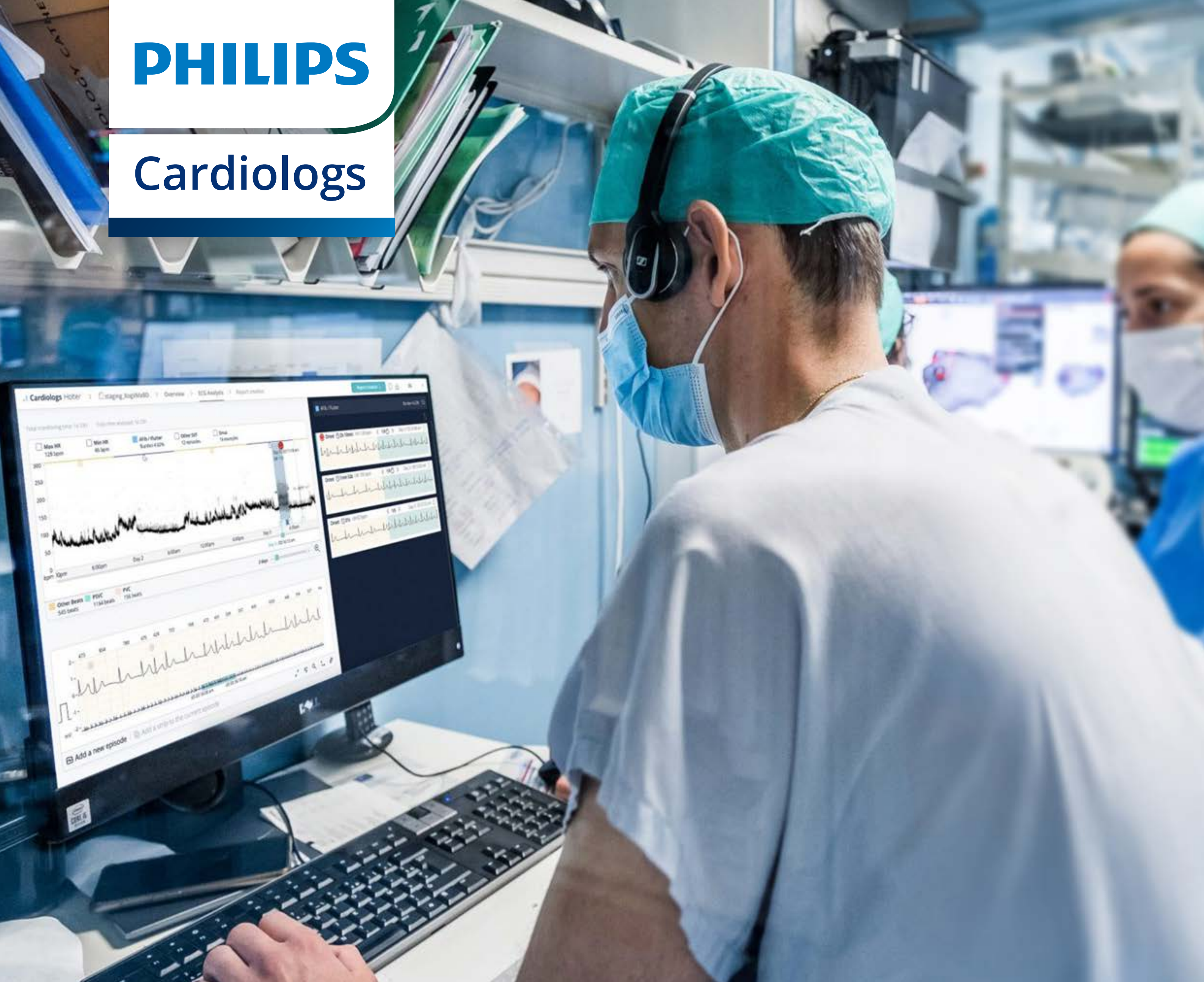
PHILIPS

Cardiologs



The role of Artificial Intelligence in transforming cardiac diagnostics

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Introduction

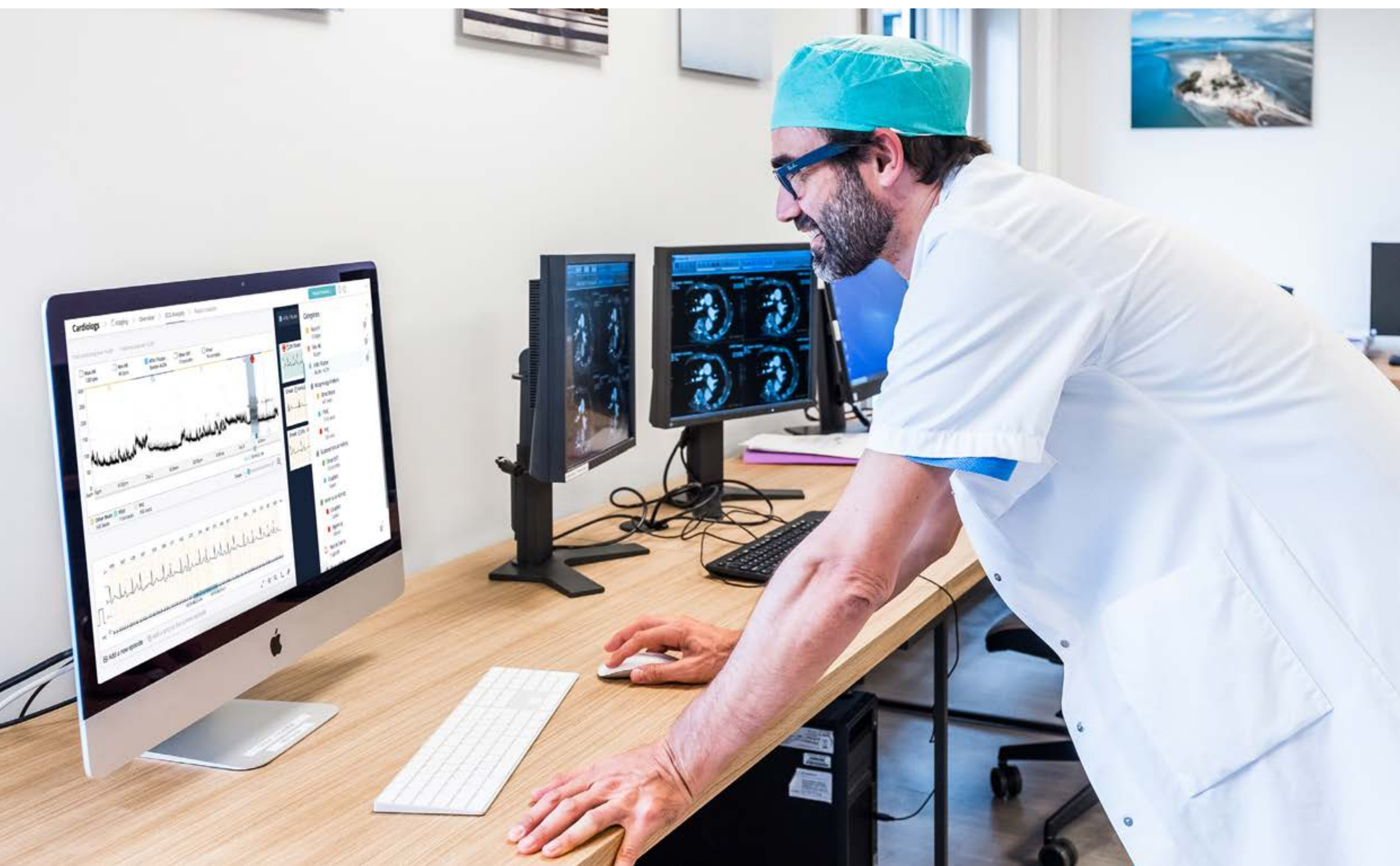
Around the world, 19.8 million people have died of cardiovascular disease in 2022, and more than six million of them were between ages 30-70.[1]

To this day, electrocardiograms (ECGs) remain the standard when it comes to diagnosing and monitoring patients with any suspected or known heart diseases.

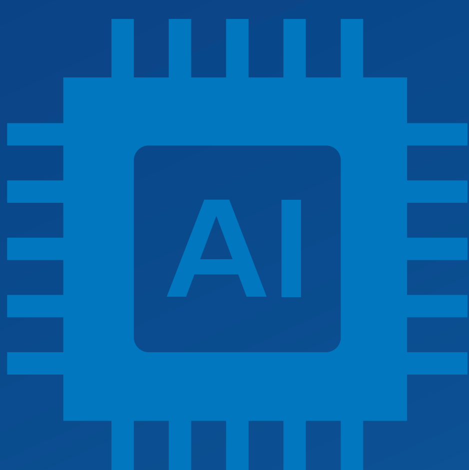
ECG analysis remains challenging for non-experts and time consuming for experts. ECG signals coming from Holter recorders, patches as well as implantable cardiacmonitors (ICM) **generate vast amounts of data which needs to be reviewed mostly manually by experts**.

By embedding Artificial Intelligence in medical devices, we can provide clinicians with solutions that can efficiently analyze and interpret those huge amounts of data.

Today, AI is becoming widely used in the field of radiology, along with Xray scans, CT scans and MRIs, but also more and more in the field of cardiology with ECGs or echocardiography, whether it would be for optimization of signal acquisition or interpretation, or to improve workflows. AI can support clinicians with efficient and expert diagnosis, allowing them to spend more time with their patients, focus on more complex cases and provide the best therapy.



