

Diagnostica in Cardiologia dello Sport e nella Diagnosi delle Aritmie

Monitoraggio remoto delle aritmie: Ruolo del monitoraggio indossabile rispetto a quello impiantabile

Emanuela Teresina Locati, MD PhD

Arrhythmology & Electrophysiology Department

IRCCS Policlinico San Donato

Milan, ITALY



IRCCS

POLICLINICO SAN DONATO

*Conflict of Interest (COI):
Nothing to declare*



History of Remote Monitoring

2000



First application of BIOTRONIK Home Monitoring for technical feasibility studies

↓

2002



Global launch as only FDA & CE approved system for remote monitoring in pacemaker and ICD patients

↓

2003

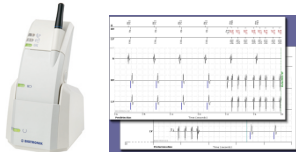


First internet-based Home Monitoring system

Internet based service center and world's first wireless and cellular transmitter for early detection

↓

2006



Bidirectional telemetry and IEGM-Online HD

Significant increase in data volume to enable remote device follow-up and transmit real-time online IEGMs

↓

2009



New system interface with **intelligent traffic light system** & **expanded FDA and CE Mark approvals** for replacement of in-clinic follow-ups and early detection

↓

2012



12+ years of experience in Home Monitoring

New unique diagnostic options for advanced heart failure under clinical investigation

Indications for the use of diagnostic implantable and external ECG loop recorders

Task Force members: Michele Brignole (Chairperson), Lavagna, Italy; Panos Vardas (Co-chairperson), Herakleion, Greece; Ellen Hoffman, Munich, Germany; Heikki Huikuri, Oulu, Finland; Angel Moya, Barcelona, Spain; Renato Ricci, Rome, Italy; Neil Sulke, Eastbourne, UK; Wouter Wieling, Amsterdam, The Netherlands

EHRA Scientific Documents Committee: Angelo Auricchio (Chairperson), Lugano, Switzerland; Gregory Y.H. Lip, Birmingham, UK; Jesus Almendral, Madrid, Spain; Paulus Kirchhof, Muenster, Germany; Etienne Aliot, Nancy, France; Maurizio Gasparini, Milan, Italy; Frieder Braunschweig, Stockholm, Sweden

3. Atrial fibrillation: therapy guided by loop recorder observations

Key points

- There is a poor correlation of symptoms with atrial fibrillation (AF), especially after rhythm control therapy is started, which makes subjective evaluation of the effect of any therapy unreliable
- There are two main potential reasons for accurate arrhythmia monitoring: in clinical practice to determine the efficacy of rhythm control therapy; in rhythm control trials when freedom from AF is the outcome parameter
- Owing to the unpredictable nature of recurrences, AF is significantly underdetected by intermittent monitoring systems
- Continuous monitoring by implantable devices further increases the detection of AF, but it is hampered by misdetections and artefacts.
- Technological improvements are required for significant reduction of maldetection. Manual analysis can improve diagnostic yield if stored electrograms are provided. The results of some on-going studies with new generation devices are awaited
- The clinical relevance of Loop Recorders to guide medical and device therapy has yet to be demonstrated

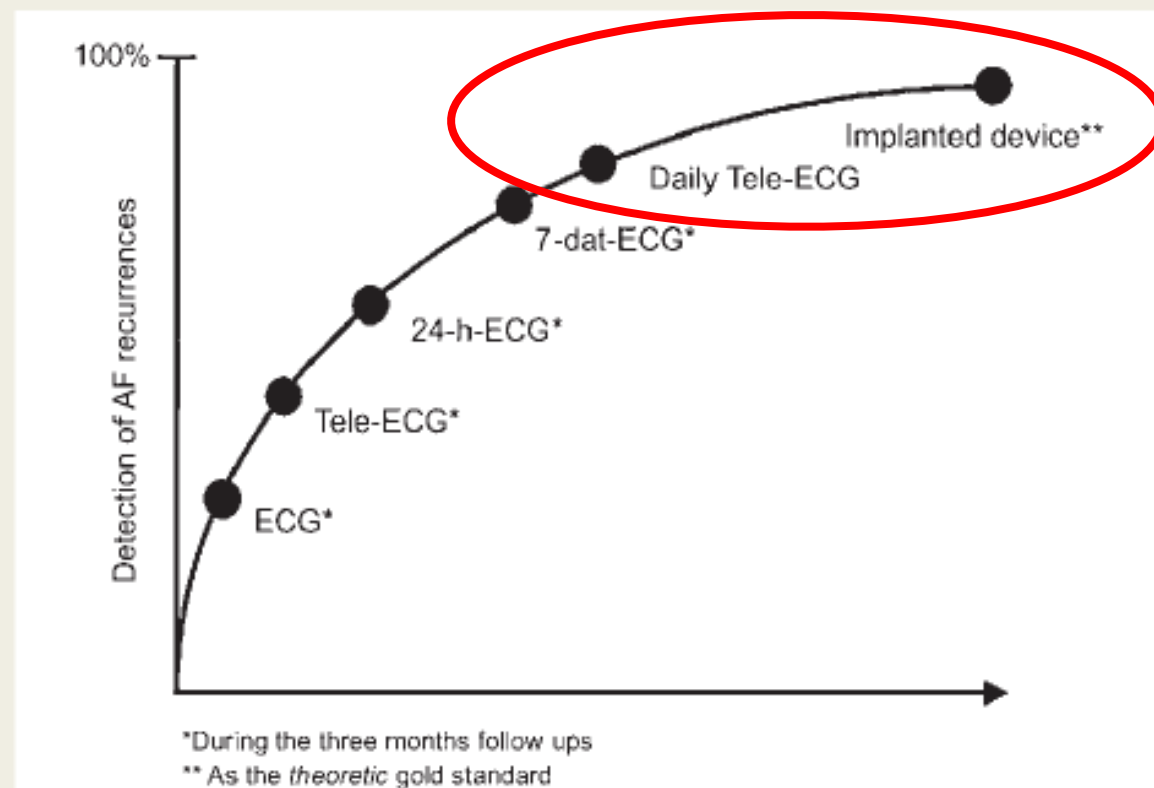


Figure 5 Estimated correlation between follow-up strategy and the rate of atrial fibrillation detection after RF ablation (from Arya⁷⁰).

2020 AF Guidelines: Screening Tools

2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS)

The Task Force for the diagnosis and management of atrial fibrillation of the European Society of Cardiology (ESC)

Developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC

Table 5 Sensitivity and specificity of various AF screening tools considering the 12-lead ECG as the gold standard¹⁷³

	Sensitivity	Specificity
Pulse taking ²⁰³	87–97%	70–81%
Automated BP monitors ^{204–207}	93–100%	86–92%
Single lead ECG ^{208–211}	94–98%	76–95%
Smartphone apps ^{188,189,191,195,212,213}	91.5–98.5%	91.4–100%
Watches ^{196,198,213,214}	97–99%	83–94%

AF = atrial fibrillation; BP = blood pressure; ECG = electrocardiogram.

© ESC 2020



Patient initiated (or medical professional) oscillometric blood pressure cuff



Pulse palpitation, auscultation



Patient initiated (or medical professional) intermittent ECG rhythm strip using smartphone or dedicated connectable device



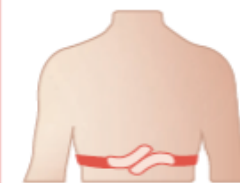
Patient initiated photoplethysmogram on smartphone



Semi-continuous photoplethysmogram on a smartwatch or wearable



Intermittent smartwatch ECG initiated by semi-continuous photoplethysmogram with prompt notification of irregular rhythm or symptoms



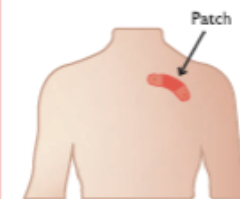
Wearable belts for continuous recordings



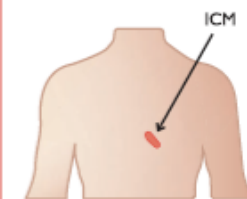
Stroke unit/in hospital telemetry monitoring



Long-term Holter



1–2 week continuous ECG patches



Implantable cardiac monitors

Use of an implantable loop recorder to increase the diagnostic yield in unexplained syncope: results from the PICTURE registry

Nils Edvardsson^{1*}, Viveka Frykman², Rob van Mechelen³, Peter Mitro⁴, Afsaneh Mohii-Oskarsson⁵, Jean-Luc Pasquié⁶, Hemanth Ramanna⁷, Frank Schwertfeger⁸, Rodolfo Ventura⁹, Despina Voulgaraki¹⁰, Claudio Garutti¹⁰, Pelle Stolt¹¹, and Nicholas J. Linker¹² on behalf of the PICTURE Study Investigators[†]

¹Division of Cardiology, Sahlgrenska Academy at Sahlgrenska University Hospital, S-413 45 Göteborg, Sweden; ²Department of Cardiology, Karolinska Institute Danderyd Hospital, Stockholm, Sweden; ³Division of Cardiology, St Franciscus Geesthuis, Rotterdam, The Netherlands; ⁴Julius Pasteur University Hospital, Kocira, Slovak Republic; ⁵Department of Medicine, St. Vincent's Hospital, Melbourne, Australia; ⁶Department of Cardiology, St. Vincent's Hospital, Melbourne, Australia; ⁷Department of Cardiology, St. Vincent's Hospital, Melbourne, Australia; ⁸Department of Cardiology, St. Vincent's Hospital, Melbourne, Australia; ⁹Department of Cardiology, St. Vincent's Hospital, Melbourne, Australia; ¹⁰Department of Cardiology, St. Vincent's Hospital, Melbourne, Australia; ¹¹Department of Cardiology, St. Vincent's Hospital, Melbourne, Australia; ¹²Department of Cardiology, St. Vincent's Hospital, Melbourne, Australia

Approx. 45-50% of patients diagnosed within 3 years

Approx. 25-30% of patients diagnosed within 90 days

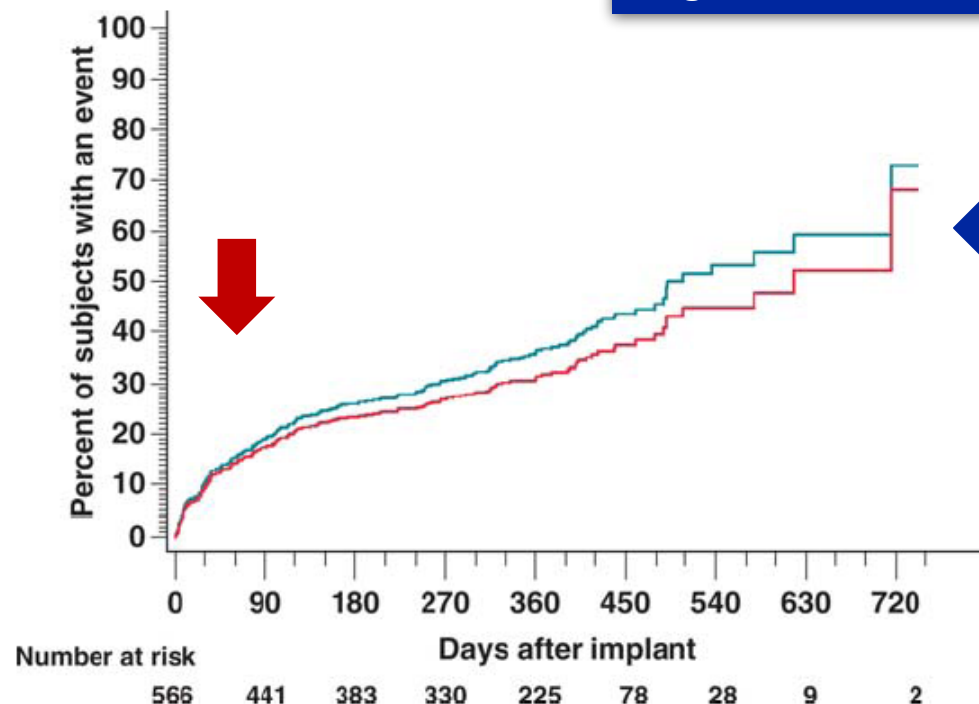


Figure 2 The Kaplan–Meier estimates of time to syncopal episode (green line) and time to syncopal episode where Reveal played a role in the diagnosis (red line).

Screening for Silent PAF

The longer you monitor, the more you find!

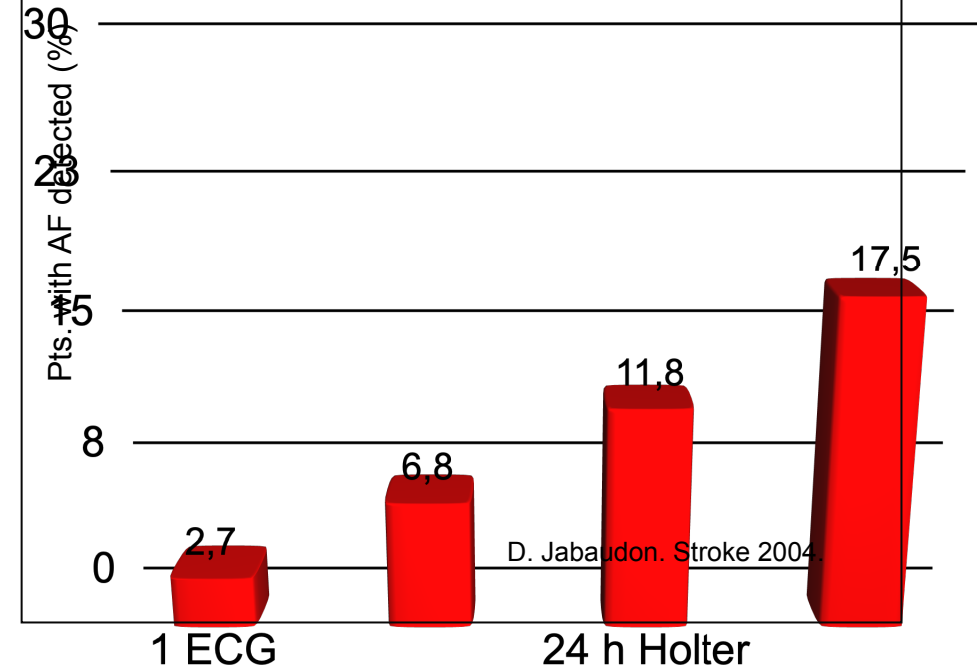
- **Symptoms?**
 - Does not correlate with AF (SOPAT study – Patten, JCE 2006)
 - 54% of AF-ECGs were asymptomatic
 - AF was only diagnosed in 37% of the symptom-triggered ECGs

M. Patten. JCE 2006.

- **30 Day Event Monitors**
 - A retrospective and a prospective study of cryptogenic stroke patients
 - 30 days of monitoring
 - Newly diagnosed AF in 20% of patients

Stroke 2008; 39, No 2: 571 and 584

More intensive monitoring results in more AF detection after stroke/TIA



CRYSTAL AF: ILR (Reveal XT, MDT) detected AF in patients with cryptogenic stroke

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Cryptogenic Stroke and Underlying Atrial Fibrillation

Tommaso Sanna, M.D., Hans-Christoph Diener, M.D., Ph.D.,
Rod S. Passman, M.D., M.S.C.E., Vincenzo Di Lazzaro, M.D.,
Richard A. Bernstein, M.D., Ph.D., Carlos A. Morillo, M.D.,
Marilyn Mollman Rymer, M.D., Vincent Thijs, M.D., Ph.D.,
Tyson Rogers, M.S., Frank Beckers, Ph.D., Kate Lindborg, Ph.D.,
and Johannes Brachmann, M.D., for the CRYSTAL AF Investigators*

ABSTRACT

Primary endpoint
was detection of AF
(>30 seconds)
within 6 mos of
randomization.

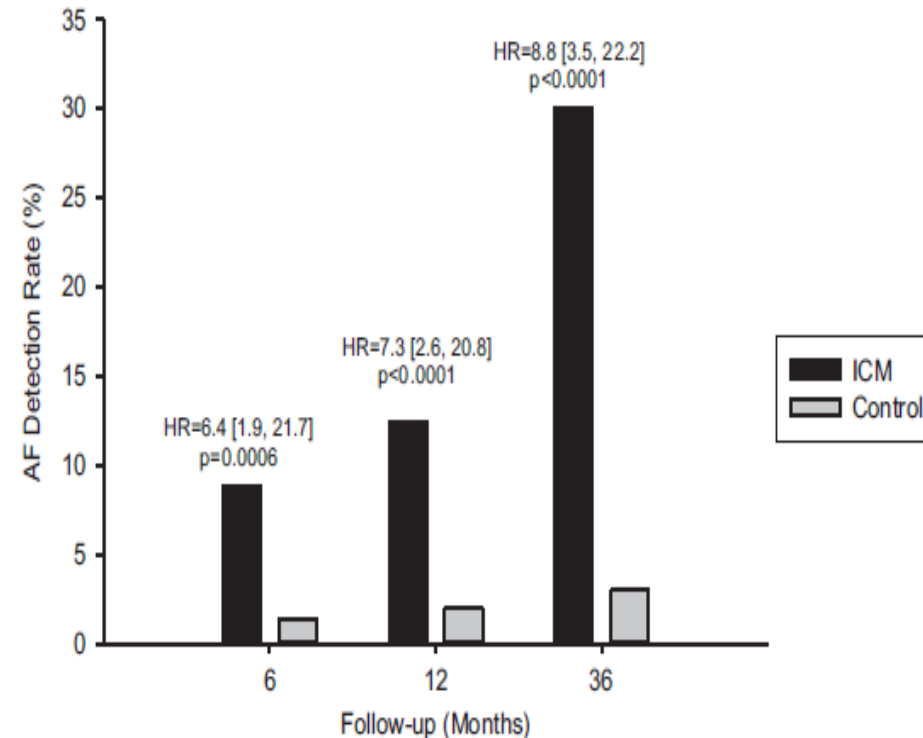
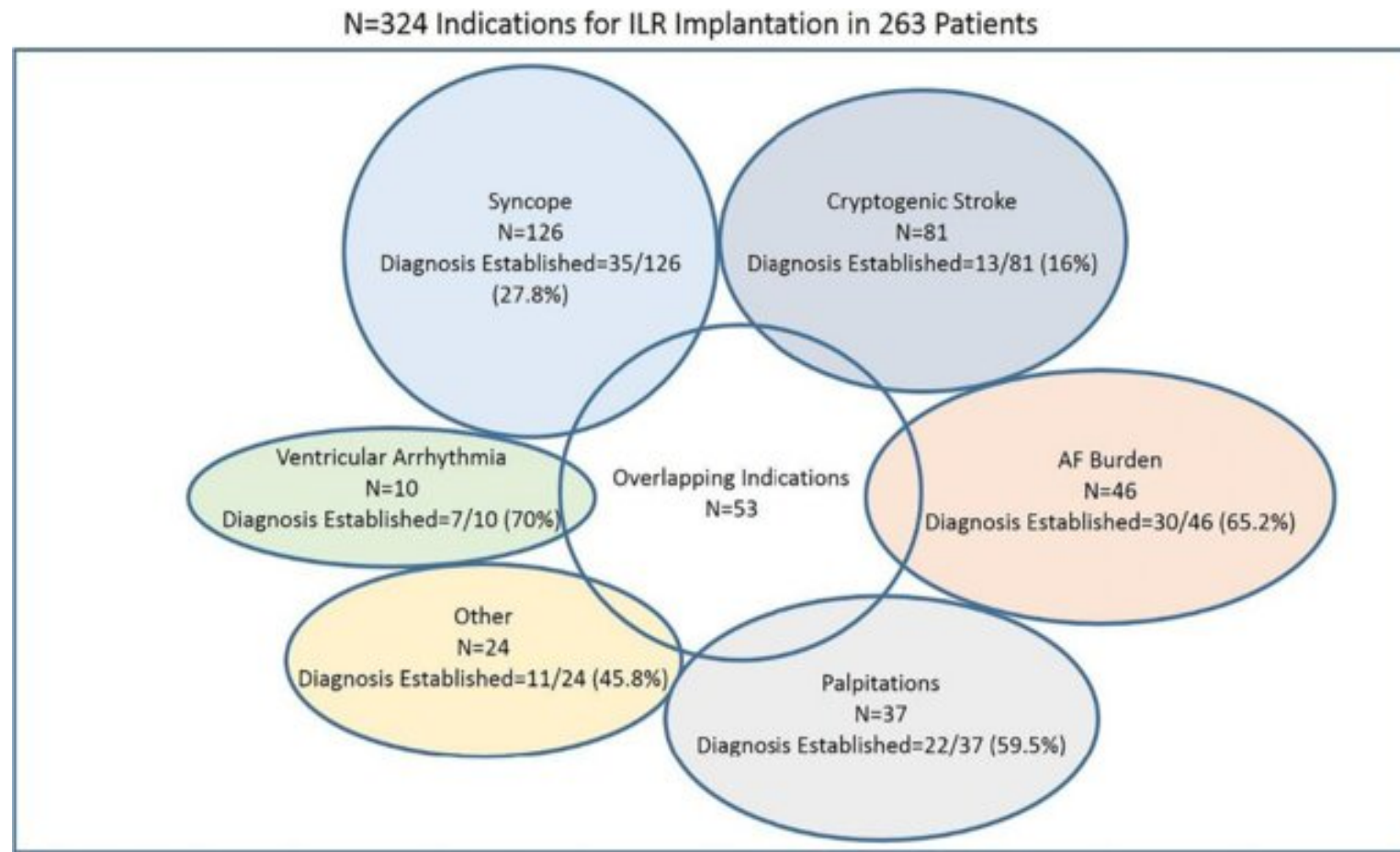


Figure 1 Atrial fibrillation (AF) detection rates for insertable cardiac monitor (ICM) and control arms in the CRYSTAL AF study¹¹ 6, 12, and 36 months after cryptogenic stroke. HR = hazard ratio.

The diagnostic yield of implantable loop recorders stratified by indication: “real-world” use in a large academic hospital

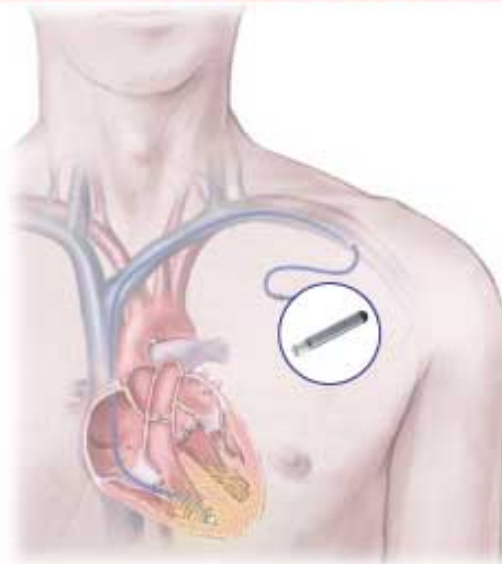


Smith A, et al. Journal of Interventional Cardiac Electrophysiology, 2021

Implantable Loop Recorders Market

Implantable Loop Recorders Market (Product: Manual and Automatic; Indication: Cardiovascular Syncope, Fibrillation, Bundle Branch Block, and Others; and End User: Hospitals, Cardiac Centers & Clinics, and Analysis, Size, Share, Growth, Trends, and Forecast, 2019 - 2027)

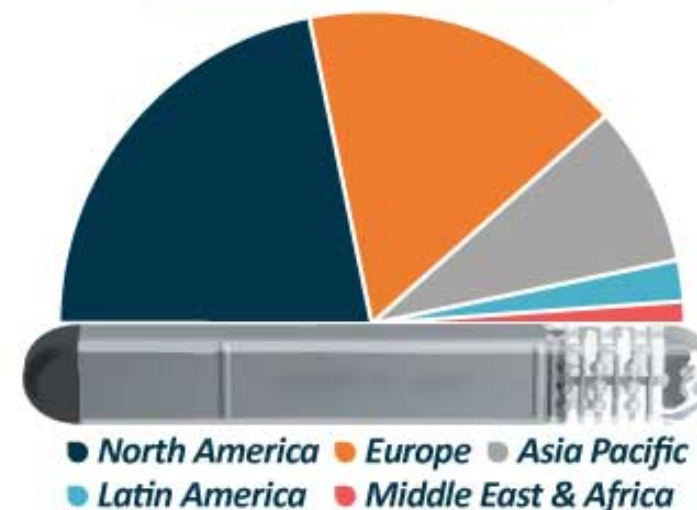
Implantable Loop Recorders Market: 2019-2027



Indication



Market by Region, 2019



7% CAGR (2019-2027)

Market Value 2027 **US\$ 1.65 Bn**

Key Market Findings

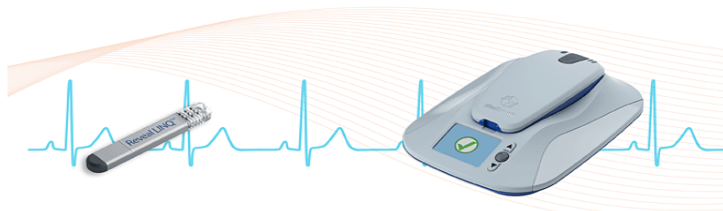
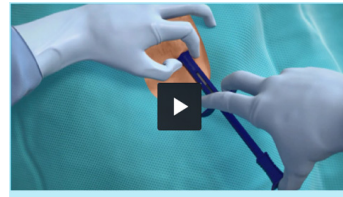


Integration of Accurate Algorithms and Advancements in Remote Monitoring to Drive Market



Companies Launch 'Smart' Implantable Loop Recorders

Insertable Loop Recorders (ILR) → Implantable Cardiac Monitors (ICM)



Reveal LINQ®
Medtronic

BioMonitor 3
Biotronik®



Confirm RX
Abbott®



2023 HRS/EHRA/APHRS/LAHS expert consensus statement on practical management of the remote device clinic @

Aileen M. Ferrick, PhD, ACNP, RN, FHRS (Co-Chair),^{1,*}
Satish R. Raj, MD, MSCI, FHRS (Co-Chair),^{2,*}
Thomas Deneke, MD, PhD, FHRS (EHRA Vice-Chair),^{3,†}
Pipin Kojodjojo, MBBS, PhD, FHRS (APHRS Vice-Chair),^{4,‡}
Nestor Lopez-Cabanillas, MD (LAHS Vice-Chair),^{5,§} Haruhiko Abe, MD, PhD,^{6,‡}
Serge Boveda, MD, PhD, FEHRA, FESC,^{7,†} Derek S. Chew, MD, MSc, FHRS,^{2,*}
Jong-Il Choi, MD, PhD, MHS,^{8,‡} Nikolaos Dagres, MD,^{9,†}
Aarti S. Dalal, DO, FACC, FHRS, CEPS-P,^{10,¶} Brynn E. Dechert, APN, FHRS, CCDS,^{11,¶}
Camille G. Frazier-Mills, MD, MHS, CCDS,^{12,*} Olivia Gilbert, MD, MSc, FACC,^{13,#}
Janet K. Han, MD, FACC, FHRS,^{14,**} Sherri Hewit, PharmD,^{††}
Christine Kneeland, BSN,^{15,*} Starr DeEllen Mirza,^{††} Suneet Mittal, MD, FHRS,^{16,*}
Renato Pietro Ricci, MD,^{17,†} Mary Runte, PhD,^{18,††} Susan Sinclair, NZCS, PGDHSc,^{19,‡}
Ricardo Alkmim-Teixeira, MD, PhD,^{20,§} Bert Vandenberg, MD, PhD,^{2,21,†}
Niraj Varma, MA, MD, PhD^{22,‡‡}

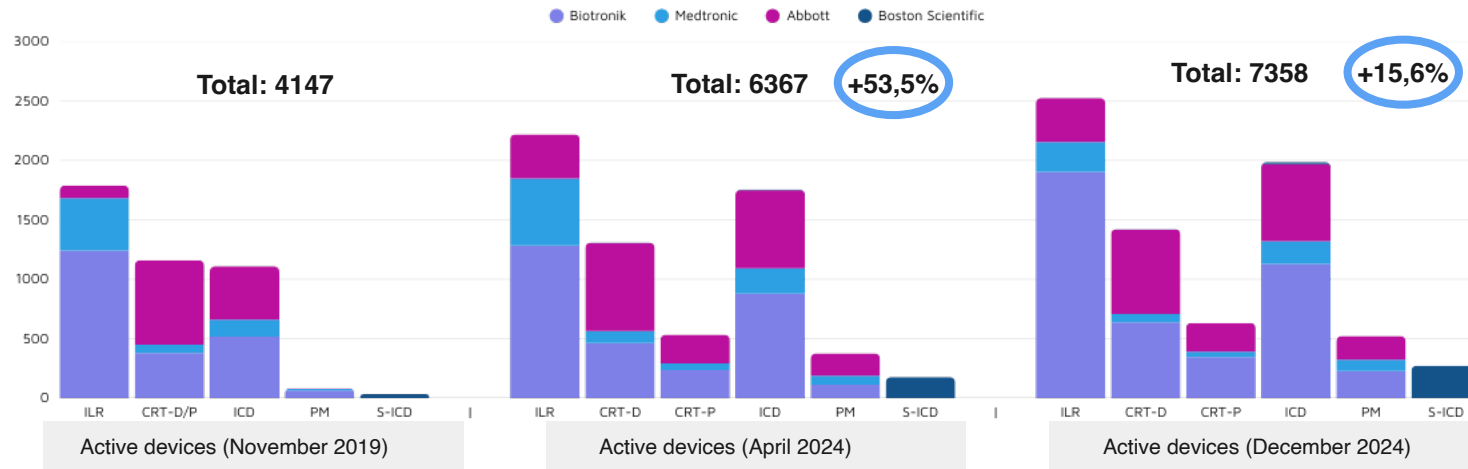
2023 Recommendations for Patient Enrollment Techniques

Recommendations for patient enrollment techniques

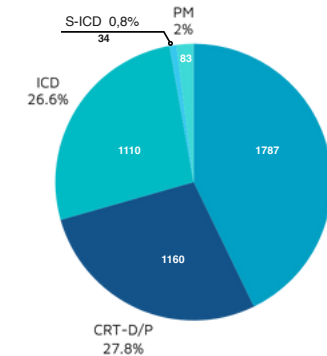
COR	LOE	Recommendations	References
1	C-EO	1. In patients with an ILR, enrollment in an RM program is recommended prior to discharge given the daily availability of diagnostic data.	
2a	B-NR	2. In patients with a CIED, it can be beneficial to initiate RM prior to discharge or within 2 weeks of CIED implantation.	97,98

REMOTE MONITORING - ARRHYTHMOLOGY DEPT – IRCCS POLICLINICO SAN DONATO

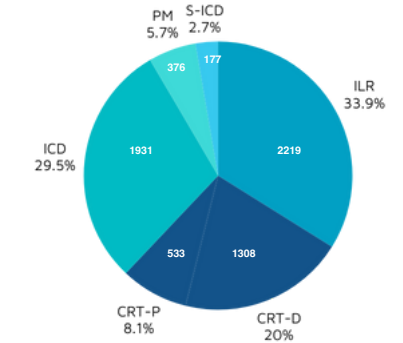
TOTAL 7358 ACTIVE PATIENTS WITH CIEDS (DECEMBER 2024)



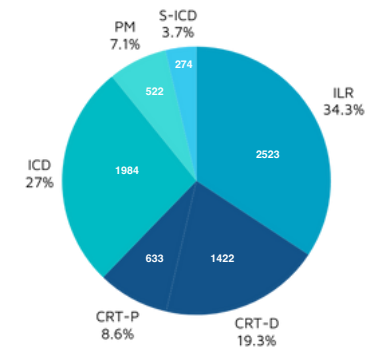
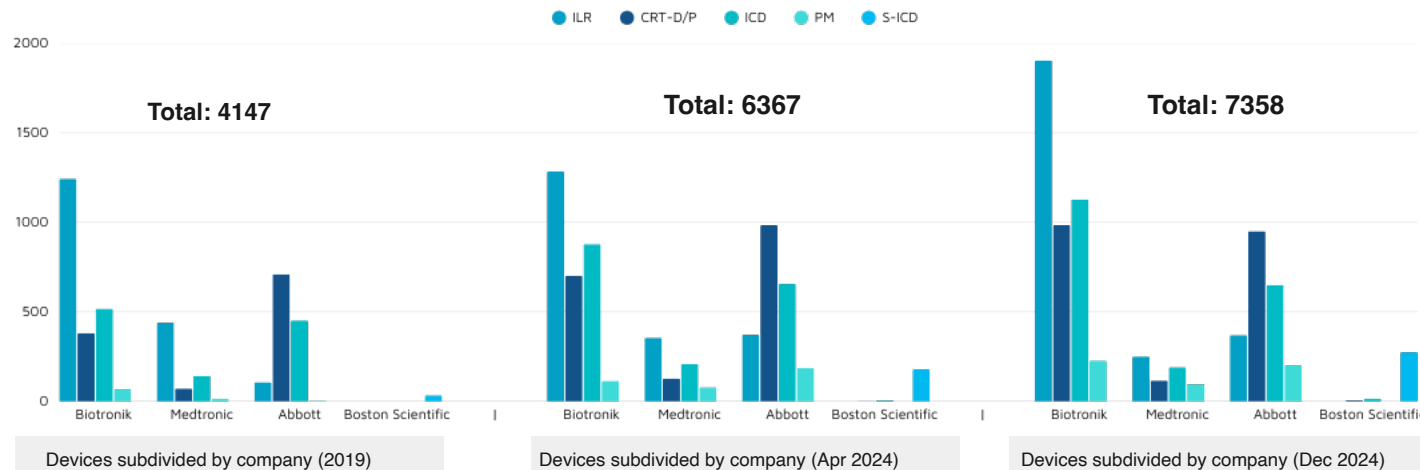
ILR: Implantable Loop Recorder
 CRT-D: Cardiac Resynchronization Therapy Defibrillators
 ICD: Implantable Cardioverter Defibrillator
 PM : Pacemaker
 CRT-P: Cardiac Resynchronization Therapy Pacemakers



Device typologies on the total (2019)



Device typologies on the total (Apr 2024)



Device typologies on the total (Dec 2024)



WHAT CIEDs ARE CAUSING THE HIGHER WORKLOAD?



