

COME L'INTELLIGENZA ARTIFICIALE STA CAMBIANDO E CAMBIERA' GLI ALGORITMI DEI DISPOSITIVI CARDIACI IMPIANTABILI

AI E LOOP RECORDER: UN NUOVO SUPPORTO DECISIONALE PER IL CLINICO?

DOTT. BANDINO STEFANO



Conflict of Interest

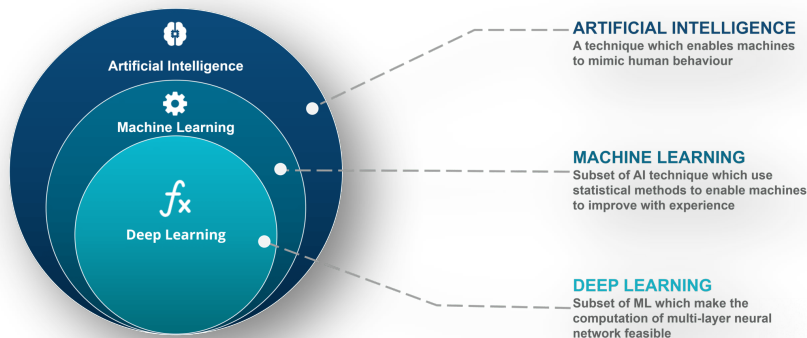
No conflict of interest to declare



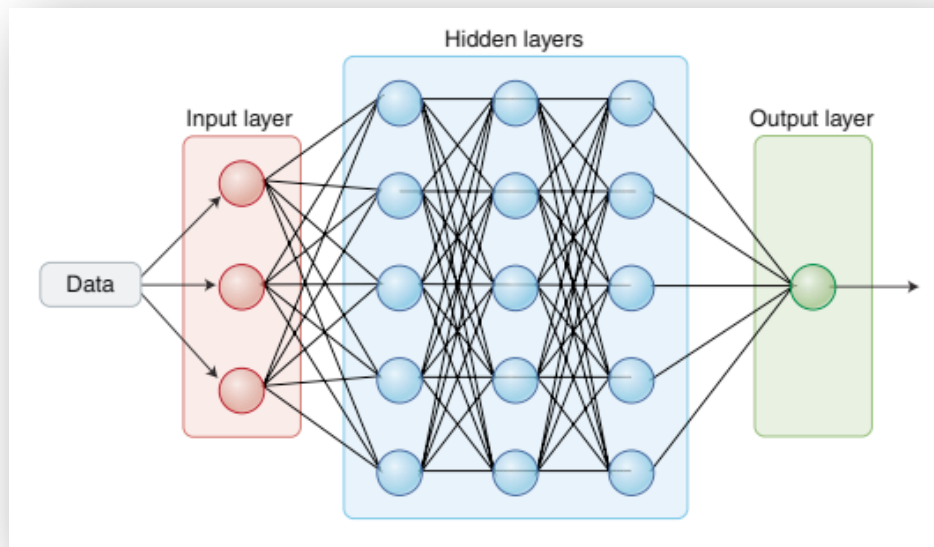
AI: Artificial Intelligence



Artificial Intelligence (AI) refers to the ability of algorithms encoded in technology to learn from data so that they can perform automated tasks without every step in the process having to be programmed explicitly by a human.



DNN (deep neural networks)

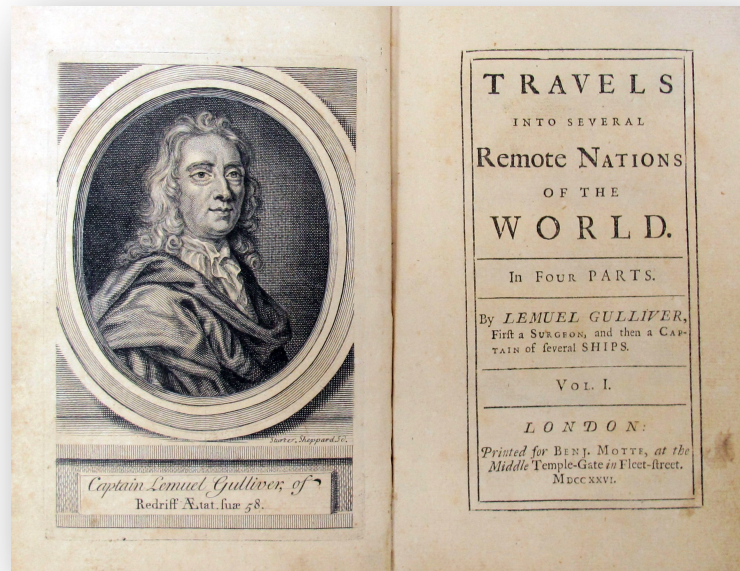


- A deep neural network (DNN) is an artificial neural network that contains multiple hidden layers between the input and output layers, enabling it to learn complex hierarchical representations of data.
- DNNs are algorithm architectures able to learn from large amounts of data without explicit instruction or pre-specified rules.

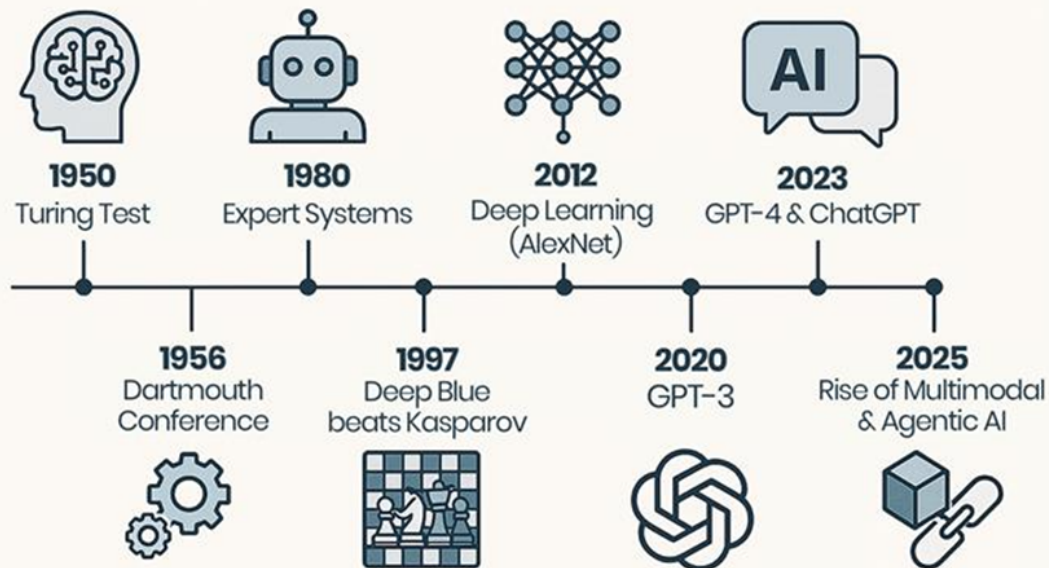


«Every one knew how laborious the usual method is of attaining to arts and sciences; whereas by his contrivance the most ignorant person, at a reasonable charge and with a little bodily labour, might write books in philosophy, poetry, politics, laws, mathematics and theology, without the least assistance from genius or study».

