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Over- and undersensing—pitfalls of arrhythmia detection with implantable devices and wearables

Introduction

Cardiac implantable electronic devices (CIEDs) are a cornerstone of arrhythmia and heart failure detection as well as management. Pacemakers and implantable cardioverter/defibrillators (ICDs) are extending and improving lives for millions, with continuously improved algorithms to enhance detection and the delivery of therapy. In recent years the “implantable” part of the CIED acronym has started to lose importance as new kinds of devices are emerging which can be used subcutaneously or worn on the skin. In particular for large-scale monitoring for arrhythmias, small, unobtrusive gadgets seem positioned to upend paradigms with a potentially profound impact on care delivery.

The clinical performance of CIEDs is only as good as their sensing and detection capacities. Sensing is defined as the process for identifying the electrical signals that indicate atrial or ventricular depolarisation events. Detection refers to the analysis and classification of sensed signals by advanced device algorithms to determine the cardiac rhythm. Thus detection follows sensing [65]. Whether for pacing, defibrillation or diagnostic monitoring of arrhythmias, the device must be able to process and filter the sensed signal to reduce noise and to exclude irrelevant physiological signals.

“We see only what we know”, Johann Wolfgang von Goethe remarked over 200 years ago. The pitfalls of over- and undersensing of electric potentials with cardiac

devices reflect their lack of “knowledge” of arrhythmia detection. Instead, they must rely on algorithms of varying sensitivity. The sensing method, whether using endocardial leads, subcutaneous/skin electrodes or analysis of digital pulse waveforms, will influence the quality of the signal received by the device. Further, the source of a sensed signal needs to be established: is it atrial or ventricular, an R-wave or a T-wave, ventricular or supraventricular extrasystole, a muscle potential or from an external electric field? **■ Figs. 1 and 2** illustrate some of these considerations.

The demands on sensing and detection quality will differ depending on how the information is applied. With a pacemaker or ICD, withheld or erroneous therapy can have severe consequences and accurate and reliable detection of cardiac function is crucial. Monitoring devices are usually used in risk assessment and management, with greater tolerance for isolated artefacts or lower quality of readings.

Three sensing methods are currently in use with cardiac monitoring devices (**■ Table 1**). Implantable devices with leads attached to cardiac tissue use direct intrinsic sensing. For electrical activity to be transmitted from the heart to the device, a closed electrical circuit must be present. With pacemakers and ICDs, modern leads are generally bipolar, allowing signals to be detected between lead tip and ring electrodes. The alternative is unipolar sensing, which detects electrical activity occurring between the

tip of the lead and the pulse generator. As the distance between lead tip and device represents a large dipole, unipolar sensing is much more prone to external interference [54].

Subcutaneous ICDs (s-ICDs) and insertable cardiac monitors (ICMs) record far-field subcutaneous electrograms obtained by sensing from a subcutaneous electrode to the can (S-ICD) or between subcutaneous electrodes on the device itself (ICM). Wearable defibrillators employ sensors placed directly on the skin of the patient. Finally, the growing number of wearable devices capable of monitoring rely on indirect measurements by photoplethysmography (PPG; digital pulse waveforms) and refine their algorithms by the use of Big Data and artificial intelligence (AI) to compensate for weaknesses in the sensing technology itself.

Pacemakers

Pacemakers rely on intracardiac electrograms for cardiac rhythm monitoring. Accurate sensing is important to deliver appropriate therapy, including minimising the amount of ventricular pacing to avoid long-term risk for complications [62], and to achieve a high percentage of biventricular pacing with resynchronisation devices [35]. Pacemakers can also be programmed to detect atrial high rate episodes (AHRE) and identify atrial fibrillation (AF) or other tachyarrhythmias (**■ Figs. 3 and 4**).

A unique approach has been developed for leadless pacemakers (which are

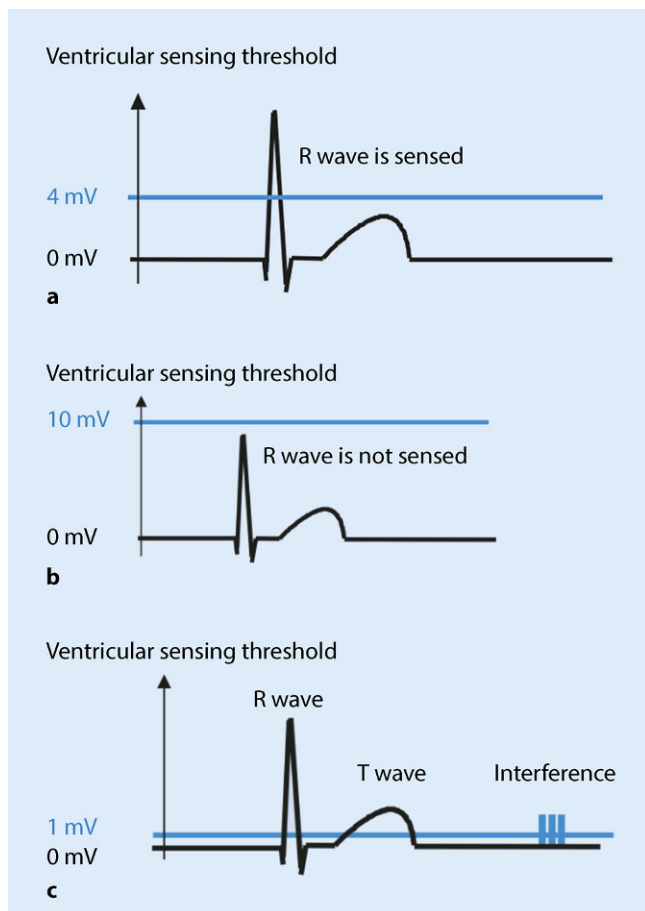


Fig. 1 ◀ a Schematic illustration of an electrogram with sensing threshold and sensed R wave. b Example of overly high sensing threshold and resulting undersensing of a true R wave. c Example of overly low sensing threshold and resulting oversensing of noise. All images in **Fig. 1** and **2** are from Morschhäuser et al. [42] and reproduced with kind permission from the publisher

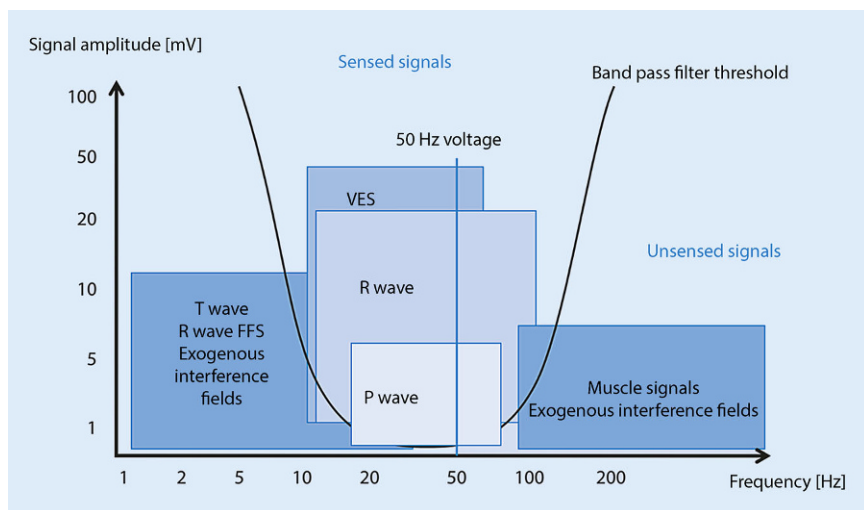


Fig. 2 ▲ Band pass filters for pacemakers. VES Ventricular Extrasystole

single-chamber devices). The algorithm uses information from a three-axis accelerometer in the device to sense atrial contraction and switches pacing mode according to the presence or absence of atrioventricular (AV) conduction, as well as high patient activity [15]. The method

has been used successfully to provide AV synchronous pacing in patients with persistent complete AV block and normal sinus rhythm [61].

