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


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. 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...
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:

<table>
<thead>
<tr>
<th>Type of device and mode of detection</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Area of application</td>
</tr>
<tr>
<td>• Placement</td>
</tr>
<tr>
<td>• Number of leads</td>
</tr>
<tr>
<td>• User feedback</td>
</tr>
</tbody>
</table>

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.2,9 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.
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. A recent meta-analysis comparing smartwatch technology (PPG or ECG) showed that smartwatches were non-inferior to routine AF monitoring strategies. 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. Importantly, generated ECG tracings still require physician oversight and analysis for rhythm diagnosis.

**Photoplethysmography 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. A smartphone camera combined with the LED flashlight has been used for both contact (finger-over-the-camera) and contactless (facial video) PPG. Photoplethysmography is currently used in clinical routine to measure oxygen saturation and pulse rate. The relative ease of PPG technology has allowed its incorporation into various wearable devices to analyse heart rate and rhythm, such as chest straps, wristbands, forearm bands, rings, and ear buds. Automated algorithms in smartwatches have been used to detect AF with high accuracy when measurements were taken in patients in a comfortable sitting position; however, in ambulatory patients, the accuracy was considerably lower.

---

**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.
due to artefacts. 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).

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.

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. 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.  

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>
<thead>
<tr>
<th>Device</th>
<th>Type</th>
<th>Area of application</th>
<th>Mode of detection</th>
<th>Cardiac sensor</th>
<th>ECG viewing</th>
<th>Battery</th>
<th>Data storage</th>
<th>Data transfer</th>
<th>Regulatory clearance</th>
<th>Validation</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apple Watch</td>
<td>Smartwatch</td>
<td>Wrist-finger ECG and PPG</td>
<td>2 electrodes; 1 lead ECG</td>
<td>Integrated and on paired device</td>
<td>Rechargeable</td>
<td>In-mApp and Cloud</td>
<td>Cloud via smartphone/tablet</td>
<td>CE and FDA</td>
<td>Yes</td>
<td>17–19</td>
<td></td>
</tr>
<tr>
<td>Fitbit</td>
<td>Smartwatch</td>
<td>Wrist-finger ECG and PPG</td>
<td>2 electrodes; 1 lead ECG</td>
<td>On paired device</td>
<td>Rechargeable</td>
<td>In-mApp and Cloud</td>
<td>Cloud via smartphone/tablet</td>
<td>CE and FDA</td>
<td>No</td>
<td>56</td>
<td></td>
</tr>
<tr>
<td>Huawei</td>
<td>Band</td>
<td>Wrist</td>
<td>PPG</td>
<td>2 electrodes</td>
<td>On paired device</td>
<td>Rechargeable</td>
<td>In-mApp and Cloud</td>
<td>Cloud via smartphone/tablet</td>
<td>Asia</td>
<td>Yes</td>
<td>37,38</td>
</tr>
<tr>
<td>Samsung</td>
<td>Smartwatch</td>
<td>Wrist-finger ECG and PPG</td>
