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# Implantable Loop Recorder

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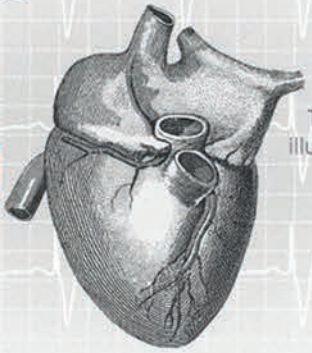

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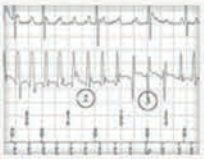

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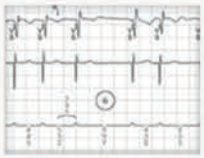

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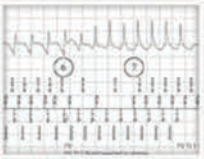

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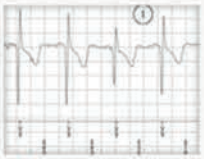

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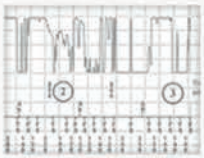

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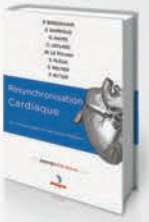


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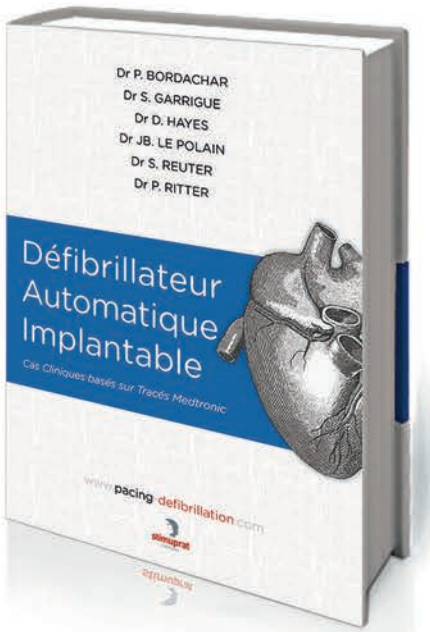
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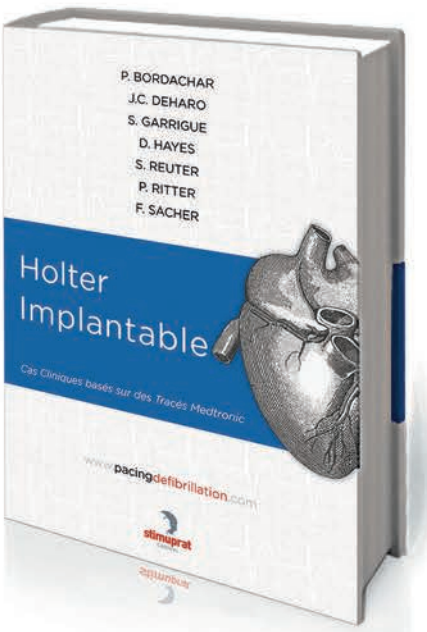
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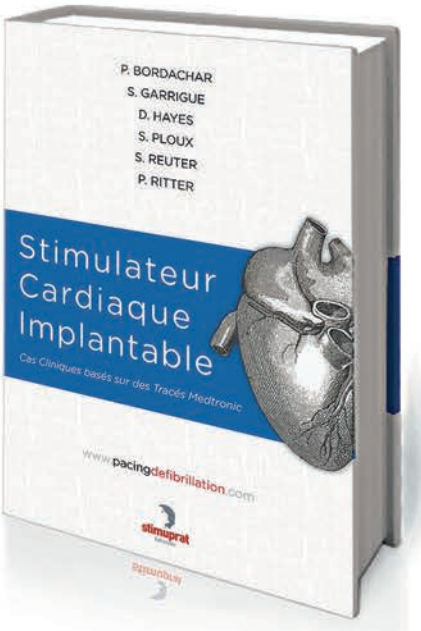
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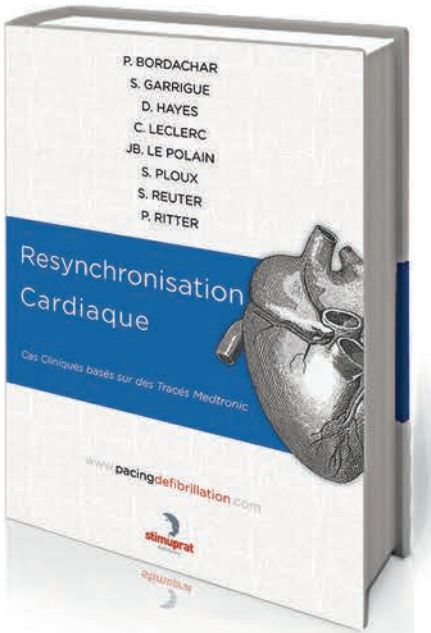
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## Introduction 1



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## Introduction

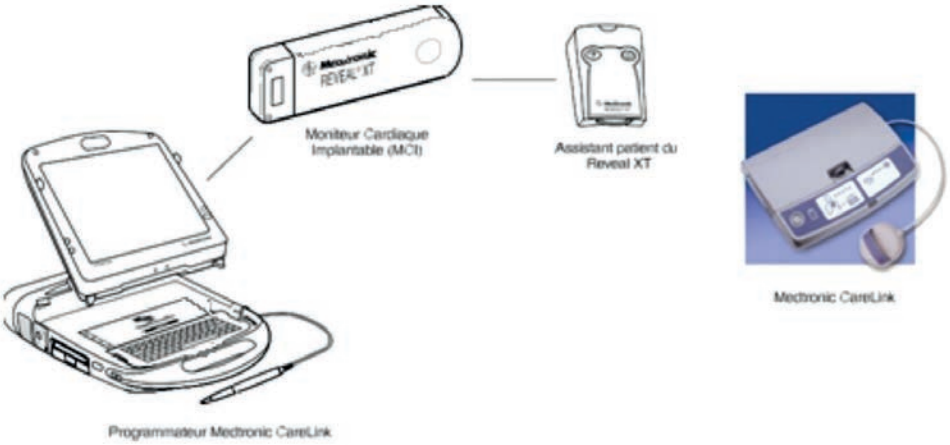
Since its introduction, approximately 15 years ago, the Implantable Loop Recorder (ILR) has become the reference tool for the diagnosis of unexplained syncope. Syncope is a major public health concern as, in a lifetime, between 40 and 50% of the general population suffer ≥1 episode(s), which account for 1 to 6% of all hospitalisations. While a thorough history and physical examination can ascertain the diagnosis in the majority of patients who present with neurocardiogenic syncope, the yield of conventional diagnostic investigations is far lower in the case of syncope of cardiac origin. While a correlation between symptoms and electrocardiographic recordings is the gold standard, it remains difficult to confirm with traditional monitoring methods because of the sporadicity of the disease manifestations.

The ILR, a subcutaneous device implanted in the left subclavian region, enables the loop recording of a bipolar electrocardiographic channel for an extended ambulatory period. The device has a loop memory, which records and memorises the electrocardiogram (ECG) upon its activation by the patient or by a bystander following a symptomatic episode, as well as automatically on the basis of pre-programmed detection criteria. Several early studies have validated the performance of the implantable Holter for the evaluation of recurrent syncope that had remained unexplained despite extensive investigations. This device might also have a place earlier in the decision-making process for patients who present with more benign forms of syncope, with a view to avoid unnecessary and costly diagnostic tests. More recently, the diagnosis of atrial fibrillation (AF) was enabled by the addition of a discrimination algorithm similar to that used by implantable cardioverter defibrillators (ICD). The recordings triggered automatically or in the wake of an episode can be remotely transmitted by the CareLink telemedicine system, allowing a shortening of the time between diagnosis and onset of therapy. Over time, further progress might allow the recording of signals other than the ECG, such as the arterial pressure, enabling the monitoring of hemodynamic function. The miniaturisation of implanted devices might also facilitate their implantation and broaden their indications.

This monograph describes 1) the technologic characteristics and the main current and future indications of this type of device, and 2) the broad principles of interrogation and programming, using the analysis of representative recordings from device recipients.

## 1 System overview

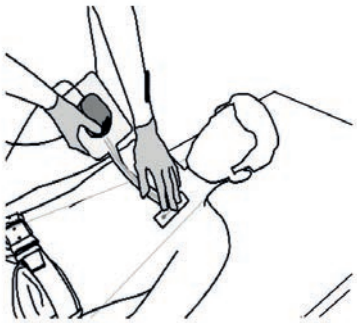
The system includes 4 elements that record the tracings and interrogate the device:
1) The implantable heart monitor proper, a leadless device with 2 electrodes located under the can, which sense the ambulatory ECG continuously and on the long term. The most recent devices store in their memory 22.5 min of patient activated and 27 min of automatically sensed electrocardiographic recordings.
2) The patient assistant, a portable, battery-powered telemetry device, which allows patients to memorise the tracings that coincide with a symptomatic episode.
3) The Medtronic programmer, which allows programming of the device after its implantation and visualising the automatically recorded or patient-activated episodes.
4) The CareLink telemedicine transmission system, which allows the remote transmission and speedy diagnosis of the episodes.



## 2 Implantation

Implantable Holters are usually implanted under local anaesthesia in the same operating suite as cardiac pacemakers. After wide disinfection of the left thoracic field, the device is placed between the first intercostal space and the 4th rib. The quality of the recordings, the prevention of oversensing noise that saturates the memories and the proper discrimination of the various types of arrhythmias hinge on an optimal implantation procedure.

Two steps must be given priority:
1) The optimisation of R wave sensing. The kit includes the Reveal Vector Check, a mapping tool, which enables the selection of the optimal site without contaminating the device. The Vector Check has 2 electrodes approximately 4 cm apart, which corresponds to the space between the electrodes of the device. These electrodes are interfaced with the device at one end and are in contact with the skin of the patient at the other. The quality of the sensed signals can be verified, using the programmer. Minor variations in the device orientation may be associated with marked variations in amplitude and morphology of the sensed signals. A satisfactory position is associated with the sensing of a stable ≥0.3 mV R wave amplitude and morphology, satisfactory visualisation of P and R waves with high R/T and R/P ratios, and absence of P and T wave sensing by the device.



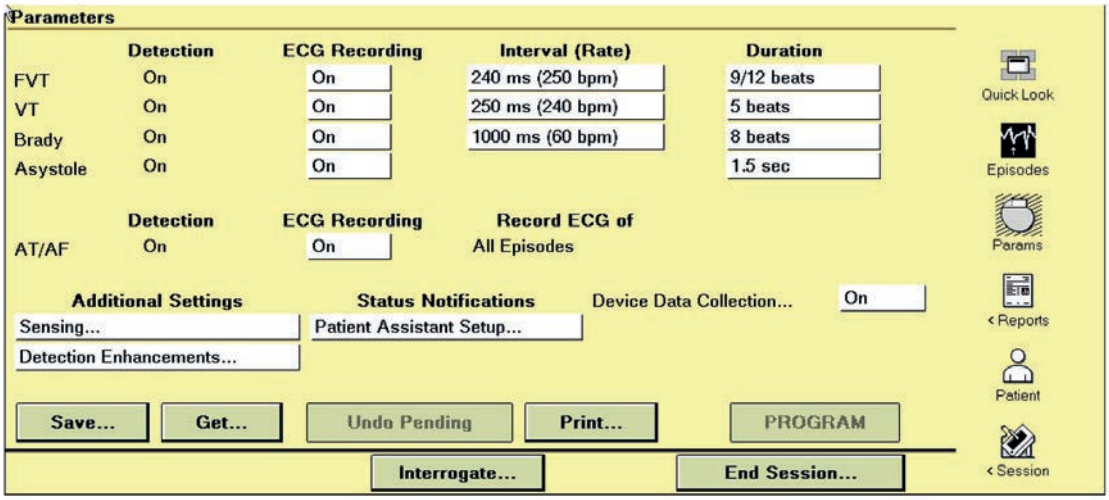
2) Minimisation of the risk of oversensing myopotentials. To guarantee the reliability of automatic sensing of the episodes, motion of the device inside its pocket must be limited as much as possible. Therefore, the pocket must be neither too large, in order to limit movements, nor to small, in order to prevent the extrusion of the device. Suture holes in the pulse generator header can be used to attach the device to the subcutaenous tissues and minimise its rotation and migration after its implantation.

Once the device has been implanted, the sensing and data collection must be configured, and the patient assistant given and explained to the patient.

## 3 Classification and recording of the episodes

### Automatic recording of the episodes

The last generation of ILR can classify and record 5 types of arrhythmic episodes:
1) Ventricular tachycardia (VT): the heart rate increases above the programmed VT threshold.
2) Fast ventricular tachycardia (FVT) or ventricular fibrillation (VF): the heart rate increases above the programmed FVT threshold.
3) Bradyarrhythmia: the heart rate slows below the programmed bradyarrhythmic threshold.
4) Asystole: no ventricular event is sensed during a programmed period.
5) 5) Atrial tachyarrhythmia (AT) or fibrillation (AF) or AF alone: The episodes of AF with atrioventricular conduction are diagnosed by analyzing the regularity of the ventricular rhythm, using an automatic algorithm.




Reveal XT, the most recent ILR, logs up to 30 arrhythmic episodes of each type. When the log is saturated, the data of the last episode replace those of the oldest of the same type. The Reveal DX and XT can also store in the device memory the ECG recorded before and during the episode. For each episode of AT/AF, the Reveal XT stores the first 2 min of ECG. For each episode of VT, FVT, bradycardia or asystole, 30 sec of ECG before the onset, and up to 27 sec before the end of the episode are recorded.
The Reveal DX and XT store 27 min of ECG for the episodes sensed automatically. When the memory reserved for the episodes detected automatically is full, a new recording replaces the oldest stored ECG. The system replaces a recording only when ≥3 episodes of the same type remain in memory.

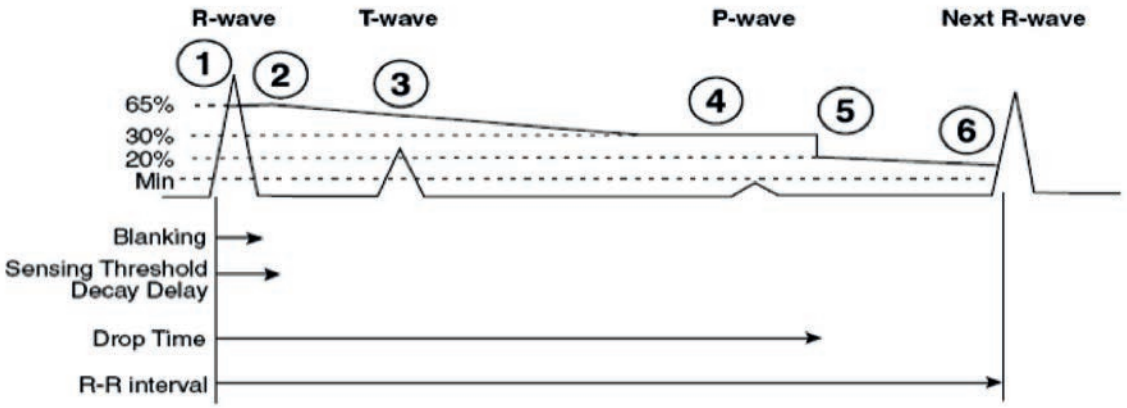
### Recordings of episodes using the patient assistant

Reveal DX and XT store up to 10 symptomatic, patient-activated episodes in the memory log. When the latter is full, the data of the latest episode replace those of the oldest. Reveal DX and XT reserve 22.5 min of ECG storage in the data log for the most recently recorded symptomatic episodes. The symptomatic episodes may be programmed to record a) 3 episodes, including 6.5 min before and 1 min after), b) 2 episodes, including 9 min before and 1 min after, or c) a single episode including 14 min before and 1 min after activation of the system. When the memory reserved for symptomatic episodes is full, the ECG of the oldest stored episode is replaced by the latest episode.

# 4 Programming

## Adjustment of the R wave sensing

The optimal placement of the ILR must allow the visualisation of the P, R and T waves to facilitate the interpretation of the recordings. On the other hand, the automatic sensing of bradycardia, VT as well as AF is strictly based on the count of the R wave and analysis of its regularity. The optimisation of the device position at the time of implantation is key, as all changes in its programming are unlikely to compensate for the recording of low quality signals. The programmable settings available to enable the sensing of R waves without sensing of either the P or T waves or the myopotentials include 1) the sensitivity, 2) the refractory period and 3) the duration of threshold stability before its decrease. The sensing threshold defines the lowest electrical amplitude associated with sensing of an event. As in implantable cardioverter defibrillators (ICD), the sensing threshold, instead of being fixed, adapts automatically to the amplitude of the sensed R wave, and increases during the cardiac cycle. After sensing of an R wave, a programmable post-Vs refractory period is initiated and the sensing threshold is set at 65% of the R wave measured. This sensing threshold remains at this level for the entire programmable duration of threshold stability before decreasing. The sensing threshold keeps decreasing until a new R wave is sensed or the lowest threshold has been reached. The latter corresponds to the programmed setting of sensitivity.




The programming of the sensitivity must allow an accurate and flawless sensing of the R wave, including an adequate safety margin, while avoiding the sensing of P and T waves. The nominal value is 0.035 mV. The setting of the post Vs refractory period must prevent a double counting of the R wave. Programming of an excessively long refractory period limits the sensing of rapid rates by the device. The nominal value is 70 ms. The duration of threshold stability before its decrease must be optimised to avoid T wave sensing. The nominal value is 100 ms.

## Configuration of automatic episodes sensing

FVT episodes

An event is classified as FVT when the ventricular cycle is shorter than the programmed FVT cycle (nominal = 300 ms). If the number of FVT events exceeds the programmed number (nominal = 12 / 16 FVT cycles), the device memorises an episode of FVT.

The FVT episode ends when one of the following criteria is fulfilled:

- Eight consecutive R waves are sensed with 1 cycle ≥ the programmed FVT cycle.
- The median ventricular cycle is ≥ the programmed FVT cycle during a 20 sec period.
- No R wave is sensed during a 10-sec period.

VT episodes

Un event is classified as VT when the ventricular cycle is shorter than the programmed VT cycle, though longer than the programmed FVT cycle (nominal value = 360 ms). If the number of VT events exceeds the programmed number (nominal = 16 consecutive cycles), an episode of VT is memorised.

The VT episode ends when one of the following criteria is fulfilled:

- Eight consecutive R waves are detected at a cycle ≥ the programmed VT cycle.
- The median ventricular cycle is ≥ the programmed VT cycle during a 20-sec period.
- No R wave is sensed during a 10-sec period.

To prevent the sensing of unstable ventricular rhythms during an AT/AF episode with a rapid ventricular response, or during sinus tachycardia, the sensing specificity may be increased by programming the stability and sudden onset settings.

- Stability: an R-R cycle capable of triggering the recording of an episode of VT is compared with 3 preceding VT cycles. If the difference between the current cycle and 1 of the 3 preceding cycles is > the programmed VT stability cycle, the R-R cycle is not classified as a VT event.
- Sudden onset: comparison between the 4 most recent and the 4 preceding RR cycles. If the mean duration of the 4 most recent RR cycles is < mean duration of the 4 preceding RR cycles, multiplied by the programmed percent sudden onset, the next 4 R-R cycles are classified as VT events.

Bradyarrhythmia episodes

An episode of bradyarrhythmia is diagnosed when the programmed number of RR cycles is > programmable duration. An RR cycle >2000 ms is nominally labelled as “Brady”.

An episode of bradyarrhythmia ends when one of the following criteria is fulfilled:

- Four consecutive R - R cycles are sensed, whose duration is ≤ programmed ventricular cycle;
- No R wave is sensed for ≥ 10 sec.

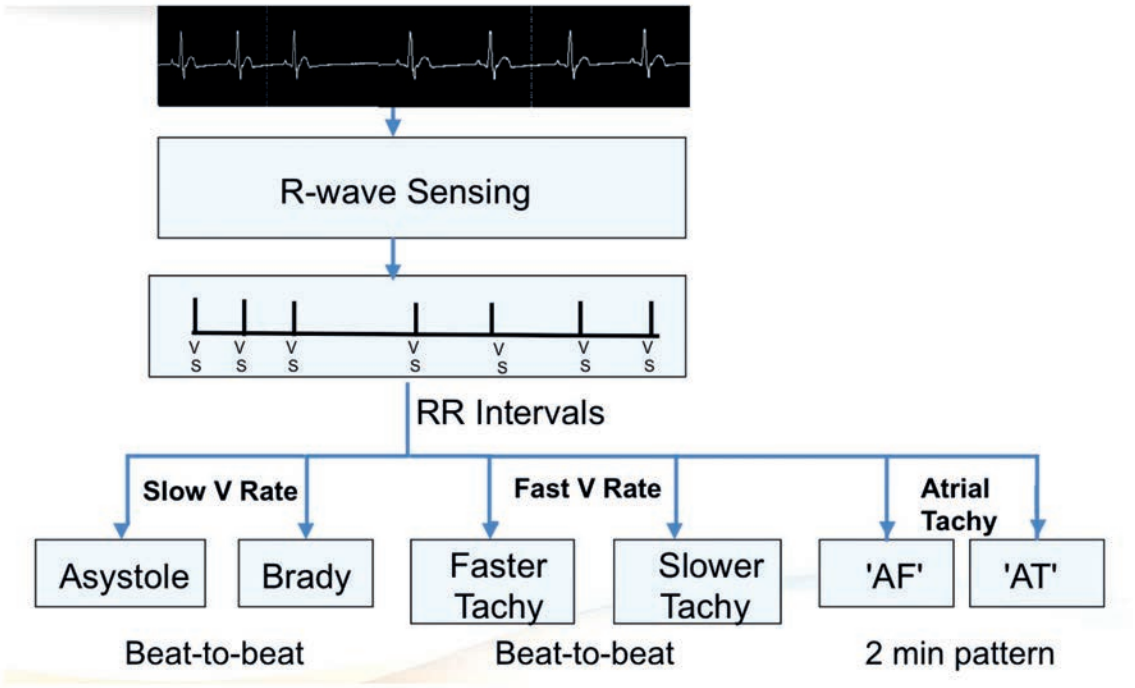
Episodes of asystole

An asystolic event begins when a cycle following a sensed R wave is longer than a programmed duration (nominal = 3 sec). Asystole ends after the sensing of 4 R waves.

Atrial tachyarrhythmias/atrial fibrillation

The episodes of AT/AF are diagnosed by means of an automatic algorithm based on the RR variability over a 2 min period. The differences among consecutive RR cycles are displayed on a Lorenz curve. The distribution of RR cycles allows the identification of the AT and AF episodes. During AF, the RR cycles are highly irregular and non-correlated in contrast with AT, when they are more regular.

Summary of arrhythmias detection: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V S
V S
V S
V S
V S
V S
RR Intervals
Slow V Rate
Fast V Rate
Atrial Tachy
Asystole
Brady
Faster Tachy
Slower Tachy
'AF'
'AT'
Beat-to-beat
Beat-to-beat
2 min pattern

## 5 Indications: broad principles

The ILR allows the ambulatory monitoring of the ECG for an extended period of time. A few important principles must be weighed when considering the implantation of this type of devices:
1) A medical history and physical examination allow a determination of the origin of syncope in a majority of patients without further investigations.
2) An initial risk stratification is essential to identify high-risk patients who have an indication for the implantation of a cardiac pacemaker or ICD.
3) The ILR is indicated only for patients at high likelihood of suffering ≥1 symptomatic recurrence during the life of the device. A mean interval between symptoms is, therefore, a determining factor and should correspond to the characteristics of the device. The external event monitors are not useful in the investigation of syncope, as they are not able to record the ECG retrospectively.
A patient who suffers weekly syncopal events should receive an external Holter for an extended period. Finally, the probability of diagnosis with an implantable Holter is low in a patient who has suffered a single episode of syncope or episodes separated by > 36 months, the battery life of the most recent devices.
4) The gold standard is the recording of an ECG coinciding with the occurrence of symptoms, allowing the confirmation or exclusion of an arrhythmic cause. The automatic recording by the device of an episode of bradycardia or tachycardia in the wake of symptoms might yield useful information, though no firm diagnosis.
5) An unequivocal diagnosis requires a recurrence, which may have disabling consequences, for example a facial trauma or a vehicular accident.
6) Some channelopathies present with characteristics, which preclude the use of an implantable Holter. In Brugada syndrome, for example, the first arrhythmic episode is often life-threatening VF, for which the ILR, being only a witness, plays no therapeutic role.

## 6 Implantable loop recorder and syncope

When used as a diagnostic tool for unexplained syncope, the ILR allows the recording of an ECG in the wake of an episode.

### Diagnostic yield

In an initial clinical study of the ILR in a highly selected patient sample who were at high risk of recurrent syncope and had suffered a mean of over 8 episodes, a correlation between symptoms and ECG was confirmed in 88% of patients over a 5-month period. The combined results of 9 studies, comprising over 500 patients presenting with unexplained syncope who had undergone extensive investigations, indicated a correlation of 35%, with asystole in 56%, tachycardia in 11%, and no arrhythmia in 33%. The yield depends on the patient selection and on the likelihood of recurrence, as well as on the life expectancy of the device's batteries, which currently reach 36 months.

### Reproducibility of the episodes

The correlation between ECG and syncopal event is the gold standard as much as the diagnosis of the different episodes is the same. Both ISSUE studies showed that, in a majority of patients, the recorded ECG is highly reproducible among recurrences.

### Patient groups in whom the diagnostic yield of the ilr is high

1) Unexplained syncope in presence of a cardiac abnormality.
Various studies have found a value of the implantable Holter in the investigations of syncope in patients presenting with:
- bundle branch block and negative electrophysiologic studies;
- old myocardial infarction or cardiomyopathy with a depressed left ventricular (LV) ejection fraction (EF) or non-sustained VT and negative electrophysiologic studies;
- congenital heart disease.

2) Identification of the mechanism of reflex syncope
The merit of permanent pacing for malignant neurocardiogenic syncope remains controversial, though implies the demonstration of a cardioinhibitory mechanism and prolonged asystole. In contrast to the tilt-table test, the implantable Holter records the ECG in the wake of a spontaneous episode and allows an orientation of the therapy.
3) Diagnosis of loss of consciousness under particular circumstances.
The ILR allows a triage of the origin of repetitive loss of consciousness under particular circumstances, like recurrences of attacks labelled epileptic despite optimal treatment, episodes occurring in a context of major depressive state, or falls in elderly patients.

### Classification of syncope

The investigators of the ISSUE study proposed a classification of the recordings obtained by the ILR at the time of syncopal events. Type 1, corresponding to asystole, is observed in 63%, type 2, corresponding to bradycardia, in 5%, type 3, corresponding to absence of anomalous recording, in 18%, and type 4, corresponding to a tachycardia, in 14% of patients. These 4 types can be subdivided, offering pathophysiologic information on the mechanism of syncope and allowing an orientation of the therapy. A reflex origin of syncope is suspected (types 1A, 1B and 2), in presence of progressive bradycardia, or a tachycardia followed by profound bradycardia, or in presence of asystole. In contrast, the sudden onset of complete atrioventricular block, without prior change in sinus rate or PR interval, suggests an intrinsic conduction disorder at the level of the His–Purkinje network (type 1C). In absence of arrhythmia at the time of syncope (type 3), a moderate slowing or acceleration of the sinus rate suggests an activation of the autonomic nervous system, a vasodilatory mechanism and a hypotensive syncopal event.

## Cost-effictiveness of a strategy based on the ilr

The initial cost of the device is relatively high. However, the introduction of the implantable Holter early in the decision-making process allows the avoidance of often unnecessary and costly investigations, and lowers the cost / efficacy ratio.

## Where to place the ilr in the decision-making process?

At first, the ILR was used as a last recourse, after extensive investigations of recurrent syncope had remained negative. It now seems clear that the relatively low sensitivity and specificity of the conventional ambulatory ECG, tilt-table test, ATP test and electrophysiologic studies make them of low value in the investigations of syncope, and that the ILR might be worth considering as a first diagnostic choice. Various studies will show that the implantation of an ILR as a first choice is appropriate and offers a higher diagnostic and economical yield than conventional investigations, as long as high-risk patients are excluded.

An initial evaluation allows the identification of high-risk patients.

In the majority of patients, the diagnostic is clear after a medical history and physical examination, and no further investigation is needed. The patients at low likelihood of suffering from syncope due to an arrhythmia are not candidates for the implantation of this type of device.

Patients presenting with recurrent syncope and one of the following characteristics should be recommended urgent hospitalisation and detailed investigations: a) syncope on exertion, b) palpitation perceived at the time of syncope, c) family history of sudden death, d) non-sustained VT, bifascicular block or intraventricular conduction abnormalities in presence of wide QRS, e) inappropriate sinus bradycardia <50 bpm or sino-atrial block, f) ventricular preexcitation, short or prolonged QT interval, ECG changes consistent with Brugada syndrome or arrhythmogenic right ventricular dysplasia (negative T wave in the right precordial, epsilon wave and late ventricular potentials), or g) anaemia or abnormal blood electrolytes concentrations. The use of an ILR will be reserved for patients in whom all investigations have failed to yield a diagnosis. Patients presenting with a firm indication for an ICD should undergo the implant, using the device's memory to identify the mechanism of syncope. Non-sustained VT in the context of a history of myocardial infarction is an indication for electrophysiologic studies and programmed ventricular stimulation. In these cases, as well as in patients whose ECG suggests the occurrence of paroxysmal bradycardia, who should undergo a period of ECG telemetry and, perhaps, electrophysiologic studies, the ILR should be used after all tests have remained negative.

In absence of risk factors, however, the ILR can be used without prior investigations.

## Recommendations

The 2009 European recommendations distinguish 2 class I and 1 class IIA indications for the implantable Holter as part of the investigations of syncope.

Class I

Early phase of evaluation in patients suffering from recurrent, unexplained syncope, in absence of risk factor and at high likelihood of sustaining a recurrence before depletion of the device's battery.

Patients who have ≥1 risk factor and in whom detailed investigations have neither revealed the cause of syncope nor suggested a specific treatment.

Class IIA

The ILR might be considered for patients presenting with recurrent, malignant neurocardiogenic syncope to identify its mechanism and orient the therapy.

## 7 Implantable ilr and palpitation

Palpitation is a common symptom caused by a variety of cardiac rhythms, ranging from appropriate or inappropriate sinus tachycardia to life-threatening VT. The diagnosis is confirmed when the ECG can be recorded during an episode of palpitation, which, with conventional tests, may be challenging if the symptoms are few and far between. As for syncope, patients presenting with risk factors must be hospitalised and undergo extensive investigations. The benign health status found in the majority of patients complaining of palpitation limits the role played by the ILR. It might, therefore, be considered despite being invasive and costly only when a) the likelihood of making a diagnosis with conventional methods, is low, including ≥ 24-h of external, ambulatory ECG, b) the symptoms are major and consistent with circulatory dysfunction, and c) all investigations have remained negative.

### Recommendations

Class IIA

The ILR can be considered for carefully selected patients presenting with infrequent palpitation associated with major symptoms, after an external, ambulatory ECG of 24 h or longer has not yielded a diagnosis.

