How to use digital devices to detect and manage arrhythmias : an EHRA practical guide

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POSITION PAPER
EHRA practical guide

How to use digital devices to detect and manage arrhythmias: an EHRA practical guide

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Introduction

The recent advances in technology combined with the need to manage patients remotely during the coronavirus disease-19 (COVID-19) pandemic, have led to a rapid adaptation of the use of digital devices in clinical practice.[1,2] The term digital devices for heart rhythm monitoring in this paper encompasses many of the novel devices, such as patches, various wearable devices, and handheld devices that

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Table 1 Categories of the consensus statement

Consensus statement	Definition	Symbol
Indicated or 'should do this'	Scientific evidence that a treatment or procedure is beneficial and effective, or is strongly supported by authors' consensus	
May be used	General agreement and/or scientific evidence favour the usefulness/efficacy of a treatment or procedure	
Should NOT be used	Scientific evidence or general agreement not to use or suggest a treatment or procedure	

The categorization for our consensus document should not be considered directly similar to the one used for official society guideline recommendations which apply a classification (I–III) and level of evidence (A, B, and C) to recommendations.

have been approved by regulatory authorities for medical purposes. Cardiac implantable electronic devices (CIEDs), devices that can deliver therapy (such as life vests) and Holter monitors fall outside the scope of this paper.

Although many perceive the potential benefits from digital workflow, recent surveys show disparities in management with concerns from healthcare professionals of data overload and unsolicited registrations from unfamiliar digital devices.[2,3]

The aim of the document is to provide up-to-date practical guidance on the use of digital devices for arrhythmias, from early detection through management and implementation, using the categories of consensus (*Table 1*). To be included, a consensus statement needed at least 80% consensus by the co-authors.

Digital heart rhythm devices in clinical practice

Digital devices for heart rhythm monitoring can be divided into two groups based on the technology used to evaluate heart rhythm:

(1) Electrocardiogram (ECG)-based and
(2) Non-ECG based, including photoplethysmography (PPG).

The choice of digital heart rhythm device should be tailored to the patient, considering symptom frequency, expected duration of monitoring, local infrastructure, and patient's preference (*Figures 1 and 4*). Regardless of digital device used, clinician over-reading of the recordings is necessary.

Electrocardiogram-based digital devices

The currently available digital heart rhythm devices using ECG differ by a number of factors:

Type of device and mode of detection

- Area of application
- Placement
- Number of leads
- User feedback

Hardware/software

- Battery: rechargeable vs. replaceable
- Data storage: in-device vs. cloud-based
- Data transfer: direct upload to cloud-based servers vs. paired smartphone/tablet vs. USB connection
- ECG display: integrated screen vs. paired device vs. no real-time display

Regulatory

- Regulatory clearance: CE/FDA
- Validation of use by clinical studies

Handheld electrocardiogram

Single-lead devices usually provide recordings from lead I. Some models can be applied to the chest to record chest-right arm leads that can yield QRS complexes of higher amplitude and with clearer P waves than in lead I.[4,5] Leads II and III can be recorded by applying the bipolar device to the left leg (the device can be placed on a dampened trouser to simplify the process), while holding the device with the right and left hand, respectively. A model with three electrodes allows simultaneous recordings of all limb leads by holding the device with both hands and applying the rear electrode against the left leg (*Table 2*).

Importantly, CE-marking as a class IIa-medical device does not ensure that the device's algorithm for heart rhythm assessment is accurate; clinician oversight is still required for diagnostic interpretation.[5,6] A manufacturer may also change the device's algorithm, thereby impacting its accuracy.[4,7] The reported diagnostic accuracy of a device will depend on its algorithm, the patient population using the device, the settings/conditions under which the recording is performed and on the physician interpreting the tracings.[7–9] In the USA, the American Food and Drug Administration (FDA) regulates the sale of medical devices. To gain approval a device needs to show evidence that it is safe and effective for a particular use.

Electrocardiogram patches

Electrocardiogram patch monitors are validated, wearable digital devices for heart rhythm monitoring and diagnosis. With their low-profile, water-resistant, wireless, and self-adhesive form-factors, they are easy-to-use, well-tolerated and have high patient adherence.[10] Patches have high accuracy and higher diagnostic yields than traditional 24-h Holter monitoring.[11] Patch monitoring is cost-effective, with many symptomatic, clinically significant arrhythmias detected within the first week of monitoring.[10,12] They are a feasible method for atrial fibrillation (AF) detection even when the observed AF burden is <15%.[10] For AF screening in moderate- to high-risk populations, patch monitoring has comparable yield to implanted loop recorders at 2 weeks and 1 month, and 10 times higher yield compared to blood pressure monitoring.[13–15] The limitation of these devices has mainly been relatively short battery life, the durability of the adhesive and, in some healthcare systems, lack of reimbursement.

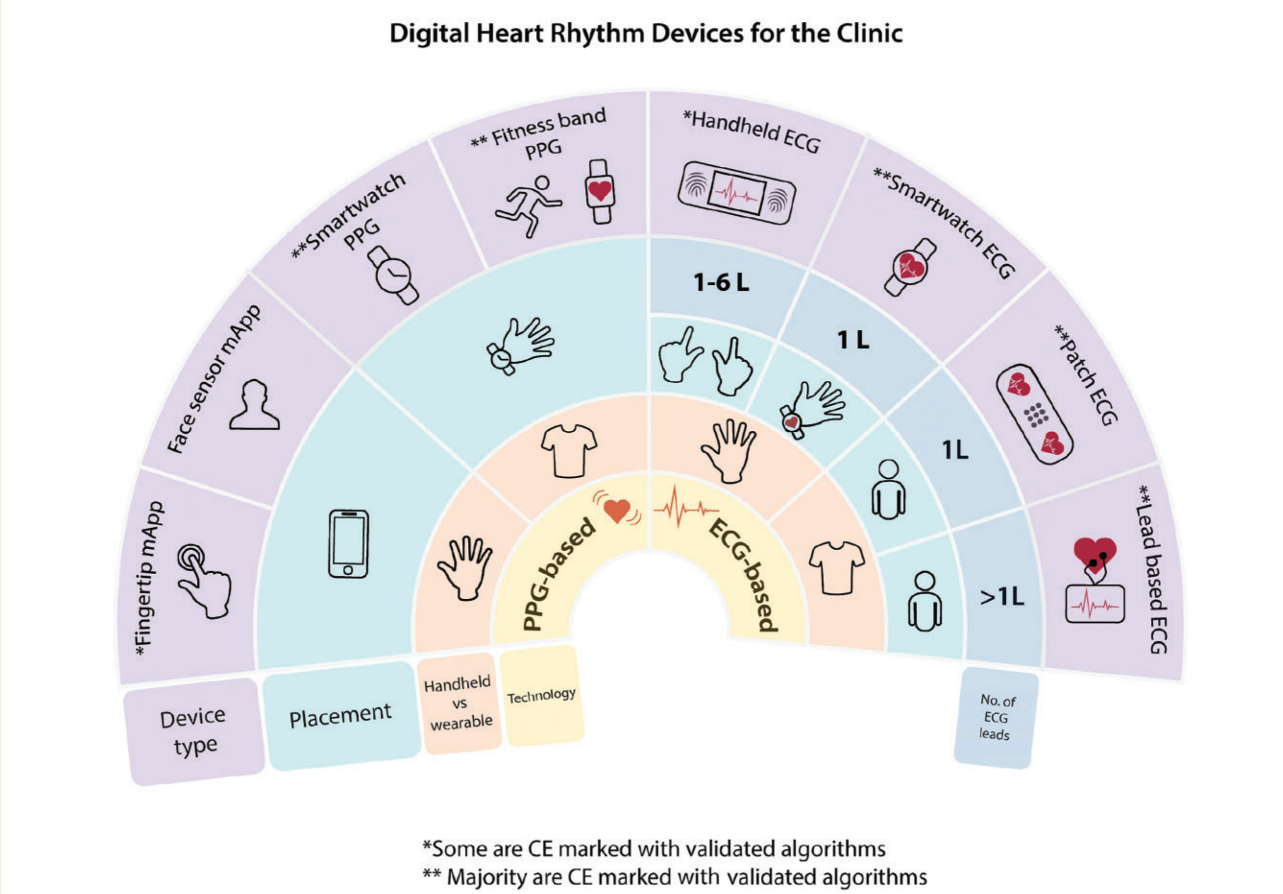


Figure 1 Overview of digital heart rhythm devices for the clinic. Suggest reading the figure from the inner circle—devices have been divided into devices that provide photoplethysmography (PPG) or electrocardiogram (ECG), followed by the mode of handheld or wearable, and then placement on the body, number of leads, and device type. */**Please see *Table 2* for further details. ECG, electrocardiogram; L, lead; mApp, mobile App; PPG, photoplethysmography.

A variety of CE marked/FDA cleared single-use ambulatory ECG patches are available, offering single channel, 5- to 30-day continuous recording with some offering live monitoring using mobile devices or cloud-based technology (*Table 2*). Several CE/FDA-marked ECG patches (one of which is reusable) offer additional vital signs monitoring and motion tracking via accelerometers. One patch monitor has been FDA cleared for ambulatory QTc monitoring.

Smartwatch electrocardiogram

Smartwatches are direct-to-consumer devices that have increasingly incorporated technology for monitoring health status. Several smartwatches on the market can record a single-lead 30-s ECG tracing by electrodes incorporated in the back of the watch and on the watch crown or case. Electrocardiograms tracings can be viewed in real-time on the watch screen and stored on a smart device mobile application (mApp), and PDFs can be generated and sent wirelessly to the healthcare team. Smartwatches have embedded AF-detection algorithms, but data on algorithm accuracy have until recently been limited.[16–19] A recent meta-analysis comparing smartwatch technology (PPG or ECG) showed that smartwatches were non-inferior to routine AF monitoring strategies.[20] A limitation with smartwatches has been their limited wear time as they require charging, but newer digital-analogue hybrid watches with single-lead ECG recording capability have extended battery life.[21] Importantly, generated ECG tracings still require physician oversight and analysis for rhythm diagnosis.

Photoplethysmograpy recorders

Photoplethysmography is capable of monitoring heart rate and detecting arrhythmias using an optical technique that analyses the peripheral pulse. A light source and a detector are used to measure changes in blood volume within the skin surface, detecting changes in reflected light intensity, generating a peripheral pulse waveform.[22] A smartphone camera combined with the LED flashlight has been used for both contact (finger-over-the-camera) and contactless (facial video) PPG.[23,24] Photoplethysmography is currently used in clinical routine to measure oxygen saturation and pulse rate.[25] The relative ease of PPG technology has allowed its incorporation into various wearable devices to analyse heart rate and rhythm,[26] such as chest straps, wristbands, forearm bands, rings, and ear buds.[27] Automated algorithms in smartwatches have been used to detect AF with high accuracy when measurements were taken in patients in a comfortable sitting position[26]; however, in ambulatory patients, the accuracy was considerably lower