<td>2 electrodes; 1 lead ECG</td>
<td>On paired device</td>
<td>Rechargeable</td>
<td>In-mApp and Cloud</td>
<td>Cloud via smartphone/tablet</td>
<td>CE and FDA</td>
<td>No NA</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Withings</td>
<td>Smartwatch</td>
<td>Wrist-finger ECG and PPG</td>
<td>2 electrodes; 1 lead ECG</td>
<td>On paired device</td>
<td>Rechargeable</td>
<td>In-mApp and Cloud</td>
<td>Cloud via smartphone/tablet</td>
<td>CE</td>
<td>No</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>Alivecor Kardia Mobile</td>
<td>Handheld</td>
<td>Fingertips, palm/chest</td>
<td>ECG</td>
<td>2 or 3 electrodes; 1 lead ECG or 6 lead ECG</td>
<td>On paired device</td>
<td>Replaceable</td>
<td>In-mApp and Cloud</td>
<td>Cloud via smartphone/tablet</td>
<td>CE and FDA</td>
<td>Yes</td>
<td>7</td>
</tr>
<tr>
<td>Beurer ME 90</td>
<td>Handheld</td>
<td>Chest-fingertip or finger-finger</td>
<td>ECG</td>
<td>2 electrodes; 1 lead ECG</td>
<td>On paired device</td>
<td>Rechargeable</td>
<td>In-device USB connector</td>
<td>CE and FDA</td>
<td>Yes</td>
<td>5,8</td>
<td></td>
</tr>
<tr>
<td>Coala Heart Monitor</td>
<td>Handheld</td>
<td>Thumb-chest ECG</td>
<td>2 electrodes; 1 lead ECG</td>
<td>On paired device</td>
<td>Rechargeable</td>
<td>In-mApp and Cloud</td>
<td>Cloud via smartphone/tablet</td>
<td>CE and FDA</td>
<td>Yes</td>
<td>39,40</td>
<td></td>
</tr>
<tr>
<td>ECGCheck</td>
<td>Handheld</td>
<td>Fingertips, palm or chest</td>
<td>ECG</td>
<td>2 electrodes; 1 lead ECG</td>
<td>On paired device</td>
<td>Rechargeable</td>
<td>In-mApp and Cloud</td>
<td>Cloud via smartphone/tablet</td>
<td>CE and FDA</td>
<td>Yes</td>
<td>41</td>
</tr>
<tr>
<td>Eko DUO</td>
<td>Handheld</td>
<td>Chest</td>
<td>ECG</td>
<td>2 electrodes; 1 lead ECG</td>
<td>On paired device</td>
<td>Rechargeable</td>
<td>In-mApp and Cloud</td>
<td>Cloud via smartphone/tablet</td>
<td>CE and FDA</td>
<td>Yes</td>
<td>42</td>
</tr>
<tr>
<td>HeartCheck</td>
<td>ECG Pen, Palm</td>
<td>Fingertips, palm/chest/hip</td>
<td>ECG</td>
<td>2 electrodes; 1 lead ECG</td>
<td>On paired device</td>
<td>Rechargeable</td>
<td>In-mApp and Cloud</td>
<td>Cloud via smartphone/tablet</td>
<td>CE and FDA</td>
<td>Yes</td>
<td>43</td>
</tr>
<tr>
<td>MyDiagnostick</td>
<td>Handheld</td>
<td>Hands</td>
<td>ECG</td>
<td>2 electrodes; 1 lead ECG</td>
<td>Via computer and software program (CardiBeat, Palm)</td>
<td>Replaceable</td>
<td>In-device USB connector</td>
<td>CE</td>
<td>Yes</td>
<td>44</td>
<td></td>
</tr>
<tr>
<td>Omron HCG-801</td>
<td>Handheld</td>
<td>Finger/chest</td>
<td>ECG</td>
<td>2 electrodes; 1 lead ECG</td>
<td>Integrated</td>
<td>Replaceable</td>
<td>In-device (SD card)</td>
<td>SD card FDA</td>
<td>Yes</td>
<td>45</td>
<td></td>
</tr>
<tr>
<td>SnapECG E-H19</td>
<td>Handheld</td>
<td>Fingertips</td>
<td>ECG</td>
<td>2 electrodes; 1 lead ECG</td>
<td>On paired device</td>
<td>Replaceable</td>
<td>Cloud</td>
<td>Unclear Asia NA</td>
<td>NA</td>
<td>46</td>
<td></td>
</tr>
<tr>
<td>Znicor-ECG</td>
<td>Handheld</td>
<td>Thumbs</td>
<td>ECG</td>
<td>2 electrodes; 1 lead ECG</td>
<td>Via web-based platform</td>
<td>Replaceable</td>
<td>In-device, transfer to cloud</td>
<td>Cloud</td>
<td>CE Yes</td>
<td>47</td>
<td></td>
</tr>
</tbody>
</table>

