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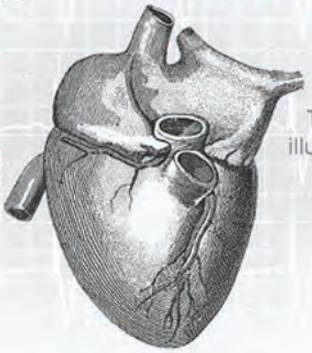

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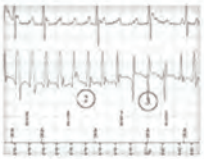

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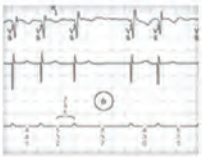

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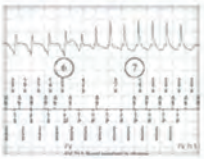

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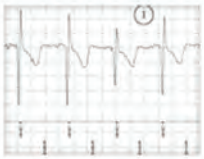

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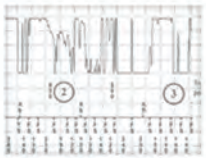

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Sommaire

Introduction

The indications for the implantation of an automatic defibrillator (ICD) have considerably evolved in the past 20 years. Initially limited to secondary prevention, for patients who had a history of aborted sudden cardiac death or sustained ventricular tachycardia, defibrillators are now implanted for primary prevention in patients at risk of sudden death though without history of sustained tachyarrhythmias. The variety of ICD recipients is wide, including young patients presenting with channelopathies in absence of structural heart disease and older patients with advanced cardiomyopathies, sedentary patients with limited mobility and active patients with professional obligations preventing their attendance to scheduled follow-ups, symptomatic patient who need regular follow-ups to limit their risk of cardiac decompensation, and asymptomatic patients who can be followed at more widely spaced intervals. One must distinguish the surveillance of the patient and heart disease, usually by the cardiologist or primary physician, from the surveillance of the ICD, usually assumed by an arrhythmia service because of the complexity of the task. ICD recipients require special surveillance because of their risk of experiencing asymptomatic cardiac events as well technical failures of the device. State-of-the-art ICDs are capable of memorising a growing amount of diagnostic information pertaining to their function, to the occurrence of ventricular or supraventricular arrhythmias, and to the patient's health status and cardiac function. The regular, or even continuous monitoring of the devices' memories might enable the early detection of their dysfunction and prevent episodes of cardiac decompensation.

The guidelines issued by professional societies recommend ICD follow-ups every 3 to 6 months, and shorter intervals near the device's end of life. The face to face physician's time spent with each visit often exceeds 15 min per patient, to which one must add the nurse's time, the registration procedure, correspondence, invoicing and record keeping. In a large number of instances, these visits, which do not prompt a change of treatment or device programming, could be omitted, which would save transportation costs that burden limited healthcare budgets. Furthermore, the uneven distribution of cardiologists throughout regions is the source of discriminatory access to care and expertise. The growing rate of device implantations, the highly variable characteristics of patient populations and the limited pools of caregivers mandate an adaptation and profound changes in the organisation of the patients' follow-ups.

Telemedicine is a technologic revolution, which might be able to meet some of the current challenges facing the various healthcare systems, such as aging of the population, increase in prevalence of chronic illnesses, uneven distribution of healthcare professionals and budgetary constraints. The objectives of telemedicine are, on the one hand, to improve the patients' quality of life by limiting the disturbances caused by commutes and absence from home as well as from the workplace and, on the other hand, to optimise their safety by shortening the delays in the management of adverse events. The remote follow-up of implantable devices has rapidly evolved in the last 10 years, from an experimental technology to a mature and broad, daily clinical application, after the publication of reports of its feasibility, safety and of several potential clinical advantages. Remote follow-up enables the surveillance of large numbers of patients in short periods of time, while preserving high quality standards. The participants in this program include the patient being followed remotely, the cardiologist in charge of the surveillance, the medical staff working under the responsibility of the cardiologist, the head of the healthcare centre, and the industrial partners involved in the technical organisation, such as the manufacturers of monitoring systems, the land lines or mobile telephone network services and other supporting entities.

The remote monitoring system developed for the Biotronik devices was a pioneer in the field, remains the reference, and is applicable to the entire range of devices, including pacemakers and ICDs. It combines scheduled remote monitoring, which regularly verifies the functions of the implanted device at times chosen by the caregiver, with event-driven monitoring, which continuously watches and automatically warns the caregiver by a message when an abnormal event is detected (event notification). The latter warns the caregiver in case of potential threat to the patient's health or function of the device. Every night, at a set time, the device transmits the contents of its memory and the technical information to a transmitter, which forwards to the manufacturer's service centre via a

mobile telephone network. This provides the caregiver with a variety of data, including status of the batteries, pacing and sensing thresholds, lead(s) impedance, arrhythmic events and manifestations of impending cardiac decompensation. This new process decreases the frequency and optimises the quality of ambulatory visits, particularly for patients who live away from medical facilities, have limited access to transportation or are physically disabled. Remote monitoring also enables the early identification of technical issues and changes in the patient's clinical status, which facilitates early and appropriate reactions. While it is not meant to manage emergencies, remote medical monitoring does enable the trigger of rapid responses for several situations that compromise the patient's safety, such as lead fracture, oversensing, inaccurate discrimination and unsuccessful shock deliveries.

The implementation of this new technology varies as a function of specific medical or governmental regulations, which take place within a broad context of constraints facing the healthcare system. Reimbursement of services, keystone of the development of telemedicine, remains an issue in several countries. Furthermore, questions pertaining to the cost/benefit ratio, the time between identification of an anomaly and corrective measure, the burden on caregivers, and the confidentiality of information, remain to be resolved.

The first part of this monograph reviews the current applications of this technology, its technologic basis, its legal and ethical ramifications, and future perspectives. In a second part, we study various clinical cases encountered during the follow-up of Biotronik ICD recipients, using a series of illustrative tracings collected from remote monitoring transmissions and by the programmer. We will also present and illustrate the specific characteristics of these devices, including normal function, and show what to do in presence of accurately or inaccurately detected arrhythmias, of successfully or unsuccessfully delivered therapies, and of the sensing of cardiac or extracardiac signals.

Chapter 1

Generalities

Definitions

Telemedicine is the remote practice of medicine, using information and communication technologies.
Telecardiology is the application of telemedicine to the field and practice of cardiology.
Teleconsultation is the application of remote communications for medical consultations without direct, face-to-face interaction.
Medical telesurveillance or telefollow-up is a remote follow-up, either scheduled at regular intervals, or prompted by symptoms, and associated with an analysis of data recorded automatically or by the patient.
Teleexpertise is a form of medical assistance contributed to a caregiver by another remotely located caregiver on the basis of remotely transmitted information. Teleexpertise has developed in particular in the field of pre-natal diagnosis, oncology (multidisciplinary consultations) and medical imaging.
Medical teleassistance enables medical professionals to remotely watch another health professional in the performance of a medical act. Its most publicized application is illustrated by telesurgery, i.e. the remote performance of surgical procedures. The Lindbergh operation is a famous example of a gallbladder removed from a patient in Strasbourg by Professor Jacques Marescaux from a hotel in New York, on September 2001.

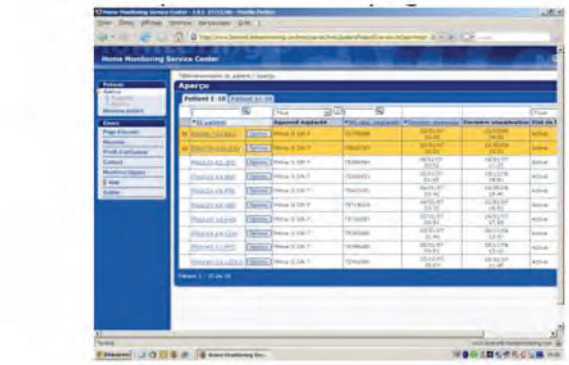
History of the remote monitoring of implantable devices

The first systems enabled the transtelephonic monitoring of cardiac pacemakers, in the beginning of the 1970s. The data transmission required the patients' cooperation and the application of a dedicated device over the pulse generator. Some limitations of this method precluded its development. Telemedicine grew rapidly in the 1990s, following the simultaneous development of medical devices enabling the conversion of data in an electronic digital format and the deployment of more and more rapid and powerful communication systems. The clinical venture of implanted devices' telemonitoring began in 2001, with the commercial launch, by Biotronik Inc., of a dual chamber pacemaker capable of transmitting data stored in the device's memory via an antenna incorporated in the pulse generator's connector, using a teletransmission device. Biotronik Inc. was the pioneer in this field and contributed thereafter to the various developmental stages and scientific validation of the technology. Today, electronic communications can be established between any points on earth via land or wireless lines, and pacemakers or defibrillators recipients represent the largest patient population benefitting from, remote, cardiology consultations or long-term monitoring.

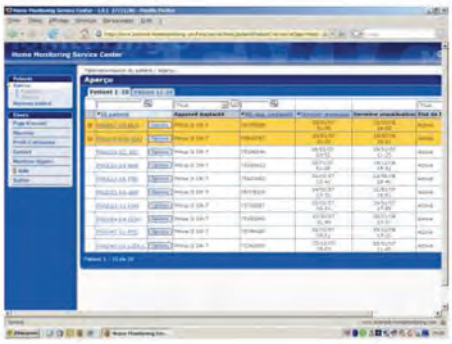
The salient developmental stages of telemonitoring of implantable devices are:
November 2000: The Home Monitoring® system receives CE approval;
December 2000: First implant of a pacemaker equipped with telecardiology BA03 DDDR, entirely wireless transmission and automatic trigger on "Medical Implant Communications Services" (MICS) band and global system for mobile communications (GSM);

BA03 DDDR pacemaker and patient RUC1000 transmitter;

April 2002: First implant of the Belos® VR-T defibrillator equipped with telemonitoring;
September 2003: The Web site for patient follow-ups goes on line;



September 2005: First transmission of an electrogram, initially analog transformed;



November 2006: Introduction of the General Packet Radio Service (GPRS) to increase the content of the transmitted messages;
June 2007: Comprehensive follow-up of the technical data of the Lumax® 340 HF-T defibrillator;
February 2009: Complete automation of the CardioMmessenger® II patient unit;
Mars 2009: New version of the Web site with management of multiple users;
January 2012: Programming of dates of teleconsultation in the device;
October 2012: First communicating BioMonitor® implantable Holter;

Operations of the remote monitoring system for Biotronik devices

Overview

The Biotronik remote monitoring system is more oriented toward telesurveillance than toward teleconsultation. Since the transmissions between the implanted pulse generator and the CardioMessenger are automatic, the patients are bystanders, free from all responsibilities. The pulse generator automatically transmits the encrypted data as a text message to Biotronik's service center, after which the data are decoded, analyzed and organized in a Cardio Report, accessible by the cardiologist on a secure Web site. In case of unusual event, defined in advance, the cardiologist may also receive alerts via fac simile, text message or e-mail. It is not however, an emergency service. The transmission is one-way, and the defibrillator cannot currently be programmed remotely. Messages may, however, be sent to the patient CardioMessenger as a light signal to indicate the need to contact the monitoring center. The energy expenditures for this kind of monitoring are low and do not significantly shorten the life of the pulse generator.

Programming of the telecardiology function

The transmission systems can only be used with devices made by the same manufacturer. Consequently, the device must be equipped with the telecardiology function and a transmitter, identified as the letter T added to the model's name: Lumax 340 HF-T. The implanted device's serial number is needed for the accurate identification and registration of the patient. The telecardiology function must then be activated with the programmer. The patient receives detailed information and must sign an informed consent, which describes the respective responsibilities of the participants in the implementation of remote monitoring. It is specified, in particular, that the cardiologist may not be able to view and be apprised of the data as soon as they have been transmitted. The patient is trained in the use of the CardioMessenger.

Transmissions between pulse generator and transmitter

The patient is equipped at home with a transmitter unit (CardioMessenger), which must be powered from a standard outlet near the bed. The distance between the CardioMessenger and the pulse generator must not be <20 cm (8 inches) to avoid all interference, and proper transmission is guaranteed over a 2-meter span. The data stored in the defibrillator are routed from a radiofrequency transmission circuit contained in the pulse generator. Using an integrated antenna and a special radio circuit, the device sends the data to the CardioMessenger, using RF-1 or RF-2 telemetry and an exclusive MICS 402 to 405 megaHz frequency bandwidth, reserved for implanted devices to limit the risk of interference with other devices. The CardioMessenger transmitter is most simple, devoid of switches and connectors, except for its power supply, and can be carried and used nearly everywhere in Europe and North Africa. For other regions of the world, the toll-free number 0 800 801 034 can be consulted for information.

Data are transmitted daily from the defibrillator to the Biotronik service center. The transmissions tend to be nocturnal, when the patient is in bed, though this can be modified according to the patient's routine, for example for night workers. The important events are immediately transmitted to the service center if the patient is near the CardioMessenger; otherwise, it is transmitted the following night. In case of unsuccessful transmission between pulse generator and CardioMessenger, the important events are stored and re-transmitted with the next attempt. Before the first transmission, the CardioMessenger and the implanted device are in a search mode to create a pair. Once connected, they set a fixed time, every night at the same time to transmit the messages. If the patient is away from the CardioMessenger, the device continues making several transmission attempts. After 3 consecutive nights without transmission, the CardioMessenger is uncoupled from the implanted device, and after 2 consecutive months without transmission, the implanted device switches to an event-driven mode. Instead of daily transmissions, only the events detected by the pulse generator are transmitted. In order to restore the daily transmissions, the pulse generator needs to be interrogated with the programmer. The main advantage of this system is its automaticity and patient-independence, allowing frequent transmissions.

Transmissions between CardioMessenger and Biotronik service center

The CardioMessenger used to automatically transmit the data as encrypted text messages to the service center of Biotronik Inc. in Berlin, Germany. The GPRS norm of the GSM is currently in use. The transmitter operates with all roaming networks that are under the partnership of T-Mobile.

Transmission between the service and the medical centers

The host collects, manages, stores and returns the data to the patient's cardiology center over the Internet, from a distant, secure server. The data, consolidated in a format similar to that retrieved with the programmer during an ambulatory visit, including tables and graphs, are accessible by the health care professionals on the Web site of the Home Monitoring service center, with a user identifier and password provided by Biotronik Inc. All interventions on the site by the various stakeholders are registered.

Transmitted data

Periodic monitoring
The system enables the daily monitoring of the memory contents and technical settings. Every night, at a fixed time, the device transmits its information via radio to the CardioMessenger, which, after having been forwarded to the Biotronik service center, becomes accessible and visible on the Web site, classified as:
- Technical data pertaining to the defibrillator (battery voltage, charge time, special mode)
- Technical data pertaining to the leads (pacing impedance, sensing amplitude, automatic capture threshold, defibrillation impedance)
- Atrial arrhythmias (atrial fibrillation episodes and burden)
- Ventricular arrhythmias (episodes of sustained and non-sustained ventricular tachycardia, episodes of ventricular fibrillation, types and outcomes of therapies delivered, and intra-cardiac atrial, ventricular and shock electrogram channels of the various episodes)
- Hemodynamic indices (% biventricular stimulation, average, resting and exercise functional capacity)
- Programmed settings (bradycardia and tachycardia function)

Messages and events
Functional abnormalities or rhythm disturbances are classified as alerts of various colors. These "alert messages" are the object of supplemental transmissions.

Transmission of electrograms
In absence of technical issues or arrhythmias, the device regularly transmits electrograms to verify the quality of the intra-cardiac signals' morphology.

Data protection and interferences

As they are being transmitted to the service center, the confidentiality of the data is preserved by a dedicated protocol and by securing the Web site visited by the caregivers. The data transmitted by the implanted device to the service center are encrypted and contain no patient identifier, except for the pulse generator's serial number. The link between that serial number and the patient can only be verified at the caregiver's institution or at the secured Web site of the service center. A risk exists of an attack of the network by hackers, who might jeopardize the confidentiality of the data, reprogram or cancel the therapies or, conversely, trigger the delivery of shocks. While this has not been observed in clinical practice, it is not out of the question, though would require a high level of technical expertise and seems highly unlikely as long as the devices cannot be reprogrammed remotely. A theoretical risk also exists for interference, although it has not been reported as a cause of system dysfunction. Furthermore, a study has found no interference between the Biotronik Home Monitoring system and various cell phones.

Maintenance

The system maintenance, the replacement of defective units and the surveillance of the reliability of the connections are usually by contract with the system's manufacturer. The replacement of defective units is guaranteed for the life of the implanted device during normal use by the patient. Telephone hotlines (no charge green numbers) are provided by Biotronik on business days, offering separate assistance for health professionals and for patients and family members. They answer technical inquiries and assist in the set up, connection and use of the transmitter, though do not answer medical inquiries from the patients.

Contraindications to the use of the system

There is not a formal contraindication regarding the use of Home Monitoring as a diagnostic tool. Its proper use, however, requires a minimum amount of cooperation from the patient. Its use is discouraged in the following circumstances:
- Inability of the patient to operate the system because of physical or mental limitations. If the patient

cannot understand or follow the instructions, a person capable of such should be designated to assist and guarantee the quality of the transmissions.
- No mobile telephone network operated by a roaming partner of T-mobile is available near the patient's residence.
- The caregiver cannot use the Internet or the medical center does not have qualified staff to analyze the data that have been collected.
- The medical center cannot contact the patient, should therapeutic actions be taken.

Scientific validation of remote monitoring

Various studies have validated the merits of remote monitoring and various evaluation criteria have been scrutinized:
- the feasibility of remote follow-up
- the safety of the implementation of this follow-up
- the early detection of events
- the intervention delay
- the patient quality of life expressed by the level of satisfaction with this mode of follow-up.

Initial studies have confirmed the feasibility of the technique and the similarity of data collected during an ambulatory visit and those collected by a remote follow-up. The use of digital technology guarantees an accurate reception of the data and minimizes the likelihood of transmission of erroneous information. However, a certain proportion of programmed transmissions are not properly executed. The transmission system depends on the GSM coverage, on the home installation, and on the presence of the patient near the remote transmitter. The absence of transmission is more often attributable to the absence of the patient from home than to a technical issue with the transmission system.
Later studies, comprising larger samples, have examined the clinical and economical merits of the system.

Advantages of remote monitoring

Telemedicine offers several improvements, including by:
- Bringing the patients closer to the delivery of care;
- Lowering the number of unnecessary ambulatory visits and lowering the costs of transportation;
- Lowering the number of work days lost by the patient and relatives;
- Preserving the quality of life, in particular by keeping patients in their residence;
- Sparing physicians' and nurses' time;
- Shortening the hospitalization for device implants without jeopardizing the patient's safety;
- Optimizing the management of the devices' ends of lives;
- Enhancing the patients' safety by alerting the caregivers of the occurrence of an instrumentation dysfunction or major clinical event, and enabling an earlier adaptation of the treatment or programming than with a standard follow-up;
- Improving the management of atrial arrhythmias (early identification of episodes of atrial fibrillation, confirmation of diagnosis by electrograms interpretation, early institution of anticoagulation);
- Improving the management of ventricular arrhythmias (detection of asymptomatic events and of repetitive capacitors charges for non-sustained tachycardias, evaluation of therapeutic efficacy);
- Lowering the incidence of inappropriate shocks (early detection of lead fracture, P, R or T waves oversensing, electromagnetic interference, episodes of atrial arrhythmias);
- Preventing episodes of cardiac decompensation by monitoring of hemodynamic indices (percent resynchronization, rest and exercise heart rates, activity level, thoracic impedance);
- Managing remotely device recalls that require closer follow-ups.

Organization of follow-ups with remote monitoring

ICD recipients need a dedicated follow-up, as they are at risk of asymptomatic adverse cardiac events, as well as technical failure of the device. They can be divided between a large population suffering from severe organic heart disease treated for primary or secondary prevention, and a smaller population without structural disease, presenting with a channelopathy or after having been rescued from aborted sudden cardiac death. The former group must be followed closely, usually by a cardiologist, who might be someone else than the implanting physician. The follow-ups of ICD recipients were traditionally almost exclusively carried out in face-to-face visits requiring the travel of patients to an arrhythmia center, which cost time and transportation expenses.

The remote follow-up of ICD, which is now included in international professional practice guidelines, enables the optimization of the follow-up of these patients. Various professional societies (expert consensus from HRS and EHRA) have issued good practice guidelines and recommend a minimum frequency of standard or remote follow-ups. A first visit must take place in presence of the physician within 72 h of the ICD implant. The second follow-up, scheduled between 2 and 12 weeks after device implantation near the end of the leads maturation, must also take place in presence of a physician. A follow-up every 3 to 6 months is recommended thereafter, which can be remote or face-to-face. It is, however, recommended to continue seeing the patient in a face-to-face visit at least once a year, as the symptoms, cardiac function and drug therapy may change in the interim, perhaps necessitating a reprogramming of the ICD. As the battery's end of life nears, the pace of face-to-face or remote follow-ups must accelerate. The contributions of the latter, therefore, are greatest during the maintenance phase of the ICD follow-up, when its function is stable, and when signs of battery depletion appear. While a certain proportion of face-to-face visits are inescapable, scheduled remote follow-ups can often take their place without loss of quality. It is, however, noteworthy that remote follow-ups do not replace medical encounters with the caregivers, when they are needed for reasons other than the ICD.

Professional societies have recommended all manufacturers to systematically include telemedicine functions in all new ICD models. Nowadays, it is recommended that all patients with ICDs should be offered remote monitoring as part of the standard follow-up management strategy (Class I, level of evidence A) the need for 24 h/day, 7 days/week surveillance has not been solidly confirmed and, for the time being, the limitation of follow-ups to working hours is fully legitimate.

Telemedicine is a major innovation, associated, like all major, new developments, with important changes in medical practices and in the organization of health care delivery. While a variety of schemes can be envisioned, a central organization with the creation of a network with a reference core that takes charge of the reception of the telesurveillance data, manages the technical issues and distributes specific information to the general practitioners or the cardiologists, seems optimal. The respective roles played by the main actors engaged in the remote follow-ups can be divided according to the programming of the event messages and according to the level of sensitivity of the alerts. The patient surveillance remains guaranteed by the cardiologist and the primary care physician with respect to the underlying disease in order to maintain a personalized network of care. A precise and rigorous definition of the respective competency and responsibilities of the various physicians, technicians and paramedical staff involved in the patient's follow-up is indispensible.

The organization of surveillance centers in charge of following patients with remote monitoring implies an ability by the medical team to manage remotely transmitted events, as well as the potential participation of specifically trained nursing or technical team and transfer of the cardiologist's activities to the paramedical staff. Under the responsibility of the cardiologist, a nurse, a clinical research monitor or a technician a) often pre-read and identify the recordings that need a cardiologist's interpretation, and b) guarantee the traceability of the entire process. A paramedical team must be trained in the detection of sensitive events that call for a medical opinion, from less significant events that do not need a validation by a physician. The latter analyses the critical tracings chosen by the technician and formulates the subsequent management strategy. The technician or the physician contacts the patient, if necessary, as well as the cardiologist or the primary physician, depending on the decision that has been made. The patient regularly receives a letter that reviews

the state of the implanted device and offers reassurance, as well as a reminder that the remote surveillance center can be contacted during working hours. Once the training period has elapsed, a precise programming of the device and a selection of events pertaining to a given patient allow a limitation of the number of alerts while preserving the quality of the follow-up. An optimal profile can be designed for each patient by rejecting alerts that are overly sensitive and non-specific. Although the transmissions are occurring daily, the data that are transmitted are scrutinized by the health care professionals on work days only. The system does not replace the emergency circuit that is usually available to the patient. In case of poor or interrupted transmission, the technician contacts the patient to determine whether the absence of transmission is due to a system failure or whether the patient has left home without carrying along the system.

Legal issues

Telemedicine is a full-fledged medical act. The specialized cardiologist is responsible for the follow-up of the technical and medical data, which he might manage alone or in collaboration with the general cardiologist, a collaboration that needs to be clearly defined. Some elements of this activity might be delegated to technicians or paramedical staff trained in the data collection. The manufacturers must a) guarantee unfettered and secure access to the patients' confidential health information, b) specify the procedure that needs to be adopted in case of technical issue in the transmission or the availability of data, c) guarantee the replacement of obsolete or non-functional equipment, d) verify and authenticate the users, define the rights and keep track of all accesses, and e) protect the system against cyberviruses. The location of the informational technology systems used for communications with the patient must be known, in order to limit their access to the physician(s) or their collaborators. Printed documents that have been transmitted remotely must be treated like confidential medical documents and filed securely in the patient's medical records.

Patients must be fully informed in plain language of the conditions of operation of remote surveillance, explaining clearly that it is not a means of managing medical emergencies, and that the device cannot be programmed or reprogrammed remotely. A written consent is increasingly recommended, as it enables, if needed, to show the proof that the consent was granted. The patients must be provided with the coordinates of the surveillance center, including names and telephone numbers of contact persons in case of difficulty, and must be explained what to do, should a problem occur outside the working hours of the remote surveillance center.

Perspectives

The application of remote follow-up of defibrillators is currently the objet of wide disparities. Some changes should enable the extension of this technique. Studies are still in progress trying to quantify the clinical and economic contributions, the medical service that it renders, as well as its qualitative and organizational contributions. Lowering the costs of transportation by decreasing the number of ambulatory visits is not the only objective of remote monitoring; it should also optimize the patient follow-ups, and indirectly represent an important source of savings. The presentation, classification and semantics of the data vary among manufacturers, which complicate their analysis and interpretation. To facilitate the follow-up with telemedicine, the data should be standardized among manufacturers, and presented in a single, simplified format, which would greatly facilitate the understanding, comparison and archiving of the data. On an international scale, the growth of the investments in this technology is mostly limited to the so-called developed countries. Electronic links can now be established with landlines or satellites anywhere in the world. The advantages offered by this technology would probably be even more apparent in countries in the process of industrialization, where the distances are often greater, the populations more isolated, the healthcare organization less developed, and the demands for care greater. Other particular circumstances should also promote the development of telecardiology such as huge countries, islands, special professional environments such as oil platforms, prisons, etc.

Chapter 2

Periodic EGM

Transmission of periodic EGM

In the absence of a technical issue or arrhythmia, the device regularly transmits a 30-sec sample of electrograms to verify the quality of the intracardiac signals' morphology. It is noteworthy that, with the Lumos and Kronos ICD, the display of the remotely transmitted EGM is slightly different than that displayed on the programmer, because the former is considerably more compressed than the latter, explaining its lower resolution. Very few of these devices remain in use, however.
While the transmission of the electrograms is periodic, it may, on occasion, diagnose episodes of asymptomatic oversensing (P or T wave, double counting of the R wave, 50 Hz), of atrial or ventricular lead fracture, or loss of left ventricular capture in recipients of CRT-D.

EGM 1: P wave oversensing

Patient

This 47-year-old woman received a single chamber Lumax 340 VR-T ICD after an episode of aborted sudden cardiac death.

Remote tracings

Three channels are available: 1) the markers with the time intervals, 2) the shock channel (FF = far field) between the ventricular lead coil and the can, and 3) the right ventricular (RV) sensing channel with 30 sec of EGM.

1: spontaneous rhythm;
2: oversensing of a supernumerary signal, probably corresponding to an atrial event; the QRS falls after the PR interval and is classified as VF (PR interval > ventricular blanking programmed at 80 ms);
3: intermittent oversensing; alternation of VS and VF cycles, the VF counter is never full and no episode is recorded;

Comments

Systematic oversensing of a supernumerary cardiac signal results from the sensing of 2 signals of different morphologies for a single cardiac cycle. P wave oversensing is likely to occur when the defibrillation electrode of an integrated bipolar lead straddles the tricuspid valve and when the sensed PR interval is longer than ventricular blanking. In this patient, oversensing was intermittent, explaining the absence of an episode stored in the defibrillator memory. P wave oversensing by the ventricular sensing channel may cause the delivery of inappropriate therapies during sinus tachycardia (if the ventricular rate is 120 bpm, the sensed rate is 240 bpm), or during atrial tachycardia. Analysis of the periodic EGM, which was transmitted systematically in absence of alert, allowed an early diagnosis. This patient was seen the morning after reception of this EGM recording. The ventricular lead had to be repositioned in order to eliminate oversensing, by advancing the entire defibrillation electrode inside the right ventricle, as no reprogramming of sensing or of the refractory periods was able to correct the problem.

This tracing illustrates the merits of periodic EGM, which reveal clinical or technical abnormalities that do not fulfill the diagnostic criteria of alert-triggering events, though warrant a medical decision.

Status report - May 10, 2012

To: Service Télécardiologie

BIOTRONIK
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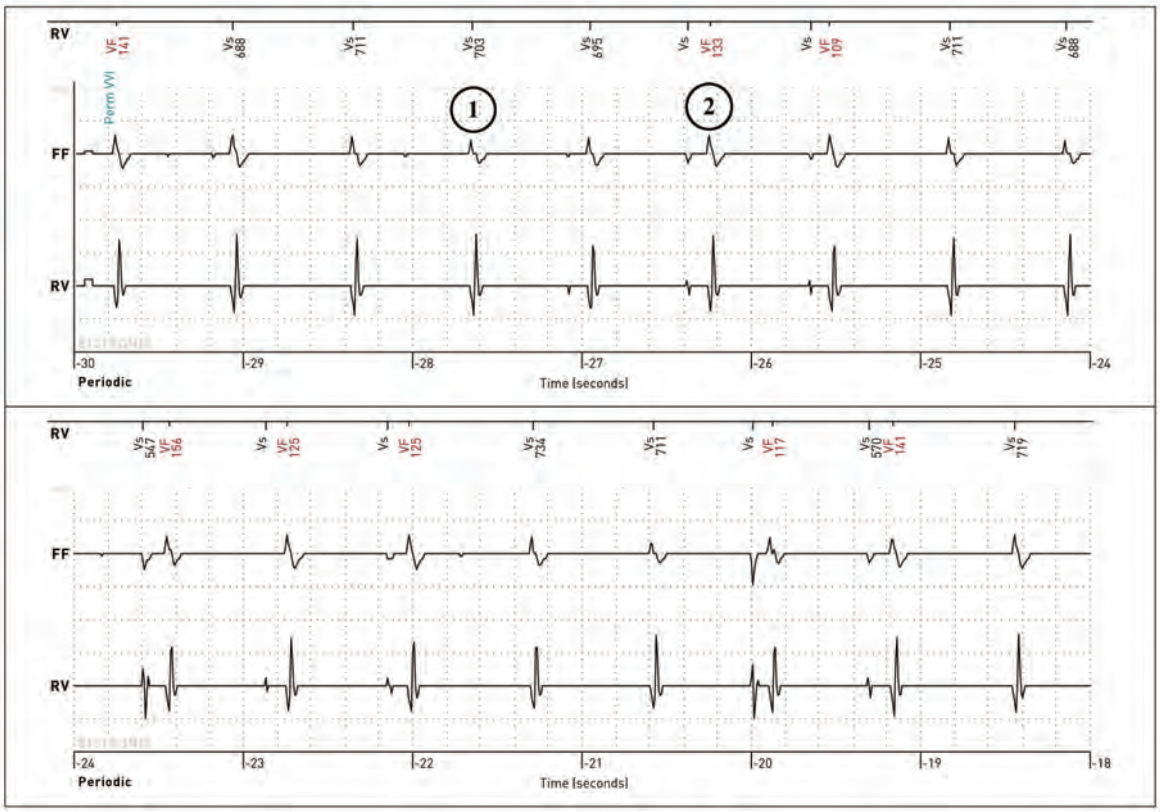
Name:	DOB:	Lumax 340 VR-T (XL)	Last message: May 10, 2012
Patient ID:	Phone: -	ICD implanted Jul 19, 2009	Last clinic follow-up: May 9, 2012

Recordings

Recordings - Episode 18:

General		Therapy	
Episode number	18	ATP in VT/VF delivered	---
Episode type	Periodic IEGM	ATP One Shot delivered	---
Detection	May 5, 2012 12:40:42 AM	Shocks delivered	---
Termination	---	Shocks aborted	---
Duration	---	Maximum energy [J]	---
Device settings no.	7	**Termination**	
Detection		Mean RR at termination [ms]	---
Mean RR at initial detection [ms]	---	**Remark**	
Onset [%]	---	none	
Stability [ms]	---		
Redetection	---		



Technical Services:
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Fax: +49 30 68905 2941

Date:

Signature:

1/2

Status report - May 10, 2012

To: Service Télécardiologie

BIOTRONIK
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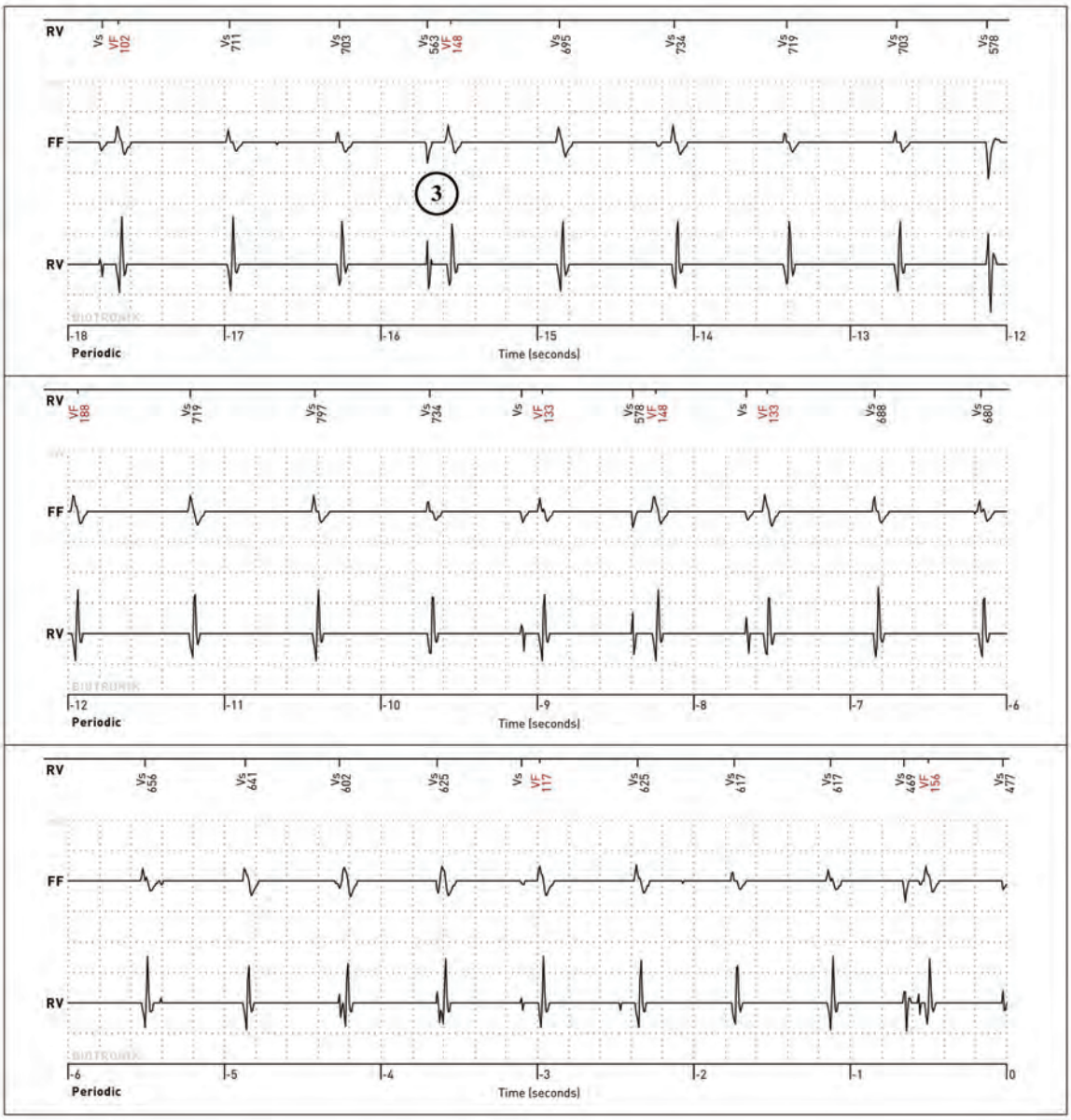
Name:	DOB:	Lumax 340 VR-T (XL)	Last message: May 10, 2012
Patient ID:	Phone: -	ICD implanted Jul 19, 2009	Last clinic follow-up: May 9, 2012



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2/2

EGM 2: double counting of the R wave

Patient

This 64-year-old man underwent implantation of a dual chamber Lumax 340 DR-T defibrillator in the context of ischemic cardiomyopathy with right bundle branch block and left anterior fascicular block; periodic EGM recording.

Telecardiology tracing

Four channels are present: 1) markers with time intervals, 2) shock channel (FF = far-field) between the ventricular lead coil and the pulse generator, 3) atrial sensing channel, 4) right ventricular (RV) sensing channel. EGMs were recorded for 30 seconds.

1: Spontaneous sinus rhythm; oversensing of a supernumerary ventricular EGM, corresponding to double counting of the R wave at the end of the ventricular blanking period;
2: Permanent oversensing; alternation of VS and VF cycles; the VF counter is never filled and no episode is recorded.

Comments

R wave double counting may occur when ventricular conduction is markedly slowed and the duration of the ventricular endocardial EGM is longer than the ventricular blanking period. With the new Lumax 740 defibrillators, the nominal post-ventricular blanking period has been extended to 110 ms. In this patient, the programmed ventricular blanking period was probably too short, and its lengthening without changes in the programmed sensitivity eliminated double counting while preserving the patient's safety. The unchanged sensitivity guaranteed the proper sensing of ventricular arrhythmias, and the blanking period programmed at 120 ms did not preclude the flawless detection of ventricular VF, since such short physiological ventricular intervals are not observable.

Status report - Jan 23, 2013

To: Service TélécΩrdiologie

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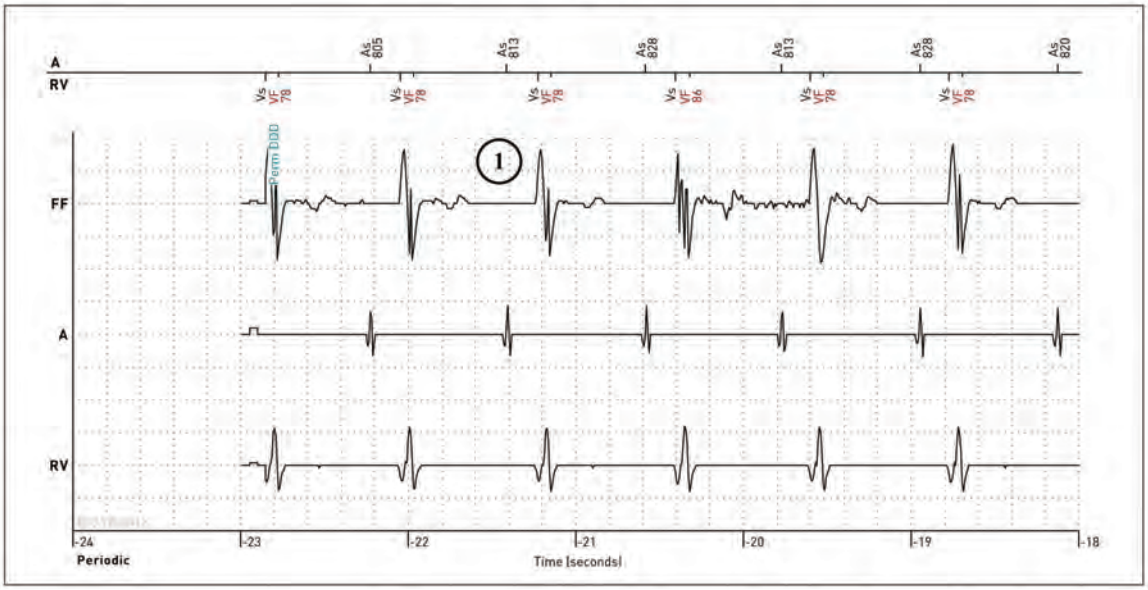
Name:	DOB:	Lumax 340 DR-T	Last message: Jan 20, 2013
Patient ID:	Phone: -	ICD implanted May 6, 2009	Last clinic follow-up: Oct 9, 2012

Recordings

Recordings - Episode 5:

General	
Episode number	5
Episode type	Periodic IEGM
Detection	Dec 13, 2009 12:40:42 AM
Termination	---
Duration	---
Device settings no.	11
Detection	
Mean PP at initial detection [ms]	---
Mean RR at initial detection [ms]	---
Onset [%]	---
Stability [ms]	---
Redetection	---

Therapy	
ATP in VT/VF delivered	---
ATP One Shot delivered	---
Shocks delivered	---
Shocks aborted	---
Maximum energy [J]	---
Termination	
Mean PP at termination [ms]	---
Mean RR at termination [ms]	---
Remark	
none	



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Status report - Jan 23, 2013

To: Service Télécardiologie

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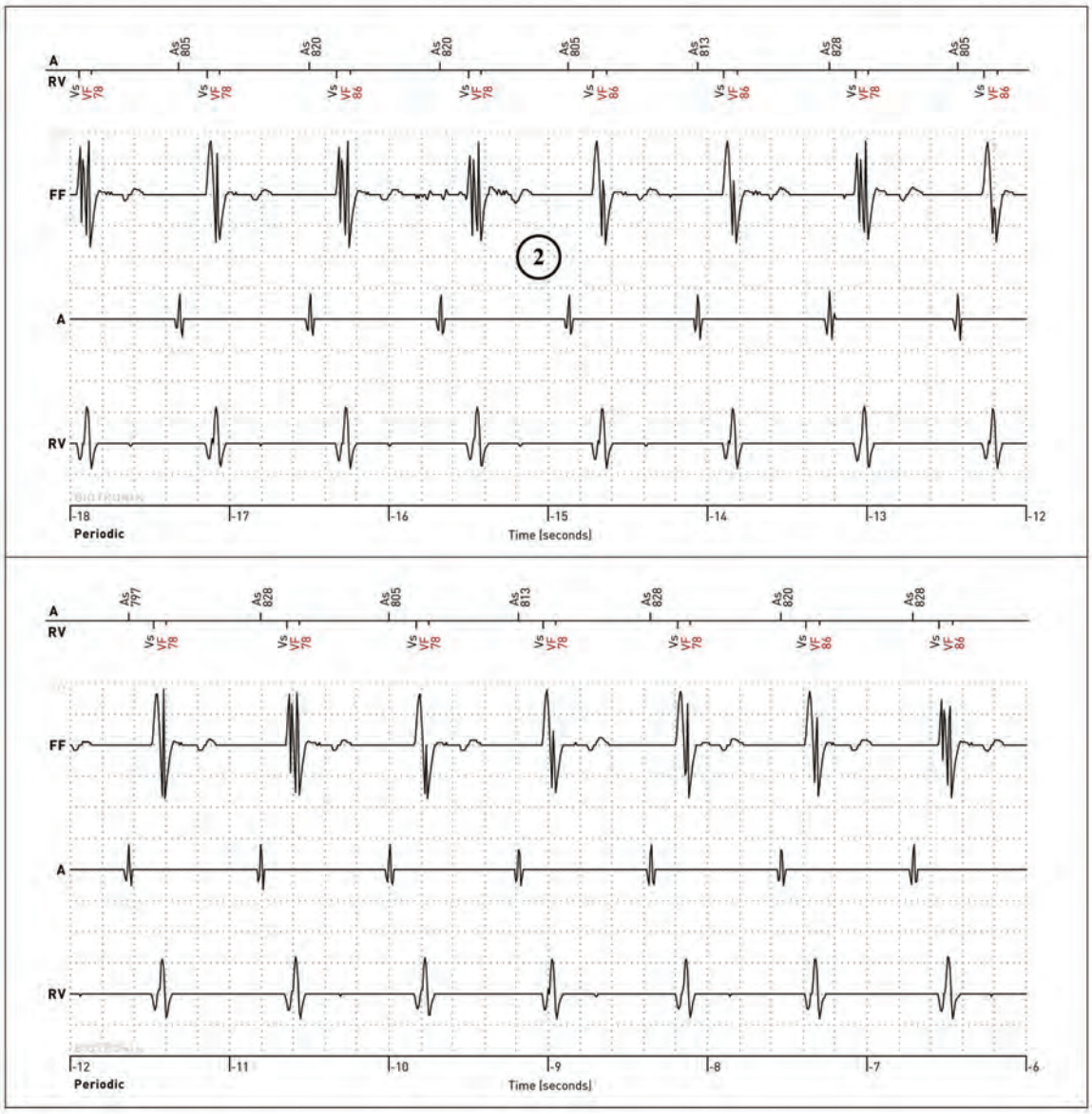
Name:	DOB:	Lumax 340 DR-T	Last message: Jan 20, 2013
Patient ID:	Phone: -	ICD implanted May 6, 2009	Last clinic follow-up: Oct 9, 2012



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Date:

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2/3

Status report - Jan 23, 2013

To: Service TélécØrdiologie

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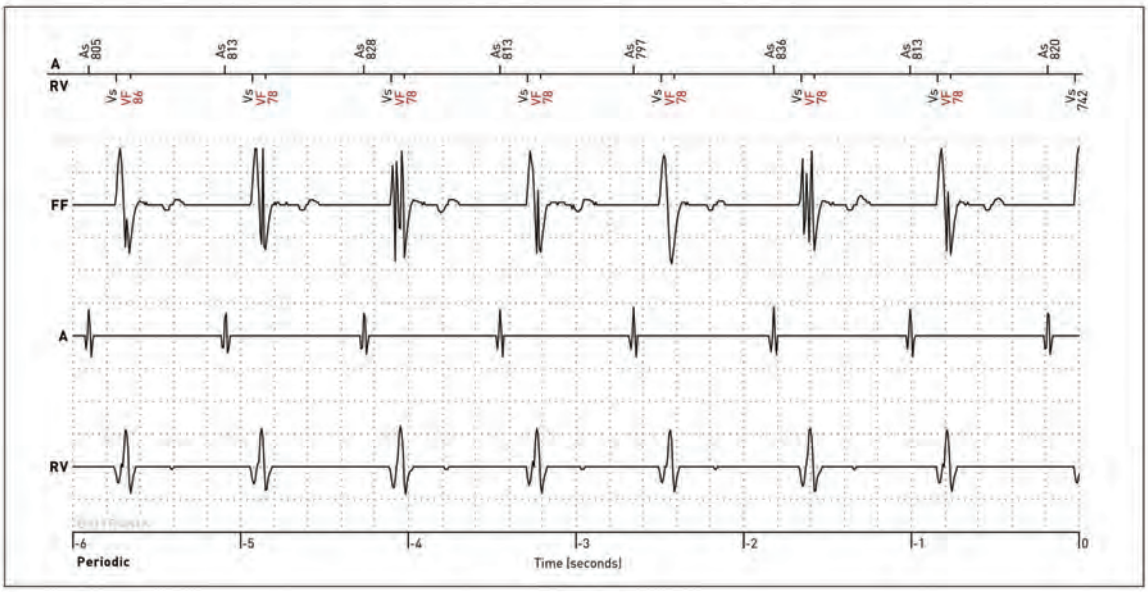
Name:	DOB:	Lumax 340 DR-T	Last message: Jan 20, 2013
Patient ID:	Phone: -	ICD implanted May 6, 2009	Last clinic follow-up: Oct 9, 2012



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3/3

EGM 3: double counting of the R wave from ventricular extrasystole

Patient

This 54-year-old man underwent implantation of a Lumax 540 HF-T triple chamber defibrillator in the context of ischemic cardiomyopathy with left bundle branch block; periodical EGM;

Telecardiology tracing

The 4 available channels are the markers with the time intervals, the atrial sensing channel, and the right and left ventricular sensing channels, each for 30 seconds.

1: sinus rhythm with biventricular stimulation;
2: P wave undersensing with spontaneous activation of the ventricles;
3: PVC, probably originating from the right ventricle, sensed first in the right then in the left ventricular channel;
4: PVC with oversensing in the right ventricular channel of a supernumerary ventricular electrogram, corresponding to the double counting of the R wave at the end of the ventricular blanking period;
5: further PVC oversensing.

Comments

This patient had to be seen in a face-to-face consultation to resolve several issues. The main one was the double counting of the R wave, limited to some VES of right ventricular origin. Should ventricular tachycardia develop, the risks associated with double counting were: 1) erroneous classification of tachycardia at 300 bpm (in the VF zone) instead of 150 bpm; 2) unnecessarily forceful therapies, such as electrical shocks instead of anti-tachycardia pacing. As in the case of the previous patient, the programming of the blanking period (80 ms) was probably too short, and a lengthening of the programmed value to 110 ms resolved the issue.
Ventriculo-atrial crosstalk requires a lengthening of the post-ventricular stimulation atrial blanking period to prevent possible erroneous diagnoses of atrial arrhythmias with mode switch to DDI pacing, which might cause a loss of biventricular resynchronization as long as the device is in mode switch.
From a clinical perspective, the PVCs were frequent at the time of the recording of the periodic EGM. A careful surveillance of their occurrence on the successive reports of telecardiology, and an understanding of their clinical consequences was in order. If frequent, a search for a metabolic abnormality and a surveillance of the evolution of left ventricular function were required in this patient suffering from heart failure.

Status report - Apr 2, 2013

To: Service Télécardiologie

BIOTRONIK
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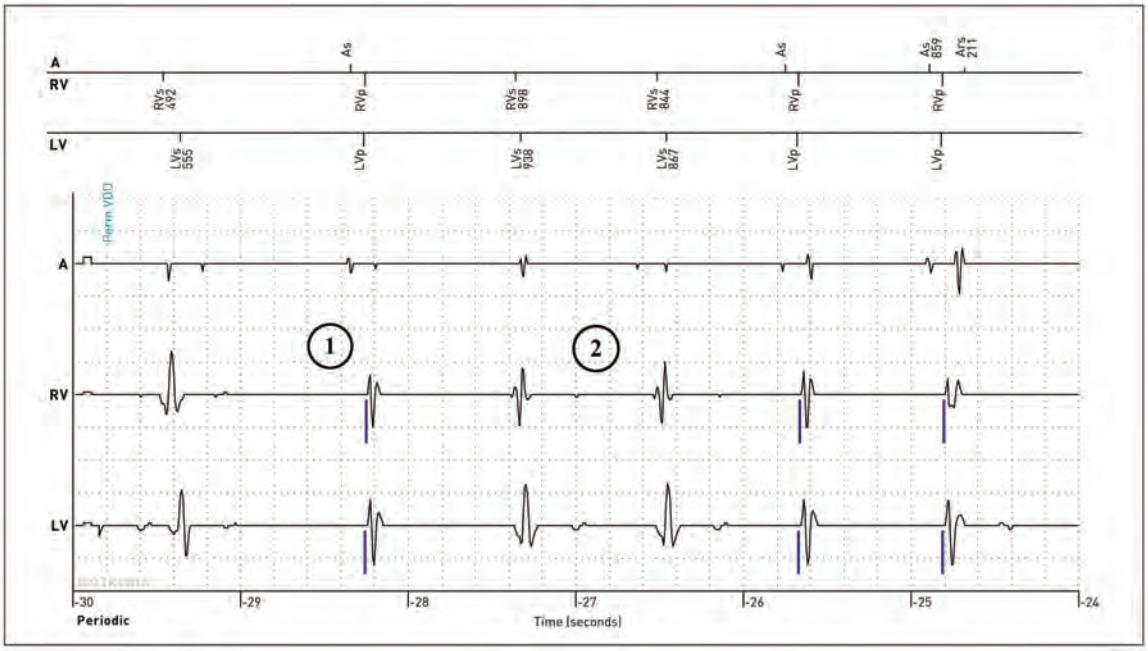
Name:	DOB:	Lumax 540 HF-T	Last message: Apr 2, 2013
Patient ID:	Phone: -	CRT-D implanted Feb 8, 2012	Last clinic follow-up: Mar 12, 2013

Recordings

Recordings - Episode 4:

General	
Episode number	4
Episode type	Periodic IEGM
Detection	Nov 11, 2012 3:00:42 AM
Termination	---
Duration	---
Device settings no.	9
Detection	
Mean PP at initial detection [ms]	---
Mean RR at initial detection [ms]	---
Onset [%]	---
Stability [ms]	---
Redetection	---

Therapy	
ATP in VT/VF delivered	---
ATP One Shot delivered	---
Shocks delivered	---
Shocks aborted	---
Maximum energy [J]	---
Termination	
Mean PP at termination [ms]	---
Mean RR at termination [ms]	---
Remark	
none	



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Status report - Apr 2, 2013

To: Service Télécardiologie

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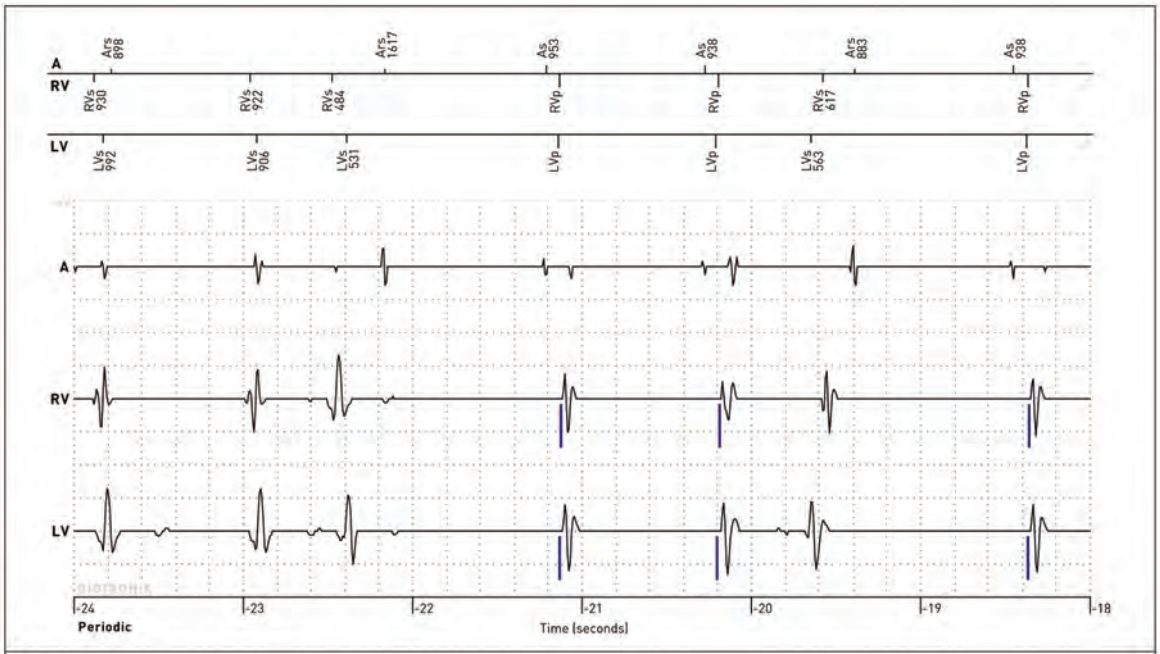
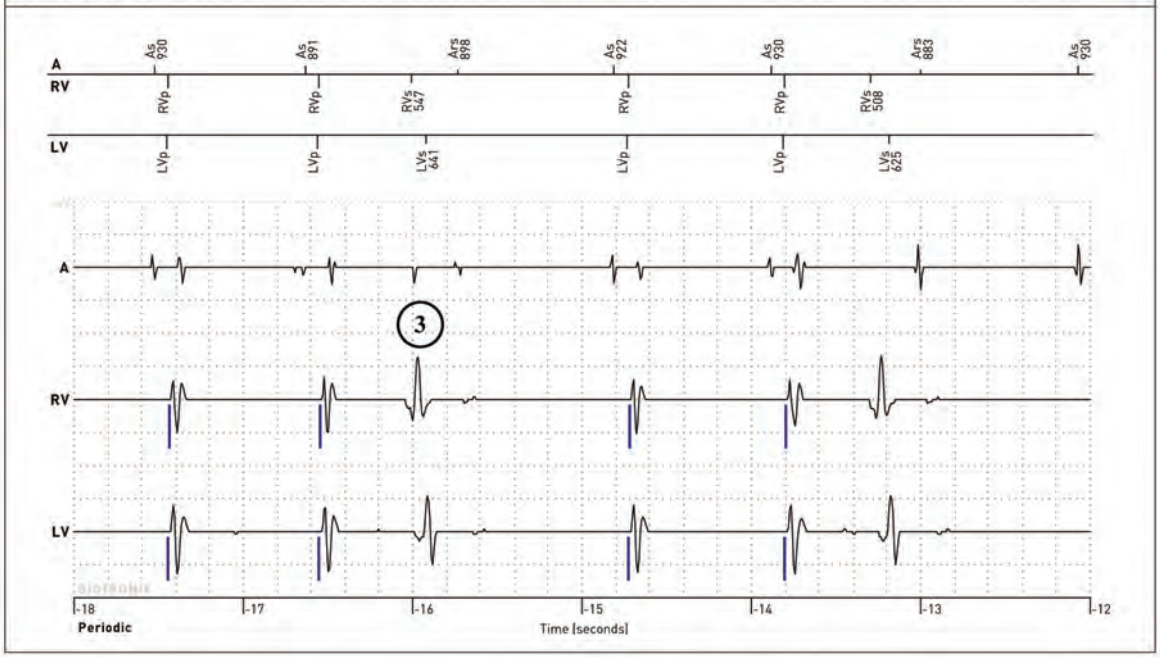
Name:	DOB:	Lumax 540 HF-T	Last message: Apr 2, 2013
Patient ID:	Phone: -	CRT-D implanted Feb 8, 2012	Last clinic follow-up: Mar 12, 2013





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Status report - Apr 2, 2013

To: Service TélécØrdiologie

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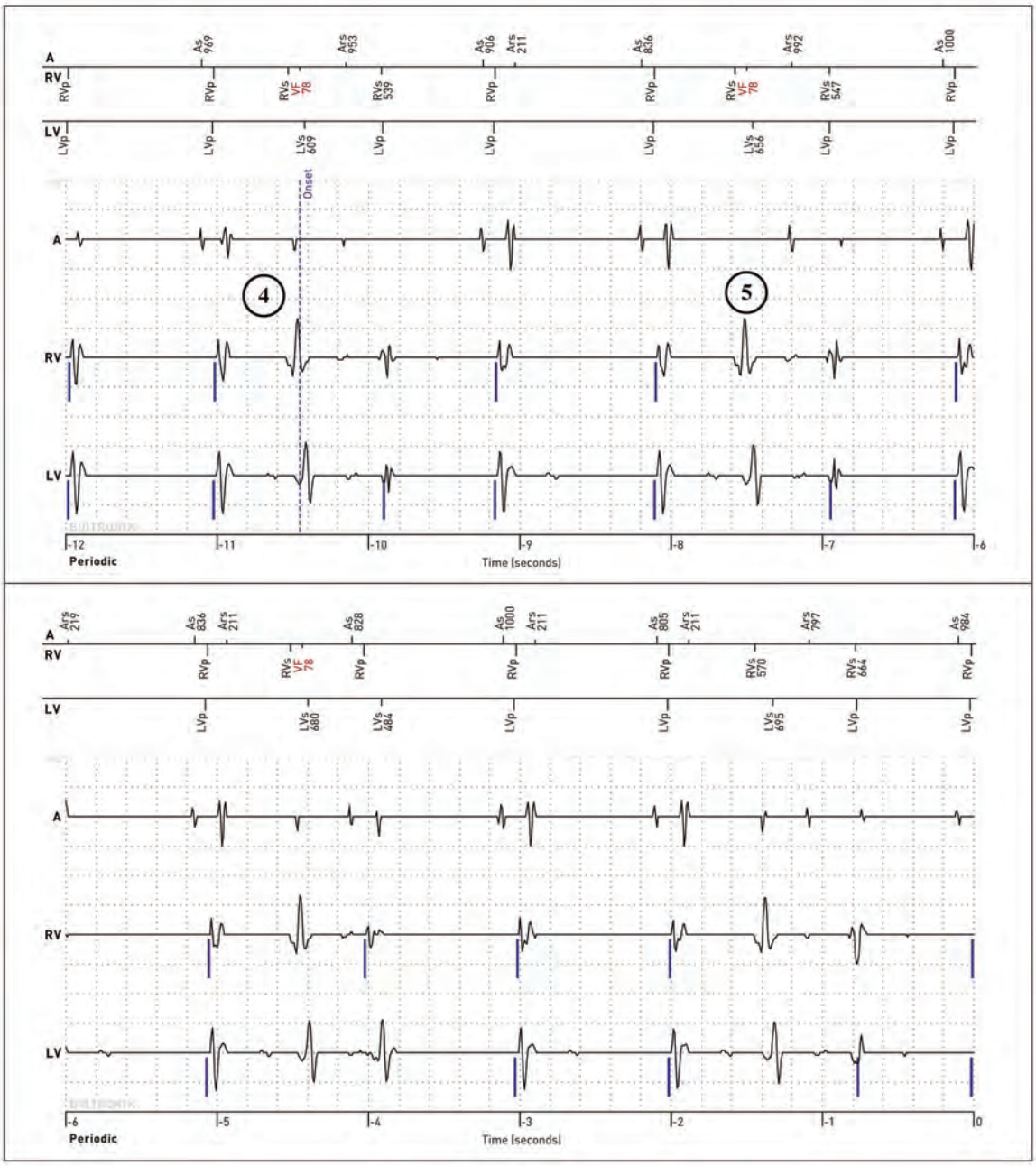
Name:	DOB:	Lumax 540 HF-T	Last message: Apr 2, 2013
Patient ID:	Phone: -	CRT-D implanted Feb 8, 2012	Last clinic follow-up: Mar 12, 2013



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3/3

EGM 4: crosstalk

Patient

This 54-year-old man presenting with dilated cardiomyopathy and conduction abnormalities underwent implantation of a Lumax 540 HF-T triple chamber defibrillator; periodic EGM.

Telecardiology tracing

The 4 channels displayed for 30 sec include 1) the markers and time intervals, 2) the atrial sensing channel, 3) the right ventricular sensing channel and 3) the left ventricular sensing channel.

1: spontaneous atrial rhythm and biventricular stimulation;
2: oversensing of a supernumerary atrial signal corresponding to the end of the stimulated QRS: ventriculo-atrial crosstalk;
3: alternation in the atrium of cycles classified AS and Ars; absence of mode switch.

Comments

Oversensing of spontaneous or stimulated ventricular activation by the atrial channel is diagnosed in presence of alternating short and long AA delays, with sensing of an atrial EGM near a ventricular EGM, and a constant V-A interval, of a duration just longer than the post-ventricular atrial blanking period. This might cause inappropriate mode switch as well as interfere with discrimination based on the counts of atrial and ventricular EGM during tachycardia. This oversensing can be prevented by lowering the atrial sensitivity or by lengthening the post-ventricular atrial blanking period (far-field blanking by default 75 ms after VP or VS). In this case, the issue was resolved by lengthening the post-ventricular stimulation atrial blanking period.

Status report - Apr 2, 2013

To: Service Télécardiologie

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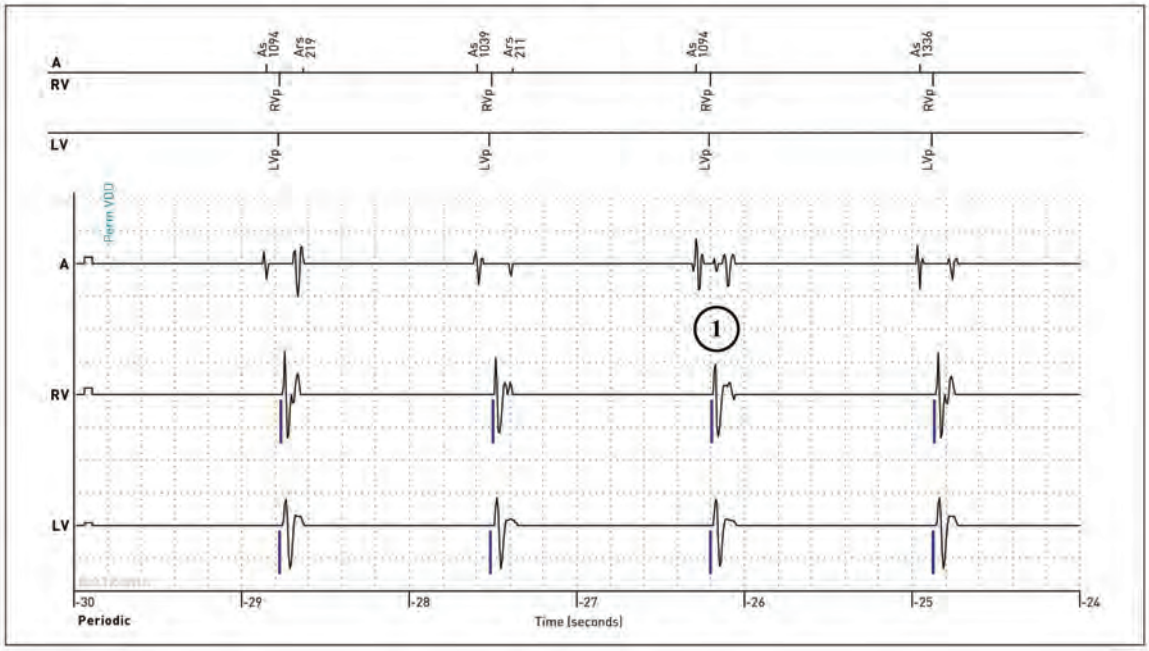
Name:	DOB:	Lumax 540 HF-T	Last message: Apr 2, 2013
Patient ID:	Phone: -	CRT-D implanted Feb 8, 2012	Last clinic follow-up: Mar 12, 2013

Recordings

Recordings - Episode 2:

General	
Episode number	2
Episode type	Periodic IEGM
Detection	May 15, 2012 3:00:43 AM
Termination	---
Duration	---
Device settings no.	8
Detection	
Mean PP at initial detection [ms]	---
Mean RR at initial detection [ms]	---
Onset [%]	---
Stability [ms]	---
Redetection	---

Therapy	
ATP in VT/VF delivered	---
ATP One Shot delivered	---
Shocks delivered	---
Shocks aborted	---
Maximum energy [J]	---
Termination	
Mean PP at termination [ms]	---
Mean RR at termination [ms]	---
Remark	
none	



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Date:

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1/3

Status report - Apr 2, 2013

To: Service Télécardiologie

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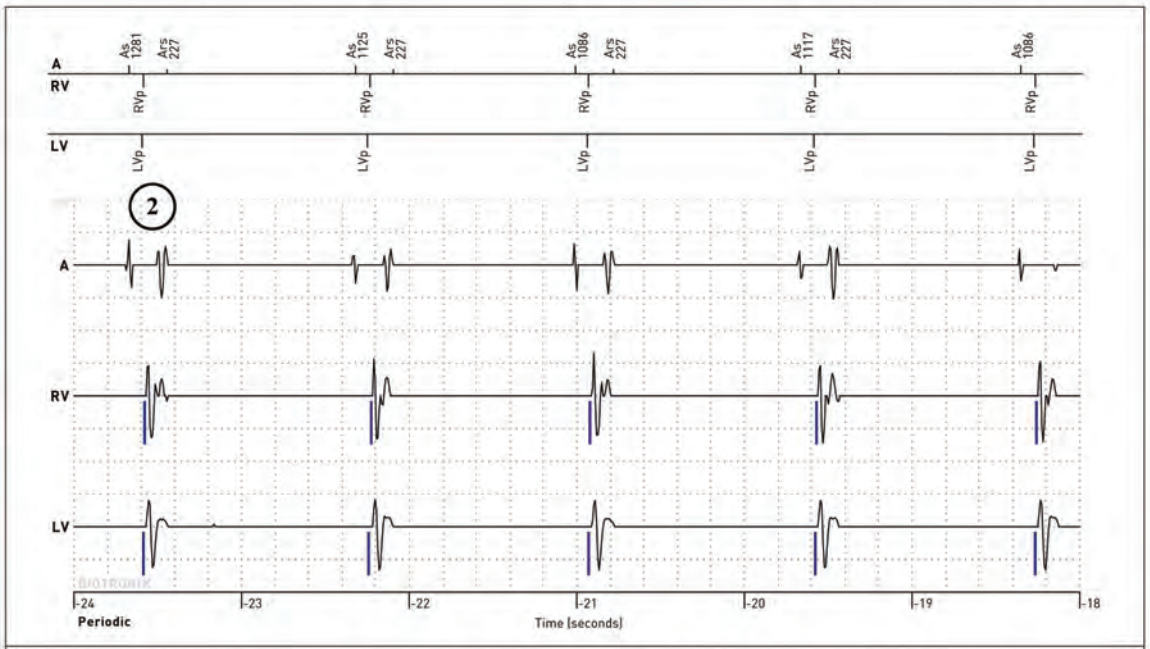
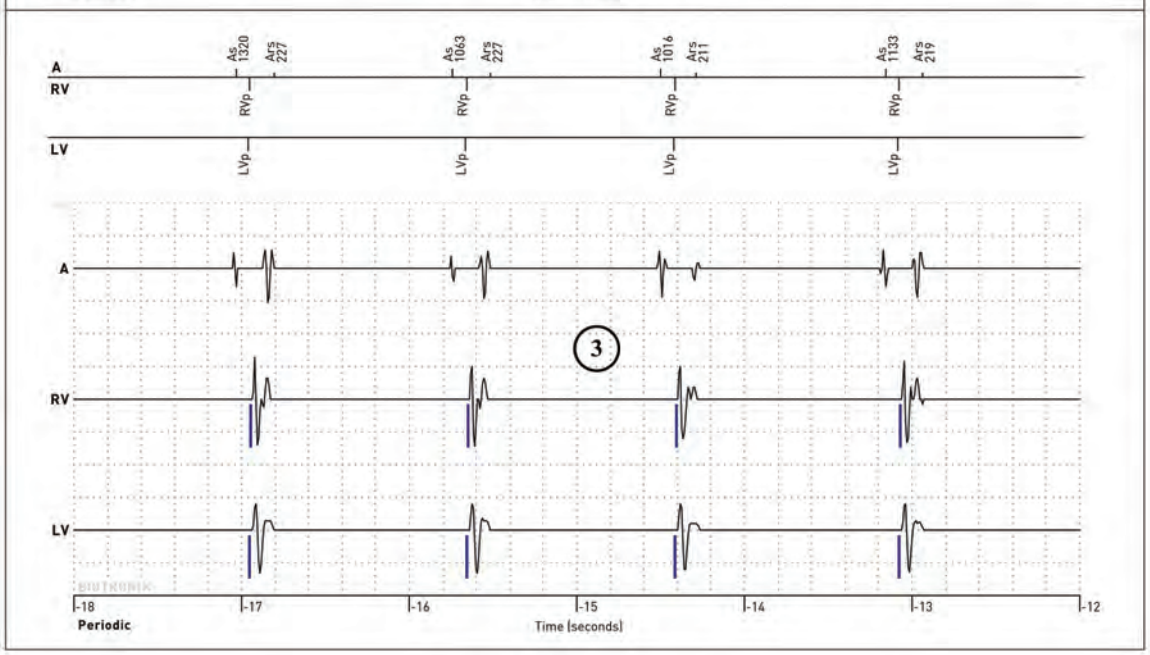
Name:	DOB:	Lumax 540 HF-T	Last message: Apr 2, 2013
Patient ID:	Phone: -	CRT-D implanted Feb 8, 2012	Last clinic follow-up: Mar 12, 2013





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Status report - Apr 2, 2013

To: Service TélécØrdiologie

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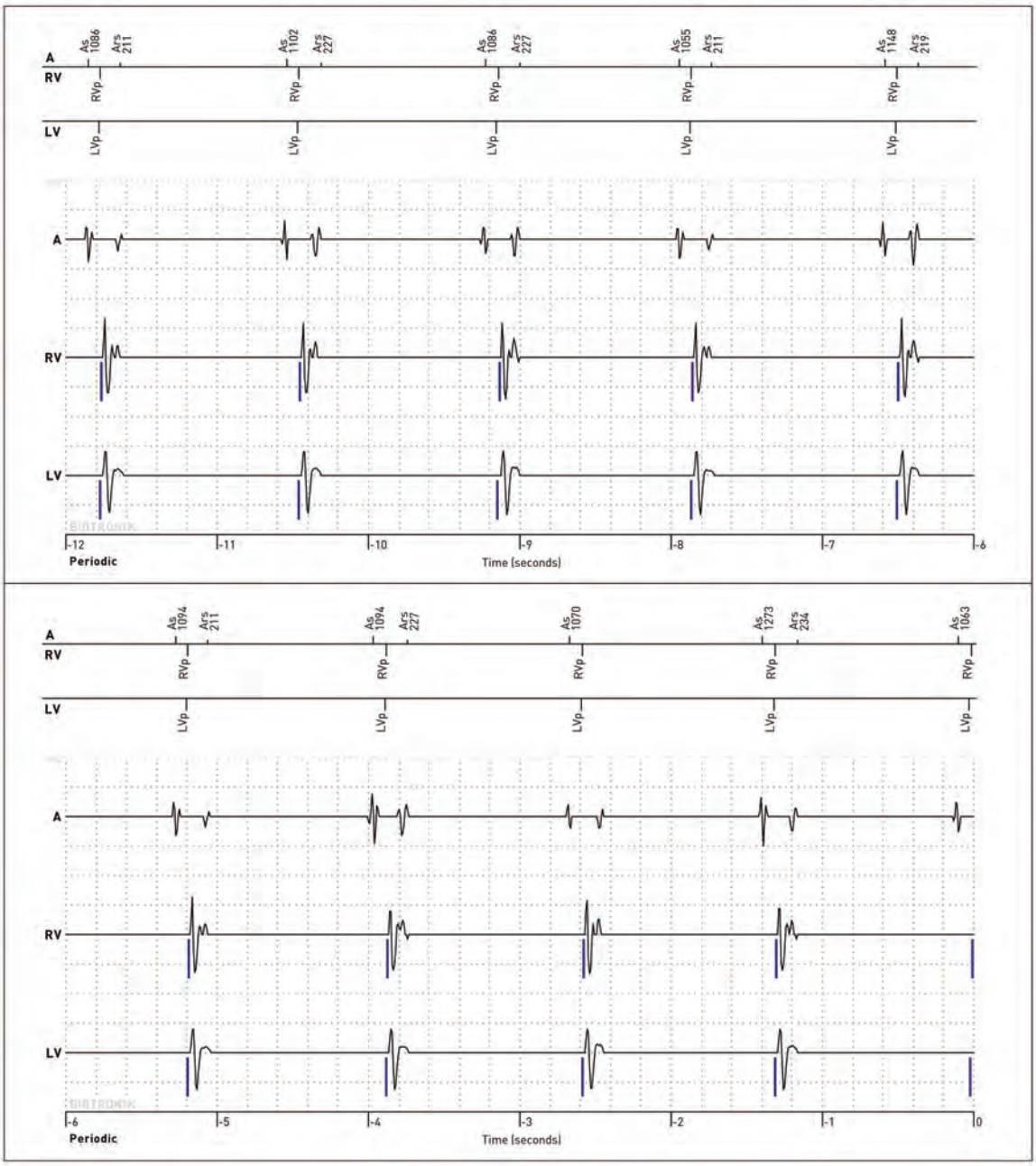
Name:	DOB:	Lumax 540 HF-T	Last message: Apr 2, 2013
Patient ID:	Phone: -	CRT-D implanted Feb 8, 2012	Last clinic follow-up: Mar 12, 2013



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3/3

EGM 5: noise oversensing in the atrial lead

Patient

This 55-year-old man received an Evia DR-T dual chamber pacemaker for paroxysmal complete atrioventricular block; periodic recording of EGM.

Telecardiology tracing

The 3 channels that are displayed for 12 sec are 1) the markers with the time intervals, 2) the atrial sensing channel and 3) the right ventricular sensing channel.

1: oversensing of noise on the atrial channel; alternating cycles classified As, Ars and Ars (FFP = far field protection);
2: the pacing mode is DDIR after a mode switch;
3: end of atrial oversensing; AS-VS cycles with long PR interval;
4: switch to DDDR mode and AS-VP cycles.

Comments

The atrial lead impedance was normal and the capture threshold was satisfactory. Therefore, the lead was not revised. Oversensing at the level of the atrial lead can, as in this case, cause an inappropriate automatic mode switch because of erroneous diagnosis of atrial arrhythmia. In a defibrillator, it can also interfere with discrimination based on the counts of atrial and ventricular electrograms during tachycardia. This dysfunction, if frequent, must be eliminated in a defibrillator recipient:
- By decreasing the maximum atrial sensitivity without compromising the detection of sinus rhythm, and of true atrial arrhythmias. This is generally ineffective because the amplitude of noisy signals from fractured leads or other types of interference is often large;
- By applying a discrimination scheme applicable in single chamber devices;

Status report - Apr 2, 2013

To: Service Télécardiologie

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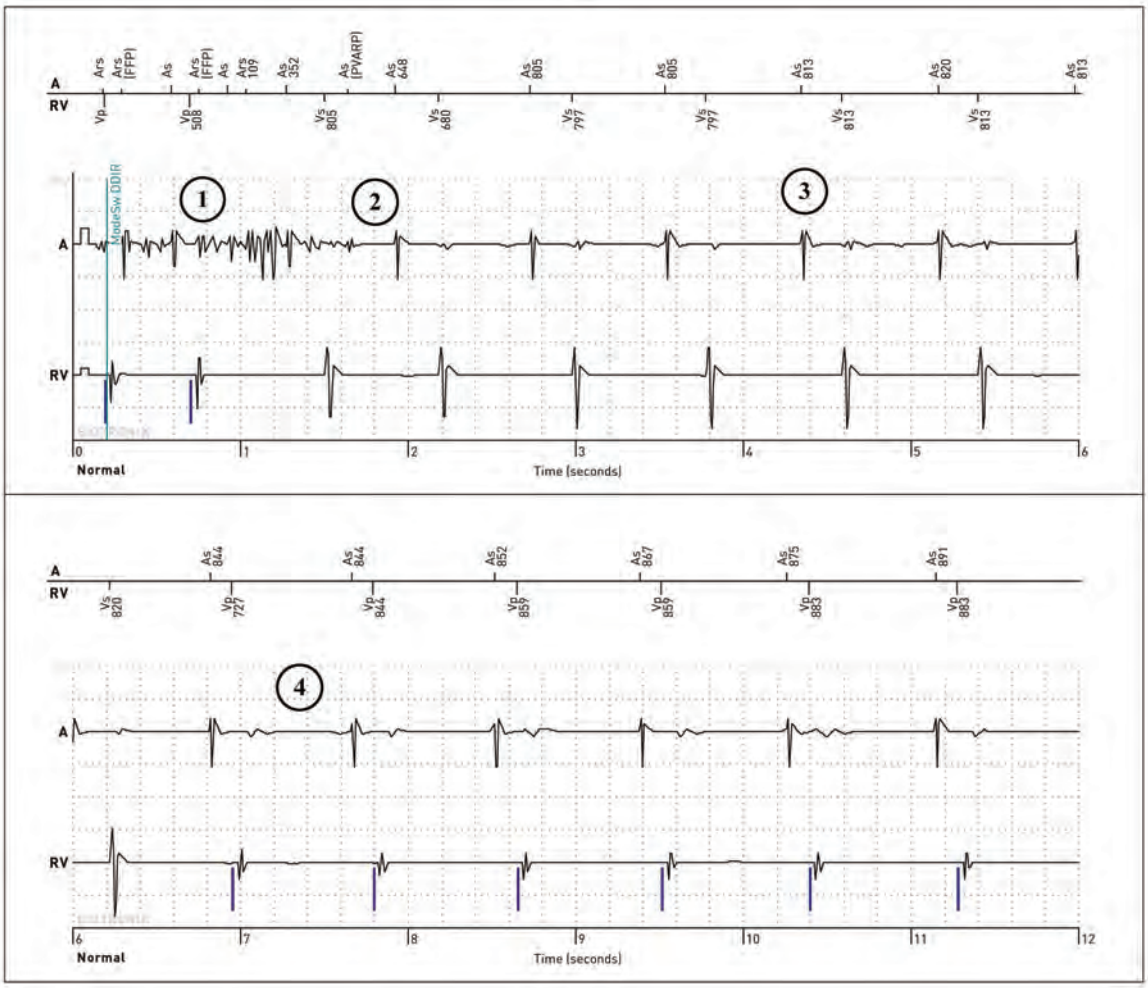
Name:	DOB:	Evia DR-T	Last message: Apr 2, 2013
Patient ID:	Phone: -	PM implanted Mar 23, 2012	Last clinic follow-up: Dec 3, 2012

Recordings

Recordings - Episode 5:

General	
Episode number	5
Episode type	Periodic IEGM
Recorded on	Nov 21, 2012 1:10:00 AM



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1/3

Status report - Apr 2, 2013

To: Service Télécardiologie

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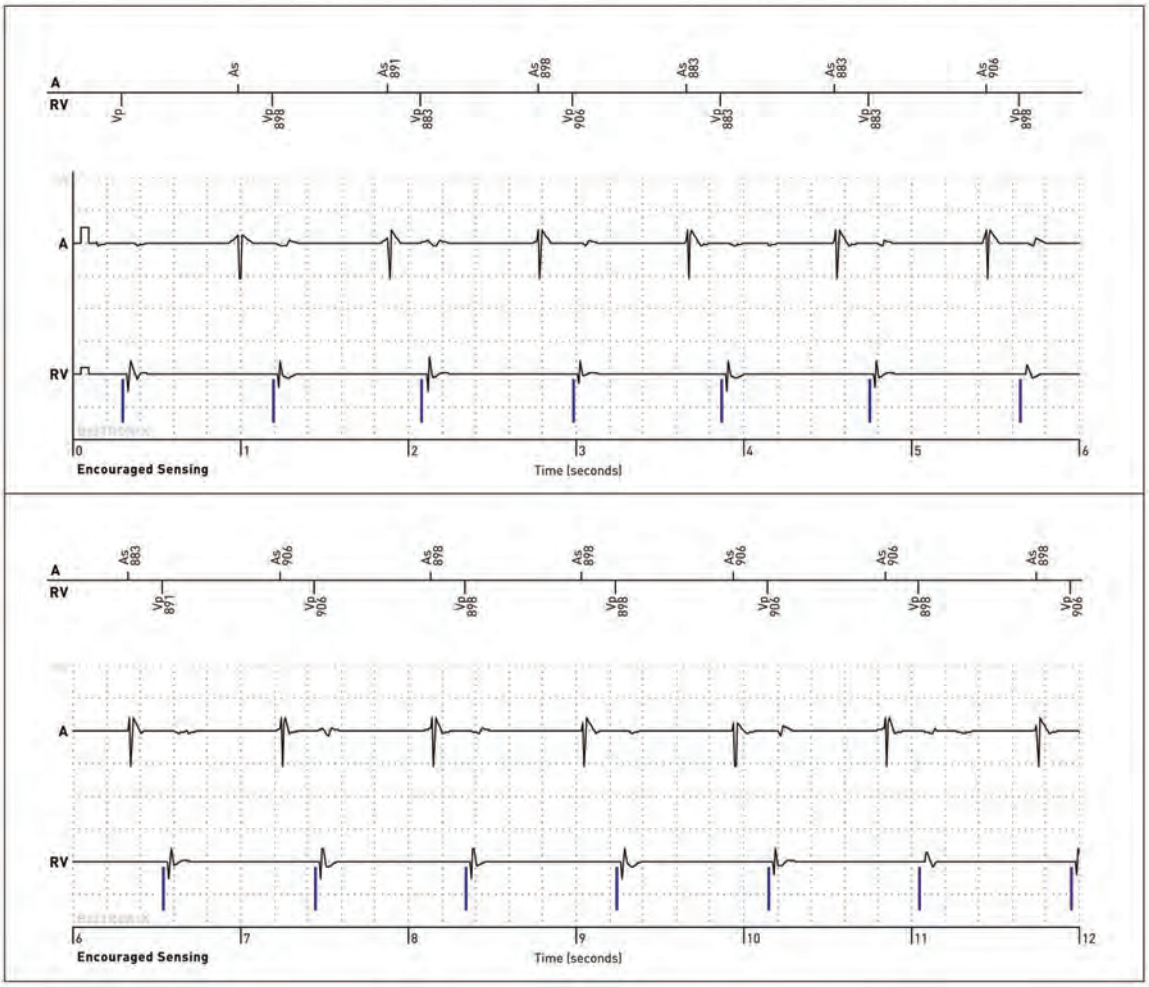
Name:	DOB:	Evia DR-T	Last message: Apr 2, 2013
Patient ID:	Phone: -	PM implanted Mar 23, 2012	Last clinic follow-up: Dec 3, 2012



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2/3

Status report - Apr 2, 2013

To: Service TélécØrdiologie

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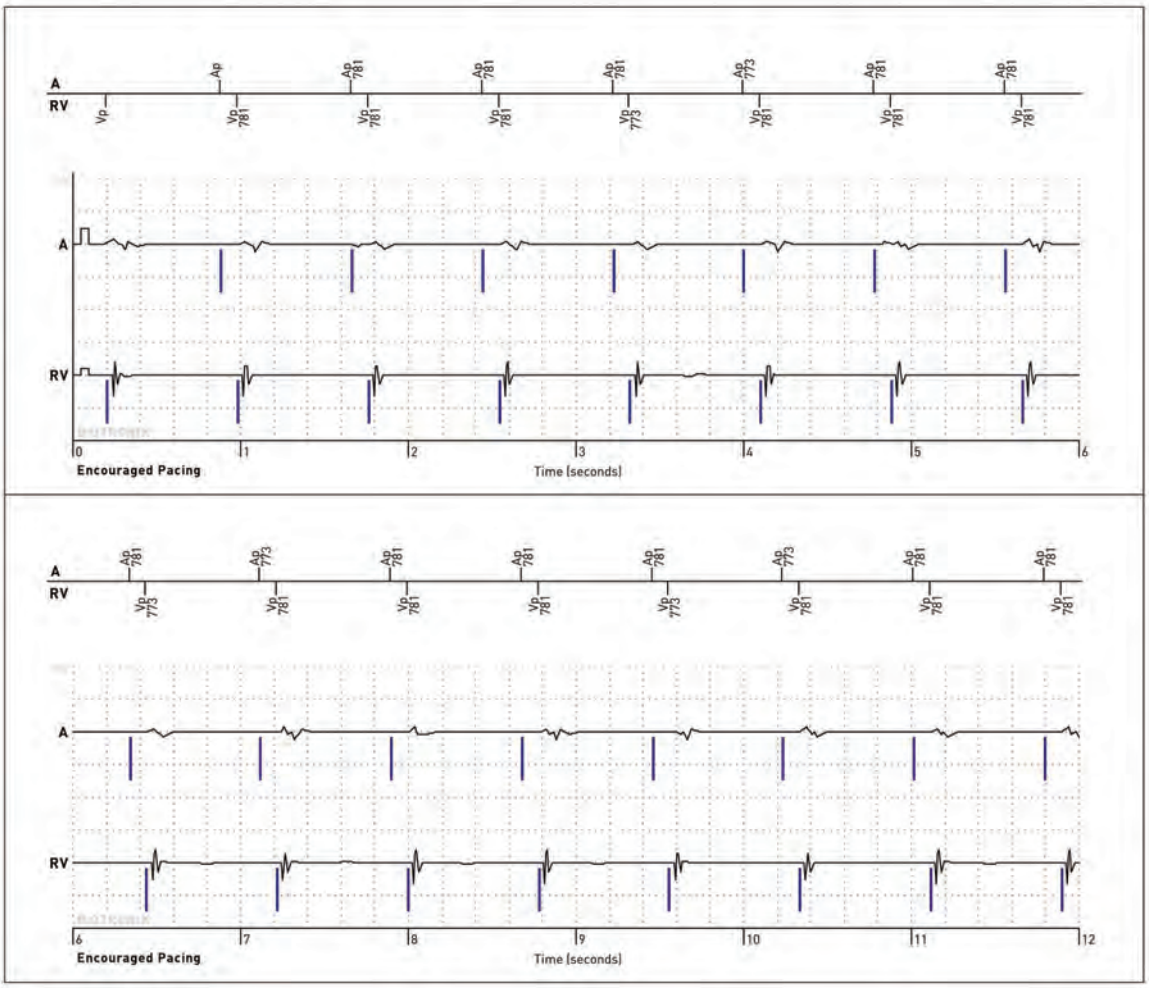
Name	DOB:	Evia DR-T	Last message: Apr 2, 2013
Patient ID:	Phone: -	PM implanted Mar 23, 2012	Last clinic follow-up: Dec 3, 2012



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Date:

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3/3

EGM 6: loss of left ventricular capture

Patient

This 78-year-old man received a Lumax 340 HF-T triple chamber defibrillator for the management of dilated cardiomyopathy with left bundle branch block. Periodic EGMs are displayed.

Remote monitoring tracing

The 4 recorded channels are the 1) markers with time intervals, 2) atrial sensing channel, 3) right ventricular sensing channel, and 4) left ventricular sensing channel, each for 30 seconds.

1: spontaneous and stimulated biventricular rhythm with probable biventricular capture;
2: probable intermittent loss of left ventricular capture; the left ventricular EGM has changed, showing the presence of a delayed signal corresponding to left ventricular activation after right ventricular capture.

Comments

Percent biventricular stimulation is one of the key pieces of information needed in the follow-up of recipients of cardiac resynchronization devices. Nearly flawless stimulation is indispensable for the delivery of effective therapy. A sudden decrease in this percentage from any cause, such as atrial arrhythmias, frequent ventricular extrasystoles, or an excessively long programmed AV delay, can trigger an alert and, consequently, can be detected by remote monitoring. However, a second element is indispensable, as incessant stimulation does not necessarily mean flawless biventricular capture.

The observed disturbance is intermittent, with a fixed delay between the pacing spike and the second ventricular signal, corresponding to the interventricular interval during right ventricular stimulation. The programmed amplitude of the left ventricular pacing spike is, therefore, near the threshold. The left ventricular EGM was not sensed by the left ventricular channel, such that the failure of left ventricular stimulation was not stored in the device memory. In this case, an increase in left ventricular capture threshold was responsible for the loss of capture. The periodic EGM enabled the diagnosis, which would have been missed, had the analysis of the statistics of biventricular stimulation been the only information available.

Status report - Apr 26, 2012

To: Service Télécardiologie

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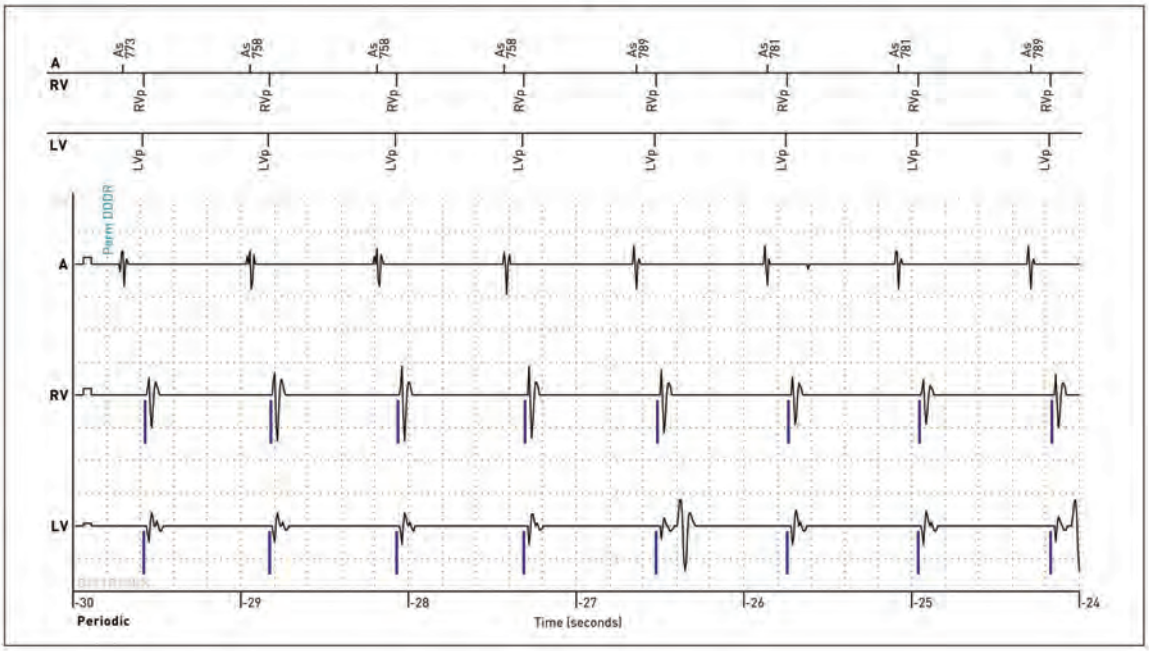
Name:	DOB:	Lumax 340 HF-T	Last message: Apr 22, 2012
Patient ID:	Phone:	CRT-D implanted Sep 18, 2007	Last clinic follow-up: Feb 26, 2012

Recordings

Recordings - Episode 56:

General	
Episode number	56
Episode type	Periodic IEGM
Detection	Dec 31, 2010 1:40:42 AM
Termination	---
Duration	---
Device settings no.	27
Detection	
Mean PP at initial detection [ms]	---
Mean RR at initial detection [ms]	---
Onset [%]	---
Stability [ms]	---
Redetection	---

Therapy	
ATP in VT/VF delivered	---
ATP One Shot delivered	---
Shocks delivered	---
Shocks aborted	---
Maximum energy [J]	---
Termination	
Mean PP at termination [ms]	---
Mean RR at termination [ms]	---
Remark	
none	



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Status report - Apr 26, 2012

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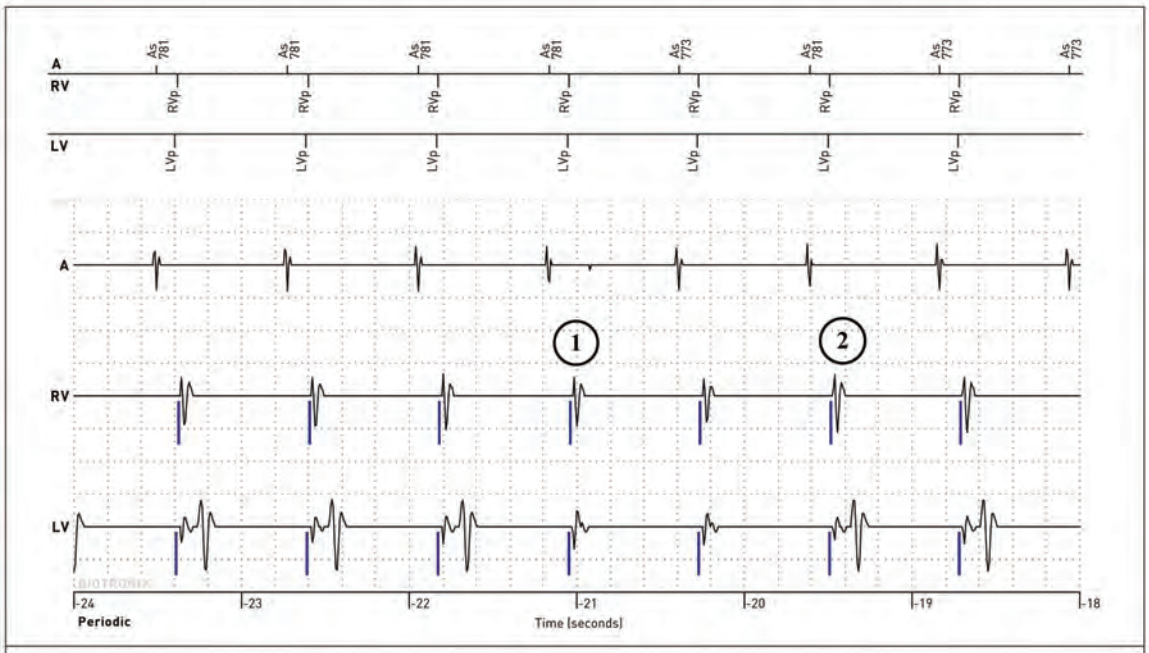
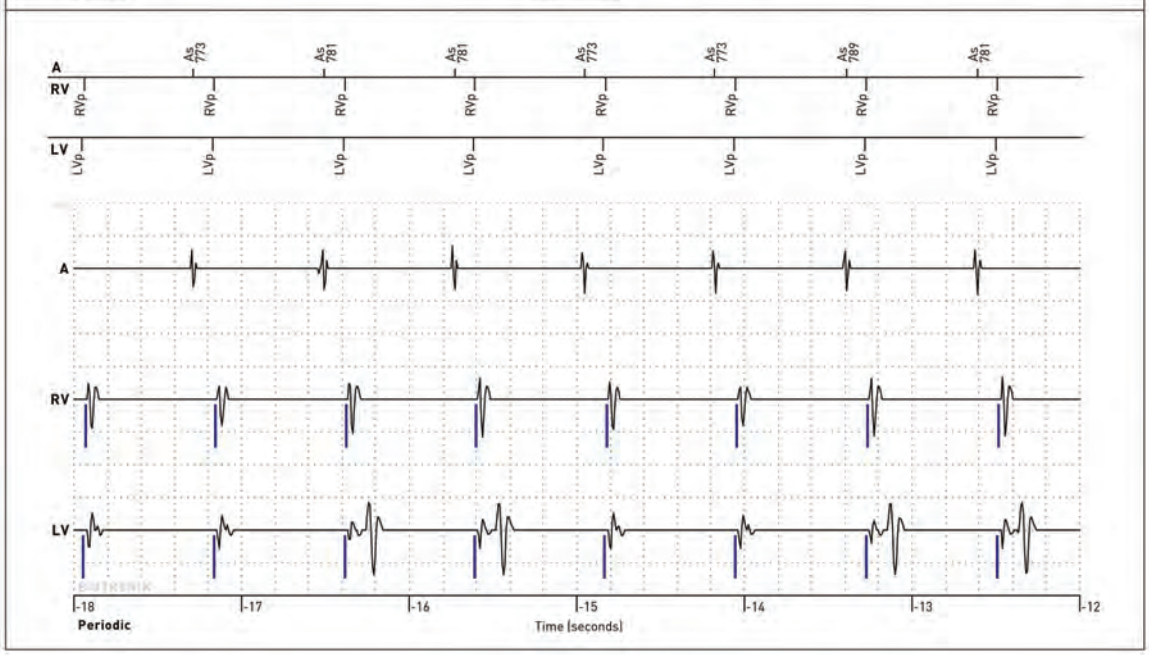
Name:	DOB:	Lumax 340 HF-T	Last message: Apr 22, 2012
Patient ID:	Phone:	CRT-D implanted Sep 18, 2007	Last clinic follow-up: Feb 26, 2012





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Status report - Apr 26, 2012

To: Service Télécardiologie

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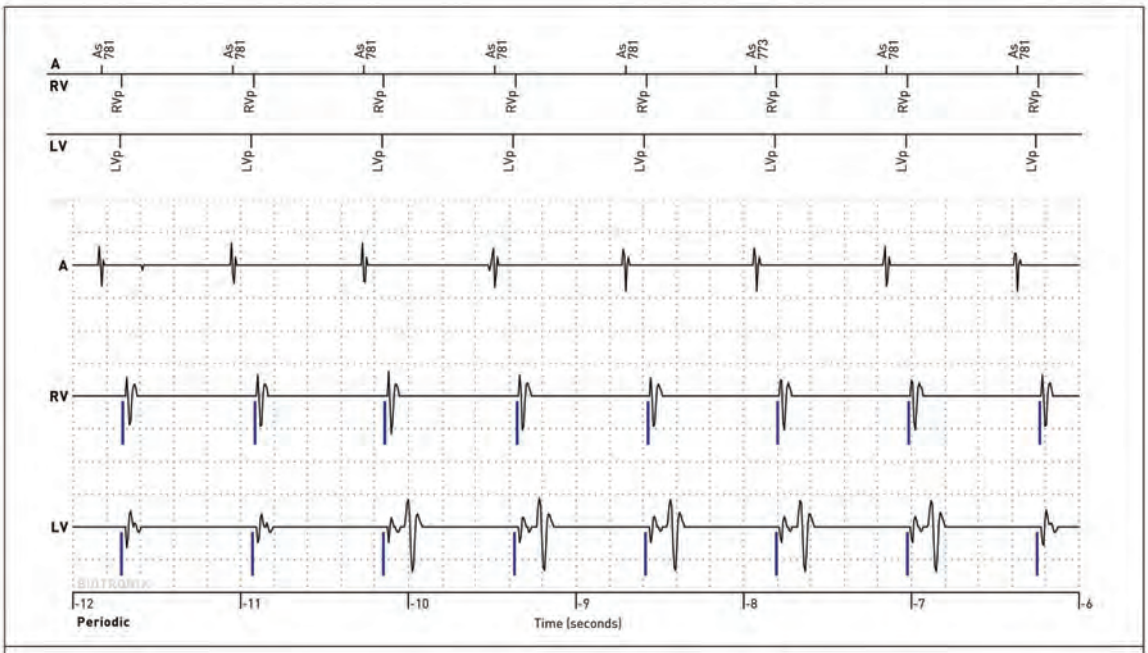
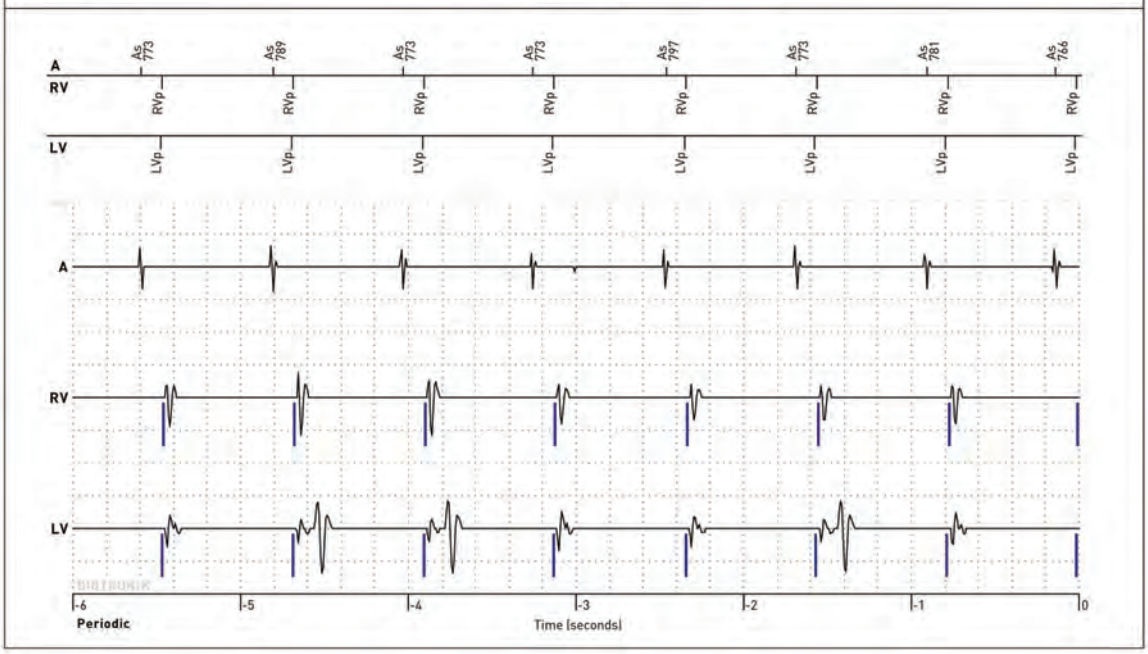
Name:	DOB:	Lumax 340 HF-T	Last message: Apr 22, 2012
Patient ID:	Phone:	CRT-D implanted Sep 18, 2007	Last clinic follow-up: Feb 26, 2012





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Chapter 3

Alerts and Messages

Messages and events

Device dysfunctions or arrhythmias are classified as alerts of different colors. These alerts are the object of supplemental transmissions named alert messages. Besides the data and measurements, the cause of the alert can be identified on the web site, as well as by facsimile or text message. Messages are also generated in case of transmission failure. At the time of registration, a standard set of event reporting and alerts is automatically selected, which defines the conditions in which the events are reported. However, the generation of messages can be personalized, and the standard settings modified on the Internet, in absence of the patient.

Alerts are grouped in messages pertaining to a) the remote transmission system (initial confirmatory message, transmission failure), b) the implanted device (elective replacement indicator, arrhythmias deprograming, programing of emergency pacing), c) the leads (abnormal high-voltage or pacing lead impedance, abnormal sensing or pacing threshold), d) incidence of atrial (electrograms, atrial fibrillation burden, ventricular response during episodes of atrial fibrillation) or ventricular (episodes of ventricular tachycardia or fibrillation, successful or unsuccessful shock deliveries) arrhythmias.

The next page shows the settings (color coding + various events) selected for a recipient of a triple chamber Lumax 540 HF-T ICD.

Status report - Oct 11, 2013

To: Service Télécardiologie

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Name:	DOB:	Lumax 540 HF-T	Last message: Oct 11, 2013
Patient ID:	Phone: -	CRT-D implanted Feb 8, 2012	Last clinic follow-up: Jul 16, 2013

Patient options

Applied: Individual options

Device	
RED + notification	Special device status, Ven. detection off, Emergency brady active, Backup mode, EOS
RED + notification	ERI
YELLOW + notification	Programmer triggered message received
Lead	
YELLOW + notification	RA pacing impedance: < 250 ohm or > 1500 ohm
YELLOW	RA sensing amplitude (daily mean): < 0.5 mV
RED + notification	RV pacing impedance: < 250 ohm or > 1500 ohm
YELLOW + notification	RV sensing amplitude (daily min.): < 2.0 mV
YELLOW + notification	RV pacing threshold safety margin (not for Lumax 300/340): < 1.0 V
YELLOW + notification	LV pacing impedance: < 250 ohm or > 1500 ohm
YELLOW + notification	LV sensing amplitude (daily mean): < 2.0 mV
YELLOW + notification	LV pacing threshold safety margin (not for Lumax 300/340): < 1.0 V
RED + notification	Daily shock impedance: < 30 ohm or > 100 ohm
RED + notification	Shock impedance: < 30 ohm or > 100 ohm
Atr. arrhythmia	
YELLOW + notification	Mean ventricular rate during atrial burden > 130 bpm for > 10% of day
YELLOW + notification	Long atrial episode detected
YELLOW	Atrial monitoring episode: every
YELLOW	SVT detected: every
Ven. arrhythmia	
YELLOW + notification	VT1 detected: every
YELLOW + notification	VT2 detected: every
YELLOW + notification	VF detected: every
RED + notification	Ineffective ven. max. energy shock(s)
Episode	
YELLOW + notification	Ven. monitoring episode with long duration: > 5 min
YELLOW + notification	Ven. therapy episode with long duration: > 2 min
YELLOW + notification	Ven. episode with acceleration of atr. rhythm below 500 ms
YELLOW + notification	Ven. episode with acceleration of ven. rhythm
YELLOW + notification	Ven. episode with fulfilled ATP time-out criterion
YELLOW + notification	Ven. episode with 2 or more started shocks
YELLOW	Episode details received
YELLOW + notification	Periodic IEGM received

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Status report - Oct 11, 2013

To: Service TélécØrdiologie

BIOTRONIK
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Name:	DOB:	Lumax 540 HF-T	Last message: Oct 11, 2013
Patient ID:	Phone: -	CRT-D implanted Feb 8, 2012	Last clinic follow-up: Jul 16, 2013

Home Monitoring	
YELLOW + notification	First message received
YELLOW + notification	No messages received for 21 days
Finding options comment	
No comments entered.	