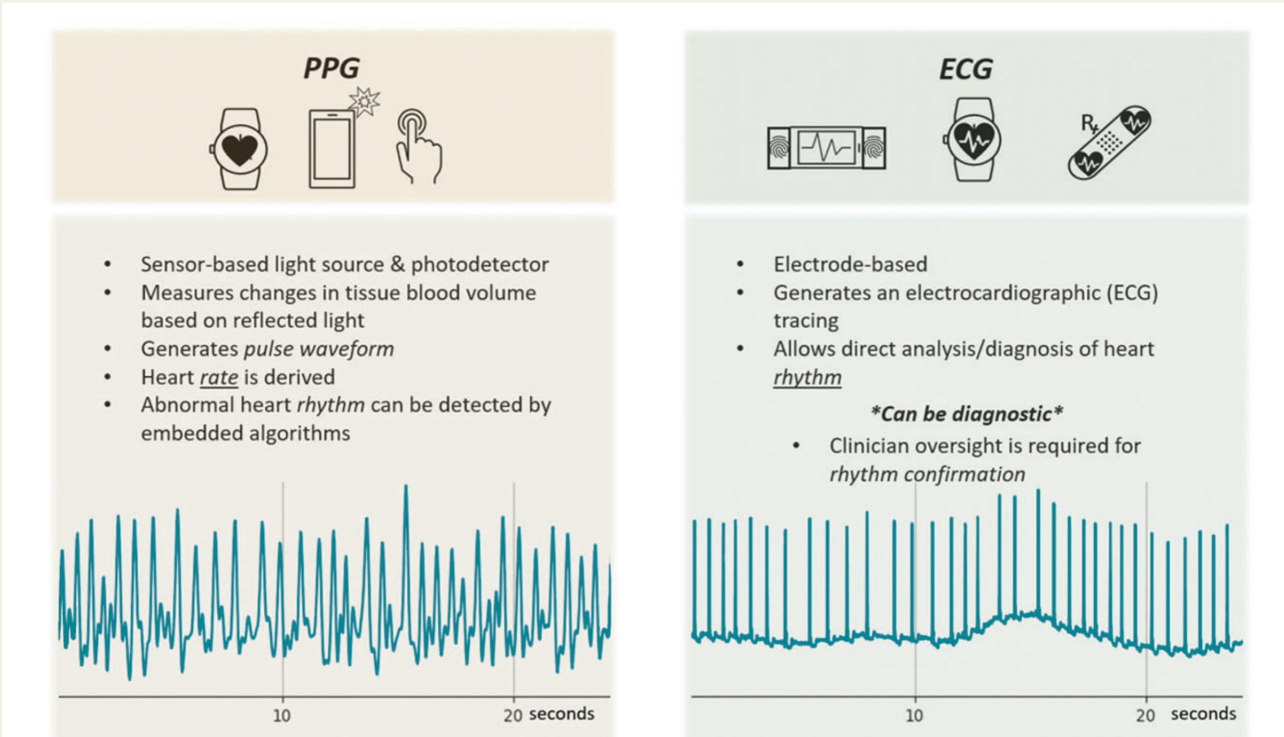


Figure 2 Comparison of photoplethysmography (PPG) vs. electrogram (ECG)-based techniques. In the lower part of the figure an example of a registration from a patient with atrial fibrillation is shown.

due to artefacts.[28] The ubiquity of smartphones and PPG-based apps may allow more convenient and affordable larger scale arrhythmia detection and management. However, AF diagnosis requires confirmation via ECG with clinician oversight (*Figure 2*).[29]

Other devices and biotextiles

Some blood pressure monitors can report heart rate. Blood pressure monitors that screen for AF using pulse irregularity have been shown to have a sensitivity of >85.[30]

Electrode-embedded garments enable wire-free heart rate and rhythm monitoring, often with an active population in mind. Compression garments, such as shirts and sports bras, multi-strap 'vests' and single chest straps paired with wristbands, are available aimed at providing wearability and comfort as well as stability to decrease motion artefact.[31–33] These and other devices are further discussed extensively in the section on athletes (*Figure 10*). Few studies using chest straps to detect arrhythmias are published, clinical data regarding the use of electrode-embedded wearables for cardiac rhythm monitoring are limited, and no dedicated algorithms exist.[34–36]

Consensus statement

Abnormal findings in digital devices should be evaluated in team including a cardiac arrhythmia specialist or a cardiologist

Digital devices in the diagnosis of symptomatic arrhythmias

The 12-lead ECG represents the gold standard for the diagnosis of arrhythmias. However, a 12-lead ECG has limitations of availability and cannot diagnose paroxysmal arrhythmias if the recording is performed during asymptomatic periods. ECG-based digital devices can overcome these limitations of availability. Although most digital devices provide ECGs with fewer than 12 leads, a single-lead ECG may be sufficient to diagnose the type of arrhythmia.

Considerations when using digital devices are

(1) Many digital devices do not continuously record the heart rhythm; in this case, recordings must be user-initiated and in case of haemodynamic compromise, this might not be possible.
(2) Initiating a recording requires several seconds followed by registration for at least 30 s. This delay renders existing digital technologies poorly suited for diagnosing brief arrhythmias.
(3) Before therapeutic decisions are made based on digital device recordings [that is initiating anticoagulation for presumed AF or considering an implantable cardioverter-defibrillator for presumed ventricular tachycardia (VT)], it is imperative to confirm the arrhythmia by carefully ruling out artefact or noise. To minimize the risk of false positives, the quality of the recording is key, and steps to minimize baseline wander and artefacts is of essence.

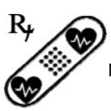
However, the additional benefit of digital devices is the widespread availability compared to standard ECGs thereby increasing the

Table 2 Summary of heart rhythm monitoring devices that have been used in the clinical setting for rhythm diagnosis with peer-reviewed publications

Device	Type	Area of application	Mode of detection	Cardiac sensor	ECG viewing	Battery	Data storage	Data transfer	Regulatory clearance	Validation	References
Apple Watch	Smartwatch	Wrist-finger	ECG and PPG	2 electrodes; 1 lead ECG	Integrated and on paired device	Rechargeable	In-mApp and Cloud	Cloud via smartphone/ tablet	CE and FDA	Yes	17–19
Fitbit	Smartwatch	Wrist-finger	ECG and PPG	2 electrodes; 1 lead ECG	On paired device	Rechargeable	In-mApp and Cloud	Cloud via smartphone/ tablet	CE and FDA	No	16
Huawei	Band	Wrist	PPG	2 electrodes	On paired device	Rechargeable	In-mApp and Cloud	Cloud via smartphone/ tablet	Asia	Yes	37,38
Samsung	Smartwatch	Wrist-finger	ECG and PPG	2 electrodes; 1 lead ECG	On paired device	Rechargeable	In-mApp and Cloud	Cloud via smartphone/ tablet	CE and FDA	No	NA
Withings	Smartwatch	Wrist-finger	ECG and PPG	2 electrodes; 1 lead ECG	On paired device	Rechargeable	In-mApp and Cloud	Cloud via smartphone/ tablet	CE	No	21
Alivecor Kardia Mobile	Handheld	Fingertips, ±leg or chest	ECG	2 or 3 electrodes; 1 lead or 6 lead ECG	On paired device	Replaceable	In-mApp and Cloud	Cloud via smartphone/ tablet	CE and FDA	Yes	7
Beurer ME 90	Handheld	Chest-fingertip or finger-finger	ECG	2 electrodes; 1 lead ECG	On paired device	Rechargeable	In-device	USB connector	CE and FDA	Yes	5,8
Coala Heart Monitor	Handheld	Thumb-chest	ECG	2 electrodes; 1 lead ECG	On paired device	Rechargeable	In-mApp and Cloud	Cloud via smartphone/ tablet	CE and FDA	Yes	39,40
ECGCheck	Handheld	Fingertips, ±leg or chest	ECG	2 electrodes; 1 lead ECG	On paired device	Rechargeable	In-mApp and Cloud	Cloud via smartphone/ tablet	CE and FDA	Yes	41
Eko DUO	Handheld	Chest	ECG	2 electrodes; 1 lead ECG	On paired device	Rechargeable	In-mApp and Cloud	Cloud via smartphone/ tablet	CE and FDA	Yes	42
HeartCheck CardiBeat, ECG Pen, Palm	Handheld	Fingertips, palm/ chest/hip	ECG	2 electrodes; 1 lead ECG	On paired device (CardiBeat); Integrated (ECG Device, ECG Pen, Palm)	Rechargeable (CardiBeat, Palm); Replaceable (ECG Device, ECG Pen)	In-mApp and Cloud (CardiBeat, Palm); In-device (ECG Device, ECG Pen)	Cloud via smartphone/ tablet (CardiBeat, Palm); USB (ECG Device, ECG Pen)	CE and FDA	Yes	43
MyDiagnostick	Handheld	Hands	ECG	2 electrodes; 1 lead ECG	Via computer and software program	Rechargeable	In-device	USB connector	CE	Yes	44
Omron HCG-801	Handheld	Finger/chest	ECG	2 electrodes; 1 lead ECG	Integrated	Replaceable	In-device (SD card)	SD card	FDA	Yes	45
SnapECG E-H19	Handheld	Fingertips	ECG	2 electrodes; 1 lead ECG	On paired device	Replaceable	Cloud	Unclear	Asia	NA	46
Zenicor-ECG	Handheld	Thumbs	ECG	2 electrodes; 1 lead ECG	Via web-based platform	Replaceable	In-device; transfer to cloud	Cloud	CE	Yes	47

Continued

Table 2 *Continued*

	Device	Type	Area of application	Mode of detection	Cardiac sensor	ECG viewing	Battery	Data storage	Data transfer	Regulatory clearance	Validation	References
	Movesense Medical (Suunto)	Chest strap	Chest	ECG	2 electrodes; 1 lead ECG	On paired device	Replaceable	In-device, 7 days continuous; in-mApp	Cloud	CE	? Yes	[35]
	Zephyr BioHarness 3.0 (Medtronic)	Chest strap	Chest	ECG	2 electrodes; 1 lead ECG	On paired device	Rechargeable	In-device	Wireless or USB	FDA	Yes	[36]
	Bardy Dx Carnation Ambulatory Monitor (CAM)	Patch	Chest, self-adhesive	ECG	2 electrodes; 1 lead ECG	Via web-based platform	Single-use	In-device, 14 days continuous	Direct download by company → cloud	CE and FDA	Yes	[48]
	BioTel Mobile Patient Telemetry (MCOT)	Patch	Chest, self-adhesive	ECG	3 electrodes; 2 lead ECG	Via web-based platform	Single-use, rechargeable	In-device, 30 days continuous	Wireless near real-time telemetry. Direct download by company → cloud	CE and FDA	Yes	[49,50]
	BodyGuardian Mini patches (Preventice)	Patch	Chest, self-adhesive	ECG	2 electrodes; 1 lead ECG	Via web-based platform	Single-use, rechargeable	In-device, 30 days continuous	Wireless near real-time telemetry. Direct download by company → cloud	CE and FDA	Yes	[51]
	Life Signal Biosensor Patch	Patch	Chest, self-adhesive	ECG	4 electrodes; 2 lead ECG	On paired device or web-based platform	Single-use	In-device, 5 days continuous	Wireless near real-time telemetry and cloud	CE and FDA	Yes	[52]
	MyPatch-SL	Patch	Chest, self-adhesive	ECG	3 electrodes; 2/3 lead ECG	Via web-based platform	Single-use	In-device, 14 days continuous (2 lead), 9 days (3 lead)	USB transfer cable	FDA	No	
	S-Patch Cardio (Samsung SDS Wellsis)	Patch	Chest, self-adhesive	ECG	2 electrodes; 1 lead ECG	Via web-based platform	Single-use	In-device, up to 100 hours continuous	Cloud	CE	Yes	[53]
	VitalPatch (VitalConnect)	Patch	Chest, self-adhesive	ECG	2 electrodes; 1 lead ECG	Via web-based platform	Single-use	In-device, 7 days continuous	Wireless near real-time telemetry and cloud	CE and FDA	Yes	[54]
	VivaLink	Patch	Chest, self-adhesive	ECG	2 electrodes; 1 lead ECG	Via mApp/web-based platform	Mulit-use, rechargeable	In-device, 96 h continuous	Wireless near real-time telemetry. Direct download by company → cloud	CE and FDA	Yes	[55,56]
	Zio XT/AT (iRhythm)	Patch	Chest, self-adhesive	ECG	2 electrodes; 1 lead ECG	Via web-based platform	Single-use	In-device, 14 days continuous	Wireless near real-time telemetry (AT); USB (XT and AT)	CE and FDA	Yes	[10,11,57]

Continued

Table 2 Continued

Device	Type	Area of application	Mode of detection	Cardiac sensor	ECG viewing	Battery	Data storage	Data transfer	Regulatory clearance	Validation	References
Cardiio Rhythm	Smartphone mApp	Fingertip or video facial detection	PPG	Smartphone camera	No ECG/HR only	NA	In mApp	NA	none	Yes	23,58,59
 Fibricheck	Smartphone mApp	Fingertip	PPG	Smartphone camera	No ECG. HR + AF detection via algorithms	NA	In mApp	In-mApp and Cloud	CE and FDA	Yes	29,60
Preventicus Heartbeats	Smartphone mApp	Fingertip	PPG	Smartphone camera	No ECG. HR + AF detection via algorithms	NA	In mApp	In-mApp	CE	Yes	26,61,62

ECG, electrocardiogram; FDA, American Food and Drug Administration; mApp, mobile application; NA, not applicable; PPG, photoplethysmography.

probability of recording paroxysmal arrhythmias at the right time (*Figure 3*).