Continued
<table>
<thead>
<tr>
<th>Device</th>
<th>Type</th>
<th>Area of application</th>
<th>Mode of detection</th>
<th>Cardiac sensor</th>
<th>ECG viewing</th>
<th>Battery</th>
<th>Data storage</th>
<th>Data transfer</th>
<th>Regulatory clearance</th>
<th>Validation</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Movesense Medical (Suunto)</td>
<td>Chest strap</td>
<td>Chest</td>
<td>ECG</td>
<td>2 electrodes; 1 lead ECG</td>
<td>On paired device</td>
<td>Replaceable</td>
<td>In-device, 7 days continuous; in-mApp</td>
<td>Cloud</td>
<td>CE</td>
<td>? Yes</td>
<td>35</td>
</tr>
<tr>
<td>Zephyr BioHarness 3.0 (Medtronic)</td>
<td>Chest strap</td>
<td>Chest</td>
<td>ECG</td>
<td>2 electrodes; 1 lead ECG</td>
<td>On paired device</td>
<td>Rechargeable</td>
<td>In-device</td>
<td>Wireless or USB</td>
<td>FDA</td>
<td>Yes</td>
<td>36</td>
</tr>
<tr>
<td>Bardy Dr. Carrington Ambulatory Monitor (CAM)</td>
<td>Patch</td>
<td>Chest, self-adhesive</td>
<td>ECG</td>
<td>2 electrodes; 1 lead ECG</td>
<td>Via web-based platform</td>
<td>Single-use</td>
<td>In-device, 14 days continuous</td>
<td>Direct download by company → cloud</td>
<td>CE and FDA</td>
<td>Yes</td>
<td>48</td>
</tr>
<tr>
<td>BoTel Mobile Patient Telemetry (MCOT)</td>
<td>Patch</td>
<td>Chest, self-adhesive</td>
<td>ECG</td>
<td>3 electrodes; 2 lead ECG</td>
<td>Via web-based platform</td>
<td>Single-use, rechargeable</td>
<td>In-device, 30 days continuous</td>
<td>Wireless near real-time telemetry. Direct download by company → cloud</td>
<td>CE and FDA</td>
<td>Yes</td>
<td>46, 50</td>
</tr>
<tr>
<td>BodyGuardian Mini patches (Preventice)</td>
<td>Patch</td>
<td>Chest, self-adhesive</td>
<td>ECG</td>
<td>2 electrodes; 1 lead ECG</td>
<td>Via web-based platform</td>
<td>Single-use, rechargeable</td>
<td>In-device, 30 days continuous</td>
<td>Wireless near real-time telemetry. Direct download by company → cloud</td>
<td>CE and FDA</td>
<td>Yes</td>
<td>53</td>
</tr>
<tr>
<td>Life Signal Biosensor Patch</td>
<td>Patch</td>
<td>Chest, self-adhesive</td>
<td>ECG</td>
<td>4 electrodes; 2 lead ECG</td>
<td>On paired device or web-based platform</td>
<td>Single-use</td>
<td>In-device, 5 days continuous</td>
<td>Wireless near real-time telemetry and cloud</td>
<td>CE and FDA</td>
<td>Yes</td>
<td>52</td>
</tr>
<tr>
<td>MyPatch-SL</td>
<td>Patch</td>
<td>Chest, self-adhesive</td>
<td>ECG</td>
<td>3 electrodes; 2/3 lead ECG</td>
<td>Via web-based platform</td>
<td>Single-use</td>
<td>In-device, 14 days continuous (2 leads), 9 days (3 leads)</td>
<td>USB transferable</td>
<td>FDA</td>
<td>No</td>
<td>53</td>
</tr>
<tr>
<td>S-Patch Cardio (Samsung SDS Wellness)</td>
<td>Patch</td>
<td>Chest, self-adhesive</td>
<td>ECG</td>
<td>2 electrodes; 1 lead ECG</td>
<td>Via web-based platform</td>
<td>Single-use</td>
<td>In-device, up to 100 hours continuous</td>
<td>Cloud</td>
<td>CE</td>
<td>Yes</td>
<td>53</td>
</tr>
<tr>
<td>VitalPatch (VitalConnect)</td>
<td>Patch</td>
<td>Chest, self-adhesive</td>
<td>ECG</td>
<td>2 electrodes; 1 lead ECG</td>
<td>Via mApp/web-based platform</td>
<td>Single-use, rechargeable</td>
<td>In-device, 7 days continuous</td>
<td>Wireless near real-time telemetry and cloud</td>
<td>CE and FDA</td>
<td>Yes</td>
<td>54</td>
</tr>
<tr>
<td>VivaLink</td>
<td>Patch</td>
<td>Chest, self-adhesive</td>
<td>ECG</td>
<td>2 electrodes; 1 lead ECG</td>
<td>Via web-based platform</td>
<td>Single-use, rechargeable</td>
<td>In-device, 96 h continuous</td>
<td>Wireless near real-time telemetry. Direct download by company → cloud</td>
<td>CE and FDA</td>
<td>Yes</td>
<td>55, 56</td>
</tr>
<tr>
<td>Zio XT/AT (iRhythm)</td>
<td>Patch</td>
<td>Chest, self-adhesive</td>
<td>ECG</td>
<td>2 electrodes; 1 lead ECG</td>
<td>Via web-based platform</td>
<td>Single-use</td>
<td>In-device, 14 days continuous</td>
<td>Wireless near real-time telemetry (AT); USB (XT and AT)</td>
<td>CE and FDA</td>
<td>Yes</td>
<td>10, 11, 57</td>
</tr>
</tbody>
</table>