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Date:

Signature:

Teletransmission of alert messages: first message received

Patient

This 44-year-old man with Brugada syndrome received a Lumax 740 VT-T single chamber defibrillator after suffering several syncopal events. He returned home 48 h after device implantation and programming of the telecardiology function.

Telemedicine report

Alert message status colored yellow: 24 h after his return home, automatic transmission of a first message.

Comments

The implanted device is a Lumax 740 VR-T. The letter T indicates that this device is equipped with telecardiology function, activated before the patient was discharged from the hospital. While in the hospital, he received detailed information regarding the functions of telemedicine and the details of his follow-up. He signed an informed consent, a form that defined the respective responsibilities of the various parties involved. Upon his return home, the patient powered the transmitter near his bedside table. The Cardiomessenger® has been markedly simplified, with the elimination of all switches, and a single connection for the power supply, enabling its use by nearly everyone. On the first evening, an event report (yellow color) accessible on the Internet, was received by the center in charge of the follow-up, to confirm the proper function of the system. The message was also sent to the cardiologist via e-mail. The device usually sends trend messages at night, when the patient is in bed.

Quick View - Feb 18, 2013

To: Service Télécardiologie

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Name:
Patient ID:

DOB:
Phone: 06-22-01-04-18

Lumax 740 VR-T
ICD implanted Feb 15, 2013

Last message: Feb 18, 2013
Last clinic follow-up: Feb 16, 2013

Device status	
Status	OK
Battery status	BOL (EOS, ERI, MOL2, MOL1, BOL)
Battery voltage	3.10 V (Feb 18, 2013)
Charge time	4.4 s for 20 J (Feb 15, 2013 11:41:21 AM)

Findings
Episode details received
First message received

Tachy settings	Zone limit	1st ATP	2nd ATP	1st shock	2nd shock	3rd - nth sho.
VT1	340 ms	3 * Burst	3 * Ramp	20 J	40 J	6 * 40 J
VT2	OFF	---	---	---	---	---
VF	280 ms	Burst		40 J	40 J	6 * 40 J

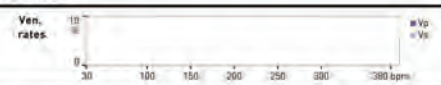
Brady settings	
Mode	VVI
Basic rate	40 bpm

Brady lead	RV lead
Pacing impedance [ohm]	476
Pacing threshold [V]	0.4
Sensing ampl. mean / min [mV]	14.8 / 12.3
Programmed [V@ms]	2.50 @ 0.40

Shock lead	
Daily shock lead imp. [ohm]	69
Last delivered shock imp. [ohm]	86 (2/15/13)

Ven. arrhythmias since Feb 18, 2013	VT1	VT2	VF
Episodes	---	---	---
ATP started / succ.	--- / ---		--- / ---
Shocks started / aborted / succ.	--- / --- / ---		
Last episode: VF (Feb 15, 2013 11:41:17 AM)			

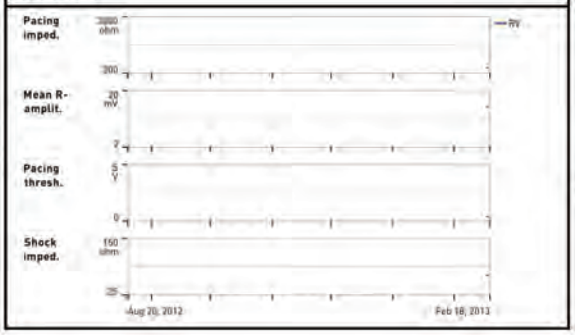
Rate histogram



Atrial arrhythmias since Feb 18, 2013	
SVT episodes	---

Event episodes since Feb 18, 2013	
Pacing	
RVp	---

Lead trends



Long term trends

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Date:

Signature:

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Status report - Feb 18, 2013

To: Service TélécØrdiologie

BIOTRONIK
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Name:	DOB:	Lumax 740 VR-T	Last message: Feb 18, 2013
Patient ID:	Phone: 06-22-01-04-18	ICD implanted Feb 15, 2013	Last clinic follow-up: Feb 16, 2013

Status: YELLOW

Status - Summary:

Status summary for patient ID

Category	Status	Finding	Info
Recordings / Episode	YELLOW	**Episode details received** Episode details were received for an induced VF episode, which was detected on Feb 15, 2013 11:41:17 AM	**New.**
Administrative	YELLOW	**First message received on Feb 18, 2013 7:03:25 PM** Please compare the status with the data of the last follow-up	**New.**
Automatic remark: none			

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Date:

Signature:

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Teletransmission of alert: no message received in last 14 days

Patient

This 40-year-old woman underwent implantation of a Lumos VR-T single chamber defibrillator after suffering an episode of aborted sudden cardiac death. A message-alert was received 5 years after device implantation.

Telemedicine report

This status message in yellow color warned that no message had been received for 14 consecutive days, a few years after device implantation.

Comments

This patient had been followed with telecardiology for several years. This alert was due to her travel to the United States, as she forgot to bring along her transmitter. It is noteworthy that the transmissions are possible in a large number of foreign countries and that the Cardiomessenger can follow patients practically everywhere in their travel. The various causes of absence of transmission include, as in this case, the failure to carry the transmitter, its inadvertent disconnection, its dysfunction (a rare occurrence), the non-activation of telecardiology in a patient that has been registered on the site, or the deprogramming of the telemedicine function by the caregiver in a patient who is normally followed by telecardiology.
The patient was contacted by telephone by the technician in charge of the remote follow-up to determine whether the non-transmission was due to a system failure or merely because the patient was away from home. Remote follow-up resumed normally when she returned from her vacations.

Status report - Dec 16, 2012

To: Service TélécØrdiologie

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Name:	DOB:	Lumos VR-T	Last message: Dec 2, 2012
Patient ID:	Phone: -	ICD implanted Mar 18, 2007	Last clinic follow-up: Oct 26, 2012

Status: YELLOW

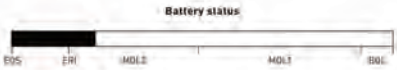
Status - Summary:

Status summary for patient ID

Category	Status	Finding	Info
Device	YELLOW	**No messages received for at least 14 days** Last message received 14 days ago. This patient will be deactivated in 75 days.	**New.**
Automatic remark:	none		

Status - Device:

Battery	
Status	MOL2 8%
Voltage [V]	5.84
Voltage measured on	Dec 2, 2012
Device	
Status	OK
Follow-up	
Date of last follow-up	Oct 25, 2012
Transmitter	
Transmitter SN	44811896
Last transmission received on	Dec 2, 2012 2:54:23 AM
Message type	time triggered



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Date:

Signature:

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Device-related alert message: emergency pacing for bradycardia

Patient

This 84-year-old man received a Lumax 740 DR-T dual chamber defibrillator for secondary prevention and a history of ischemic cardiomyopathy, 25% left ventricular ejection fraction and episodes of VT causing syncope; the telecardiology function was programmed and the patient returned home.

Telemedicine report

Within 24 h after his discharge from the hospital, a first alert message was transmitted systematically (yellow color status);
Another alert corresponding to the programming of emergency pacing for bradycardia (red color status) was also transmitted.

Comments

After his discharge from the hospital and activation of telecardiology, the patient powered the transmitter. On the first evening, an event report (yellow color) was received by the center in charge of the follow-up confirming the proper function of the system. The center also received a red alert related to the programming of emergency pacing for bradycardia. This function, which causes the programming of emergency VVI pacing at 70 bpm and 7.5 V/1.5 ms (maximum amplitude), can be activated by a switch located on the programmer wand or from the programmer screen. It can be useful in emergency, to immediately restore effective pacing after a programming error (for example a pacing amplitude below threshold) in a pacemaker-dependent patient.
In this case, the last in-hospital programming was performed with wireless telemetry. At the end of programming, the physician did not close the patient's session and, when putting away the programmer, inadvertently activated the emergency pacing switch. Telemedicine enabled the early diagnosis of this programming error, which, otherwise, would only have been diagnosed at the next face-to-face visit.

Quick View - Feb 19, 2013

To: Service TélécØrdiologie

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Name:	DOB:	Lumax 740 DR-T	Last message: Feb 19, 2013
Patient ID:	Phone: -	ICD implanted Feb 15, 2013	Last clinic follow-up: Feb 18, 2013

Device status	
Status	NOT OK
Battery status	BOL (EOS, ERI, MOL2, MOL1, BOL)
Battery voltage	3.09 V (Feb 17, 2013)
Charge time	9.9 s for 40 J (Feb 3, 2013 12:16:17 AM)

Findings
Emergency brady pacing active
First message received

Tachy settings	Zone limit	1st ATP	2nd ATP	1st shock	2nd shock	3rd - nth sho.
VT1	400 ms	5 * Burst	5 * Burst	20 J	40 J	6 * 40 J
VT2	OFF	---	---	---	---	---
VF	290 ms	Burst		40 J	40 J	6 * 40 J

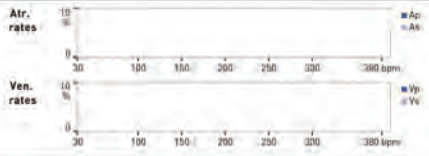
Brady / AF settings	
Mode	---
Basic rate / UTR [bpm]	--- / ---
AV delay	---
Mode switching	---

Brady leads	RA lead	RV lead
Pacing impedance [ohm]	---	---
Pacing threshold [V]		---
Sensing ampl. mean / min [mV]	--- / 0.9	--- / ---
Programmed [V@ms]	--- @ ---	--- @ ---

Shock lead	
Daily shock lead imp. [ohm]	---
Last delivered shock imp. [ohm]	---

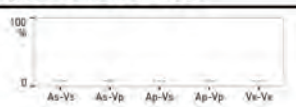
Ven. arrhythmias since Feb 19, 2013	VT1	VT2	VF
Episodes	---	---	---
ATP started / succ.	--- / ---		--- / ---
Shocks started / aborted / succ.	--- / --- / ---		
Last episode: ---			

Rate histogram



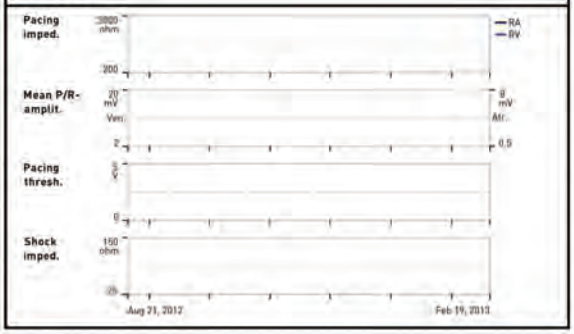
Atrial arrhythmias since Feb 19, 2013	
Atrial burden	---
Mean ven. heart rate during atr. burden	---
Atrial arrhythmia ongoing at end of mon. interv.	NO
Atrial monitoring episodes	---
Number of mode switching per day	---
SVT episodes	---

Event episodes since Feb 19, 2013

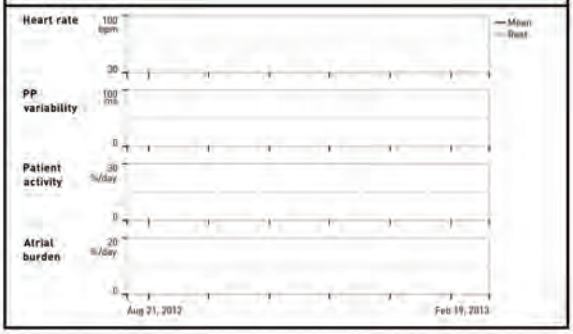


Pacing	
Ap	---
RVp	---

Lead trends



Long term trends



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Status report - Feb 19, 2013

To: Service TélécØrdiologie

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Name: Jan GAMRACY	DOB: Jul 6, 1928	Lumax 740 DR-T	Last message: Feb 19, 2013
Patient ID: 04-44296	Phone: -	ICD implanted Feb 15, 2013	Last clinic follow-up: Feb 18, 2013

Status: RED

Status - Summary:

Status summary for patient ID

Category	Status	Finding	Info
Device settings / Bradycardia/CRT	**RED**	**Emergency brady pacing active** Only limited pacing therapy available at least since Feb 18, 2013 12:28:14 PM	**New.**
Administrative	YELLOW	**First message received on Feb 19, 2013 4:54:24 PM** Please compare the status with the data of the last follow-up	**New.**
Automatic remark:	Follow-up recommended		

Status - Device:

Battery	
Status	BOL
Voltage [V]	3.09
Date of last battery voltage measurement	Feb 17, 2013
Max. charge time since last follow-up [s]	---
Device	
Device status	Emergency brady pacing active
Device model	Lumax 740 DR-T
Date of implantation	Feb 15, 2013
Last MRI mode activation	---
Last entry of shock list	
Time	Feb 3, 2013 12:16:17 AM
Charge time [s]	9.9
Energy [J]	40
Impedance [ohm]	---
Remark	Automatic formation
Home Monitoring	
Message type	event triggered
Device message created on	Feb 19, 2013 1:36:30 AM
End of last monitoring interval	---
Date of last HM follow-up	---
Transmitter	
Transmitter SN	48177738
Last transmission received on	Feb 19, 2013 4:54:24 PM

Technical Services:
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Date:

Signature:

Device-related alert message: de-activated ventricular classification

Patient

This 43-year-old man received a Lumax 340 VR-T single chamber defibrillator for hypertrophic cardiomyopathy with episodes of sustained ventricular tachycardia. He underwent elective surgery on a salivary gland.

Telemedicine report

Within 24 h after his return home, a systematic alert message was transmitted warning that the detection arrhythmias had been turned 'off' (red color status).

Comments

This patient underwent elective surgery, in which case 2 choices were available:
1) apply a magnet over the defibrillator throughout the procedure, inhibiting all therapies and preventing the memorization of the artefacts. If the magnet is applied continuously, the therapies are inhibited for a maximum of 8 h. If the inhibition needs to be prolonged beyond 8 h, the magnet must be removed for a few seconds and reapplied.
2) deactivate or turn 'off' the detection and the defibrillator therapies to prevent the delivery of shocks during the use of an electric scalpel. This second method was chosen for this patient who saw his cardiologist 24 h before undergoing surgery. The detection of episodes was turned off, in order to prevent overloading of the device memory and intraoperative delivery of therapy. The previous programming could be restored by reprogramming the detection.
In this case, the detection was turned off before surgery, and the defibrillator was neither interrogated nor reprogrammed at the end of the operation. This could have had catastrophic consequences, had a serious arrhythmia developed. Telemedicine enabled the early diagnosis of this management error, the patient was called in the next day, and the detection and therapies were programmed back 'on'.
This example illustrates one of the advantages of remote follow-up. This patient would not have been protected by his defibrillator for several months had he been seen exclusively for standard face-to-face ambulatory visits.

Quick View - Jul 20, 2011

To: Service Télécardiologie

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Name:
Patient ID:

DOB:
Phone: -

Lumax 340 VR-T (XL)
ICD implanted Apr 13, 2008

Last message: Jul 20, 2011
Last clinic follow-up: Jul 19, 2011

Device status	
Status	NOT OK
Battery status	MOL1 50% (EOS, ERI, MOL2, MOL1, BOL)
Battery voltage	3.10 V (Jul 18, 2011)
Charge time	2.9 s for 40 J (Jul 18, 2011 8:15:18 AM)

Findings
Ven. detection off

Tachy settings						
	Zone limit	1st ATP	2nd ATP	1st shock	2nd shock	3rd - nth sho.
VT1	OFF	---	---	---	---	---
VT2	OFF	---	---	---	---	---
VF	OFF	---		---	---	---

Brady settings	
Mode	VVI
Basic rate	40 bpm

Brady lead	RV lead
Pacing impedance [ohm]	674
Pacing threshold [V]	---
Sensing ampl. mean / min [mV]	5.9 / 5.9
Programmed [V@ms]	2.5 @ 0.5

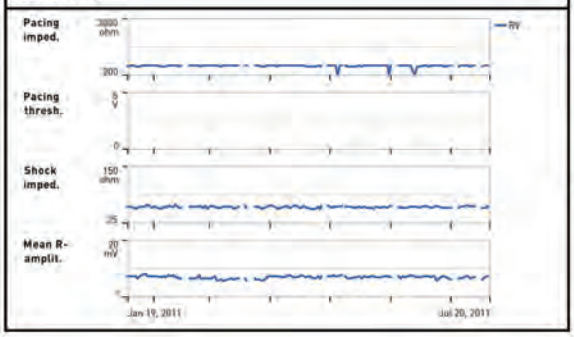
Shock lead	
Daily shock lead imp. [ohm]	54
Last delivered shock imp. [ohm]	67 (4/14/08)

Ven. arrhythmias since Jul 19, 2011	VT1	VT2	VF
Episodes	0	0	0
ATP started / succ.	0 / 0		0 / 0
Shocks started / aborted / succ.	0 / 0 / 0		
Last episode: VF (Jul 18, 2011 8:15:15 AM)			

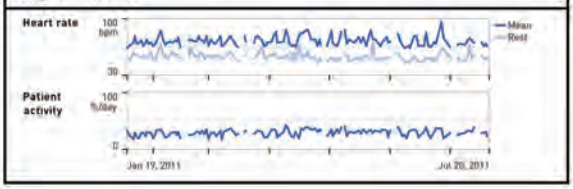
Event episodes since Jul 19, 2011	
Pacing	
Vp	---

Atrial arrhythmias since Jul 19, 2011	
SVT episodes	0

Lead trends



Long term trends



Technical Services:
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Date:

Signature:

1/2

Status report - Jul 20, 2011

To: Service TélécØrdiologie

BIOTRONIK
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Name:	DOB:	Lumax 340 VR-T [XL]	Last message: Jul 20, 2011
Patient ID:	Phone: -	ICD implanted Apr 13, 2008	Last clinic follow-up: Jul 19, 2011

Status: RED

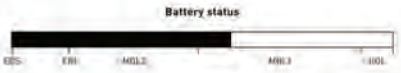
Status - Summary:

Status summary for patient ID

Category	Status	Finding	Info
Device	**RED**	**VT/VF detection inactive** No therapies available at least since Jul 19, 2011 7:05:08 PM	Acknowledged Jul 20, 2011 10:50 AM.
Automatic remark:	No therapies active - Follow-up recommended		

Status - Device:

Battery	
Status	MOL1 50%
Voltage [V]	3.10
Date of last battery voltage measurement	Jul 18, 2011
Device	
Device status	VT/VF therapy inactive
Device model	Lumax 340 VR-T
Date of implantation	[not for Lumax 300/340]
Last entry of shock list	
Time	Jul 18, 2011 8:15:18 AM
Charge time [s]	2.9
Energy [J]	40
Impedance [ohm]	---
Remark	Termination without shock
Home Monitoring	
Message type	time triggered
Device message created on	Jul 20, 2011 1:55:36 AM
End of last monitoring interval	Jul 20, 2011 1:55:36 AM
Transmitter	
Transmitter SN	46811026
Last transmission received on	Jul 20, 2011 1:55:03 AM



Technical Services:
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Date:

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2/2

Device alert: elective replacement indicator

Patient

This 44-year-old man received a Lumos VR-T single chamber defibrillator for primary prevention of idiopathic cardiomyopathy with a left ventricular ejection fraction of 20%; regular telemedicine follow-ups.

Telemedicine report

Regular evaluations over time (MOL 1 and MOL 2) of the battery status by telemedicine. BOL = beginning of life, MOL1 = midlife 1, MOL 2 = midlife 2.
An alert was delivered (RED status) when the elective replacement indicator (ERI) was reached, which can be caused by 1) a battery voltage below the threshold value (for this defibrillator model = 5.7 V), 2) a measurement of the current continuously below the threshold, indicated by an energy gauge posted at 0%, or 3) charge time of the capacitors >20 sec.

Comments

Telemedicine optimizes the management of the devices' end of life. Before telemedicine became available, when the indicators indicated that the end of battery life was approaching, the frequency of follow-ups was increased along with the anxiety of some patients. Teleconsultations enable a follow-up of the battery depletion without increasing the number of visits, which offers several advantages, including
1) reassurance and greater autonomy of the patient,
2) lower cost related to the repetitive transportation for ambulatory visits,
3) avoidance of a) premature device replacements, and b) dangerously approaching the end of battery life by missing the ERI.

Status report - Mar 27, 2009

To: Service TélécØrdiologie

BIOTRONIK
excellence for life

Name:	DOB:	Lumos VR-T	Last message: Mar 27, 2009
Patient ID:	Phone: 05 59 60 25 00	ICD implanted Mar 22, 2007	Last clinic follow-up: Dec 9, 2008

Status: No anomalies

Status - Summary:

Status summary for patient

Automatic remark: No anomalies detected.

Status - Device:

Battery	
Status	MOL1 82%
Voltage [V]	6.22
Voltage measured on	Mar 27, 2009
Device	
Status	OK
Follow-up	
Date of last follow-up	Dec 8, 2008
Transmitter	
Transmitter SN	44811921
Last transmission received on	Mar 27, 2009 2:19:35 AM
Message type	time triggered

Technical Services:
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Fax: +49 30 68905 2941

Date:

Signature:

1/1

Status report - Jan 1, 2011

To: Service TélécØrdiologie

BIOTRONIK
excellence for life

Name:	DOB:	Lumos VR-T	Last message: Jan 1, 2011
Patient ID:	Phone: 05 59 60 25 00	ICD implanted Mar 22, 2007	Last clinic follow-up: Oct 8, 2010

Status: No anomalies

Status - Summary:

Status summary for patient ID

Automatic remark: No anomalies detected.

Status - Device:

Battery	
Status	MOL1 42%
Voltage [V]	6.20
Voltage measured on	Jan 1, 2011
Device	
Status	OK
Follow-up	
Date of last follow-up	Oct 7, 2010
Transmitter	
Transmitter SN	44811921
Last transmission received on	Jan 1, 2011 3:45:42 AM
Message type	time triggered

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Date:

Signature:

1/1

Status report - Jul 3, 2012

To: Service TélécØrdiologie

BIOTRONIK
excellence for life

Name:	DOB:	Lumos VR-T	Last message: Jul 3, 2012
Patient ID:	Phone:	ICD implanted Mar 22, 2007	Last clinic follow-up: Apr 13, 2012

Status: No anomalies

Status - Summary:

Status summary for patient

Automatic remark: No anomalies detected.

Status - Device:

Battery	
Status	MOL2 9%
Voltage [V]	5.93
Voltage measured on	Jul 3, 2012
Device	
Status	OK
Follow-up	
Date of last follow-up	Apr 12, 2012
Transmitter	
Transmitter SN	44811921
Last transmission received on	Jul 3, 2012 2:16:53 AM
Message type	time triggered

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1/1

Status report - Nov 3, 2012

To: Service TélécØrdiologie

BIOTRONIK
excellence for life

Name:	DOB:	Lumos VR-T	Last message: Nov 3, 2012
Patient ID:	Phone:	ICD implanted Mar 22, 2007	Last clinic follow-up: Oct 19, 2012

Status: RED

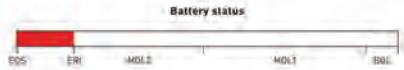
Status - Summary:

Status summary for patient ID

Category	Status	Finding	Info
Device	**RED**	**ERI detected** First received on Nov 3, 2012 1:10:25 AM	**New.**
Automatic remark:	Follow-up recommended		

Status - Device:

Battery	
Status	ERI
Voltage [V]	5.88
Voltage measured on	Nov 3, 2012
Device	
Status	OK
Follow-up	
Date of last follow-up	Oct 18, 2012
Transmitter	
Transmitter SN	44811921
Last transmission received on	Nov 3, 2012 1:10:25 AM
Message type	time triggered



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1/1

Lead alert: right ventricular pacing lead impedance out of range

Patient

This 38-year-old man presenting with familial hypertrophic cardiomyopathy, a 33-mm thick septum and episodes of non-sustained ventricular tachycardia, received a Lumos VR-T single chamber defibrillator. He experienced no episode of sustained arrhythmia in the 6 years since the device implantation.

Telemedicine report

A first alert (red status) was delivered for a <250 Ohms right ventricular pacing lead impedance. A second alert (yellow status) was delivered for episodes classified as ventricular fibrillation. However, the EGM analysis revealed that the episodes were due to oversensing of an extracardiac signal instead of a true arrhythmia.

Comments

This patient presented with episodes diagnosed as non-sustained ventricular fibrillation by the device, with very short ventricular cycles and charge of the capacitors without shock delivered (short episodes of oversensing), associated with a low right ventricular pacing lead impedance, highly suggestive of breakdown of the defibrillation lead insulation. Lead fracture or insulation breakdown are major challenges during the follow-up of defibrillators. They can be the cause of multiple asymptomatic capacitor charges, wasting energy, or of inappropriate shocks poorly tolerated by the patient. In this patient, the expedited diagnosis by telemedicine enabled an early management and prevented the delivery of inappropriate therapies. The patient was rapidly contacted, hospitalized in emergency, and the defibrillator was temporarily deactivated before the extraction of the defective lead and implantation of a new one.

Status report - Aug 29, 2012

To: Service Télécardiologie

BIOTRONIK
excellence for life

Name:	DOB:	Lumos VR-T	Last message: Aug 26, 2012
Patient ID:	Phone:	ICD implanted Oct 30, 2006	Last clinic follow-up: Aug 2, 2012

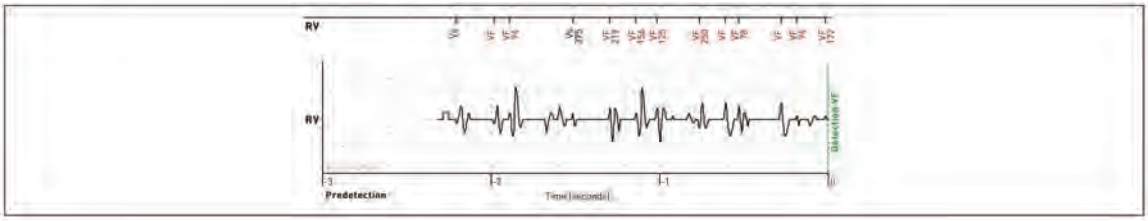
Recordings

Recordings - Episode list:

No.	Detection time	Type	Details
3	Jul 14, 2012 3:29:03 PM	VF	No therapies
2	Oct 31, 2006 9:08:44 AM	VF	Induced, Shocks: 1

Recordings - Episode 3:

General		Therapy	
Episode number	3	ATP delivered	0
Episode type	VF	Shocks delivered	0
Detection	Jul 14, 2012 3:29:03 PM	**Remark**	
Termination	Jul 14, 2012 3:29:16 PM	none	
Duration	13s		
Detection			
Redetection	none		



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2/2

Lead alert: shock impedance out of range

Patient

This 73-year-old woman received a Lumax VR-T DX single chamber defibrillator for primary prevention in the context of ischemic cardiomyopathy with a 28% left ventricular ejection fraction. She was monitored by telecardiology and, 6 months after device implantation, an alert was delivered.

Telemedicine report

Alert (red status) for <30 or >100 Ohms defibrillation shock impedance.
The shock impedance was 105 ohms. The curve shows an initially stable impedance, near 80 ohms, which is slightly elevated, though acceptable for a single-coil lead, before increasing relatively rapidly above the 100-Ohms threshold, prompting an alert message. The right ventricular pacing lead impedance remained within normal limits, with a slight increase within the last days. The quality of sensing by the right ventricular pacing lead remained normal and without any recent variations.

Comments

This example illustrates one of the challenges of the follow-up of recipients of defibrillators. Telemedicine enables the detection of shock impedance values that are judged abnormal. It also enables the tracking of the dynamic changes in these measurements. In this patient, the value exceeded the programmed limit, prompting an alert message. Several choices were available: 1) consider that this high impedance was a manifestation of lead dysfunction; since the lead had been recently implanted, it could easily be extracted and replaced by a new one, a choice, however, that seemed overly invasive and probably premature; 2) induce ventricular fibrillation, to verify the efficacy of defibrillation and measure the impedance of a shock that has been effectively delivered; 3) continue the surveillance and measure daily the shock and pacing impedance, verify the efficacy of sensing and stimulation and, scrutinize the changes in the evolution of the measurements. This last choice was favored for this patient and the shock impedance gradually stabilized near 120 ohms.

Quick View - Dec 30, 2012

To: Service Télécardiologie

BIOTRONIK
excellence for life

Name:
Patient ID:

DOB:
Phone: -

Lumax 740 VR-T DX
ICD implanted Jul 27, 2012

Last message: Dec 30, 2012
Last clinic follow-up: Nov 6, 2012

Device status	
Status	OK
Battery status	BOL (EOS, ERI, MOL2, MOL1, BOL)
Battery voltage	3.12 V (Dec 30, 2012)
Charge time	9.6 s for 40 J (Oct 17, 2012 12:59:16 AM)

Findings
Daily shock impedance out of range

Tachy settings	Zone limit	1st ATP	2nd ATP	1st shock	2nd shock	3rd - nth sho.
VT1	370 ms	OFF	OFF	OFF	---	---
VT2	OFF	---	---	---	---	---
VF	280 ms	Burst		40 J	40 J	6 * 40 J

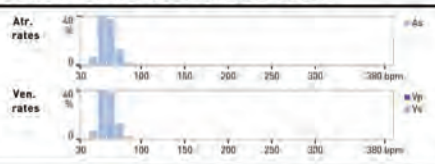
Brady / AF settings	
Mode	VVI
Basic rate / UTR [bpm]	40 / ---
AV delay	---
Mode switching	---

Brady leads	RA lead	RV lead
Pacing impedance [ohm]		680
Pacing threshold [V]		0.5
Sensing ampl. mean / min [mV]	4.8 / 4.3	5.4 / 4.9
Programmed [V@ms]		1.5 AUTO @ 0.40

Shock lead	
Daily shock lead imp. [ohm]	**105**
Last delivered shock imp. [ohm]	---

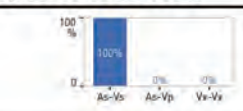
Ven. arrhythmias since Nov 7, 2012	VT1	VT2	VF
Episodes	0	0	0
ATP started / succ.	0 / 0		0 / 0
Shocks started / aborted / succ.	0 / 0 / 0		
Last episode: Periodic IEGM (Dec 13, 2012 1:42:20 AM)			

Rate histogram from Nov 7, 2012 until Dec 13, 2012



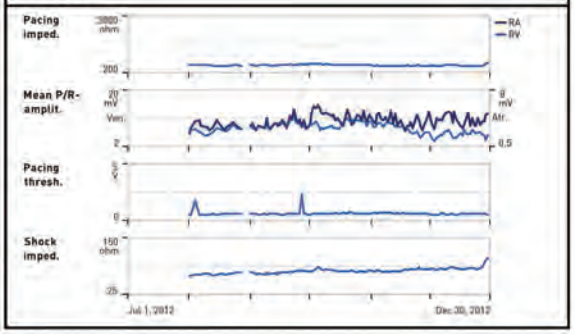
Atrial arrhythmias since Nov 7, 2012	
Atrial burden	0.0% of day
Mean ven. heart rate during atr. burden	---
Atrial arrhythmia ongoing at end of mon. interv.	NO
Atrial monitoring episodes	0
Number of mode switching per day	---
SVT episodes	0

Event episodes since Nov 7, 2012

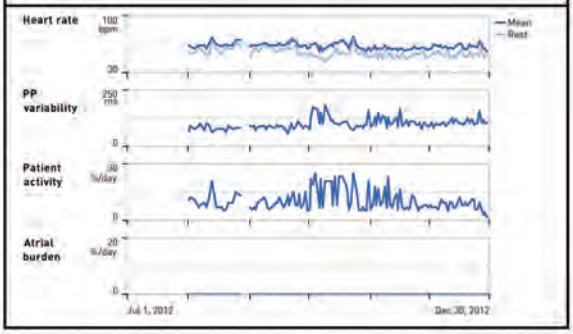


Pacing	
RVp	0%

Lead trends



Long term trends



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Date:

Signature:

Status report - Dec 30, 2012

To: Service TélécØrdiologie

BIOTRONIK
excellence for life

Name:	DOB:	Lumax 740 VR-T DX	Last message: Dec 30, 2012
Patient ID:	Phone: -	ICD implanted Jul 27, 2012	Last clinic follow-up: Nov 6, 2012

Status: RED

Status - Summary:

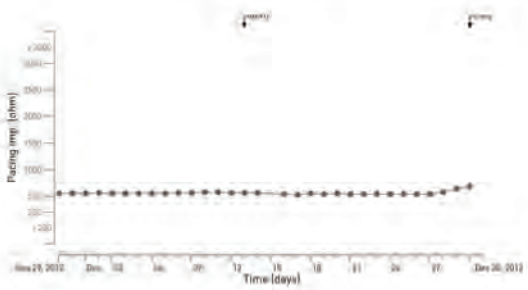
Status summary for patient ID

Category	Status	Finding	Info
Lead	**RED**	**Daily shock impedance out of range (< 30 ohm or > 100 ohm)** Last value 105 ohm measured on Dec 30, 2012 1:43:30 AM	**New.**
Automatic remark:	Follow-up recommended		

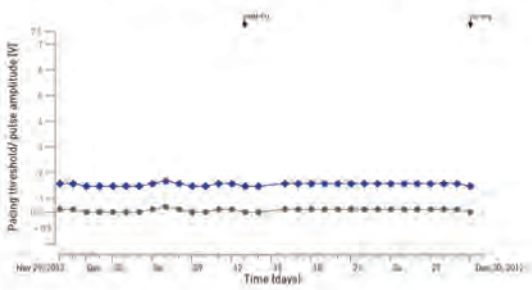
Status - Lead:

RA lead	**24 h**	**Since Nov 7, 2012 1:43:30 AM Mean values, ** Min values**
Sensing amplitude (daily mean) [mV]	4.8	3.9
Sensing amplitude (daily min.) [mV]	4.3	2.2**
RV lead		
Pacing impedance [ohm]	680	554
Pacing threshold [V]	0.5	0.6
Pulse amplitude (AUTO) [V]	1.5	1.6
Sensing amplitude (daily mean) [mV]	5.4	6.5
Sensing amplitude (daily min.) [mV]	4.9	3.3**
Shock lead		
Daily shock lead impedance [ohm]	105	81
Latest available impedance of a delivered shock [ohm]	---	measured on ---

Pacing impedance



RV pacing threshold and pulse amplitude



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2/3

Status report - Dec 30, 2012

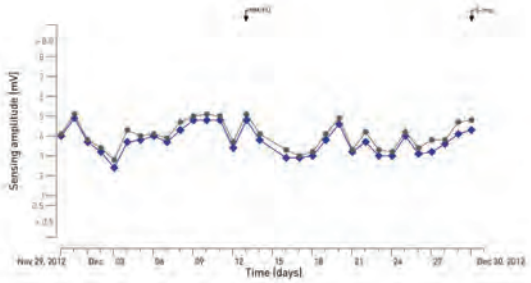
To: Service TélécØrdiologie

BIOTRONIK
excellence for life

Name:	DOB:	Lumax 740 VR-T DX	Last message: Dec 30, 2012
Patient ID:	Phone: -	ICD implanted Jul 27, 2012	Last clinic follow-up: Nov 6, 2012

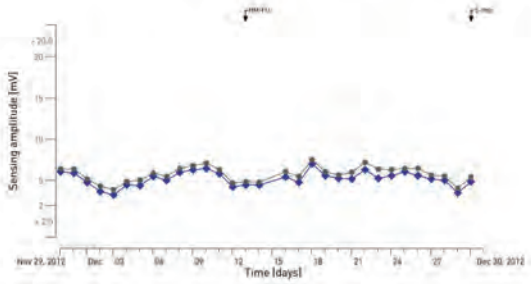
RA sensing amplitude

• Mean RA sensing amplitude [mV] ◆ Min. RA sensing amplitude [mV]



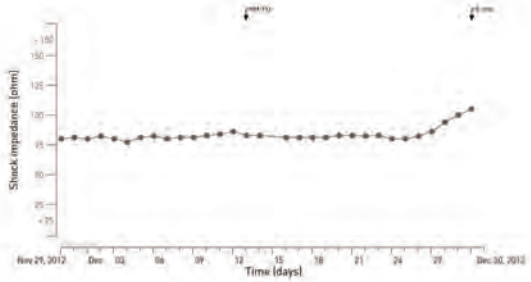
RV sensing amplitude

• Mean RV sensing amplitude [mV] ◆ Min. RV sensing amplitude [mV]



Shock impedance

• Daily shock lead impedance [ohm] ◆ Standard shock impedance [ohm]



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3/3

Atrial arrhythmia alert: classified episode of atrial monitoring

Patient

This 67-year-old man received a Lumax 540 HF-T triple chamber defibrillator for primary prevention, in the context of dilated cardiomyopathy with a 25% left ventricular ejection fraction and complete atrioventricular block. He was monitored by telecardiology and, within a few months after device implantation, an alert message was delivered.

Telemedicine report

Alert message (yellow status) for a classified episode of atrial monitoring.
This report shows that the patient developed several episodes of atrial fibrillation (increase in the arrhythmia burden in the first 24 hours) with mode switch. The ventricular rate remained controlled in this patient in complete atrioventricular block. The percentage of biventricular stimulation, therefore, remained near 100%. The episode lasted over 2 ½ hour. The EGM shows one atrial extrasystole, followed by the onset of the arrhythmia and the time of occurrence of the switch to DDI mode. The patient remained in biventricular stimulation. The EGM also shows the return of sinus rhythm.

Comments

Atrial fibrillation is the most common arrhythmia among recipients of implantable defibrillators, and is associated with an increase in morbidity and mortality. Optimizing the management of patients who develop episodes of atrial fibrillation is one of the main contributions of monitoring with telecardiology. Atrial fibrillation is associated with two main risks: 1) a poor hemodynamic tolerance, and 2) an increase in thromboembolic events. Telemedicine enables an early diagnosis of the arrhythmia, particularly when the episodes are asymptomatic, allows confirmation of the diagnosis and elimination of other, such as crosstalk or noise oversensing by the atrial lead, and enables an adaptation of the medical antiarrhythmic treatment and rapid initiation of anticoagulation.
The telemedicine report shows the atrial fibrillation burden and the number of mode switch episodes, and provides histograms, atrial and ventricular rate graphs, and percentage of stimulation. The recording of EGM begins a few seconds before the episode and ends after its termination, revealing the trigger (atrial extrasystole), confirming the accurate diagnosis made by the device and the return to sinus rhythm. In this patient in complete atrioventricular block, the episodes of atrial arrhythmia were asymptomatic, as the ventricular rate remained normal. The occurrence of subclinical episodes of atrial arrhythmia increases the risk of cerebrovascular accident and systemic embolisms. In this patient, telemedicine enabled an early diagnosis and the expedited introduction of an anticoagulant and antiarrhythmic treatment, whereas with a standard face-to-face follow-up, this treatment would have been initiated only weeks or months later.

Quick View - Feb 26, 2013

To: Service Télécardiologie

BIOTRONIK
excellence for life

Name:
Patient ID:

DOB:
Phone:

Lumax 540 HF-T
CRT-D implanted Jul 2, 2012

Last message: Feb 26, 2013
Last clinic follow-up: Nov 2, 2012

Device status	
Status	OK
Battery status	BOL (EOS, ERI, MDL2, MDL3, BOL)
Battery voltage	3.05 V (Feb 26, 2013)
Charge time	10.3 s for 40 J (Jan 18, 2013 12:00:15 AM)

Findings
Atrial monitoring episode detected
Episode details received

Tachy settings	Zone limit	1st ATP	2nd ATP	1st shock	2nd shock	3rd - nth sho.
VT1	340 ms	3 * Burst	3 * Ramp	20 J	40 J	6 * 40 J
VT2	OFF	---	---	---	---	---
VF	270 ms	Burst		40 J	40 J	6 * 40 J

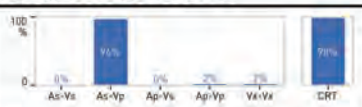
Brady / CRT / AF settings	
Mode	DDD / BiV-LV
Basic rate / UTR [bpm]	60 / 130
AV delay at 60 bpm / 130 bpm	150 / 120 ms
Mode switching	160 bpm / DDI

Brady leads	RA lead	RV lead	LV lead
Pacing impedance [ohm]	402	497	810
Pacing threshold [V]		0.4	0.8
Sensing ampl. mean / min [mV]	5.0 / 5.0	--- / ---	--- / ---
Programmed [V@ms]	2.8 @ 0.4	2.8 @ 0.4	2.8 @ 0.4

Shock lead	
Daily shock lead imp. [ohm]	79
Last delivered shock imp. [ohm]	---

Ven. arrhythmias since Nov 3, 2012	VT1	VT2	VF
Episodes	0	0	0
ATP started / succ.	0 / 0		0 / 0
Shocks started / aborted / succ.	0 / 0 / 0		
Last episode: Atr. monitoring (Feb 25, 2013 7:17:04 PM)			

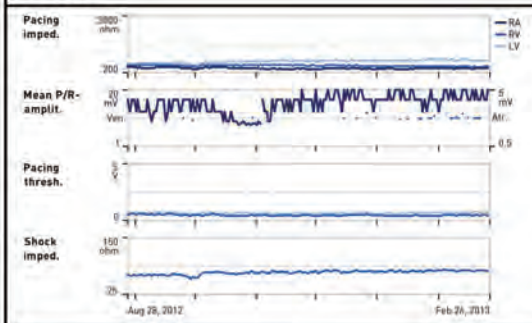
Event episodes since Nov 3, 2012



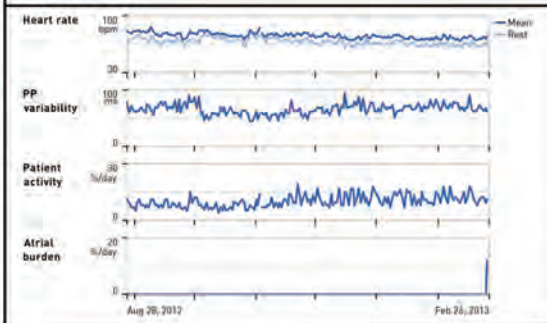
Pacing	
Ap	2%
Vp	98%

Atrial arrhythmias since Nov 3, 2012	
Atrial burden	0% of day
Mean ven. heart rate during atr. burden	71 bpm
Atrial arrhythmia ongoing at end of mon. interv.	NO
Atrial monitoring episodes	4
Number of mode switching per day	0
SVT episodes	0

Lead trends



Long term trends



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Date:

Signature:

Status report - Feb 26, 2013

To: Service Télécardiologie

BIOTRONIK
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Name:	DOB:	Lumax 540 HF-T	Last message: Feb 26, 2013
Patient ID:	Phone:	CRT-D implanted Jul 2, 2012	Last clinic follow-up: Nov 2, 2012

Status: No anomalies

Status - Summary:

Status summary for patient ID

Category	Status	Finding	Info
Atr. arrhythmia	WHITE	**Atrial monitoring episode detected** 2 atrial monitoring episode(s) detected between Feb 25, 2013 2:57:36 AM and Feb 26, 2013 2:57:36 AM	Acknowledged Feb 26, 2013 10:54 AM.
Recordings / Episode	WHITE	**Episode details received** Episode details were received for a spontaneous Atr. monitoring episode, which was detected on Feb 25, 2013 7:17:04 PM	Acknowledged Feb 26, 2013 10:55 AM.
Automatic remark:	none		

Status - Atr. arrhythmia:

Atrial burden	**24 h**	**Since Nov 3, 2012 1:49:36 AM Mean values, * Max values**
Atrial burden [% of day]	12	0
Atrial arrhythmia ongoing at end of mon. interv.	NO	
Mean ven. heart rate during atr. burden [bpm]	71	71
Max. ven. heart rate during atr. burden [bpm]	73	73*
Number of mode switching per day	7	0
Atrial monitoring episodes	**Since Nov 3, 2012 1:49:36 AM**	**Since implantation**
Atrial monitoring episodes	4	17
Long ongoing atrial episode detected	NO	
SVT		
SVT episodes (total)	0	0
SVT episodes (SMART only)	0	0
SMART episode details		
Atrial fibrillation	0	0
Atrial flutter	0	0
Sinus tachycardia	0	0
1:1 (atr. : ven.)	0	0
Last episode		
No.	21	
Type	Atr. monitoring	
Detection	Feb 25, 2013 7:17:04 PM	

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Date:

Signature:

Status report - Feb 26, 2013

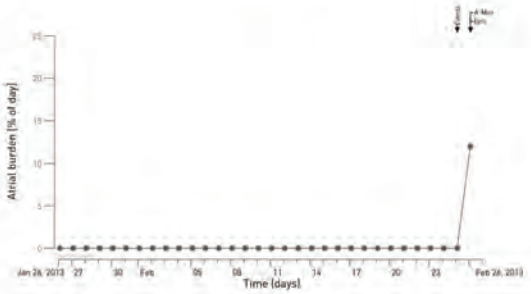
To: Service Télécardiologie

BIOTRONIK
excellence for life

Name:	DOB:	Lumax 540 HF-T	Last message: Feb 26, 2013
Patient ID:	Phone:	CRT-D implanted Jul 2, 2012	Last clinic follow-up: Nov 2, 2012

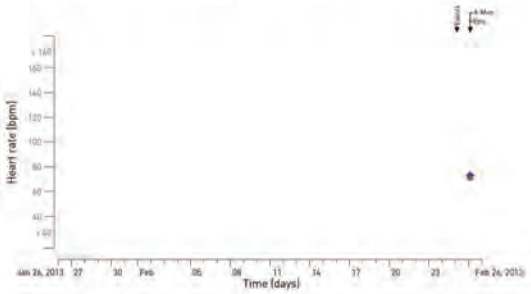
Atrial burden

• Atrial burden [% of day]



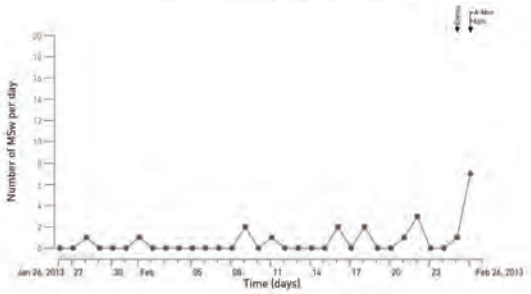
Ven. heart rate during atrial burden

• Mean ven. heart rate during atr. burden [bpm] ◆ Max. ven. heart rate during atr. burden [bpm]



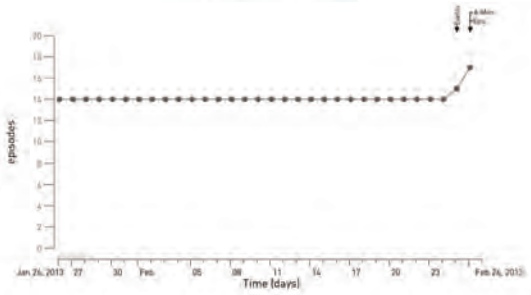
Mode switching

• Number of MSw per day



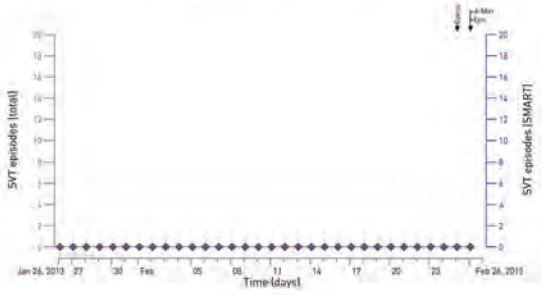
Atrial monitoring episodes

• Atrial monitoring episodes



SVT episodes

• SVT episodes (total) ◆ SVT episodes (SMART)



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Status report - Feb 26, 2013

To: Service Télécardiologie

BIOTRONIK
excellence for life

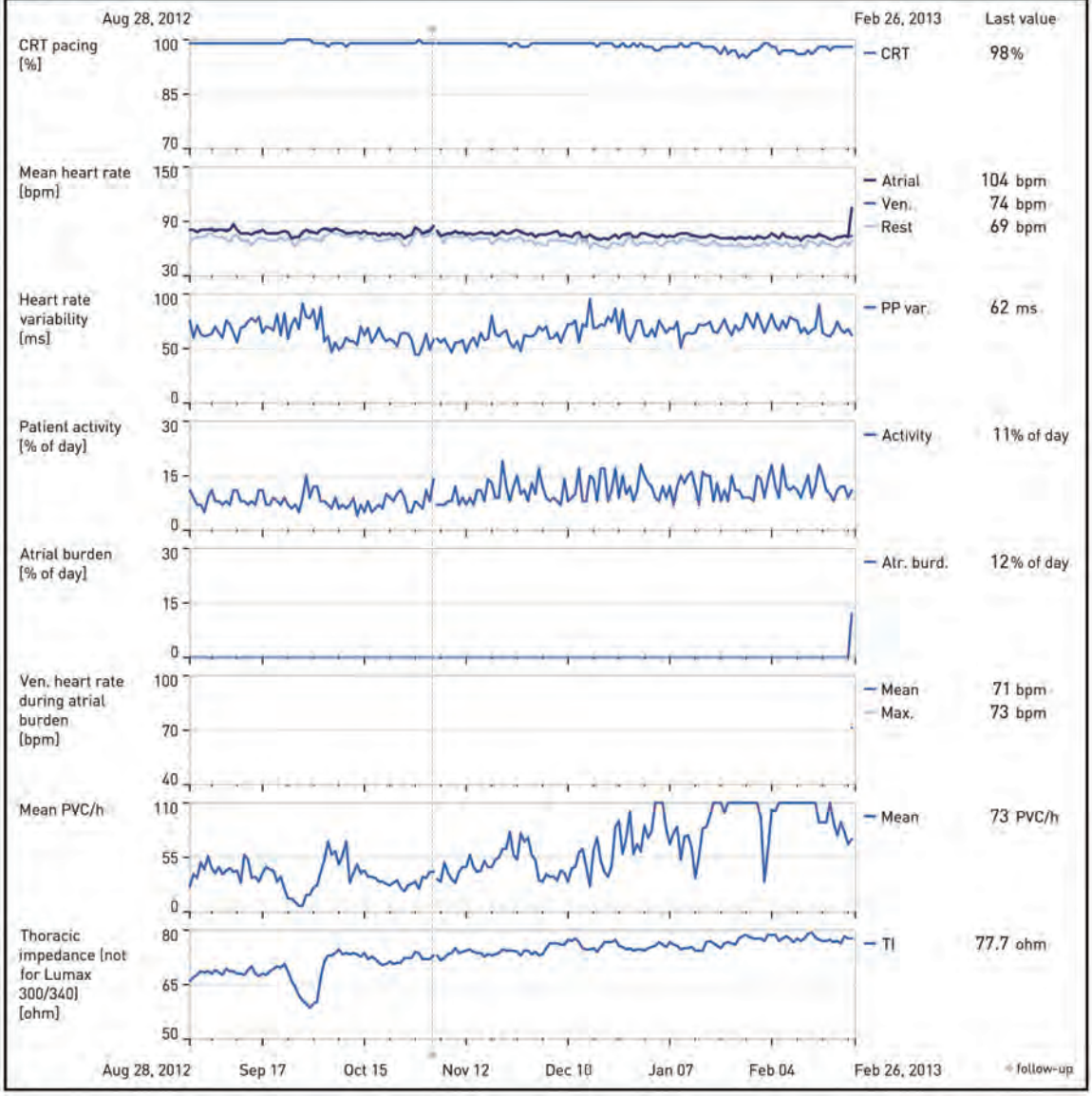
Name:	DOB:	Lumax 540 HF-T	Last message: Feb 26, 2013
Patient ID:	Phone:	CRT-D implanted Jul 2, 2012	Last clinic follow-up: Nov 2, 2012

Status - HF monitor:

Device status Feb 26, 2013	
Device status	OK
Battery status	OK (BOL)
Pacing mode	DDD (BiV-LV)

Arrhythmias since Nov 3, 2012	VT1	VT2	VF	Atr.
Episodes	0	0	0	4
ATP started / succ.	0 / 0		0 / 0	-
Shocks started / aborted / succ.	0 / 0 / 0			-

Long term trends



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Status report - Feb 26, 2013

To: Service Télécardiologie

BIOTRONIK
excellence for life

Name:	DOB:	Lumax 540 HF-T	Last message: Feb 26, 2013
Patient ID:	Phone:	CRT-D implanted Jul 2, 2012	Last clinic follow-up: Nov 2, 2012

Recordings

Recordings - Episode list:

No.	Detection time	Type	Details	Predetection PP/RR	Pretermination PP/RR
21	Feb 25, 2013 7:17:04 PM	Atr. monitoring	Monitoring only	187 / 874	714 / 713
19	Feb 24, 2013 6:01:10 PM	Atr. monitoring	Monitoring only	216 / 874	615 / 614
18	Jan 5, 2013 2:42:42 AM	Periodic IEGM	Monitoring only	--- / ---	--- / ---
17	Dec 13, 2012 5:10:53 PM	Atr. monitoring	Monitoring only	226 / 860	588 / 588
16	Nov 6, 2012 2:42:42 AM	Periodic IEGM	Monitoring only	--- / ---	--- / ---
	Nov 2, 2012 3:40:47 PM	Follow-up			
15	Sep 7, 2012 2:42:42 AM	Periodic IEGM	Monitoring only	--- / ---	--- / ---
14	Aug 4, 2012 3:57:55 PM	Atr. monitoring	Monitoring only	197 / 855	814 / 819
12	Aug 4, 2012 12:02:58 AM	Atr. monitoring	Monitoring only	285 / 860	689 / 692
10	Jul 9, 2012 2:42:42 AM	Periodic IEGM	Monitoring only	--- / ---	--- / ---
	Jul 2, 2012 12:47:33 PM	Follow-up			

Recordings - Episode 21:

General	
Episode number	21
Episode type	Atr. monitoring
Detection	Feb 25, 2013 7:17:04 PM
Termination	Feb 25, 2013 9:48:25 PM
Duration	2h 31min 21s
Device settings no.	5
Detection	
Mean PP at initial detection [ms]	187
Mean RR at initial detection [ms]	874
Onset [%]	---
Stability [ms]	31
Redetection	---

Therapy	
ATP in VT/VF delivered	0
ATP One Shot delivered	NO
Shocks delivered	0
Shocks aborted	0
Maximum energy [J]	---
Termination	
Mean PP at termination [ms]	714
Mean RR at termination [ms]	713
Remark	
none	

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Status report - Feb 26, 2013

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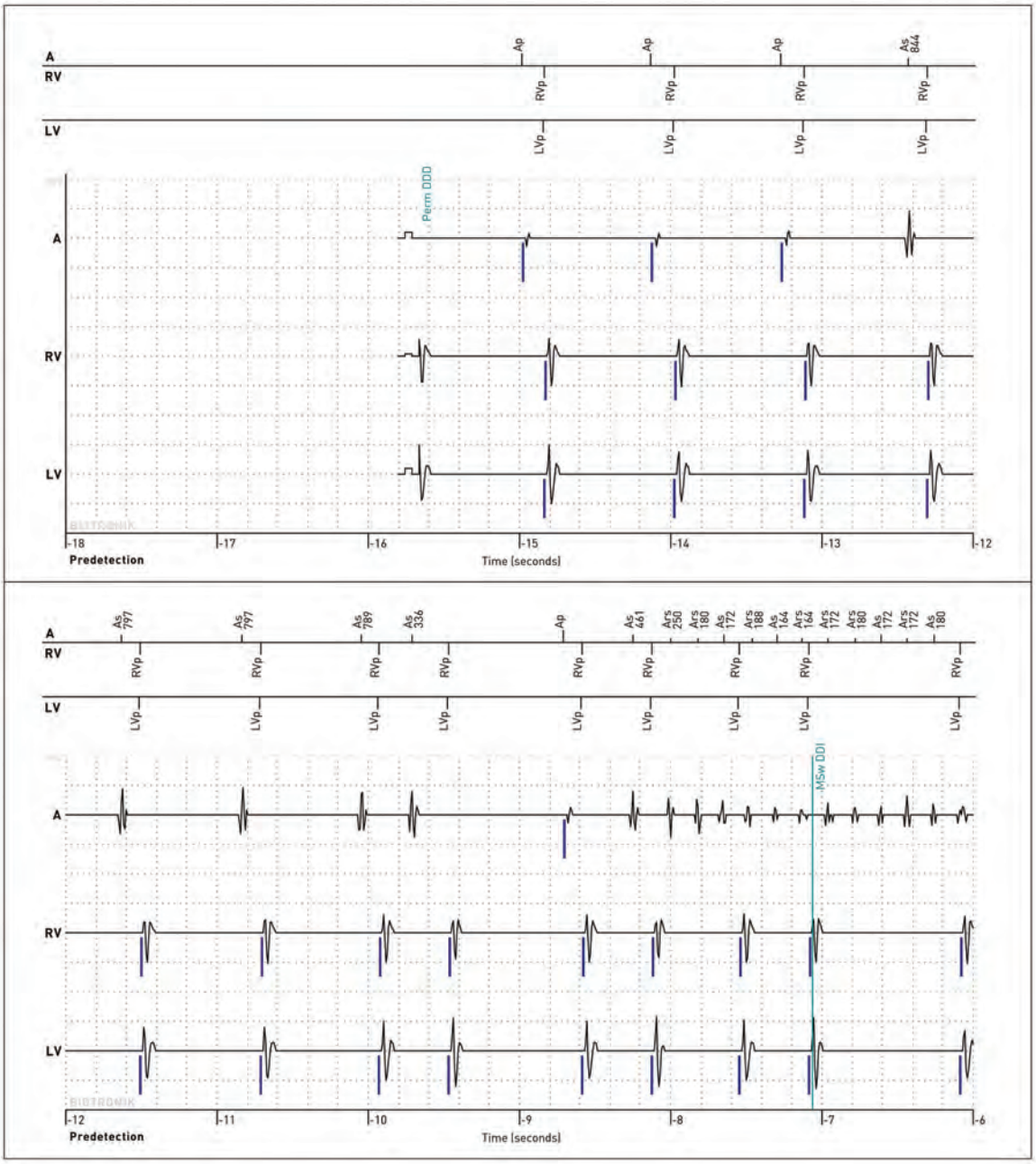
Name:	DOB:	Lumax 540 HF-T	Last message: Feb 26, 2013
Patient ID:	Phone:	CRT-D implanted Jul 2, 2012	Last clinic follow-up: Nov 2, 2012



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Status report - Feb 26, 2013

To: Service Télécardiologie

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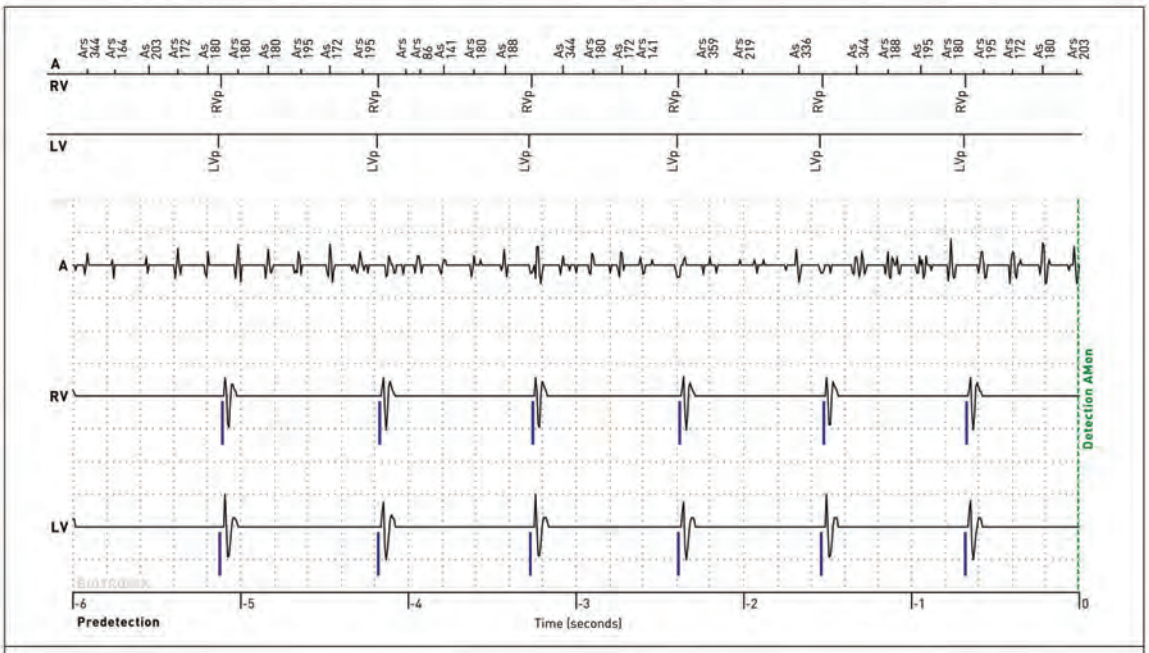
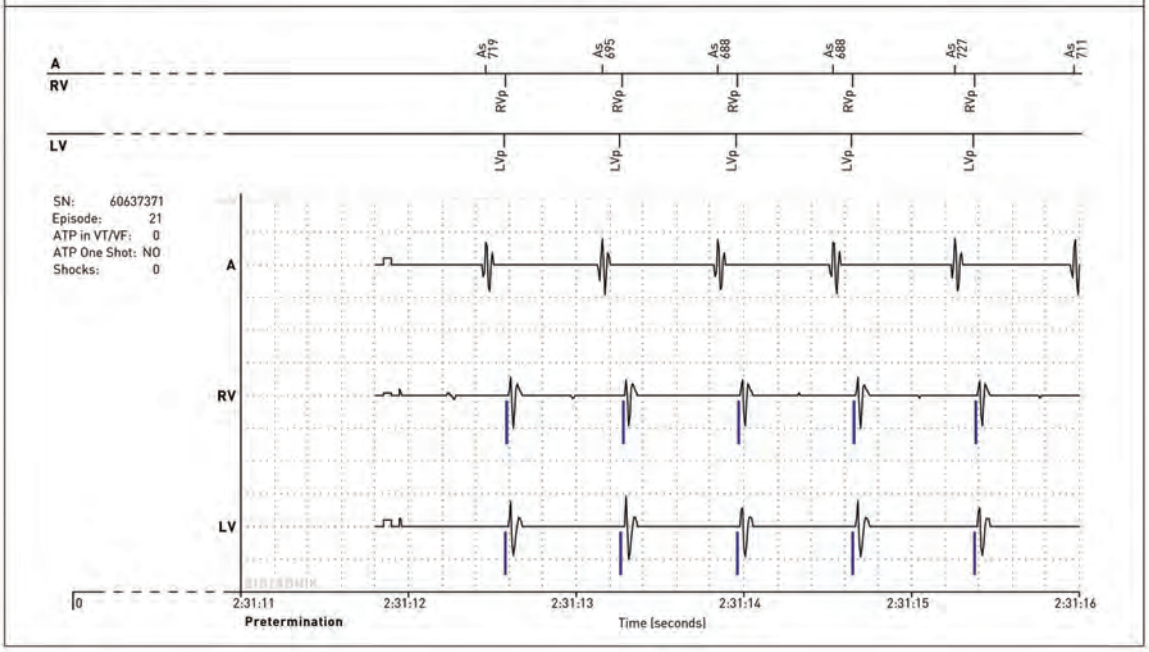
Name:	DOB:	Lumax 540 HF-T	Last message: Feb 26, 2013
Patient ID:	Phone:	CRT-D implanted Jul 2, 2012	Last clinic follow-up: Nov 2, 2012





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Status report - Feb 26, 2013

To: Service TéléCardiologie

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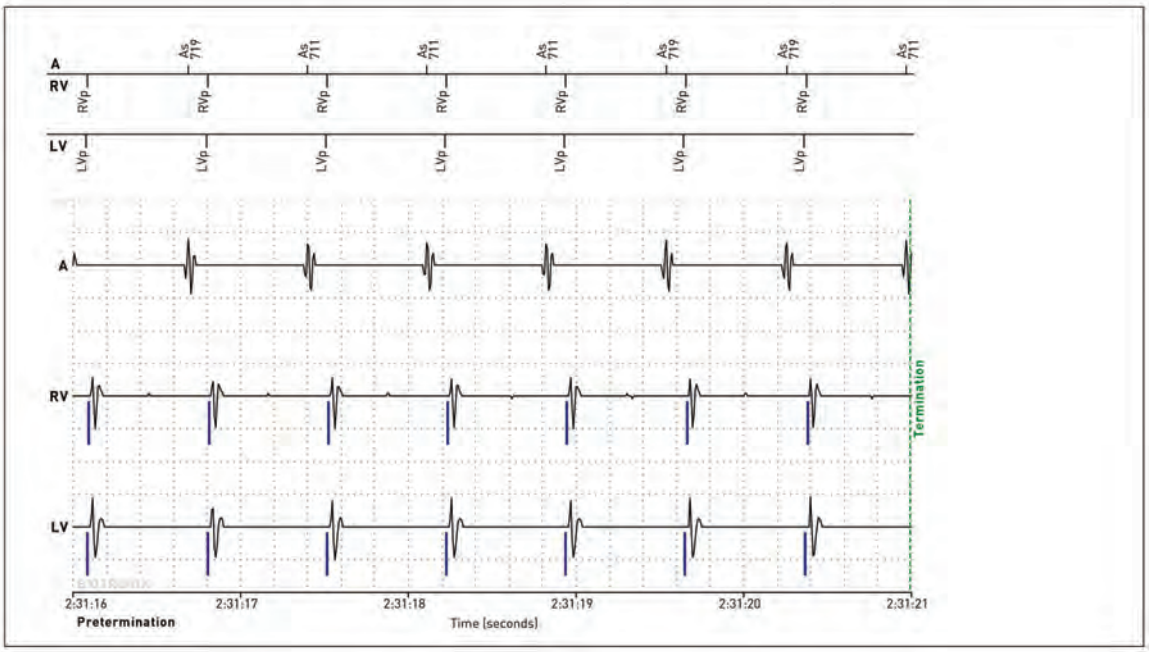
Name:	DOB:	Lumax 540 HF-T	Last message: Feb 26, 2013
Patient ID:	Phone:	CRT-D implanted Jul 2, 2012	Last clinic follow-up: Nov 2, 2012



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Alert message for atrial arrhythmia: episode of classified atrial monitoring and decrease in percentage of biventricular stimulation

Patient

This 42-year-old man received a Lumax 340 HF-T triple chamber defibrillator for primary prevention in the context of dilated cardiomyopathy with a 20% left ventricular ejection fraction and left bundle branch block. He was monitored by telecardiology and, 3 years after device implantation, an alert message was delivered

Telemedicine report

Alert message (yellow status) for a long classified episode of atrial monitoring and decrease in the percentage of biventricular stimulation below the lower limit of 85%. This patient developed several episodes of atrial fibrillation (increase in atrial fibrillation burden) with mode switch. Before the arrhythmia became permanent, several mode switches occurred without prominent increase in the atrial fibrillation burden, indicating that the arrhythmic episodes were brief. Simultaneously, the percentage of atrial stimulation decreased as the atrial rate increased progressively. As the atrial fibrillation burden increased, the spontaneous ventricular rate increased, (proof of a preserved atrioventricular conduction) with a sudden decrease in the percentage of biventricular stimulation. The analysis of the remotely transmitted tracing confirmed the development of atrial fibrillation conducted through the atrioventricular node, with a rapid ventricular rate and loss of biventricular resynchronization. A close review of all the information gathered in these various panels, allowed a reconstitution of the patient's history.

Comments

An important contribution of telemedicine consists in the ambulatory surveillance of chronic diseases. Heart failure is the main indication for the implantation of a defibrillator. Its prevalence keeps increasing, involving 1-2% of the Western populations. State-of-the-art devices are capable of analysing multiple physiologic measurements, including thoracic impedance, heart rate variability, resting and exercise heart rate and activity level, allowing the monitoring of the device recipient's hemodynamic status. The role of telemedicine is probably not to decrease the number of ambulatory visits for the management of heart failure, as they are needed for the clinical and echocardiographic follow-up of the patient. On the other hand, telemedicine optimizes the follow up by analysing the variations in these measurements, enabling an early detection of hemodynamic deteriorations. The prevention of re-hospitalization is a major objective of the delivery of public healthcare, and of remote monitoring. Studies have shown that the early manifestations of heart failure develop between 8 and 12 days before hospitalization. Telemedicine allows an early detection of the signs of impending cardiac decompensation, before the patient can no longer be treated in an ambulatory setting.

With respect to the follow-up of cardiac resynchronization, telemedicine contributes also some key information. In this patient the development of atrial fibrillation was responsible for the loss of biventricular stimulation, interfering with the efficacy of resynchronization. A threshold for the minimum percentage of biventricular stimulation is programmable. Various studies have found that this threshold needs to be near 100%. Different measures could be considered for this patient: 1) Control of the heart rate by pharmaceutical treatment or by ablation of the atrioventricular junction; or 2) control of the rhythm. This patient had been treated with amiodarone in the past, and no new drug treatment seemed appropriate. Consequently, he underwent ablation of the pulmonary veins.

Whichever the chosen strategy, telemedicine optimizes the subsequent follow-up, by analyzing the mean and maximal heart rate if a strategy of rate control was chosen, and by the detection of arrhythmic recurrences if a strategy of rhythm control was adopted.

Quick View - Nov 26, 2011

To: Service Télécardiologie

BIOTRONIK
excellence for life

Name:
Patient ID:

DOB:
Phone: -

Lumax 340 HF-T
CRT-D implanted Sep 1, 2008

Last message: Nov 26, 2011
Last clinic follow-up: Oct 21, 2011

Device status	
Status	OK
Battery status	MOL1 60% (EOS, ERI, MOL2, MOL1, BOL)
Battery voltage	2.90 V (Nov 26, 2011)
Charge time	12.3 s for 40 J (Nov 16, 2011 12:00:17 AM)

Findings
Long atrial episode detected
Atrial monitoring episode detected
SVT detected
There are more findings.

Tachy settings	Zone limit	1st ATP	2nd ATP	1st shock	2nd shock	3rd - nth sho.
VT1	430 ms	OFF	OFF	OFF	---	---
VT2	330 ms	3 * Burst	2 * Ramp	40 J	40 J	6 * 40 J
VF	270 ms	Burst		40 J	40 J	6 * 40 J

Brady / CRT / AF settings	
Mode	DDD / BiV-LV
Basic rate / UTR [bpm]	60 / 130
AV delay at 60 bpm / 130 bpm	150 / 120 ms
Mode switching	160 bpm / DDI

Brady leads	RA lead	RV lead	LV lead
Pacing impedance [ohm]	388	483	619
Pacing threshold [V]		---	---
Sensing ampl. mean / min [mV]	4.2 / 4.2	--- / ---	11.5 / 10.8
Programmed [V@ms]	2.0 @ 0.5	2.0 @ 0.5	2.5 @ 0.5

Shock lead	
Daily shock lead imp. [ohm]	48
Last delivered shock imp. [ohm]	---

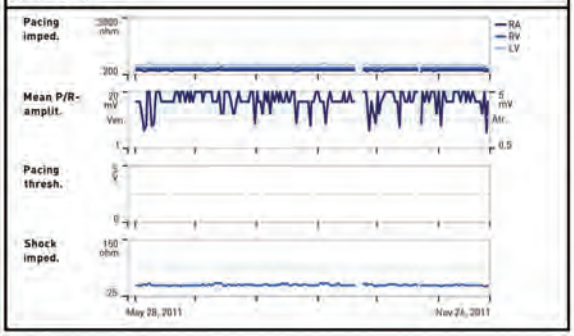
Ven. arrhythmias since Oct 22, 2011	VT1	VT2	VF
Episodes	0	0	0
ATP started / succ.	0 / 0		0 / 0
Shocks started / aborted / succ.	0 / 0 / 0		
Last episode: SVT (Nov 26, 2011 12:44:25 AM)			

Event episodes since Oct 22, 2011

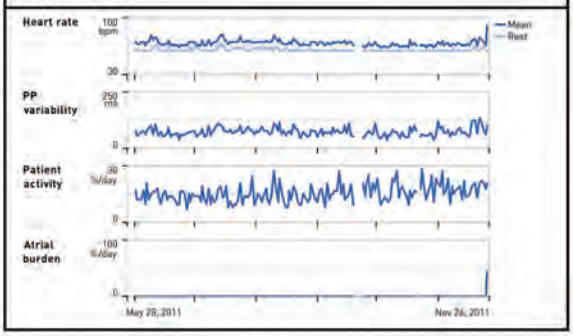
Pacing	
Ap	29%
Vp	98%

Atrial arrhythmias since Oct 22, 2011	
Atrial burden	1% of day
Mean ven. heart rate during atr. burden	---
Atrial arrhythmia ongoing at end of mon. interv.	YES
Atrial monitoring episodes	2
Number of mode switching per day	26
SVT episodes	50

Lead trends



Long term trends



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1/11

Status report - Nov 26, 2011

To: Service Télécardiologie

BIOTRONIK
excellence for life

Name:	DOB:	Lumax 340 HF-T	Last message: Nov 26, 2011
Patient ID:	Phone: -	CRT-D implanted Sep 1, 2008	Last clinic follow-up: Oct 21, 2011

Status: YELLOW

Status - Summary:

Status summary for patient ID

Category	Status	Finding	Info
Atr. arrhythmia	YELLOW	**Long atrial episode detected** 1 episode(s) detected between Nov 25, 2011 2:55:36 AM and Nov 26, 2011 4:28:00 AM - The programmed episode duration limit was 12.0 h	**New.**
		Atrial monitoring episode detected 1 atrial monitoring episode(s) detected between Nov 25, 2011 2:55:36 AM and Nov 26, 2011 4:28:00 AM	**New.**
		SVT detected 50 SVT detected between Nov 25, 2011 2:55:36 AM and Nov 26, 2011 4:28:00 AM	**New.**
HF monitor	YELLOW	**CRT pacing below limit (< 85%)** Last value 59% measured on Nov 26, 2011 2:55:36 AM	**New.**
Recordings / Episode	YELLOW	**Episode details received** Episode details were received for a spontaneous SVT episode, which was detected on Nov 26, 2011 12:44:25 AM	**New.**
Automatic remark:	none		

Status - Bradycardia/CRT:

Paced rhythm	24 h	Since Oct 22, 2011 2:55:36 AM Mean values
Atrial pacing (Ap) [%]	8	29
Ven. pacing (Vp) [%]	42	98
AV sequences (except during mode switching)		
Intrinsic rhythm (As - Vs) [%]	0	0
VAT stimulation (As - Vp) [%]	54	70
Conducted atrial pacing (Ap - Vs) [%]	0	0
Dual-chamber pacing (Ap - Vp) [%]	45	30
VV sequence (Vx - Vx) [%]	0	0
CRT		
CRT pacing [%]	59	99
LV-RV sequences		
BiV stimulation [%]	42	98
RVp without LVp [%]	0	0
RVs triggered LVp [%]	17	1
RVs without LVp [%]	41	1
LVp exclusive [%]	0	0
LVp exclusive inhibited [%]	0	0
PVC triggered LVp [%]	0	0
PVC without LVp [%]	0	0

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Status report - Nov 26, 2011

To: Service Télécardiologie

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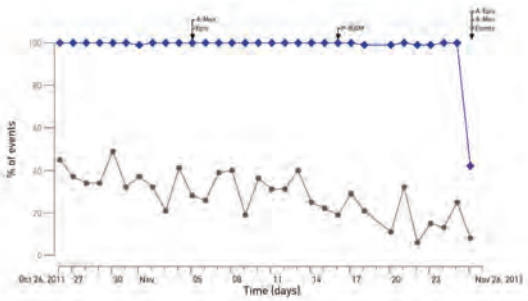
Name:	DOB:	Lumax 340 HF-T	Last message: Nov 26, 2011
Patient ID:	Phone: -	CRT-D implanted Sep 1, 2008	Last clinic follow-up: Oct 21, 2011

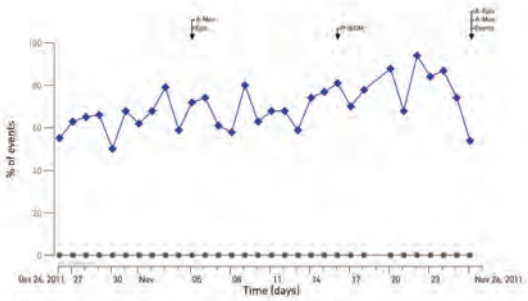
Paced rhythm

• Atrial pacing (Ap) [%] ◆ Ven. pacing (Vp) [%]



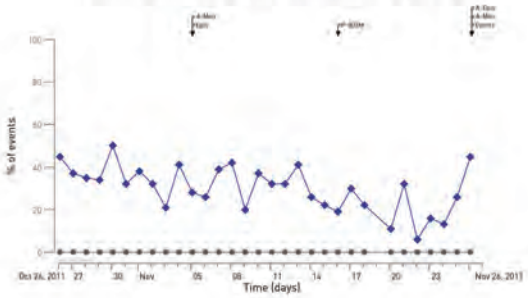
AV sequence (A sensed)

• Intrinsic rhythm (As - Vs) [%] ◆ VAT stimulation (As - Vp) [%]



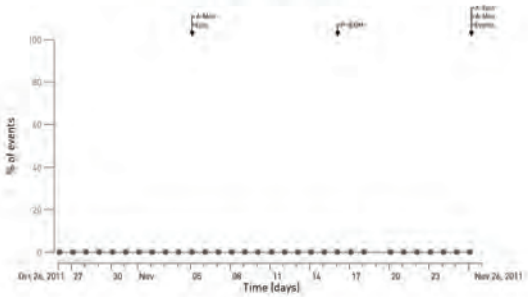
AV sequence (A paced)

• Conducted atrial pacing (Ap - Vs) [%] ◆ Dual-chamber pacing (Ap - Vp) [%]



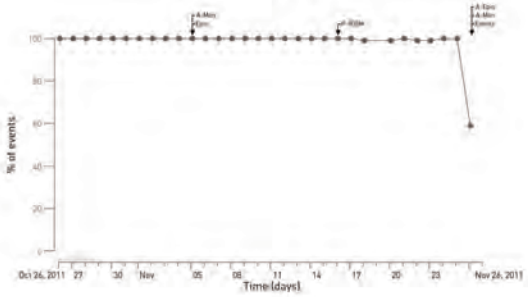
AV sequence (VV sequence)

• VV sequence (Vx - Vx) [%]



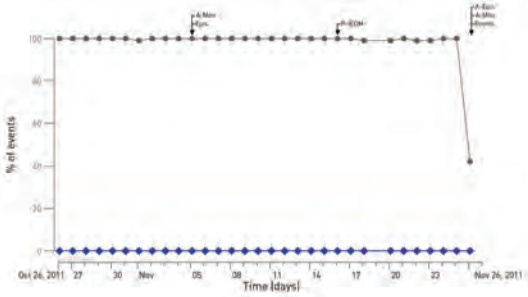
CRT pacing

• CRT pacing [%]



Events with paced RV

• BiV stimulation [%] ◆ RVp without LVp [%]



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Status report - Nov 26, 2011

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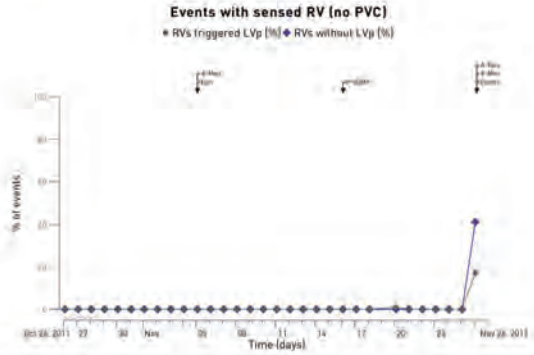
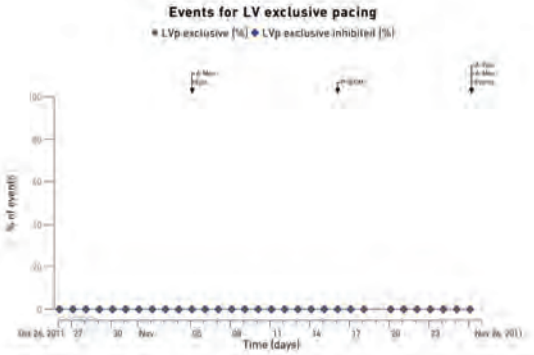
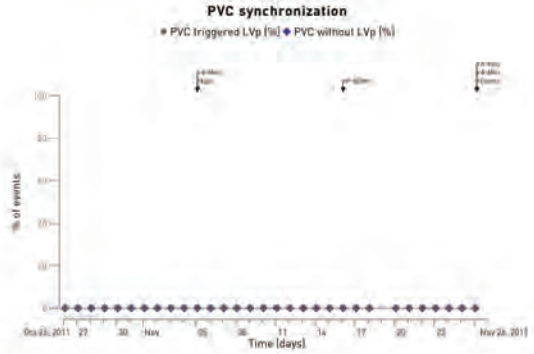
Name:	DOB:	Lumax 340 HF-T	Last message: Nov 26, 2011
Patient ID:	Phone: -	CRT-D implanted Sep 1, 2008	Last clinic follow-up: Oct 21, 2011







Status - Atr. arrhythmia:

Atrial burden	**24 h**	**Since Oct 22, 2011 2:55:36 AM Mean values, * Max values**
Atrial burden [% of day]	43	1
Atrial arrhythmia ongoing at end of mon. interv.	YES	
Mean ven. heart rate during atr. burden [bpm]	125	---
Max. ven. heart rate during atr. burden [bpm]	164	164*
Number of mode switching per day	18	26
Atrial monitoring episodes	**Since Oct 22, 2011 2:55:36 AM**	**Since implantation**
Atrial monitoring episodes	2	4
Long ongoing atrial episode detected	YES	
SVT		
SVT episodes (total)	50	99
SVT episodes (SMART only)	0	0
SMART episode details		
Atrial fibrillation	0	0
Atrial flutter	0	0
Sinus tachycardia	0	0
1:1 (atr. : ven.)	0	0

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Status report - Nov 26, 2011

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BIOTRONIK
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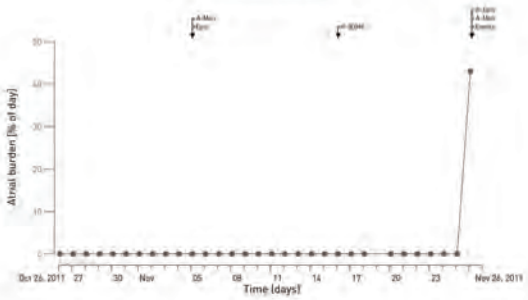
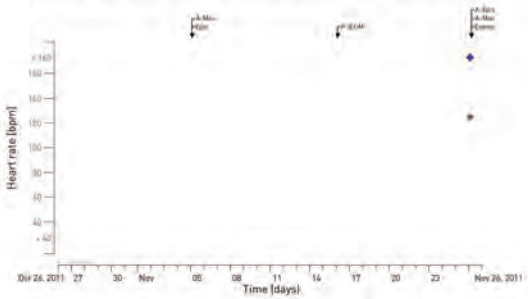
Name:	DOB:	Lumax 340 HF-T	Last message: Nov 26, 2011
Patient ID:	Phone: -	CRT-D implanted Sep 1, 2008	Last clinic follow-up: Oct 21, 2011

Last episode	
No.	126
Type	SVT
Detection	Nov 26, 2011 12:44:25 AM

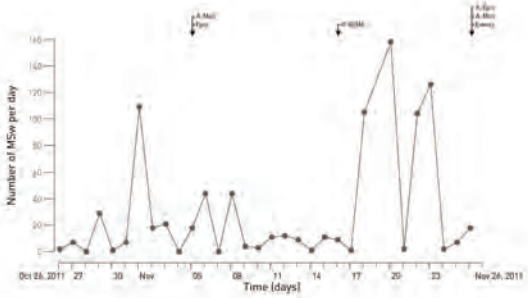
Atrial burden



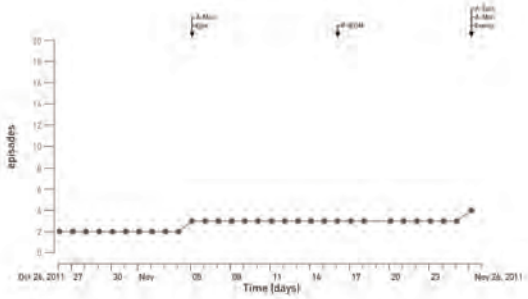
Ven. heart rate during atrial burden



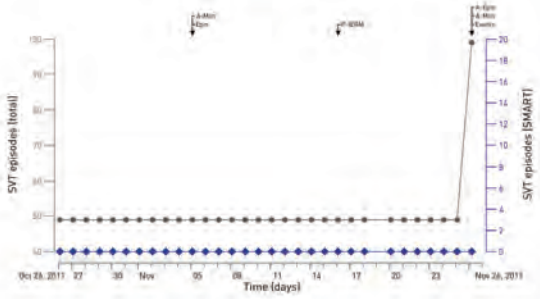
Mode switching



Atrial monitoring episodes



SVT episodes



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Status report - Nov 26, 2011

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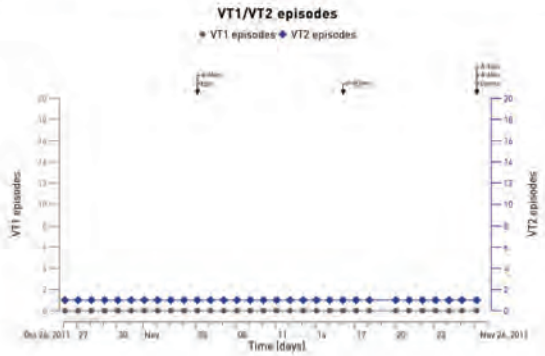
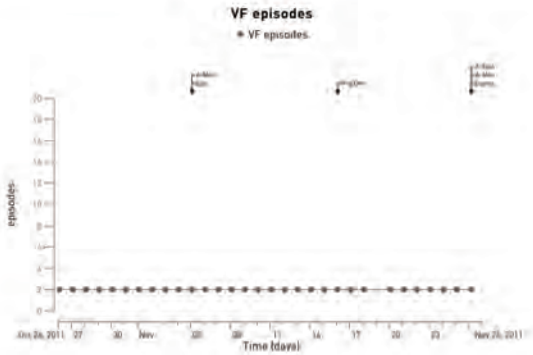
Name:	DOB:	Lumax 340 HF-T	Last message: Nov 26, 2011
Patient ID:	Phone: -	CRT-D implanted Sep 1, 2008	Last clinic follow-up: Oct 21, 2011

Status - Ven. arrhythmia:

Ven. detection	Since Oct 22, 2011 2:55:36 AM	Since implantation
VT1 episodes	0	0
VT2 episodes	0	1
VF episodes	0	2
Episodes during temporary program	0	1
SVT episodes (total)	50	99
Ven. ATP		
ATP in VT zones started	0	1
ATP in VT zones successful	0	1
ATP One Shot started	0	0
ATP One Shot successful	0	0
Ven. shocks		
Shocks started	0	2
Shocks aborted	0	2
Shocks successful	0	0
Ineffective ven. max. energy shocks	0	0
PVC	**24 h**	**Since Oct 22, 2011 2:55:36 AM Mean values**
Mean PVC/h	56	4
Last episode		
No.	126	
Type	SVT	
Detection	Nov 26, 2011 12:44:25 AM	





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Status report - Nov 26, 2011

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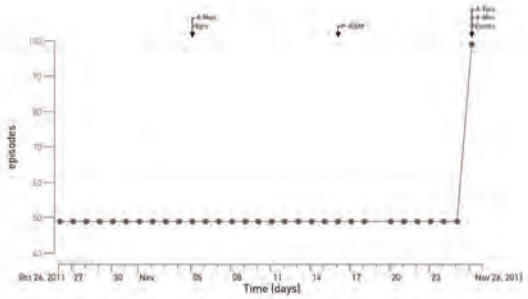
Name:	DOB:	Lumax 340 HF-T	Last message: Nov 26, 2011
Patient ID:	Phone: -	CRT-D implanted Sep 1, 2008	Last clinic follow-up: Oct 21, 2011

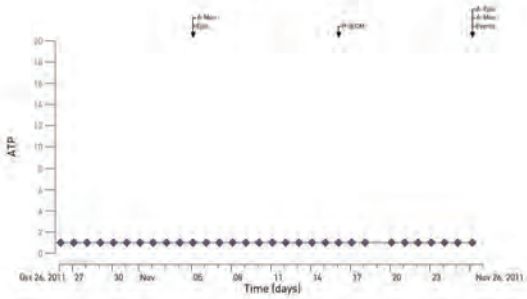
SVT episodes

SVT episodes (total)



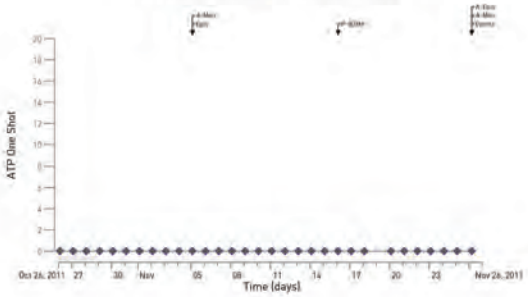
Ven. ATP

ATPs started ATPs successful



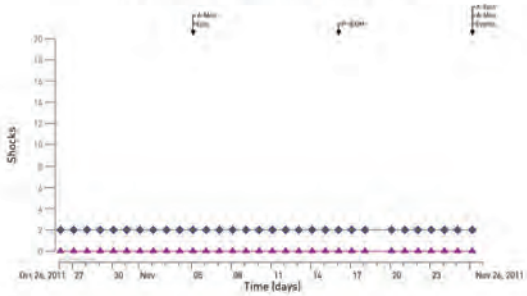
ATP One Shot

ATP One Shot started ATP One Shot successful



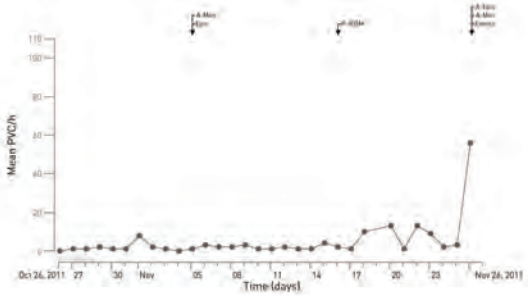
Ven. shocks

Shocks started Shocks aborted Shocks successful



Mean PVC/h

Mean PVC/h



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7/11

Status report - Nov 26, 2011

To: Service Télécardiologie

BIOTRONIK
excellence for life

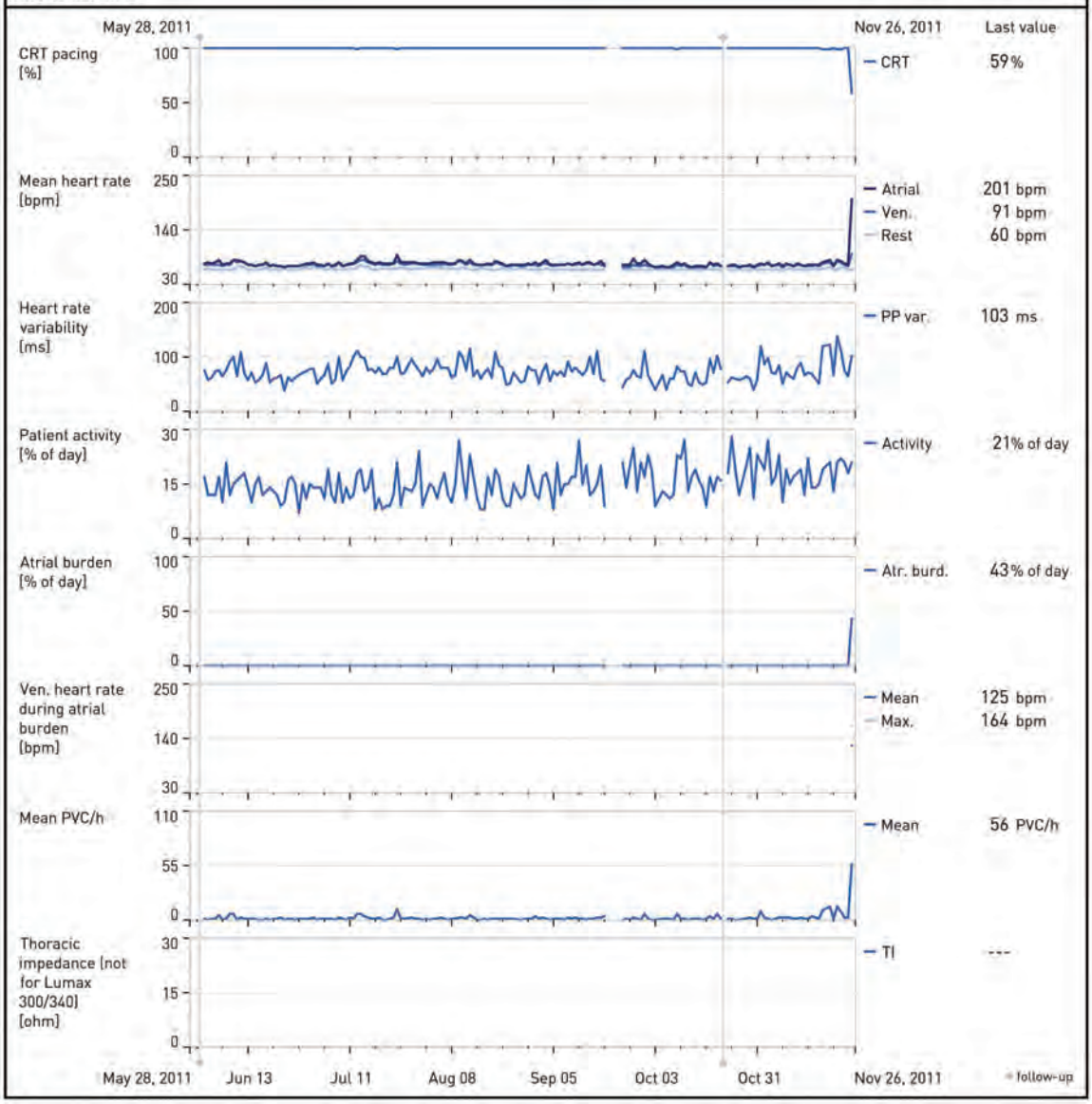
Name:	DOB:	Lumax 340 HF-T	Last message: Nov 26, 2011
Patient ID:	Phone: -	CRT-D implanted Sep 1, 2008	Last clinic follow-up: Oct 21, 2011

Status - HF monitor:

Device status Nov 26, 2011	
Device status	OK
Battery status	OK (MOL1)
Pacing mode	DDD (BiV-LV)

Arrhythmias since Oct 22, 2011	VT1	VT2	VF	Atr.
Episodes	0	0	0	2
ATP started / succ.	0 / 0		0 / 0	-
Shocks started / aborted / succ.	0 / 0 / 0			-

Long term trends



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8/11

Status report - Nov 26, 2011

To: Service Télécardiologie

BIOTRONIK
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Name:	DOB:	Lumax 340 HF-T	Last message: Nov 26, 2011
Patient ID:	Phone: -	CRT-D implanted Sep 1, 2008	Last clinic follow-up: Oct 21, 2011

Recordings

Recordings - Episode list:

No.	Detection time	Type	Details	Predetection PP/RR	Pretermination PP/RR
126	Nov 26, 2011 12:44:25 AM	SVT	Monitoring only	130 / 350	103 / 754
75	Nov 16, 2011 2:40:42 AM	Periodic IEGM	Monitoring only	--- / ---	--- / ---
74	Nov 4, 2011 7:16:24 PM	Atr. monitoring	Monitoring only	140 / 773	791 / 789
	Oct 21, 2011 4:40:31 PM	Follow-up			
73	Oct 8, 2011 11:15:31 PM	Atr. monitoring	Monitoring only	167 / 543	404 / 535
71	Sep 17, 2011 2:40:42 AM	Periodic IEGM	Monitoring only	--- / ---	--- / ---
70	Jul 19, 2011 2:40:42 AM	Periodic IEGM	Monitoring only	--- / ---	--- / ---
	May 30, 2011 4:08:32 PM	Follow-up			
	---	Follow-up			
69	May 20, 2011 3:10:42 AM	Periodic IEGM	Monitoring only	--- / ---	--- / ---

Recordings - Episode 126:

General	
Episode number	126
Episode type	SVT
Detection	Nov 26, 2011 12:44:25 AM
Termination	Nov 26, 2011 12:44:50 AM
Duration	25s
Device settings no.	20
Detection	
Mean PP at initial detection [ms]	130
Mean RR at initial detection [ms]	350
Onset [%]	40, fulfilled
Stability [ms]	68
Redetection	---

Therapy	
ATP in VT/VF delivered	0
ATP One Shot delivered	NO
Shocks delivered	0
Shocks aborted	0
Maximum energy [J]	---
Termination	
Mean PP at termination [ms]	103
Mean RR at termination [ms]	754
Remark	
Detection	SVT (RR unstable)

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9/11

Status report - Nov 26, 2011

To: Service TélécØrdiologie

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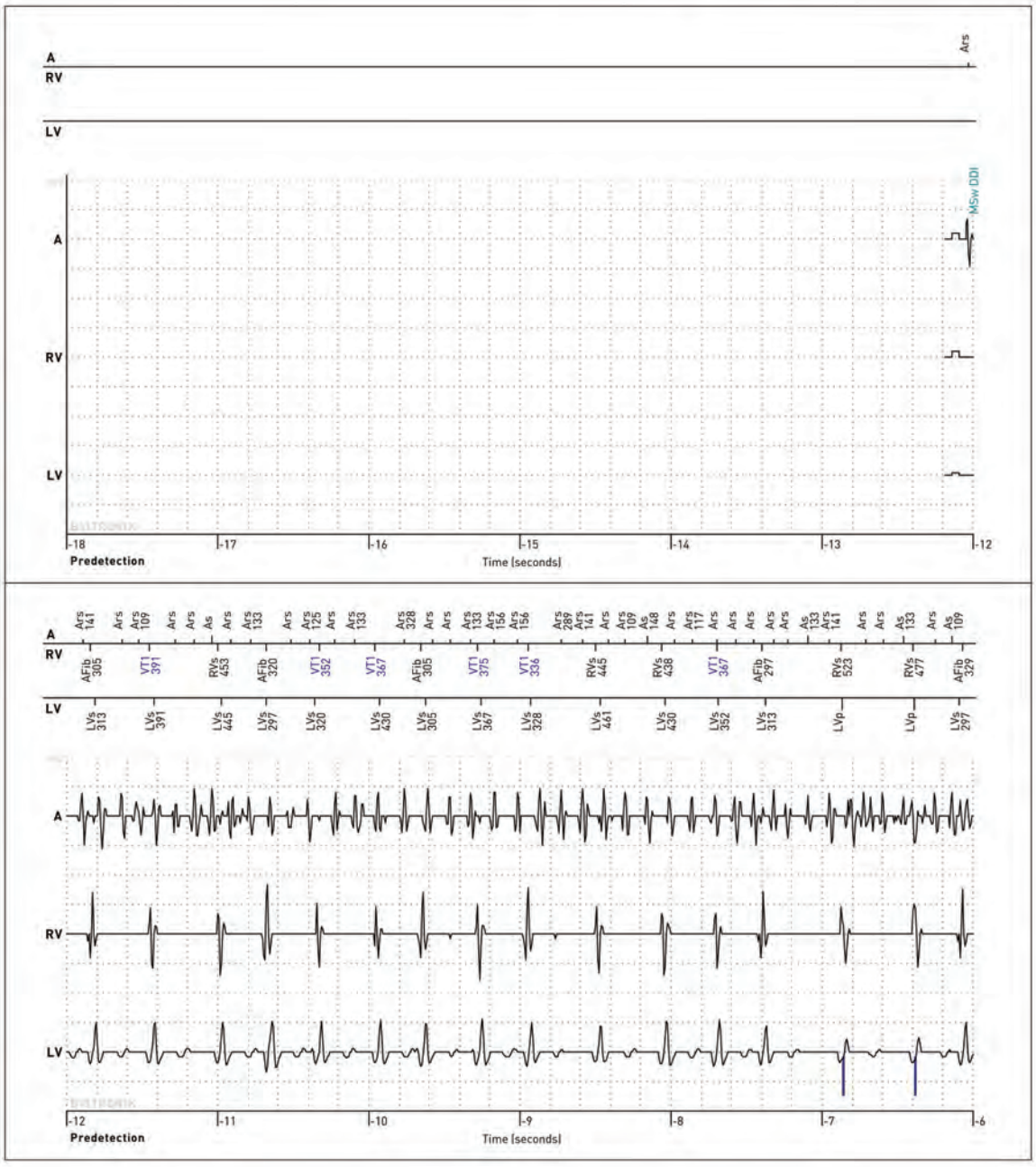
Name:	DOB:	Lumax 340 HF-T	Last message: Nov 26, 2011
Patient ID:	Phone: -	CRT-D implanted Sep 1, 2008	Last clinic follow-up: Oct 21, 2011



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Date:

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10/11

Status report - Nov 26, 2011

To: Service Télécardiologie

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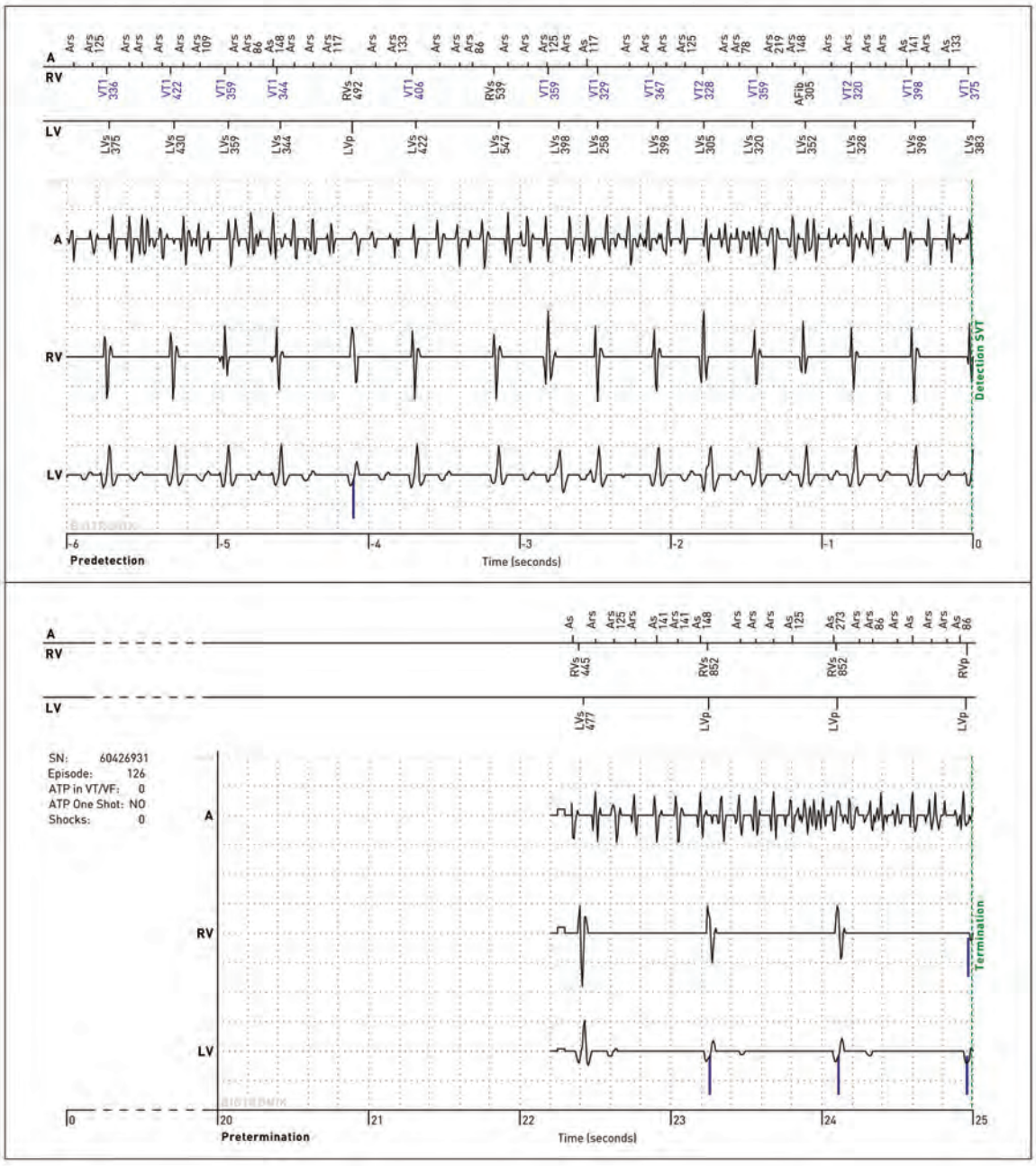
Name:	DOB:	Lumax 340 HF-T	Last message: Nov 26, 2011
Patient ID:	Phone: -	CRT-D implanted Sep 1, 2008	Last clinic follow-up: Oct 21, 2011



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11/11

Alert Message for atrial arrhythmia: episode of classified atrial monitoring by a DX single chamber defibrillator

Patient

This 66-year-old man received a Lumax 740 VR-T DX defibrillator, connected to a single VDD lead with an atrial sensing dipole, implanted for primary prevention in the context of dilated cardiomyopathy and depressed left ventricular ejection fraction. He was followed by telecardiology and an alert message was transmitted.

Telemedicine report

Alert message (yellow status) for episode of classified atrial monitoring.
As in a standard dual chamber defibrillator, four channels are displayed: the markers with time intervals, the shock delivery channels (Far Field, FF), the atrial sensing channel, and the right ventricular sensing channel. The EGM show a rapid, irregular rhythm correctly detected at the ventricular level and a very rapid and irregular rhythm, consistent with conducted atrial fibrillation.