Photoplethysmography recordings may be of aid in symptomatic patients with a very low probability of symptoms being caused by arrhythmias to document a normal rhythm and normal heart rate. Any arrhythmias detected using PPG recordings should be confirmed by a 12-lead ECG if possible or an ECG-based device when 12-lead ECG is not available, or the duration of arrhythmia does not allow an ECG-based recording. However, even a normal heart rate and rhythm in a PPG recording does not completely exclude atrial arrhythmia (e.g. atrial flutter or focal atrial tachycardia with regular conduction) and should trigger confirmation by an ECG when in doubt (*Figure 4*).

Consensus statement
Symptom-rhythm correlation for diagnosis of symptomatic arrhythmias can be achieved with ECG-based digital devices
For paroxysmal arrhythmias, ECG-based digital devices can be used as an event recorder to document and diagnose arrhythmias
For establishing a diagnosis, ECG-based wearables are preferred over PPG

Screening for atrial fibrillation

Atrial fibrillation prevalence has been constantly rising and this increase is projected to continue in the years to come.[63] Manifestation and characteristics of AF-related symptoms strongly vary among patients and about one-third of patients remain asymptomatic. Asymptomatic, undiagnosed, and undertreated AF contributes to ischaemic strokes and therefore screening for AF bears the potential of preventing stroke and death.[64,65] Early diagnosis of AF can also enable early rhythm treatment, which has been shown to reduce mortality, stroke, and cardiovascular hospitalization in clinical AF.[66]

When considering screening for AF, individuals referred for screening should be informed of the implications of screening and receive information about the next steps in case of positive or ambiguous findings.[67]

Screening strategies differentiate between opportunistic or systematic screening (*Table 3*) but other factors are also of importance (*Table 4*).[68] Strategies should be chosen by carefully weighing the risks and benefits of screening.[67]

Screening for AF can be performed in a variety of settings and in different cohorts ranging from the general population to high-risk patients.[17,44,69–96] Detection rates of newly diagnosed AF depend on the screening setting, target population and duration of monitoring

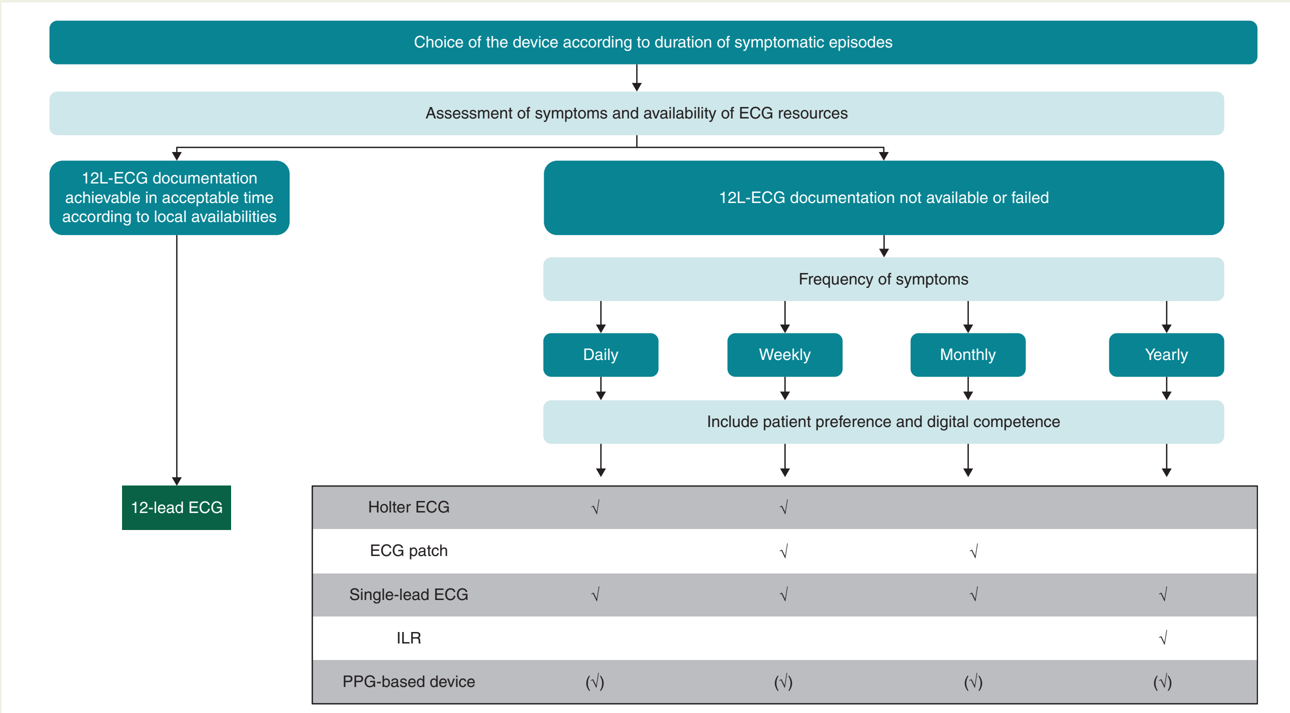


Figure 3 Choice of ECG device in symptomatic patient. If possible, subject to availability and duration of symptoms a 12-lead ECG should be achieved to evaluate symptomatic arrhythmias. In case of difficulties achieving a 12-lead ECG during symptomatic episodes, assess the frequency of symptoms and patient preference prior to choosing long-term ECG device for heart rhythm monitoring. (✓) possible use; 12 L, 12 lead; ECG, electrocardiogram; ILR, implantable loop recorder.

and can vary from <1–3.8% in non-selected cohorts of individuals[72,73] to as high as to 6.8–7.4% in patients with higher risk.[71,73] Increasing the duration and/or the frequency of screening measurements increases the detection rates. Therefore, a screening setting with more than a single measurement should be preferred to increase the screening yield.[97]

The clinical impact and clinical consequences of AF identified and diagnosed in asymptomatic individuals in the context of screening programmes here termed 'screening-detected AF' is not fully elucidated. Based on the current evidence, screening-detected AF should be confirmed by a physician and treated according to current guidelines.[67] Two randomized controlled trials (RCTs) on clinical outcomes in screening-detected AF have been published.[98,99] In the STROKESTOP study, using a screening intervention of 2 weeks twice daily intermittent single-lead ECGs, a small benefit on the combined endpoint mortality, stroke and major bleeding was seen in the group invited to screening as compared to the control group.[98] In the LOOP study, individuals were randomized to be screened for AF using implantable loop recorders, and there was no significant reduction in the primary outcome of stroke and systemic embolism in the screened group.[99] These studies raise several topics that need to be investigated further; the difficulties getting the population at highest risk to participate in screening programmes, possible negative aspects of screening such as anxiety, the high background detection of AF in control groups and different subtypes of AF including severity of AF burden and the substrate severity necessitating oral anticoagulant (OAC) therapy.[67] Further randomized studies aiming to investigate screening effects on long-term clinical outcomes are currently recruiting, Supplementary material online, *Table S2*.

Important efforts for evaluation of the effects of systematic screening strategies are currently underway and aim to further clarify strategic pathways, best-suited target cohorts, device selection, screening mode and setting, effect on stroke reduction and more (Supplementary material online, *Table S3*, *Table 4*, *Figure 5*). The additional potential of wearable devices in this context seems evident, but nevertheless requires more evidence to prove a positive risk-benefit ratio.

Figure 6 provides a suggested workflow to assign the most appropriate screening strategy and screening mode to the respective patient.

Consensus statement
Systematic screening by intermittent ECG[a] is beneficial to detect AF in individuals aged ≥75 years
Systematic screening by intermittent ECG[a] may be beneficial to detect AF in individuals aged ≥65 years with comorbidities increasing the risk of stroke
Opportunistic screening for AF may be beneficial in patients aged ≥65 years without comorbidities or <65 years with comorbidities
PPG-based or ECG-based devices are preferred to pulse palpation for AF screening
In systematic screening for AF, PPG-based or ECG-based devices can be used
If PPG screening is indicative of AF, an ECG-based method should be used to confirm the diagnosis of AF
If AF is diagnosed during screening, patients should be informed, appraised for OAC treatment, and AF risk factors managed
Screening for AF at multiple time points or over a prolonged time should be preferred over single time-point screening to increase the diagnostic yield regardless of symptoms
The term 'screening-detected AF' should be used for AF diagnosed in a screening setting and the diagnosis should be confirmed by a physician

[a]Studies using intermittent ECG recordings have used 2-week intermittent ECG recordings twice-four times daily[98,103] or twice weekly for a year.[104]

Patient engagement perspective

The majority of available trials of patients' perspectives in digital devices are small, of short duration, use self-reported outcomes and rarely take into consideration potential harms and financial implications.[105] A few studies evaluating the value of digital devices from the patients' perspective exist, such as studies showing that digital devices can improve patients' adherence to cardiovascular medications.[1,8] In the recent mobile application (app) in AF (mAFA) trial, a randomized trial of mobile health technology in patients with AF used a dedicated app that incorporated patient educational programmes, self-care, and structured follow-up tools. Patients' satisfaction, drug adherence, anticoagulation satisfaction, and quality of life were significantly improved in the digital devices arm vs. usual care.[106]

Potential barriers and side effects

Patient engagement might be improved by digital health technology and co-design is a key factor for success of digital devices. In a systematic review of barriers to and facilitators of health technology, patient engagement was highlighted, revealing that acceptability was highly variable, with dropout rates ranging up to 44%. Usability issues were the most cited reasons for dropout. Other barriers included health status, motivation, perceived utility and value, convenience, and accessibility of digital tools.[107]

Other barriers and side-effects exist

(1) patients may choose a to buy a device over the counter that is not approved as a medical device and hence does not adequately provide optimal diagnostic benefits;
(2) reimbursement for costs related to digital devices vary;
(3) a focus on self-monitoring may increase anxiety;
(4) concerns may exist regarding data protection;
(5) not all patients can or want to engage in their care in the way that is necessary for digital device arrhythmia detection or monitoring; and
(6) for healthcare personnel large amounts of data, unsolicited recordings and recordings sent out of hours can lead to increased workload, and cause legal unclarities.

Before engaging a patient in digital health technologies, the pathway outlined in *Figure* 7 can be consulted. To ensure adoption of and adherence to digital devices, involving patients and caregivers as early as possible in the development process can be beneficial.[8,9] Co-design will be essential to create apps and devices with intuitive user interfaces, and which better fulfil patients' expectations, thereby increasing adherence.