Continued
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).

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.

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.

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.
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. \(^{\text{Supplementary material online, Table S2}}\)

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 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.
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. 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. 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.

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.

Other barriers and side-effects exist

1. patients may choose not 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. 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’ is crucial to ensure digital equity and inclusivity. Digital literacy requires both technical and cognitive skills. 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. Variables such as age, educational background, health, and socioeconomic status can impact the ability to develop digital health literacy. Assessing patient digital health literacy, identifying individual needs, and improving both knowledge and skills will be
**Symptomatic arrhythmia**

- Palpitations
- Tachycardia
- Bradycardia

Can be considered to rule out normal heart rate and rhythm

**PPG-based wearable device**

Preferred

**ECG-based wearable device**

Yes

Normal heart rate and rhythm

No

**ECG-based diagnosis**

**Consider causes other than arrhythmia**

---

**Figure 4** Suggested workflow for the management of symptomatic arrhythmias.

---

**Table 3** Definitions of screening strategies

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Definition</th>
<th>Examples</th>
</tr>
</thead>
</table>
| 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  
  - In-hospital screening  
  - Monitoring post-discharge |
| Screening in risk groups | Screening performed in individuals who sustained a prior stroke or transient ischaemic attack | |
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, including remote rate and rhythm monitoring. This can be organized as on-demand mobile health prescriptions. Self-management can increase patient...
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 outcomes.
cardiovascular outcomes. 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. 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. 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. 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).

**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
Diagnosis and management of AF, 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.

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. Regular assessment of rate control and the use of a simple preprocedural medication adjustment protocol is effective in optimizing peri-cardioversion rate control.

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. 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. 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. 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.

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. 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. 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. 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. 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.

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 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 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.

Syncpe

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. 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. 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. Early work has suggested that features extracted from ECG and PPG might aid in predicting neurally mediated syncope. Future development of retrospective documentation of the underlying rhythm after triggering an event in haemodynamically 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. 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.