The basics on Artificial Intelligence, Machine Learning and Deep Learning

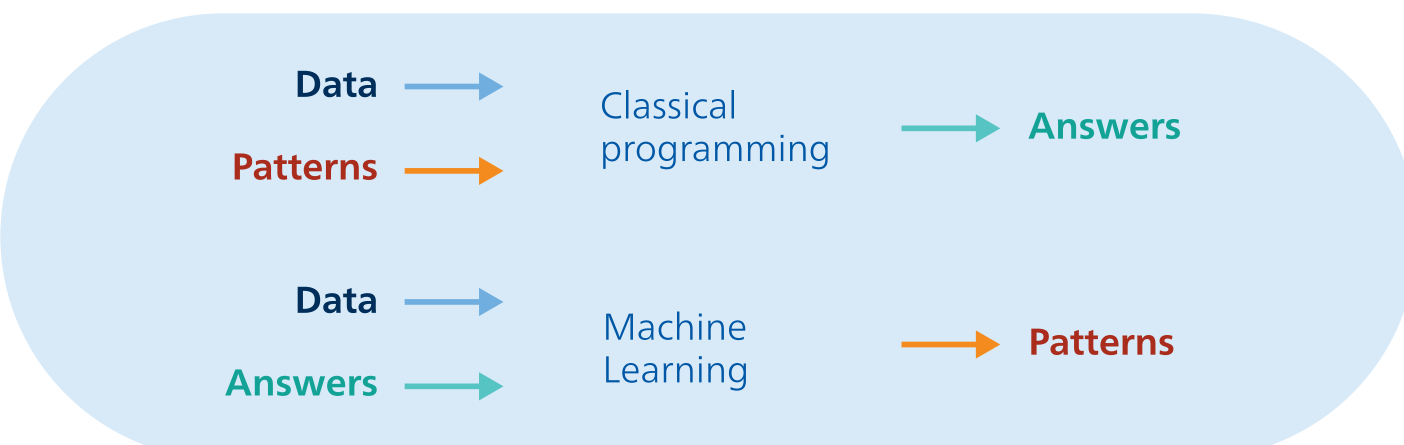


What is Artificial Intelligence?

We hear about Artificial Intelligence (AI), Machine Learning (ML) and Deep Learning (DL) constantly and for a variety of applications. One can easily get confused with those terms, and while they are related, it is important to understand the differences between them.

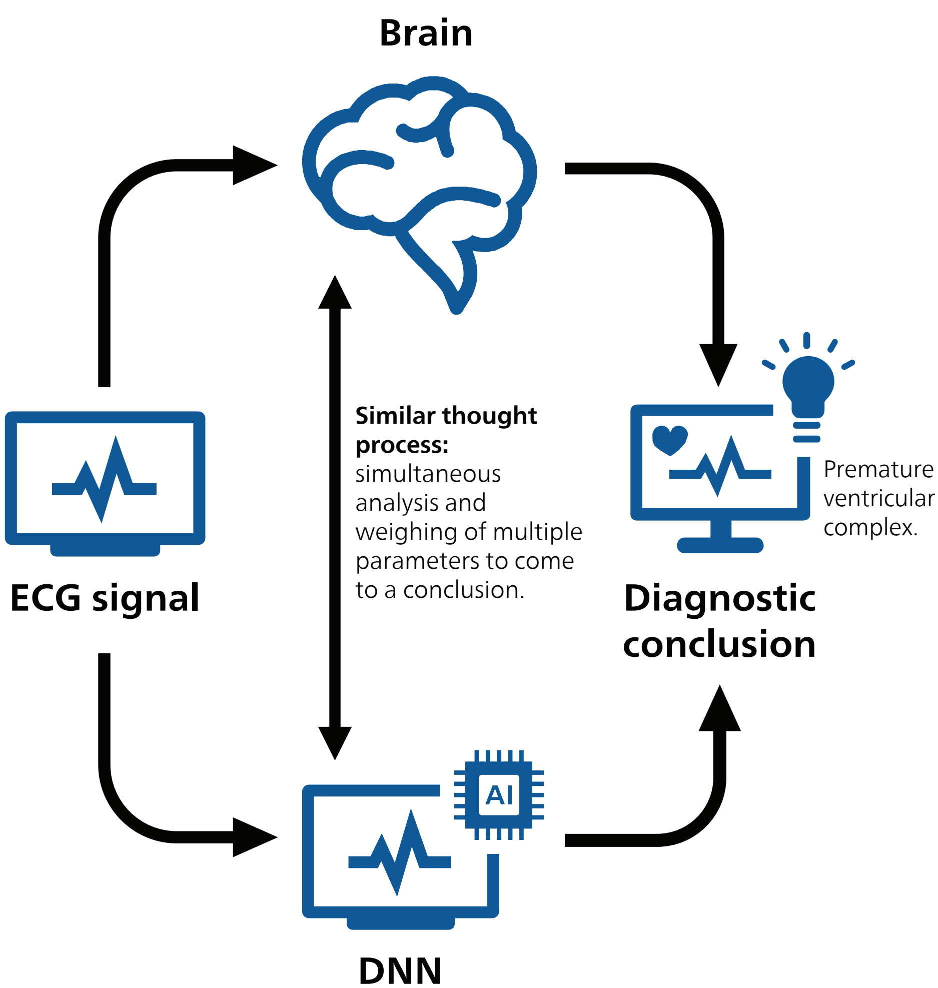
The term **Artificial Intelligence** was first used in the 1950s by John McCarthy to describe self-learning machines.[2] Generally speaking, AI refers to intelligent machines and programs able to perform human-like tasks such as image or speech recognition. **Machine Learning** is a subset of AI, which appeared much later in the 1980s, and refers to the ability for a program to figure out patterns from data on its own, without being explicitly taught rules.

Classical programming implies creating an algorithm with rules and sending a data input to get an answer, but machine learning algorithms are created by feeding input data and answers (annotated data) into a program, and letting the program create its own interpretation patterns.



What is Deep Learning?

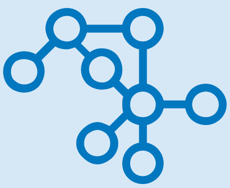
In the past two decades, Deep Learning was developed as yet another subset of Machine Learning techniques. Deep Learning is defined by the use of algorithms called Deep Neural Networks (DNN), which are loosely modeled after the human cerebral cortex, and specifically designed to recognize patterns from large amounts of data and solve problems involving complex reasoning.



Deep Neural Networks learn by themselves how to interpret data by analyzing vast amounts of data and coming up with their own interpretation patterns. Although the programmer is able to control the data that is fed into the DNN to train it, as well as the performance of the DNN by comparing its output to reality, **the functioning of neural networks involves thousands of computations which are hard to describe simply with a limited set of rules**.