Comments

This kind of device is specific to Biotronik Inc., allowing the analysis of atrial activation by a single lead VDD system. The Lumax VR-T DX is connected to a dedicated defibrillation lead, equipped with a floating atrial dipole, which senses the atrial signals. The atrial information is the same as that provided by a standard dual chamber defibrillator. The management of atrial fibrillation can be optimized by combining telecardiology and the entire atrial diagnostics. In this patient, the analysis of the atrial EGM ascertained the diagnosis, allowing an adaptation of the management and therapy. The atrial information can also be used to discriminate the arrhythmias. The single or dual chamber SMART algorithms are available and can be used according to the physician's choice, which hinges on the quality of atrial sensing. The initial signals are amplified, though sensing by a floating dipole can be imperfect, as it was in this patient. While dual chamber might be slightly superior to single chamber discrimination when atrial sensing is flawless, it probably should be avoided when sensing is of fair or low quality. In this patient, we chose the programming of single chamber discrimination, since the atrial information had allowed a distinction of the characteristics of the arrhythmia (paroxysmal versus persistent), as well as an evaluation of the efficacy of the antiarrhythmic treatment that had been implemented.

Quick View - Dec 1, 2012

To: Service Télécardiologie

BIOTRONIK
excellence for life

Name:
Patient ID:

DOB:
Phone: -

Lumax 740 VR-T DX
ICD implanted Jul 27, 2012

Last message: Dec 1, 2012
Last clinic follow-up: Jul 30, 2012

Device status	
Status	OK
Battery status	BOL (EOS, ERI, MOL2, MOL1, BOL)
Battery voltage	3.12 V (Dec 1, 2012)
Charge time	9.8 s for 40 J (Oct 17, 2012 12:58:16 AM)

Findings
Atrial monitoring episode detected
Episode details received

Tachy settings						
	Zone limit	1st ATP	2nd ATP	1st shock	2nd shock	3rd - nth sho.
VT1	OFF	---	---	---	---	---
VT2	OFF	---	---	---	---	---
VF	280 ms	Burst		40 J	40 J	6 * 40 J

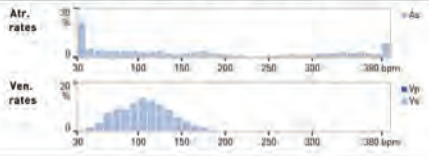
Brady / AF settings	
Mode	VVI
Basic rate / UTR [bpm]	40 / ---
AV delay	---
Mode switching	---

Brady leads	RA lead	RV lead
Pacing impedance [ohm]		579
Pacing threshold [V]		0.7
Sensing ampl. mean / min [mV]	0.7 / < 0.5	8.0 / 5.6
Programmed [V@ms]		3.50 @ 0.40

Shock lead	
Daily shock lead imp. [ohm]	82
Last delivered shock imp. [ohm]	---

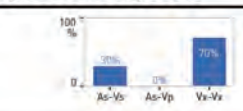
Ven. arrhythmias since Aug 8, 2012	VT1	VT2	VF
Episodes	0	0	0
ATP started / succ.	0 / 0		0 / 0
Shocks started / aborted / succ.	0 / 0 / 0		
Last episode: Atr. monitoring (Dec 1, 2012 12:58:12 AM)			

Rate histogram from Jul 31, 2012 until Nov 4, 2012



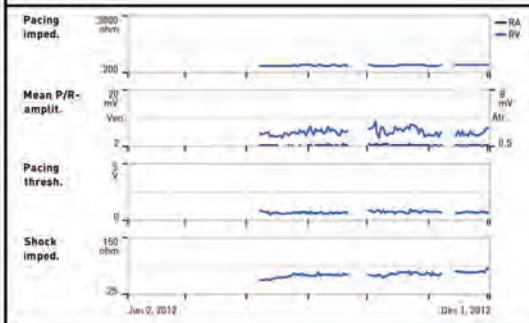
Atrial arrhythmias since Aug 8, 2012	
Atrial burden	0.2% of day
Mean ven. heart rate during atr. burden	100 bpm
Atrial arrhythmia ongoing at end of mon. interv.	NO
Atrial monitoring episodes	134
Number of mode switching per day	---
SVT episodes	0

Event episodes since Aug 8, 2012

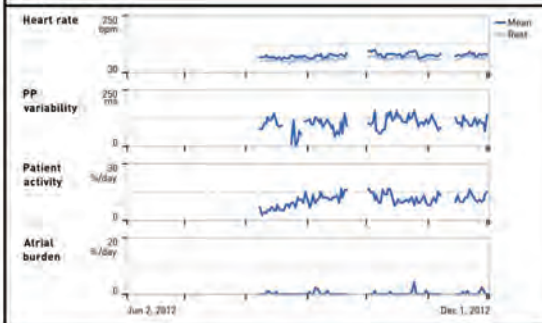


Pacing	
RVp	0%

Lead trends



Long term trends



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Status report - Dec 1, 2012

To: Service Télécardiologie

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Name:	DOB:	Lumax 740 VR-T DX	Last message: Dec 1, 2012
Patient ID:	Phone: -	ICD implanted Jul 27, 2012	Last clinic follow-up: Jul 30, 2012

Status: YELLOW

Status - Summary:

Status summary for patient ID

Category	Status	Finding	Info
Atr. arrhythmia	YELLOW	**Atrial monitoring episode detected** 4 atrial monitoring episode(s) detected between Nov 30, 2012 1:42:30 AM and Dec 1, 2012 1:42:30 AM	**New.**
Recordings / Episode	YELLOW	**Episode details received** Episode details were received for a spontaneous Atr. monitoring episode, which was detected on Dec 1, 2012 12:58:12 AM	**New.**
Automatic remark:	none		

Status - Atr. arrhythmia:

Atrial burden	**24 h**	**Since Aug 8, 2012 1:42:30 AM Mean values, * Max values**
Atrial burden [% of day]	0.0	0.2
Atrial arrhythmia ongoing at end of mon. interv.	NO	Last atrial burden measured on Dec 1, 2012 12:58:12 AM
Duration of longest atrial episode	2min	22min*
Mean ven. heart rate during atr. burden [bpm]	109	100
Max. ven. heart rate during atr. burden [bpm]	115	136*
Number of atrial episodes per day	4	1
Number of mode switching per day	---	---
Atrial monitoring episodes	**Since Aug 8, 2012 1:42:30 AM**	**Since implantation**
Atrial monitoring episodes	134	157
Long ongoing atrial episode detected	NO	
SVT		
SVT episodes (total)	0	0
SVT episodes (SMART only)	0	0
SMART episode details		
Atrial fibrillation	0	0
Atrial flutter	0	0
Sinus tachycardia	0	0
1:1 (atr. : ven.)	0	0
Last episode		
No.	161	
Type	Atr. monitoring	
Detection	Dec 1, 2012 12:58:12 AM	

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Signature:

Status report - Dec 1, 2012

To: Service Télécardiologie

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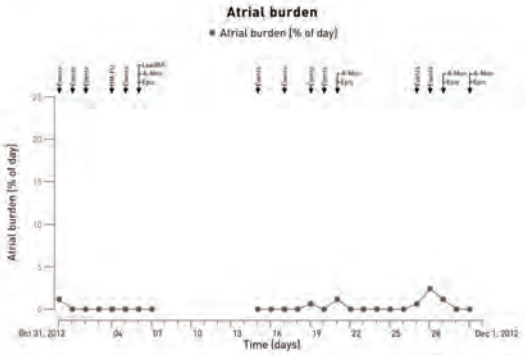
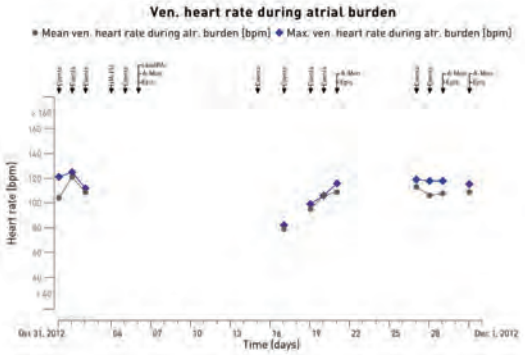
Name:	DOB:	Lumax 740 VR-T DX	Last message: Dec 1, 2012
Patient ID:	Phone: -	ICD implanted Jul 27, 2012	Last clinic follow-up: Jul 30, 2012

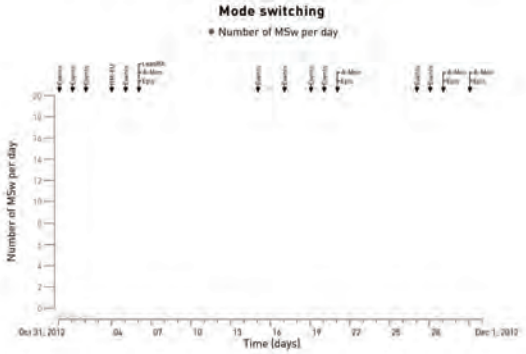
Atrial burden



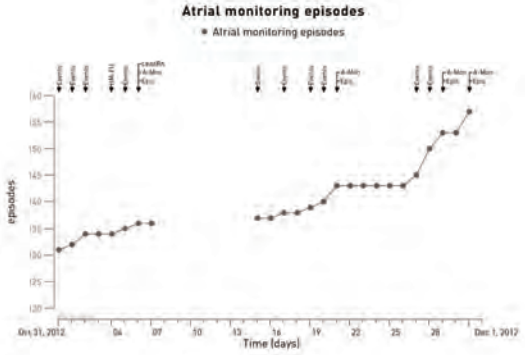
Ven. heart rate during atrial burden



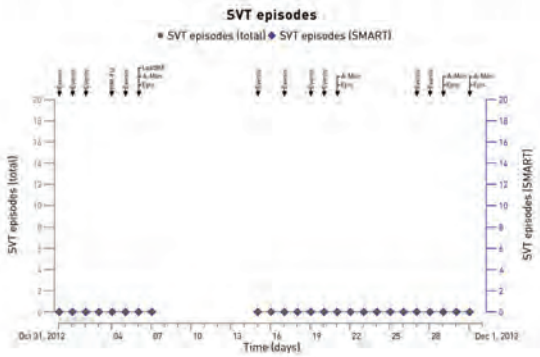
Mode switching



Atrial monitoring episodes



SVT episodes



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Status report - Dec 1, 2012

To: Service Télécardiologie

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Name:
Patient ID:

DOB:
Phone: -

Lumax 740 VR-T DX
ICD implanted Jul 27, 2012

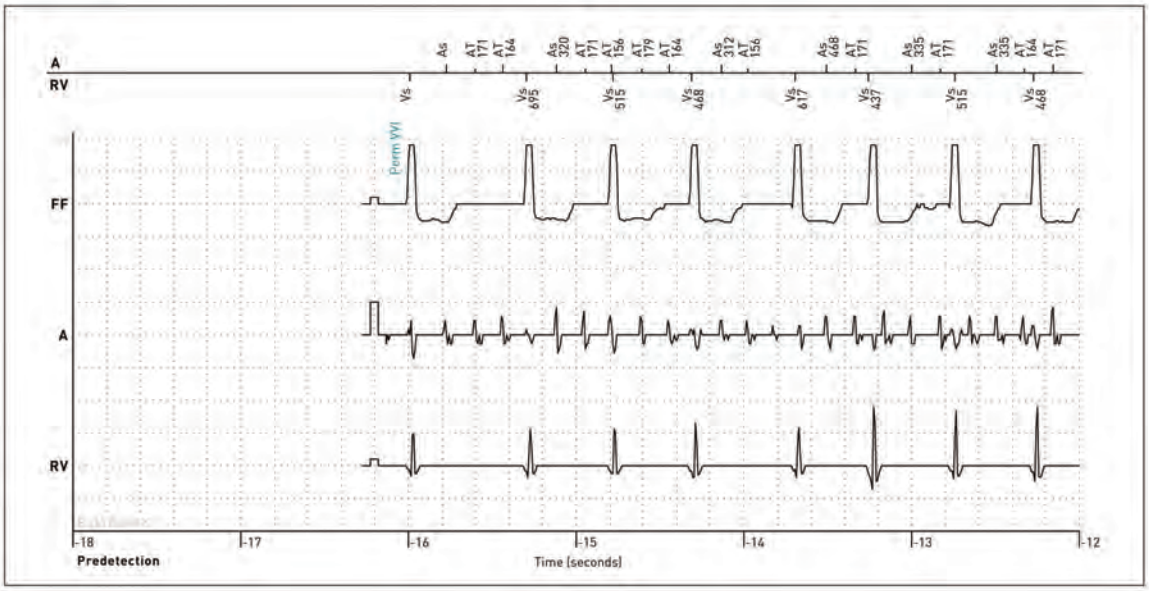
Last message: Dec 1, 2012
Last clinic follow-up: Jul 30, 2012

Recordings

Recordings - Episode 161:

General	
Episode number	161
Episode type	Atr. monitoring
Detection	Dec 1, 2012 12:58:12 AM
Termination	Dec 1, 2012 1:00:18 AM
Duration	2min 6s
Device settings no.	7
Detection	
Mean PP at initial detection [ms]	243
Mean RR at initial detection [ms]	614
Onset [%]	---
Stability [ms]	> 247
Redetection	---

Therapy	
ATP in VT/VF delivered	0
ATP One Shot delivered	NO
Shocks delivered	0
Shocks aborted	0
Maximum energy [J]	---
Termination	
Mean PP at termination [ms]	---
Mean RR at termination [ms]	618
Remark	
none	



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Status report - Dec 1, 2012

To: Service Télécardiologie

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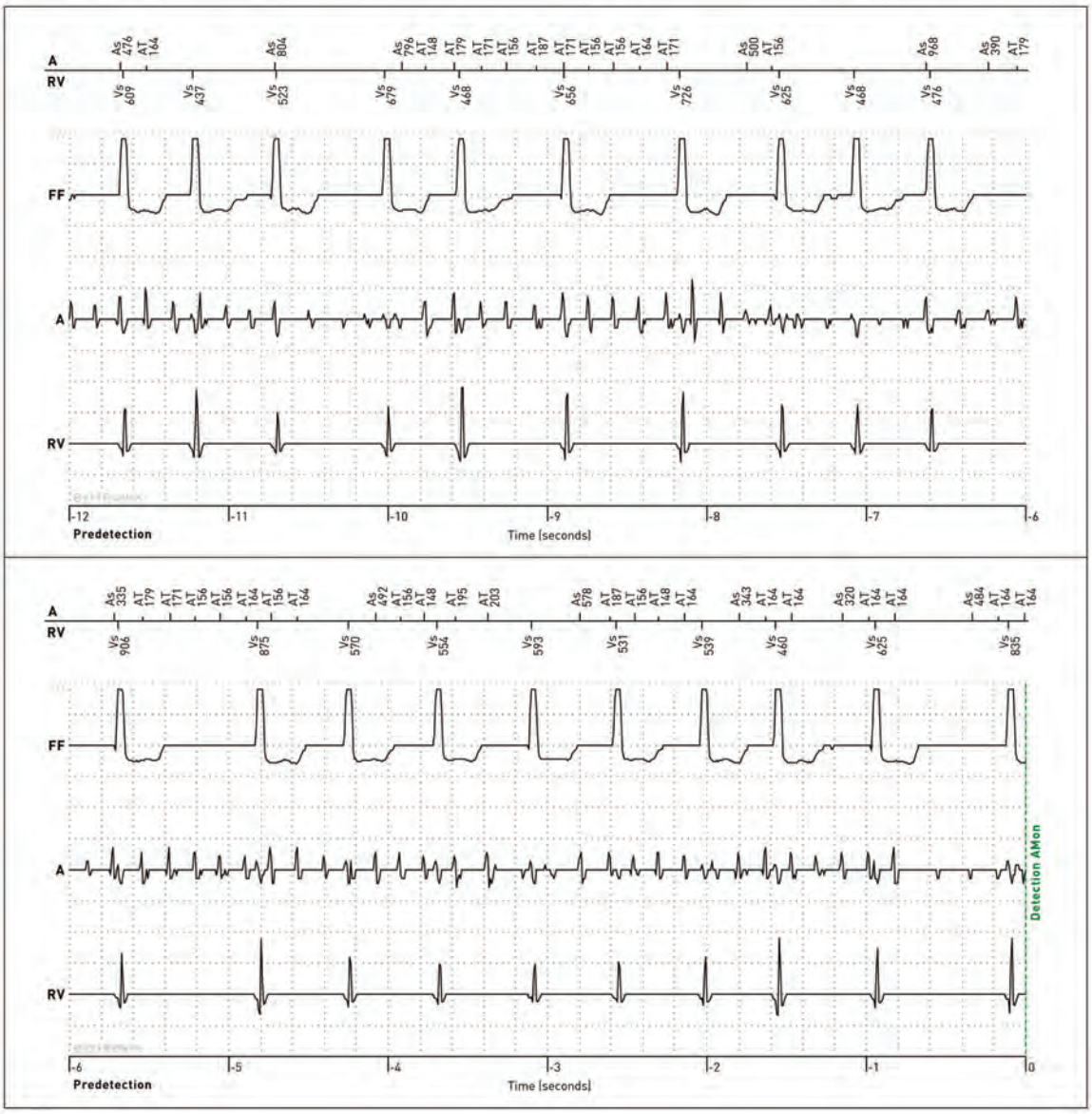
Name:	DOB:	Lumax 740 VR-T DX	Last message: Dec 1, 2012
Patient ID:	Phone: -	ICD implanted Jul 27, 2012	Last clinic follow-up: Jul 30, 2012



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Status report - Dec 1, 2012

To: Service TélécØrdiologie

BIOTRONIK
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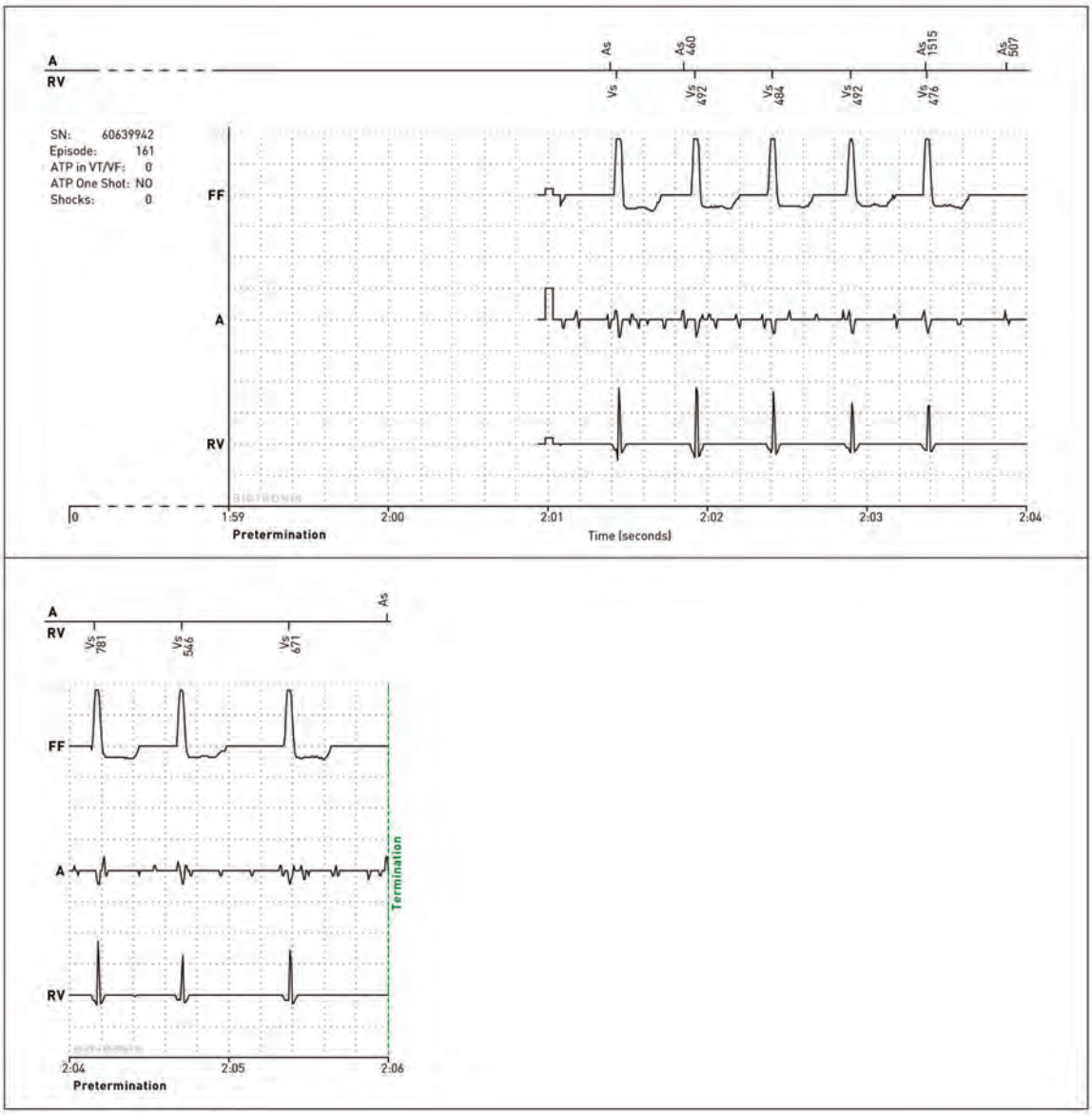
Name:	DOB:	Lumax 740 VR-T DX	Last message: Dec 1, 2012
Patient ID:	Phone: -	ICD implanted Jul 27, 2012	Last clinic follow-up: Jul 30, 2012



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6/6

Alert message for ventricular arrhythmia: episode of classified ventricular fibrillation

Patient

This 85-year-old man presenting with dilated cardiomyopathy, left bundle branch block and a 25% left ventricular ejection fraction, received a Lumax 540 HF-T triple chamber defibrillator for secondary prevention. He underwent a first device implantation 7 years and pulse generator replacement a few months earlier. He was followed by telecardiology and an alert was transmitted.

Telemedicine report

Alert message (yellow status) for episode of classified ventricular fibrillation.
This report indicates that the patient developed an episode of fast ventricular tachycardia (VT) diagnosed in the ventricular fibrillation zone, treated successfully by a sequence of anti-tachycardia pacing. No DC shock was delivered

Comments

Telecardiology enables a detailed monitoring of ventricular arrhythmias, and allows the programming of an alert in case of VT in the monitor zone, VT in the VT1 or VT2 zone, ventricular fibrillation, or of successful shock delivery. The EGM allows the verification of the appropriate delivery of therapies. It is noteworthy that the EGM is interrupted at the time of diagnosis and resumes after the delivery of the last therapy. The various therapies and the phase of capacitors charge are not visible.
In this patient, anti-tachycardia pacing one shot of this organized VT was successful. This represents an appropriate function of the defibrillator: detection of a ventricular arrhythmia and termination by a painless therapy. The energy consumption was low, since the charge began after the burst of anti-tachycardia pacing and ended as soon as the device diagnosed the return of sinus rhythm.
Since this episode was isolated and asymptomatic, it was not necessary to see the patient in order to change the programming or the medical treatment. On the other hand, if telecardiology detected several such episodes, it would become necessary to see the patient in a face-to-face visit, in an attempt to optimize the medical treatment and, perhaps, offer an ablation of this ventricular arrhythmia. The device programming might also be modified. The ventricular fibrillation zone was relatively wide (starting at 320 ms) and could probably have been narrowed to promote anti-tachycardia pacing therapy of this organized arrhythmia with a single burst in the ventricular fibrillation zone versus several sequences in the VT zone.

Quick View - Dec 14, 2012

To: Service Télécardiologie

BIOTRONIK
excellence for life

Name:
Patient ID:

DOB:
Phone: -

Lumax 540 HF-T
CRT-D implanted Apr 6, 2012

Last message: Dec 14, 2012
Last clinic follow-up: Oct 2, 2012

Device status	
Status	OK
Battery status	BOL (EOS, ERI, MOL2, MOL1, BOL)
Battery voltage	2.95 V (Dec 14, 2012)
Charge time	2.5 s for 40 J (Dec 14, 2012 5:30:34 AM)

Findings
VF detected
Episode details received

Tachy settings	Zone limit	1st ATP	2nd ATP	1st shock	2nd shock	3rd - nth sho.
VT1	450 ms	OFF	OFF	OFF	---	---
VT2	400 ms	3 * Burst	3 * Ramp	10 J	40 J	6 * 40 J
VF	320 ms	Burst		40 J	40 J	6 * 40 J

Brady / CRT / AF settings	
Mode	VVIR / BiV-LV
Basic rate / UTR [bpm]	70 / ---
AV delay	---
Mode switching	---

Brady leads	RA lead	RV lead	LV lead
Pacing impedance [ohm]	OFF	495	522
Pacing threshold [V]		0.7	OFF
Sensing ampl. mean / min [mV]	--- / ---	--- / ---	--- / ---
Programmed [V@ms]	--- @ ---	2.0 @ 0.4	5.0 @ 1.0

Shock lead	
Daily shock lead imp. [ohm]	38
Last delivered shock imp. [ohm]	---

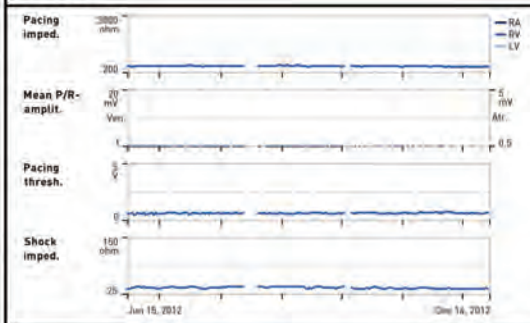
Ven. arrhythmias since Oct 6, 2012	VT1	VT2	VF
Episodes	0	0	1
ATP started / succ.	0 / 0		1 / 1
Shocks started / aborted / succ.	1 / 1 / 0		
Last episode: VF (Dec 14, 2012 5:30:29 AM)			

Event episodes since Oct 6, 2012

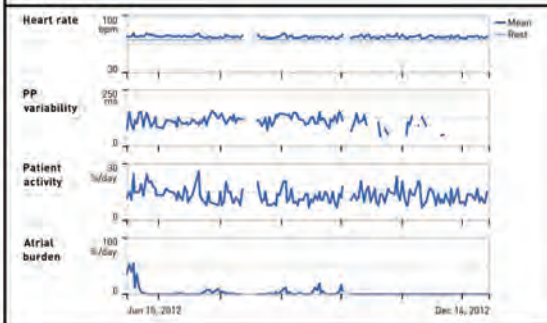
Pacing	
Ap	---
Vp	99%

Atrial arrhythmias since Oct 6, 2012	
Atrial burden	0% of day
Mean ven. heart rate during atr. burden	---
Atrial arrhythmia ongoing at end of mon. interv.	NO
Atrial monitoring episodes	0
Number of mode switching per day	---
SVT episodes	0

Lead trends



Long term trends



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Date:

Signature:

Status report - Dec 14, 2012

To: Service Télécardiologie

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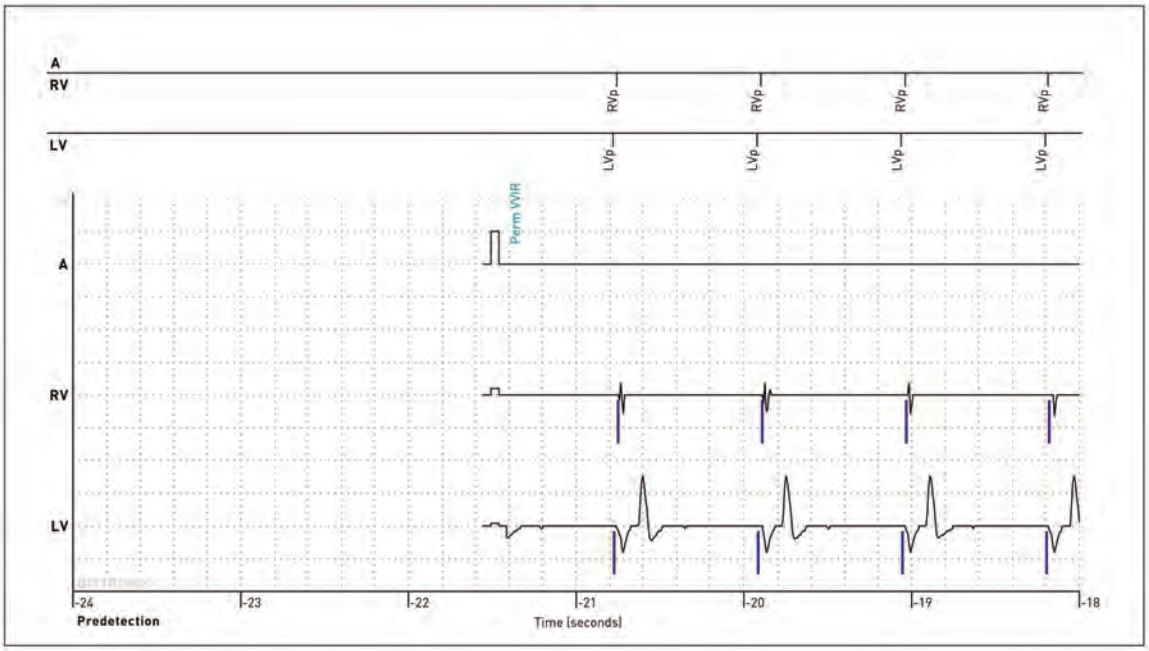
Name:	DOB:	Lumax 540 HF-T	Last message: Dec 14, 2012
Patient ID:	Phone: -	CRT-D implanted Apr 6, 2012	Last clinic follow-up: Oct 2, 2012

Recordings

Recordings - Episode 4619:

General	
Episode number	4619
Episode type	VF
Detection	Dec 14, 2012 5:30:29 AM
Termination	Dec 14, 2012 5:30:44 AM
Duration	15s
Device settings no.	11
Detection	
Mean PP at initial detection [ms]	> 1998
Mean RR at initial detection [ms]	300
Onset [%]	62, fulfilled
Stability [ms]	24
Redetection	---

Therapy	
ATP in VT/VF delivered	1
ATP One Shot delivered	YES
Shocks delivered	0
Shocks aborted	1
Maximum energy [J]	40
Termination	
Mean PP at termination [ms]	> 1998
Mean RR at termination [ms]	856
Remark	
none	



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Date:

Signature:

Status report - Dec 14, 2012

To: Service Télécardiologie

BIOTRONIK
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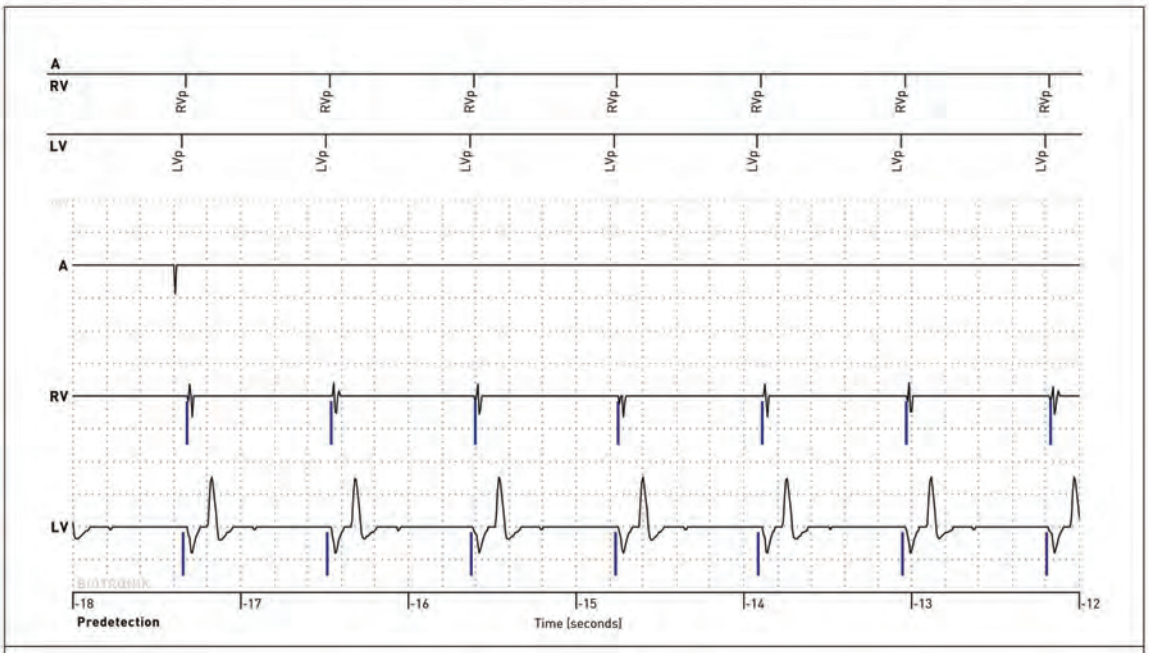
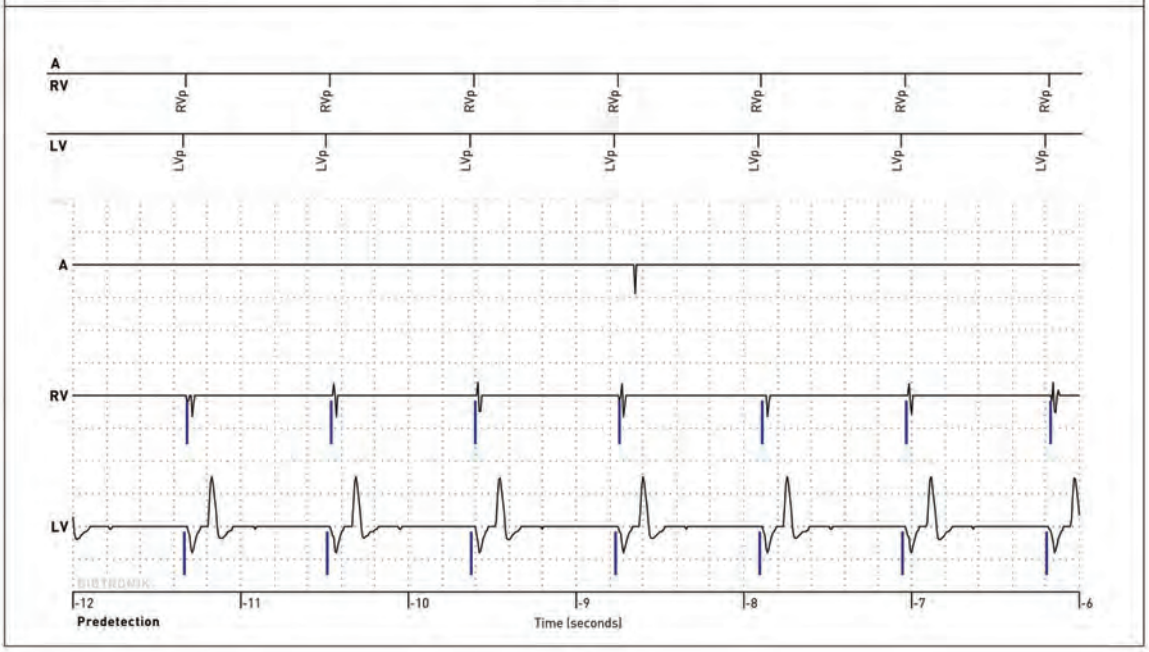
Name:	DOB:	Lumax 540 HF-T	Last message: Dec 14, 2012
Patient ID:	Phone: -	CRT-D implanted Apr 6, 2012	Last clinic follow-up: Oct 2, 2012





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Date:

Signature:

3/5

Status report - Dec 14, 2012

To: Service Télécardiologie

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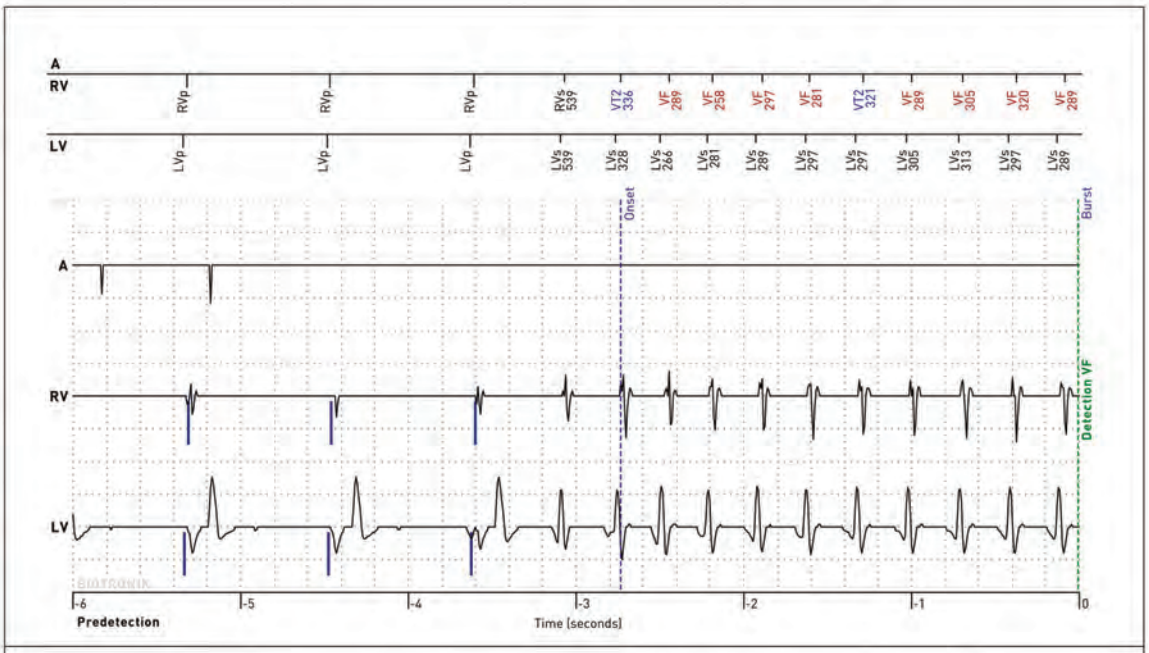
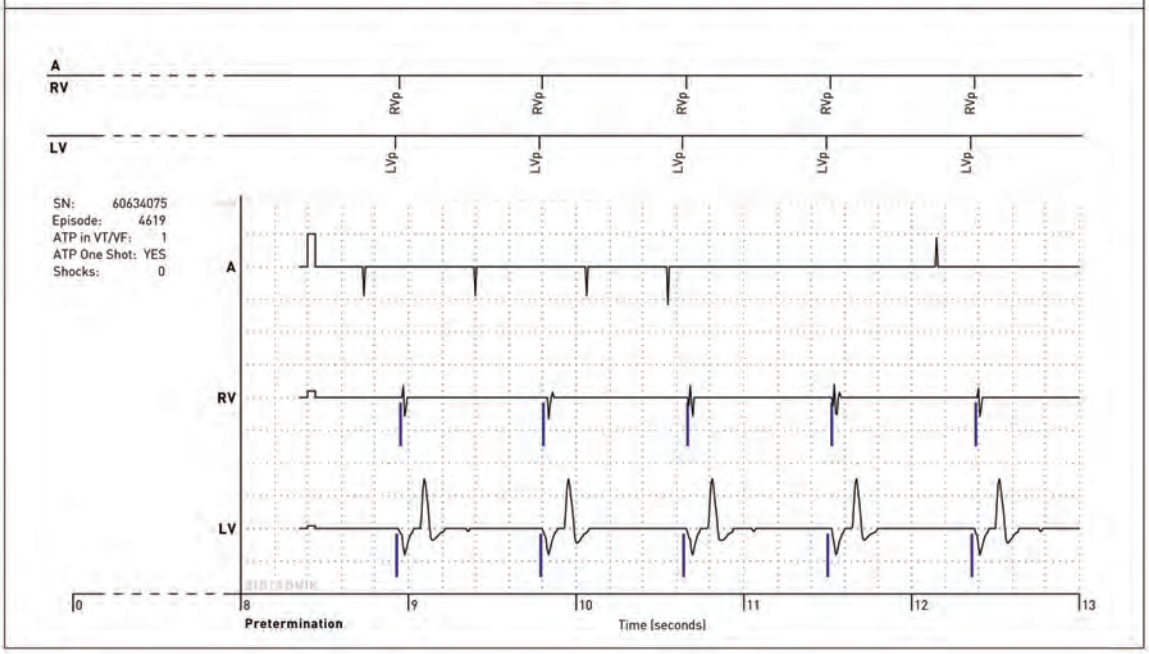
Name:	DOB:	Lumax 540 HF-T	Last message: Dec 14, 2012
Patient ID:	Phone: -	CRT-D implanted Apr 6, 2012	Last clinic follow-up: Oct 2, 2012





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Status report - Dec 14, 2012

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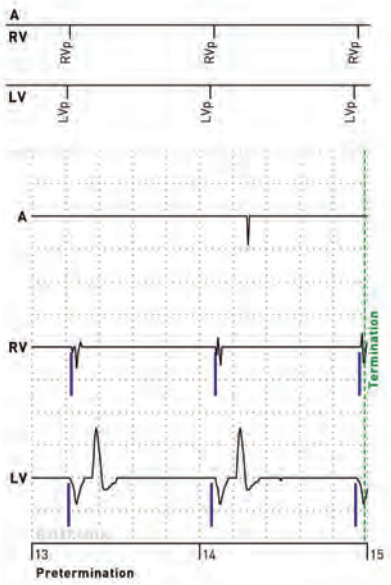
Name:	DOB:	Lumax 540 HF-T	Last message: Dec 14, 2012
Patient ID:	Phone: -	CRT-D implanted Apr 6, 2012	Last clinic follow-up: Oct 2, 2012



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5/5

Alert message for ventricular arrhythmia: episode of classified ventricular fibrillation

Patient

This 57-year-old woman received a Lumax 540 HF-T triple chamber defibrillator for primary prevention in the context of dilated cardiomyopathy with a depressed left ventricular ejection fraction and left bundle branch block. An alert message was transmitted a few months after device implantation.

Telemedicine report

Alert message (yellow status) for episode of classified ventricular fibrillation.
The report indicates that the patient suffered an episode diagnosed in the VF zone, with interruption of the capacitors charge and without shock delivery. The analysis of the EGM shows typical intermittent oversensing of a 50 Hz signal (presence of overload of the baseline on the various channels).

Comments

In view of this alert, the patient was called the next day. The emitting source of this signal was easily identified as a poorly insulated household appliance. The early diagnosis prevented the delivery of inappropriate therapy, one of the most disabling complications in recipients of defibrillators.

Quick View - Nov 5, 2012

To: Service Télécardiologie

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Name:
Patient ID:

DOB: Sep 29, 1955
Phone:

Lumax 540 HF-T
CRT-D implanted May 21, 2012

Last message: Nov 5, 2012
Last clinic follow-up: Oct 17, 2012

Device status	
Status	OK
Battery status	BOL (EOS, ERI, MOL2, MOL1, BOL)
Battery voltage	3.15 V (Nov 5, 2012)
Charge time	4.4 s for 40 J (Nov 5, 2012 11:43:36 PM)

Findings
VF detected
Episode details received

Tachy settings	Zone limit	1st ATP	2nd ATP	1st shock	2nd shock	3rd - nth sho.
VT1	350 ms	3 * Burst	3 * Ramp	40 J	40 J	6 * 40 J
VT2	OFF	---	---	---	---	---
VF	280 ms	Burst		40 J	40 J	6 * 40 J

Brady / CRT / AF settings	
Mode	VVIR / BiV-LV
Basic rate / UTR [bpm]	60 / ---
AV delay	---
Mode switching	---

Brady leads	RA lead	RV lead	LV lead
Pacing impedance [ohm]	OFF	537	686
Pacing threshold [V]		---	OFF
Sensing ampl. mean / min [mV]	OFF / OFF	--- / ---	15.0 / 12.7
Programmed [V@ms]	--- @ ---	2.5 @ 0.4	2.5 @ 1.0

Shock lead	
Daily shock lead imp. [ohm]	39
Last delivered shock imp. [ohm]	---

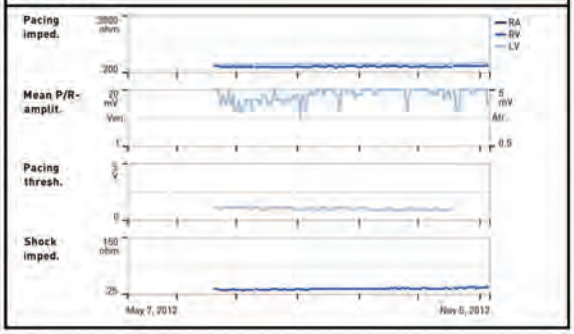
Ven. arrhythmias since Oct 18, 2012	VT1	VT2	VF
Episodes	0	0	1
ATP started / succ.	0 / 0		0 / 0
Shocks started / aborted / succ.	1 / 1 / 0		
Last episode: VF (Nov 5, 2012 11:43:31 PM)			

Event episodes since Oct 18, 2012

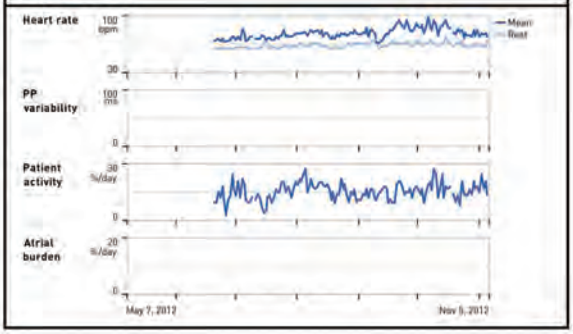
Pacing	
Ap	---
Vp	38%

Atrial arrhythmias since Oct 18, 2012	
Atrial burden	---
Mean ven. heart rate during atr. burden	---
Atrial arrhythmia ongoing at end of mon. interv.	OFF
Atrial monitoring episodes	0
Number of mode switching per day	---
SVT episodes	0

Lead trends



Long term trends



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Signature:

Status report - Nov 5, 2012

To: Service Télécardiologie

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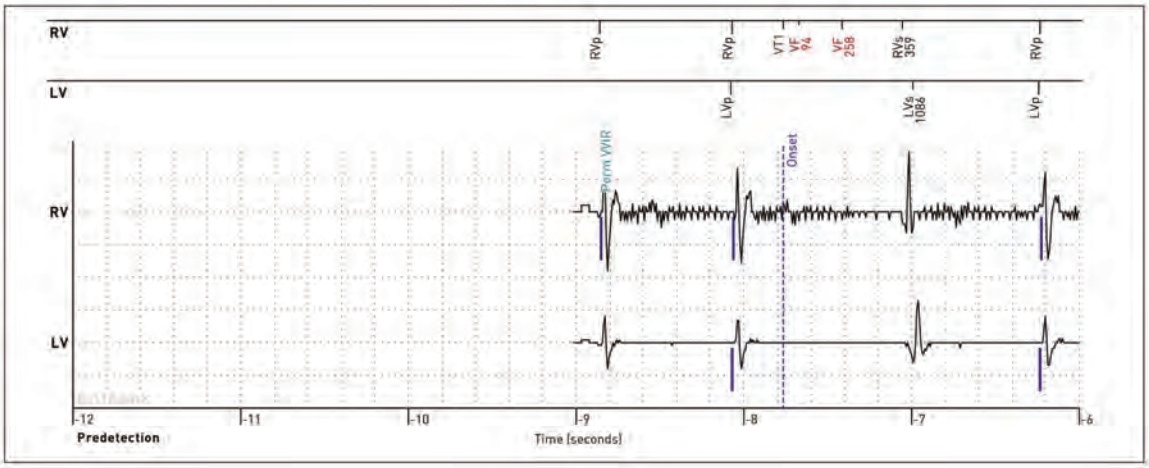
Name:	DOB: Sep 29, 1955	Lumax 540 HF-T	Last message: Nov 5, 2012
Patient ID:	Phone:	CRT-D implanted May 21, 2012	Last clinic follow-up: Oct 17, 2012

Recordings

Recordings - Episode 3:

General	
Episode number	3
Episode type	VF
Detection	Nov 5, 2012 11:43:31 PM
Termination	Nov 5, 2012 11:43:45 PM
Duration	14s
Device settings no.	28
Detection	
Mean PP at initial detection [ms]	---
Mean RR at initial detection [ms]	142
Onset [%]	80, fulfilled
Stability [ms]	221
Redetection	---

Therapy	
ATP in VT/VF delivered	0
ATP One Shot delivered	NO
Shocks delivered	0
Shocks aborted	1
Maximum energy [J]	40
Termination	
Mean PP at termination [ms]	---
Mean RR at termination [ms]	628
Remark	
none	



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Status report - Nov 5, 2012

To: Service TéléCardiologie

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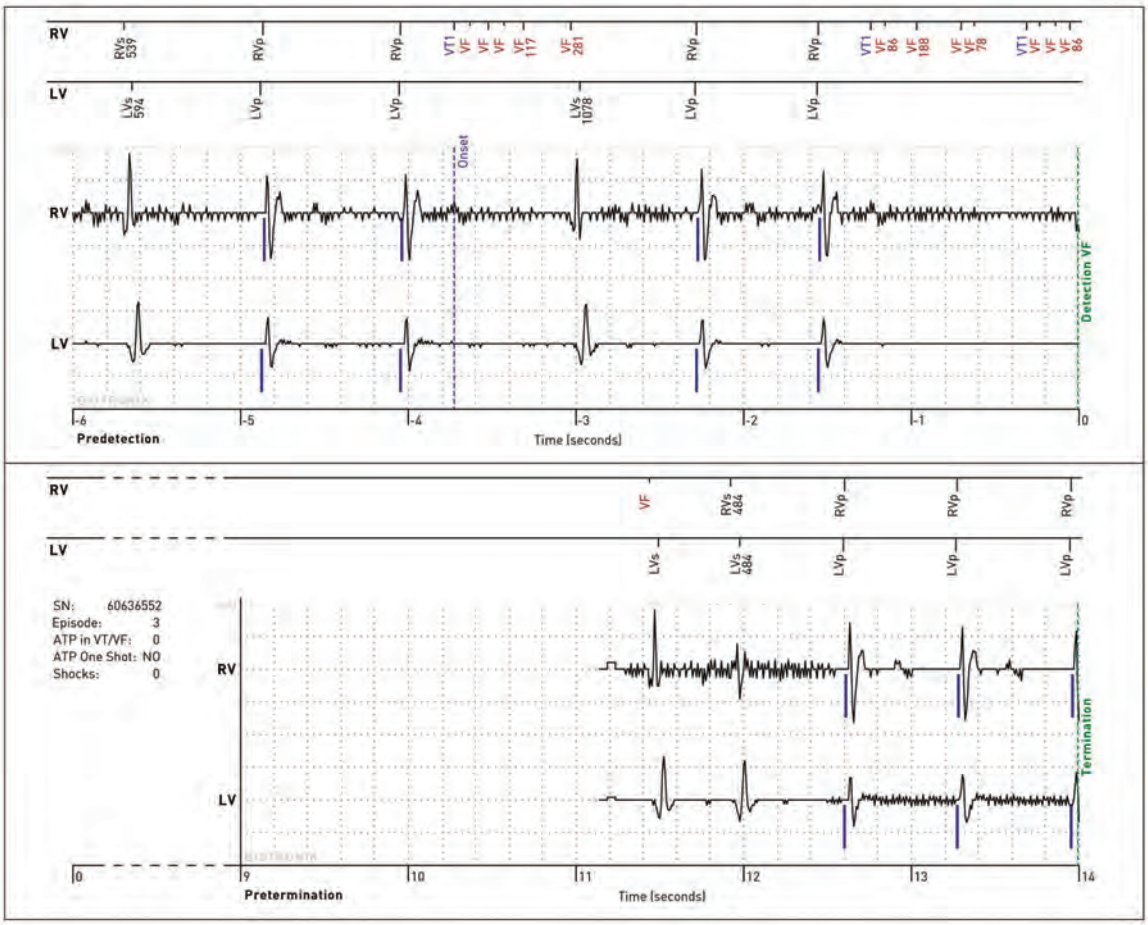
Name:	DOB: Sep 29, 1955	Lumax 540 HF-T	Last message: Nov 5, 2012
Patient ID:	Phone:	CRT-D implanted May 21, 2012	Last clinic follow-up: Oct 17, 2012



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3/3

Alert message for ventricular arrhythmia: episode of classified ventricular fibrillation Patient

Patient

This 39-year-old man received a Lumax 340 VR-T single chamber defibrillator for management of Brugada syndrome with syncope; an alert message was transmitted 2 years after device implantation.

Telemedicine report

Alert message (yellow status) for episode of classified ventricular fibrillation.
The report shows that the patient sustained an episode diagnosed in the ventricular fibrillation zone, with interruption of the capacitors charge and no shock delivery. Analysis of the EGM shows a typical aspect of intermittent oversensing of the T wave.

Comments

The last two tracings illustrate an important advantage of follow-ups with telemedicine: prevention of inappropriate therapies. In view of this alert message, the patient was contacted the next day, and seen in face-to-face consultation to the Enhanced T-wave suppression algorithm which solved the problem and prevented all further inappropriate therapies. We caution however physicians to the routine implementation and programming of this algorithm which in turn may compromise proper VF detection.
The last three tracings correspond to the same diagnosis of ventricular fibrillation by the device; however, they represent different circumstances, namely a) a true ventricular tachycardia, b) oversensing of 50 Hz signal, and c) oversensing of the T-wave. Analysis of the EGM allows the confirmation or rejection of the diagnosis made by the device and adapts the subsequent follow-up.

Quick View - Nov 16, 2012

To: Service Télécardiologie

BIOTRONIK
excellence for life

Name:	DOB: Feb 28, 1973	Lumax 340 VR-T (XL)	Last message: Nov 17, 2012
Patient ID:	Phone:	ICD implanted Jan 15, 2010	Last clinic follow-up: Jul 30, 2012

Device status	
Status	OK
Battery status	MOL1 81% (EOS, ERI, MOL2, MOL3, BOL)
Battery voltage	2.94 V (Nov 16, 2012)
Charge time	1.1 s for 40 J (Nov 16, 2012 2:25:34 PM)

Findings
VF detected
Episode details received

Tachy settings	Zone limit	1st ATP	2nd ATP	1st shock	2nd shock	3rd - nth sho.
VT1	OFF	---	---	---	---	---
VT2	OFF	---	---	---	---	---
VF	290 ms	Burst		40 J	40 J	6 * 40 J

Brady settings	
Mode	VVI
Basic rate	30 bpm

Brady lead	RV lead
Pacing impedance [ohm]	593
Pacing threshold [V]	---
Sensing ampl. mean / min [mV]	5.0 / 4.3
Programmed [V@ms]	2.8 @ 0.5

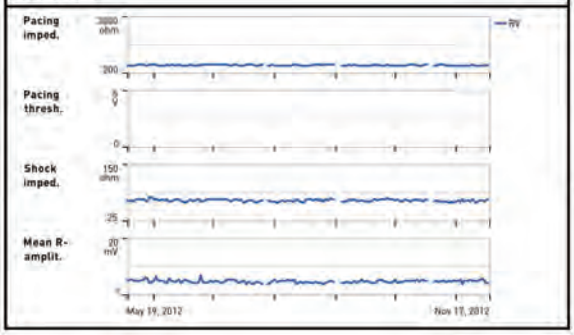
Shock lead	
Daily shock lead imp. [ohm]	72
Last delivered shock imp. [ohm]	69 (7/26/12)

Ven. arrhythmias since Jul 31, 2012	VT1	VT2	VF
Episodes	0	0	1
ATP started / succ.	0 / 0		0 / 0
Shocks started / aborted / succ.	1 / 1 / 0		
Last episode: VF (Nov 16, 2012 2:25:33 PM)			

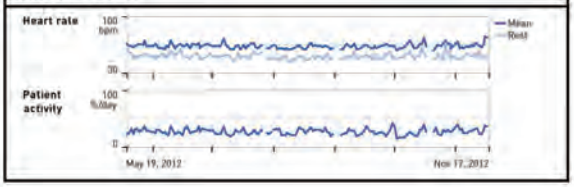
Event episodes since Jul 31, 2012	
Pacing	
Vp	0%

Atrial arrhythmias since Jul 31, 2012	
SVT episodes	0

Lead trends



Long term trends



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Signature:

1/4

Status report - Nov 16, 2012

To: Service Télécardiologie

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Name:	DOB: Feb 28, 1973	Lumax 340 VR-T (XL)	Last message: Nov 17, 2012
Patient ID:	Phone:	ICD implanted Jan 15, 2010	Last clinic follow-up: Jul 30, 2012

Device settings no. 10 (Jul 30, 2012 3:24:08 PM)

Device settings - Overview:

General			
Last follow-up	Jul 30, 2012 3:24:08 PM	Device settings no.	10

Tachy						
	Zone limit [ms]	1st ATP	2nd ATP	1st shock [J]	2nd shock [J]	3rd - nth shock
VT1	OFF	---	---	---	---	---
VT2	OFF	---	---	---	---	---
VF	290	Burst		40	40	6 * 40 J
				Progressive course of therapy		---

Brady			
Mode	VVI		RV
Basic rate [bpm]	30	Pulse amplitude [V]	2.8
		Pulse width [ms]	0.5

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Status report - Nov 16, 2012

To: Service Télécardiologie

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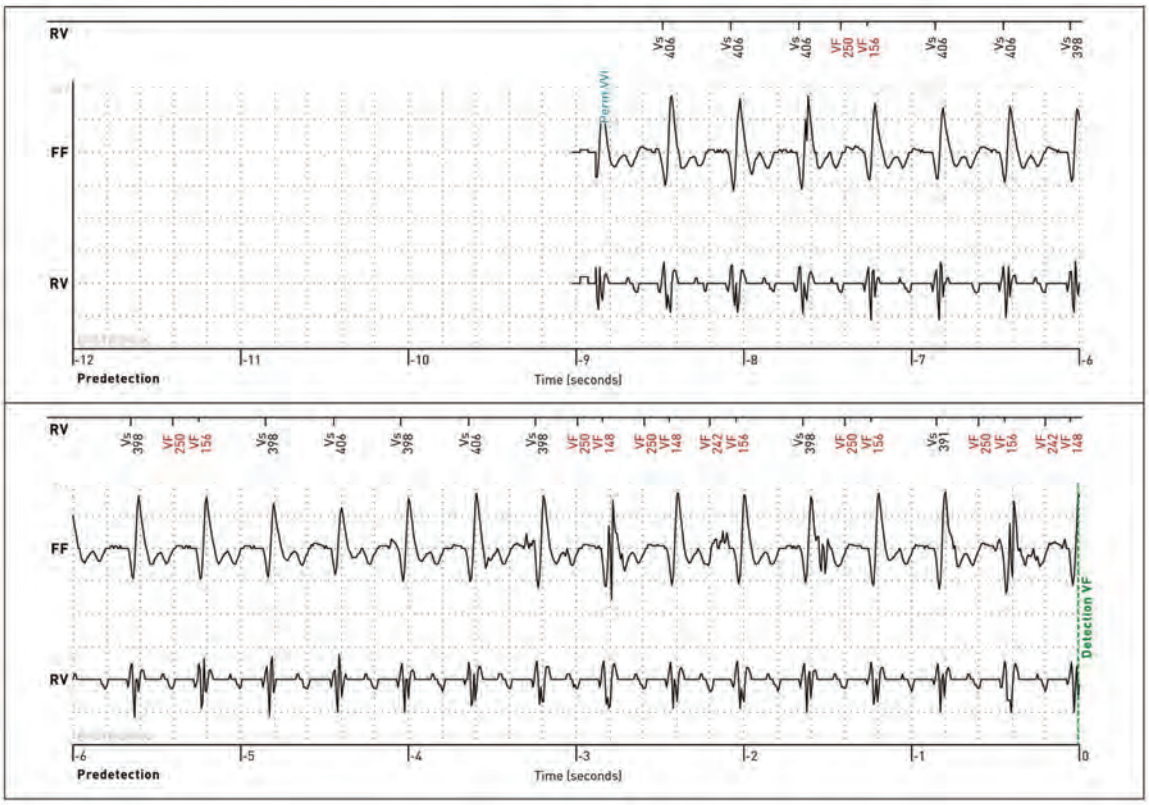
Name:	DOB: Feb 28, 1973	Lumax 340 VR-T (XL)	Last message: Nov 17, 2012
Patient ID:	Phone:	ICD implanted Jan 15, 2010	Last clinic follow-up: Jul 30, 2012

Recordings

Recordings - Episode 23:

General	
Episode number	23
Episode type	VF
Detection	Nov 16, 2012 2:25:33 PM
Termination	Nov 16, 2012 2:25:41 PM
Duration	8s
Device settings no.	10
Detection	
Mean RR at initial detection [ms]	198
Onset [%]	58
Stability [ms]	97
Redetection	---

Therapy	
ATP in VT/VF delivered	0
ATP One Shot delivered	NO
Shocks delivered	0
Shocks aborted	1
Maximum energy [J]	40
Termination	
Mean RR at termination [ms]	410
Remark	
none	



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Date:

Signature:

3/4

Status report - Nov 16, 2012

To: Service TélécØrdiologie

BIOTRONIK
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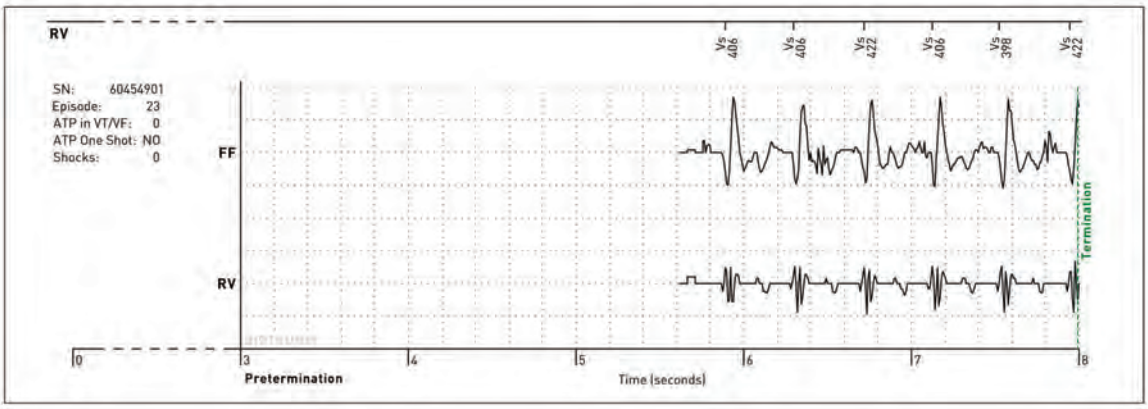
Name:	DOB: Feb 28, 1973	Lumax 340 VR-T (XL)	Last message: Nov 17, 2012
Patient ID:	Phone:	ICD implanted Jan 15, 2010	Last clinic follow-up: Jul 30, 2012



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Chapter 4

Functioning

Signals analysis and sensing

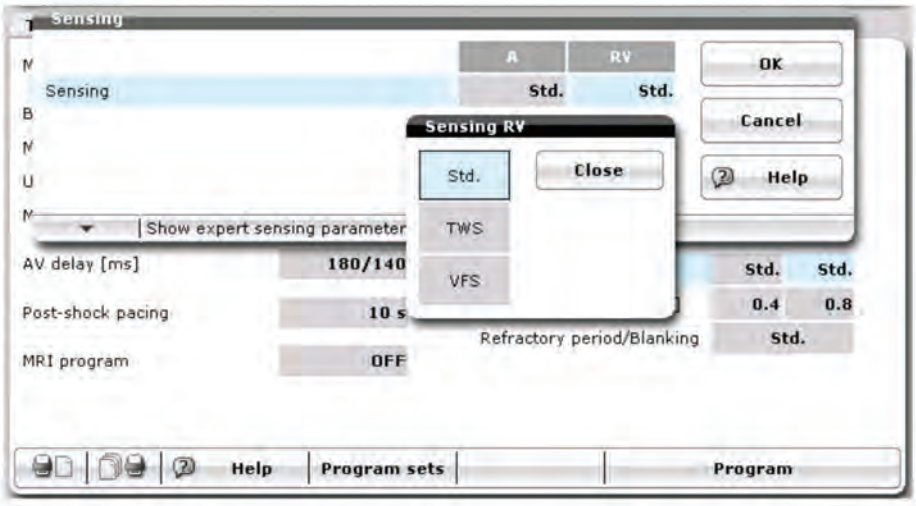
Introduction

A properly functioning defibrillator is capable of sensing rapid, low-amplitude signals, during ventricular fibrillation (VF), without sensing the T wave or extracardiac signals during sinus rhythm. This implies the programming of a high sensitivity and short refractory periods. The sensing threshold, instead of being set at a fixed value as in a cardiac pacemaker, is automatically adapted as a function of the preceding R wave's amplitude. The detection circuit is blind during the blanking period, which is programmed at a short value to prevent multiple detection of the same depolarization, while maintaining the ability of detecting very fast tachycardia. At the end of the blanking period, the adaptation of the sensitivity begins at a percentage of the sensed R wave's amplitude, before gradually decreasing to the lowest programmed value. Each manufacturer has chosen specific values of a) baseline sensitivity from the time the R wave was sensed, and b) the rate of rise of the sensitivity during the cycle. The nominal minimum sensing is 0.8 mV, and the blanking period (absolute post-ventricular sensing ventricular refractory period) is 110 ms in the latest defibrillators and 80 ms in the earlier models. These values allow a proper detection of VF in the majority of patients when the R wave amplitude during sinus rhythm is >5 mV. The programmed refractory period and minimum sensitivity can be validated during the induction of VF, enabling its flawless detection, while avoiding oversensing of the T wave or any other extracardiac signal.

SelectSense function

A choice of 3 settings is available to control the sensing function and analysis of the right ventricular EGM:

1) standard programming (Std)
2) enhanced T wave suppression (TWS)
3) enhanced VF sensitivity (VFS)

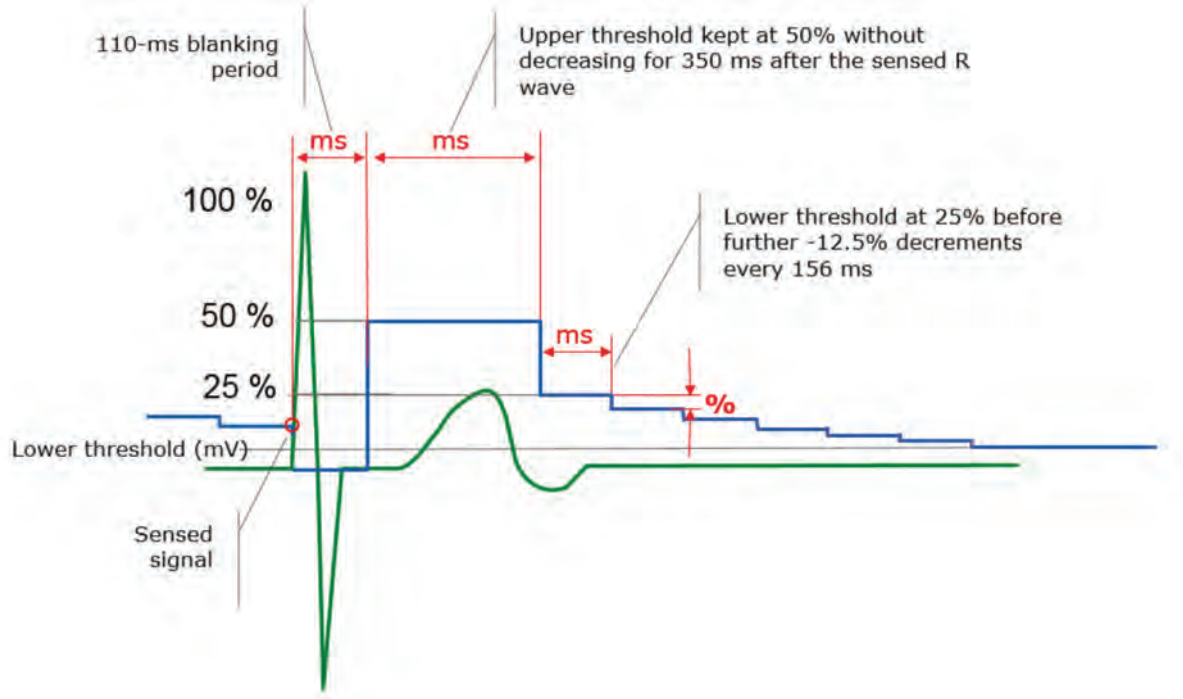


Programming of the sensing mode

In Biotronik defibrillators older than the Lumax 740, the bandwidth ranged between 24 and 60 Hz. Since the 740 model, the bandwidth has been widened to between 24 and 100 Hz.

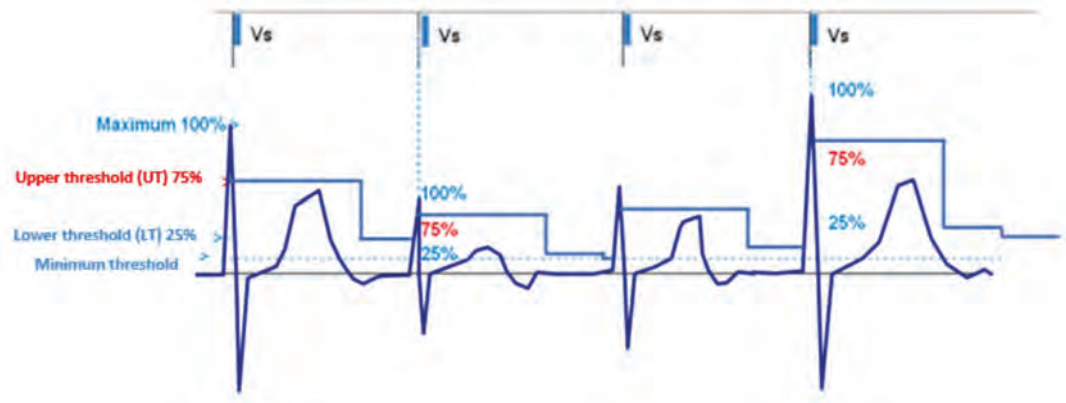
Standard programming

The analysis of a ventricular EGM includes a positive and a negative component. Biotronik defibrillators measure the amplitude of the highest positive or negative peak. The onset of an R wave is followed by a 110-ms blanking period, after which ventricular sensing begins for amplitudes >50% of the sensed R wave (upper threshold at 50%). This threshold persists for 350 ms (360 ms for defibrillators older than the 740 model) after sensing of the R wave (240 ms after the end of the blanking period). Thereafter, the sensitivity increases to a 25% threshold (25% lower threshold) for a 156-ms duration. In the Lumax 740 defibrillators, the sensitivity increases regularly throughout the cardiac cycle in further decremental steps of -12.5% every 156 ms until it reaches either the nominal sensitivity of 0.8 mV, or a value programmable between 0.5 and 2.5 mV. In older models, the steps were 0.125 mV every 156 ms.



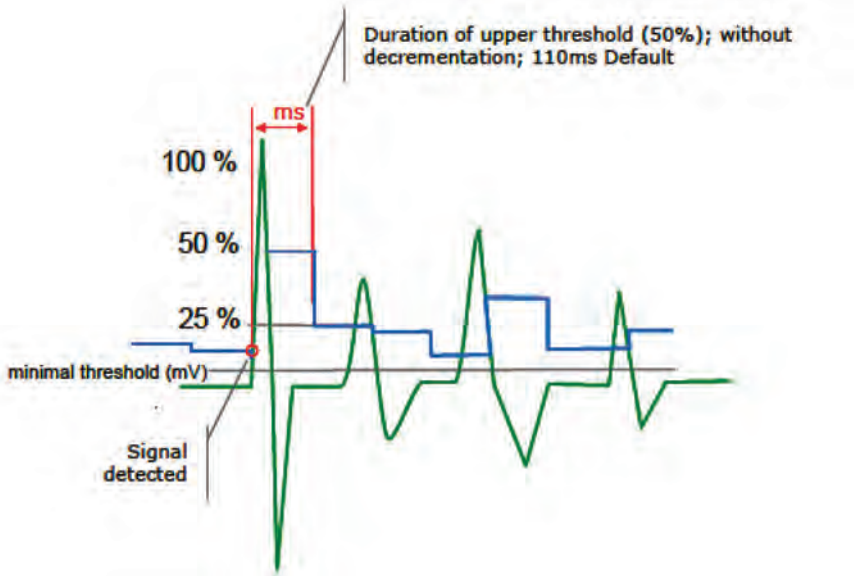
Enhanced T wave suppression

This programming, designed to prevent T wave oversensing by decreasing the defibrillator's sensitivity in the beginning of the cardiac cycle, modifies 2 settings: 1) the upper threshold is increased to 75% of the R wave amplitude (instead of 50% in the case of standard programming) for a 350-ms period, while the lower threshold is at 25%; 2) the filters are modified to prevent the amplification and sensing of the T wave: the high-pass filter is increased to 32 Hz (24 Hz in the case of standard programming). This programming is discouraged when the quality of sensing is low or medium.



Programming of enhanced VF sensitivity

This programming sensitizes the defibrillator to prevent undersensing of the R wave. This is achieved by maintaining the upper threshold at 50% of the R wave amplitude for 110 ms. In older device models, the blanking period lasted 80 ms, such that the the upper threshold was maintained at 50% for 30 ms, while the lower threshold was at 25% of the R wave amplitude. In the newer models, sensing begins directly at 25% of the R wave, at the end of the 110 ms blanking period. The high-pass filter is also increased to 32 Hz to prevent oversensing of the T wave. This setting should not be used if the T wave is oversensed.



Supplemental settings

Some settings can be programmed independently and individually to optimize the quality of ventricular sensing. However, the access to these settings is protected by a code known only by the employees of Biotronik Inc.

Sensing

	A	RV
Sensing	Std.	Std.
Thresholds		
Upper threshold [%]	50	50
Upper threshold duration after sens. [ms]		350
Upper threshold duration after pacing [ms]		400
Lower threshold RV [%]		25
Post pace T-wave suppression		OFF
Post pace T-wave suppression sensitivity [mV]		
Blanking		
after atrial pace [ms]	140	50
after RV pace [ms]		120
PVC		
Discrimination after As [ms]		350
Extended		
Initial noise interval [ms]		110
Filter		
High pass RV [Hz]		24

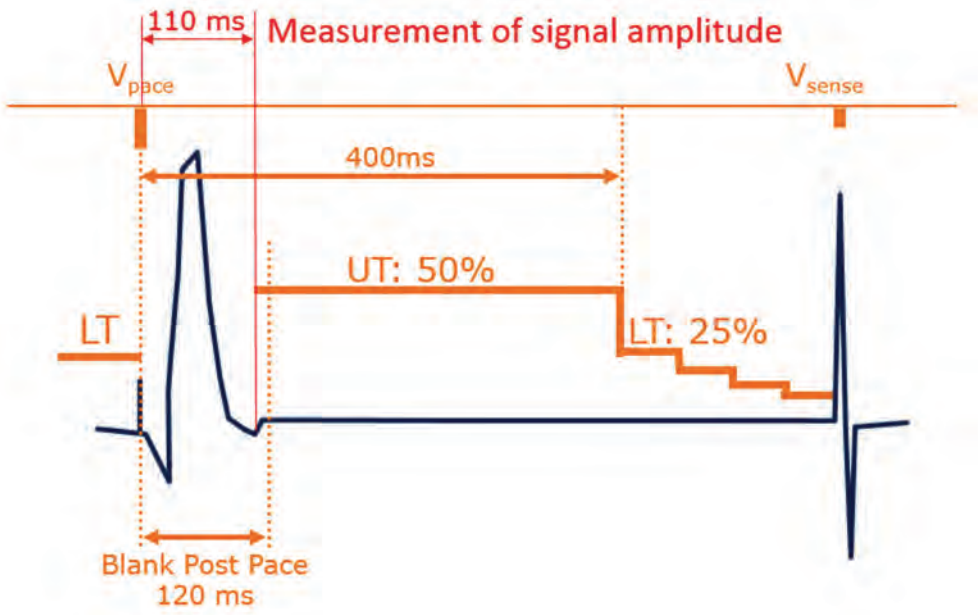
OK | Cancel | Help

Hide expert sensing parameters

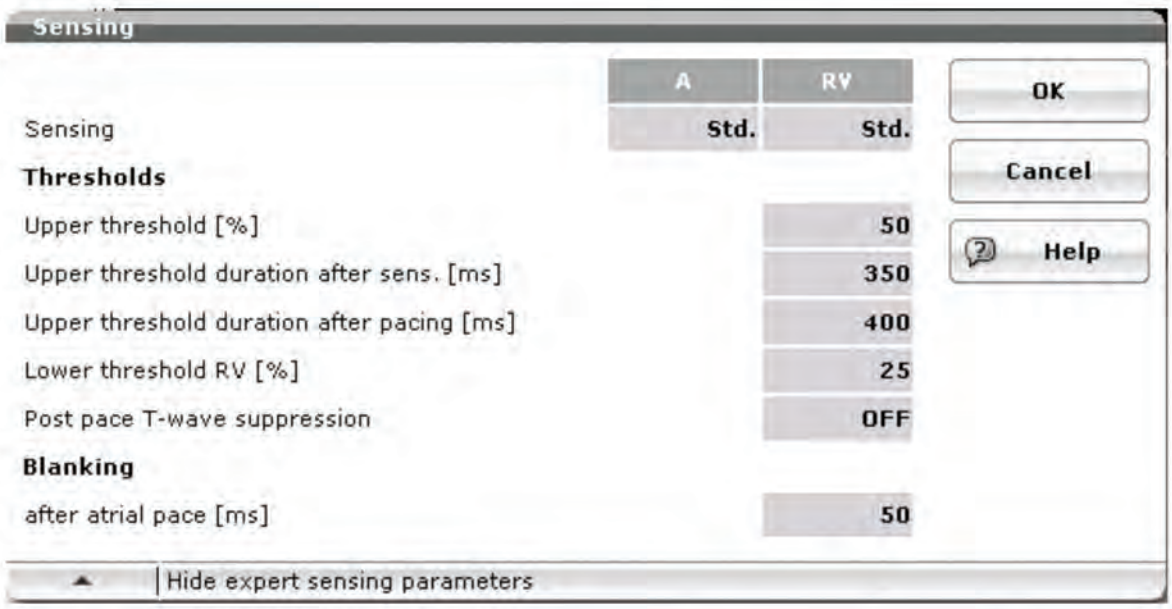
Settings that can be programmed to optimize sensing

Standard sensing after ventricular pacing

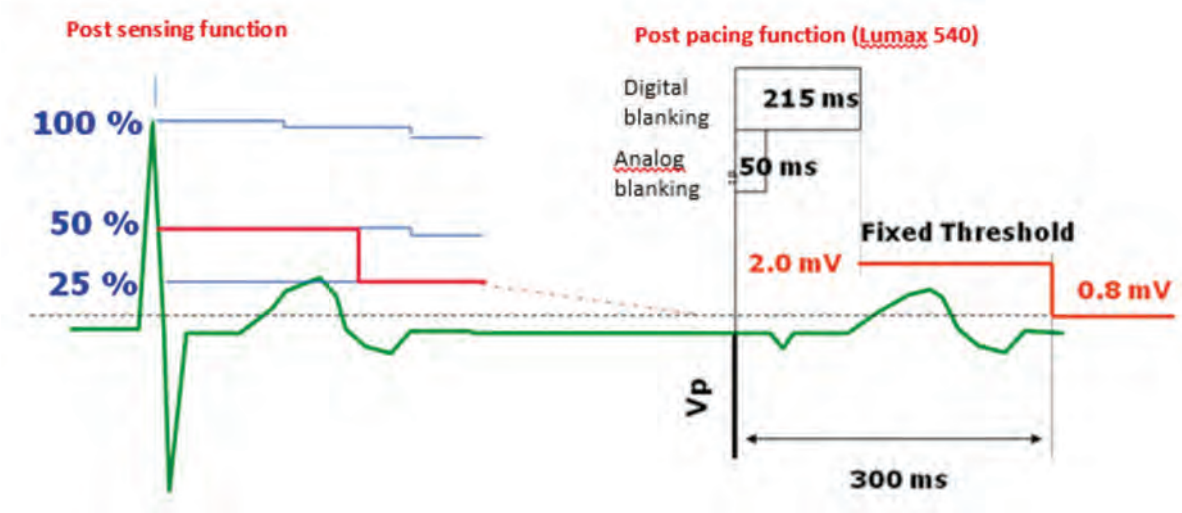
In defibrillators older than the Lumax 740, a 50-ms analog blanking period begins after ventricular pacing during which no signal is sensed or visualized and a 215-ms digital blanking period during which the signal is not sensed though is visualized. Sensing begins at 2 mV for 85 ms after the end of blanking, then decreases to the programmed value of 0.8 mV. Starting with the Lumax 740 generation, a 19.5 ms analog blanking period begins after ventricular pacing and a digital blanking period of 120 ms. The upper threshold, which corresponds to a value equal to 50% of the post-pacing evoked response, is maintained for 400 ms. Then the sensitivity increases as the threshold falls to 25% (25% lower threshold) for 156 ms. The sensitivity then increases gradually throughout the cardiac cycle, with an additional -12.5% decrement every 156 ms, until the programmed sensitivity is reached.



Post-paced T wave suppression



This option was introduced with the Lumax 540 model. A 2-mV sensitivity is maintained for a 300-ms period after ventricular pacing, while in the Lumax 740 model, the sensitivity is set by default at 3 mV and maintained for a 400-ms period after ventricular pacing. These settings can be changed by unlocking a code.



Programming of the sensing and therapy zones

The setting of the defibrillator's zones of heart rates that prompt the various therapeutic responses is a key-programming step. State-of-the-art defibrillators enable the programming of several zones of arrhythmias detected on the basis of the sensed RR intervals. Each zone can be specifically programmed with respect to discrimination and therapies delivered. The number of zones and the range of heart rates that are programmed must be adapted to the characteristics, history and implant indications of each patient.

In the case of secondary prevention, in presence of heart failure, the programming of the heart rate zones is adapted to the cycle length of the VT that has prompted the device implant. The lower limit of the VT zone is usually programmed 20 bpm below the clinical VT, since the introduction of, or an increase in antiarrhythmic drug therapy after the implant may change the rate of the tachycardia.

In the case of primary prevention

In presence of heart failure, the risk of developing VT after device implant must be considered and probably justifies the programming of 2 zones of detection and treatment. The main rationale for the programming of 2 separate zones is the ability to treat very rapid tachycardias, specifically favoring painless antitachycardia pacing (ATP) over the delivery of electrical shocks, which represents a significant improvement in quality of life. These results justify the systematic programming of a sequence of ATP as initial therapy in the zone of fast VT.

In a patient in complete atrioventricular block

The risk of inappropriate therapy for a supraventricular tachycardia with conduction over the atrioventricular node is inexistent, allowing the setting of relatively slow heart rates prompting interventions by the device, without detriment to the specificity. The discrimination algorithms are unnecessary, as all spontaneous tachycardias are ventricular in origin.

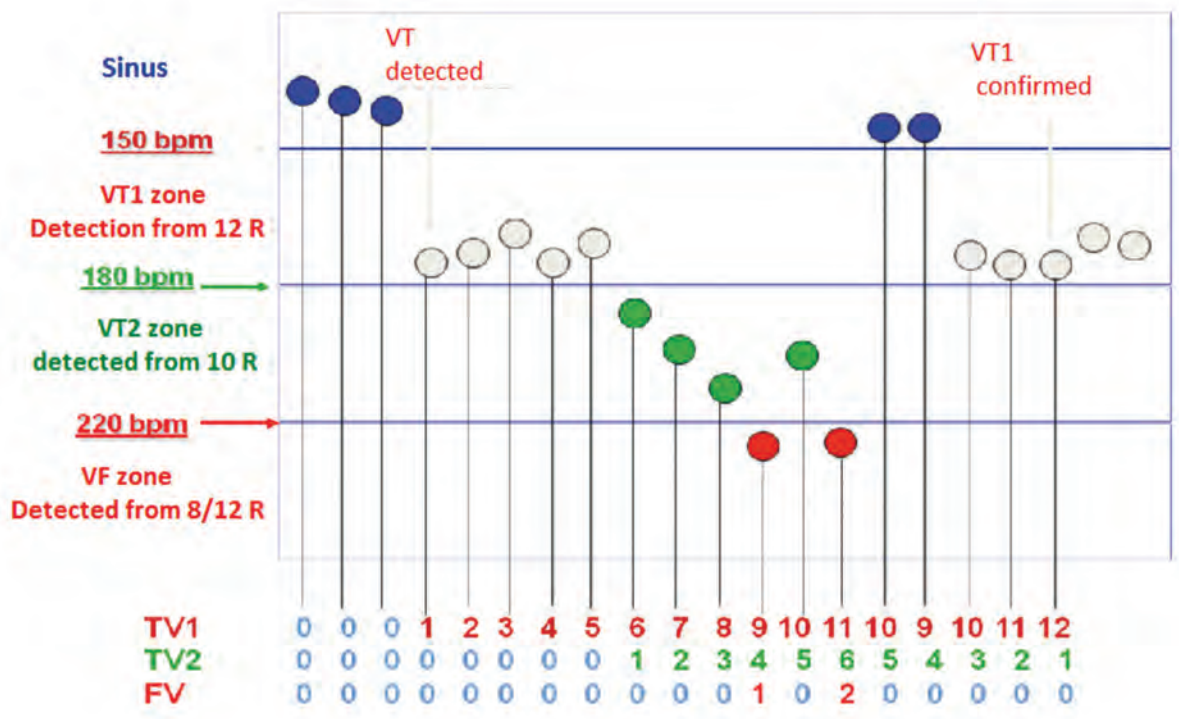
In a young and active patient

The risk of inappropriate therapy for a normal acceleration of the heart rate, or for atrial fibrillation with rapid atrioventricular conduction must be taken in consideration when several treatment zones are being programmed, minimizing overlaps of heart rates prompting defibrillator interventions and physiologic heart rates.

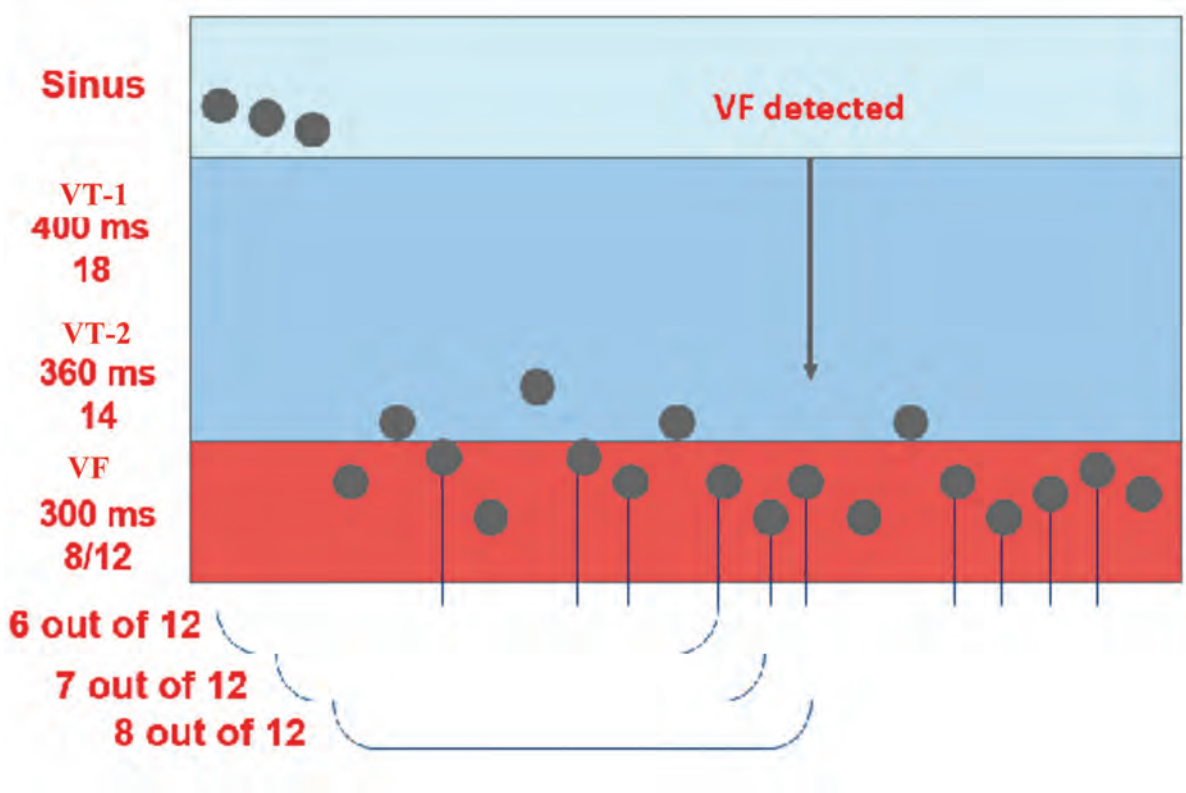
In a patient presenting with Brugada syndrome
Stable VT is extremely rare, whereas the risk of atrial fibrillation is increased. Consequently, the programming of a zone of detection and treatment of VT besides a VF zone is probably unnecessary and perhaps risky. The programming of an additional zone of monitoring only allows the recording of possible slower tachyarrhythmias and an adaptation of the setting. A single VF zone is usually programmed with a relatively rapid lower limit (> 210 bpm).

Count of the cycles and detection zones

The various ventricular events are classified as a function of the RR cycles during ventricular pacing, sinus rhythm, VT1, VT2 or VF. The lower limit of each zone is programmable, and the several zones are continuous. Each cycle in a tachycardia or VF zone increases the count by 1 in that zone, and the detection of a cycle in a fast zone increments by 1 the counter in a slower tachycardia zone. A cycle in the sinus zone decrements all prior counters by 1. When the counter has reached the number of required cycles (26 in the VT1 and 16 in the VT2 zone by default, 8 out 12 cycles in a sliding window in the VF zone), the diagnosis is made and the associated therapy is delivered.



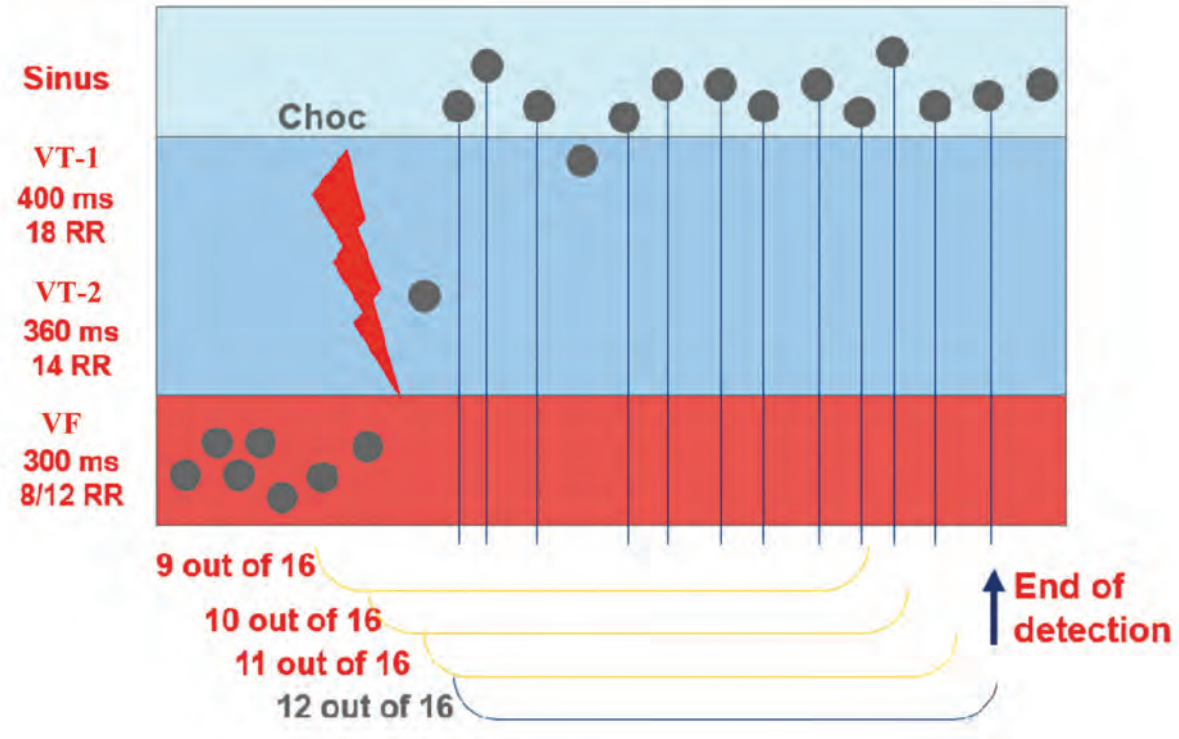
In this example, the counter of VT1 is filled first. A cycle in the sinus zone decrements by 1 the VT1 counter. A cycle in the VT2 or in the VF zone increments the VT1 counter by 1.



Redetection and end of detection

Redetection of VF **Applies the same criteria as for the initial detection**
Redetection of VT **Utilises the same heart rate zone than for the initial detection, though the cycle counter is different** **No inhibitory criterion for single chamber devices**
End of detection **End of episode validated when 12/16 cycles are slower than the slowest programmed VT zone** **This counter is non-programmable**

The phase of redetection begins when a therapy has been delivered. The programmed counts in the VT1 and VT2 zones must be lower than those applied in the initial detection in order to not delay the delivery of a new therapy when the first was unsuccessful (20 cycles for the VT1 and 14 cycles for the VT2 zone by default). The same X/Y cycles ratio is applied in the VF zone for the initial detection and the redetection.



Example of redetection after delivery of a shock the VF zone; 12 of 16 cycles are in the sinus zone: end of episode.

Discrimination

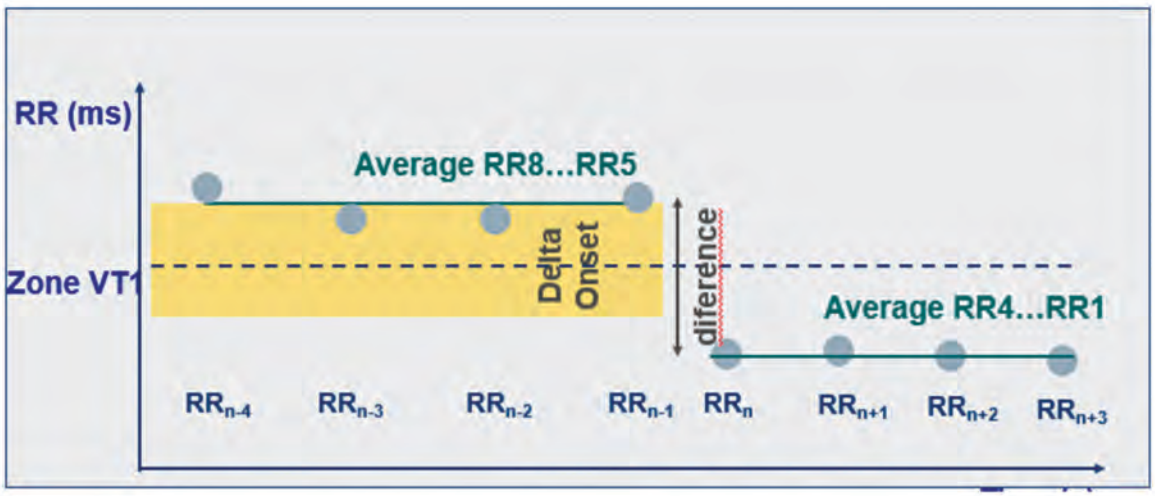
As described earlier, the initial detection is based on rate and duration criteria. While heart rate is indispensable, it is insufficient to distinguish ventricular from supraventricular tachyarrhythmias. The application of this criterion in isolation is associated with a 100% sensitivity and a 60% specificity. A more reliable detection depends on discrimination, which is the ability of defibrillators to determine supraventricular versus ventricular origin of an episode of tachycardia, using characteristics like stability of the RR intervals, mode of onset, association atrium to ventricle, and others, programmed alone or in combination. The discrimination algorithms are only applied in the VT zones, where the detection of an episode must be confirmed by VT/SVT discriminators before the delivery of a programmed therapy. In the VF zone, the safety criteria prevail, and the detection of a high ventricular rate in the zone "VF detected" by the defibrillator triggers the programmed therapies, without scrutiny of the episode by an algorithm of discrimination. These algorithms must be activated only in patients at risk of developing a supraventricular tachycardia conducted to the ventricles and, therefore, must be deactivated in patients presenting with complete and permanent atrioventricular block. If all discrimination criteria are deactivated, the therapy is delivered regardless of the origin of the tachycardia. The design of discrimination algorithms differs between a simple chamber (absence of atrial signal) and a dual chamber defibrillator, and among models. The addition of an atrial lead offers a supplemental and precious detection tool, allowing a continual comparison of the atrial and ventricular cycles. In nominal programming, the detection of an episode, whether supraventricular or ventricular, triggers the memorization of EGM, signals recorded by the leads accessible upon interrogation of the defibrillator, which allow a critical analysis of its diagnosis and, perhaps, its reprogramming in case a tachycardia was misclassified.

Single chamber discrimination

The discrimination by single chamber Biotronik devices is based on an analysis of the arrhythmia onset and the stability of the rhythm. The diagnosis of VT is based on observation of a sudden onset and a stable rhythm.

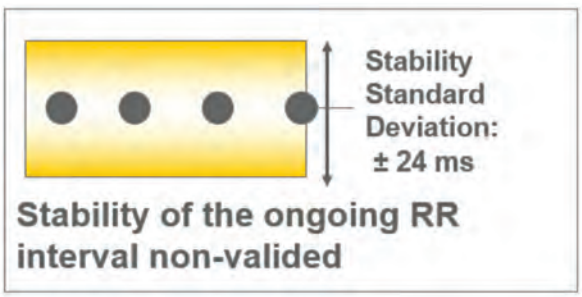
Sudden onset

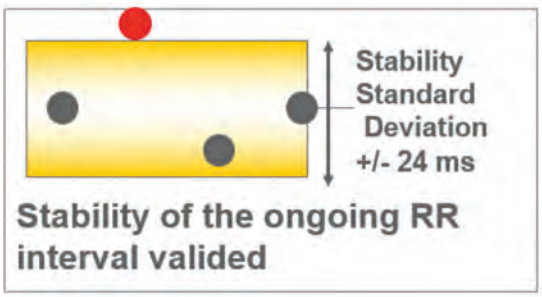
The sudden onset criterion theoretically allows the discrimination of sinus (gradual onset) from ventricular tachycardia. It does not allow, however, the discrimination of atrial fibrillation or flutter from VT. The average of the last 4 RR intervals is compared with the average of the next 4 RR intervals. The calculation is made on 8 sliding cycles, and the criterion is fulfilled when the difference between the 2 averages is greater than the programmed "sudden onset", which, by default, is set at 20%. When the sudden onset criterion is verified, it remains valid for all episodes, including for redetections.



Stability

The stability criterion allows theoretically the discrimination of atrial fibrillation (usually irregular) from VT (usually regular). However, it does not discriminate sinus tachycardia, from atrial tachycardia or flutter, from VT. The stability criterion is fulfilled (the rhythm is considered stable) when, for a ventricular cycle, the difference between the RR interval and one of 3 previous RR intervals is shorter than the programmed value. The default setting is 24 ms. The programming of the stability criterion in the VT1 and VT2 zones can be different. The stability criterion is applied during the detection and redetection phases.





Dual chamber discrimination

The SMART algorithm applies several criteria to discriminate VT from SVT, including the atrial and ventricular rates, the atrial and ventricular rate stability, the multiplicity, i.e. the n:1 A and V ratio and the presence or absence of sudden onset of the arrhythmia. Depending on the analysis of these criteria, the arrhythmia is classified as VT or SVT. For each interval corresponding to a VT zone, the discrimination algorithm undergoes a series of analyses to conclude to a diagnosis of VT versus SVT. An interval classified as VT is labeled VT1 or VT2 depending on the zone of rate in which it belongs. An interval classified SVT is labeled "AFib" for atrial fibrillation, "AFlut" for atrial flutter, SinT for sinus tachycardia, or 1:1 for atrial tachycardia. VT and SVT counters are competing for the final episode classification. The detection criteria for SVT is twice the VT zone count but SVT intervals decrement the VT counters. Note that VF intervals "freeze" the VT counters.

Average RR and PP intervals

The SMART algorithm uses sliding windows of 4 cycles in the atrium and in the ventricle to compare these 2 rhythms, which determines whether the ventricular rhythm is faster, identical or slower than the atrial rhythm. For each new interval, the average is recalculated by eliminating the first of the 4 previous cycles. This analysis is key because, if the ventricular rhythm is found to be faster than the atrial rhythm, the device diagnoses VT without further discrimination.

Criterion of RR and PP stability

While stability is independently determined and programmed in the atrium and the ventricle, the default is 12%. An interval is considered stable when the difference between this and the 3 previous intervals is not longer than the programmed value (12% of the mean interval in a 4 cycles window).

Sudden onset criterion

The function is the same as that described for single chamber defibrillators, with a default value = 20%.

Multiple of the PP / RR rate (ratio n/1)

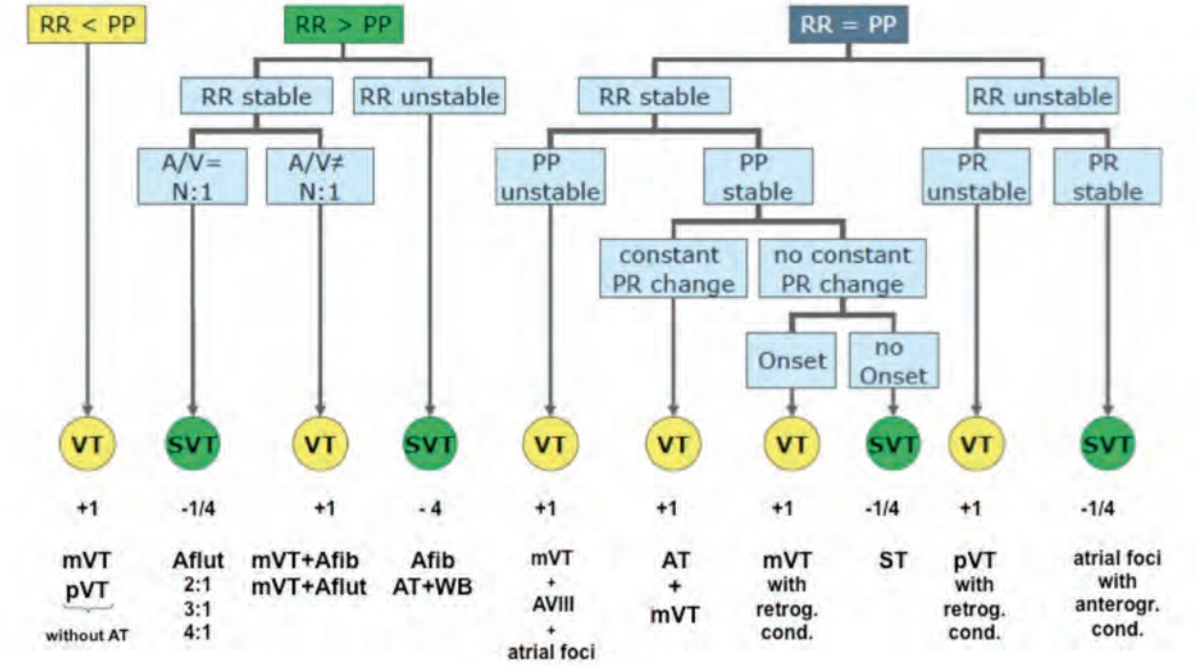
To determine whether atrial flutter with n:1 conduction is present, the defibrillator looks for an n:1 ratio between atrial and ventricular rhythm. A multiplicity (n:1 ratio) is present when the average atrial rate is a multiple of the average ventricular rate (with a 12-ms tolerance).

Criterion of regularity of the PR interval

A PR interval is classified regular if the difference between its duration (PR1) and the duration of the 3 previous PR intervals (PR2, PR3 and PR4) is not greater than the programmed value (6% by default, corresponding to half the stability value).

Trend in PR interval

When the atrial and ventricular rates are stable and equal, SMART ® Detection determines whether an AV trend exists. With each new ventricular interval, the algorithm checks to see whether the four most recently measured AV intervals are in strict increasing or decreasing order (i.e., AV n < AV n-1< AV n-2 < AV n-3 or AV n > AV n-1> AV n-2 > AV n-3). This strict order defines AV creep or AV trend indicative of AV dissociation.



Smart algorithm

Branch 1: RR<PP

The easiest case of AV discrimination: diagnosis of VT based on a comparison of rates, the ventricular rate being faster than the atrial rate.

Branch 2-3: discrimination between Atrial Flutter and VT

Differentiation between dual tachycardia (VT+flutter) and conducted atrial flutter is difficult for an algorithm that does not include a morphology criterion. For both, RR intervals > PP intervals and RR intervals are stable. The device analyzes the relationship between atrial and ventricular signals. If there is a N:1 relationship (2:1, 3:1 or 4:1 with a 12 ms tolerance), the ventricular interval is classified as an atrial flutter beat and labeled with an AFlut marker. This interval will decrement the VT counter by -1. If the multiplicity cannot be established, a VT with concurrent atrial tachycardia or atrial fibrillation is identified. Each beat will be marked with a VT marker

Branch 4: discrimination of Atrial Fibrillation

The algorithm identifies irregular conduction and declares atrial fibrillation when the atrial rate is greater than the ventricular rate and the ventricular intervals are unstable. Each ventricular interval is marked with an AFib marker. An event declared as Atrial Fibrillation will decrease the VT counter by (-4).

Branch 5: VT with an unstable atrial arrhythmia

The algorithm identifies six different classification pathways when the atrial and ventricular rates are considered equal.

When the algorithm identifies equal atrial and ventricular rates, the algorithm tests stability in both chambers. If the ventricle is stable and the atrium is unstable, the algorithm concludes that the rhythms are disassociated (stable VT with unstable atrial arrhythmia).

Branch 6-7-8: discrimination between dual tachycardia, VT with retrograde conduction and sinus tachycardia

When atrial and ventricular rhythms are stable and similar in rate, several different rhythms may exist. If an AV trend exists, (i.e., successive AV intervals are present in strict increasing or decreasing length), the atrial and ventricular rhythms are close in rate, but can be considered independent. The small but

consistent difference between the atrial and ventricular rate causes the AV interval to gradually shrink or expand over time: diagnosis of dual tachycardia (branch 6).
When atrial and ventricular rates are similar and stable with no AV trend, the algorithm uses Onset to differentiate VT with 1:1 retrograde conduction (branch 7) from sinus tachycardia (branch 8). Intervals classified as Sinus Tachycardia are labeled with a SinusT marker and will decrease the VT counter by (1/4).

Branch 9: polymorphic VT with Retrograde Conduction
The algorithm identifies polymorphic VT with retrograde conduction when atrial and ventricular rates are equal, both chambers are unstable, and the AV interval is irregular.