## 8 Ilr and atrial fibrillation

The diagnosis of AF and the evaluation of the efficacy of its therapy might represent an important upcoming area of investigation for the ILR. If a heart rate control strategy has been chosen, no complicated investigation is necessary, as the patient follow-up is based on the clinical status. On the other hand, if a rhythm control strategy has been chosen, a precise knowledge of the occurrence, duration and frequency of AF recurrences is essential to adjust the antiarrhythmic and antithrombotic treatments. An accurate evaluation of the duration of the episodes of paroxysmal AF seems also critical, as episodes lasting > 24 h are associated with an increased risk of thromboembolic complications. Several studies have found a weak correlation between symptoms and ECG confirmation of AF. Indeed, symptoms were perceived in only 46% of episodes of AF confirmed electrocardiographically. Recurrences of AF may be asymptomatic in patients previously symptomatic. Furthermore, sinus tachycardia or repetitive extrasystoles might be erroneously perceived as recurrences, causing an overestimation of the AF burden. The correlation is particularly weak when a rhythm control strategy has been chosen. The memory of early devices, which were not equipped with a specific algorithm, was saturated by the sensing of myopotentials, precluding the automatic analysis of episodes of atrial arrhythmias and an accurate quantification of the arrhythmic burden. Technologic progress was therefore needed to reliably differentiate sinus rhythm from atrial arrhythmias. The newest devices include an algorithm similar to that used in ICD, which identify episodes of atrial arrhythmias on the basis of rhythm irregularity. Several large studies are examining the performance of this type of device in the qualitative and quantitative diagnosis of AF episodes as well as in their ability to identify the source of cryptogenic cerebral vascular accidents.

### Recommendations

No guideline has been issued by the European Society of Cardiology with regard to the monitoring or diagnosis of AF with the ILR.

## 9 Perspectives

Several technologic advances and the completion of studies including new patient profiles should allow the broadening of the indications and implantation of this type of device.
Further miniaturisation of the device will facilitate its implantation and acceptance by patients and caregivers. Despite the indications clearly formulated by professional societies, the ILR is currently largely underutilised. The invasive nature of the implant procedure, which must be performed in an electrophysiology laboratory may, at least partially explain the discrepancy between indications and actual device implantations. The very small size of upcoming devices should allow their implant in an ambulatory setting, in a non-specialized environment, and should minimize their aesthetic consequences.
The device's life expectancy is directly correlated with the probability of recording a spontaneous symptomatic episode. The 36-month life expectancy of current batteries might increase considerably in the near future.
The information collected by the device can be remotely transmitted by the CareLink system. Its adaptation by the medical centres to the follow-up of ILR should shorten the delays between diagnosis and introduction of therapy, when indicated. The remote follow-up and ambulatory management of AF, and the decision of introducing or discontinuing antithrombotic therapy might represent an important application of the system.
New hemodynamic sensors could be added to the functions of the ILR, allowing the follow-up of heart failure and adaptation of its treatment. Furthermore, the monitoring of arterial pressure might contribute key information toward the identification of the mechanism(s) of syncope and allow the continuous surveillance of the efficacy of treatment of arterial hypertension.
Progress in the morphologic analysis of ECG signals should allow the follow-up of changes in ST segment and the detection of episodes of silent ischemia.
Randomized studies are needed to determine the optimal place of the ILR in the diagnosis of unexplained syncope and identification of the causes of palpitation.

## Recording 1

### Representative case

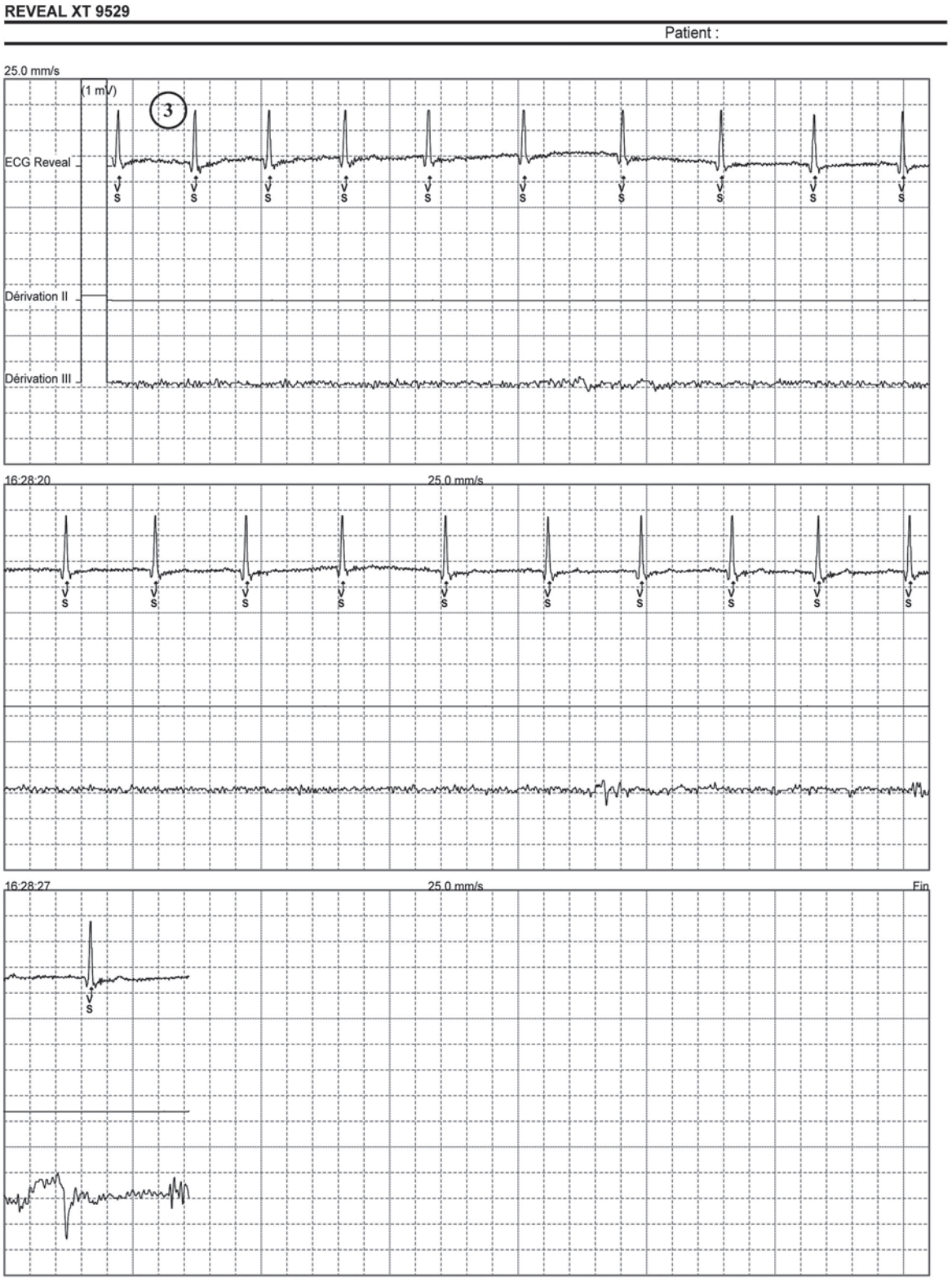
A 64-year-woman with a history of inferior myocardial infarction and 58% LVEF presented after 3 sudden episodes of syncope without apparent cause. A 12-lead ECG showed sinus rhythm, incomplete right bundle branch block and signs of old inferior myocardial infarction. The remainder of the diagnostic investigations, including electrophysiologic studies and programmed ventricular stimulation was negative. The device placement was optimized with Vector Check immediately before its implant.

### ILR recording

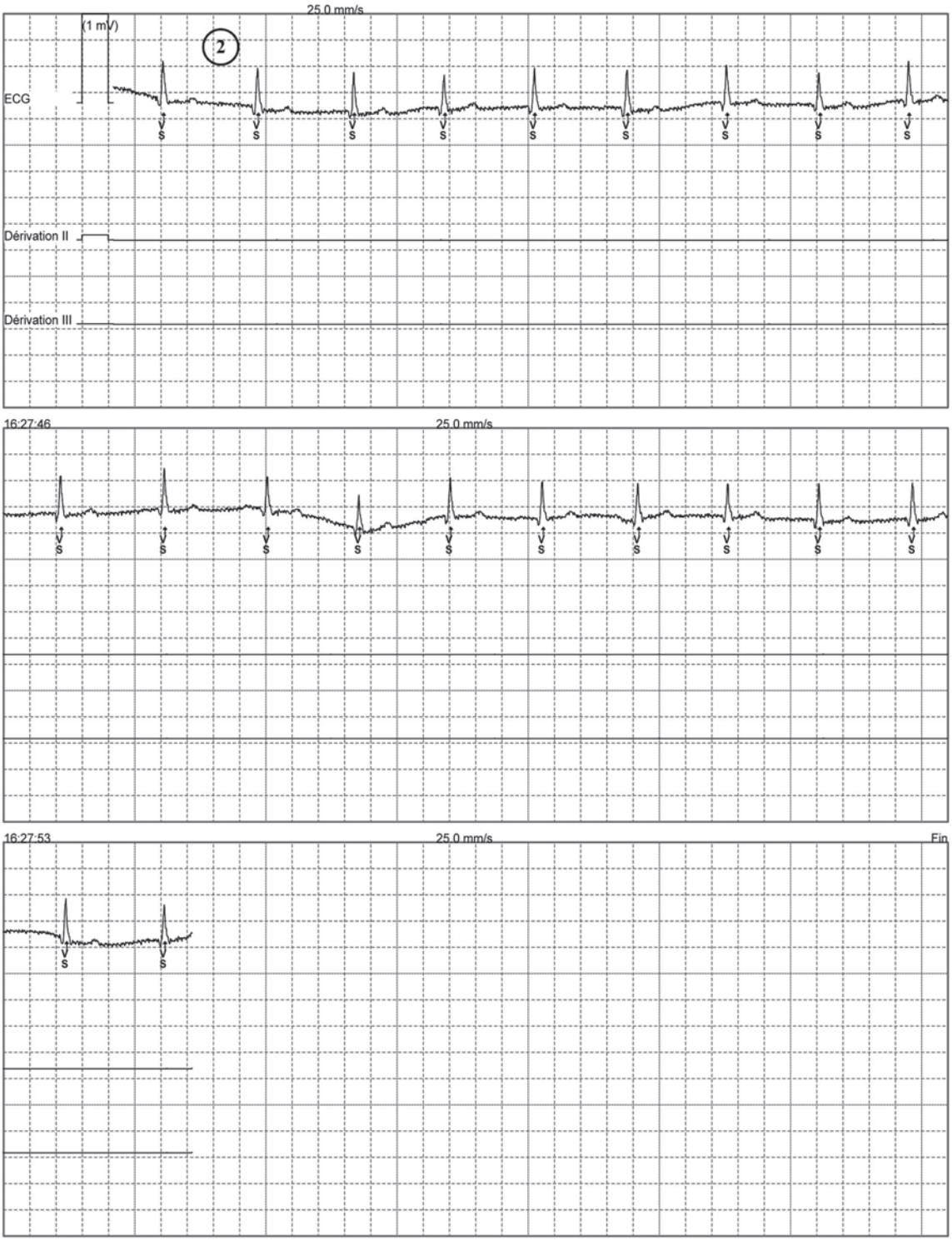
The 4 tracings were recorded at the same sensing level and amplification. The device was implanted at the level of the 4th intercostal space in a horizontal axis on the 1st tracing, becoming progressively more vertical in the other 4 tracings. The ventricular electrograms are accurately sensed (VS) by the device suggesting a proper function of the device, regardless of its position. It is, however, clear that on the 1st tracing the ventricular electrogram is damped and neither P nor T waves are visible. On the 2nd tracing, the QRS amplitude is slightly higher and a low-amplitude T wave is visible. On the 3rd tracing, the amplitude of the ventricular electrogram is slightly higher, though the T and P waves remain indistinct. On the last tracing, the ventricular electrograms, P and T waves are clearly visible, with minor variations in the morphology and amplitude of the signals. This last position was selected for this patient.

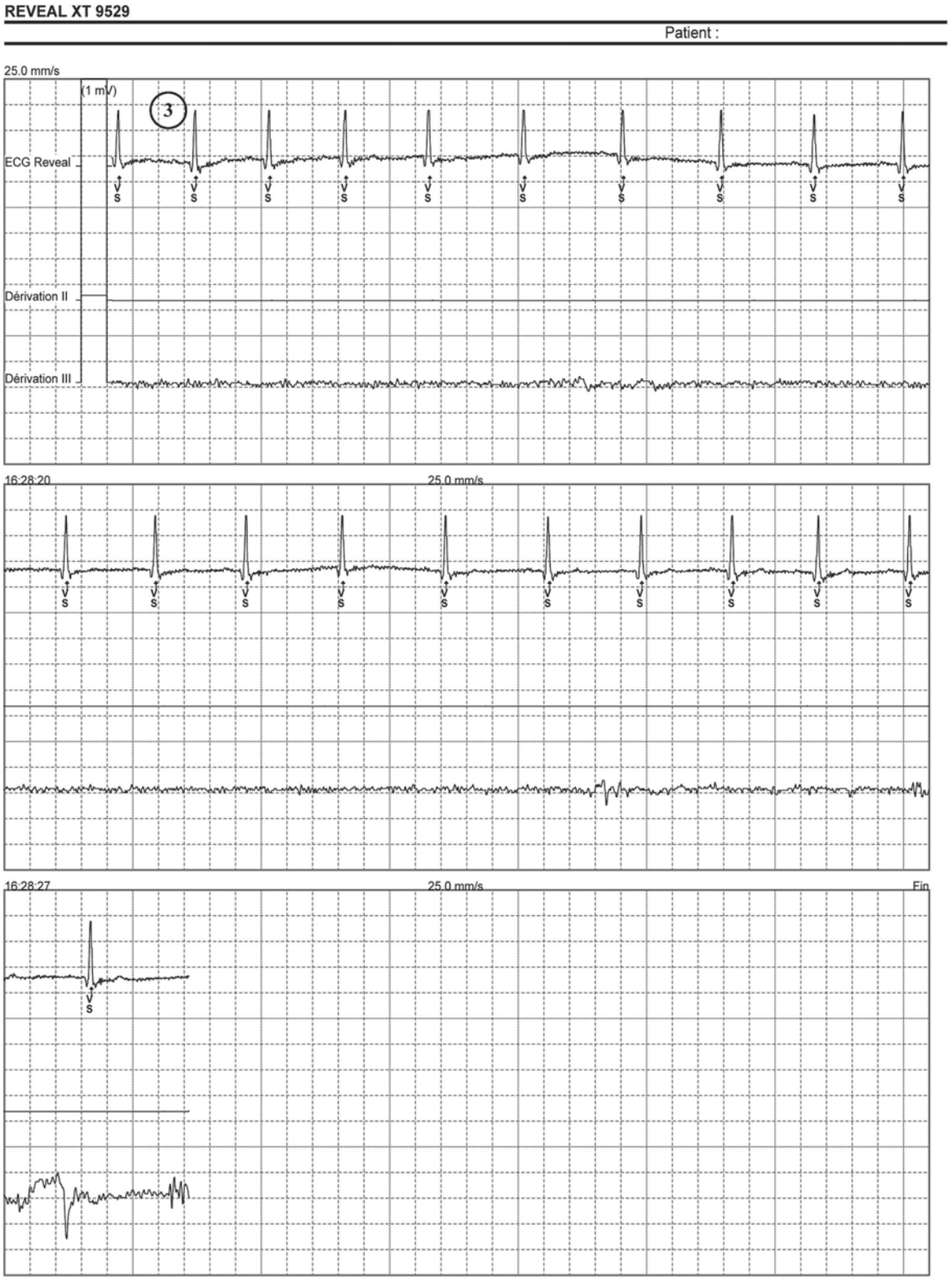
### Comments

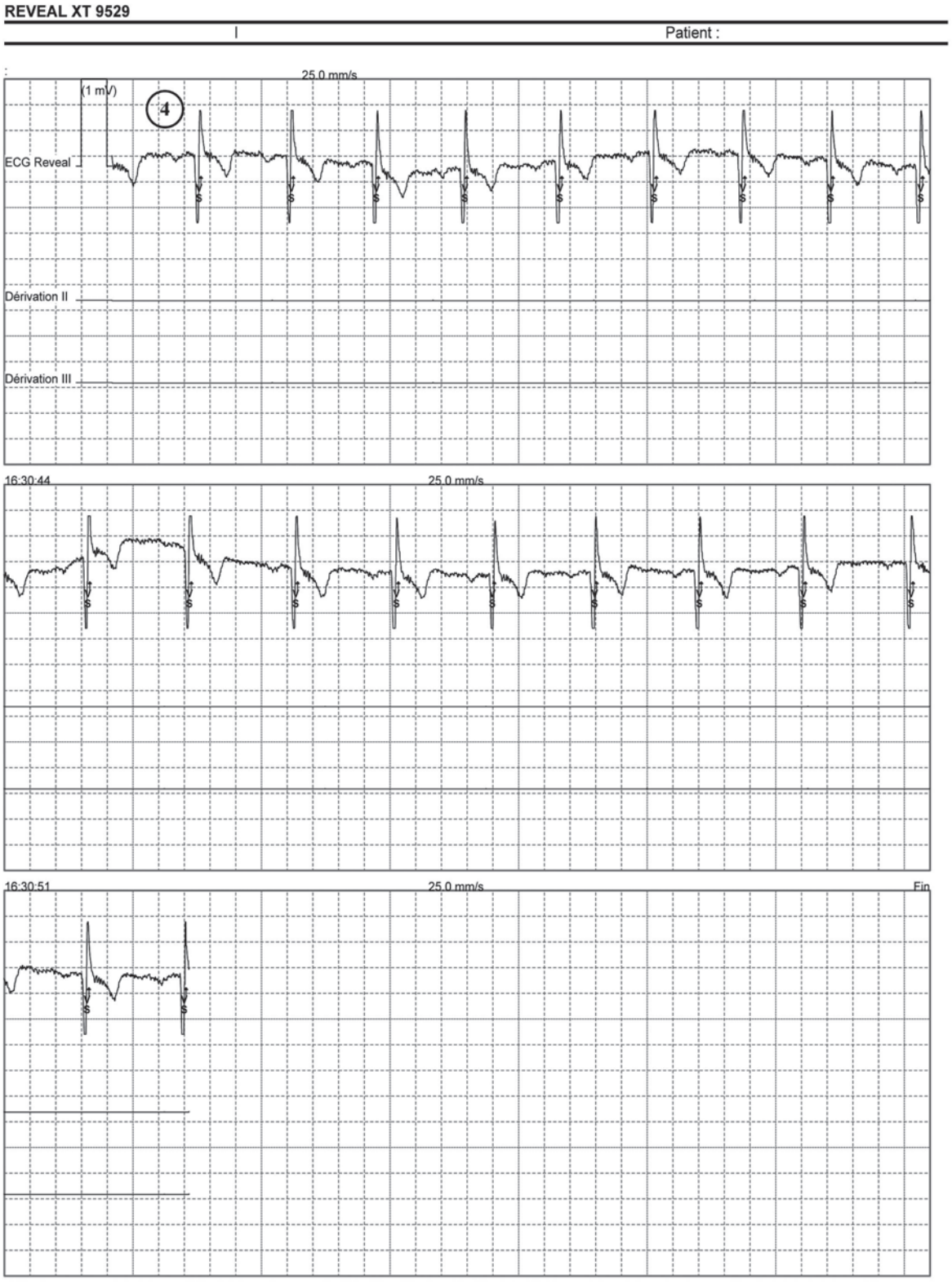
The Reveal was implanted during a brief procedure performed after anaesthesia of the left subclavian region. The pocket was optimised to be neither to small, which might cause an extrusion of the device, nor too wide, in order to limit the risk of oversensing of motion artefacts.
The recordings may be a) triggered by the patient in response to the perception of symptoms, or b) automatic upon the sensing of a bradycardia or tachycardia. In the case of patient-triggered recordings, a clear visualization of P, R and T waves facilitates the recognition of VT versus supraventricular tachycardia, as well as the distinction of sinus pauses versus atrioventricular block. Since automatic recordings rely strictly on the analysis of the ventricular rhythm and count of the R waves, their specificity can easily be lowered by the oversensing of P and T waves.
Therefore, at the time of device implantation, it is critically important to emphasize 1) the sensing of high-amplitude R waves, 2) a reliable visualization of P and T waves, while maintaining high R/T and R/P ratios, and 3) the occurrence of minor variations in the amplitude and morphology of the sensed ventricular signals.
The ILR kit contains a Reveal Vector Check, a mapping tool, which allows the detection of an optimal position without contaminating the device. Data collection must be activated with the programmer before proceeding with the mapping procedure.


REVEAL XT 9529
Patient :
25.0 mm/s
(1 mV)
3
ECG Reveal
Dérivation II
Dérivation III
16:28:20
25.0 mm/s
16:28:27
25.0 mm/s
Fin

Patient :


25.0 mm/s
(1 mV)
2
ECG
Dérivation II
Dérivation III
16:27:46
25.0 mm/s
16:27:53
25.0 mm/s
Fin


REVEAL XT 9529
Patient :
25.0 mm/s
(1 mV)
3
ECG Reveal
Dérivation II
Dérivation III
16:28:20
25.0 mm/s
16:28:27
25.0 mm/s
Fin


REVEAL XT 9529
Patient :
25.0 mm/s
(1 mV)
4
ECG Reveal
Dérivation II
Dérivation III
16:30:44
25.0 mm/s
16:30:51
25.0 mm/s
Fin

## Recording 2

### Representative case

A 62-year-old man presented with recurrent, malignant, vagal syncope, including a few episodes complicated by traumas. A tilt-table test elicited a mixed vasodilatory and bradycardia response. A ILR was implanted in hope of observing a spontaneous episode.

### ILR recording

The patient suffered a syncopal episode preceded by diaphoresis and sensation of warmth upon lying down after breakfast. His wife, who witnessed the episode, confirmed that the patient was unconscious for several dozens of seconds. The automatic recording, activated neither by the patient nor by his wife, diagnosed a 24-sec long asystole; the device was programmed to record > 3 sec asystolic events.

1: normal sinus rhythm;
2: acceleration of sinus rhythm;
3: slowing sinus rhythm;
4: prolonged sinus pause; the tracing is of high quality, as the patient was in a lying position, and remained free from muscle artefacts;
5: AD: detection of asystole;
6: first junctional escape (B) followed by 4 junctional complexes;
7: return of sinus rhythm.

### Comments

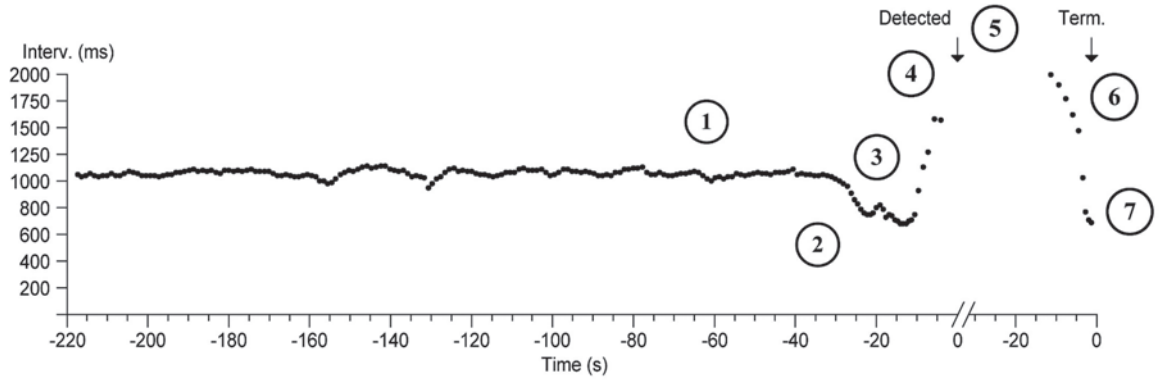
The ILR allows correlations between ECG and symptoms, though does not monitor arterial pressure or cerebral perfusion. The ISSUE classification was developed from the analysis of ILR records in attempt to identify the pathophysiologic mechanisms of syncope. This patient's ECG was a typical Class IA recording, including acceleration of sinus rate, followed by bradycardia and, finally, a long sinus pause. These observations, made in typical circumstances (in this case a meal) strongly suggest a vagal mechanism. Whether cardiac pacing is indicated for patients suffering from major, recurrent, vagally-mediated syncope, is controversial. It is now clear that pacing cannot be expected to be effective when the mechanism of syncope is vasodilatation, and loss of consciousness is due to a fall in arterial pressure. It seems, therefore, appropriate to strictly reserve pacing for patients who develop profound bradycardia. The identification of the culpable mechanism is, therefore, a critical stage of the diagnosis-making process, as well as indispensable information to plan the therapy. Furthermore, the results of tilt-table or ATP tests are weakly correlated with the implantable Holter records obtained at the time of a spontaneous episode of syncope. It does not seem appropriate, therefore, to recommend the implantation of a pacemaker for vagally-mediated syncope after the observation of a long pause during tilt-table testing. Finally, the ILR serves to either confirm or exclude a bradycardia during a vagallymediated episode. By selecting patients who present with long sinus pauses or prolonged, complete atrioventricular block, the yield of implanting a pacemaker appears much higher than in an unselected population of patients presenting with poorly defined vagally-mediated syncope. In this particular patient, while a vagal mechanism was unequivocal, the pause was of such long duration that, despite the possible complications that are associated with permanent pacing, the implantation of a pacemaker was probably indicated, in hope of lowering the risk of recurrences and gravity of symptoms.

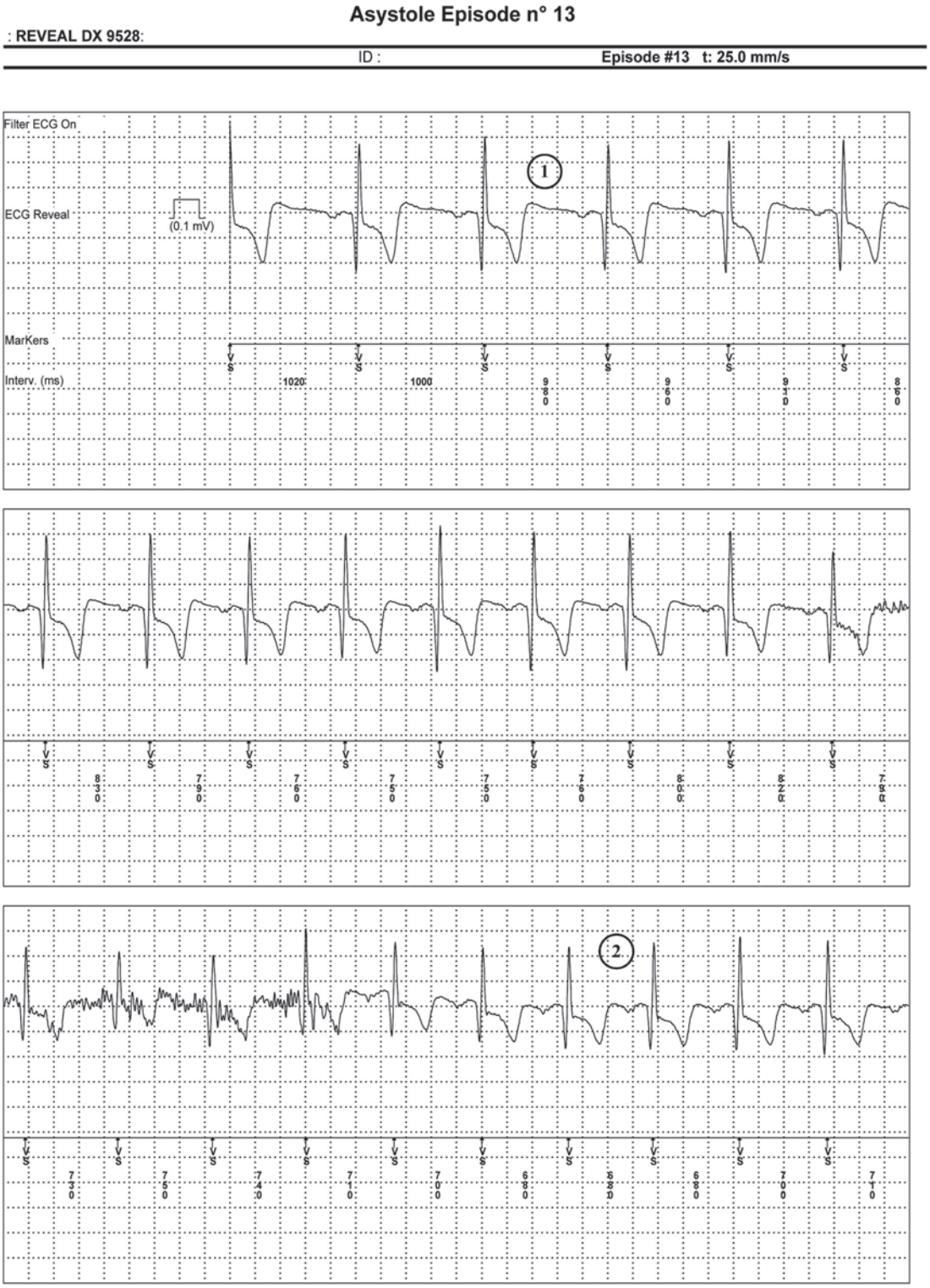
## Asystole Episode n° 13

**REVEAL DX 9528**:

| N° | Type | Date | time hh:mm | Duration hh:mm:ss | Max V Rate | Median V Rate |
|---|---|---|---|---|---|---|
| 13 | Asystole | 08-Jan- | 09:34 | :24 | | 80 bpm (750 ms) |