What is Supervised learning?

We hear about Artificial Intelligence (AI), Machine Learning (ML) and Deep Learning (DL) constantly and for a variety of applications. One can easily get confused with those terms, and while they are related, it is important to understand the differences between them.



Deep Learning relies on training a neural network to perform like a human and recognize patterns in images or data. The most common one is supervised learning. The DNN needs to be first fed with vast amounts of data annotated with regards to the specific question that the DNN needs to answer. Then, the algorithm needs to be validated and tested on separate datasets, in order to control and validate its performance without bias.

It is important to understand the meaning and implications of vast amounts of annotated data. Vast because similarly to a human expert, the algorithm needs to acquire a lot of experience to be able to create its own interpretation patterns and differentiate in the end one pattern from another one. The data must not only be vast, it must also be representative of real world data. If we want to be able to recognize various types of abnormalities for instance, then we'll need all of those to be available in enough quantities in the training dataset.

The data needs to be annotated, meaning that each ECG strip is labeled according to pre-specified abnormalities, so that the algorithm may discern what characteristics of ECGs are associated with any given type of arrhythmia.

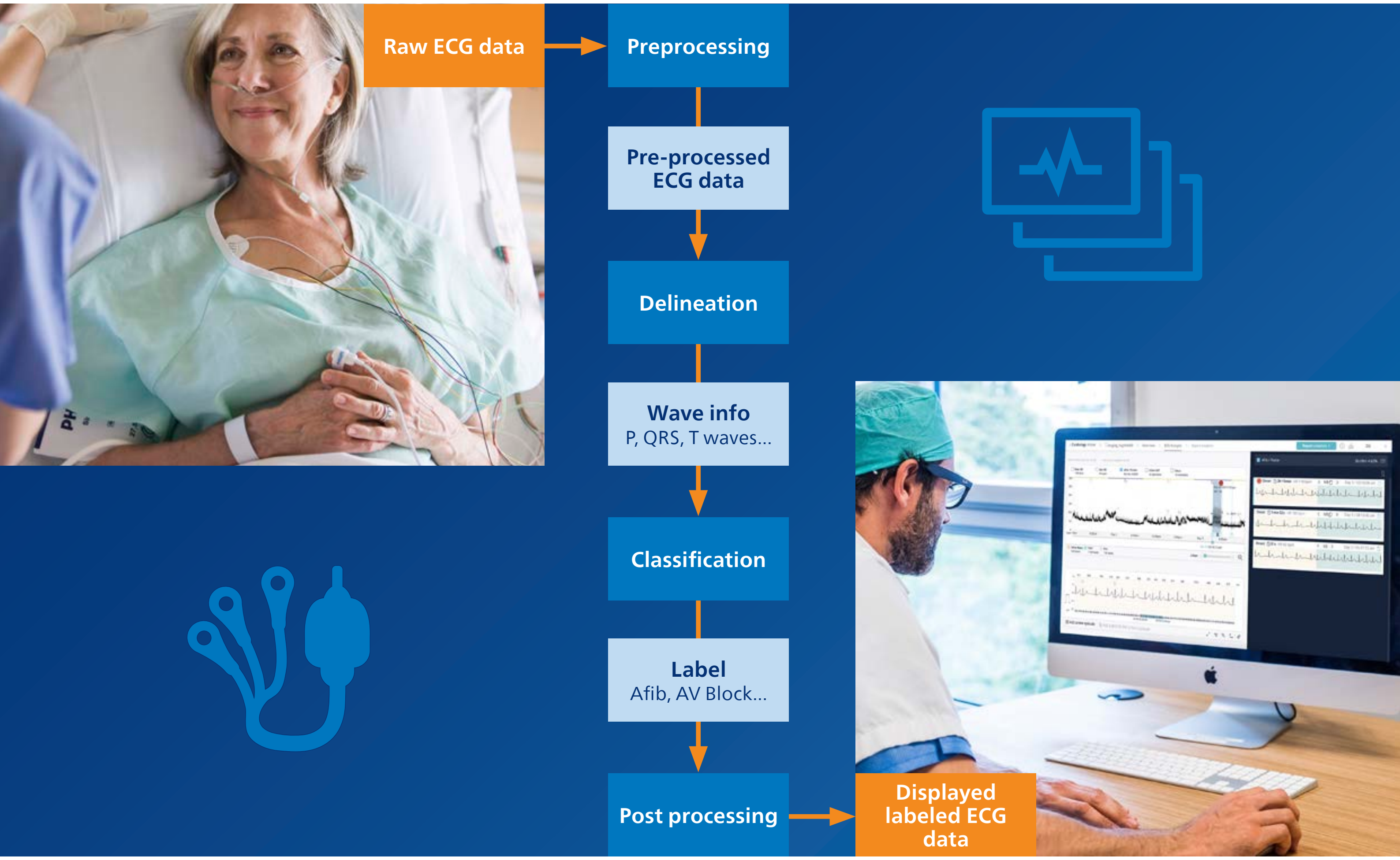
Unlike traditional rule-based algorithms, ML algorithms have the ability to keep learning and improving as more and more data, with accurate corresponding expert interpretations and outcomes ("annotations"), accrue. This is why the DNNs are regularly re-trained (and validated) with new labeled data, in order to continue improving their performance.