Dual-chamber pacemakers have the advantage over single-chamber devices of providing direct atrial sensing in addition

to ventricular sensing. The disadvantage is the need for an additional lead. There is also a risk of oversensing. Dual-chamber pacemakers may interpret a ventricular depolarisation signal received by the atrial channel as a P wave, a phenomenon known as far-field R-wave oversensing. This is more likely to occur in cases of atrial unipolar sensing, ventricular pacing, long bipole spacing and septal or low right atrial implants [25, 30, 38, 48, 53]. There is also concern that atrial pacing may be sensed by the ventricular lead.

The accuracy of arrhythmia detection can further be influenced by variables such as lead sensitivity, cut-off detection rate, cardiac tissue refractory period and unipolar vs bipolar lead configuration. The device may under-detect AF due to undersensing of the atrial electrogram, or incorrectly log a long episode as multiple short episodes [39]. Retrograde conduction may lead to pacemaker-mediated tachycardia [32], although most modern dual-chamber pacemakers include algorithms to minimise this risk. False-positive detections due to far-field R-wave oversensing of ventricular signals in the atrium can be minimised by individual adjustment of the postventricular atrial blanking period [34].

The positive predictive value (PPV) of AHREs is lower when short detection durations (less than 5 min) are programmed, but even for longer episodes, the PPV for AHREs lasting between 6 min and 6 h may be only a modest 83% [32]. The PPV for AF detection has been reported as 95 and 91% for Medtronic and Biotronik devices, respectively [41]. Abbott devices report a PPV of 97% for AHRE episodes >6 h [44]. For short episodes, manual adjudication may be necessary [59].

Implantable cardioverter-defibrillators

Transvenous ICDs combine pacemaker and defibrillator functions. These may rely on different electrograms. Sensing is either true bipolar (sensing between the tip and ring electrodes) or integrated bipolar (sensing between the tip and right ventricular [RV] coil electrodes integrating pace-sense and defibrillation func-

tions) (■ Fig. 5). The shock electrogram records a more global far-field signal between widely separated, high-voltage electrodes, usually the RV coil and device can. ICDs often employ an automatic sensitivity adjustment algorithm, which measures the highest amplitude peak of the signal for each sensed event and sets the sensing threshold at a programmable percentage of the peak, subsequently reducing the threshold until there is a new sensed event.

If the pace-sense functions of transvenous ICDs are similar to pacemakers, the key challenge of the devices is the correct discrimination of arrhythmias to terminate potentially lethal ventricular tachycardias while keeping the rate of inappropriate shocks to a minimum. Inappropriate shocks are painful and frightening to patients. They also increase mortality compared with no shocks [51] as well as with non-shocking methods such as antitachycardia pacing [63].

In most cases, inappropriate shocks are caused by erroneous discrimination of supraventricular tachycardia [20]. Although they lack an atrial lead, single-chamber devices are still able to detect atrial arrhythmias by close analysis of the ventricular signal. Tachycardias, whether ventricular or atrial, are characterised by changes in the morphology of the ventricular electrogram. Sinus tachycardia typically has a gradual onset and a parallel acceleration of atrial and conducted ventricular intervals, whereas ventricular tachycardia is abrupt, with at least transient AV dissociation [68]. However, inappropriate classification can happen, e.g. when an atrial tachycardia has an abrupt onset and is regular, even if the morphology is consistent with supraventricular tachycardia [24]. Also, morphology as a single discriminator has limited sensitivity for appropriate diagnosis of ventricular arrhythmias [66]. Similar to pacemakers, dual-chamber devices are associated with improved detection of AHRE as well as with fewer inappropriate shocks [9, 24].

A more recent development is a single-chamber system with complete atrial diagnostics. Here, atrial signals can be sensed by the atrial dipole of the RV lead (similar to a VDD pacemaker). In addition

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Over- and undersensing—pitfalls of arrhythmia detection with implantable devices and wearables

Abstract

Cardiac implantable electronic devices (CIEDs) are a cornerstone of arrhythmia and heart failure detection as well as management. In recent years new kinds of devices have emerged which can be used subcutaneously or worn on the skin. In particular for large-scale arrhythmia monitoring, small, unobtrusive gadgets seem positioned to upend paradigms and care delivery. However, the performance of CIEDs and wearables is only as good as their sensing and detection capacities. Whether for pacing, defibrillation or diagnostic monitoring, the device must be able to process and filter the sensed signal to reduce noise and to exclude irrelevant physiological signals. The demands on sensing and detection quality will differ depending on how the

information is applied. With a pacemaker or implantable cardioverter/defibrillator, withheld or erroneous therapy can have severe consequences and accurate and reliable detection of cardiac function is crucial. Monitoring devices are usually used in risk assessment and management, with greater tolerance for isolated artefacts or lower quality of readings. This review discusses sensing and detection and the performance to date by CIEDs as well as subcutaneous and wearable devices.

Keywords

Over- and undersensing · Pacemaker · Defibrillator · Wearables · Arrhythmia detection

Over- und Undersensing – Fallstricke der Arrhythmiedetektion mit implantierbaren Geräten und Wearables

Zusammenfassung

Kardiale implantierbare elektronische Systeme (CIED) stellen Eckpfeiler in der Diagnostik und Therapie von Herzrhythmusstörungen und Herzinsuffizienz dar. In den letzten Jahren wurden neue Geräte entwickelt, die subkutan implantiert oder als sogenannte Wearables getragen werden können. Insbesondere im permanenten Arrhythmie-Monitoring scheinen kleine, unauffällige Geräte das Potenzial zu haben, Paradigmen umzustößeln und die Versorgung zu verändern. Die Leistung von CIED und Wearables ist jedoch nur so gut wie deren Wahrnehmungs- und Detektionseigenschaften. Unabhängig von der Nutzung als Herzschrittmacher, Defibrillator oder Monitoring-Device muss durch spezielle Filter und Algorithmen sichergestellt werden, dass das wahrgenommene intrinsische Signal von Störsignalen oder irrelevanten physiologischen Signalen differenziert werden kann. Die Anforderungen an die Wahrnehmungs- und Detektionsqualität sind davon abhängig, wie die Informationen

genutzt werden. Eine durch Oversensing oder Undersensing zurückgehaltene oder falsche Therapie bei Patienten mit Herzschrittmacher oder implantierbarem Kardioverter/Defibrillator kann zu schweren Komplikationen führen, weshalb eine genaue und verlässliche Detektion der Herzfunktion hier kritisch ist. Systeme zum alleinigen Monitoring finden vor allem in der Risikoabschätzung und Therapieoptimierung Verwendung, wobei vereinzelte Artefakte oder eine geringere Messqualität hier tolerabler sind. Die vorliegende Übersicht beschreibt die Wahrnehmungs- und Detektionsfunktion sowie die resultierende Qualität der verfügbaren CIED, subkutanen Systeme und Wearables.