Jonathan Swift's Gulliver's Travels (1726)



HISTORY OF ARTIFICIAL INTELLIGENCE



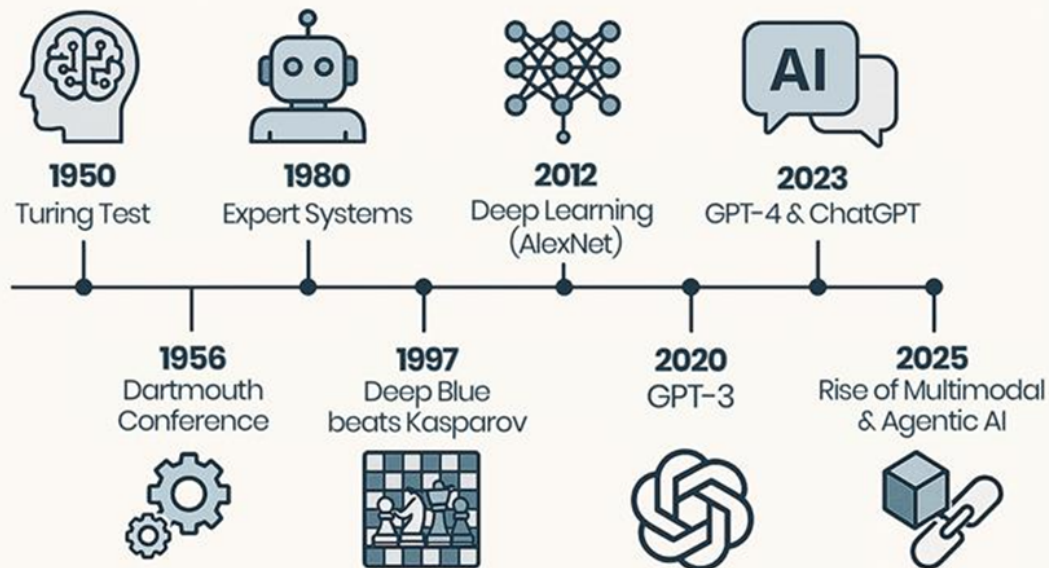
History



Enigma - 1939



HISTORY OF ARTIFICIAL INTELLIGENCE



1956 Dartmouth Conference: The Founding Fathers of AI



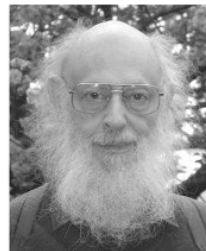
John McCarthy



Marvin Minsky



Claude Shannon



Ray Solomonoff



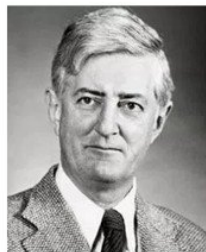
Alan Newell



Herbert Simon



Arthur Samuel



Oliver Selfridge



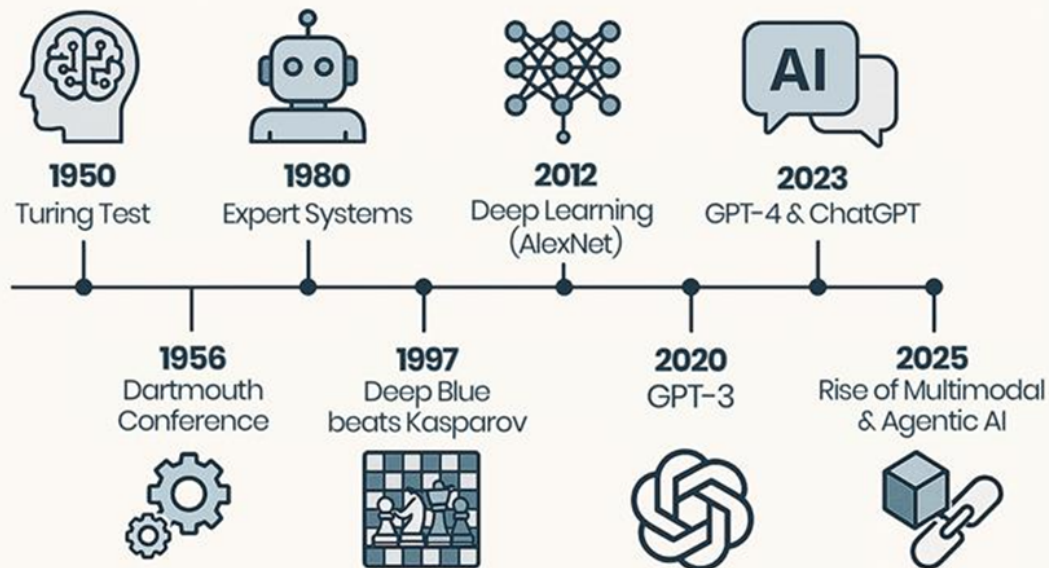
Nathaniel Rochester

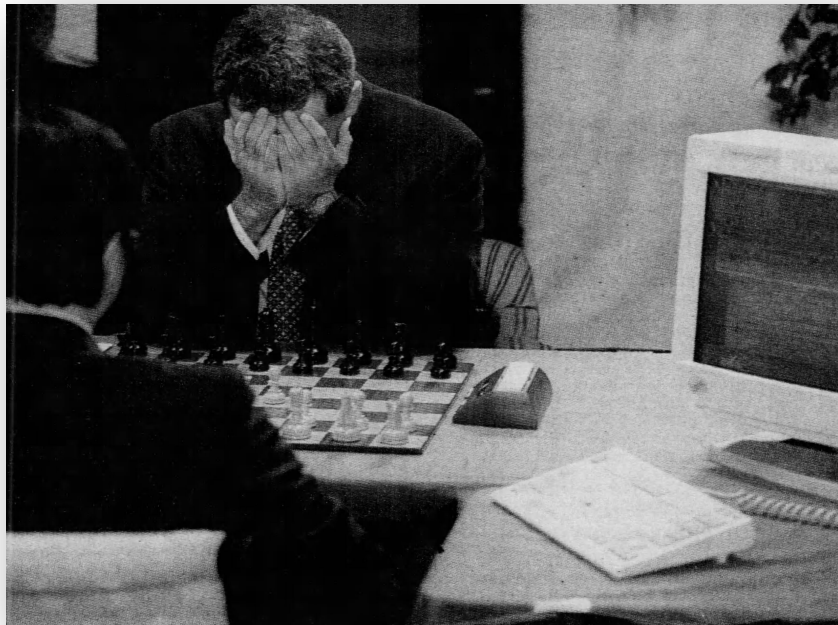


Trenchard More



HISTORY OF ARTIFICIAL INTELLIGENCE

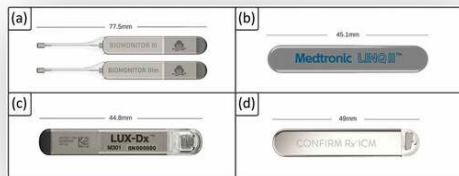
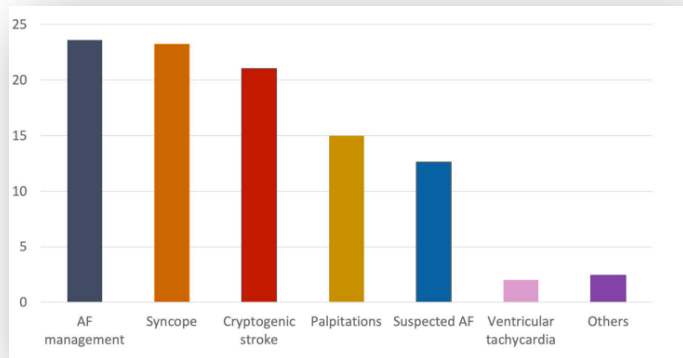




Deep Blue - 1997



Loop Recorders



Indication for ILR implant in patients with unexplained syncope occurrence or undocumented palpitations

Class I

1. In an early phase of evaluation of patients with recurrent syncope of uncertain origin who have:
 - absence of high-risk criteria that require immediate hospitalization or intensive evaluation; (**Level of evidence A**)
 - a likely recurrence within battery longevity of the device (**Level of evidence A**)
2. In high-risk patients in whom a complete evaluation did not demonstrate a cause of syncope or lead to specific treatment (**Level of evidence A**)