Asystole = 3.0 s

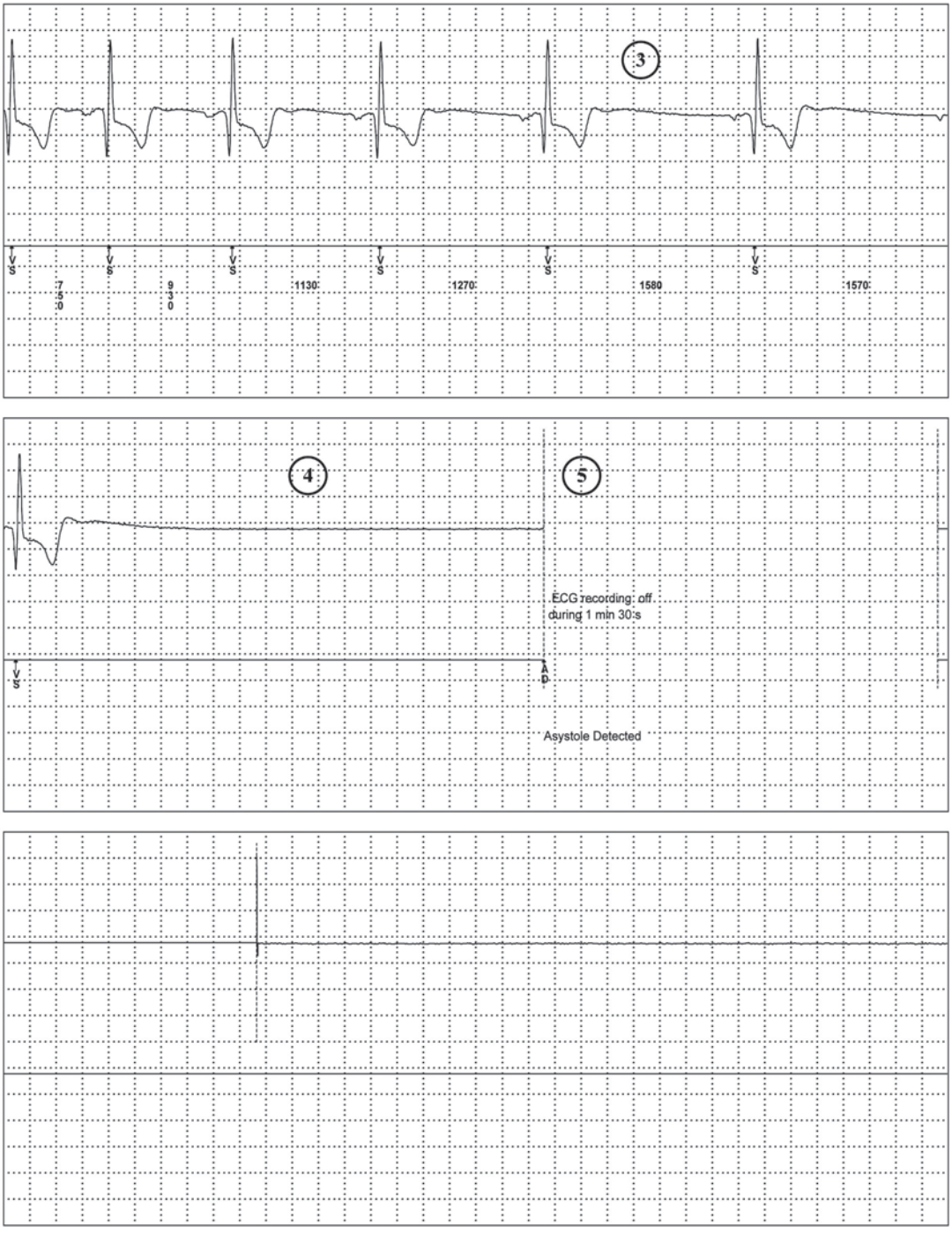


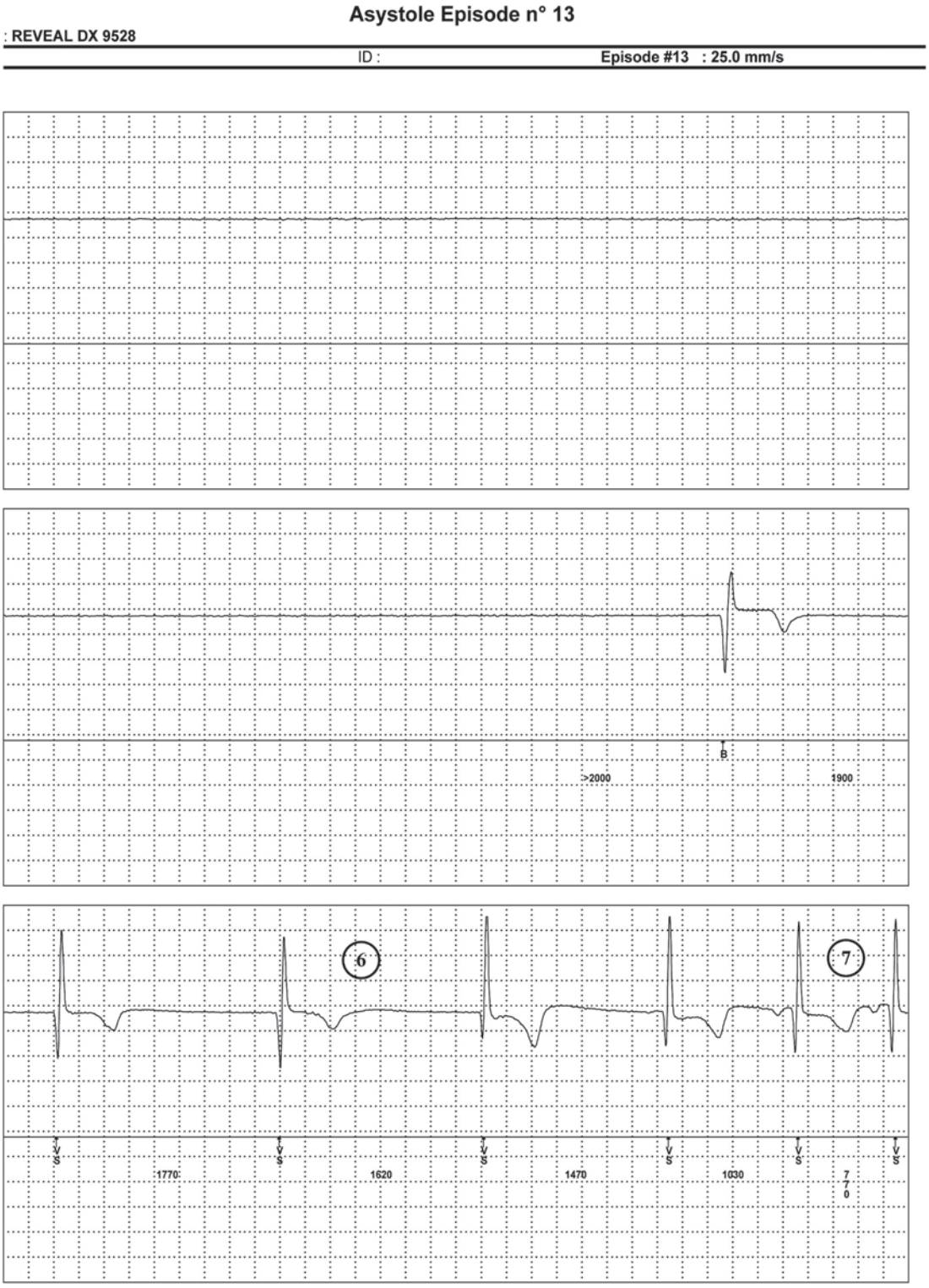

Asystole Episode n° 13
: REVEAL DX 9528:
ID :
Episode #13 t: 25.0 mm/s
Filter ECG On
ECG Reveal
(0.1 mV)
1
MarKers
Interv. (ms)
1020
1000
2

## Asystole Episode n° 13

**REVEAL DX 9528:**

ID : **Episode #13 : 25.0 mm/s**




Asystole Episode n° 13
: REVEAL DX 9528
ID :
Episode #13 : 25.0 mm/s
>2000
1900
6
7
1770
1620
1470
1030
7
7
0

## Asystole Episode n° 13

**REVEAL DX 9528**

ID : Patient :

**Episode #13:03**

**Episode**

| | |
|---|---|
| Type | Asystole |
| Duration | 24.0 s |
| Median V. Rate | 80 bpm (750 ms) |
| Activity Level | Inactive |

| Parameter Settings | ECG recording | Duration |
|---|---|---|
| Asystole | On | 3.0 s |

**Sensing**

| | |
|---|---|
| Sensitivity | 0.035 mV ( 35 µV ) |
| Sensing Threshold Decay Delay | 150 ms |

## Recording 3

### Representative case

A 48-year-old man presented with a several-year history of multiple syncopal events occurring in circumstances of enhanced vagal activity, such as after meals, or in church. The episodes were associated with prodromes, including perspiration and a sensation of warmth. He presented after 2 recent episodes of sudden loss of consciousness without prodrome, the latter complicated by a fall and facial trauma. The surface ECG revealed the presence of right bundle branch block and a tilt-table test elicited a mixed response, with bradycardia to 30 bpm and a precipitous fall in arterial pressure, followed by loss of consciousness. The prodromes were reminiscent of those associated with syncope occurring in the most distant past. Electrophysiologic studies revealed the presence of a borderline HV interval at 68 ms. Because of the changes in the severity of symptoms and the borderline HV interval, a Reveal DX Holter was implanted. This patient is currently being remotely followed.

### ILR recording

The remotely transmitted episode corresponded to the spontaneous symptoms reported by the patient. The recording was triggered by syncope preceded by postprandial prodromes. The graph provides an overall illustration of the episode, while the ECG recording allows a more precise diagnosis:

1: the sinus rhythm is nearly regular at 60 bpm, with visible P waves, albeit low in amplitude;
2: noise was sensed, with a very short RR interval (FS), which, when repetitive, is ignored by the device (ignored); the VR annotation indicates sensing during the ventricular refractory period. When several events are sensed consecutively in the refractory period, the interval is classified as a noisy interval. VS annotates an event that ends a noisy episode.
3: rate acceleration to approximately 110 bpm. The mediocre quality of the recording with presence of noise and prominent variations in the ventricular electrograms are noteworthy;
4: >3-sec asystole. The noisy baseline probably reflects the fall associated with syncope. While it is unclear whether the diagnosis is a sinus pause versus complete atrioventricular block, the former seems more likely, as conducted P waves are visible in absence of atrioventricular block; the double counting of ventricular electrograms is noteworthy;
5: return of normal sinus rhythm;
6: device activation by the patient (Symptom).

### Comments

This and the previous recording have similarities. While the quality of this tracing is lower, complicating the distinction between atrioventricular block and sinus node dysfunction, the sinus rate accelerates before what appears to be a sinus pause considerably shorter than in the previous example. Thus, this tracing belongs to the IA classification of ISSUE. The clinical circumstances and the recording strongly suggest a vagally-mediated episode. However, whereas in the previous patient the length of the pause and frequent occurrence of the episodes seemed to support the implantation of a pacemaker, in this patient this recommendation was less clear.

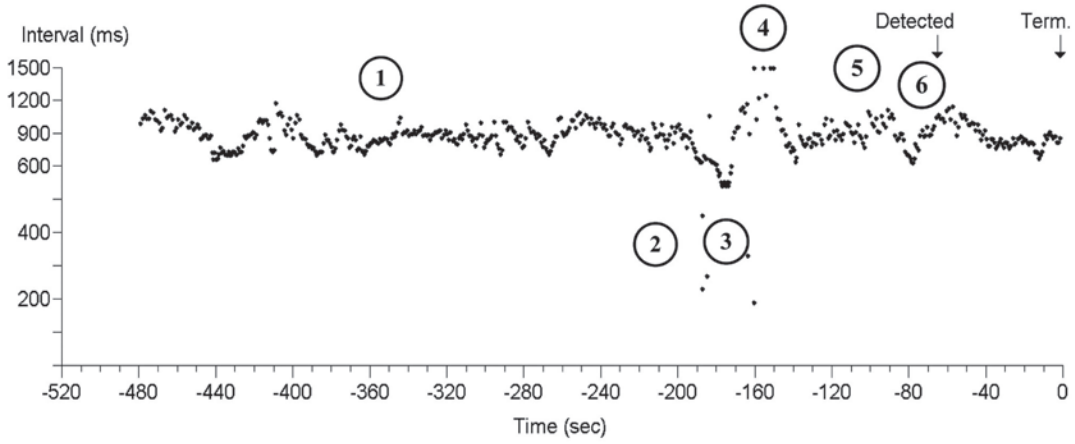
Some elements, in this case, were against the implantation of a pacemaker: 1) the patient was young and the risk of long-term complications was high; 2) while the mechanism of syncope and bradycardia was clearly vagal, the pause was not particularly long; 3) in these cases, the efficacy of permanent pacing has not been confirmed, although, on the short term, the ISSUE 3 study suggested a benefit. The point highlighted by this and the following cases, is the importance of a decision to implant a pacemaker based on the clinical context and individual characteristics of each patient, including when a pause is recorded at the time of a symptomatic event

Medtronic

## SYMPTOM Episode #31

Device: **Reveal® DX 9528** Serial Number: Date of Interrogation:**3**

| ID# | Type | Date | Time hh:mm | Duration hh:mm:ss | Max V. Rate | Median V. Rate |
|---|---|---|---|---|---|---|
| 31 | SYMPTOM | 08-Nov | 23:42 | | | |

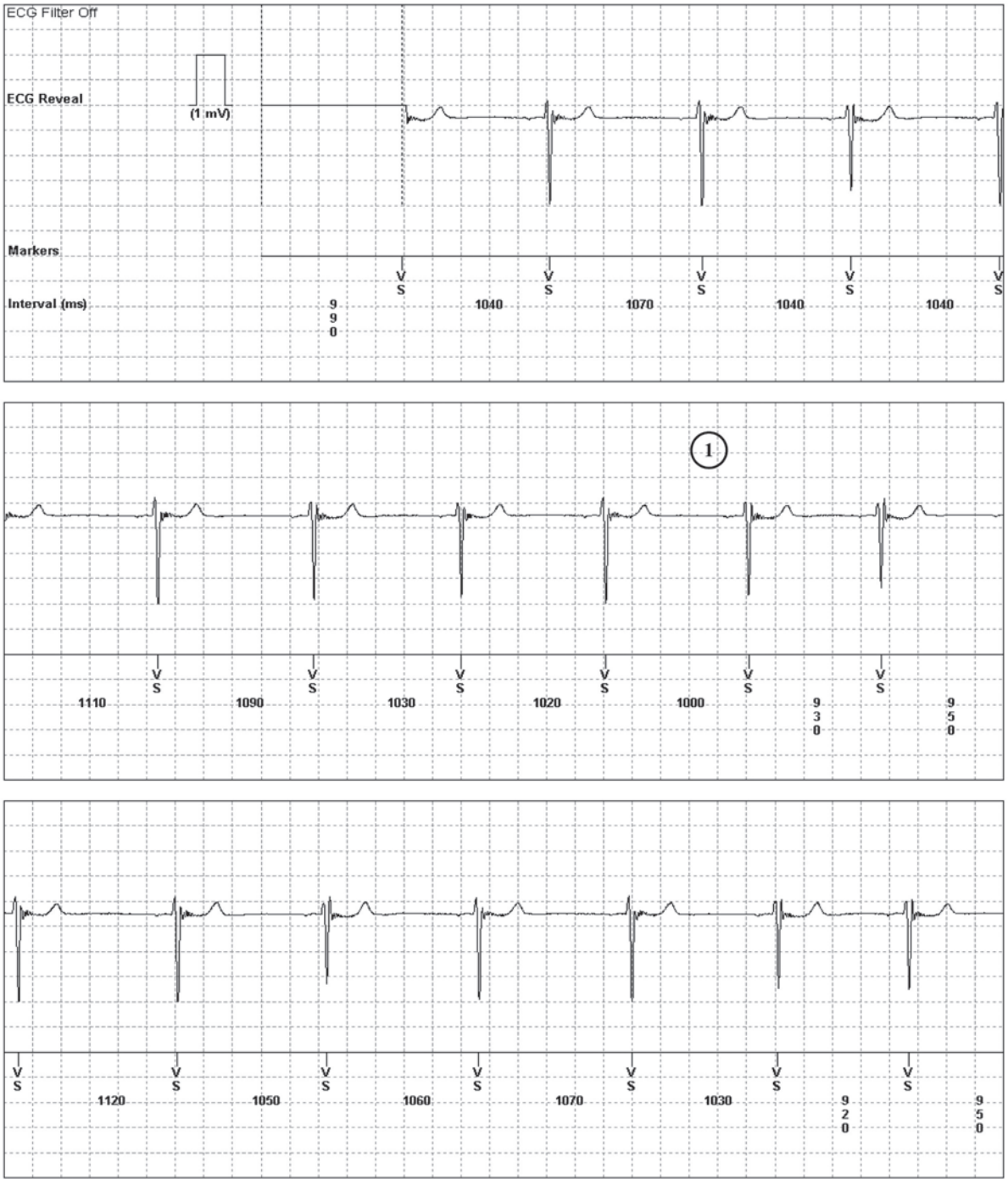


Medtronic

## SYMPTOM Episode #31

Device: **Reveal® DX 9528** Serial Number: Date of Interrogation:

Episode #31 **Chart speed: 25.0 mm/sec**

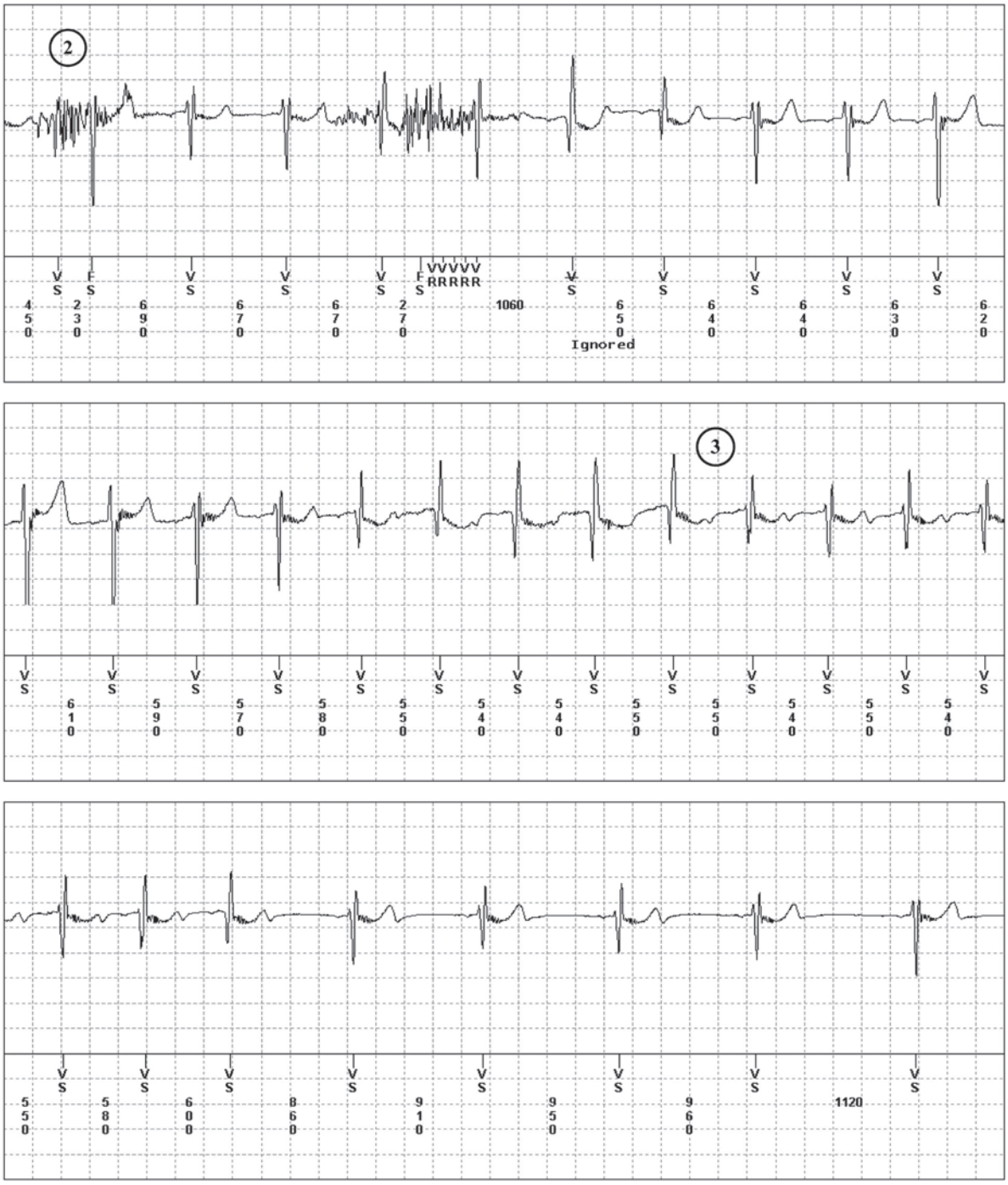


Medtronic

## SYMPTOM Episode #31

Device: **Reveal® DX 9528** Serial Number: Date of Interrogation:

Episode #31 **Chart speed: 25.0 mm/sec**

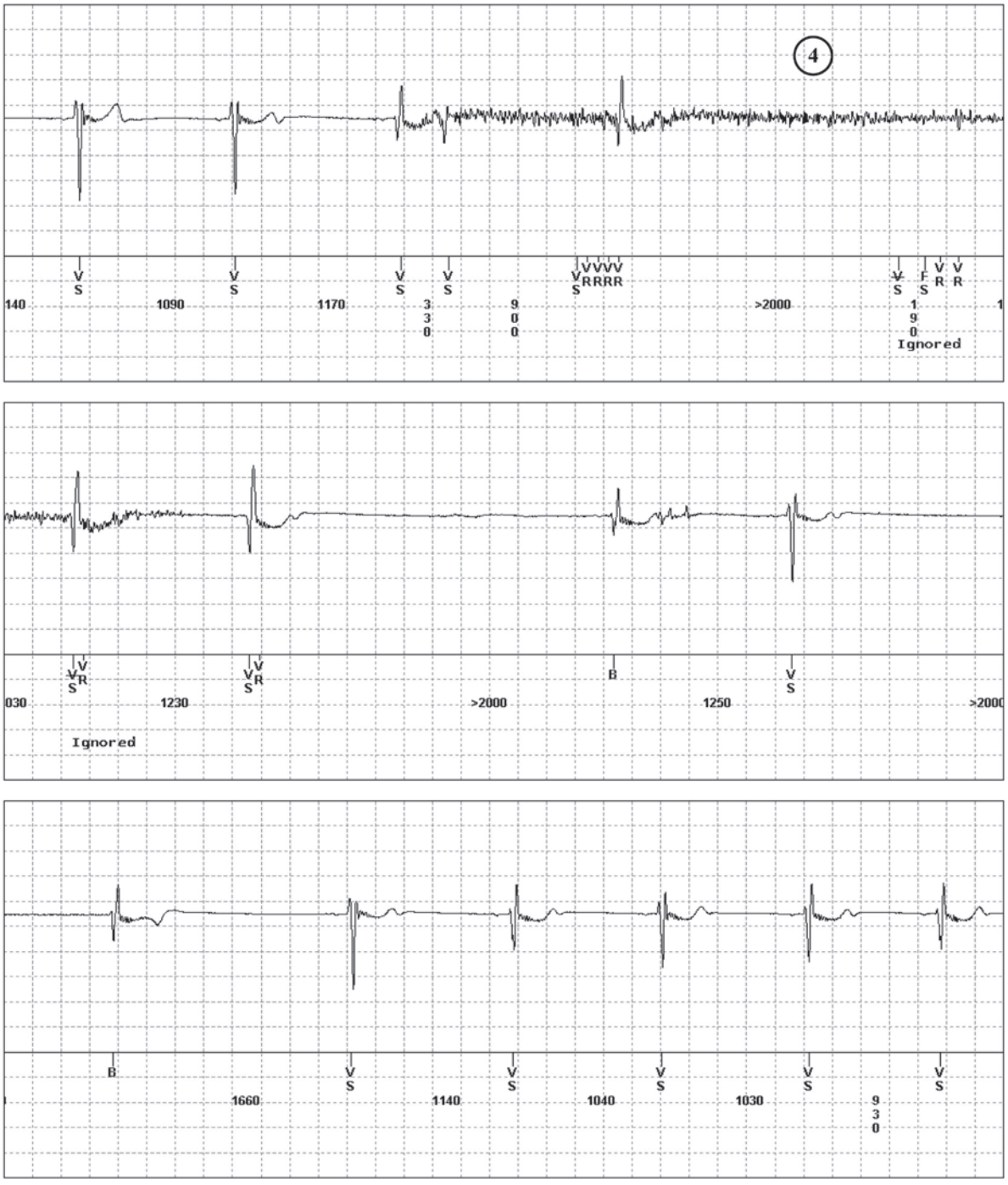


Medtronic

## SYMPTOM Episode #31

Device: **Reveal® DX 9528** Serial Number: Date of Interrogation:

Episode #31 **Chart speed: 25.0 mm/sec**

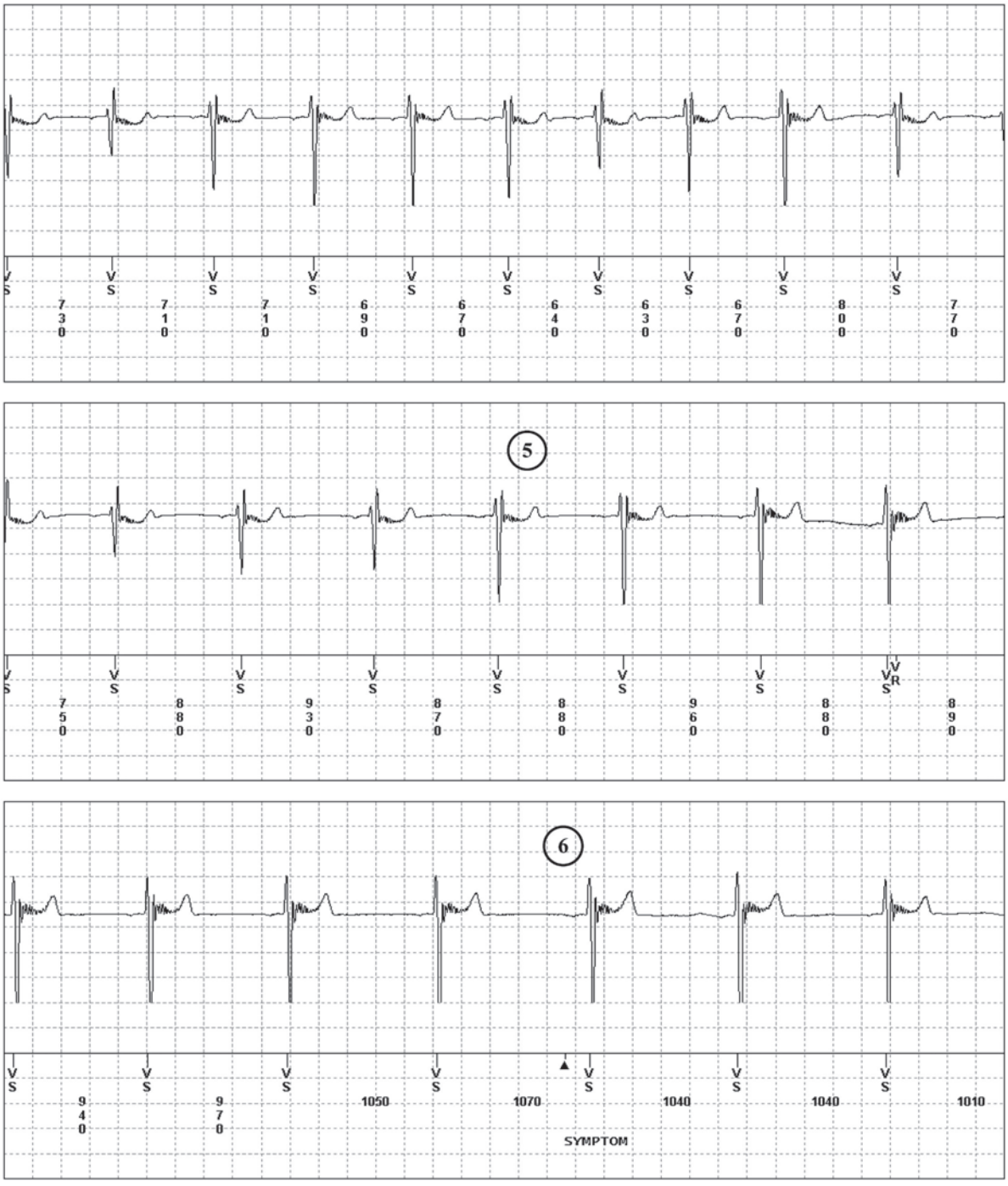


Medtronic

## SYMPTOM Episode #31

Device: **Reveal® DX 9528** Serial Number: Date of Interrogation:

Episode #31 **Chart speed: 25.0 mm/sec**



## Recording 4

### Representative case

An 81-year-old woman presented with 2 sudden episodes of syncope without trauma. The ECG reveals normal PR and QRS intervals at 190 and 95 ms, respectively. A 48-h ambulatory ECG was normal. Electrophysiologic studies revealed no intra or infra-hisian block. A Reveal DX Holter was implanted.

### ILR recording

The patient suffered an episode of syncope with facial trauma. Since the patient was unable to record the episode, the following information was automatically collected by the device:

1: normal sinus rhythm with 1/1 conduction, a normal PR interval and a narrow QRS;
2: Slight lengthening of the PR interval;
3: development of 2:1 2nd degree atrioventricular block;
4: Several consecutive P waves were blocked, with diagnosis of bradycardia (B);
5: detection of asystole (AD).

### Comments

This clinical and electrocardiographic presentation corresponds probably to idiopathic paroxysmal atrioventricular block with 1) several episodes of unexplained syncope without clear trigger, 2) an initial ECG that shows no conduction abnormality, 3) absence of structural heart disease, 4) observation, in the wake of syncope, of sudden complete atrioventricular block, without marked increase in the PR interval or change in heart rate preceding the episode. In this patient, the increase in PR interval before the pause is minimal, and the heart rate remains stable, while the atrial rate accelerates moderately at the time of the pause.

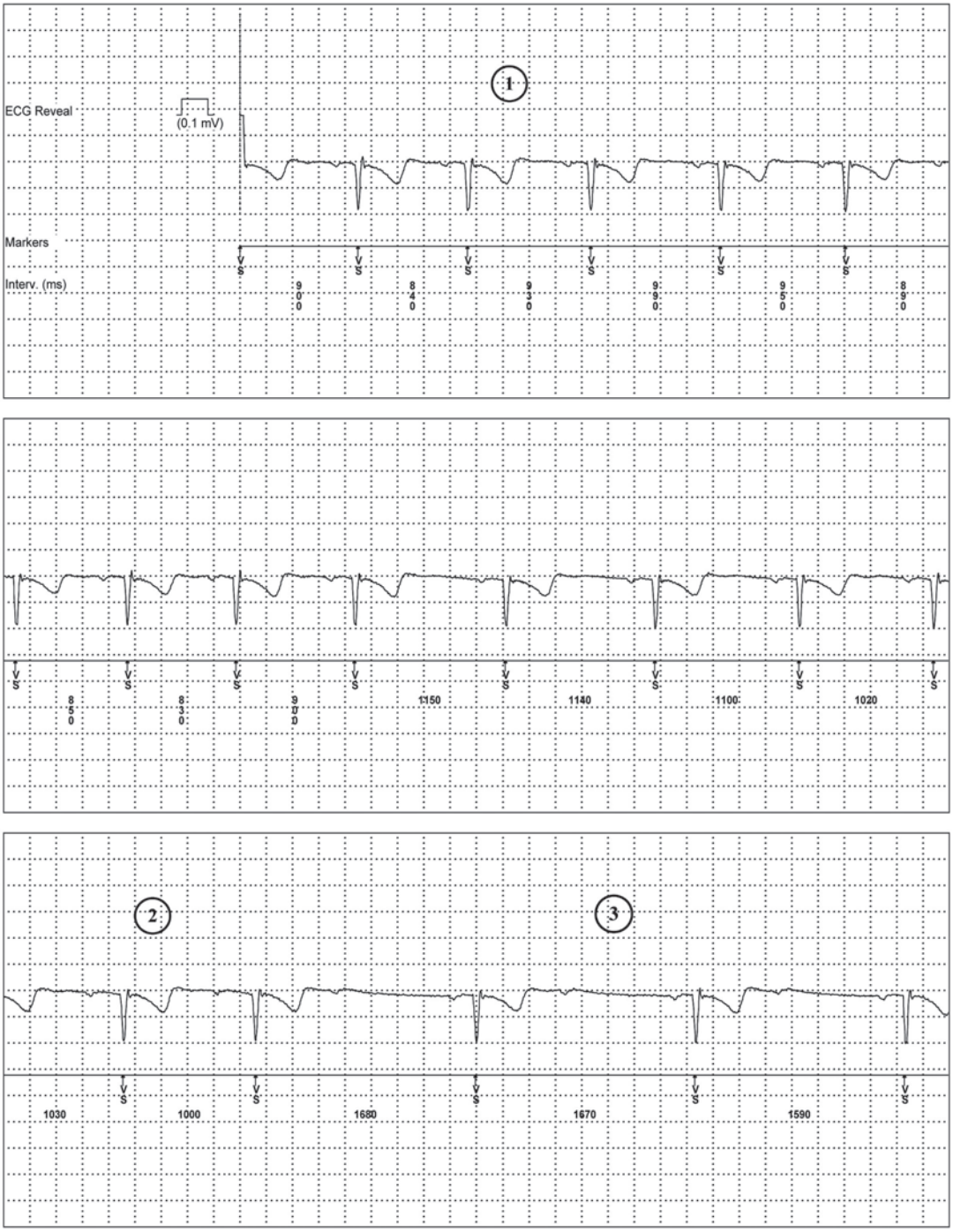
The ILR revealed a conduction disorder previously difficult to demonstrate. This patient underwent implantation of a pacemaker, which prevented further recurrences. Permanent pacing has been uniformly effective in similar cases published in the medical literature. This clinical case highlights the advantages and limitations of this type of device. On the one hand, a diagnosis was made after recurrence of syncope complicated by facial trauma. On the other, it seemed unacceptable to proceed with a pacemaker implant as a first step in this patient, whose ECG was normal and electrophysiologic studies non-contributory.