Schlüsselwörter

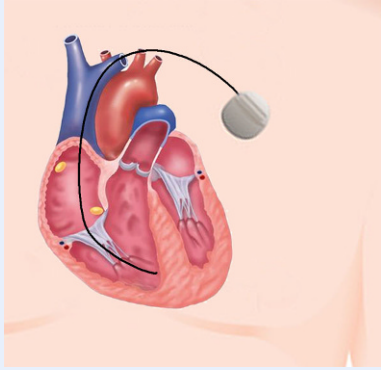
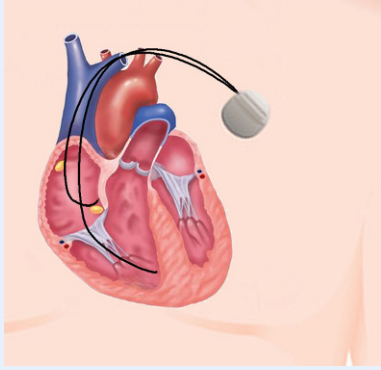
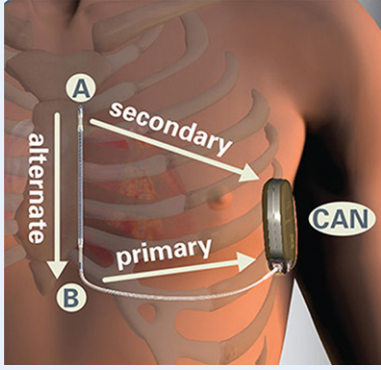
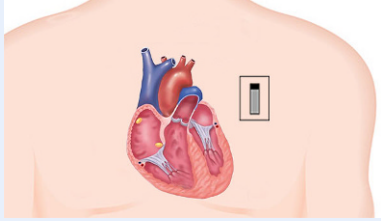
Over- und Undersensing · Herzschrittmacher · Implantierter Defibrillator/Cardioverter · Wearables · Arrhythmiedetektion

tion to the detection of atrial fibrillation, the advantage is improved discrimination between atrial and ventricular tachyarrhythmias.

Oversensing, often of T waves, makes a relevant contribution to inappropriate

shocks. In earlier generations of defibrillators, T-wave oversensing was responsible for around 14% of inappropriate shocks [67], but improved algorithms have reduced the risk to less than 5% [4]. In contrast to the static programmed

Table 1 Overview of devices discussed in this survey

System	Sensing method	Sensing vectors	VA sensing	AA sensing	Implantation
Single-chamber pacemaker/ICD	Intrinsic in RA and/or RV		Direct by atrial or ventricular electrode	Indirect through analysis of ventricular signals	Invasive: device + lead
Dual-chamber pacemaker/ICD/CRT	Intrinsic in RA and RV		Direct by atrial and/or ventricular electrode	Direct by atrial electrode	Invasive: device + up to three leads
S-ICD	Far-field subcutaneous electrograms		Direct by subcutaneous electrode and can	Indirect through analysis of ventricular signals	Invasive: device + lead
ICM	Far-field subcutaneous electrograms		Direct by subcutaneous electrodes on device	Indirect through analysis of ventricular signals	Minimally invasive: device

sensing of pacemakers, ICDs have established algorithms with dynamic adjustment of sensing parameters.

Pitfalls in sensing—between oversensing and undersensing



Case Study: Reduced RV Sensing after ICD Upgrade. An ICD system

changeover, including a change of the pulse generator, was carried out in a patient born in 1947. The RV lead provided good measurements during surgery (RV sensing 8.5 mV, capture threshold 1 V@0.5 ms). However, after surgery, the average RV sensing was about 4.2 mV. Potential damage to the lead during surgery was considered to

be the reason, but the capture threshold was stable. Other causes for the reduced RV sensing needed to be found.

It turned out that the low frequency attenuation (LFA) filter in the new device was switched off. The LFA filter was designed to help mitigate T-wave oversensing. When the filter is programmed on, it attenuates, or reduces, the ampli-

Table 1 (Continued)

System	Sensing method	Sensing vectors	VA sensing	AA sensing	Implantation
Wearable defibrillator	Sensors on skin		Direct by sensors on skin	Indirect through analysis of ventricular signals	Non-invasive
Wearables	Indirect measurements (photoplethysmography)		Indirect measurements	Indirect through analysis of ventricular signals	Non-invasive

ICD implantable cardioverter/defibrillator, RA right atrial, RV right ventricular, CRT cardiac resynchronization therapy, S-ICD subcutaneous ICD, ICM insertable cardiac monitor

tude of low-frequency signals. As a result, there is a significant reduction in T-wave oversensing (■ Fig. 6a,b).

In the authors' patient, the deactivated LFA filter resulted in reduced RV sensing. Activating the filter led to acceptable RV sensing with no need for RV lead revision (■ Fig. 7a,b).

Subcutaneous ICDs

The S-ICD is placed as an alternative to transvenous ICD when there are concerns about risk of vascular occlusion, systemic infection or adverse effects of lead extraction. As they are limited by their inability to treat bradyarrhythmia or provide antitachycardia pacing, current guidelines recommend S-ICDs in patients without a pacing indication or an indication for CRT and in whom it is not expected that such indications will develop [2, 52].

In addition to these limitations, the S-ICD is associated with a greater risk of inappropriate shock therapy, particularly

in patients with hypertrophic cardiomyopathy or a history of AF [43, 45, 56, 69]. Lacking a transvenous lead, the S-ICD relies on far-field electrograms (resembling a surface electrocardiogram; ■ Fig. 8). Algorithms discriminate supraventricular arrhythmias based on morphology and R/T ratio [27]. Compared with endocardial sensing electrograms, the far-field variety has lower amplitude (0.3–4.0 mV), longer duration, lower frequency content and greater postural variation [64]. In contrast to transvenous ICDs, the driver of inappropriate shocks with S-ICDs is not erroneous supraventricular tachycardia diagnosis, where the performances are comparable [27], but oversensing, especially T-wave oversensing [37]. Higher 12-lead electrocardiographic R-wave amplitude and abnormal T-wave inversions have been reported to be independent predictors of increased risk of inappropriate shocks, whereas the presence of T-wave inversions was associated with a significantly lower risk of inappropriate shocks [43].

Inappropriate shocks may also be triggered by oversensing of low-amplitude signals related to myopotentials during exercise [1]. A systematic evaluation of consecutive S-ICD patients for myopotential inducibility in 2019 found that exercise such as isometric chest press, weight-lifting and side plank exercise could all induce myopotentials which led to undersensing in up to 66% and oversensing in up to 22% of patients [11]. S-ICD lead and generator position did not appear to affect the induction of myopotentials. In a single-centre study of S-ICD patients with 6-month follow-up, appropriate shocks caused by myopotentials were almost exclusively registered on the primary sensing vector, an association not found for shocks caused by T-wave oversensing [56].

As with transvenous ICD, algorithms that reduce the risk of T-wave oversensing are being continually refined. The latest complex algorithm was developed using a database of recorded episodes and a computer model that simulates

- 1: A sensing, enhanced automatic scaling (2.2 mm/mV)
- 2: V sensing, enhanced automatic scaling (1.4 mm/mV)
- 3: Cableless ECG, automatic scaling (1.4 mm/mV)