Class II A

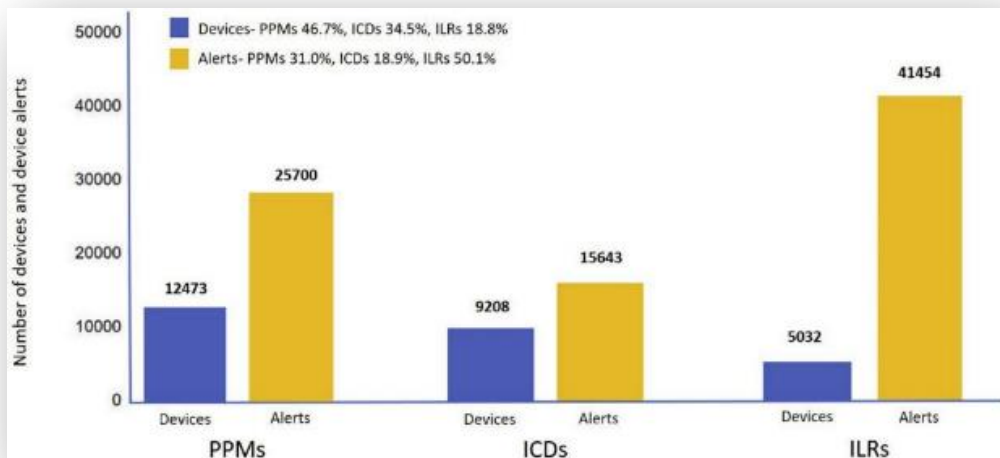
1. To assess the contribution of bradycardia in patients with suspected or certain neurally mediated syncope presenting with frequent or traumatic syncopal episodes, before starting with cardiac pacing (**Level of evidence B**)
2. ILRs may be indicated in selected cases with severe infrequent symptoms when other ECG monitoring systems fail to document the underlying cause (**Level of evidence B**)

Class II B

- In patients with Transient loss of consciousness of uncertain syncopal origin in order to definitely exclude an arrhythmic mechanism (**Level of evidence C**)



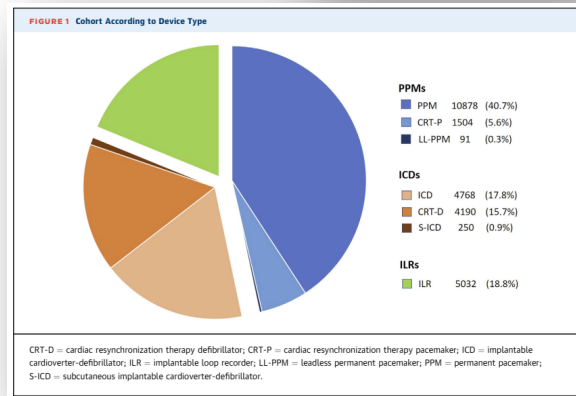
Remote Monitoring Alert Burden



Remote Monitoring Alert Burden

An Analysis of Transmission in >26,000 Patients

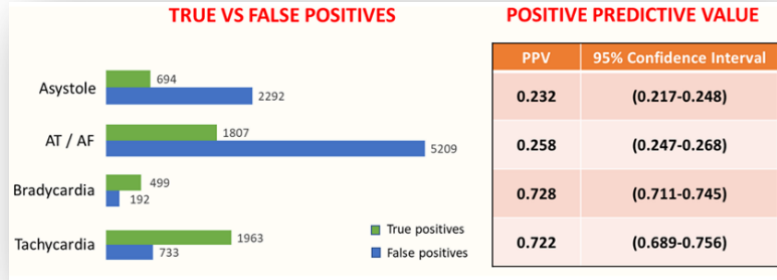
Catherine J. O'Brien, MBS, PhD^{1,2}; Melissa E. Middendorf, PhD^{1,2}; James H. Brundage, PhD^{1,2}; Anthony G. Brooks, PhD^{1,2}; Dennis H. Lau, MBS, PhD^{1,2}; Roberto M. Lazzari, MD^{1,2}; Ricardo M. Lazzari, MD^{1,2}; David Thompson, MBS^{1,2}; Suzanne Englehardt, MD^{1,2}; Jason C. Lippman, MD^{1,2}; Ross Yarns, MD, PhD^{1,2}; Scott Campbell, MD^{1,2}; Production Leaders, MBS, PhD^{1,2}