Digital health literacy

Digital literacy, defined as 'the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem'[108] is crucial to ensure digital equity and inclusivity. Digital literacy requires both technical and cognitive skills.[109] Digitally health literate patients have the necessary knowledge to use a smartphone-based app or other mobile device, *and* understand how collected health data or electronic health information can help better manage their health.[110–112] Variables such as age, educational background, health, and socioeconomic status can impact the ability to develop digital health literacy.[112] Assessing patient digital health literacy, identifying individual needs, and improving both knowledge and skills will be

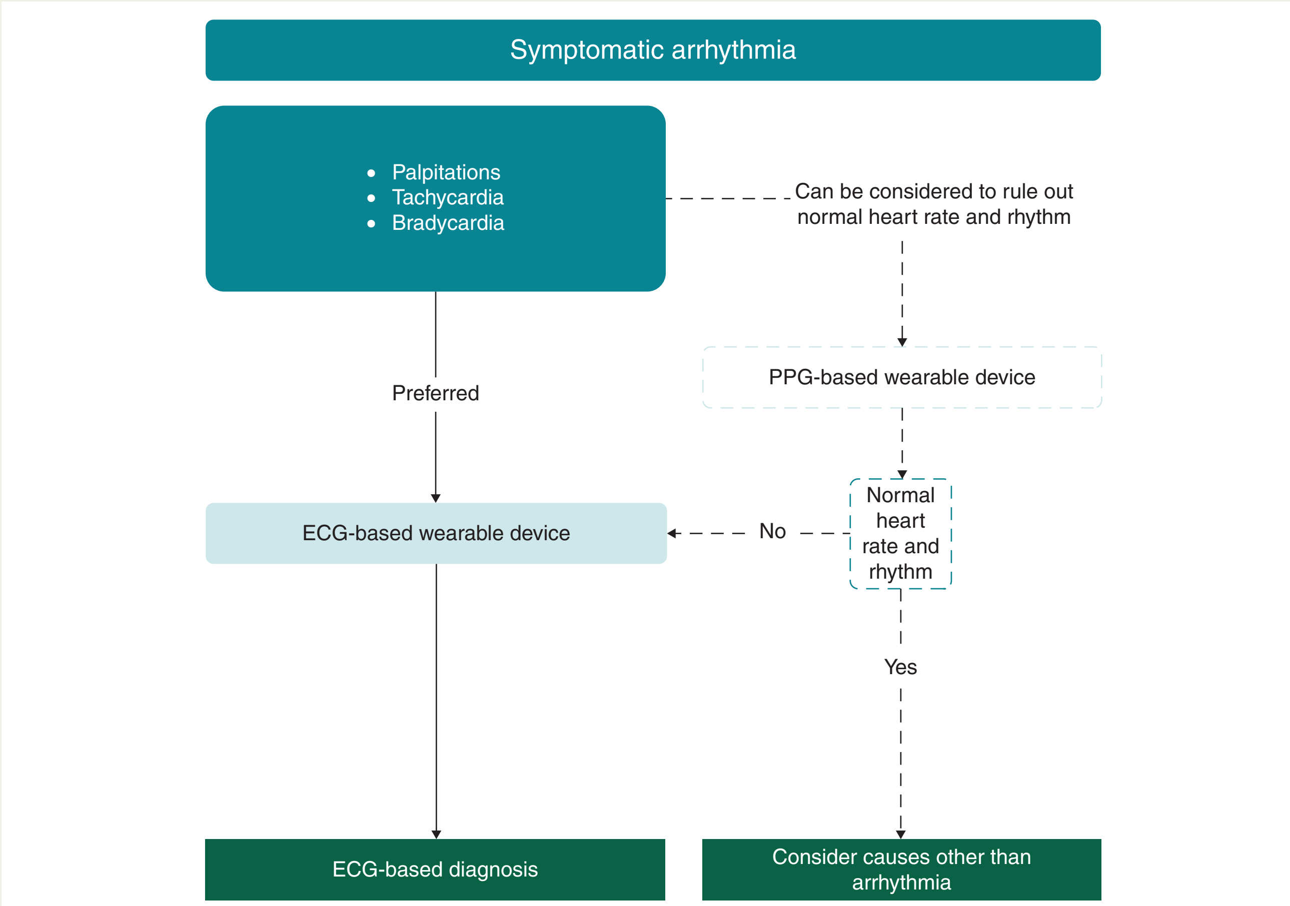


Figure 4 Suggested workflow for the management of symptomatic arrhythmias.

Table 3 Definitions of screening strategies

Strategy	Definition	Examples
Opportunistic screening	Screening performed as a part of clinical contacts for any other reason than screening	• During a routine GP consultation • Including during cardiovascular risk factor management • Screening of pharmacy customers • Screening during vaccination appointments • In contact with healthcare personnel where pulse palpation might be performed
Systematic screening	Screening programme performed continuously irrespective of medical contacts or need	• Population-based screening programme • Systematic screening during health campaigns
Screening in risk groups	Screening performed in individuals who sustained a prior stroke or transient ischaemic attack	• In-hospital screening • Monitoring post-discharge

Table 4 Factors to consider when choosing screening mode

For the choice of screening mode take into account:		Screening strategies:	
Age	• ≥65 • ≥75	Single time	• Pulse taking • BP monitor • PPG • Single-lead ECG • 12-lead ECG

Comorbidities	• Hypertension
	• Sleep apnoea
	• Prior MI
	• Obesity
	• Diabetes
	• Heart failure
	• COPD
	• CKD
		Intermittent	• 30-60s:
			  • pulse
			• 1-4x per day:
			  • BP monitor
			  • PPG
			  • Single-lead ECG
			• Every 1-4 weeks:
			  • 12-lead ECG

Biomarkers	• NT-proBNP ≥ 125 ng/l		
Consumer screening	• PPG indicating irregular rhythm		

Screening opportunities	• Systematic
	• Opportunistic
		Continuous	• ECG patch
			  • 7-day
			  • 14-day
			  • 2x 14-day

Digital competence of the patient	• Limited • Full		
Device available	• PPG-based • ECG-based	Continuous long-term	• ILR

BP, blood pressure; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; ECG, electrocardiogram; ILR, implantable loop recorder; MI, myocardial infarction; NT-proBNP, N-terminal-pro hormone brain natriuretic peptide; PPG, photoplethysmography.

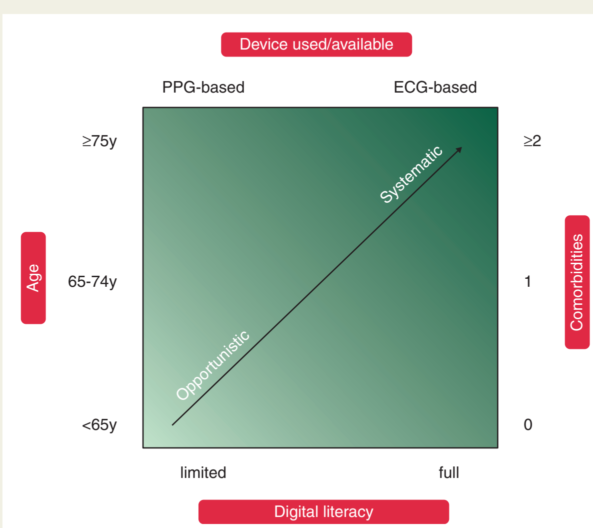


Figure 5 Considerations for atrial fibrillation screening programme (systematic or opportunistic) and digital device based on patient age, comorbidities, and digital literacy.

critical to successful patient engagement with, and future adherence to digital health technologies (*Figure 7*).

Consensus statement

Following a structured patient pathway is beneficial when engaging patients in the use of digital health technology

Atrial fibrillation care using digital devices

For patients with AF digital devices can be of aid in the guideline-recommended integrated management approach,[67] including remote rate and rhythm monitoring. This can be organized as on-demand mobile health prescriptions.[113] Self-management can increase patient

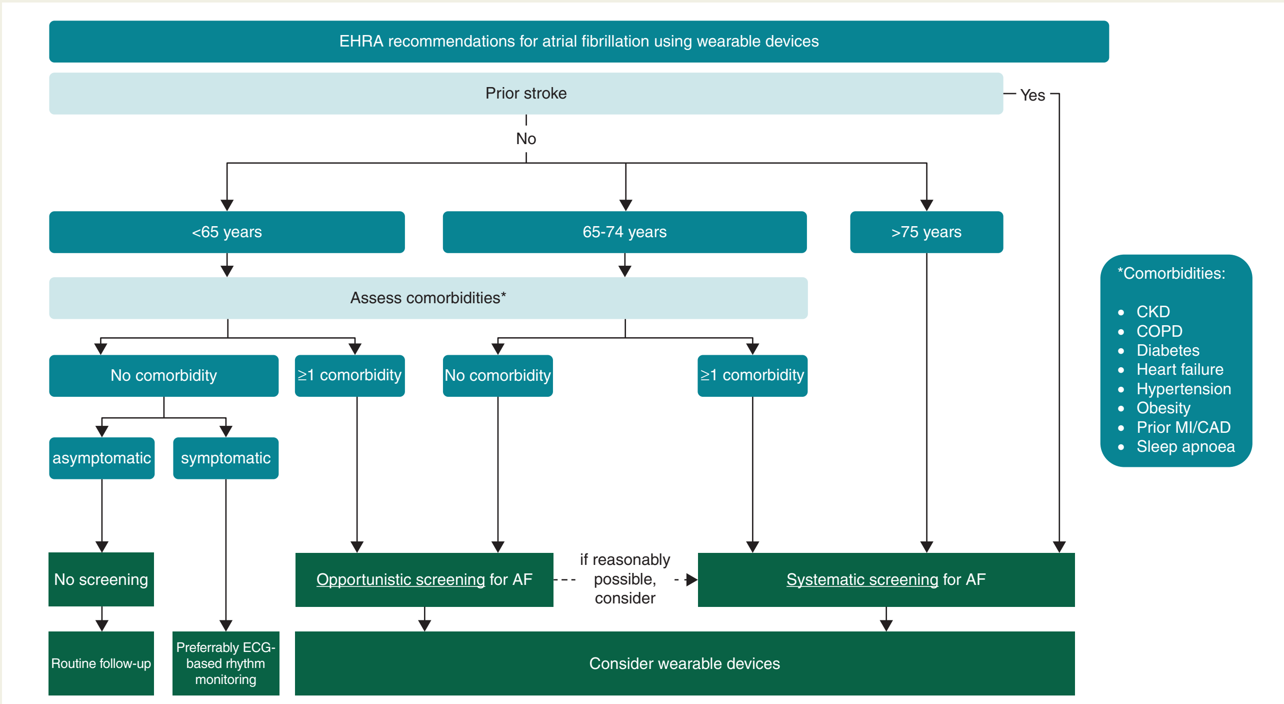


Figure 6 EHRA suggestions for screening for atrial fibrillation using digital devices. For patients with a prior stroke, a systematic screening approach for AF should always be implemented, preferably immediately after the event. As age is the most important risk factor for stroke, suggestions are based on age, with individuals at or above 75 at highest risk. For younger individuals, screening might still be warranted based on their risk factors as per the CHA_2DS_2-VASc score, and in addition for individuals at higher risk such as patients with CKD (chronic kidney disease), COPD (chronic obstructive pulmonary disease),[100] obesity,[101] and sleep apnoea.[67,102] AF, atrial fibrillation; CAD, coronary artery disease; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; ECG, electrocardiogram; MI, myocardial infarction.

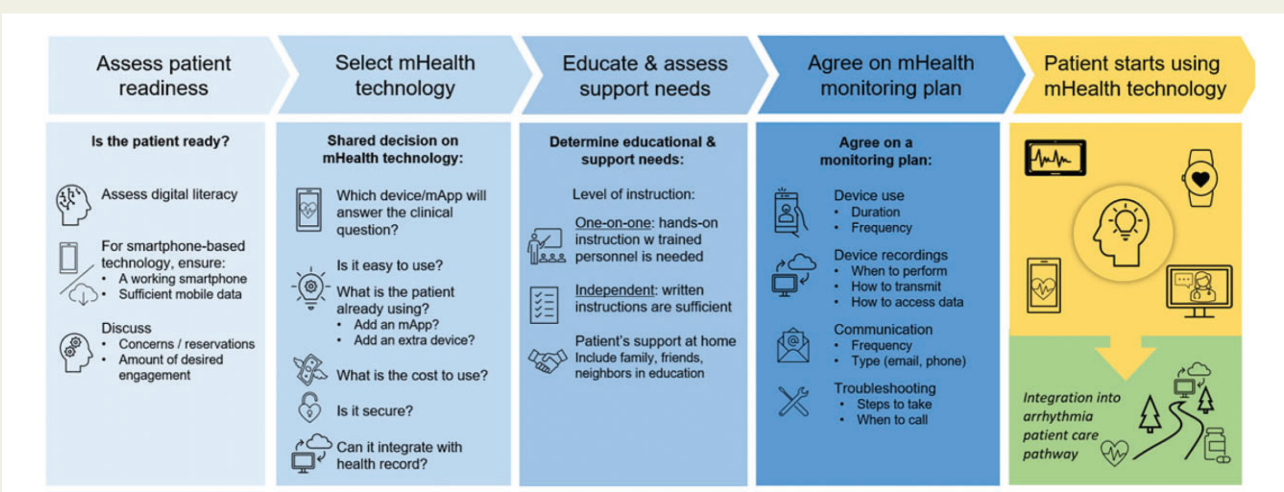


Figure 7 Patient engagement.

involvement in the care process and treatment decision-making. Widespread use of digital devices for continuous or on-demand monitoring require new and adapted (digital) infrastructures to accommodate new processes and increased data loads.