4: Marker

Sweep speed: 25 mm/s

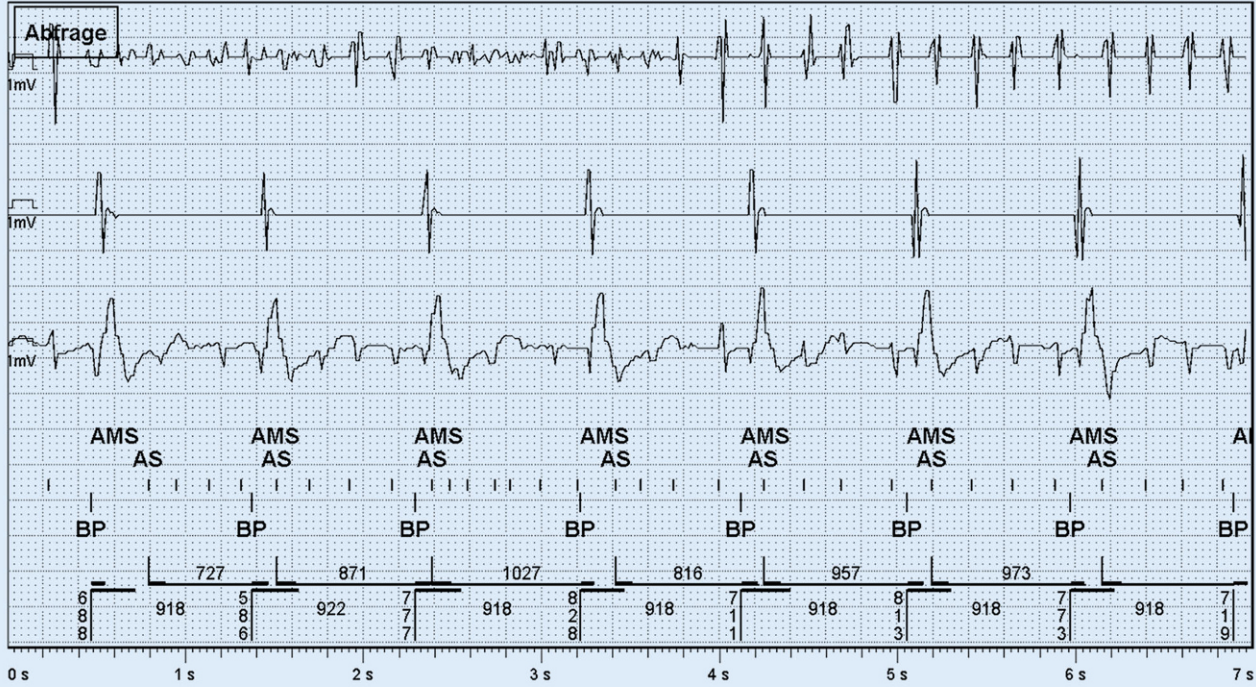


Fig. 3 ▲ Automatic mode switch during atrial fibrillation

- 1: V bipolar automatic scaling (3.0 mm/mV)
- 2: Marker
- 3: V sensing, enhanced automatic scaling (1.8 mm/mV)

Sweep speed: 25 mm/s

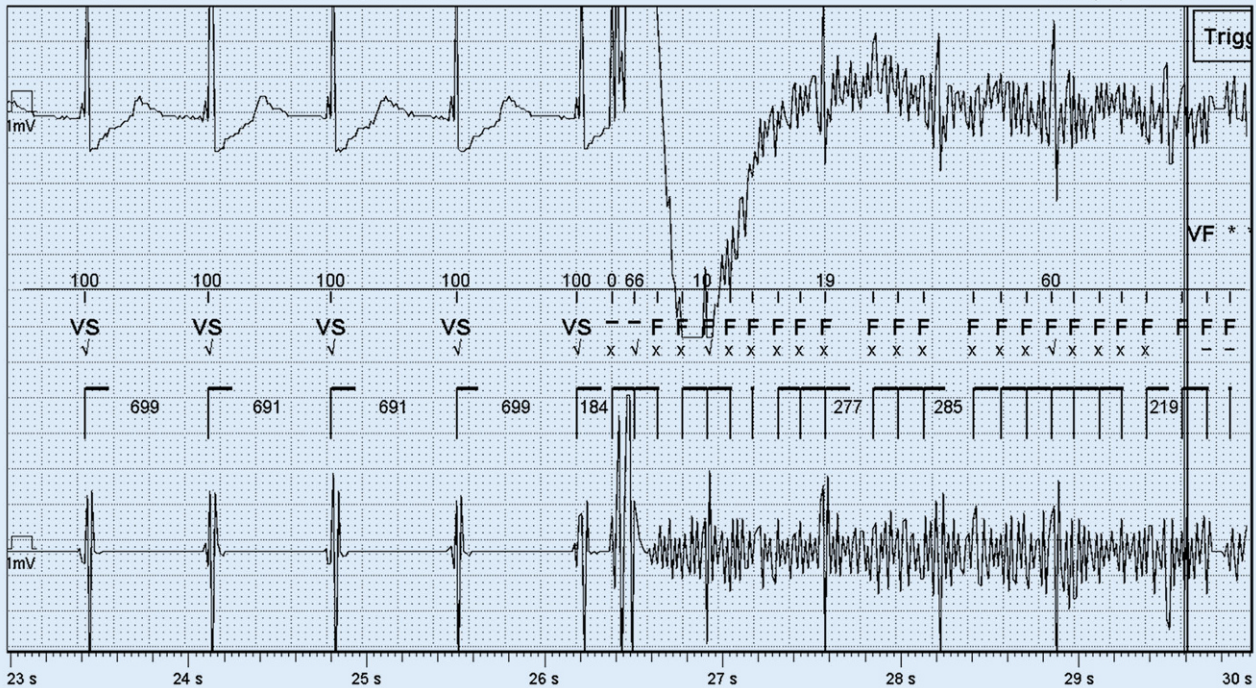


Fig. 4 ▲ Incorrect detection of ventricular fibrillation due to noise

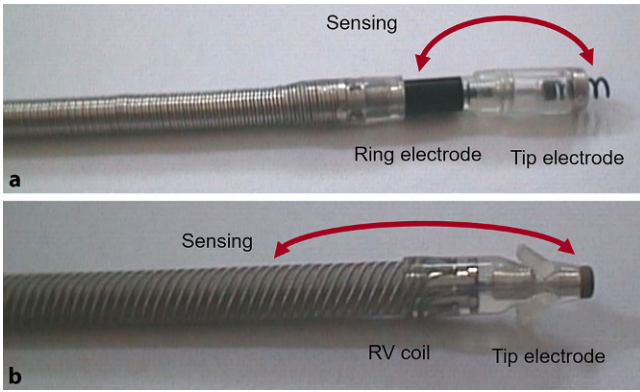


Fig. 5 ◀ **a** True bipolar sensing; **b** Integrated bipolar sensing. *RV* right ventricular