The activation of the ILR after the onset of an episode, using the patient assistant, may be impossible by patients who have 1) suffered a trauma and are temporarily motionless or stunned by a fall, 2) a permanent cognitive disorder, or 3) limited mobility or manual dexterity. In such cases, an automatic recording may allow the making of a diagnosis, as illustrated here.

## Asystole Episode n° 3

Device: **REVEAL DX 9528** Serial Number :

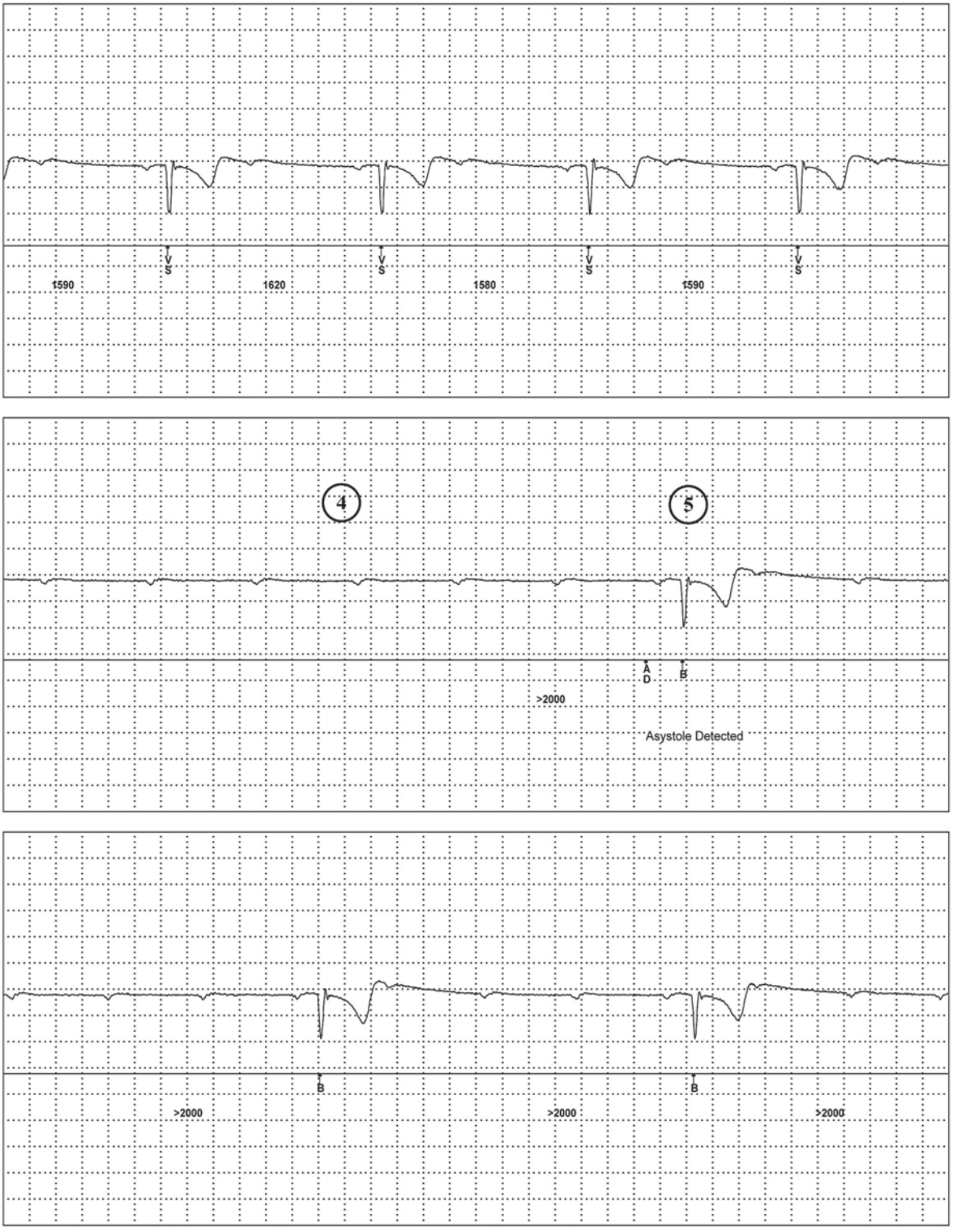
ID : **Episode #3 : 25.0 mm/s**



## Asystole Episode n° 3

Device : **REVEAL DX 9528** Serial Number Date :

ID : **Episode #3 25.0 mm/s**



## Recording 5

### Representative case

A 63-year-old man suffering from ischemic cardiomyopathy, old anterior myocardial infarction with a 48% LVEF, non-specific bundle branch block and 120-ms QRS duration, underwent negative electrophysiologic studies and programmed ventricular stimulation after a sudden episode of syncope. A Reveal DX Holter was implanted.

### ILR recording

This patient suffered 3 syncopal episodes within 2 days, of which one was complicated by trauma. He triggered a recording for the 3rd episode only, labelled "symptom" on the episodes log. The first 2 syncopal episodes coincided with both episodes diagnosed as VT. The analysed episode, diagnosed as VT by the device, lasted over 1 min, at a mean rate of 200 bpm. It is noteworthy that the device programming is similar to that of an ICD, including 1 VT and 1 FVT zone, and a discrimination algorithm with sudden onset and stability operating like in an ICD. Sensing is also similar to that of an ICD, with a programmed post VS refractory period of 150 ms, and a 150 ms plateau from where sensitivity increases (the value decreases) to a highest programmable of 0.035 mV.

1: sinus rhythm;
2: wide ventricular extrasystoles isolated or in triplets with ≥3 different morphologies;
3: ventricular extrasystole with sudden onset of a wide complex, regular tachycardia at 200 bpm;
4: TD: detection of a VT episode by the device; the rate, sudden onset and stability criteria were fulfilled, prompting the diagnosis of VT, which is highly probable given the clinical presentation, and the ECG characteristics of wide QRS and probable atrioventricular dissociation;
5: spontaneous termination after over 1 min of tachycardia.

### Comments

This was a Class 4D syncope (VT) in the ISSUE classification. The identification of a ventricular tachyarrhythmia in the wake of syncope is relatively rare after detailed investigations, including programmed ventricular stimulation. A depressed LVEF and the inducibility of a tachycardia are the 2 most reliable predictors of a ventricular arrhythmia causing syncope. Therefore, this patient's presentation was relatively atypical. The confirmation of a ventricular arrhythmia causing syncope in this patient presenting with ischemic heart disease is a Class I indication for the implantation of an ICD. This clinical case highlights the high diagnostic value of this type of device, as well as its lack of therapeutic contribution. The diagnosis was made and the patient was appropriately treated after the spontaneous termination of a life-threatening tachyarrhythmia.

## Episodes

Device : **REVEAL DX 9528** : Date :

ID : Patient :

**Episodes:**

| N° | Type | Date | Time hh:mm | Duration hh:mm:ss | Max V Rate | Median V Rate |
|---|---|---|---|---|---|---|
| 11 | SYMPTOM | 23-Fév- | 10:40 | | | |
| 10 | VT | 22-Fév- | 15:26 | :01:25 | 207 bpm (290 ms) | 200 bpm (300 ms) |
| 9 | VT | 22-Fév- | 13:07 | :01:40 | 200 bpm (300 ms) | 200 bpm (300 ms) |
| 8 | Brady | 15-Fév- | 20:46 | :07 | Min = 50 bpm | 50 bpm(1210 ms) |
| 7 | Brady | 13-Fév- | 05:07 | :07 | Min <30 bpm | <30 bpm (>2000 ms) |
| 6 | Brady | 30-Jan- | 04:09 | :10 | Min = 33 bpm | 47 bpm (1280 ms) |
| 5 | Brady | 30-Jan- | 02:57 | :15 | Min <30 bpm | 45 bpm (1330 ms) |
| 4 | Brady | 30-Jan- | 00:55 | :10 | Min = 37 bpm | 52 bpm (1150 ms) |
| 3 | Brady | 30-Jan- | 00:54 | :11 | Min <30 bpm | 43 bpm (1410 ms) |
| 2 | Brady | 30-Jan- | 00:51 | :12 | Min <30 bpm | 50 bpm (1210 ms) |
| 1 | SYMPTOM | 27-Jan | 12:28 | | | |

## VT Episode n° 10

Device : **REVEAL DX 9528** Date

ID : Patient :

**Episode #10**

**Episode Summary**

| | |
|---|---|
| Type | VT |
| Duration | 1.4 min |
| Max V Rate | 207 bpm (290 ms) |
| Median V rate | 200 bpm (300 ms) |
| Average. V. Rate | 200 bpm (300 ms) |
| Activity Level | Inactive |

| Parameters | ECG recorded | Interval V. (fréq.) | Duration |
|---|---|---|---|
| FVT | --- | 60 ms (231 bpm) | 30/40 beats. |
| VT | On | 40 ms (176 bpm) | 16 beats. |

**Detection Enhancements**

| | | |
|---|---|---|
| VT Detection | | |
| | Stability VT | 40 ms |
| | Onset VT | On (81%) |

**Sensing**

| | |
|---|---|
| Sensivity | 0.035 mV ( 35 µV ) |
| Sensing Threshold Dcay Delay | 150 ms |

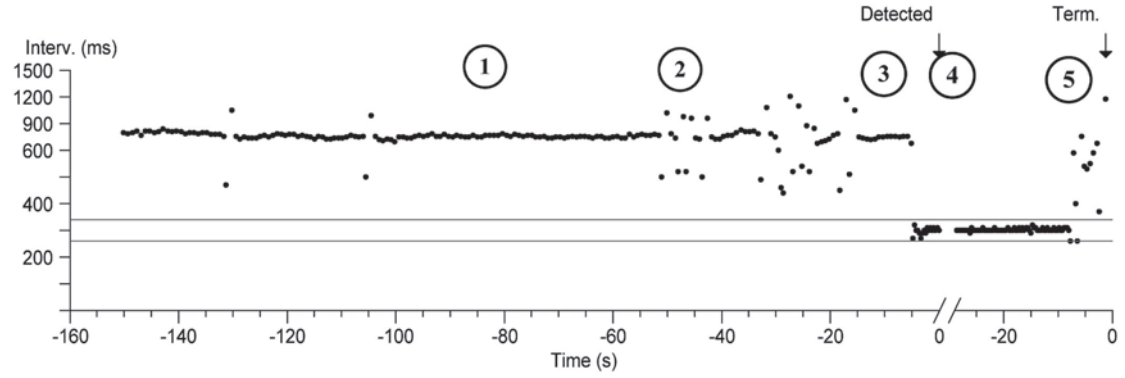
**TV Episode n° 10** Device

: **REVEAL DX 9528** Date :

ID : Patient :

| N° | Type | Date | Time hh:mm | Duration hh:mm:ss | Max V Rate | Median V Rate |
|---|---|---|---|---|---|---|
| 10 | TV | 22-Fév-2012 | 15:26 | :01:25 | 207 bpm (290 ms) | 200 bpm (300 ms) |

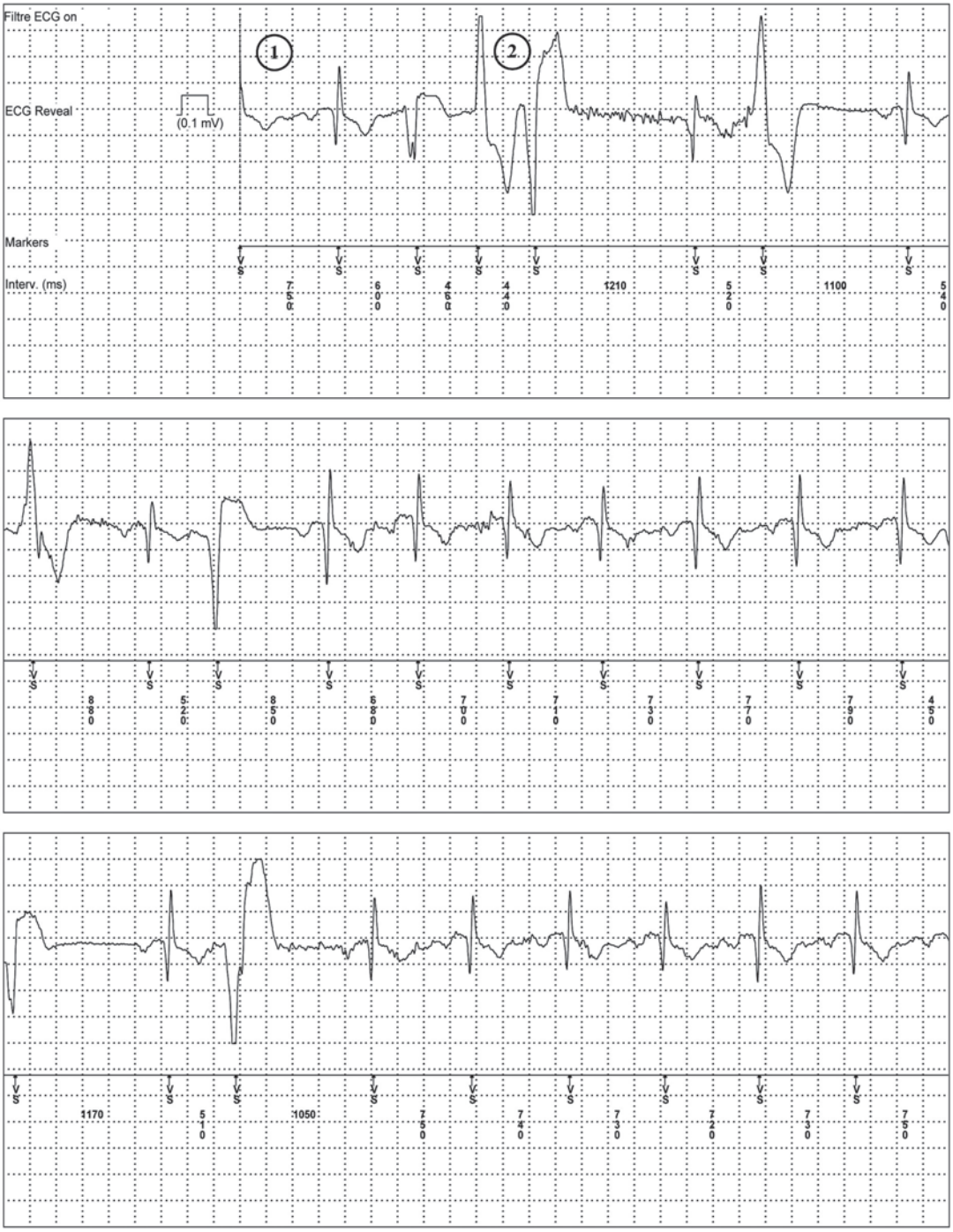
FVT = 260 ms VT= 340 ms

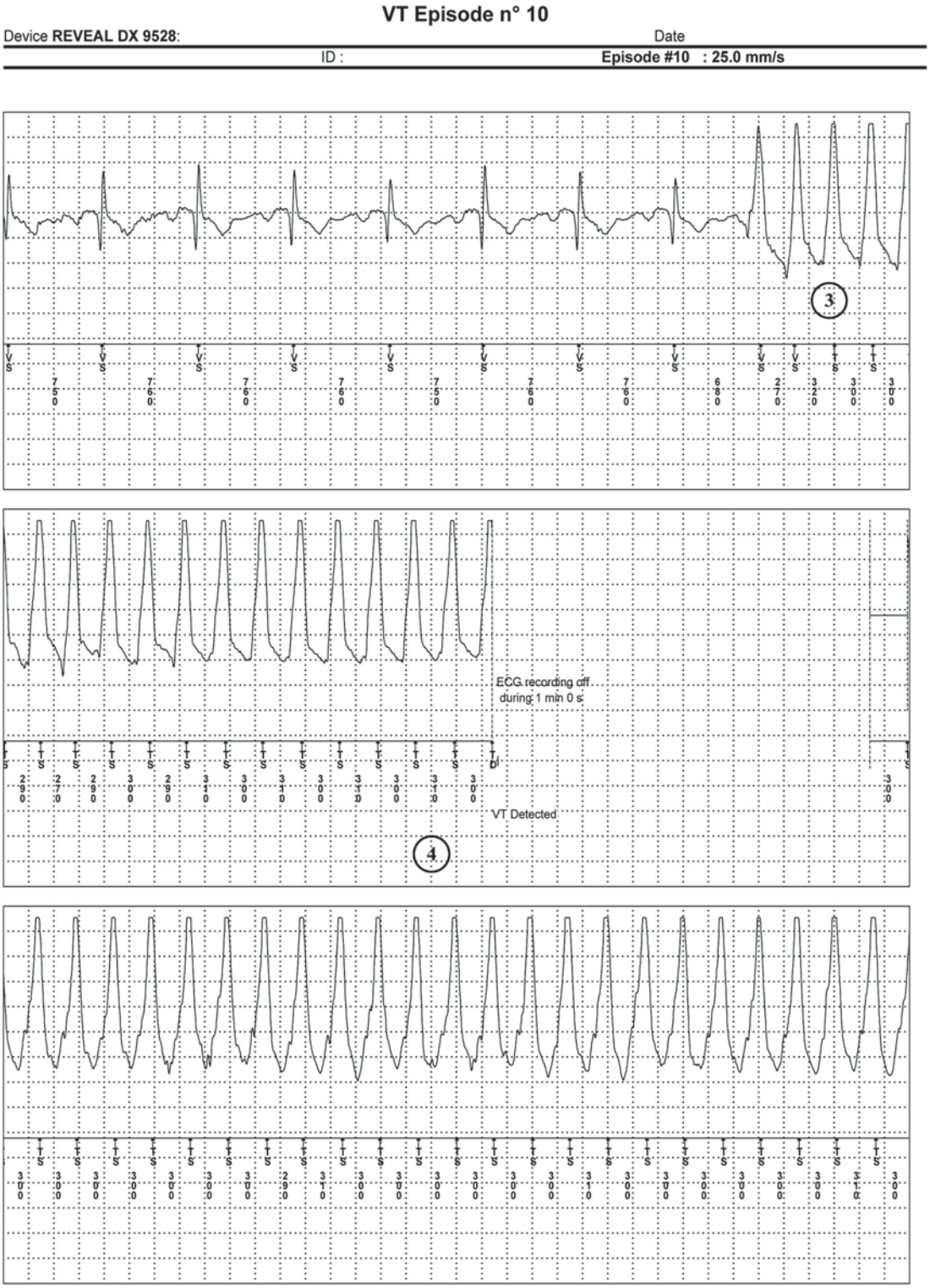


## VT Episode n° 10

Device : **REVEAL DX 9528** Date :

ID : **Episode #10 : 25.0 mm/s**

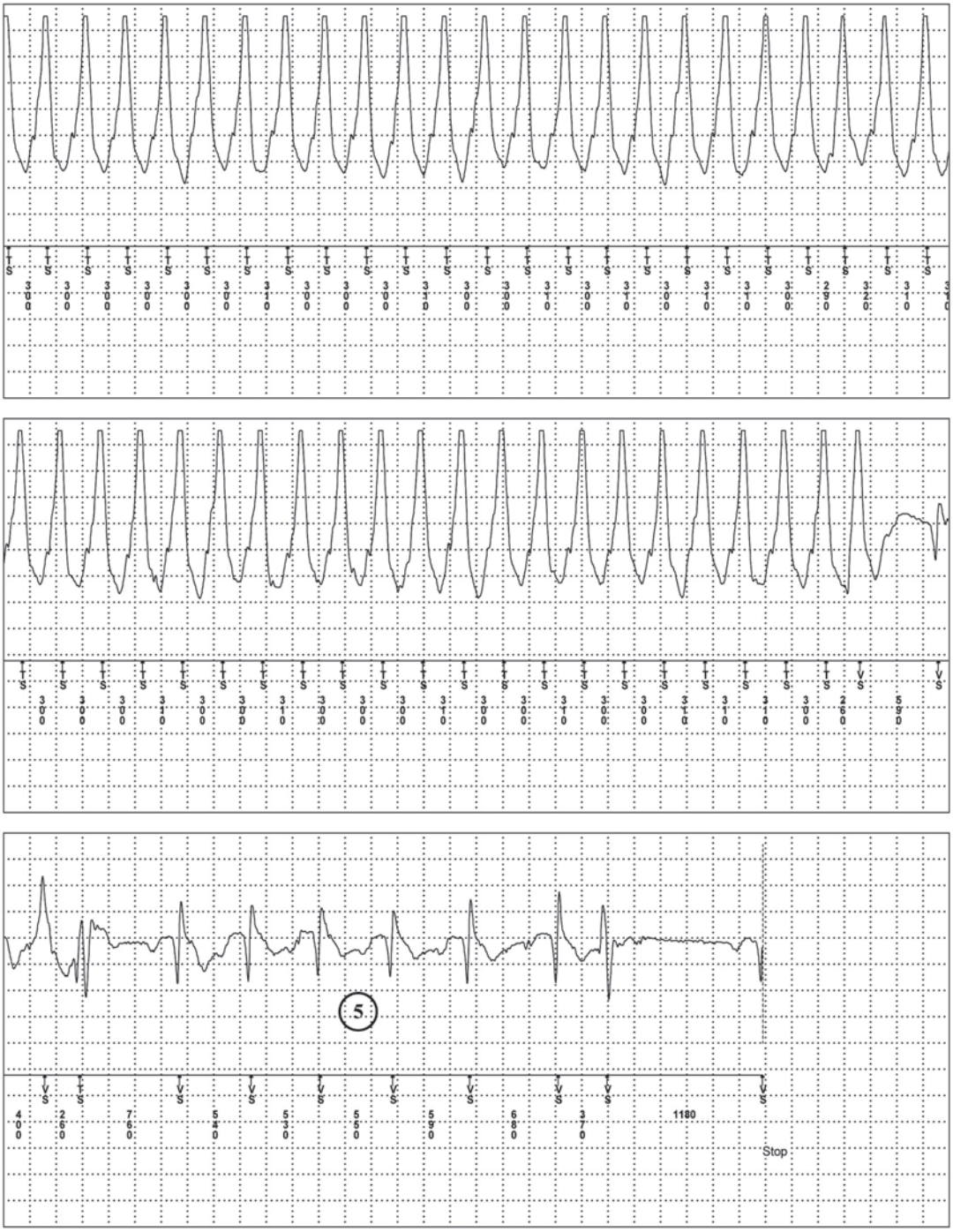



VT Episode n° 10
Device REVEAL DX 9528:
Date
ID :
Episode #10 : 25.0 mm/s
3
ECG recording off
during 1 min 0 s
VT Detected
4

## VT Episode n° 10

Device : **REVEAL DX 9528** Date :

ID : **Episode #10 : 25.0 mm/s**



## Recording 6

### Representative case

A 14-year-old adolescent without personal or family medical history presented after 4 episodes of syncope. Except for early repolarisation in the inferior ECG leads and ventricular extrasystoles originating from the left ventricular outflow tract, all investigations were negative. Following another syncopal episode, antiepileptic therapy was introduced because of electroencephalographic abnormalities and a Reveal DX Holter was implanted because of early repolarisation recently described as a putative predictor of sudden death.

### ILR recording

An event was automatically recorded by the device. The text described an episode detected in the FVT zone, which lasted 5 sec.

1: normal sinus rhythm;
2: prominent ventricular ectopy and bigeminy;
3: polymorphous VT at a rate near 400 bpm;
4: spontaneous termination with persistence of ventricular ectopy.

### Comments

This young patient was treated with quinidine and received an ICD. This case illustrates several important points:
1) He was initially treated with an antiepileptic regimen for recurrent syncope, a common observation in case of catecholamine-mediated VT or congenital long QT syndrome; 2) the ECG showed early repolarisation, a common observation in the healthy population, seriously complicating the risk stratification of sudden cardiac death. The place of the ILR in this context is equally delicate. As in this case, it allows to revisit the diagnosis, eliminate a probably useless antiepileptic treatment, consider a cardiac cause and reorganize the treatment. On the other hand, this episode was particularly concerning, as it evoked a clear risk of fatal outcome. The role of the ILR in the risk of sudden death stratification in patients presenting with Brugada syndrome or early repolarisation remains controversial and in need of further investigation.

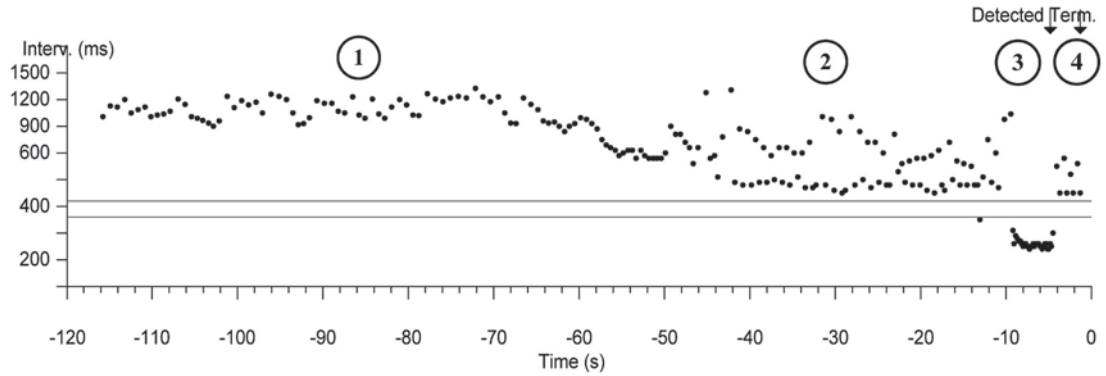
## FVT Episode n° 1

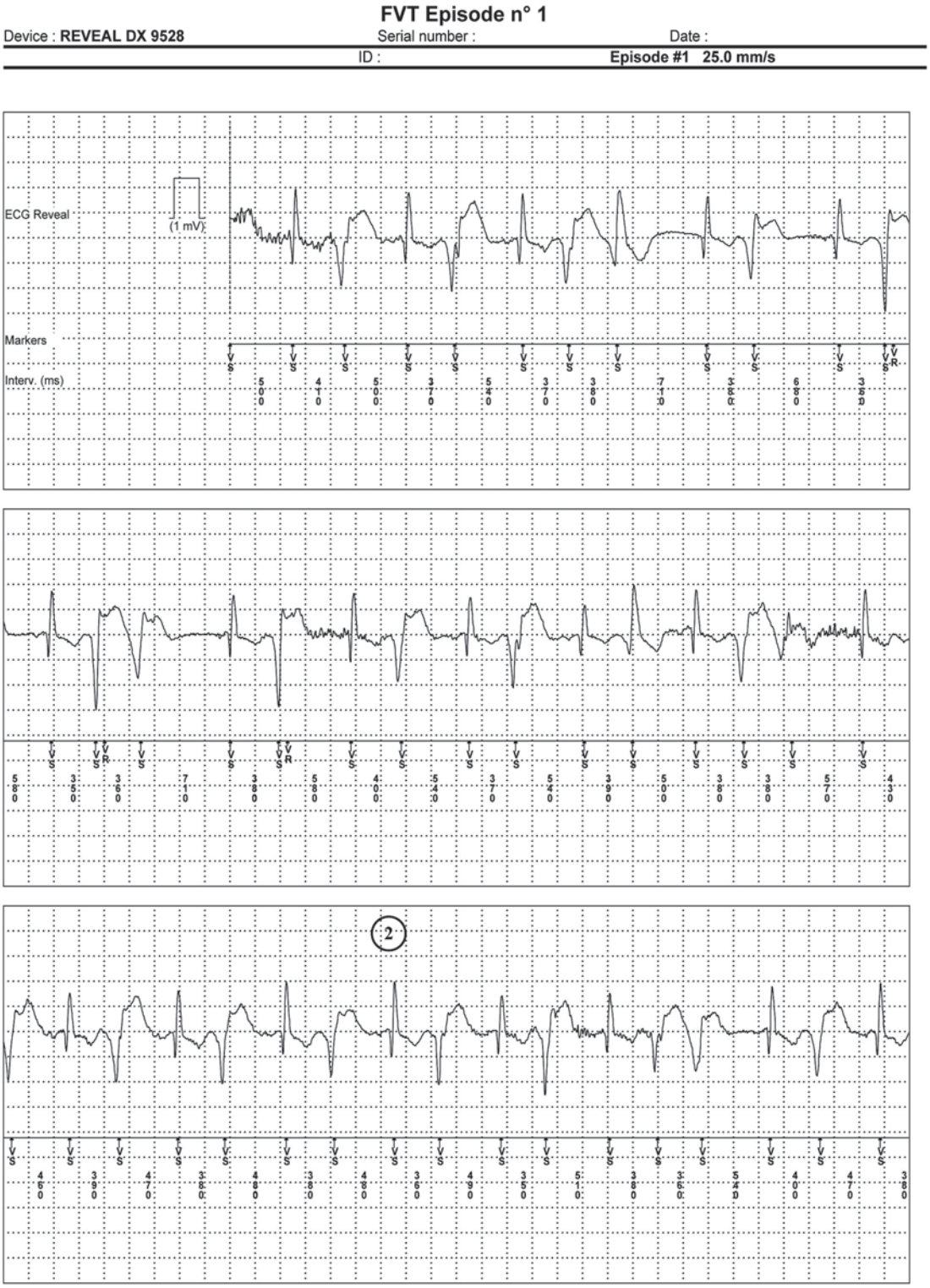
Device : **REVEAL DX 9528**: Date :