Transition from screening to early atrial fibrillation management

Early detection of AF allows for early initiation of AF management, and early rhythm control therapy lowers the risk of adverse

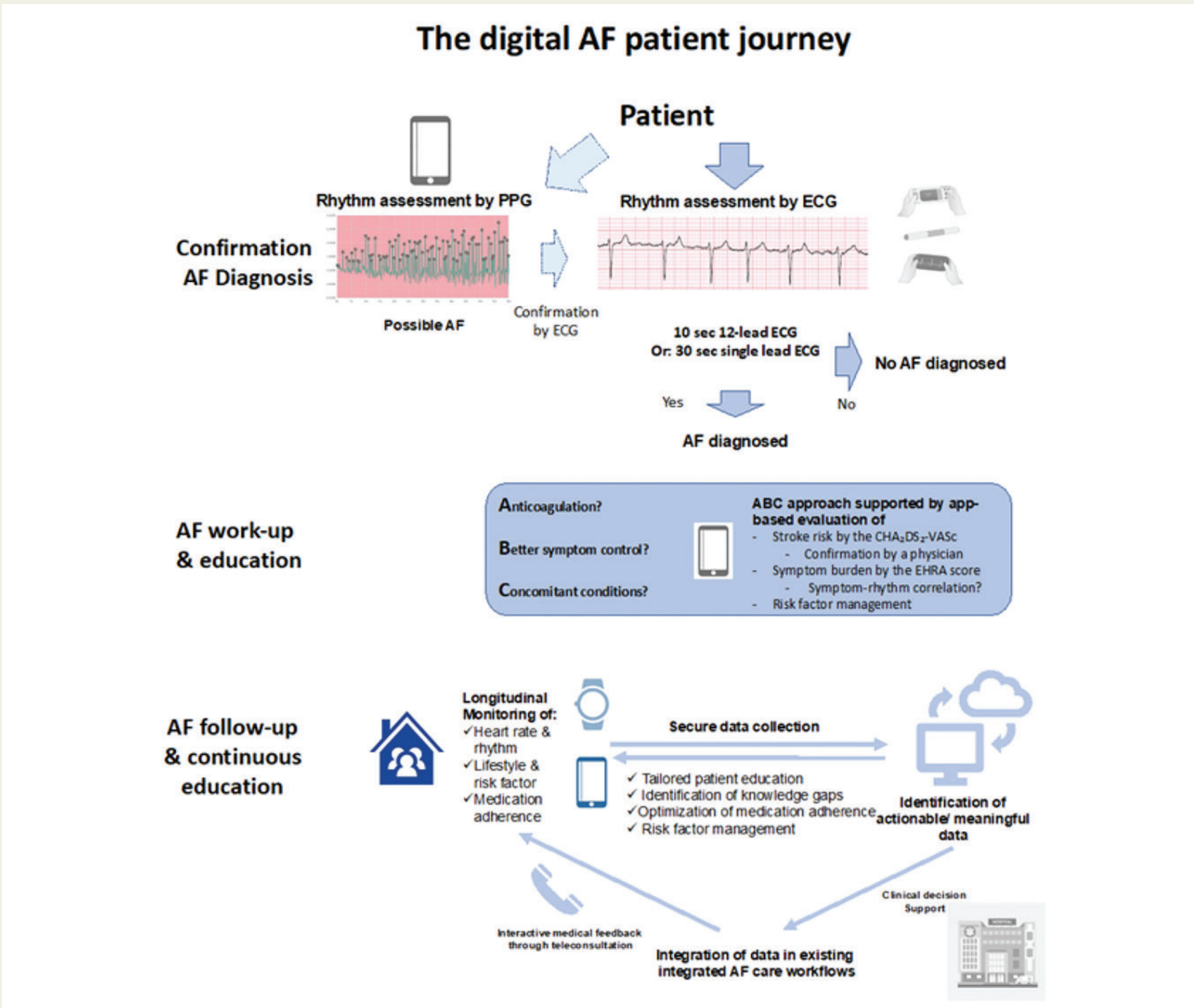


Figure 8 The potential uses of digital devices in patients with atrial fibrillation.

cardiovascular outcomes.[66] Strategies for early AF detection should be linked to a comprehensive work-up organized within an integrated management pathway to allow initiation and guidance of AF treatment in newly detected AF patients.[114] This transition from AF detection to early AF management can be supported by digital technology (*Figure 8*).

Atrial fibrillation work-up and education

Adherence to the ABC-integrated care strategy has been shown to be associated with improved clinical outcomes, and consists of: A, Avoid stroke; B, Better symptom management; and C, Cardiovascular and other comorbidity risk reduction.[115,116] Digital devices can be of aid in assessment of stroke risk (A), symptom burden and symptom-rhythm correlation (B), and management of concomitant risk factors (C). Continuous patient education can be provided by a digital infrastructure collecting data longitudinally, which can be managed by intelligent data processing and finally imbedded in an existing multidisciplinary and integrated care approach in an AF clinic.

The mAFA programme included a prospective cluster-randomized clinical trial, which randomized patients to receive usual care, or integrated care based on the ABC Pathway.[117] The trial showed that rates of the composite outcome of ischaemic stroke/systemic thromboembolism, death, and rehospitalization were lower with the App-based mAFA intervention. In a long-term extension cohort, the beneficial effects were maintained, with high adherence (conformity to recommendation about day-to-day treatment) at >70% and persistence (continuity) >90% with OACs using the mAFA app-based intervention, and a reduction in bleeding risk (*Figure 9*).[118,119]

Rhythm monitoring of atrial fibrillation

Although PPG technology is not diagnostic of AF according to the 2020 European Society of Cardiology (ESC) Guidelines for the

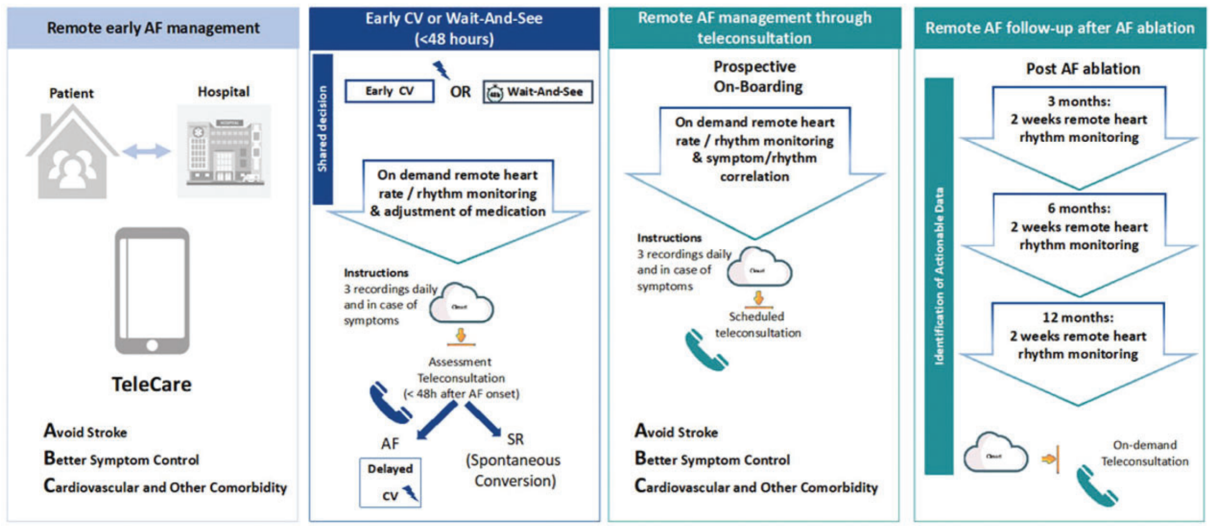


Figure 9 Practical examples of digital AF management. Note that for Panels 2–4 randomized controlled trials are still lacking, and these should be views as examples of ongoing practical applications of digital tools. For all on demand remote heart rate/rhythm monitoring, an experienced physician should verify the findings by the device.

diagnosis and management of AF,[67] its widespread accessibility and low cost make it an interesting tool for remote heart rate and rhythm monitoring in patients with known AF. Challenges of PPG recordings include underestimation of the heart rate in AF by up to 10 b.p.m. due to a pulse deficit, inaccurate data in case of for example poor skin contact, activity and variations in skin tone. Precise cut-off values for PPG-based rate control are being determined.[120,121]

For both PPG-based and single-lead ECG devices diagnosis of regular tachyarrhythmias from the atria can be challenging, based on the lack of (PPG) or difficulty to detect (ECG) p-waves. The distinction between AF, typical atrial flutter, atrial tachycardia, and junctional tachycardia can be difficult to make but is important if considering an ablation strategy. In case of single-lead ECG recordings from a watch placing the watch on an alternative position, such as the ankle or the precordium, can facilitate the detection of P waves.

Peri-cardioversion

Achieving optimal rate control of AF patients waiting for elective cardioversion or patients followed-up using a wait-and-see strategy at the emergency department (ED), can be challenging.[67,122] Regular assessment of rate control and the use of a simple preprocedural medication adjustment protocol is effective in optimizing peri-cardioversion rate control.[123]

The TeleWAS-AF approach supports the management of AF patients peri-cardioversion via remote rate and rhythm monitoring using digital devices, allowing for remote adjustment of rate control medication and detection of spontaneous conversion to sinus rhythm.[124] In general, all stable patients who present to the ED with recent-onset symptomatic AF planned for a wait-and-see approach who can use digital solutions for remote heart rate and rhythm monitoring are eligible for this approach. Whether the implementation of digital devices can facilitate the management of AF in the ED and reduce the burden on the ED system is currently investigated in ongoing studies (*Figure 9*).

Post-ablation

Holter-ECG is frequently used to monitor rhythm at 3, 6, and 12 months after AF ablation to test for AF recurrence. During the COVID-19 pandemic, several centres collected experience on using on-demand digital devices for follow-up after AF ablation.[125] In a pilot study from a single-centre patients using digital devices 3 months after AF ablation had similar AF detection rates and a reduced need for additional ECG-monitoring compared to standard-of-care.[111] A caveat here is that validation of most devices has not been performed in the post-ablation population, which might be more prone to atrial tachycardias other than AF, which is notably more difficult to diagnose with digital devices using single-lead ECG or PPG. Prior studies have shown that 2 weeks of long-term intermittent monitoring by digital devices more effectively detected AF recurrences and had a higher patients' usability than short continuous Holter monitoring.[126]

Atrial fibrillation follow-up

During the COVID-19 pandemic, an on-demand digital approach for the remote management of AF through teleconsultation was used in 40 centres in Europe. The TeleCheck-AF approach implements remote PPG rate and rhythm monitoring in patients managed through teleconsultation.[127,128] Patients were instructed to use the PPG app three times daily and in case of symptoms 1 week prior to teleconsultation. This information was then used during teleconsultation (*Figure 9*). Data indicate a positive centre and patient experience.[29] The effect of this intervention on clinical outcomes will be investigated in an RCT.