- ILRs representing **19%** of all patients in device clinics, but accounted for **50%** of the transmitted alerts generated;
- **47.3%** of all transmitted ILR alerts as false positives;
- patient-activated symptom alerts are common (12% of all ILR recordings), the majority (**54%**) of which have been shown to correspond with normal sinus rhythm;



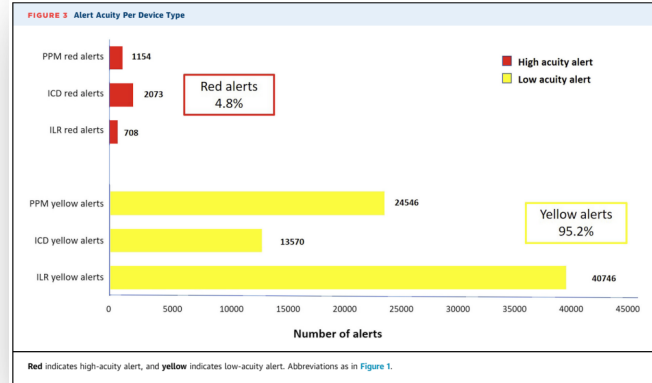
Remote Monitoring Alert Burden



AT/AF alerts

74.2% false-positive

- 90.2% frequent ectopy
- 9.4% noise/artifact
- 0.2% oversensing
- 0.2% undetermined



Asystole alerts

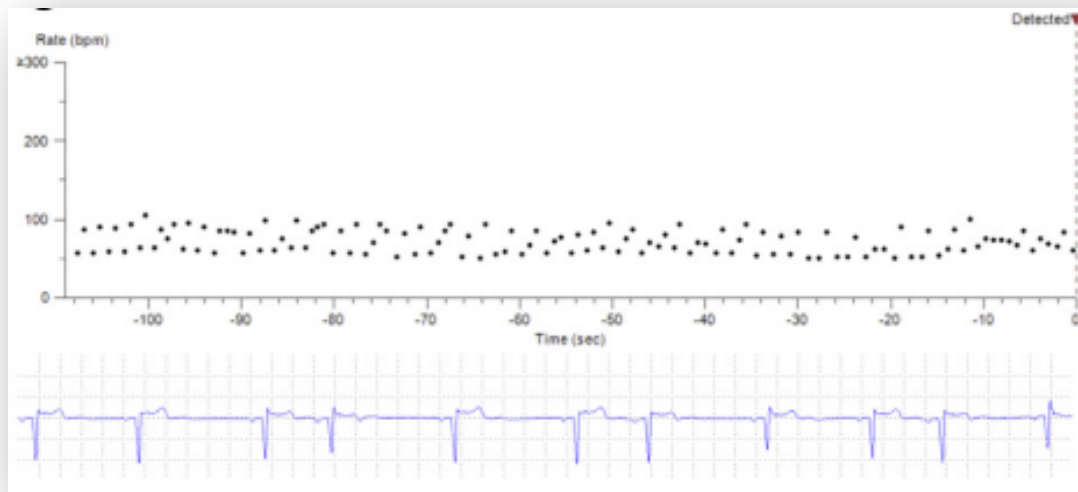
76.8% false-positive

- 100% undersensing

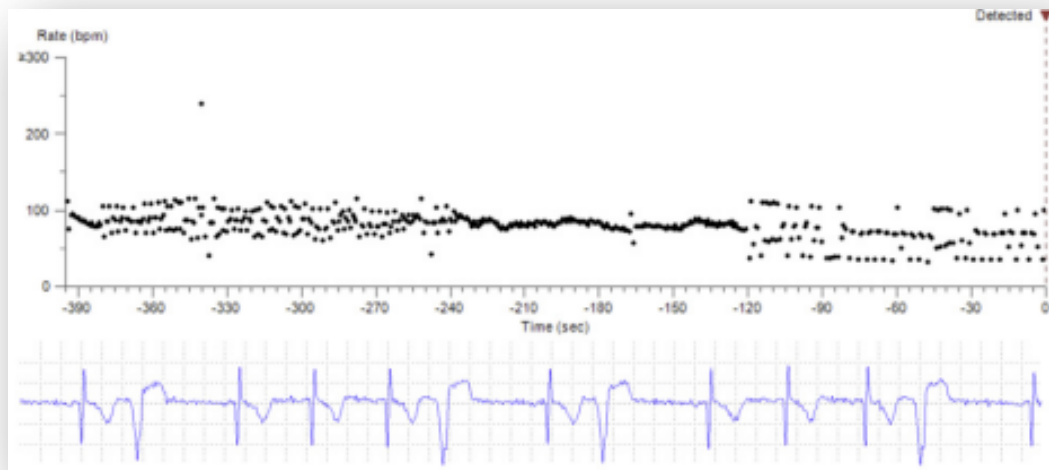
Indeed, **55.6%** of patients transmitted at least 1 false-positive alert.