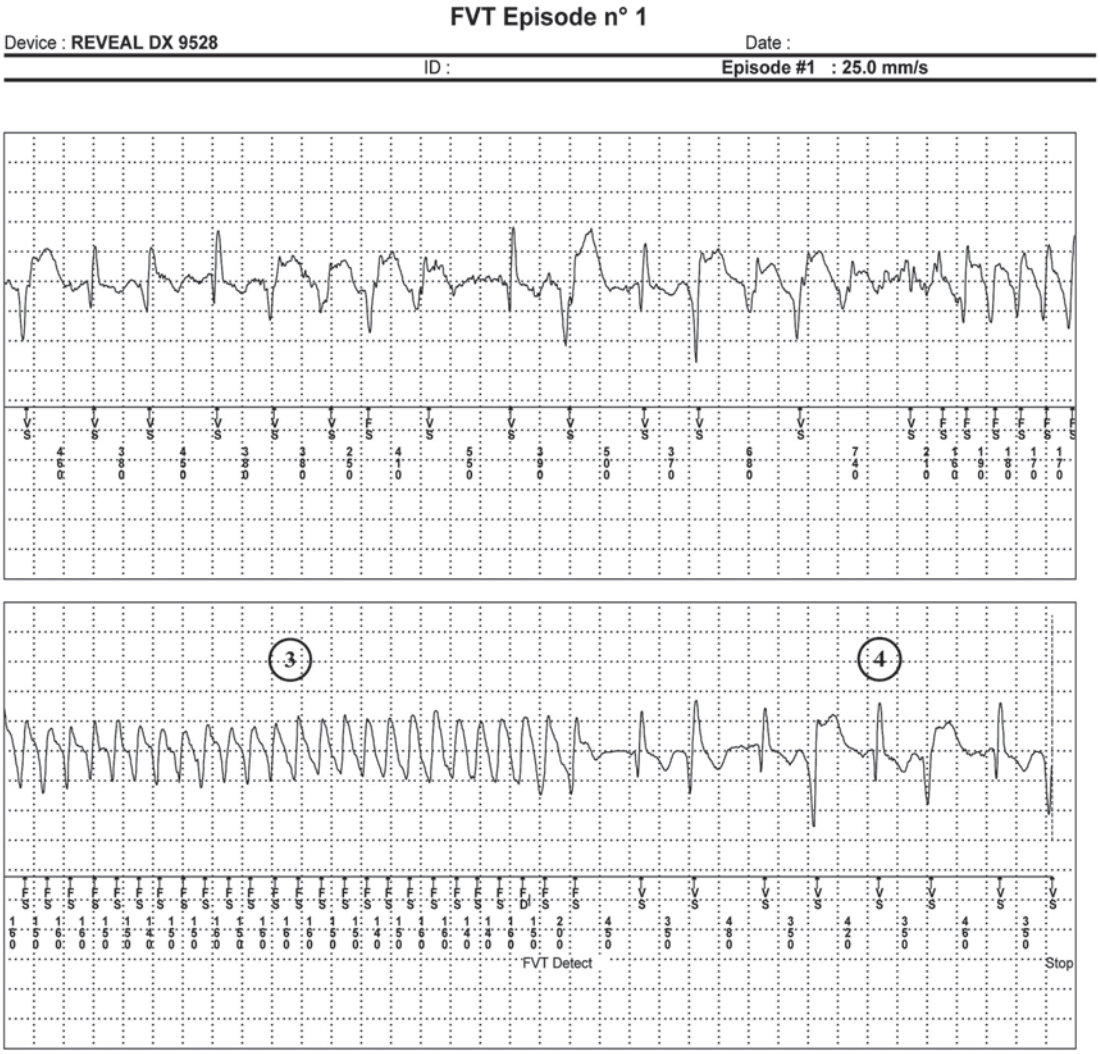
ID : Patient :

| N° | Type | Date | Time hh:mm | Duration hh:mm:ss | Max V Rate | Median V Rate |
|---|---|---|---|---|---|---|

FVT = 260 ms VT = 320 ms




FVT Episode n° 1
Device : REVEAL DX 9528
Serial number :
Date :
ID :
Episode #1 25.0 mm/s
ECG Reveal
(1 mV)
Markers
Interv. (ms)
2


FVT Episode n° 1
Device : REVEAL DX 9528
Date :
ID :
Episode #1 : 25.0 mm/s
3
4
FVT Detect
Stop

## FVT Episode n° 1

Device : **REVEAL DX 9528** Date

ID : Patient :

**Episode #1 :**

**Episode Summary**

| | |
|---|---|
| Type | FVT |
| Duration | 5 s |
| Max V.Rate | 400 bpm (150 ms) |
| Médian V. Rate | 375 bpm (160 ms) |
| Average V. Rate | 400 bpm (150 ms) |
| Activity Level | Active |

| Parameter Settings | ECG recording | Interval V. (rate) | Duration |
|---|---|---|---|
| FVT | On | 260 ms (231 bpm) | 30/40 beats. |
| VT | On | 320 ms (188 bpm) | 16 beats. |

**Detection Enhancements**

| | | |
|---|---|---|
| VT Detection | | |
| | Stability VT | Off |
| | Onset VT | Off |

**Sensing**

| | |
|---|---|
| Sensibility | 0.035 mV ( 35 µV ) |
| Sensing Threshold Decay Delay | 100 ms |

## Recording 7

### Representative case

A 47-year-old, severely depressed man without heart disease complained of multiple atypical episodes of syncope without prodrome, triggering event or trauma. ECG and imaging studies were unremarkable. Under pressure from his relatives, a Reveal DX was implanted and the patient was followed remotely by home monitoring.

### ILR recording

A recording was triggered by the patient following a syncopal event and transmitted via home monitoring.

1: normal sinus rhythm;
2: oversensing of an artefact during a cardiac cycle creating a spurious appearance of short RR;
3: sinus rhythm persisting throughout the recording without change in heart rate;
4: trigger by the patient (symptom).

### Comments

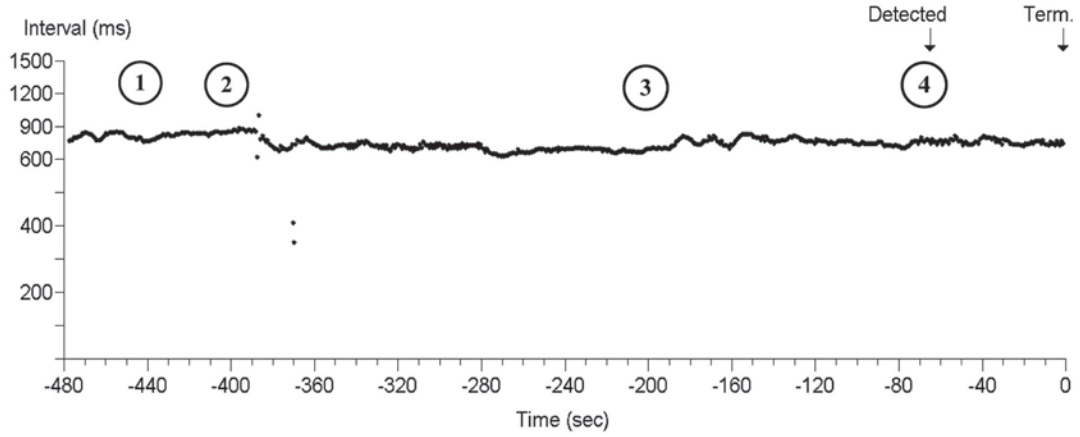
The ILR serves to record an ECG at the time of occurrence of symptoms. A diagnosis is made 1) when a bradycardia is recorded, 2) when a tachycardia is recorded, 3) a normal ECG is recorded, eliminating a bradyarrhythmic cause of syncope. The majority of studies report making the latter observation in approximately 1/3 of ILR recipients who develop a recurrence of syncope, classified as an ISSUE Class 3A episode. This patient suffered several episodes without ECG changes. While this long-term monitoring does not allow the making of a definitive diagnosis, it eliminates a rhythmic cause and reassures the patient, which might be therapeutic. After having explained the results and introduced an antidepressive regimen, the symptoms have gradually abated and the patient has remained syncope-free for the past few months.

Medtronic

## SYMPTOM Episode #3

Device: **Reveal® DX 9528** Date of Interrogation:

| ID# | Type | Date | Time hh:mm | Duration hh:mm:ss | Max V. Rate | Median V. Rate |
|---|---|---|---|---|---|---|
| 3 | SYMPTOM | | | | | |



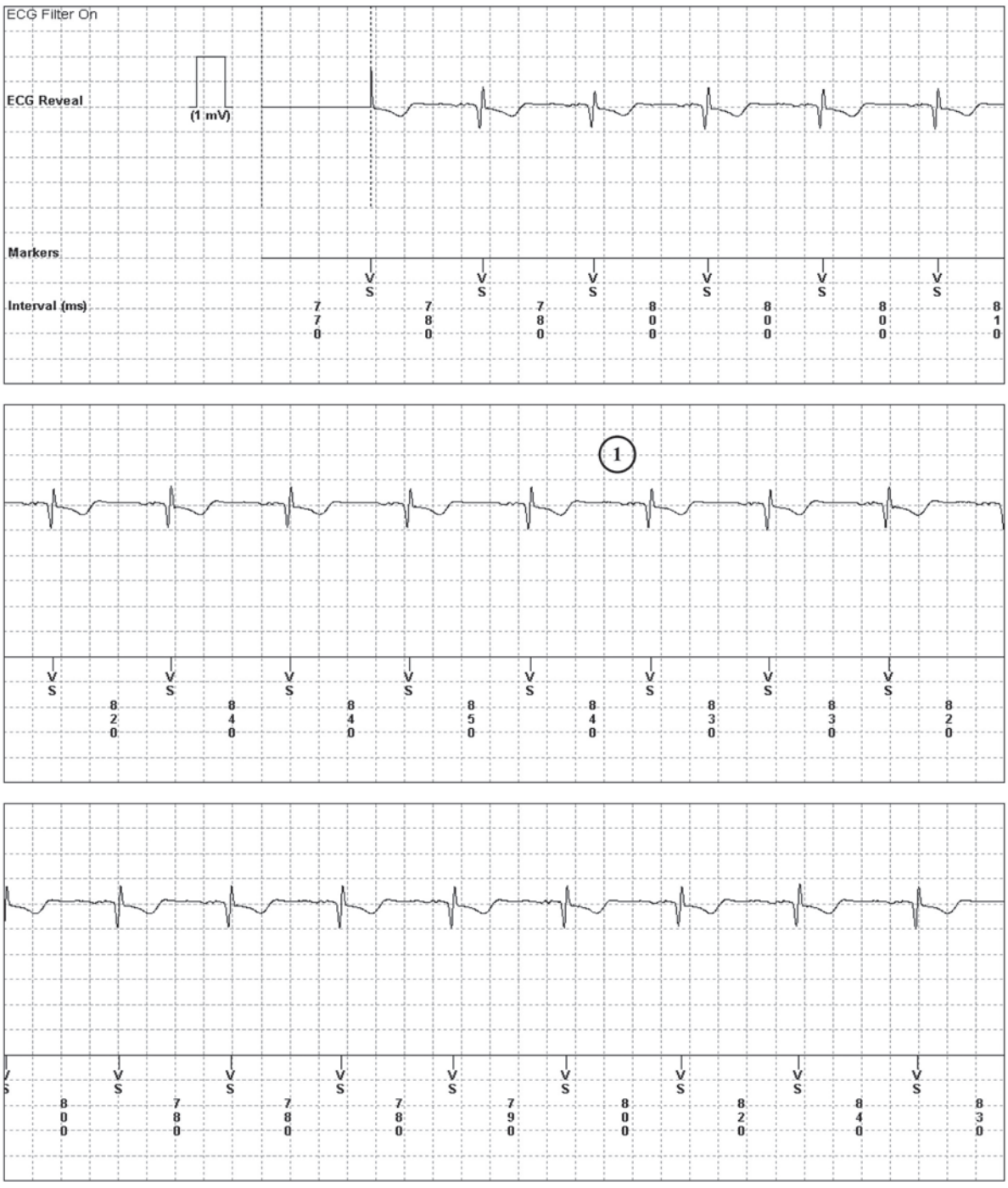
Medtronic

## SYMPTOM Episode #3

Device: **Reveal® DX 9528**

Date of Interrogation:

Episode #3 **Chart speed: 25.0 mm/sec**



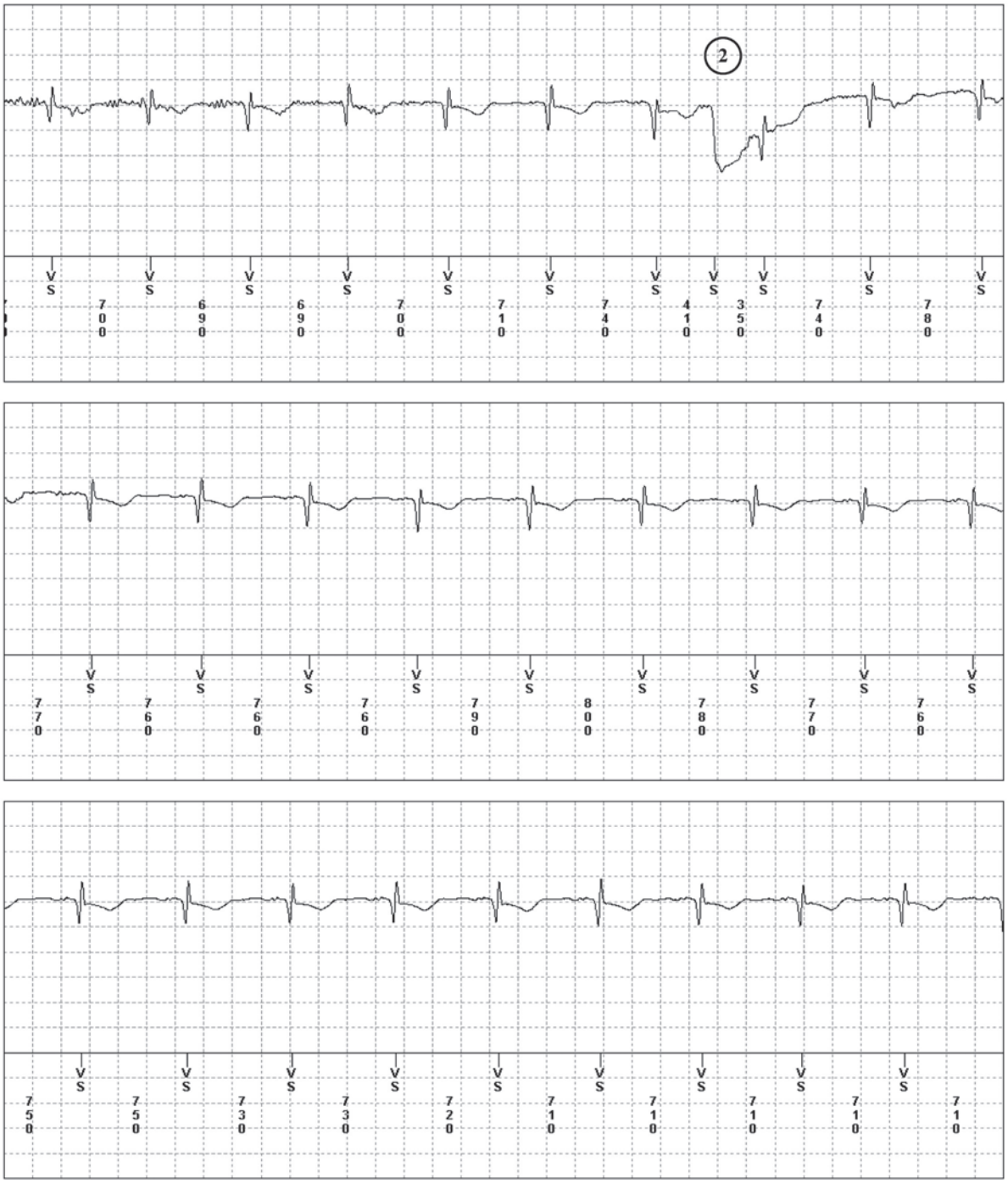
Medtronic

## SYMPTOM Episode #3

Device: **Reveal® DX 9528**

Date of Interrogation:

Episode #3 **Chart speed: 25.0 mm/sec**



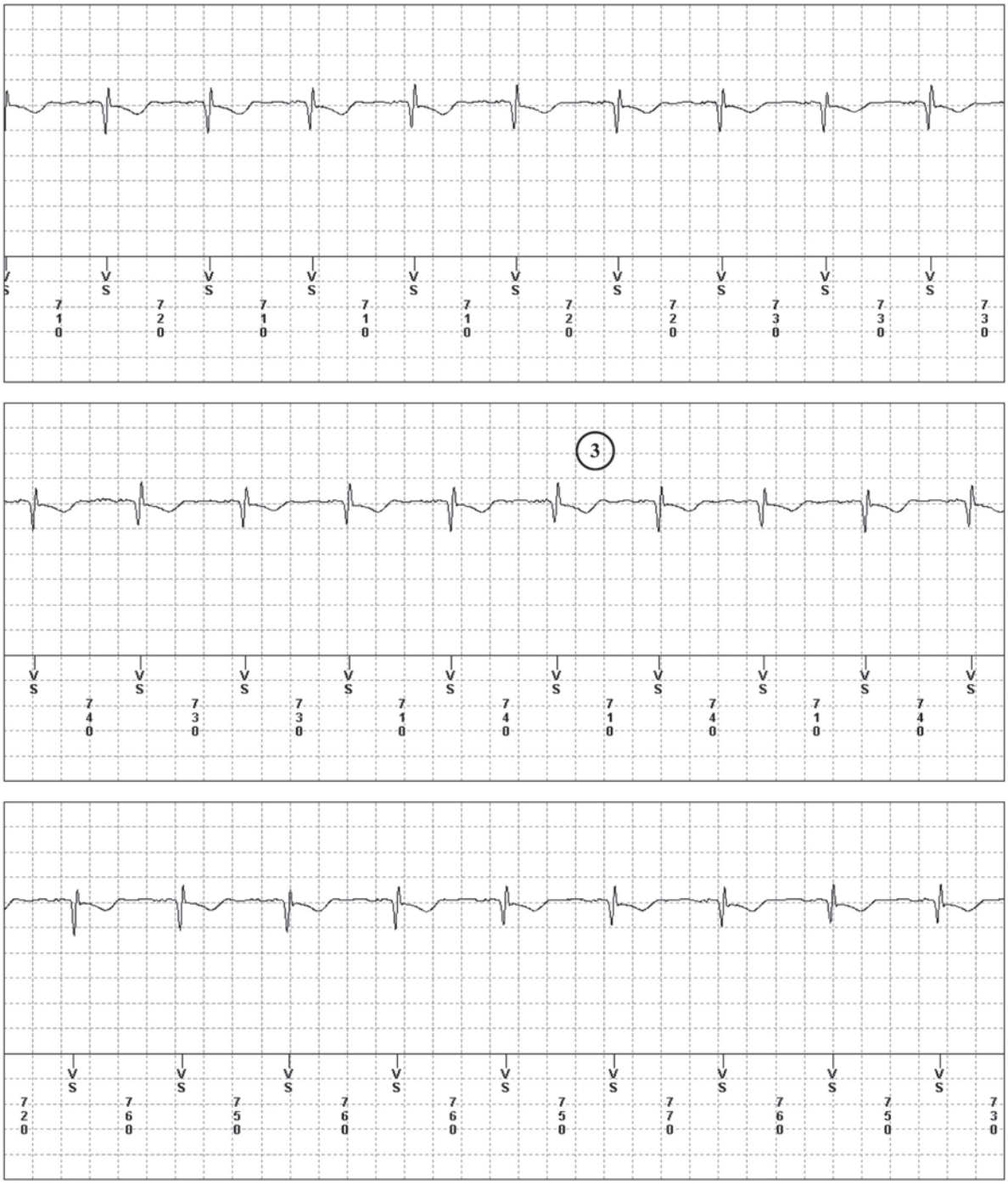
Medtronic

## SYMPTOM Episode #3

Device: **Reveal® DX 9528**

Date of Interrogation:

Episode #3 **Chart speed: 25.0 mm/sec**



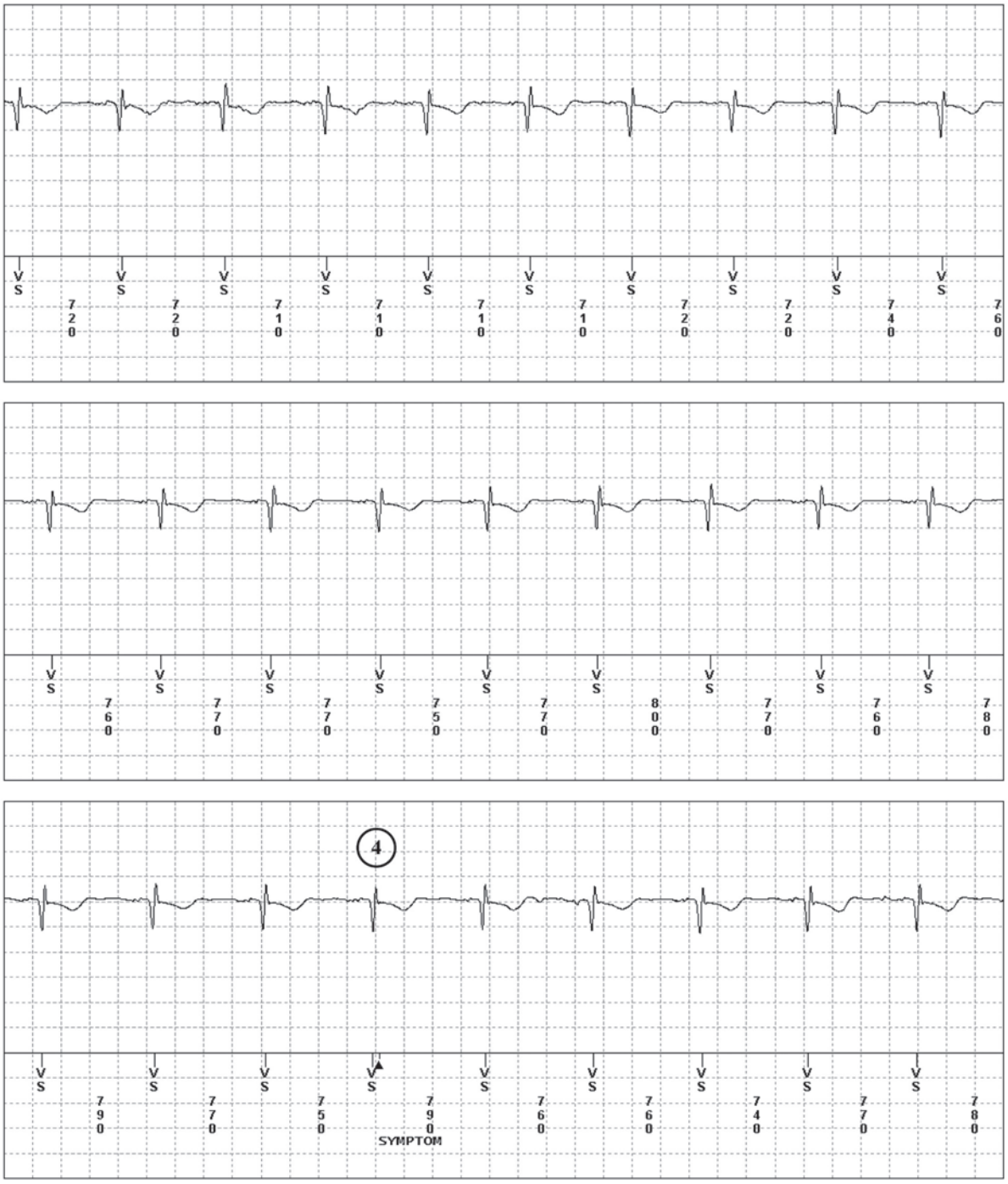
Medtronic

## SYMPTOM Episode #3

Device: **Reveal® DX 9528**

Date of Interrogation:

Episode #3 **Chart speed: 25.0 mm/sec**



## Recording 8

### Illustrative case

A 66-year-old man underwent implantation of a Reveal XT for recurrent syncope without apparent precipitating cause. An ECG and echocardiogram were normal.

### ILR recording

An episode was recorded automatically and transmitted via telemedicine.

1: clear undersensing of the ventricular electrograms causing spurious diagnoses of bradycardia (B) and asystole (AD). Some of the ventricular electrograms are accurately sensed (VS). On the graph, the longest R-R interval is 2000 ms long, which is the programmed bradycardia rate. Should the R-R interval be longer, it will appear as 2000 ms on the graph and >2000 ms on the tracing.

### Texte

The device diagnosed bradycardia. The low bradycardia rate is indeed <30 bpm (>2000 ms).
Sensing was programmed at 0.025 mV.

### Comments

The automatic recording of episodes of bradycardia or tachycardia increases the diagnostic yield of the ILR. The asymptomatic and symptomatic episodes occurring in patients incapable of triggering the system are, therefore, memorised. However, an important limitation of this function is the frequent spurious recording of a) bradycardia due to undersensing of ventricular signals, or b) tachycardia due to the sensing of noise, other cardiac signals, such as P or T waves or double counting of the R wave. This implies a verification of all episodes stored in the device's memory.
Spurious arrhythmic episodes are recorded in >75% of ILR recipients.

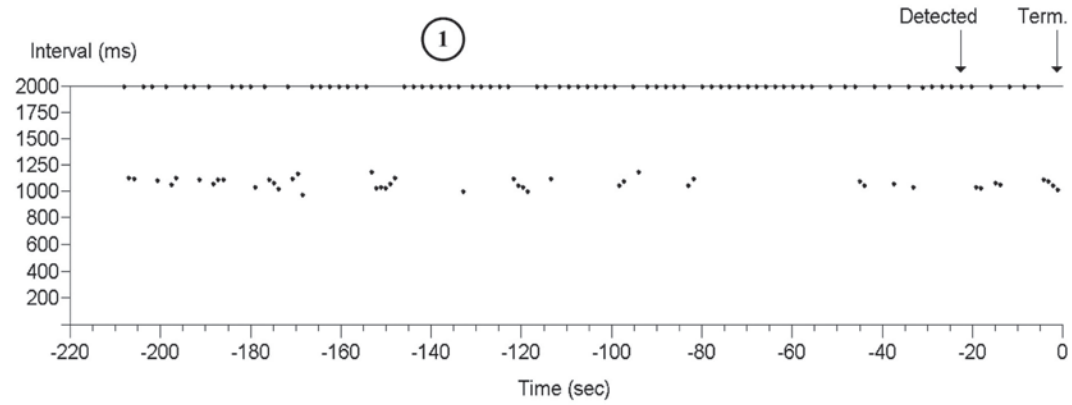
Medtronic

## Brady Episode #720

Device: **Reveal® XT 9529** Date of Interrogation:

| ID# | Type | Date | Time hh:mm | Duration hh:mm:ss | Max V. Rate | Median V. Rate |
|---|---|---|---|---|---|---|
| 720 | Brady | 08-Jul- | 20:00 | :24 | Min <30 bpm | <30 bpm (>2000 ms) |

Brady = 2000 ms



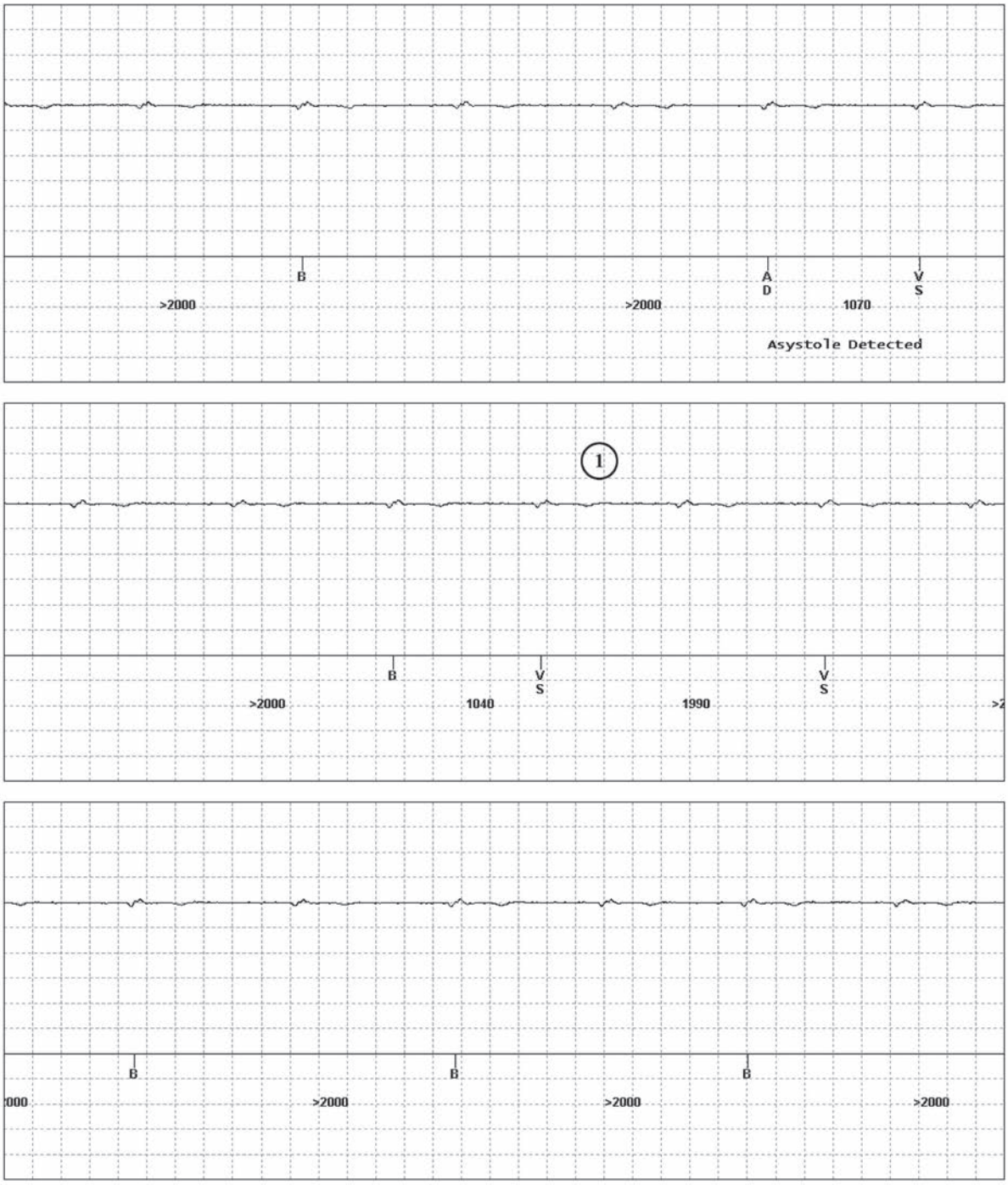
Medtronic

## Brady Episode #720

Device: **Reveal® XT 9529**

Date of Interrogation:

Episode #720 **Chart speed: 25.0 mm/sec**



Medtronic

# Brady Episode #720

Device: **Reveal® XT 9529** Date of Interrogation:

Physician:

**Episode #720:**

| **Episode Summary** | |
|---|---|
| Type | Brady |
| Duration | 24 sec |
| Min V. Rate | <30 bpm (>2000 ms) |
| Median V. Rate | <30 bpm (>2000 ms) |
| Average V. Rate | <30 bpm (>2000 ms) |
| Activity Level | Inactive |

| **Parameter Settings** | **ECG Recording** | **V. Interval (Rate)** | **Duration** |
|---|---|---|---|
| Brady | On | 2000 ms (30 bpm) | 4 beats |

| **Sensing** | |
|---|---|
| Sensitivity | 0.025 mV (25 µV) |
| Sensing Threshold Decay Delay | 100 ms |

## Recording 9

### Illustrative case

A 74-year-old man with a history of inferior myocardial infraction and 45% LVEF underwent implantation of a Reveal DX for the diagnosis of syncope preceded by palpitation. The ECG shows complete right bundle branch block and electrophysiologic studies reveal a HV interval at 63 ms.
Programmed ventricular stimulation was unremarkable.