Branch 10: multifocal atrial tachycardia with anterograde conduction
If the ventricular and atrial rhythms are unstable, while the average atrial and ventricular rates are equal and if the AV intervals are regular suggesting a direct AV association between the atrial and ventricular rhythms, the algorithm identifies an atrial tachycardia with 1:1 anterograde conduction. Each beat is labeled with a 1:1 marker and will decrease the VT counter by (1/4).

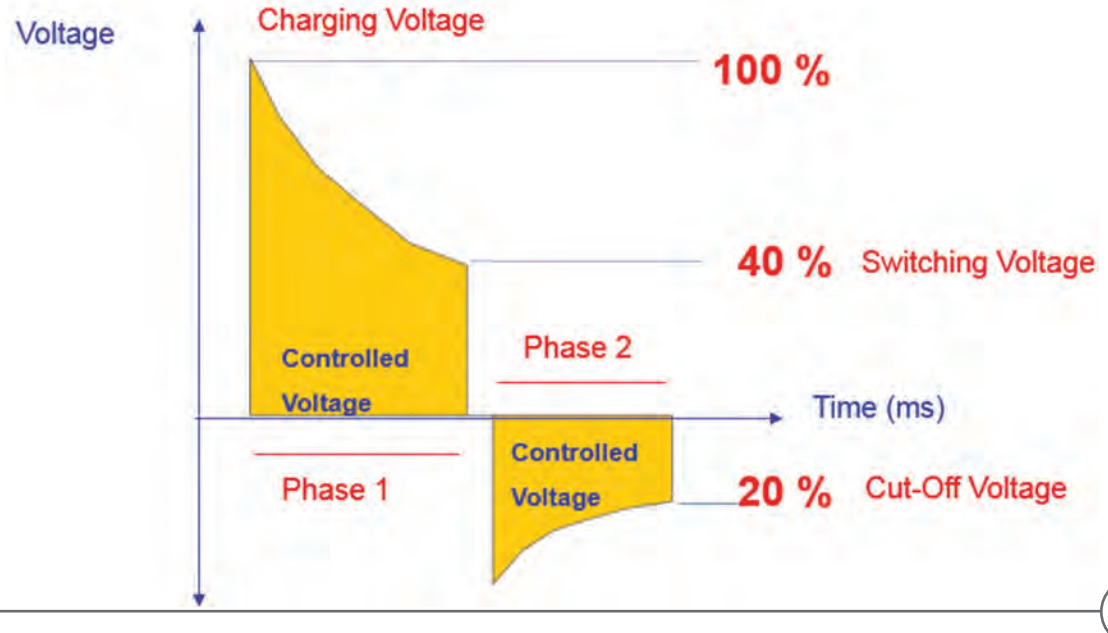
Therapies

Electrical shocks

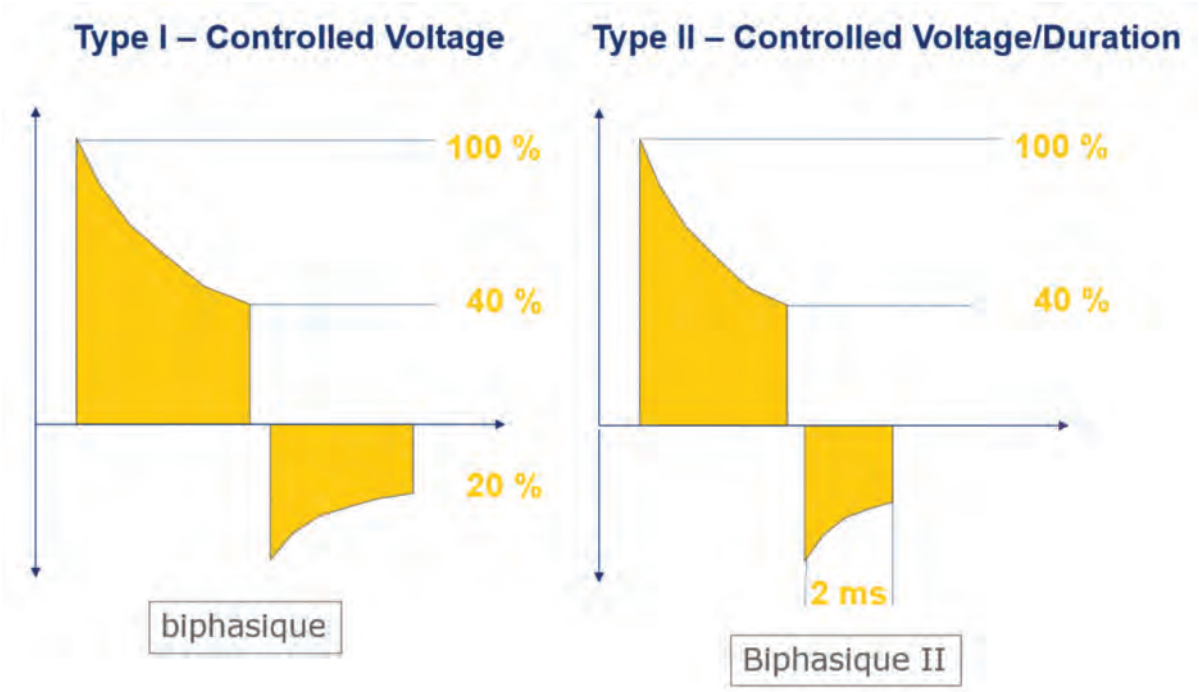
Defibrillators were historically developed to terminate life-threatening ventricular arrhythmias with an electrical shock. Several shock wave characteristics, such as the vector, the amplitude and the number delivered can be programmed.

Shock wave configuration

The initially monophasic waveforms became biphasic in more recent defibrillators, which lowered the defibrillation threshold. The first phase of a biphasic shock is equivalent to that of a monophasic shock with a lesser critical mass; the second phase returns the membrane potential to as near to zero as possible to prevent the re-induction of VT tachycardia or VF. For a voltage-controlled shock, the charged voltage is 100%, tilt of the first phase is 40% meaning that 60% of the initial voltage is delivered during the first phase (fixed tilt at 60). The cut-off voltage of the second phase is 20%, meaning that 50% of the remaining voltage (40%/2) is delivered during the second phase (tilt at 50). This is a 60/50 fixed-tilt, voltage-controlled biphasic shock. The delivered voltage is constant, and the duration of each phase varies depending on the shock impedance, i.e. increasing as the impedance increases.

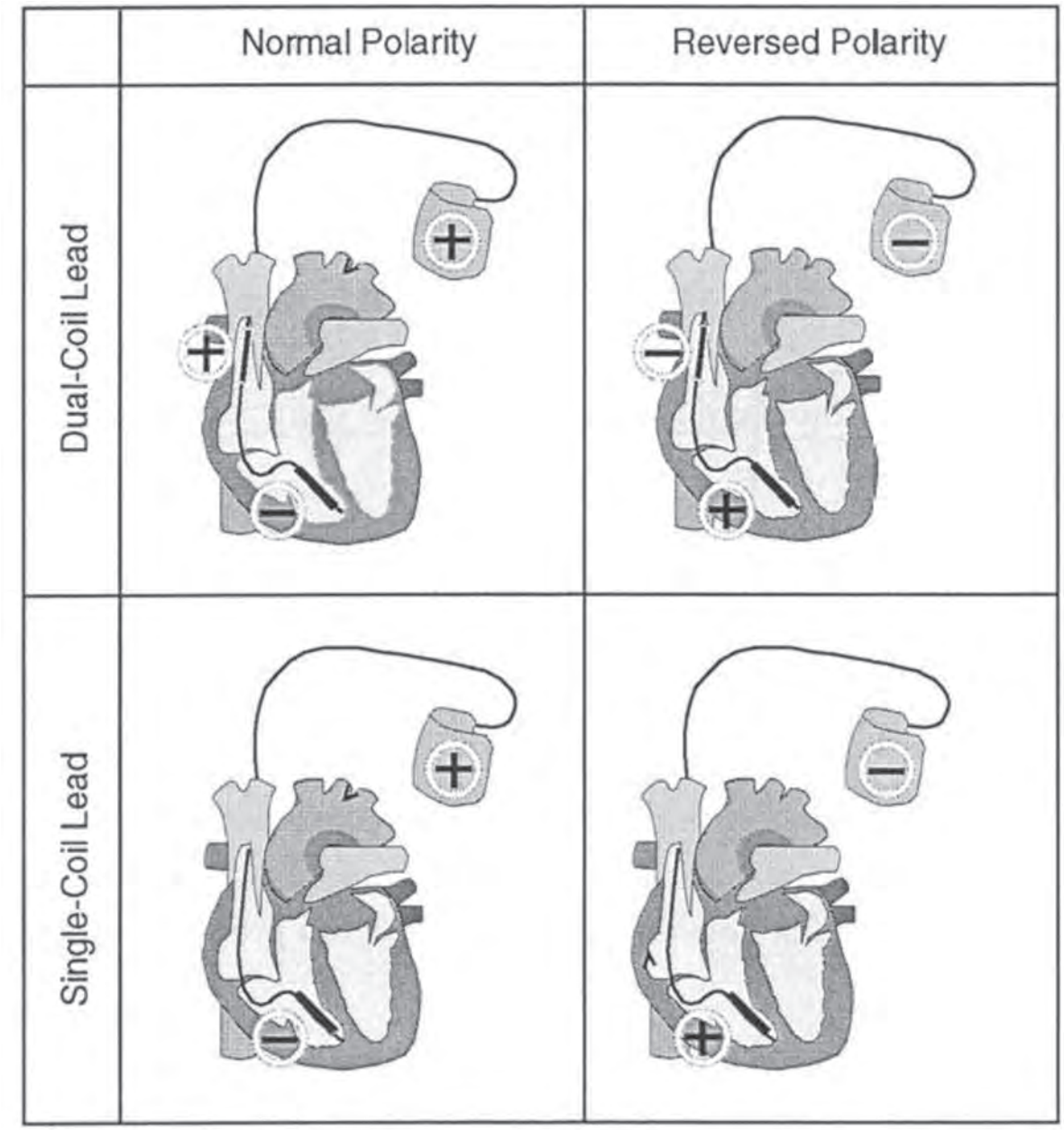


A second shock wave can be programmed (biphasic II, voltage/controlled pulse duration). The voltage load is 100% and the tilt of the first phase is 40%. The cut-off of the second phase occurs after a fixed, 2-ms pulse duration. This can be programmed in patients whose defibrillation threshold is high, particularly when treated with amiodarone, which increases the threshold.



Polarity and shock vector

Most state-of-the-art defibrillators enable the programming of the polarity and shock vector. These choices can be useful in case of high defibrillation threshold, and offer the highest likelihood of effective shock delivery. The shock polarity can be set on normal, reversed or alternating. With a single coil lead, a normal polarity for Biotronik defibrillators means that the shock is delivered between the can, as the anode, and the right ventricular coil as the cathode. With a reversal of polarity, the right ventricular coil becomes the anode, which inverses the 2 phases of a biphasic shock (negative first phase and positive second phase). With a dual coil lead and a normal polarity, the shock is delivered between the can and the distal, right ventricular apical coil and between the proximal shock coil in the superior vena cava and the distal right ventricular apical coil. With a reversed polarity, the current direction is opposite. When the polarity is set on alternating, the first shocks' polarity is normal, then alternates between normal and reversed after the delivery of a first shock of maximum energy.



Shocks energy: the energy of first shock delivered in the various zones is programmable between 2 J and maximum, while the energy of the second shock is programmable between 4 J and maximum; the energy of the second shock must be greater than that of the first. The following shocks are delivered at the highest energy. In the VF zone, the energy of the first and next shocks is usually programmed at the highest capacity of the device. The setting of the defibrillation shocks amplitude can be guided by the defibrillation threshold, defined as the lowest energy that converts VF to sinus rhythm. In the VT zone, the first shock amplitude can be programmed empirically between 5 and 10 J, which spares the battery and shortens the charge of the capacitors, or at high amplitude to increase the likelihood of arrhythmia termination.

Number of shocks

In the VF zone, the number of consecutive shocks is programmable, up to a maximum of 8, limiting the risk of an endless series of inappropriate shocks. While the amplitude of the first 2 shocks is programmable, the next 6 shocks are delivered at the maximum energy of 40 J.

Shock confirmation

If a) the shock confirmation is programmed ON, and b) the defibrillator detects 3 cycles in the sinus or bradycardia zones out of 4 cycles during the charge of the capacitors, the charge is interrupted and a phase of redetection/termination of episode begins. In absence of detection of 3 slow cycles out of 4, the charge goes on uninterrupted and, at the end of the charge, the device delivers a shock 30 ms after a short cycle. That short cycle at the end of the charge is indispensable. If, at the end of the charge, 3 long cycles are detected, the charge is abandoned and the capacitors loose progressively their charge over a period of up to 10 minutes. During that period, if another episode is detected, the charge is shorter, using the residual energy already charged up. After a shock has been delivered, the next shock undergoes confirmation (uncommitted). However, after a charge has been interrupted, the next shock does not undergo confirmation (committed). Therefore, two consecutive charges cannot be interrupted, which might be problematic in case of VF undersensing. If the shock confirmation is OFF, an on-going charge cannot be interrupted. At the end of the charge, an attempt is made by the device to synchronize the shock; however in absence of a detectable R wave, a non-synchronized shock is delivered 2 sec after the end of the charge. At the end of the charge, a 50 ms ventricular blanking period prevents the occurrence of any detection.

Post-shock pacing

A 1-sec blanking period without detection or pacing follows the delivery of all shocks. After that blanking period, post-shock pacing begins for a duration that is programmable between OFF and 10 min, with a default of 10 sec. Post-shock pacing is in DDI for the DDD(R), DDI(R), or AAI(R) modes, in VVI for the VVI(R) mode, and in VDI for the VDD(R) or VDI(R) modes.

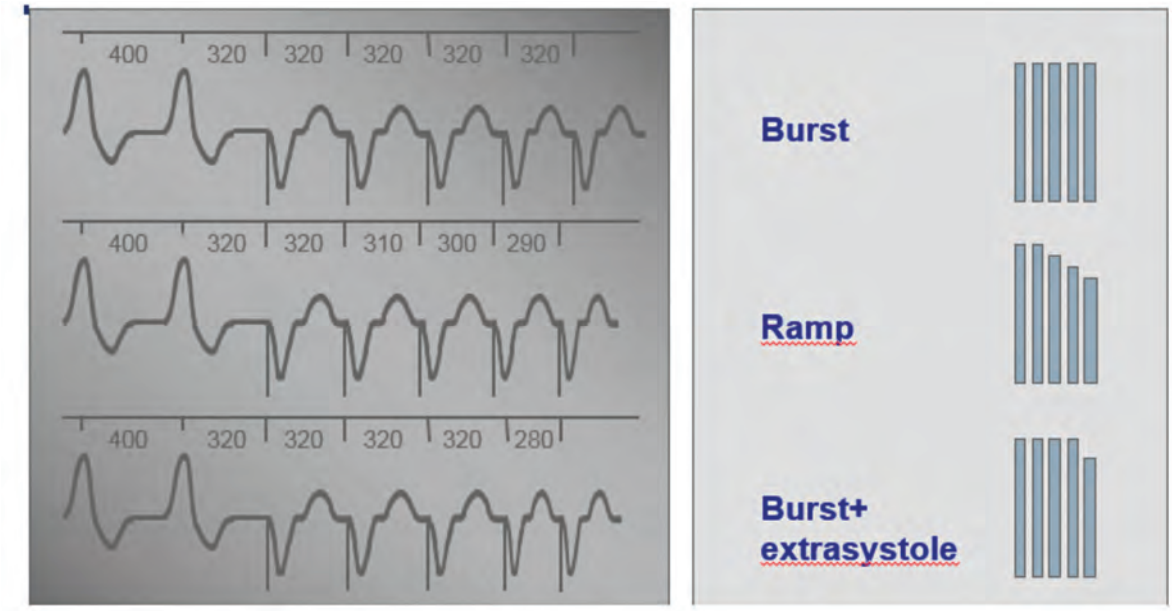
Antitachycardia pacing

A priority of device programming is to limit the delivery of electrical shock therapy without compromising the patient's safety. The least aggressive and painful method should be adopted to terminate the tachyarrhythmias. The principle behind ATP is to capture and interrupt an organised VT by penetrating its circuit propagating through the ventricles. Therefore, the ventricle must be paced at a rate faster than that of the tachycardia. ATP is painless and, by lowering energy consumption, spares the pulse generator's batteries. It must, therefore, be favored as a first choice for the treatment of organized, even very rapid ventricular rhythms. The efficacy of this type of therapy has been confirmed for a wide range of VT, from slow to as fast as 240 bpm. Consequently, the defibrillators manufactured by Biotronik Inc. enable the programming of a salvo of ATP in the fast VT zone, as well as in the VF zone before the charge of the capacitors. Durant a sequence of ATP, the pacing mode is VOO with 7.5-V/1.5-ms pulse amplitude.

The efficacy of ATP can be optimized by the programming of various settings:

ATP schemes: burst, ramp or burst + extrasystole

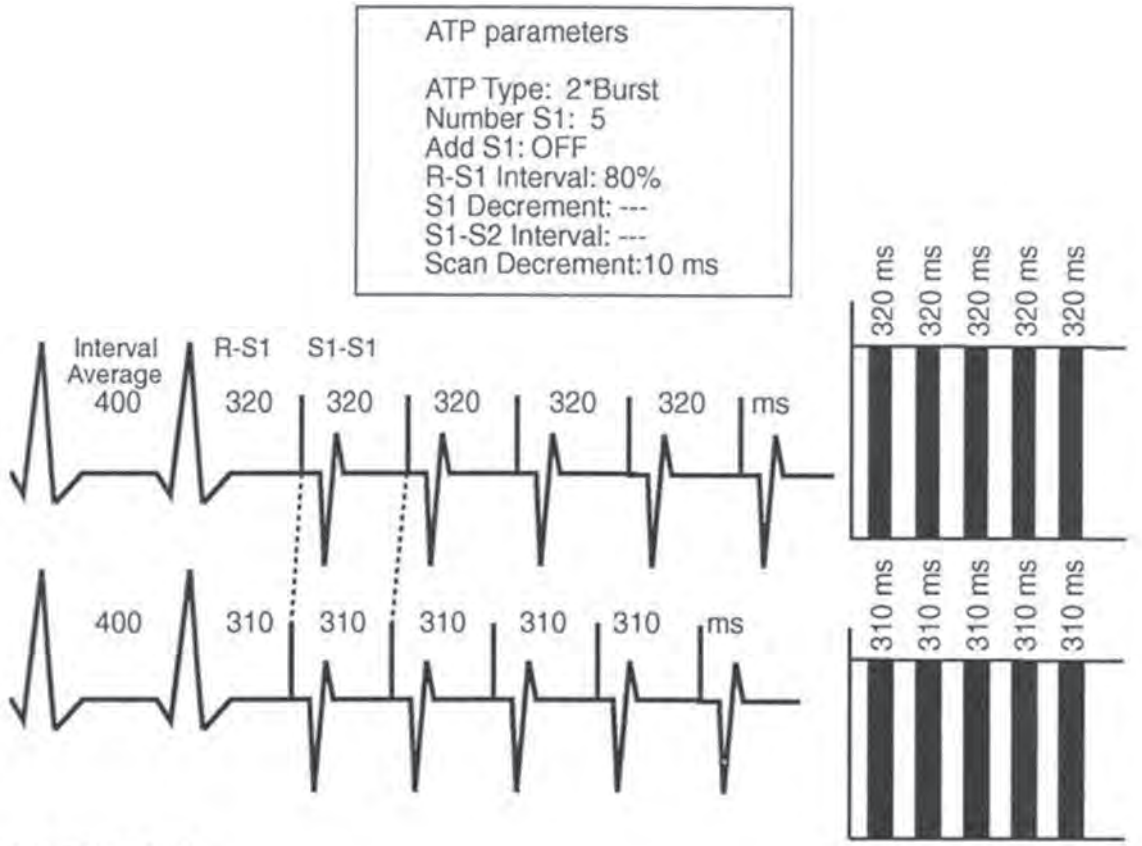
In a burst, the number of pulses in each sequence is fixed, or a cycle may be added to each sequence, though the duration of the cycles within the sequence remains constant. The pacing rate, however, might change from one sequence to the next if the rate of the tachycardia changes. In a ramp, the cycle length decreases from one pulse to the next by a programmable decrement. For example, if the programmed decrement duration is 10 ms, each pacing cycle is shorter than the previous one by 10 ms. In a burst + extrasystole, a premature stimulus is delivered at the end of the burst, an option that is no longer available from the Lumax 740 model onward.



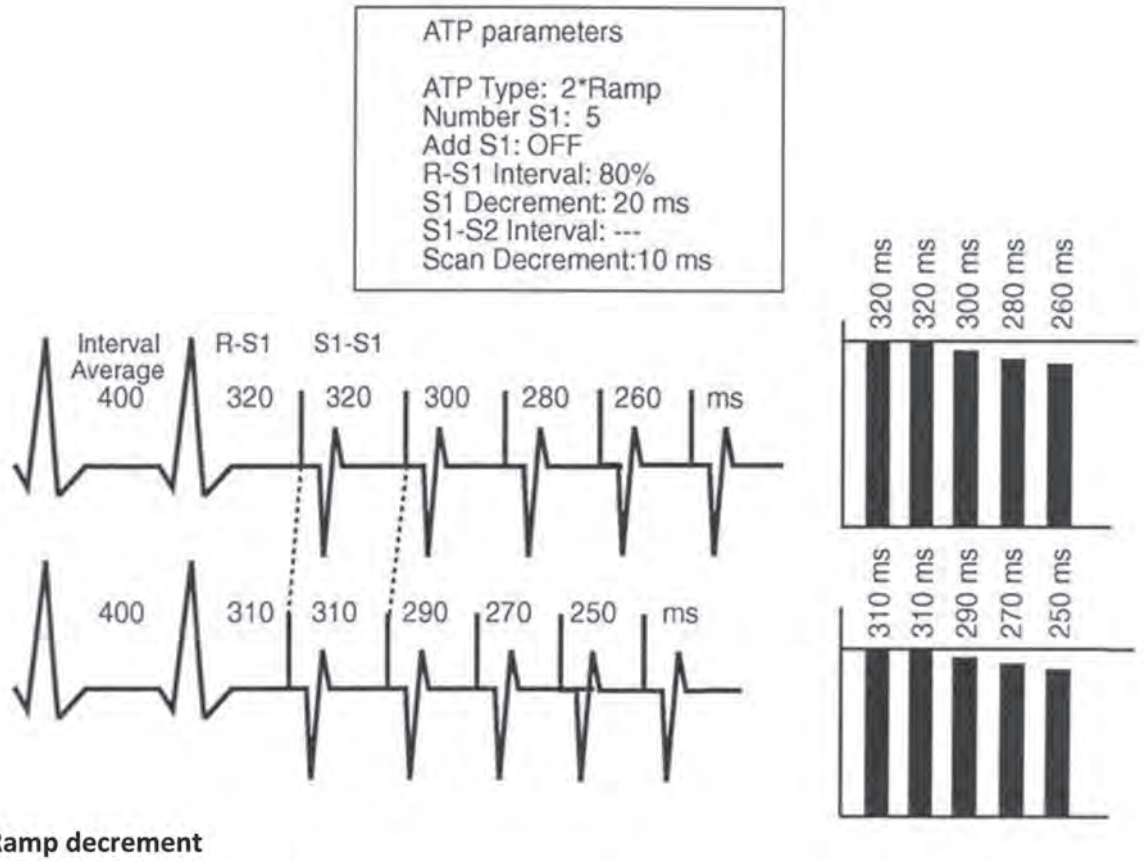
The number of programmed consecutive pulses vary between 5 and 10 per pacing sequence. Between 1 and 10 cycles are programmable for a burst or ramp. An insufficient number of pulses do not penetrate the tachycardia circuit and the salvo is ineffective. Conversely, too many pulses risk of terminate then re-induce the tachycardia. It is possible to add a cycle between each sequence.

The duration of the pacing cycles is expressed as a programmable percentage of the tachycardia cycle length between 70 and 95%, and is usually programmed between 80 and 90% of the detected interval. The shorter that duration, the faster is the pacing rate and the higher is the risk of accelerating the tachycardia. A ramp requires the programming of a 5- to 40-ms increment between each cycle. The device cannot, however, exceed a 300 bpm pacing rate (200 ms cycle length).

The scan decrement: if the rate of the tachycardia remains unchanged, the cycle length of the next pacing sequence decreases by programmed scan decrement.



Burst decrement



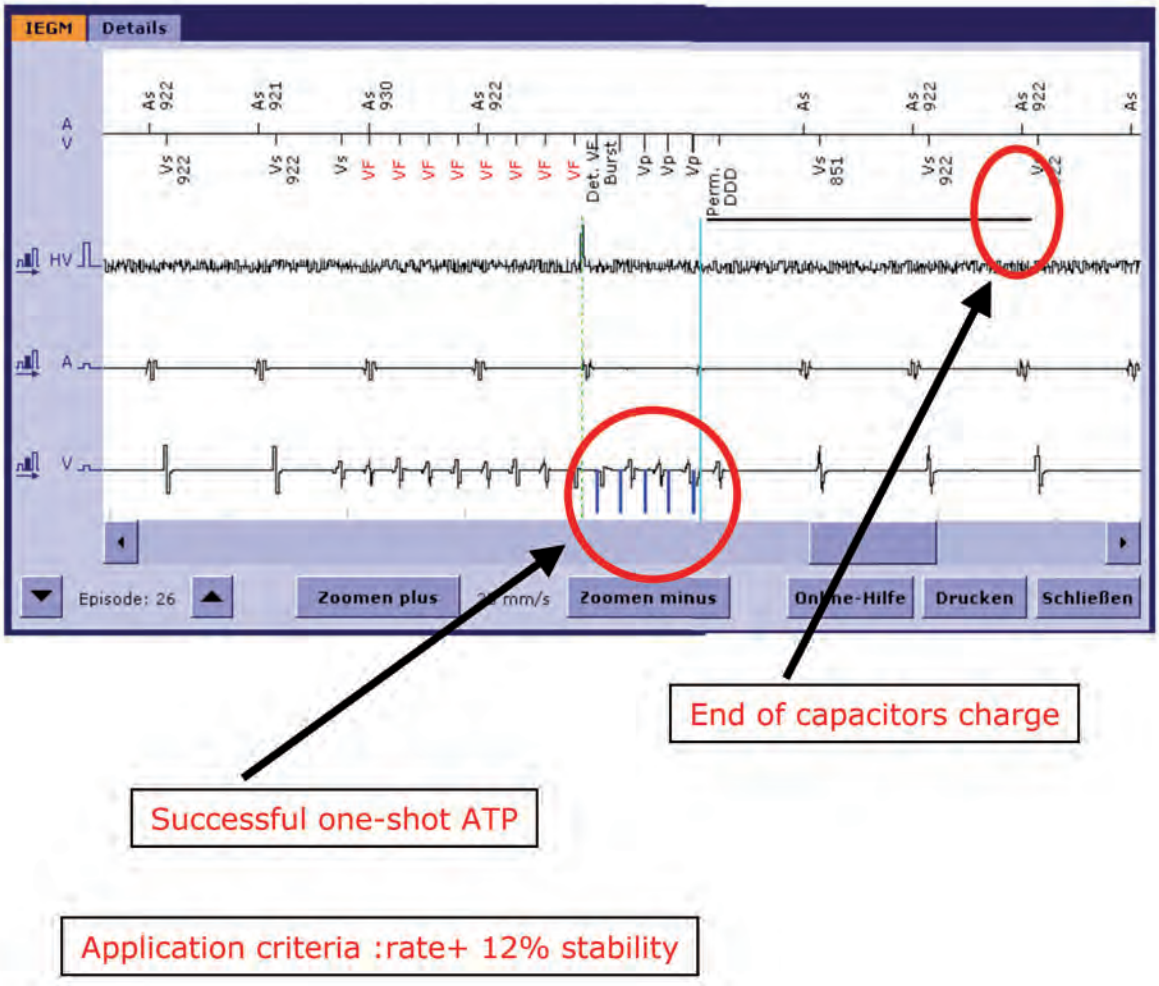
Ramp decrement

The number of pacing sequences varies as a function of the rate of the tachycardia. Between 1 and 10 sequences of the same therapy are programmable. For a slow VT, several sequences can be programmed in order to delay as much as possible the delivery of shocks for tachycardias that do not immediately threaten the patient's survival. One might even, in a slow VT zone, forgo altogether the programming of an electrical shock. For tachycardias between 150 and 200 bpm, 3 to 6 consecutive sequences of ATP are usually programmed, while for faster VT, a single sequence is programmed, to lower the risk of unsuccessful therapy and delayed delivery of shocks for a tachycardia that is hemodynamically unstable and threatens the patient's prognosis.

Pacing configuration: in single or dual chamber mode, pacing is necessarily right ventricular. With a triple chamber device, the pacing mode can be biventricular or right ventricular. While the initial programming is empiric, it must, thereafter, be adapted a) to the various arrhythmias recorded by the device and analyzed during the patient's follow-up, and b) according to the anticipated efficacy (arrhythmia termination) / adverse effect (acceleration of arrhythmia) ratio associated with a given pacing sequence.

Antitachycardia pacing in the VF zone

ATP is capable of terminating fast VT. In the most recent devices, burst can be programmed to be delivered in the VF zone, before the charge of the capacitors. Successful one-shot ATP is a painless and energy saving treatment of VT. The tachycardia, first of all, must be regular (≤12% stability threshold). Once the diagnosis of VF confirmed, the device delivers a burst of ATP (8 stimuli at a cycle length corresponding to 85% of the tachycardia cycle length by default). As soon the burst delivered, the capacitors begin charging. If the burst is successful (3 of 4 cycles in the sinus zone), the charge is interrupted and the tachycardia painlessly terminated, sparing much of the capacitors' load. Otherwise, the charge goes on and a minimally delayed shock is delivered. The kind of ATP, whether burst or ramp, and the various characteristics of a standard sequence (for instance the number of cycles) are programmable. One-shot ATP is automatically de-programmed after 4 consecutive unsuccessful attempts.



Tracing 1: sustained VT treated by a burst

Patient

This 67-year-old man received a Lumax 540 VR-T single chamber defibrillator in the context of ischemic cardiomyopathy with a 20% left ventricular ejection fraction; event report (yellow color) issued in the context of a classified ventricular tachycardia (VT2).

Main programmed settings

- Ventricular fibrillation (VF) zone (280 ms limit), VT2 zone (420 ms limit) and VT1 zone (480 ms limit)
- 12/16 cycles in the VF zone, 24 cycles in the VT2 zone and 26 cycles in the VT1 zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.8 mV
- VF zone: delivery of a single burst of ATP one shot, followed by 8 shocks of maximum strength (40 J); VT2 zone: 4 bursts, followed by 4 ramps, followed by 1 shock at 20 J, followed by 7 shocks of maximum strength; VT1 zone: 4 bursts, followed by 4 ramps; no shock programmed
- Effective discrimination in both VT zones
- Pacing mode: VVI at 30 bpm

Remote tracing

The 3 channels available are: 1) the markers with the time intervals, 2) the shock channel (FF = far field) between the coil of the RV lead and the pulse generator, and 3) the right ventricular (RV) sensing channel.

1: spontaneous rhythm; the label "PermVVI" at the beginning of the tracing indicates that the defibrillator operates in the programmed VVI pacing mode;
2: ventricular extrasystole (VES);
3: sudden onset of tachycardia detected in the VT2 zone, with change in the QRS morphology compared to sinus rhythm; the label "onset" marks the first cycle where the sudden onset criterion was confirmed; the averages of the 4 previous (680 ms) and 4 following (367 ms) cycles explain the sudden onset value (46%) that is posted;
4: classification of VT2 episode after 24 cycles in the VT2 zone without interposed cycle classified VT1 or VS; the average RR at the time of initial detection (413 ms) corresponds to the average of the 4 cycles preceding the diagnosis; the posted stability value (3 ms) is the difference between the longest and the shortest cycles among the last 4 cycles preceding the classification. It is noteworthy that the sample rates of the tracing (128 Hz) versus the defibrillator (512 Hz starting with Lumax 740 model) are different. Consequently, the resolution of the tracing is 8 ms versus 2 ms by the device, explaining the less precise measurements on the tracing than those used by the device, for example in the monitoring of stability. The coupling of the last 4 cycles shown on this tracing is 414 ms, implying a 0-ms stability. The more precise analysis by the device indicates a 3-ms variability among these 4 cycles;
5: the burst of ATP delivered is not visible;
6: termination of the arrhythmia;
7: end of the episode after 12 consecutive cycles classified Vs (12/16 Vs); the average RR at the end of the episode (884 ms) corresponds to the average of the 4 cycles preceding the end of the episode.

Programmer tracing (same episode)

The 3 channels are the same as for the remote tracing;
8: visualization of the burst (10 stimuli at a fixed 80% of the rate of the tachycardia); the label "PermVVI" at the end of the burst indicates that the defibrillator remains in a permanent VVI pacing mode during the episode of tachycardia and after the ATP sequence.

Comments

The EGM transmitted by telemedicine lasts a maximum of 30 sec before the initial classification, followed by a maximum of 10 sec before the classification of the end of the episode. Since the maximum amount of information that can be transmitted is limited, these values may sometimes be smaller. The transmitted EGM correspond to the EGM retrieved by the programmer, with some filtering of the baseline to limit the amount of transmitted information.

The EGM retrieved by the programmer do not last longer than 3 min 30 sec per episode. The EGM recording begins 5 sec before the sudden onset diagnosis or 30 sec before the classification, if the sudden onset criterion is not fulfilled. If the episode is >3.5 min, the recording is interrupted, while the start and end of the episode remain visible.

This tracing is an example of VT terminated by a burst of ATP, the first therapy programmed for the treatment of VT at <200 bpm. This painless therapy, which limits the consumption of energy and preserves the battery longevity, must be favored. In a <200 bpm VT zone, ATP can be programmed in a majority of patients suffering from heart failure and treated for secondary or primary prevention indications, unless it has previously been found ineffective or arrhythmogenic.

Status report - Jan 9, 2012

To: Service Télécardiologie

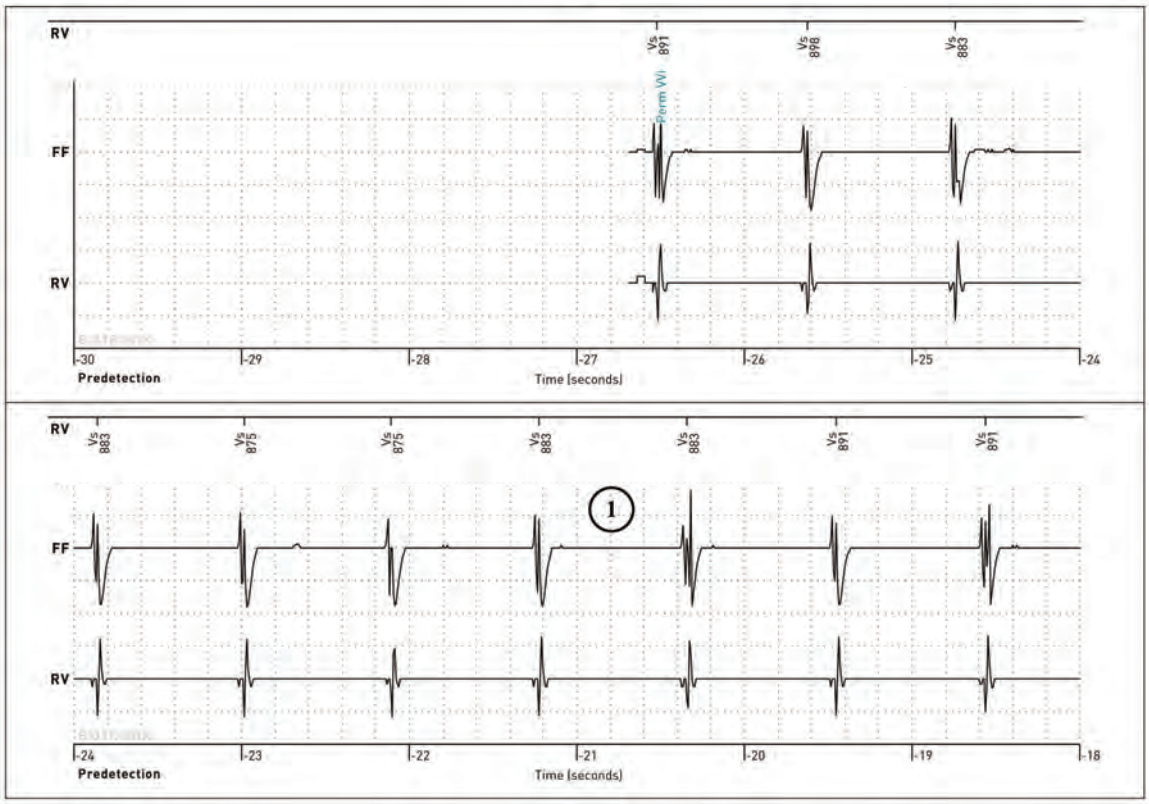
BIOTRONIK
excellence for life

Name:	DOB:	Lumax 540 VR-T	Last message: Jan 9, 2012
Patient ID:	Phone:	ICD implanted Aug 17, 2011	Last clinic follow-up: Oct 6, 2011

Recordings

Recordings - Episode 35:

General		Therapy	
Episode number	35	ATP in VT/VF delivered	1
Episode type	VT2	ATP One Shot delivered	NO
Detection	Jan 9, 2012 1:48:14 PM	Shocks delivered	0
Termination	Jan 9, 2012 1:48:27 PM	Shocks aborted	0
Duration	13s	Maximum energy [J]	---
Device settings no.	7	**Termination**	
Detection		Mean RR at termination [ms]	884
Mean RR at initial detection [ms]	413	**Remark**	
Onset [%]	46, fulfilled	none	
Stability [ms]	3		
Redetection	---		



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1/3

Status report - Jan 9, 2012

To: Service Télécardiologie

BIOTRONIK
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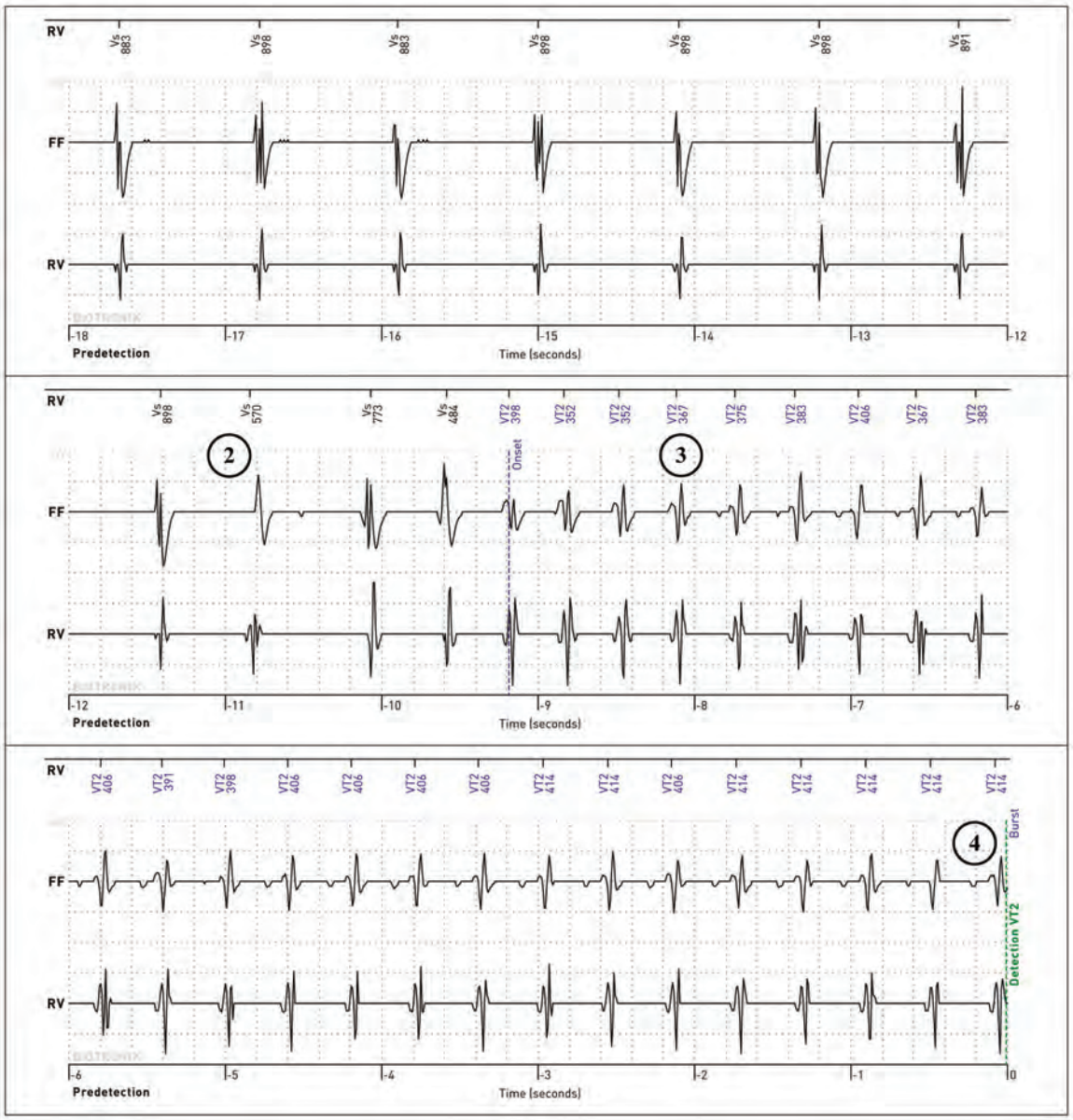
Name:	DOB:	Lumax 540 VR-T	Last message: Jan 9, 2012
Patient ID:	Phone:	ICD implanted Aug 17, 2011	Last clinic follow-up: Oct 6, 2011



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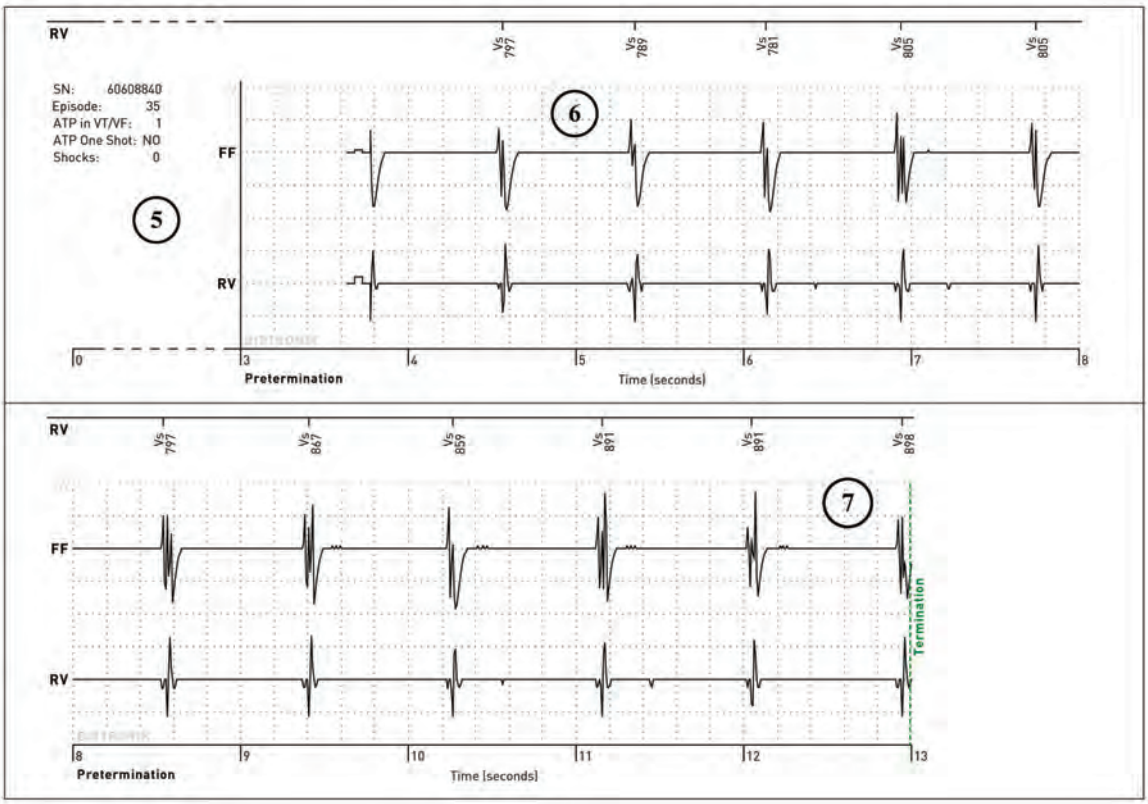
2/3

Status report - Jan 9, 2012

To: Service TéléCardiologie

BIOTRONIK
excellence for life

Name:	DOB:	Lumax 540 VR-T	Last message: Jan 9, 2012
Patient ID:	Phone:	ICD implanted Aug 17, 2011	Last clinic follow-up: Oct 6, 2011



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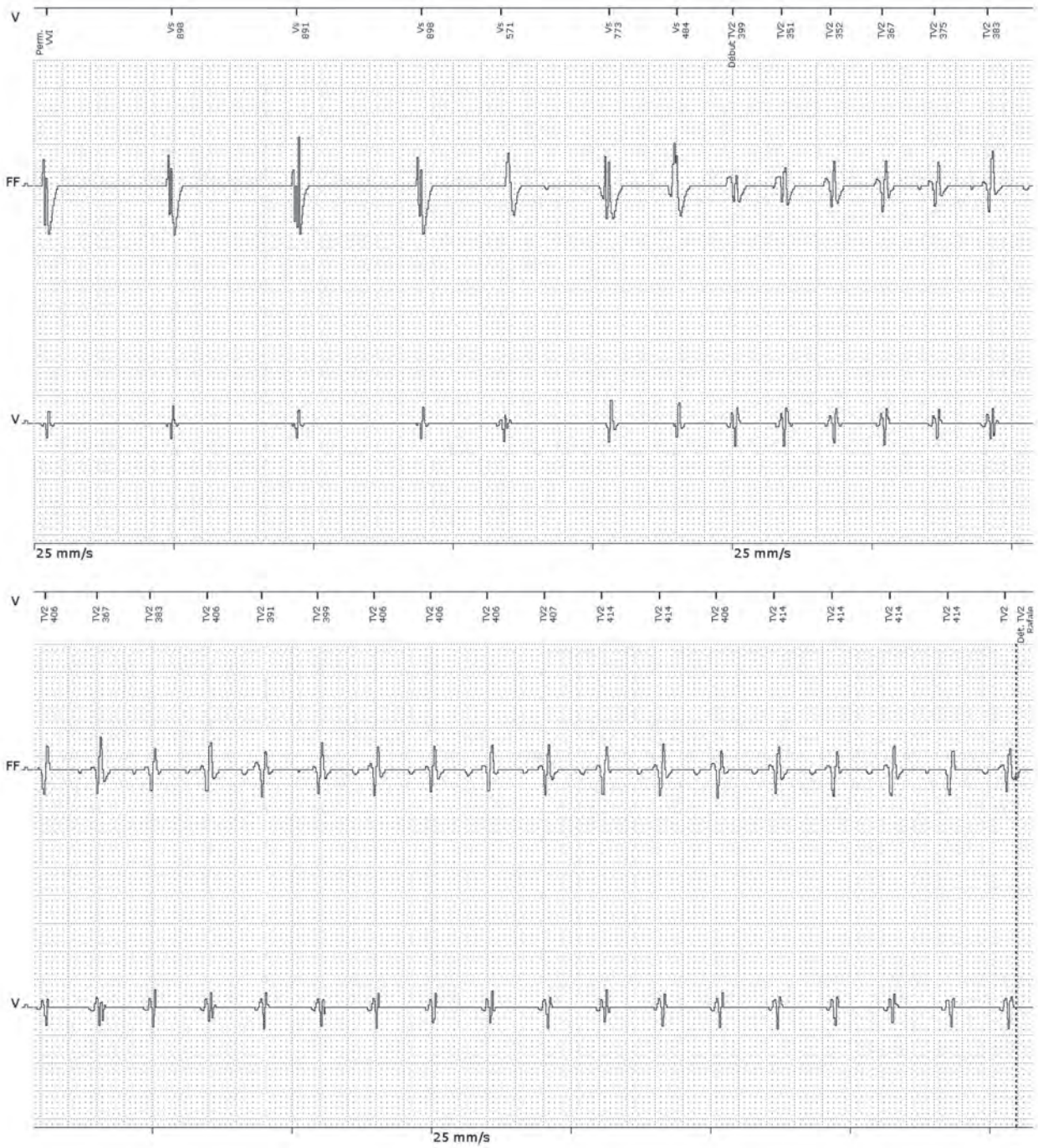
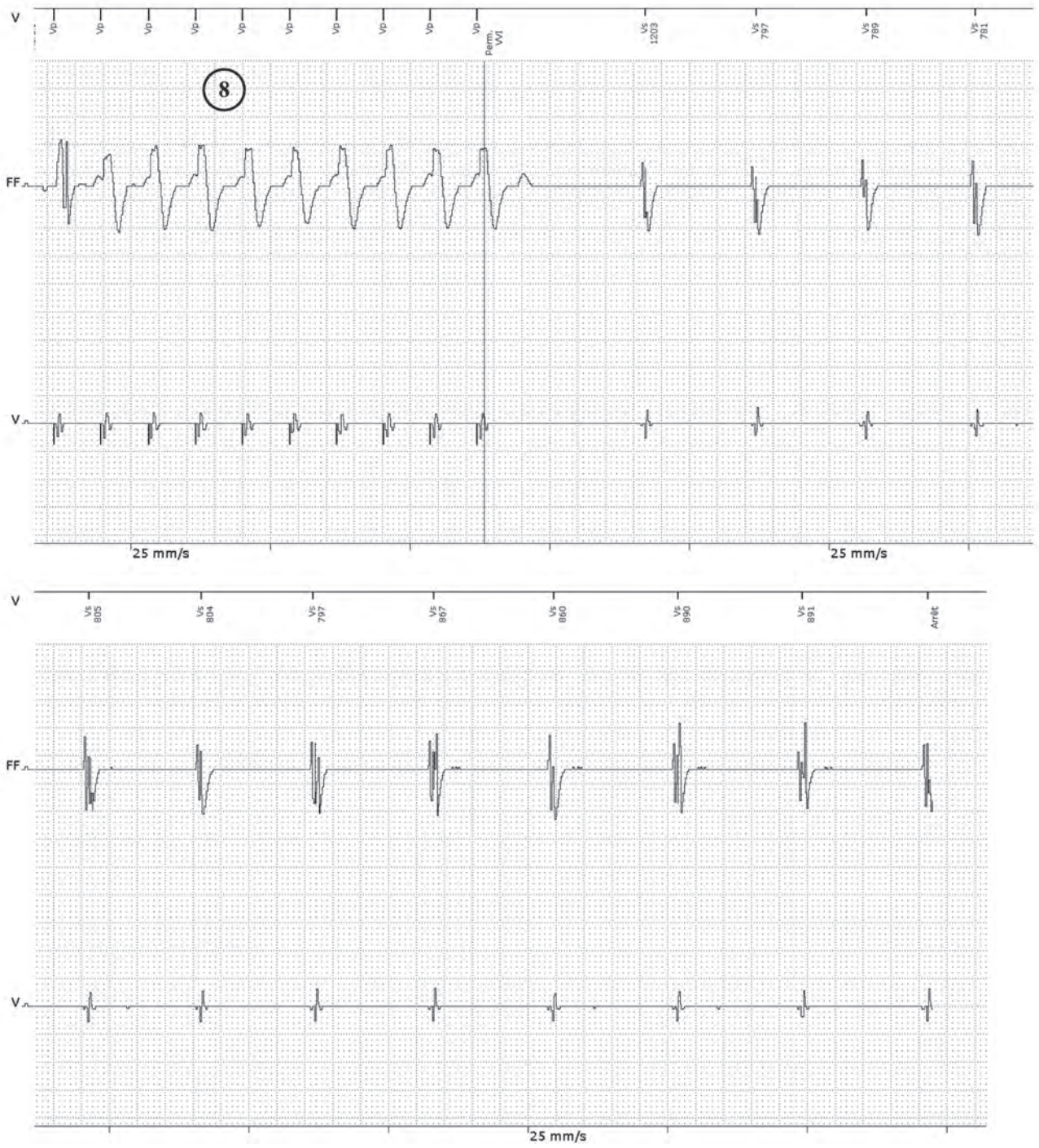
PDF: BIOTRONIK - Lumax 540 VR-T - [redacted] - [redacted] 9 / 43




V
Vp
Perm. VVI
Vs 1203
Vs 797
Vs 789
Vs 781
8
FF
V
25 mm/s
25 mm/s
V
Vs 805
Vs 804
Vs 797
Vs 867
Vs 860
Vs 890
Vs 891
Arrêt
FF
V
25 mm/s

Tracing 2: multiples episodes of VT treated by burst pacing

Patient

This 58-year-old man received a Lumax 540 HF-T triple chamber defibrillator, implanted for a primary prevention indication in the context of ischemic cardiomyopathy with a 30% left ventricular ejection fraction, left bundle branch block and sinus node dysfunction; event report issued (yellow color) in the context of multiples episodes of VT and one episode of VF.

Main programmed settings

- VF zone (280 ms limit), VT2 zone (400 ms limit) and VT1 zone (460 ms limit)
- 12/16 cycles in the VF zone, 16 cycles in the VT2 zone and 26 cycles in the VT1 zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.8 mV
- VF zone: delivery of a single burst of ATP one shot, followed by 8 shocks of maximum strength (40 J); VT2 zone: 3 bursts, followed by 3 ramps, followed by 1 shock at 16 J, followed by 7 shocks of maximum strength; VT1 zone: 3 bursts, followed by 3 ramps; no shock programmed
- Effective discrimination in both VT zones
- Pacing mode: DDDR at 60 bpm with biventricular stimulation

Remote report

Multiples episodes classified in VT2 zone with 1 to 2 ATP delivered over approximately 6 months. One episode was classified in the VF zone with a cancelled shock.

Remote tracing 1 (no 35)

The 4 channels available are: 1) the markers with the time intervals, 2) the atrial (A) channel, 3) the right ventricular (RV) sensing channel and 4) the left ventricular (LV) channel.
On the summary table, the type of episode (VT2) corresponds to the first classification; the VT2 reclassification indicates that, after the first therapy (burst), the reclassifying VT2 counter was filled, prompting the delivery of a second therapy.

1: atrial paced rhythm (sensor-driven rate) and biventricular stimulation. The "PermDDDR" labeling at the onset of the tracing indicates that the defibrillator operated in the permanently programmed (DDDR) pacing mode;
2: late VES of LV origin, as the LV falls before VS, after atrial pacing; the VES, on the right hand side, falls in the post atrial pacing safety window. The device paced during the safety window, explaining the 2 closely spaced lines on the RV markers (sensing followed by pacing); a pacing artifact is visible at the level of the ventricular EGM (inside the extrasystole);
3: sudden onset of tachycardia detected in the VT2 zone; atrioventricular dissociation with a very slow atrial rate, in this patient presenting with known sinus node dysfunction. The atrial cycle is classified "Ars" as it fell in the post ventricular atrial refractory period (PVARP). It is noteworthy that the defibrillator treated it as a succession of VES, causing the systematic lengthening of the PVARP, which, starting with the Lumax 740 model, is nominally programmed at 225 ms with a 150-ms extension after a VES;
4: classification of a VT2 episode after 16 cycles in the VT2 zone without interposed cycle classified VT1 or VS. The device diagnosed VT because the ventricular rate was faster than the atrial rate (RR<PP);
5: two sequences of ATP were needed to terminate the arrhythmia. The end of the second sequence of ATP is visible, consisting of a burst of RV pacing. Triple chamber devices allow the programming of RV, LV or biventricular bursts;
6: termination of the arrhythmia;
7: end of the episode after 12 consecutive paced ventricular cycles (≥12 out of 16 slow cycles);

Remote tracing 2 (no 24)

8: episode of VT identical to the previous;
9: the end of the sequence of ATP is visible;

Remote tracing 3 (no 20)

10: spontaneously terminated, nonsustained VT;
11: new salvo of 10 complexes of nonsustained VT;
12: longer salvo classified as VT2 when the counter is full; burst of ATP and termination; it is noteworthy that the VT is consistently the same, with identical RV and LV morphologies of all episodes;

Remote tracing 4 (no 38)

13: episode classified VF;
14: an extremely rapid signal is intermittently detected on the atrial, RV and LV channels (As, Ars, Vs VT1, VF markers);
15: episode classified VF; if one counts from this classification backward, 12 of the 16 previous cycles are classified VF, which corresponds precisely to the VF zone counter;
16: start of the charge of the defibrillator's capacitors;
17: when the EGM return, the ultra rapid signal is only visible on the atrial channel, with intermittent oversensing; the noise on the RV channel has disappeared, explaining why the device considered that the episode had ended.

Comments

It is important, first of all, to confirm the accuracy of the diagnosis made by the device. In this case, it reported multiple episodes of actual VT and one erroneous diagnosis of VF due to oversensing of a 50 Hz signal. This patient was recalled for search and rapid identification of the source of the noisy signal (a defective household appliance), which eliminated all recurrences of inappropriate therapies. This example brings up several important points: 1) this patient developed multiple episodes of VT of variable duration, sometimes ending spontaneously. In such cases the number of cycles needed for the diagnosis can be increased in order to facilitate a possible spontaneous termination, and to prevent ATP, which may not be inappropriate, though is sometimes unnecessary. 2) This completely asymptomatic patient presented with multiple episodes of VT, successfully treated by a sequence of ATP, which improved his quality of life preventing a succession of electrical shocks. 3) The programming of two zones of tachycardia allows the different treatment of two tachycardias with different rates. In the VT1 zone, which corresponds to tachycardias with rates below 170 bpm, it is customary to program different sequences of ATP (one series of 3 to 5 bursts of pacing at a fixed rate, followed by a series of 3 to 5 ramps of more aggressive bursts, with a programmable decrement of the pacing interval from one cycle to the next, before programming the delivery of a series of electrical shocks). For tachycardias detected between 190 bpm and the VF zone, it may be helpful to program a VT2 zone including fewer sequences of ATP in order to avoid an immediate treatment by shock, while not excessively delaying the delivery of shocks for these rapid tachyarrhythmias, which can compromise the patient's hemodynamic status if ATP is unsuccessful.

Status report - Sep 26, 2012

To: Service Télécardiologie

BIOTRONIK
excellence for life

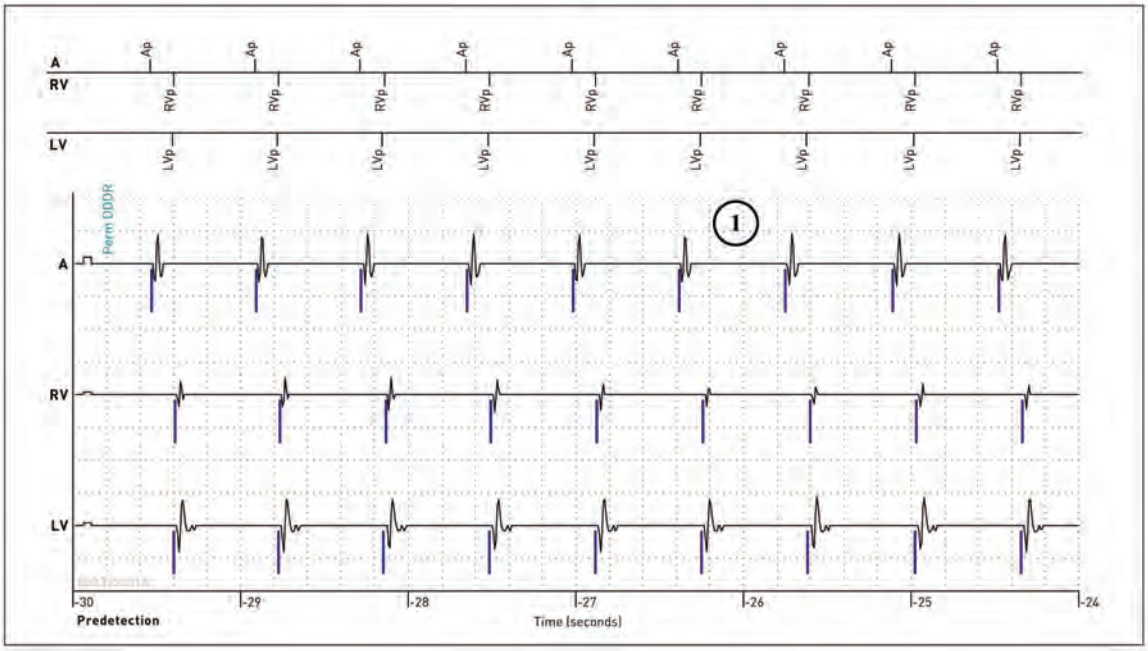
Name:	DOB:	Lumax 540 HF-T	Last message: Sep 26, 2012
Patient ID:	Phone:	CRT-D implanted Apr 23, 2012	Last clinic follow-up: Sep 13, 2012

Recordings

Recordings - Episode 35:

General	
Episode number	35
Episode type	VT2
Detection	Sep 26, 2012 2:26:58 PM
Termination	Sep 26, 2012 2:27:21 PM
Duration	23s
Device settings no.	13
Detection	
Mean PP at initial detection [ms]	> 1998
Mean RR at initial detection [ms]	370
Onset [%]	41
Stability [ms]	15
Redetection	VT2: 1

Therapy	
ATP in VT/VF delivered	2
ATP One Shot delivered	NO
Shocks delivered	0
Shocks aborted	0
Maximum energy [J]	---
Termination	
Mean PP at termination [ms]	720
Mean RR at termination [ms]	720
Remark	
none	



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Status report - Sep 26, 2012

To: Service Télécardiologie

BIOTRONIK
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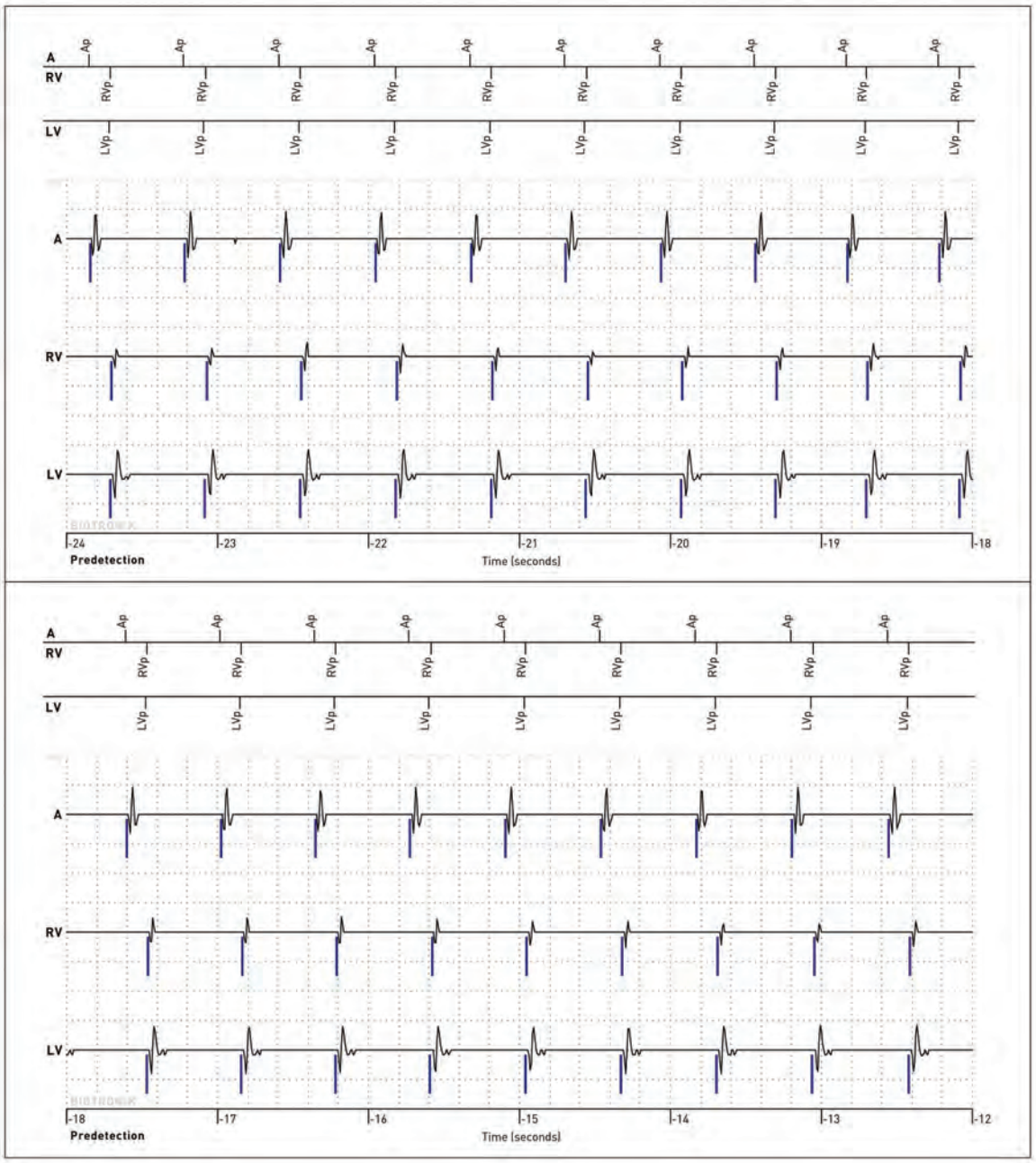
Name:	DOB:	Lumax 540 HF-T	Last message: Sep 26, 2012
Patient ID:	Phone:	CRT-D implanted Apr 23, 2012	Last clinic follow-up: Sep 13, 2012



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Status report - Sep 26, 2012

To: Service Télécardiologie

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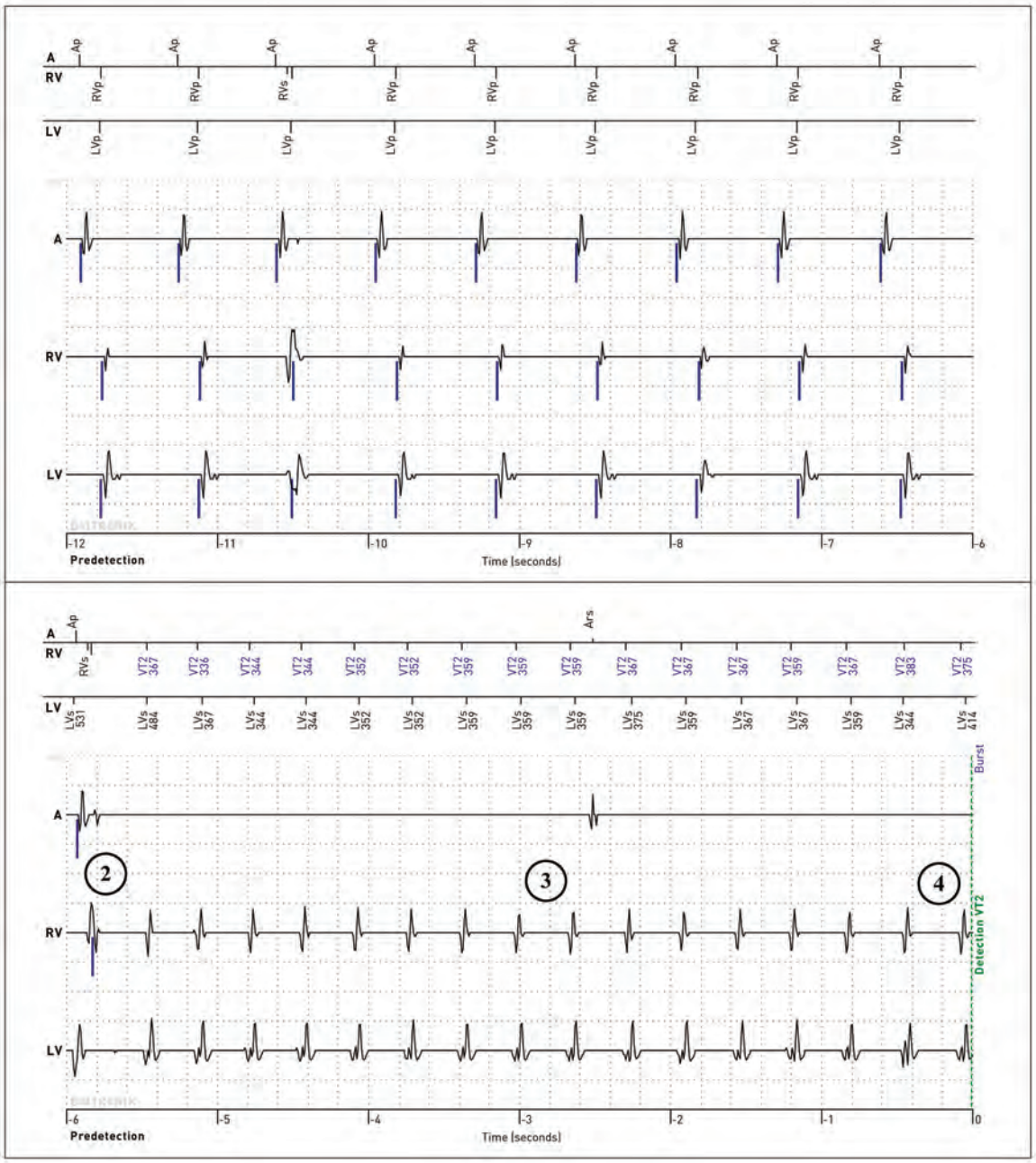
Name:	DOB:	Lumax 540 HF-T	Last message: Sep 26, 2012
Patient ID:	Phone:	CRT-D implanted Apr 23, 2012	Last clinic follow-up: Sep 13, 2012



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Status report - Sep 26, 2012

To: Service TélécØrdiologie

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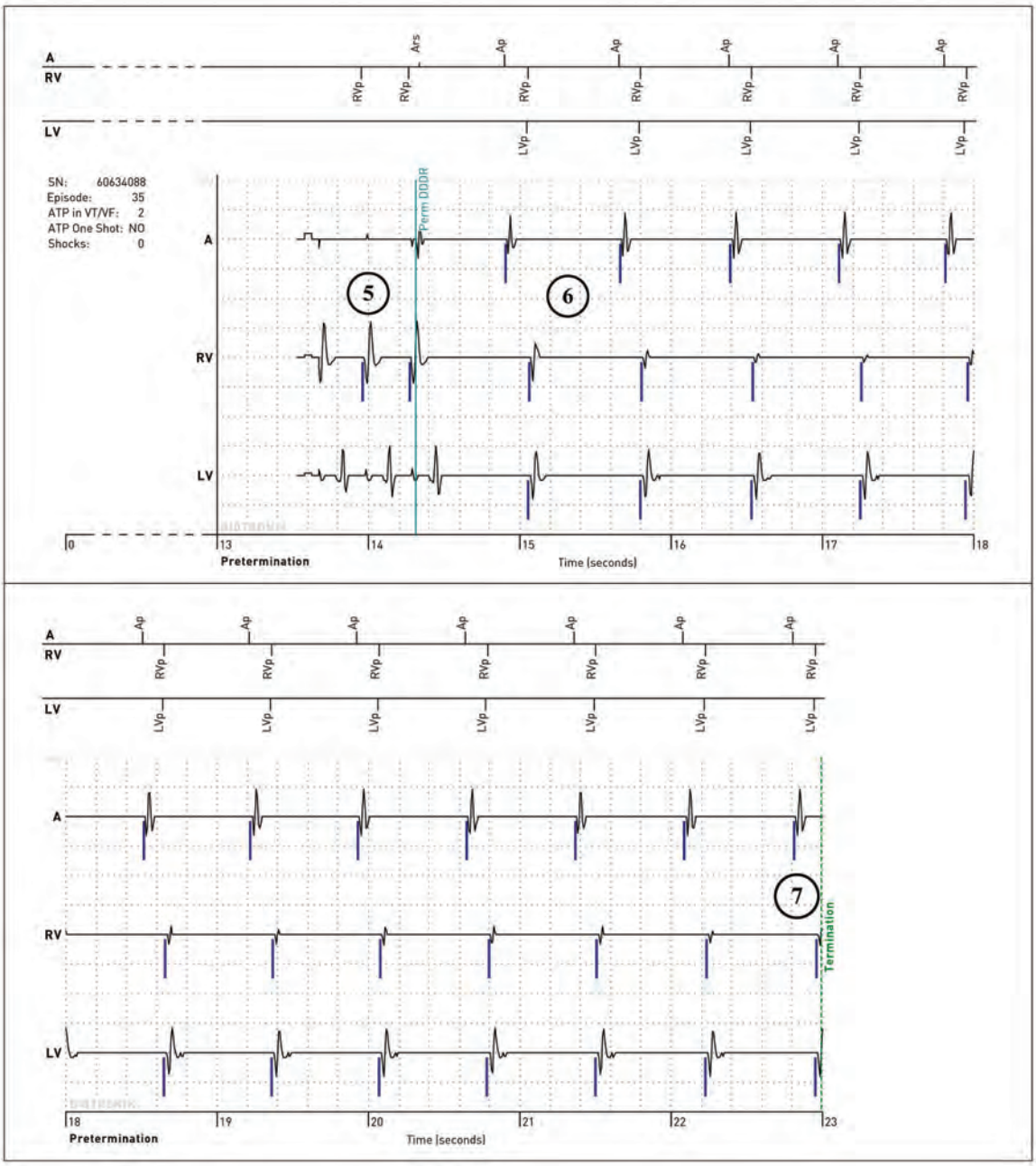
Name:	DOB:	Lumax 540 HF-T	Last message: Sep 26, 2012
Patient ID:	Phone:	CRT-D implanted Apr 23, 2012	Last clinic follow-up: Sep 13, 2012



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Status report - Sep 26, 2012

To: Service TélécØrdiologie

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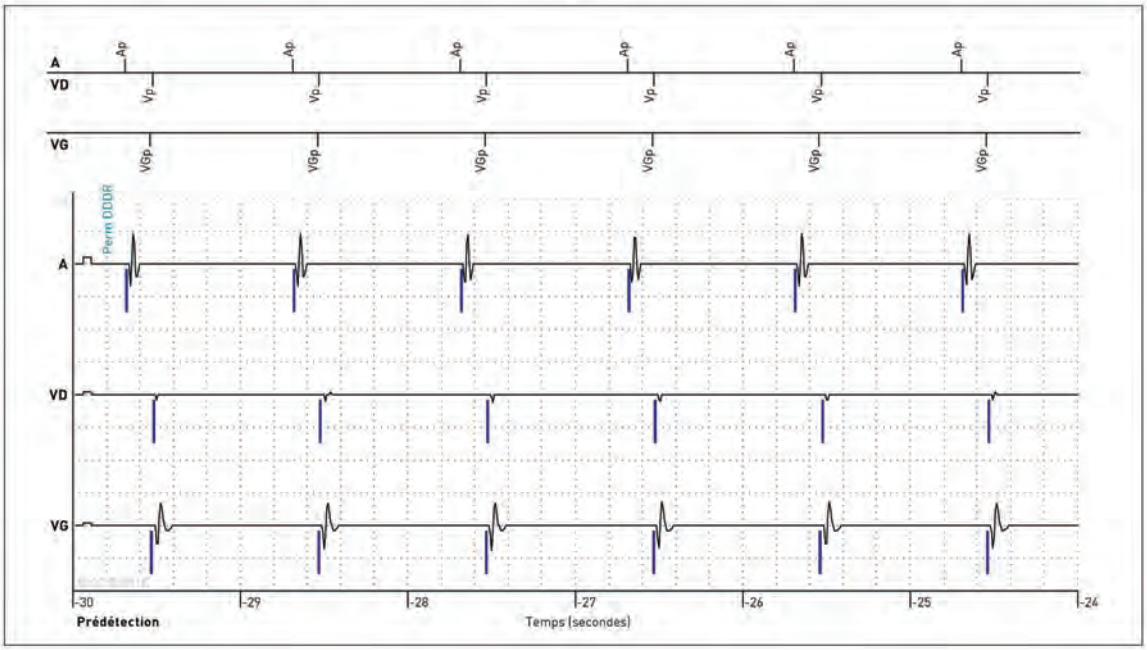
Name:	DOB:	Lumax 540 HF-T	Last message: Sep 26, 2012
Patient ID:	Phone:	CRT-D implanted Apr 23, 2012	Last clinic follow-up: Sep 13, 2012

Enregistrements - Episode 24:

Généralités	
Numéro d'épisode	24
Type d'épisode	TV2
Classification	21 sept. 2012 05:42:52
Fin	21 sept. 2012 05:43:06
Durée	14s
Réglages n°	13
Classification	
PP moyen lors de classification initiale [ms]	> 1998
RR moyen lors de classification initiale [ms]	382
Début [%]	64
Stabilité [ms]	30
Reclassification	---

Traitement	
ATP délivrée en TV/FV	1
ATP One Shot délivrées	NON
Choc(s) délivré(s)	0
Chocs annulés	0
Energie maximale [J]	---
Fin	
PP moyen en fin d'épisode [ms]	1179
RR moyen en fin d'épisode [ms]	1038
Remarque	
aucun	



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5/13

Status report - Sep 26, 2012

To: Service Télécardiologie

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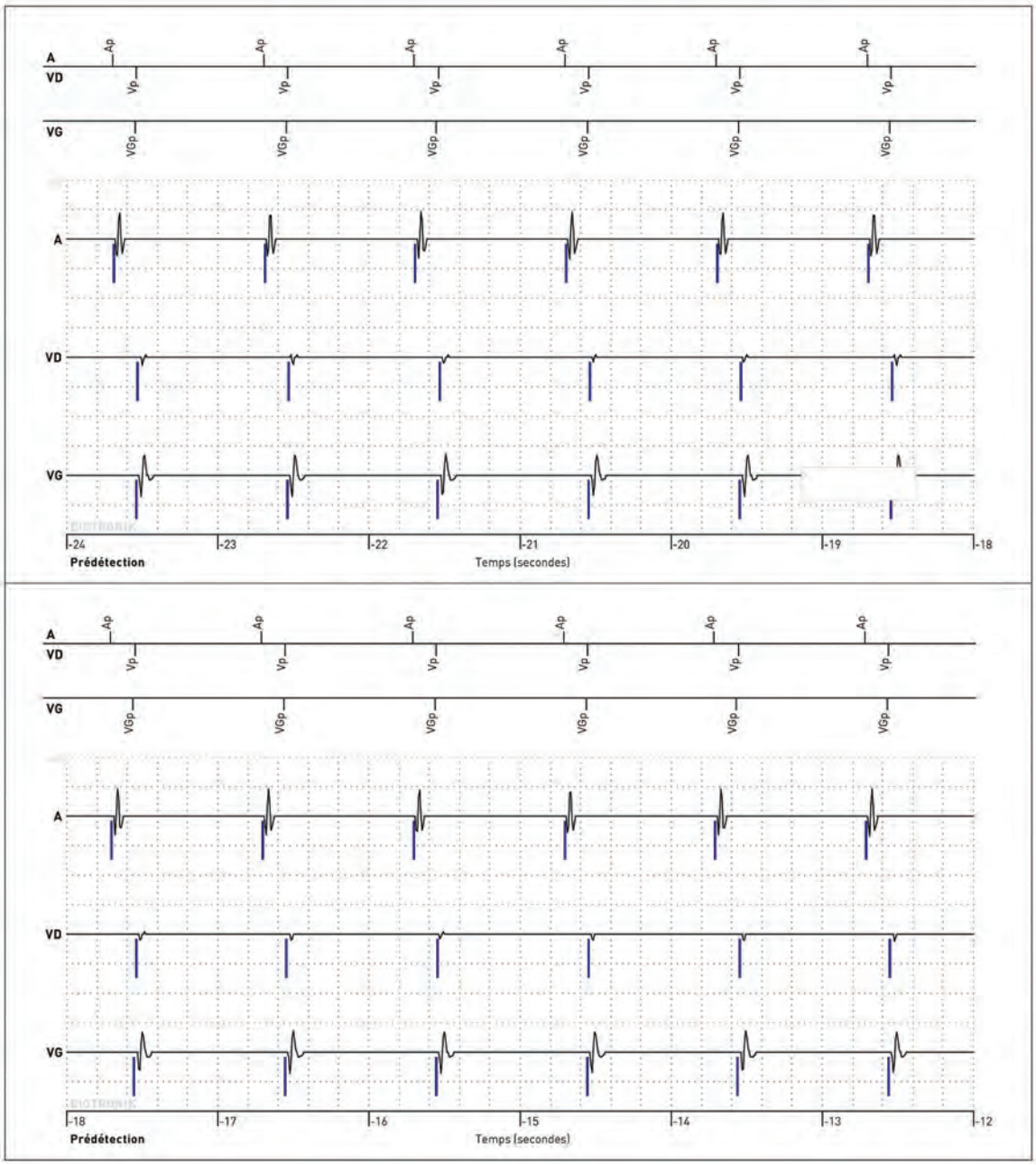
Name:	DOB:	Lumax 540 HF-T	Last message: Sep 26, 2012
Patient ID:	Phone:	CRT-D implanted Apr 23, 2012	Last clinic follow-up: Sep 13, 2012



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6/13

Status report - Sep 26, 2012

To: Service TélécΩrdiologie

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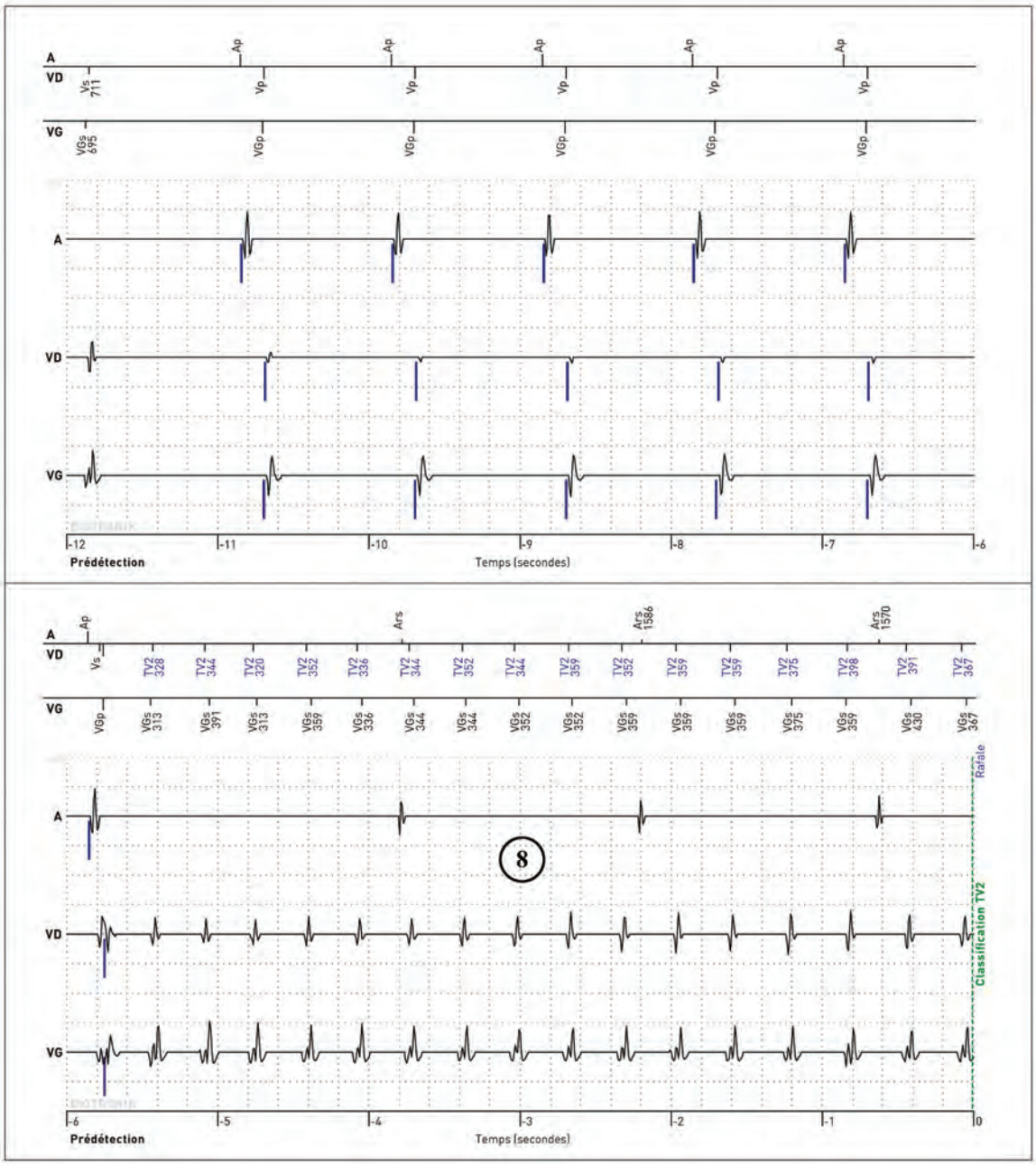
Name:	DOB:	Lumax 540 HF-T	Last message: Sep 26, 2012
Patient ID:	Phone:	CRT-D implanted Apr 23, 2012	Last clinic follow-up: Sep 13, 2012



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7/13

Status report - Sep 26, 2012

To: Service Télécardiologie

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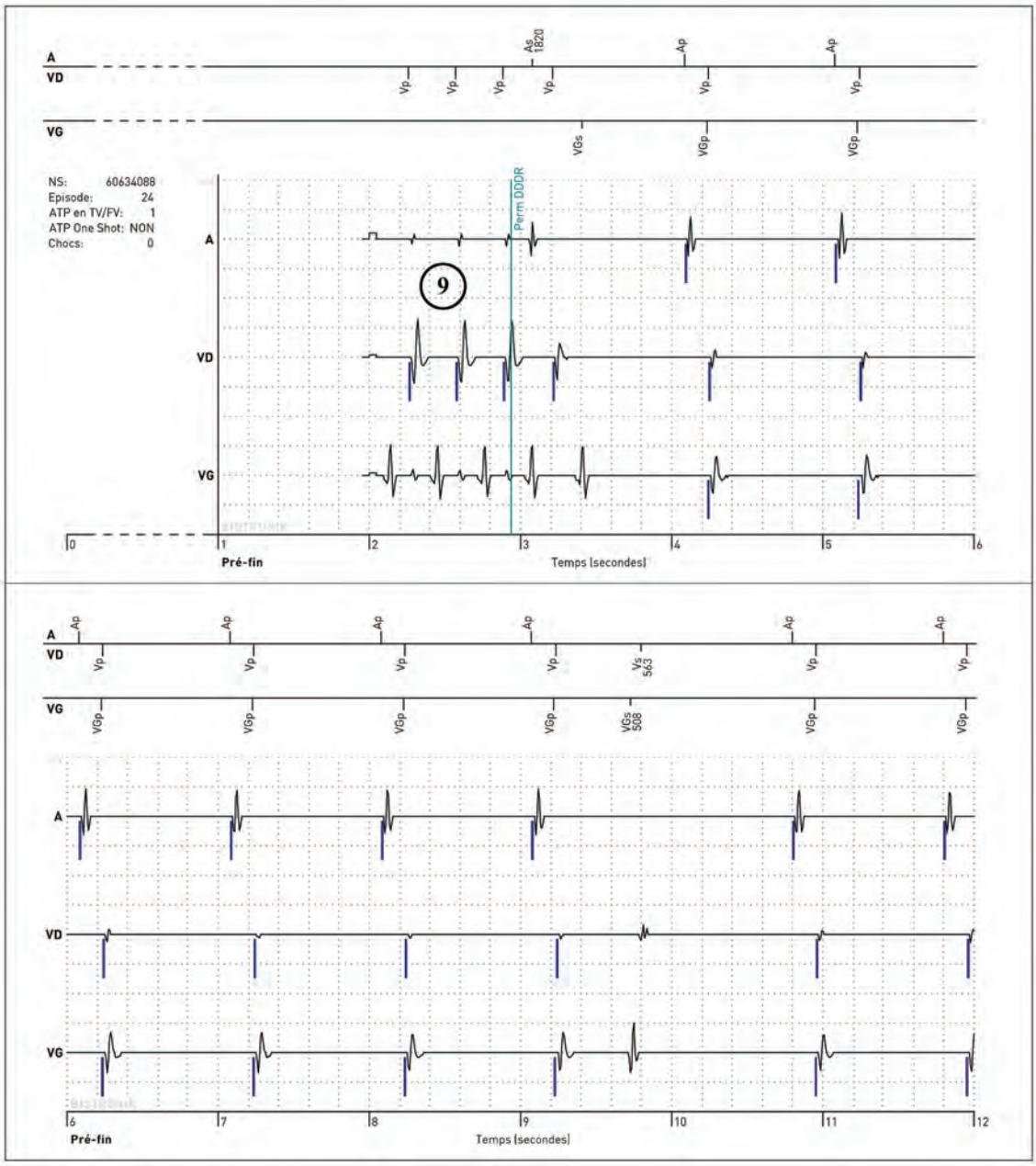
Name:	DOB:	Lumax 540 HF-T	Last message: Sep 26, 2012
Patient ID:	Phone:	CRT-D implanted Apr 23, 2012	Last clinic follow-up: Sep 13, 2012



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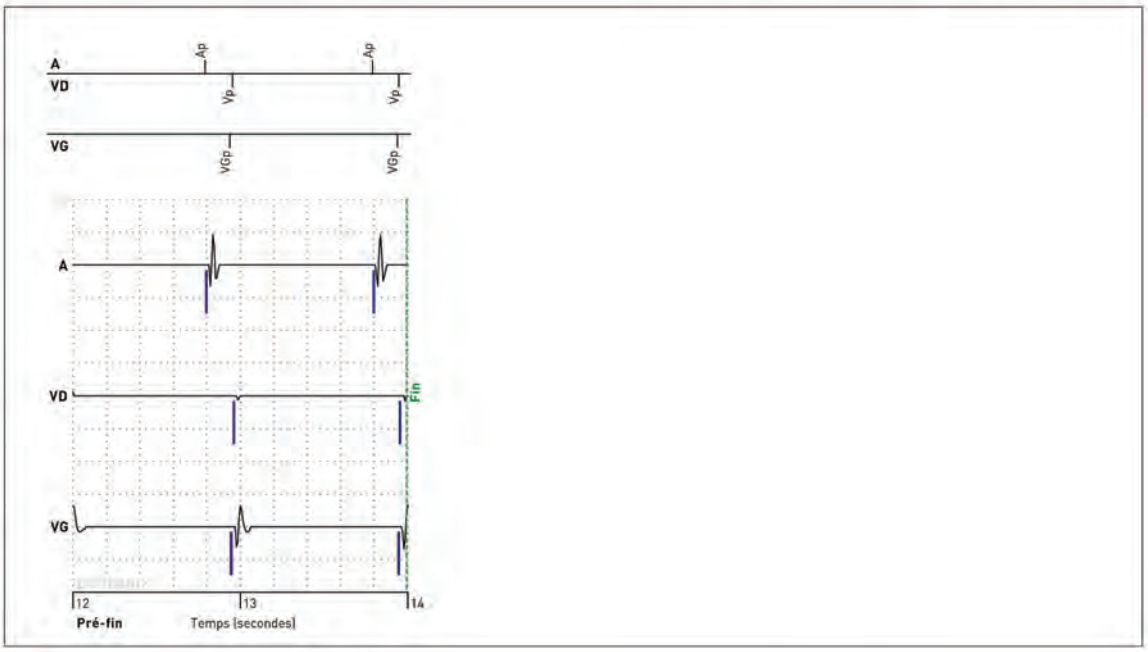
Status report - Sep 26, 2012

To: Service TélécØrdiologie

BIOTRONIK
excellence for life

Name:	DOB:	Lumax 540 HF-T	Last message: Sep 26, 2012
Patient ID:	Phone:	CRT-D implanted Apr 23, 2012	Last clinic follow-up: Sep 13, 2012



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Status report - Sep 26, 2012

To: Service TélécØrdiologie

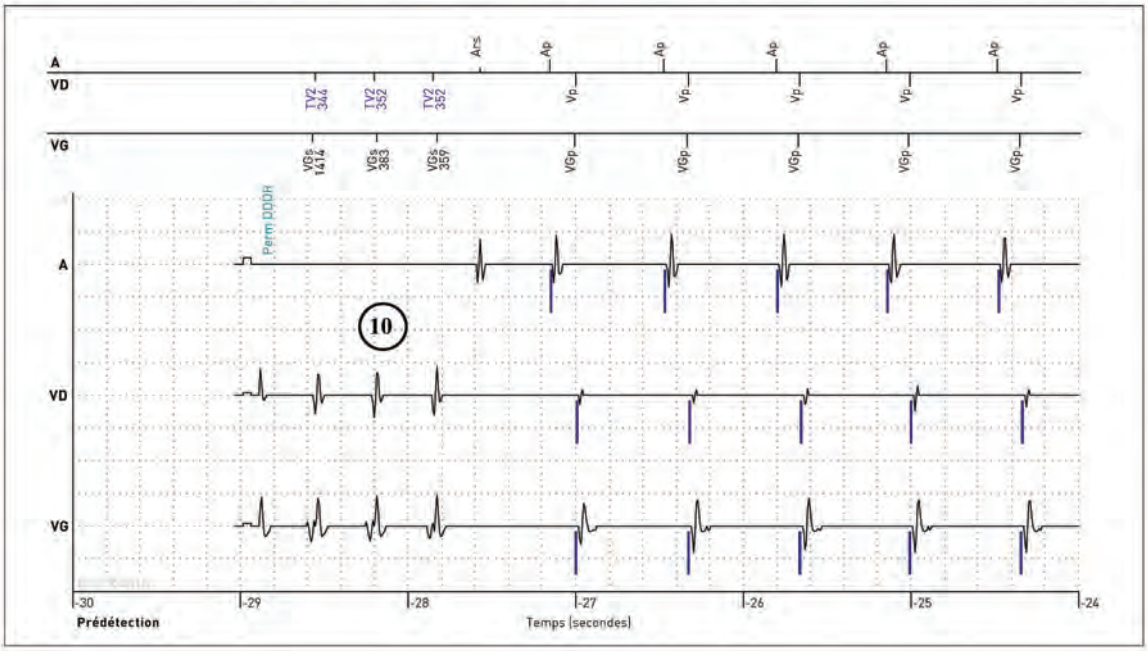
BIOTRONIK
excellence for life

Name:	DOB:	Lumax 540 HF-T	Last message: Sep 26, 2012
Patient ID:	Phone:	CRT-D implanted Apr 23, 2012	Last clinic follow-up: Sep 13, 2012

Enregistrements - Episode 20:

Généralités	
Numéro d'épisode	20
Type d'épisode	TV2
Classification	17 sept. 2012 08:11:15
Fin	17 sept. 2012 08:11:39
Durée	24s
Réglages n°	13
Classification	
PP moyen lors de classification initiale [ms]	> 1998
RR moyen lors de classification initiale [ms]	361
Début [%]	41
Stabilité [ms]	12
Reclassification	TV2:1

Traitement	
ATP délivrée en TV/FV	2
ATP One Shot délivrées	NON
Choc(s) délivré(s)	0
Chocs annulés	0
Energie maximale [J]	---
Fin	
PP moyen en fin d'épisode [ms]	747
RR moyen en fin d'épisode [ms]	747
Remarque	
aucun	



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Status report - Sep 26, 2012

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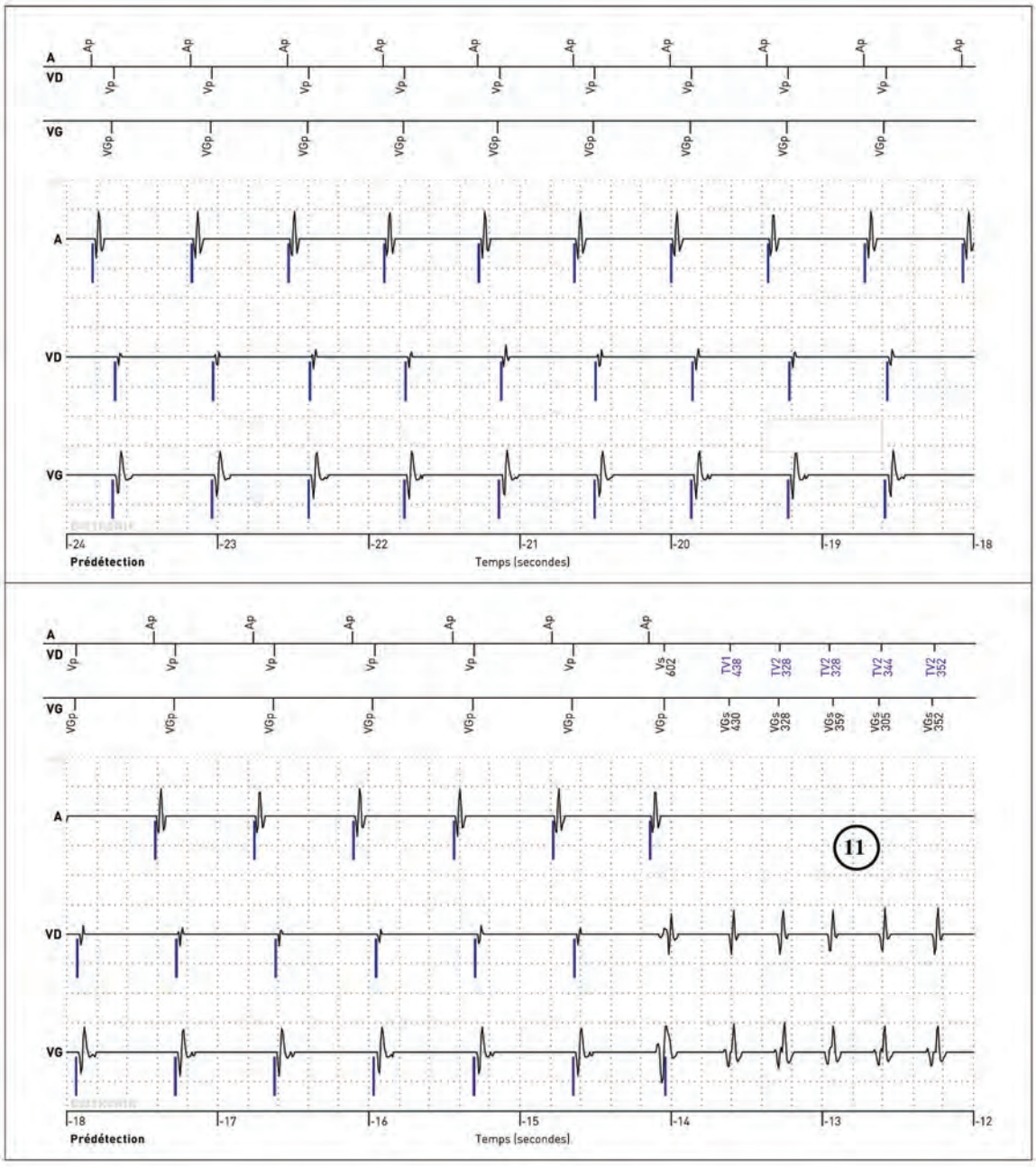
Name:	DOB:	Lumax 540 HF-T	Last message: Sep 26, 2012
Patient ID:	Phone:	CRT-D implanted Apr 23, 2012	Last clinic follow-up: Sep 13, 2012



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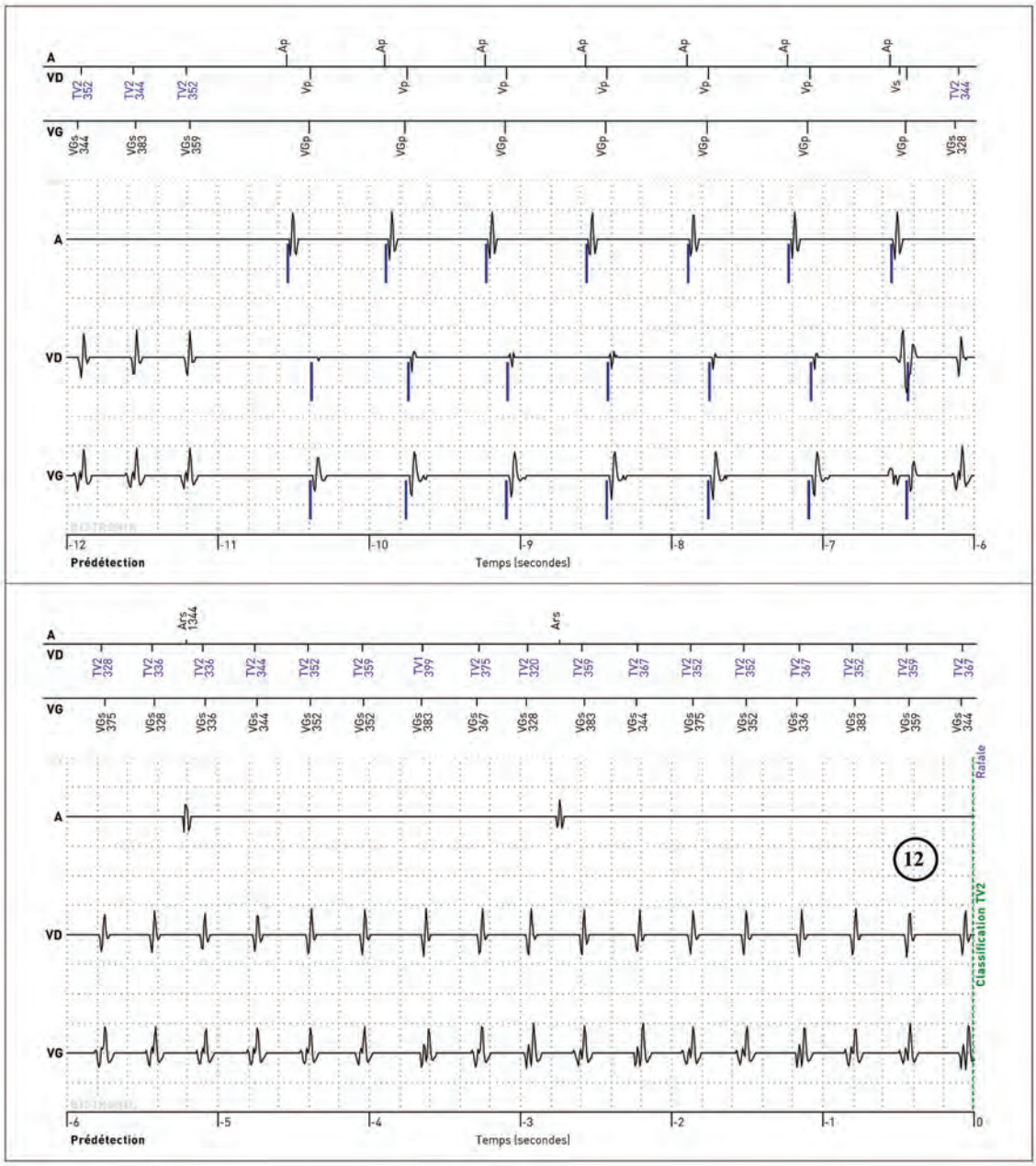
11/13

Status report - Sep 26, 2012

To: Service Téléc@rdiologie

BIOTRONIK
excellence for life

Name:	DOB:	Lumax 540 HF-T	Last message: Sep 26, 2012
Patient ID:	Phone:	CRT-D implanted Apr 23, 2012	Last clinic follow-up: Sep 13, 2012



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12/13

Status report - Sep 26, 2012

To: Service TélécØrdiologie

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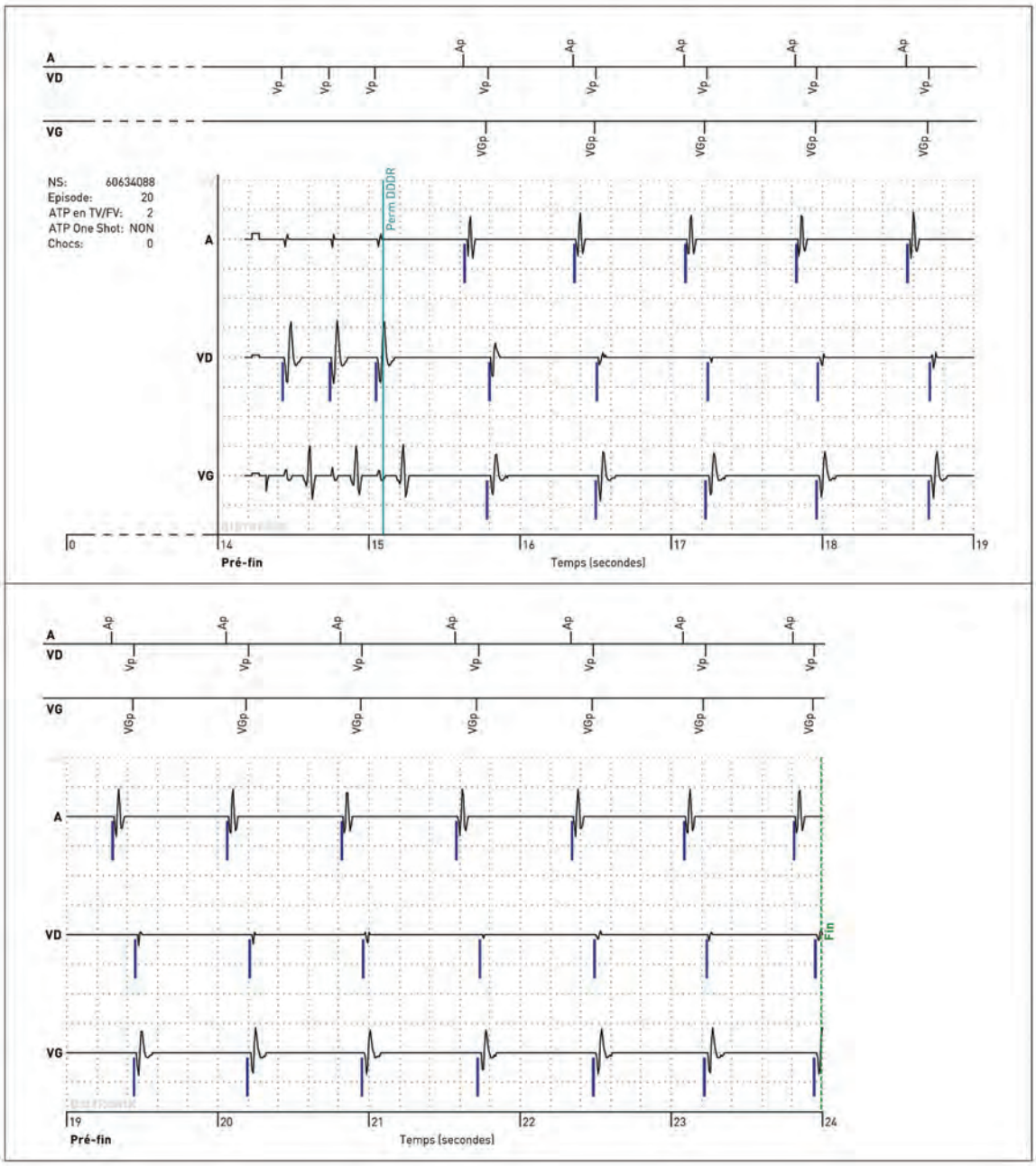
excellence for life

Name:	DOB:	Lumax 540 HF-T	Last message: Sep 26, 2012
Patient ID:	Phone:	CRT-D implanted Apr 23, 2012	Last clinic follow-up: Sep 13, 2012



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13/13

Status report - Sep 26, 2012

To: Service Téléc@rdiologie

BIOTRONIK
excellence for life

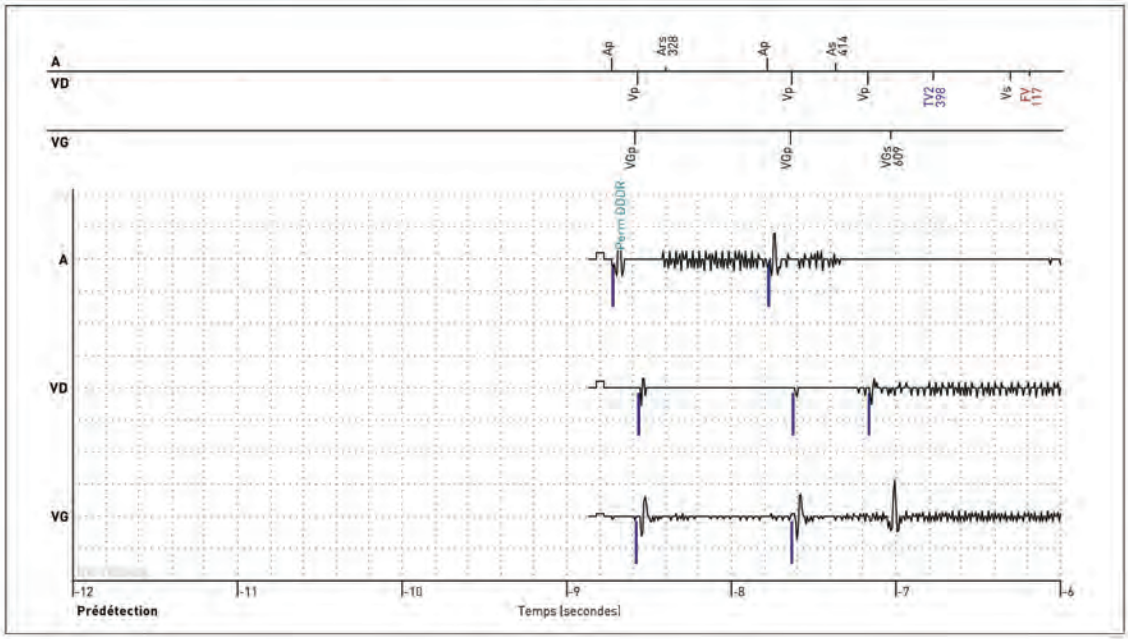
Name:	DOB:	Lumax 540 HF-T	Last message: Sep 26, 2012
Patient ID:	Phone:	CRT-D implanted Apr 23, 2012	Last clinic follow-up: Sep 13, 2012

Enregistrements

Enregistrements - Episode 38: (13)

Généralités	
Numéro d'épisode	38
Type d'épisode	FV
Classification	28 oct. 2012 15:54:09
Fin	28 oct. 2012 15:54:22
Durée	13s
Réglages n°	13
Classification	
PP moyen lors de classification initiale [ms]	901
RR moyen lors de classification initiale [ms]	126
Début [%]	79
Stabilité [ms]	148
Reclassification	---

Traitement	
ATP délivrée en TV/FV	0
ATP One Shot délivrées	NON
Choc(s) délivré(s)	0
Chocs annulés	1
Energie maximale [J]	40
Fin	
PP moyen en fin d'épisode [ms]	629
RR moyen en fin d'épisode [ms]	835
Remarque	
aucun	



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Status report - Sep 26, 2012

To: Service TélécØrdiologie

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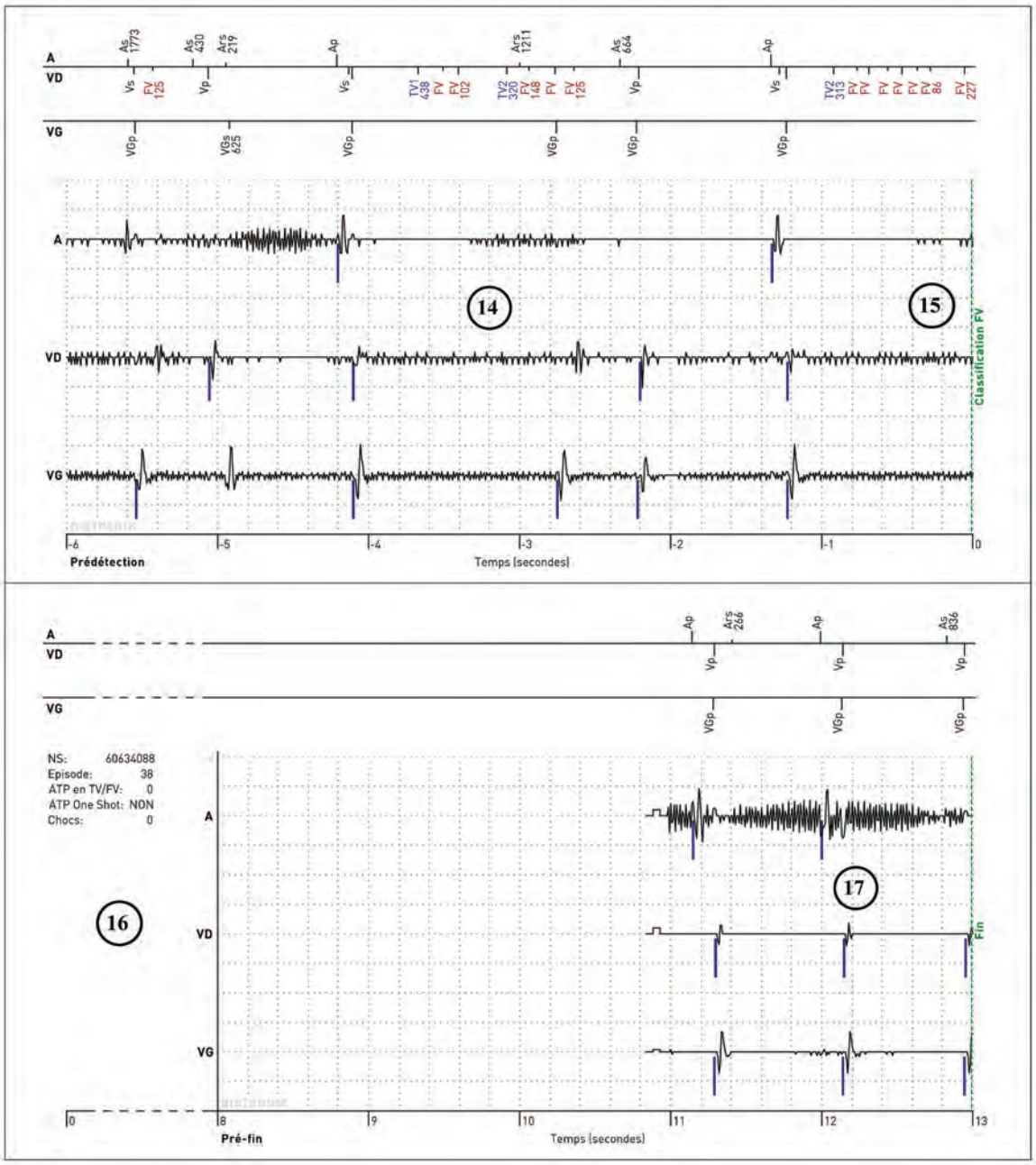
Name:	DOB:	Lumax 540 HF-T	Last message: Sep 26, 2012
Patient ID:	Phone:	CRT-D implanted Apr 23, 2012	Last clinic follow-up: Sep 13, 2012



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2/2

Tracing 3: VT treated by a series of bursts

Patient

This 76-year-old man received a Lumax 540 VR-T single chamber defibrillator for idiopathic cardiomyopathy with a 25% left ventricular ejection fraction; event report (yellow color) issued in the context of a classified VT1.