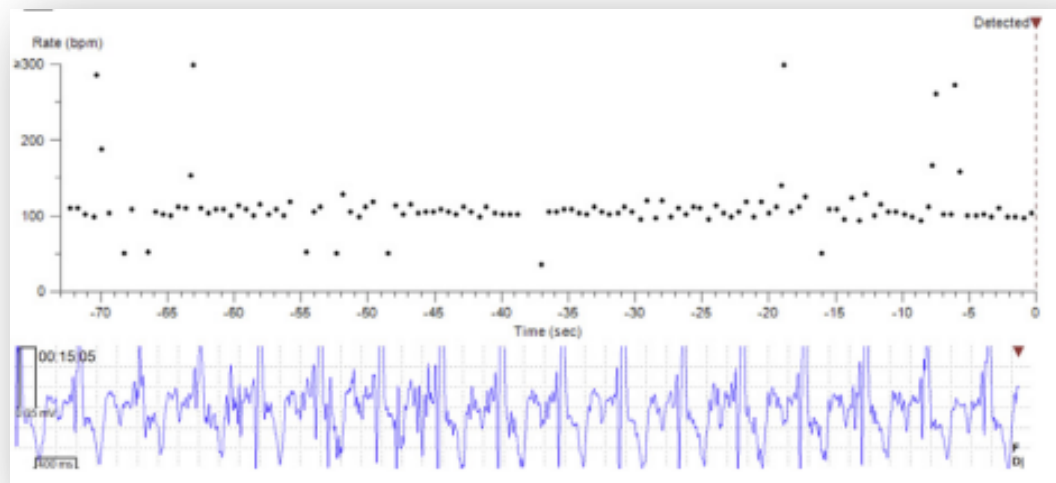
False positive



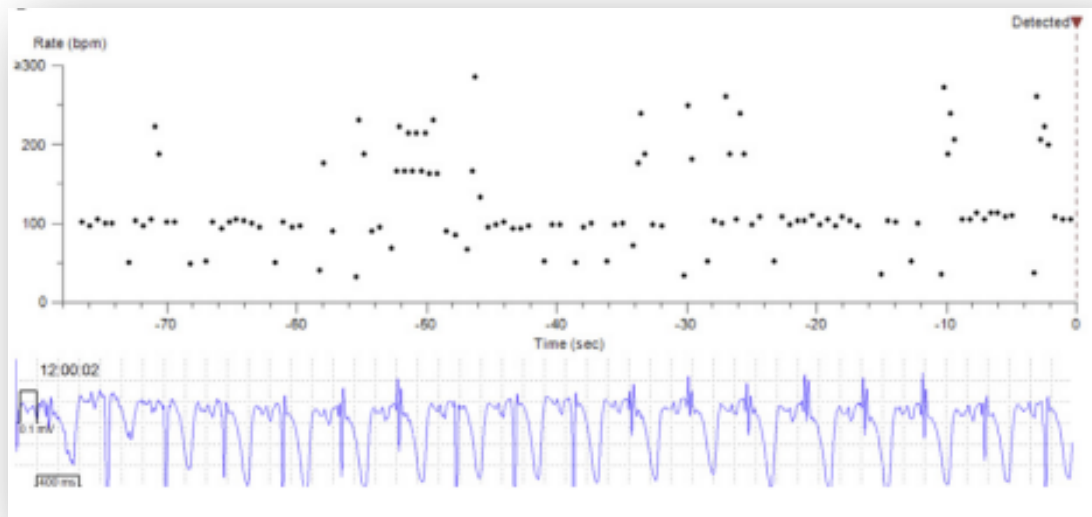
False positive



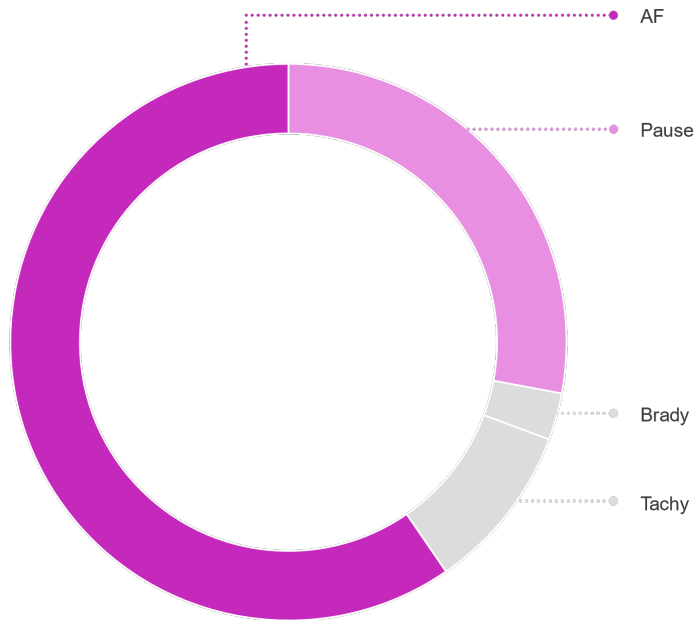
False positive



False positive



Remote Monitoring Alert Burden



AF and Pause generate the highest review burden
~90% of false alerts in the ICM space



Staff time per remote transmission

Table 1. Mean cumulative staff time required per remote transmission review and in-person clinic visit.

Workflow activity	United States				Europe			
	PM ^a	ICD ^b	CRT ^c	ICM ^d	PM	ICD	CRT	ICM
Remote device transmission review								
Staff time per average transmission ^e , minutes	13.5	12.7	11.9	12.9	9.4	11.6	12.4	11.3
Number of transmissions per year (both scheduled and unscheduled transmissions) ^f	3.7	4.6	5.1	38.9	3.6	5.1	5.9	35.6
Annual staff time for remote transmissions per patient, hours	0.8	1.0	1.2	8.4	0.6	1.0	1.2	6.7
In-person clinic visits								
Staff time per visit, minutes	50.1	51.0	43.4	45.8	41.2	37.8	40.9	39.9
Number of visits per year (both routine and event-driven visits)	1.5	1.7	1.7	1.3	1.5	1.7	1.7	1.3
Annual staff time for clinic visits per patient, hours	1.3	1.4	1.2	1.0	1.0	1.1	1.1	1.0
Total annual per patient staff time, hours	2.1	2.4	2.4	9.3	1.6	2.0	2.4	7.7

- 11 participating clinics (6 US - 5 Europe) managing an average of 5758 patients;
- The mean time per remote and in-person device checks was calculated, including ***all clinical tasks and any administrative tasks related to that device check (eg, software access, documentation, scheduling follow-up, and sending information for billing)***;
- It was assumed that **27%** of transmissions would be actionable;
- **8.2%** of transmissions would be sent for second-line review;

In-person Clinic Visit Activities	Remote Transmission Review Activities
Diagnostic tasks:	Diagnostic tasks:
Take vitals and history	Initial review of transmission
Device Interrogation	Advanced Practitioner reviews transmission
Manual Threshold test/sensing	Review report for follow-up action
Initial results review	Medical actions taken:
Advanced Practitioner Consultation and review	Communication to patient care team
Review Advanced Practitioner report for follow-up action	Contact patient regarding alert received
Medical actions taken:	Implement care change (e.g. change medication, order tests, etc.) as follow-up to remote transmission
Re-Program device therapy in-person	Administrative, documentation, and logistical tasks:
Reprogram device alerts in-person	Access patient file on EHR
Discuss results with the patient	Verify transmissions transferred from PaceArt
Change in care (e.g. change medication, order tests, etc.) as follow-up to visit	Open transmission
Administrative and logistical tasks:	Add notation/comments
Access patient file on EHR	Send transmissions to Advanced Practitioner
Bring programmer into the exam room	Sign off transmissions
Add notation/ comments to EHR	Finalize report