### ILR recording

The device automatically recorded an event labelled FVT. The patient remained asymptomatic in the wake of the episode. The recording was analysed by the cardiologist during a routine ambulatory visit.

1: normal sinus rhythm;
2: noise oversensing and ultra-short interval between ventricular electrograms (FS) and undersensing of the next true ventricular event with spurious appearance of a pause;
3: major noise artefacts and sensing of ultra-rapid ventricular electrograms (FS). Noise is accurately diagnosed intermittently by the device (ultra-rapid VR: ignored); a VR label indicates oversensing in the ventricular refractory period. When multiple events are consecutively sensed in the refractory period, the interval is classified as noise. A VS annotation labels an event that ends
a noisy episode;
4: FD: sensing of an episode of FVT; sensing of noise is intermittent. While the device correctly labels some segments as noise, others are erroneously interpreted a ventricular arrhythmias;
5: end of episode.

### Comments

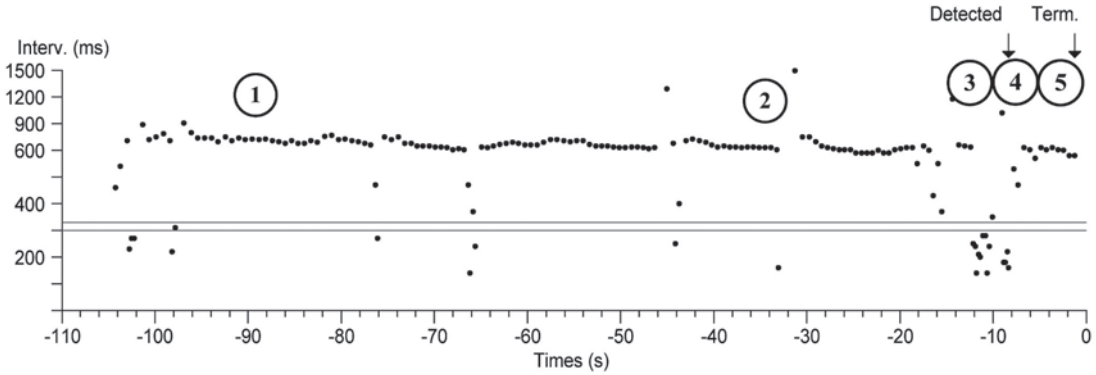
The recording and erroneous interpretation of multiple episodes of noise that saturate the device's memory can be limited by the optimisation of the device's position at the time of implantation, in order to record ventricular electrograms of high enough amplitude and without prominent cycleto-cycle variations. It is also important to a) create a pocket of small enough dimensions to prevent motion of the device, which may promote the oversensing of noisy signals, and b) program the device with a view to minimise oversensing of P and T wave, as well as the likelihood of double counting of the R wave.

## TVR Episode n° 26

Device: **REVEAL DX 9528** Date

| N° | Type | Date | Time hh:mm | Duration hh:mm:ss | max V Rate | médian V Rate |
|---|---|---|---|---|---|---|
| 26 | FVT | 19-Oct | 19:33 | :06 | 286 bpm (210 ms) | 286 bpm (210 ms) |

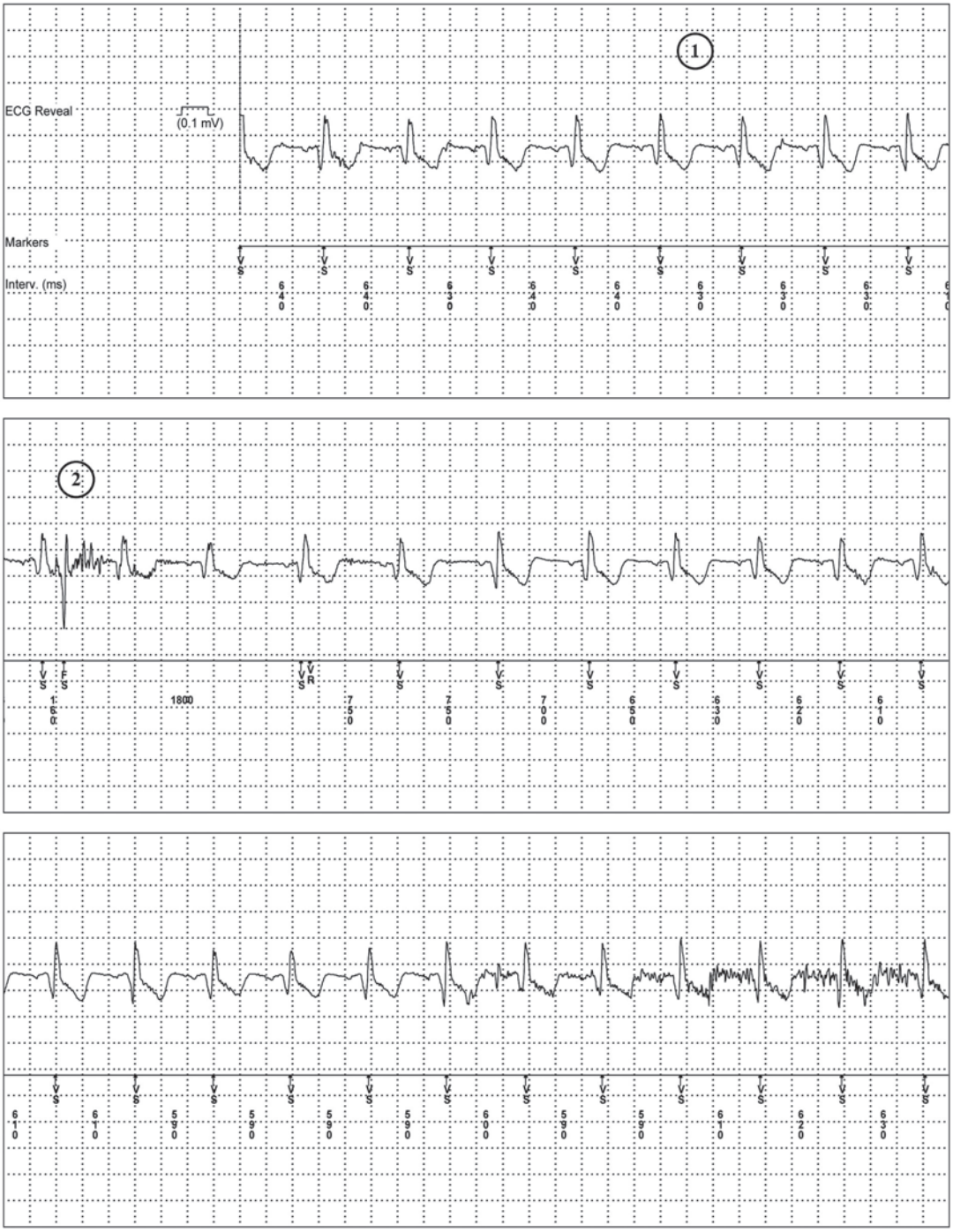
FVT = 300 ms VT = 330 ms

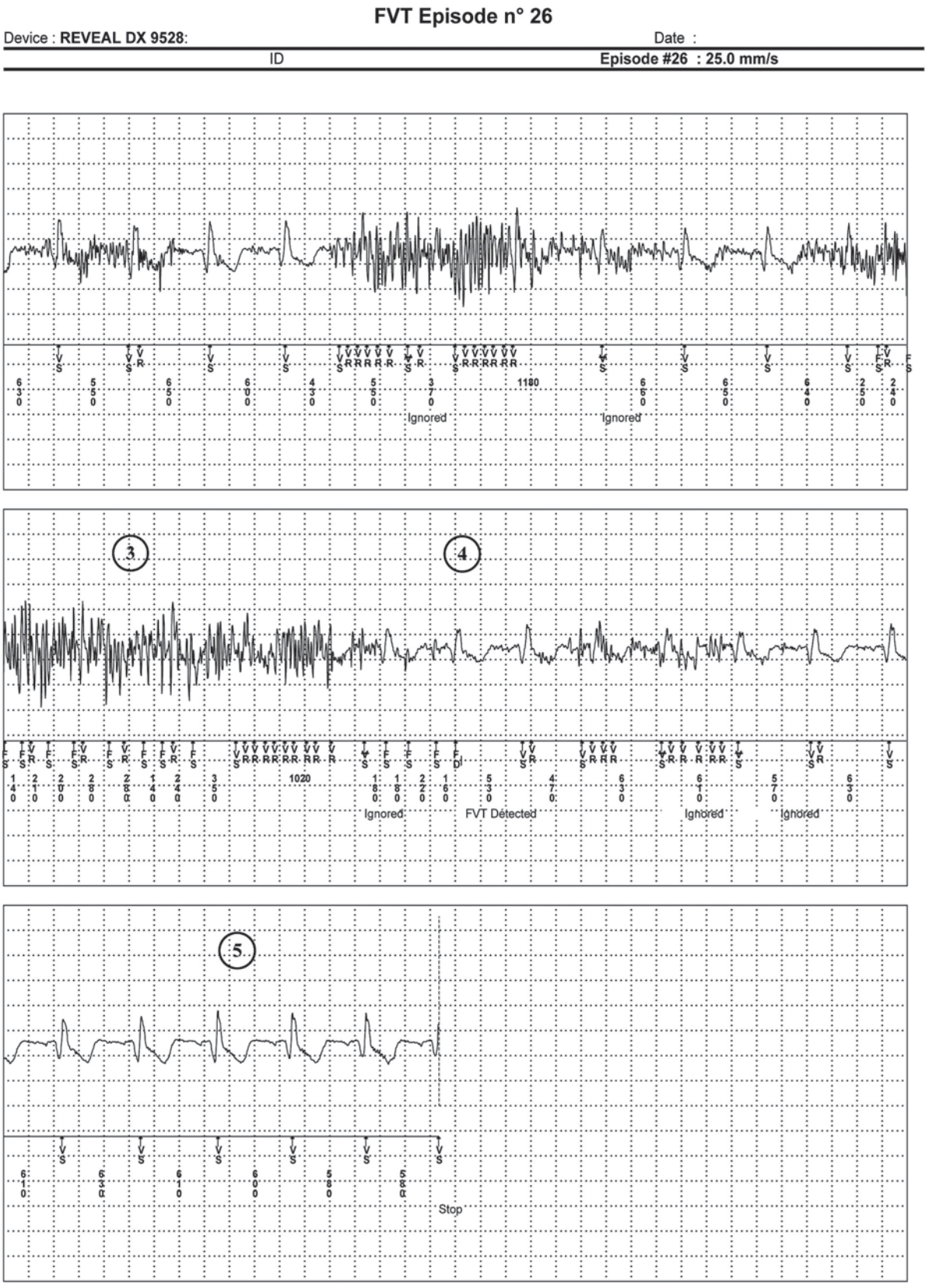


## FVT Episode n° 26

Device : **REVEAL DX 9528** : Date :

ID : **Episode #26 : 25.0 mm/s**




FVT Episode n° 26
Device : REVEAL DX 9528:
Date :
ID
Episode #26 : 25.0 mm/s
Ignored
Ignored
3
4
Ignored
FVT Detected
Ighored
Ighored
5
Stop

## Recording 10

### Illustrative case

A 54-year old man suffering from ischemic cardiomyopathy with a LVEF of 56% presented after 2 syncopal episodes. After undergoing negative electrophysiologic studies and programmed ventricular stimulation, the patient underwent implantation of a Reveal DX Holter.

### ILR recording

In absence of recurrent syncope, the ILR recorded 2 FVT and 1 VT episodes.

### Graph of the VT episode

1: sinus rhythm;
2: railroad appearance probably indicative of a supernumerary cardiac signal; the actual ECG recording corresponds to an episode of FVT.
3: no oversensing in presence of high-amplitude ventricular electrograms;
4: oversensing of the T wave when the R wave amplitude decreased; while the T wave amplitude remained fixed throughout the recording, the R wave amplitude varied prominently; the railroad appearance of the graph is explained by the alternating incidence of the 2 signals (short RT, long TR);
5: an episode of FVT was detected.

### Comments

This episode displays characteristics often observed in presence of T wave oversensing: 1) it occurred during exercise, which is often associated with a decrease in the R wave amplitude while the T wave remains stable or increases; 2) T wave oversensing is promoted by a decrease in the R wave amplitude. This tracing shows distinctly that oversensing does not occur when the R wave is of high amplitude. Indeed, the sensing threshold detection adapts according to the previous R wave. Thus, for a T wave of the same amplitude, the likelihood of oversensing increases as the previous R wave amplitude decreases; 3) the railroad appearance on the graph is a characteristic finding due to the sensing of a supernumerary cardiac signal (double counting of the R wave, oversensing of P or T wave) with alternating incidence and morphology of the 2 signals.
The programmable settings that can prevent this oversensing are a) the refractory period and b) the duration of threshold stability before its decrease, which, in these patients, must be increased.

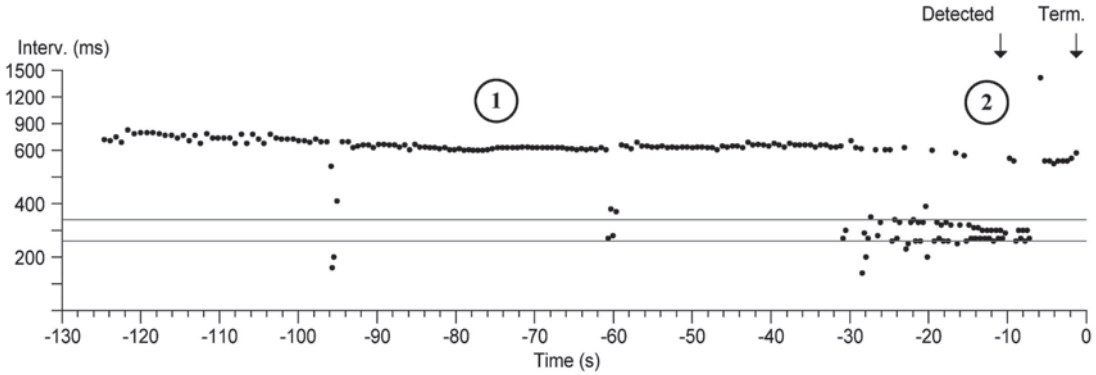
## TV Episode n° 9

Device : **REVEAL DX 9528** : Date :

ID : Patient :

| N° | Type | Date | Time hh:mm | Duration hh:mm:ss | max V rate | médian V rate |
|---|---|---|---|---|---|---|
| 9 | VT | 07-Mar- | 00:02 | :18 | 207 bpm (290 ms) | 200 bpm (300 ms) |

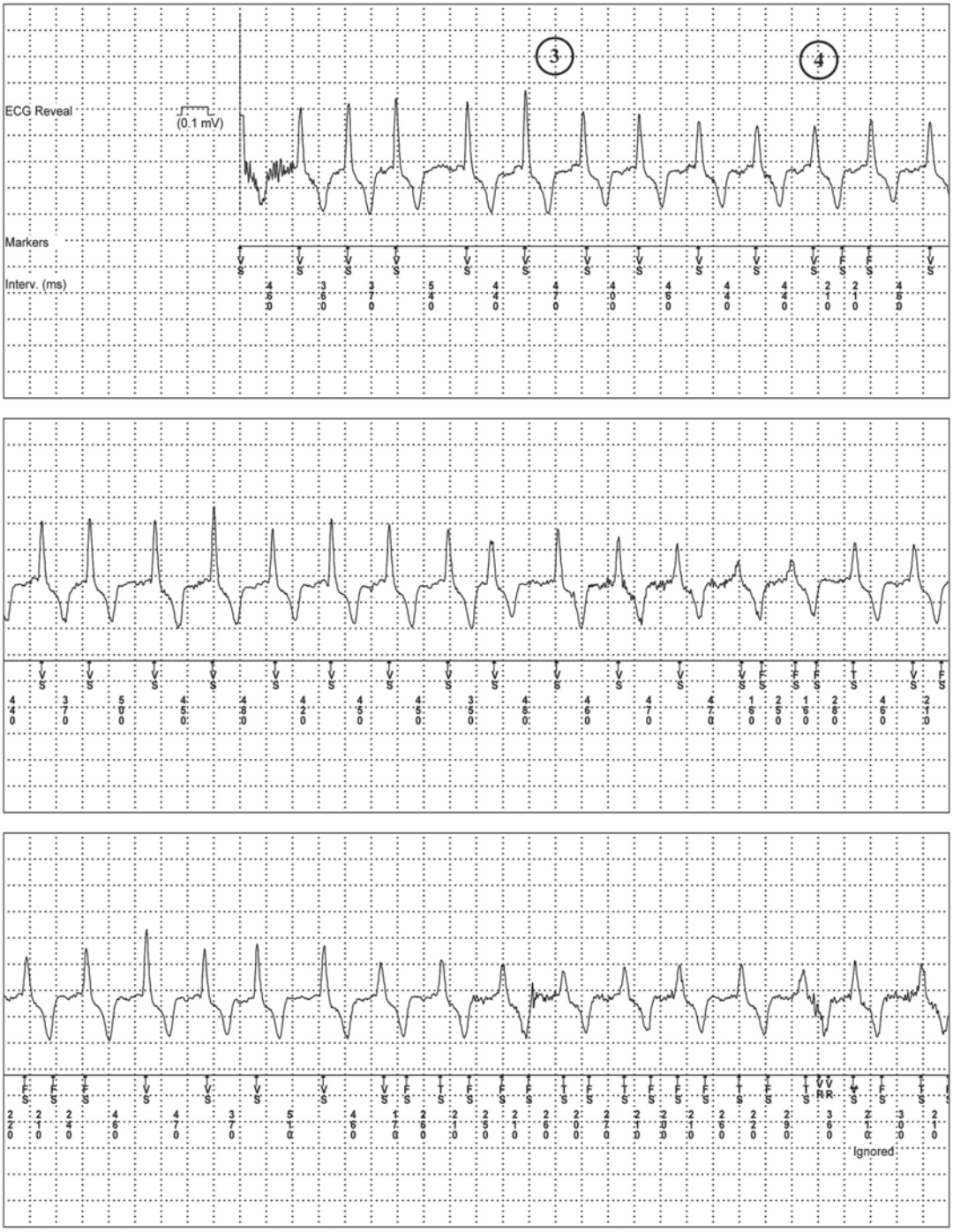
FVT = 260 ms VT = 340 ms

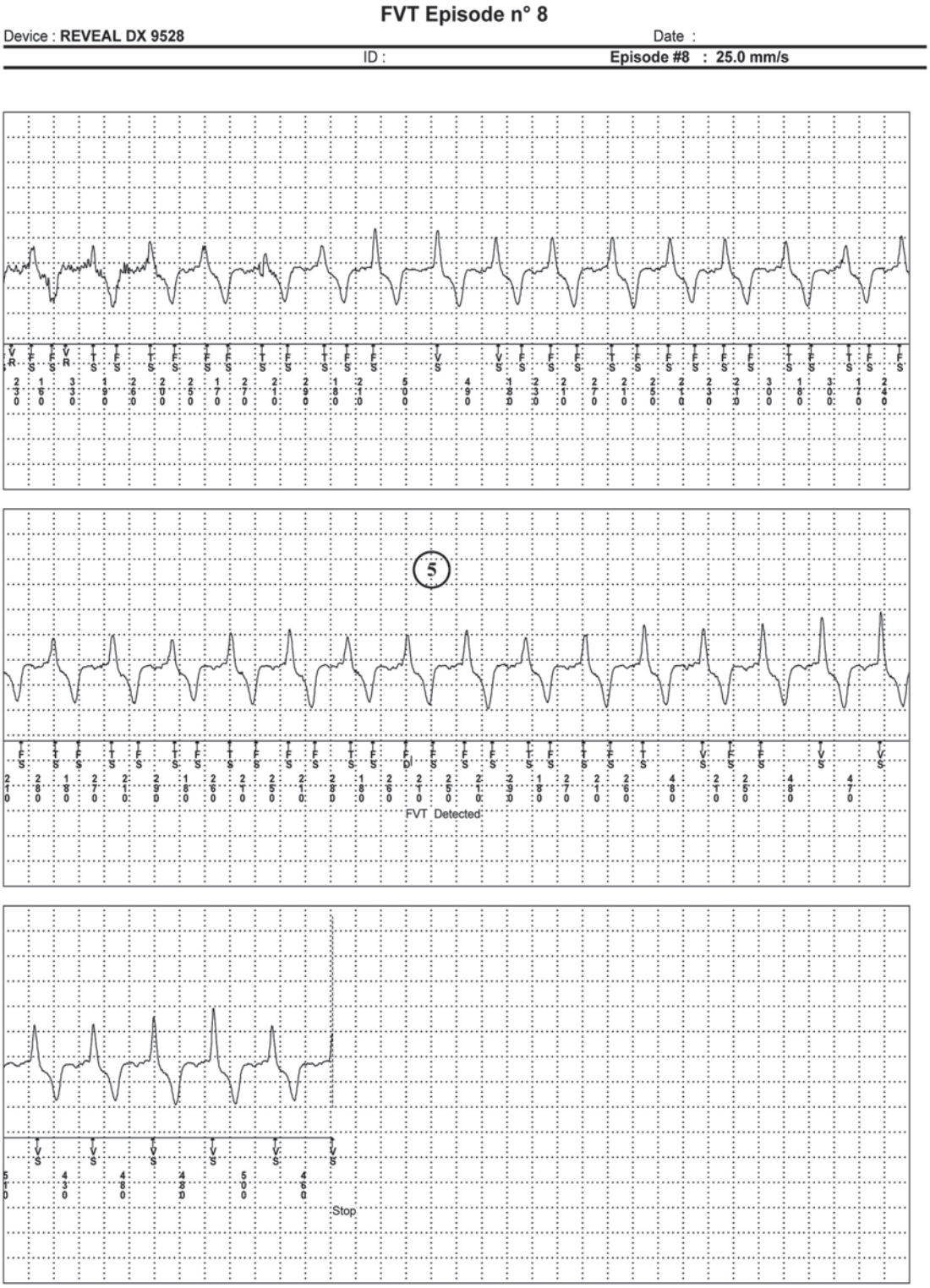


**FVT Episode n° 8**

Device : **REVEAL DX 9528** Date :

ID : **Episode #8 : 25.0 mm/s**




FVT Episode n° 8
Device : REVEAL DX 9528
Date :
ID :
Episode #8 : 25.0 mm/s
5
FVT Detected
Stop

## Quick Look

Device: **REVEAL DX 9528**: Date :

ID : Patient :

**Battery Status**

| | |
|---|---|
| Battery | OK |

**Episodes Summary (3)**

| | |
|---|---|
| Symptom | 0 |
| VF | 2 |
| VT | 1 |
| Asystole | 0 |
| Brady | 0 |

**NOTES**

## Recording 11

### Episodes

A 44-year-old, non-hypertensive man presenting with hypertrophic cardiomyopathy and a history of first transient, cerebral vascular accident 2 years earlier, was hospitalised after a 2nd ischemic accident associated with a transient motor deficit of the left side of the body. A computed tomography scan, magnetic resonance imaging study, transoesophageal echocardiogram, ECG, 48-h ambulatory ECG and carotid Doppler were normal. Because of the young age of this patient, who suffered an unexplained transient ischemic attack, a Reveal XT Holter was implanted and followed remotely by home monitoring.

### ILR recording

The patient remained symptom-free, including palpitation. An asymptomatic AF episode, lasting 22 min, was detected automatically by the ILR and transmitted by CareLink.

1: the graph shows a prominent variability of the R-R interval, without bradycardia or rapid, nonphysiologic VS. The ECG confirms the marked variability of the R-R interval, with diastolic intervals >1,500 ms and shorter RR intervals near 700 ms. It is noteworthy that the ventricular electrograms are sometimes sensed twice (VS-VR). The second signal, which falls in the refractory period, is not included in the heart rate calculation.

2: FD: AF detected.

### Comments

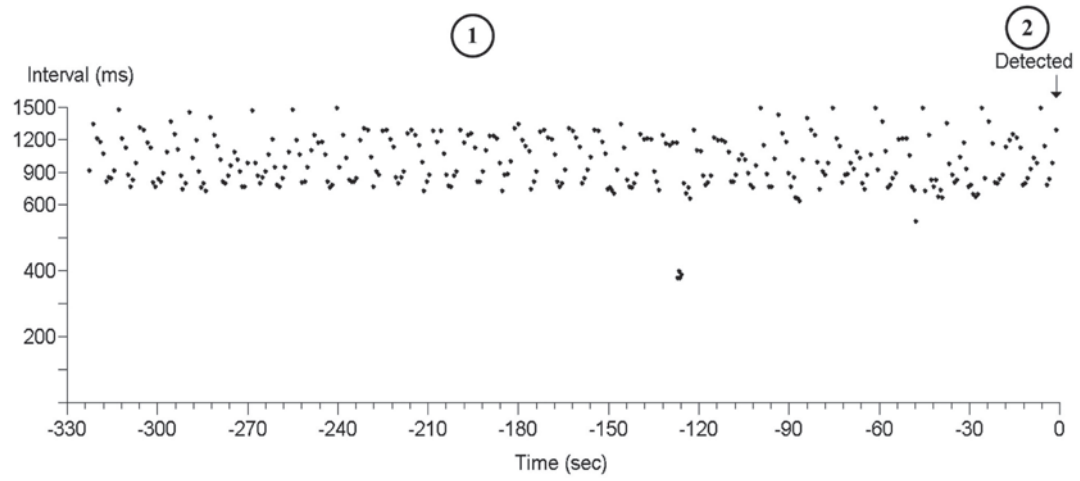
This tracing illustrates the merits of long-term ECG monitoring to diagnose asymptomatic bouts of AF. The diagnosis of AF is based on an algorithm which tracks the stability of the ventricular electrograms. By measuring the AF burden, the device helps deciding whether a treatment is needed, as well as verifying its efficacy. In 25% of instances, ischemic cerebral vascular accidents remain unexplained and are considered cryptogenic after detailed investigations, including telemetry monitoring and recording of a 48-h ambulatory ECG. The likelihood of recording a symptomatic or asymptomatic atrial arrhythmia in a context of cryptogenic cerebral vascular accident increases in parallel with an increase in the duration of ECG monitoring. This patient developed prolonged episodes of atrial arrhythmia without marked increase in heart rate, explaining the paucity of symptoms. The absence of correlation between symptoms and arrhythmic episodes might justify an implantable Holter, which automatically records asymptomatic episodes. In this patient, the longest episode diagnosed by the device lasted >24 h, justifying the introduction of an antithrombotic regimen as well a conversation regarding the need to introduce an antiarrhythmic medication. An expeditious diagnosis was enabled by the CareLink remote transmission, which limited the delay in onset of therapy.