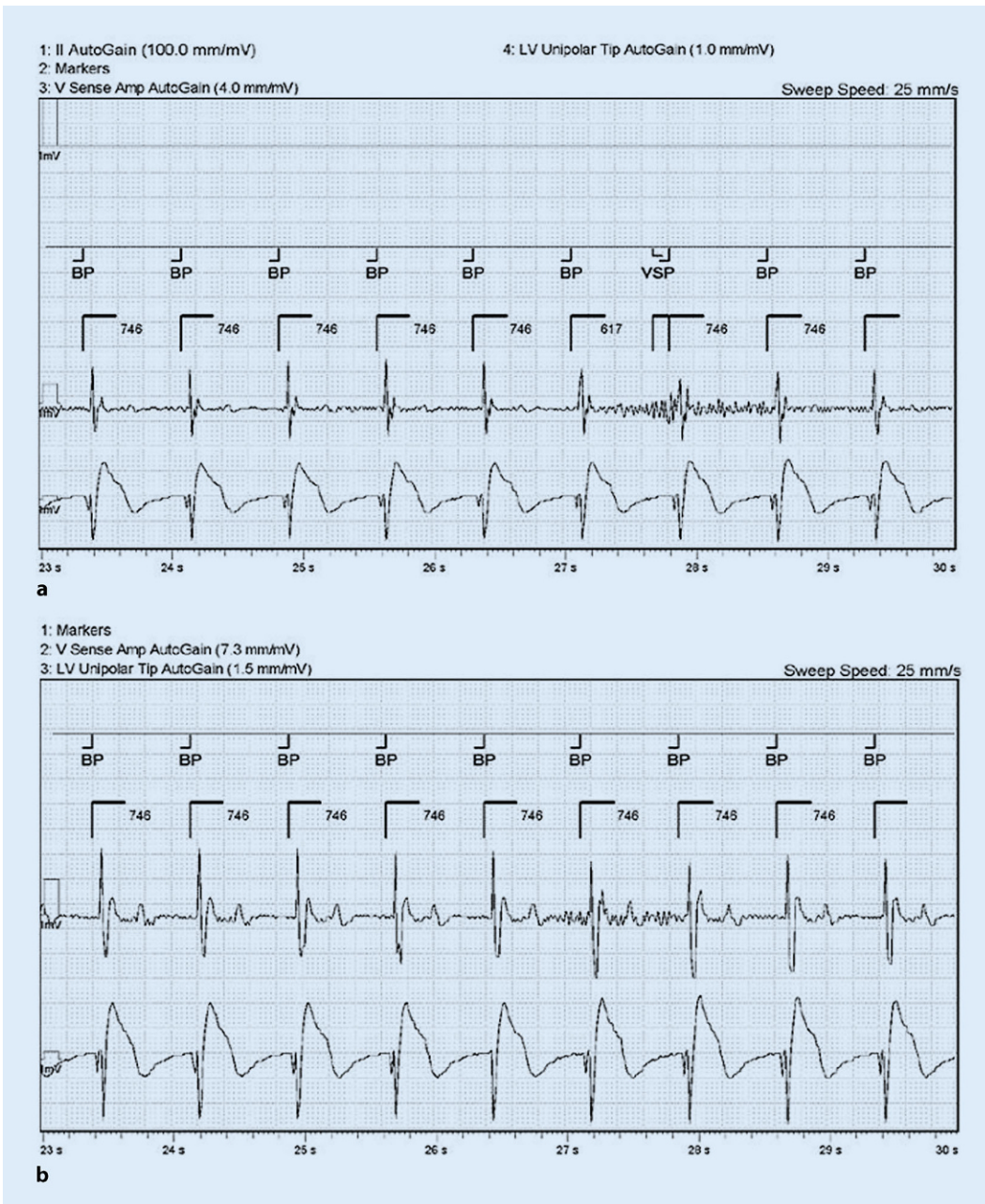


Fig. 6 ◀ **a** Myopotential signals (~0.8 mV) are oversensed with the low frequency attenuation on. **b** Signals (~0.27 mV) are still present but not oversensed. *V* ventricular, *LV* left ventricular

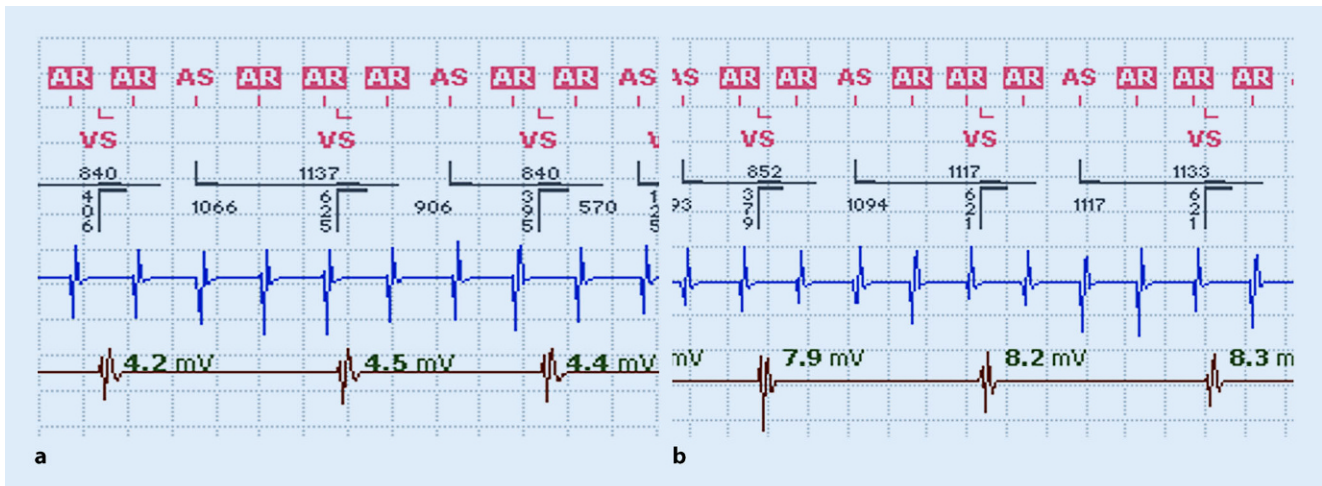


Fig. 7 ▲ **a** Right ventricular (RV) sensing with the low frequency attenuation (LFA) filter off in a patient with a replaced ICD system. **b** RV sensing with LFA Filter on

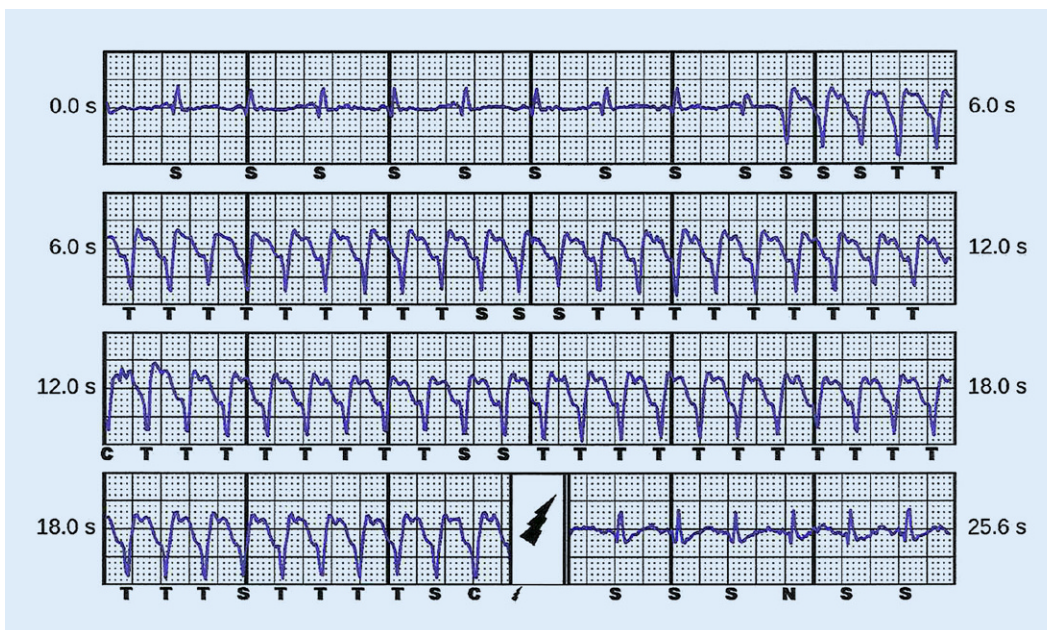


Fig. 8 ◀ Example of subcutaneous implantable cardioverter/defibrillator electrogram

the S-ICD system. It analyses the three sensing vectors and selects the one least likely to oversense. The complex is then compared with previous complexes [10]. However, if a patient develops new conduction abnormalities, it is important that the S-ICD should be reinterrogated immediately and templates updated to rule out oversensing [57].