ILR	3.85	CRT-P	1.36	CRT-D	5.90	ICD	0.96	PM	0.63	TOTAL BIOTRONIK	2.54
-----	------	-------	------	-------	------	-----	------	----	------	-----------------	------



ILR	5.87	CRT-P	1.35	CRT-D	2.58	ICD	1.18	PM	4.42	TOTAL ABBOTT	3.08
-----	------	-------	------	-------	------	-----	------	----	------	--------------	------



ILR	1.15	CRT-P	2.10	CRT-D	0.88	ICD	0.22	PM	0.32	TOTAL MEDTRONIC	0.93
-----	------	-------	------	-------	------	-----	------	----	------	-----------------	------

MEAN ILR	3.62	MEAN CRT-P	1.6	MEAN CRT-D	3.12	MEAN ICD	0.78	MEAN PM	1.79
----------	------	------------	-----	------------	------	----------	------	---------	------



Remote Monitoring Arrhythmology Dpt. San Donato Hospital
Approximately 300 Alarms per month requiring Physician's supervision (10% of all Alarms, 54% generated by ICM/ILR)

Conteggio

PM

1,8%

CRT-P

4,1%

CRT-D

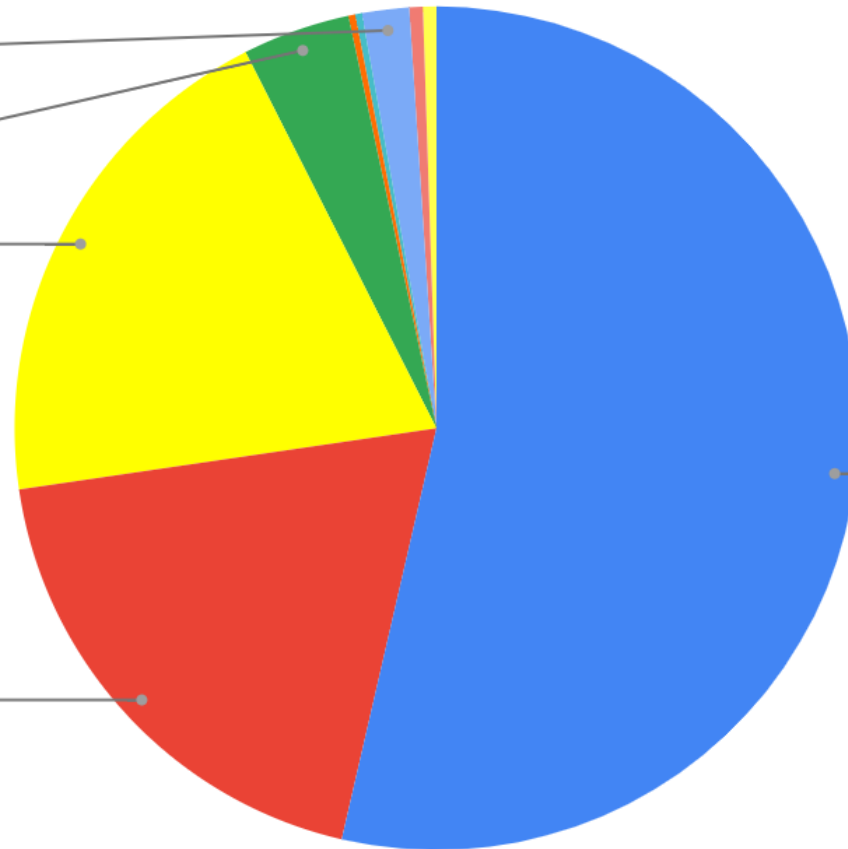
19,8%

ICD

19,1%

Loop Recorder

53,6%



2023 HRS/EHRA/APHRS/LAHRs expert consensus statement on practical management of the remote device clinic

Aileen M. Ferrick, PhD, ACNP, RN, FHRS (Co-Chair),^{1,*}
 Satish R. Raj, MD, MSCI, FHRS (Co-Chair),^{2,*}
 Thomas Deneke, MD, PhD, FHRS (EHRA Vice-Chair),^{3,†}
 Pipin Kojodjojo, MBBS, PhD, FHRS (APHRS Vice-Chair),^{4,‡}
 Nestor Lopez-Cabanillas, MD (LAHRs Vice-Chair),^{5,§} Haruhiko Abe, MD, PhD,^{6,‡}
 Serge Boveda, MD, PhD, FEHRA, FESC,^{7,†} Derek S. Chew, MD, MSc, FHRS,^{2,*}
 Jong-Il Choi, MD, PhD, MHS,^{8,‡} Nikolaos Dargatzis, MD,^{9,†}
 Aarti S. Dalal, DO, FACC, FHRS, CEPS-P,^{10,¶} Brynn E. Dechert, APN, FHRS, CCDS,^{11,¶}
 Camille G. Frazier-Mills, MD, MHS, CCDS,^{12,*} Olivia Gilbert, MD, MSc, FACC,^{13,#}

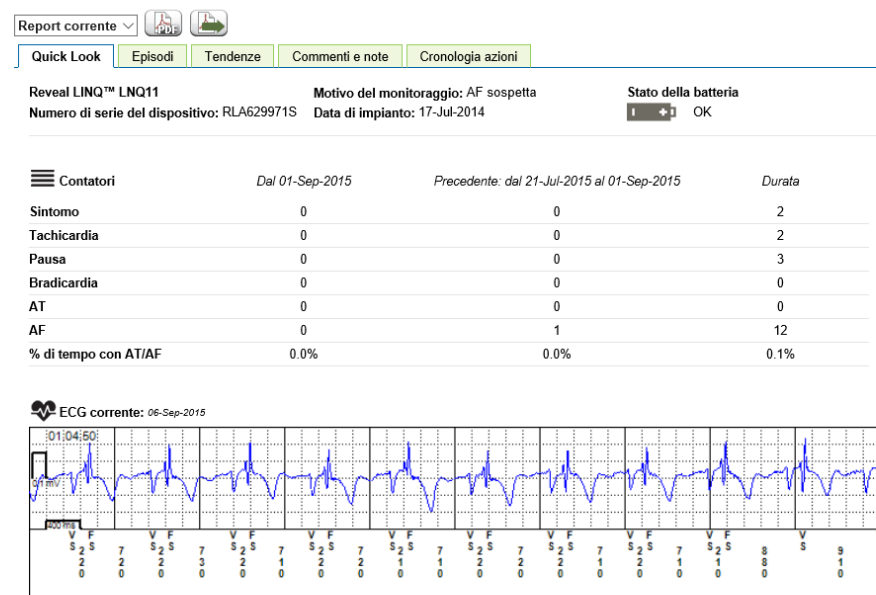
Janet I
 Christi
 Renato
 Ricardo
 Niraj V

2023 Recommendations for Special Programming Considerations for ILRs/ICMs

Recommendations for special programming considerations for ILRs

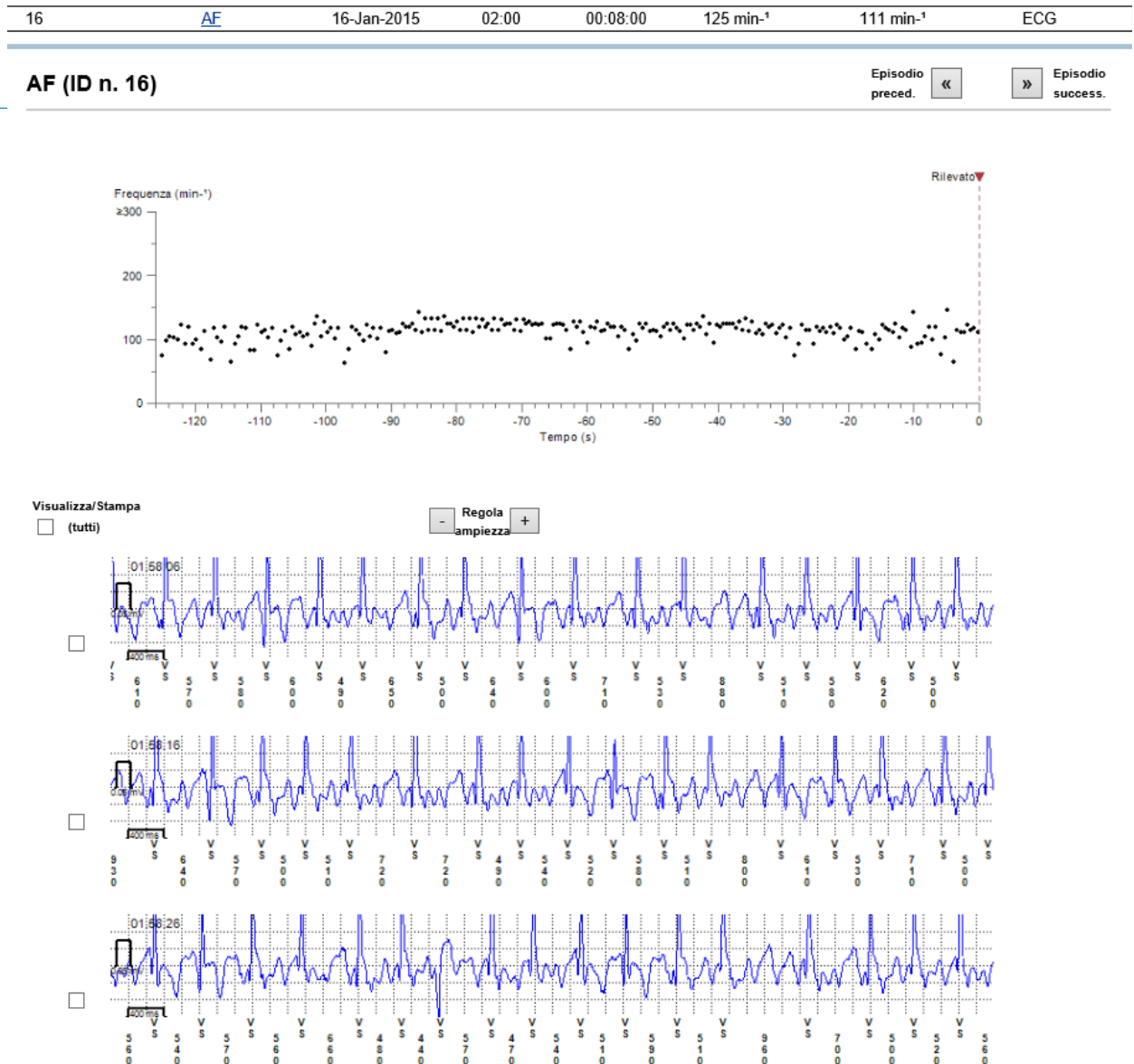
COR	LOE	Recommendations	References
1	B-NR	1. In patients with ILRs on RM, it is recommended that clinic staff confirm an actionable event transmission by reviewing the electrograms to exclude misdiagnoses.	3,25,149,150
1	B-NR	2. In patients with ILRs on RM, it is recommended that programmed alerts be tailored to the clinical indication.	3,25,149
1	B-NR	3. In patients with ILRs on RM and frequent undersensing and/or oversensing, reprogramming is recommended.	3,25,149,150
1	B-NR	4. In patients with ILRs on RM for unexplained syncope, it is recommended to emphasize to the patient the need to perform a symptom marking or manual transmission immediately following syncope to obtain a symptom-rhythm correlation.	25,149
2a	B-NR	5. In patients with ILRs on RM for cryptogenic stroke, it is reasonable to adjust the sensitivity to improve detection of AF.	25,149
3: No benefit	C-EO	6. In patients with ILRs on RM with consistent connectivity, in-office visits are not indicated for routine patient care.	

Insertable Loop Recorder: MDT LINQ® for Detecting PAF



Female, 70 yrs, Hx of TIA

Started NAO



Misdetection of PAF by ICM: Need of Manual Validation

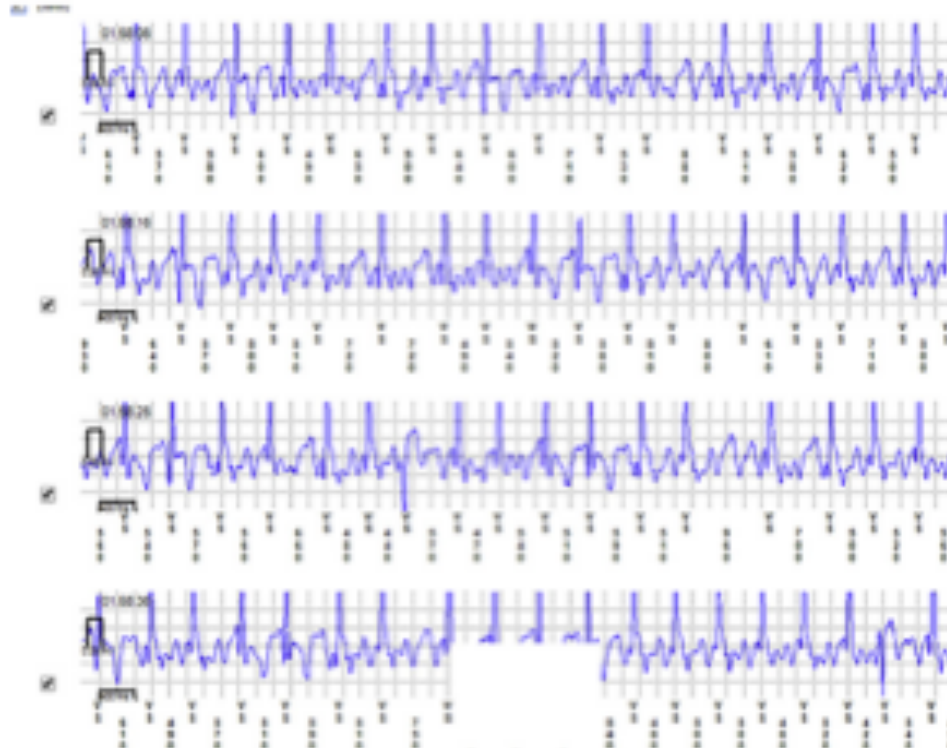
P Wave Analysis in the Era of Atrial Fibrillation Ablation

Fabio Leonelli^a, Emanuela Locati^b, Giuseppe Bagliani^{c,d,*},
Roberto De Ponti^e, Luigi Padeletti^f, Laura Cipolletta^g,
Alessandro Capucci^g

Female, 70 yrs, Hx of TIA

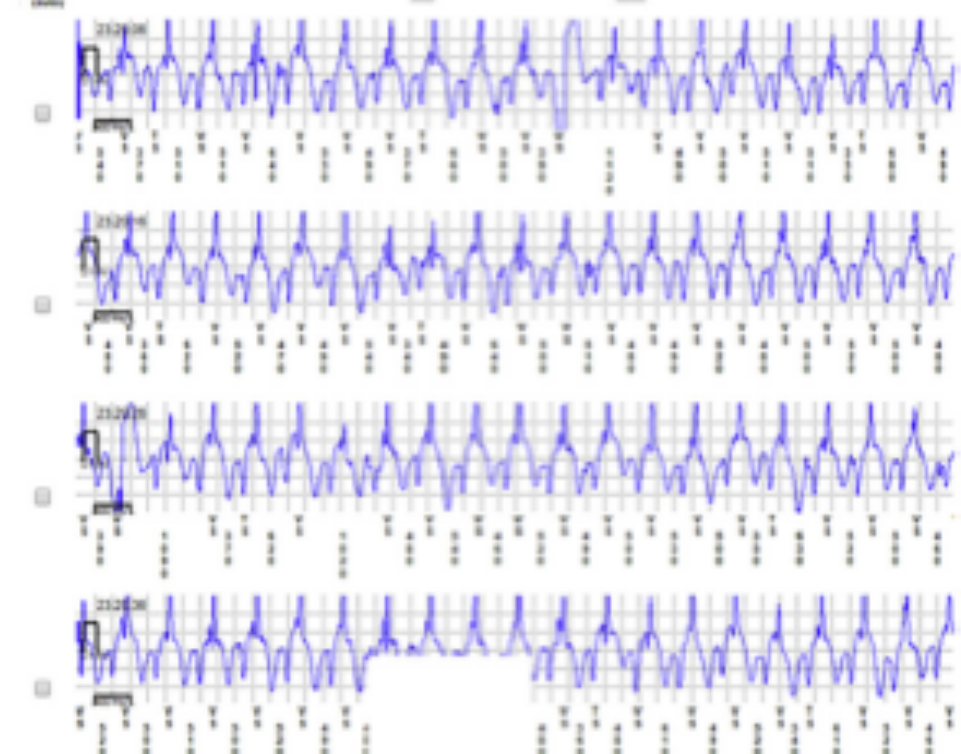
A

FAP



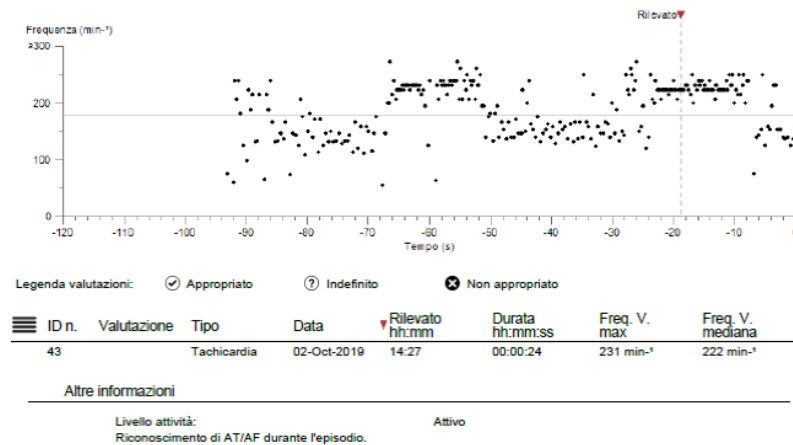
B

Sinus Tachicardia



ICM can guide therapy: Detection of aberrant PAF during ICM

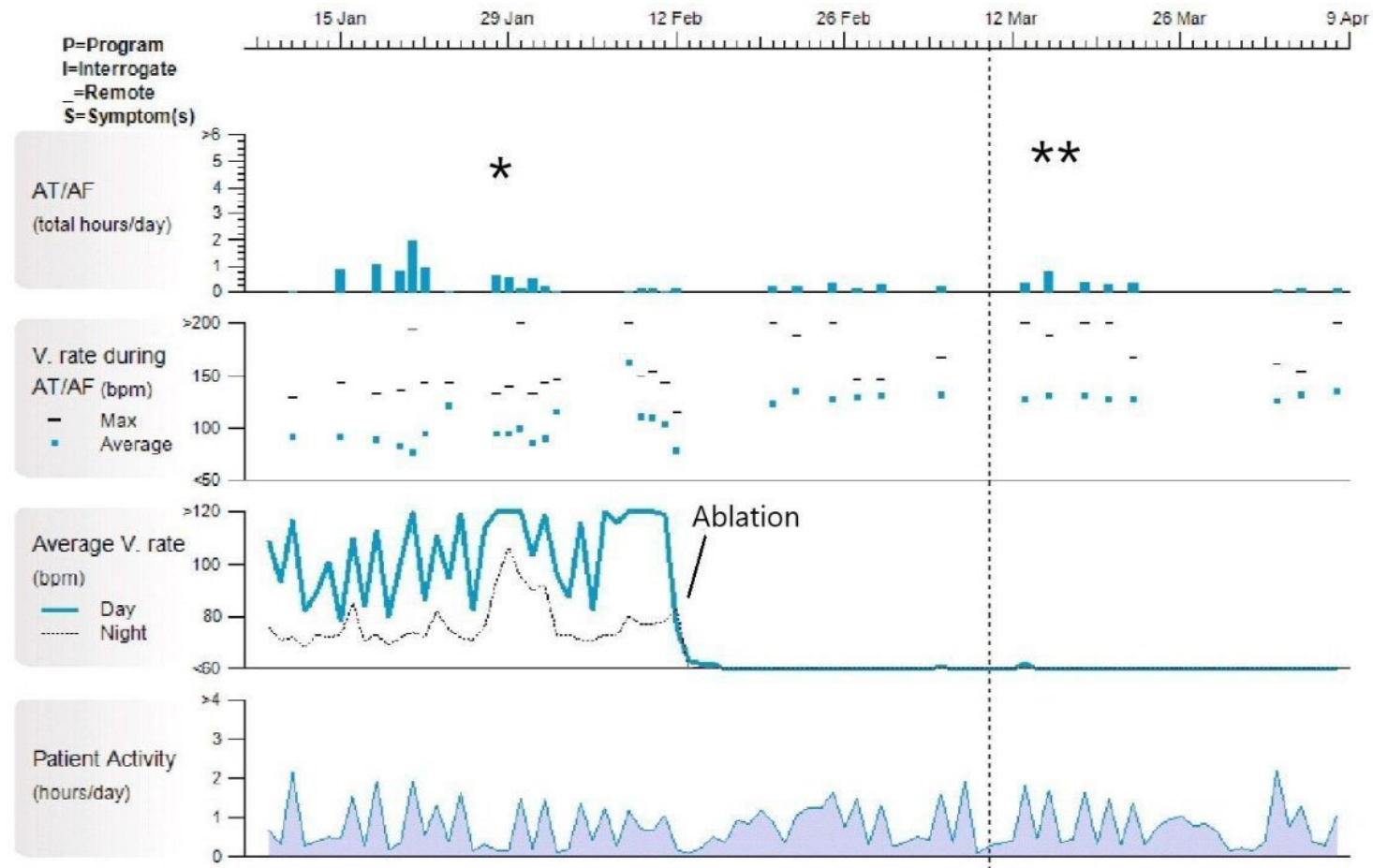
*Male, 53 yrs, Hx of PAF,
Therapy with NAO and
Flecainide*



**Stop Flecainide, start Sotalol
Schedule ATC**



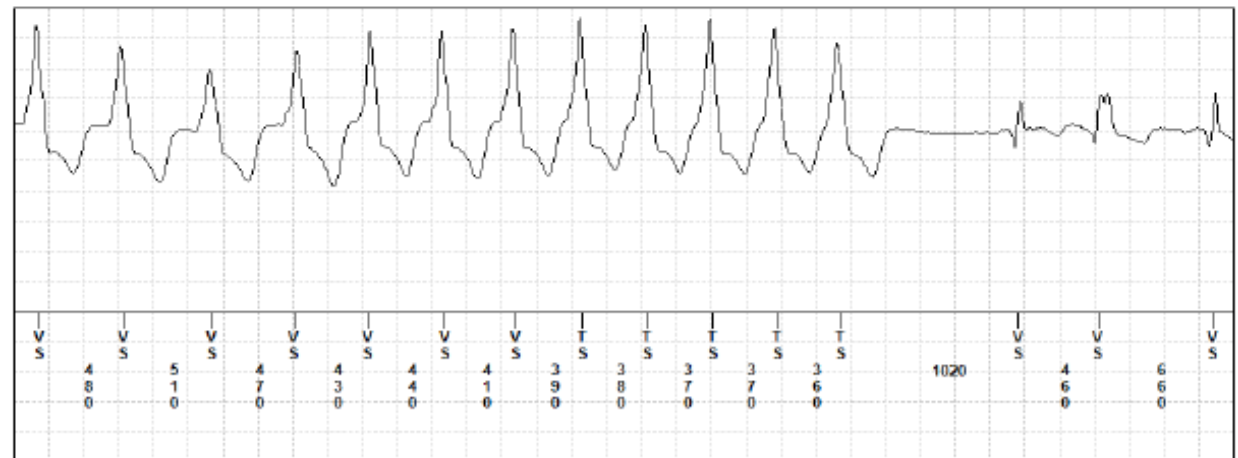
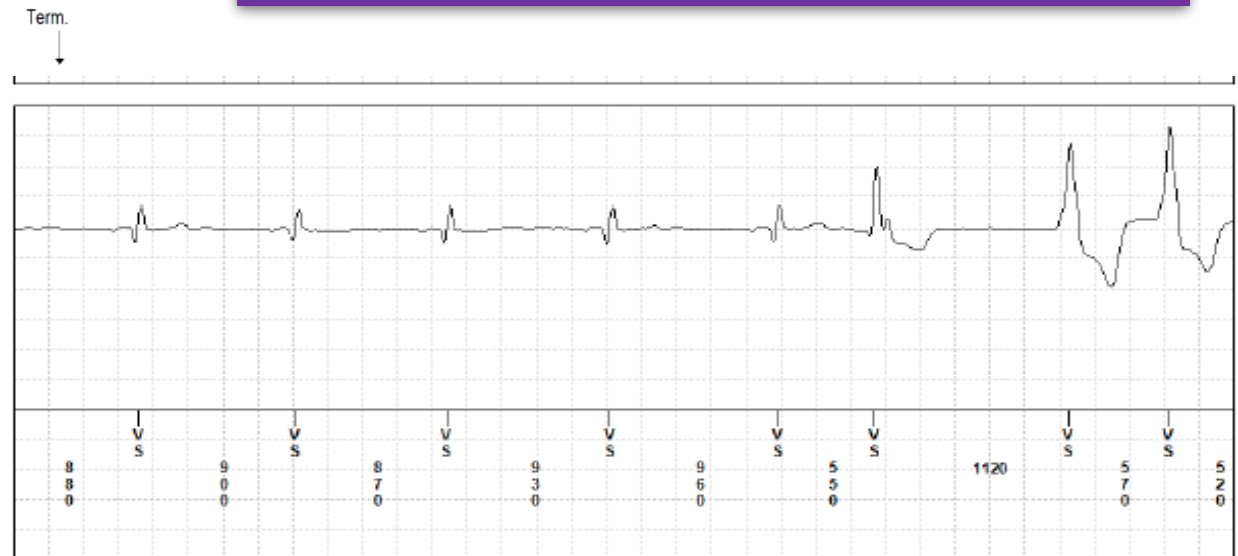
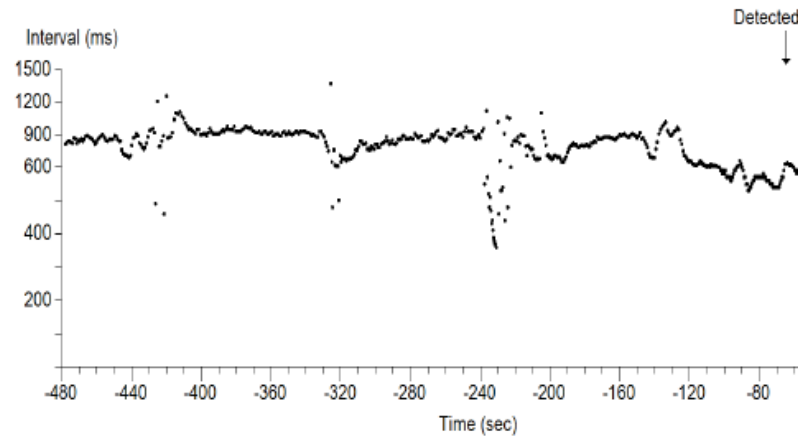
FA Burden after VV-PP-ATC: Possible Guide for NOAC Therapy?



Reveal – ILR missed detection of NSVT

*Male, 57 yrs, Hx of syncope and presyncope,
16 beat NSVT*

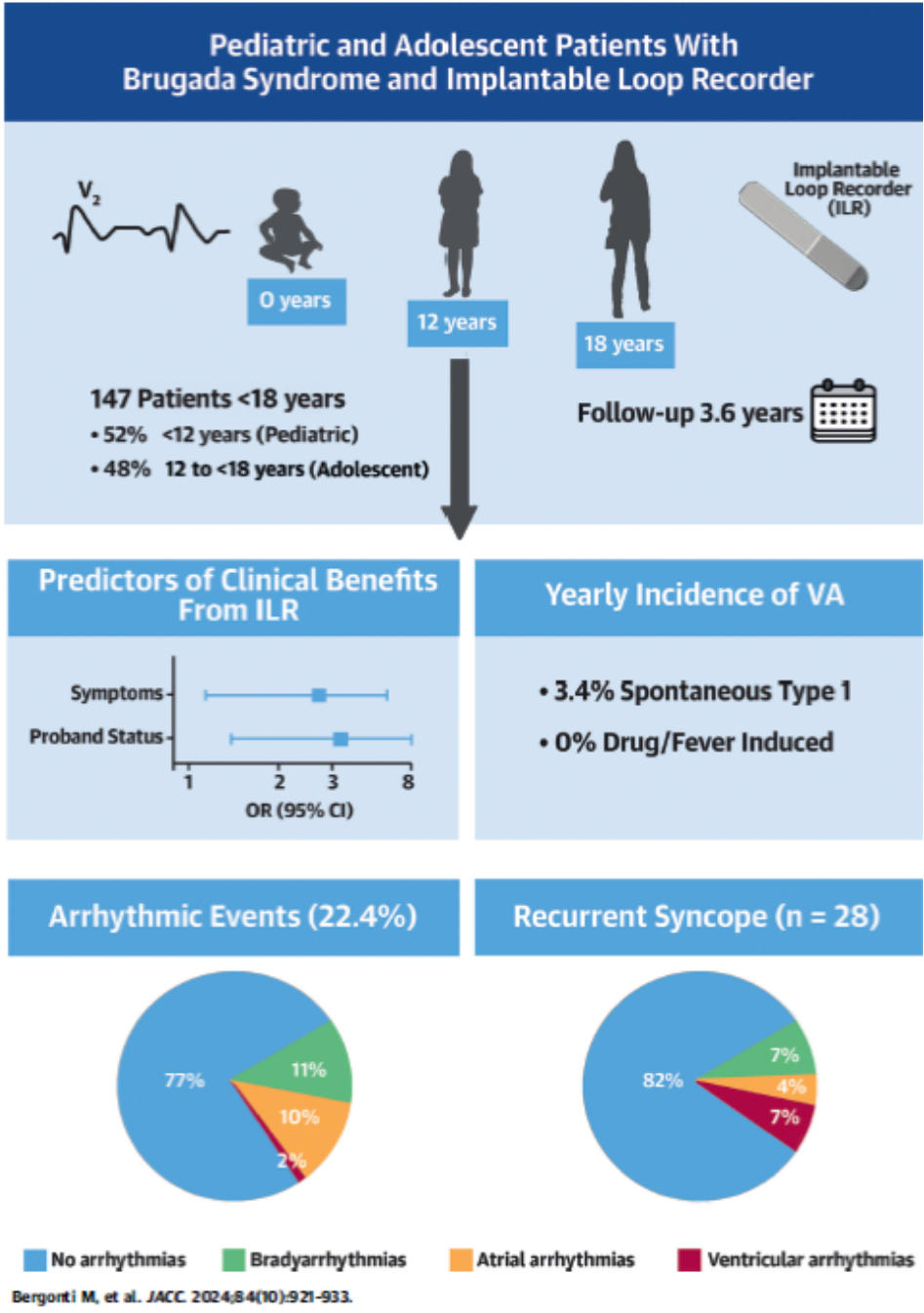
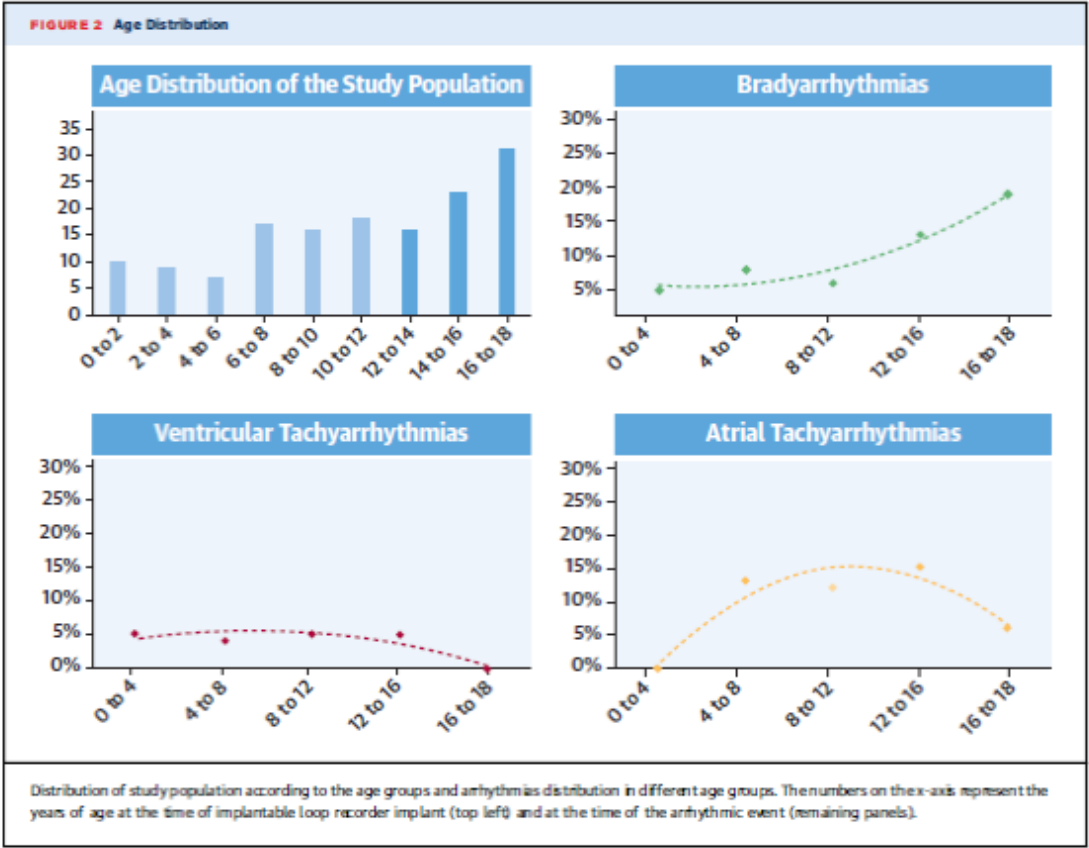
ID#	Type	Date	Time hh:mm	Duration hh:mm:ss	Max V. Rate	Median V. Rate
57	SYMPTOM	20-Sep-2015	21:58			



*Symptomatic per palpitation
NOT RECOGNIZED BY AUTOTRIGGER*

Continuous Rhythm Monitoring With Implanted Loop Recorders in Children and Adolescents With Brugada Syndrome

Marco Bergonti, MD, PhD,^{a,*} Giuseppe Cicone, MD, PhD,^{b,c,*} Jose Cruzalegui Gomez, MD,^{d,e} Lia Crotti, MD,^{e,g} Elena Arbelo, MD,^h Michela Casella, MD, PhD,^{i,j} Johan Saenen, MD, PhD,^k Andrea Rossi, MD,^l Luigi Pannone, MD,^m Estefania Martinez-Barrios, MD,^{d,e} Paolo Compagnucci, MD, PhD,^{i,j} Vincenzo Russo, MD,ⁿ Paola Beme, MD,^o Olivier Van Leuven, MD,^z Antonio Boccellino, MD,^{b,c} Lorenzo Marcon, MD,^{p,q} Federica Dagnadi, MD,^r Federico Landra, MD,^l Tardu Özkartal, MD,^s Angelo Comune, MD,ⁿ Sergio Conti, MD, PhD,^t Valentina Ribatti, MD, PhD,^{p,q} Oscar Campuzano, PhD,^s Pedro Brugada, MD, PhD,^m Carlo de Asmundis, MD, PhD,^m Josep Brugada, MD,^h Carlo Pappone, MD,^{b,c} Claudio Tondo, MD, PhD,^{p,q} Peter J. Schwartz, MD,^r Angelo Auricchio, MD, PhD,^{u,t} Georgia Sarquella-Brugada, MD, PhD,^{d,e,u,v,w} Giulio Conte, MD, PhD,^{x,t}



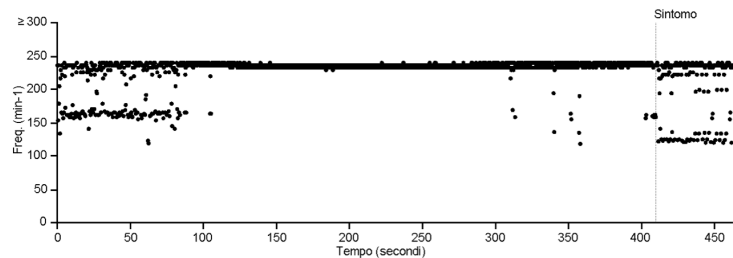
How RM Can Help in Emergency

30 mag 2022
13:56 (MESZ)
Remoto

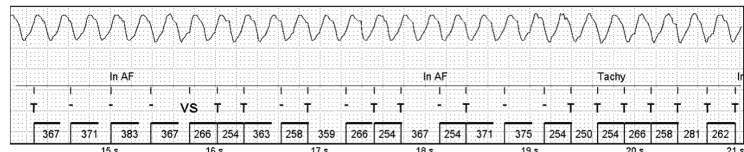
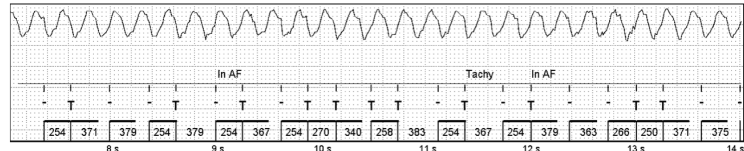
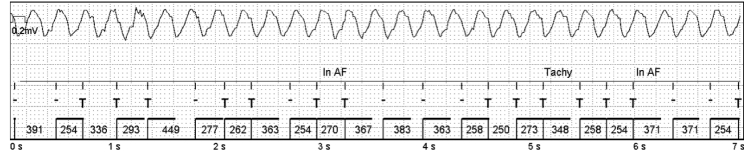
Episodio da sintomo (con Rilevamento)

Pagina 1 di 14

Data e Ora 30 mag 2022 13:55
Sintomo con episodio rilevato dal dispositivo
Sintomo del paziente Svenimento



1: VEGM AutoGain (8.5 mm/mV)
2: Marker Velocità di scorrimento: 25 mm/s



Confirm Rx™ ICM 3500 (6370573 pr04.10.93.10)
myMerlin™ APP1000 v1.0.5 MN5000 v7.8.rev6

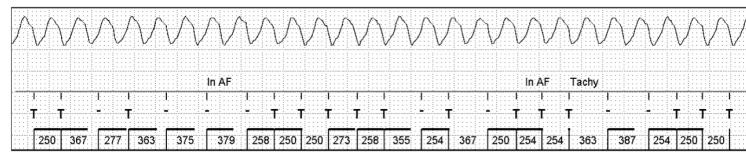
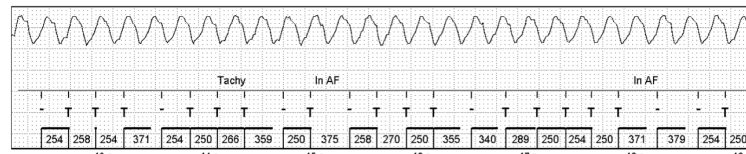
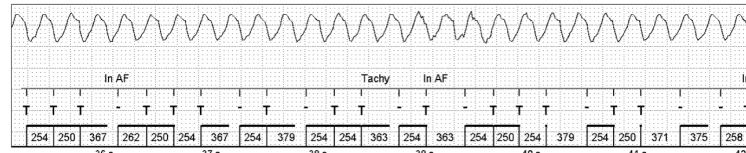
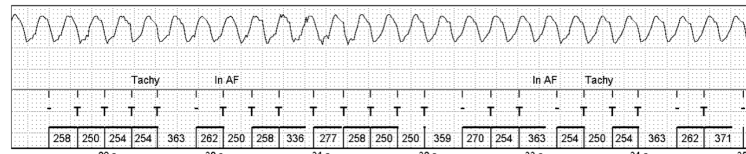
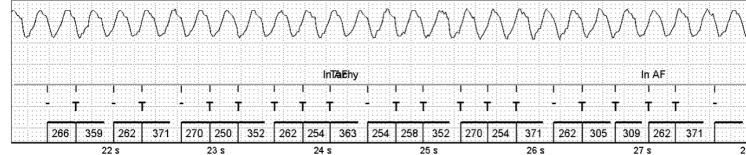
Episodio da sintomo (con Rilevamento) Pagina 1 di 14
30 mag 2022 13:56 (MESZ)

30 mag 2022
13:56 (MESZ)
Remoto

Episodio da sintomo (con Rilevamento)

Pagina 2 di 14

1: VEGM AutoGain (8.5 mm/mV)
2: Marker Velocità di scorrimento: 25 mm/s



Confirm Rx™ ICM 3500 (6370573 pr04.10.93.10)
myMerlin™ APP1000 v1.0.5 MN5000 v7.8.rev6

Episodio da sintomo (con Rilevamento) Pagina 2 di 14
30 mag 2022 13:56 (MESZ)

Man, 63 yrs old, previous history of PAF, 3/2022 RF-TCA (CPVA)

30/5/2022 Syncope while bicycling in the mountains above Bergamo.