Mobile platforms and support systems

Despite widespread availability, most AF mobile platforms and support systems are not evaluated for effectiveness and only a minority are CE-approved. The ESC has together with the CATCH-ME Consortium, developed a patient app to enhance patient education, self-management and interaction with healthcare providers and an app for healthcare providers that simplifies treatment choice and optimizes AF guideline adherence.[129] Neither app has been studied with regards to clinical outcomes. The Health Buddies application was developed to improve OAC adherence in elderly AF patients, via daily health challenges for them and their grandchildren. This resulted in a small increase in knowledge and continued high adherence to OAC therapy.[130] A summary of decision tools and applications available for healthcare professionals is available in the 2020 ESC Guidelines for the diagnosis and management of AF.[67]

Consensus statement
Digital AF management workflows should be structured according to an integrated care approach, such as the ABC (Atrial fibrillation Better Care) pathway
Digital AF management pathways should be integrated in existing AF care workflows provided there is patient engagement
In structured remote follow-up of patients with already diagnosed AF the use of digital devices may be beneficial
AF management via teleconsultation supported by digital device-based rate and rhythm monitoring may be an alternative to traditional face-to-face consultations in AF outpatient clinics in accordance with patient preference
In clinical follow-up after pulmonary vein isolation intermittent rhythm monitoring by digital devices may be suitable

Ventricular arrhythmias and syncope

Digital devices may be an adjunct to conventional arrhythmia monitoring as they can allow ECG documentation during symptomatic episodes and in follow-up after therapy. However, patient-activated digital devices do not replace regular continuous monitoring in case of non-responsive (syncope) or non-tolerated (ventricular arrhythmias) events. In these scenarios, implanted cardiac rhythm monitors have advantages.

Digital devices using ECG can be potentially effective in differentiating VT from supraventricular tachycardia (SVT), whereas PPG cannot distinguish ventricular from supraventricular rhythms. Software algorithms and clinical adjudication is not yet established for ventricular arrhythmias.

Syncope

Implantable or wearable medical ambulatory continuous monitoring for prolonged periods have been used for the evaluation of heart rhythm during syncope. Current direct-to-consumer devices lack patient-activated systems loop recording by post-syncope activation.

A multicentre RCT comparing the use of a handheld ECG device vs. standard care in participants who presented to the ED with palpitations or presyncope showed an increased detection rate of symptomatic arrhythmias in the handheld ECG group.[131]

Falls associated with syncope lead to accidents that are especially disabling for the elderly. Devices with accelerometers and gyroscopes, such as smart watches, can detect a fall, and if no response is obtained from the wearer, can trigger an emergency response. A recent study suggested its sensitivity needs to be improved.[132] Mobile apps that combine analysis of heart rate monitoring together with fall detection, GPS positioning, video recording with a display of patients' surroundings, and the capability to send alerts either triggered by patients in case of symptoms or automatically in case of detected falls, may become useful.[133] Early work has suggested that features extracted from ECG and PPG might aid in predicting neurally mediated syncope.[134] Future development of retrospective documentation of the underlying rhythm after triggering an event in haemodynamic compromised or syncopal consumers, and possibilities to combine analysis of continuous rhythm and blood pressure is needed.

Ventricular tachycardia

The use of digital devices for VT detection lags far behind its use for AF. This is due to two issues: (i) sustained VTs may not be haemodynamically tolerated and thus preclude user-initiated recordings, and (ii) tachycardia discriminators need improvement. Sudden increase in pulse rate by digital devices suggests possible paroxysmal tachycardias, but PPGs are not able to discern the origin of the tachyarrhythmias, and most digital devices using ECGs need to be activated through an active process that might not be possible in non-tolerated VT cases. An exception is ECG patches, which provide continuous recording. For other ECG devices, a high burden of premature ventricular contractions or symptom-documented broad complex tachycardias may trigger further cardiology investigations leading to a diagnosis of VT.

There have been case reports of symptomatic VT that patients have recorded with handheld ECG devices or smart watches.[135,136] Although it is challenging to diagnose VT without ECG recording, in one case using a wearable smartphone-enabled 'smart sock' cardiac monitoring device detected rapid rhythm in an infant and prompted the parents to seek medical attention, which resulted in a diagnosis of fascicular VT.[137]

Ventricular tachycardia is usually adjudicated only if broad-complex tachycardia is documented in wearable technology *and* replicated in

ECGs or invasive studies. In the future, the 12 leads, bluetooth/smart phone-based ECG acquisition and monitoring system (cvrPhone) with potential to analyse beat-to-beat variability of ECG morphology, detect myocardial ischaemia and lethal arrhythmia susceptibility,[138] and 6-lead ECG devices may help to diagnose VT more precisely. In symptomatic patients without structural heart disease wearable technology may be helpful to document arrhythmia ECG in symptomatic VT episodes and can supplement conventional rhythm monitoring.

As there is an increase in the use of digital devices incidental findings of broad complex tachycardias might become more common. Any incidental findings of suspected VT using digital devices it should prompt further diagnostic work-up.

Broad complex tachycardia documented in wearables should prompt cardiology work-up for underlying structural heart disease and trigger further non-invasive and invasive arrhythmia documentation. In the future developments of wearable technologies may help diagnose symptomatic VT and aid in clinical decision-making. Currently, conventional ECG-based continuous rhythm monitoring is still suggested to record episodes of VT.

Consensus statement

- Conventional ECG-based continuous rhythm monitoring is preferable to record episodes of VT
- Digital devices using ECG may supplement conventional rhythm monitoring in patients with symptoms and without haemodynamic compromise
- The detection of broad complex tachycardia in digital devices should prompt immediate cardiology evaluation

Digital approaches in class I and III antiarrhythmic drug therapy

Predominantly, antiarrhythmic drugs exert their effects by prolonging QRS width (Class 1) or QT intervals (Class III).[139] In general, the occurrence of prolongation of the QRS >25% or of the corrected QT above 125% from baseline (or QTc above 500 ms) should lead to termination or dose reduction of antiarrhythmics in most cases.[140] Ventricular premature beats and non-sustained VT might be signs of impending proarrhythmic fatal events due to VT or ventricular fibrillation. Due to concerns for QT prolongation and polymorphic VT[67] controversy exists regarding the safety of outpatient antiarrhythmic drug initiation.[140]

Digital devices using ECG tracings can, in some cases, allow a more detailed ECG interpretation incorporating QRS duration and QT interval.[141–146]

Monitoring QT interval

Few digital devices are FDA-approved for QTc monitoring (KardiaMobile 6L, AliveCor and Biotel Heart MCOT, Philips), but there is a lack of studies on initiation and titration of antiarrhythmic drugs. Therefore, digital devices should be used with caution to monitor drug effects.

Overall, studies of QT intervals in digital devices are small and conflicting. In a small trial comparing a remote wearable monitoring system with manual measurements of QT intervals, there was relatively good accuracy.[147] A recent study compared QT intervals in sinus rhythm between a smartphone-ECG with a 12-lead ECG in patients receiving sotalol or dofetilide.[148] The smartphone recording was capable of detecting QTc prolongation, with smartphone lead I most accurate in measuring the QTc if <500 ms.[148] In contrast, another ECG smartwatch study showed that accurate QT measurements were only achieved in 85% of patients.[145] The use of artificial intelligence algorithms in smartwatches to examine the QT intervals in patients treated with macrolide antibiotics, revealed just fair agreement with manual measurements on 12-lead ECGs.[21]

Studies of single-lead digital devices show variable results, and overall, single-lead ECGs might miss significant information about the QT intervals if the recordings are not validated with a baseline ECG.[149] An individual adjustment of the recording vector and comparison to surface 12-lead ECG intervals is necessary at baseline. In case of an observed, potentially clinically relevant, digital device-recorded abnormal ECG finding, a surface 12-lead ECG should be obtained for validation.

In summary, studies on digital devices on initiation of antiarrhythmic drugs are scare, and automatic arrhythmia detection algorithm might miss arrhythmic events, hence more studies are needed before wearable digital devices can be safely used in patients during antiarrhythmic drug initiation, titration and treatment.[150]

Consensus statement

- Measurements of heart rhythm during initiation of antiarrhythmic drug therapy in outpatients using ECG-based digital devices may be of use
- Measurements of symptomatic/asymptomatic arrhythmic events (supraventricular/VT, ectopic beats) using ECG-based digital devices after initiation of antiarrhythmic drug therapy in outpatients may be of use
- In case a digital device shows an abnormal ECG finding after initiation of antiarrhythmic drug therapy a 12-lead ECG should promptly be taken

Use of digital devices in patients with inherited arrhythmogenic diseases

Inherited arrhythmogenic diseases include genetic disorders (arrhythmia syndromes and cardiomyopathies) presenting with a large spectrum of phenotypes that require non-uniform monitoring intensity.[151] The benefit of digital devices in these patients is the ease of use, providing physicians with means to perform ECG monitoring more frequently during everyday activities, but also in specific settings/recognized triggers such as exercise, post-exercise, arousal from sleep, fever, and emotional stress. In addition, digital devices offer the possibility of identifying the arrhythmia during a symptomatic episode, which can aid in obtaining ECG documentation of symptomatic arrhythmias (e.g. malignant ventricular rhythms vs. supraventricular arrhythmias) and to refine patient's risk stratification (e.g. detection of non-sustained VT in hypertrophic cardiomyopathy or arrhythmogenic cardiomyopathy) but can also to reassure the patient if the cause of their symptoms (e.g. pre-syncope) is not related to a cardiac arrhythmia.[152] However, studies of digital devices in this patient group prone to severe arrhythmias are scarce and more studies are needed prior to clinical implementation.

The future clinical application of digital devices in this setting relates to diagnosis, arrhythmia detection and ECG parameter monitoring. There are dynamic features on the ambulatory ECG that may point to certain genetic conditions; the QT interval for the long-QT syndrome (LQTS) or the type 1 ECG in the right precordial chest leads for Brugada syndrome (BrS).[151] A 24-h continuous 12-lead ECGs assessment can lead to the detection of a spontaneous type 1 pattern at least once over 24 h in up to 34% initially classified as 'drug-induced BrS'.[152] Specific ECG features of LQTS associated with torsade de pointes (microvolt T-wave alternans) have been detected by using ambulatory ECG monitoring.[153]

In patients with inherited arrhythmogenic diseases, there are recognized triggers of malignant arrhythmias which require more frequent ECG and rhythm monitoring:[151,154]

- LQTS: electrolyte abnormalities, QT-prolonging drugs, COVID-19 infection
- LQTS-2: post-partum
- BrS: fever
- LQTS-1/arrhythmogenic right ventricular cardiomyopathy/hypertrophic cardiomyopathy/catecholaminergic polymorph VT: sport

Studies of QT intervals in digital devices have shown contradictory results, see section on antiarrhythmic drugs. Certain developments show promise, such as a 6-lead ECG device approved for use in the measurement of a patient's QTc intervals, and the use of artificial intelligence in digital devices to detect QTc values ≥500 ms.[143,145] For patients with LQTS, this may allow early detection of QTc and to assess the response to antiarrhythmic drug therapy. Hence, digital devices have the potential for remote QT monitoring but need to be further assessed in patients with LQTS.[145]

Consensus statement	
Digital devices may be used in patients with inherited arrhythmogenic diseases to aid diagnosis, arrhythmia detection and monitoring of ECG parameters	
QT measurement by digital devices validated for QT measurement, may be reasonable in patients with LQTS during drug treatment that might prolong QT interval, trigger exposure (e.g. post-partum, exercise, COVID-19 infection) and to assess drug efficacy	

Common digital technologies used in athletes

Athletes have been early adopters of digital devices for training guidance with a focus on heart rate monitoring. A plethora of heart rate monitors (HRMs) are commonly worn during athletic training and competition. These use either electrocardiac sensors in chest-worn devices, or PPG technology. The latter is integrated into wrist-, arm- (e.g.), forehead-, and ear-worn devices (*Figure 10*).