Deep neural networks applied to ECG analysis

An example of DNN applied to ECG analysis

Despite ECGs being one of the most common cardiac diagnostic tests that enable cardiologists to diagnose a variety of pathologies, ECG signals are quite complex to analyze, as they encompass subtle details and complex interactions. This makes ECGs a good use case for analysis with deep neural networks.

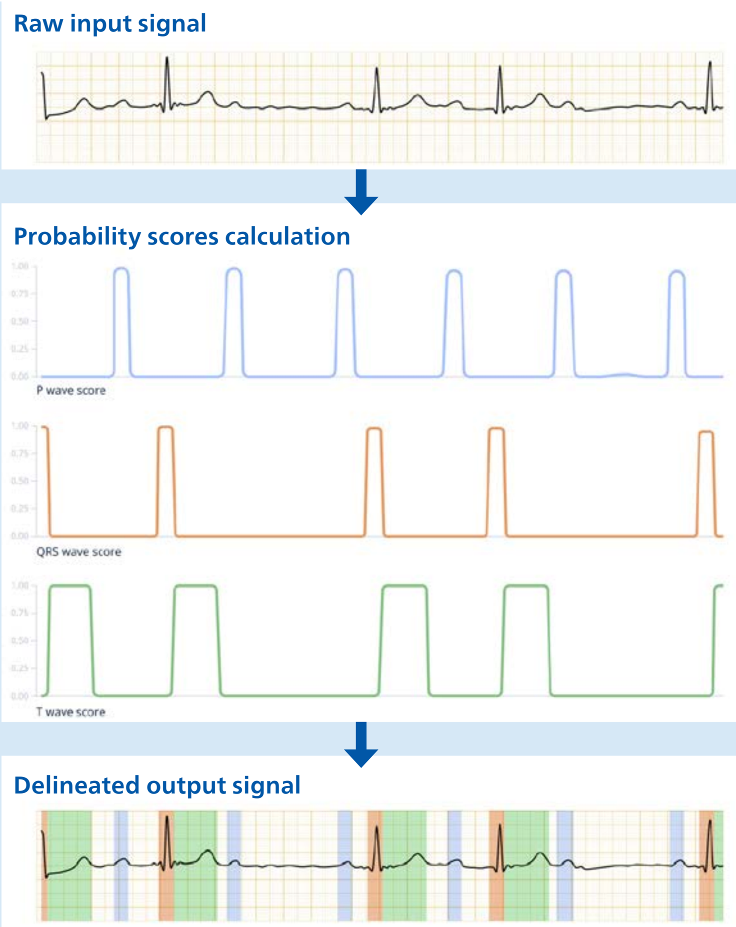
When a clinician uploads an ECG into the Cardiologs platform, the signal first goes through what is called **a delineation network**, which consists in segmenting the different electrical waves (P, QRS, T) in the signal. This delineation of the electrical waves provides clinical insights into the algorithm's thinking. This representative map is then fed through **a classification network**, which analyzes the map to detect abnormalities in the ECG signal, and present them to the clinician.



How are electrical waves detected?

This figure shows how, when the Cardiolog's AI engine receives the ECG, it first scans it to detect the beats, and segments the signal into the different electrical waves (P, QRS, T) that compose it. The algorithm computes the probability of presence of each type of wave along the signal. Any given portion of the signal above a 0.5 probability threshold is detected as part of the wave.

The final output consists in the initial ECG signal annotated with the P, QRS and T waves identified and positioned by the delineation algorithm.



The delineation network is trained using internal databases where the three types of waves (P, QRS, T) have been annotated. The DNN creates its own set of rules and is then able to learn to detect the presence of one or the other wave in a given strip.

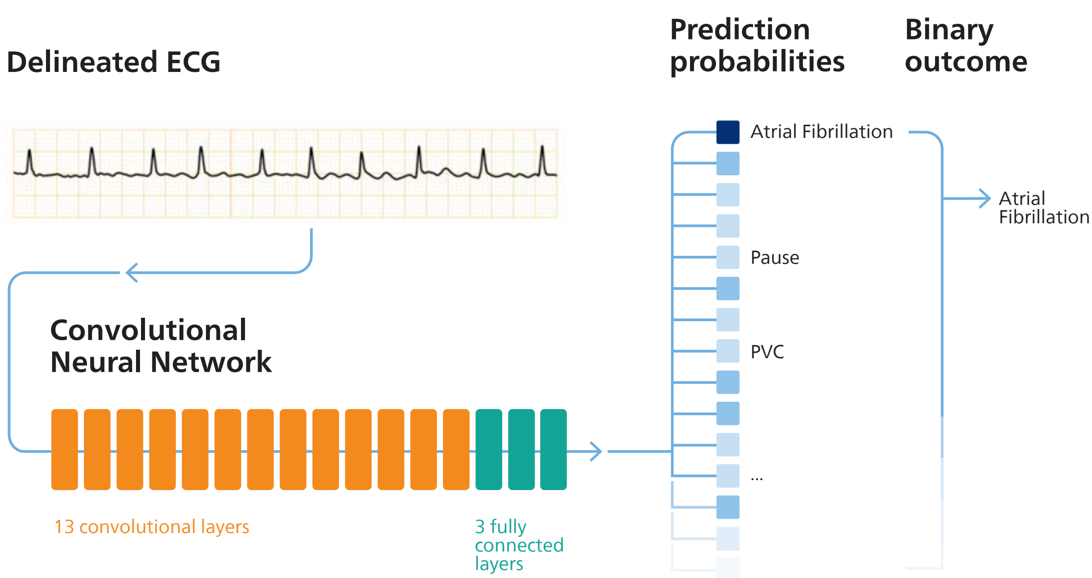
The power of the DNN is that by looking at the signal as a whole, it learns on its own that most of the time QRS waves are preceded by P waves, but not always. Similarly, it understands that a QRS wave is most often associated with a subsequent T wave.