Insertable cardiac monitors

ICMs are used to obtain ambulatory electrocardiograms (ECG) and detect subclinical AF as well as unexplained syncope and to find possible arrhythmic ori-

gins of palpitations. The devices have been miniaturised since their first introduction and the original ICM is now about as obsolete as the memory stick it resembled. Devices are inserted near the left fourth intercostal space corresponding to the V2–V3 ECG lead location and an ECG tracing is measured between two electrodes at the ends [26]. Most present-day ICMs use automatic arrhythmia detection which is then confirmed by remote monitoring. Compared with pacemakers, ICM algorithms are more limited and based on R-R interval stability, although some advanced algorithms have added P-wave detection once the

R-R variability exceeds the AF threshold, to improve specificity for AF [17].

The performance of ICMs in AF detection has been evaluated in comparison with 48-h Holter monitoring in a number of studies, which have reported high sensitivity (96–100%) and high negative predictive values (98% for the absence of AF in the XPECT trial [29]). But specificity has been less constantly impressive, ranging from 67 to 86% [7, 18, 29]. The rate of false positives for AF detection can be as high as 42% [7]. A randomised comparison in 2016 reported significantly higher rates of correct AF identification with pacemakers than with

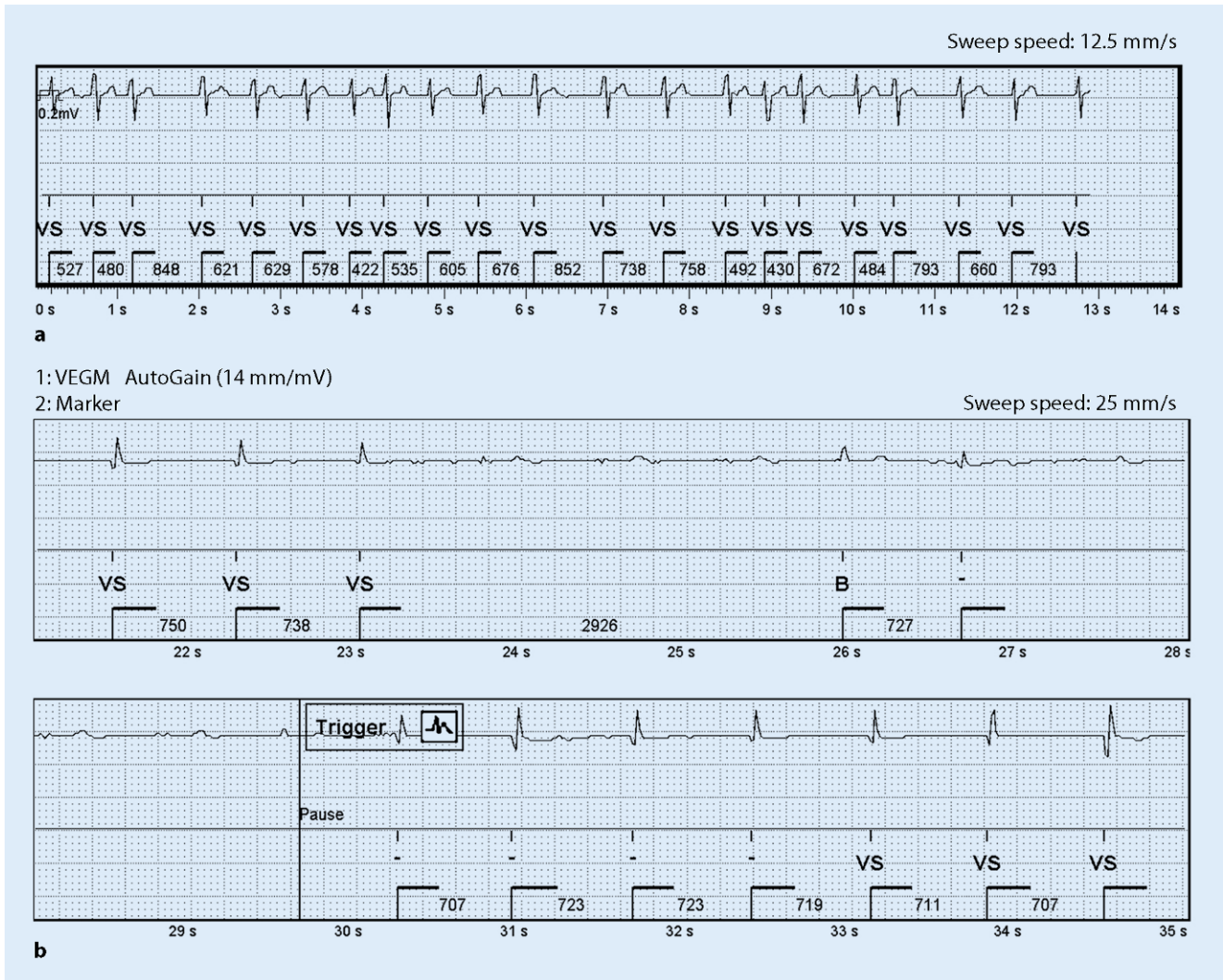


Fig. 9 **a** Example of atrial fibrillation on insertable cardiac monitor electrogram. **b** Incorrect detection due to undersensing. VEGM ventricular electrogram using a can to header vector

ICM (97% vs 55%) as well as significantly greater sensitivity and specificity and PPV [50]. For risk assessment purposes, these differences may not be as important as the numbers imply. ICMs appear to perform similarly to pacemakers in assessing the total AF burden, with false-positive and false-negative episodes to some extent cancelling each other out in the total assessment [7, 50]. For other arrhythmias, Maines et al. reported 20% false bradycardia detection by ICM due to undersensing and 3% false tachycardia detection due to oversensing [40].

The false positive arrhythmia alerts which drive the inaccurate diagnostic performance of ICM are mostly related to inadequate R-wave sensing. As the ICM electrodes are positioned at some

distance from the cardiac muscle, there is greater scope for interference and artefacts [6, 7, 47]. Typically, an R-wave sensing value of at least 0.3 mV is targeted [21]. Undersensing due to a decrease in R-wave amplitude is more common than oversensing and can lead to false diagnosis of bradycardia or pauses as well as false AF alerts [21]. Continual refinements to algorithms include enhanced noise rejection techniques to reduce inappropriate identification of arrhythmias, but at the cost of slightly reduced sensitivity and detection of appropriate arrhythmias [8]. Nonparasternal implant sites appear to be associated with more inadequate R-wave sensing and false arrhythmia diagnoses than parasternal sites [21]. In contrast to S-ICDs, the orientation of the device

may influence detection; the R-wave amplitude is known to change with changing patient postures and associated orientations of the heart [19]. Sudden reductions in amplitude may also lead to loss of signal detection by ICMs (■ Fig. 9).

The main problem with ICMs remains the inability to obtain a clear and accurate signal during subcutaneous ECG monitoring, with a high frequency of artefacts leading to frequent non-diagnostic interrogations [17].