Heart rate chest strap devices consist of two parts: an electrocardiac sensor-embedded chest strap that directly measures cardiac electrical activity, and a wrist-worn receiver displaying heart rate metrics. Heart rate is measured by counting RR intervals without ECG recordings. These devices have high R-wave detection accuracy when compared to Holter as the gold standard.[155–157] Key limitations are artefacts due to transmission interference between the strap and the receiver—often caused by inadequate contact, interaction of bras with the strap in female athletes, and general discomfort while wearing.[158,159]

Wrist-, arm-, forehead-, or ear-worn PPG devices are smaller, more easily worn, and lower cost which make these more widespread, albeit less reliable.[160] Algorithms that apply noise filtering and calculate the heart rate using PPG data are a major determinant of heart rate accuracy but are often closed systems. Validation studies using Holter monitor as controls reveal that high-end chest strap devices have superior performance (accuracy of >0.90) compared to PPG-based wrist-worn monitors (highly variable accuracy range, 0.36–0.99).[156,157,161–163] None of these devices is designated as a medical-grade HRM during exercise. Nevertheless, some athletes may seek medical attention due to high or (extreme) low heart rate on their monitors, with or without concomitant symptoms. Both athletes and medical professionals should critically evaluate and validate that information, especially when based on PPG during exercise. Abnormal heart rate measurements should be confirmed by simple pulse palpation and ideally ECG recording (*Figure 12*). The emergence of (single-lead) ECG recording embedded in HRMs is a significant advancement[158,164–167]; some can provide a three-limb lead ECG.[168] Electrocardiogram confirmation is especially important for bradyarrhythmias, to correct for missed pulse detection by the digital device. Other metrics obtained by digital devices such as heart rate variability, acceleration, body position, temperature, and oxygen levels may be of value in athletic monitoring, but will not be discussed in this text.

Diagnostic scenarios in athletes with abnormal heart rate readings and/or suspected arrhythmias

There are scenarios in which HRMs with current digital devices may be of value in athletes. We distinguish two base scenarios for which we propose diagnostic evaluation flowcharts (*Figure 11*): (A) athlete who presents with an abnormal HRM read-out (tachy- or bradyarrhythmia); and (B) symptomatic athlete with a suspected arrhythmia: potential use of an HRM device.

Recent position papers provide guidance, sometimes indicating upper activity levels and/or heart rate, for patients with known arrhythmia syndromes or potentially arrhythmogenic conditions that participate in leisure activities or competitive sports.[169,170] For these patients, HRM devices—preferably chest strap devices rather than PPG-based ones—could be used for monitoring maximal heart rate levels as set by their physician (*Figure 12*).

Consensus statement

When athletes seek medical attention for abnormal heart rates captured on consumer HRMs, the data should be critically evaluated by an experienced physician (especially when based on PPG technology) to distinguish suspected arrhythmia noise or oversensing

In athletes using HRMs abnormal readings should be confirmed by ECG recordings

In case of an abnormal cardiac evaluation, consumer heart rate devices alone do not suffice for diagnosis: an ECG confirmation is mandatory

Processing health data—the General Data Protection Regulation

Deployment of digital devices and wearables to monitor and manage arrhythmias implies the processing (for example collection and interpretation) of large amounts of individual data. If using these technologies implies the processing of personal data, and if this is carried out by a data controller or data processor (company or organization) established in the EU, the norms of the General Data Protection Regulation (GDPR) apply.[171] Cross-border traffic of large amounts of personal data must be considered, since data are sometimes stored on servers in different countries. If data is transferred within the EU, a high level of data protection is secured. Problems arise when data lands in a country outside the EU; then, a contract (providing the same level of data protection) or explicit consent of the data subject is required.

The GDPR came into force on 25 May 2018 in response to new technological developments that required an updated and stricter European data protection framework. Failure to comply with its requirements, may lead to high financial penalties (imposed by supervisory authorities).[6]

Data recorded and/or transmitted by digital and wearable technologies are mainly physical or mental health data.[172] The GDPR identifies health data as 'sensitive data'; its processing requires the highest level of protection. The processing of health data is generally prohibited, but circumstances allow the prohibition to be lifted (see Article 9, paragraph 2 GDPR). Processing data from digital devices necessary for the provision of care (detecting and managing arrhythmias) that a patient consented to in the context of a regular treatment relationship is within legal bounds. If a device is employed within the context of a research protocol, the legal ground is that the processing is necessary to carry out the research, provided that specific measures are taken to safeguard the fundamental rights and the interests of the data subject. Would, however, the purpose of the data processing go beyond these goals (commercial aims, pursued by companies), the patient's free and informed consent is the proper basis; written consent is not required, but the data controller should be able to demonstrate that the person concerned has freely consented to the data processing. If, for instance, a tech company delivering digital devices to hospitals agrees with the care providers that it may collect and use identifiable patient data for its own company purposes, informed consent is required.

Medical professionals, organizations, and companies involved in the application of digital devices and wearables, have in their role of controller or processor important responsibilities regarding data protection; these should be clearly defined in a data processing agreement, as well as the goal and nature of the data processing. The entire 'cycle of data processing' should be made transparent and subjected to a data privacy impact assessment which evaluates among other things whether principles of purpose specification (is further processing not incompatible with the defined purpose?) and data minimization (are only data collected that are required for the purpose?) are observed, as well as the involvement of a data protection officer.

An important section of the GDPR is dedicated to data subjects' rights (chapter III), such as a right to information about the data that are collected, the storage period, who may use them, and so on. Other rights concern e.g. the access to data and the erasure of data. In case of a health data breach the individuals concerned should be notified within 72 h (*Figure 13*).

Consensus statement

For the collection or processing of individual data of EU citizens when digital devices and wearables are used it is necessary to ensure compliance with the requirements of the General Data Protection Regulation (GDPR)

Future perspectives

Currently, a 30-s single-lead ECG strip is sufficient to diagnose AF.[67] Manual interpretation of single-lead tracings using handheld recorders is still recommended by the 2020 ESC Guidelines for the diagnosis and management of AF, but the accuracy of algorithms automated interpretations of single-lead ECG and PPG are improving rapidly.[7,67,173] Hence, the accuracy of automated interpretation of handheld ECG and PPG recordings may one day be such that manual interpretation may no longer be mandatory for AF diagnosis.

Artificial intelligence has been applied to predict the risk of dysrhythmias from electronic health records,[174] to identify patients with electrographically concealed LQTS,[142] to predict the risk of developing AF by analysing an ECG in sinus rhythm,[175] or to evaluate clinically meaningful QTc prolongation from ECGs acquired using a handheld recorder.[143] Machine learning has promising applications in the field of rhythm diagnosis, but results need to be properly validated across different patient populations and have to be reproducible in different settings.

A field undergoing development is contactless rhythm monitoring. Video plethysmography detects and analyses PPG data collected from the user's face, using a cell phone camera. Video plethysmography has been demonstrated to correlate with contact PPG, as well as ECG tracings obtained simultaneously on single users,[23] and more recently, demonstrated to be feasible for screening multiple persons in the same video.[24] These advances raise the prospects of utilizing this technology for mass AF screening in an ambulatory setting. A current limitation is that the subjects need to keep still to stay in focus and yet another is privacy and confidentiality. Moreover, new research has demonstrated that commonly used smart speakers can be turned into short-range active sonars, capable of measuring heart rate and

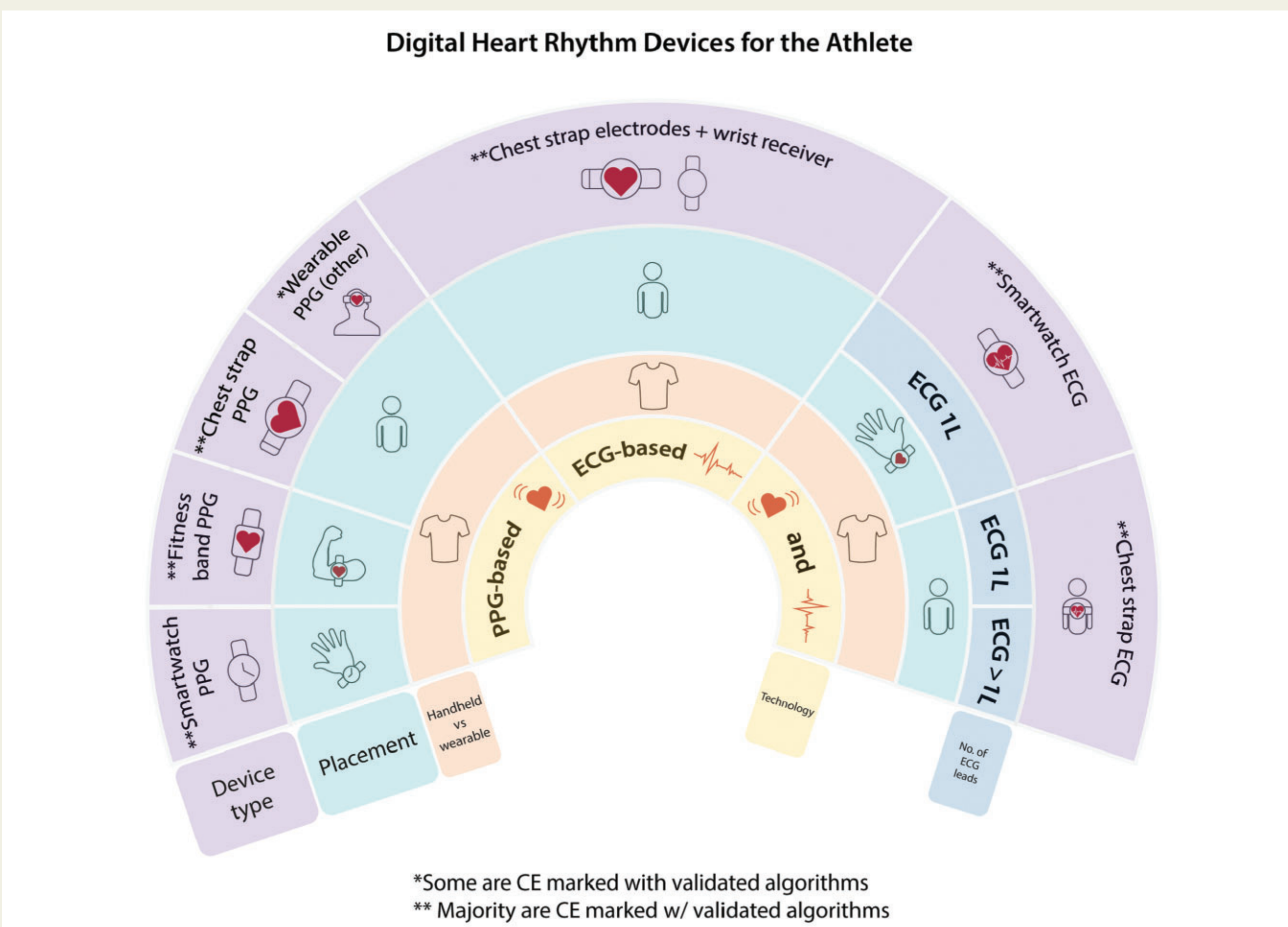


Figure 10 Overview of digital devices for athletes.