Medtronic

## AF Episode #694

Device: **Reveal® XT 9529** Date of Interrogation:

| ID# | Type | Date | Time hh:mm | Duration hh:mm:ss | Max V. Rate | Median V. Rate |
|---|---|---|---|---|---|---|
| 694 | AF | 05-Jul-2 | 07:10 | :22:00 | 125 bpm (480 ms) | 61 bpm (990 ms) |



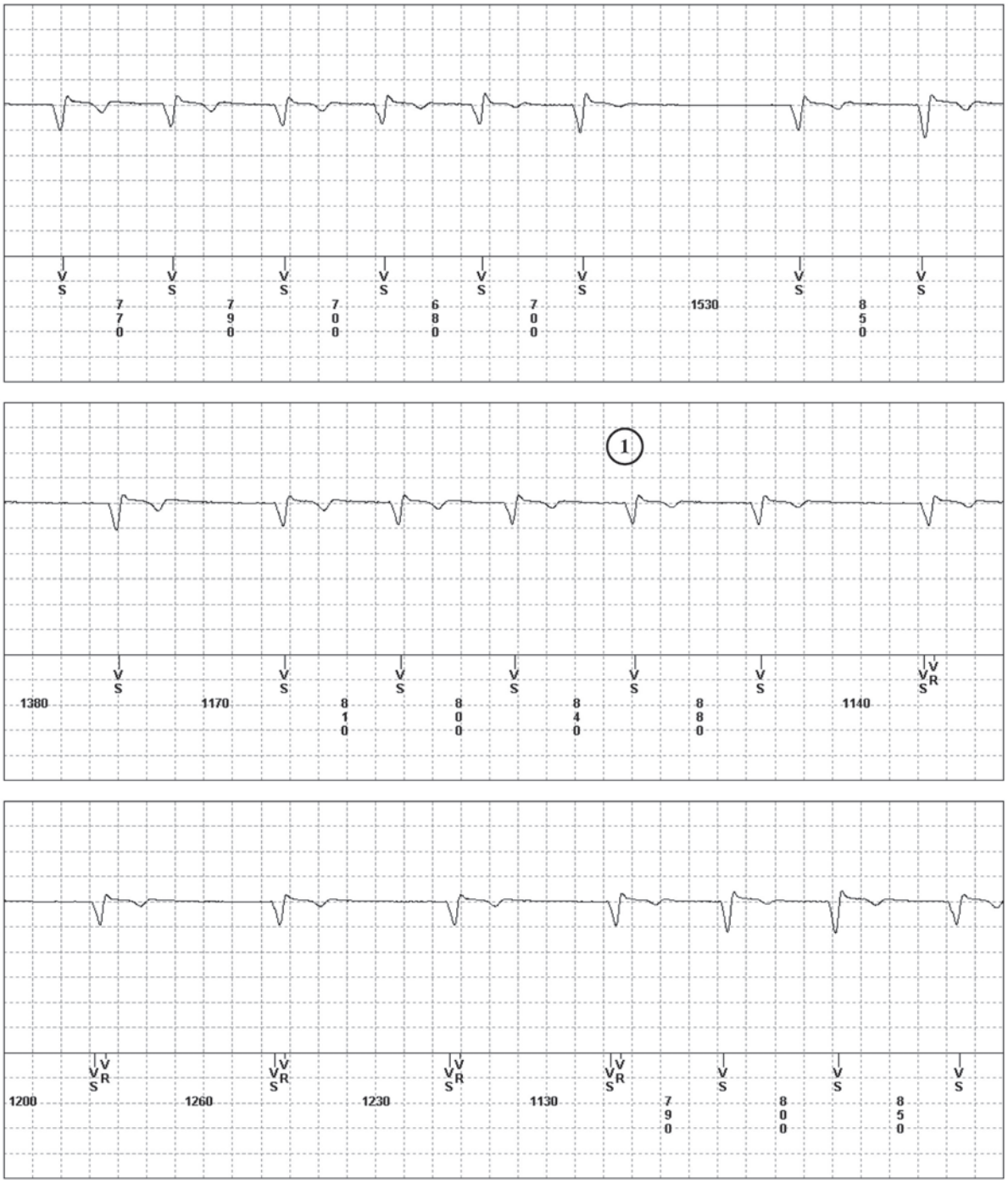
Medtronic

## AF Episode #694

Device: **Reveal® XT 9529**

Date of Interrogation:

Episode #694 **Chart speed: 25.0 mm/sec**



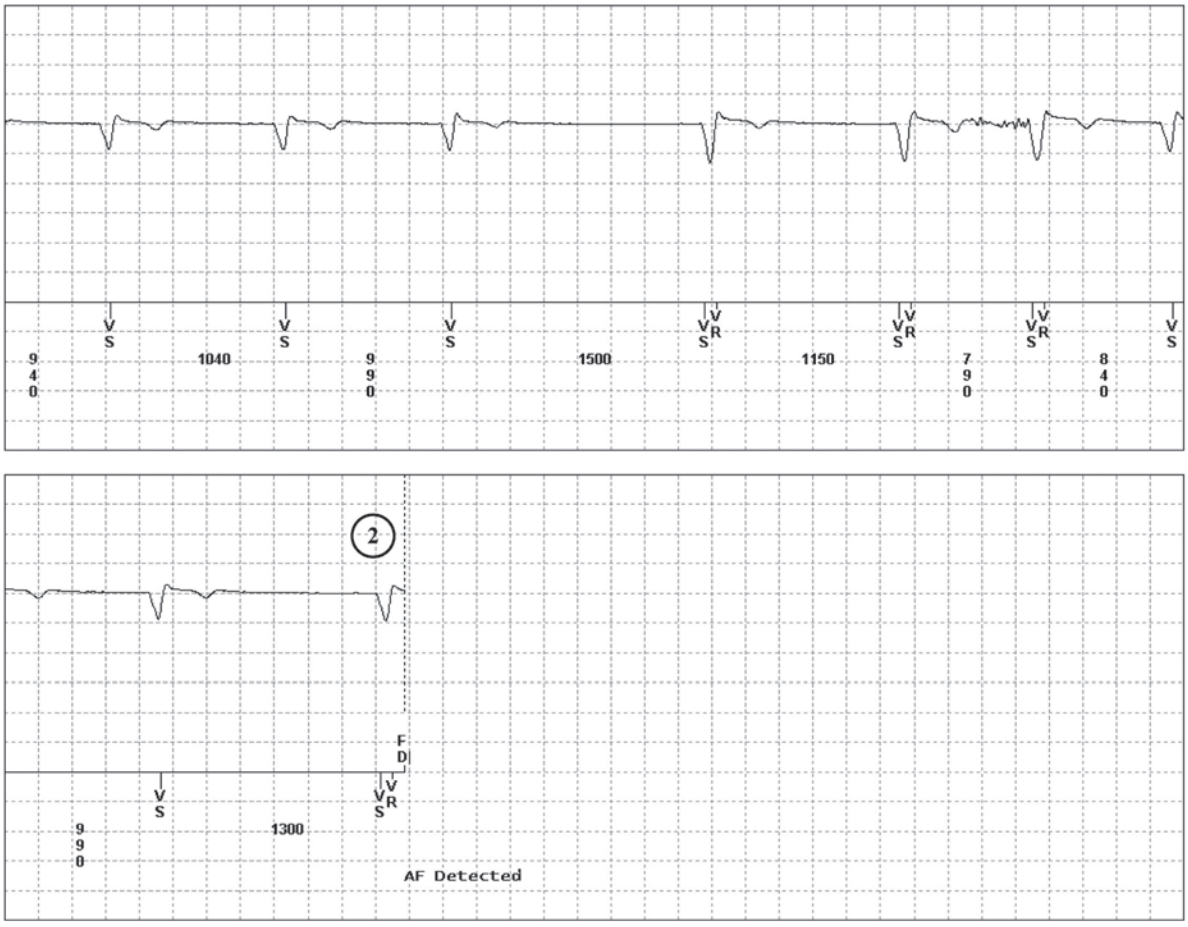
Medtronic

## AF Episode #694

Device: **Reveal® XT 9529**

Date of Interrogation:

Episode #694 **Chart speed: 25.0 mm/sec**



Medtronic

# AF Episode #694

Device: **Reveal® XT 9529** Date of Interrogation:

Physician:

**Episode #694:**

| **Episode Summary** | |
|---|---|
| Type | AF |
| Duration | 22 min |
| Max V. Rate | 125 bpm (480 ms) |
| Median V. Rate | 61 bpm (990 ms) |
| Activity Level | Inactive |

| **Parameter Settings** | **ECG Recording** |
|---|---|
| AT/AF | On |

| **Detection Enhancements** | | |
|---|---|---|
| AT/AF Detection | | |
| | Type | AF Only |
| | AF Detection | Balanced Sensitivity |
| | Ectopy Rejection | Off |

| **Sensing** | |
|---|---|
| Sensitivity | 0.025 mV (25 µV) |
| Sensing Threshold Decay Delay | 100 ms |

## Recording 12

### Illustrative case

A Reveal XT Holter was implanted for monitoring of atrial arrhythmias.

### ILR recording

Automatically recorded episode
1: sinus rhythm;
2: acceleration of heart rate and development of regular narrow QRS tachycardia, most likely common atrial flutter or atrial tachycardia. However, the device diagnosed VT based on a) the heart rate >120 bpm (above the programmed lower VT limit of 120 bpm), b) the stability of the rhythm (programmed at 40 ms), and c) the sudden onset (programmed at 81%);
3: evolution to AF; the graph shows a dispersion of data points, confirmed by the instability of the R-R interval on the ECG;
4: diagnosis of AF after 2 min of arrhythmia.

### Complete report

The report shows the duration of arrhythmias, time of onset, ventricular rate during the arrhythmia and activity.

### Comments

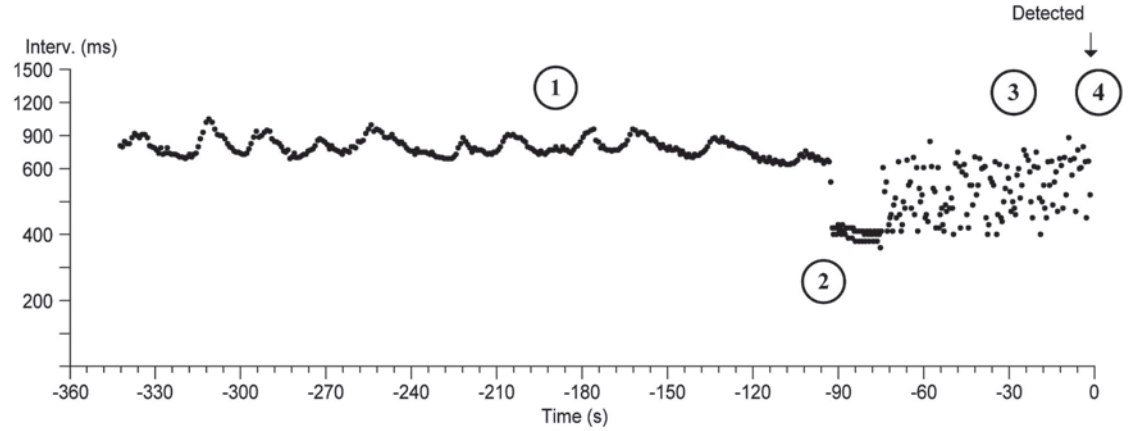
This report offers a global description of the arrhythmic burden, which may have important therapeutic consequences. The duration of the episodes must be included when pondering whether to introduce an antithrombotic regimen. While the shortest duration justifying its introduction is ill defined, the thromboembolic risk seems to increase significantly after 24 h. The time of onset of the episodes might also influence the decision to introduce an antiarrhythmic regimen. Should the episodes systematically occur at night, a vagal mechanism is suspected and beta-adrenergic blockade avoided. Conversely, beta-adrenergic blockade should be strongly considered if the episodes develop systematically during exercise. Furthermore, the ventricular rate following an arrhythmic episode helps modulating a rate-slowing treatment.

## AF Episode n° 1230

Device: **REVEAL XT 9529**: Date

ID : Patient :

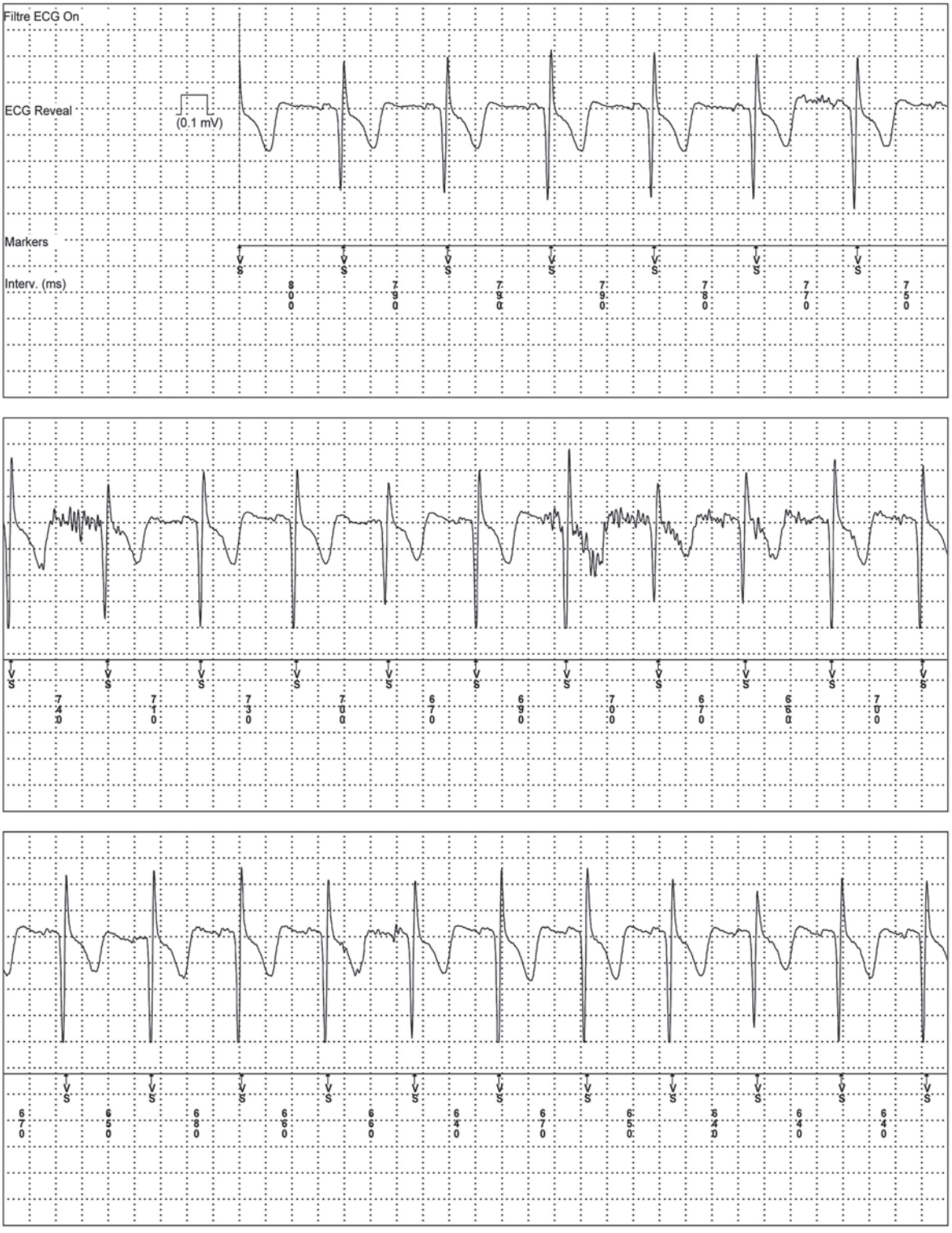
| N° | Type | Date | Time hh:mm | Duration hh:mm:ss | max V rate | médian V rate |
|---|---|---|---|---|---|---|
| 1230 | AF | -Jun- | 00:49 | 05:02:00 | 154 bpm (390 ms) | 91 bpm (660 ms) |



## AF Episode n° 1230

Device : **REVEAL XT 9529** Serial number : Date :

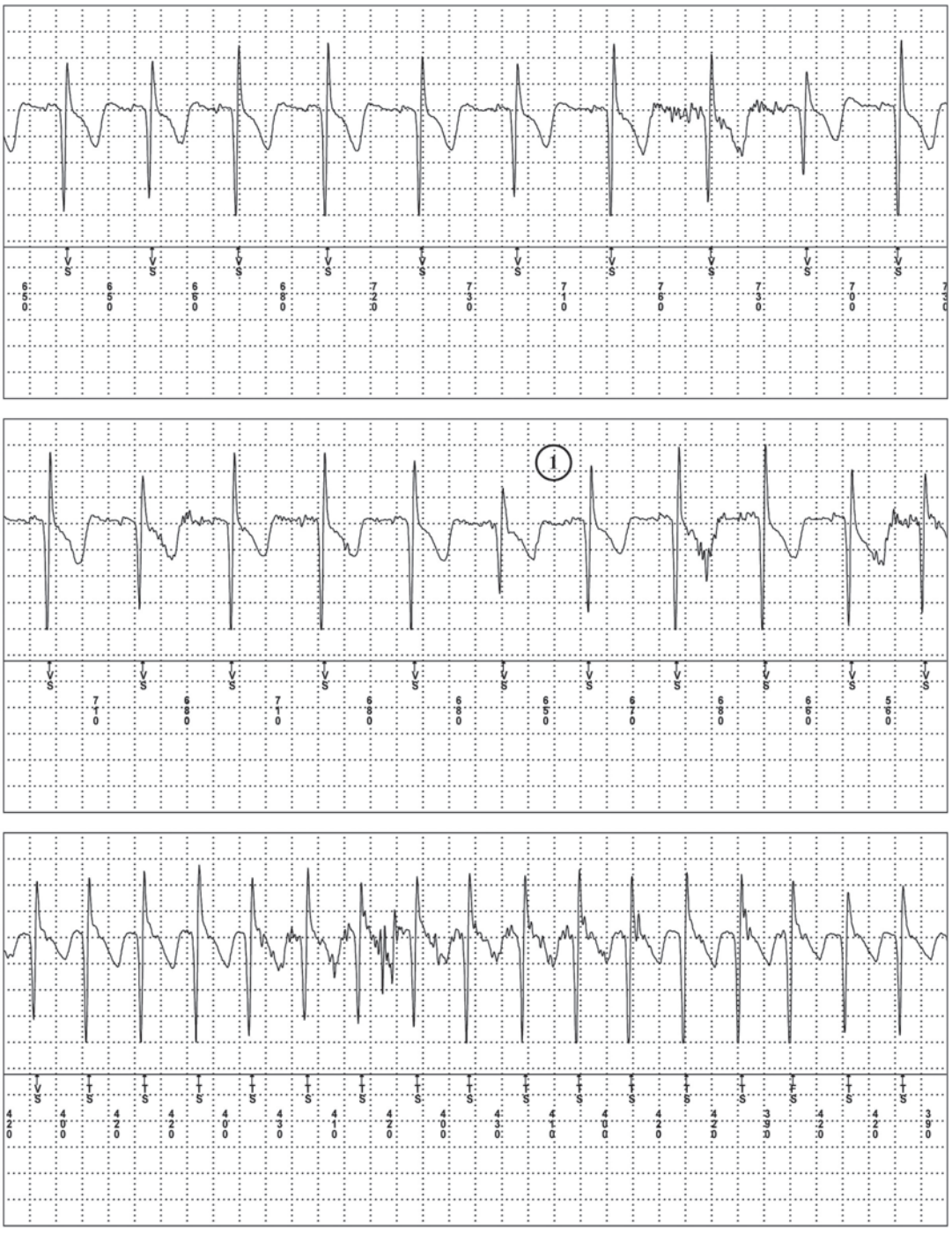
ID : **Episode #1230 : 25.0 mm/s**



**AF Episode n° 1230**

Device : **REVEAL XT 9529** Serial number : Date :

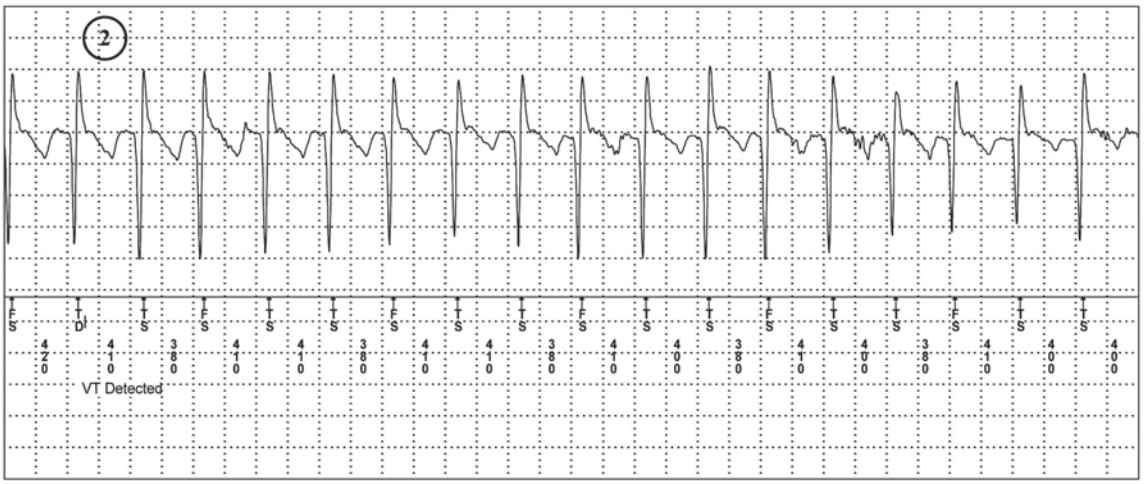
ID : **Episode #1230 : 25.0 mm/s**

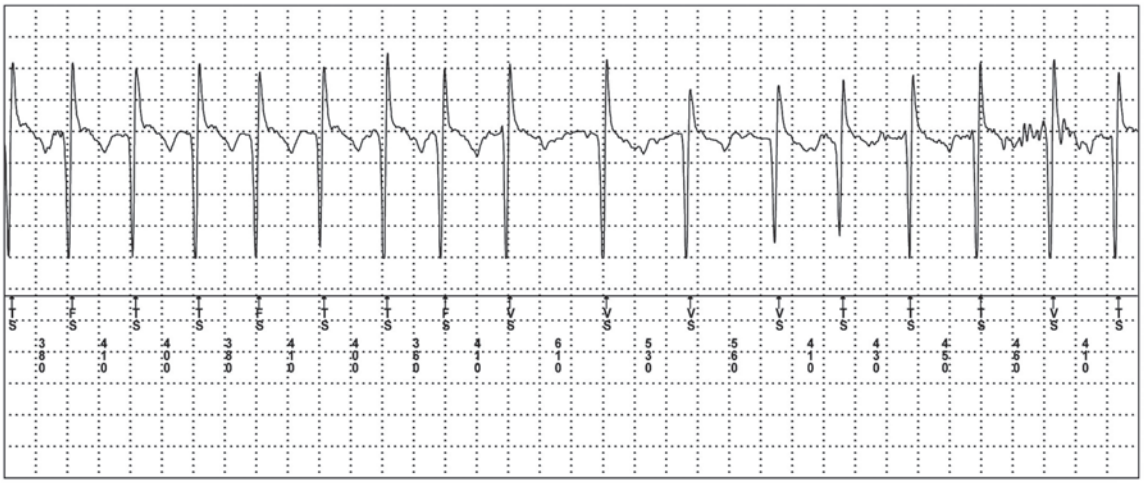


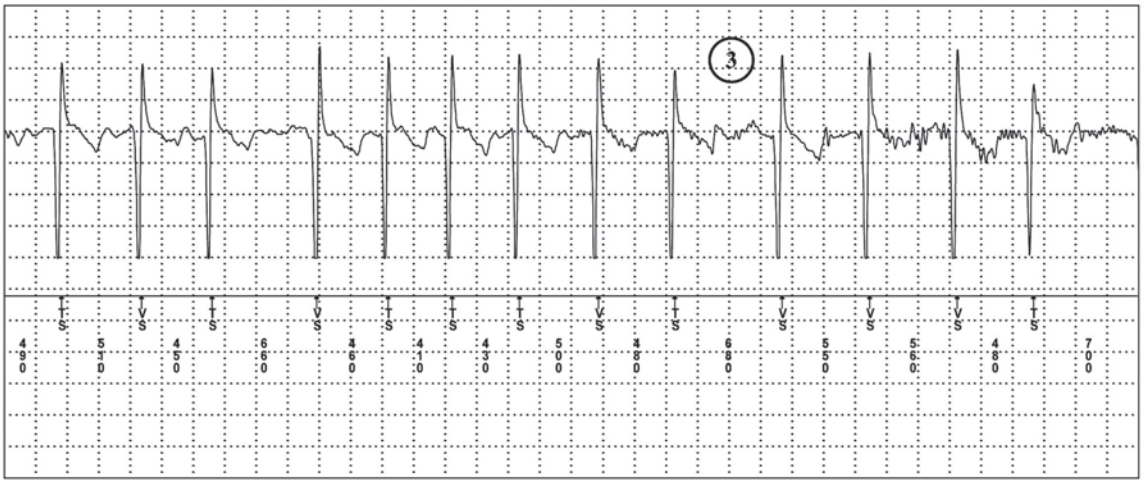
## AF Episode n° 1230

Device: **REVEAL**

ID :



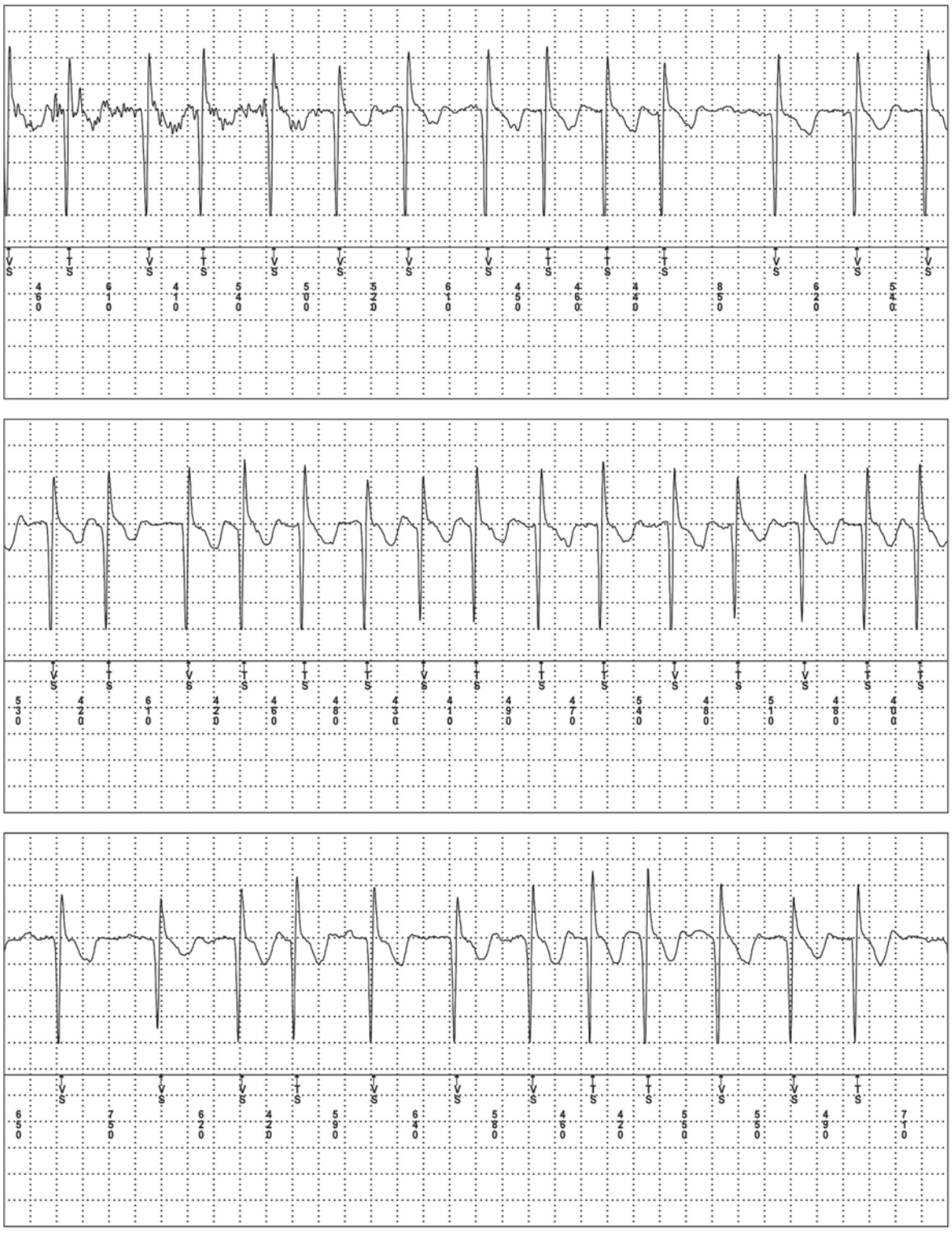





**AF Episode n° 1230**

Dievice : **REVEAL XT 9529** Serial number : Date :

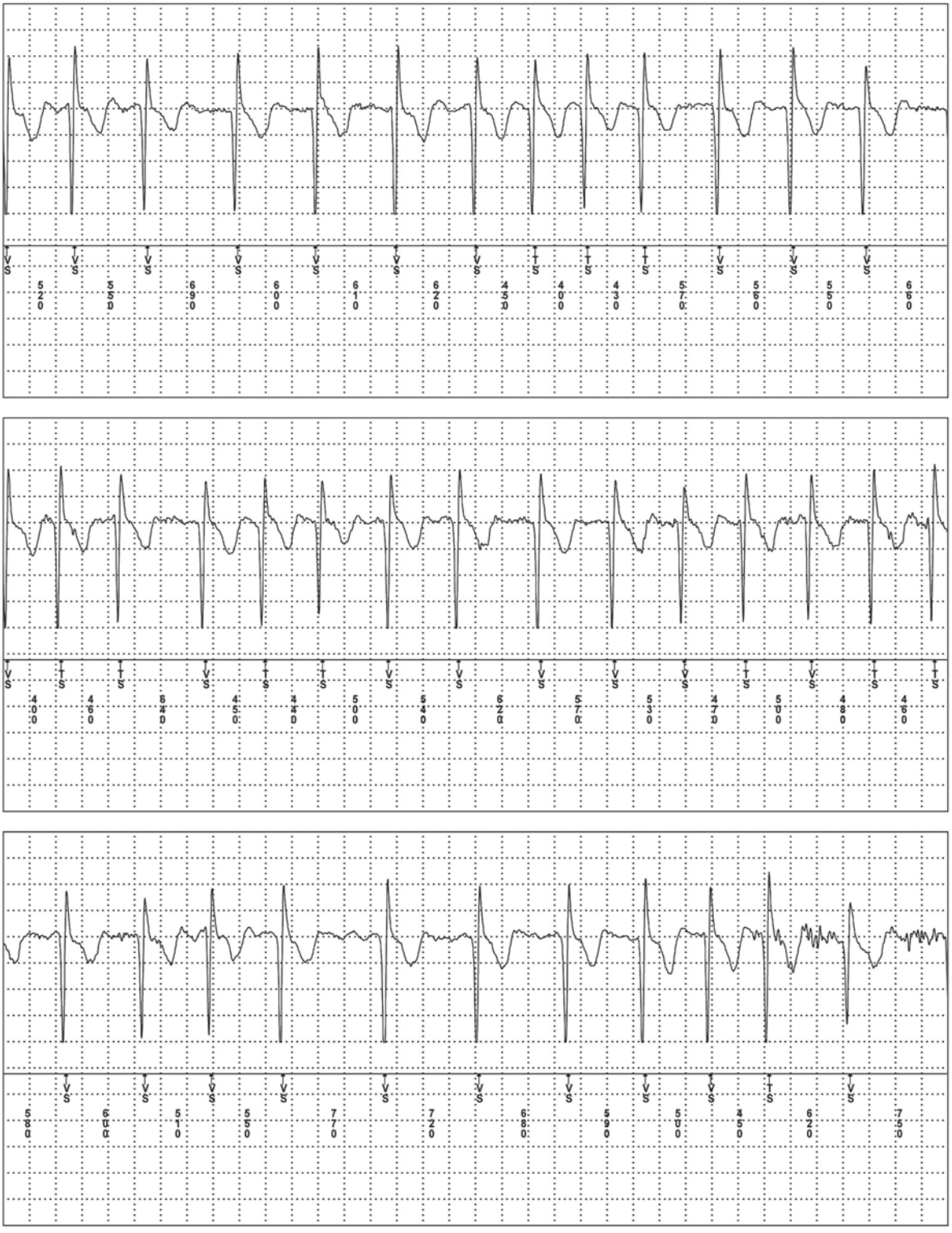
ID : **.0 mm/s**



## AF Episode n° 1230

Device : **REVEAL XT 9529** Serial number : Date :

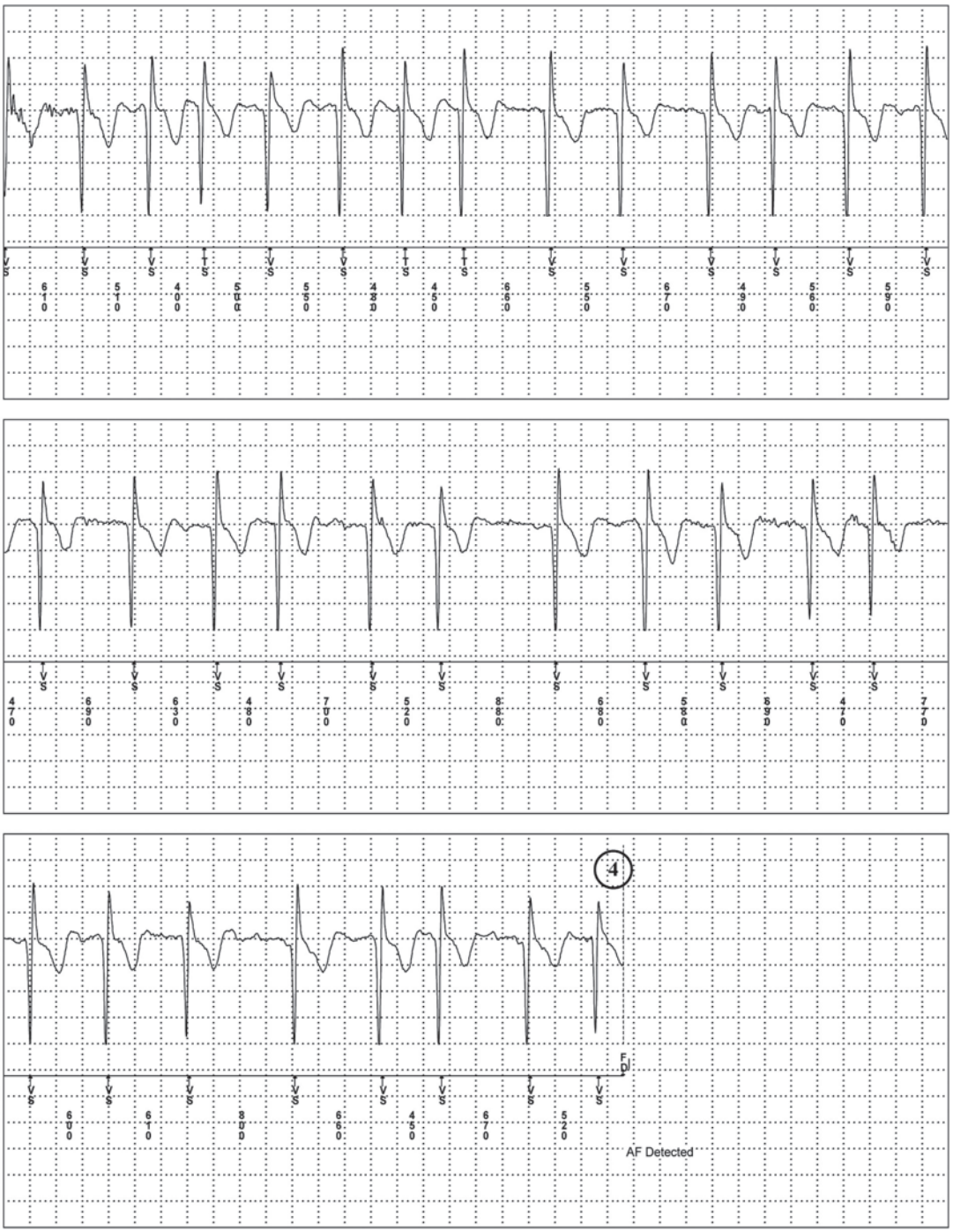
ID : **Episode #1230 : 25.0 mm/s**



**AF Episode n° 1230**

Device : **REVEAL XT 9529** Serial number :