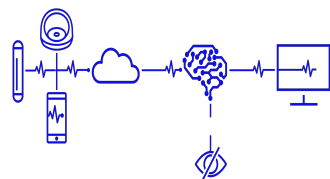


- **Automated arrhythmia detection algorithms**, particularly for AF episodes (i.e. R-R interval variability adding P wave detection with adaptive AF detection sensitivity, adaptive algorithms assessing QRS morphology, noise discrimination and pattern detection, and 3 R-wave sensing anomaly identifiers to exclude T- or P-wave oversensing or R-wave undersensing);
- **Customized programming and remote reprogramming** of ILRSs reduced the median number of alerts per day, without the need for an in-person clinic visit. ILR alerts be programmed tailored to clinical indications and reprogramming be performed if there is oversensing or undersensing





The Secret Behind Companies That Truly Do AI



Cloud-based AI filters

The AI algorithm development in 3 steps:

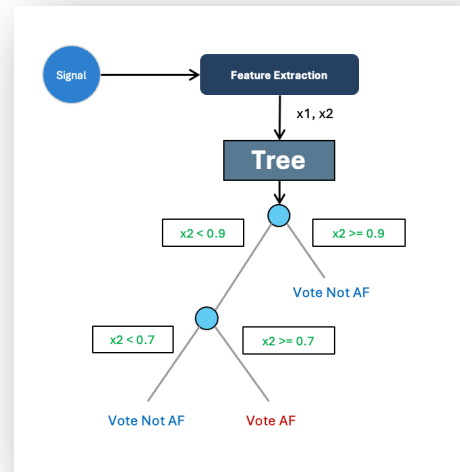
1. Data collection



2. Training phase



3. Test phase



Sensitivity is prioritized to avoid missed arrhythmias at the expense of increased FPs





AccuRhythm™ AI



Assert-IQ™ ICM



SmartECG

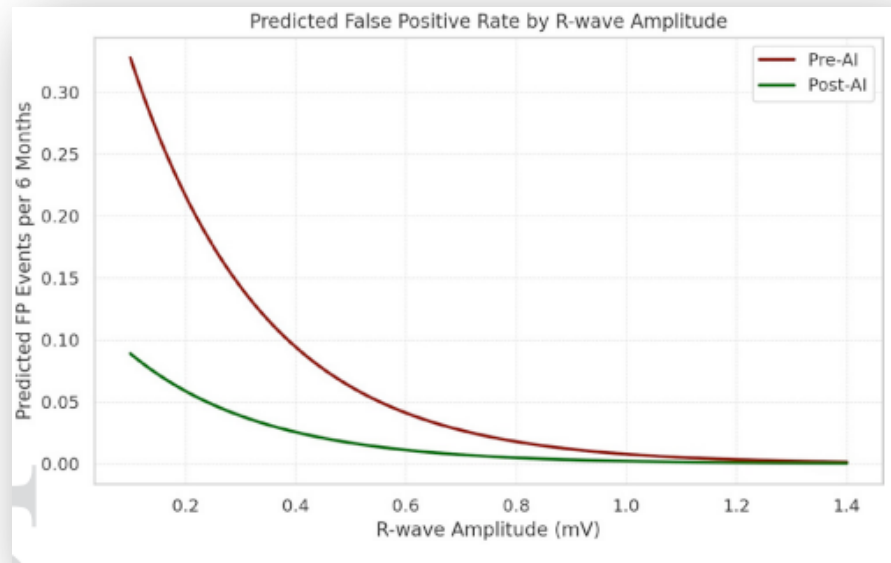


LUX-Dx II+™



- **R wave sensing**, it does not remain constant over time. Its changes can be influenced by:

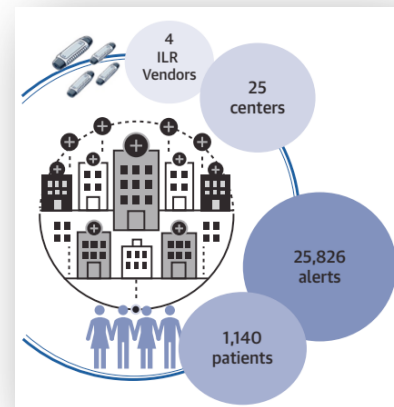
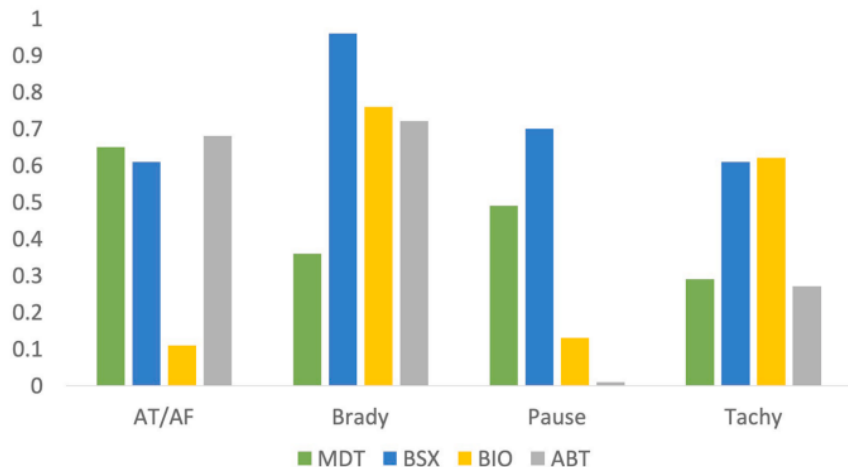
- sex;
- posture;
- physical activity;
- device orientation;
- increased body mass index;
- position of the ILR;



- **P wave sensing**;



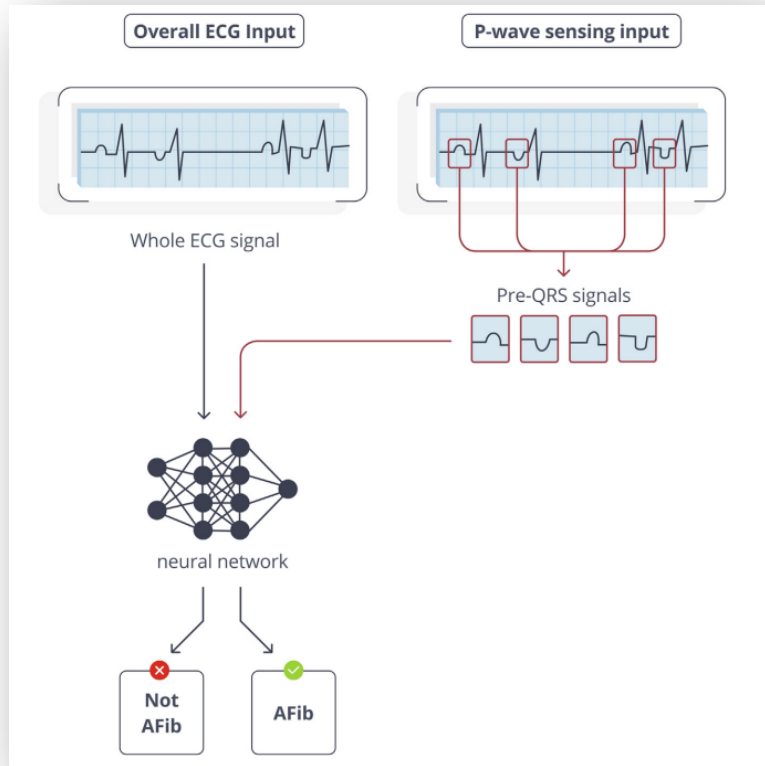
FIGURE 4 Positive Predictive Values Across Different Arrhythmia Episodes and Device Types