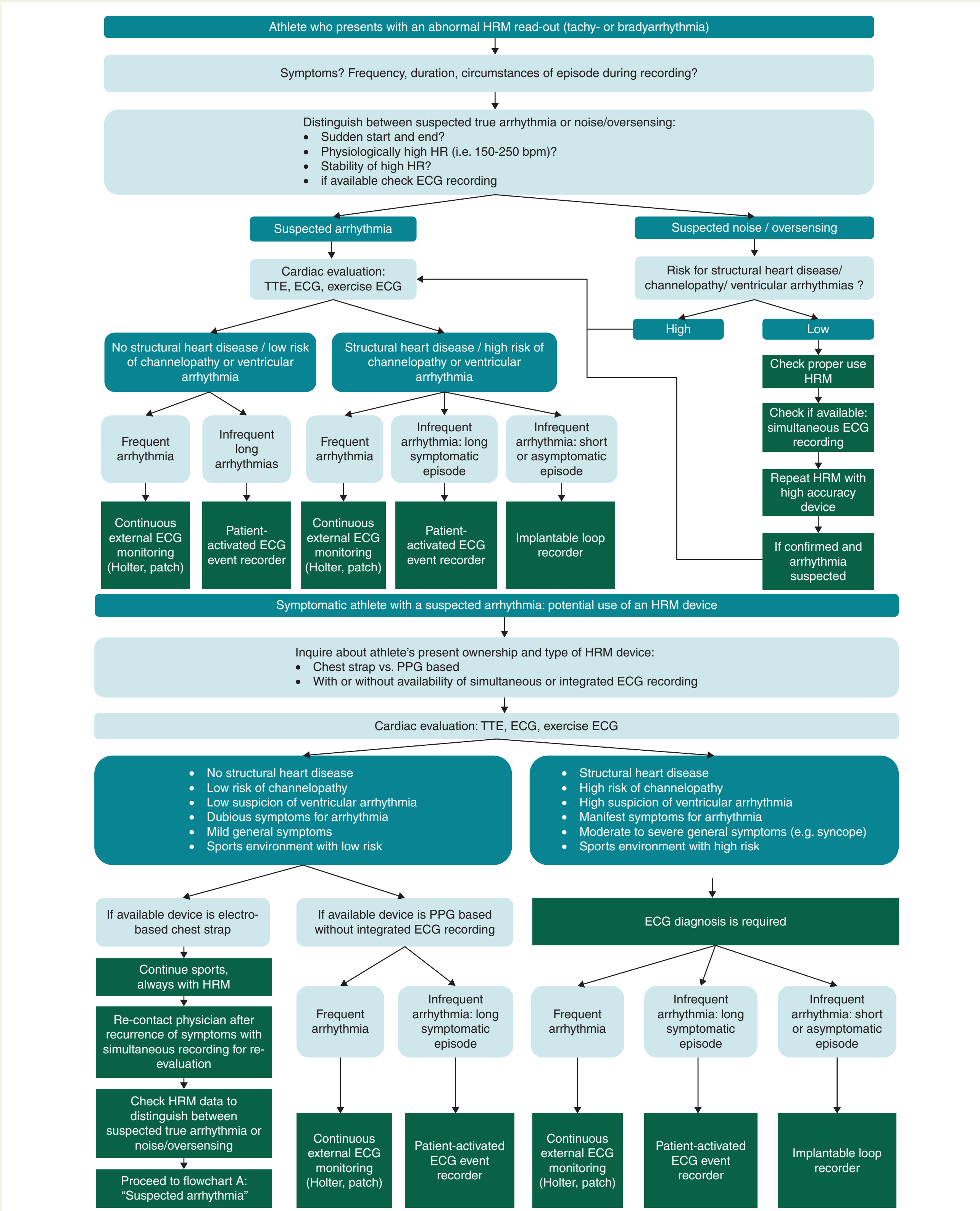


Figure 11 Flowcharts diagnostic scenarios in athletes with (*A*) abnormal heart rate monitor (HRM) readings and/or (*B*) suspected arrhythmias. bpm, beats per minute; ECG, electrocardiogram; HR, heart rate; HRM, heart rate monitor; PPG, photoplethysmography; TTE, transthoracic echocardiogram.

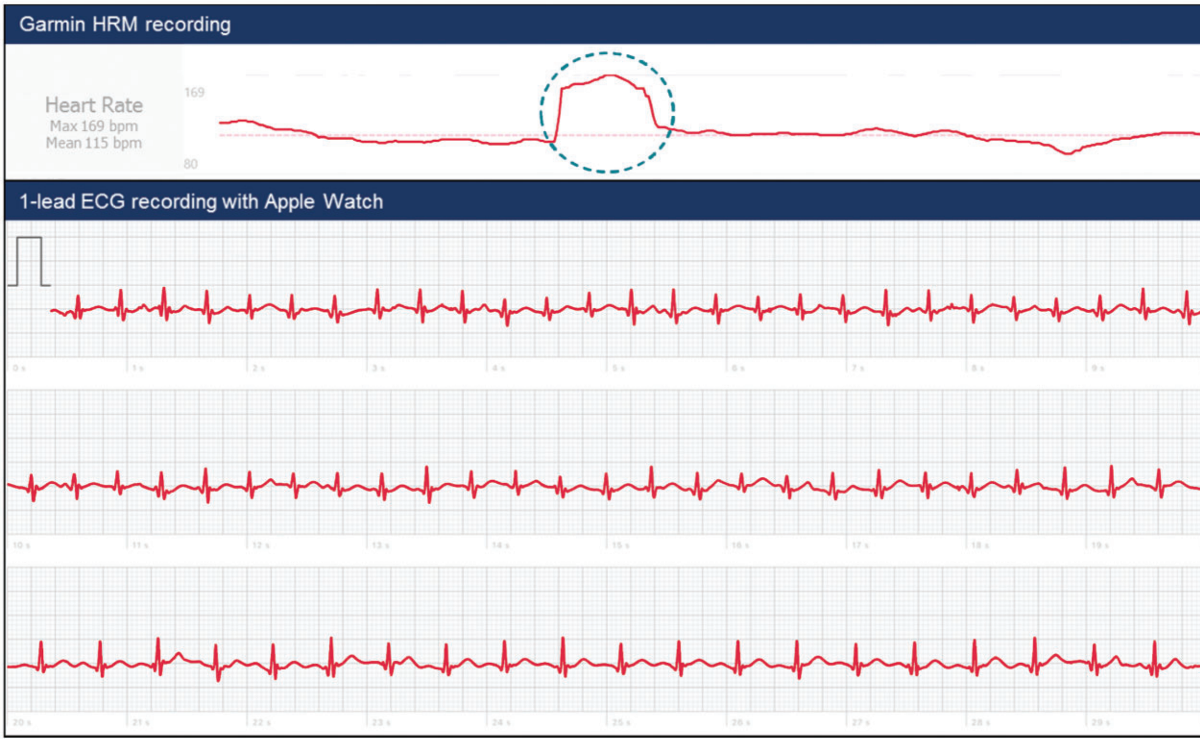


Figure 12 Athlete with sudden heart rate accelerations documented on heart rate monitoring device. An athlete (48-year old male) presented to the outpatient clinic with palpitations during cycling exercise with heart rate accelerations from 120 to 180 b.p.m. without any clear triggers. His chest strap band (Garmin Edge 1030) output showed a sudden start and onset of the episodes, which coincided with subjective palpitations. The combination of known chest strap accuracy and symptoms made an arrhythmia likely. Since cardiac evaluation ruled out structural heart disease, and the episodes were of longer duration (see Flowchart A), patient-activated ECG recording was deemed necessary. The patient also happened to have an Apple Watch 4 and was instructed to record an ECG on recurrence of symptoms and/or heart rate accelerations (see Flowchart B, left-sided scenario). He subsequently presented with a recording taken after an heart rate jump and complaints of palpitations (blue dotted circle), which confirmed an SVT (which terminated at the end of recording).

changes in the beat-to-beat intervals in hospitalized patients[176] and were shown to accurately detect cardiac arrests.[177] Potential applications of this technology include hospital contactless rhythm monitoring for contagious, quarantined patients or burn victims, and contactless home rhythm monitoring for screening and surveillance of common arrhythmias like AF or cardiac arrests.

Rhythm monitoring devices may have sensors able to monitor additional parameters such as daily activity, sleep, oxygen saturation etc., which may contribute to data overload. As with remote monitoring of CIEDs,[178] cloud-based algorithms may be developed which integrate different diagnostic parameters to provide scores that facilitate interpretation and allow risk-stratification and triage of these data.

There is growing evidence that systematic screening for AF in high-risk populations (e.g. individuals >75 years old) may reduce the incidence of stroke, which may save costs.[98,179] Early detection enables early treatment, which in clinically detected AF been shown to be advantageous.[66,180] Telecare services are likely to play an increasing role in logistics, e.g. by implementing low-cost screening of AF by PPG Apps, followed by confirmation with patch ECGs.[179] These telecare services unload the diagnostic burden from cardiologists, who can focus on managing patients with confirmed arrhythmias.

The biggest challenge facing widespread utilization of new technologies is the high cost which remains a barrier for a lot of communities across the globe. In addition, improved digital health literacy among patients, and healthcare personnel will be key for successful implementation, and more educational efforts are needed. Clarifications on legal aspects with regards to unsolicited recordings sent to healthcare personnel are needed. Partnerships between health policy makers, industry, and research communities are the key to ensuring accessibility, equity, reimbursement, and inclusion.

Conclusions

Overall digital devices for heart rhythm monitoring are abundant, and with the rapid advancement of technologies likely to increase further. In this practical guide we have shown some examples of possibilities with current devices with regards to early detection, diagnosis, and management of patients with arrhythmias, but also described some of the barriers in implementation. It is also clear that although there is ample data for patients with AF, other arrhythmias have been less well studied.

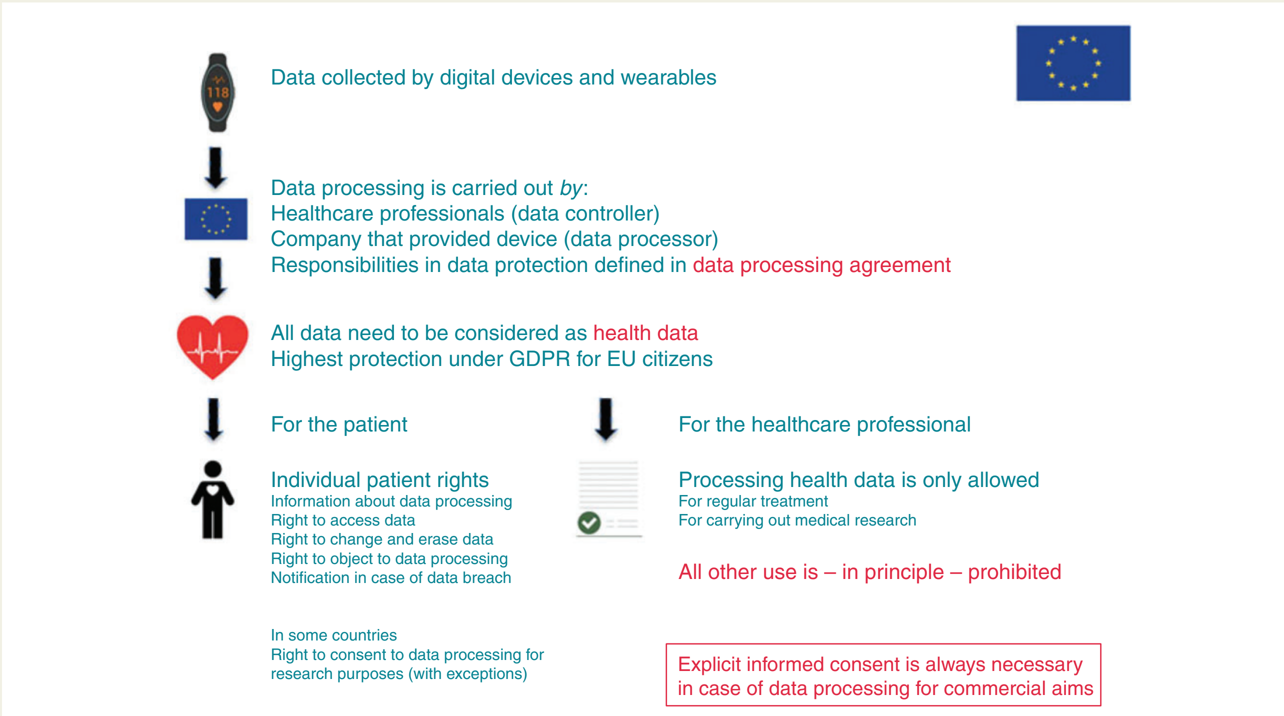


Figure 13 Processing health data.

In the future, a digital workflow will likely be implemented at most cardiology clinics, and the devices available will likely have additional monitoring capabilities and features. We hope that this guide will provide practical guidance for all healthcare professionals interested in heart rhythm monitoring.

Supplementary material

Supplementary material is available at *Europace* online.

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Corrigendum

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In the originally published version of this manuscript, the fifth author's name was incorrect. The fifth author's name should read "Luigi Di Biase" instead of "Luigi Di Biaise".

This error has been corrected.