Wearable defibrillators

The wearable cardioverter defibrillator (WCD) received US Food and Drug Administration market approval and the European CE Mark in 2001. It is used in

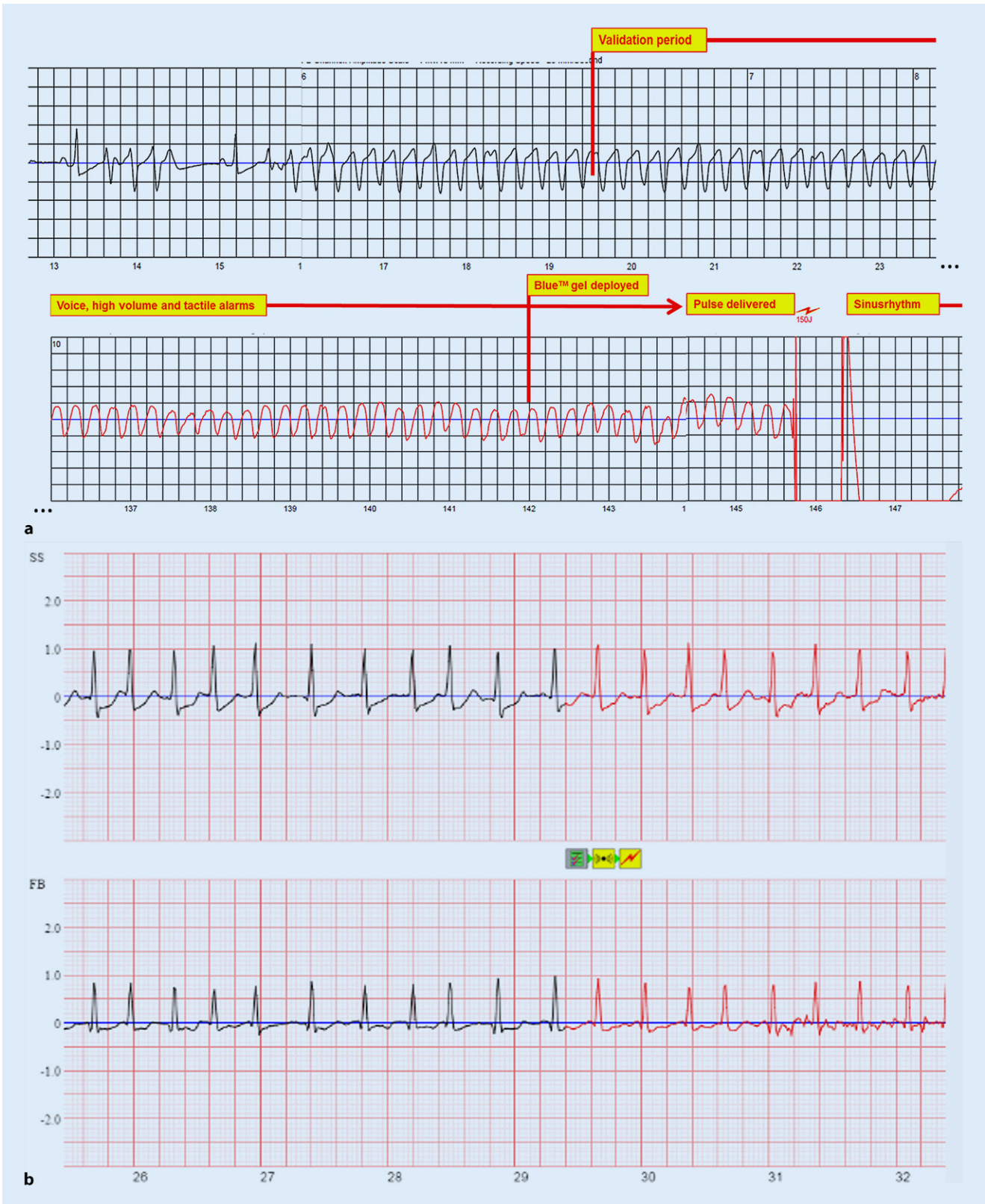


Fig. 10 ▲ Wearable defibrillator electrograms showing a ventricular tachycardia and b atrial fibrillation

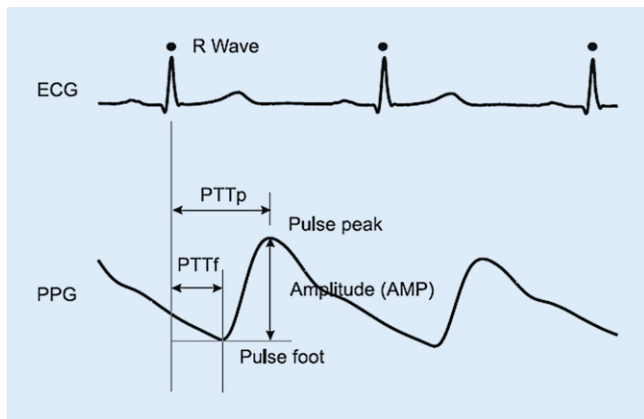


Fig. 11 ▲ The pulsatile (AC) component of the photoplethysmography signal and corresponding electrocardiogram. In actual use, the AC component is superimposed on the much larger quasi-DC component. *PTTf* beat-to-beat pulse transit time to the foot of the pulse, *PTTp* pulse transit time to the peak of the pulse. The pulse landmarks can be used to calculate the normalised pulse contour. From Allen [3], used with permission

patients at temporary high risk for ventricular arrhythmias, or those with evolving cardiac conditions who may need an ICD in future, but in whom in-hospital monitoring would be impracticable [60]. WCD use is recommended in current European Society of Cardiology (ESC) guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death [52].

The WCD is a vest which incorporates three defibrillation electrode pads (positioned for apex-to-posterior defibrillation), a defibrillation unit and four dry, nonadhesive ECG-sensing electrodes which provide continuous electrocardiographic monitoring of front-back and left-right site bipolar surface ECG leads [16, 23]. The monitoring electrodes are placed circumferentially around the chest and pushed against it by tension from an elastic belt. Ventricular tachycardia and ventricular fibrillation are detected by an algorithm which uses ECG morphology analysis and programmable threshold heart rates, with a VF zone programmable between 120 and 250 beats/min, and a VT zone programmable between 120 beats/min and the VF detection rate (■ Fig. 10). Suspected arrhythmias trigger an alarm during which the patient has the option to withhold treatment. This means that most treated ventricular arrhythmias occur in unconscious patients. Perhaps for

the same reason, rates of inappropriate shocks are low [31, 46, 55].

Wearable monitors and consumer electronics

Wearable devices equipped with monitors and algorithms to detect heart rate, ECG or other biorhythms are becoming alternatives to CIEDs when direct electrical stimulation of the heart is not necessary. A survey in 2018 showed that even among “elderly” people (>65 years old) there was great interest in the future use of wearable devices to obtain various health benefits [33]. The pressure to reduce personal routine visits to healthcare providers in the wake of the coronavirus pandemic will probably act in wearable monitors’ favour as it facilitates diagnosis and risk assessment without the use of face-to-face encounters.

The ability of smartwatches and wearable fitness trackers to detect irregularities in the heart rhythm is based on PPG. The process compares the amount of infrared light reflected back from the skin from a green-light emitting diode. As haemoglobin absorbs some of the original light, changes in capillary volume with each pulsation will be indicated by changes in the intensity of the reflected light (■ Fig. 11; [3]). The pulsatile component of the PPG waveform is often called the “AC” component and is superimposed on a large “quasi-DC” com-

ponent that relates to the tissues and to the average blood volume. Several relevant variables can be extrapolated from the analysis of the PPG waveform morphology and its features, including heart rate and rhythm, blood pressure and arterial stiffness, cardiac output, arterial ageing, endothelial function, microvascular blood flow, autonomic function or respiratory rate [3, 13].

The technology has the great advantage of being non-invasive and easy to incorporate into accessories which do not need to be primarily medical but would be worn by a patient on a daily basis. This may make them serious alternatives, e.g. to ICMs for AF monitoring. The challenges are the need for sufficient capillary blood flow to generate a reliable signal, which means the analysis works less well in cases of low blood pressure or vasoconstriction. The accuracy may be affected by patient movement as well as by beats, and it is also not immune to light conditions or the ambient temperature.