ID : **Episode #1230 : 25.0 mm/s**



## AF Episode n° 1230

Device : **REVEAL XT 9529** Serial number : Date :

ID : :

**Episode #1230 :**

**Episode**

| | |
|---|---|
| Type | AF |
| Duration | 5.0 h |
| Max V Rate | 154 min-¹ (390 ms) |
| Median V Rate | 91 min-¹ (660 ms) |
| Activity Level | Inactive |

FVT/TV detected during the episode

**Parameter Settings ECG Recording**

| | |
|---|---|
| AT/AF | On |

**Detection Enhancements**

AT/AF Detection

| | |
|---|---|
| Type | AF |
| AF Sensing | Normal sensivity |
| PAC/PVC filter | Stop |

**Sensing**

| | |
|---|---|
| Sensivity | 0.05 mV ( 50 µV ) |
| Sensing Threshold Decay Delay | 100 ms |

## Rate Chart

Device : **REVEAL XT 9529** Serial Number : Date :

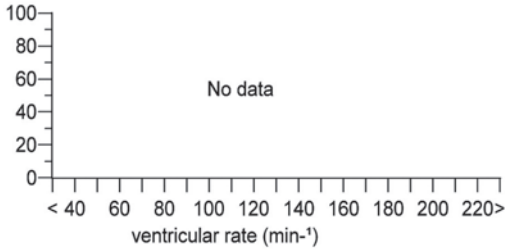
ID : Patient :

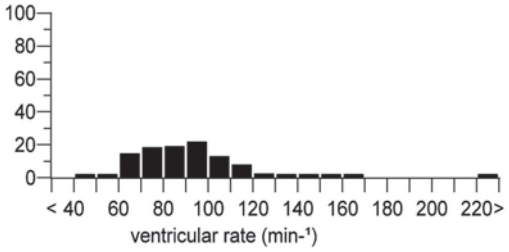
**Prior to last session**
no prior session

**Since last session**
27-Avr- au 29-Jun-
63 days

**Ventricular**
% time

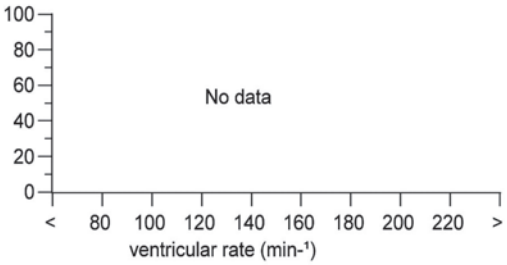
■VS



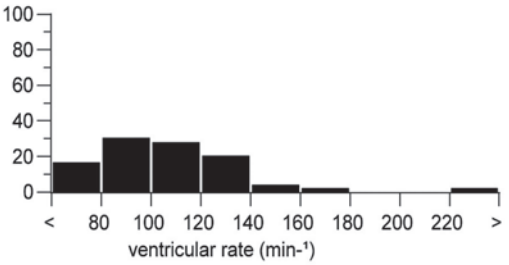




**Ventricular rate during AT/AF**
% AT/AF

■VS




**Duration AT/AF= 5 hours**



## AT/AF Summary

Device : **REVEAL XT 9529** Serial Number: Date :

ID : Patient :

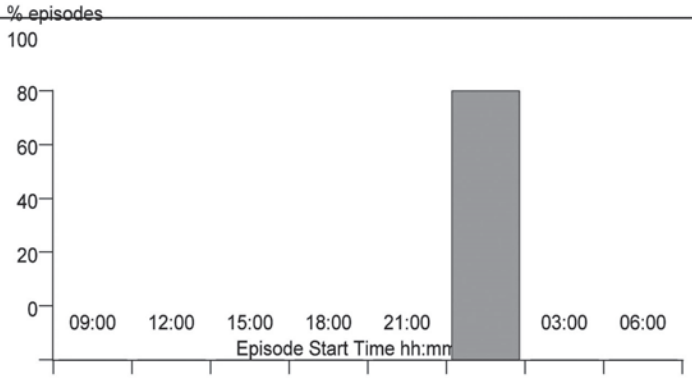
| **AT/AF** | **prior last session** | **Last session** 63 Days |
|---|---|---|
| % AT/AF | no data | 0.3 % |
| Average AF/AT time/day | | <0.1 hours/day |

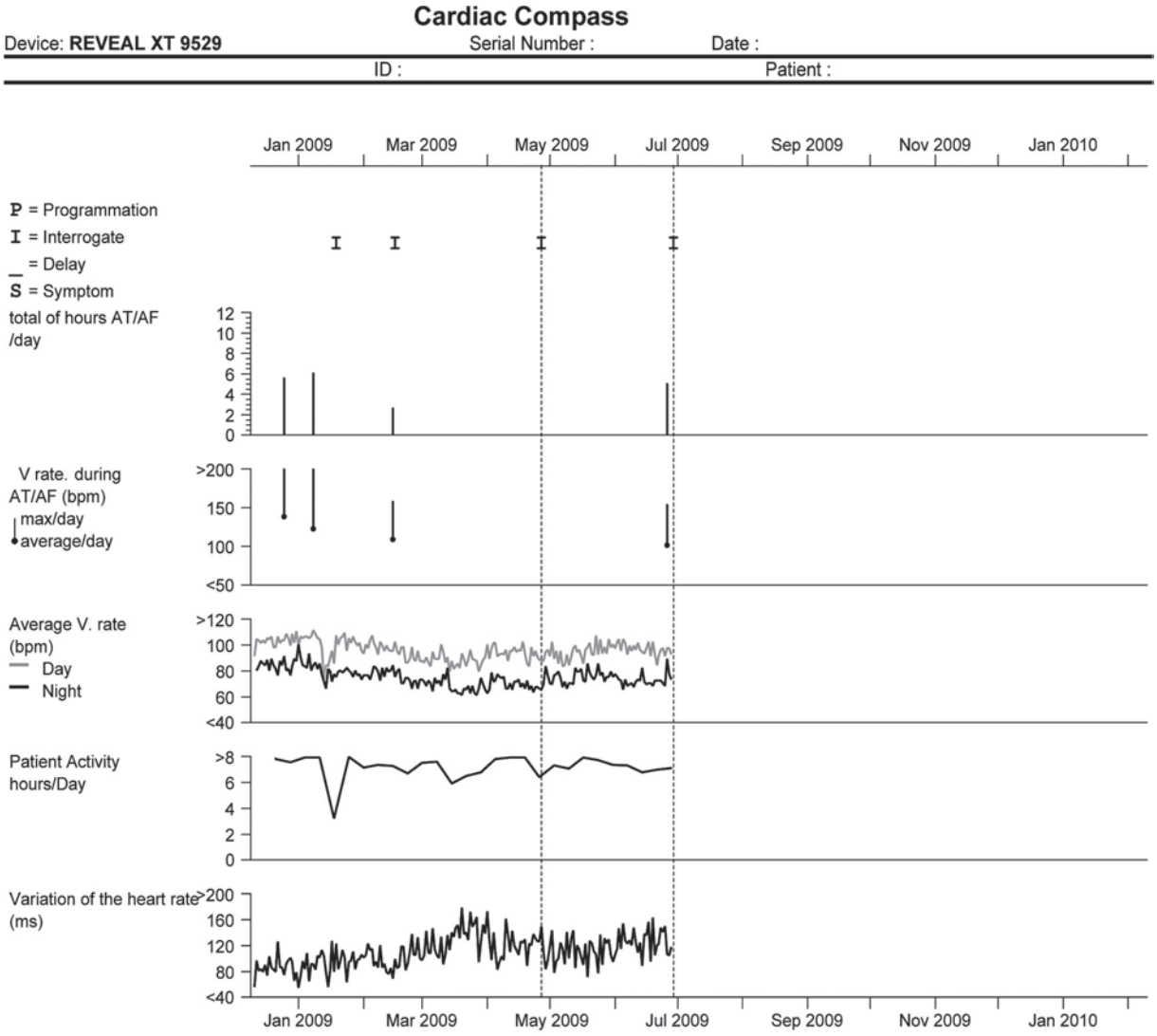
**Since last session** 27-Avr-au 29-Jun-

**Duration AT/AF**

| Duration | Episodes |
|---|---|
| >72 h | 0 |
| 48 à 72 h | 0 |
| 24 à 48 h | 0 |
| 12 à 24 h | 0 |
| 4 à 12 h | 1 |
| 1 à 4 h | 0 |
| 10 min à 1 h | 0 |
| 2 à 10 min | 0 |

**AT/AF Episode Start Time**




Cardiac Compass
Device: REVEAL XT 9529
Serial Number :
Date :
ID :
Patient :
Jan 2009
Mar 2009
May 2009
Jul 2009
Sep 2009
Nov 2009
Jan 2010
P = Programmation
I = Interrogate
_ = Delay
S = Symptom
total of hours AT/AF /day
12
10
8
6
4
2
0
V rate. during AT/AF (bpm)
max/day
average/day
>200
150
100
<50
Average V. rate (bpm)
Day
Night
>120
100
80
60
<40
Patient Activity hours/Day
>8
6
4
2
0
Variation of the heart rate (ms)
>200
160
120
80
<40

## Episode Counters

Device : **REVEAL XT 9529** Serial number : Date :

ID : Patient :

| Episode Counters | Prior to last Session<br>no session | Last session<br>27-Av<br>29-Jun-<br>63 days | Device Lifetime Total<br>(Since 11-Déc-<br>7 months |
|---|---|---|---|
| Symptom | | 0 | 0 |
| FVT | 28 | 78 | |
| VT | 380 | 1,156 | |
| Asystole | 0 | | 4 |
| Brady | 0 | | 0 |
| AT | 0 | | 0 |
| AF | 1 | | 4 |

## Recording 13

### Illustrative case

A 67-year-old man complained of recurrent syncope with perception of palpitation before losing consciousness. He has a history of treated systemic hypertension and concentric LV hypertrophy. The 12-lead ECG showed right bundle branch block and electrophysiologic studies were negative.
A Reveal DX Holter was implanted.

### ILR recording

The patient suffered a syncopal event associated with convulsions; his wife used the activator to trigger a recording by the ILR.

1: episode of AF with wide ventricular electrograms, irregular and morphologically similar to those recorded during sinus rhythm;
2: prolonged asystole detected;
3: recording triggered by the patient's wife;
4: resumption of a relatively regular, probably slow sinus rhythm, though the analysis of atrial activity is challenging. Note the noise after the fall, the loss of consciousness and the sudden recovery.

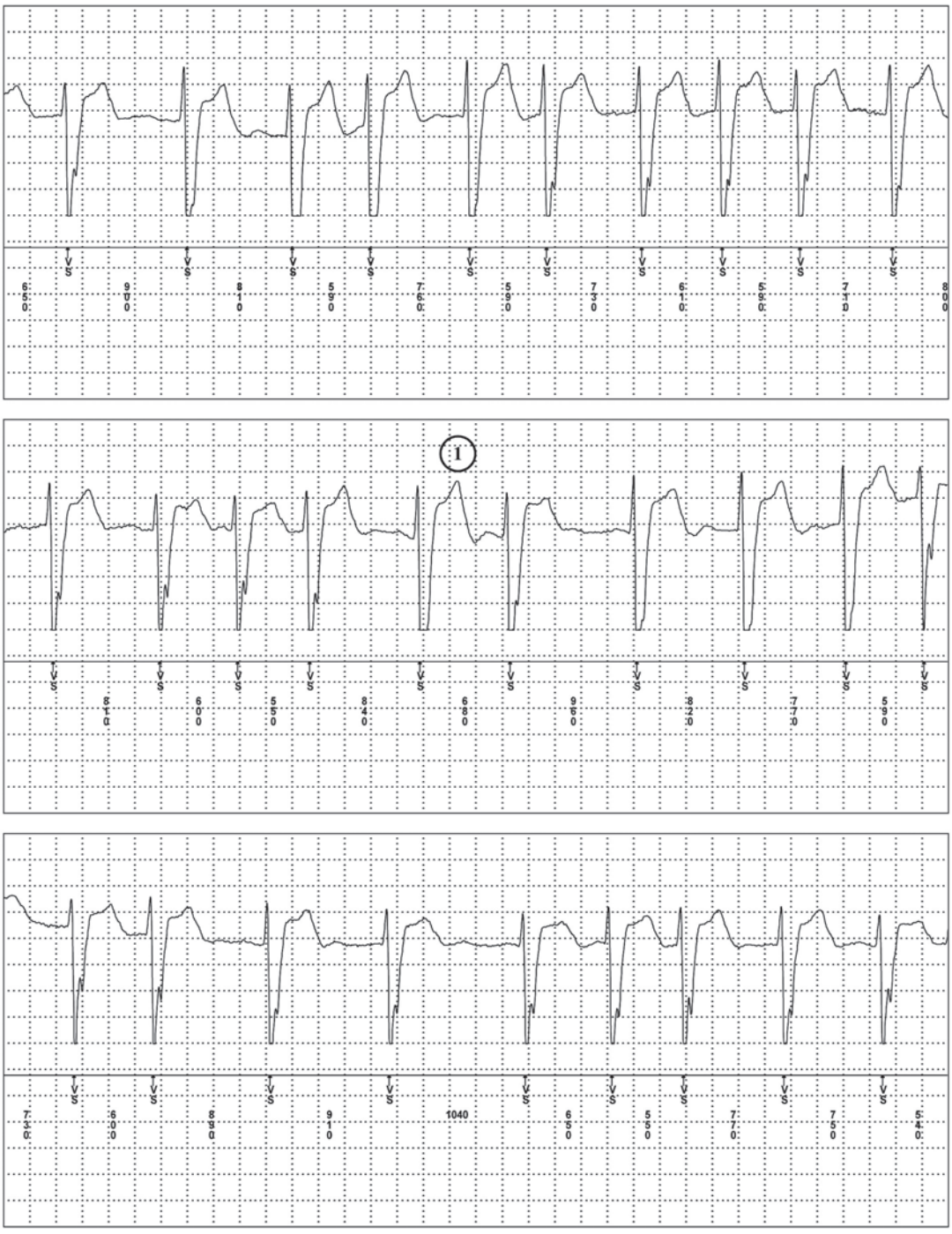
### Comments

This is a typical ECG recording of sick sinus syndrome, combining episodes of AF, sinus dysfunction and long pause at the time of tachyarrhythmia termination. The palpitation was, therefore, related to AF, and syncope was related to the pause. From the standpoint of therapy, a CHADS 3 score in this patient justified the introduction of antithrombotic therapy. The management of syncope hinges on the adoption of 1 of 2 strategies. The first assumes that the pause is the consequence of the abrupt termination of AF, which the treatment must target. A study revealed, for example, that the ablation of pulmonary veins in these patients suppressed the recurrences of arrhythmia as well as syncope. The second strategy assumes that the pause after the end of an episode of AF is a manifestation of sinus node dysfunction, justifying the implantation of a permanent pacemaker. This patient presented with sinus bradycardia at 50 bpm at rest and some degree of chronotropic insufficiency. He received a pacemaker, which prevented recurrences of syncope, while AF was moderately well controlled by an antiarrhythmic regimen.

**SYMPTOM Episode n° 30**

Device : **REVEAL DX 9528** Serial Number : Date

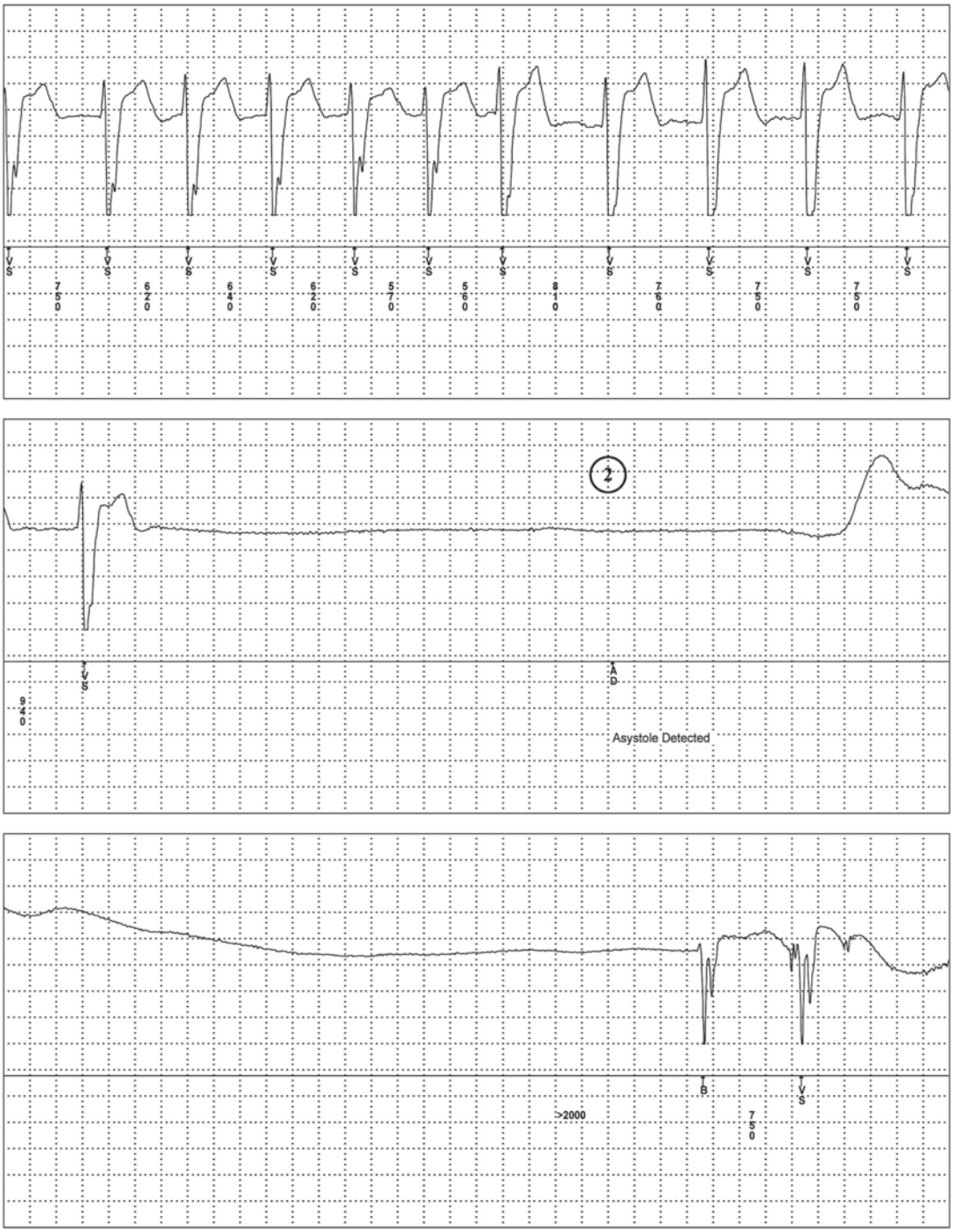
ID : **Episode #30 : 25.0 mm/s**



**SYMPTOM Episode n° 30**

Device : **REVEAL DX 9528** Serial number: Date :

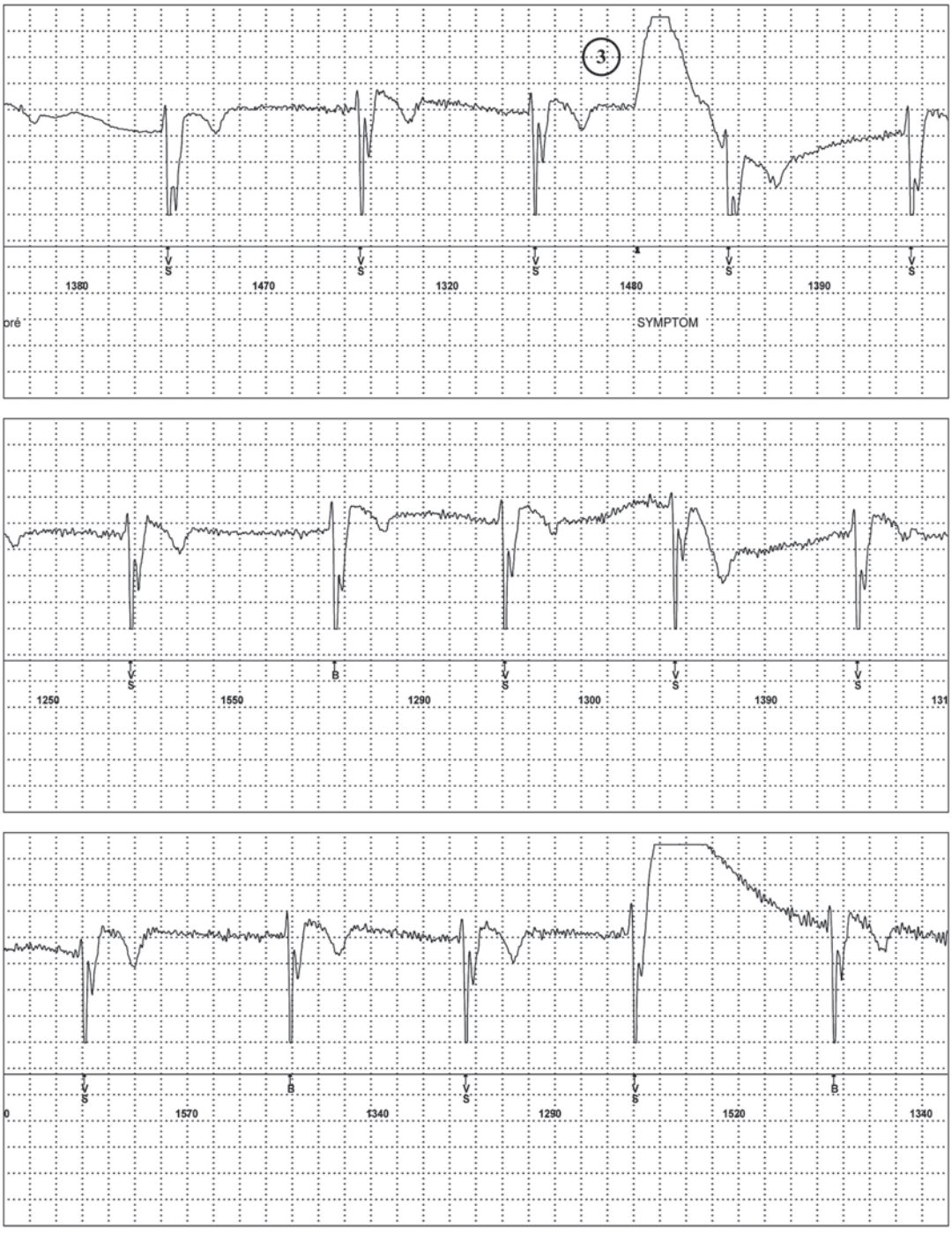
ID : **Episode #30 : 25.0 mm/s**



**SYMPTOM Episode n° 30**

Device : **REVEAL DX 9528** Serial number : Date :

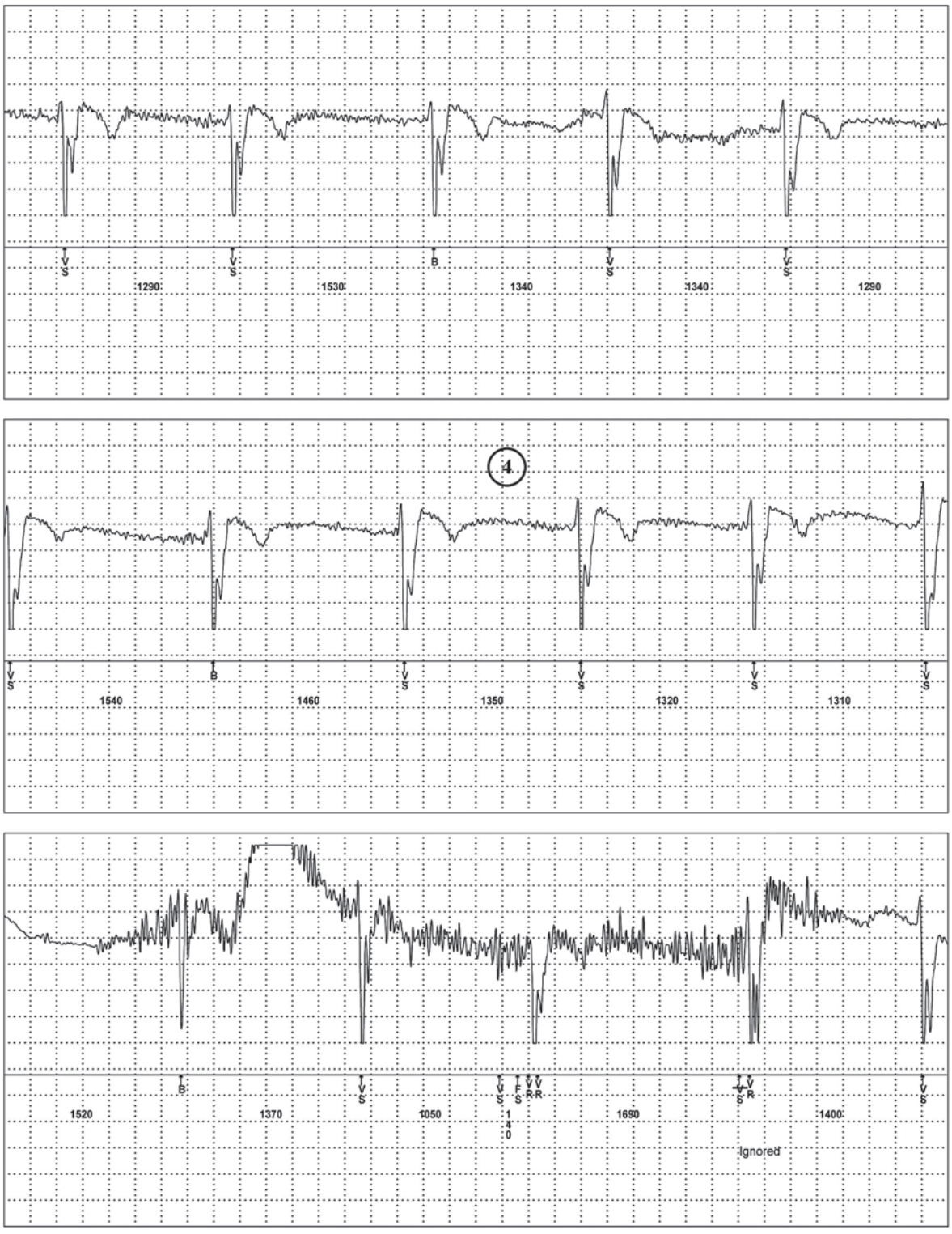
ID : **Episode #30 : 25.0 mm/s**



## SYMPTOM Episode n° 30

Device : **REVEAL DX 9528** Serial Number :

ID : **Episode #30 : 25.0 mm/s**



## Recording 14

### Illustrative case

A 62-year-old woman suffered a possible episode of syncope while driving, complicated by a car accident. All diagnostic tests were normal, including an echocardiogram and an ECG, which showed a narrow QRS. Because of the seriousness and consequences of the accident, a Reveal DX Holter was implanted after this first and only episode.

### Report of telemedicine

The report from home monitoring revealed neither automatically nor patient-activated recording of an event.

### Comments

Syncope while driving might be challenging to diagnose and manage, since it may be difficult to distinguish falling asleep from losing consciousness, and since the consequences may be catastrophic. A large proportion of patients suffer no recurrence during the life of the implanted device. This can only be helped by a) increasing the pre-implant likelihood of a recurrent event, and b) increasing the life expectancy of the device's batteries. In this patient, the pre-implant probability that she would suffer a recurrence was low, as she had suffered a single event, the characteristics of which were unclear. She underwent implantation of a Holter outside of the practice guidelines, being indicated in patients who have had recurrent syncope, precisely to increase the diagnostic yield. The strictly normal clinical investigations, ECG and echocardiogram suggested a very low risk of syncope of cardiac origin. Furthermore, the history did not suggest a vagally-mediated event. Thus, the implantation of a ILR was justified by the consequences of the episode and by the risk incurred by the patient, rather than by the clinical presentation.

The batteries of the newest devices can last up to 36 months. It is often important to wait long enough for a recurrence, since the longer the monitoring, the highest the likelihood of diagnosis.

Medtronic

# Parameters

Device: **Reveal® DX 9528** Date of Interrogation:

**Parameters**

| | Detection | ECG Recording | Interval (Rate) | Duration |
|---|---|---|---|---|
| FVT | On | On | 260 ms (231 bpm) | 30/40 beats |
| VT | On | On | 340 ms (176 bpm) | 16 beats |
| Asystole | On | On | | 3 sec |
| Brady | On | On | 2000 ms (30 bpm) | 4 beats |

**Sensing**

| | |
|---|---|
| Sensitivity | 0.035 mV (35 µV) |
| Blank after Sense | 70 ms |
| Sensing Threshold Decay Delay | 100 ms |

**Detection Enhancements**

| | |
|---|---|
| VT Detection | |
| VT Stability | Off |
| VT Onset | Off |

**Device Data Collection**

| | |
|---|---|
| Device Data Collection | On |
| Device Date/Time | 10-Oct-2010 19:15 |

**Device Information**

| | | | |
|---|---|---|---|
| Device | Medtronic | REVEAL DX 9528 | Implanted: |

**Notes**

syncope

Medtronic

# Episode Counters

Device: **Reveal® DX 9528** Date of Interrogation:

| | **Prior to Last Session**<br>16-Apr-2010 to<br>11-Jul-2010<br>86 days | **Since Last Session**<br>11-Jul-2010 to<br>10-Oct-2010<br>91 days | **Device Lifetime Total**<br>(Since 16-Apr-2010)<br>6 months |
|---|---|---|---|
| **Episode Counters** | | | |
| Symptom | 0 | 0 | 0 |
| FVT | 0 | 0 | 0 |
| VT | 0 | 0 | 0 |
| Asystole | 0 | 0 | 0 |
| Brady | 0 | 0 | 0 |