Call Emergency upon recovery, unable to move

SYMPTOM RECORDED & ARRHYTHMIA DETECTED → TRANSMISSION SENT TO PSD

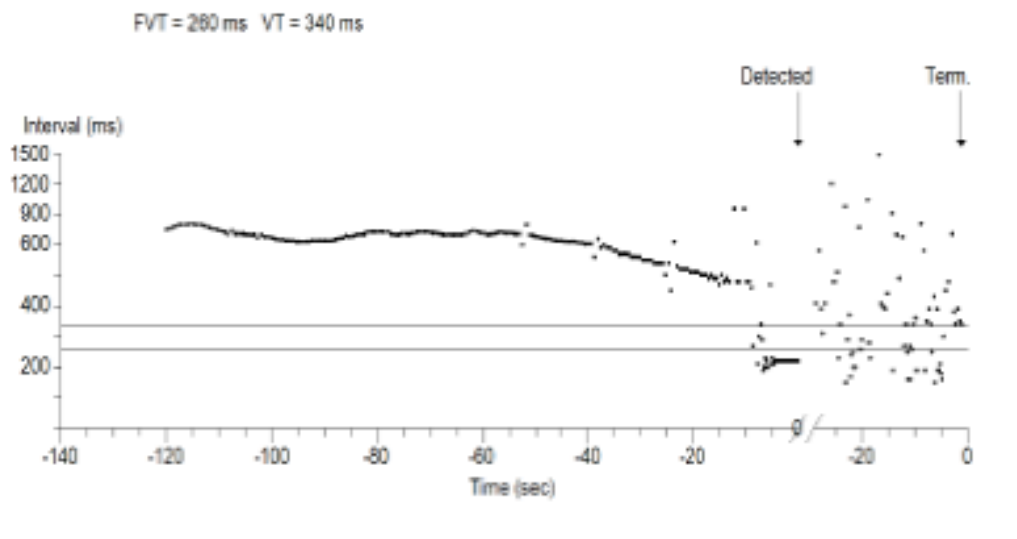
We call the patient, while already on the Ambulance, and recommend access to a major Hospital

ECV upon arrival in PS → SR recovery

Transferred to PSD → Diagnosis of sustained VT, LDA occluded on CGF, LV dysfunction with 30% EF

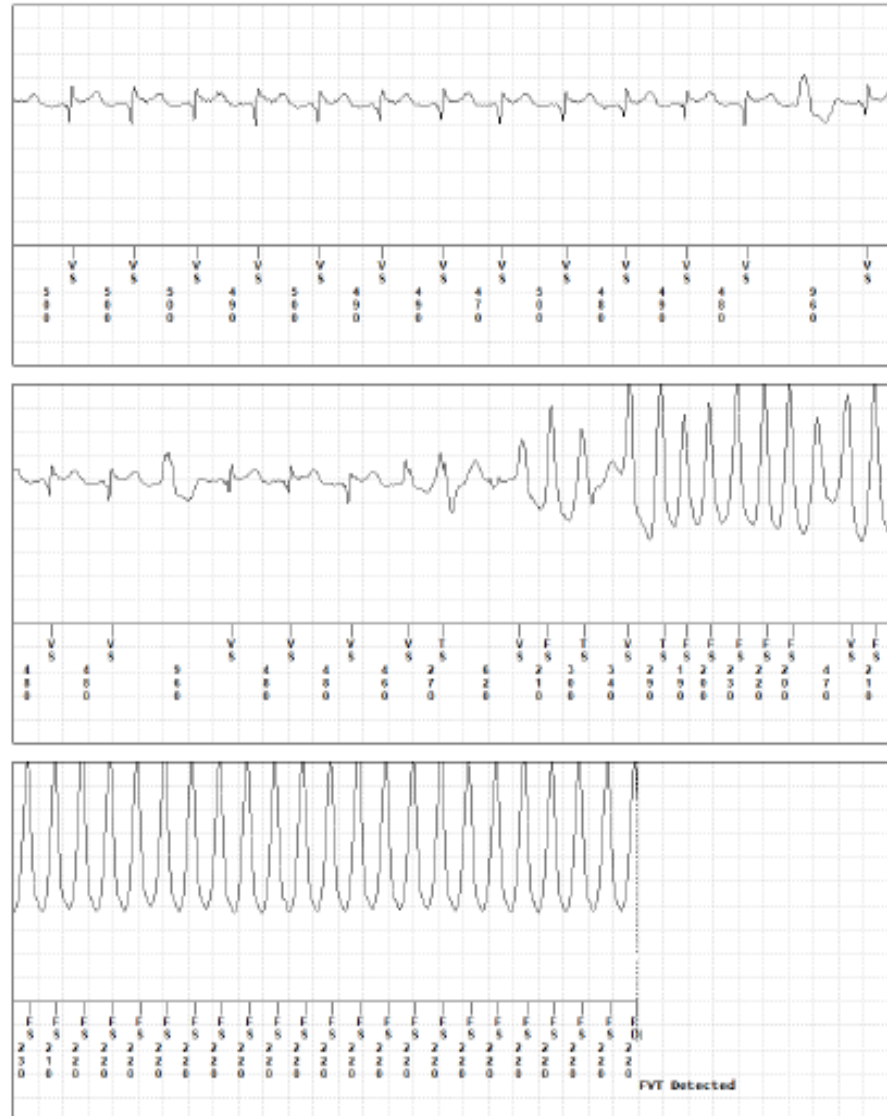
→ CRT-D implant

Detection of SD due to VF during ILR monitoring

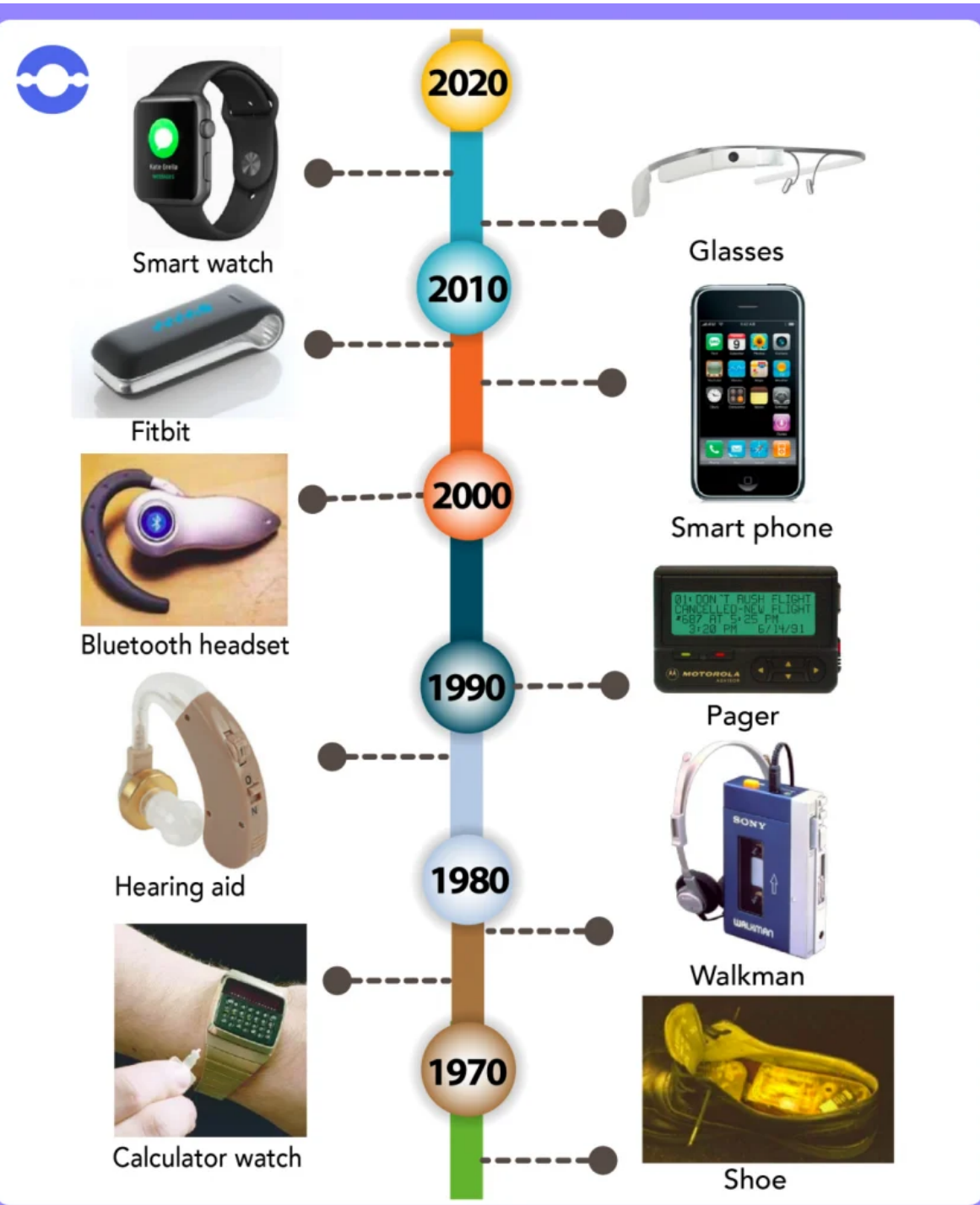


Male, 56 yrs, NICM, FE 45%, Negative EP test, recurrent nightmares

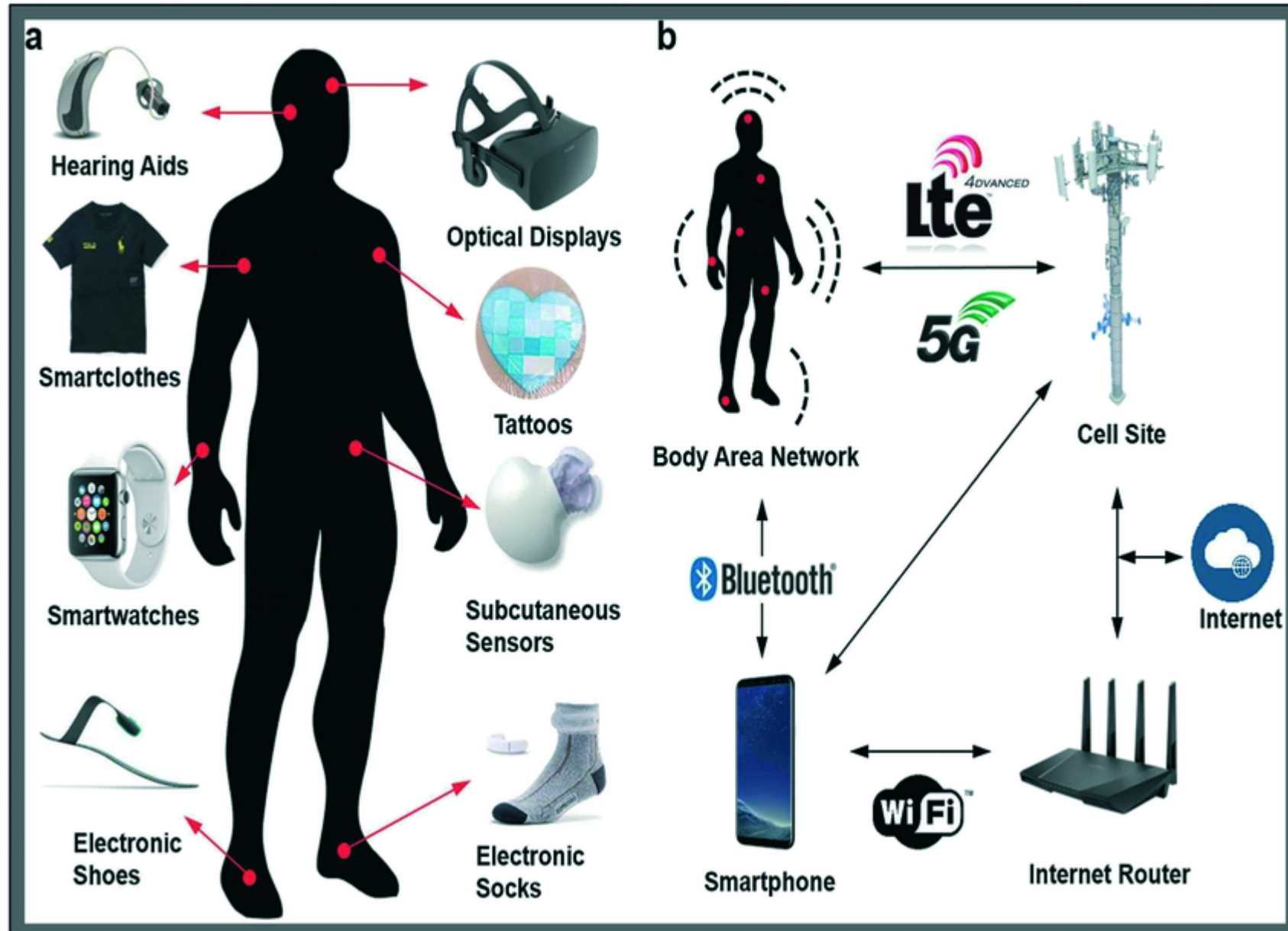
Sudden death due to VF recorded during ILR monitoring



History of Wearable Technology



Healthcare Wearable Technology and Telemedicine



Healthcare Wearable Devices Market

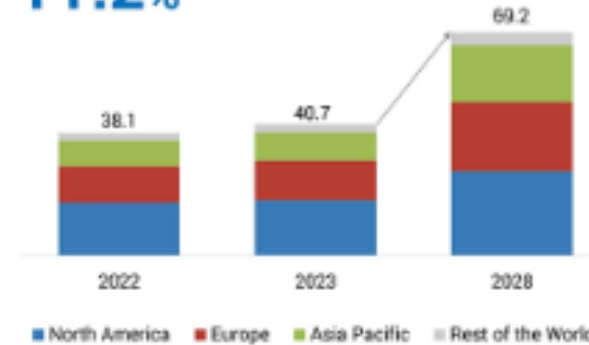
WEARABLE HEALTHCARE DEVICES MARKET

Market Size, Market Dynamics & Ecosystem



CAGR of 2023-2028

11.2%



MARKET SIZE (USD BILLION)



MARKET DYNAMICS (DRIVERS AND RESTRAINTS)

DRIVERS

- Growing awareness about lifestyle management and home healthcare
- Development of technologically advanced products
- Growth in geriatric population and subsequent rise in chronic diseases

RESTRAINTS

- Inadequate regulatory standardization
- Issues related to accuracy & analysis of wearable-generated data



COMPANY EVALUATION MATRIX: KEY PLAYERS



ECOSYSTEM ANALYSIS



Abbott

PHILIPS

fitbit

dexcom

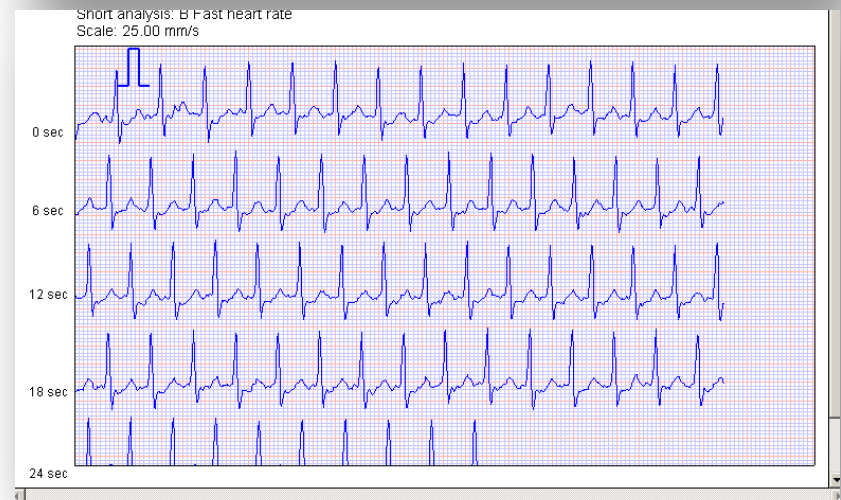
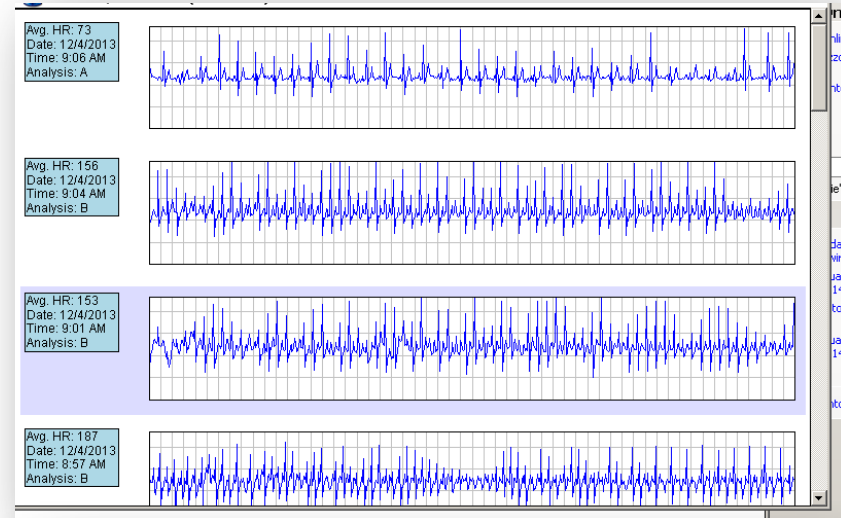
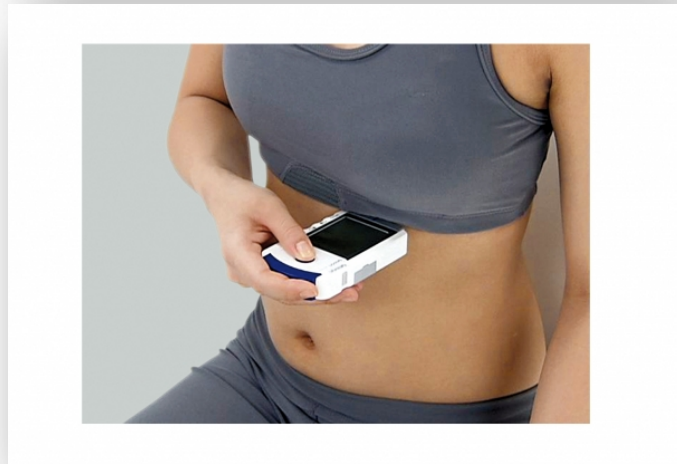
GARMIN

Masimo

biotricity

OMRON

Detection of FAP by Omron Event Recorder



Different ECG Patch Monitoring (EPM) Systems



Continuous long term electrocardiogram (ECG) monitoring is highly useful for patients with difficult to diagnose arrhythmias. As the diagnostic yield increases with longer monitoring period, continuous ECG monitoring can aid in timely medical decisions for patients who recently underwent a stroke, cardiac surgery or post-ED (emergency department) discharge. Today's existing cardiac monitoring devices are heavy, typically only last one to two days, and are highly uncomfortable to the patient, requiring multiple placements of cumbersome electrodes and cables.

Introducing **CardioLeaf® ULTRA** - the world's thinnest, cable-free 3-lead ECG continuous long-term monitoring device. CardioLeaf® ULTRA is a medical-grade device that allows clinicians and researchers to easily administer prolonged ECG monitoring for up to 7 days as a single-use device. Initial capital expenditure are lowered and less manpower for operations and maintenance are required.

Features



3-Lead ECG Recording



Activity Index Calculation



Up To 7 Days of Continuous Recording



Wireless Connectivity

System Architecture



CardioLeaf



Smartphone Application



Telco Station



Clinicians also have the flexibility to scale-up monitoring as and when required. Made from biocompatible and body-conformable material, it is friendly to the skin and is a comfortable alternative to existing Holter monitoring device. Patients wear the device continuously for seven days to monitor their heart activity as they go about their regular life. The **CardioLeaf® ULTRA** is targeted towards medical and research applications such as post cardiac surgery or stroke recovery patients, drug discovery companies and clinical research organizations.

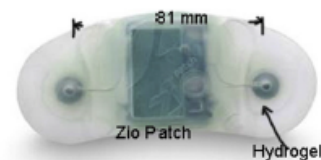
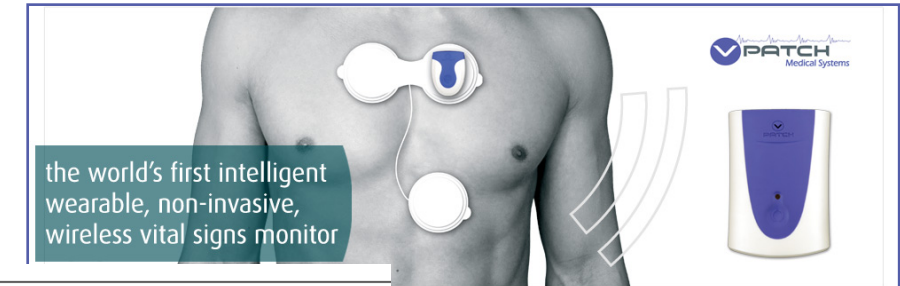
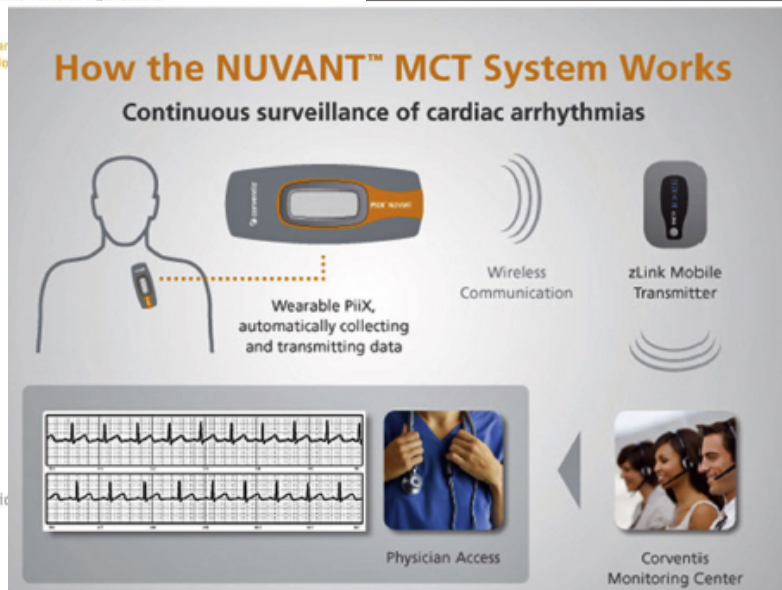


Fig 3 – ZIO Patch assembly and Company recommended placement on the body.



monitoring

challenging with traditional, leaded monitoring solutions.



SEEQ Mobile Cardiac Telemetry System

The SEEQ MCT System is ideal for patients experiencing frequent symptoms that require short-term cardiac monitoring up to 30 days.



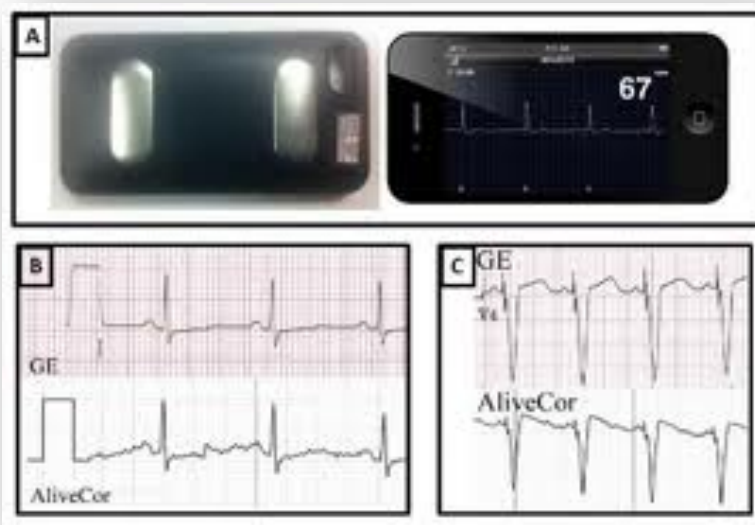
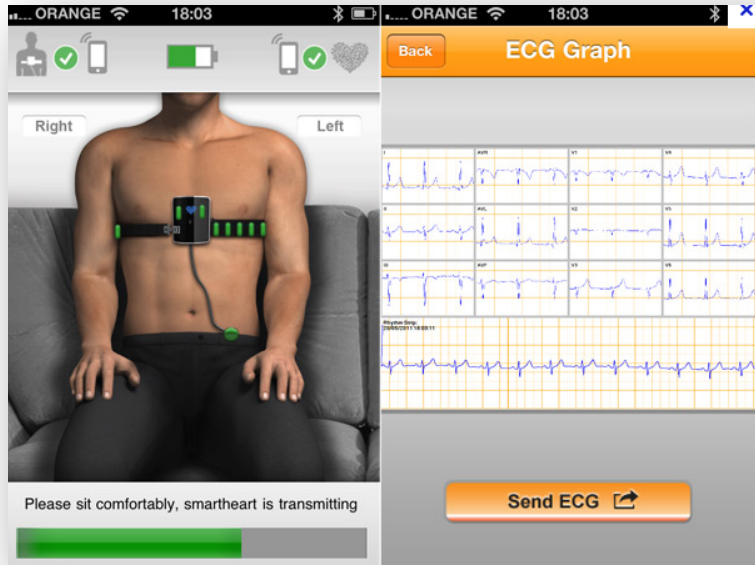
Wearable Sensor is simple to apply – patients just peel and stick.



Wireless SEEQ Transmitter sends cardiac data to a staffed Monitoring Center, 24/7

The External Short-Term Solution

SmartPhone Based Event Recorders



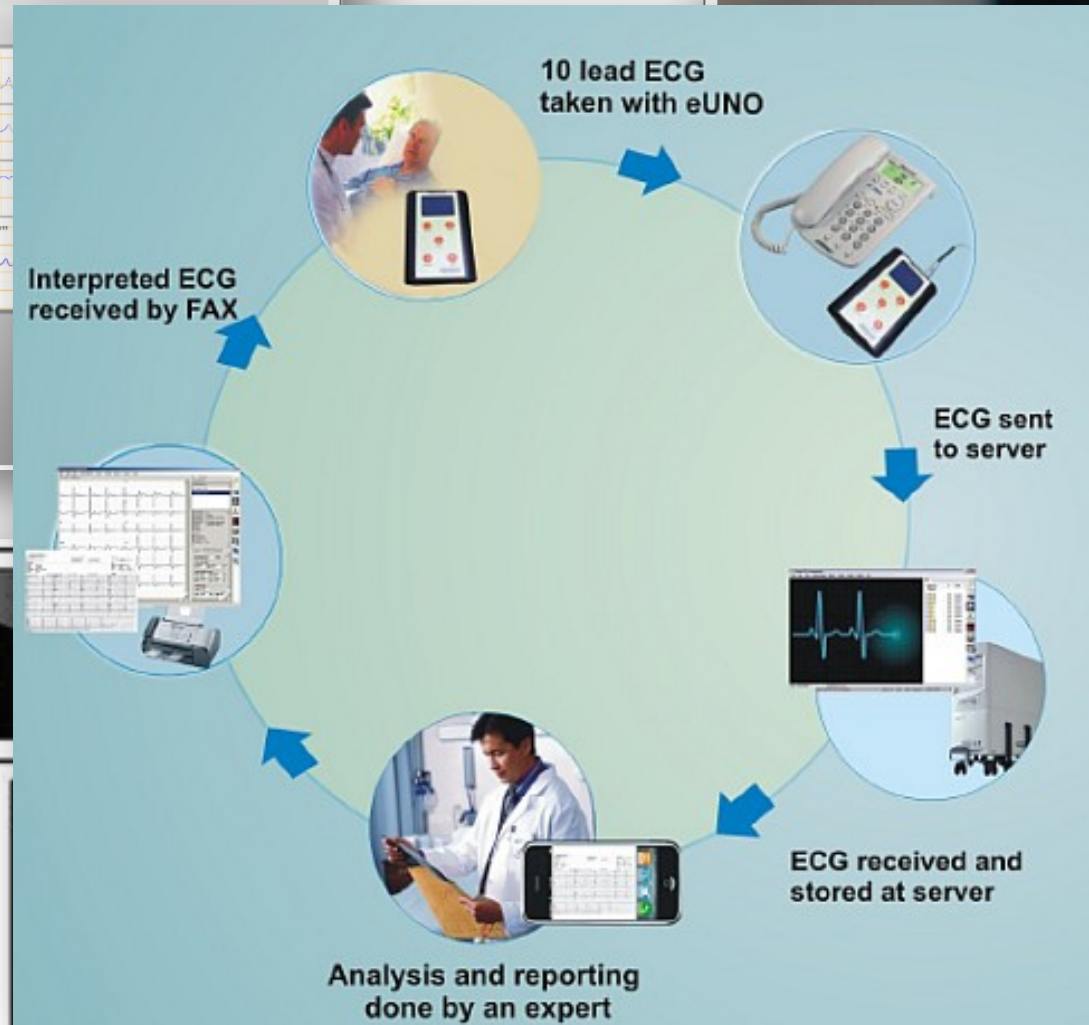
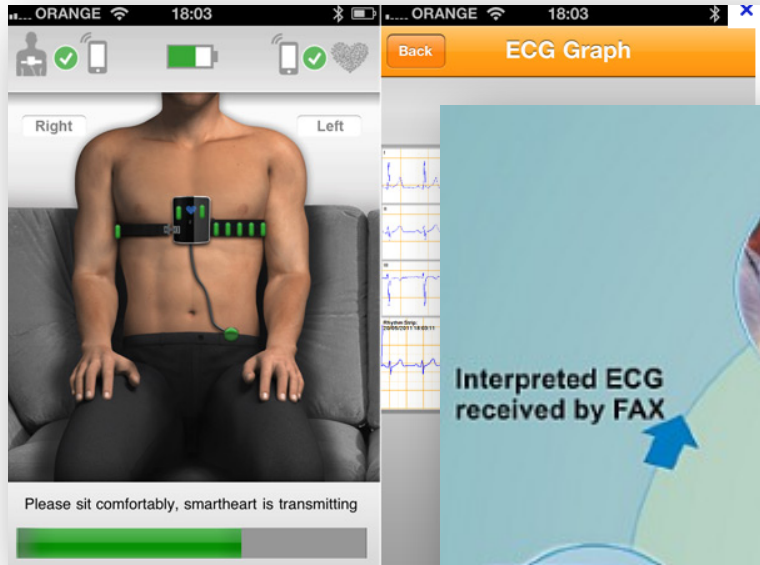
CardioDefender

CardioDefender is the first system to deliver mobile, real-time, beat-by-beat, and quantitative heart monitoring and automated reporting by combining patented analytical smartphone software with a **wireless** device and electrodes.



The HTC product names and services are trademarks of HTC Corporation. The W8M logo and the Cool Watch are trademarks of W8M Labs.

SmartPhone Based Event Recorders: Need of RM



Apple i-Watch for Arrhythmia Detection



Technical and Feature Description

Apple Watch Series 4 incorporates a titanium electrode in the Digital Crown and an ultrathin chromium silicon carbon nitride layer applied to the sapphire crystal on the back of Apple Watch. The ECG app reads and records the electrical impulses that control the heart from the user's fingertip (Digital Crown) and the wrist (back of Apple Watch), which creates a closed circuit. To use the ECG app on Apple Watch, a user must first complete onboarding within the Health app on the user's paired iPhone to learn how to use the feature and receive education regarding AF. To generate an ECG, a user must open the ECG app installed on Apple Watch, then apply a finger from the hand contralateral to the wrist where Apple Watch is worn to the Digital Crown for 30 seconds. Lead polarity is determined by the wrist placement of Apple Watch selected in Settings.

After obtaining the ECG, a proprietary algorithm is used to classify the ECG tracing as SR, AF, or inconclusive. This rhythm classification, average heart rate, user-reported symptoms, and waveform are all stored in HealthKit and can be shared by the user as a PDF from the Health app on the user's paired iPhone. To learn more about the user experience, visit <https://support.apple.com/kb/HT208955>.

Table 5. Sensitivity and Specificity Analysis—Classifiable Strips

Parameter	Value	Lower Confidence Bound*	p-value**
Final ECG Reference Result = AF (n)	240		
ECG App Device Result = AF	236/240 (98.3%)		
ECG App Device Result = SR	4/240 (1.7%)		
Sensitivity	236/240 (98.3%)	95.8%	< 0.0001
Final ECG Reference Result = SR (n)	239		
ECG App Device Result = AF	1/239 (0.4%)		
ECG App Device Result = SR	238/239 (99.6%)		
Specificity	238/239 (99.6%)	97.7%	< 0.0001

*Lower exact binomial one-sided confidence bound.