Main programmed settings

- VF zone (270 ms limit), VT2 zone (340 ms limit), VT1 zone (420 ms limit)
- 12/16 cycles in the VF zone, 16 cycles in the VT2 zone and 26 cycles in the VT1 zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.8 mV
- VF zone: one ATP one shot, followed by 8 shocks of maximum strength (40 J); VT2 zone: 4 bursts, followed by 4 bursts, followed by 1 shock at 10 J, followed by 7 shocks of maximum strength; VT1 zone: 8 bursts, followed by 4 ramps, followed by 1 shock at 10 J, followed by 7 shocks of maximum strength
- Effective discrimination in both VT zones
- Pacing mode: VVI at 35 bpm

Remote tracing

The 3 channels available are: 1) the markers with the time intervals, 2) the shock channel (FF = far field) between the coil of the RV lead and the pulse generator, and 3) the RV sensing channel.

1: first cycle classified VT1, increasing the VT1 counter by 1 cycle;
2: cycle classified Vs (430 ms >lower limit of VT1) decreasing the VT1 counter which returns to 0;
3: succession of cycles classified in the VT1 zone;
4: when the VT1 counter reached 26, the episode was classified VT1;
5: 6 sequences of ATP were delivered (not visible on the remote report);
6: termination of the arrhythmia (end of episode after 12 cycles classified Vs).

Programmer tracing (same episode)

The 3 channels are the same as on the remote tracing.

7: same VT tracing;
8: first burst (10 stimuli at fixed 80% of the tachycardia rate);
9: after 20 cycles in VT1, the reclassification counter of the VT1 zone is filled;
10: second burst (11 stimuli at a fixed cycle length, 10 ms shorter than the preceding burst);
11: third burst (12 stimuli at a fixed cycle length, 10 ms shorter than the preceding burst);
12: fourth burst (13 stimuli at a fixed cycle length, 10 ms shorter than the preceding burst);
13: fifth burst (14 stimuli at a fixed cycle length, 10 ms shorter than the preceding burst);
14: sixth burst (15 stimuli at a fixed cycle length, 10 ms shorter than the preceding burst);
15: termination of the arrhythmia.

Comments

In a VT1 zone, various sequences can be programmed, beginning, for example, by a series of bursts (fixed rate pacing), followed by a series of ramps (programmable decrement of the pacing interval from one cycle to the next), followed by a series of electrical shocks. The episode analyzed was a relatively slow (<150 bpm) VT. For relatively slow VT: 1) the number of cycles needed to make a diagnosis can be increased in order to facilitate a spontaneous termination; 2) ATP should be favored, keeping in mind that the efficacy of a given sequence is unpredictable. In this patient, after 5 ineffective bursts, a sixth attempt was successful. It is noteworthy that a stimulus was added to each consecutive burst in order to increase the strength of each attempt. A considerable number of pacing sequences can be programmed with a view to increase the likelihood of a painless termination. It is

important, however, to avoid the delivery of overly aggressive therapies (ramps with very short cycles and large number of stimuli) to limit the risk of acceleration of the tachycardia; 3) the programming of electrical shocks is optional and depends on the tolerability of the arrhythmia.

Status report - Mar 14, 2012

To: Service Télécardiologie

BIOTRONIK
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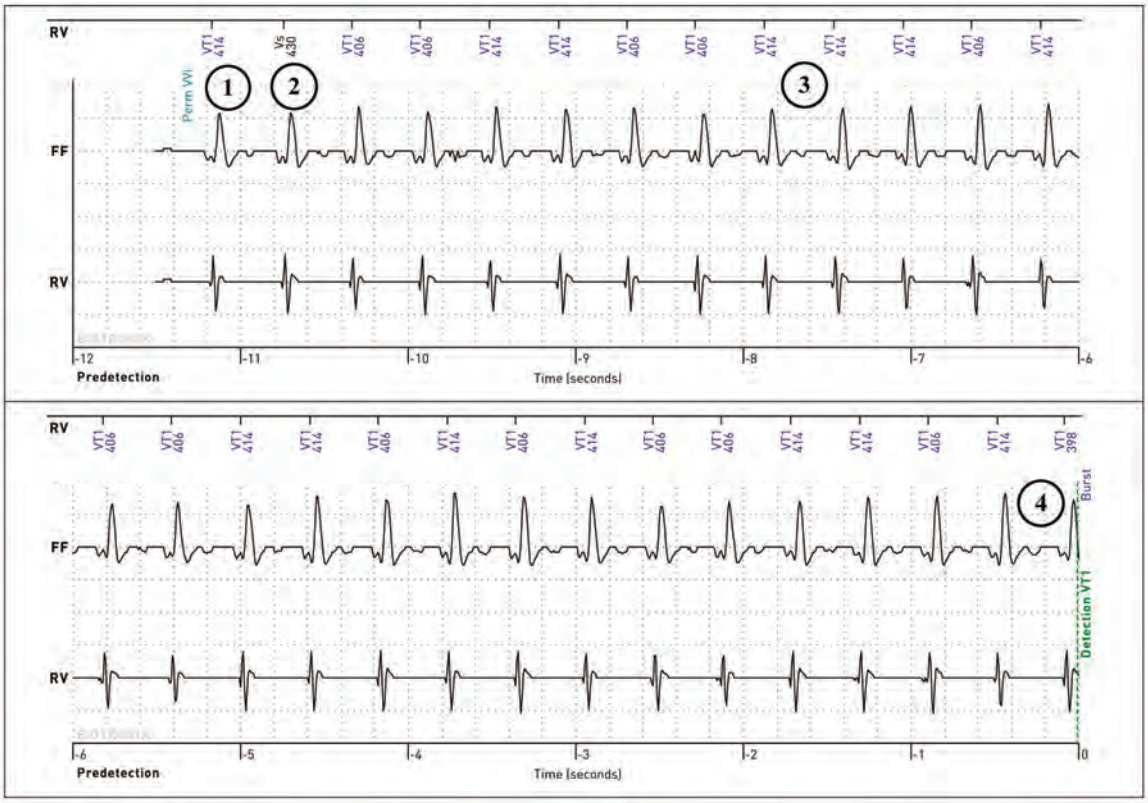
Name	DOB:	Lumax 540 VR-T	Last message: Mar 14, 2012
Patient ID:	Phone:	ICD implanted Feb 21, 2012	Last clinic follow-up: Feb 24, 2012

Recordings

Recordings - Episode 8:

General		Therapy	
Episode number	8	ATP in VT/VF delivered	6
Episode type	VT1	ATP One Shot delivered	NO
Detection	Mar 14, 2012 12:02:32 AM	Shocks delivered	0
Termination	Mar 14, 2012 12:03:50 AM	Shocks aborted	0
Duration	1min 18s	Maximum energy [J]	---
Device settings no.	17	**Termination**	
Detection		Mean RR at termination [ms]	815
Mean RR at initial detection [ms]	407	**Remark**	
Onset [%]	10	none	
Stability [ms]	11		
Redetection	VT1: 5		



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Date:

Signature:

Status report - Mar 14, 2012

To: Service TéléCardiologie

BIOTRONIK
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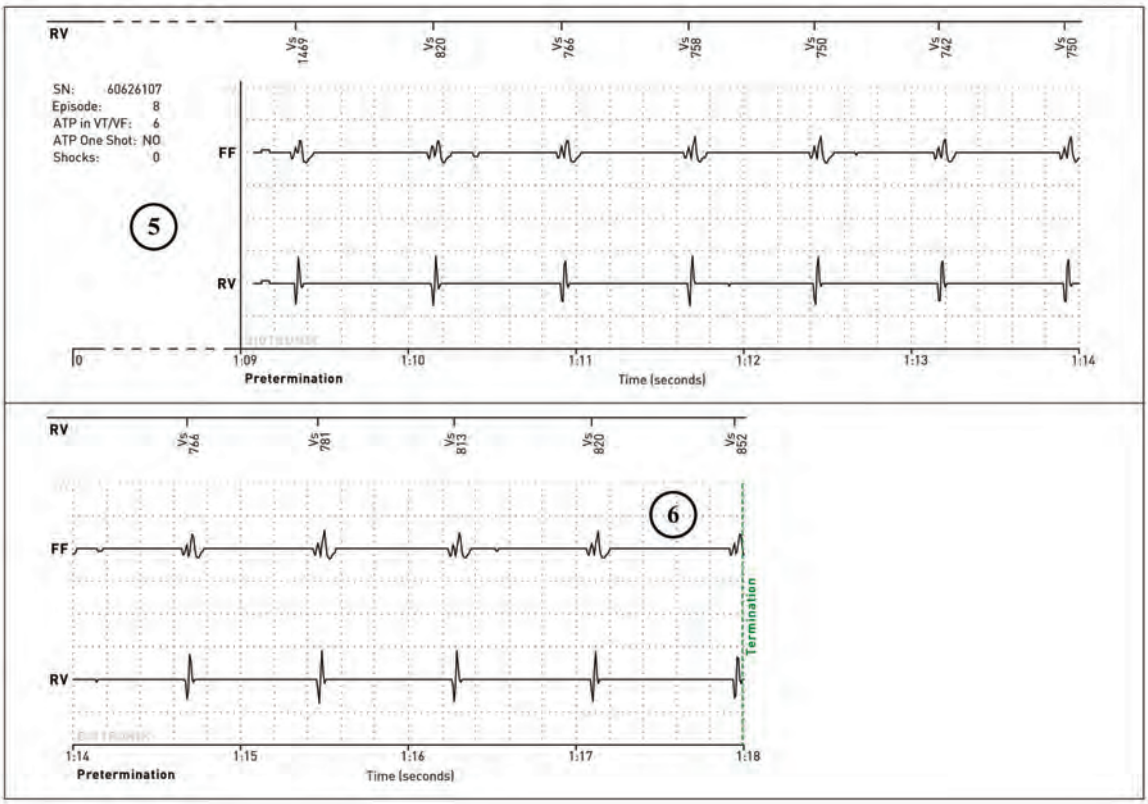
Name:	DOB:	Lumax 540 VR-T	Last message: Mar 14, 2012
Patient ID:	Phone:	ICD implanted Feb 21, 2012	Last clinic follow-up: Feb 24, 2012



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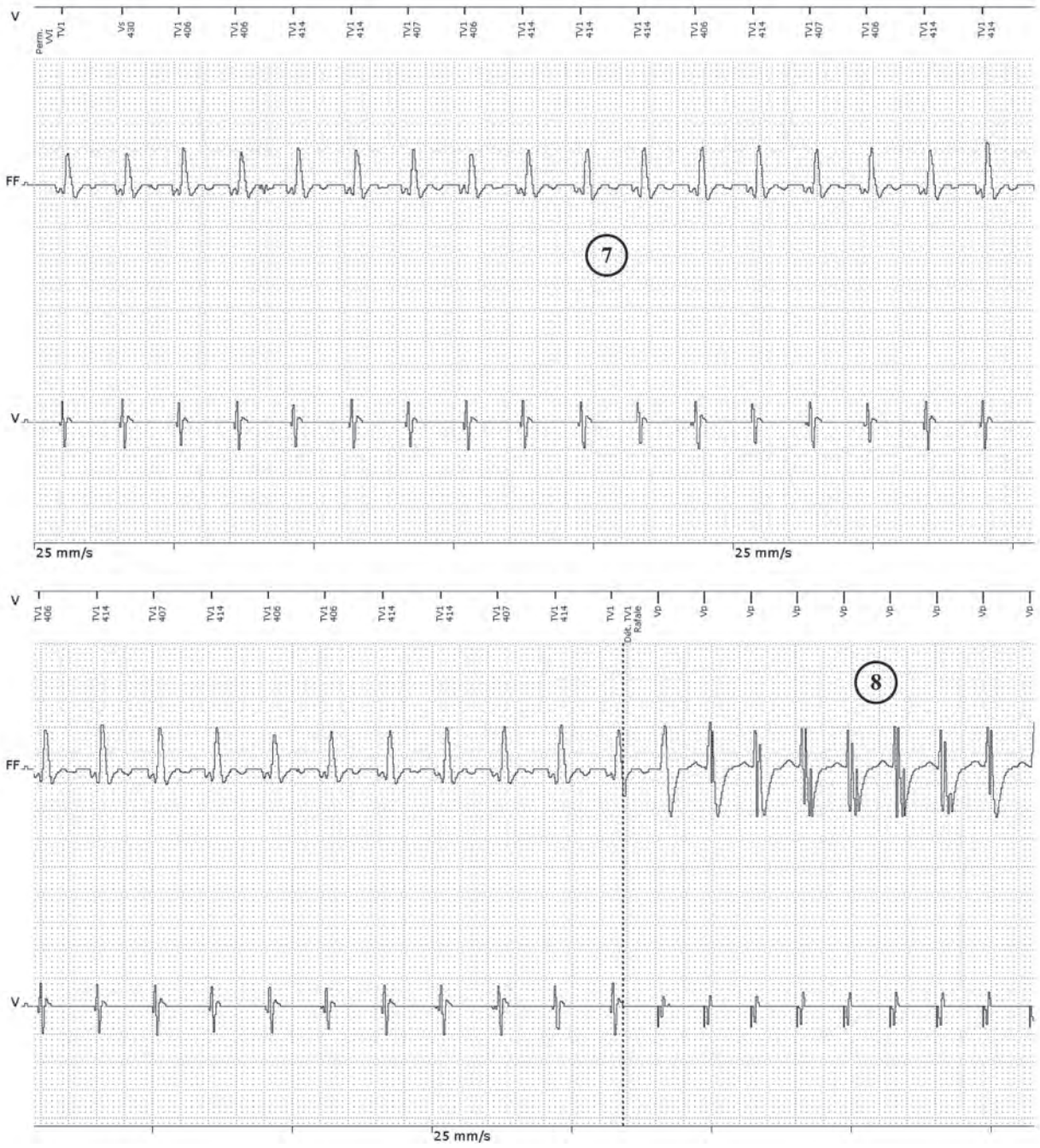
2/2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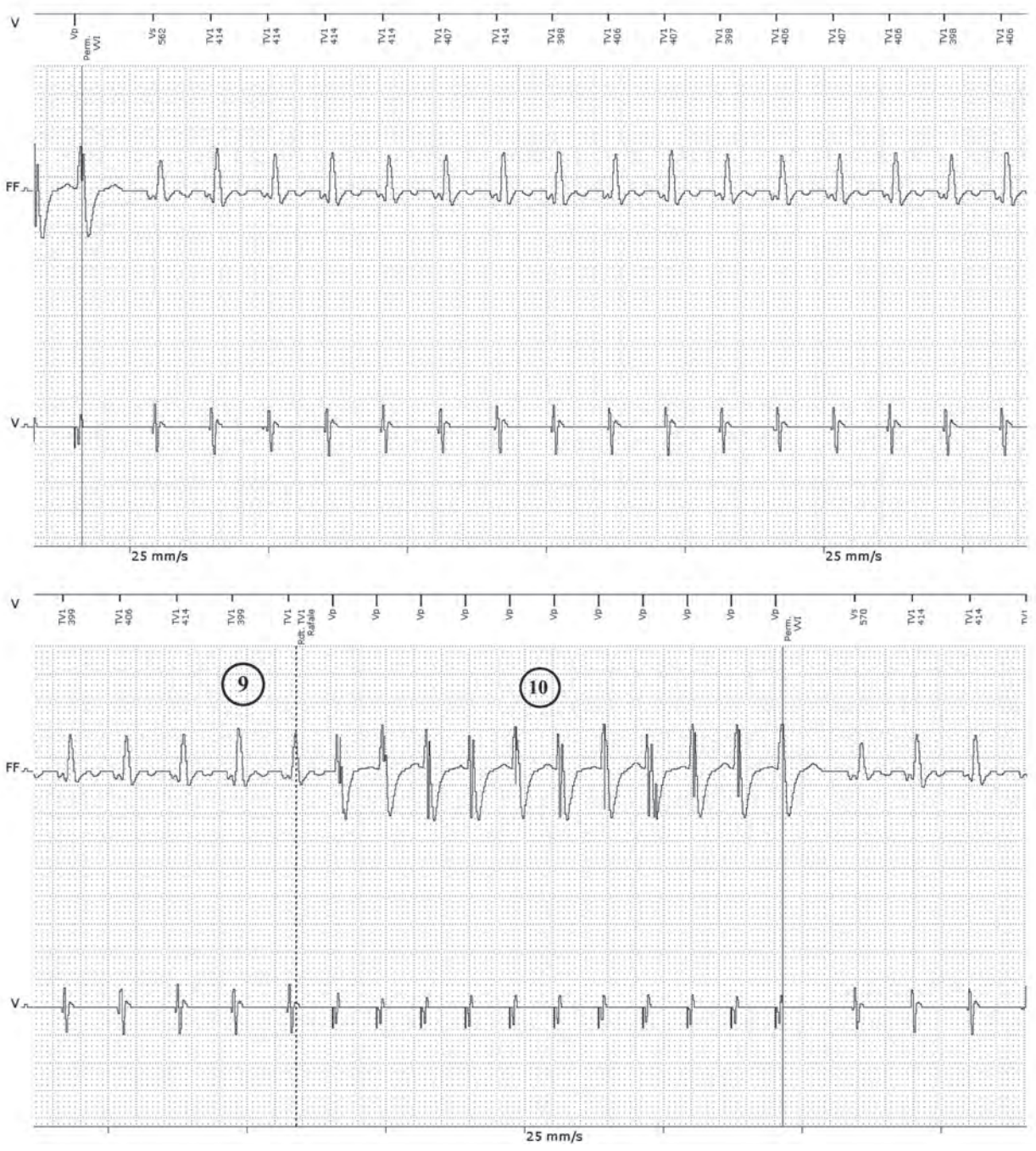

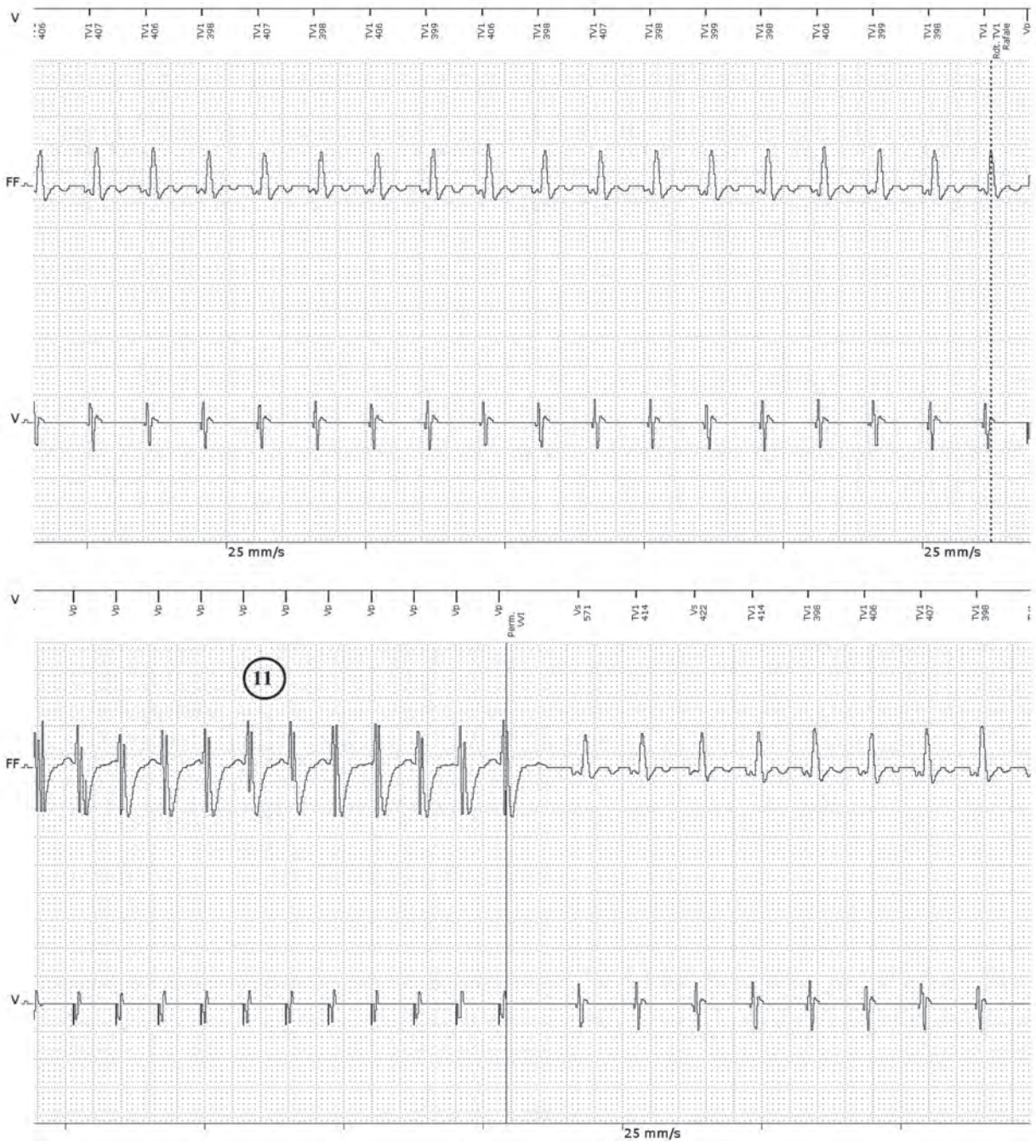
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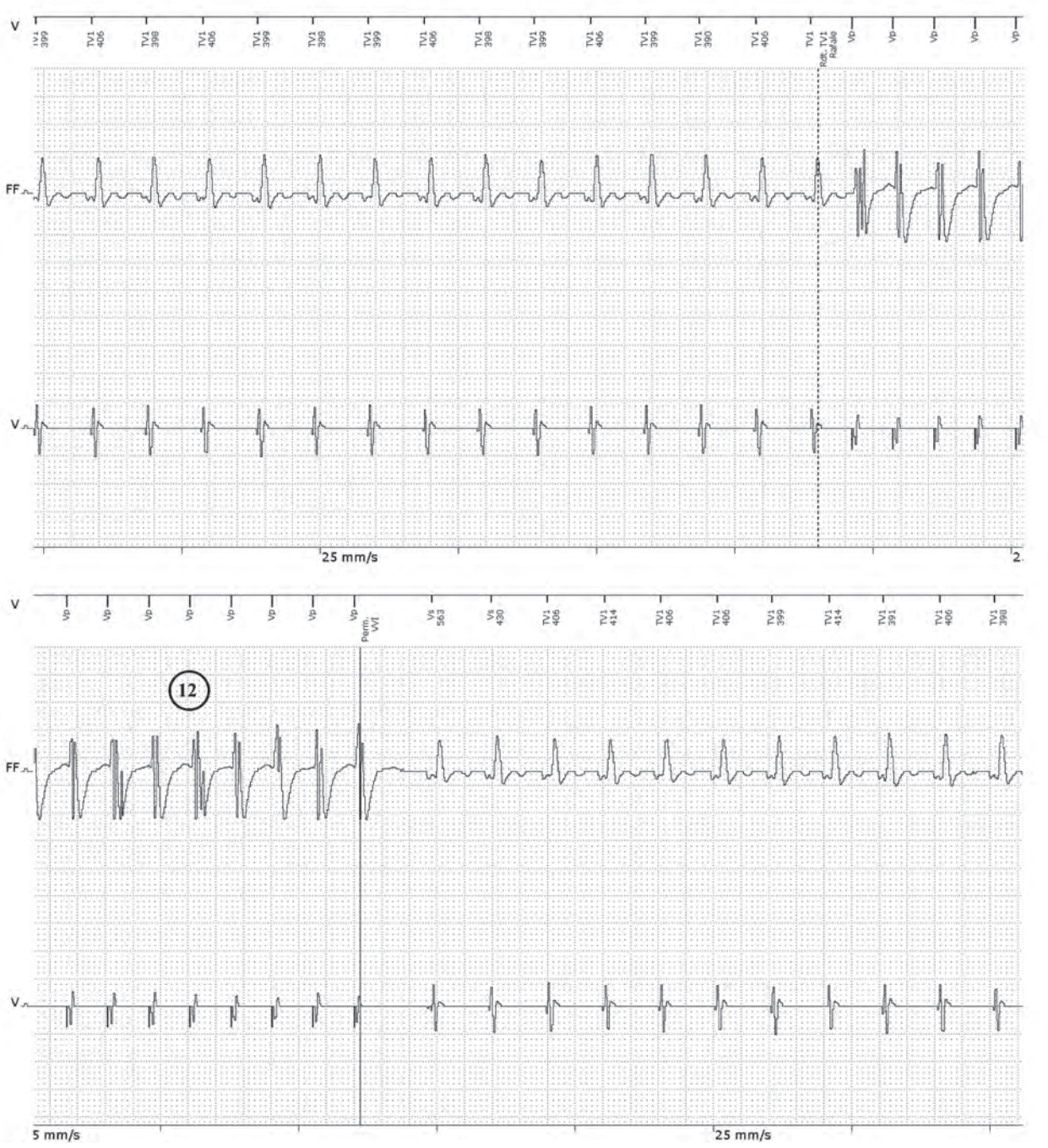
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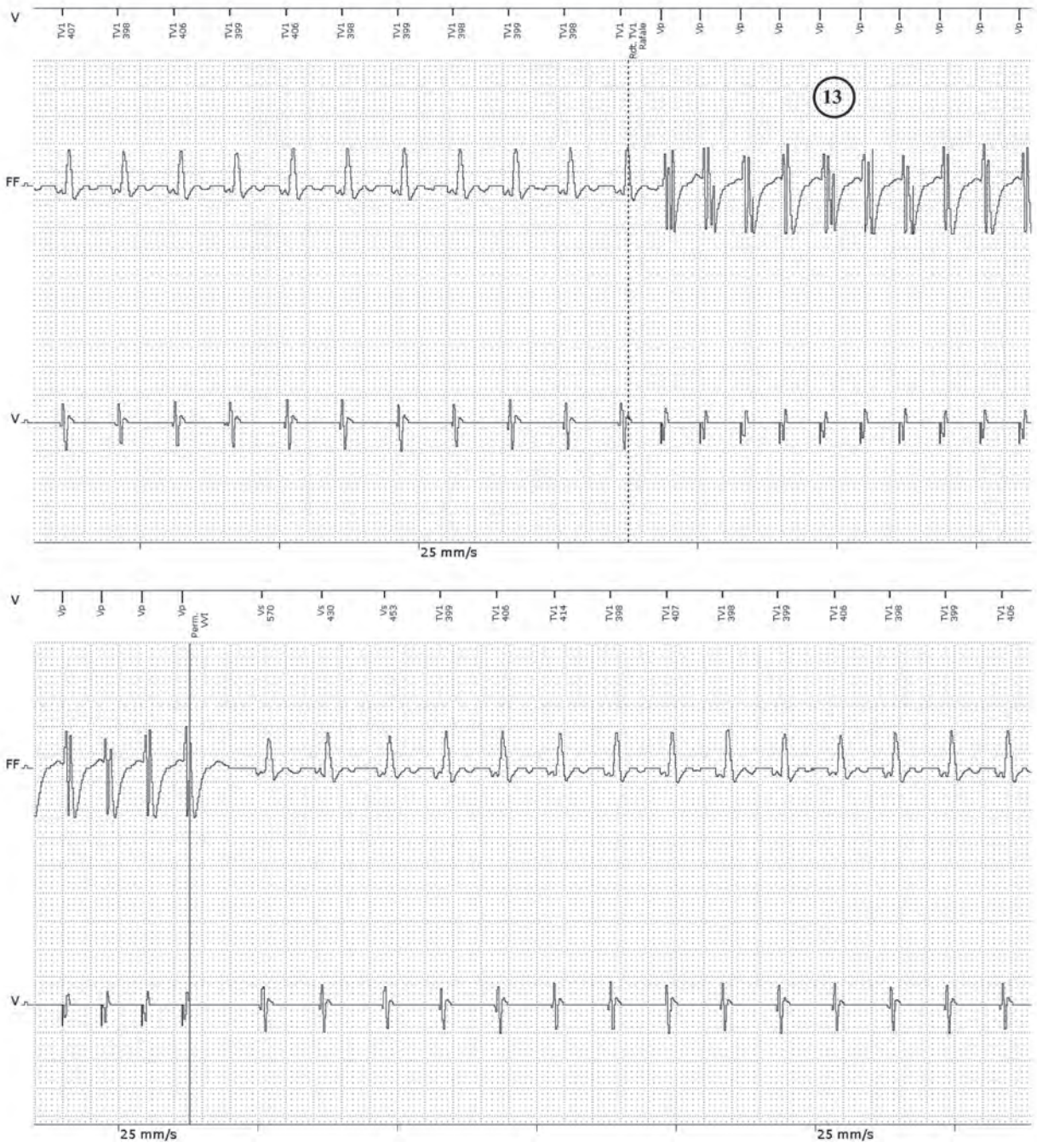
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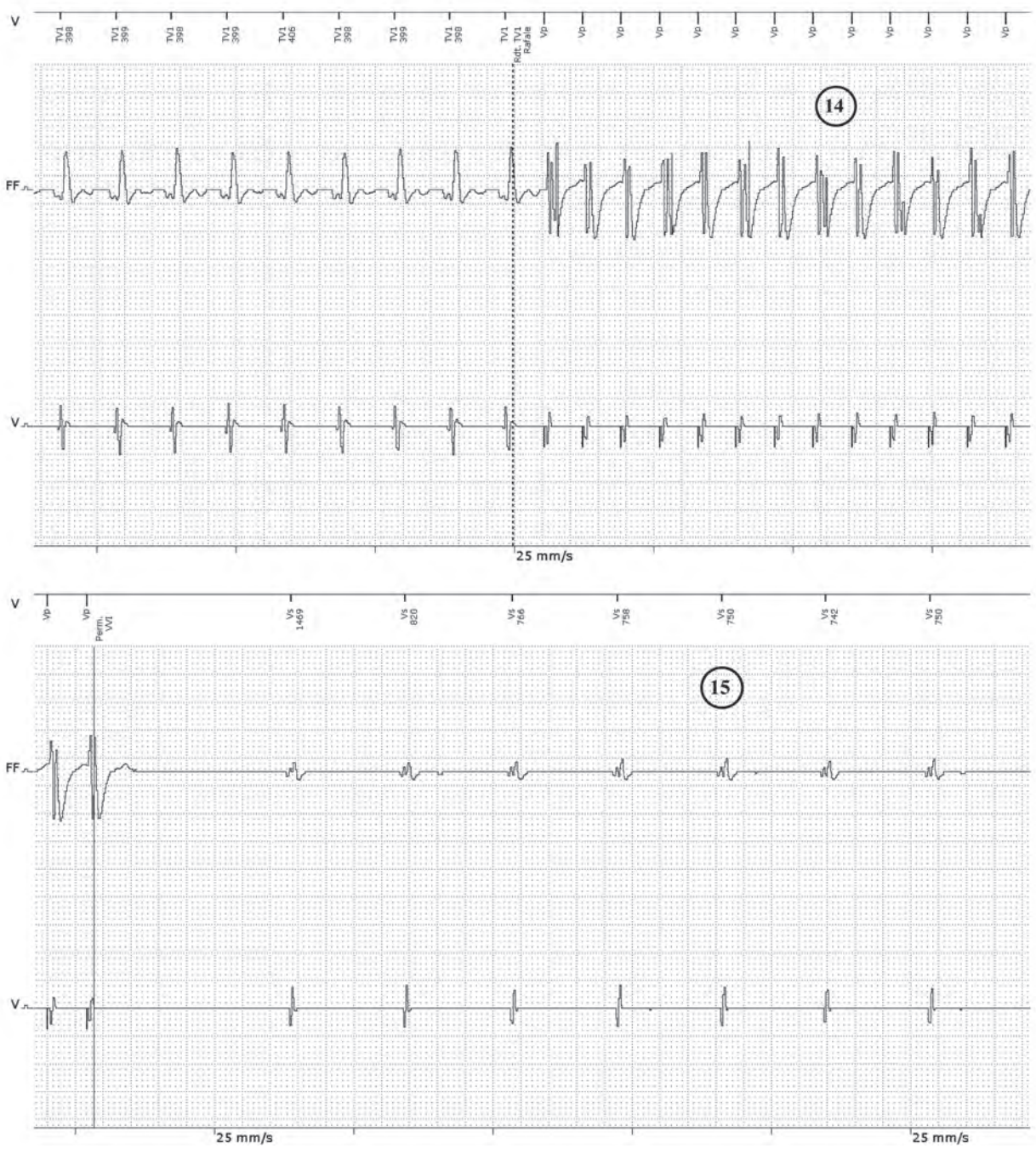
V
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TV1 Tachy
Vp
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Vs 750
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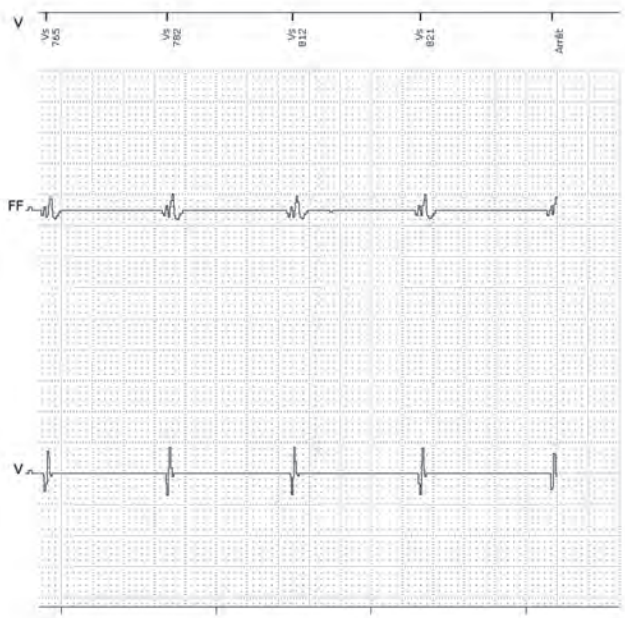

Classification

Zone		TV1	
Début soudain mesuré dans V		10 %	
Stabilité mesurée dans V		11 ms	
	TV1	TV2	FV
Redétections	5	0	0

Traitement

ATP	6
Chocs	0
Energie max.	*** J
ATP One Shot	Non

Temps

Classification	14/03/2012 00:02:32
Fin	14/03/2012 00:03:50
Durée	0:01:18
N° programme	17

Remarque

Paramètres (perm.)

Date: **02/04/2012**
Heure: **10:04**

Résumé

Classification de la tachycardie: Activé

	Fréquence	1ère ATP	2ème ATP	Chocs 1er	Chocs 2e	Chocs 3.-n
TV1	143 bpm	8×Rafale	4×Rampe	10J	40J	6×40J
TV2	176 bpm	4×Rafale	4×Rafale	10J	40J	6×40J
FV	222 bpm	Rafale		40J	40J	6×40J

Processus progressiv du traitement ON

Mode	VVI		V
Fréquence de base	35 cpn	Ampl. impulsion	2.8 V
		Durée impulsion	0.4 ms

Tracing 4: sustained VT treated par electrical shock

Patient

This 77-year-old man received a Lumax 340 HF-T triple chamber defibrillator for primary prevention in the context of ischemic cardiomyopathy with a 25% left ventricular ejection fraction and right bundle branch block; the event report (yellow color) was issued in the context of a classified VT2 with ineffective shock.

Main programmed settings

- VF zone (270 ms limit), VT2 zone (400 ms limit), VT1 zone (500 ms limit)
- 8/12 cycles in the VF zone, 16 cycles in the VT2 zone and 30 cycles in the VT1 zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.8 mV
- VF zone: one ATP one shot, followed by 8 shocks of maximum strength (40 J); VT2 zone: 3 bursts, followed by 3 bursts, followed by 1 shock at 10 J, followed by 7 shocks of maximum amplitude; VT1 zone: monitor only; no programmed therapy;
- Discrimination SMART;
- Pacing mode: DDDR 70 bpm, biventricular pacing

Remote tracing

1: VT with atrioventricular dissociation;
2: cycles alternating between VT1 and VT2 zones; it is noteworthy that the VT1 zone was programmed as monitor only; the VT1 counters were full (previous episode of VT1 retrieved at interrogation) without delivery of therapy;
3: classification of a VT2 episode;
4: 6 ATP sequences were delivered and 2 electrical shocks; the last 40-J electrical shock is visible (shock impedance = 54 Ohms); the summary table shows an initial diagnosis of VT2 with 6 ATP and reclassification to the VT2 zone, followed by 2 shocks delivered and 1 cancelled shock (2 reclassifications to the VF zone);
5: termination of the arrhythmia; the " PostSh DDI" label after the shock indicates that the defibrillator operated in the programmed DDI pacing mode for a nominal 10-sec duration;
6: end of episode after 12 consecutive cycles classified Vs or paced.

Programmer tracing (same episode)

7: first burst (10 biventricular stimuli delivered at a fixed 80% of the rate of the tachycardia);
8: unsuccessful burst and persistence of the tachycardia;
9: cycles classified RVs; as confirmation after treatment of a VT2, the cycle was classified as RVs when it fell in the VT1 zone;
10: the VT2 reclassification counter, programmed at 14, was full (before redetection: 16 cycles VT2 and 2 cycles RVs) without the end of episode counter ever being filled (12 slow out of 16 cycles);
11: second burst with 1 additional stimulus;
12: unsuccessful burst and reclassification VT2 (counter at 14);
13: third burst;
14: fourth burst;
15: fifth burst;
16: sixth burst;
17: unsuccessful therapy; the next therapy was a 10-J shock;
18: the short charge of the capacitors is marked by a dark, horizontal line for a low shock strength;
19: at the end of the charge, search for a short cycle and delivery of a 10-J electrical shock with a 56-Ohm impedance, synchronized to the R wave. In this patient, LV preceded RV and the

electrical shock is delivered during LV repolarization;
20: blanking without detection for 1 sec after the shock;
21: transformation of the rhythm to VF;
22: undersensing of the arrhythmia in the RV channel (more reliable sensing in the LV channel); it is noteworthy that the LV and RV detections are different, with different stages;
23: redetection of VF (8 cycles classified VF out of 12);
24: new charge of the capacitors;
25: at the end of the charge, search for a short cycle;
26: because of marked RV undersensing, 3 consecutive cycles are marked VDs and the shock is aborted;
27: further redetection of VF: (8 out of 12 cycles are classified VF);
28: new ultra short charge, as the capacitors had not discharged;
29: shock delivered (unconfirmed);
30: successful shock, termination of the arrhythmia and end of the episode after 12 RVs or RVp cycles.

Comments

This episode initially diagnosed in the VT2 zone triggered several consecutive therapies. The arrhythmia was not terminated by 6 bursts, which were followed by a first 10-J shock. The first shock, in the VT zone, may be arbitrarily programmed at low strength to terminate the tachycardia, while limiting the pain it causes. This is an effective programming for a majority of episodes of organized VT. On the other hand, the delivery of a low-strength shock increases the risk of being below the upper limit of vulnerability. This patient presented with episodes of VT of LV origin (LV preceding RV EGM). The electrical shock was synchronized to RV sensing (30 ms later). On this type of arrhythmia, the EGM suggests that the shock was delivered in the beginning of the phase of LV repolarization. The delivery of a shock of moderate strength during the LV vulnerable period explains the arrhythmogenic properties of the shock and the transformation of the arrhythmia to VF.
An alternative solution is the programming of a first shock of maximum strength, to increase the likelihood of terminating VT in a first attempt, to minimize the number of shocks delivered and to be above the upper limit of ventricular vulnerability at the cost of more discomfort. Electrical shocks usually terminate the arrhythmias and are the primary treatment of defibrillators. However, the shock may be arrhythmogenic and, as in this patient, transform an organized VT to potentially lethal VF. Sensing, during this episode of VF, was imperfect: the diagnosis was moderately delayed and, above all, the diagnosis of return of sinus rhythm was inaccurate and the charge temporarily interrupted. Sensing improved later, enabling the arrhythmia termination by an electrical shock. RV sensing had been programmed on "enhanced T wave suppression" without prior oversensing of the T wave. LV sensing was on "Standard". In this patient, standard RV sensing needed to be programmed, or even an enhanced detection of VF. The efficacy of the new programming could later be confirmed by induction of VF and verification of its proper detection.

Status report - Oct 2, 2010

To: Service Télécardiologie

BIOTRONIK
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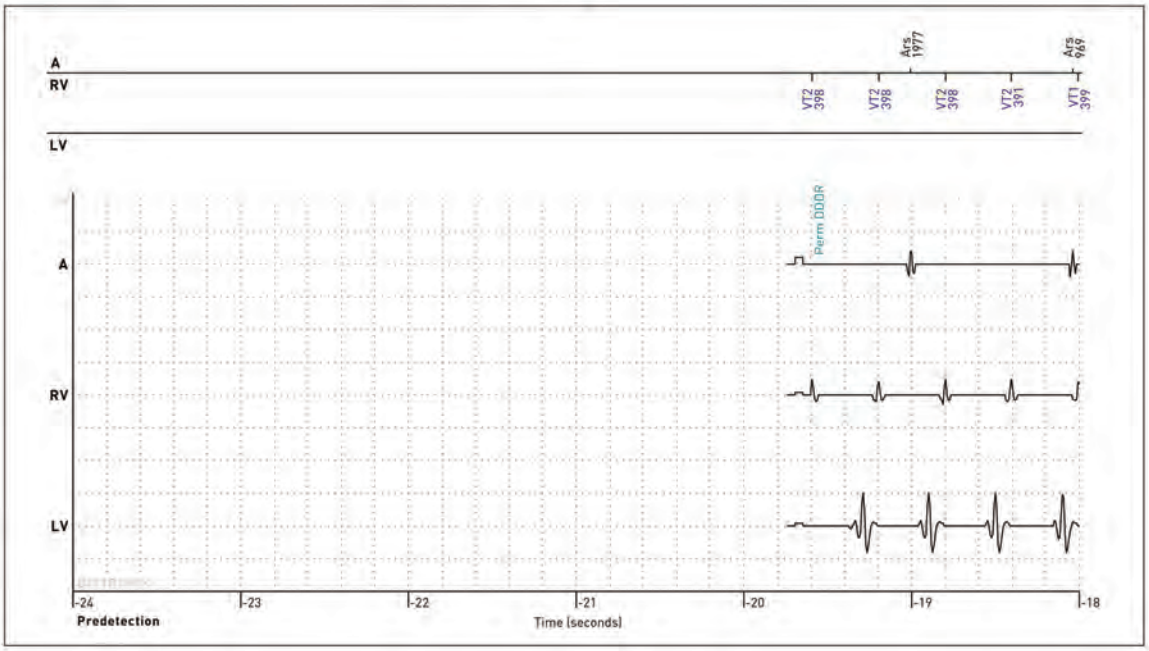
Name:	DOB:	Lumax 340 HF-T	Last message: Oct 3, 2010
Patient ID:	Phone: -	CRT-D implanted Jul 23, 2009	Last clinic follow-up: Sep 27, 2010

Recordings

Recordings - Episode 10322:

General	
Episode number	10322
Episode type	VT2
Detection	Oct 2, 2010 10:24:56 AM
Termination	Oct 2, 2010 10:27:02 AM
Duration	2min 6s
Device settings no.	75
Detection	
Mean PP at initial detection [ms]	1686
Mean RR at initial detection [ms]	394
Onset [%]	45
Stability [ms]	5
Redetection	VT2: 6, VF: 2

Therapy	
ATP in VT/VF delivered	6
ATP One Shot delivered	NO
Shocks delivered	2
Shocks aborted	1
Maximum energy [J]	40
Termination	
Mean PP at termination [ms]	992
Mean RR at termination [ms]	985
Remark	
Therapy	first shock ineffective, progressive course of therapy (PCOT) applied, surge guard applied



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1/4

Status report - Oct 2, 2010

To: Service Télécardiologie

BIOTRONIK
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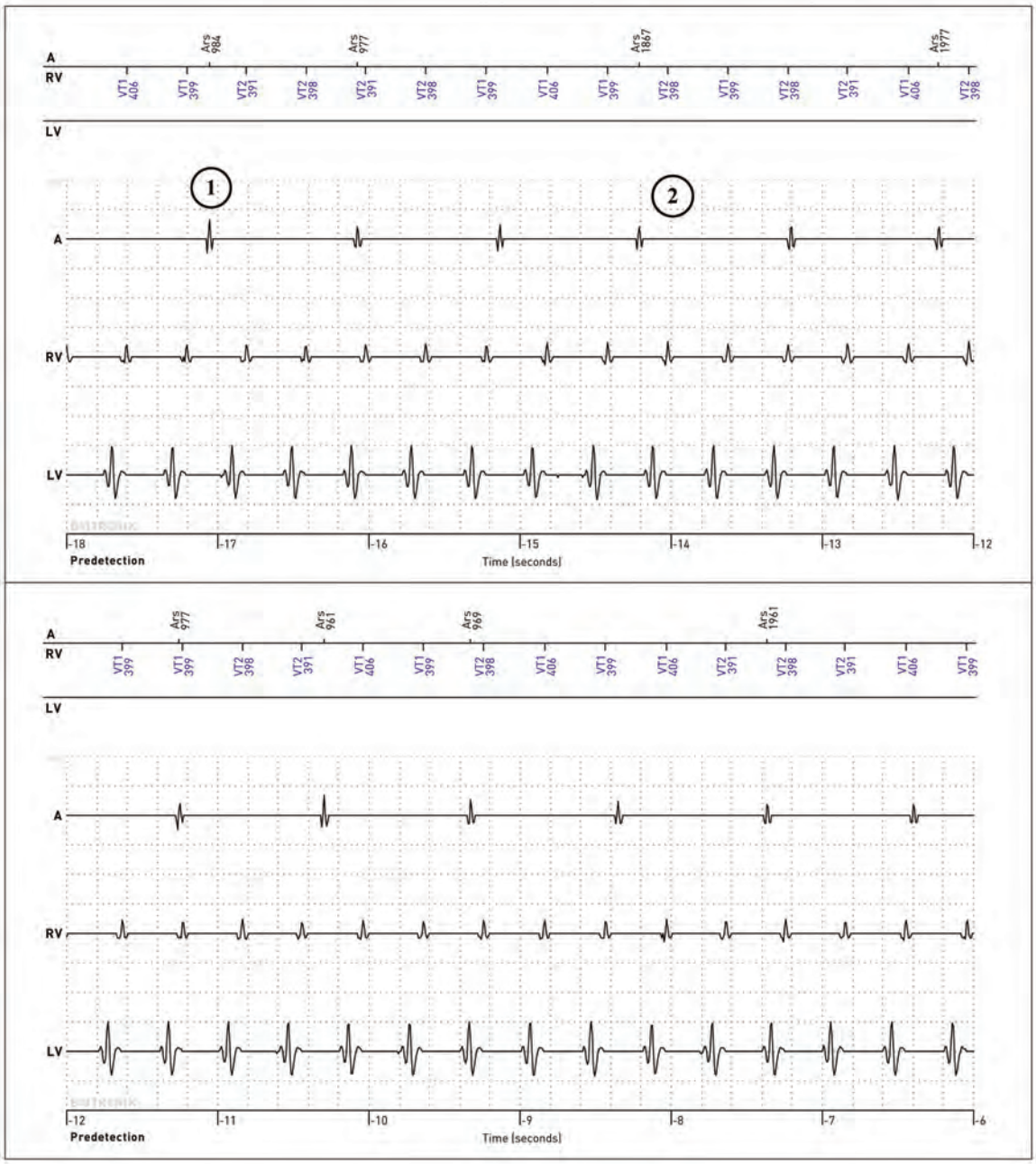
Name:	DOB:	Lumax 340 HF-T	Last message: Oct 3, 2010
Patient ID:	Phone: -	CRT-D implanted Jul 23, 2009	Last clinic follow-up: Sep 27, 2010



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Date:

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Status report - Oct 2, 2010

To: Service Télécardiologie

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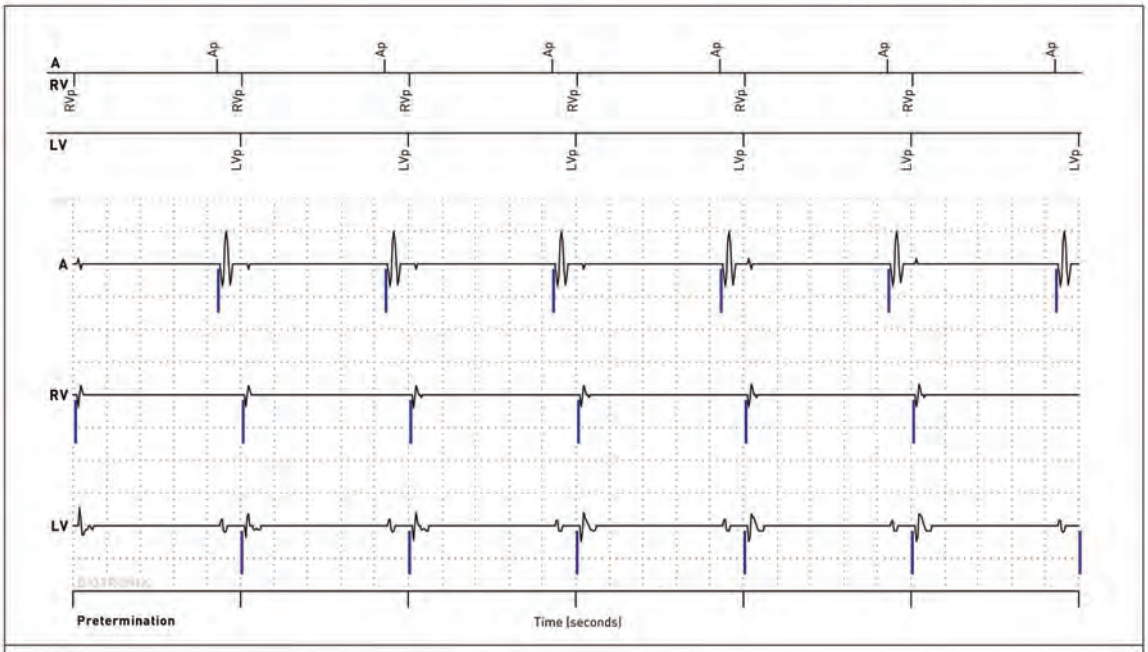
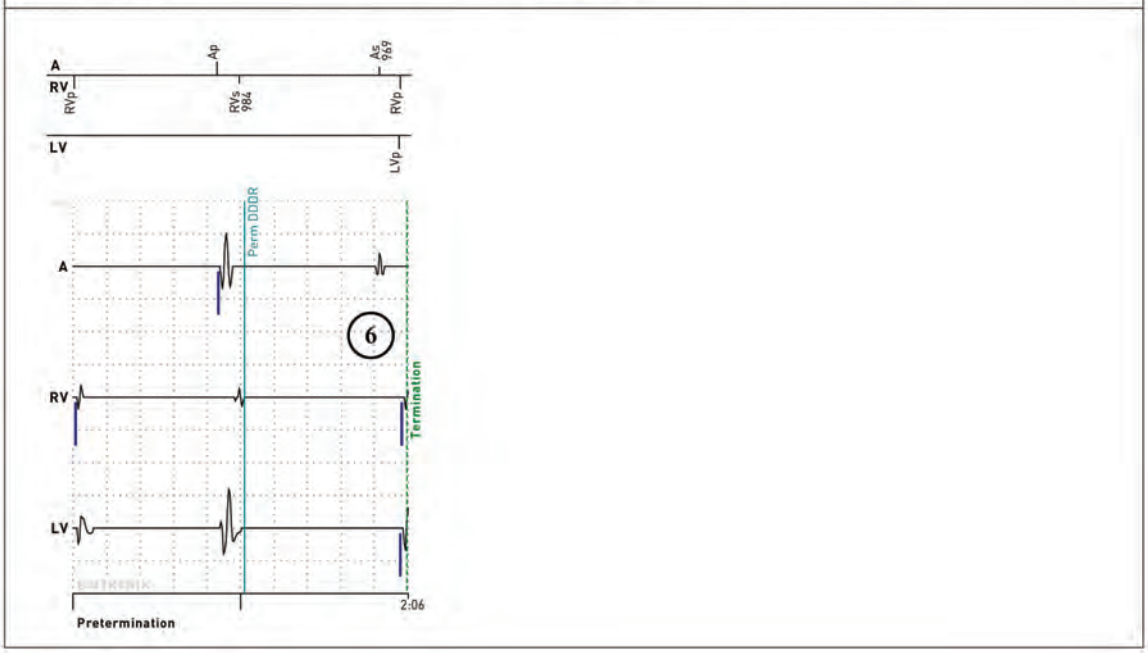
Name:	DOB:	Lumax 340 HF-T	Last message: Oct 3, 2010
Patient ID:	Phone: -	CRT-D implanted Jul 23, 2009	Last clinic follow-up: Sep 27, 2010





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Date:

Signature:

4/4

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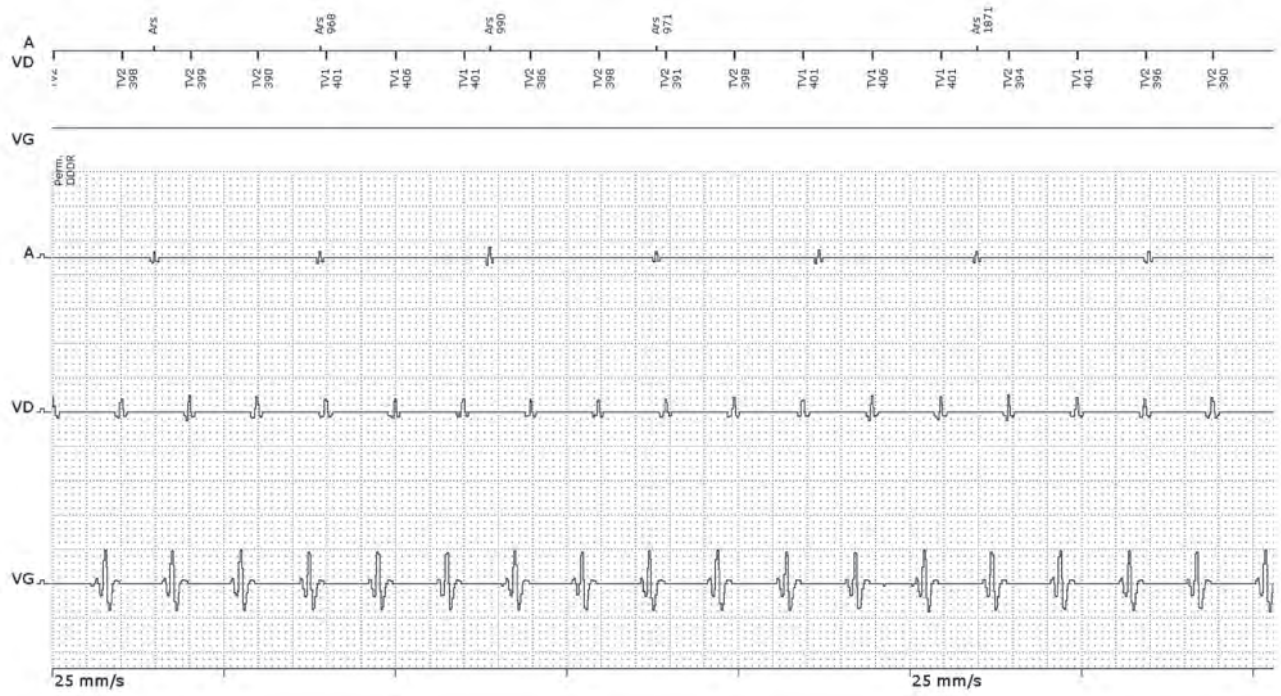

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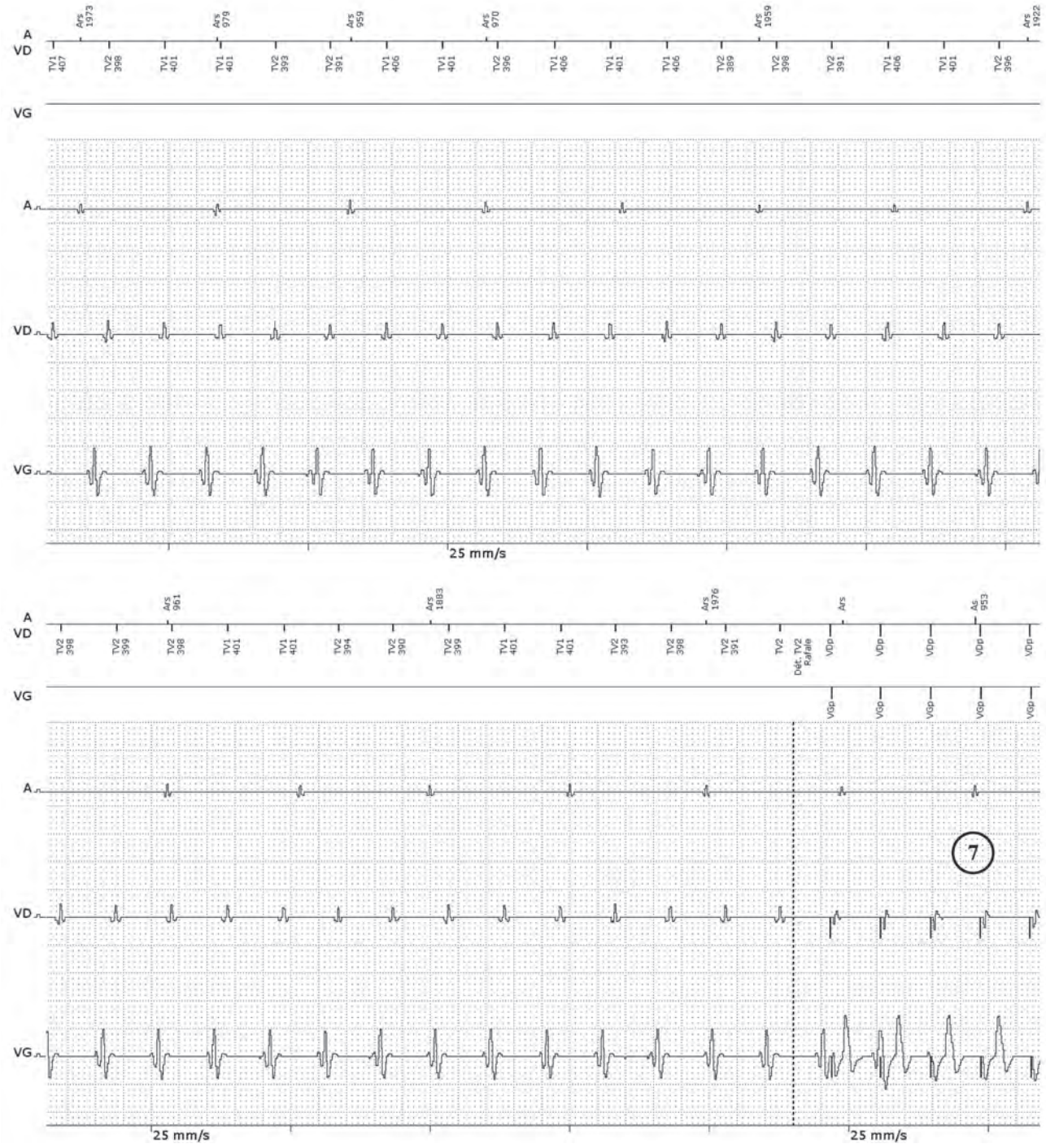

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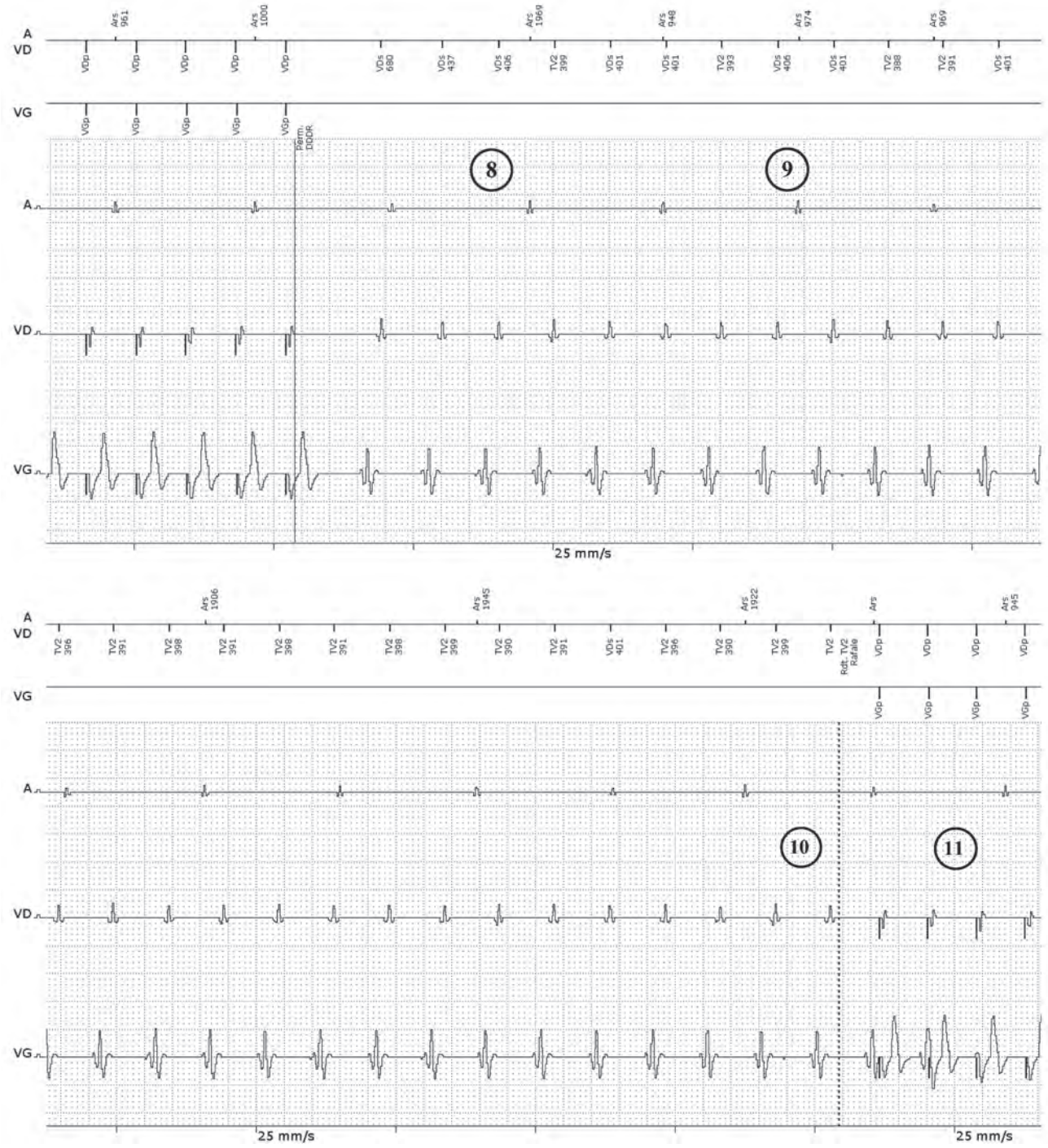

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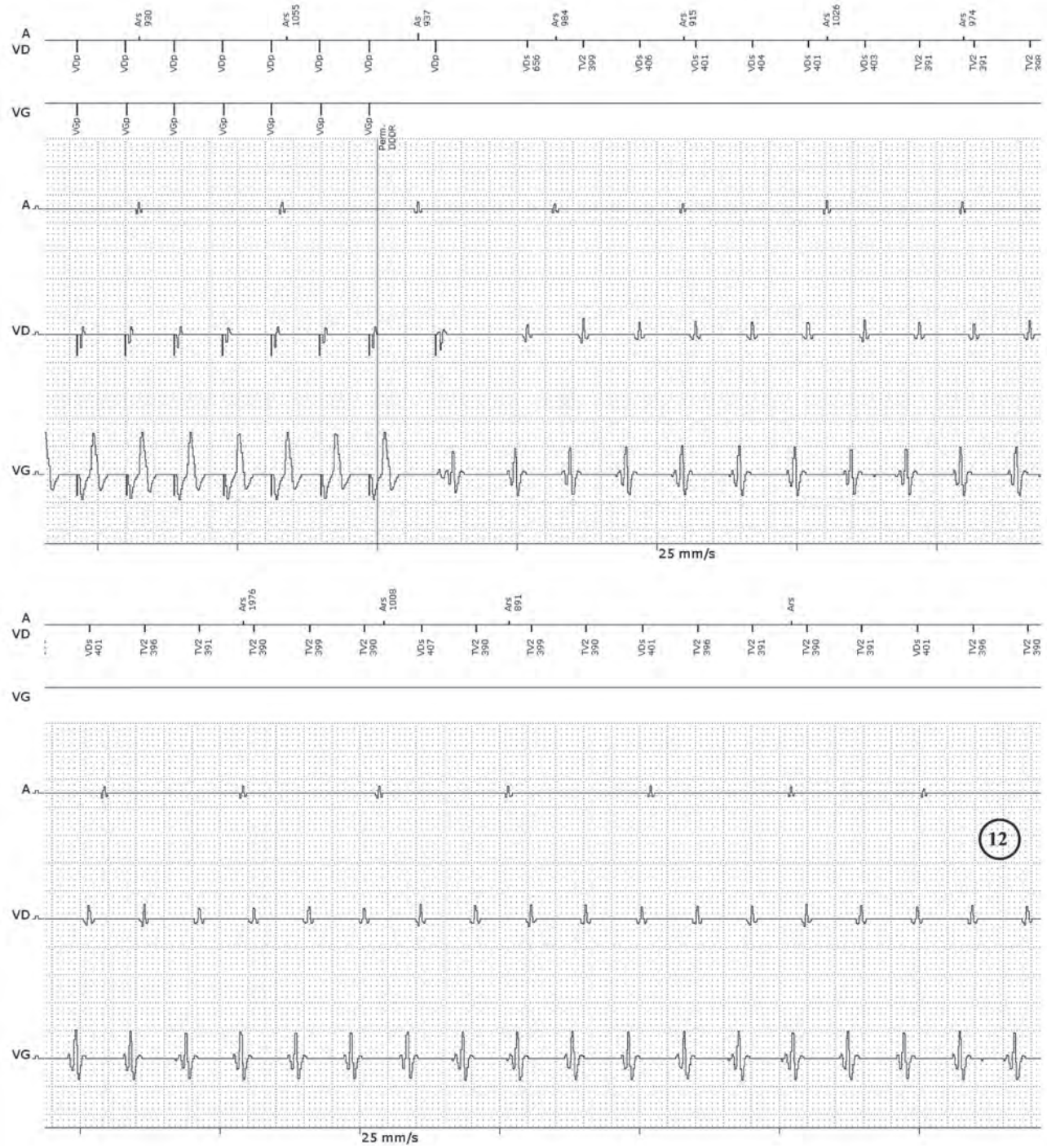

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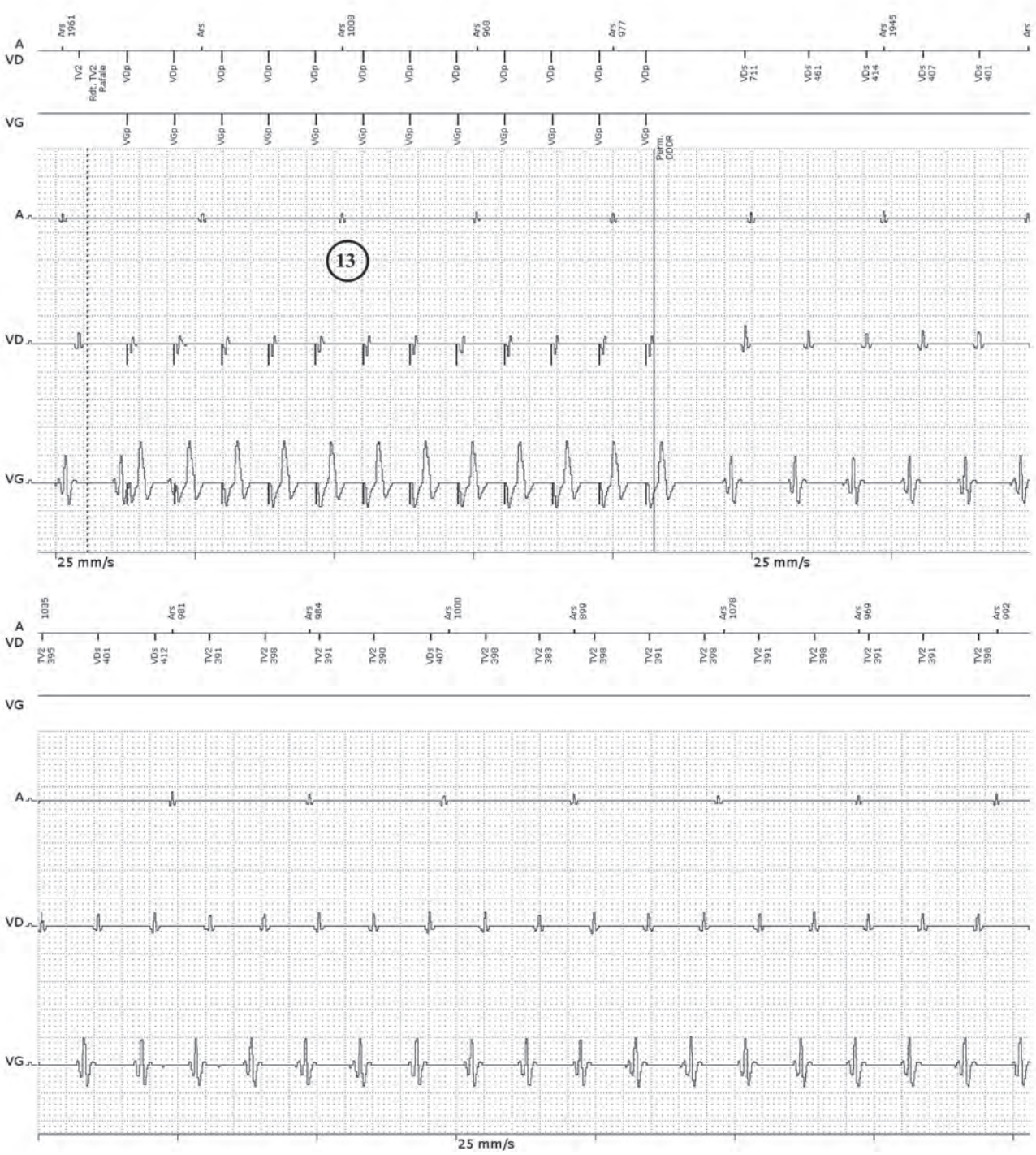

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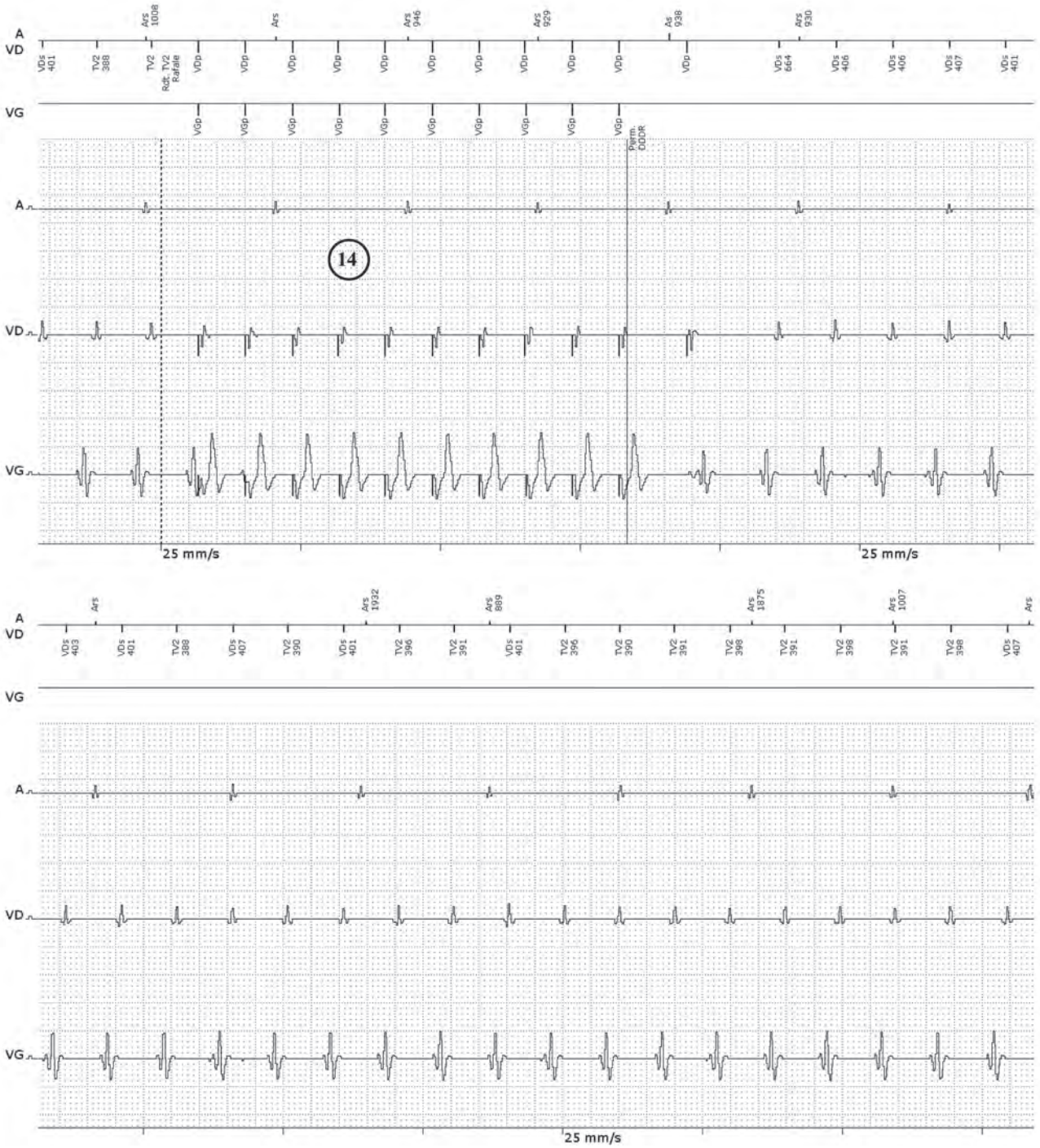

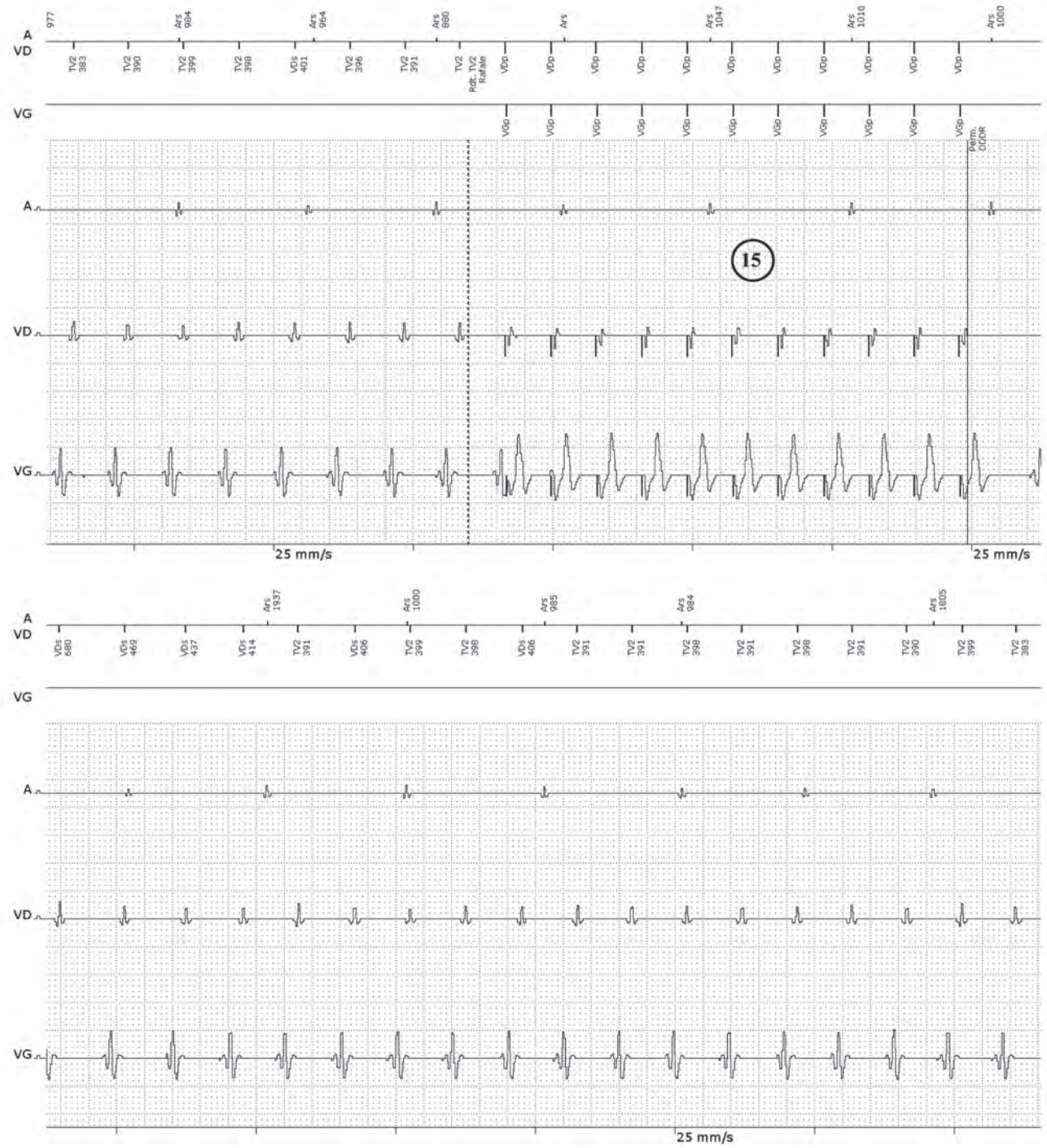
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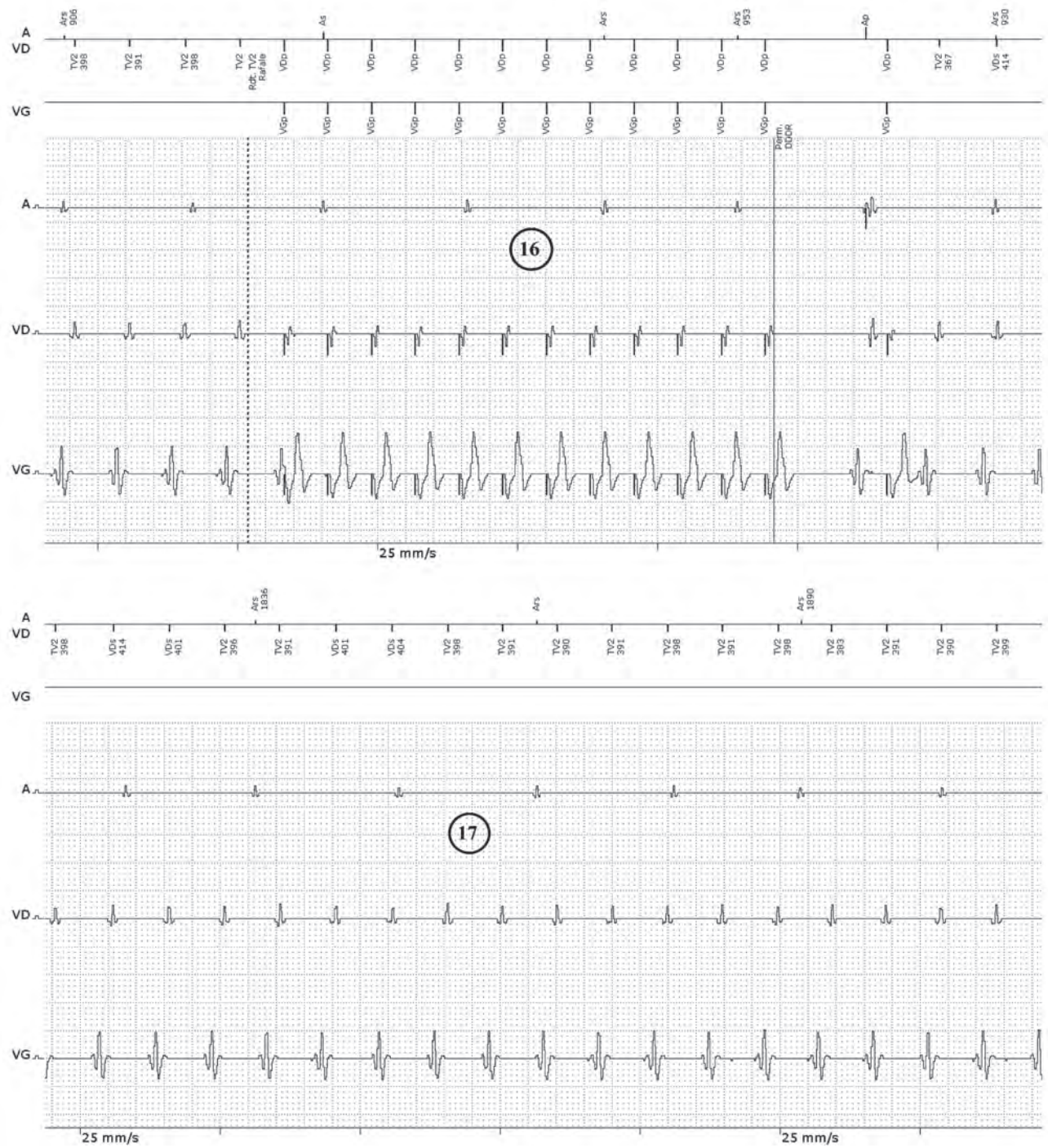
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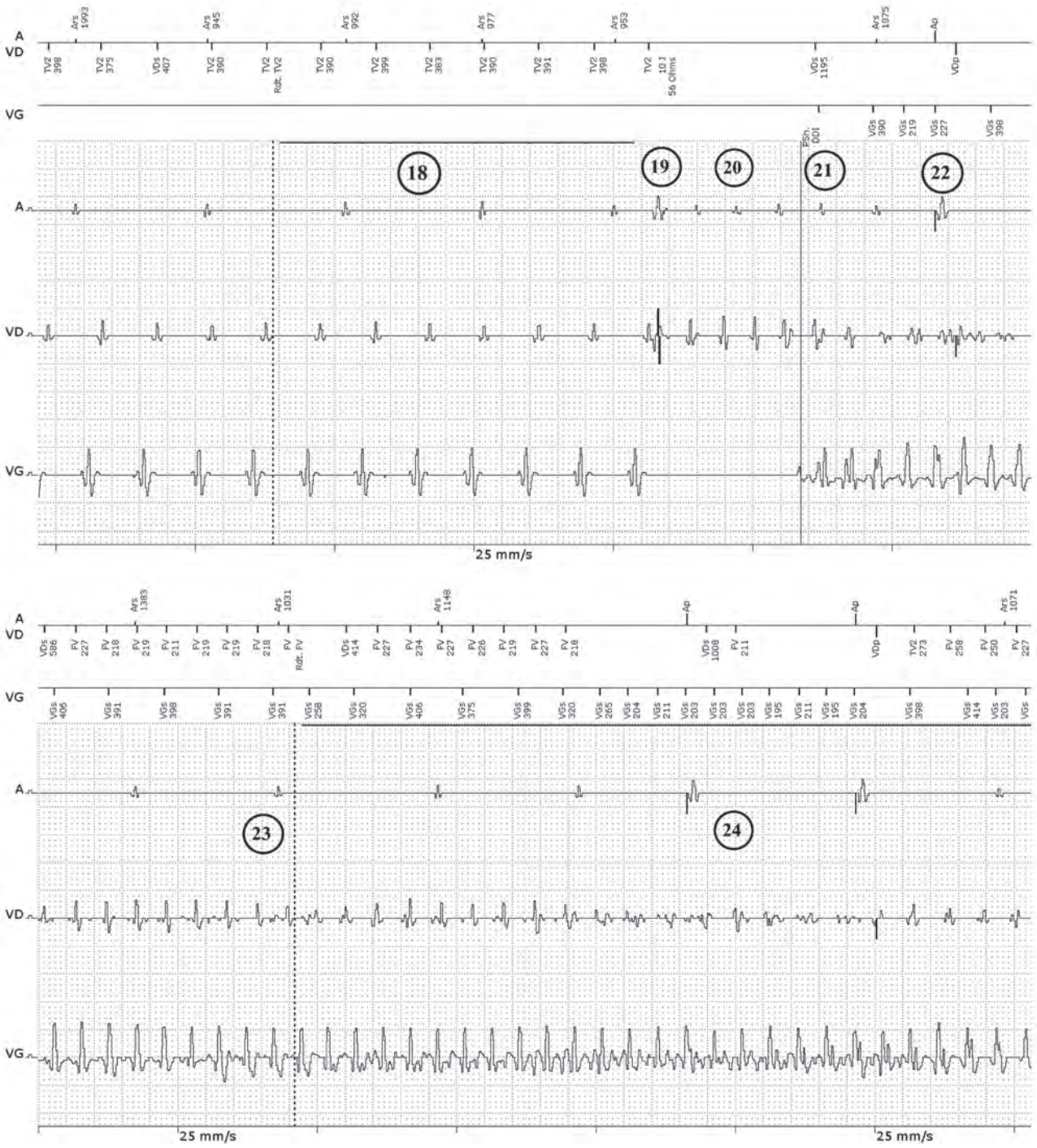

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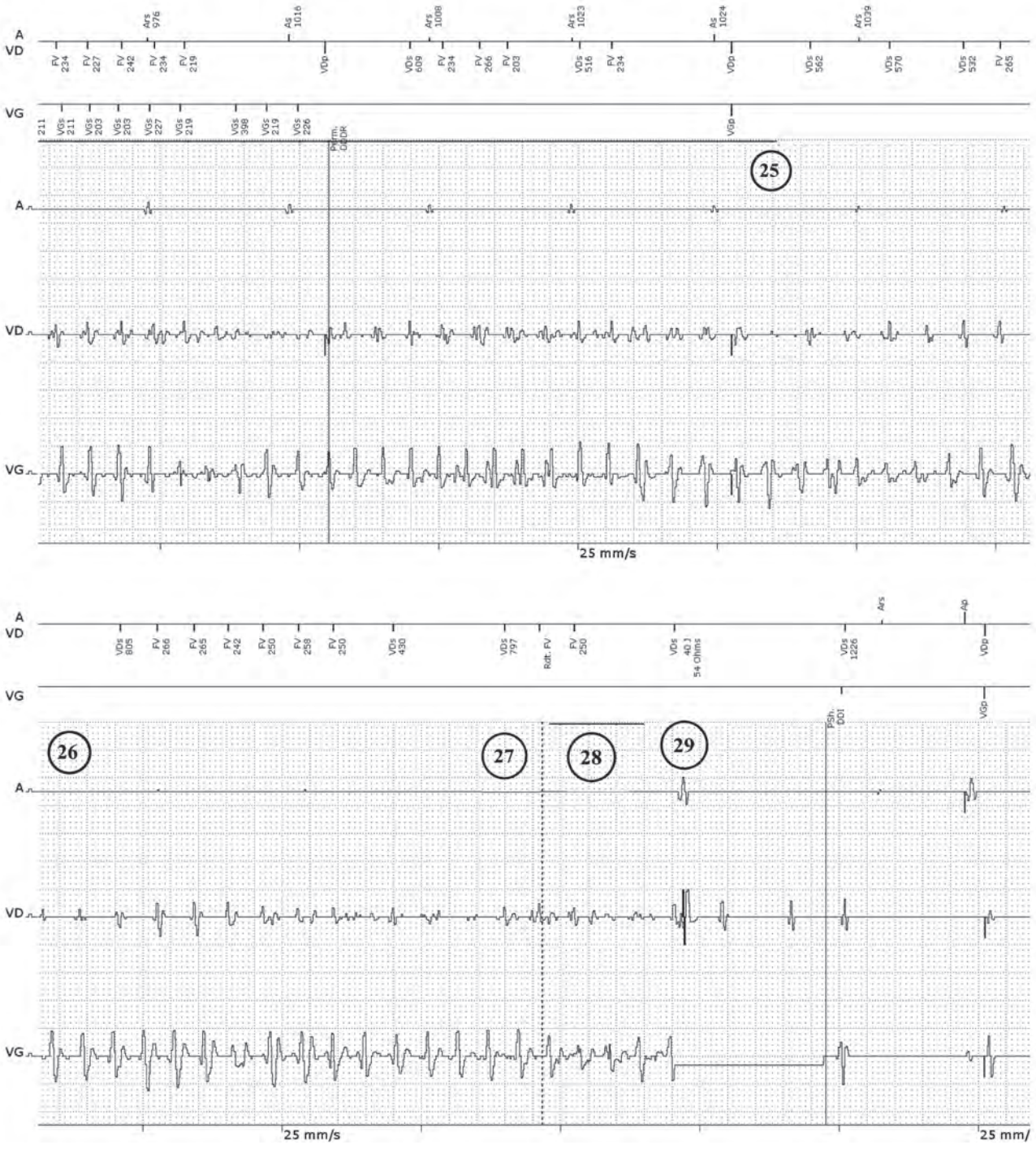

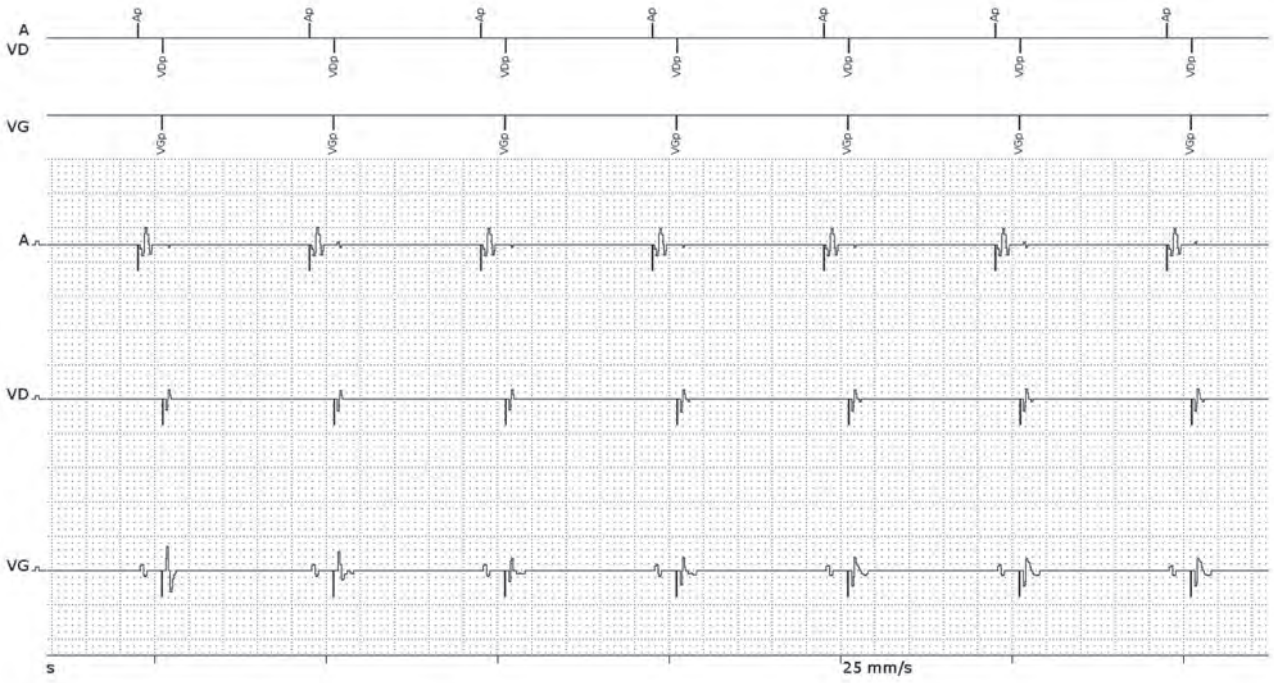
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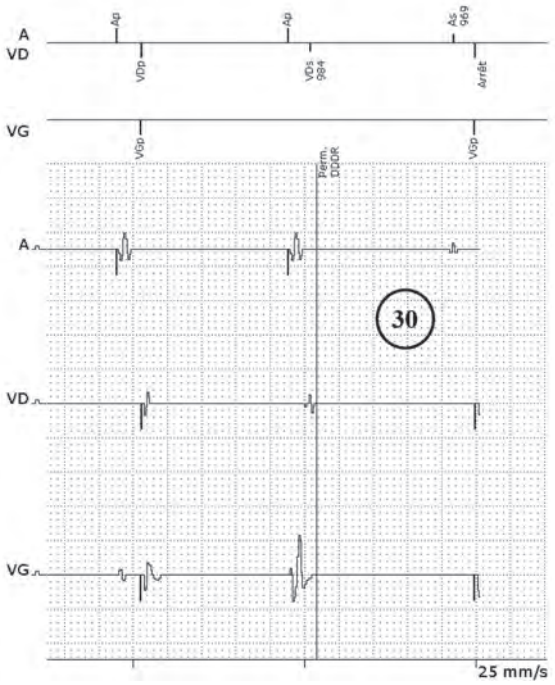
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Tracing 5: VF treated by an electrical shock

Patient

This 31-year-old man received a Lumax 340 VR-T single chamber defibrillator for the management of Brugada syndrome and history of aborted sudden death; he suffered a syncopal episode and an event report (yellow color) was issued in the context of a classified VF.

Main programmed settings

- VF zone (270 ms limit), VT1 zone (330 ms limit)
- 8 /12 cycles in the VF zone and 10 cycles in the VT1 zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.8 mV
- VF zone: 8 shocks of maximum strength (40 J); VT1 zone: monitor only; no therapy programmed;
- Pacing mode: VVI at 30 bpm

Remote tracing

The 3 channels available are: 1) the markers with the time intervals, 2) the shock channel (FF = far field) between the coil of the RV lead and the pulse generator, and 3) the RV sensing channel.

1: spontaneous rhythm;
2: VES;
3: irregular, polymorphous tachycardia with ultra short cycles detected in the VF zone;
4: classification of the episode in the VF zone after 8 cycles classified VF (the counter was 8/12 filled); the average RR at the time of initial detection (167 ms) is the average of 4 cycles preceding the diagnosis, consistent with an extremely rapid tachycardia (>350 bpm); in the VF zone the stability and sudden onset criteria were analyzed though were not integrated in the discrimination (no discrimination other than the rate in that zone);
5: 40-J electrical shock;
6: termination of the arrhythmia;
7: end of the episode after 12 consecutive cycles classified Vs (12/16 Vs cycles); the average RR at the end of the episode (660 ms) corresponds to the average of 4 cycles preceding the end of the episode;

Programmer tracing (same episode)

The 3 channels are the same as for the remote tracing.

8: after the classification in the VF zone, the onset of the charge of the capacitors (dark horizontal line); continuation of the polymorphous and rapid arrhythmia during the charge;
9: end of the charge;
10: at the end of the charge, one ventricle is not sensed; this is, however, not due to undersensing. This ventricular event fell in the blanking period, 50 ms after the end of the charge. The defibrillator was looking for a short cycle at the end of the charge, and had to wait to deliver the shock on the next Vs classified cycle;
11: cycle classified VF and delivery of a 40-J and 53-Ohm impedance;
12: successful shock and termination of the arrhythmia.

Comments

The main function of a defibrillator is to prevent sudden death and terminate VF with an electrical shock. This tracing illustrates the normal function of a defibrillator. The episode, diagnosed in the VF zone was properly detected and successfully treated with an electrical shock. The arrhythmia was immediately extremely rapid, polymorphous and disorganized. Any attempt at terminating this type of arrhythmia by ATP seemed futile, and an electrical shock was the therapy of choice. No discrimination of the arrhythmia origin is attempted in this rate range, despite the attempts by the device to find stability and sudden onset values. It is, however, noteworthy, that a stability analysis is applied in the

decision to deliverer an ATP one shot. A series of defibrillating shocks is usually programmed in the VF zone. The strength of the first shock is programmed either at the maximum capable by the device (as in this case), or at a strength 10-J lower, or at a lower strength tested after the implant procedure. The higher the strength of the first shock, the longer the charge time and the longer the time between the onset of arrhythmia and the delivery of the shock. In this patient, the delay between the onset of arrhythmia and the shock was 14 sec, explaining the occurrence of syncope. The following shocks are usually programmed at a maximum strength. In the Biotronik defibrillators, the maximum number of shocks delivered for a given episode is limited to 8, with the last 6 necessarily at maximum strength. The likelihood of a successful shock after 8 failed attempts at maximum strength is, indeed, very low. The shock polarity (positive versus negative) can be alternated, starting with the first shock at maximum strength. On the other hand, the number of shocks must be limited in order to avoid a disastrous situation during the delivery of a series of inappropriate therapies.