1. LINQ II with AccuRhythm AI (MDT)
2. Confirm Rx with SharpSense Technology (ABT)
3. Biomonitor III with RhythmCheck (BIO)
4. LUX-Dx with Dual-Stage Algorithm (BSX)

The primary findings demonstrate that nearly one half of all transmitted alerts (**49.7%**) were false positives.





PRE-AI

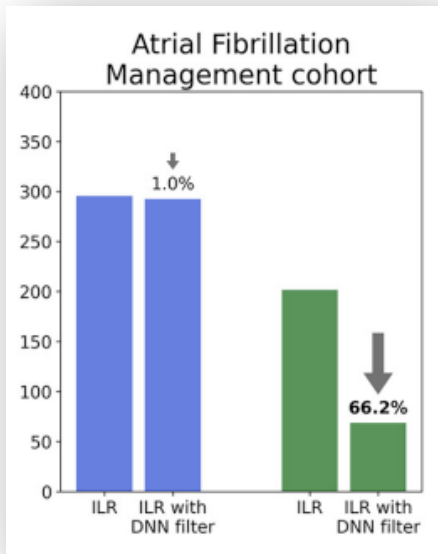
- RR intervals (every 2 min);
- P-wave evidence algorithm (P-Sense);
- adaptive P-sense score;

DNN FILTER FOR AF DETECTION

- QRS complex detector;
- AF detector (whole ECG signal and 500-ms window preceding all QRS onset);

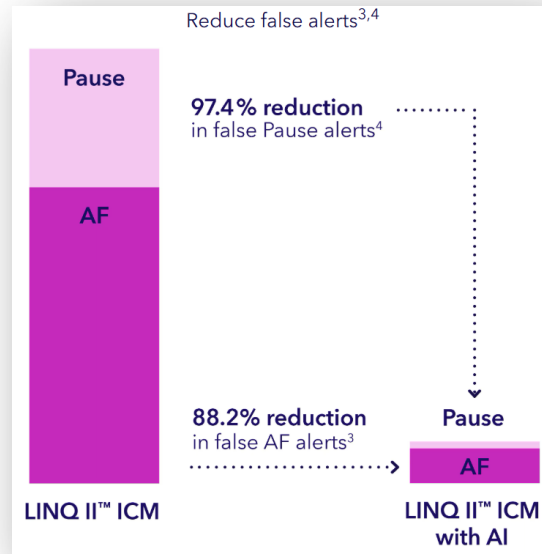


AccuRhythm AI AF – V1 2021

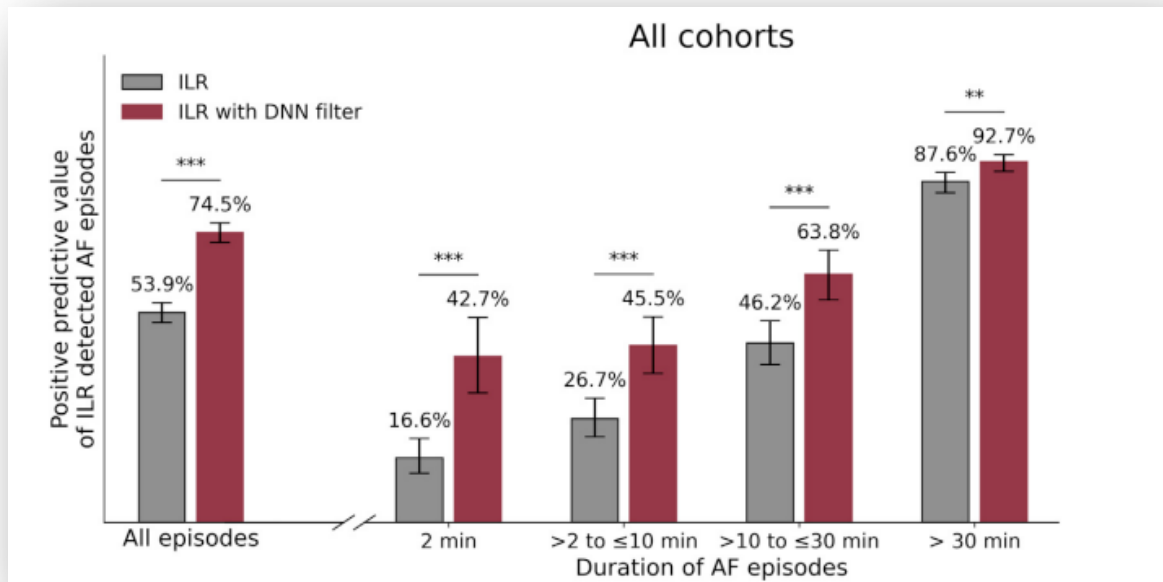


doi: [10.1016/j.jacep.2020.12.006](https://doi.org/10.1016/j.jacep.2020.12.006)