**Test of hypothesis for sensitivity > 0.9 and specificity > 0.92.

Abbreviations: AF = Atrial Fibrillation, SR = Sinus Rhythm

REHEARSE-AF Study

Assessment of Remote Heart Rhythm Sampling Using the AliveCor Heart Monitor to Screen for Atrial Fibrillation The REHEARSE-AF Study

Halcox JPJ et al Circulation 2017

Table 1. Baseline Characteristics of the Study Participants

	IECG (n=500)	RC (n=501)	P Value
Sex, MF, n (%)	241/259 (48/52)	225/275 (45/55)	0.30
Mean age (SD), y	72.6 y (5.4)	72.6 y (5.4)	0.98
Age 65–74 y, n	328	330	0.93
Age ≥75 y, n*	172	171	0.93
Heart failure, n (%)	5 (1)	9 (2)	0.28
Hypertension, n (%)	268 (54)	272 (55)	0.75
Diabetes mellitus, n (%)	129 (26)	140 (28)	0.43
Stroke or TIA, n (%)	35 (7)	28 (6)	0.37
Vascular disease, n (%)	71 (14)	79 (16)	0.50
CHADS-VASc score (SD)	3.0 (1.0)	3.0 (1.0)	0.57

IECG indicates iPod ECG; RC, routine care; and TIA, transient Ischemic attack.

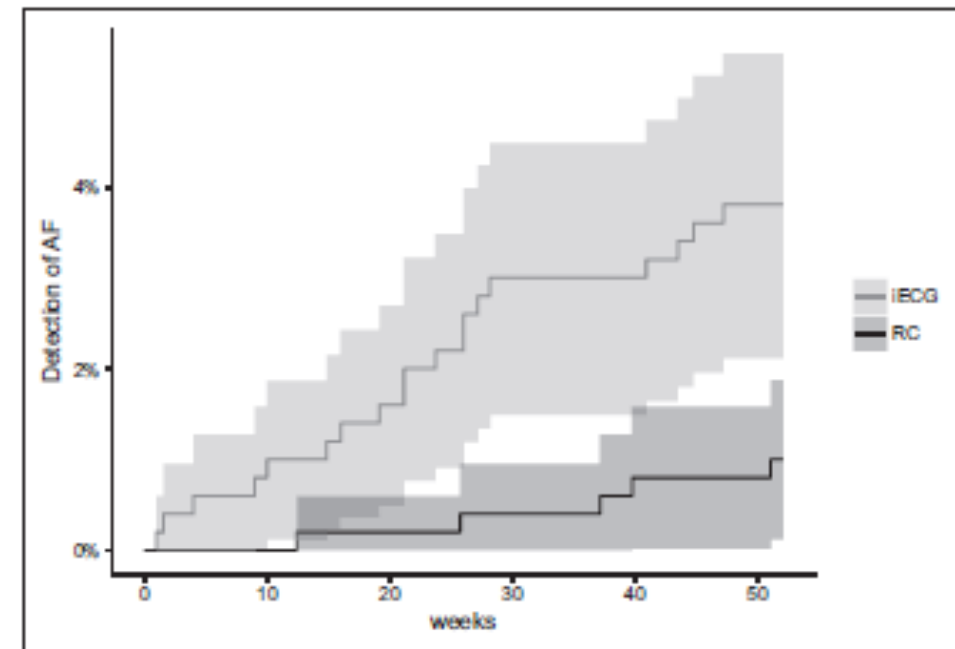
*Sixty-five patients in the IECG arm and 56 in the RC arm were at least 80 years of age.

Table 2. Baseline Variables as Predictors of Atrial Fibrillation

	Hazard Ratio (95% CI)	P Value
MF sex	1.9 (0.9–4.5)	0.11
Age ≥75 y	2.3 (1.0–5.1)	0.04
Hypertension	0.91 (0.6–1.4)	0.68
Diabetes mellitus	1.1 (0.7–1.6)	0.79
Stroke or TIA	1.2 (0.6–2.5)	0.64
Arterial disease	1.5 (1.0–2.4)	0.05
CHADS-VASc score ≥4	2.3 (1.0–5.1)	0.04

The table shows results from separate Cox regression models. When variables were combined in a multivariable model, only CHADS-VASc score of ≥4 was independently associated with an increased risk of being diagnosed with AF.

CI indicates confidence interval; and TIA, transient Ischemic attack.



AHRES: Look and you will find – Then what?

Waldo & Camm, Editorial, REHEARSE Study, Circulation 2017

EDITORIAL

Atrial Fibrillation

Atrial High-Rate Events (AHRES): Look and You Will Find–Then What?

Article, see p XXX

The article by Halcox et al¹ describes the REHEARSE-AF study (Assessment of Remote Heart Rhythm Sampling Using the AliveCor Heart Monitor to Screen for Atrial Fibrillation), a randomized trial of screening for atrial fibrillation (AF) with a smartphone-based single-lead electrocardiographic capture system in 1001 patients ≥ 65 years of age with a CHA₂DS₂-VASc score of ≥ 2 and without a history of AF. Patients were randomized either to biweekly electrocardiographic

Albert L. Waldo, MD, PhD
(Hon)
A. John Camm, MD

...Clearly, we have more work to do.

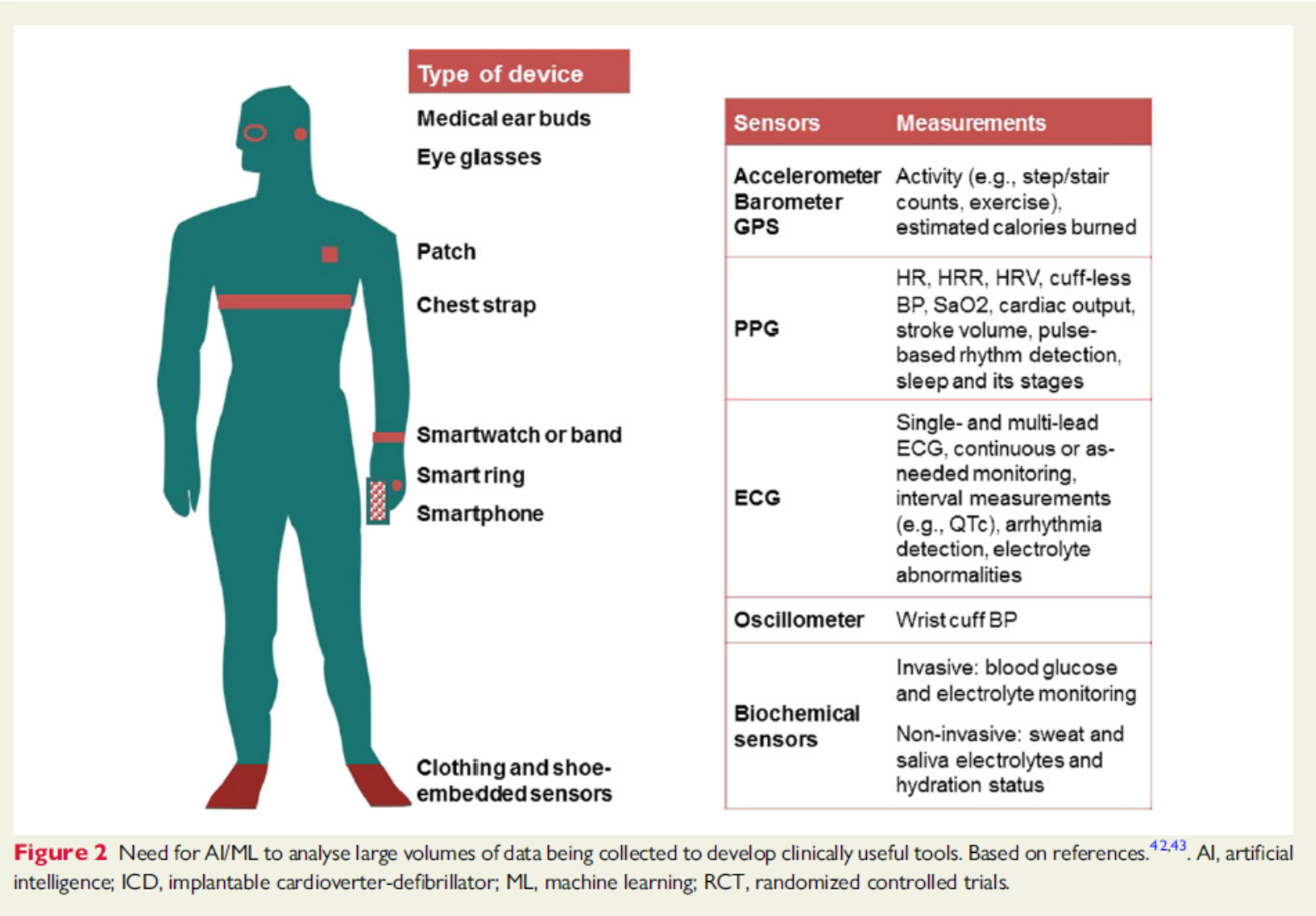
How does the REHEARSE-AF study help? Halcox and colleagues used biweekly, short recordings to identify AF in patients at risk of thrombogenesis. Is using intermittent, short iECG recordings rather than implantable device monitoring a “poor man’s” version of arrhythmia monitoring? Certainly, the frequent iECG recording, well outside the clinical norm, will tend to reveal infrequent arrhythmia, but the short recording period gives little idea of the duration of the arrhythmia, and mere identification is not enough. Finally, the results of the REHEARSE-AF study also serve to focus on issues seen in virtually all the previous AHRE studies. First, the adverse event rate (stroke and systemic embolism) in the 1001 participants was quite low (0.02%). Second, of the 16 total strokes, 14 were either causally unrelated to AF or of undetermined origin.

As far as choosing whether to anticoagulate the patient, we might as well follow the advice of Yogi Berra: “When you come to a fork in the road [decision], take it [guess].” Perhaps it is better not to look for it. After all, “what is left unsought will not be discovered.” But we cannot leave it there, thinking “out of sight, out of mind,” because what Victor Hugo actually wrote was “When a man is out of [his] sight [blind], it is not too long before he is out of [his] mind [crazy],” and we would not want that nor all the other adverse complications of AF to come tumbling down on our patients just because we were not prepared to look, find, and further evaluate what can be discovered with simple clinical techniques. Clearly, we have more work to do.

Wearables, telemedicine, and artificial intelligence in arrhythmias and heart failure

Proceedings of the European Society of Cardiology Cardiovascular Round Table

Christophe Leclercq^{1*}, Henning Witt², Gerhard Hindricks³, Rodolphe P. Katra⁴, Dave Albert⁵, Andrea Bellinger⁶, Martin R. Cowie⁷, Thomas Deneke⁸, Paul Friedman⁹, Mehdiyar Haschemi¹⁰, Trudie Loh¹¹, Isabelle Lordereau¹², Michael V. McConnell¹³, Leonardo Rapallini¹⁴, Eigil Samset¹⁵, Mintu P. Turakhia^{16,17}, Jagmeet P. Singh¹⁸, Emma Sveinsson¹⁹, Manish Wadhwa²⁰, and Franz Weidinger²¹





Wearables, telemedicine, and artificial intelligence in arrhythmias and heart failure: Proceedings of the European Society of Cardiology Cardiovascular Round Table

Christophe Leclercq^{1*}, Henning Witt², Gerhard Hindricks³, Rodolphe P. Katra⁴, Dave Albert⁵, Andrea Bellinger⁶, Martin R. Cowie⁷, Thomas Deneke⁸, Paul Friedman⁹, Mehdiyar Haschemi¹⁰, Trudie Lobban¹¹, Isabelle Lordereau¹², Michael V. McConnell¹³, Leonardo Rapallini¹⁴, Eigil Samset¹⁵, Mintu P. Turakhia^{16,17}, Jagmeet P. Singh¹⁸, Emma Svennberg¹⁹, Manish Wadhwa²⁰, and Franz Weidinger²¹

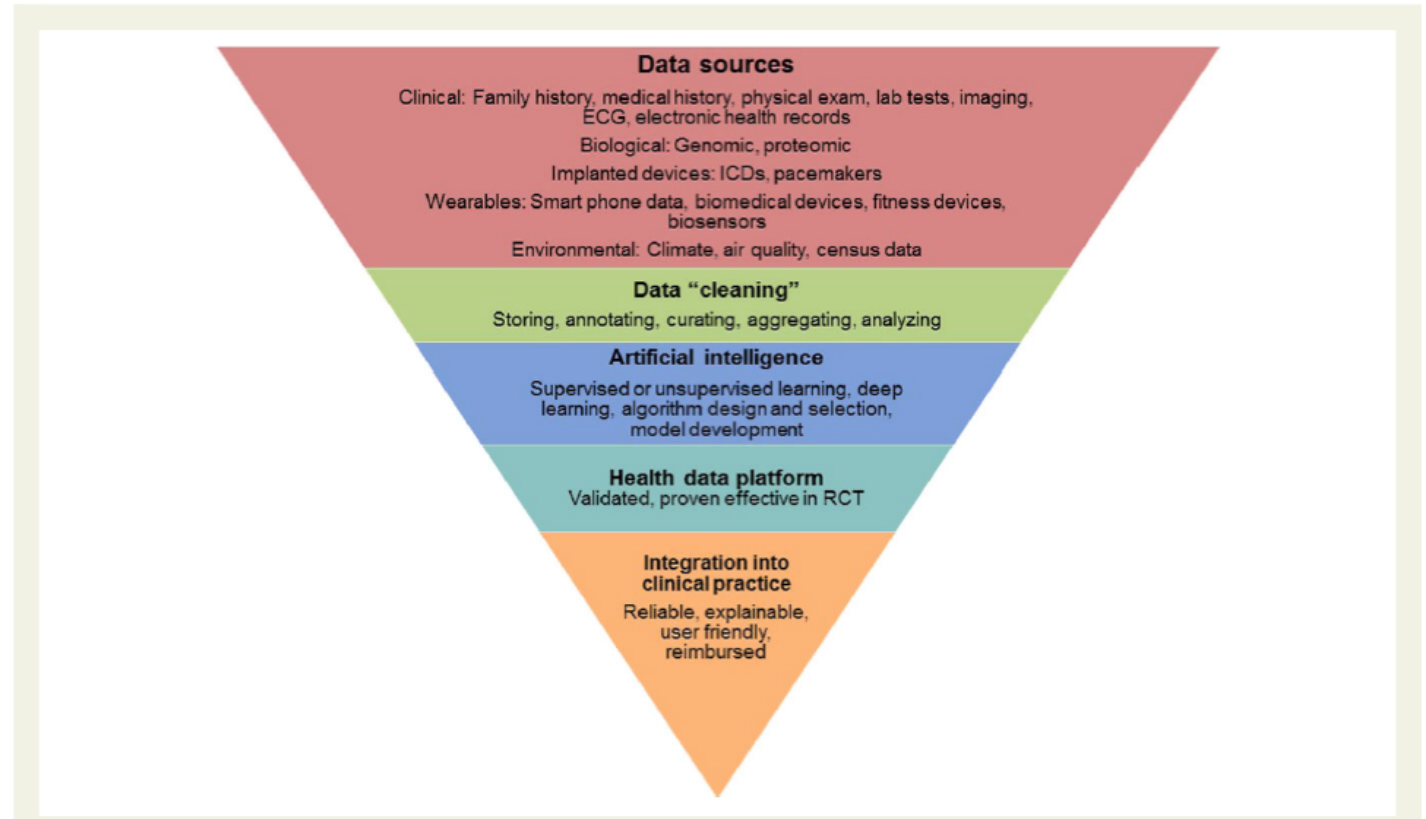


Figure 1 Summary of some of the types of smart wearable devices, where they are worn, sensors, and measurement. Based on references. ^{6, 17, 18}
This is not an inclusive list. Photoplethysmography (PPG) measures HR, HRR, HRV, cuff-less BP, SaO₂, cardiac output, stroke volume, pulse-based rhythm detection, and sleep and its stages. BP, blood pressure; ECG, electrocardiogram; GPS, Global Positioning System; HR, heart rate; HRR, heart rate recovery; HRV, heart rate variability; PPG, photoplethysmography; SaO₂, oxygen saturation.

Studies of Nonimplantable Devices to Detect AF

Table 3. Studies of Nonimplantable Devices to Detect AF

Source	Study Population	Means of Detection	Comparator	Primary Outcome
SEARCH-AF, ⁸² 2014	People visiting a community pharmacy	Smartphone ECG	None	Newly diagnosed AF
STROKESTOP, ⁸³ 2015	Patients registered to live in 2 regions of Sweden	Intermittent use of single-lead ECG recorder for 2 wk	None	Untreated AF
mSToPS ⁸⁴	Patients without a diagnosis of AF in claims data	14-d Ambulatory ECG patch at baseline and approximately 4 mo later	14-d Ambulatory ECG patch at approximately 4 and 8 mo after enrollment	Newly diagnosed AF
SCREEN-AF ⁸⁵	Patients receiving primary care	14-d Ambulatory ECG patch at baseline and 3 mo later	Pulse check, heart auscultation by physician at 6 mo	New diagnosis of ECG-confirmed AF or atrial flutter
SEARCH-AF ⁸⁶	Patients after cardiac surgery	30-d Ambulatory ECG patch	Usual care	AF or atrial flutter of ≥6 min or documentation by ECG

Abbreviations: AF, atrial fibrillation; ECG, electrocardiography; mSToPS, mHealth Screening to Prevent Strokes; SCREEN-AF, Home-Based Screening for Early Detection of Atrial Fibrillation in Primary Care Patients Aged 75 Years and Older; SEARCH-AF, Screening Education And Recognition in Community Pharmacies of Atrial Fibrillation; STROKESTOP, Systematic ECG Screening for Atrial Fibrillation Among 75-Year-Old Subjects in the Region of Stockholm and Halland, Sweden.

Consumer-Led Screening for Atrial Fibrillation: Frontier Review of the AF-SCREEN International Collaboration

Axel Brandes¹, MD^{*}; Stavros Stavrakis², MD, PhD^{*}; Ben Freedman³, MD; Sotiris Antoniou⁴, MSc; Giuseppe Boriani⁵, MD; A. John Camm⁶, MD; Clara K. Chow⁷, MD, PhD; Eric Ding⁸, BS; Johan Engdahl, MD; Michael M. Gibson, MD; Gregory Golovchiner, MD; Taya Glotzer, MD; Yutao Guo⁹, MD; Jeff S. Healey¹⁰, MD, MSc; Mellanie T. Hills¹¹, CSP; Linda Johnson¹², MD; Gregory Y. H. Lip¹³, MD; Trudie Lobban, MBE; Peter W. Macfarlane¹⁴, PhD; Gregory M. Marcus¹⁵, MD, MAS; David D. McManus, MD; Lis Neubeck, PhD; Jessica Orchard¹⁶, PhD, MPH; Marco V. Perez¹⁷, MD; Renate B. Schnabel¹⁸, MD, PhD; Breda Smyth, MPH; Steven Steinhubl¹⁹, MD; Mintu P. Turakhia²⁰, MD

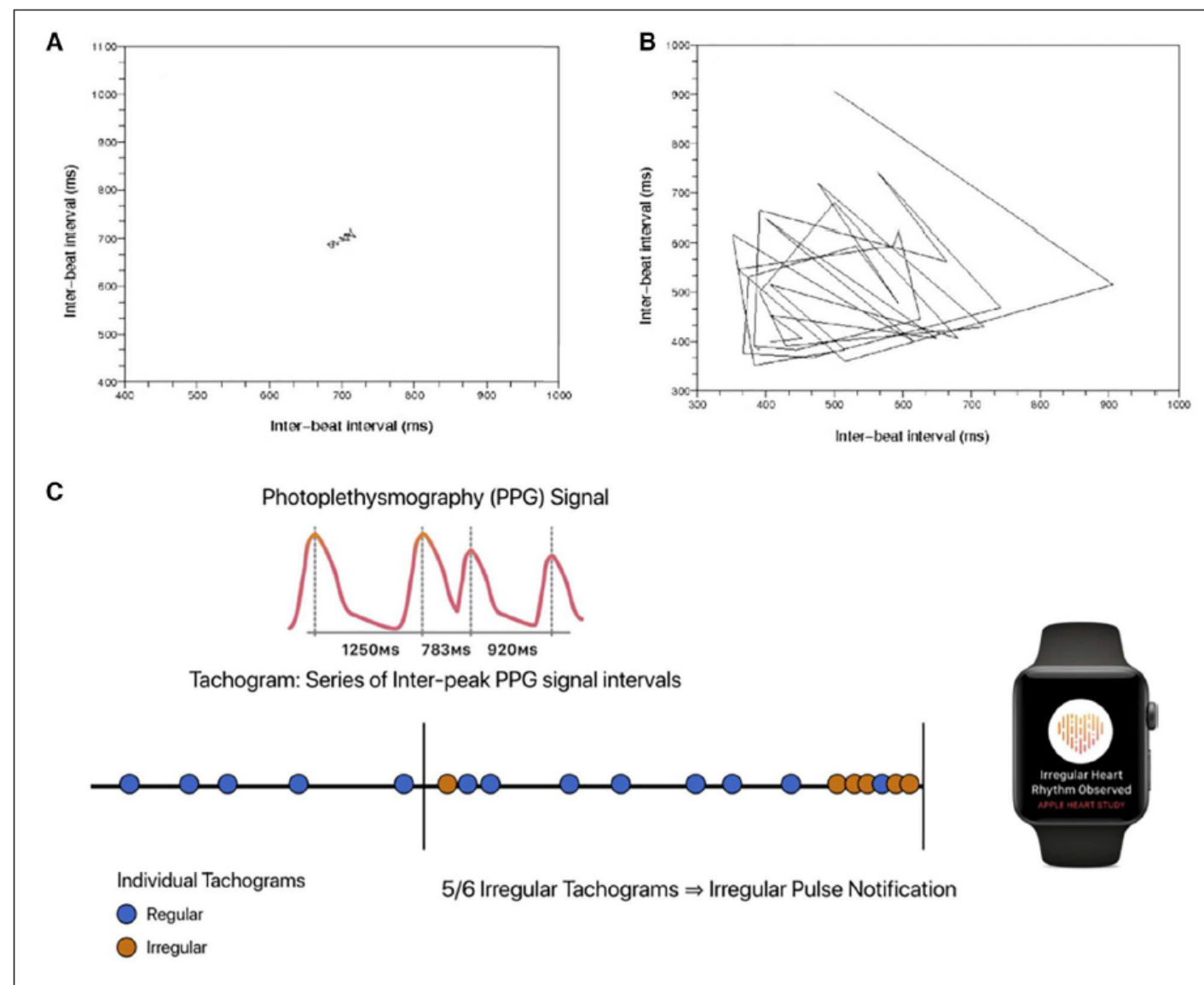


Figure 1. Algorithms to detect atrial fibrillation.

Depicted are Poincaré plots of (A) sinus rhythm and (B) atrial fibrillation, as well as (C) the algorithm used by the irregular pulse notification algorithm on the Apple Watch. One-minute pulse intervals are taken intermittently during rest, and if an irregular pulse is detected, the pulse is sampled more frequently. If 5 of 6 pulse measurements are irregular, a possible atrial fibrillation alert is generated. Similar approaches have been taken by other manufacturers to increase specificity, some with greater stringency (eg, Fitbit, which required 11 consecutive irregular overlapping 5-min tachograms, or >30 min irregular).

Consumer-Led Screening for Atrial Fibrillation: Frontier Review of the AF-SCREEN International Collaboration

Axel Brandes¹, MD; Stavros Stavrakis², MD, PhD; Ben Freedman³, MD; Sotiris Antoniou⁴, MSc; Giuseppe Boriani⁵, MD; A. John Camm⁶, MD; Clara K. Chow⁷, MD, PhD; Eric Ding⁸, BS; Johan Engdahl, MD; Michael M. Gibson, MD; Gregory Golovchiner, MD; Taya Glotzer, MD; Yutao Guo⁹, MD; Jeff S. Healey¹⁰, MD, MSc; Mellanie T. Hills¹¹, CSP; Linda Johnson¹², MD; Gregory Y. H. Lip¹³, MD; Trudie Lobban, MBE; Peter W. Macfarlane¹⁴, PhD; Gregory M. Marcus¹⁵, MD, MAS; David D. McManus, MD; Lis Neubeck, PhD; Jessica Orchard¹⁶, PhD, MPH; Marco V. Perez¹⁷, MD; Renate B. Schnabel¹⁸, MD, PhD; Breda Smyth, MPH; Steven Steinhilb¹⁹, MD; Mintu P. Turakhia²⁰, MD

Table 2. Screening for AF Using Commercially Available Wearable Devices

Study	Number of subjects	Device	Inclusion criteria	AF detected by monitor	Comments
Apple Heart ¹⁶	419 297	Apple Watch	Age ≥ 22 y, possession of Apple Watch	0.52% received notification for irregular rhythm; AF confirmed in 34%	Virtual study Mean age 41 y PPV: 84%
Huawei study ¹⁷	187 912	Wristband (Honor Band 4) or wrist-watch (Huawei Watch GT)	Age ≥ 18 y	0.23% received a "suspected AF" notification; AF confirmed in 87%	Mean age 35 y PPV: 92%
Verbrugge et al ⁵⁶	12 328	PPG only technology	Not specified	1.1% diagnosed with possible AF	Participants were invited through an article in a local newspaper Mean age 49 y
Heartline study (NCT04276441)		Apple Watch	Age ≥ 65 y Possession of iPhone 6s or later Medicare coverage	Ongoing	Virtual study
Fitbit Heart study ¹⁸	455 699	Fitbit	Age ≥ 22 y No previous history of AF Fitbit account, with a compatible device paired	0.07% received notification for irregular rhythm; AF confirmed in 32%	Median age 47 y PPV: 98% AF algorithm operated only during periods of inactivity

AF indicates atrial fibrillation; PPG, photoplethysmogram; and PPV, positive predictive value.

Consumer-Led Screening for Atrial Fibrillation: Frontier Review of the AF-SCREEN International Collaboration

Axel Brandes¹, MD¹; Stavros Stavrakis², MD, PhD²; Ben Freedman³, MD; Sotiris Antoniou⁴, MSc; Giuseppe Boriani⁵, MD; A. John Camm⁶, MD; Clara K. Chow⁷, MD, PhD; Eric Ding⁸, BS; Johan Engdahl, MD; Michael M. Gibson, MD; Gregory Golovchiner, MD; Taya Glotzer, MD; Yutao Guo⁹, MD; Jeff S. Healey¹⁰, MD, MSc; Mellanie T. Hills¹¹, CSP; Linda Johnson¹², MD; Gregory Y. H. Lip¹³, MD; Trudie Lobban, MBE; Peter W. Macfarlane¹⁴, PhD; Gregory M. Marcus¹⁵, MD, MAS; David D. McManus, MD; Lis Neubeck, PhD; Jessica Orchard¹⁶, PhD, MPH; Marco V. Perez¹⁷, MD; Renate B. Schnabel¹⁸, MD, PhD; Breda Smyth, MPH; Steven Steinhubl¹⁹, MD; Mintu P. Turakhia²⁰, MD

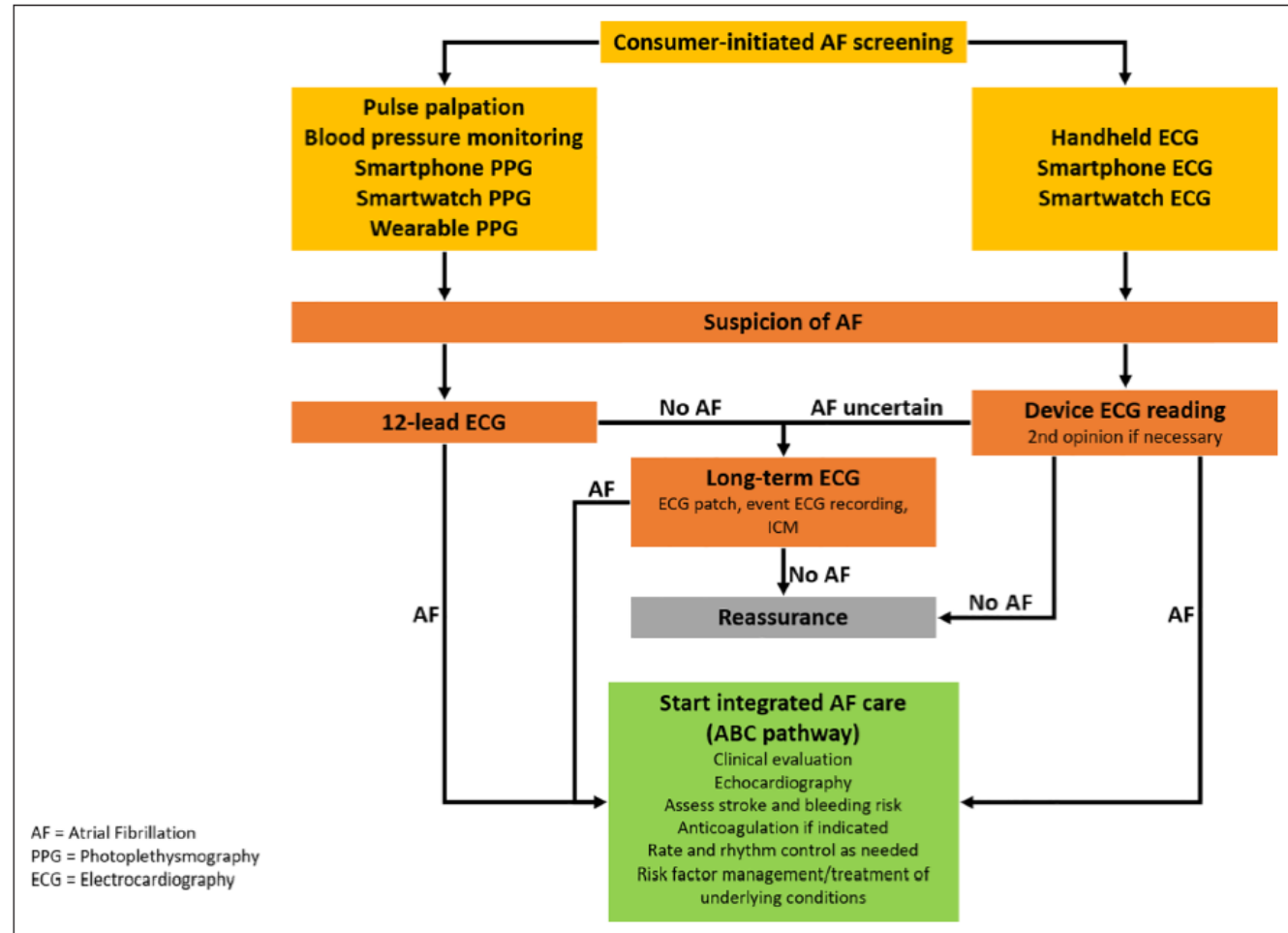


Figure 3. Workflow when there is a suspicion of AF during consumer-led AF screening.

Consumer-initiated ECG recordings suggesting possible AF always require confirmation by a health care professional experienced in ECG reading, whereas suspicion of AF on the basis of photoplethysmography must be confirmed with an ECG. If AF is confirmed, an integrated care approach, including appropriate anticoagulation, risk factor modification, and treatment of underlying cardiovascular comorbidities, should be undertaken to reduce complications. ABC indicates anticoagulation, better symptom control, and control of comorbidities; AF, atrial fibrillation; ICM, intracardiac monitor; and PPG, photoplethysmogram.

Consumer-Led Screening for Atrial Fibrillation: Frontier Review of the AF-SCREEN International Collaboration

Axel Brandes¹, MD¹; Stavros Stavrakis², MD, PhD²; Ben Freedman³, MD; Sotiris Antoniou⁴, MSc; Giuseppe Boriani⁵, MD; A. John Camm⁶, MD; Clara K. Chow⁷, MD, PhD; Eric Ding⁸, BS; Johan Engdahl⁹, MD; Michael M. Gibson¹⁰, MD; Gregory Golovchiner¹¹, MD; Taya Glotzer¹², MD; Yutao Guo¹³, MD; Jeff S. Healey¹⁴, MD; Mellanie T. Hills¹⁵, CSP; Linda Johnson¹⁶, MD; Gregory Y. H. Lip¹⁷, MD; Trudie Lobban, MBE; Peter W. Macfarlane¹⁸, PhD; Gregory M. Marcus¹⁹, MD, MAS; David D. McManus, MD; Lis Neubeck, PhD; Jessica Orchard²⁰, PhD, MPH; Marco V. Perez²¹, MD; Renate B. Schnabel²², MD, PhD; Breda Smyth, MPH; Steven Steinhubl²³, MD; Mintu P. Turakhia²⁴, MD

Although increased screening increases AF detection rate, [...] the minimum AF burden at which the risk of stroke is sufficient to justify the initiation of DOAC remains unclear.

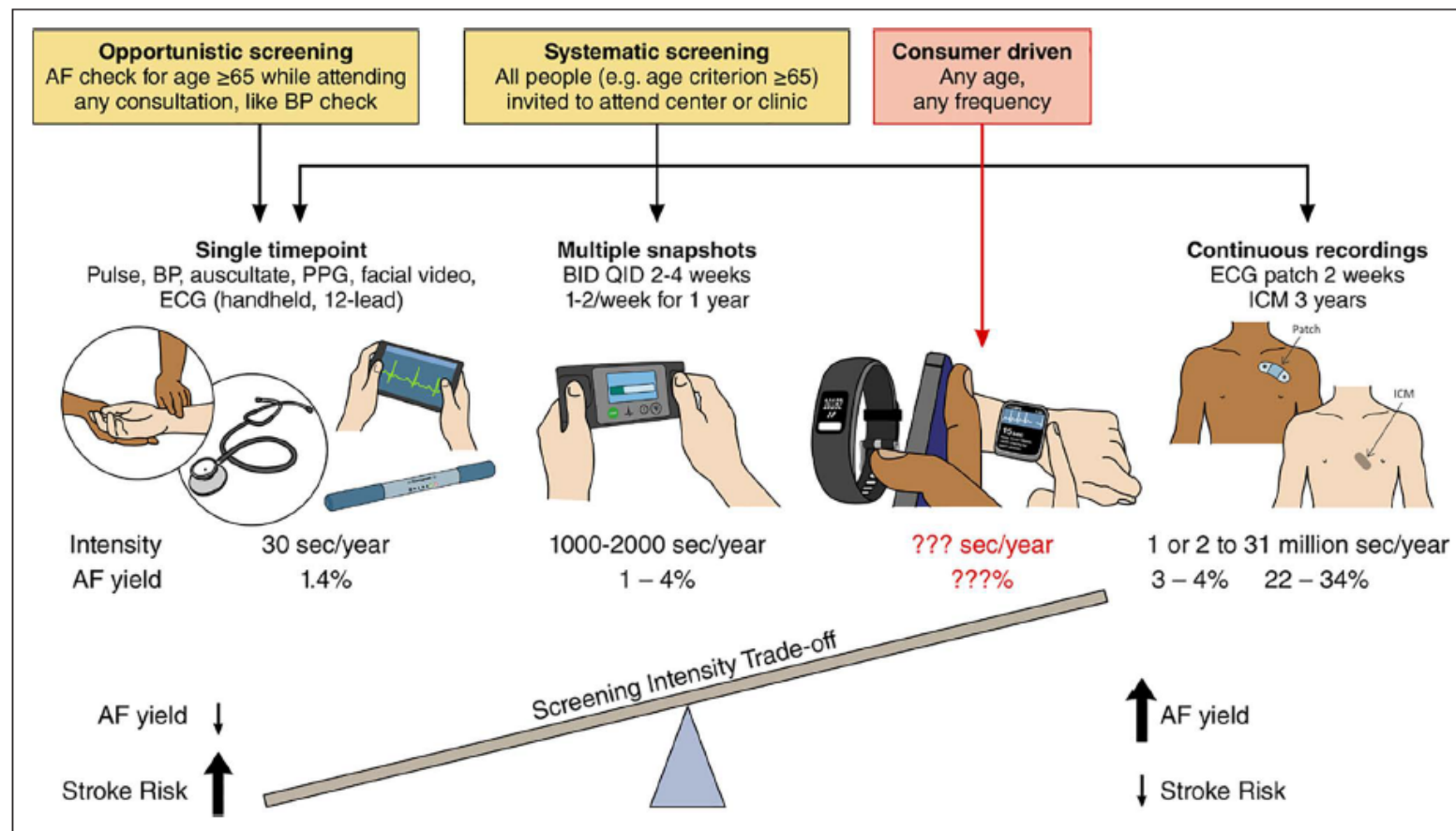


Figure 2. Tradeoff between duration/intensity of screening for detection of AF and AF stroke risk.