Status report - Sep 23, 2011

To: Service Télécardiologie

BIOTRONIK
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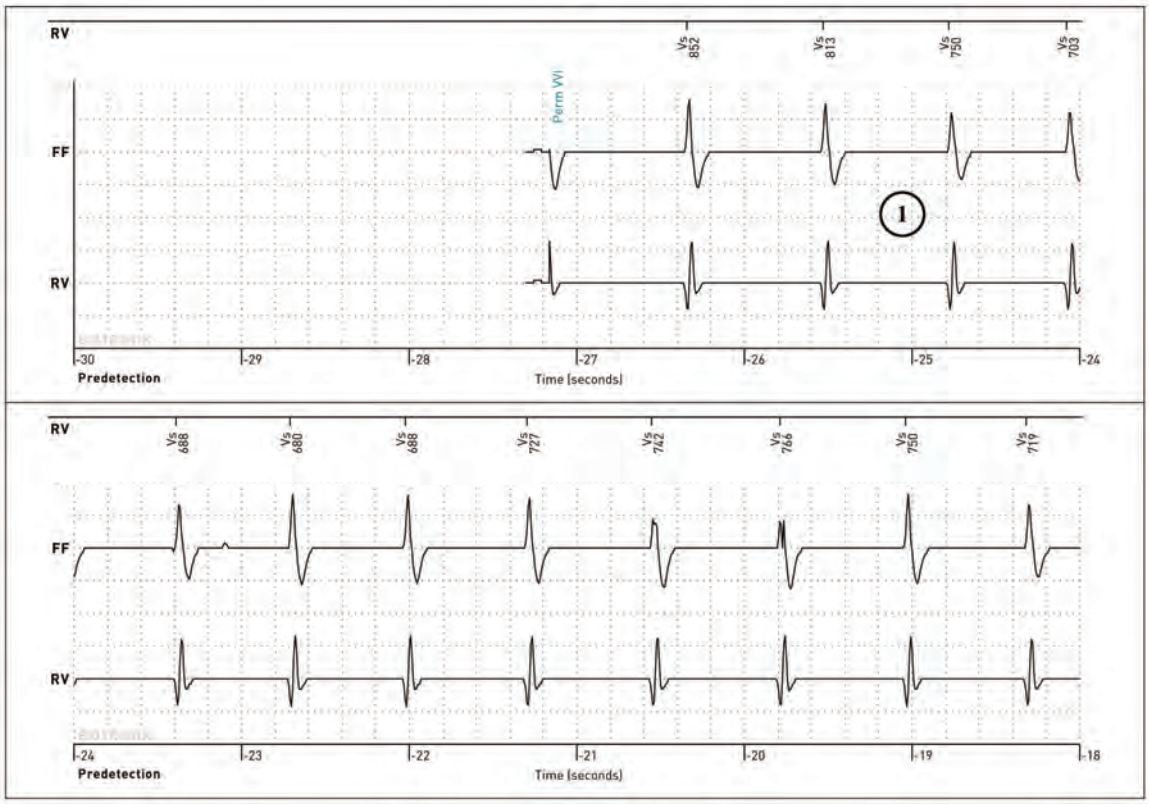
Name:	DOB:	Lumax 340 VR-T [XL]	Last message: Sep 23, 2011
Patient ID:	Phone: -	ICD implanted Jul 22, 2008	Last clinic follow-up: Nov 18, 2010

Recordings

Recordings - Episode 13:

General		Therapy	
Episode number	13	ATP in VT/VF delivered	0
Episode type	VF	ATP One Shot delivered	NO
Detection	Sep 23, 2011 11:27:57 PM	Shocks delivered	1
Termination	Sep 23, 2011 11:28:18 PM	Shocks aborted	0
Duration	21s	Maximum energy [J]	40
Device settings no.	13	**Termination**	
Detection		Mean RR at termination [ms]	660
Mean RR at initial detection [ms]	167	**Remark**	
Onset [%]	67, fulfilled	none	
Stability [ms]	19		
Redetection	---		



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Status report - Sep 23, 2011

To: Service Télécardiologie

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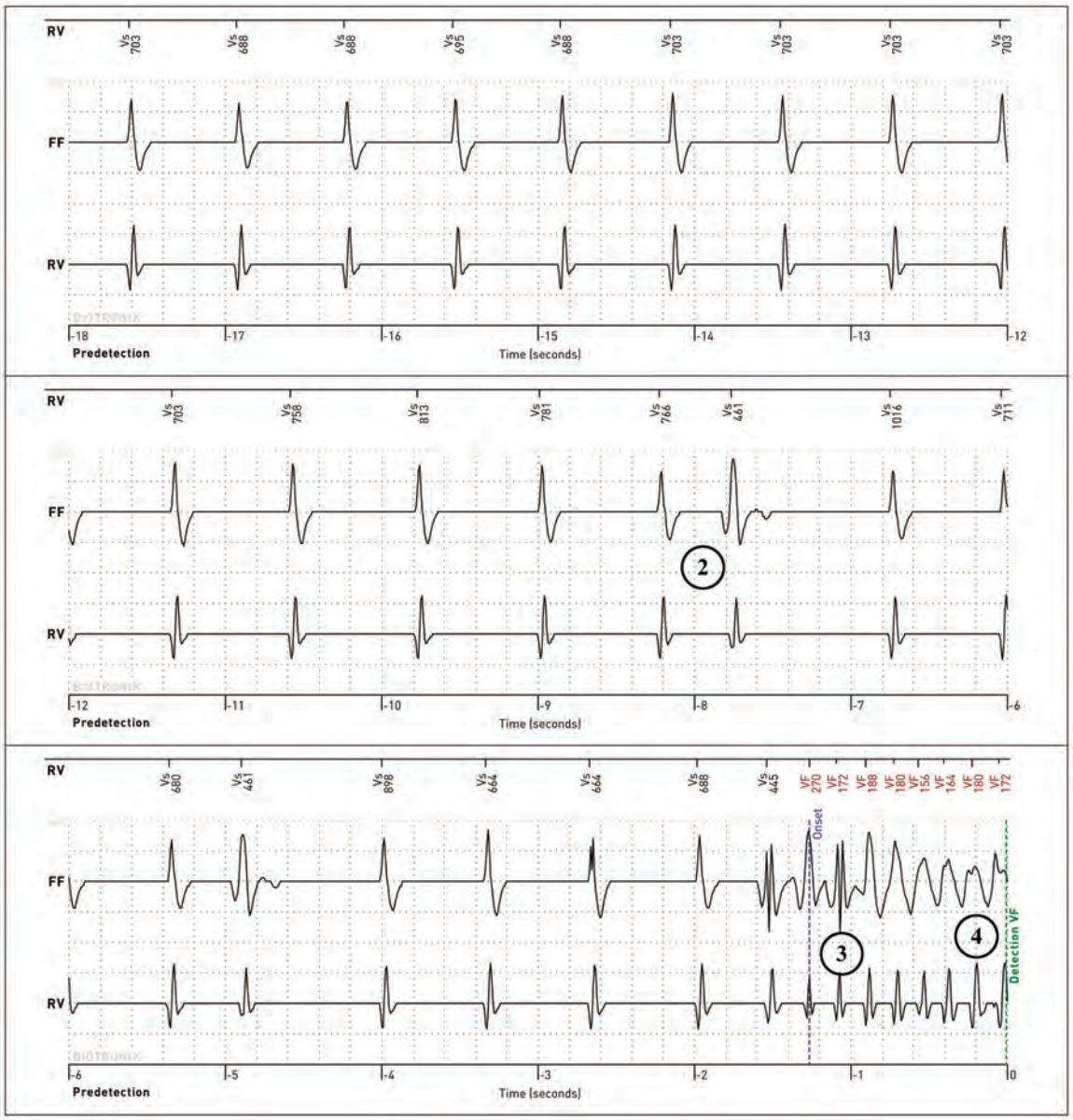
Name:	DOB:	Lumax 340 VR-T [XL]	Last message: Sep 23, 2011
Patient ID:	Phone: -	ICD implanted Jul 22, 2008	Last clinic follow-up: Nov 18, 2010



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Status report - Sep 23, 2011

To: Service TélécØrdiologie

BIOTRONIK
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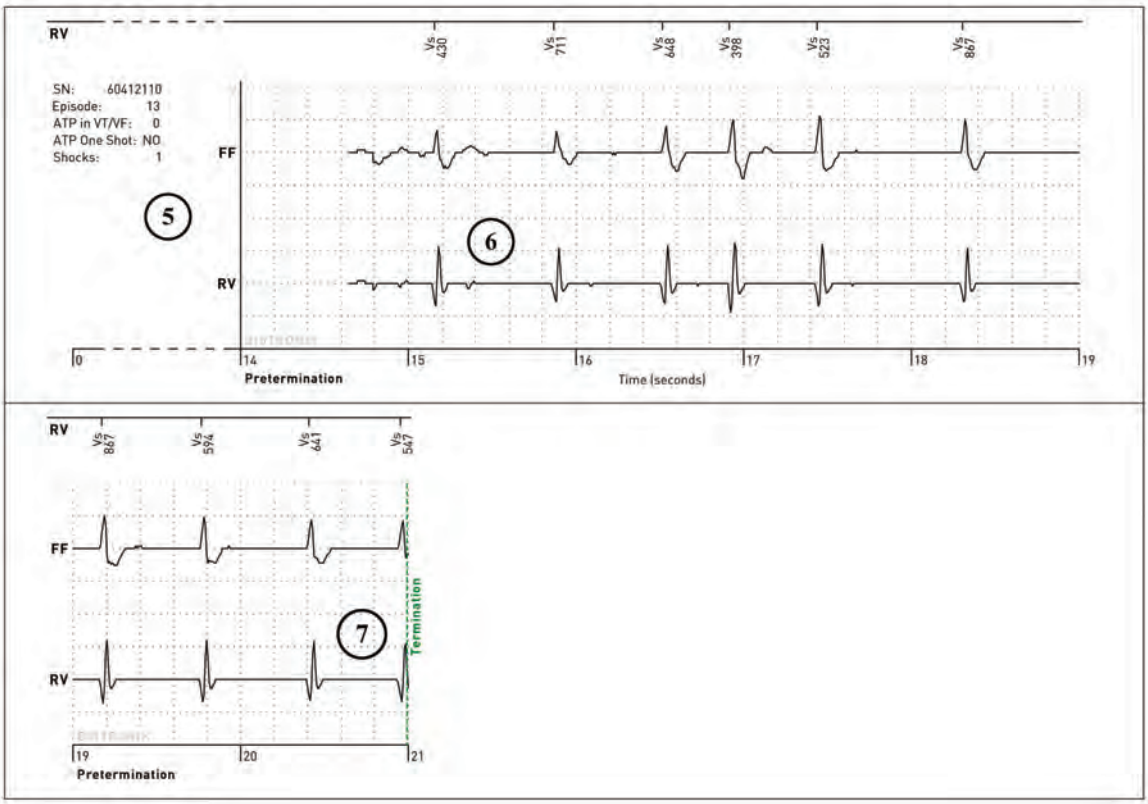
Name:	DOB:	Lumax 340 VR-T (XL)	Last message: Sep 23, 2011
Patient ID:	Phone: -	ICD implanted Jul 22, 2008	Last clinic follow-up: Nov 18, 2010



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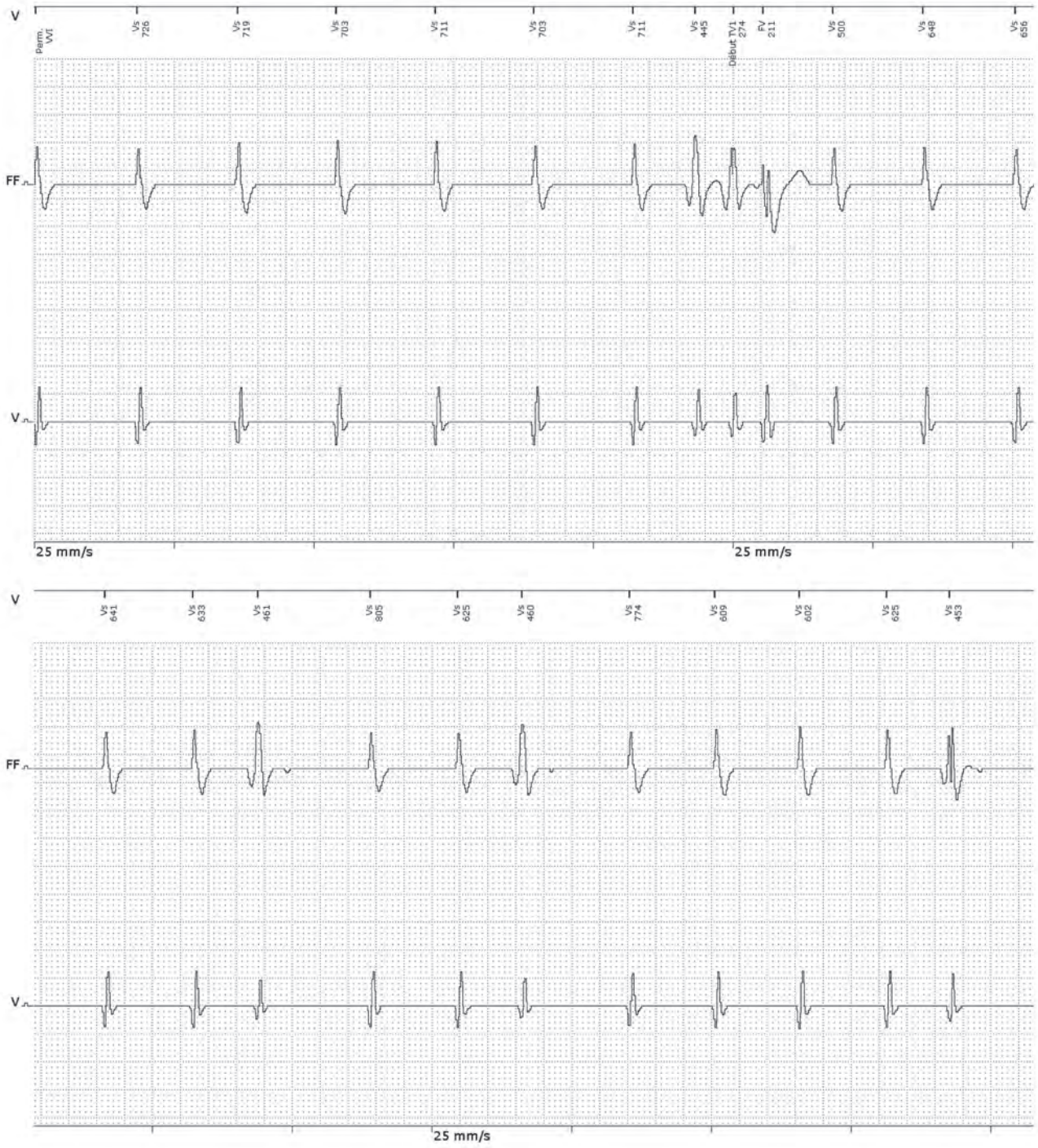
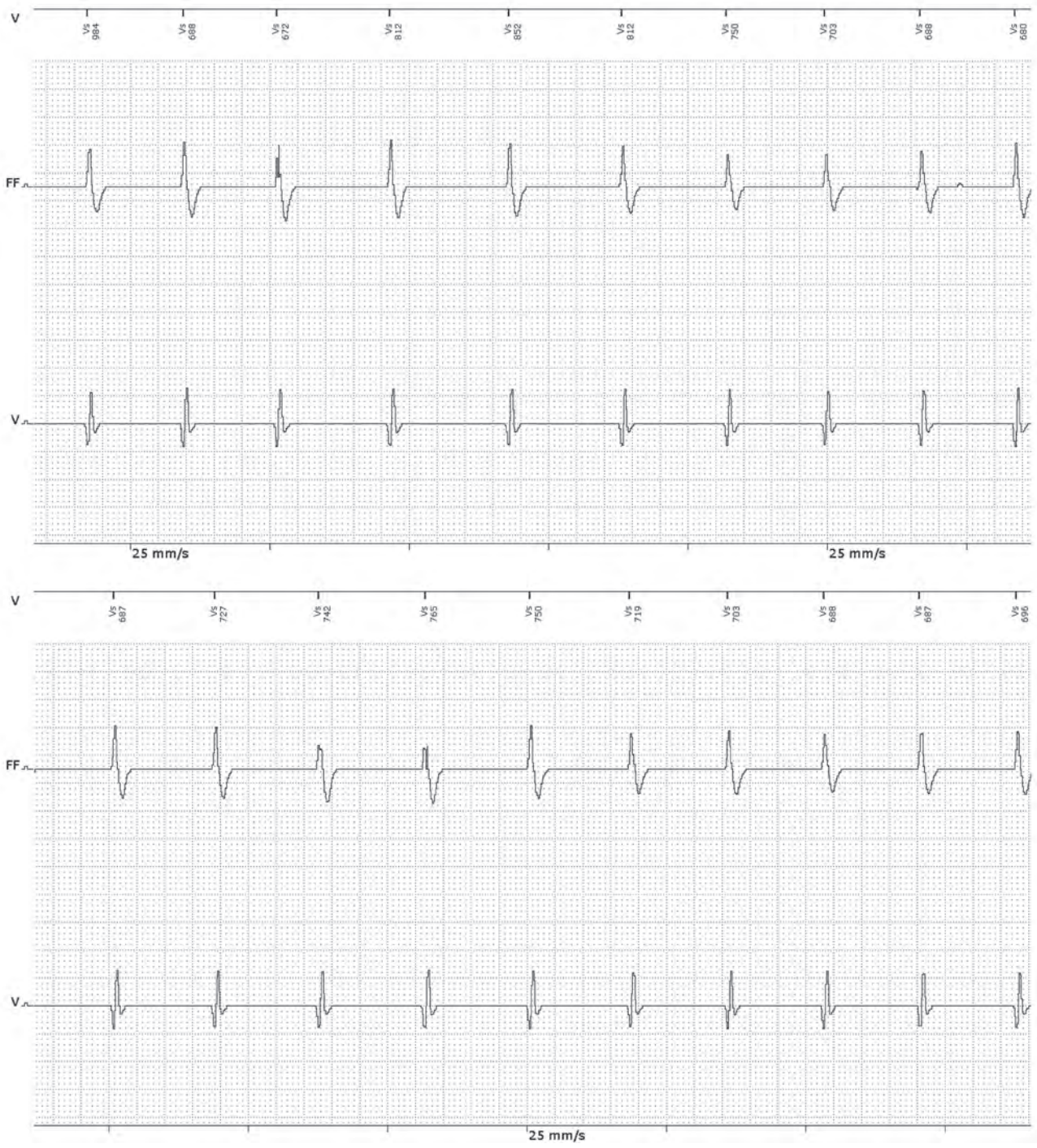
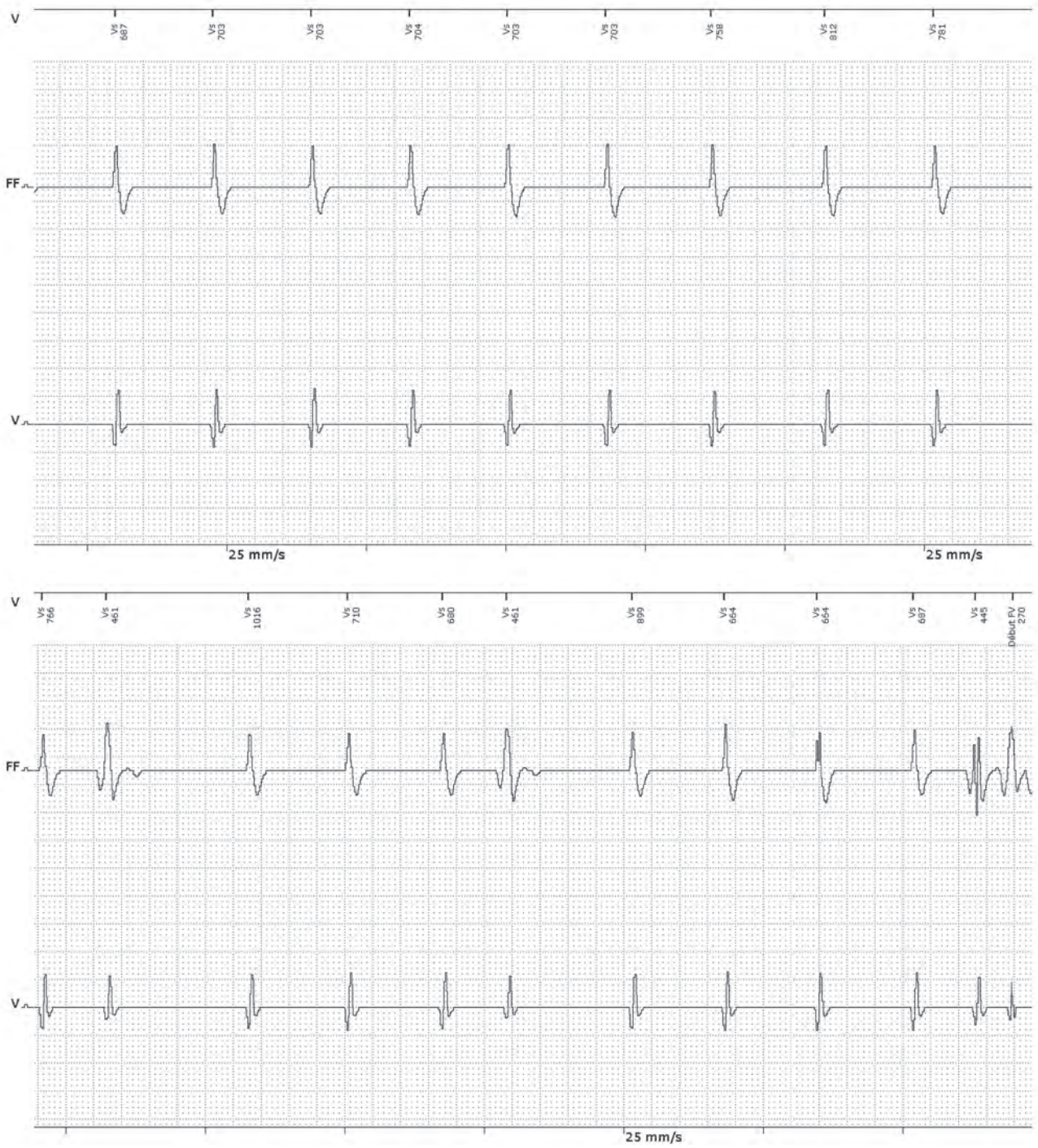
PDF: BIOTRONIK - Lumax 340 VR-T - 9 / 14

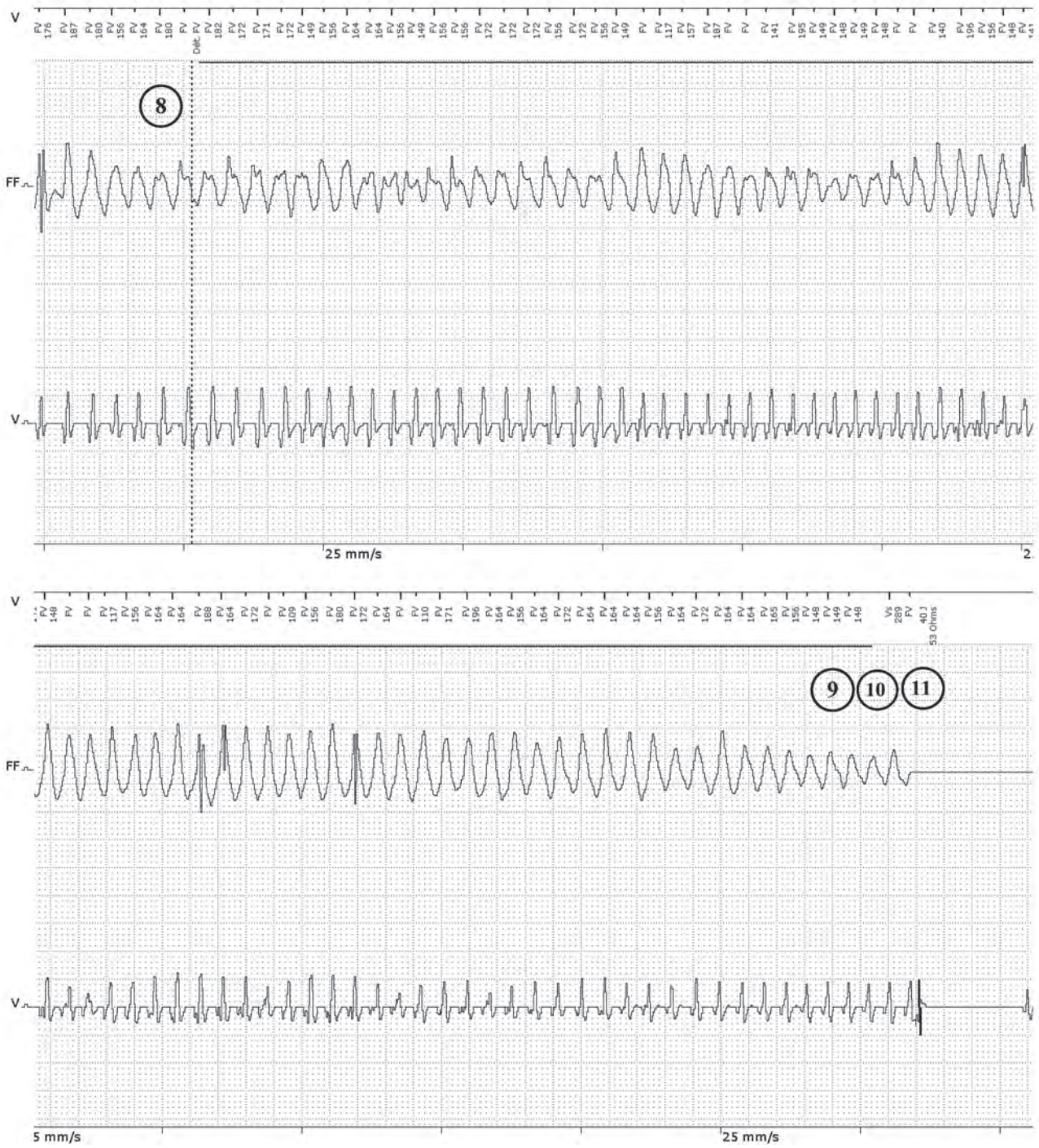


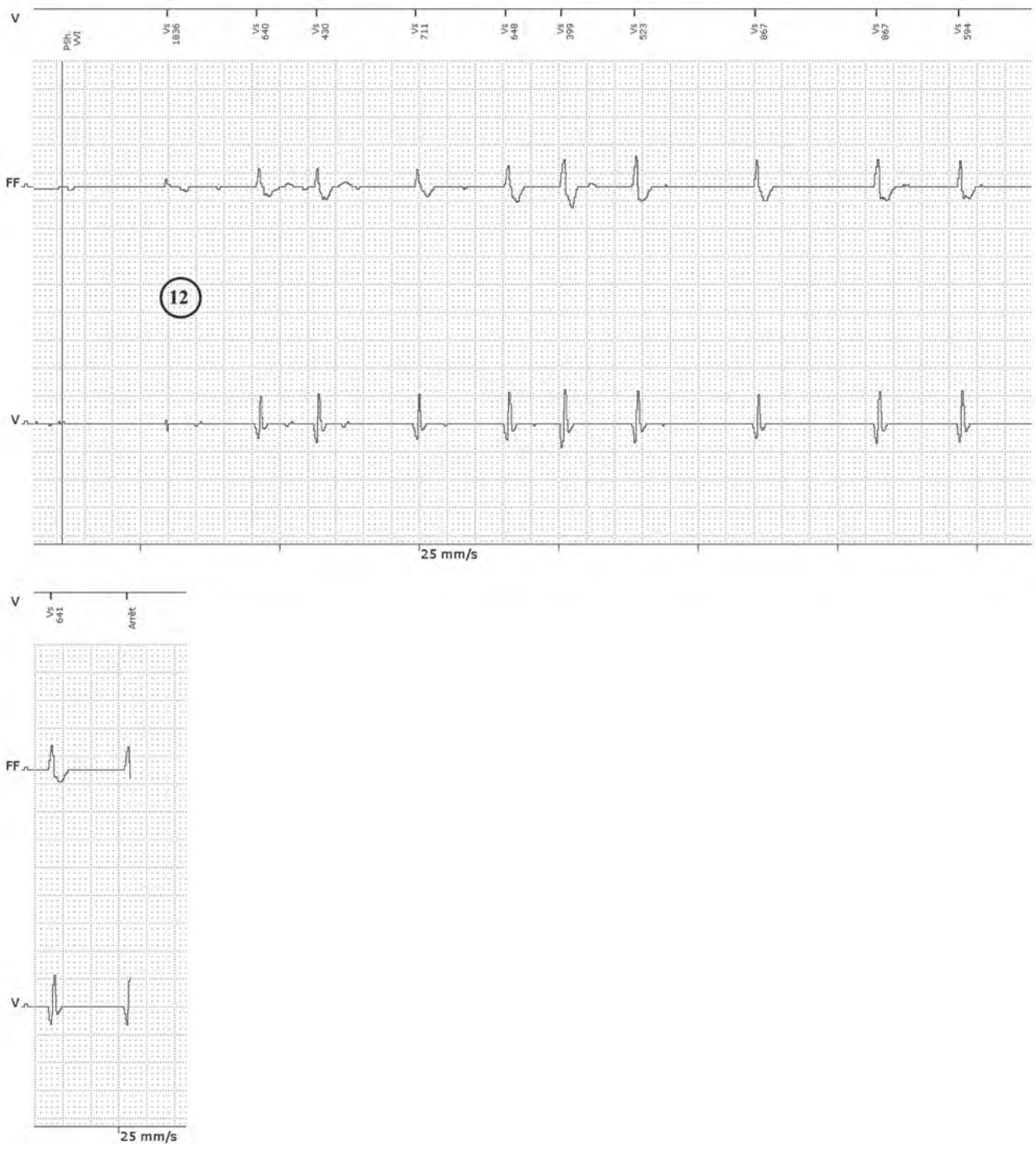

V
Vs 984
Vs 688
Vs 672
Vs 812
Vs 852
Vs 812
Vs 750
Vs 703
Vs 688
Vs 680
FF
V
25 mm/s
25 mm/s
V
Vs 687
Vs 727
Vs 742
Vs 765
Vs 750
Vs 719
Vs 703
Vs 688
Vs 687
Vs 696
FF
V
25 mm/s

PDF: BIOTRONIK - Lumax 340 VR-T - 11 / 14



PDF: BIOTRONIK - Lumax 340 VR-T - [redacted] - [redacted] 12 / 14




V
Psh.
VVI
Vs
1836
Vs
640
Vs
430
Vs
711
Vs
648
Vs
399
Vs
523
Vs
867
Vs
867
Vs
594
FF
12
V
25 mm/s
V
Vs
641
Arrêt
FF
V
25 mm/s

Tracing 6: VT in the VF zone treated by ATP one shot

Patient

This 75-year-old man in permanent atrial fibrillation received a Lumax 340 VR-T single chamber defibrillator for primary prevention in the context of ischemic cardiomyopathy with a depressed left ventricular ejection fraction. An event report (yellow color) was issued in the context of a classified VF.

Main programmed settings

- VF zone (270 ms limit) and VT1 zone (370 ms limit)
- 8 /12 cycles in the VF zone and 26 cycles in the VT1 zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.8 mV
- VF zone: one ATP one shot (burst of 8 stimuli at 80% of the tachycardia cycle length), followed by 8 shocks of maximum strength (40 J); VT1 zone: 3 bursts, followed by 3 ramps, followed by 1 shock at 10 J, followed by 1 shock at 20 J, followed by 6 shocks of maximum strength
- Effective discrimination in the VT zone
- Pacing mode: VVI 60 bpm

Remote tracing

The 3 channels available are: 1) the markers with the time intervals, 2) the shock channel (FF = far field) between the coil of the RV lead and the pulse generator, and 3) the RV sensing channel;

1: atrial fibrillation (the Vs cycles are irregular, though their morphology does not vary);
2: VES (the Vs cycles are short and their morphology varies);
3: sudden onset of stable tachycardia detected in the VF zone; the morphology of the ventricular EGM is unlike the ventricular extrasystoles;
4: classification of the episode in the VF zone after 8 cycles in the VF zone without interposed cycle classified VT1 or Vs (full 8/12 VF counter);
5: the delivered ATP is not visible;
6: termination of the arrhythmia; a dark horizontal line marking the interrupted charge is visible;
7: end of the episode after 12 consecutive cycles classified Vs or Vp (12/16 cycles classified Vs or Vp);

Programmer tracing (same episode)

The 3 channels are the same as for the remote tracing.

8: visible burst of 8 cycles at fixed rate;
9: at the end of the burst, onset of the charge marked by the dark horizontal line;
10: end of charge after 3 cycles classified Vs (3 slow cycles out of 4) as the device considered that the burst was successful;
11: end of the episode after 12 consecutive cycles classified Vs or Vp (12/16 cycles classified Vs or Vp).

Comments

One of the priorities of device programming is to lower to a maximum the risk of delivery of an electrical shock while preserving the patient's safety. A large number of fast tachycardias diagnosed in the VF zone are organized and monomorphic, thus likely to be terminated by ATP instead of an electrical shock.

The defibrillator first examines the rhythm stability (a criterion fulfilled in this case), before delivering an ATP sequence. At the end of the sequence, the charge of the capacitors begins. The burst was successful, the device diagnosed 3 consecutive Vs and interrupted the charge. Thus, the charge time is extremely short when ATP is successful, preventing a painful and prognostically detrimental shock, and saving energy.

Status report - Mar 20, 2011

To: Service Télécardiologie

BIOTRONIK
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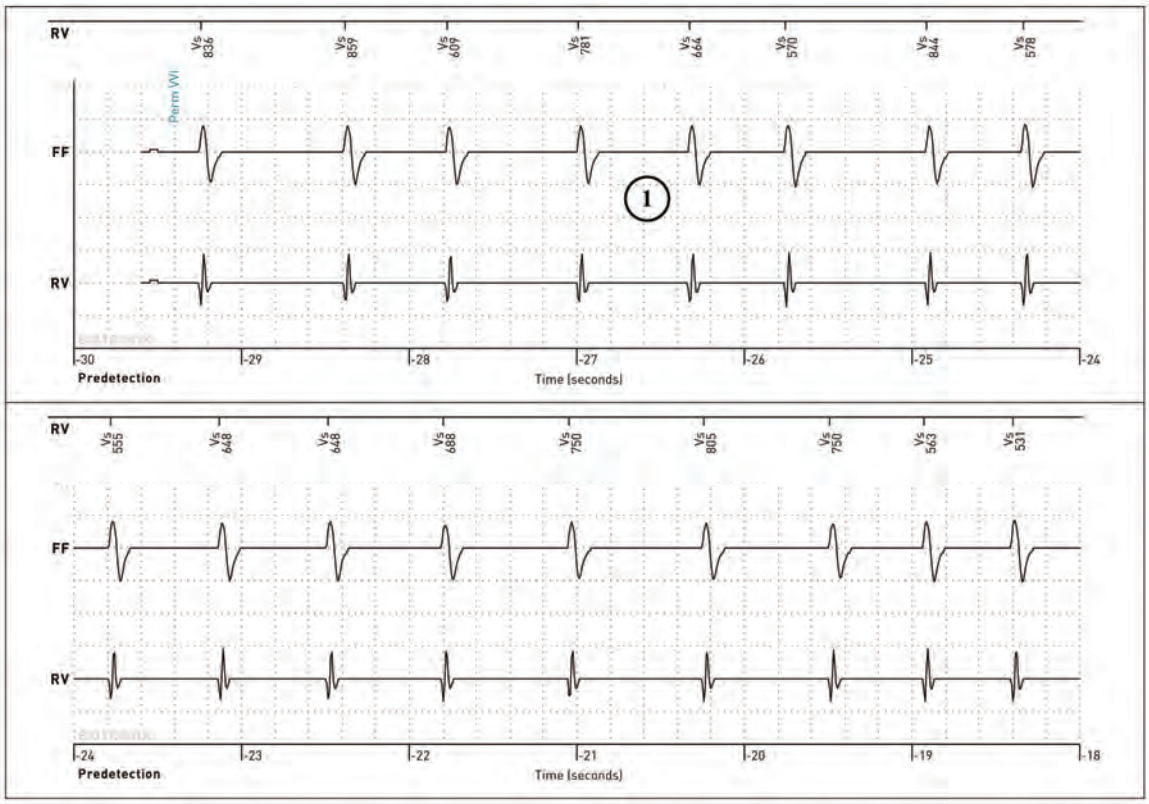
Name:	DOB:	Lumax 340 VR-T [XL]	Last message: Mar 20, 2011
Patient ID:	Phone: -	ICD implanted Nov 16, 2009	Last clinic follow-up: Nov 22, 2010

Recordings

Recordings - Episode 9:

General		Therapy	
Episode number	9	ATP in VT/VF delivered	1
Episode type	VF	ATP One Shot delivered	YES
Detection	Mar 20, 2011 5:03:43 AM	Shocks delivered	0
Termination	Mar 20, 2011 5:03:55 AM	Shocks aborted	1
Duration	12s	Maximum energy [J]	40
Device settings no.	5	**Termination**	
Detection		Mean RR at termination [ms]	722
Mean RR at initial detection [ms]	259	**Remark**	
Onset [%]	59, fulfilled	none	
Stability [ms]	13		
Redetection	---		



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Status report - Mar 20, 2011

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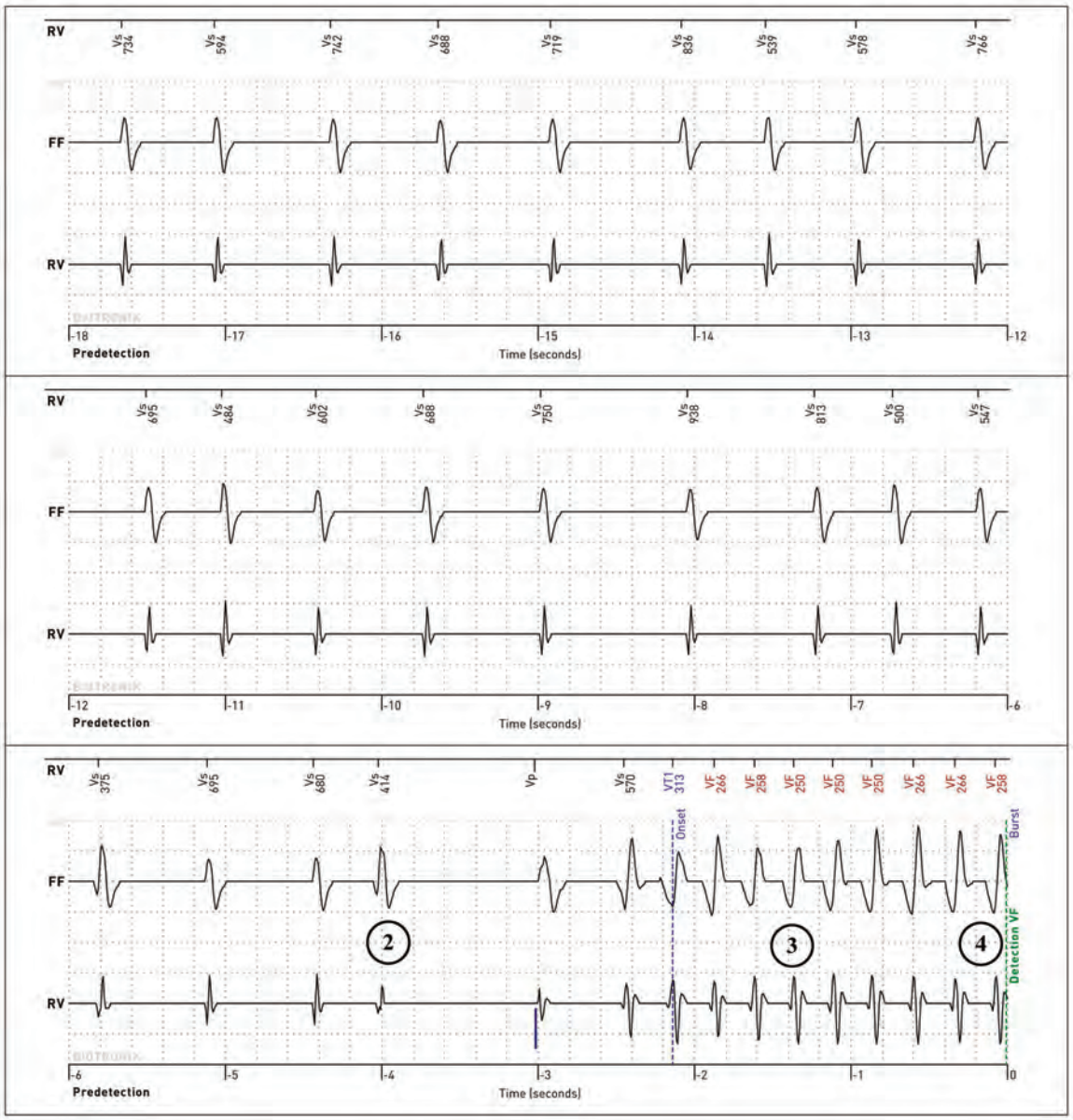
Name:	DOB:	Lumax 340 VR-T (XL)	Last message: Mar 20, 2011
Patient ID:	Phone: -	ICD implanted Nov 16, 2009	Last clinic follow-up: Nov 22, 2010



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Status report - Mar 20, 2011

To: Service TéléCardiologie

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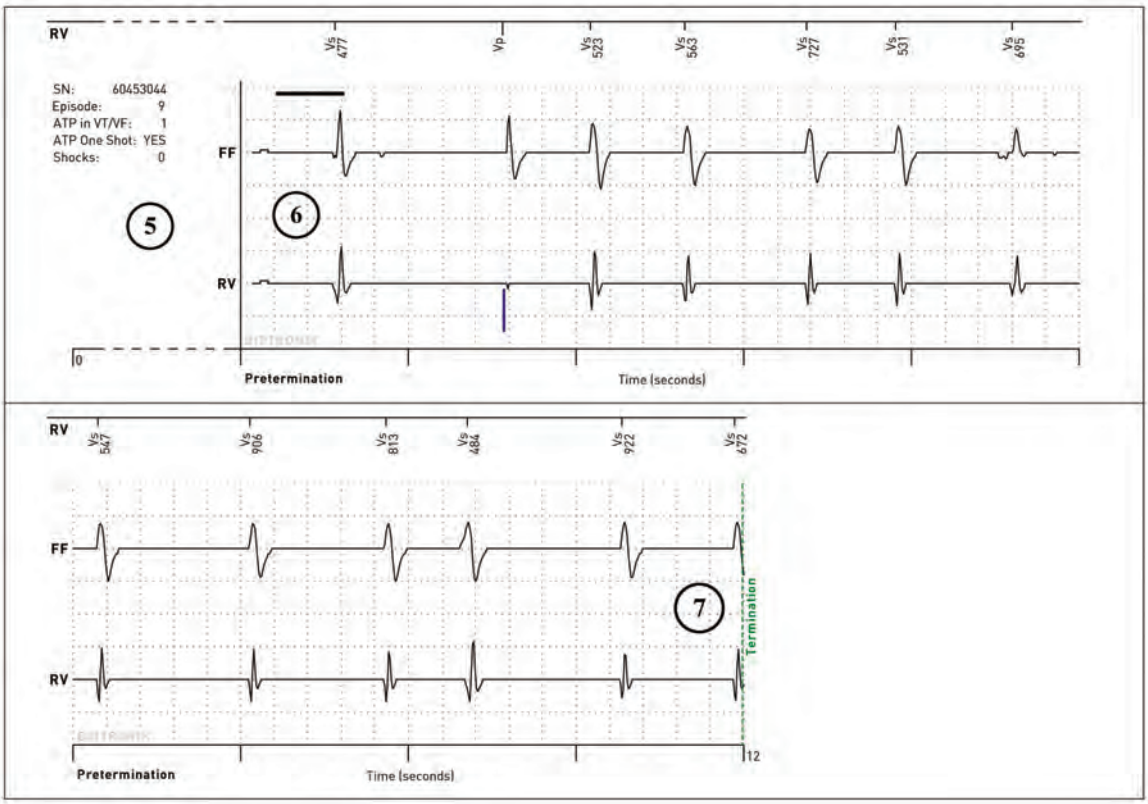
Name:	DOB:	Lumax 340 VR-T [XL]	Last message: Mar 20, 2011
Patient ID:	Phone: -	ICD implanted Nov 16, 2009	Last clinic follow-up: Nov 22, 2010



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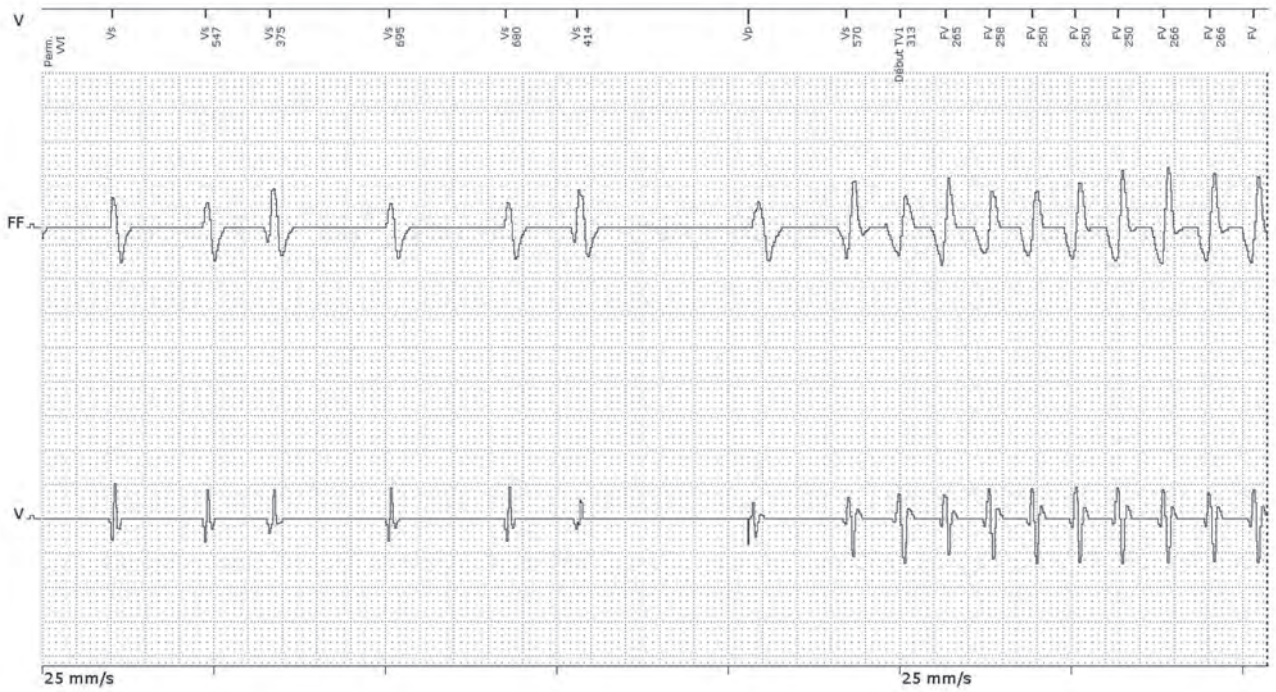
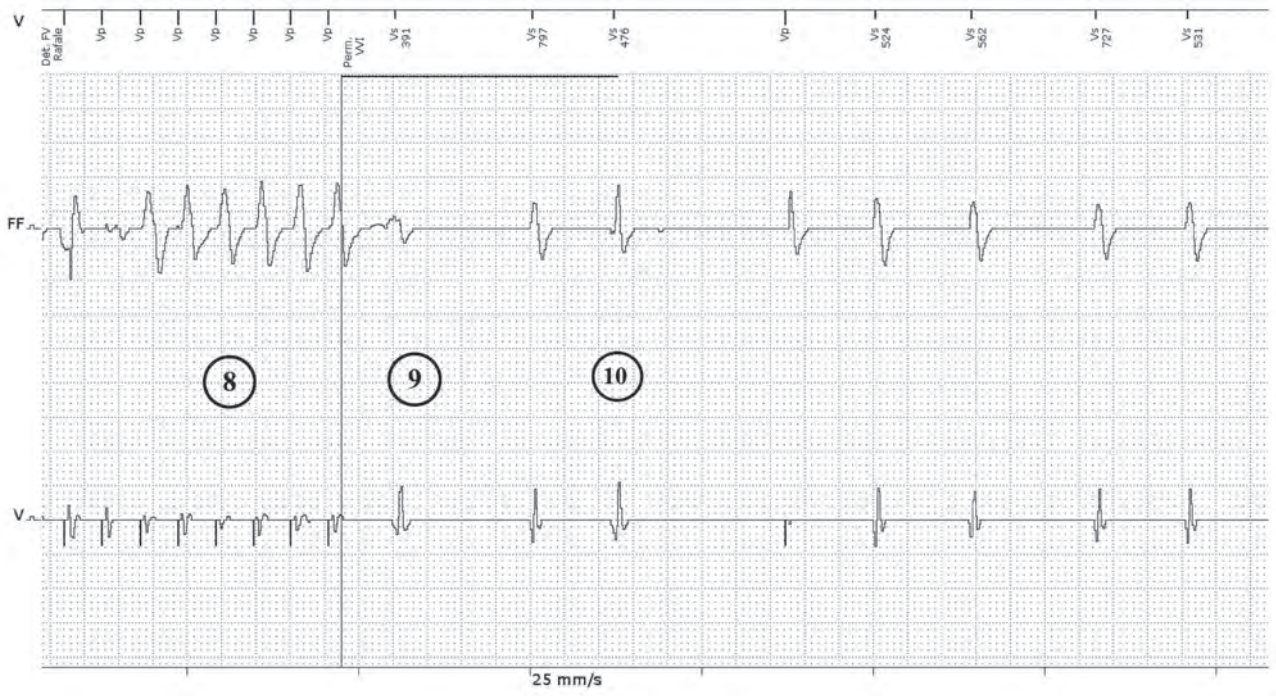
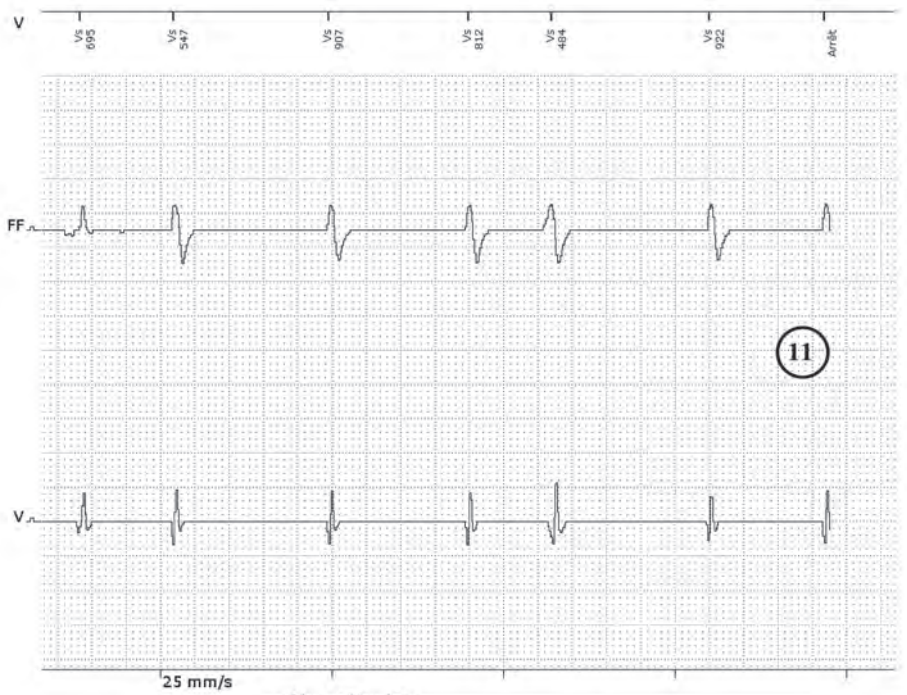
PDF: BIOTRONIK - Lumax 340 VR-T XL - [redacted] - [redacted] 8 / 9







Classification

Zone			FV
Début soudain mesuré dans V			59 % (rempli)
Stabilité mesurée dans V			13 ms
	TV1	TV2	FV
Redétections	0	0	0

Traitement

ATP	1
Chocs	0
Energie max.	40 J
ATP One Shot	Oui

Temps

Classification	20/03/2011 05:03:43
Fin	20/03/2011 05:03:55
Durée	0:00:12
N° programme	5

Remarque

1 Choc(s) interrompus

Tracing 7: failure of ATP one shot and electrical shock

Patient

This 48-year-old man underwent implantation of a Lumax 540 VR-T single chamber defibrillator in the context of ischemic cardiomyopathy with a depressed left ventricular ejection fraction; an event report (yellow color) was issued in the context of a classified VF.

Main programmed settings

- VF zone (250 ms limit) and VT1 zone (340 ms limit)
- 18/24 cycles in the VF zone and 26 cycles in the VT1 zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.8 mV
- VF zone: one ATP one shot (burst of 8 stimuli at 80% of the tachycardia cycle length), followed by 8 shocks of maximum strength (40 J); VT1 zone: 3 bursts, followed by 3 ramps, followed by 1 shock at 10 J, followed by 1 shock at 20 J, followed by 6 shocks of maximum strength;
- Effective discrimination in the VT zone
- Pacing mode: VVI 40 bpm

Remote tracing

The 3 channels available are: 1) the markers with the time intervals, 2) the shock channel (FF = far field) between the coil of the RV lead and the pulse generator, and 3) the RV sensing channel;

1: atrial fibrillation with probable VES (the morphology of the short cycles is different from that of the long cycles on the FF channel);
2: sudden onset of tachycardia initially detected in the VT1 zone, then in the VF zone; irregular and polymorphous tachycardia;
3: cycles classified VT1;
4: stabilization of the arrhythmia in the VF zone;
5: classification of the episode in the VF zone after 18 out of 24 cycles (3 VT1 cycles) in the VF zone;
6: the delivery of ATP and the shock are not visible;
7: termination of the arrhythmia;
8: end of the episode after 12 consecutive cycles classified Vs or Vp.

Programmer tracing (same episode)

The 3 channels are the same as for the remote tracing.

9: detection of VF and delivery of burst of 8 stimuli;
10: at the end of the burst, onset of the charge of the capacitors (dark horizontal line);
11: unsuccessful burst, cycles classified VF and continuation of the charge;
12: end of the charge;
13: synchronized 40-J shock at 78-Ohm impedance, delivered on the first cycle classified VF after the end of the charge;
14: successful shock.

Comments

This tracing illustrates the operation of the defibrillator when ATP one shot is ineffective. The arrhythmia was sensed as stable, at the limit of the programmed threshold. ATP did not terminate the arrhythmia. Compared with the programming of an electrical shock delivered outright, the charge of the capacitors is delayed only by the duration of an ATP sequence (~ 1 sec).

Status report - Oct 24, 2012

To: Service Télécardiologie

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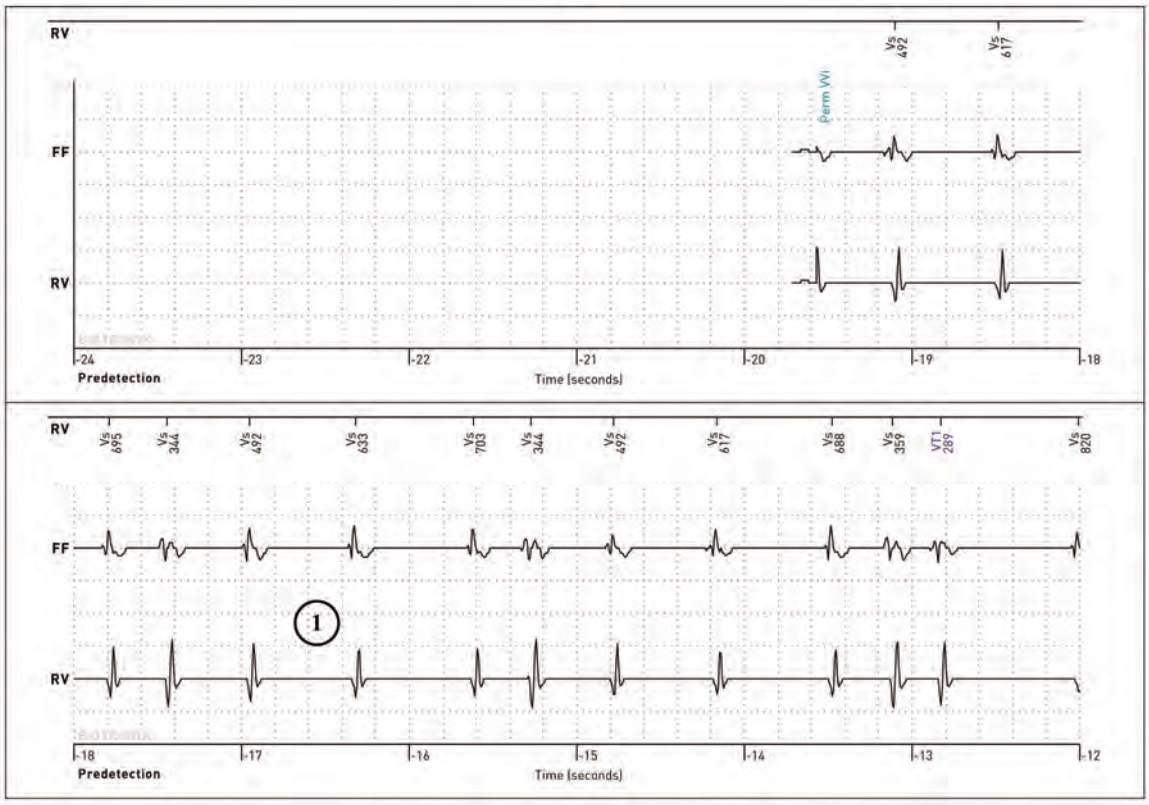
Name:	DOB:	Lumax 540 VR-T	Last message: Oct 24, 2012
Patient ID:	Phone: -	ICD implanted Jun 14, 2010	Last clinic follow-up: Oct 22, 2012

Recordings

Recordings - Episode 31:

General	
Episode number	31
Episode type	VF
Detection	Oct 24, 2012 2:02:42 AM
Termination	Oct 24, 2012 2:03:05 AM
Duration	23s
Device settings no.	8
Detection	
Mean RR at initial detection [ms]	213
Onset [%]	54, fulfilled
Stability [ms]	24
Redetection	---

Therapy	
ATP in VT/VF delivered	1
ATP One Shot delivered	YES
Shocks delivered	1
Shocks aborted	0
Maximum energy [J]	40
Termination	
Mean RR at termination [ms]	617
Remark	
none	



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Status report - Oct 24, 2012

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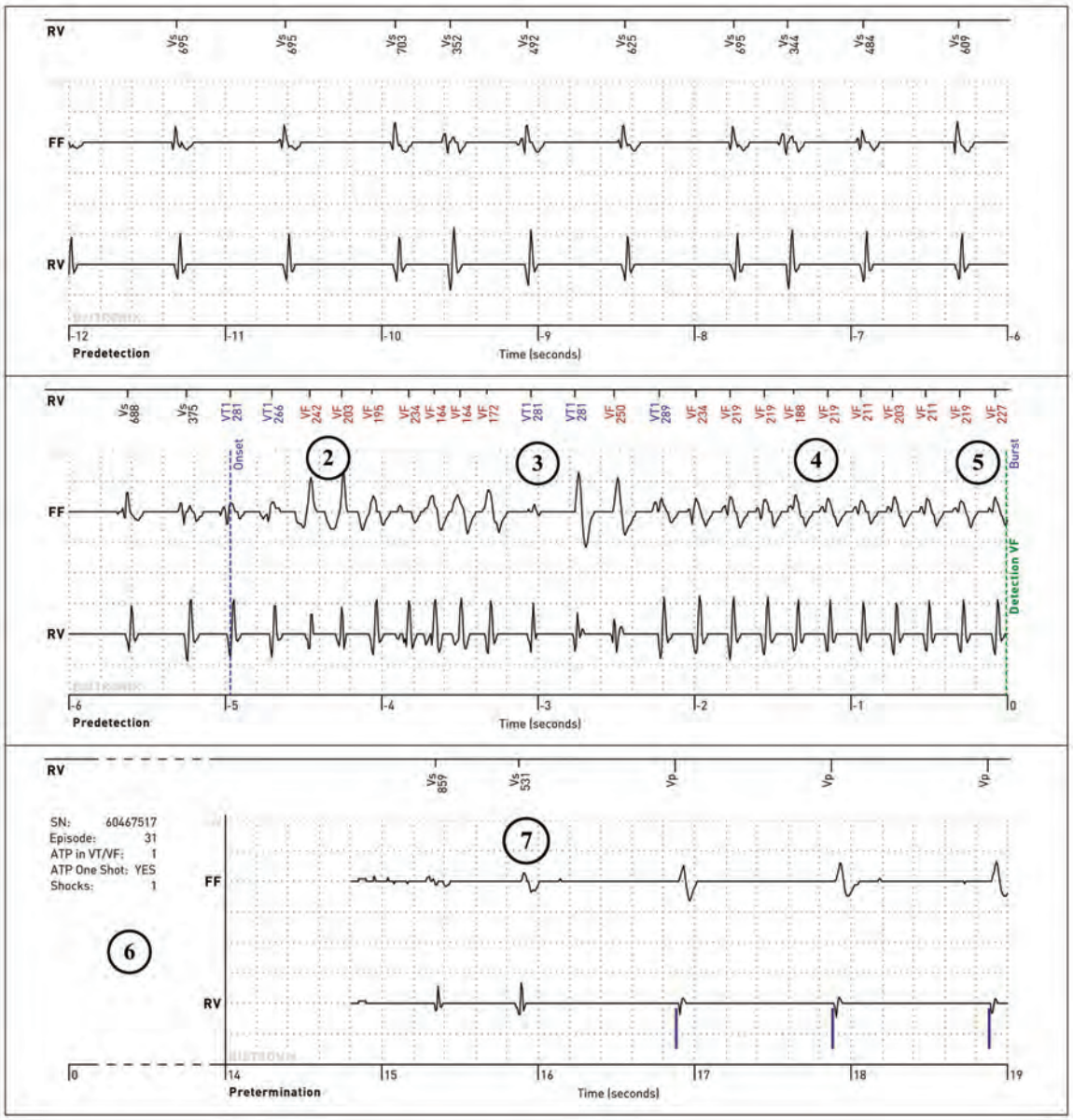
Name:	DOB:	Lumax 540 VR-T	Last message: Oct 24, 2012
Patient ID:	Phone: -	ICD implanted Jun 14, 2010	Last clinic follow-up: Oct 22, 2012



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Status report - Oct 24, 2012

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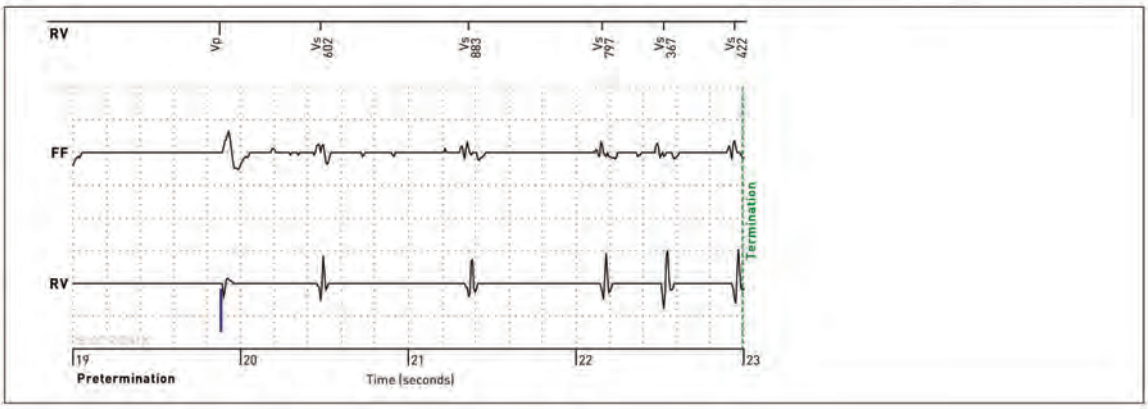
Name:	DOB:	Lumax 540 VR-T	Last message: Oct 24, 2012
Patient ID:	Phone: -	ICD implanted Jun 14, 2010	Last clinic follow-up: Oct 22, 2012



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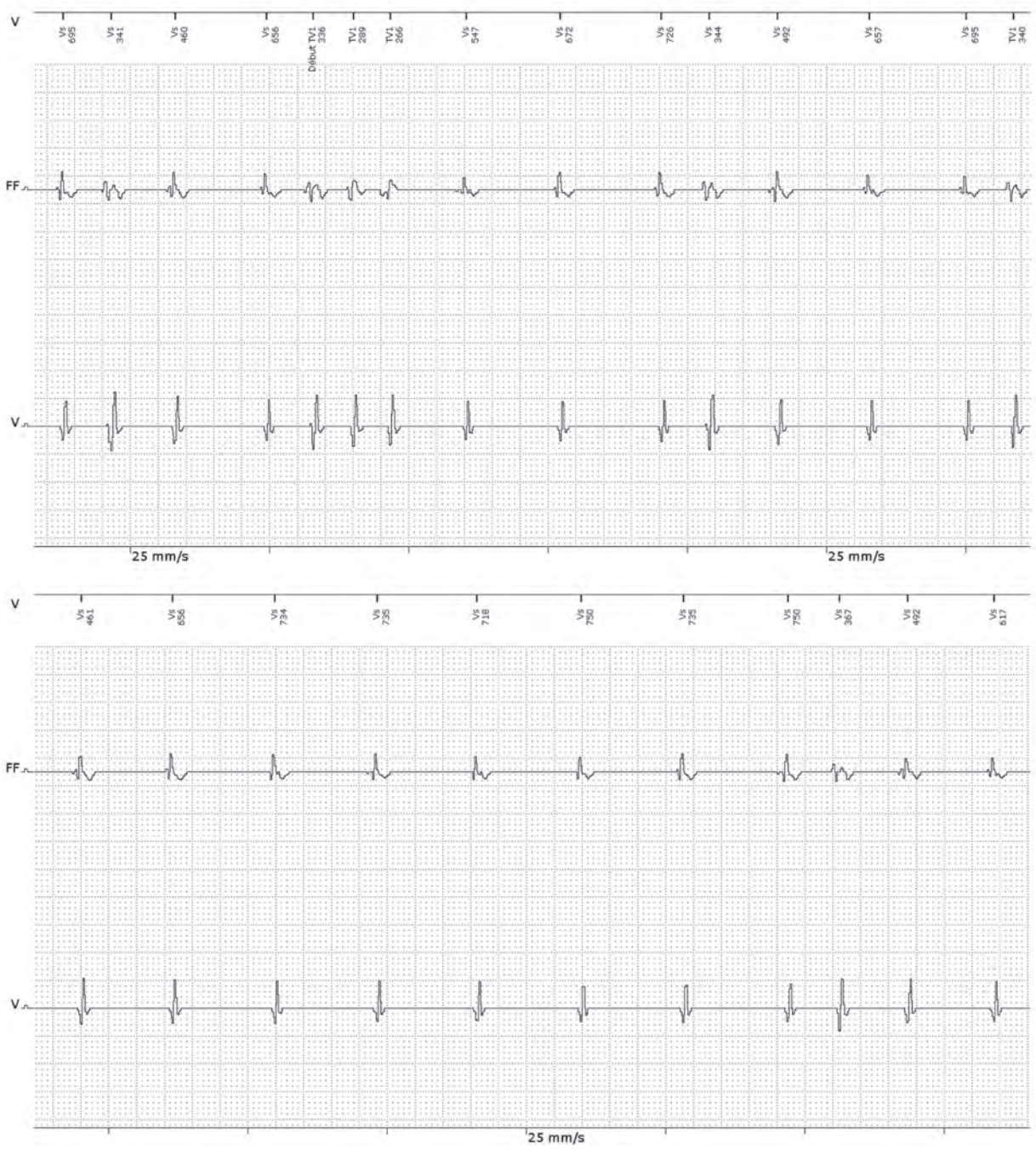
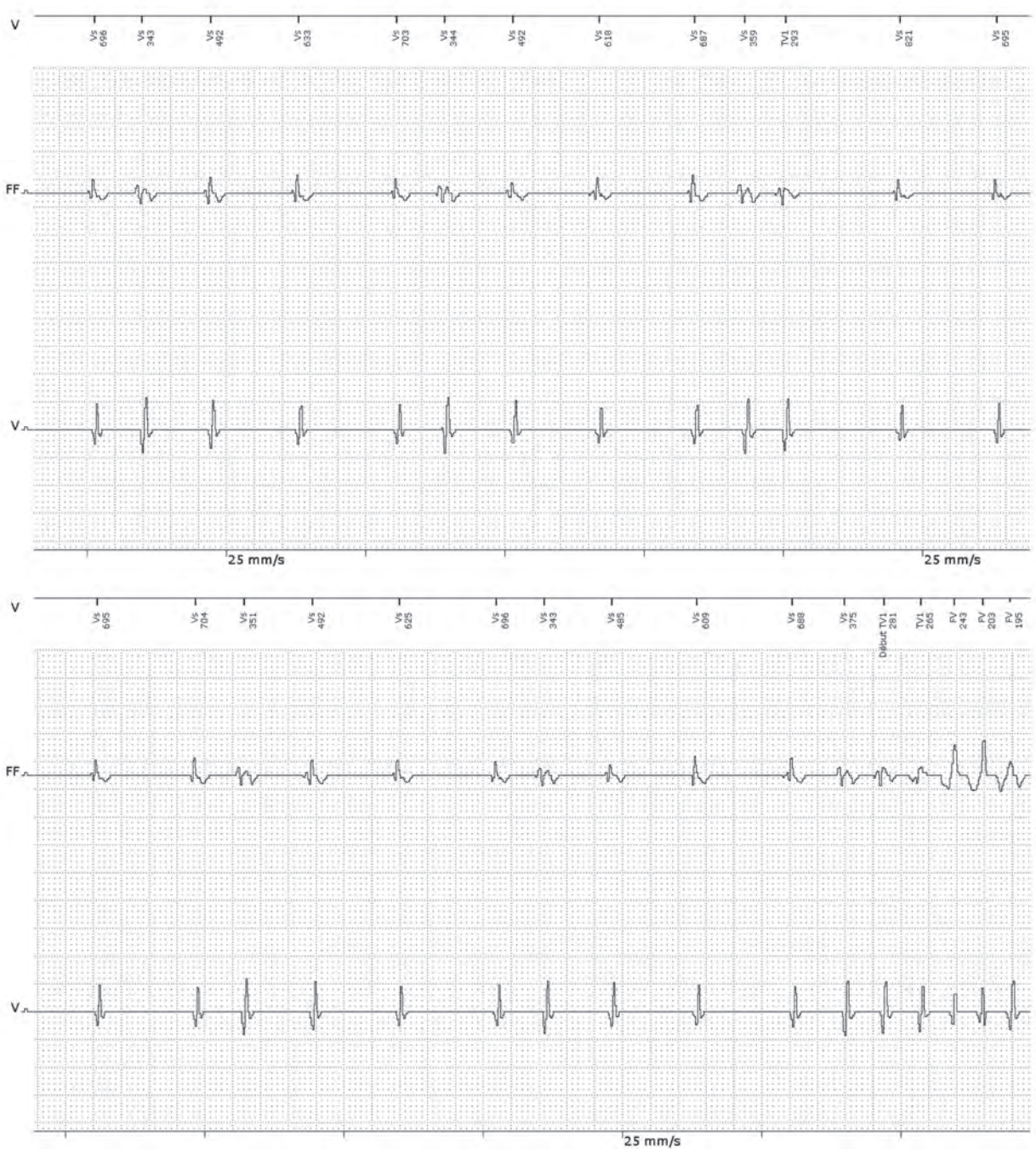
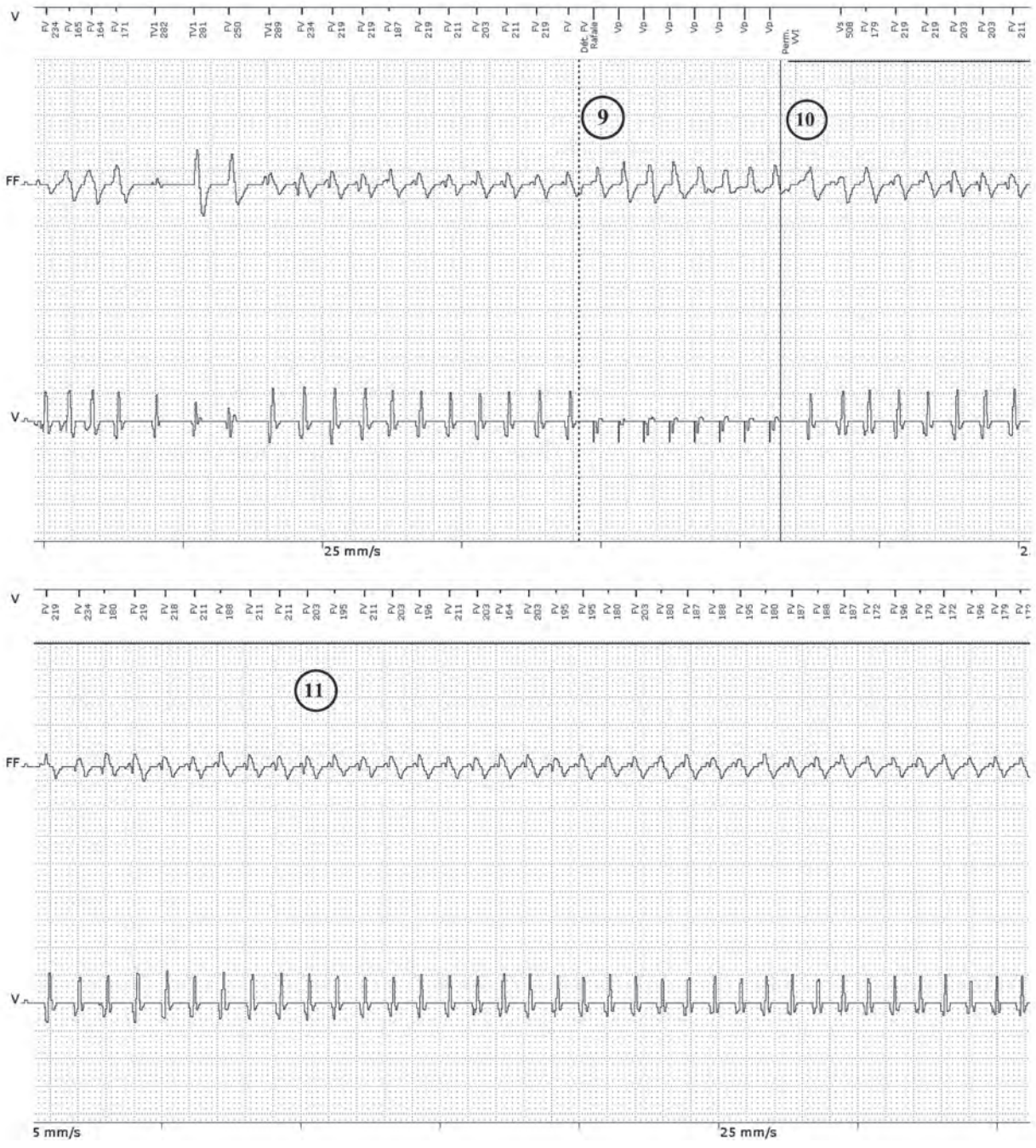
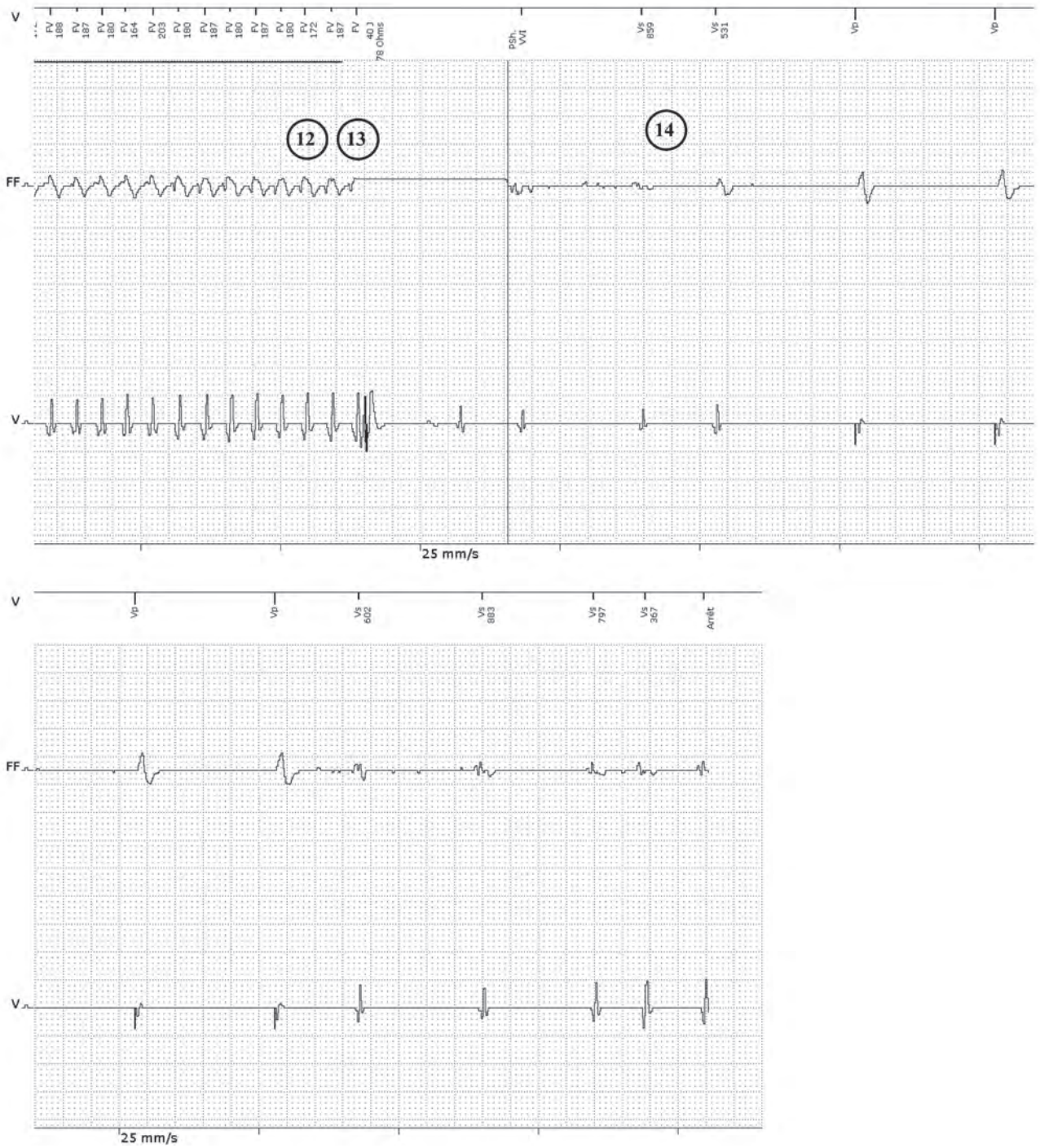
PDF: BIOTRONIK - Lumax 540 VR-T - 13 / 20




V
Vs 696
Vs 343
Vs 492
Vs 633
Vs 703
Vs 344
Vs 492
Vs 618
Vs 687
Vs 359
TV1 293
Vs 821
Vs 695
FF
V
25 mm/s
25 mm/s
V
Vs 695
Vs 704
Vs 351
Vs 492
Vs 625
Vs 696
Vs 343
Vs 485
Vs 609
Vs 688
Vs 375
Début TV1 281
TV1 265
FV 243
FV 203
FV 195
FF
V
25 mm/s

PDF: BIOTRONIK - Lumax 540 VR-T - 15 / 20




V
FV 188
FV 187
FV 180
FV 164
FV 203
FV 180
FV 187
FV 180
FV 187
FV 180
FV 172
FV 187
FV
40 J
78 Ohms
Psh. VVI
Vs 859
Vs 531
Vp
Vp
12
13
14
FF
V
25 mm/s
V
Vp
Vp
Vs 602
Vs 883
Vs 797
Vs 367
Arrêt
FF
V
25 mm/s

Tracing 8: shock delivery prompted by T wave oversensing

Patient

This 53-year-old man presenting with Brugada syndrome and syncope received a Lumax 340 VR-T single chamber defibrillator. An event report (yellow color) was issued in the context of classified VF.

Main programmed settings

- Single VF zone
- 12/16 cycles in the VF zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.8 mV
- VF zone: 8 shocks of maximum strength (40 J)
- Pacing mode: VVI at 40 bpm

Remote tracing

The 3 channels available are 1) the markers with the time intervals, 2) the shock channel (FF = far field) between the coil of the RV lead and the pulse generator, and 3) the right ventricular (RV) sensing channel;

1: spontaneous rhythm; the "PermVVI" labelling at the beginning of the tracing indicates that the defibrillator operates according to the permanently programmed VVI pacing mode;
2: oversensing the T wave of spontaneous ventricular event;
3: oversensing the T wave of spontaneous ventricular event;
4: intermittent T wave oversensing with cycles classified VS alternating with cycles classified VF;
5: episode classified VF after 8 out of 12 cycles classified in the VF zone (VF counter full);
6: no therapy delivered;
7: persistence of intermittent oversensing;

Programmer tracing (different episode)

The 3 channels are the same as for the remote tracing;

8: T wave oversensing;
9: detection of VF (VF counter full, with 8 out of 12 cycles in VF);
10: charge of the capacitors;
11: interruption of the charge following 3 consecutive VS classified cycles;
12: at the end of the charge, the VF redetection (8/12 cycles in VF) and the end of episode counters (8/16 cycles classified VS or VP) are competing;
13: the VF redetection counter is full; further charge of the capacitors;
14: the charge is brief, as the capacitors are already partially charged;
15: end of charge;
16: electrical shock (40 J, 68 Ohms) synchronized to the first VF classified cycle at the end of the charge;
17: after the shock, a brief run of spontaneous ventricular extrasystoles were classified VS, as they fell outside of the tachycardia zones.

Comments

This patient developed several episodes of T wave oversensing during exercise, prompting the delivery of shocks or of interrupted charges of the capacitors. The systematic oversensing of a supernumerary cardiac signal causes the sensing of 2 signals of different morphology for a single cardiac cycle with alternation between a short and a longer cycle. This form of oversensing is facilitated by exercise, as effort may be associated with a decrease in the R wave and an increase in the T wave amplitudes. T wave oversensing after a spontaneous ventricular event is more likely to occur in presence of a low-amplitude R wave, as in this patient's case. The sensitivity and the gain are automatically set, based on the amplitude of the previously sensed R wave: when that amplitude

is low, the likelihood of rapidly reaching the following level of maximum sensitivity is high. This limits the risk of rectifying this oversensing by a decrease in the ventricular sensitivity that might cause undersensing of VF. These difficult situations may result in programming compromises. The various settings can be modified separately (these settings can be accessed by a code known by the staff of Biotronik) or one can program an enhanced suppression of the T wave, which, compared with standard programming, increases the upper threshold to 75% of the R wave amplitude (instead of 50% with standard programming) and increases the high-pass filter to 32 Hz to filter the T wave, which is a lower-frequency signal than the R wave. While Enhanced T-wave Suppression can eliminate T-wave oversensing, the setting should be used with caution if the R-wave signal amplitude is small (e.g., less than 4 mV). After this had been chosen for this patient, the proper detection of VF was verified by an induction procedure. It is noteworthy that starting from the Lumax 740 series, the sensing circuit has been entirely revised, which has resulted in suppression of the T wave oversensing. This tracing also illustrates the potential danger represented by the delivery of inappropriate shocks, which resulted in a run of VT. In other instances, VF can be triggered by a shock delivered in the vulnerable period of a spontaneous QRS.

Status report - Oct 11, 2013

To: Service TélécØrdiologie

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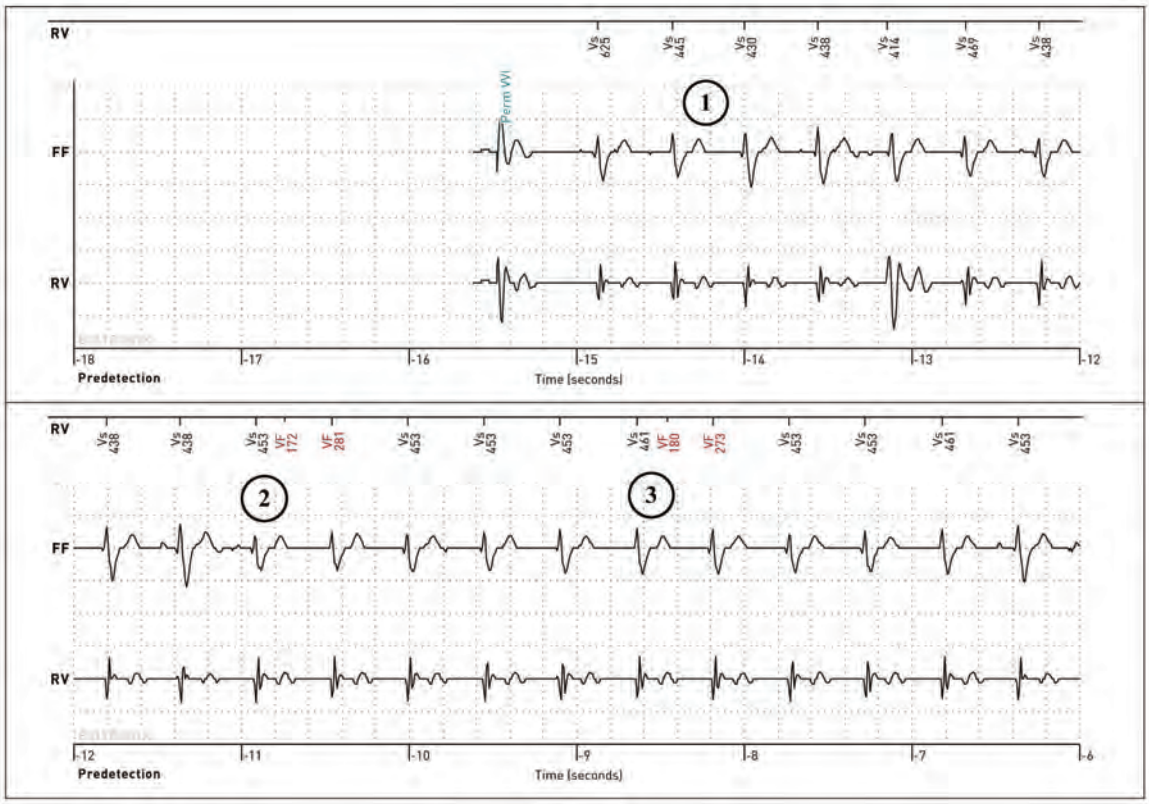
Name:	DOB:	Lumax 340 VR-T	Last message: Oct 11, 2013
Patient ID:	Phone: -	ICD implanted May 17, 2010	Last clinic follow-up: Oct 29, 2012

Recordings

Recordings - Episode 15:

General	
Episode number	15
Episode type	VF
Detection	Jul 26, 2012 3:36:15 PM
Termination	Jul 26, 2012 3:36:33 PM
Duration	18s
Device settings no.	7
Detection	
Mean RR at initial detection [ms]	225
Onset [%]	59
Stability [ms]	105
Redetection	---

Therapy	
ATP in VT/VF delivered	0
ATP One Shot delivered	NO
Shocks delivered	0
Shocks aborted	1
Maximum energy [J]	40
Termination	
Mean RR at termination [ms]	366
Remark	
none	



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Status report - Oct 11, 2013

To: Service TélécØrdiologie

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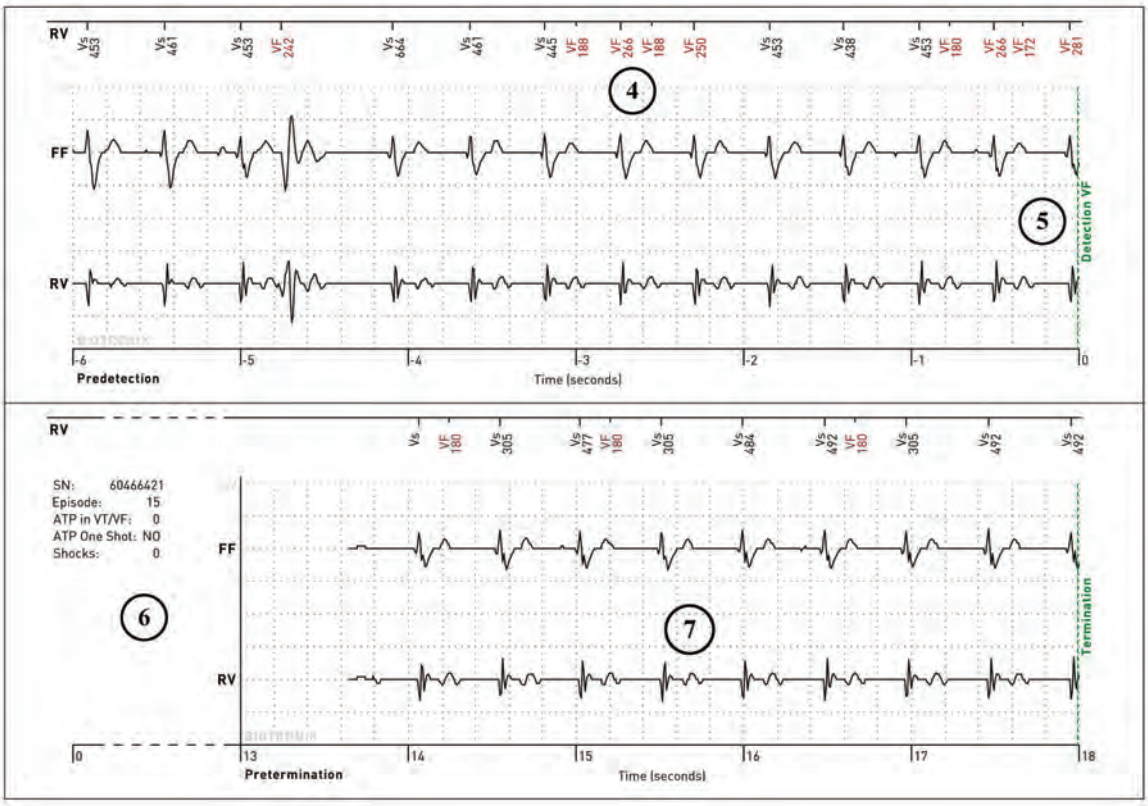
Name:	DOB:	Lumax 340 VR-T [XL]	Last message: Oct 11, 2013
Patient ID:	Phone: -	ICD implanted May 17, 2010	Last clinic follow-up: Oct 29, 2012



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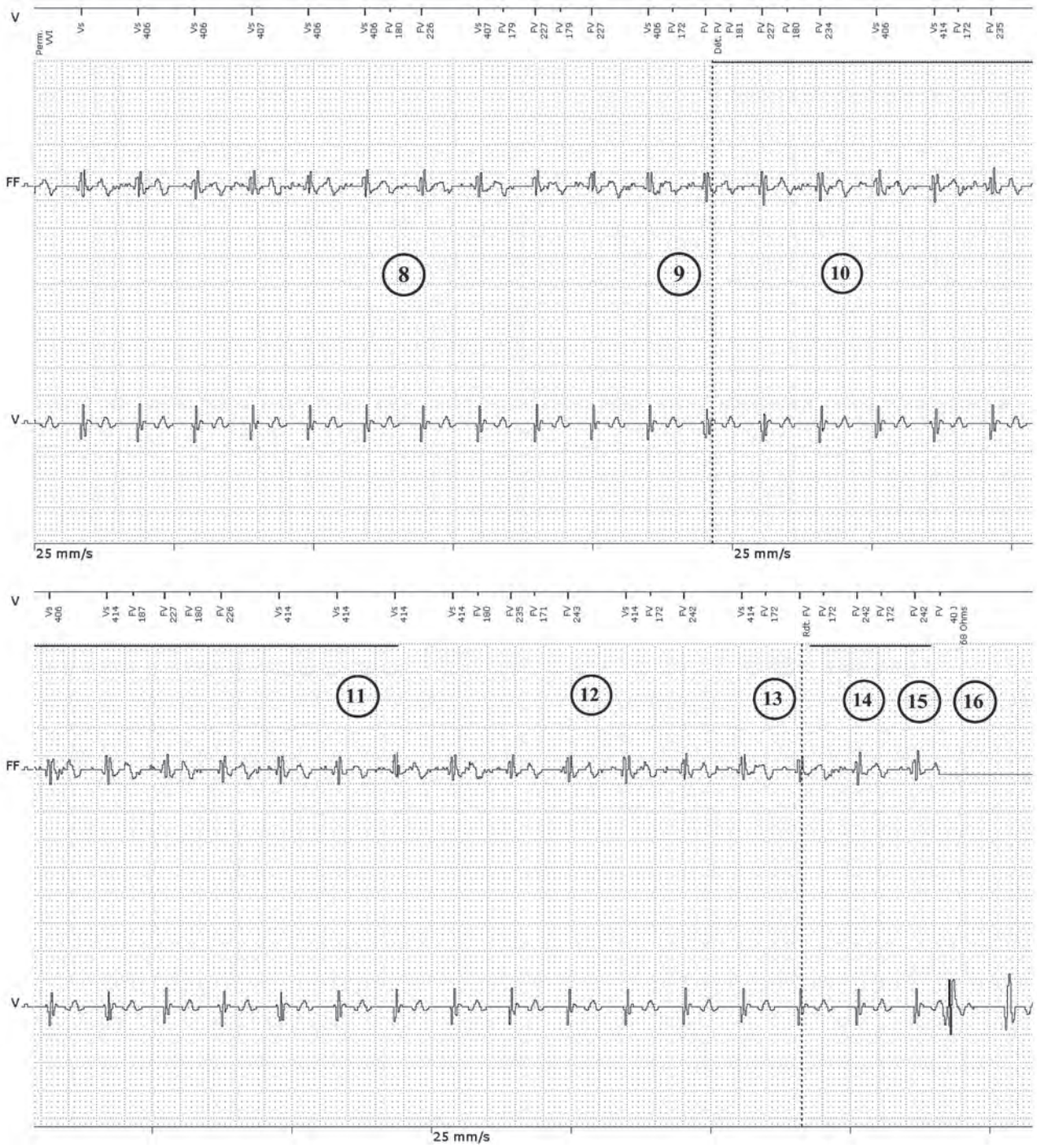
Date:

Signature:

2/2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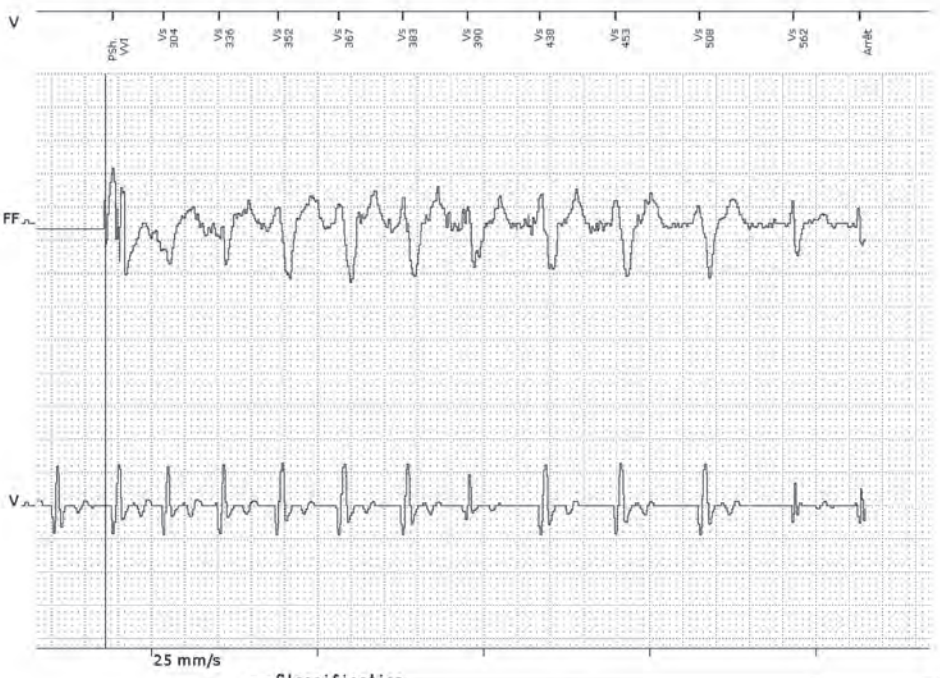

Classification			
Zone		FV	
Début soudain mesuré dans V		56 %	
Stabilité mesurée dans V		175 ms	
	TV1	TV2	FV
Redétections	0	0	1

Traitement	
ATP	0
Chocs	1
Energie max.	40 J
ATP One Shot	Non

Temps	
Classification	26/07/2012 15:34:11
Fin	26/07/2012 15:34:25
Durée	0:00:14
N° programme	7

Remarque
1 Choc(s) interrompus

Enregistrements

Date: **29/10/2012**
Heure: **09:06**

EGM 14

Zone	FV
EGM de l'épisode N°.	14
Classification	26/07/2012 15:35:22
N° programme	7

Tracing 9: ventricular undersensing

Patient

This 28-year-old woman received a Lumax 540 VR-T single chamber defibrillator after an episode of aborted sudden cardiac death. An event report (yellow color) was issued in the context of supraventricular tachycardia (SVT).

Main programmed settings

- VF zone (270 ms) and VT1 zone (350 ms)
- 12/16 cycles in the VF zone and 26 cycles in the VT1 zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.5 mV
- Effective discrimination in the VT1 zone
- VF zone: 1 burst of ATP, followed by 8 shocks of maximum strength (40 J); VT1 zone: monitor zone without programmed therapy
- Pacing mode: VVI at 30 bpm

Remote tracing

The 3 channels available are 1) the markers with the time intervals, 2) the shock channel (FF = far field) between the coil of the RV lead and the pulse generator, and 3) the right ventricular (RV) sensing channel.

1: fast, spontaneous rhythm with cycles classified in the VT1 zone;
2: ventricular extrasystole classified in the VF zone;
3: ventricular undersensing with following cycle classified VS;
4: ventricular extrasystole classified in the VF zone with compensatory pause and following cycle classified VS;
5: episode classified SVT when the VT1 counter is full; VS cycles decrease the counter by 1 and VF cycles increase the VT1 counter by 1. This episode was classified SVT because of its irregularity (99 ms) after the sudden onset criterion was fulfilled;
6: no delivery of therapy;
7: persistence of ventricular undersensing.

Programmer tracing (same episode)

The 3 channels are the same as for the remote tracing.

8: the undersensed cycles are low-amplitude signals occurring after a higher-amplitude ventricular event (probable extrasystole);
9: undersensing after a non-premature ventricular event.

Comments

This tracing illustrates the limits of the programming implemented in the patient of the previous tracing. In this young patient, enhanced T wave suppression had been systematically programmed to limit the risk of delivery of inappropriate therapy due to T wave oversensing. The wide variability of the ventricular electrograms' amplitude present on this tracing is noteworthy, and the spontaneous, low-amplitude, ventricular signals occurring after higher-amplitude electrograms were not sensed, because, as mentioned earlier, the sensing level hinges on the amplitude of the preceding QRS. This explains the high likelihood of undersensing low-amplitude signals falling after high-amplitude electrograms. This undersensing is highly worrisome, as an accurate detection of all arrhythmias is an indispensable prerequisite for the delivery of all therapies. The sensitivity programmed at 0.5 mV leaves little room for the reprogramming of a higher sensitivity. It is, however, possible to return to a standard programming or to the programming of an enhanced detection of VF. In this patient, it seemed clinically critical to induce VF to verify the reliability of its detection. If in doubt, the RV lead may be repositioned.