How are abnormalities detected?

The Cardiologs' classification network evaluates the delineated ECG map to detect abnormalities in the signal. The classification network predicts probabilities for the presence of each main type of abnormality in ECG strips.

The final post-processing step is to reconcile and aggregate the information from all of those analyzed strips and to provide the user with a comprehensive overview of the signal.

The Cardiologs classification network is built on a specific type of DNN, called **convolutional neural network**, which all together contains about 4M parameters. The predicted diagnosis for a strip is composed of all abnormality labels with probability higher than 0.5. From this predicted diagnosis, a binary outcome is calculated according to what is being studied, for instance: **is Atrial Fibrillation present or not in this episode?**



What is special with our classification algorithm is that we use **a single model** to predict the presence or absence of all labels simultaneously and interpret the entire ECG rhythm.[3] This enables the model to take into account the dependence between pathologies.

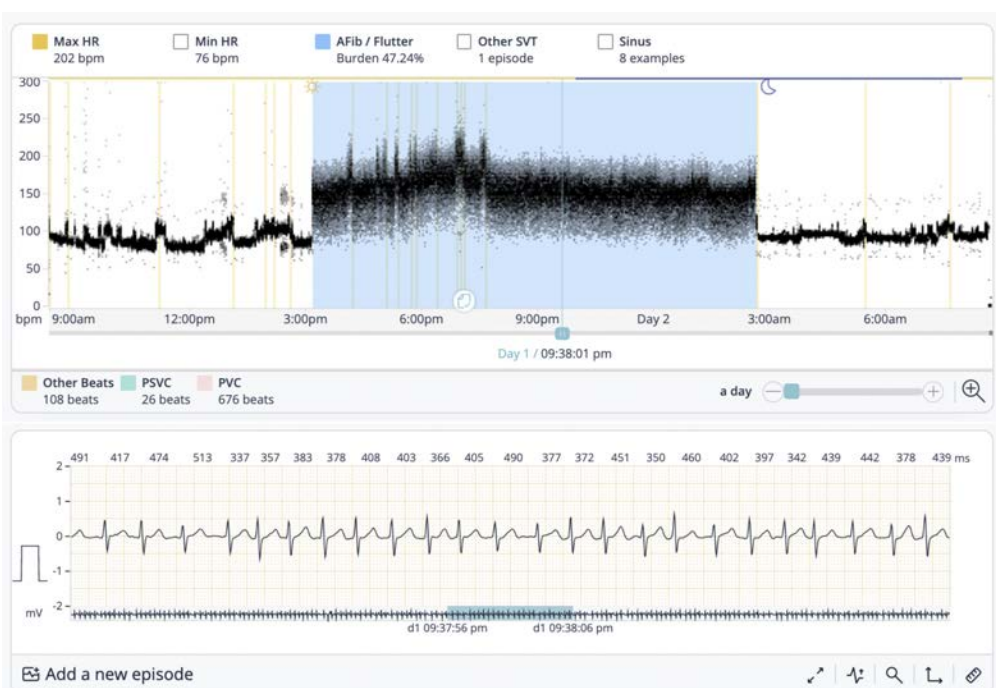
How does Deep Learning compare with traditional algorithms for ECG analysis?

1 DNNs can better identify electrical waves

In order for an algorithm to be able to interpret the ECG trace, that trace needs first to be translated into a **data representation**, e.g. converted into numbers, that a program can read. Then, the program can provide an answer based on that data representation using defined rules or criteria. In the past, computer programs have traditionally used handcrafted methods to perform both the data representation and decision criteria, which has limited their ability to perform as well as humans in some situations. If we use the example of atrial fibrillation, **traditional handcrafted algorithms are limited in their ability to convert an ECG trace into a rich data representation**, because they cannot easily capture the absence or presence of P-waves. Detection of P-waves is challenging because of their low signal to noise ratio, their possible overlapping with T-waves, and their absence and variability due to some specific morphologies or diseases.

The most commonly used method for delineation in traditional ECG analysis solutions is called the wavelet analysis. The usual process involves identifying QRS complexes first (the largest in amplitude), then P-waves (generally the smallest in amplitude), and finally the T-waves are deduced. This simplified approach fails to identify multiple P-waves and "hidden" P-waves.

Therefore, traditional algorithms miss a key factor for understanding the signal, and limit both their representation and criteria to the remaining elements, such as the RR interval variability.



This figures shows AF detected by the Cardiologs algorithm by anlyzing P waves

2 DNNs can better detect abnormalities

The second typical limitation of traditional ECG algorithms is related to the classification methods. **ECG analysis algorithms are traditionally conventional instructional algorithms**, meaning they produce rule-based automated interpretations (“if, then”). They work like decision trees based on a limited and pre-defined number of rules.

Identifying abnormalities in most algorithms is performed using rules based on temporal and morphological indicators computed using the delineation, such as the PR interval, RR interval, QT interval, QRS width, level of the ST segment, slope of the T-wave, etc. But oftentimes, those algorithms[4] are crude simplifications and do not reflect the way cardiologists analyze the ECGs, because they’re unable to handle as many parameters or take into account complex conflicting information.