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/smartphone-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, 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

<table>
<thead>
<tr>
<th>Digital approaches in class I and III antiarrhythmic drug therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Predominantly, antiarrhythmic drugs exert their effects by prolonging QRS width (Class I) or QT intervals (Class III). In general, the occurrence of prolongation of the QRS &gt;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. 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 controversy exists regarding the safety of outpatient antiarrhythmic drug initiation. Digital devices using ECG tracings can, in some cases, allow a more detailed ECG interpretation incorporating QRS duration and QT interval.</td>
</tr>
</tbody>
</table>

### 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. A recent study compared QT intervals in sinus rhythm between a smartphone-ECG with a 12-lead ECG in patients receiving sotalol or dofetilide. The smartphone recording was capable of detecting QTc prolongation, with smartphone lead I most accurate in measuring the QTc if <500 ms. In contrast, another ECG smartwatch study that accurate QT measurements were only achieved in 85% of patients. 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.

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. 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.

### Consensus statement

<table>
<thead>
<tr>
<th>Digital approaches in class I and III antiarrhythmic drug therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>
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. 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-malignant ventricular rhythms vs. supraventricular arrhythmias) and to assess drug efficacy (e.g. pre-syncope) is not related to a cardiac arrhythmia. 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). 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’. Specific ECG features of LQTS associated with torsade de pointes (micrivoct T-wave alternans) have been detected by using ambulatory ECG monitoring.

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

- 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. 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 remoteQT monitoring but need to be further assessed in patients with LQTS.

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-, forehead-, and ear-worn devices (Figure 10).

Heart rate strap chest 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. Key limitations are artefacts due to transmission interference between the strap and the receiver—often caused by inadequate contact, interaction of brass with the strap in female athletes, and general discomfort while wearing.

Wrist-, arm-, forehead-, or ear-worn PPG devices are smaller, more easily worn, and lower cost which make these more widespread, albeit less reliable. 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). 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; some can provide a three-lead lead ECG. 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. 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. 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).

Data recorded and/or transmitted by digital and wearable technologies are mainly physical or mental health data. 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).
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 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.
changes in the beat-to-beat intervals in hospitalized patients\textsuperscript{176} and were shown to accurately detect cardiac arrests.\textsuperscript{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,\textsuperscript{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.\textsuperscript{98,179} Early detection enables early treatment, which in clinically detected AF been shown to be advantageous.\textsuperscript{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.\textsuperscript{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.
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.

**Acknowledgements**

The authors thank Dr Harald Jorstad (sports cardiologist, Amsterdam UMC, Amsterdam, The Netherlands) who provided us with the case described in the athletes section.

The authors thank the EHRA Scientific Document Committee: Dr Nikolaos Dagher, Prof. Thomas Deneke, Prof. Arthur Wilde, Prof. Frank R. Heinzelt, Prof. Christian Meyer, Prof. Lucas Boersma, Prof. Radoslaw Lenarczyk, Prof. Luigi di Biase, Dr Elena Arbelo, Dr Avi Sabbag, Prof. Pierre Jais, Prof. Milos Taborsky, and Asso. Prof. Markus Stühlinger.

**Conflict of interest:** Akoum Nazem: Nothing to be declared.

Bordachar Pierre: Nothing to be declared.

Boriani Giuseppe: Has received direct personal payment from healthcare industry from Bayer, Boston Scientific, Medtronic.


Conte Giulio: Payment from healthcare industry to institution: Boston Scientific Research funding from: Swiss National Science Foundation.

Deharo Jean-Claude: Has received direct personal payment from healthcare industry Abbott, Boston Scientific, Medtronic, Micropor, Bayer, Boehringer-Ingeleim, Novartis, Bristol Myers Squibb Research funding from: Abbott, Boston Scientific, Biotronik, Micropor.

Di Biase Luigi: Has received direct personal payment from healthcare industry: Abbott, Boston Scientific, Medtronic, Biotronik, Stereotaxis, Biosense Webster, RMG.