Although increased screening intensity increases AF detection rates, it may also identify AF associated with low stroke risk. Nonetheless, the minimum AF burden at which the risk of stroke is sufficient to justify initiation of anticoagulation remains unclear. Therefore, the tradeoff between increased detection of low-burden, possibly low-risk AF by continuous monitoring strategies could be minimized by defining an intermittent monitoring strategy that would diminish the potential for missing individuals with a high burden, which in turn is associated with a higher risk of stroke. AF indicates atrial fibrillation; BID, twice daily; BP, blood pressure; ICM, implantable cardiac monitor; PPG, photoplethysmography; and QID, 4 times a day. Modified from Benjamin et al.⁸

Consumer-Led Screening for Atrial Fibrillation: Frontier Review of the AF-SCREEN International Collaboration

Axel Brandes¹, MD; Stavros Stavrakis², MD, PhD; Ben Freedman³, MD; Sotiris Antoniou⁴, MS
Giuseppe Boriani⁵, MD; A. John Camm⁶, MD; Clara K. Chow⁷, MD, PhD; Eric Ding⁸, BS; Johan
Michael M. Gibson, MD; Gregory Golovchiner, MD; Taya Glotzer, MD; Yutao Guo⁹, MD; Jeff S. Heal
Mellanie T. Hills¹⁰, CSP; Linda Johnson¹¹, MD; Gregory Y. H. Lip¹², MD; Trudie Lobban, MBE;
Peter W. Macfarlane¹³, PhD; Gregory M. Marcus¹⁴, MD, MAS; David D. McManus, MD; Lis Neubeck
Jessica Orchard¹⁵, PhD, MPH; Marco V. Perez¹⁶, MD; Renate B. Schnabel¹⁷, MD, PhD; Breda Smyt
Steven Steinhilb¹⁸, MD; Mintu P. Turakhia¹⁹, MD

Legal and ethical issues with consumer-led screening



- consumer expectation of health information privacy
- tend not to read privacy policies which are long/complex and 'take it or leave it'
- data not owned by consumer



- app privacy policies vary substantially
- use/misuse of data
- storage and security of data



- gaps in existing health information, device/app quality and privacy regulation
- existing consumer protection legislation covers marketing claims

Figure 4. Legal and ethical issues with consumer-led atrial fibrillation screening.

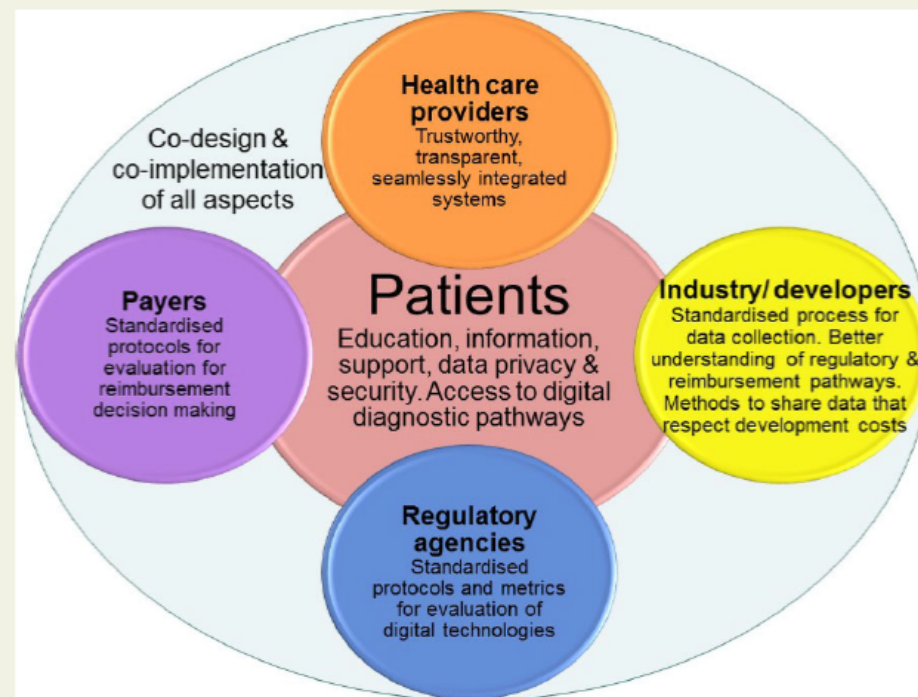
Important legal and ethical gaps in relation to data and registration of consumer screening apps and devices are shown.



Wearables, telemedicine, and artificial intelligence in arrhythmias and heart failure: Proceedings of the European Society of Cardiology Cardiovascular Round Table

Christophe Leclercq^{1*}, Henning Witt², Gerhard Hindricks³, Rodolphe P. Katra⁴, Dave Albert⁵, Andrea Bellinger⁶, Martin R. Cowie⁷, Thomas Deneke⁸, Paul Friedman⁹, Mehdiyar Haschemi¹⁰, Trudie Lobban¹¹, Isabelle Lordereau¹², Michael V. McConnell¹³, Leonardo Rapallini¹⁴, Eigil Samset¹⁵, Mintu P. Turakhia^{16,17}, Jagmeet P. Singh¹⁸, Emma Svennberg¹⁹, Manish Wadhwa²⁰, and Franz Weidinger²¹

Graphical Abstract



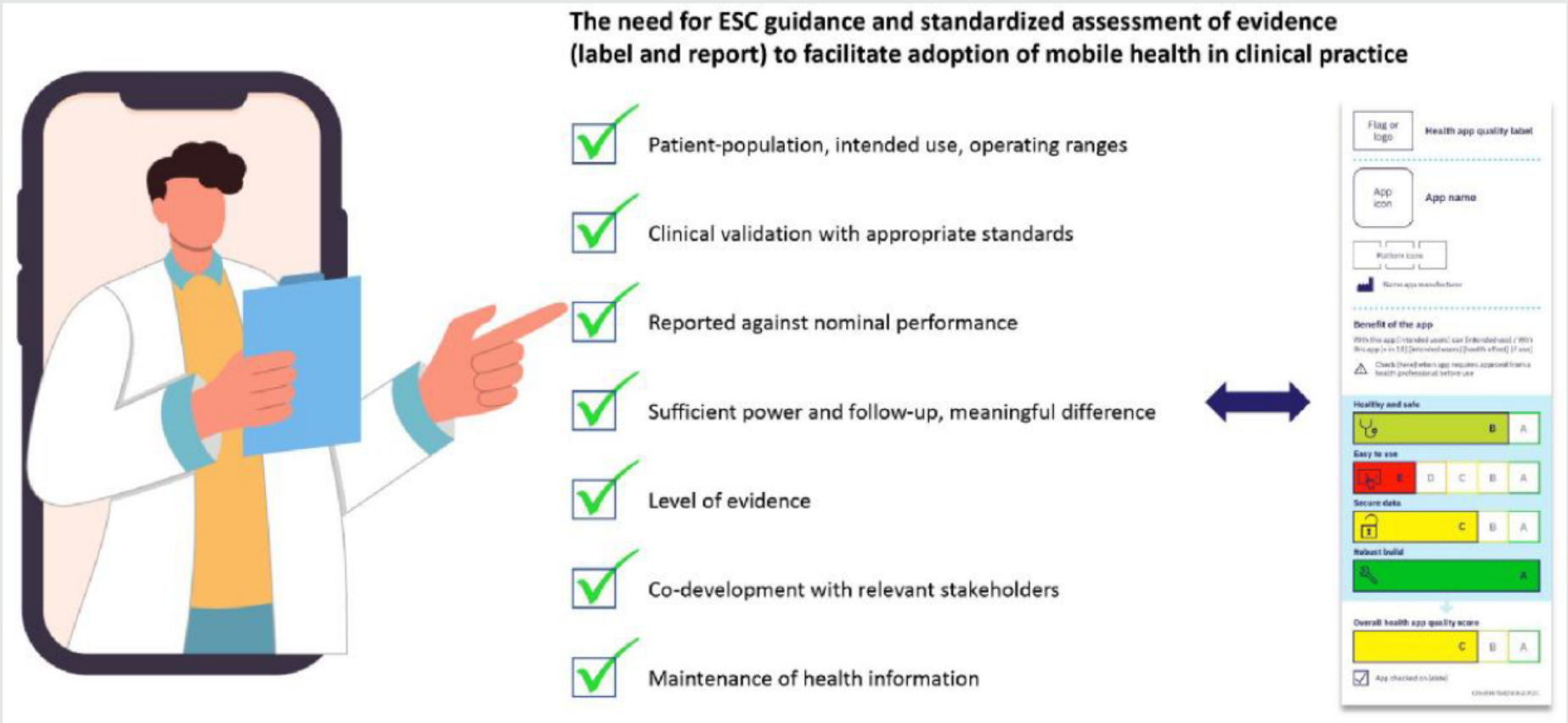
Fundamental needs of stakeholders involved in digital healthcare.

Keywords

M-health • Wearable devices • Monitoring • Early detection • Digital healthcare solutions • Artificial intelligence

Standardized assessment of evidence supporting the adoption of mobile health solutions: A Clinical Consensus Statement of the ESC Regulatory Affairs Committee

Developed in collaboration with the European Heart Rhythm Association (EHRA), the Association of Cardiovascular Nursing & Allied Professions (ACNAP) of the ESC, the ESC Association (HFA) of the ESC, the ESC Working Group on e-Cardiology, the ESC Practice, the ESC Council of Cardio-Clinical Hypertension, the ESC Patient Forum, the ESC Regulatory Affairs Committee, and the European Association of Cardiovascular Pharmacology (EAPC)



Standardized assessment of evidence supporting the adoption of mobile health solutions: A Clinical Consensus Statement of the ESC Regulatory Affairs Committee

Developed in collaboration with the European Heart Rhythm Association (EHRA), the Association of Cardiovascular Nursing Allied Professions (ACNAP) of the ESC, the Heart Failure Association (HFA) of the ESC, the ESC Young Community, the Working Group on e-Cardiology, the ESC Council for Cardiology Practice, the ESC Council of Cardio-Oncology, the ESC Council of Hypertension, the ESC Patient Forum, the ESC Digital Health Committee, and the European Association of Preventive Cardiology (EAPC)

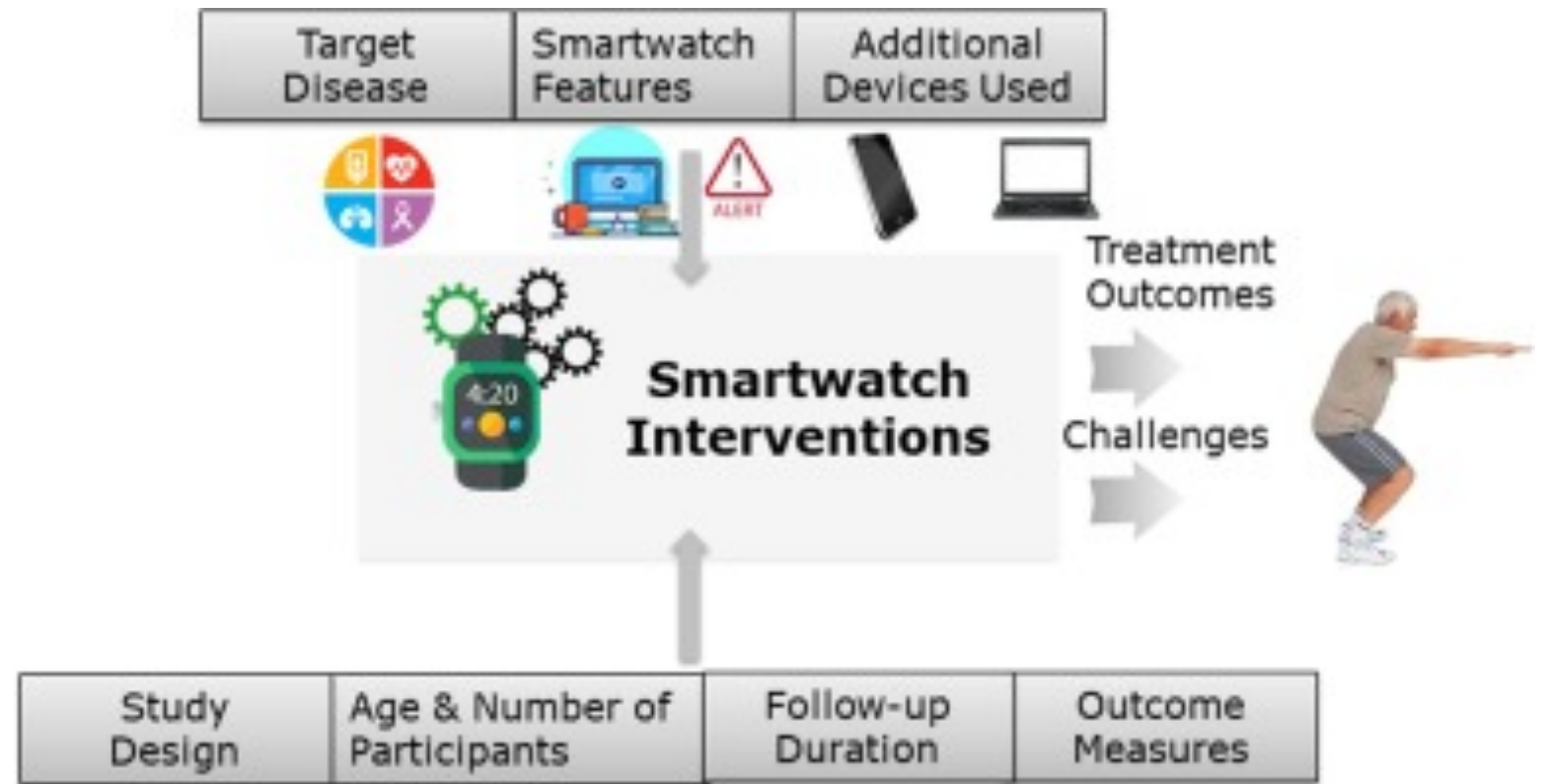
- Trust in content with clinical evidence to support claims
- Accessibility of inserted data
- Company credibility
- Data about accuracy, reliability and usability
- Co-design including patients and clinicians
- Intuitive and easy to use user interface
- Transparent costs
- Clear user guide and specific purpose for using it

Figure 1 Aspects of mHealth solutions important both from patient's and HCP's point of view.

Review article

Smartwatch interventions in healthcare: A systematic review of the literature

Andreas Triantafyllidis ^a, , Haridimos Kondylakis ^b,
Dimitrios Katehakis ^b, Angelina Kouroubali ^b,
Anastasios Alexiadis ^a, Sofia Segkouli ^a, Konstantinos Votis ^a,
Dimitrios Tzovaras ^a



Highlights

- Automated collection of health-related data and triggering of notifications were the main reasons for using smartwatches in interventional studies.
- Smartwatch interventions have shown positive health outcomes for patients in most studies.
- Challenges include Charging frequency, Internet connection, data quality.
- The evaluation of the implementation strategy in smartwatch research studies is needed.
- The methodological quality of smartwatch studies should be improved.

2017 ISHNE-HRS Expert Consensus:

Estimated diagnostic yield of different AECG recording modalities

Received: 3 February 2017 | Accepted: 6 February 2017
DOI: 10.1111/ane.12447

CONSENSUS STATEMENT

WILEY

2017 ISHNE-HRS expert consensus statement on ambulatory ECG and external cardiac monitoring/telemetry

Jonathan S. Steinberg MD (Co-Chair)^{1,2} | Niraj Varma MD, PhD (Co-Chair)³ | Iwona Cygankiewicz MD, PhD (Co-Chair)⁴ | Peter Aziz MD³ | Paweł Balsam MD⁵ | Adrian Baranchuk MD⁶ | Daniel J. Cantillon MD³ | Polychronis Dilaveris MD, PhD⁷ | Sergio J. Dubner MD⁸ | Nabil El-Sherif MD⁹ | Jarosław Krol MD¹⁰ | Malgorzata Kurpesa MD, PhD¹¹ | Maria Teresa La Rovere MD¹² | Suave S. Lobodzinski PhD, DrSc¹³ | Emanuela T. Locati MD, PhD¹⁴ | Suneet Mittal MD¹⁵ | Brian Olshansky MD¹⁶ | Ewa Piotrowicz MD, PhD¹⁷ | Leslie Saxon MD¹⁸ | Peter H. Stone MD¹⁹ | Larisa Tereshchenko MD, PhD^{20,21} | Gioia Turitto MD²² | Neil J. Wimmer MD¹⁹ | Richard L. Verrier PhD²³ | Wojciech Zareba MD, PhD¹ | Ryszard Piotrowicz MD, PhD (Chair)²⁴

Duration of recording	Type of recorder	Palpitations (%)	Syncope (%)	Cryptogenic stroke (%) (Silent AF)
<60 s	Event recorder	50–60	Not applicable	Not applicable
24–48 hr	Standard Holter	10–15	1–5	1–5
3–7 days	Patch/Vest/Belt Recorder/ MCT/ELR	50–70	5–10	5–10 (?)
1–4 weeks	ELR/Patch/Vest/Belt Recorder/MCT	70–85	15–25	10–15 (?)
<36 months	ILR	80–90	30–50	15–20 (?)

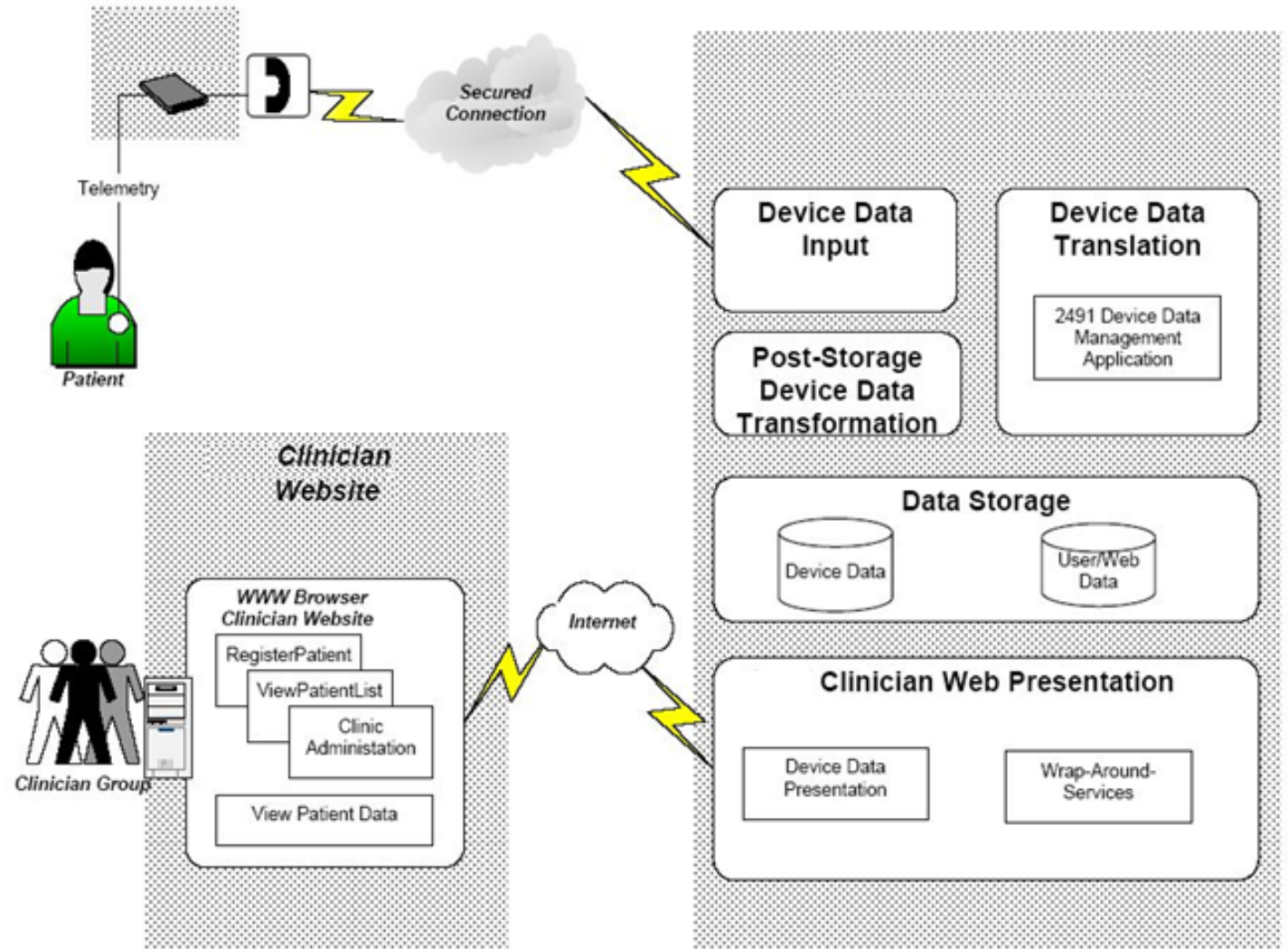
MCT, mobile cardiac telemetry; ELR, external loop recorder; ILR, implantable loop recorder.

Advantages and disadvantages of ECG monitoring strategies for detection of atrial fibrillation.

ECG Monitoring Technology	Advantages	Disadvantages
24–72h Holter	low cost	likely to miss AF
7-day Holter	low cost, longer recording	inconvenient
patch recorder	7–14 days recording, better adherence	recording length similar to Holter, higher cost, limited leads
patient monitors–intermittent short ECG recordings	low cost, convenient (no wires)	likely to miss asymptomatic, short-lasting arrhythmias, requires patients action
pulse-based AF detection (smartwatch, bands)	convenient, affordable	a high proportion of false alerts needs ECG confirmation
implantable cardiac monitors (ICM)	long term monitoring (years)	an invasive procedure, high cost

Remote Management

Remote Monitoring





Wearables, telemedicine, and artificial intelligence in arrhythmias and heart failure: Proceedings of the European Society of Cardiology Cardiovascular Round Table

Christophe Leclercq^{1*}, Henning Witt², Gerhard Hindricks³,
Rodolphe P. Katra⁴, Dave Albert⁵, Andrea Beller⁶, Martin R. Cowie⁷,
Thomas Deneke⁸, Paul Friedman⁹, Mehdiyar Hascher
Isabelle Lordereau¹², Michael V. McConnell¹³, Leonar
Eigil Samset¹⁵, Mintu P. Turakhia^{16,17}, Jagmeet P. Singh
Manish Wadhwa²⁰, and Franz Weidinger²¹

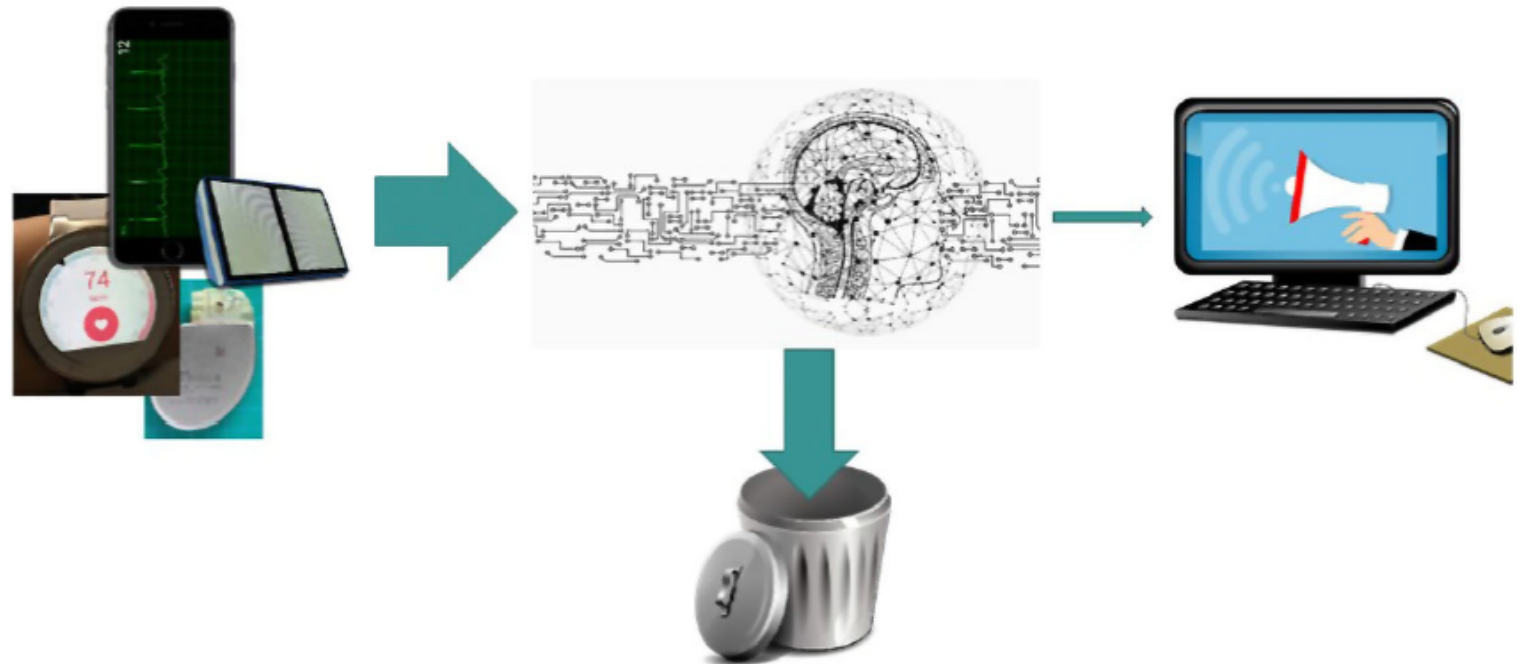
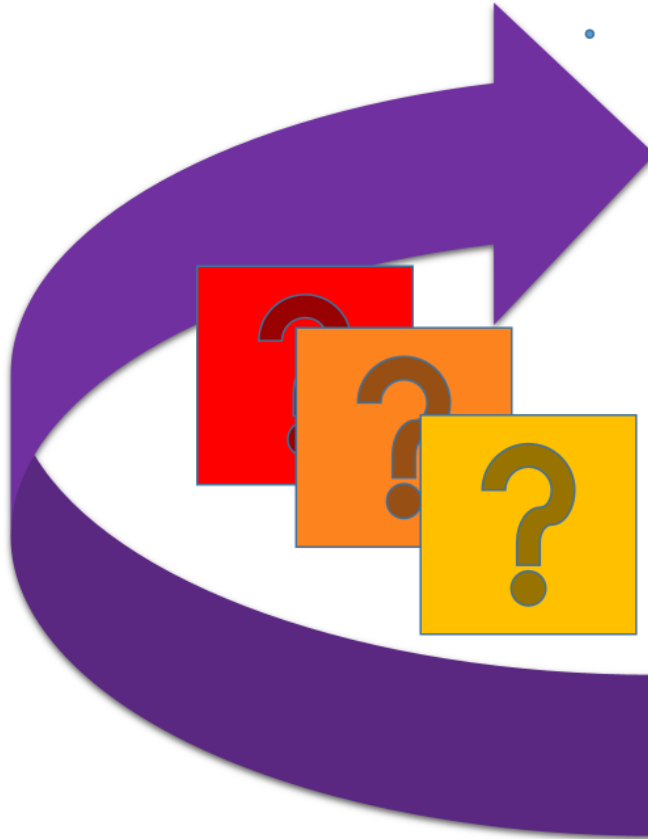


Figure 3 Using devices and AI algorithms in clinical practice to curate data^{44,45}. AF, atrial fibrillation; AI, artificial intelligence.

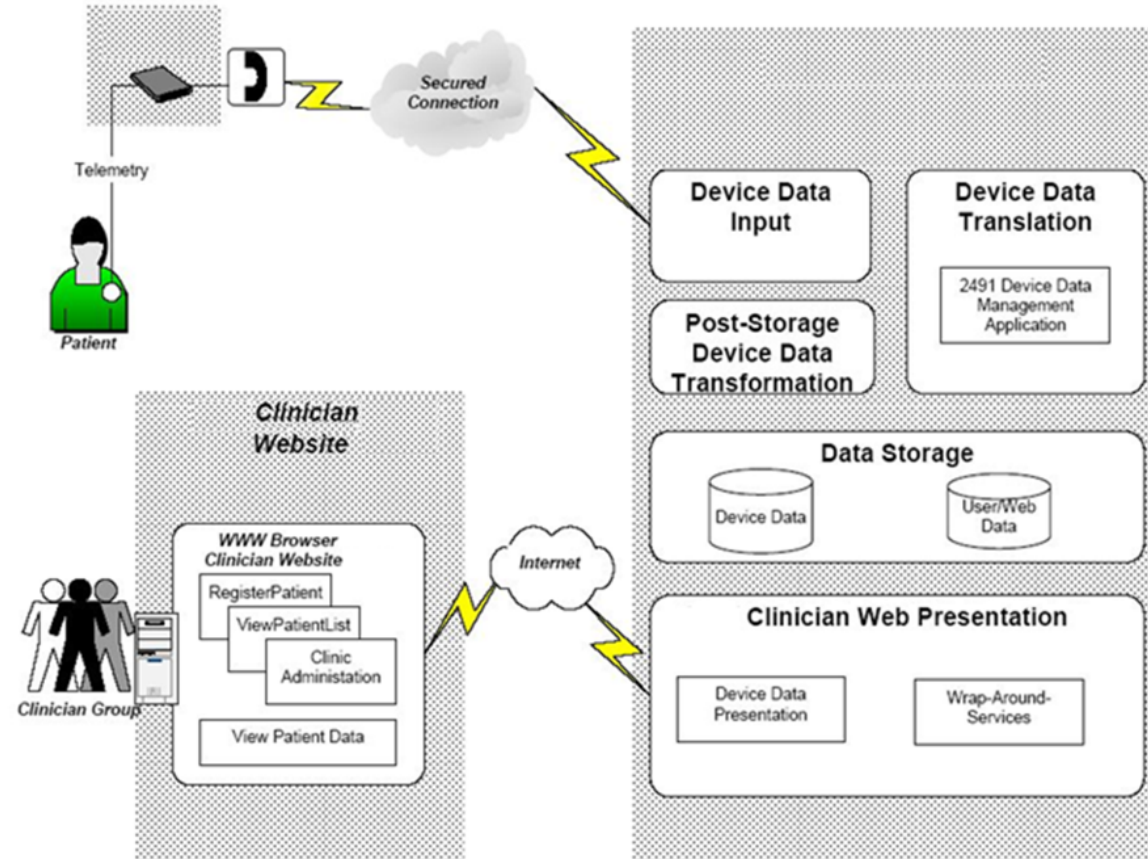
Grazie per l'attenzione!