Status report - Oct 11, 2013

To: Service Télécardiologie

BIOTRONIK
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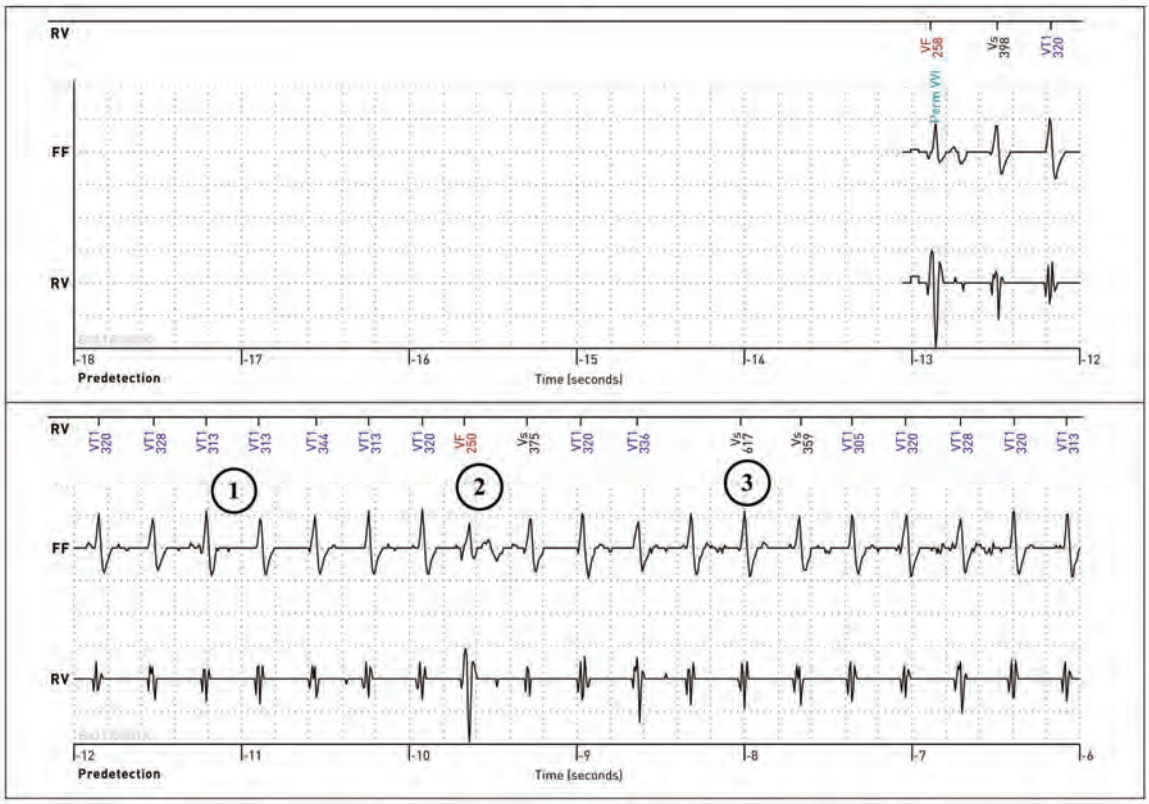
Name:	DOB: -	Lumax 540 VR-T	Last message: Oct 9, 2013
Patient ID:	Phone:	ICD implanted Aug 16, 2010	Last clinic follow-up: Sep 23, 2013

Recordings

Recordings - Episode 22:

General	
Episode number	22
Episode type	SVT
Detection	Jun 18, 2012 12:28:00 AM
Termination	Jun 18, 2012 12:28:03 AM
Duration	3s
Device settings no.	14
Detection	
Mean RR at initial detection [ms]	319
Onset [%]	51, fulfilled
Stability [ms]	99
Redetection	---

Therapy	
ATP in VT/VF delivered	0
ATP One Shot delivered	NO
Shocks delivered	0
Shocks aborted	0
Maximum energy [J]	---
Termination	
Mean RR at termination [ms]	494
Remark	
Detection	SVT (RR unstable)



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Status report - Oct 11, 2013

To: Service TélécArdiologie

BIOTRONIK
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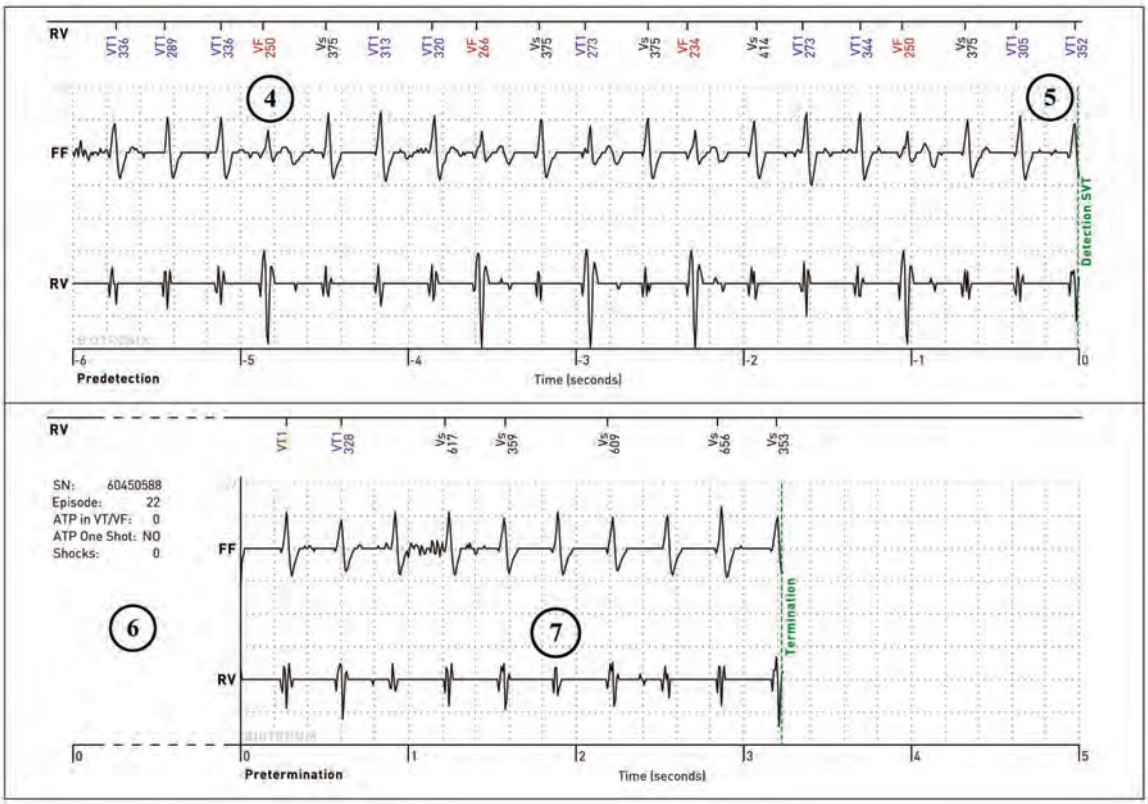
Name:	DOB: -	Lumax 540 VR-T	Last message: Oct 9, 2013
Patient ID:	Phone:	ICD implanted Aug 16, 2010	Last clinic follow-up: Sep 23, 2013



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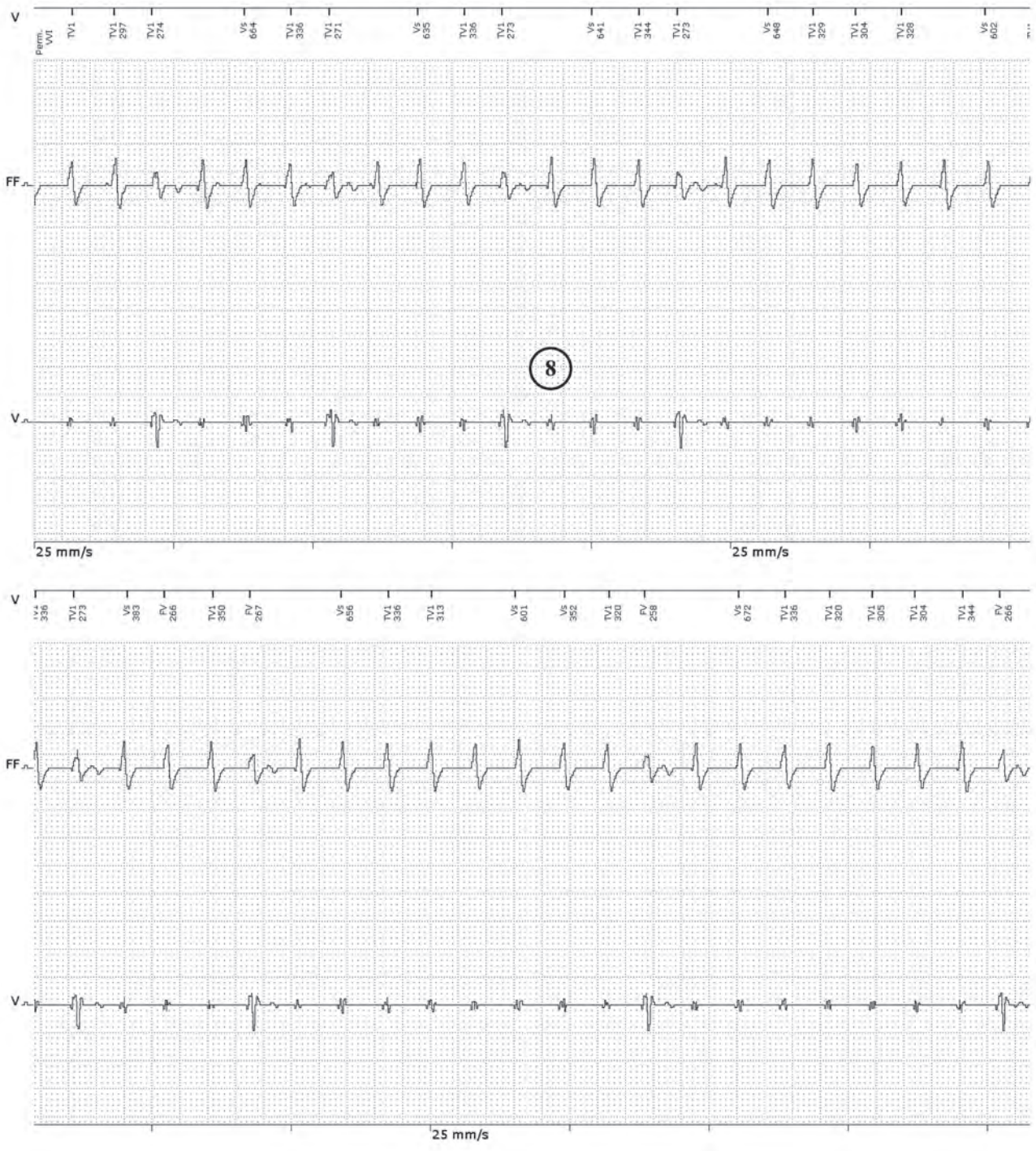
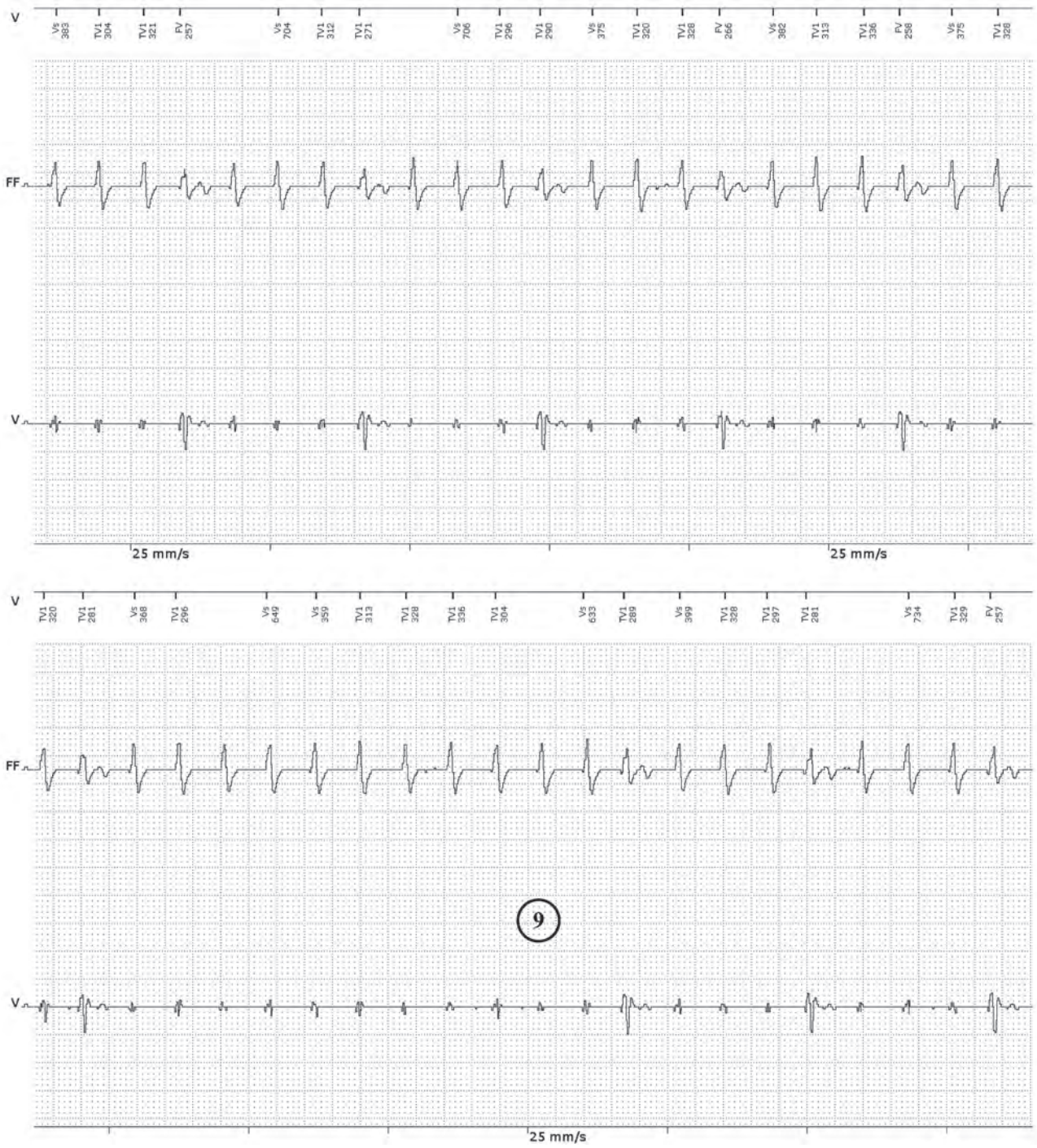
Date:

Signature:

2/2

PDF: BIOTRONIK - Lumax 540 VR-T -

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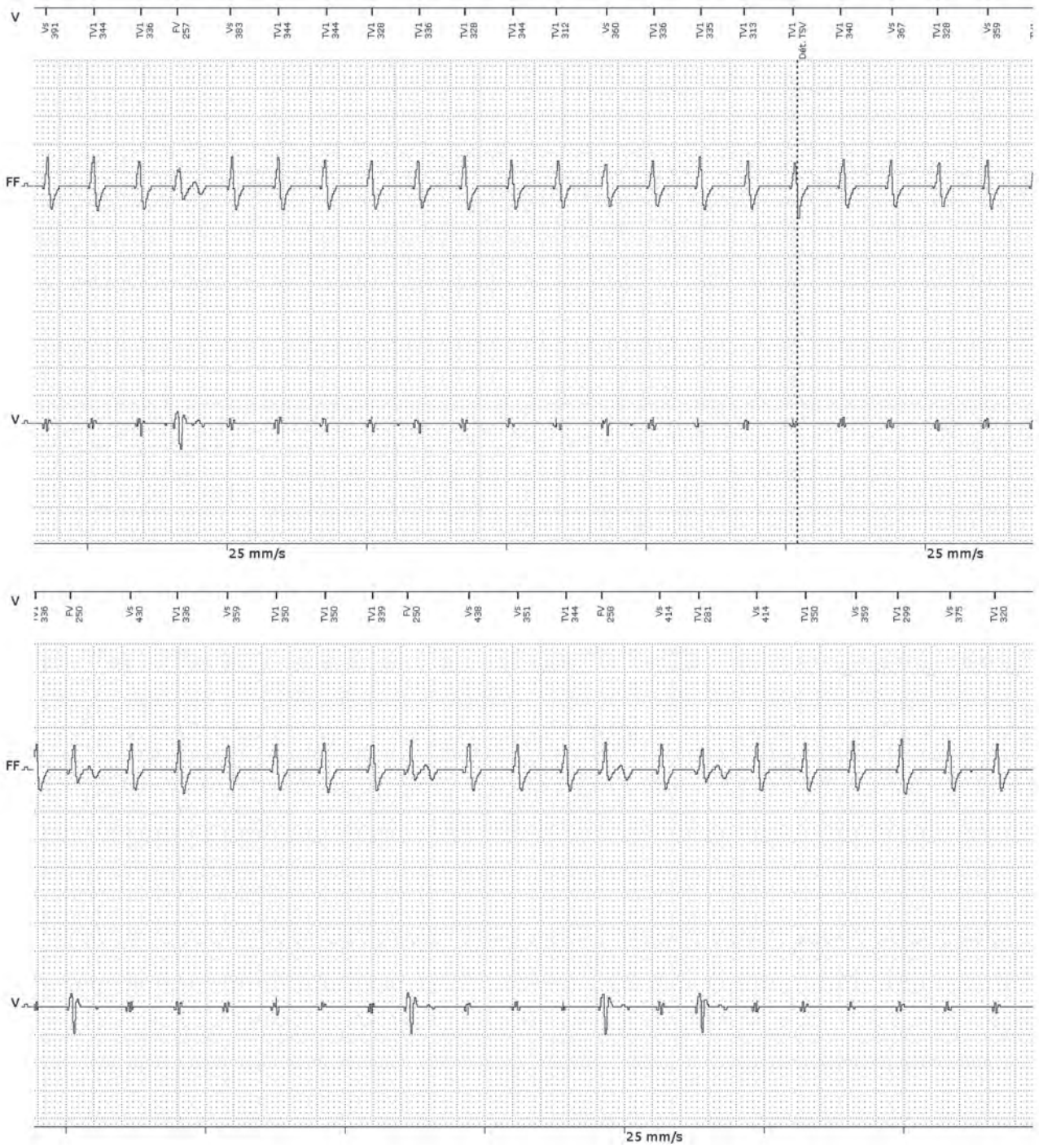
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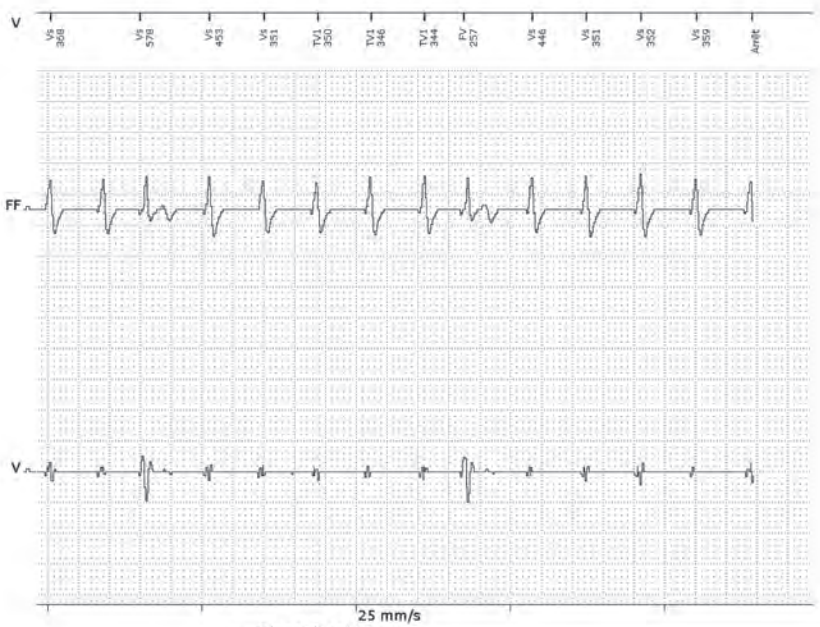


Classification

Zone		TSV	
Début soudain mesuré dans V		37 %	(rempli)
Stabilité mesurée dans V		34 ms	
	TV1	TV2	FV
Redétections	0	0	0

Traitement

ATP	0
Chocs	0
Energie max.	*** J
ATP One Shot	Non

Temps

Classification	07/02/2012 19:57:56
Fin	07/02/2012 19:58:09
Durée	0:00:13
N° programme	14

Remarque

TSV (RR instable)

Paramètres (perm.)

Date: **25/06/2012**
Heure: **11:20**

Résumé

Classification de la tachycardie: Activé

	Fréquence	1ère ATP	2ème ATP	Chocs 1er	Chocs 2e	Chocs 3.-n
TV1	171 bpm	...	...	OFF		
TV2	OFF					
FV	222 bpm	Rafale		40J	40J	6×40J

Processus progressiv du traitement ON

Mode	VVI		V
Fréquence de base	30 cpm	Ampl. impulsion	2.8 V
		Durée impulsion	0.4 ms

Tracing 10: electrical scalpel

Patient

This 67-year-old man received a Lumax 340 HF-T triple chamber defibrillator in the context of dilated cardiomyopathy with left bundle branch block, before undergoing prostate surgery.

Main programmed settings

- VF zone at 231 bpm and VT1 zone at 150 bpm
- 8 /12 cycles in the VF zone and 26 cycles in the VT1 zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.5 mV
- VF zone: ATP one shot and 8 shocks of maximum strength (40 J); VT1 zone: 3 bursts of ATP, followed by 3 ramps, followed by a single 15-J shock and 7 shocks of maximum strength
- Pacing mode: DDIR RV pacing at 50 bpm, (very high LV threshold)

Programmer tracing

1: atrial and RV only paced rhythm;
2: rapid, polymorphous signals are visible on the 3 channels;
3: detection at the atrial (Ars) and ventricular (VF) channels;
4: episode of VF detected after 8 VF classified cycles;
5: charge of the capacitors;
6: end of oversensing;
7: interruption of the charge after 3 consecutive VP cycles;
8: competition between VF redetection (8/12 cycles in the VF zone) and end of episode (12/16 VS or VP cycles) counters;
9: further oversensing;
10: VF redetection counter full (8/10 cycles in the VF zone); charge of the capacitors;
11: short charge;
12: end of charge;
13: at the end of the charge, delivery of an electrical shock on the first short (VF or VT1) or long (VS or VP) cycle following the charge; this is the second charge for a single episode (the first was interrupted) and the electrical shock was delivered despite the slow rhythm. The" PSh DDI" labeling after the shock explains that the defibrillator operated in the programmed post-shock pacing mode (DDI) for a programmable duration (nominal = 10 sec);
14: end of episode.

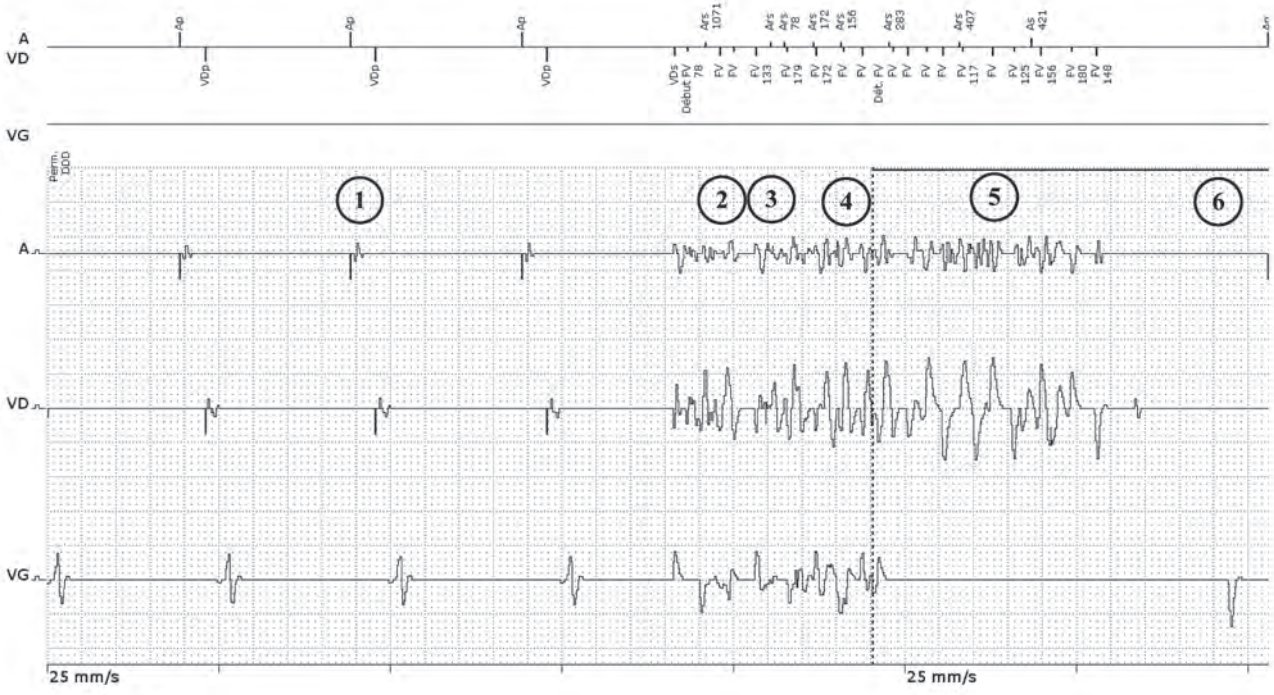
Comments

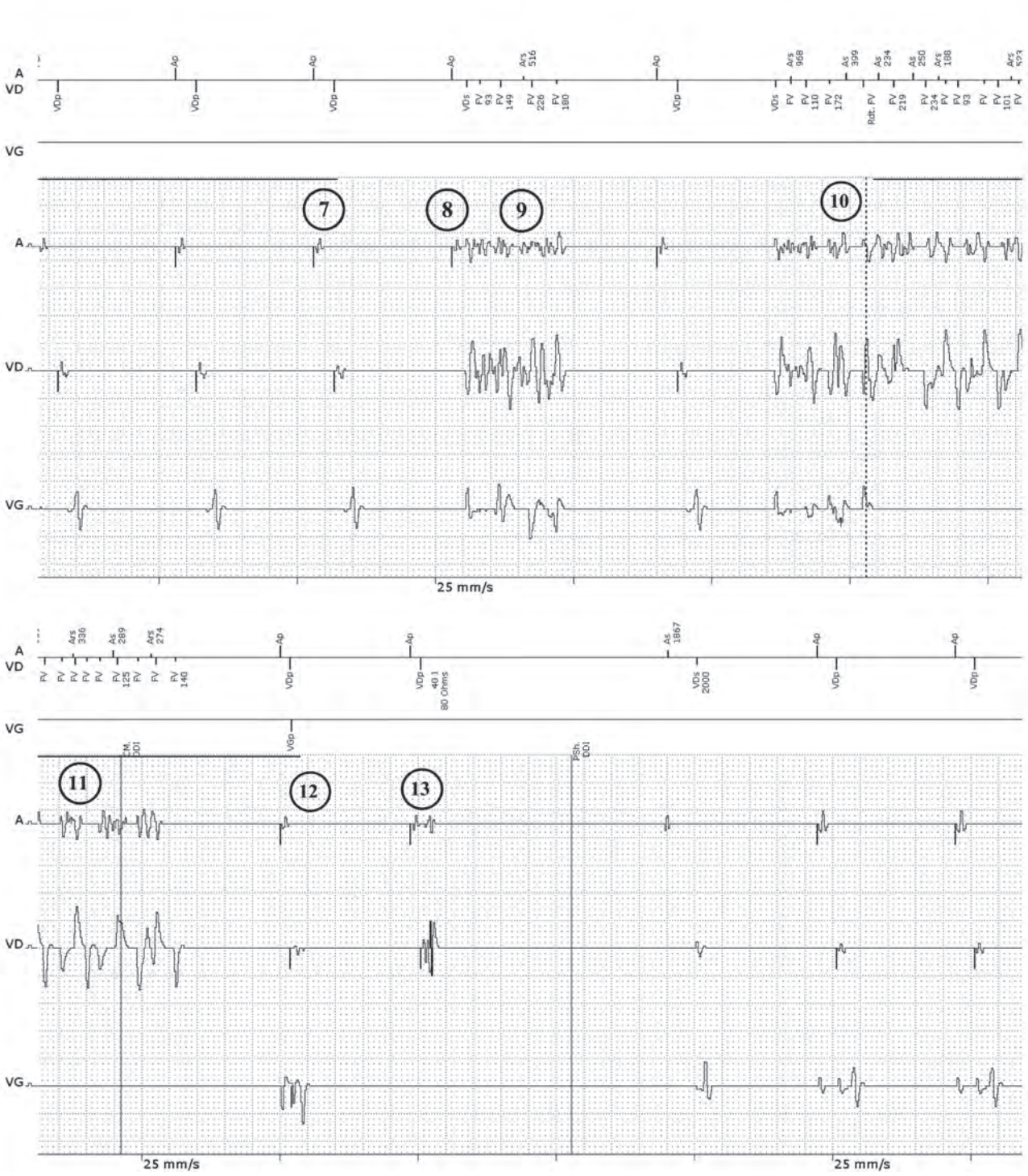
When a recipient of defibrillator undergoes surgery, the surgeon must be advised a) to use the electrical scalpel in the bipolar mode, b) to use it for very short periods of time, and c) to place the plates of the scalpel away from the pulse generator of the defibrillator.

To completely eliminate the risk of clinically significant interference, pacing must be programmed to an asynchronous mode (available from the Lumax 740 model and subsequent models) and detection and therapies must be turned off. This burdensome strategy mandates the pre-operative programming and the postoperative interrogation and re-programming of the device with verification of the thresholds.

One other option consists in placing a magnet over the pulse generator to inhibit all therapies. The magnet also prevents the memorization of artifacts interpreted as arrhythmic episodes, avoiding the need to delete the genuine episodes that occurred before exposure to the interferences (since this is a looping memory of finite storage capacity). The magnet effect is reversible, and the therapies and memorization of the episodes resume upon removal of the magnet. The patient, who is no longer protected by the defibrillator, must be monitored throughout the procedure. The use of a magnet must not prevent a full postoperative interrogation of the device.

PDF: BIOTRONIK - Lumax 340 HF-T - 17 / 37

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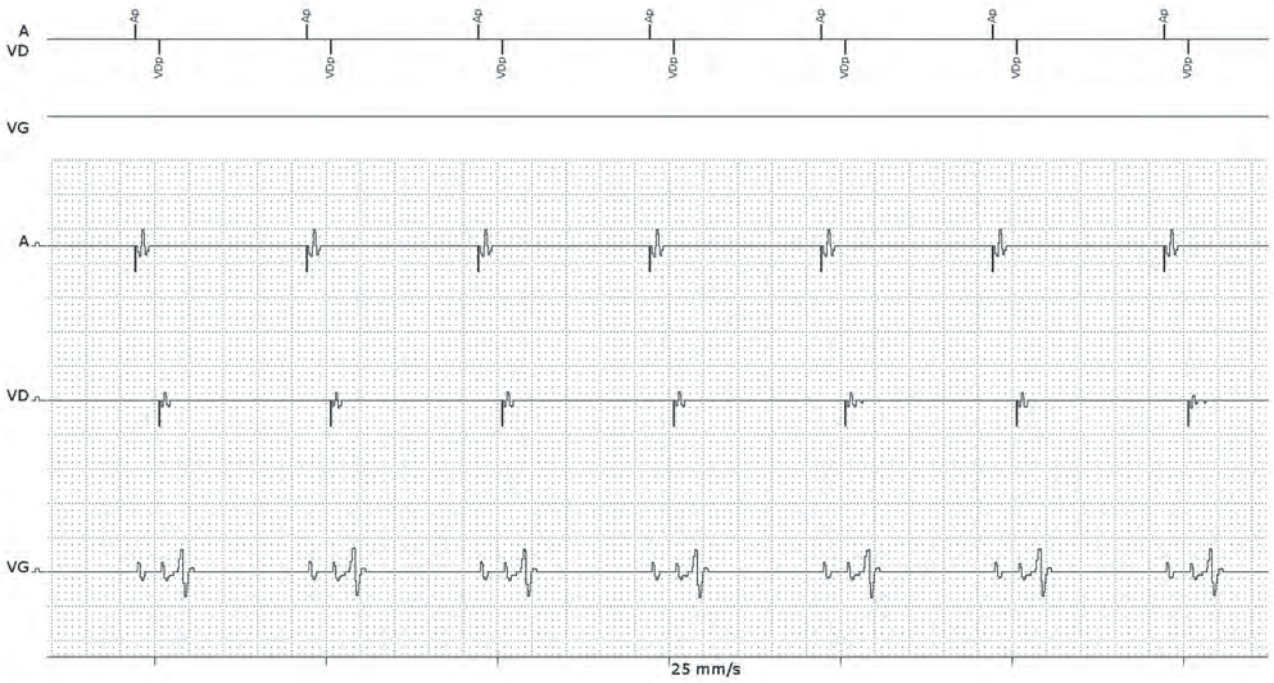
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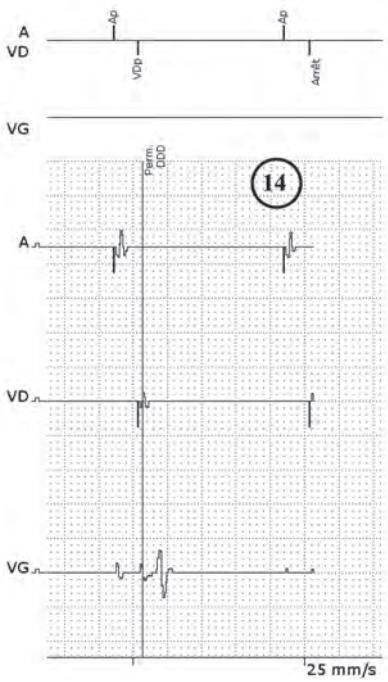
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Tracing 11: oversensing of diaphragmatic myopotentials

Patient

This 69-year-old man received a Lumax 340 HF-T triple chamber defibrillator for ischemic cardiomyopathy with left bundle branch block. An event report (yellow color) was issued in the context of a classified VF.

Main programmed settings

- VF zone (270 ms) and VT1 zone (330 ms)
- 12/16 cycles in the VF zone and 26 cycles in the VT1 zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.5 mV
- VF zone: ATP one shot and 8 shocks of maximum strength (40 J); VT1 zone: 3 bursts of ATP, followed by 3 ramps of ATP, followed by 8 shocks of maximum strength;
- Pacing mode: biventricular DDDR pacing at 50 bpm.

Remote tracing

1: atrial and biventricular paced rhythm;
2: oversensing of a high-frequency low-amplitude signal in the VF zone on the RV channel;
3: classification of VF episode after 12/16 cycles (3 VS and 1 VT2, 12 VF: VF counter full) classified in the VF zone;
4: no therapy delivered;
5: end of episode.

Programmer tracing (same episode)

6: onset of the charge of the capacitors (dark horizontal line);
7: end of oversensing and interruption of the charge after 3 ventricular paced cycles.

Comments

This patient presented with oversensing of diaphragmatic myopotentials, a phenomenon that might be reproduced with deep breathing. Oversensing of diaphragmatic myopotentials is suspected when low-amplitude signals are observed, preferentially visualized in the RV sensing channel, while often invisible on the shock channel. Oversensing is most likely to occur at the end of the cardiac cycle when gain and sensitivity are highest. This oversensing is most common in recipients of RV apical leads. In this patient, the sensitivity was reprogrammed to 0.8 mV, which eliminated this oversensing.

Status report - Mar 1, 2013

To: Service Télécardiologie

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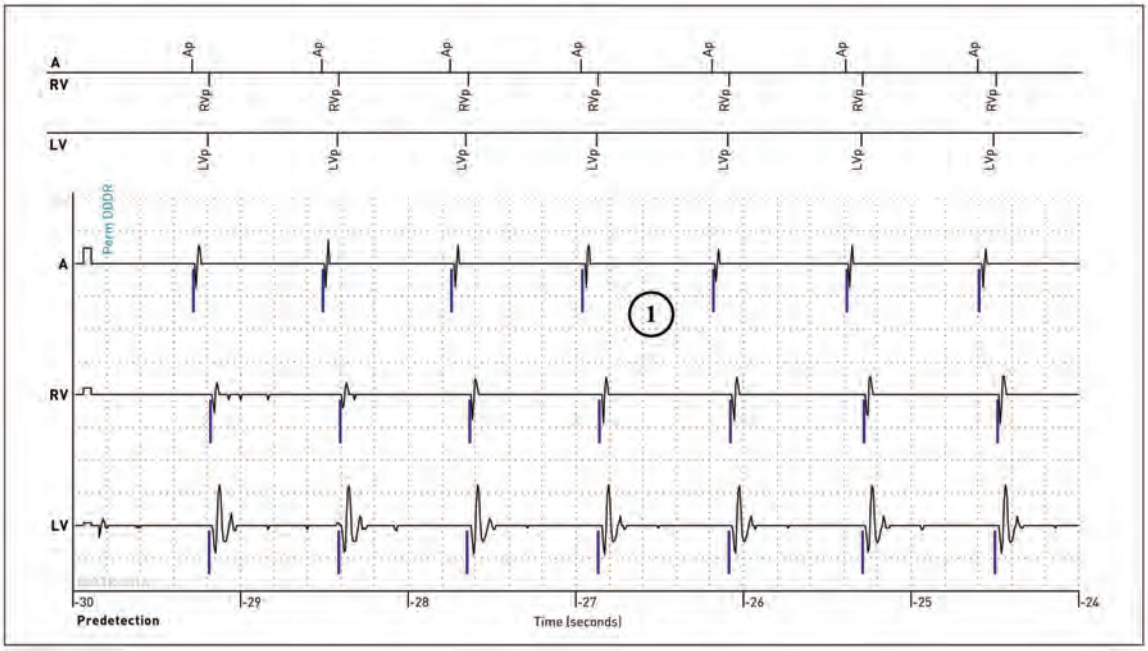
Name:	DOB: -	Lumax 340 HF-T	Last message: Mar 1, 2013
Patient ID:	Phone: -	CRT-D implanted Feb 8, 2010	Last clinic follow-up: Feb 20, 2013

Recordings

Recordings - Episode 18:

General	
Episode number	18
Episode type	VF
Detection	Jan 7, 2013 12:54:50 AM
Termination	Jan 7, 2013 12:55:02 AM
Duration	12s
Device settings no.	125
Detection	
Mean PP at initial detection [ms]	1089
Mean RR at initial detection [ms]	284
Onset [%]	82, fulfilled
Stability [ms]	> 247
Redetection	---

Therapy	
ATP in VT/VF delivered	0
ATP One Shot delivered	NO
Shocks delivered	0
Shocks aborted	1
Maximum energy [J]	40
Termination	
Mean PP at termination [ms]	841
Mean RR at termination [ms]	841
Remark	
none	



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Date:

Signature:

Status report - Mar 1, 2013

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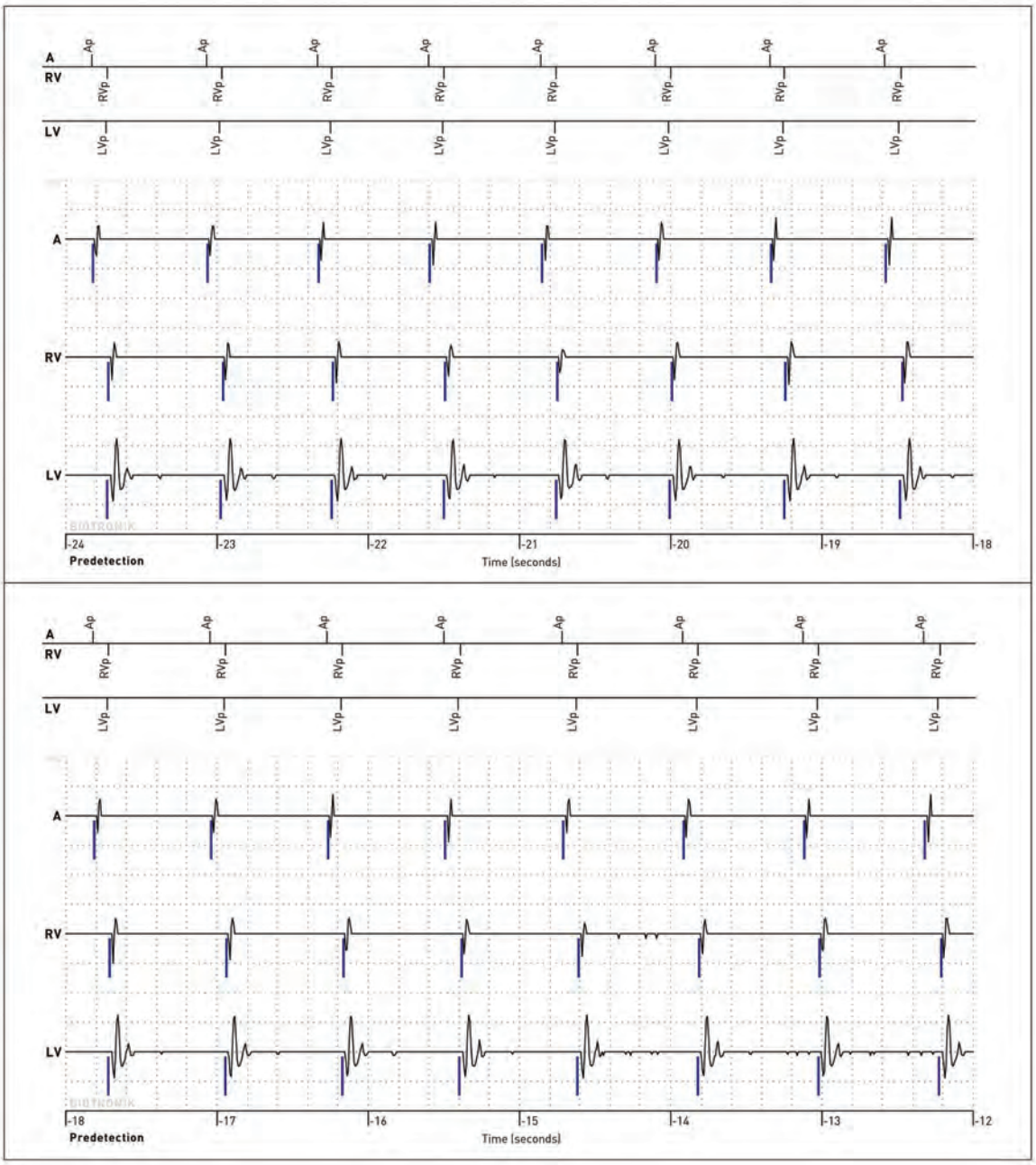
Name:	DOB: -	Lumax 340 HF-T	Last message: Mar 1, 2013
Patient ID:	Phone: -	CRT-D implanted Feb 8, 2010	Last clinic follow-up: Feb 20, 2013



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Date:

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2/4

Status report - Mar 1, 2013

To: Service Télécardiologie

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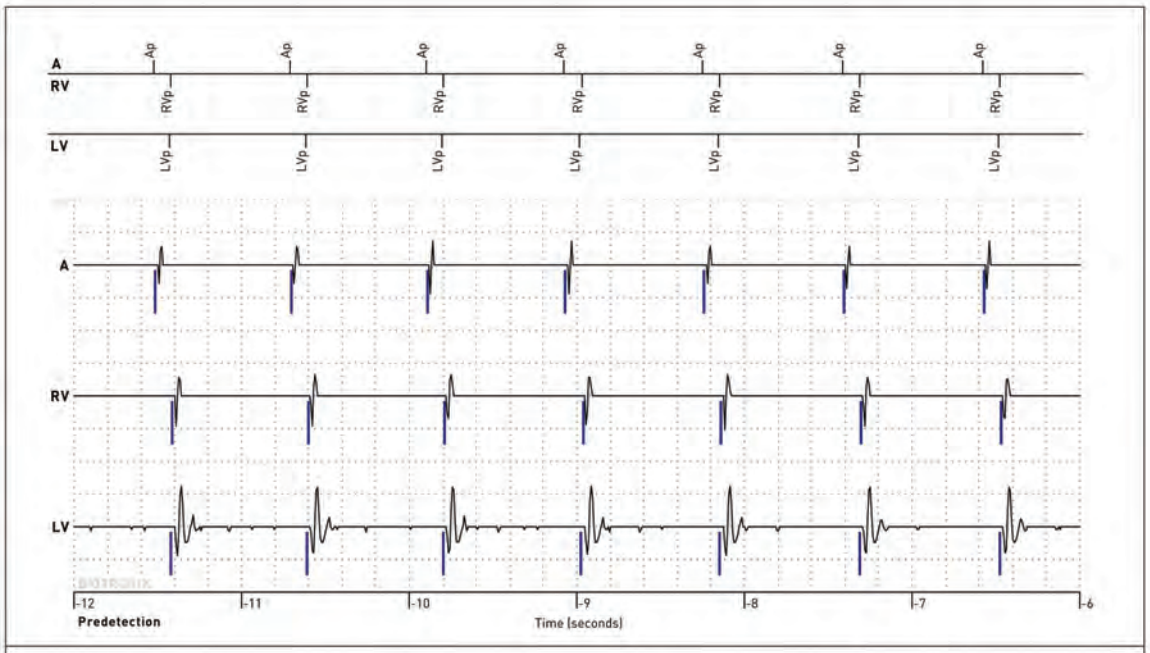
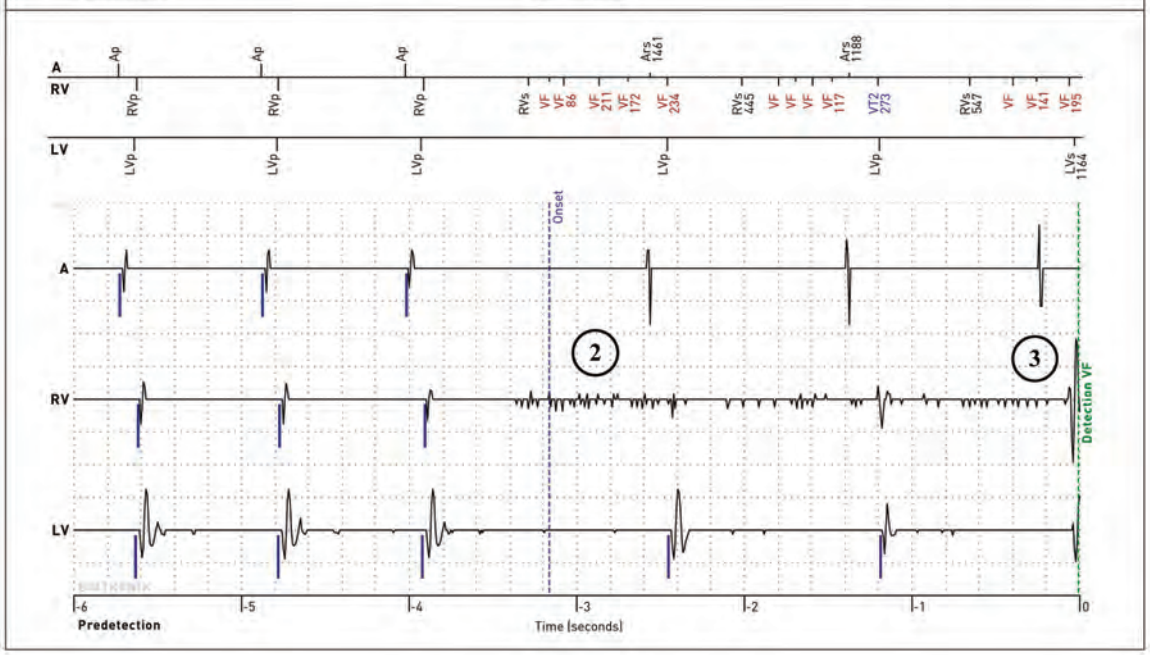
Name:	DOB: -	Lumax 340 HF-T	Last message: Mar 1, 2013
Patient ID:	Phone: -	CRT-D implanted Feb 8, 2010	Last clinic follow-up: Feb 20, 2013





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Date:

Signature:

3/4

Status report - Mar 1, 2013

To: Service Télécardiologie

BIOTRONIK
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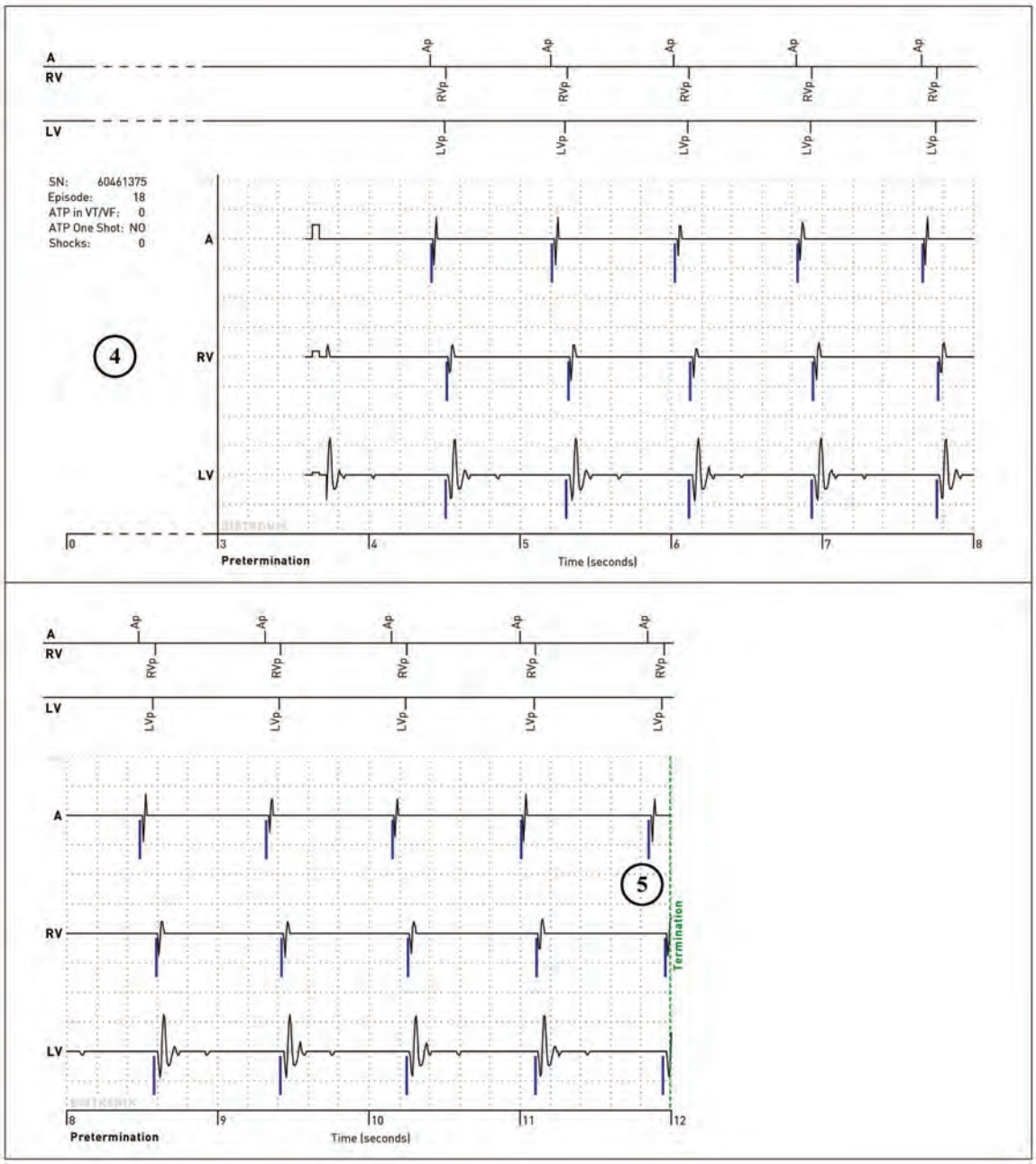
Name:	DOB: -	Lumax 340 HF-T	Last message: Mar 1, 2013
Patient ID:	Phone: -	CRT-D implanted Feb 8, 2010	Last clinic follow-up: Feb 20, 2013



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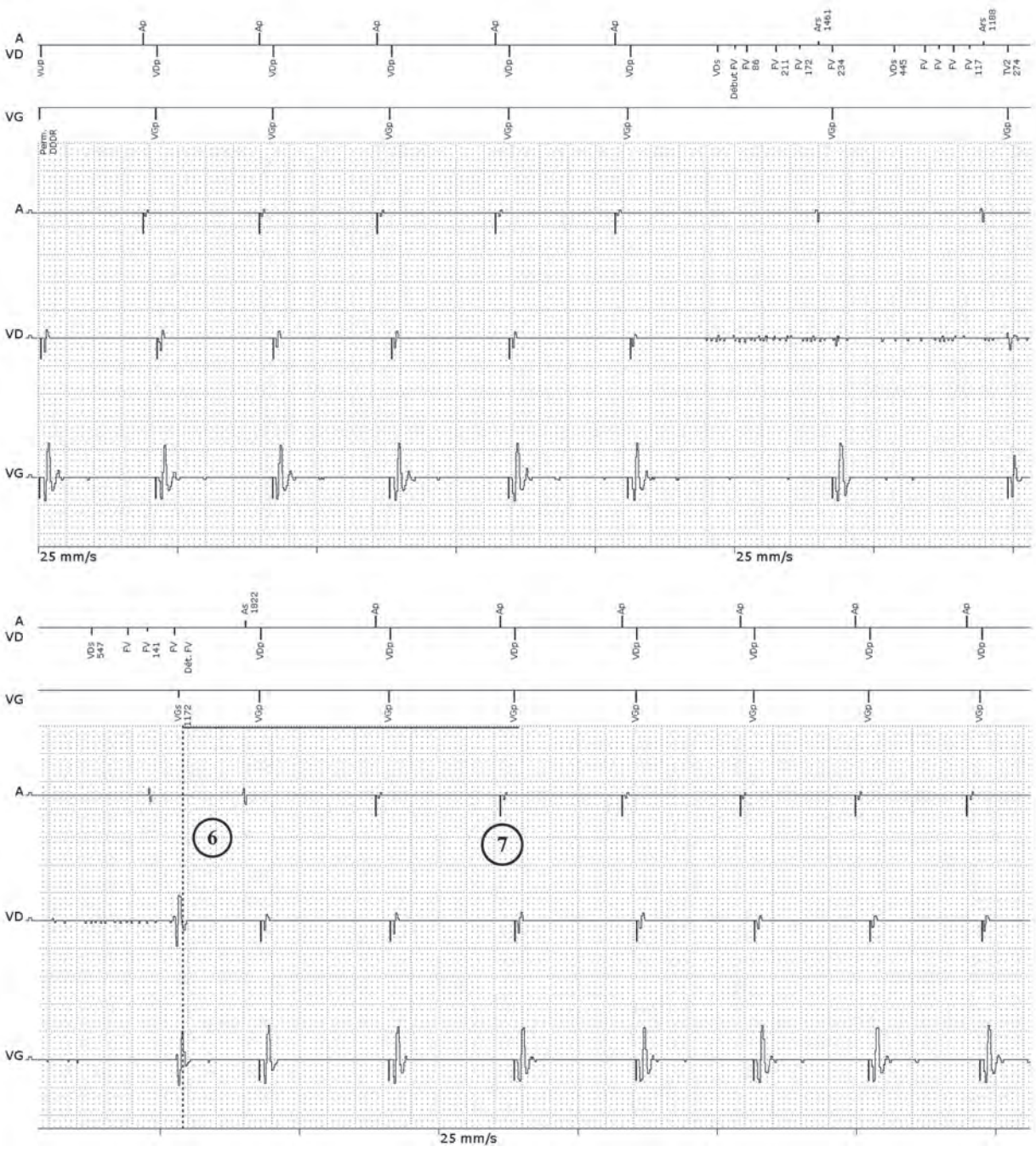
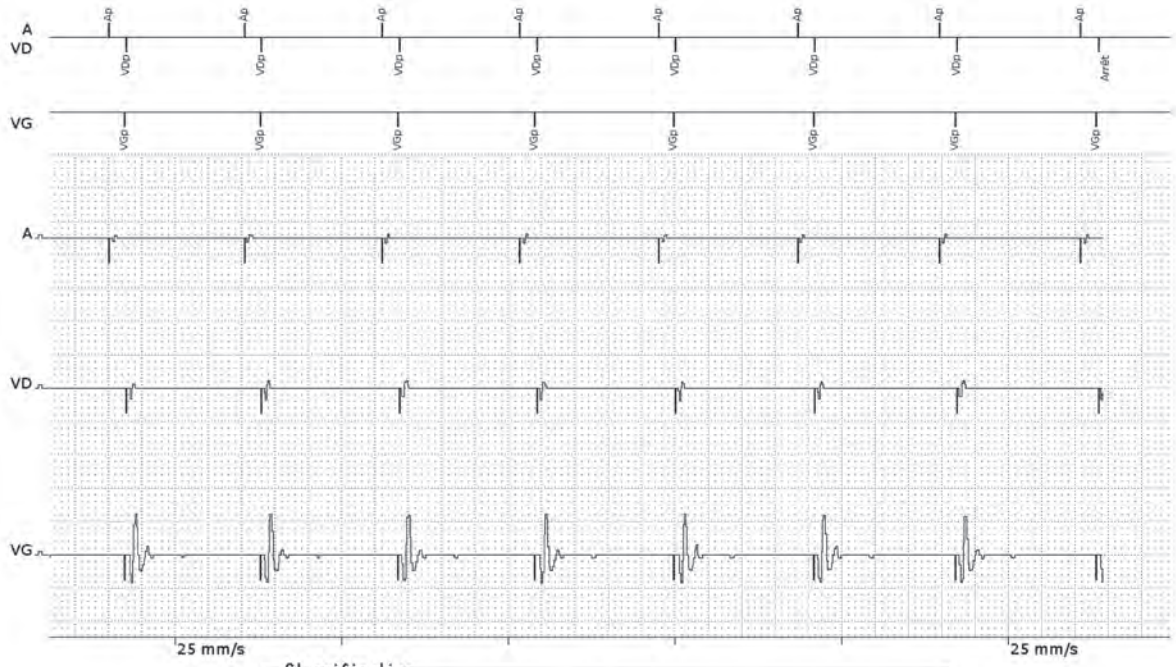
4/4

PDF: BIOTRONIK - Lumax 340 HF-T - 2 / 14





Classification			
Zone		FV	
Début soudain mesuré dans V		82 %	(rempli)
Stabilité mesurée dans V		> 247 ms	
	TV1	TV2	FV
Redétections	0	0	0
Traitement			
ATP		0	
Chocs		0	
Energie max.		40 J	
ATP One Shot		Non	
Temps			
Classification		07/01/2013 00:54:50	
Fin		07/01/2013 00:55:02	
Durée		0:00:12	
N° programme		125	
Remarque			
1 Choc(s) interrompus			

Enregistrements

Date: **08/01/2013**
Heure: **10:19**

EGM 17

Zone	---
EGM de l'épisode N°.	17
Classification	
N° programme	125

Tracing 12: lead fracture

Patient

This 52-year-old woman received a Lumos VR-T single chamber defibrillator for Brugada syndrome. An event report (yellow color) was issued in the context of several VF episodes.

Main programmed settings

- Single VF zone (250 ms)
- 8/12 cycles in the VF zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.5 mV
- VF zone: 8 shocks of maximum strength (30 J)
- Pacing mode: VVI at 30 bpm

Remote report

Multiples episodes of VF.

Remote tracing 1

1: oversensing, in the RV channel, of supernumerary signals of various morphologies, occurring after sensing of the R wave;
2: classification of VF (8/12 cycles classified in the VF zone); no therapy delivered.

Remote tracing 2

3: tracing nearly identical to the previous tracing;

Remote tracing 3

4: tracing nearly identical to the previous tracing.

Comments

This patient received a Lumos defibrillator (a relatively old model), which explains the short duration (6 sec before the classification) of remote electrograms recorded. The signals typical of lead fracture are usually identified by the absence of a fixed relationship between the supernumerary signals and the cardiac cycle. The presence of high-amplitude signals saturating the amplifiers is concordant with fracture currents. The tracings are characteristic, with supernumerary signals and interspersed QRS complexes. This indicates the presence of a rupture in the intracardiac segment of the lead, with the various signals generated by the cardiac contraction. While the pacing lead impedance is not systematically affected, an insulation breakdown should be suspected if it is <200 Ohms, versus a lead fracture if it is >2,000 Ohms. Likewise, shock impedance usually varies between 25 and 75 Ohms. A lower value suggests loss of insulation integrity, while a higher value suggests lead fracture.
If an impedance curve has been memorized by the device, it is important to recognize a sudden change in that curve, even if it remains within normal limits. The association of an abnormal impedance and the detection of <140 ms RR cycles is highly suggestive of lead dysfunction. Chest radiographs show a fracture in <50% of cases of lead fractures. This patient was asymptomatic and the interrogation of the device's memory revealed several episodes of temporary oversensing and charge of the capacitor without therapy delivery. These repetitive charges cause premature depletion of the batteries. Remote monitoring is highly contributory in this kind of subclinical lead dysfunction, by offering an early diagnosis after the first episode of aborted shock, or when the lead impedances changes suddenly, preventing the premature depletion of the pulse generator and the delivery of inappropriate therapies. The patient underwent explantation of the dysfunctional lead and implantation of a new ipsilateral lead.

Rapport d'état - 5 nov. 2009

A :

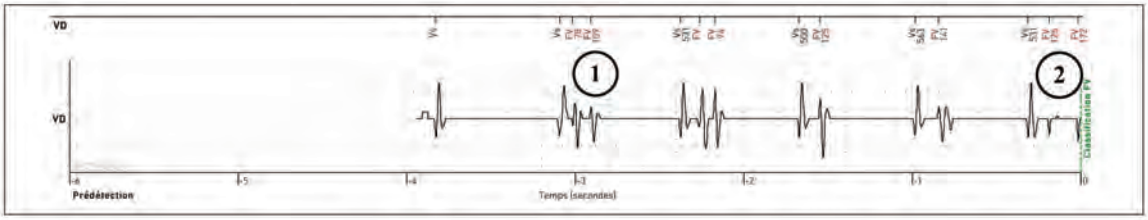
BIOTRONIK
excellence for life

Nom :	DdN :	Lumos VR-T	Dernier message : 15 oct. 2009
ID patient :	Téléphone : -	ICD implanté le 18 févr. 2007	Dernier suivi : 13 oct. 2009

Enregistrements

Enregistrements - Episode 10:

Généralités		**Traitement**	
Numéro d'épisode	10	ATP délivrées	0
Type d'épisode	FV	Choc(s) délivré(s)	0
Classification	12 oct. 2009 10:27:25	**Remarque**	
Fin	12 oct. 2009 10:27:32	aucun	
Durée	7s		
Classification			
Reclassification	aucun		



Service Client Télécardiologie :
Tél.: +49 30 68905 2440
Fax: +49 30 68905 2941

Date:

Signature:

1/3

Rapport d'état - 5 nov. 2009

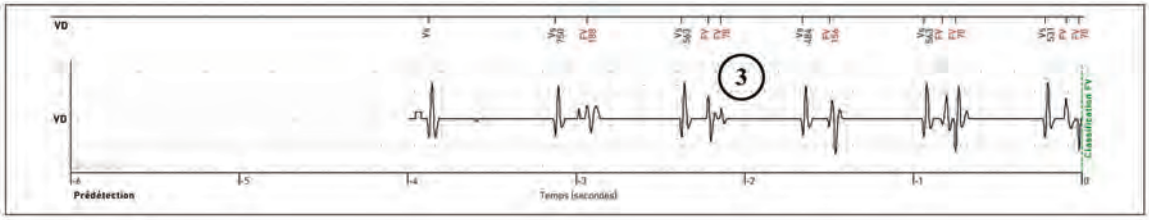
A :

BIOTRONIK
excellence for life

Nom :	DdN :	Lumos VR-T	Dernier message : 15 oct. 2009
ID patient :	Téléphone : -	ICD implanté le 18 févr. 2007	Dernier suivi : 13 oct. 2009

Enregistrements - Episode 9:

Généralités		**Traitement**	
Numéro d'épisode	9	ATP délivrées	0
Type d'épisode	FV	Choc(s) délivré(s)	0
Classification	12 oct. 2009 09:33:42	**Remarque**	
Fin	12 oct. 2009 09:33:52	aucun	
Durée	10s		
Classification			
Reclassification	aucun		



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Rapport d'état - 5 nov. 2009

A :

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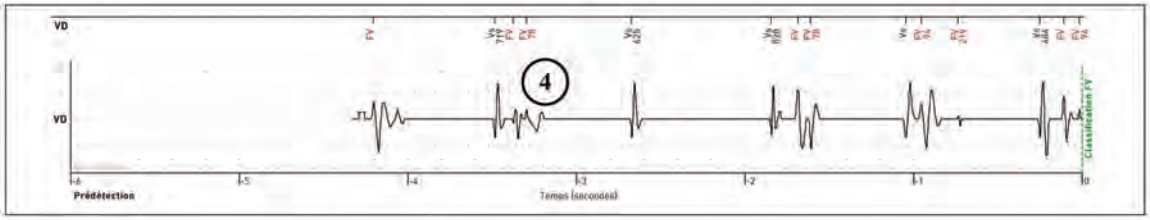
Nom :	DdN :	Lumos VR-T	Dernier message : 15 oct. 2009
ID patient :	Téléphone : -	ICD implanté le 18 févr. 2007	Dernier suivi : 13 oct. 2009

Enregistrements - Episode 8:

Généralités		Traitement	
Numéro d'épisode	8	ATP délivrées	0
Type d'épisode	FV	Choc(s) délivré(s)	0
Classification	12 oct. 2009 08:35:22	**Remarque**	
Fin	12 oct. 2009 08:35:32	aucun	
Durée	10s		
Classification			
Reclassification	aucun		



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Tracing 13: lead fracture

Patient

This 23-year-old woman received a dual chamber Lumax DR-T defibrillator after an episode of aborted sudden cardiac death. An event report (yellow color) was issued in the context of an episode de VF.

Main programmed settings

- Single VF zone (280 ms)
- 24/30 cycles in the VF zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.5 mV
- VF zone: ATP one shot, followed by 8 shocks of maximum strength (30 J)
- Pacing mode: AAI at 70 bpm

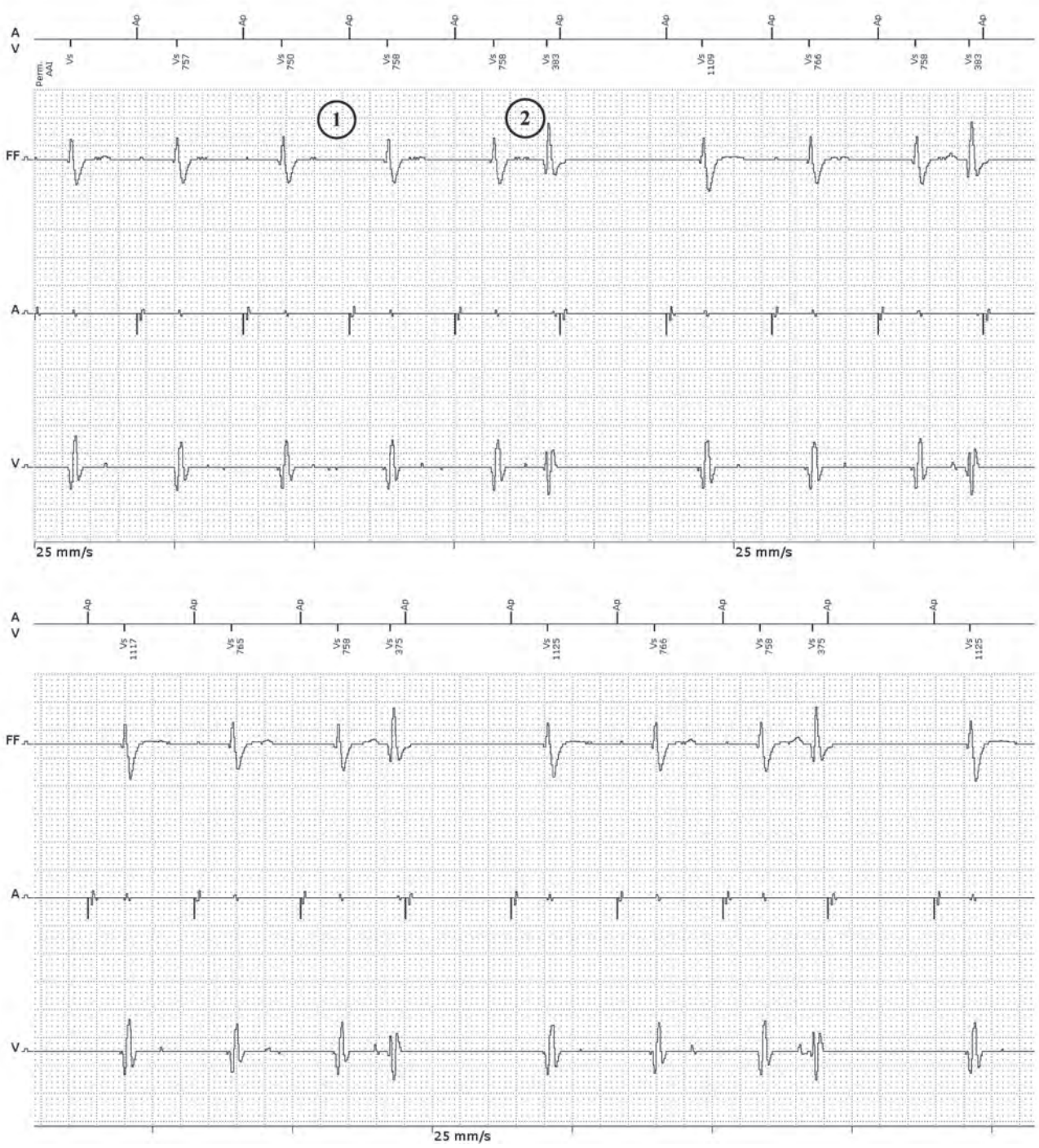
Programmer tracing

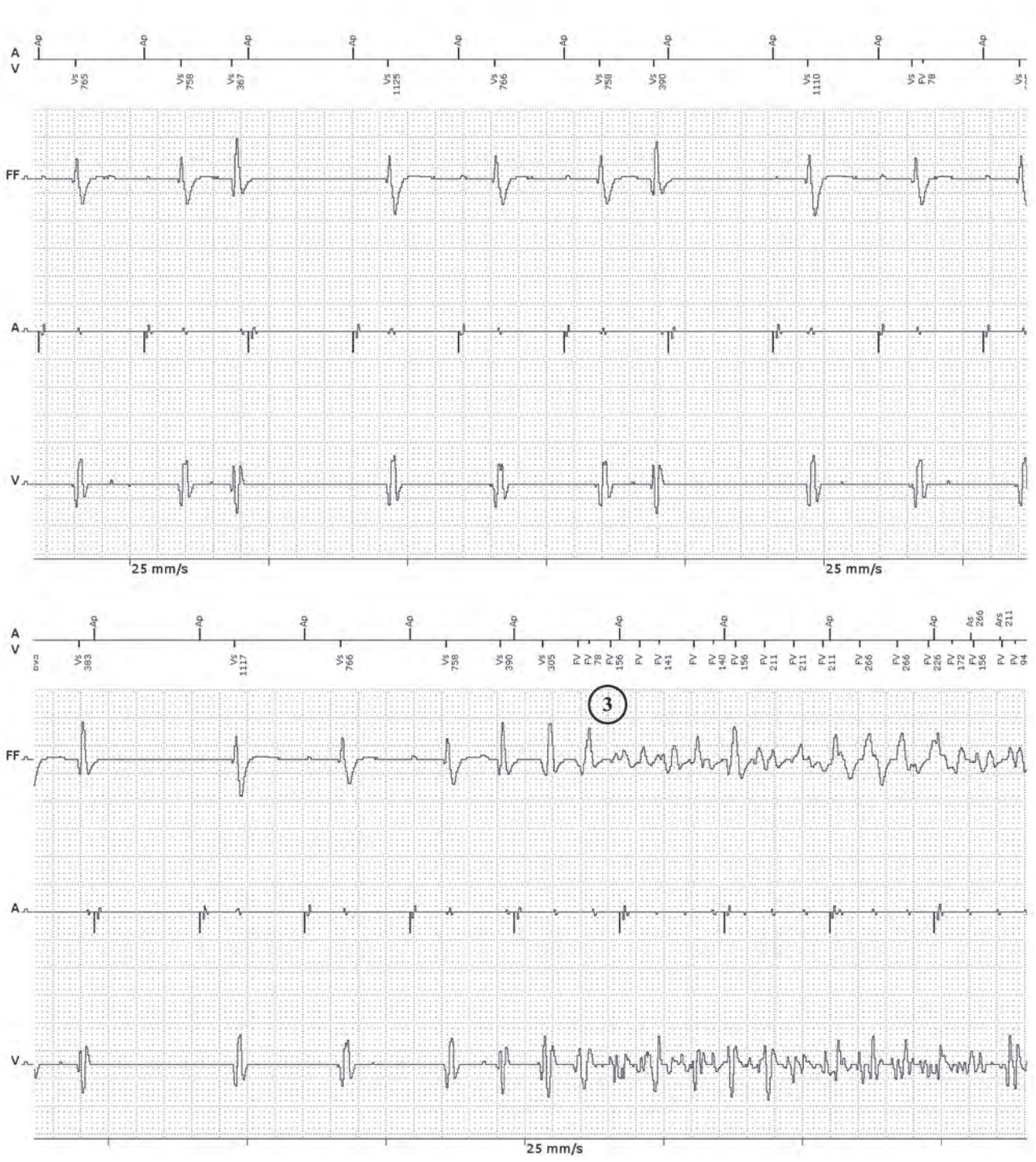
1: atrial paced ventricular sensed rhythm;
2: ventricular extrasystole;
3: polymorphous ventricular arrhythmia detected in the VF zone;
4: episode of VF detected and charge of the capacitors;
5: end of the charge;
6: shock delivered (40 J, 65 Ohms) on the first VF classified cycle following the charge;
7: successful shock;
8: oversensing of a high-amplitude ventricular signal at the level of the sensing and shock channels initially following the R wave;
9: prominent increase in oversensing of the signals, no longer synchronized with QRS complexes;
10: oversensing persists, though the VF redetection counter (24/30 cycles) is not filled.

Comments

Lead fracture is revealed here after the detection of an episode of VF and the delivery of an electrical shock, which occasionally stretches the already taut lead as the patient is shocked, which might damage an already fragile lead. The shock was successful and its impedance was within normal limits. The pacing impedance, also normal before this episode, increased suddenly thereafter. The association of very short cycles and high impedance is clearly in favor of a lead rupture. This patient underwent extraction of the fractured lead and implantation of a new, ipsilateral lead.

PDF: BIOTRONIK - Lumax 340 DR-T - - 18 / 28




A
V
FF
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3
FF
A
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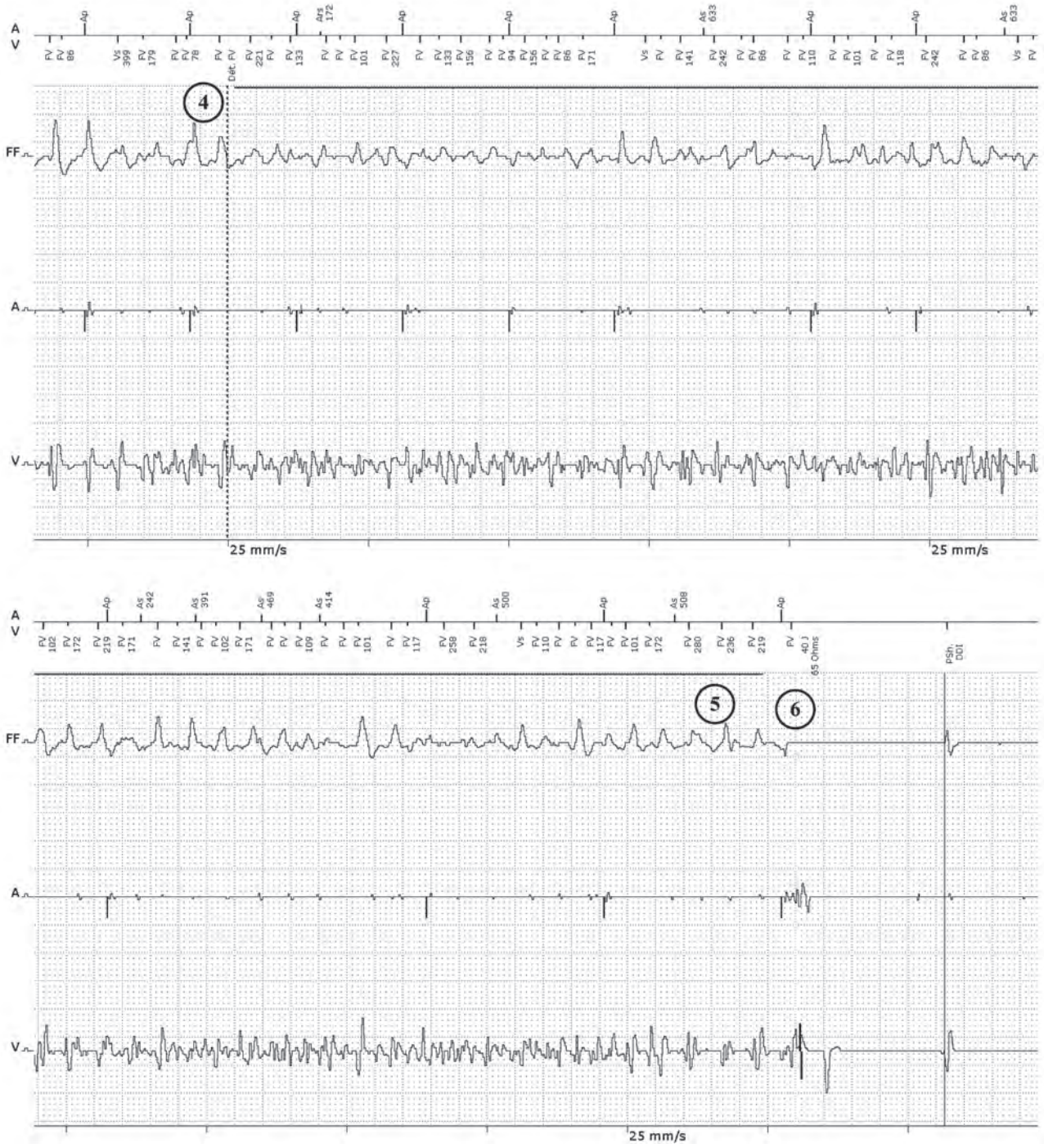
25 mm/s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25 mm/s
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A
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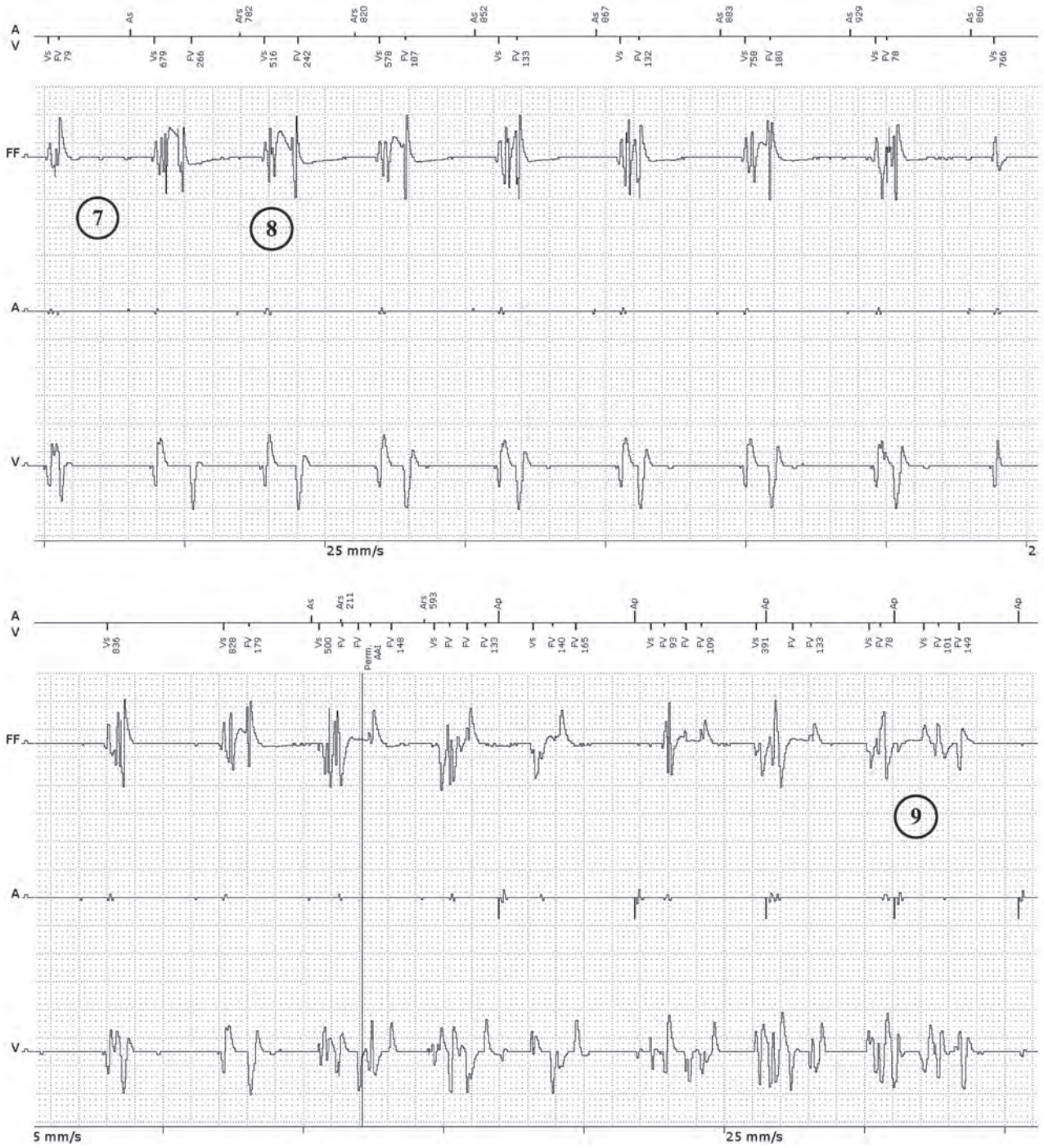
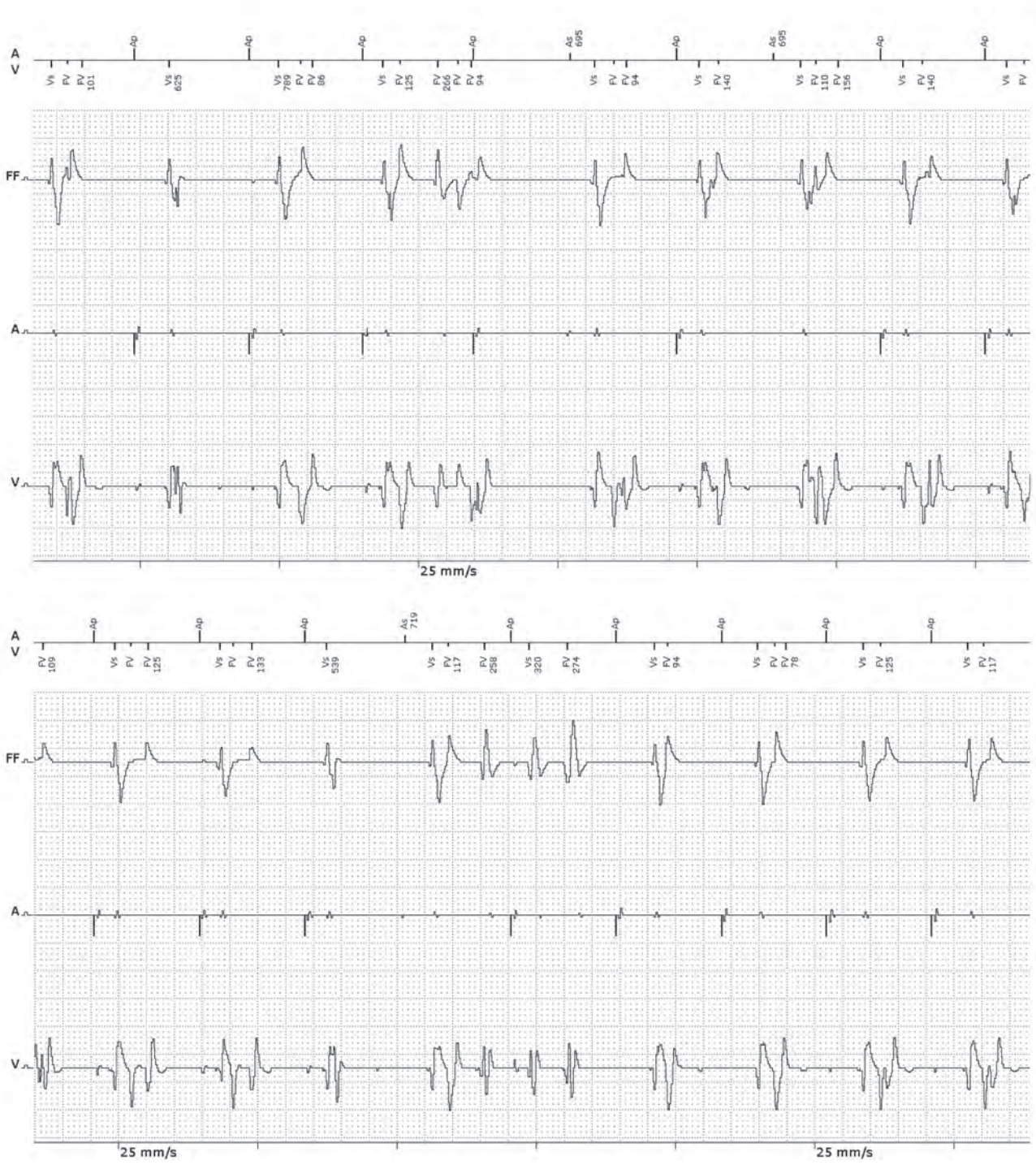
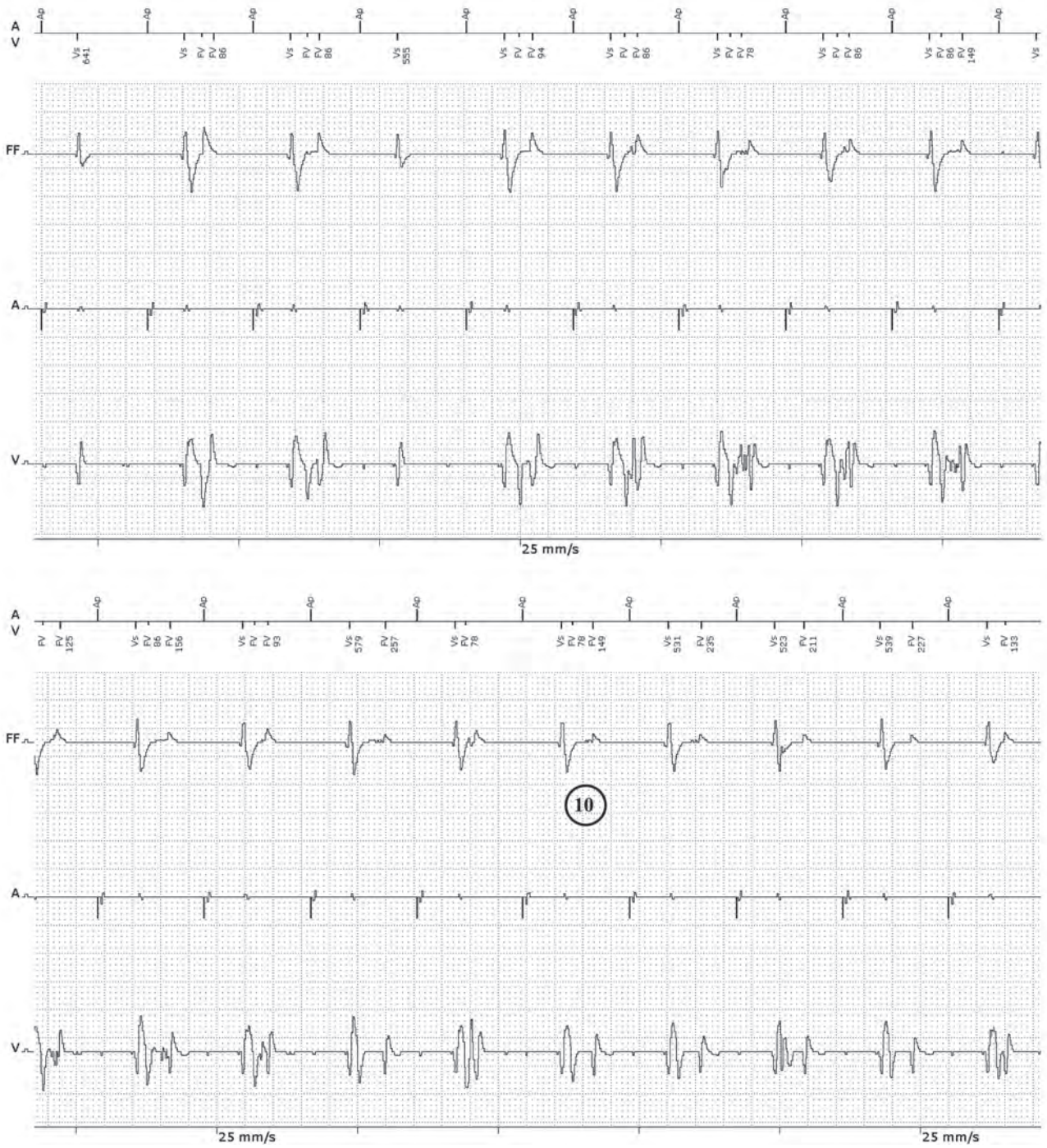
PDF: BIOTRONIK - Lumax 340 DR-T - [redacted] 21 / 28



PDF: BIOTRONIK - Lumax 340 DR-T - [redacted] - [redacted] 22 / 28

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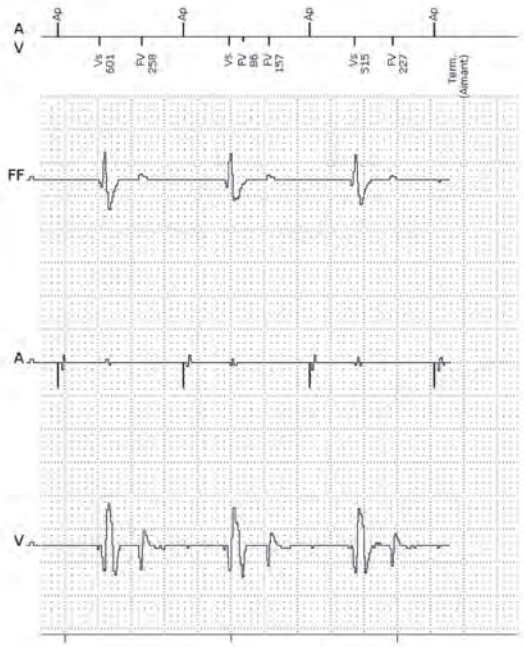

Classification

Zone			FV
Début soudain mesuré dans V			82 %
Stabilité mesurée dans V			153 ms
	TV1	TV2	FV
Redétections	0	0	0

Traitement

ATP	0
Chocs	1
Energie max.	40 J
ATP One Shot	Non

Temps

Classification	25/04/2012 23:29:31
Fin	25/04/2012 23:30:29
Durée	0:00:58
N° programme	55

Remarque

Abandon par effet aimant

Holter

Date: **30/05/2012**
Heure: **18:15**

EGM 22

Zone	Monitorage TA/FA
EGM de l'épisode N°.	22
Classification	16/05/2012 05:25:05
N° programme	57

Tracing 14: VT accurately detected by a single chamber defibrillator

Patient

This 48-year-old man received a Lumax 540 VR-T single chamber defibrillator in the context of ischemic cardiomyopathy with a depressed left ventricular ejection fraction. An event report (yellow color) was issued in the context of a classified VT1.

Main programmed settings

- VF zone (limit at 250 ms), VT1 zone (limit at 400 ms)
- 18/24 cycles in the VF zone and 26 cycles in the VT1 zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.8 mV
- VF zone: single ATP one shot, followed by 8 shocks of maximum strength (40 J); VT1 zone: 5 bursts of ATP, followed by 3 ramps of ATP, followed by a single 10-J shock, followed by a single 20-J shock, followed by 6 shocks of maximum strength
- Effective discrimination in the VT zone (onset 20%, stability 24 ms)
- Pacing mode: VVI at 40 bpm

Remote tracing

The 3 channels available are 1) the markers with the time intervals, 2) the shock channel (FF = far field) between the coil of the RV lead and the pulse generator, and 3) the right ventricular (RV) sensing channel.

1: spontaneous rhythm;
2: ventricular pair;
3: sudden onset of tachycardia alternating in the beginning between the VT1 and the VF zones. The sudden onset was calculated on the basis of 8 sliding cycles, with the average of the last 4 RR intervals compared with the average of the next 4 RR intervals. The criterion was fulfilled when the difference between the 2 averages (61% in this case) exceeded the programmed sudden onset (20% in this patient);
4: the morphology criterion is not included in the discrimination; the difference in morphology during the tachycardia versus spontaneous rhythm is visible on both the sensing and the high-voltage (shock) channel;
5: the tachycardia stabilized. The stability criterion is fulfilled (rhythm sensed as stable) when, for a ventricular cycle, the difference between one RR interval and one of the 3 preceding RR intervals is shorter than the programmed value (24 ms in this patient). For this episode, the criterion was fulfilled, as the difference between 1 cycle and the 3 preceding RR never exceeded the 24-ms threshold. The 7-ms value shown in the table corresponds to the average difference among the last 4 cycles before the VT classification;
6: classification of the VT1 episode. The average RR interval during the initial classification corresponds to the average of the 4 cycles preceding the classification;
7: delivery of a burst of ATP (not visible);
8: termination of the arrhythmia.

Comments

Single chamber defibrillators cannot measure the atrial rate. Biotronik defibrillators identify the origin of arrhythmias by analyzing the sudden versus gradual onset of the tachycardia and the stability versus instability of the rhythm. While neither criterion alone guarantees a flawless discrimination of all tachycardias, their specificity increases when they are combined. Depending on their settings, the sensitivity and specificity of each measurement can be increased or decreased. In this example, the sudden onset and regularity of the rhythm favored VT. Likewise, the variation in the morphology of the ventricular electrograms (which are not included in the device's discrimination algorithm) was in favor of VT.

Status report - Oct 11, 2013

To: Service Télécardiologie

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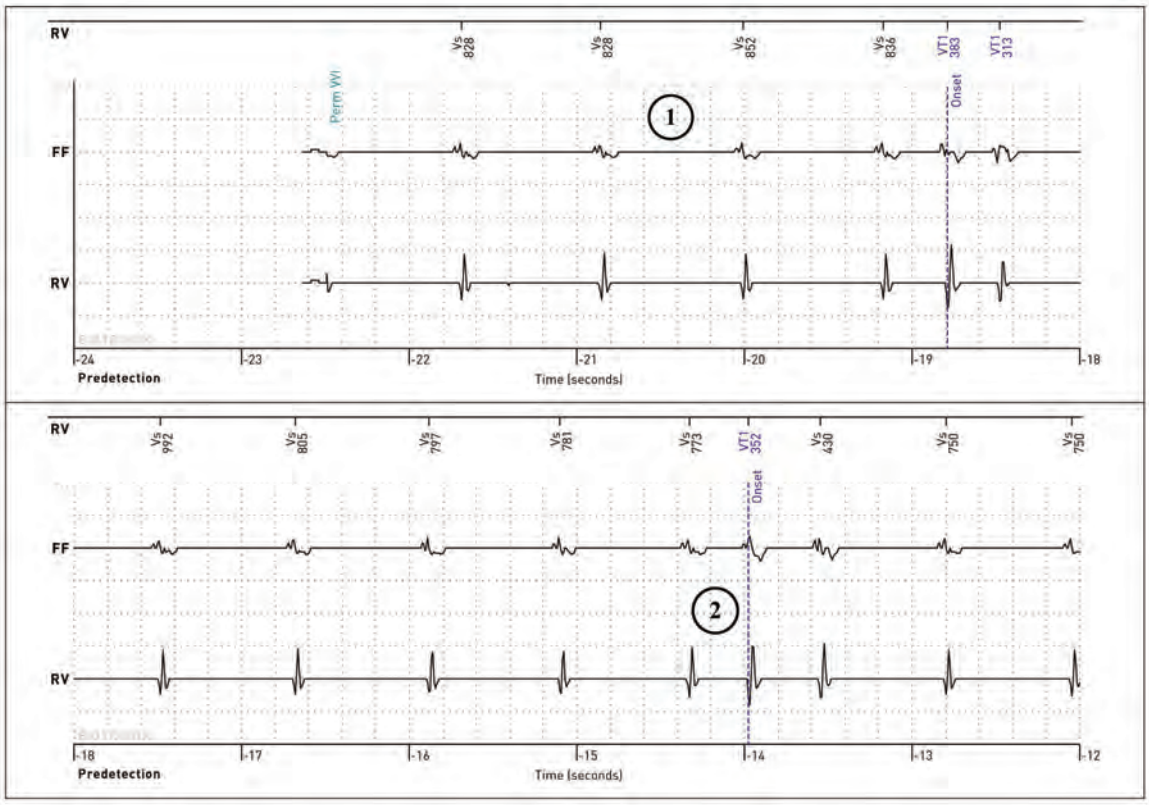
Name:	DOB:	Lumax 540 VR-T	Last message: Oct 11, 2013
Patient ID:	Phone: -	ICD implanted Jun 14, 2010	Last clinic follow-up: Feb 7, 2013

Recordings

Recordings - Episode 33:

General		Therapy	
Episode number	33	ATP in VT/VF delivered	1
Episode type	VT1	ATP One Shot delivered	NO
Detection	Nov 19, 2012 4:29:31 AM	Shocks delivered	0
Termination	Nov 19, 2012 4:29:43 AM	Shocks aborted	0
Duration	12s	Maximum energy [J]	---
Device settings no.	9	**Termination**	
Detection		Mean RR at termination [ms]	861
Mean RR at initial detection [ms]	277	**Remark**	
Onset [%]	61, fulfilled	none	
Stability [ms]	7		
Redetection	---		



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Status report - Oct 11, 2013

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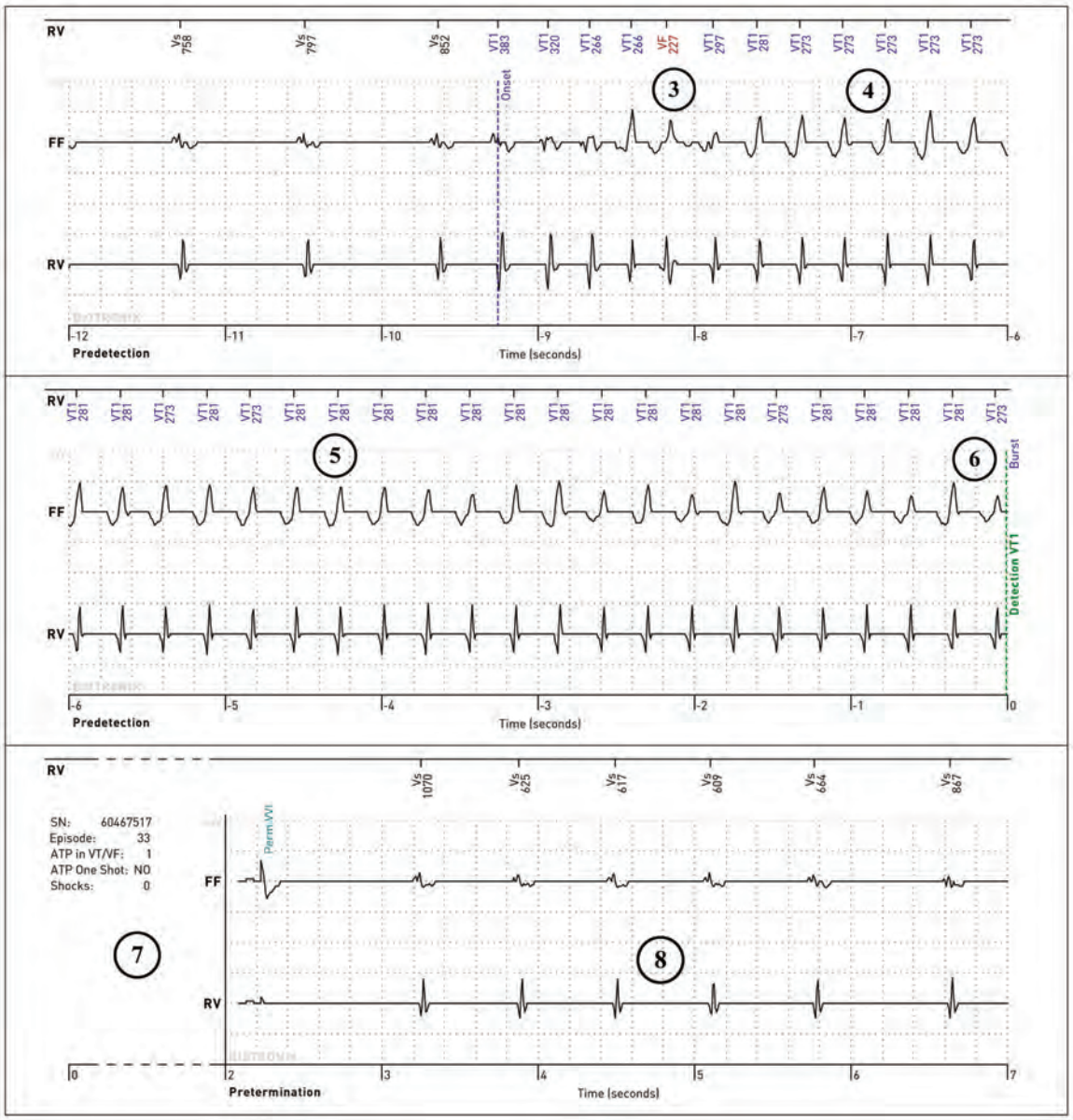
Name:	DOB:	Lumax 540 VR-T	Last message: Oct 11, 2013
Patient ID:	Phone: -	ICD implanted Jun 14, 2010	Last clinic follow-up: Feb 7, 2013



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Status report - Oct 11, 2013

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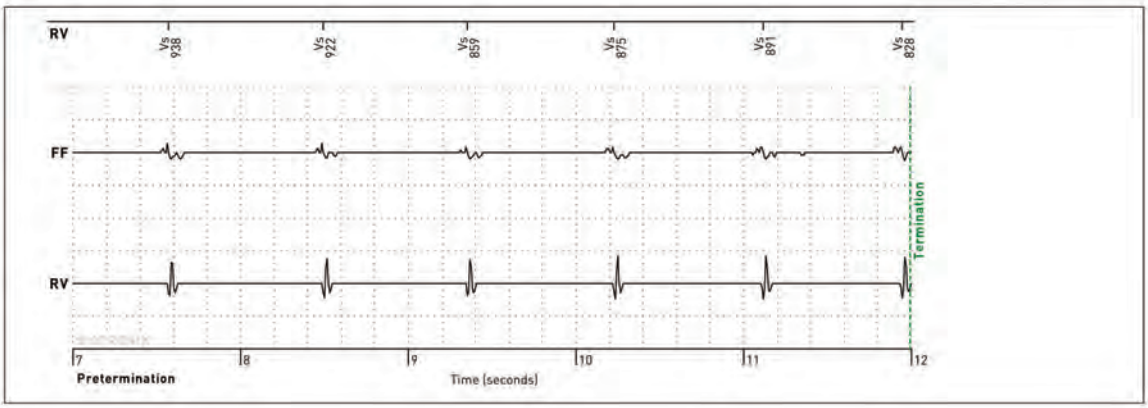
Patient ID:	Phone: -	ICD implanted Jun 14, 2010	Last clinic follow-up: Feb 7, 2013



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Tracing 15: poorly discriminated VT by a single chamber defibrillator

Patient

This 53-year-old man received a Lumax 340 VR-T single chamber defibrillator for idiopathic cardiomyopathy and a depressed left ventricular ejection fraction. An event report (yellow color) was issued in the context of a classified SVT.

Main programmed settings

- VF zone (limit at 260 ms) and VT1 zone (limit at 330 ms)
- 12/16 cycles in the VF zone and 26 cycles in the VT1 zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.8 mV
- VF zone: ATP one shot, followed by 8 shocks of maximum strength (40 J); VT1 zone: 3 bursts of ATP, followed by 3 ramps of ATP, followed by a single 10-J shock, a single 20-J shock, followed by 6 shocks of maximum strength
- Effective discrimination in the VT zone (onset = 20%, stability = 24 ms)
- Pacing mode: VVI at 30 bpm

Remote tracing

The 3 channels available are 1) the markers with the time intervals, 2) the shock channel (FF = far field) between the coil of the RV lead and the pulse generator, and 3) the right ventricular (RV) sensing channel.

1: tachycardia with cycles hovering near the VT1 zone limit (330 ms);
2: regular tachycardia;
3: diagnosis of SVT in absence of sudden onset (value shown in the table = 5%). Since the SVT counter is twice the VT counter; 52 cycles (26 x 2) were needed to reach an SVT classification;
4: persistence of the tachycardia hovering near the VT1 zone limit.

Comments

This patient presented with VT episodes, the rate of which oscillated around the lower limit of the tachycardia zone. The onset of the tachycardia is not visible, as it was slightly slower than the programmed zone. Consequently, the choice of rate of the VT zone has a direct influence on the quality of discrimination. The sudden onset criterion, designed to discriminate sinus tachycardia, on the principle that sinus tachycardia accelerates gradually, as opposed to VT that starts suddenly. This criterion is applied in initial classifications, though not in reclassifications. It may be the source of erroneous diagnosis in 2 types of patients: 1) those who develop VT upon exercise, where a clear demarcation between the rate of sinus tachycardia immediately preceding the VT and the VT rate is absent, and 2) those in whom, as illustrated here, the rate of the VT oscillates around the lower limit of the VT zone. These examples illustrate a) the limits of the use of a single criterion to accurately discriminate tachycardias, and b) the need to associate criteria.
In this patient, a change in the lower limit of the VT1 zone (to 400 ms) enabled an accurate classification and discrimination of the episodes and appropriate delivery of therapies.

Status report - Oct 11, 2013

To: Service Télécardiologie

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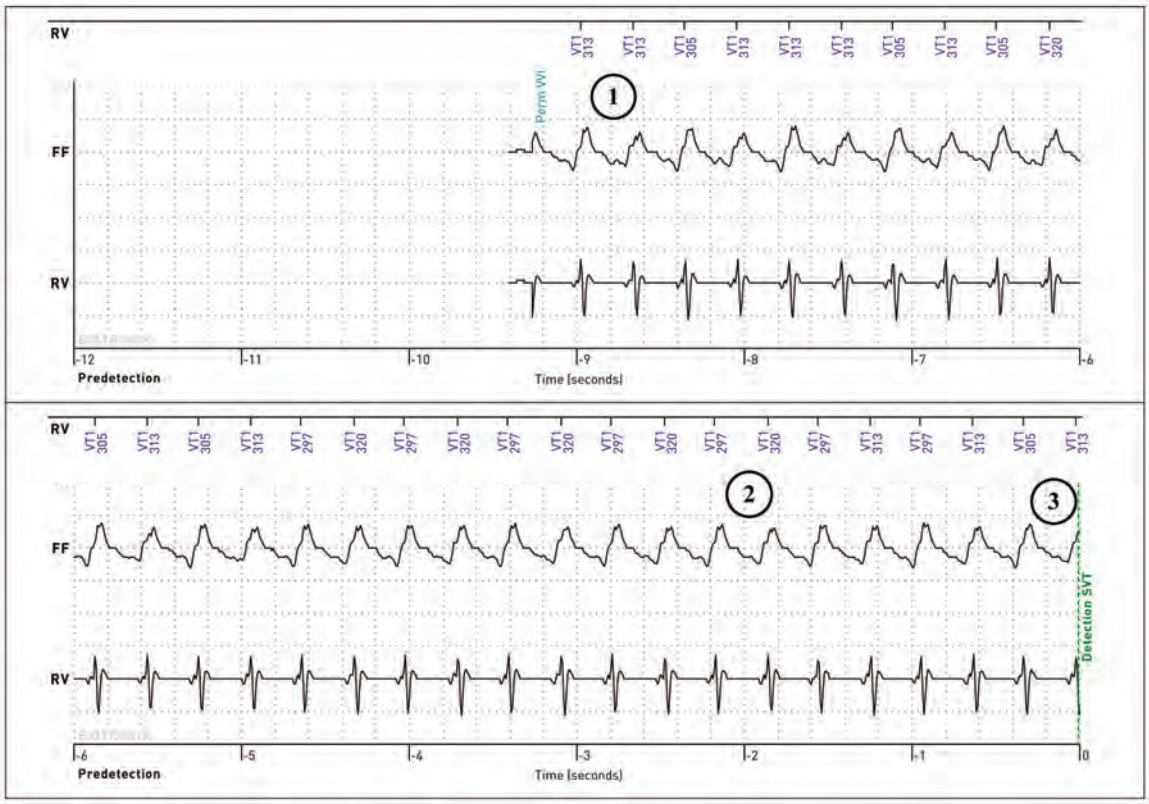
Name:	DOB:	Lumax 340 VR-T [XL]	Last message: Oct 11, 2013
Patient ID:	Phone: -	ICD implanted Sep 14, 2009	Last clinic follow-up: Jun 25, 2013

Recordings

Recordings - Episode 2:

General		Therapy	
Episode number	2	ATP in VT/VF delivered	0
Episode type	SVT	ATP One Shot delivered	NO
Detection	Sep 15, 2009 10:01:23 AM	Shocks delivered	0
Termination	Sep 15, 2009 10:28:35 AM	Shocks aborted	0
Duration	27min 12s	Maximum energy [J]	---
Device settings no.	6	**Termination**	
Detection		Mean RR at termination [ms]	329
Mean RR at initial detection [ms]	306	**Remark**	
Onset [%]	5	**Detection** SVT (onset not fulfilled)	
Stability [ms]	15		
Redetection	---		



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Status report - Oct 11, 2013

To: Service TéléCardiologie

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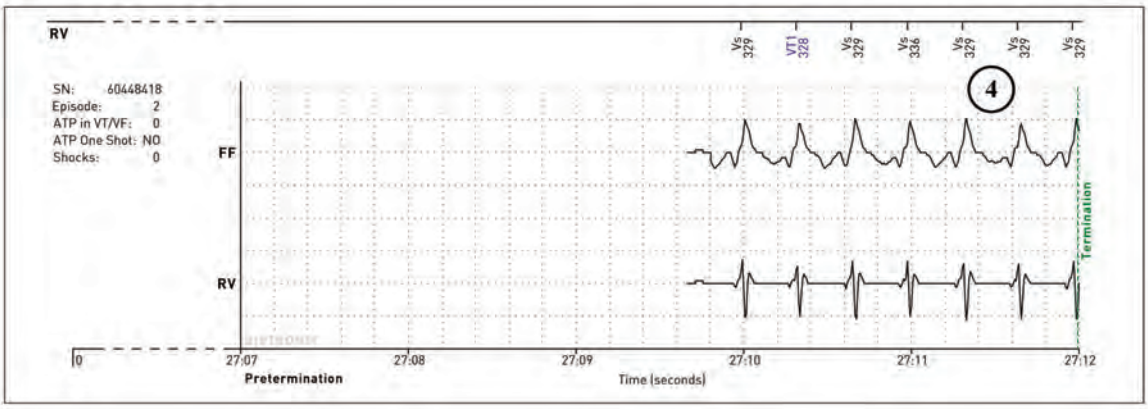
Name:	DOB:	Lumax 340 VR-T [XL]	Last message: Oct 11, 2013
Patient ID:	Phone: -	ICD implanted Sep 14, 2009	Last clinic follow-up: Jun 25, 2013



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Tracing 16: accurate discrimination of sinus tachycardia by a single chamber defibrillator

Patient

This 35-year-old man received a Lumos VR-T single chamber defibrillator for the management of episodes of sustained VT in the background of hypertrophic cardiomyopathy. An event report (yellow color) was issued in the context of classified SVT.

Main programmed settings

- VF zone (280 ms limit), VT1 zone (400 ms limit)
- 8/12 cycles in the VF zone and 26 cycles in the VT1 zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.8 mV
- VF zone: 8 shocks of maximum strength (30 J); VT1 zone: 5 bursts of ATP, followed by 5 ramps of ATP, followed by a single 10-J shock, followed by 7 shocks of maximum strength
- Effective discrimination in the VT zone (onset 20%, stability 24 ms)
- Pacing mode: VVI at 40 bpm

Remote tracing

A very short EGM (Lumos defibrillator) was available, revealing a ventricular rhythm at the limit of the VT1 zone. In absence of sudden onset, the episode classification was SVT.

Programmer tracing

1: gradual acceleration of the ventricular rhythm, initially to the limit of the VT1 zone;
2: detection of episode of SVT in absence of sudden onset explained by the gradual acceleration of the tachycardia;
3: shortest cycle = 359 ms;
4: gradual slowing of the tachycardia to the limit of the VT1 zone.

Comments

This tracing shows an episode of sinus tachycardia accurately identified by the defibrillator in absence of sudden onset. The evolution of the heart rate is characteristic, with a gradual acceleration, followed by a gradual slowing at the end of exercise. In this young patient, the programming of the lower limit of the VT1 zone (150 bpm) was probably too low, as the acceleration of the sinus rate was in the range of rates reached during relatively vigorous exercise, despite properly prescribed treatment with a beta-adrenergic blocker. In these young patients, whose chronotropic function is preserved, the best discrimination probably consists of avoiding, whenever possible, the overlap between a) the zone of diagnosis and therapies and b) the zone of sinus acceleration. The heart rate during the episodes of sustained VT preceding the defibrillator implantation ranged between 180 and 200 bpm (the patient was already treated with the same doses of beta-adrenergic blocker). An increase in the lower limit of the VT1 zone to 160 bpm eliminated the overlap.