Drossart Inga: Nothing to be declared.

David Duncker: Has received direct personal payment from healthcare industry: Abbott, Astra Zeneca, Bayer, Biotronik, Boehringer Ingelheim, Boston Scientific, Bristol Myers Squibb, CVRx, Medtronic, Micropor, Pfizer, Zoll.

Figueiredo Marcio Jansen De Oliveira: Nothing to be declared.

Goette Andreas: Has received direct personal payment from healthcare industry: Abbott, Boston Scientific, Medtronic, Boehringer-Ingeleim, Daiichi Sankyo, Pfizer, Bayer Healthcare, Bristol Myers Squibb, Berlin Chemie AG, OMEICOS, Astra Zeneca.

Han Janet: Has received direct personal payment from healthcare industry: Abbott, Boston Scientific.

Heidbuchel Hein: Has received direct personal payment from healthcare industry: Abbott, Biotronik, Daiichi-Sankyo, Pfizer-BMS, Medscape, and Springer Healthcare Ltd Research funding from: Biotronik, Abbott, Boston Scientific, Medtronic, Daiichi Sankyo, Pfizer/BMS. Jais Pierre: Has received direct personal payment from...
healthcare industry: AFFERA, FARAPULSE. Research funding from: Boston Scientific, Biosense Webster Direct ownership of shares: Healthcare, InHeart, AFFERA, FARAPULSE.

Leclercq Christophe: Has received direct personal payment from healthcare industry: Biontronik, Abbott, Boston Scientific, Medtronic, Microport.

Linz Dominik: Payment from healthcare industry to institution: Bayer, Medtronic, Microport, Zoll.

Lip Gregory: Consultant and speaker for BMS/Pfizer, Boehringer Ingelheim and Daiichi-Sankyo. No fees are received personally. Research funding from: Boehringer-Ingelheim, BMS.

Malaczynska-Rajpold Katarzyna: Nothing to be declared.

Marquez Murillo Manlio Fabio: Nothing to be declared.

Ploem Corrette: Nothing to be declared.

Soejima Kyoko: Has received direct personal payment from healthcare industry: Abbott Japan, Boehringer-Ingelheim, Daiichi Sankyo, Medtronic Japan.

Stiles Martin: Lecture fees and Consulting from Abbott, Boehringer-Ingelheim, Biosense Webster, Boston Scientific, Ceryx Medical and Medtronic.

Svennberg Emma: Payment from healthcare industry to institution: Bayer, Bristol-Myers Squibb-Pfizer, Boehringer-Ingelheim, Johnson & Johnson, Merck Sharp & Dohme.

Tjong Fleur: Payment from healthcare industry to institution: Boston Scientific, Daiichi Sankyo, Abbott.

Vernooi Kevin: Has received no direct personal payment from healthcare industry. Payment from healthcare industry to institution: Medtronic, Abbott, Philips, Biosense Webster. Research funding from healthcare industry to institution under your direct/personal responsibility: Medtronic, Abbott, Biosense Webster, Biontronik.

Wierda Eric: Nothing to be declare.

References


35. Vernooy Kevin: Has received no direct personal payment from healthcare industry. Payment from healthcare industry to institution: Medtronic, Abbott, Philips, Biosense Webster. Research funding from healthcare industry to institution under your direct/personal responsibility: Medtronic, Abbott, Biosense Webster, Biontronik.

Wierda Eric: Nothing to be declare.
rhythm monitoring infrastructure for the management of atrial fibrillation through teleconsultation: teleCheck-AF. Europace 2021;23:345–52.


137. Bos JM, Atta ZI, Albert DE, Noseworthy PA, Friedman PA, Ackerman MJ. Use of artificial intelligence and deep neural networks in evaluation of patients with electrocardiographically concealed long Q-T syndrome from the surface 12-lead electrocardiogram. JAMA Cardiol 2019;4:632.