Clinical Remote Management



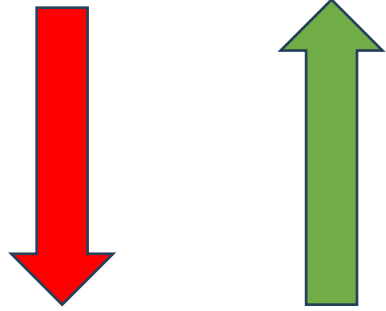
CIED Remote Monitoring



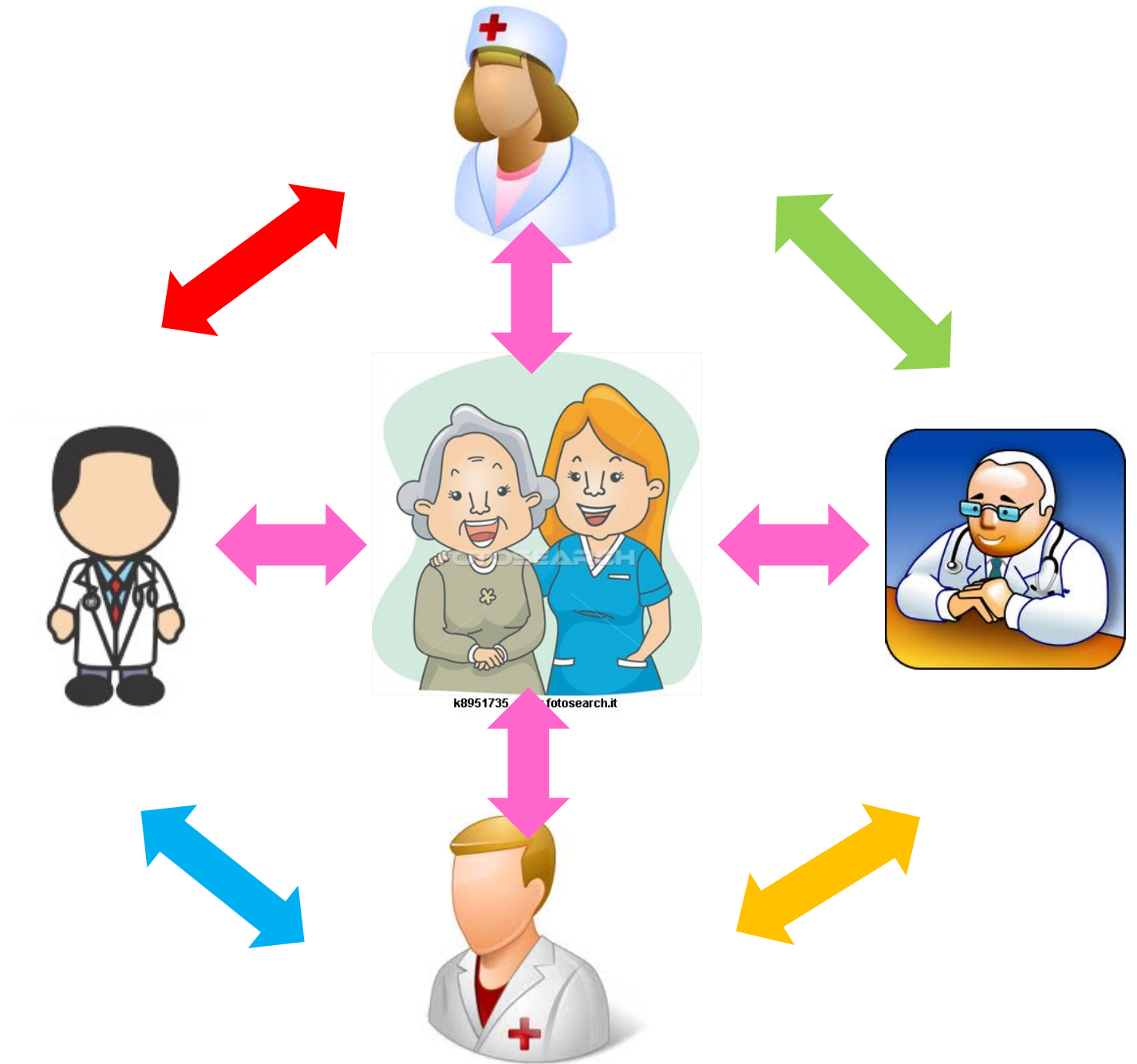


***Thank for your attention!
...And greetings from Milan!***

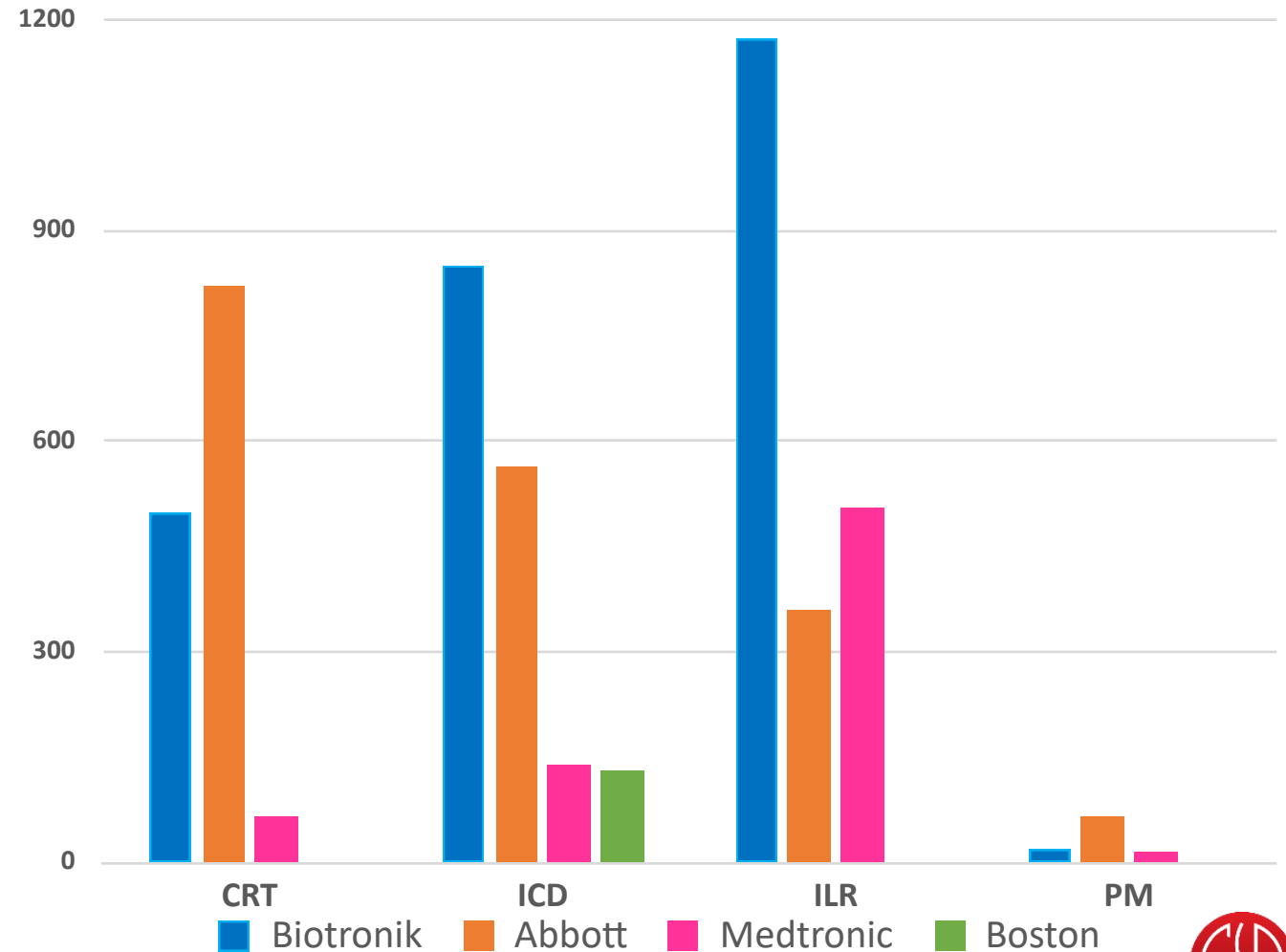
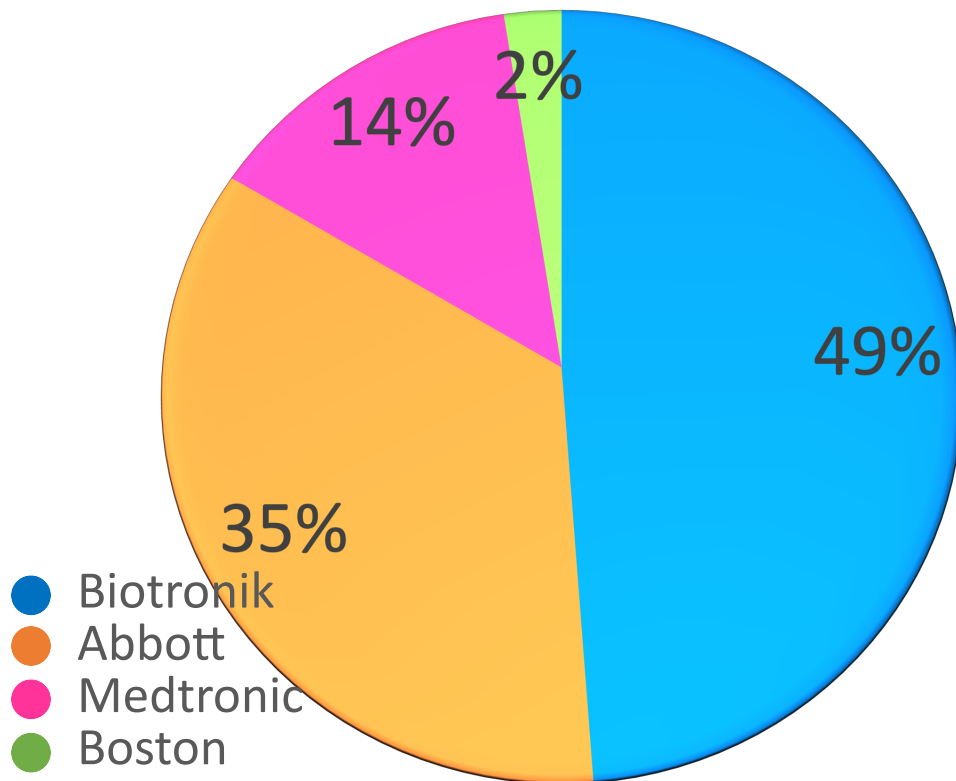
Models of CIEDs Remote Monitoring



Networks for Remote Patient Management



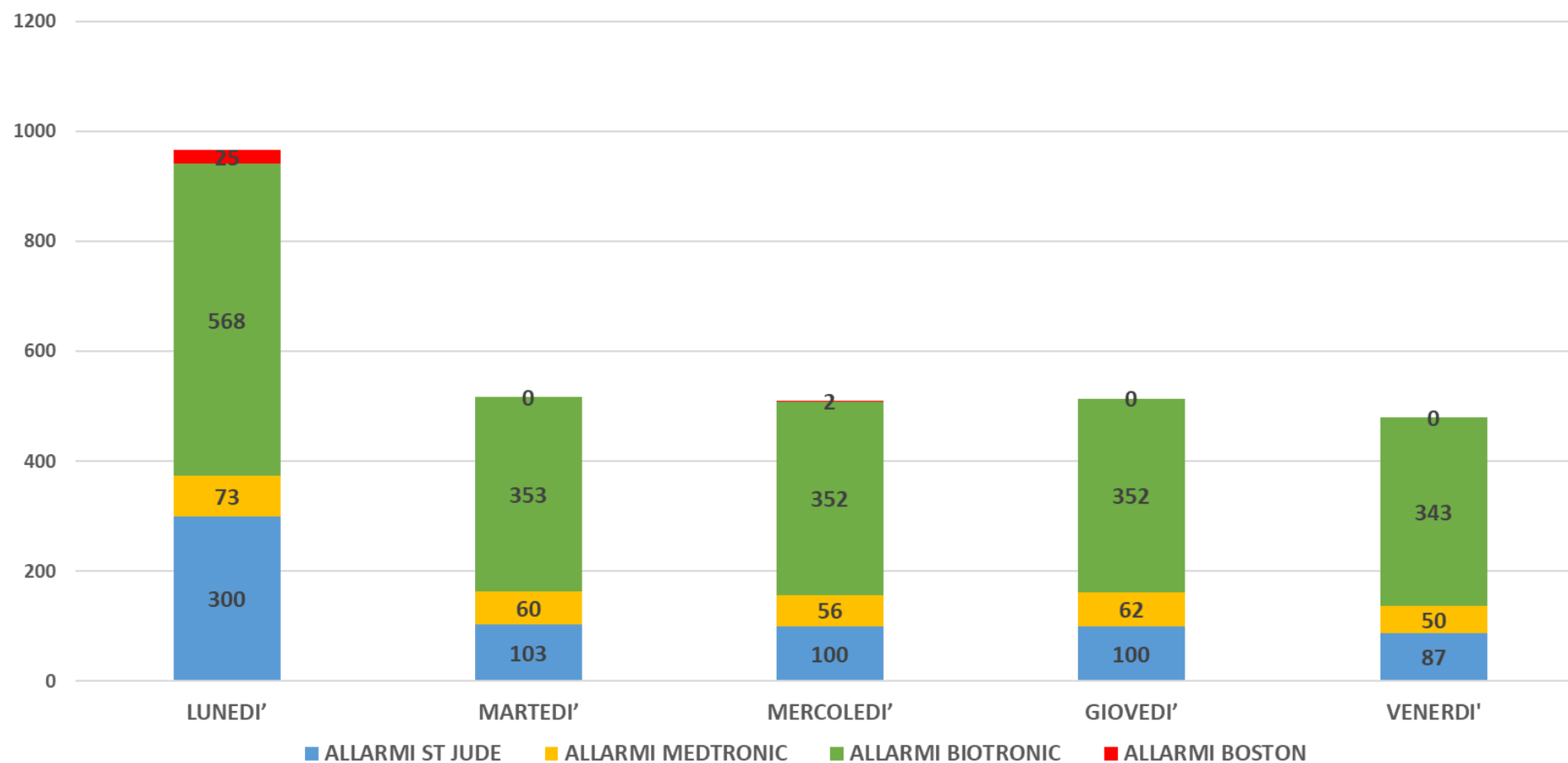
REMOTE MONITORING - ARRHYTHMOLOGY DEPT - POLICLINICO SAN DONATO TOTAL 5213 ACTIVE PATIENTS WITH CIEDS (APRIL 2022)



Remote Monitoring Arrhythmology Dpt. San Donato Hospital

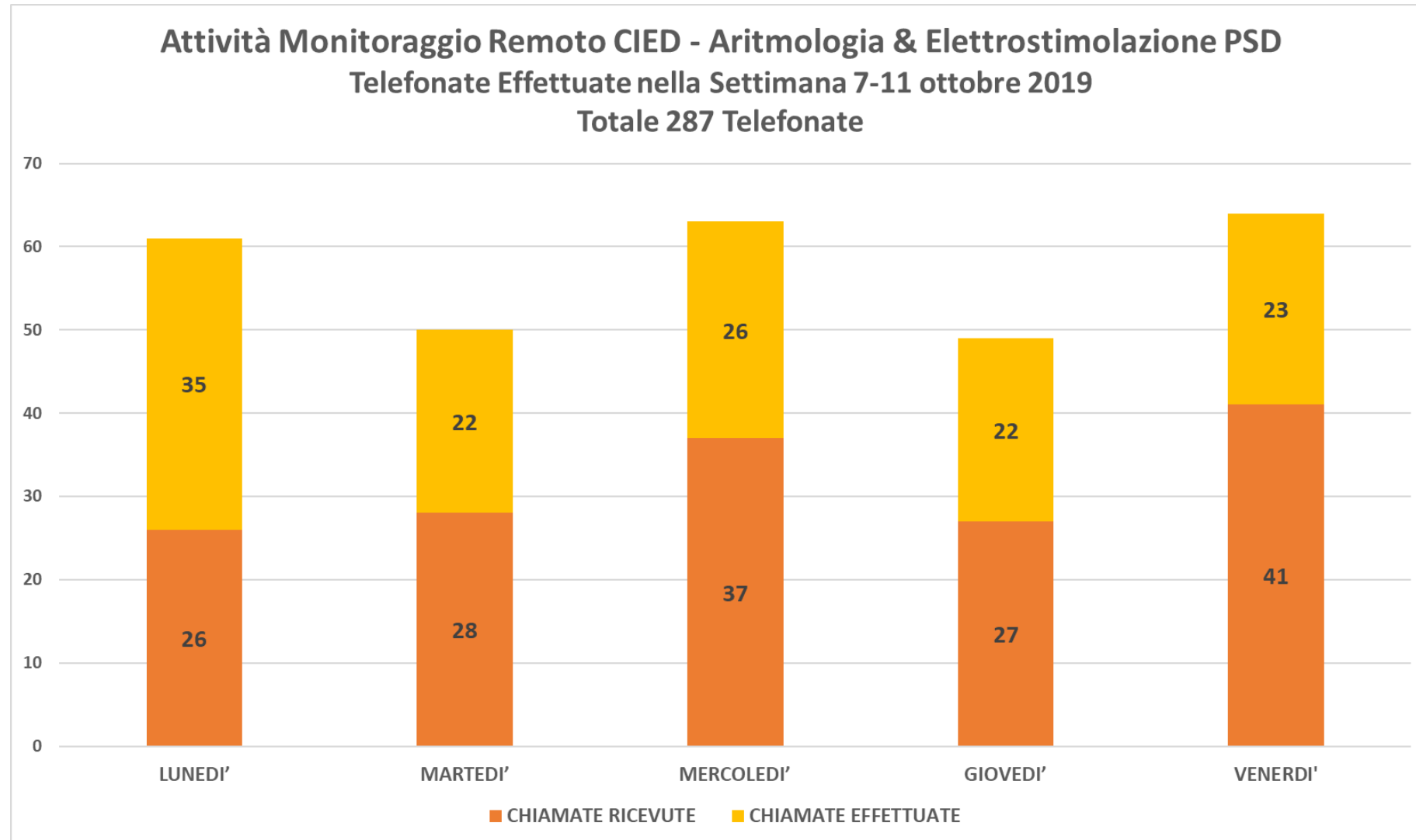
2986 Alarms per Week

Attività Monitoraggio Remoto CIED - Aritmologia & Elettrostimolazione PSD
Allarmi Gestiti nella settimana 7-11 ottobre 2019
Totale 2986 Allarmi



Remote Monitoring Arrhythmology Dpt. San Donato Hospital

287 Phone Calls per Week

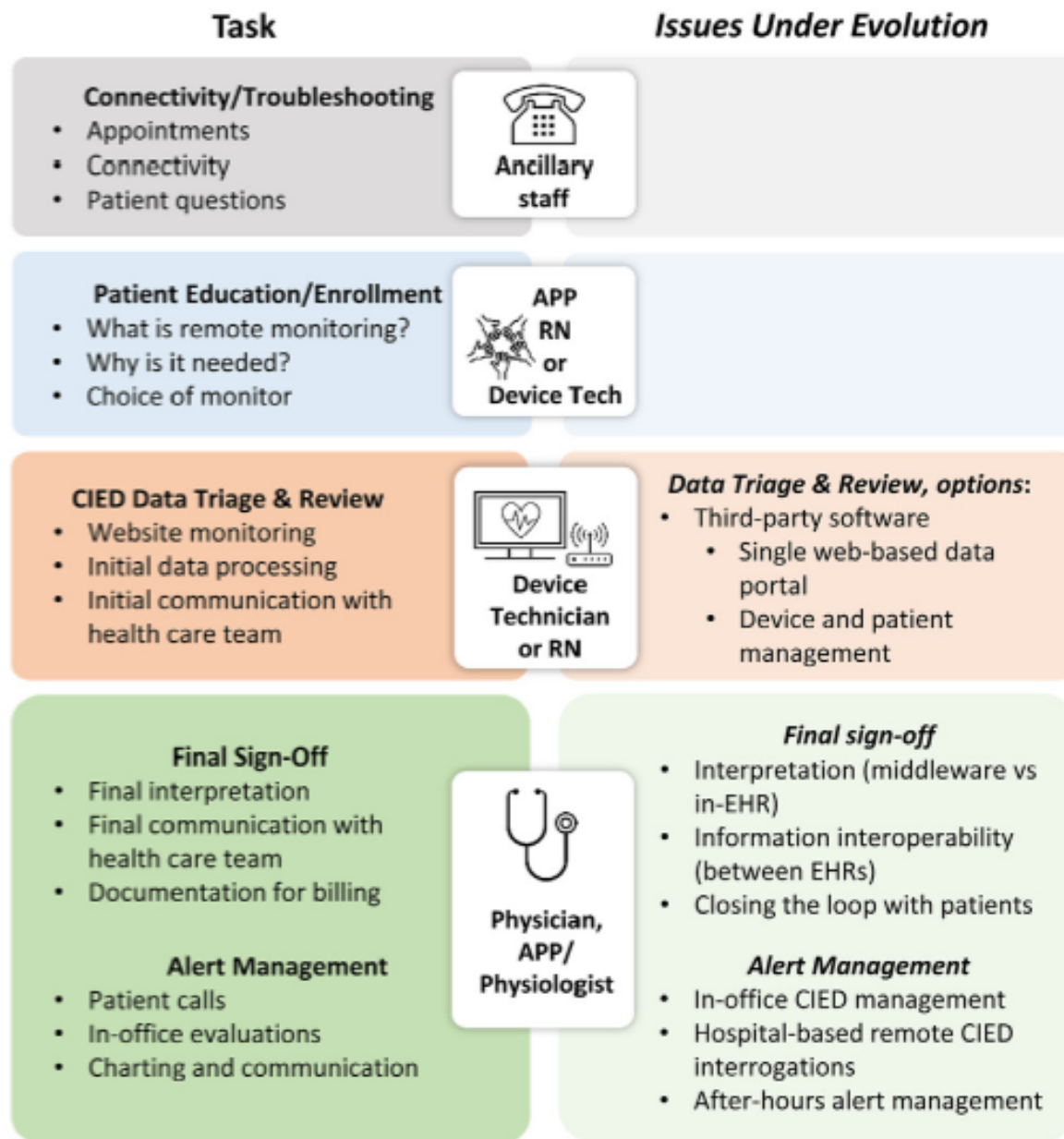


2023 HRS/EHRA/APHRS/LAHRs expert consensus statement on practical management of the remote device clinic @

Aileen M. Ferrick, PhD, ACNP, RN, FHRS (Co-Chair),^{1,*}
 Satish R. Raj, MD, MSCI, FHRS (Co-Chair),^{2,*}
 Thomas Deneke, MD, PhD, FHRS (EHRA Vice-Chair),^{3,†}
 Pipin Kojodjojo, MBBS, PhD, FHRS (APHRS Vice-Chair),^{4,‡}
 Nestor Lopez-Cabanillas, MD (LAHRs Vice-Chair),^{5,§} Haruhiko Abe, MD, PhD,^{6,‡}
 Serge Boveda, MD, PhD, FEHRA, FESC,^{7,†} Derek S. Chew, MD, MSc, FHRS,^{2,*}
 Jong-Il Choi, MD, PhD, MHS,^{8,‡} Nikolaos Dagres, MD,^{9,†}
 Aarti S. Dalal, DO, FACC, FHRS, CEPS-P,^{10,¶} Brynn E. Dechert, APN, FHRS, CCDS,^{11,¶}
 Camille G. Frazier-Mills, MD, MHS, CCDS,^{12,*} Olivia Gilbert, MD, MSc, FACC,^{13,#}
 Janet K. Han, MD, FACC, FHRS,^{14,**} Sherri Hewit, PharmD,^{††}
 Christine Kneeland, BSN,^{15,*} Starr DeEllen Mirza,^{††} Suneet Mittal, MD, FHRS,^{16,*}
 Renato Pietro Ricci, MD,^{17,†} Mary Runte, PhD,^{18,††} Susan Sinclair, NZCS, PGDHSc,^{19,‡}
 Ricardo Alkmim-Teixeira, MD, PhD,^{20,§} Bert Vandenberg, MD, PhD,^{2,21,†}
 Niraj Varma, MA, MD, PhD^{22,‡‡}

2023 Recommendations: Task Based RM Activity

2023 HRS Guidelines: Task Based (Implications for Staffing)





Europace (2016) 18, iii1–iii79
doi:10.1093/europace/euw244

CLINICAL RESEARCH

Access to and clinical use of cardiac implantable electronic devices and interventional electrophysiological procedures in the European Society of Cardiology Countries: 2016 Report from the European Heart Rhythm Association

M.J. Pekka Raatikainen^{1*}, David O. Amar², Bela Merkely³, A. John Camm^{4,5}, and Gerhard Hindricks⁶

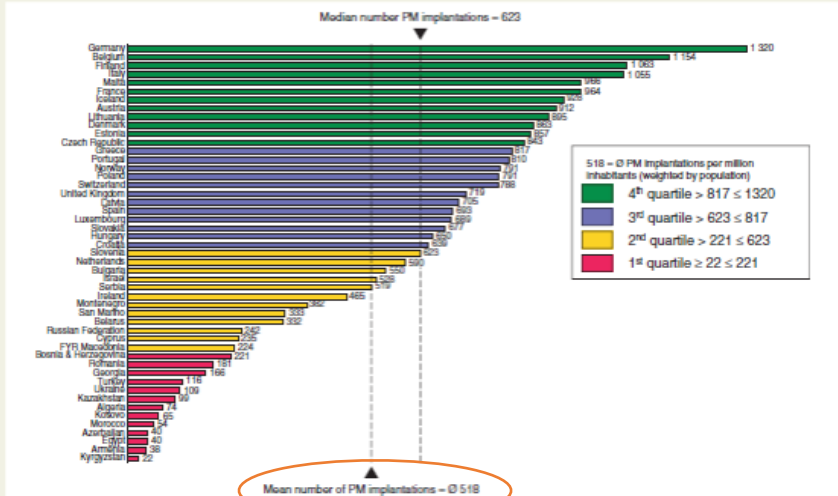


Figure 11 Pacemaker implantations per million inhabitants in the ESC countries in 2015. The mean number of implantations is weighted by population.

Europace 2016

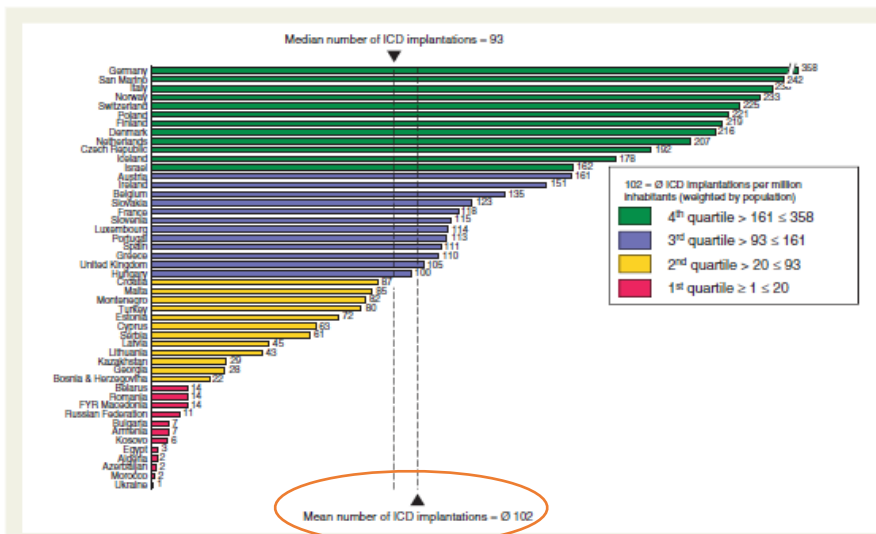


Figure 26 Implantable cardioverter-defibrillator implantations per million inhabitants in 2015. The mean number of implantations is weighted by population.

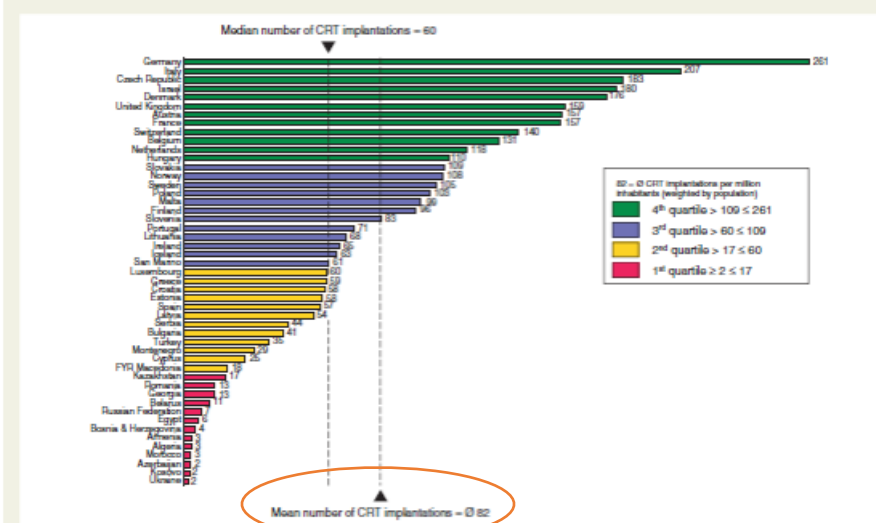


Figure 41 Cardiac resynchronization therapy device implantations per million inhabitants 2015. The mean number of CRT implantations is weighted by population.

THE CHALLENGE

“While there will always be more patients to manage. There will never be more time to manage them.”¹

Gimbel, 2012

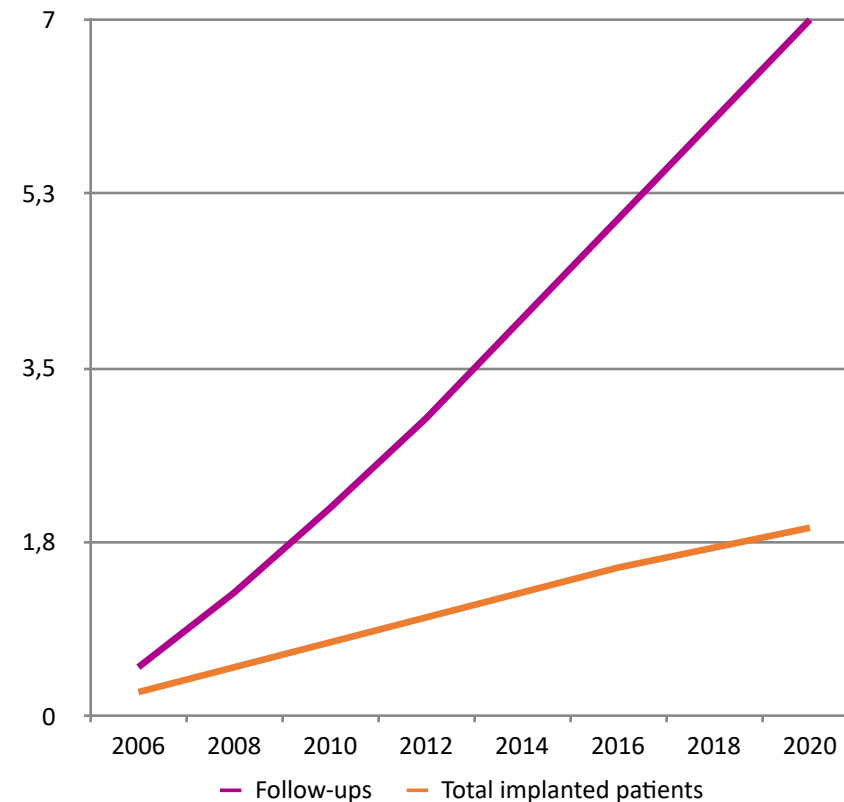
As the number of patients with implants increases, so does demand for follow-ups. **How can hospitals solve this growing problem?**

¹ Gimbel, 2012, Heart Rhythm, vol 9, n°12

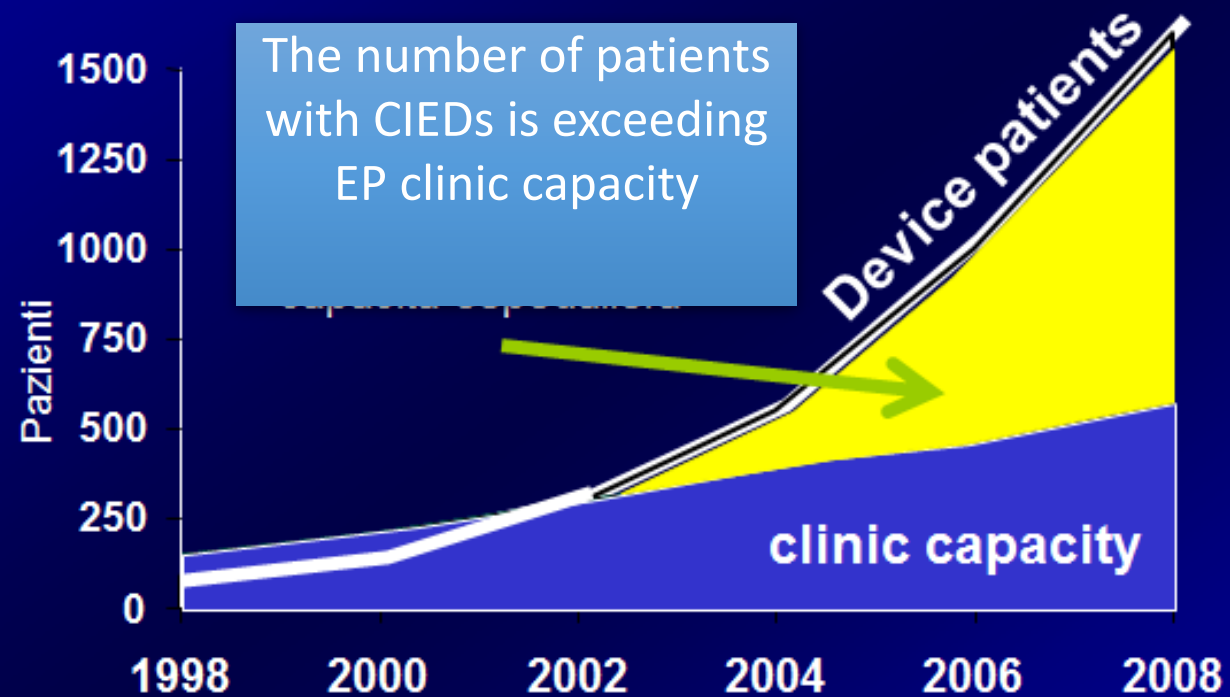
² Data from projected figures modelled using 2013/14 UK CRM NICOR dataset.

https://www.ucl.ac.uk/nicor/nicor-news-publication/CRM_Report_2013-14

EUROPE IMPLANTED PATIENTS & FOLLOW-UPS, 2006–2020² (MILLIONS)



Impact of Clinical Indications of ICD/CRT Implants on Resources Availability



* ACC/AHA/NASPE 2002 guideline update.

HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices

David Slotwiner, MD, FHRS, FACC (Chair),^{1#} Niraj Varna, MD, PhD, FRCP (Co-chair),^{2#} Joseph G. Alar, MD, PhD,³ George Annas, JD, MPH,⁴ Marianne Beardsall, MN/NP, CCDS, FHRS,⁵ Richard I. Fogel, MD, FHRS,⁶ Nestor O. Galizio, MD,^{7*} Taya V. Glotzer, MD, FHRS, FACC,⁸ Robin A. Leahy, RN, BSN, CCDS, FHRS,⁹ Charles J. Love, MD, CCDS, FHRS, FACC, FAHA,¹⁰ Rhondalyn C. McLean, MD,^{11†} Suneet Mittal, MD, FHRS,¹² Loredana Morichelli, RN, MSN,¹³ Kristen K. Patton, MD,^{14‡} Merritt H. Raitt, MD, FHRS,¹⁵ Renato Pietro Ricci, MD,^{13§} John Rickard, MD, MPH,¹⁶ Mark H. Schoenfeld, MD, CCDS, FHRS, FACC, FAHA,¹⁷ Gerald A. Serwer, MD, FHRS, FACC,^{18||} Julie Shea, MS, RNCS, FHRS, CCDS,¹⁹ Paul Varosy, MD, FHRS, FACC, FAHA,²⁰ Atul Verma, MD, FHRS, FRCPC,⁵ Cheuk-Man Yu, MD, FACC, FRCP, FRACP^{21¶}

Heart Rhythm 2015

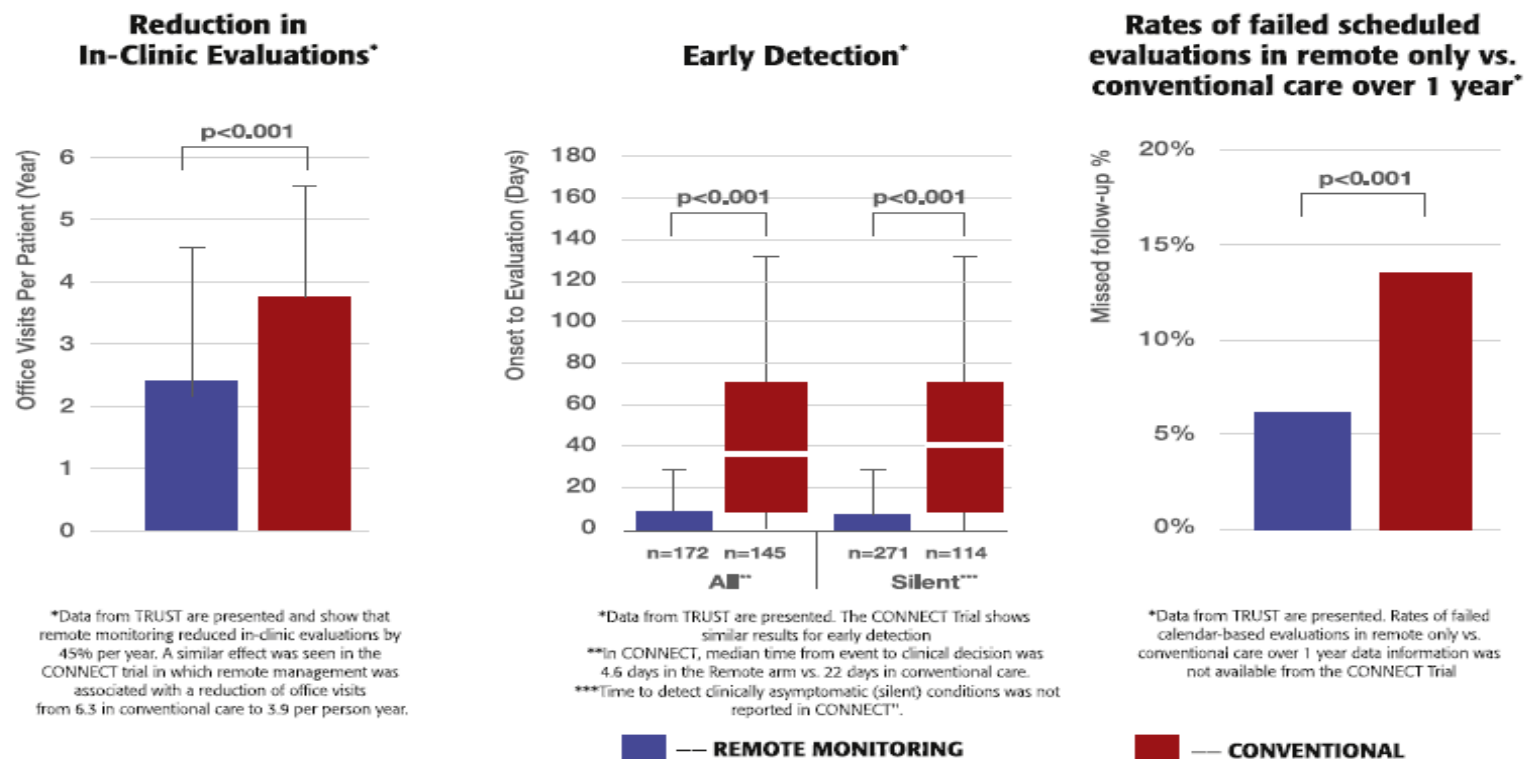


Figure 2 Benefits of remote monitoring. CONNECT = Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision; TRUST = Lum Safety Reduces Routine Office Device Follow-Up.

HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices

David Slotwiner, MD, FHRS, FACC (Chair),^{1#} Niraj Varna, MD, PhD, FRCP (Co-chair),^{2#} Joseph G. Akar, MD, PhD,³ George Annas, JD, MPH,⁴ Marianne Beardsall, MN/NP, CCDS, FHRS,⁵ Richard I. Fogel, MD, FHRS,⁶ Nestor O. Galizio, MD,^{7*} Taya V. Glotzer, MD, FHRS, FACC,⁸ Robin A. Leahy, RN, BSN, CCDS, FHRS,⁹ Charles J. Love, MD, CCDS, FHRS, FACC, FAHA,¹⁰ Rhondalyn C. McLean, MD,^{11†} Suneet Mittal, MD, FHRS,¹² Loredana Morichelli, RN, MSN,¹³ Kristen K. Patton, MD,^{14‡} Merritt H. Raitt, MD, FHRS,¹⁵ Renato Pietro Ricci, MD,^{13§} John Rickard, MD, MPH,¹⁶ Mark H. Schoenfeld, MD, CCDS, FHRS, FACC, FAHA,¹⁷ Gerald A. Serwer, MD, FHRS, FACC,^{18||} Julie Shea, MS, RNCS, FHRS, CCDS,¹⁹ Paul Varosy, MD, FHRS, FACC, FAHA,²⁰ Atul Verma, MD, FHRS, FRCPC,⁵ Cheuk-Man Yu, MD, FACC, FRCP, FRACP^{21¶}

Heart Rhythm 2015

According to HRS Consensus Statement, all patients with CIEDs should be offered remote monitoring (RM) as part of standard follow-up management strategy
CLASS 1A RECOMENDATION

Today we have to justify why we cannot provide remote monitoring to patients with CIEDs.

Device Follow-Up Paradigm	Class of Recommendation	Level of Evidence
A strategy of remote CIED monitoring and interrogation, combined with at least annual IPE, is recommended over a calendar-based schedule of in-person CIED evaluation alone (when technically feasible).	I	A
All patients with CIEDs should be offered RM as part of the standard follow-up management strategy.	I	A
Before implementing RM, it is recommended that each patient be educated about the nature of RM, their responsibilities and expectations, potential benefits, and limitations. The occurrence of this discussion should be documented in the medical record.	I	E
It is recommended that all CIEDs be checked through direct patient contact 2–12 weeks postimplantation.	I	E
It may be beneficial to initiate RM within the 2 weeks of CIED implantation.	IIa	C
All patients with an implantable loop recorder with wireless data transfer capability should be enrolled in an RM program, given the daily availability of diagnostic data.	I	E
It is recommended that allied health care professionals responsible for interpreting RM transmissions and who are involved in subsequent patient management decisions have the same qualifications as those performing in-clinic assessments and should ideally possess IBHRE certification for device follow-up or equivalent experience.	I	E
It is recommended that RM programs develop and document appropriate policies and procedures to govern program operations, the roles and responsibilities of those involved in the program, and the expected timelines for providing service.	I	E
CIED = cardiac implantable electronic device; HRS = Heart Rhythm Society; IBHRE = International Board of Heart Rhythm Examiners; IPE = in-person evaluation; RM = remote monitoring.		
Device and Disease Management	Class of Recommendation	Level of Evidence
RM should be performed for surveillance of lead function and battery conservation.	I	A
Patients with a CIED component that has been recalled or is on advisory should be enrolled in RM to enable early detection of actionable events.	I	E
RM is useful to reduce the incidence of inappropriate ICD shocks.	I	B-R
RM is useful for the early detection and quantification of atrial fibrillation.	I	A

2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic

Aileen M. Ferrick, PhD, ACNP, RN, FHRS (Co-Chair),^{1,*}
Satish R. Raj, MD, MSCI, FHRS (Co-Chair),^{2,*}
Thomas Deneke, MD, PhD, FHRS (EHRA Vice-Chair),^{3,†}
Pipin Kojodjojo, MBBS, PhD, FHRS (APHRS Vice-Chair),^{4,‡}
Nestor Lopez-Cabanillas, MD (LAHRS Vice-Chair),^{5,§} Haruhiko Abe, MD, PhD,^{6,‡}
Serge Boveda, MD, PhD, FEHRA, FESC,^{7,†} Derek S. Chew, MD, MSc, FHRS,^{2,*}
Jong-Il Choi, MD, PhD, MHS,^{8,‡} Nikolaos Dargatzis, MD,^{9,†}
Aarti S. Dalal, DO, FACC, FHRS, CEPS-P,^{10,¶} Brynn E. Dechert, APN, FHRS, CCDS,^{11,¶}
Camille G. Frazier-Mills, MD, MHS, CCDS,^{12,*} Olivia Gilbert, MD, MSc, FACC,^{13,#}
Janet K. Han, MD, FACC, FHRS,^{14,**} Sherri Hewitt, PharmD,^{††}
Christine Kneeland, BSN,^{15,*} Starr DeEllen Mirza,^{††} Suneet Mittal, MD, FHRS,^{16,*}
Renato Pietro Ricci, MD,^{17,†} Mary Runte, PhD,^{18,††} Susan Sinclair, NZCS, PGDhSc,^{19,‡}
Ricardo Alkmim-Teixeira, MD, PhD,^{20,§} Bert Vandenberg, MD, PhD,^{2,21,†}
Niraj Varma, MA, MD, PhD^{22,‡‡}

2023 General Recommendations

In patients with CIEDs, RM is recommended as part of the standard care.

Recommendations for RM considerations

COR	LOE	Recommendations	References
1	A	1. In patients with CIEDs, RM is recommended as part of the standard of care.	1,11,30-38
1	B-R	2. In patients with CIEDs on RM, routine surveillance of lead function and battery status is recommended to ensure device integrity.	30,39,40
1	C-EO	3. In patients with CIEDs on RM with a device capable of continuous connectivity, connectivity should be maintained.	

2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic

Aileen M. Ferrick, PhD, ACNP, RN, FHRS (Co-Chair),^{1,*}
Satish R. Raj, MD, MSCI, FHRS (Co-Chair),^{2,*}
Thomas Deneke, MD, PhD, FHRS (EHRA Vice-Chair),^{3,†}
Pipin Kojodjojo, MBBS, PhD, FHRS (APHRS Vice-Chair),^{4,‡}
Nestor Lopez-Cabanillas, MD (LAHRS Vice-Chair),^{5,§} Haruhiko Abe, MD, PhD,^{6,‡}
Serge Boveda, MD, PhD, FEHRA, FESC,^{7,†} Derek S. Chew, MD, MSc, FHRS,^{2,*}
Jong-Il Choi, MD, PhD, MHS,^{8,‡} Nikolaos Dagres, MD,^{9,†}
Aarti S. Dalal, DO, FACC, FHRS, CEPS-P,^{10,¶} Brynn E. Dechert, APN, FHRS, CCDS,^{11,¶}
Camille G. Frazier-Mills, MD, MHS, CCDS,^{12,*} Olivia Gilbert, MD, MSc, FACC,^{13,#}
Janet K. Han, MD, FACC, FHRS,^{14,**} Sherri Hewit, PharmD,^{††}
Christine Kneeland, BSN,^{15,*} Starr DeEllen Mirza,^{††} Suneet Mittal, MD, FHRS,^{16,*}
Renato Pietro Ricci, MD,^{17,†} Mary Runte, PhD,^{18,††} Susan Sinclair, NZCS, PGDHSc,^{19,‡}
Ricardo Alkmim-Teixeira, MD, PhD,^{20,§} Bert Vandenberg, MD, PhD,^{2,21,†}
Niraj Varma, MA, MD, PhD^{22,‡‡}

Modalities of RM Transmissions

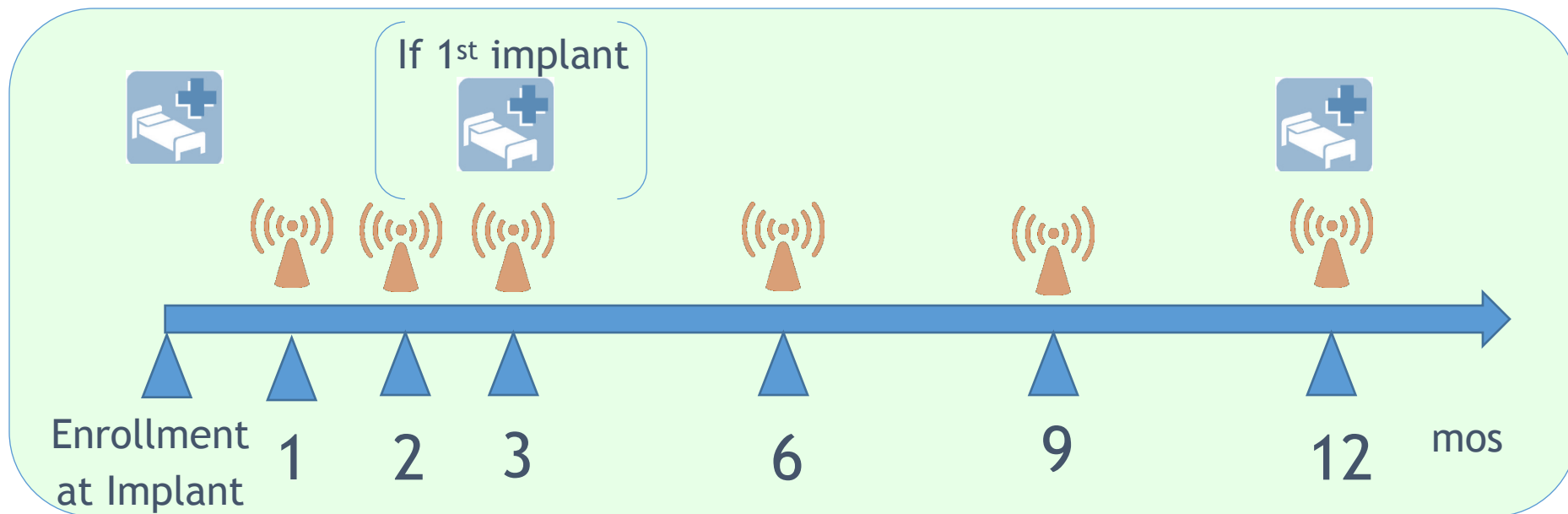
Scheduled transmission	Programmable scheduled transmissions during which routine CIED parameters are collected remotely from the RM platform by members of the remote device clinic team in a format like that obtained during a routine in-person clinic visit.
Nonscheduled transmission	
• Patient-initiated interrogation	Nonscheduled data transmission initiated by the patient due to experiencing real or perceived clinical events, for which the patient is seeking expert evaluation.
• Alert-initiated Interrogation	Nonscheduled data transmission initiated by predefined programmed parameters for alerting the clinic of a potentially actionable event.
Actionable event	Device-related or clinical event that requires intervention prior to the next scheduled in-person clinic visit.
Continuous connectivity	Continuous data collection within the device with automatic transmission using manufacturer-specific transmission frequency, which often occurs once daily. While the data collection is continuous, the transmissions and monitoring are not continuous.
Noncontinuous monitoring	Noncontinuous data collection requiring manual transmission using manufacturer-specific transmission either scheduled by the clinic or initiated by the patient.

Previous Standard: Non-continuous Monitoring

→ *Periodic RM Transmissions*

SCHEDULE OF ROUTINE CONTROLS

- Remote transmissions every 1-3 months
- Clinic visits every 12 months



Current Standard: Continuous Connectivity

→ *Smartphone-Based Daily Transmissions*



- ❑ **Device transmits data to a patient receiver**
→ **Every 24 hrs and immediately in case of an event**
- ❑ **Patient receiver encrypts and sends the data via the cellular **GSM** network to the service center**
- ❑ **Service center updates the patient data base and provides statistics, trend curves and IEGMs on the internet**
- ❑ **Physician has immediate access to the patient data via internet**
→ *Automatic notifications, interpretation, adjustment of thresholds*

2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic ^e

Aileen M. Ferrick, PhD, ACNP, RN, FHRS (Co-Chair),^{1,*}
 Satish R. Raj, MD, MSCI, FHRS (Co-Chair),^{2,*}
 Thomas Deneke, MD, PhD, FHRS (EHRA Vice-Chair),^{3,†}
 Pipin Kojodjojo, MBBS, PhD, FHRS (APHRS Vice-Chair),^{4,‡}
 Nestor Lopez-Cabanillas, MD (LAHRS Vice-Chair),^{5,§} Haruhiko Abe, MD, PhD,^{6,‡}
 Serge Boveda, MD, PhD, FEHRA, FESC,^{7,†} Derek S. Chew, MD, MSc, FHRS,^{2,*}
 Jong-Il Choi, MD, PhD, MHS,^{8,‡} Nikolaos Dagres, MD,^{9,†}
 Aarti S. Dalal, DO, FACC, FHRS, CEPS-P,^{10,¶} Brynn E. Deche
 Camille G. Frazier-Mills, MD, MHS, CCDS,^{12,*} Olivia Gilbert,
 Janet K. Han, MD, FACC, FHRS,^{14,**} Sherri Hewit, PharmD,
 Christine Kneeland, BSN,^{15,*} Starr DeEllen Mirza,^{††} Suneet
 Renato Pietro Ricci, MD,^{17,†} Mary Runte, PhD,^{18,††} Susan S
 Ricardo Alkmim-Teixeira, MD, PhD,^{20,§} Bert Vandenberg, M
 Niraj Varma, MA, MD, PhD^{22,‡‡}

Different Timelines for CIED RM

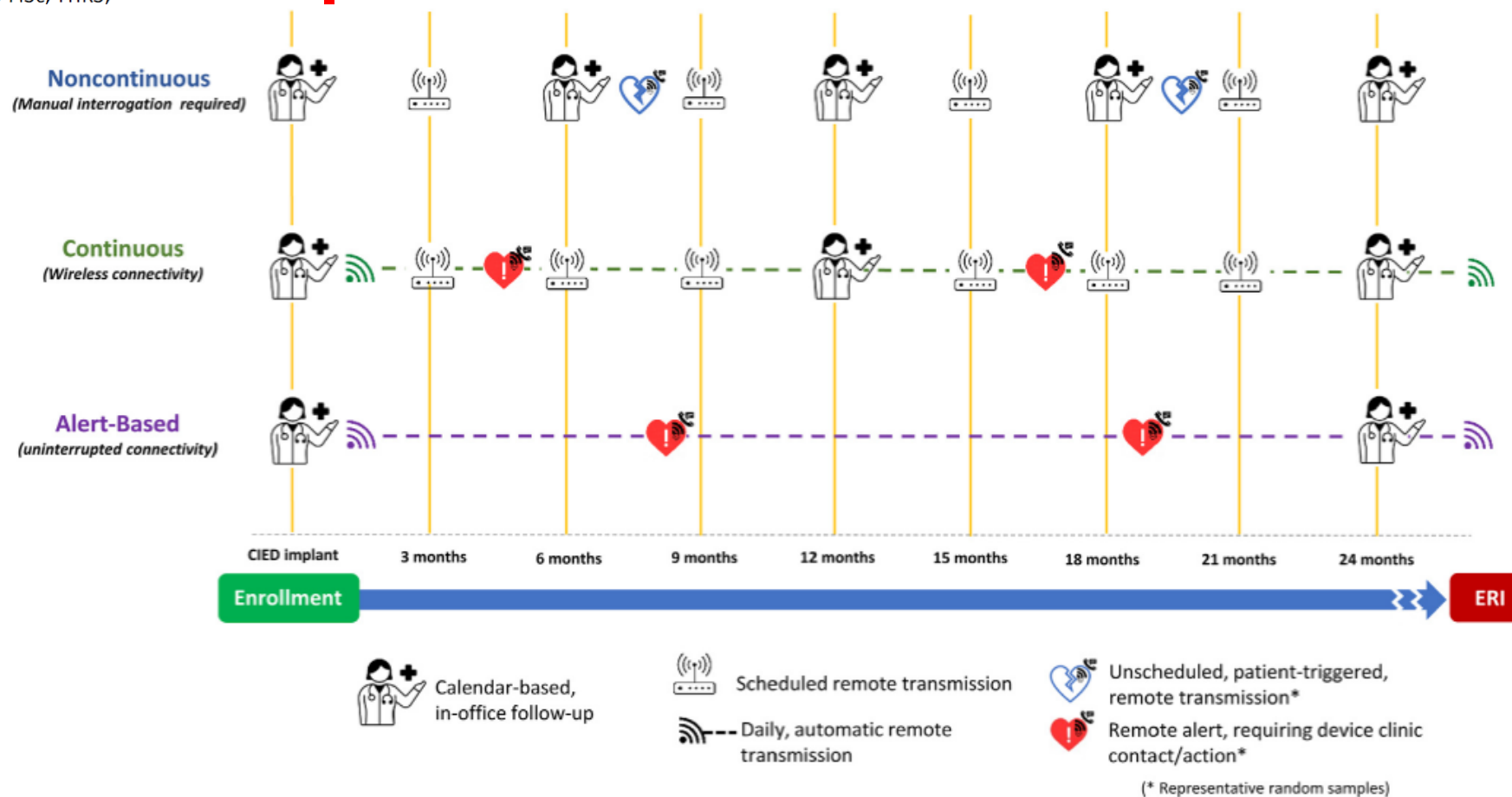
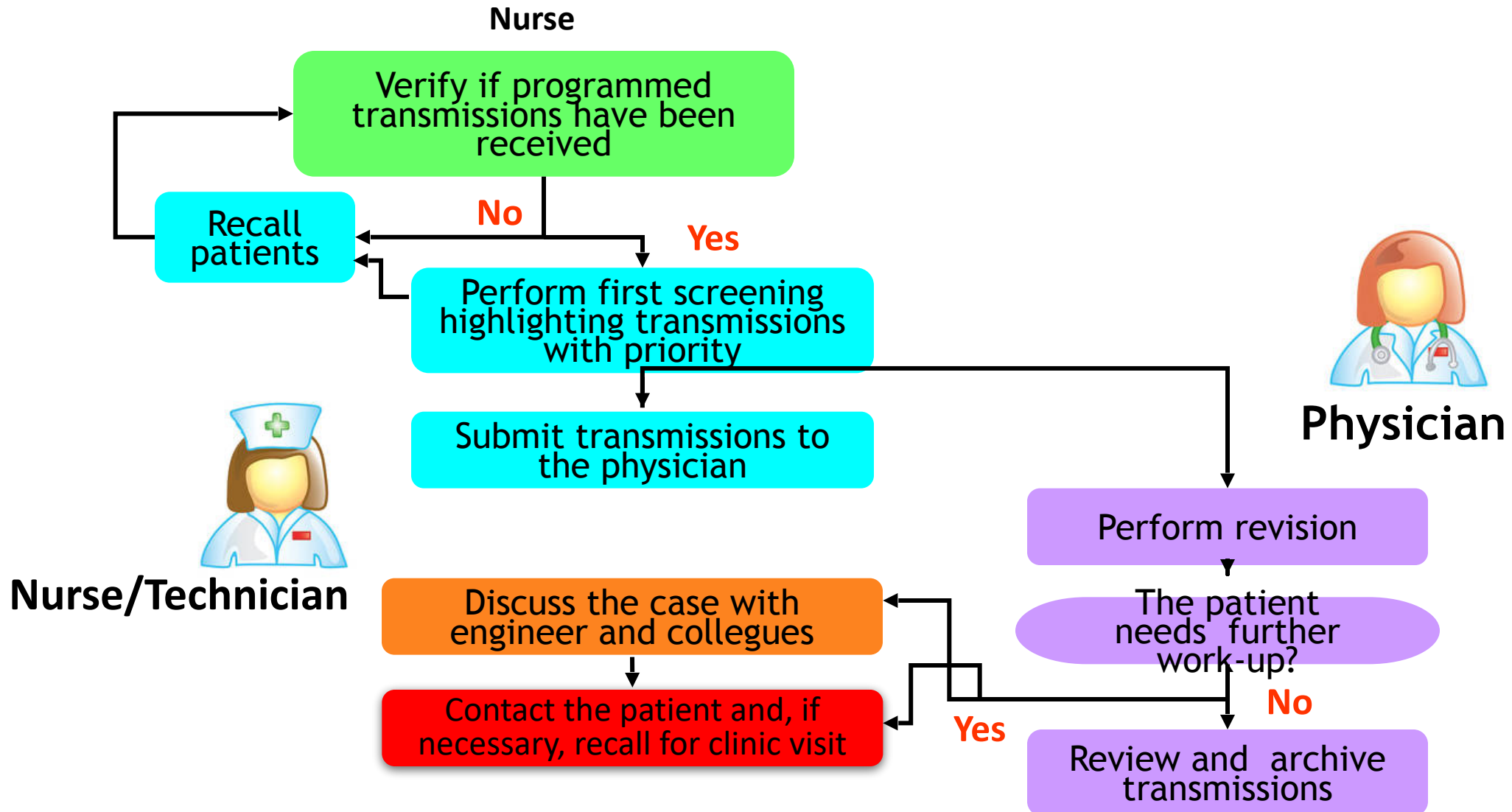


Figure 3 Example of a timeline for patients with cardiovascular implantable electronic devices on remote monitoring. CIED = cardiovascular implantable electronic device; ERI = elective replacement indicator.

«Primary Nursing Model»: Revision of Transmissions



2023 HRS/EHRA/APHRS/LAHRs expert consensus statement on practical management of the remote device clinic

Aileen M. Ferrick, PhD, ACNP, RN, FHRS (Co-Chair),^{1,*}
Satish R. Raj, MD, MSCI, FHRS (Co-Chair),^{2,*}
Thomas Deneke, MD, PhD, FHRS (EHRA Vice-Chair),^{3,†}
Pipin Kojodjojo, MBBS, PhD, FHRS (APHRS Vice-Chair),^{4,‡}
Nestor Lopez-Cabanillas, MD (LAHRS Vice-Chair),^{5,§} Haruhiko Abe, MD, PhD,^{6,‡}
Serge Boveda, MD, PhD, FEHRA, FESC,^{7,†} Derek S. Chew, MD, MSc, FHRS,^{2,*}
Jong-Il Choi, MD, PhD, MHS,^{8,‡} Nikolaos Dages, MD,^{9,†}
Aarti S. Dalal, DO, FACC, FHRS, CEPS-P,^{10,¶} Brynn E. Dechert, APN, FHRS, CCDS,^{11,¶}
Camille G. Frazier-Mills, MD, MHS, CCDS,^{12,*} Olivia Gilbert, MD, MSc, FACC,^{13,#}
Janet K. Han, MD, FACC, FHRS,^{14,**} Sherri Hewit, PharmD,^{††}
Christine Kneeland, BSN,^{15,*} Starr DeEllen Mirza,^{††} Suneet Mittal, MD, FHRS,^{16,*}
Renato Pietro Ricci, MD,^{17,†} Mary Runte, PhD,^{18,††} Susan Sinclair, NZCS, PGDHSc,^{19,‡}
Ricardo Alkmim-Teixeira, MD, PhD,^{20,§} Bert Vandenberg, MD, PhD,^{2,21,†}
Niraj Varma, MA, MD, PhD^{22,‡‡}

2023 Recommendations for Staff Requirements

Recommendations for staffing requirements for RM			
COR	LOE	Recommendations	References
1	B-NR	1. For the care of patients with CIEDs on RM, a team-based organizational model with formal policies, procedures, and clear definitions of the roles and responsibilities of qualified staff is recommended to optimize all related RM tasks.	1,25,28,29,53,90,102-109
1	B-NR	2. For the care of patients with CIEDs on RM, it is recommended that there is adequate dedicated time to perform all RM tasks, including scheduled and nonscheduled transmissions, patient follow-up, and administrative tasks.	25,28,57,104,106,110
1	B-NR	3. For the care of patients with CIEDs on RM, it is recommended that the staff-to-patient ratios in RM clinics reflect the increasing unscheduled transmission workload.	3,28,59,111,112
2a	C-LD	4. For the care of patients with CIEDs on RM, it is reasonable for clinics to have a minimum of 3.0 full-time equivalents per 1000 patients on RM, comprising both clinical and administrative staff.	27

2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic

Aileen M. Ferrick, PhD, ACNP, RN, FHRS (Co-Chair),^{1,*}
Satish R. Raj, MD, MSCI, FHRS (Co-Chair),^{2,*}
Thomas Deneke, MD, PhD, FHRS (EHRA Vice-Chair),^{3,†}
Pipin Kojodjojo, MBBS, PhD, FHRS (APHRS Vice-Chair),^{4,‡}
Nestor Lopez-Cabanillas, MD (LAHRS Vice-Chair),^{5,§} Haruhiko Abe, MD, PhD,^{6,‡}
Serge Boveda, MD, PhD, FEHRA, FESC,^{7,†} Derek S. Chew, MD, MSc, FHRS,^{2,*}
Jong-Il Choi, MD, PhD, MHS,^{8,‡} Nikolaos Dargatzis, MD,^{9,†}
Aarti S. Dalal, DO, FACC, FHRS, CEPS-P,^{10,¶} Brynn E. Dechert, APN, FHRS, CCDS,^{11,¶}
Camille G. Frazier-Mills, MD, MHS, CCDS,^{12,*} Olivia Gilbert, MD, MSc, FACC,^{13,#}
Janet K. Han, MD, FACC, FHRS,^{14,**} Sherri Hewitt, PharmD,^{††}
Christine Kneeland, BSN,^{15,*} Starr DeEllen Mirza,^{††} Suneet Mittal, MD, FHRS,^{16,*}
Renato Pietro Ricci, MD,^{17,†} Mary Runte, PhD,^{18,††} Susan Sinclair, NZCS, PGDHSc,^{19,‡}
Ricardo Alkmim-Teixeira, MD, PhD,^{20,§} Bert Vandenberg, MD, PhD,^{2,21,†}
Niraj Varma, MA, MD, PhD^{22,‡‡}

2023 Recommendations for Staff Credentials and Qualification for RM

Recommendations for staff credentialing and qualifications for RM			
COR	LOE	Recommendations	References
1	C-EO	1. For the care of patients with CIEDs on RM, it is recommended that clinical providers who independently prescribe, interpret, and document RM possess appropriate education and/or certification.	
1	C-EO	2. For the care of patients with CIEDs on RM, it is recommended that clinics regularly conduct quality improvement reviews to support current evidence-based standards.	

2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic

Aileen M. Ferrick, PhD, ACNP, RN
 Satish R. Raj, MD, MSCI, FHRS (C)
 Thomas Deneke, MD, PhD, FHRS
 Pipin Kojodjojo, MBBS, PhD, FHR
 Nestor Lopez-Cabanillas, MD (LAI)
 Serge Boveda, MD, PhD, FEHRA,
 Jong-Il Choi, MD, PhD, MHS,^{8,†} N
 Aarti S. Dalal, DO, FACC, FHRS, CI
 Camille G. Frazier-Mills, MD, MHS
 Janet K. Han, MD, FACC, FHRS,¹⁴
 Christine Kneeland, BSN,^{15,*} Stai
 Renato Pietro Ricci, MD,^{17,†} Mary
 Ricardo Alkmim-Teixeira, MD, Ph
 Niraj Varma, MA, MD, PhD^{22,††}

2015 HRS Guidelines: Personnel Based



Physician

- Provides final interpretation & documentation
- Has appropriate certification*
- Supervises mid-level providers



Mid-level
Provider
(NP/PA)

- Obtains medical history, reviews transmissions, make recommendations for management
- Participates in patient enrollment & education, interpretation of routine transmissions, documentation and billing
- Provides oversight of allied professionals



Allied
Professional

- Has IBHRE certification or experience on par with certification
- Reviews data with criteria for involving physician or mid-level & patient contact



Ancillary
staff

- Performs nonclinical actions:
 - Appointment reminders
 - Patient connectivity/troubleshooting
- Clinic technology/customer support
- Collects data for review

*American Board of Internal Medicine (ABIM) Clinical Cardiac Electrophysiology certification, American Board of Pediatrics Cardiology certification, or the International Board of Heart Rhythm Examiners (IBHRE) device certification.

2023 Recommendations: Task Based RM Activity

2023 HRS Guidelines: Task Based (Implications for Staffing)

Task

Connectivity/Troubleshooting

- Appointments
- Connectivity
- Patient questions



Ancillary
staff

Patient Education/Enrollment

- What is remote monitoring?
- Why is it needed?
- Choice of monitor



APP
RN
or
Device Tech

CIED Data Triage & Review

- Website monitoring
- Initial data processing
- Initial communication with health care team



Device
Technician
or RN

Data Triage & Review, options:

- Third-party software
 - Single web-based data portal
 - Device and patient management

Final Sign-Off

- Final interpretation
- Final communication with health care team
- Documentation for billing



Physician,
APP/
Physiologist

Alert Management

- Patient calls
- In-office evaluations
- Charting and communication

Final sign-off

- Interpretation (middleware vs in-EHR)
- Information interoperability (between EHRs)
- Closing the loop with patients

Alert Management

- In-office CIED management
- Hospital-based remote CIED interrogations
- After-hours alert management

2023 HRS/EHRA/APHRS/LAHRs expert consensus statement on practical management of the remote device clinic

Aileen M. Ferrick, PhD, ACNP, RN, FHRS (Co-Chair),^{1,*}
 Satish R. Raj, MD, MSCI, FHRS (Co-Chair),^{2,*}
 Thomas Deneke, MD, PhD, FHRS (EHRA Vice-Chair),^{3,†}
 Pipin Kojodjojo, MBBS, PhD, FHRS (APHRS Vice-Chair),^{4,‡}
 Nestor Lopez-Cabanillas, MD (LAHRs Vice-Chair),^{5,§} Haruhiko Abe
 Serge Boveda, MD, PhD, FEHRA, FESC,^{7,†} Derek S. Chew, MD, MSc
 Jong-Il Choi, MD, PhD, MHS,^{8,‡} Nikolaos Dagres, MD,^{9,†}
 Aarti S. Dalal, DO, FACC, FHRS, CEPS-P,^{10,¶} Brynn E. Dechert, API
 Camille G. Frazier-Mills, MD, MHS, CCDS,^{12,*} Olivia Gilbert, MD, M
 Janet K. Han, MD, FACC, FHRS,^{14,*} Sherri Hewit, PharmD,^{††}
 Christine Kneeland, BSN,^{15,*} Starr DeEllen Mirza,^{††} Suneet Mittal
 Renato Pietro Ricci, MD,^{17,†} Mary Runte, PhD,^{18,††} Susan Sinclair
 Ricardo Alkmim-Teixeira, MD, PhD,^{20,§} Bert Vandenberk, MD, PhD
 Niraj Varma, MA, MD, PhD^{22,‡‡}

Remote Monitoring Staffing Challenges

Challenges in obtaining staff



Lack of dedicated RM personnel



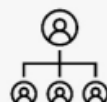
Poor understanding of RM value/benefits



Lack of adequate reimbursement arrangement



Poor understanding of RM data burden & RM-related work tasks ("invisible work")



Poor understanding of need for RM organizational model (roles/responsibilities)



Lack of resources & need for outsourcing

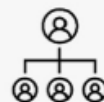
Challenges facing staff



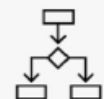
Overwhelming RM data burden ("data deluge")



Lack of dedicated RM personnel



Need for organizational workflow



Need for decision trees for RM transmission review/standardization of alert criteria



- Alert-based RM transmission review
- Programming optimization
- AI algorithms



Need for outsourcing

Challenges facing staff



Lack of dedicated time for RM management ("invisible work")



Transmission triage (Access software, ID alerts/events/routine transmissions)



Initial transmission review



Triage for secondary review



Patient management activities/telephone work



Technology/connectivity troubleshooting



Administrative (documentation/EHR, billing, scheduling)

From Theory to Practice...

...How to follow a patient by remote monitoring

Informed
Consent

Patient Training

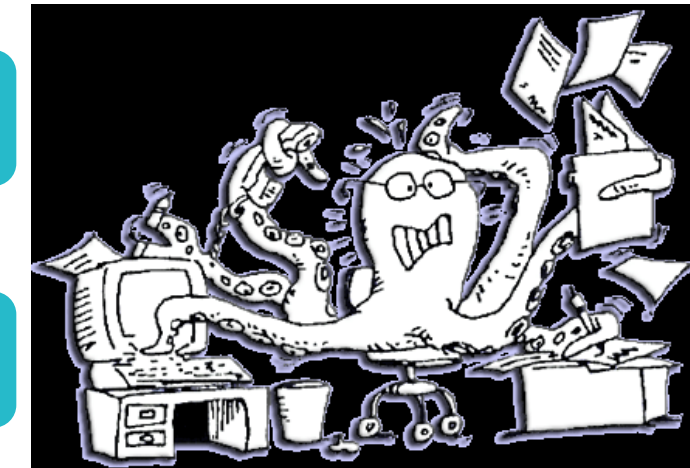
Inserting data in
web site

Patient Recall

Device
Programming

Theraputic
Decisions

Alarm
Programming



Remote FUP
Revision

Alarm Revision

NEED OF A WELL-DEFINED WORKING MODEL!

2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic

Aileen M. Ferrick, PhD, ACNP, RN, FHRS (Co-Chair),^{1,*}

Satish R. Raj, MD, MSCI, FHRS (Co-Chair),^{2,*}

Thomas Deneke, MD, PhD, FHRS (EHRA Vice-Chair),^{3,†}

Pipin Kojodjojo, MBBS, PhD, FHRS (APHRS Vice-Chair),^{4,‡}

Nestor Lopez-Cabanillas, MD (LAHRS Vice-Chair),^{5,§} Haruhiko Abe, MD, PhD,^{6,‡}

Serge Boveda, MD, PhD, FEHRA, FESC,^{7,†} Derek S. Chew, MD, MSc, FHRS,^{2,*}

Jong-Il Choi, MD, PhD, MHS,^{8,‡} Nikolaos Dargatzis, MD,^{9,†}

Aarti S. Dalal, DO, FACC, FHRS, CEPS-P,^{10,¶} Brynn E. Dechert, APN, FHRS, CCDS,^{11,¶}

Camille G. Frazier-Mills, MD, MHS, CCDS,^{12,*} Olivia Gilbert, MD, MSc, FACC,^{13,#}

Janet K. Han, MD, FACC, FHRS,^{14,**} Sherri Hewitt, PharmD,^{††}

Christine Kneeland, BSN,^{15,*} Starr DeEllen Mirza,^{††} Suneet Mittal, MD, FHRS,^{16,*}

Renato Pietro Ricci, MD,^{17,†} Mary Runte, PhD,^{18,††} Susan Sinclair, NZCS, PGDHSc,^{19,‡}

Ricardo Alkmim-Teixeira, MD, PhD,^{20,§} Bert Vandenberg, MD, PhD,^{2,21,†}

Niraj Varma, MA, MD, PhD^{22,‡‡}

2023 Recommendations: Techniques to Optimize Patient Connectivity

Recommendations for techniques to optimize patient connectivity			
COR	LOE	Recommendations	References
1	C-EO	1. For the care of patients with CIEDs on RM who lose connectivity, it is recommended that clinics have an established process that includes dedicated clinic staff to facilitate reconnection.	