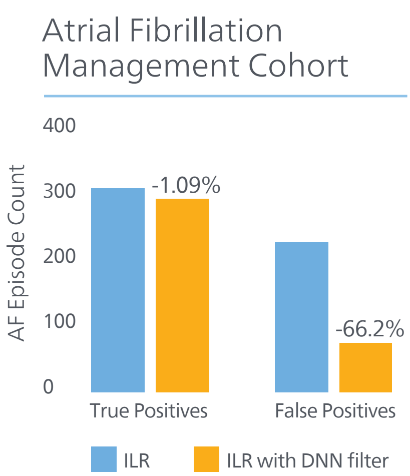
They don’t capture the complexity of the signal as a whole, because they don’t look at the signal like a human would, taking into account complex relationships between parameters. If we take the example of the AV block, the key element to detecting an AV block in an ECG signal is understanding whether P waves conduct a QRS wave or not. P waves and QRS waves may well both be present, but if they’re not correlated and the former does not conduct the latter, then one may be facing an AV block. Unlike DNNs, traditional solutions are not good at recognizing AV blocks for instance, because they always look for the P wave before the QRS signal, whereas a DNN has no “a priori” and accepts that they may overlap and actually be disjointed.

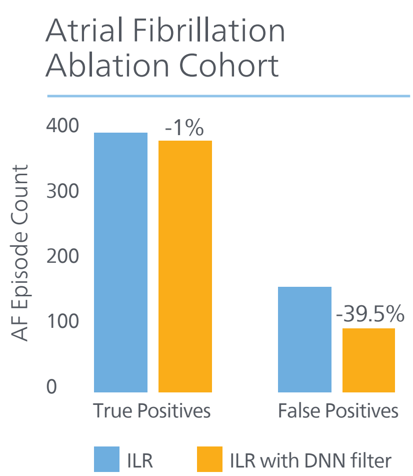
This figures shows AV Block detected by the Cardiologs algorithm

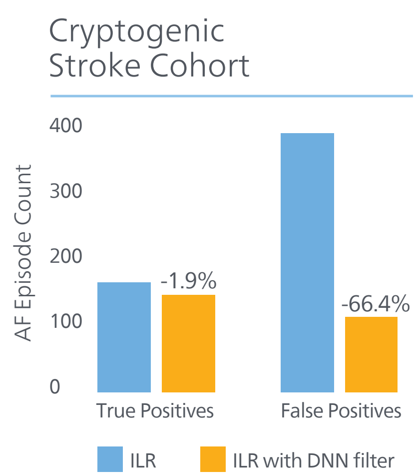
3 DNNs can reduce the number of false positives

Traditional algorithms are optimized to avoid missing abnormalities during classification. Their parameters and rules are created in such a way that they are very sensitive. But on the other hand, they lack specificity, creating a lot of false alarms which are a burden to manage. In a study on Implantable Cardiac Monitors, Dr. Suneet Mittal showed that such devices created a huge amount of false positive Afib episodes and demonstrated **up to 66% of those false alarms could be eliminated with the use of one of our DNN algorithms**.[5]

On the other hand, if physicians don't filter false alarms, patients may end up being treated for a condition they don't actually have. Dr. John Mandrola commented on the bias induced by 12L ECG machine algorithms, describing cases where patients were anti-coagulated following an overdetection of Atrial Fibrillation[6] and suffered from bleeds as a consequence of that treatment.







> "The high false positive rate of AFib detected by some Implantable Loop Recorders(ILRs) has created a clinical burden. Since ILRs transmit data daily, these false positives are one of the Achilles heels of remote cardiac monitoring. This study demonstrates that Cardiologs' advanced AI can filter up to 2/3 of false positive AF episodes, which should improve clinical efficiency.[5]"

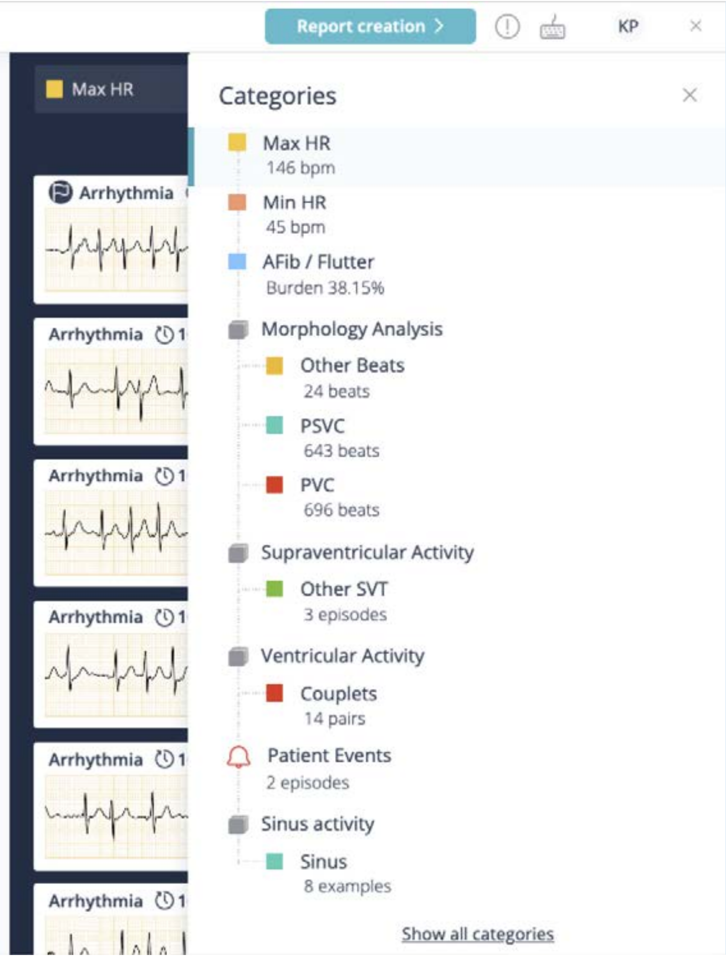
Dr. Suneet Mittal, BA, MD
Director of the Electrophysiology Laboratory and Associate Chief of Cardiology at the Valley Hospital in Ridgewood, NJ.