AccuRhythm AI AF – V2 2023

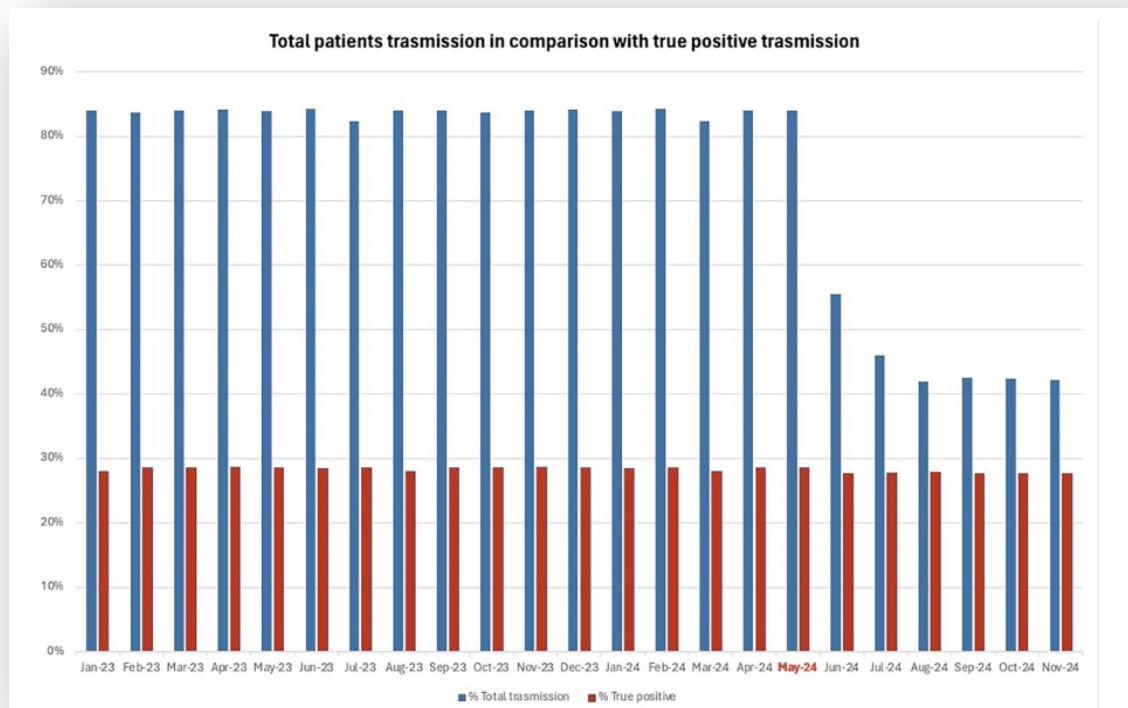


doi: [10.1016/j.hrthm.2023.03.1049](https://doi.org/10.1016/j.hrthm.2023.03.1049)



- **1%** of true AF episodes were «missed»;
- in **50%** of patients, AF was recognized the same month, in the other half, AF was missed altogether;
- the duration of «missed» AF in 50% of patients **ranged only from 2 to 12 min**;

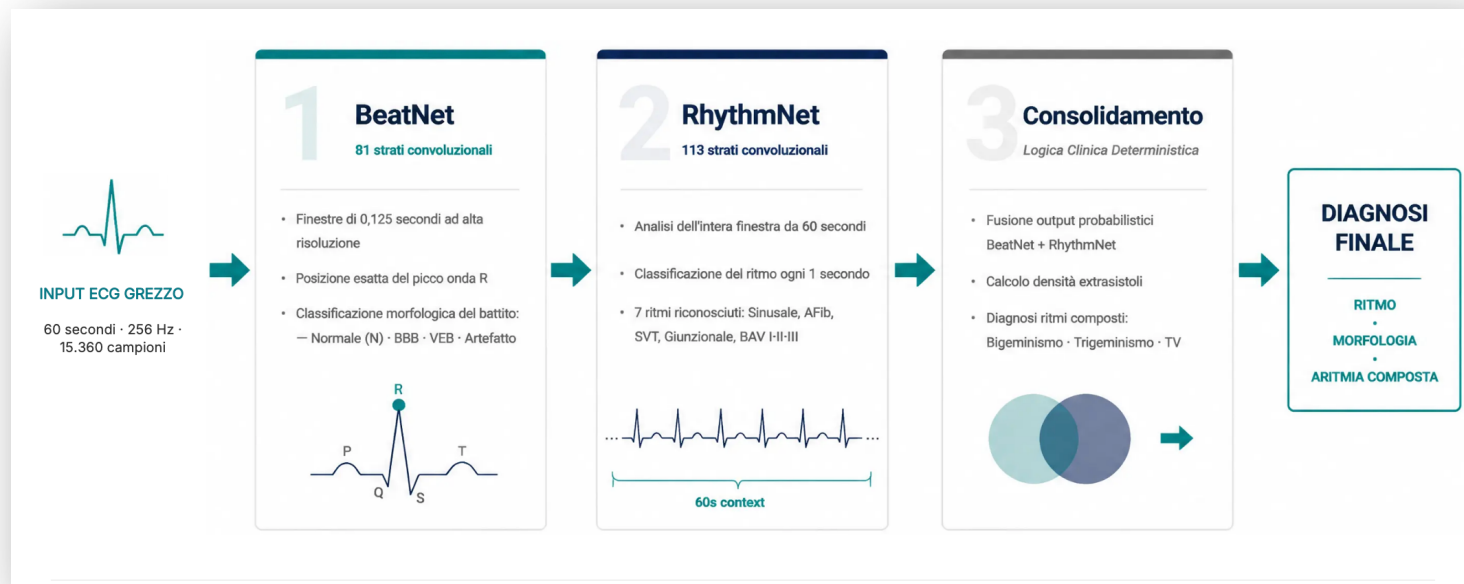




Comparison of total patients with transmissions and patients with true positive transmissions before and after AccuRhythm AI implementation in the Reveal LINQ cohort.



BeatNet e RhythmNet



Medtronic

AccuRhythm™ AI algorithms



AccuRhythm™ AI AF & Pause algorithms for the LINQ™ Family of Insertable Cardiac Monitors (ICMs)
Real-World Results for:

Ospedale SS Annunziata Sassari

Enrolled LINQ II patients: 319

Date range: 25-05-2022 - 31-05-2026

Enrolled Reveal LINQ patients: 153

Date range: 29-05-2024 - 31-05-2026

Alert reduction



Time savings

1093

Estimated hours saved during data range¹

343

Projected hours saved per year

22

Approximate % of FTE²

AccuRhythm™ AI

Clinic efficiency results from AccuRhythm AI during data range²:

- False AF Alerts eliminated by AI = 2495
- False Pause Alerts eliminated by AI = 3311
- Total (AF + Pause) False Alerts eliminated by AI = 5806

- 472 Patients with LINQ and CareLink
- **False AF Alert** eliminated by AI= 2495
- **False Pause Alert** eliminated by AI = 3311

Alert eliminated by AI = 5806

(5806 x 11.3 min):60 min) = 1093 h saved



TAKE-HOME-MESSAGES

- Implantable loop recorders generate a large volume of clinical data.
- Artificial intelligence improves the accuracy of event classification.
- It helps reduce the clinical workload.
- Ongoing advances in AI may enable increasingly sophisticated predictive models.
- The clinician remains the **final decision-maker**.



“Our future is a race between the growing power of technology and the wisdom with which we use it.”

Stephen Hawking