2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic

Aileen M. Ferrick, PhD, ACNP, RN, FHRS (Co-Chair),^{1,*}
Satish R. Raj, MD, MSCI, FHRS (Co-Chair),^{2,*}
Thomas Deneke, MD, PhD, FHRS (EHRA Vice-Chair),^{3,†}
Pipin Kojodjojo, MBBS, PhD, FHRS (APHRS Vice-Chair),^{4,‡}
Nestor Lopez-Cabanillas, MD (LAHRS Vice-Chair),^{5,§} Haruhiko Abe, MD, PhD,^{6,‡}
Serge Boveda, MD, PhD, FEHRA, FESC,^{7,†} Derek S. Chew, MD, MSc, FHRS,^{2,*}
Jong-Il Choi, MD, PhD, MHS,^{8,‡} Nikolaos Dargatzis, MD,^{9,†}
Aarti S. Dalal, DO, FACC, FHRS, CEPS-P,^{10,¶} Brynn E. Dechert, APN, FHRS, CCDS,^{11,¶}
Camille G. Frazier-Mills, MD, MHS, CCDS,^{12,*} Olivia Gilbert, MD, MSc, FACC,^{13,#}
Janet K. Han, MD, FACC, FHRS,^{14,**} Sherri Hewitt, PharmD,^{††}
Christine Kneeland, BSN,^{15,*} Starr DeEllen Mirza,^{††} Suneet Mittal, MD, FHRS,^{16,*}
Renato Pietro Ricci, MD,^{17,†} Mary Runte, PhD,^{18,††} Susan Sinclair, NZCS, PGDHSc,^{19,‡}
Ricardo Alkmim-Teixeira, MD, PhD,^{20,§} Bert Vandenberg, MD, PhD,^{2,21,†}
Niraj Varma, MA, MD, PhD^{22,‡‡}

2023 Recommendations for Payment/Reimbursement

Recommendations for RM payment/reimbursement models			
COR	LOE	Recommendations	References
1	B-NR	1. For the care of patients with CIEDs on RM, it is recommended that health care payers adopt adequate reimbursement for RM that is tailored to regional health system care patterns and facilitates sustainable and cost-effective CIED follow-up care.	35,57-60,62,66,79-89

Current status of reimbursement practices for remote monitoring of cardiac implantable electrical devices across Europe

Giuseppe Boriani ^{1,2*}, Haran Burri ³, Emma Svennberg ⁴,
Jacopo Francesco Imberti ^{1,5}, José Luis Merino ⁶, and Christophe Leclercq ⁷

Table 2 Reimbursement of in-clinic and remote CIED device checks and for HF disease management in different European countries

Country	Reimbursement tariff for in-clinic device check	Reimbursement tariff for remote CIED management	Reimbursement specific for hardware and services for remote monitoring	Reimbursement tariff for HF disease management
Austria	Yes	No	No	Yes, from 2022
Belgium	Yes	No	No	No
Bulgaria	No	No	No	No
Czech Republic	Yes	Yes	Yes	No
Denmark	Yes	Yes	No	No
Finland	Yes	Yes	Yes	No
France	Yes	Yes ^a	Yes ^b	No
Germany	Yes	Yes ^c	Yes for some health insurance	No
Hungary	Yes	Yes	No	No
Italy	Yes	Yes (in 10 of 20 regional health services)	No	No
Norway	Yes	Yes	No	No
Poland	No	No	No	No
Portugal	Yes	Yes	No	Yes
Russia	No	No	No	No
Slovakia	No	No	No	No
Spain	Funded, no tariff	Funded, no tariff	N/A	No
Sweden	Yes	Yes	No	No
Switzerland	Yes	Yes	Yes	Yes
The Netherlands	Yes	Yes	No	Yes ^d
UK	Yes	Not at a national level, it is dependent on Clinical Commissioning Groups and NHS Trusts	Ordered by NHS Trusts	No

The data were collected from expert physicians of the European Heart Rhythm Association and data available from regulatory institutions.

CIED, cardiac implantable electronic device; CRT, cardiac resynchronization therapy; HF, heart failure; ICD, implantable cardioverter-defibrillator; PM, pacemaker; RM, remote monitoring.

^aFrench MoH pilot 2018–22: Expérimentations de Télémedecine pour l'Amélioration des Parcours en Santé programme.

^bPremium price for ICD and PM with RM.

^cOnly for ICDs and CRT devices.

^dSame as regular heart failure management.

2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic

Aileen M. Ferrick, PhD, ACNP, RN, FHRS (Co-Chair),^{1,*}
Satish R. Raj, MD, MSCI, FHRS (Co-Chair),^{2,*}
Thomas Deneke, MD, PhD, FHRS (EHRA Vice-Chair),^{3,†}
Pipin Kojodjojo, MBBS, PhD, FHRS (APHRS Vice-Chair),^{4,‡}
Nestor Lopez-Cabanillas, MD (LAHRS Vice-Chair),^{5,§} Haruhiko Abe, MD, PhD,^{6,‡}
Serge Boveda, MD, PhD, FEHRA, FESC,^{7,†} Derek S. Chew, MD, MSc, FHRS,^{2,*}
Jong-Il Choi, MD, PhD, MHS,^{8,‡} Nikolaos Dargatzis, MD,^{9,†}
Aarti S. Dalal, DO, FACC, FHRS, CEPS-P,^{10,¶} Brynn E. Dechert, APN, FHRS, CCDS,^{11,¶}
Camille G. Frazier-Mills, MD, MHS, CCDS,^{12,*} Olivia Gilbert, MD, MSc, FACC,^{13,#}
Janet K. Han, MD, FACC, FHRS,^{14,**} Sherri Hewitt, PharmD,^{††}
Christine Kneeland, BSN,^{15,*} Starr DeEllen Mirza,^{††} Suneet Mittal, MD, FHRS,^{16,*}
Renato Pietro Ricci, MD,^{17,†} Mary Runte, PhD,^{18,††} Susan Sinclair, NZCS, PGDHSc,^{19,‡}
Ricardo Alkmim-Teixeira, MD, PhD,^{20,§} Bert Vandenberg, MD, PhD,^{2,21,†}
Niraj Varma, MA, MD, PhD^{22,‡‡}

2023 Recommendations for Staff Awareness for Manufacturer and Device Specific Differences for RM

Recommendations for manufacturer and device-specific knowledge			
COR	LOE	Recommendations	References
1	C-EO	1. For the care of patients with CIEDs on RM, it is recommended that clinic staff are knowledgeable about the specific differences between, and within, manufacturers’ devices and their RM platforms to optimize patient care.	

2023 HRS/EHRA/APHRS/LAHR expert consensus statement on practical management of the remote device clinic ^e

Aileen M. Ferrick, PhD, ACNP, RN, FHRS (C
Satish R. Raj, MD, MSCI, FHRS (Co-Chair),
Thomas Deneke, MD, PhD, FHRS (EHRA Vice
Pipin Kojodjojo, MBBS, PhD, FHRS (APHRS
Nestor Lopez-Cabanillas, MD (LAHRS Vice-
Serge Boveda, MD, PhD, FEHRA, FESC,^{7,†} D
Jong-Il Choi, MD, PhD, MHS,^{8,‡} Nikolaos D
Aarti S. Dalal, DO, FACC, FHRS, CEPS-P,^{10,¶}
Camille G. Frazier-Mills, MD, MHS, CCDS,¹²
Janet K. Han, MD, FACC, FHRS,^{14,*,*} Sherri
Christine Kneeland, BSN,^{15,*} Starr DeEllen
Renato Pietro Ricci, MD,^{17,†} Mary Runte, F
Ricardo Alkmim-Teixeira, MD, PhD,^{20,§} Ber
Niraj Varma, MA, MD, PhD^{22,‡‡}

Differences Between Manufacturers

Manufacturer	Abbott	Biotronik	Boston Scientific	Medtronic	MicroPort
RM system	Merlin.net	Home Monitoring	LATITUDE	CareLink	SmartView
Home monitor	Merlin@home	CardioMessenger II CardioMessenger II-S CardioMessenger Smart	LATITUDE NXT Remote Patient Management System	MyCareLink Relay home communicator MyCareLink monitor	SmartView SmartView Connect (Bluetooth-enabled CIED)
Smartphone-based RM applications	myMerlinPulse mobile app (ICD and CRT-D) myMerlin mobile app (ILR)	No	No	MyCareLink Heart mobile app (Bluetooth ILR, IPG, CRT-P, ICD, CRT-D) MyCareLink Smart (IPG, including leadless IPG)	Yes; limited to a dedicated smartphone delivered to the patient
Patient smartphone applications without RM	No	Biotronik patient app (Biomonitor III or III _m)	MyLATITUDE Patient App	No	No
Transmitter	Stationary or mobile	Stationary or mobile	Stationary	Stationary or mobile	Stationary or mobile
Connectivity	Bluetooth; mobile network; Wi-Fi; analog phonline; RF; inductive telemetry	Mobile network; analog phonline	Mobile network; Wi-Fi; ethernet; analog phonline	Bluetooth; mobile network; Wi-Fi; analog phonline	Bluetooth; mobile network
Frequency of transmissions	Scheduled FU; daily FU; alert events	Scheduled FU; daily FU; alert events	Scheduled FU; daily FU; alert events	Scheduled FU; daily FU; alert events	Scheduled FU; daily FU; alert events

2023 HRS/EHRA/APHRS/LAHRs expert consensus statement on practical management of the remote device clinic ^e

Aileen M. Ferrick, PhD, ACNP, RN, FHRS (Co-Chair),^{1,*}
 Satish R. Raj, MD, MSCI, FHRS (Co-Chair),^{2,*}
 Thomas Deneke, MD, PhD, FHRS (EHRA Vice-Chair),^{3,†}
 Pipin Kojodjojo, MBBS, PhD, FHRS (APHRS Vice-Chair),^{4,‡}
 Nestor Lopez-Cabanillas, MD (LAHRs Vice-Chair),^{5,§} Haruhiko Abe, MD, PhD,^{6,‡}
 Serge Boveda, MD, PhD, FEHRA, FESC,^{7,†} Derek S. Chew, MD, MSc, FHRS,^{2,*}
 Jong-Il Choi, MD, PhD, MHS,^{8,‡} Nikolaos Dagres, MD,^{9,†}
 Aarti S. Dalal, DO, FACC, FHRS, CEPS-P,^{10,¶} Brynn E. Dechert, APN, FHRS, CCDS,^{11,¶}
 Camille G. Frazier-Mills, MD, MHS, CCDS,^{12,*} Olivia Gilbert, MD, MSc, FACC,^{13,#}
 Janet K. Han, MD, FACC, FHRS,^{14,**} Sherri Hewit, PharmD,^{††}
 Christine Kneeland, BSN,^{15,*} Starr DeEllen Mirza,^{††} Suneet Mittal, MD, FHRS,^{16,*}
 Renato Pietro Ricci, MD,^{17,†} Mary Runte, PhD,^{18,††} Susan Sinclair, NZCS, PGDHSc,^{19,‡}
 Ricardo Alkmim-Teixeira, MD, PhD,^{20,§} Bert Vandenberg, MD, PhD,^{2,21,†}
 Niraj Varma, MA, MD, PhD^{22,‡‡}

Differences Between Manufacturers

Manufacturer	Abbott	Biotronik	Boston Scientific	Medtronic	MicroPort
Programmability of frequency of transmissions	Yes	No	Yes	Yes	Yes
Programmability of alerts and parameters	Alerts fully configurable online (settings, such as alert notifications, report settings, and data export settings can be done online; adjustments to the patient's device settings must be done in person).	Alerts can be customized by users into high, medium, and low priorities according to their preferences. Some alerts and parameters can be programmed online. Certain life-threatening alerts cannot be changed as a safety feature.	RM alerts and parameters can be programmed online through the LATITUDE website.	BlueSync devices: parameters and alerts are configurable via in-clinic programming; notifications for alerts are remotely configurable. BlueSync device (LINQ II only): parameters, alerts, and notifications are configurable remotely. Connex devices: parameters and alerts are configurable via in-clinic programming; notifications for alerts are configurable remotely; alerts may be manually reset remotely (awaiting approval).	Alerts can be programmed.
Patient-initiated transmission	Yes	No	Yes	Yes	Yes
Recommended distance from transmitter	<2 meters	<2 meters	<3 meters	<3 meters	<2 meters
Real-time IEGM at remote follow-up	30 seconds	30 seconds	10 seconds	10 seconds	7 seconds
IEGM of arrhythmic episodes	All memorized	All memorized	All memorized	All memorized	All memorized
Provider communication method	E-mail, SMS, fax	E-mail, SMS, fax	E-mail, SMS, fax	E-mail, SMS, website	E-mail, SMS, pager, voicemail, mobile app
FDA and CE Mark approved	Yes	Yes	Yes	Yes	Yes
Additional features	Electronic health record export compatibility; patient callback feature; CorVue fluid status alert; integrated heart failure website for patients with both CardioMEMS (pulmonary artery pressures) and Abbott CIED.	Electronic health record export compatibility; patient callback feature; HeartInsight heart failure monitoring.	Electronic health record export compatibility; HeartLogic heart failure monitoring; optional Bluetooth weight scales and blood pressure cuffs; configurable data transmission to associated caregivers.	Electronic health record export compatibility; OptiVol thoracic impedance alert; Cardiac Compass HF report; TriageHF integrated HF risk assessment tool.	Electronic health record export compatibility.

2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic

Aileen M. Ferrick, PhD, ACNP, RN, FHRS (Co-Chair),^{1,*}
Satish R. Raj, MD, MSCI, FHRS (Co-Chair),^{2,*}
Thomas Deneke, MD, PhD, FHRS (EHRA Vice-Chair),^{3,†}
Pipin Kojodjojo, MBBS, PhD, FHRS (APHRS Vice-Chair),^{4,‡}
Nestor Lopez-Cabanillas, MD (LAHRS Vice-Chair),^{5,§} Haruhiko Abe, MD, PhD,^{6,‡}
Serge Boveda, MD, PhD, FEHRA, FESC,^{7,†} Derek S. Chew, MD, MSc, FHRS,^{2,*}
Jong-Il Choi, MD, PhD, MHS,^{8,‡} Nikolaos Dagues, MD,^{9,†}
Aarti S. Dalal, DO, FACC, FHRS, CEPS-P,^{10,¶} Brynn E. Dechert, APN, FHRS, CCDS,^{11,¶}
Camille G. Frazier-Mills, MD, MHS, CCDS,^{12,*} Olivia Gilbert, MD, MSc, FACC,^{13,#}
Janet K. Han, MD, FACC, FHRS,^{14,**} Sherri Hewit, PharmD,^{††}
Christine Kneeland, BSN,^{15,*} Starr DeEllen Mirza,^{††} Suneet Mittal, MD, FHRS,^{16,*}
Renato Pietro Ricci, MD,^{17,†} Mary Runte, PhD,^{18,††} Susan Sinclair, NZCS, PGDHSc,^{19,‡}
Ricardo Alkmim-Teixeira, MD, PhD,^{20,§} Bert Vandenberg, MD, PhD,^{2,21,†}
Niraj Varma, MA, MD, PhD^{22,‡‡}

2023 Recommendations for Patient Education of Clinic Specific Policies for RM

Recommendations for patient education of clinic-specific policies			
COR	LOE	Recommendations	References
2a	C-EO	1. In patients with CIEDs on RM, it is reasonable to communicate clinic-specific policies associated with RM to the patient.	

Remote Monitoring Guideline for Patients with CIEDs

ARRHYTHMOLOGY DEPT - POLICLINICO SAN DONATO



Info-RM 14/12/2021

DIPARTIMENTO DI ARITMOLOGIA ED ELETTROFISIOLOGIA
Direttore: **Professor Carlo PAPPONE**
Responsabile Servizio di Monitoraggio Remoto: **Dr.ssa Emanuela T. LOCATI**
Tecnici di Elettrofisiologia:
Dr. Salvatore Famà - Dr. Flavio Mastrocinque - Dr.ssa Francesca Castellani - Dr. Stefano Puzzo
Tel: 02-5277-4199 // 02-5277-4323 // 02-5277-4293 // 02-5277-4218
e-mail: monitoraggio.remoto@grupposandonato.it

INFORMATIVA: MONITORAGGIO TELEMETRICO REMOTO
IN PAZIENTE PORTATORE DI DISPOSITIVO CARDIACO IMPIANTABILE

Gentile Signora/e,

Le è stato proposto di partecipare ad un programma di controllo telemetrico remoto in portatore di dispositivo cardiaco impiantabile (defibrillatore o ICD, pacemaker o PM, resincronizzatore o CRT, registratore loop recorder impiantabile o IIR) organizzato da Dipartimento di Aritmologia, dell'IRCCS Policlinico San Donato, allo scopo di trasmettere, attraverso un Monitor dedicato, i dati memorizzati nel Suo dispositivo cardiaco impiantato direttamente al Servizio di Monitoraggio Remoto del Dipartimento di Aritmologia.

IMPORTANTE
IL SISTEMA DI MONITORAGGIO REMOTO **NON È UN SERVIZIO DI EMERGENZA**, MA SERVE PER CONTROLLARE IN REMOTO (A DISTANZA) I PARAMETRI DI FUNZIONAMENTO E LE ARITMIE CARDIACHE RILEVATE DAL SUO DISPOSITIVO.

1. ATTIVAZIONE DEL MONITORAGGIO REMOTO

Il Monitor dedicato al controllo remoto le sarà consegnato gratuitamente direttamente in Ospedale, da parte del personale sanitario della Dipartimento di Aritmologia dedicato al Servizio di Monitoraggio Remoto.

Nella confezione del Monitor troverà tutta la documentazione dettagliata riguardante l'utilizzo del Monitor ed il suo funzionamento.

Per attivare il funzionamento basterà collegare il trasmettitore ad una presa della corrente e, se richiesto, effettuare una prima trasmissione secondo la procedura che le è stata spiegata dal personale sanitario dedicato del Dipartimento di Aritmologia (e di cui troverà ulteriori istruzioni nella confezione del Monitor).

I.R.C.C.S. Policlinico San Donato S.p.A. - Sede Unico

Via Morandi 30 - 20097 San Donato Milanese (MI)
Tel. +39 02.527741 / Fax 02.52747171 info.psd@grupposandonato.it
C.F. e P.A.A. Reg. Imp. Milano 05853300153
Capitale Sociale € 4.845.789 i.v.

www.grupposandonato.it



Info-RM 14/12/2021

Le trasmissioni saranno poi in genere automatiche senza necessità di un suo intervento, e solo in un caso specifici, che le verranno comunicati da parte del personale sanitario dedicato della Dipartimento di Aritmologia, sarà necessario effettuare trasmissioni manuali.

2. MODALITÀ OPERATIVE DEL MONITORAGGIO REMOTO

Come le è stato spiegato, il Monitoraggio Remoto è stato ritenuto necessario effettuare dei controlli regolari del suo dispositivo impiantato per controllare ed ottimizzare tutti i parametri ed assicurarle la migliore ed appropriata terapia.

Le modalità di controllo tramite Monitoraggio Remoto sono le seguenti:

- Il controllo remoto avviene quando il Monitor dedicato invia automaticamente (o in alcuni casi manualmente) i dati memorizzati nel suo stimolatore cardiaco per essere rivisti dal personale sanitario dedicato del Dipartimento di Aritmologia.
- Il Personale dedicato del Dipartimento di Aritmologia programmerà le sue trasmissioni in modo che vengano effettuate automaticamente (o manualmente a seconda delle caratteristiche tecniche del suo dispositivo), secondo la tempistica ritenuta ottimale per la sua patologia.
- La tempistica delle trasmissioni potrà variare (programmando quindi trasmissioni più frequenti) nel caso emergano specifiche problematiche tecniche o cliniche, come rilevato e ritenuto opportuno dal Personale del Dipartimento di Aritmologia.
- In caso di riscontro di elementi patologici, o comunque qualora sia ritenuto necessario, sarà contattato dal Personale dedicato del Servizio di Monitoraggio Remoto perché si rechi in Ospedale per una visita ambulatoriale o per un eventuale ricovero (e le verranno quindi comunicate la modalità e la logistica di tale visita o ricovero).
- In alcuni casi è possibile che le venga richiesto da parte del Personale dedicato del Dipartimento di Aritmologia di effettuare trasmissioni manuali attraverso il Monitor, secondo la semplice procedura che le è stata illustrata, il che non implica che ci siano problemi o rischi specifici, ma è solo richiesto un ulteriore controllo per ragioni cliniche o tecniche.

3. REVISIONE DELLE TRASMISSIONI INViate DAL SUO STIMOLATORE CARDIACO

- Quando il Servizio di Monitoraggio Remoto riceverà una trasmissione, i dati inviati saranno revisionati dal Personale dedicato entro 5 (cinque) giorni lavorativi.
- Segnaliamo che il paziente sarà contattato telefonicamente da parte del Personale del Dipartimento di Aritmologia soltanto nei seguenti casi:
 - a) Dal controllo dei dati trasmessi emergano problemi di natura tecnica o clinica.
 - b) Il Servizio di Monitoraggio Remoto non riceva eventuali trasmissioni programmate

I.R.C.C.S. Policlinico San Donato S.p.A. - Sede Unico

Via Morandi 30 - 20097 San Donato Milanese (MI)
Tel. +39 02.527741 / Fax 02.52747171 info.psd@grupposandonato.it
C.F. e P.A.A. Reg. Imp. Milano 05853300153
Capitale Sociale € 4.845.789 i.v.

www.grupposandonato.it



Info-RM 14/12/2021

4. MANCATE TRASMISSIONI DA PARTE DEL SUO STIMOLATORE CARDIACO

- I dati del Suo apparecchio impiantabile verranno inviati tramite il sistema di monitoraggio remoto ad un server sicuro dedicato ed il Personale autorizzato (Personale dedicato del Dipartimento di Aritmologia) può accedervi solo con un identificativo e una password attraverso Internet.
- Per svariati ed imprevedibili motivi tecnici può accadere che il suo modem a casa non riesca a mettersi in contatto con il suo apparecchio impiantato e quindi non riesca ad inviare una trasmissione al Server dedicato.
- In tale caso il Servizio di Monitoraggio Remoto potrebbe non ricevere delle trasmissioni, ed in qualche caso anche delle trasmissioni che potenzialmente potrebbero contenere informazioni importanti.
- Il Servizio di Monitoraggio non ha modo di venire a conoscenza in tempi brevi e certi di eventuali trasmissioni mancate, ma ha informazioni solo sulle trasmissioni che sono state correttamente trasmesse al server e visualizzabili sul sito Internet.
- In caso di mancate trasmissioni, il Servizio di Monitoraggio Remoto non potrà in alcun modo essere ritenuto responsabile di eventuali problematiche cliniche o tecniche relative a tali mancate trasmissioni.

5. DURATA E SOSPENSIONE DEL SERVIZIO

- Il Dipartimento di Aritmologia si riserva di interrompere il servizio di Monitoraggio Remoto, previa comunicazione scritta con preavviso non inferiore ad 1 (un) mese.
- Il Dipartimento di Aritmologia si riserva di sospendere il servizio controllo remoto ai pazienti che risultano non compatibili con tale servizio per motivi tecnici o logistici.
- E' intesa da parte Sua la facoltà di recedere dalla partecipazione al programma in qualsiasi momento con effetto immediato. Di questa intenzione dovrà fornire comunicazione scritta (via fax o via e-mail) al Personale del Dipartimento di Aritmologia dedicato al Servizio di Monitoraggio Remoto.
- Nel caso di cessazione del servizio di Monitoraggio Remoto per qualunque motivo, il Personale del Dipartimento di Aritmologia Le indicherà come restituire o smaltire il Monitor usato.
- In assenza di comunicazioni, la partecipazione al programma di Monitoraggio Remoto si intende tacitamente rinnovata senza limiti di tempo.

6. GRATUITÀ DEL SERVIZIO DI MONITORAGGIO REMOTO

- Il monitor (modem) dedicato verrà fornito gratuitamente, e in caso di guasto verrà sostituito gratuitamente da parte del Personale del Servizio di Monitoraggio Remoto del Dipartimento di Aritmologia.
- Segnaliamo che il Servizio di Monitoraggio Remoto non è ancora incluso tra le prestazioni erogate tramite il Sistema Sanitario, ciò nonostante vista l'importanza di questa modalità di controllo, il

I.R.C.C.S. Policlinico San Donato S.p.A. - Sede Unico

Via Morandi 30 - 20097 San Donato Milanese (MI)
Tel. +39 02.527741 / Fax 02.52747171 info.psd@grupposandonato.it
C.F. e P.A.A. Reg. Imp. Milano 05853300153
Capitale Sociale € 4.845.789 i.v.

www.grupposandonato.it



Info-RM 14/12/2021

Dipartimento di Aritmologia ha deciso almeno temporaneamente di fornire questo servizio a **TITOLO GRATUITO**.

7. VANTAGGI DEL MONITORAGGIO REMOTO

Le attuali Linee Guida per la gestione dei pazienti portatori di dispositivi cardiaci impiantabili raccomandano il monitoraggio remoto per il riconoscimento precoce di problemi clinici (es. tachiaritmie ventricolari, fibrillazione atriale...) e tecnici (frattura degli elettrodi, rottura dell'isolante, esaurimento della batteria...).

L'utilizzo del monitoraggio remoto è stato dimostrato efficace nel sostituire controlli ambulatoriali frequenti e ripetuti e ad evitare accessi non necessari alla struttura ospedaliera. Secondo gli studi clinici più recenti, aderire alla modalità di monitoraggio remoto dei dispositivi impiantabili, potrebbe portare dei benefici sulla evoluzione clinica della sua patologia.

In particolare, il monitoraggio remoto è utile e oltremodo raccomandato in caso sopravvengano richiami tecnici da parte delle Aziende produttrici o nella gestione dei dispositivi nella fase di esaurimento della batteria.

8. LIMITI DEL MONITORAGGIO REMOTO

Il monitoraggio remoto può sostituire alcuni controlli ambulatoriali frequenti e ripetuti e evitare accessi non necessari alla struttura ospedaliera, ma non può fornire informazioni dettagliate relative ad alcuni problemi clinici (quali ad esempio scompenso cardiaco, mancanza di fiato, dispnea, precordalgia).

Nel caso di tali **PROBLEMI URGENTI** è necessario effettuare una visita cardiologica dallo specialista cardiologo di fiducia o nei casi più gravi rivolgersi in Pronto Soccorso.

Nel caso di problemi clinici **NON URGENTI** può comunque mettersi in contatto con il Servizio di Monitoraggio remoto e, nei limiti del possibile, Le forniremo consigli e/o istruzioni in base ai dati a noi disponibili tramite il monitoraggio e, nel caso sia necessario, le chiederemo di effettuare una trasmissione manuale.

9. TRATTAMENTO DATI

Il Regolamento Europeo 2016/679 (anche conosciuto come GDPR), unitamente alla normativa nazionale italiana, prevede la tutela delle persone rispetto al trattamento dei dati personali. Tale trattamento pertanto sarà improntato ai principi di correttezza, liceità, trasparenza e tutela della Sua riservatezza e dei Suoi diritti.

Titolare del trattamento dei Suoi dati è IRCCS Policlinico San Donato S.p.A., mentre l'azienda fornitrice del monitor dedicato collegato al Suo dispositivo impiantabile agirà a titolo di Responsabile del Trattamento e come tale sarà appositamente designato con atto scritto da parte del Titolare che impartirà allo stesso tutte le istruzioni necessarie ad assicurare liceità e correttezza nel trattamento

I.R.C.C.S. Policlinico San Donato S.p.A. - Sede Unico

Via Morandi 30 - 20097 San Donato Milanese (MI)
Tel. +39 02.527741 / Fax 02.52747171 info.psd@grupposandonato.it
C.F. e P.A.A. Reg. Imp. Milano 05853300153
Capitale Sociale € 4.845.789 i.v.

www.grupposandonato.it



Info-RM 14/12/2021

dei Suoi dati personali. Un' apposita e più dettagliata informativa relativa al trattamento dei Suoi dati Le verrà separatamente fornita.

10. SEGNALEAZIONE DI EVENTUALI ASSENZE DA CASA O RICOVERI

La preghiamo di segnalare sempre al Servizio di Monitoraggio Remoto eventuali assenze prolungate da casa (per periodi maggiori di una settimana) ed in particolare di avvertire il servizio in caso di eventuali ricoveri (sia presso il nostro Ospedale che presso altre Strutture Sanitarie).

11. VIAGGIARE CON IL MONITOR

Le consigliamo di portare il Monitor con sé anche se si trova in viaggio o in vacanza. Il Monitor funziona gratuitamente su tutto il territorio italiano. In caso di viaggi all'estero contatti il nostro servizio per informarsi delle zone di copertura (che variano per le differenti Aziende fabbricanti).

INFORMAZIONI IMPORTANTI

EMERGENZA

Se ha un'emergenza e ha bisogno di un controllo medico **URGENTE** chiami il **118** o si rechi in Pronto Soccorso. **NON UTILIZZI IL MONITOR IN CASO DI EMERGENZA**, in quanto le trasmissioni inviate tramite Monitoraggio remoto non vengono visionate in tempo reale.

MODALITA' DI COMUNICAZIONE CON IL SERVIZIO DI MONITORAGGIO REMOTO

Per eventuali richieste di informazioni sul Servizio di Monitoraggio Remoto o sull'utilizzo del Modem dedicato può contattarci ai numeri telefonici **02-5277-4293 oppure 02-5277-4199**

nell'orario 08:30-17:00 dei giorni feriali (dal lunedì al venerdì), dove potrà parlare con i Sanitari della Dipartimento di Aritmologia dedicati al Servizio di Monitoraggio Remoto, oppure tramite e-mail all'indirizzo monitoraggio.remoto@grupposandonato.it.

RIBADIAMO CHE **NON** GARANTIAMO LA PRESENZA DI UN OPERATORE IN PERMANENZA A TALE NUMERO, CHE QUINDI **NON** DEVE ESSERE UTILIZZATO PER COMUNICAZIONI URGENTI.

I.R.C.C.S. Policlinico San Donato S.p.A. - Sede Unico

Via Morandi 30 - 20097 San Donato Milanese (MI)
Tel. +39 02.527741 / Fax 02.52747171 info.psd@grupposandonato.it
C.F. e P.A.A. Reg. Imp. Milano 05853300153
Capitale Sociale € 4.845.789 i.v.

www.grupposandonato.it



INTERNAL RM GUIDELINES: Discussed and Agreed with the Sanitary Direction of IRCCS Policlinico San Donato



I.R.C.C.S.
POLICLINICO SAN DONATO

General Data Protection Regulation – External Treatment of Patients' Data ex art 28 GDPR

Official Statement of Milan Niguarda Hospital Legal Service

Da: Marco Ciboldi <marco.ciboldi@ospedale.niguarda.it>
Inviato: mercoledì 24 ottobre 2018 17:41
A: Marco Finotti
Cc: Emanuela Teresa Locati; Riccardo Sforza; Stefano Vitello; Giuseppe Micali; Alberto Giovanni Ambrosio; Marco Trivelli
Oggetto: R: (External) Re: R: autorizzazione

Grazie

Condivido in pieno quanto esposto

Marco Ciboldi

Da: Marco Finotti [mailto:marco.finotti@ospedale.niguarda.it]
Inviato: mercoledì 24 ottobre 2018 16:35
A: Marco Ciboldi
Cc: Emanuela Teresa Locati; Riccardo Sforza; Stefano Vitello; Trivelli
Oggetto: Re: (External) Re: R: autorizzazione

Gent.mo,

faccio seguito alle mail in calce, trasmettendo in allegato il documento sul trattamento dei dati personali, unitamente al documento di gestione dei pazienti".

I suddetti documenti sono stati integrati con gli atti del rischio. Su quest'ultimo aspetto rilevo che Boston ha dichiarato - avente valore contrattuale - di conformarsi al trattamento dei dati.

Inoltre telefonicamente Boston ha confermato che ha provveduto all'adeguamento al GDPR. Resta comunque inteso che la responsabilità del trattamento dei dati è del Titolare (ASST Niguarda).

Allo stato ed in considerazione di un ponderato bilanciamento di interessi, risulta agevole cogliere la prevalenza del diritto alla salute rispetto alla privacy, potendo dunque ipotizzare di ritenere sufficienti le garanzie già poste da Boston, riservandosi un'analisi più accurata degli aspetti relativi al trattamento dei dati in una fase successiva alla sottoscrizione delle nomine ex art. 28 GDPR.

Infatti, il paventato "rischio clinico" connesso al mancato avvio del trattamento da parte di Boston - potenzialmente derivante dalla mancata nomina a Responsabile esterno del trattamento - potrebbe ingenerare un documento destinato a ripercuotersi sulla salute dei pazienti.

Alla luce di quanto sopra, condivido la Sua indicazione di procedere alla successione delle nomine.

Cordiali saluti.

Marco Finotti

Allo stato ed in considerazione di un ponderato bilanciamento di interessi, risulta agevole cogliere la prevalenza del diritto alla salute rispetto alla privacy, potendo dunque ipotizzare di ritenere sufficienti le garanzie già poste da Boston, riservandosi un'analisi più accurata degli aspetti relativi al trattamento dei dati in una fase successiva alla sottoscrizione delle nomine ex art. 28 GDPR.

Infatti, il paventato "rischio clinico" connesso al mancato avvio del trattamento da parte di Boston - potenzialmente derivante dalla mancata nomina a Responsabile esterno del trattamento - potrebbe ingenerare un documento destinato a ripercuotersi sulla salute dei pazienti.

Alla luce di quanto sopra, condivido la Sua indicazione di procedere alla successione delle nomine.

«In consideration of a balanced evaluation of patients' interests, it is possible to establish the prevalence of the Right to Health rather than the Privacy Protection»

2023 HRS/EHRA/APHRS/LAHRs expert consensus statement on practical management of the remote device clinic

Aileen M. Ferrick, PhD, ACNP, RN, FHRS (Co-Chair),^{1,*}
Satish R. Raj, MD, MSCI, FHRS (Co-Chair),^{2,*}
Thomas Deneke, MD, PhD, FHRS (EHRA Vice-Chair),^{3,†}
Pipin Kojodjojo, MBBS, PhD, FHRS (APHRS Vice-Chair),^{4,‡}
Nestor Lopez-Cabanillas, MD (LAHRs Vice-Chair),^{5,§} Haruhiko Abe, MD, PhD,^{6,‡}
Serge Boveda, MD, PhD, FEHRA, FESC,^{7,†} Derek S. Chew, MD, MSc, FHRS,^{2,*}
Jong-Il Choi, MD, PhD, MHS,^{8,‡} Nikolaos Dagres, MD,^{9,†}
Aarti S. Dalal, DO, FACC, FHRS, CEPS-P,^{10,¶} Brynn E. Dechert, APN, FHRS, CCDS,^{11,¶}
Camille G. Frazier-Mills, MD, MHS, CCDS,^{12,*} Olivia Gilbert, MD, MSc, FACC,^{13,#}
Janet K. Han, MD, FACC, FHRS,^{14,**} Sherri Hewit, PharmD,^{††}
Christine Kneeland, BSN,^{15,*} Starr DeEllen Mirza,^{††} Suneet Mittal, MD, FHRS,^{16,*}
Renato Pietro Ricci, MD,^{17,†} Mary Runte, PhD,^{18,††} Susan Sinclair, NZCS, PGDHCs,^{19,‡}
Ricardo Alkmim-Teixeira, MD, PhD,^{20,§} Bert Vandenberg, MD, PhD,^{2,21,†}
Niraj Varma, MA, MD, PhD^{22,‡‡}

2023 Recommendations for Alert-Based RM: Need for In-person Visits

Recommendations for alert-based RM

COR	LOE	Recommendations	References
1	B-R	1. In patients with CIEDs and a component with a safety advisory, it is recommended that continuous connectivity be added to scheduled remote or in-person interrogation to enable early detection of actionable events.	18,29,31,32,35,39,42,123,124
2a	B-R	2. In patients with PMs on RM with consistent and continuous connectivity, and in the absence of recent alerts or other cardiac comorbidity, it is reasonable to schedule in-person visits every 24 months.	37,125,126
2a	B-R	3. In patients with ICDs on RM with consistent and continuous connectivity, and in the absence of recent alerts or other cardiac comorbidity, it is reasonable to schedule in-person visits every 24 months.	31,35,57,92,98