Wearable devices use different proprietary algorithms to determine heart rate from the PPG signals. Today there is little information on how these algorithms work, which gives the devices a “black box” characteristic. Moreover, PPG cannot identify atrial activity (P waves) and thus are not suitable for atrial arrhythmia monitoring unless combined with ECG for confirmation (■ Fig. 12). Devices have been developed which carry PPG and ECG systems, but ECGs are designed to be recorded while subjects are inactive and PPG signals may be confounded by movement [14]. A comparison in 2020 of four common wearable PPG-using devices found all to be poor at detecting short episodes of supraventricular tachycardias, particularly for episodes shorter than 60 s [58].

Large-scale studies on AF identification have shown the strengths and weaknesses of wearables. In the Apple Heart Study [49] patients with device notifications of AF were provided with an ECG patch for confirmatory analysis. Although 84% of notifications of an irregular pulse were concordant with AF on subsequent ECG patch readings, the diagnostic yield was only 34%. In the WATCH AF study the diagnostic accu-

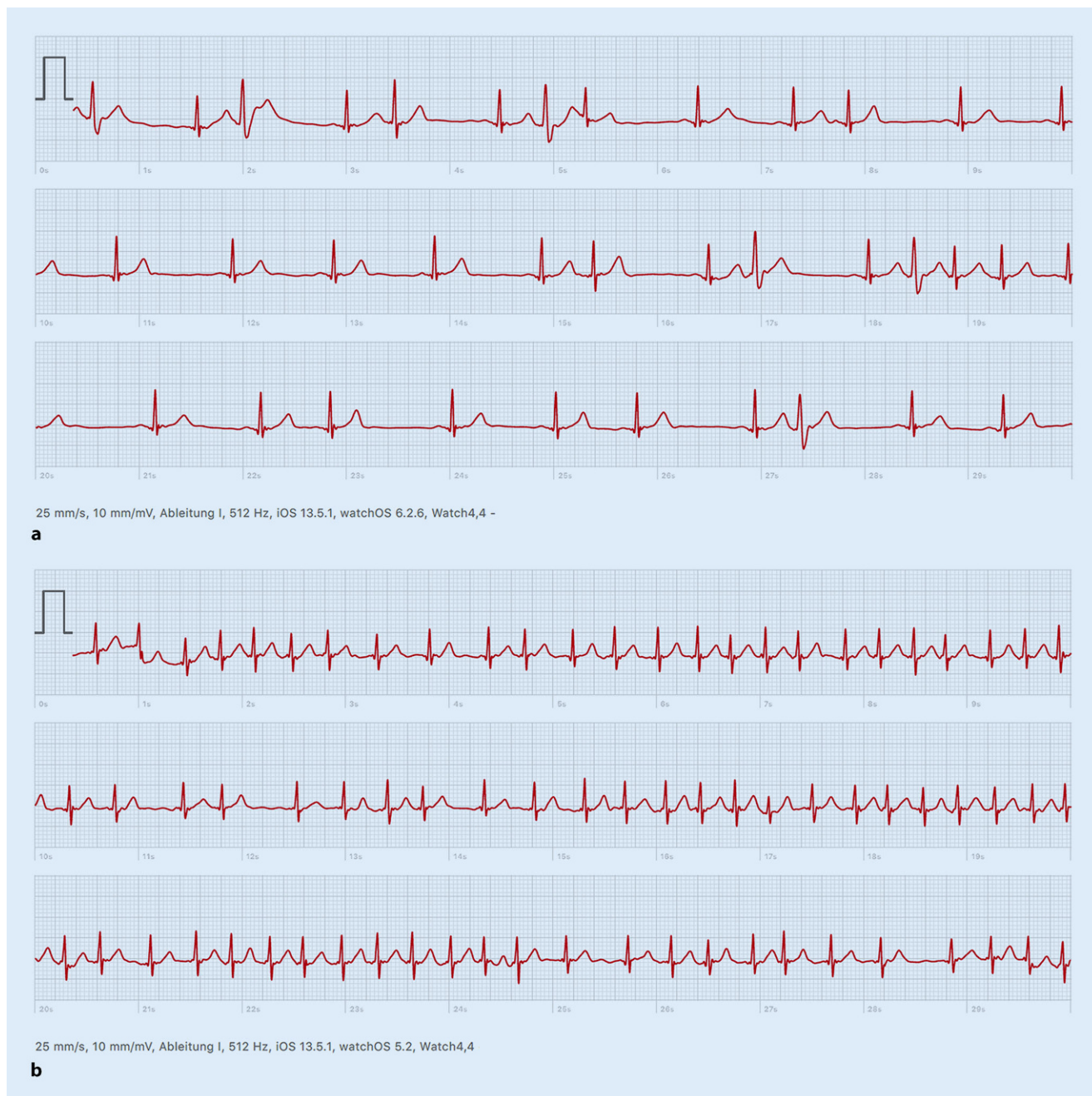


Fig. 12 ▲ Apple watch tracings showing **a** extrasystole and **b** atrial fibrillation

racy was high but 22% of the datasets were not suitable for PPG analysis [22]. None of the trials could assess sensitivity and the rate of failed detections is unknown.

Similar problems were reported with the Kardia Band for which 34% of readings were interpreted as unclassified by the automated algorithm [12]. In the Huawei Heart Study, “possible AF” episodes identified by the device were adjudicated by health providers, but

38% of patients with notification of AF were not assessed for validation and less than half of the notified patients entered follow-up [28].

In general, a lower population prevalence will reduce the PPV, given the smaller proportion of true positives relative to false positives. Accordingly, the PPV of wearable devices will be reduced with an increased use of wearable monitors in the general population. The studies discussed above were huge:

187,912 subjects in the Huawei Heart and 419,297 participants in the Apple Heart studies, respectively. In these megatrials, the AF yield in an unselected population was very small: 0.2 and 0.5%, respectively [28, 49]. This is not surprising given that most smartwatch wearers are young and relatively healthy—in the Huawei study the average age overall was 36 years compared with 54 years in those (0.23%) that received a notification of suspected AF. This indicates

a need to select target populations to reduce the data tsunami generated by devices, as well as for automated filtering of transmitted information. It may also be relevant to note that most wearables are used by men [28, 49] and women may need to be actively targeted.

Outlook

The development of new cardiac devices and therapies is continuing at a rapid pace. What has changed in more recent years is the contribution of Big Data and AI, which has moved monitoring into the public domain, with uncertain consequences. Wearable and other mobile communication technologies have become a powerful driver of change in healthcare by influencing the expectations of patients (as well as of many healthy individuals). However, wearable monitors bring new risks together with the new opportunities. Continuous monitoring is likely to identify occasional arrhythmias in the healthiest of hearts and the challenge is for the general public and physicians alike to know what information to take seriously and what to dismiss. To monitor a huge population of the “worried well” may flood doctors’ offices with low-risk patients that have received an alert from their watch, to the detriment of healthcare infrastructure and to the care of patients that need intervention [36].

The application of AI to healthcare is complicated by the “black-box” nature of deep learning and by the “move fast and break things” business model of Big Tech. The introduction of bug-ridden products, which are then refined by incremental updates as data on performance and shortcomings become available, may be acceptable in consumer electronics and possibly risk assessment. But where users’ health and even lives may be at stake, devices will need to perform reliably from the start. Without a clear understanding of machine learning, even among experts, it will be very difficult to deal with confounding factors.

On the upside, given the immense amount of data, machine learning algorithms can be expected to improve enormously in quality and may feed back into

improved CIEDs to improve detection and therapy delivery if applied in dialogue with available knowledge.

The coronavirus pandemic will supercharge changes in healthcare provision which were already underway. Health authorities globally are trying to increase access to telemedicine and patients are becoming increasingly comfortable with attending virtual consulting sessions rather than travelling to treatment centres and exposing themselves to the risk of infections [5]. Monitoring will grow in importance in this shifting landscape.

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Compliance with ethical guidelines

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