History of Machine Learning applied to ECG analysis

In the past decade, machine learning has been applied to ECG analysis to try and improve algorithms performance in the detection of arrhythmia, in particular atrial fibrillation. In 2013, Colloca et al. introduced an incremental approach towards machine learning by using handcrafted data representation, but machine-learned decision criteria.[7]

The Cardiologs approach introduced in 2016[8] is the first fully automatic approach, where both the data representation and the decision criteria are machine-learned, and not hand-crafted. Cardiologs uses DNN technology to learn from, and interpret, the whole ECG, thus handling multiple abnormalities at once.

Our full deep learning approach enabled for the first time to successively use RR irregularity as well as P-wave morphologies in combination, and thereby surpass state-of-the-art performance.



Cardiologs detects more than 20 types of events, including the main arrhythmias:

- Pause
- Atrioventricular Block (second-degree, third-degree, advanced high-grade AV block)
- Atrial Fibrillation or Atrial Flutter
- Ventricular Tachycardia
- Premature Supraventricular Complexes(PSVCs), PSVC Couplets
- Premature Ventricular Complexes (PVCs)
- Ventricular Couplets, Ventricular Bigeminy, Ventricular Trigeminy
- Sinus rhythm, Bradycardia, Tachycardia

Performance of Cardiologs algorithms was tested and validated following requirements of the standard IEC60601-2-25: 2011(Part 2-25). It was also tested on MIT-BIH, AHA and NST databases, according to the requirements of the ANSI AAMI EC57 - 2012 and IEC60601-2-47:2012 standards.

Reinventing cardiology

History of Machine Learning applied to ECG analysis

Healthcare professionals are facing an epidemic of patients with cardiological diseases requiring ECG diagnostics, such as Atrial Fibrillation, due to growing prevalence of risk factors and ageing population.

"Initially, I had to get used to trusting AI, not having to reclassify all the events, and then little by little, the more you use it, the more you realize that you can trust it, because errors are rare. Studies have been published to evaluate and demonstrate the diagnostic performance of the algorithm in comparison with other systems. The results are at least equivalent, and often even superior, depending on the studies and the pathologies studied, which gives us all the confidence we need.[9,10]"

Dr. Fiorella Salerno
Cardiologist and Rhythmologist at the
Institut cardiovasculaire Paris-Sud (ICPS)

The volume of ECG data to analyze for diagnostics will further explode in the years to come with the advent and rapid adoption of sensors and wearables, such as smartwatches. The ongoing trend towards longer monitoring periods, which has been demonstrated clinically to bring benefits in terms of detection performances, puts pressure on healthcare systems to find cost-effective solutions.

AI carries the promise of a future where patient access to the best of healthcare is universal, where caregivers are liberated from mundane technical and administrative tasks, and where health systems are able to face the economic pressure of an ageing population.

At Cardiologs, we aim to make cardiology diagnostics scalable and accessible to everyone, and provide tools for clinicians and service providers across the globe to face the increased demand for cardiological diagnosis.

For more information, visit www.cardiologs.com


Cardiologs Holter
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Overview
ECG Analysis
Report creation
Report creation
DD
Max HR
202 bpm
Min HR
76 bpm
AFib / Flutter
Burden 47.24%
Other SVT
1 episode
Sinus
8 examples
Other Beats
108 beats
PSVC
26 beats
Monitoring time: 1d
Analyzable time: 1d
Day 1 · 16:11:22
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Add a new episode
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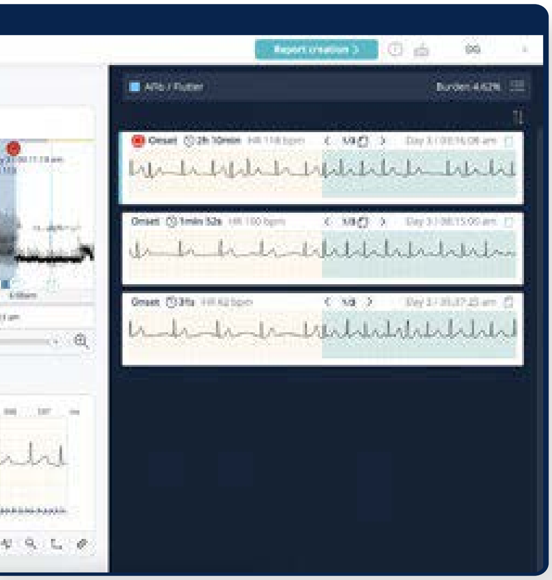

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Visit our website
www.cardiologs.com
for more information.

Medical device

The Cardiologs Holter Platform is a medical device intended for use by qualified healthcare professionals for the assessment of arrhythmias using ECG data. It is CE marked and cleared by the FDA under 510(k).

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