Status report - Feb 13, 2013

To: Service TéléCardiologie

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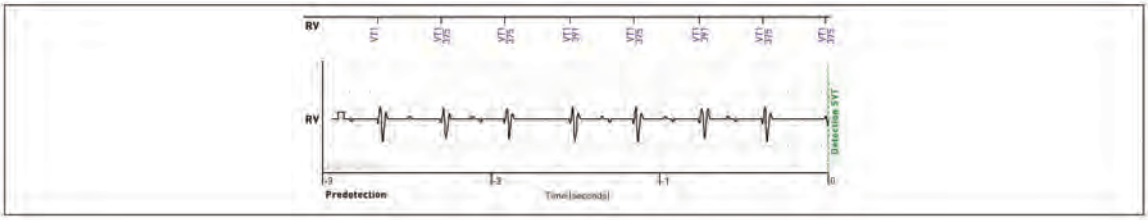
Name:	DOB: -	Lumos VR-T	Last message: Jan 10, 2013
Patient ID:	Phone:	ICD implanted Oct 11, 2007	Last clinic follow-up: Dec 4, 2012

Recordings

Recordings - Episode 14:

General		Therapy	
Episode number	14	ATP delivered	0
Episode type	SVT	Shocks delivered	0
Detection	May 18, 2011 1:36:24 PM	**Remark**	
Termination	May 18, 2011 1:37:08 PM	**Detection**	SVT (no onset), SVT in VT1 detected
Duration	44s		
Detection			
Redetection	---		



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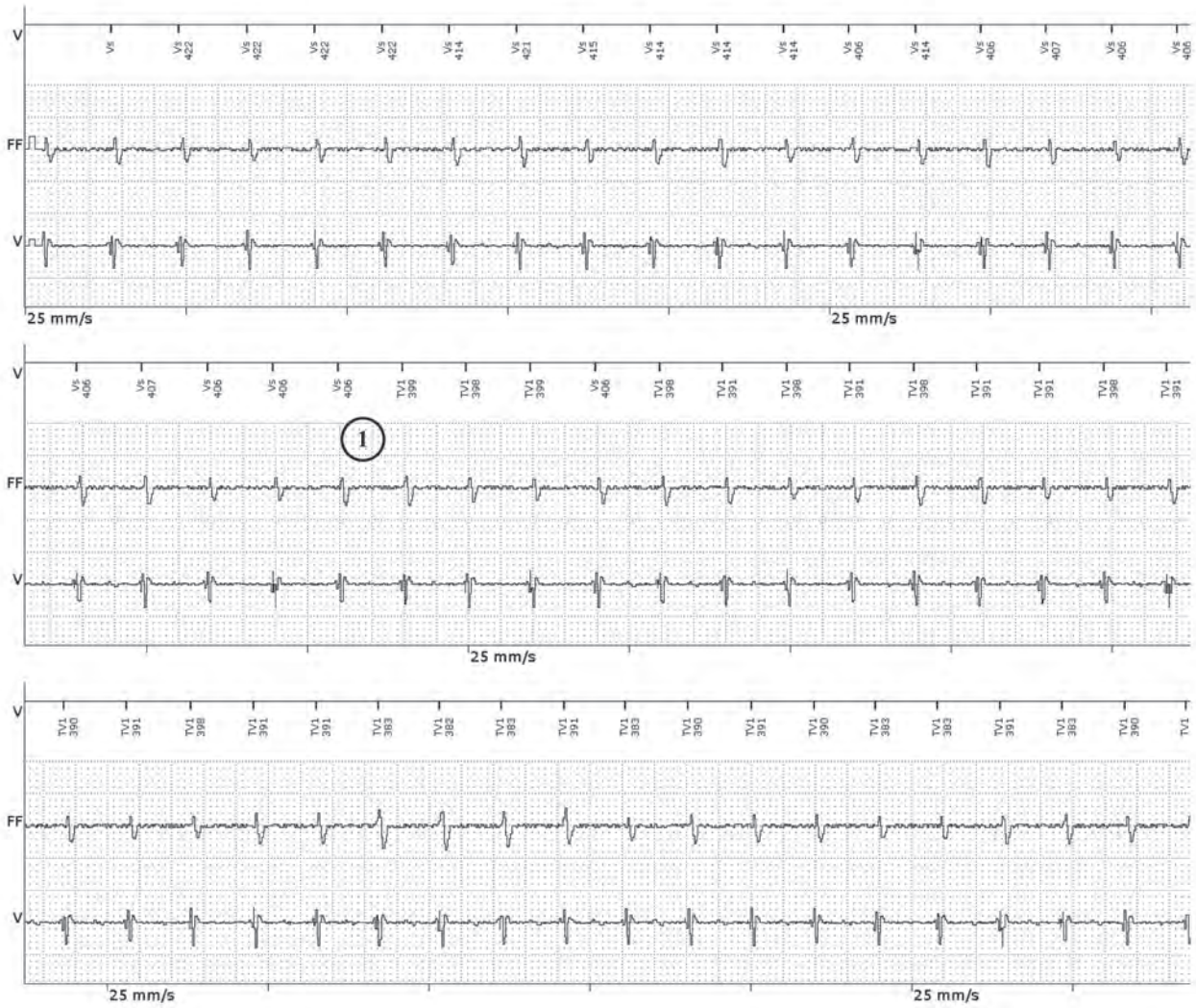
PDF: BIOTRONIK - Lumos VR-T - [redacted] - [redacted] 4 / 15



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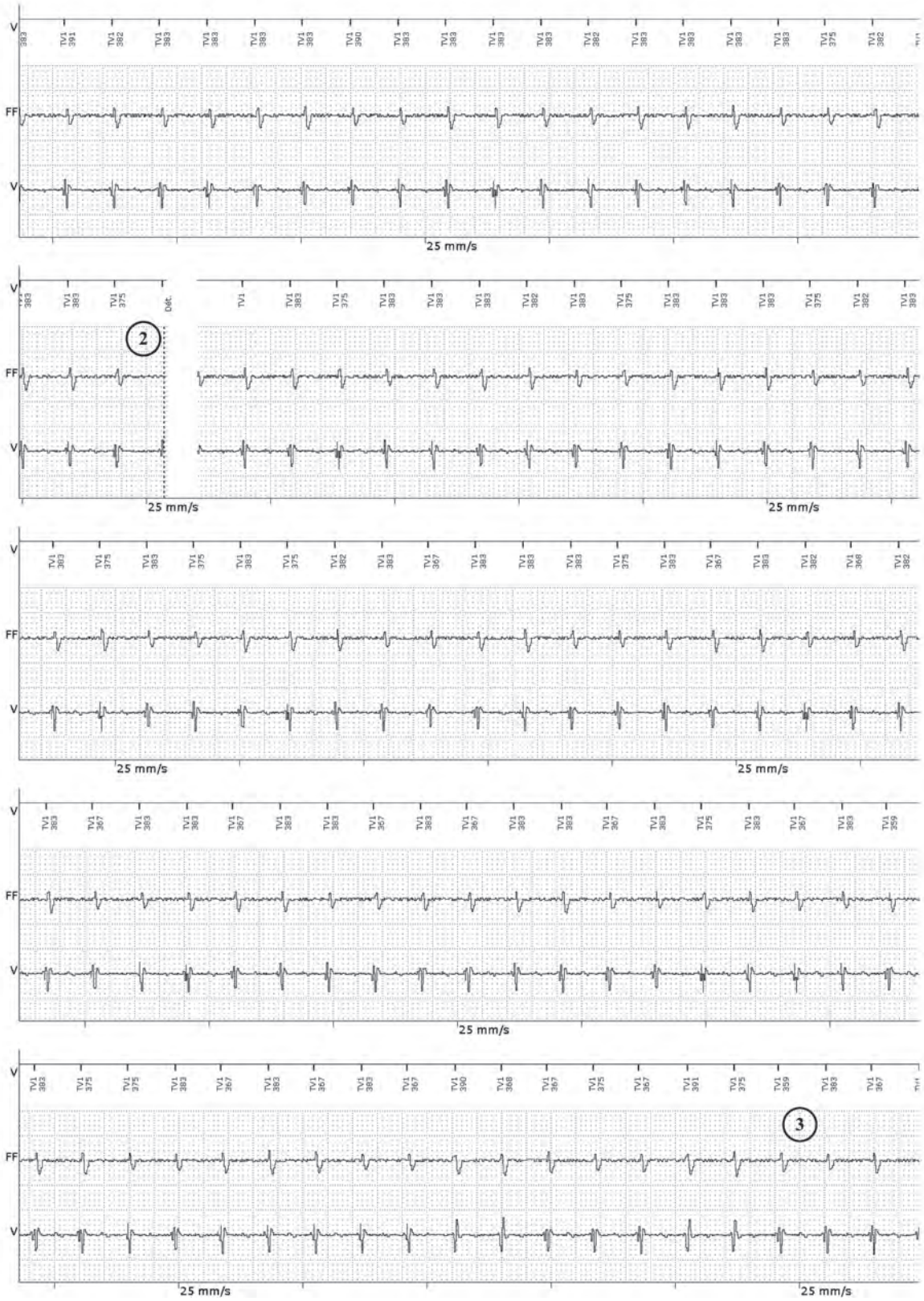

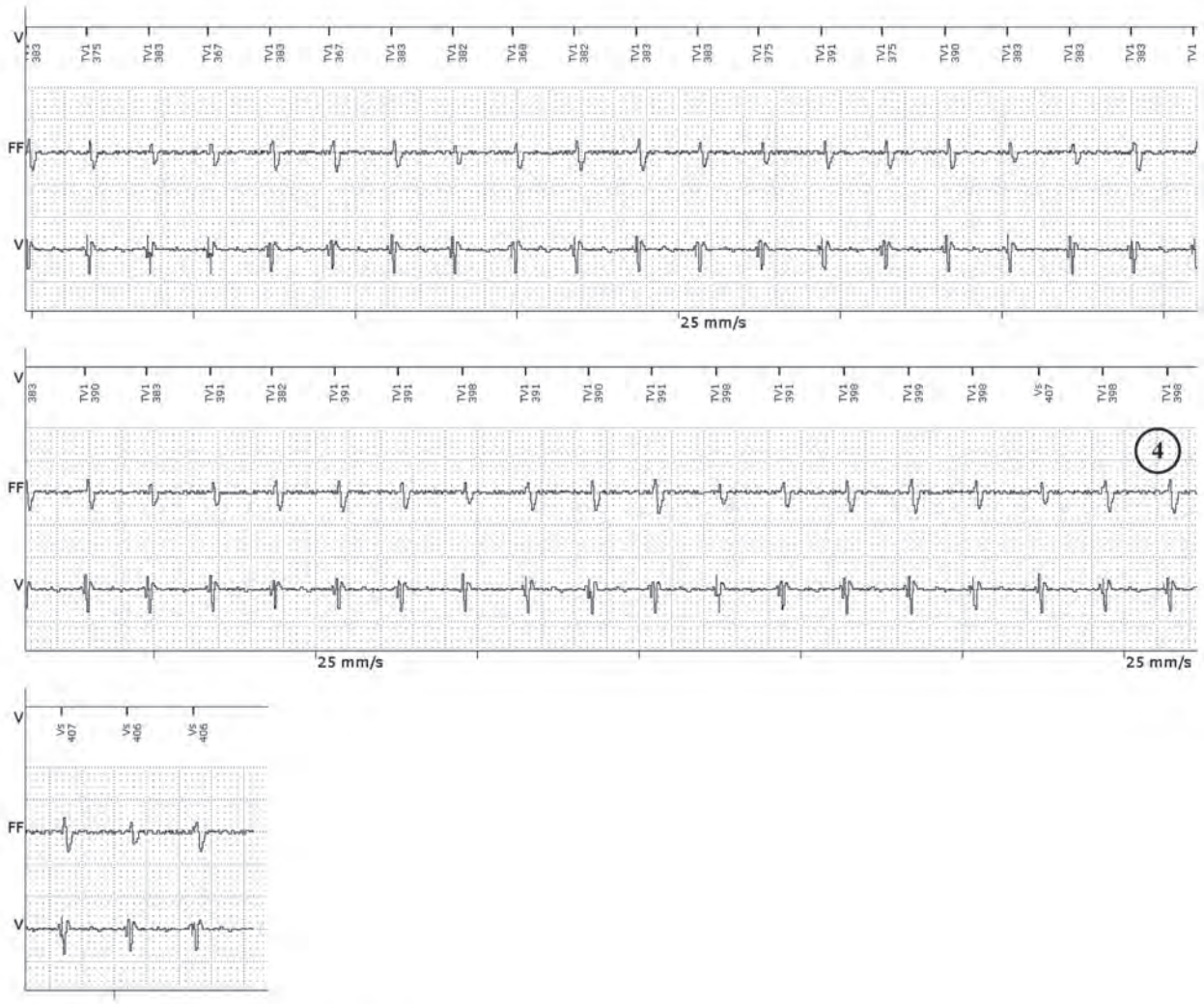

Détails de l'épisode

N° 14

Classification	18.05.11 13:36:24		dans TSV
Fin	18.05.11 13:37:08	Durée	00:00:44
Début mesuré	1 %		
Mesure de la stabilité	4 ms	Reclassific.	dans TV1 = 0
			dans TV2 = 0
			dans FV = 0
ATP délivrées	0		
Chocs délivrés	0		

Remarque TSV détectée par déclenchement

EGM 18.05.11 13:33:51 **03/12/2012 11:24**

Tracing 17: atrial tachycardia poorly discriminated by a single chamber defibrillator

Patient

This 76-year-old man received a Lumax 540 VR-T single chamber defibrillator in the context of dilated cardiomyopathy with a left ventricular ejection fraction at 25%. An event report (yellow color) was issued in the context of a classified VT1.

Main programmed settings

- VF zone (290 ms limit), VT1 zone (350 ms limit)
- 18/24 cycles in the VF zone and 30 cycles in the VT1 zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.8 mV
- VF zone: ATP one shot, followed by 8 shocks of maximum strength (40 J); VT1 zone: 3 bursts of ATP, followed by 3 ramps of ATP, followed by a single 20-J shock, followed by 7 shocks of maximum strength
- Effective discrimination in the VT zone (onset 20%, stability = 24 ms)
- Pacing mode: VVI at 40 bpm

Remote tracing

The 3 channels available are 1) the markers with the time intervals, 2) the shock channel (FF = far field) between the coil of the RV lead and the pulse generator, and 3) the right ventricular (RV) sensing channel.

1: spontaneous rhythm with probable sinus tachycardia;
2: sudden onset tachycardia detected in the VT1 zone. The 38% sudden onset of this episode fulfilled the >20% programmed criterion;
3: the morphology criterion was not included in the discrimination. It is noteworthy that the morphology is the same during the tachycardia and during slow, spontaneous rhythm, on the sensing, as well as the shock channels;
4: the tachycardia was stable and the 8 ms stability criterion was fulfilled;
5: in presence of sudden onset and stable rate, the rhythm was classified as an episode of VT1;
6: a burst of ATP was delivered, of which the last 2 cycles are visible;
7: successful burst and termination of the arrhythmia.

Comments

This tracing illustrates the challenge represented by the discrimination of atrial tachycardia or flutter. These tachycardias are, like VT, stable rhythms, which start suddenly. In this patient, the signal morphology (not included in the discrimination algorithm) was in favor of a supraventricular origin (same morphology). The sequence of ATP was, therefore, inappropriate, though it did terminate the arrhythmia. The termination by ventricular ATP of an atrial tachycardia that just started is relatively common. Consequently, the termination of the tachycardia by a burst of ATP should not be taken as an argument in favor of a ventricular origin of the tachycardia. In this patient, the device programming was left unchanged.

Status report - Oct 11, 2013

To: Service Télécardiologie

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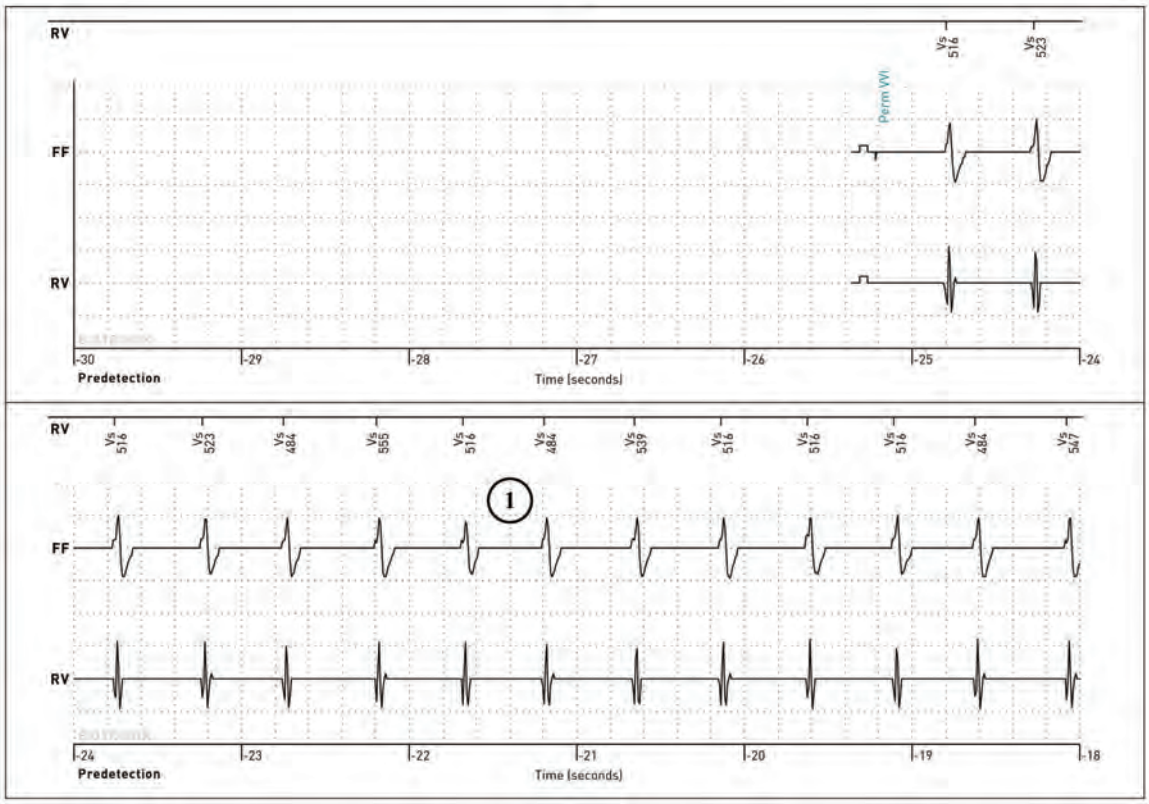
Name:	DOB:	Lumax 540 VR-T	Last message: Oct 11, 2013
Patient ID:	Phone:	ICD implanted Mar 18, 1936	Last clinic follow-up: Jun 10, 2013

Recordings

Recordings - Episode 6:

General	
Episode number	6
Episode type	VT1
Detection	Feb 28, 2013 4:34:01 PM
Termination	Feb 28, 2013 4:34:11 PM
Duration	10s
Device settings no.	4
Detection	
Mean RR at initial detection [ms]	329
Onset [%]	38, fulfilled
Stability [ms]	8
Redetection	---

Therapy	
ATP in VT/VF delivered	1
ATP One Shot delivered	NO
Shocks delivered	0
Shocks aborted	0
Maximum energy [J]	---
Termination	
Mean RR at termination [ms]	530
Remark	
none	



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1/3

Status report - Oct 11, 2013

To: Service Télécardiologie

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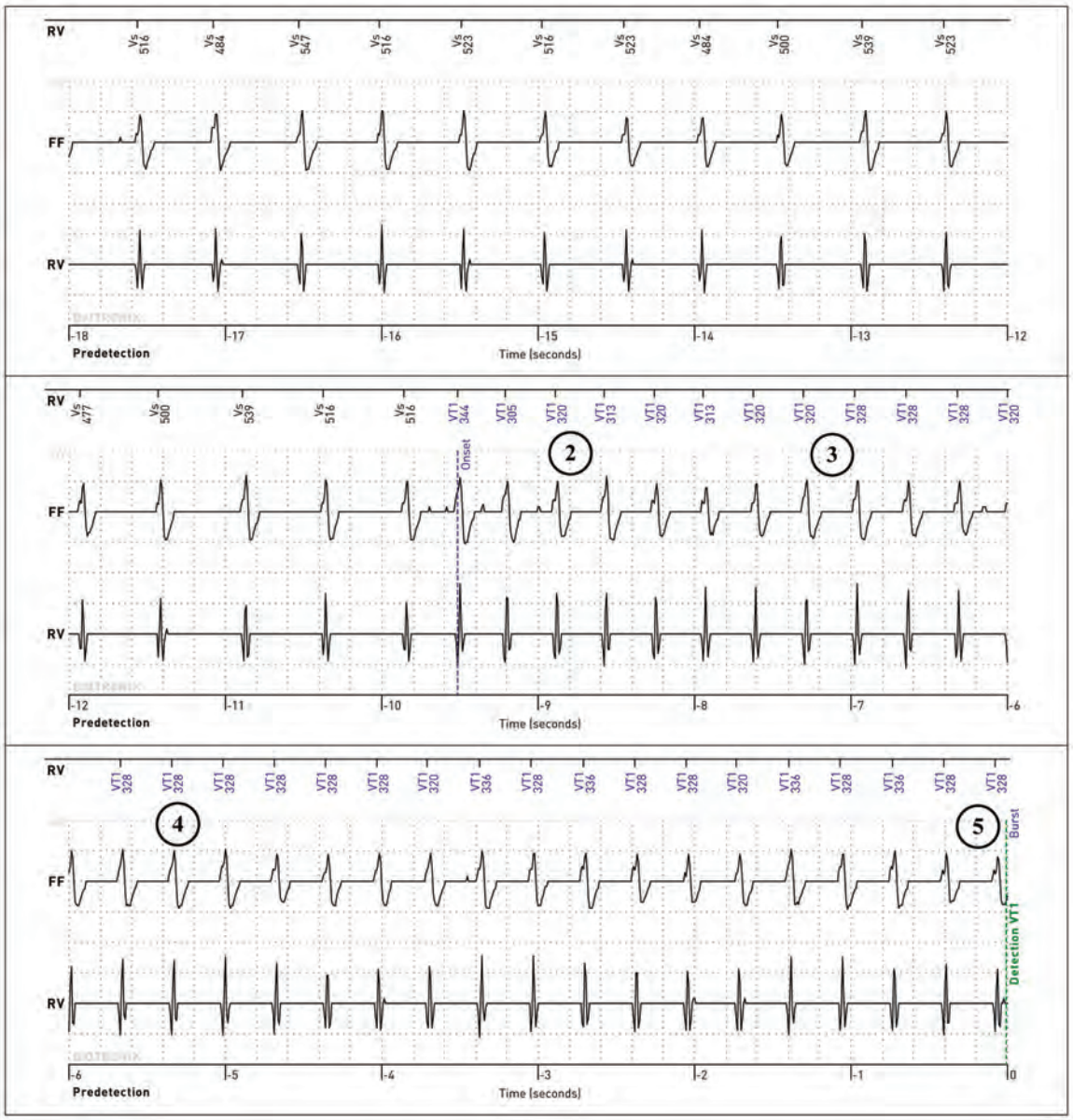
Name:	DOB:	Lumax 540 VR-T	Last message: Oct 11, 2013
Patient ID:	Phone:	ICD implanted Mar 18, 1936	Last clinic follow-up: Jun 10, 2013



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Status report - Oct 11, 2013

To: Service TéléCardiologie

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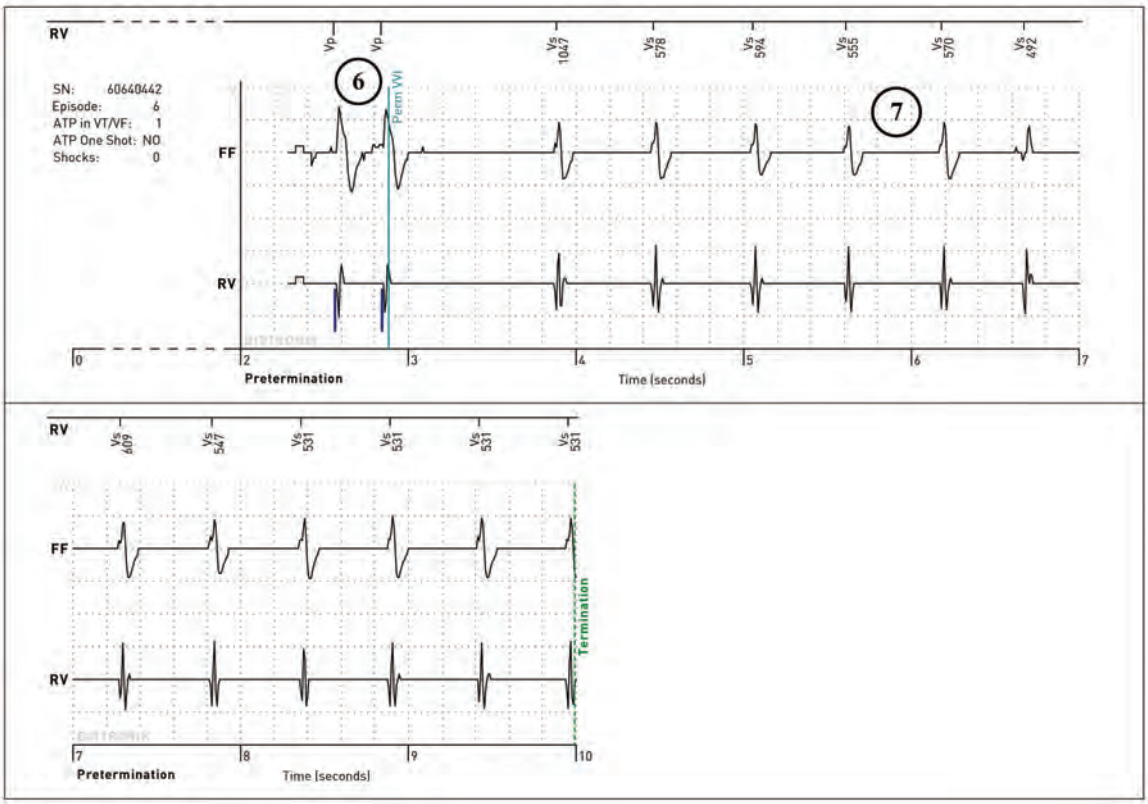
Name:	DOB:	Lumax 540 VR-T	Last message: Oct 11, 2013
Patient ID:	Phone:	ICD implanted Mar 18, 1936	Last clinic follow-up: Jun 10, 2013



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Tracing 18: accurate discrimination of ventricular tachycardia by a dual chamber defibrillator

Patient

This 36-year-old man received a Lumax 540 DR-T dual chamber defibrillator in the context of non-obstructive, hypertrophic cardiomyopathy, with a 32-mm septum thickness and episodes of non-sustained VT. An event report (yellow color) was issued in the context of a classified VT1.

Main programmed settings

- VF zone (270 ms limit), VT1 zone (360 ms limit)
- 8/12 cycles in the VF zone and 26 cycles in the VT1 zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.8 mV
- VF zone: ATP one shot, followed by 8 shocks of maximum strength (40 J); VT1 zone: 3 bursts of ATP, followed by 3 ramps of ATP, followed by a single 20-J shock, followed by 7 shocks of maximum strength
- Effective discrimination in the VT1 zone (SMART discrimination)
- Pacing mode: DDD at 60 bpm

Remote tracing

The 4 channels available are 1) the markers with the time intervals, 2) the shock channel (FF = far field) between the coil of the RV lead and the pulse generator, 3) the atrial sensing channel (A), and 4) the RV sensing channel;

1: spontaneous rhythm in the atrium and the ventricle;
2: ventricular extrasystole;
3: probable VT with retrograde conduction;
4: interruption of retrograde conduction (diagnosis ascertained by excess of ventricular compared with atrial events)
5: atrioventricular dissociation;
6: diagnosis of VT after 26 cycles classified VT1; discrimination in the PP>RR arm. The mean PP (606 ms) during initial classification was the average of 4 PP cycles (383 + 672 + 695 + 680) before the classification, while the average RR (344 ms) during initial classification was the average of 4 RR cycles (344 + 359 + 328 + 344) before the classification;
7: burst of ATP (the last 5 stimuli are visible);
8: successful burst and termination of the arrhythmia;
9: end of episode after 12 VP or VS cycles.

Comments

Dual chamber discrimination is based on a combined analysis of the atrial and ventricular electrograms. When, as on this tracing, the ventricular cycle (the average of 4 ventricular cycles of tachycardia) is shorter than the atrial cycle (the average of 4 atrial cycles of tachycardia), the tachycardia is classified as VT by the SMART algorithm and no other discrimination criterion is considered.

Status report - Oct 11, 2013

To: Service Télécardiologie

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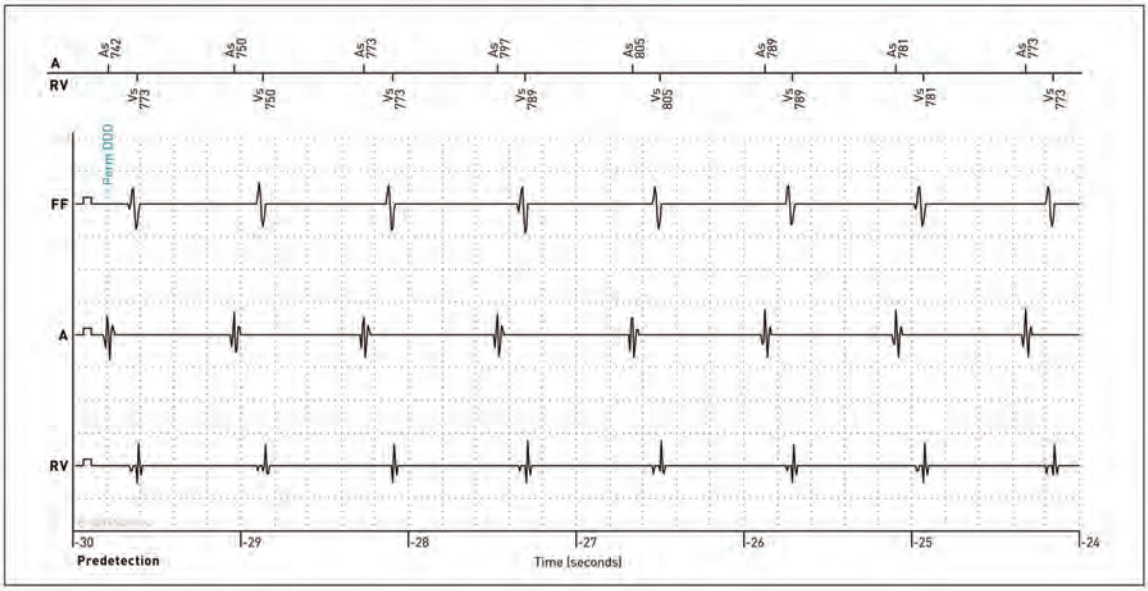
Name:	DOB:	Lumax 540 DR-T	Last message: Oct 11, 2013
Patient ID:	Phone:	ICD implanted Jun 13, 2012	Last clinic follow-up: Sep 18, 2013

Recordings

Recordings - Episode 3:

General	
Episode number	3
Episode type	VT1
Detection	Jul 30, 2012 7:24:04 PM
Termination	Jul 30, 2012 7:24:14 PM
Duration	10s
Device settings no.	7
Detection	
Mean PP at initial detection [ms]	606
Mean RR at initial detection [ms]	344
Onset [%]	48, fulfilled
Stability [ms]	19
Redetection	---

Therapy	
ATP in VT/VF delivered	1
ATP One Shot delivered	NO
Shocks delivered	0
Shocks aborted	0
Maximum energy [J]	---
Termination	
Mean PP at termination [ms]	750
Mean RR at termination [ms]	749
Remark	
Therapy	ATP optimization in VT1 applied



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Status report - Oct 11, 2013

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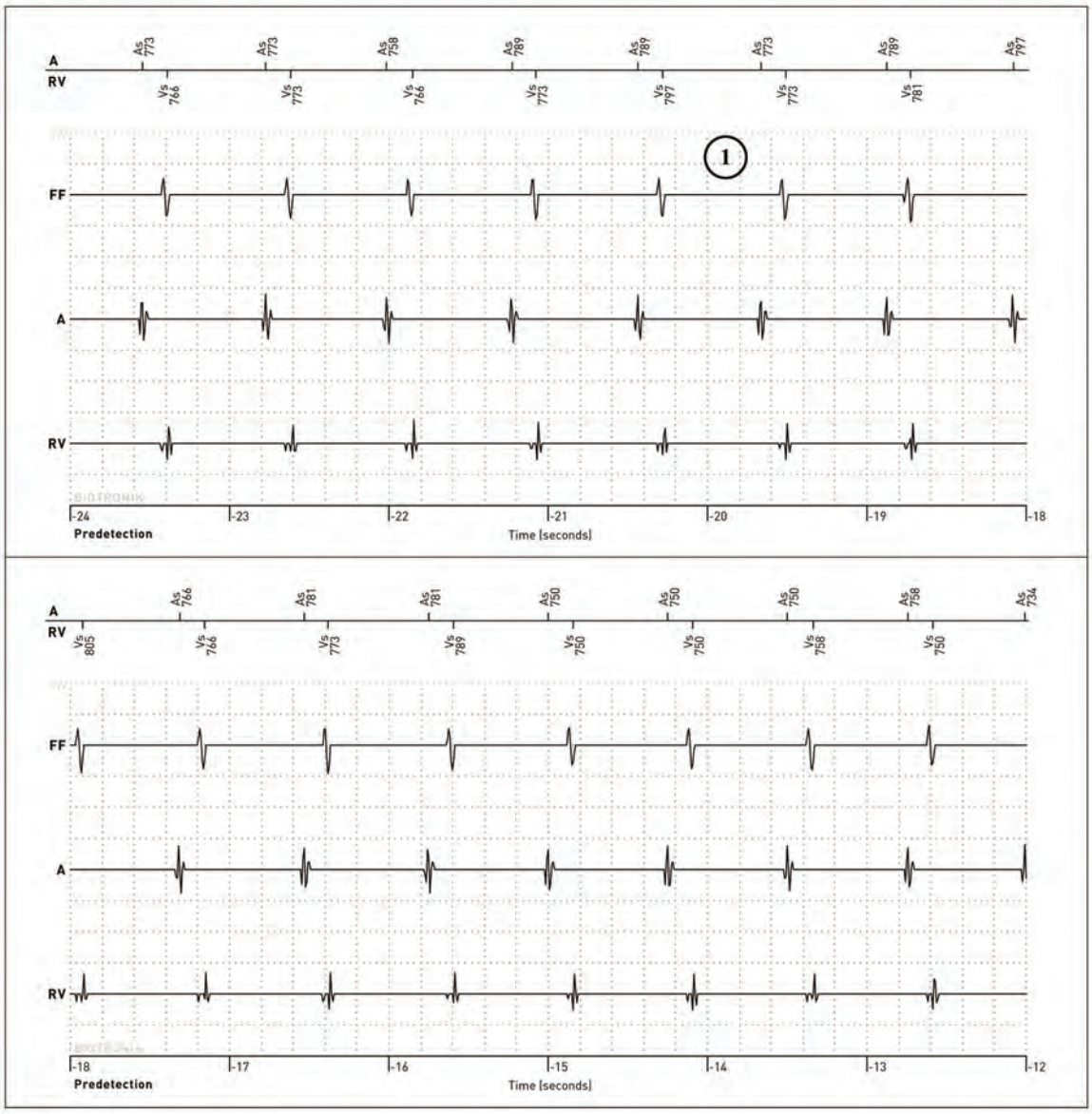
Name:	DOB:	Lumax 540 DR-T	Last message: Oct 11, 2013
Patient ID:	Phone:	ICD implanted Jun 13, 2012	Last clinic follow-up: Sep 18, 2013



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Status report - Oct 11, 2013

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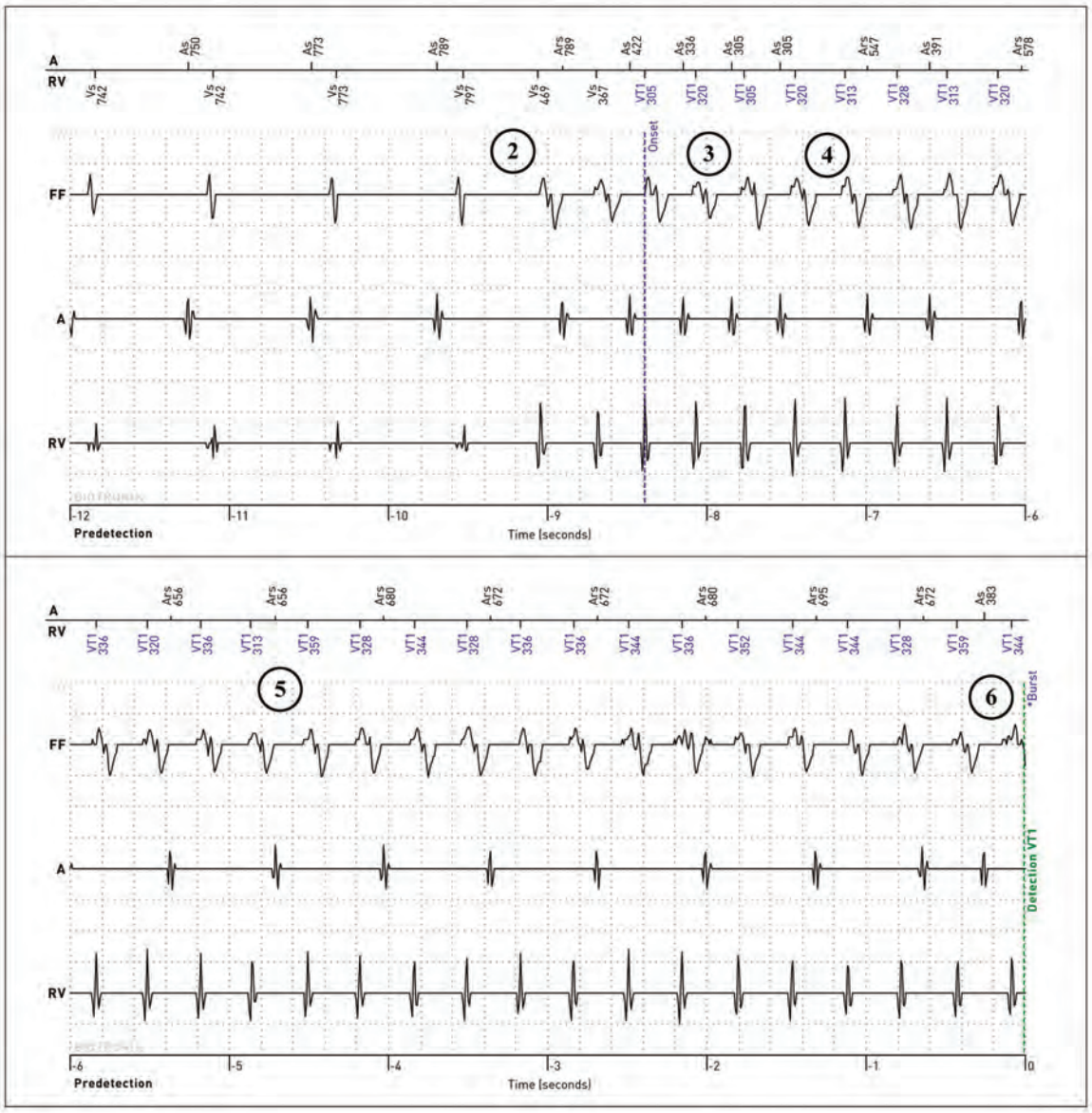
Name:	DOB:	Lumax 540 DR-T	Last message: Oct 11, 2013
Patient ID:	Phone:	ICD implanted Jun 13, 2012	Last clinic follow-up: Sep 18, 2013



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Status report - Oct 11, 2013

To: Service TélécØrdiologie

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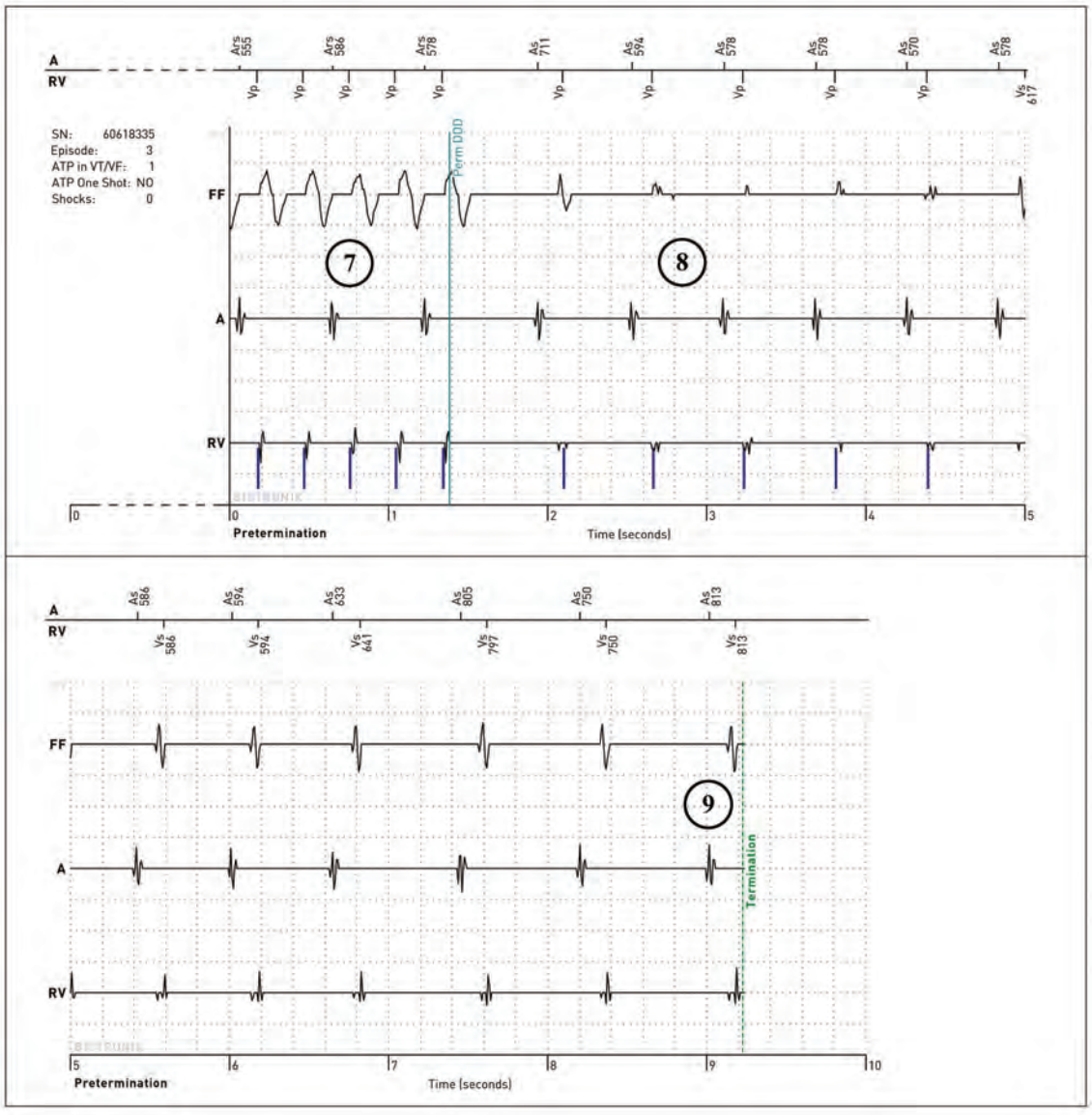
Name:	DOB:	Lumax 540 DR-T	Last message: Oct 11, 2013
Patient ID:	Phone:	ICD implanted Jun 13, 2012	Last clinic follow-up: Sep 18, 2013



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Tracing 19: accurate discrimination of ventricular tachycardia despite atrial undersensing

Patient

This 60-year-old man received a Lumax 340 DR-T dual chamber defibrillator for the management of episodes of VT in the context of dilated cardiomyopathy. An event report (yellow color) was issued in the context of a classified VT2.

Main programmed settings

- VF zone (300 ms limit), VT2 zone (370 ms limit), VT1 zone (430 ms limit)
- 8/12 cycles in the VF zone, 16 cycles in the VT2 zone and 26 cycles in the VT1 zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.8 mV
- VF zone: ATP one shot, followed by a single 30-J shock, followed by 7 shocks of maximum strength (40 J); VT2 zone: 3 bursts of ATP, followed by 3 ramps of ATP, followed by a single 10-J shock, followed by a single 24-J shock, followed by 6 shocks of maximum strength; VT1 zone: monitor only
- Effective discrimination in the VT2 zone (SMART discrimination)
- Pacing mode: DDD at 60 bpm

Remote tracing

The 4 channels available are 1) the markers with the time intervals, 2) the shock channel (FF = far field) between the coil of the RV lead and the pulse generator, 3) the atrial (A) sensing channel, and 4) the right ventricular (RV) sensing channel.

1: spontaneous rhythm in the atria and the ventricles;
2: tachycardia initially detected in the VT1 zone;
3: atrioventricular dissociation; the atrial activity is visible on the atrial electrogram channel, however without markers because it fell in the post-ventricular sensing atrial blanking period;
4: the atrial activity is more clearly visible;
5: VT2 classification after 16 classified cycles; discrimination in the PP>RR arm; average PP and RR during the initial classifications = 683 and 314 ms, respectively;
6: burst of ATP not visible;
7: successful burst of ATP and termination of the arrhythmia;
8: end of episode after 12 VP or VS cycles.

Comments

The first discrimination level of the SMART algorithm is a comparative analysis of the atrial and ventricular rhythms. In this patient, the episode was accurately diagnosed (VT) despite an error in the count of the atrial electrograms (P wave in the post ventricular sensing atrial blanking period). An accurate sensing at the level of both chambers is indispensable for the proper function of this dual chamber discrimination algorithm. A dislodgement of the atrial lead, a crosstalk with oversensing of the R wave in the atrium, undersensing of the atrial activity due to low-voltage activity in atrial fibrillation, and the occurrence of atrial activity in the post ventricular sensing atrial blanking period can be associated with inaccurate dual chamber discrimination. The post ventricular sensing atrial blanking period must be programmed long enough to prevent crosstalk, though not too long in order to preserve an accurate count of the atrial electrograms. It is noteworthy that the atrial cycles falling in the PVARP (Ars) were included in the atrial rate count.

Status report - Oct 10, 2013

To: Service Télécardiologie

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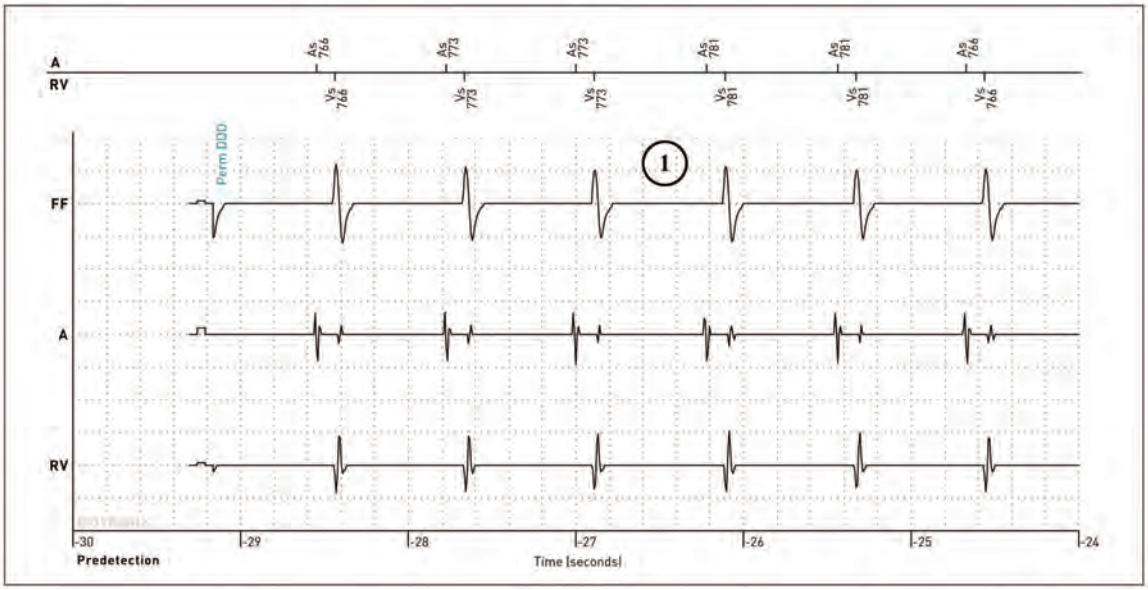
Name:	DOB:	Lumax 340 DR-T	Last message: Aug 3, 2013
Patient ID:	Phone:	ICD implanted Dec 8, 2008	Last clinic follow-up: Jun 25, 2013

Recordings

Recordings - Episode 20:

General		Therapy	
Episode number	20	ATP in VT/VF delivered	1
Episode type	VT2	ATP One Shot delivered	NO
Detection	Dec 3, 2011 12:16:43 PM	Shocks delivered	0
Termination	Dec 3, 2011 12:16:54 PM	Shocks aborted	0
Duration	11s	Maximum energy [J]	---
Device settings no.	7	**Termination**	
Detection		Mean PP at termination [ms]	782
Mean PP at initial detection [ms]	683	Mean RR at termination [ms]	782
Mean RR at initial detection [ms]	314	**Remark**	
Onset [%]	40, fulfilled	none	
Stability [ms]	8		
Redetection	---		



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Status report - Oct 10, 2013

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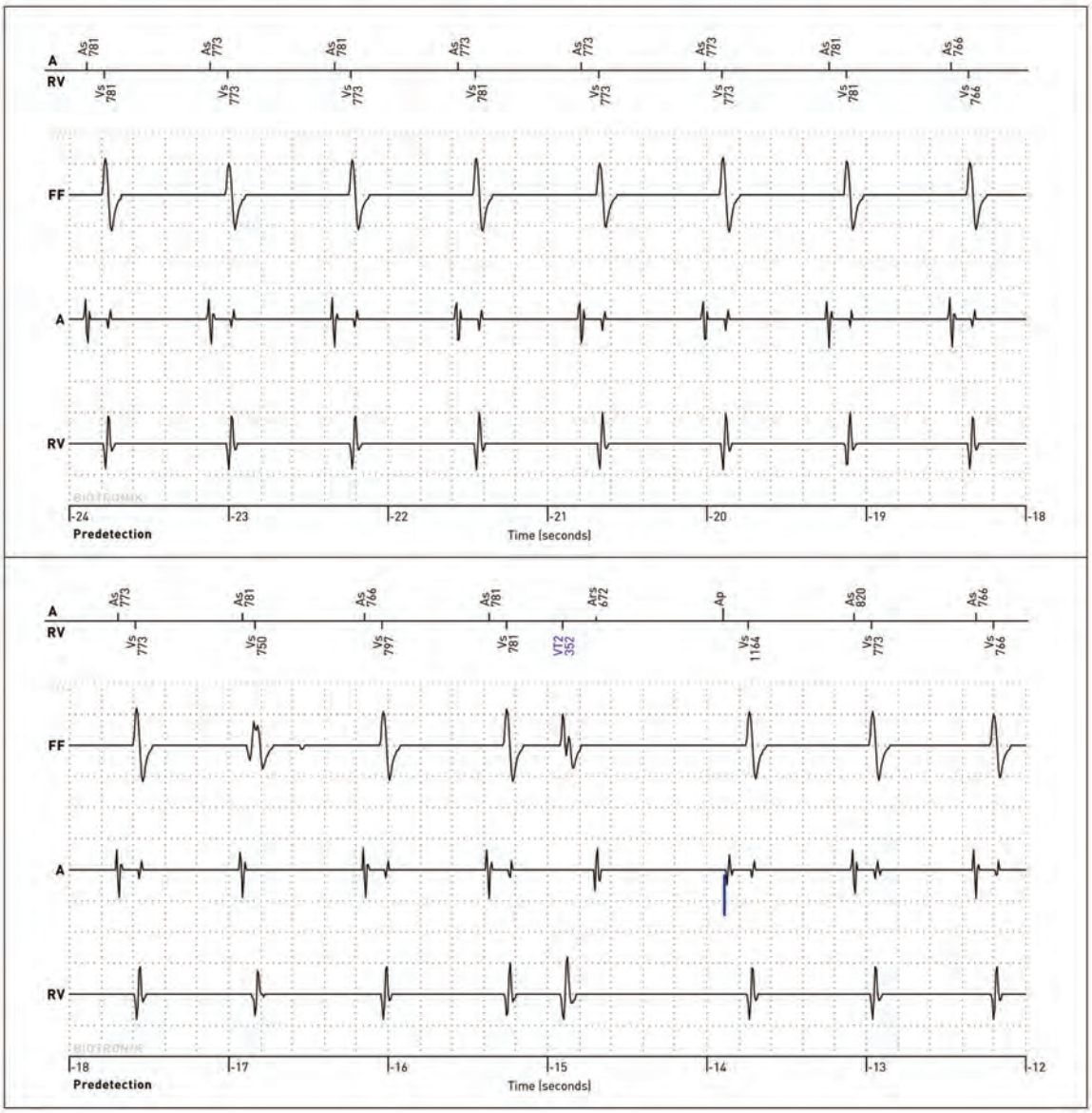
Name:	DOB:	Lumax 340 DR-T	Last message: Aug 3, 2013
Patient ID:	Phone:	ICD implanted Dec 8, 2008	Last clinic follow-up: Jun 25, 2013



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Status report - Oct 10, 2013

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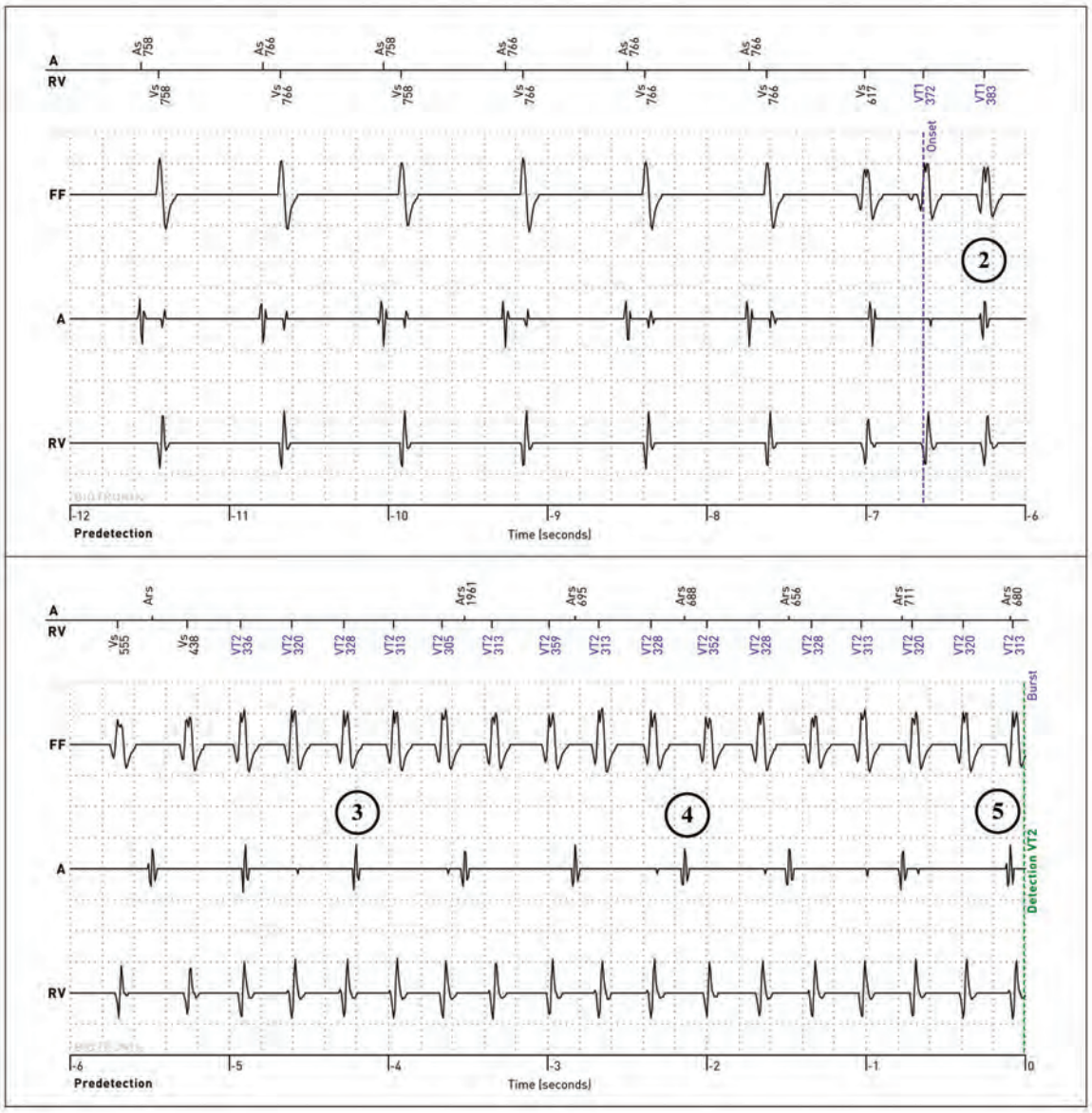
Name:	DOB:	Lumax 340 DR-T	Last message: Aug 3, 2013
Patient ID:	Phone:	ICD implanted Dec 8, 2008	Last clinic follow-up: Jun 25, 2013



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Status report - Oct 10, 2013

To: Service Télécardiologie

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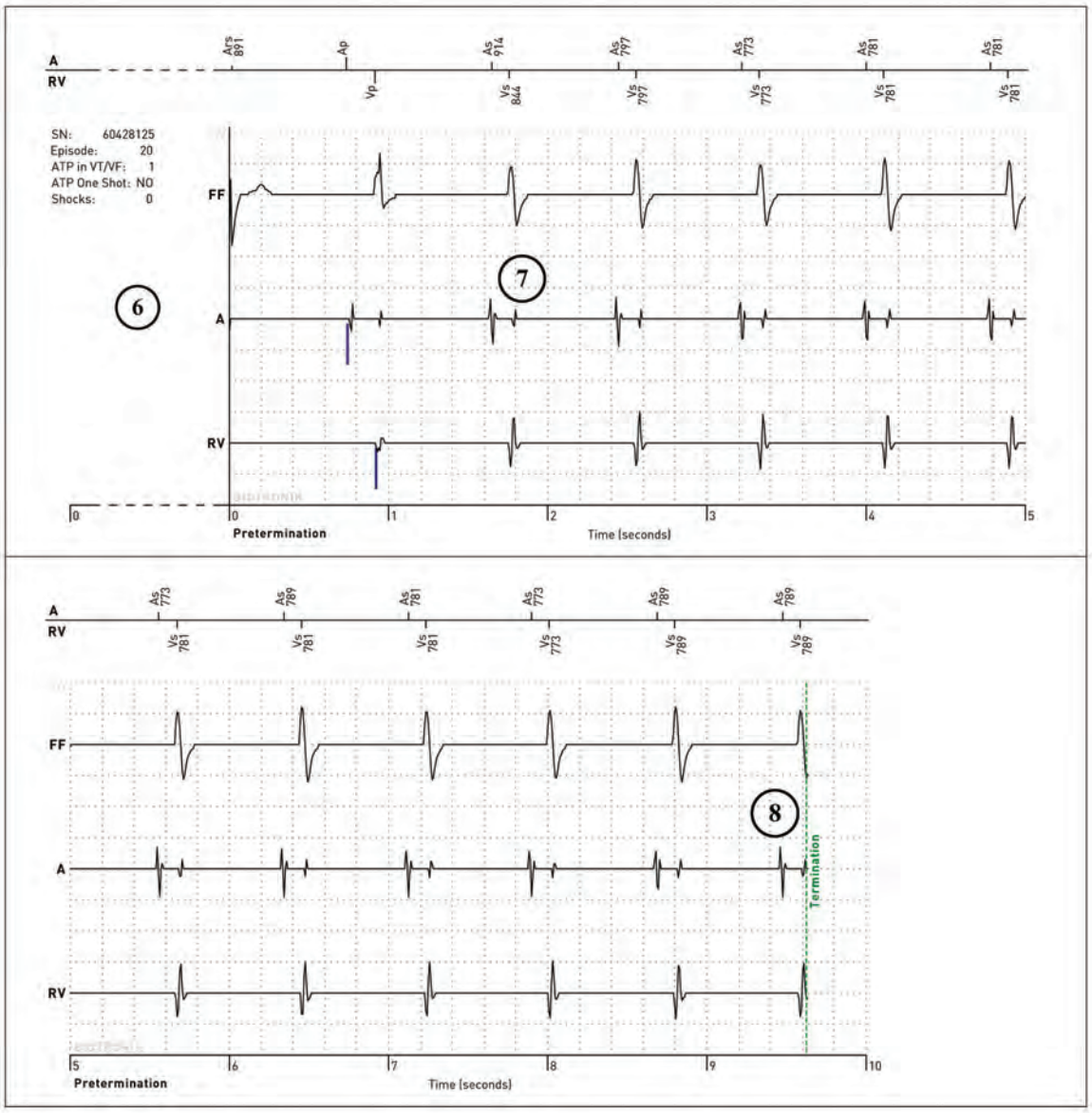
Name:	DOB:	Lumax 340 DR-T	Last message: Aug 3, 2013
Patient ID:	Phone:	ICD implanted Dec 8, 2008	Last clinic follow-up: Jun 25, 2013



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Tracing 20: poor discrimination of atrial tachycardia by a dual chamber defibrillator

Patient

This 59-year-old man received a Lumax 540 HF-T triple chamber defibrillator in the context of ischemic cardiomyopathy with conduction disorder. An event report (yellow color) was issued in the context of a classified VT1.

Main programmed settings

- VF zone (250 ms limit), VT1 zone (360 ms limit)
- 8/12 cycles in the VF zone and 32 cycles in the VT1 zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.8 mV
- VF zone: ATP one shot, followed by 8 shocks of maximum strength (40 J); VT1 zone: monitor only without programmed therapy
- Effective discrimination in the VT1 zone (SMART discrimination)
- Pacing mode: DDD biventricular at 50 bpm

Remote tracing

The 4 channels available are 1) the markers with the time intervals, 2) the atrial (A) sensing channel, 3) the right ventricular (RV) sensing channel, and 4) the left ventricular (LV) sensing channel.

1: 1:1 tachycardia; however, the atrial activity was sensed intermittently, as it fell in the post ventricular sensing atrial blanking period;
2: mode switch (MSW, DDI) because 5 of 8 atrial cycles were classified Ars, and the average atrial rate measured on the last 4 cycles was >160 bpm;
3: more reliable atrial sensing with 1:1 rhythm;
4: monitor VT1 classification; discrimination in the PP = RR arm (average PP and RR during the initial classifications = 353 and 348 ms, respectively; in the PP = RR arm, the first analysis is stability (this rhythm was stable, with an 8 ms measurement of stability for a 24 ms threshold). The second analysis is the stability of PP (stable during episode). Since PR was stable, no monotonous change is observed. The last analysis is sudden onset, which was fulfilled at 24% for a threshold programmed at 20%. The device therefore diagnosed VT1;
5: monitor zone only without delivery of therapy;
6: spontaneous termination of the tachycardia after a ventricular event (favors an atrial tachycardia).

Programmer tracing

7: the programmer tracing allows a scrutiny of the onset of the tachycardia, which initially started with an atrial extrasystole (in favor of an atrial tachycardia).

Comments

This patient presented with multiple episodes of 1:1 tachycardia detected in the monitor zone. Programming in the monitor zone may enable 1) the recording of the episodes, 2) the clarification of the origin of the arrhythmia, and 3) depending on the diagnosis and on the tolerance of the rhythm, the programming of therapies. This episode began with an atrial extrasystole and ended with a ventricular event, both in favor of a supraventricular origin.
Initially, the atrial electrograms were miscounted because some of them fell in the post-ventricular atrial blanking period. Later, the defibrillator sensed the 1:1 ratio. The discrimination between 1:1 VT and 1:1 atrial tachycardia is probably the most challenging for double or triple chambers defibrillators. Indeed, the RR and PP cycles are regular, the PR intervals are fixed, and the defibrillator detects a sudden onset, thus diagnosing VT.

Status report - Oct 11, 2013

To: Service Télécardiologie

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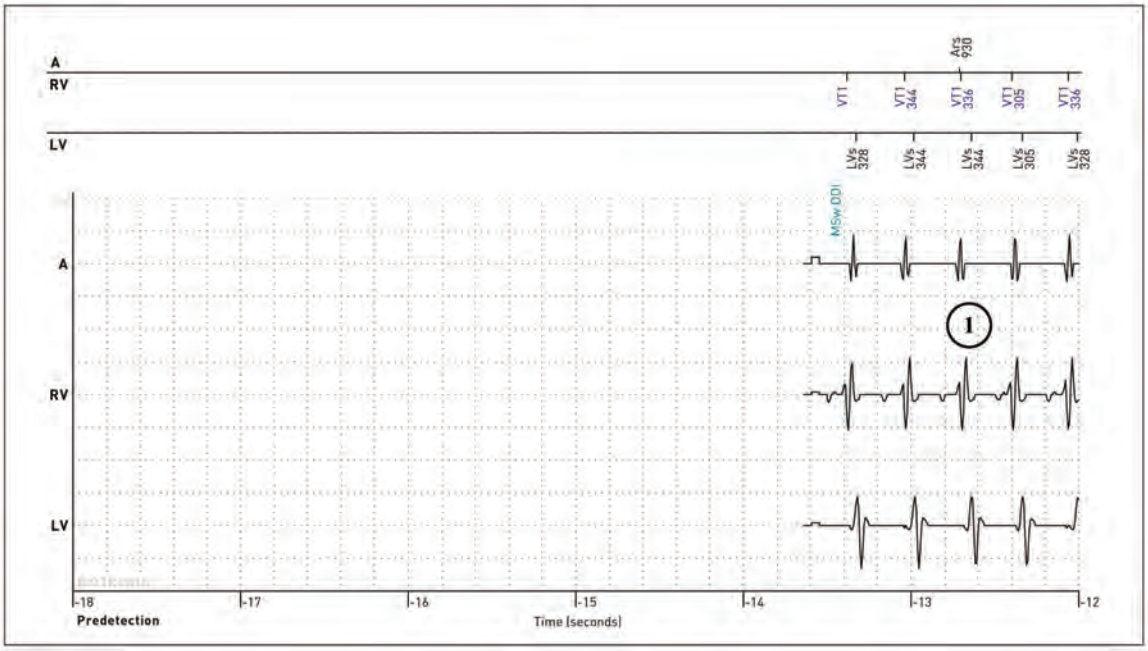
Name:	DOB:	Lumax 540 HF-T	Last message: Oct 11, 2013
Patient ID:	Phone:	CRT-D implanted Feb 25, 2011	Last clinic follow-up: Jun 10, 2013

Recordings

Recordings - Episode 82:

General	
Episode number	82
Episode type	Ven. monitoring
Detection	Oct 2, 2012 11:55:34 AM
Termination	Oct 2, 2012 11:55:47 AM
Duration	13s
Device settings no.	83
Detection	
Mean PP at initial detection [ms]	353
Mean RR at initial detection [ms]	348
Onset [%]	24, fulfilled
Stability [ms]	8
Redetection	---

Therapy	
ATP in VT/VF delivered	0
ATP One Shot delivered	NO
Shocks delivered	0
Shocks aborted	0
Maximum energy [J]	---
Termination	
Mean PP at termination [ms]	716
Mean RR at termination [ms]	688
Remark	
none	



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Status report - Oct 11, 2013

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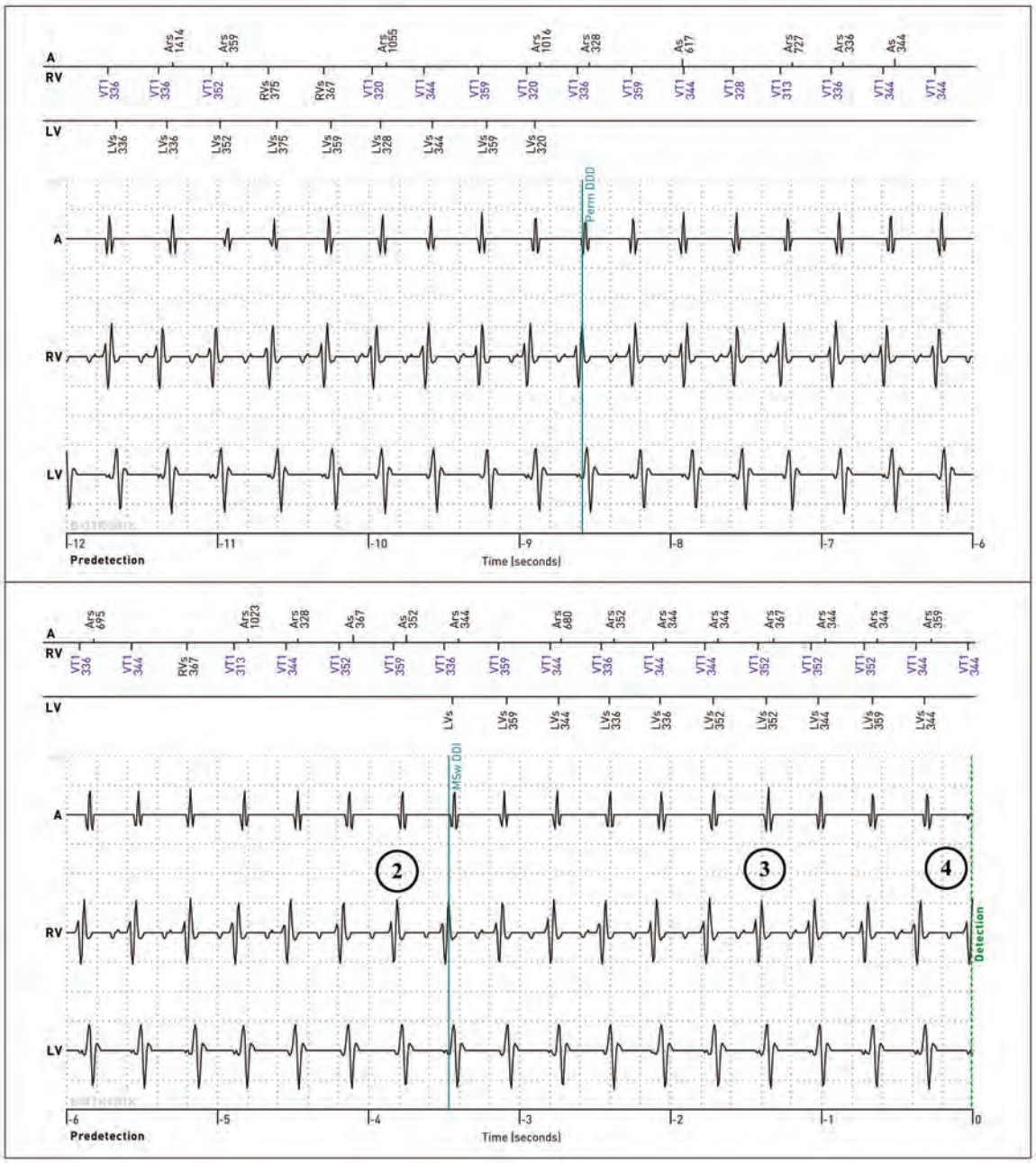
Name:	DOB:	Lumax 540 HF-T	Last message: Oct 11, 2013
Patient ID:	Phone:	CRT-D implanted Feb 25, 2011	Last clinic follow-up: Jun 10, 2013



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Status report - Oct 11, 2013

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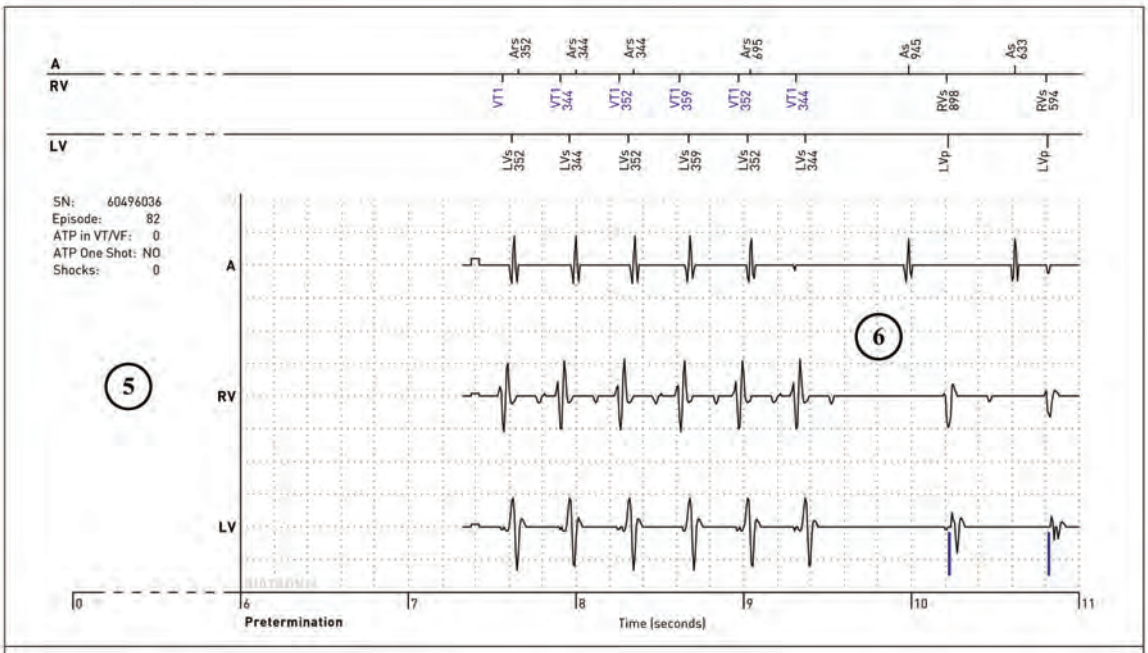
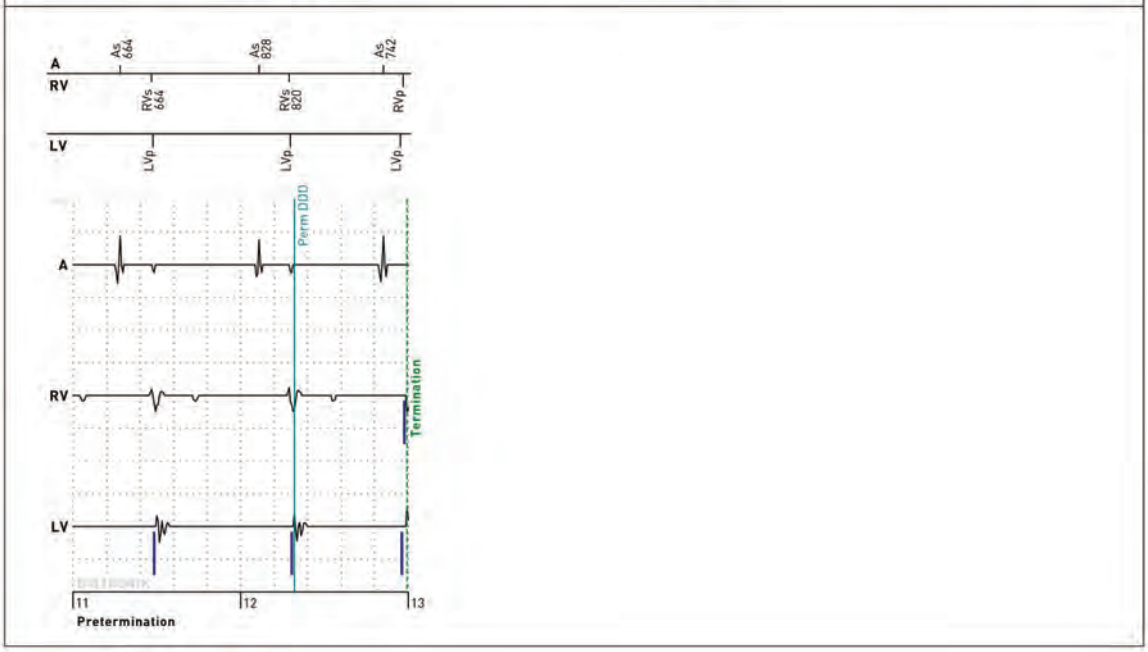
Name:	DOB:	Lumax 540 HF-T	Last message: Oct 11, 2013
Patient ID:	Phone:	CRT-D implanted Feb 25, 2011	Last clinic follow-up: Jun 10, 2013





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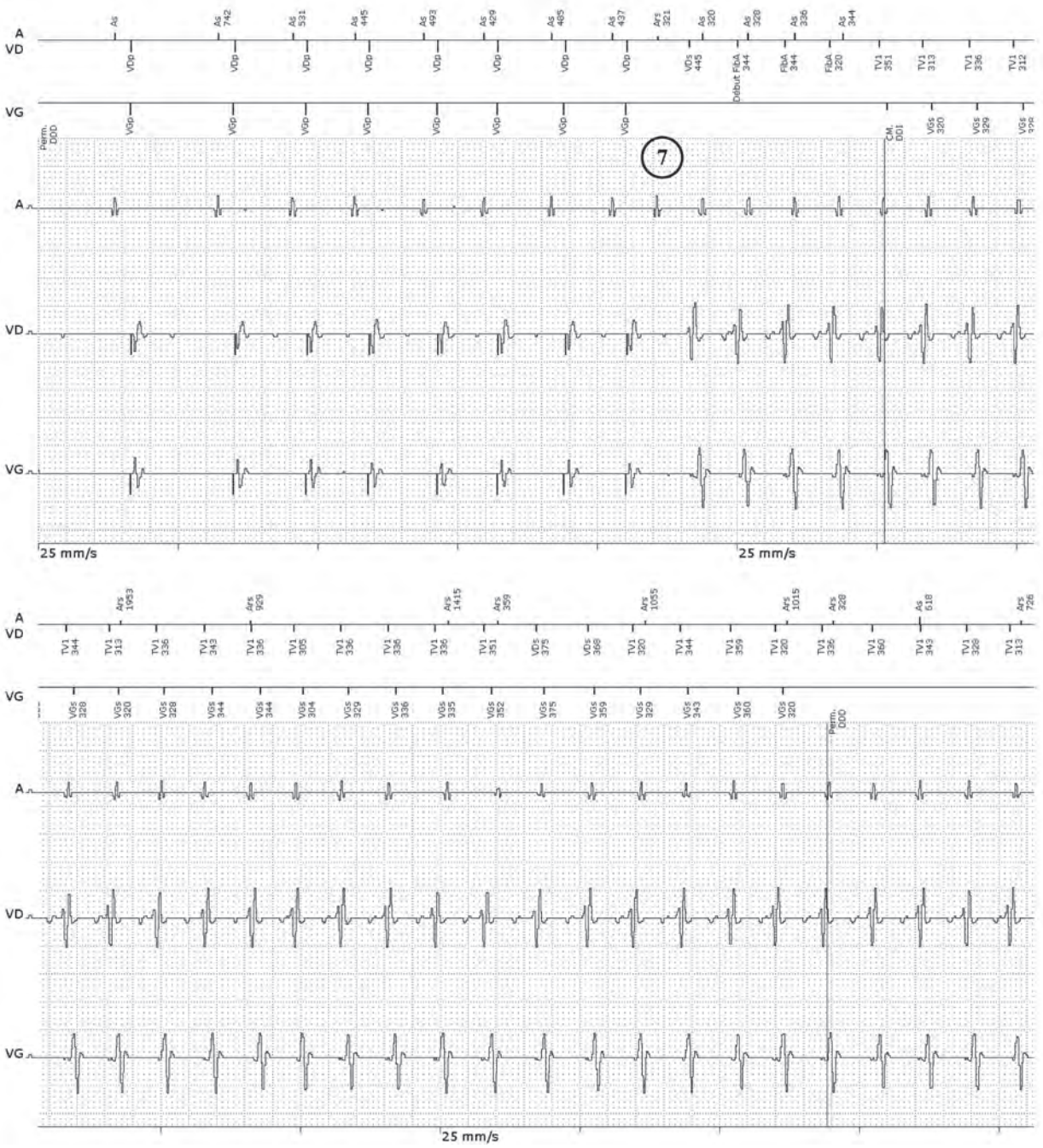
PDF: BIOTRONIK - Lumax 540 HF-T - [redacted] - [redacted] 12 / 24



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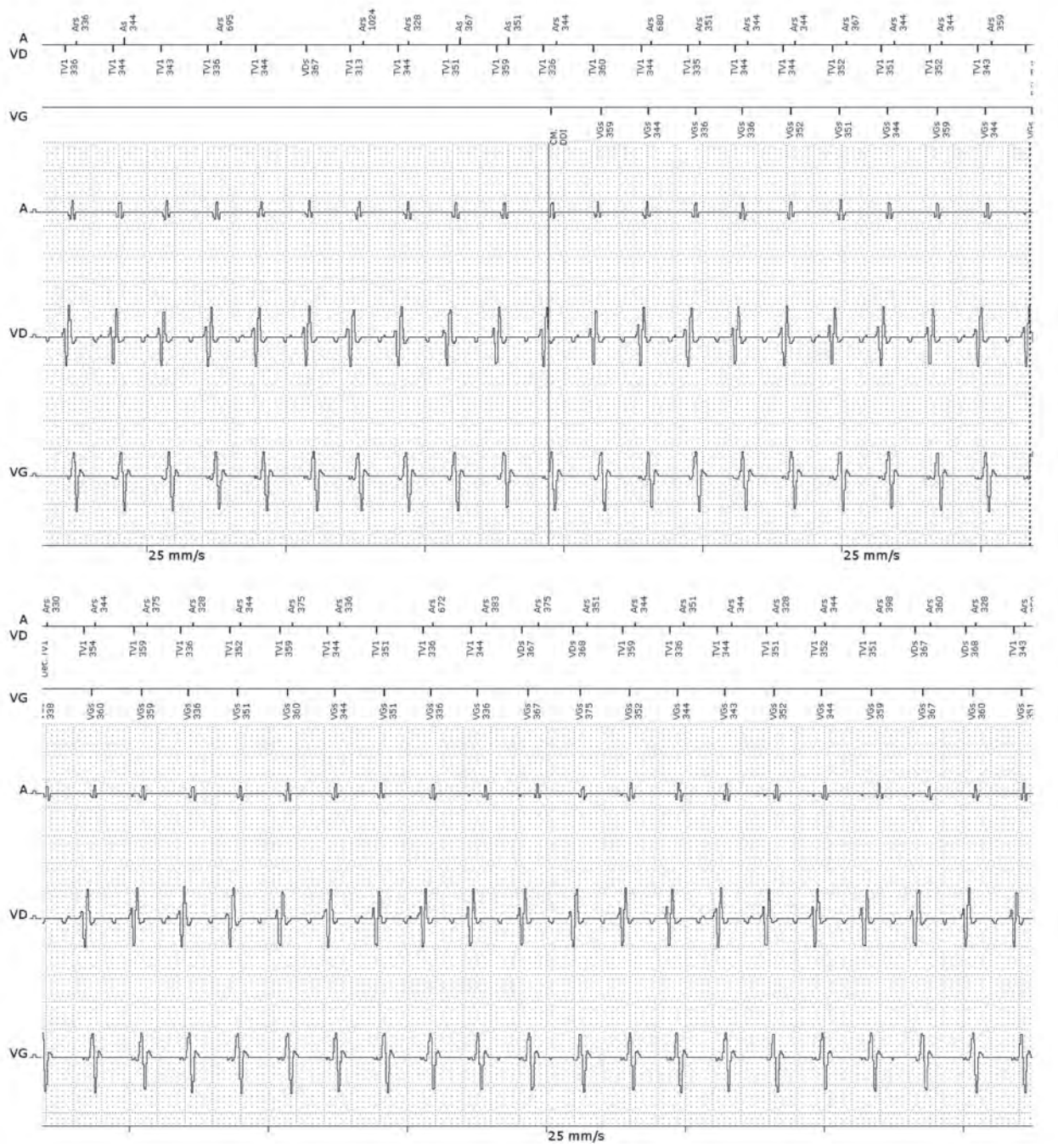

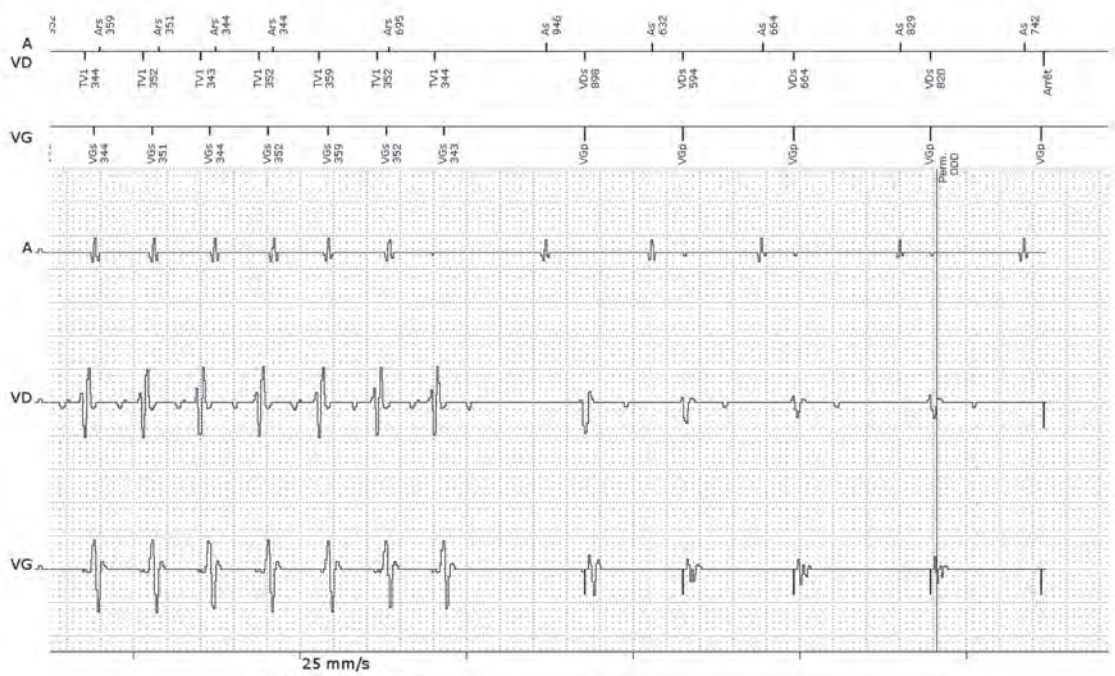

Classification

Zone	Monitorage TV1		
Début soudain mesuré dans V	24 %	(rempli)	
Stabilité mesurée dans V	8 ms		
	TV1	TV2	FV
Redétections	0	0	0

Traitement

ATP	0
Chocs	0
Energie max.	*** J
ATP One Shot	Non

Temps

Classification	02/10/2012 11:55:34
Fin	02/10/2012 11:55:47
Durée	0:00:13
N° programme	83

Remarque

Enregistrements

Date: **27/11/2012**
Heure: **14:40**

EGM 81

Zone	---
EGM de l'épisode N°.	81
Classification	
N° programme	83

Tracing 21: accurate discrimination of sinus tachycardia by dual chamber defibrillator

Patient

This 61-year-old man received a Lumax 740 DR-T dual chamber defibrillator in the context of ischemic cardiomyopathy with a depressed left ventricular ejection fraction. An event report (yellow color) was issued in the context of classified SVT.

Main programmed settings

- VF zone (280 ms limit), VT1 zone (400 ms limit)
- 8/12 cycles in the VF zone and 26 cycles in the VT1 zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.8 mV
- VF zone: ATP one shot, followed by 8 shocks of maximum strength (40 J); VT1 zone: 5 bursts of ATP, followed by 5 ramps of ATP, followed by a single 14-J shock, followed by a single 20-J shock, followed by 6 shocks of maximum strength
- Effective discrimination in the VT1 zone (SMART discrimination)
- Pacing mode: DDD at 50 bpm

Remote tracing

The 4 channels available are 1) the markers with the time intervals, 2) the shock channel (FF = far field) between the coil of the RV lead and the pulse generator, 3) the atrial (A) sensing channel, and 4) the right ventricular (RV) sensing channel.

1: tachycardia in the VT1 zone with a 1:1 atrioventricular ratio. The ventricular events are classified Tsin (sinus tachycardia);

2: classification SVT in the PP = RR arm; (the average PP and RR intervals during the initial classifications both measure 379 ms; stable rhythm, with a 2 ms stability for a 24-ms programmed threshold; stable PP and PR intervals without monotonous change). In this case, the sudden onset criterion was not fulfilled, since it measured 1% for a 20% programmed threshold. Consequently, the diagnosis made by the device was SVT (sinus tachycardia);

3: gradual slowing of the heart rate at the end of exercise and exit from the VT1 zone (VS cycles).

Comments

The vast majority of 1:1 tachycardias are supraventricular in origin, while VT with 1:1 retrograde conduction represents only 10% of these tachycardias. The dual chamber discrimination algorithms must be systematically activated in patients with preserved atrioventricular conduction and properly functioning atrial lead. On the other hand, in presence of complete atrioventricular block, these algorithms are useless, since all spontaneous tachycardias are of ventricular origin. In a patient whose atrial lead is dysfunctional and either under- or oversenses, the programming of simple chamber discrimination should be considered in order to avoid erroneous classifications and the risk of delivering inappropriate therapies.

This was an episode of accurately discriminated sinus tachycardia, with gradual acceleration of a stable rhythm.

Status report - Oct 11, 2013

To: Service Télécardiologie

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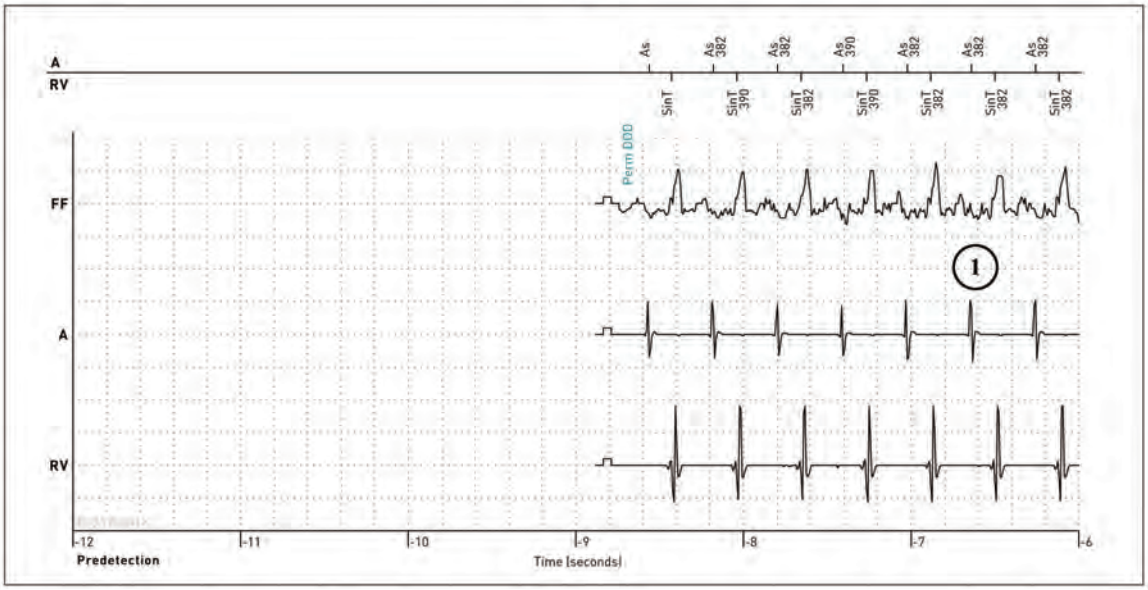
Name:	DOB:	Lumax 740 DR-T	Last message: Oct 11, 2013
Patient ID:	Phone:	ICD implanted Jan 16, 2013	Last clinic follow-up: Jun 13, 2013

Recordings

Recordings - Episode 5:

General	
Episode number	5
Episode type	SVT
Detection	Feb 10, 2013 7:08:20 AM
Termination	Feb 10, 2013 7:08:24 AM
Duration	4s
Device settings no.	5
Detection	
Mean PP at initial detection [ms]	379
Mean RR at initial detection [ms]	379
Onset [%]	1
Stability [ms]	2
Redetection	---

Therapy	
ATP in VT/VF delivered	0
ATP One Shot delivered	NO
Shocks delivered	0
Shocks aborted	0
Maximum energy [J]	---
Termination	
Mean PP at termination [ms]	408
Mean RR at termination [ms]	409
Remark	
Detection	Sinus tachycardia (PP = RR, PP and RR stable, onset not fulfilled)



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Status report - Oct 11, 2013

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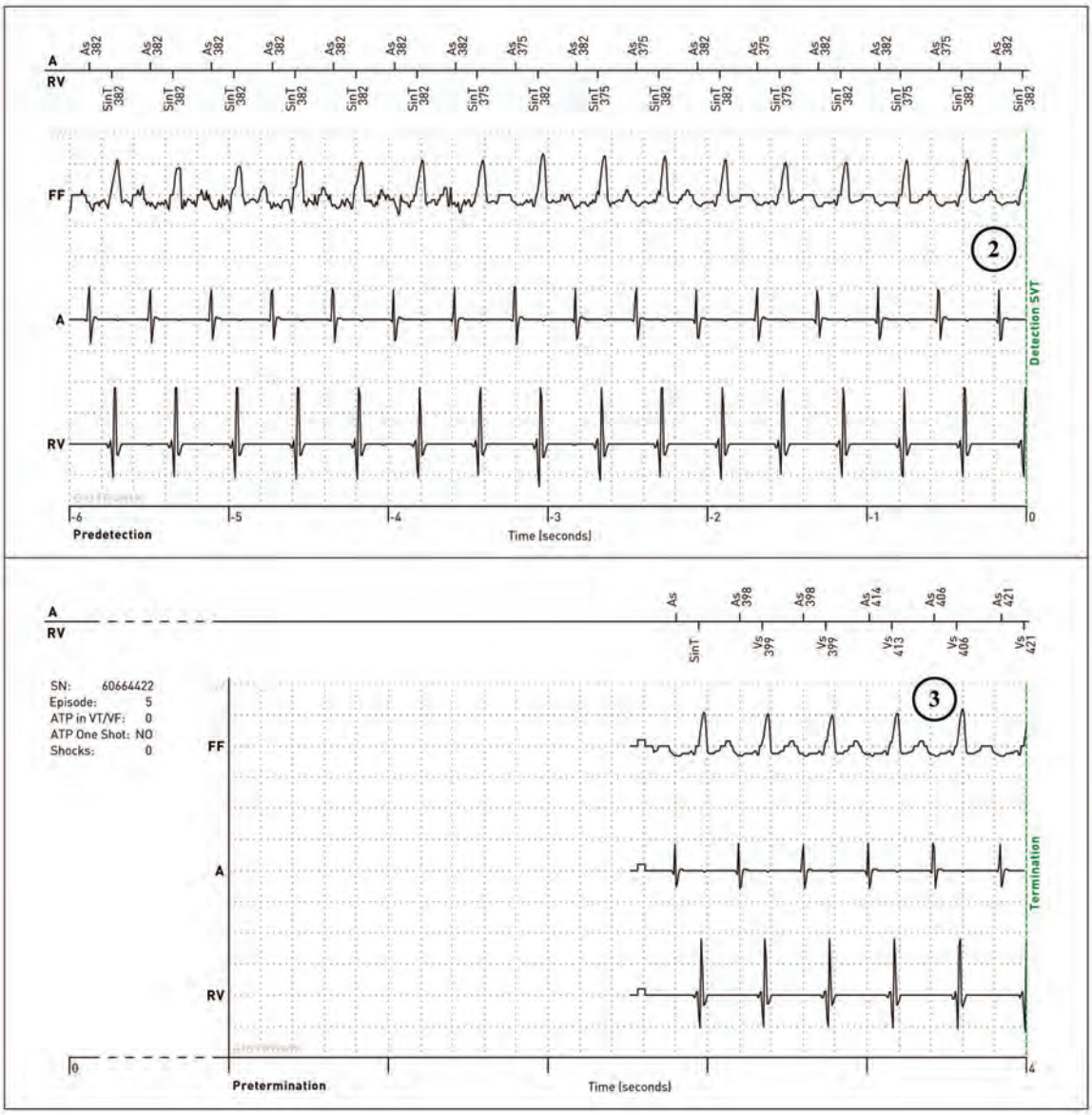
Name:	DOB:	Lumax 740 DR-T	Last message: Oct 11, 2013
Patient ID:	Phone:	ICD implanted Jan 16, 2013	Last clinic follow-up: Jun 13, 2013



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Tracing 22: poorly discriminated ventricular tachycardia

Patient

This 59-year-old man received a Lumax 740 DR-T dual chamber defibrillator for the management of episodes of VT in the background of dilated cardiomyopathy. An event report (yellow color) was issued in the context of a classified VT1 and SVT.

Main programmed settings

- VF zone (260 ms limit), VT2 zone (290 ms limit), VT1 zone (340 ms limit)
- 8/12 cycles in the VF zone, 16 cycles in the VT2 zone and 26 cycles in the VT1 zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.8 mV
- VF zone: ATP one shot, followed by 8 shocks of maximum strength (40 J); VT2 zone: 2 bursts of ATP, followed by 2 ramps of ATP, followed by 8 shocks of maximum strength; VT1 zone: 5 bursts of ATP, followed by 5 ramps of ATP, followed by a single 20-J shock, followed by 7 shocks of maximum strength;
- Effective discrimination in the VT2 and VT1 zones (SMART discrimination)
- Pacing mode: DDD at 60 bpm

Remote tracing 1

The 4 channels available are 1) the markers with the time intervals, 2) the shock channel (FF = far field) between the coil of the RV lead and the pulse generator, 3) the atrial (A) sensing channel and 4) the right ventricular (RV) sensing channel.

1: tachycardia initially in the VT1 zone with a 1:1 atrioventricular ratio; the ventricular events are classified Tsin (sinus tachycardia);
2: interruption of retrograde conduction with faster ventricular than atrial rate (indicative of VT); discrimination in the PP>RR zone;
3: diagnosis of VT1 in the PP>RR arn;
4: delivery of 6 sequences of ATP.

Remote tracing 2

5: tachycardia in the VT1 zone with 1:1 atrioventricular ratio; the ventricular events are classified Tsin (sinus tachycardia). It is noteworthy that the ventricular morphology is similar to that of the previous episode;
6: classification SVT in the PP=RR arm; the average PP and RR at initial classifications = 332 and 336 ms, respectively. Stable rhythm, with 8-ms stability for a 24 ms programmed threshold. Stable PP cycles and PR interval without monotonous change. In this case, the sudden onset criterion was not fulfilled since it measured 18% for a 20% programmed threshold. Consequently, the diagnosis made by the device was SVT (sinus tachycardia).

Comments

During a 1:1 tachycardia, the observation of a transitory ventriculo-atrial block is diagnostic of VT. The second episode was diagnosed as SVT (sinus tachycardia) by the device. The differential diagnosis between VT and sinus tachycardia is highly challenging, if not impossible, on the basis of the analysis of this tracing only. The diagnosis of the first episode is unequivocal, as the interruption of retrograde conduction (V>A) discloses the ventricular origin of the tachycardia. In a patient presenting with multiple episodes of 1:1 tachycardia, all tracings must be scrutinized, in search of anterograde (SVT) or retrograde (VT) block, confirming the diagnosis.

Status report - Oct 11, 2013

To: Service Télécardiologie

BIOTRONIK
excellence for life

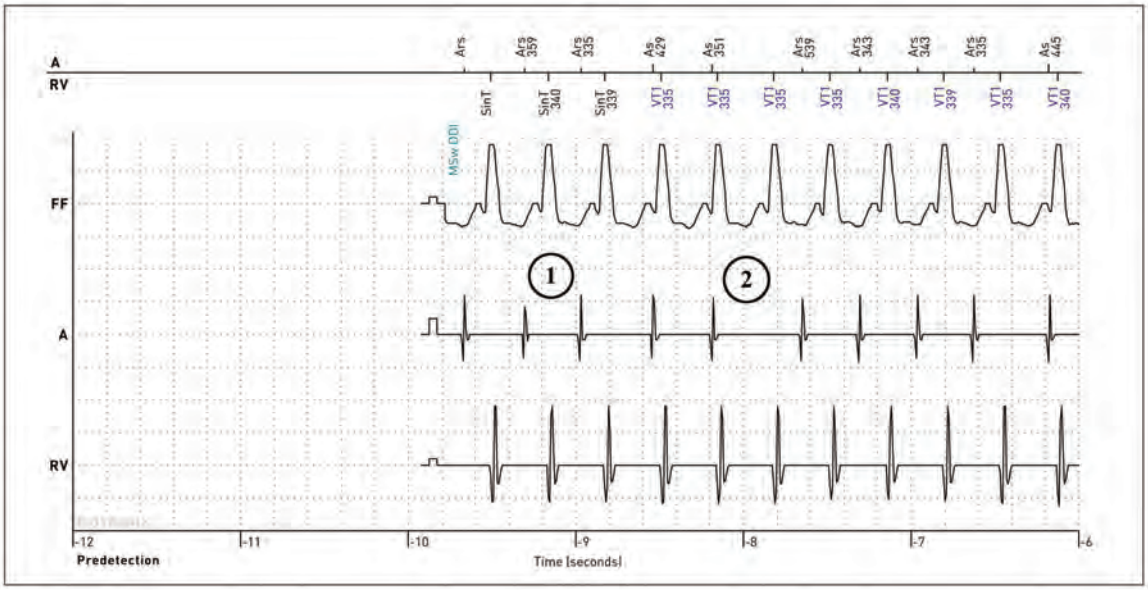
Name:	DOB:	Lumax 740 DR-T	Last message: Oct 11, 2013
Patient ID:	Phone:	ICD implanted Nov 20, 2012	Last clinic follow-up: Jul 1, 2013

Recordings

Recordings - Episode 20:

General	
Episode number	20
Episode type	VT1
Detection	Dec 2, 2012 4:59:29 PM
Termination	Dec 2, 2012 5:02:47 PM
Duration	3min 18s
Device settings no.	4
Detection	
Mean PP at initial detection [ms]	371
Mean RR at initial detection [ms]	337
Onset [%]	20
Stability [ms]	4
Redetection	VT1: 5

Therapy	
ATP in VT/VF delivered	6
ATP One Shot delivered	NO
Shocks delivered	0
Shocks aborted	0
Maximum energy [J]	---
Termination	
Mean PP at termination [ms]	425
Mean RR at termination [ms]	336
Remark	
Termination forced termination	



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Status report - Oct 11, 2013

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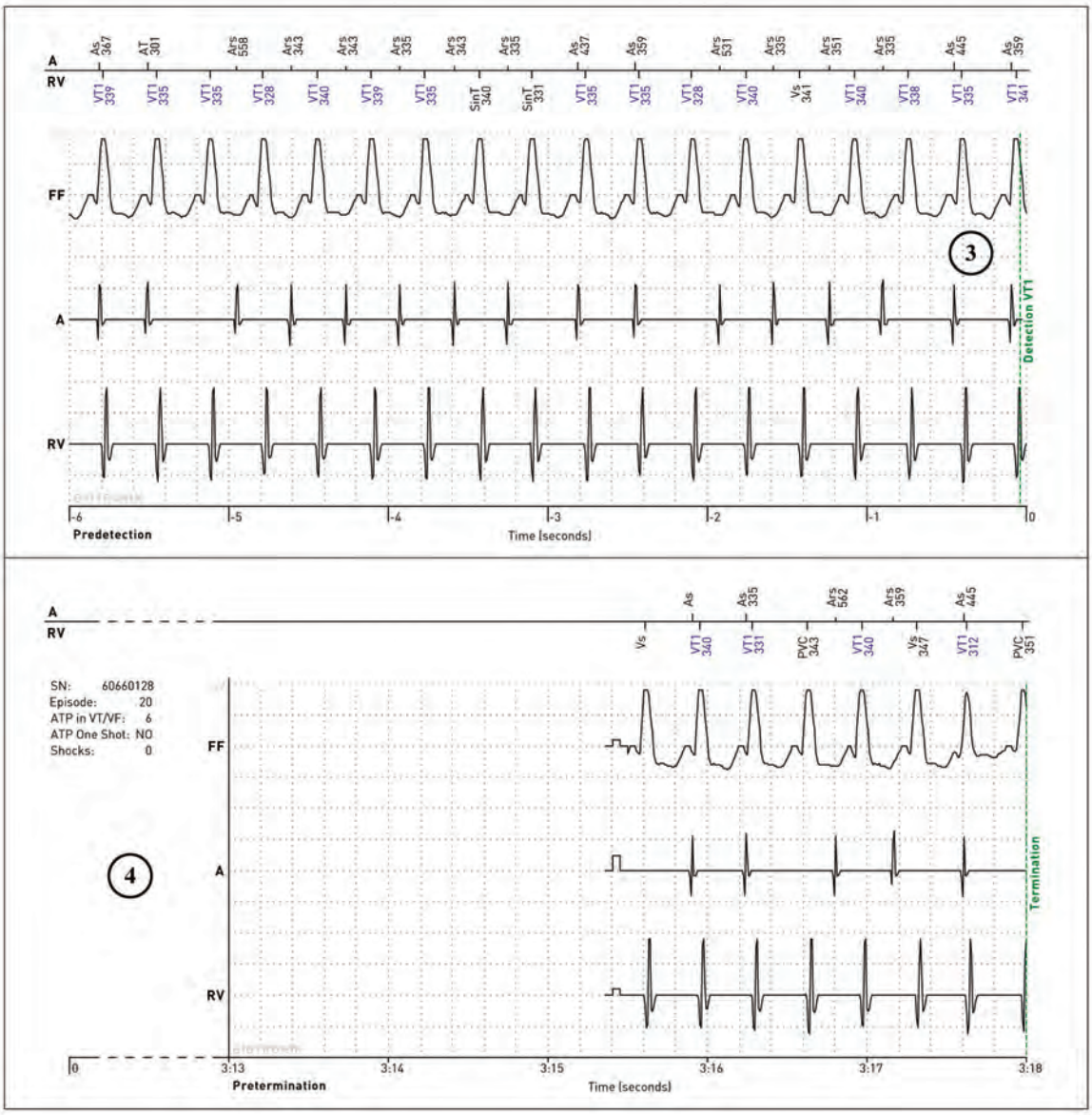
Name:	DOB:	Lumax 740 DR-T	Last message: Oct 11, 2013
Patient ID:	Phone:	ICD implanted Nov 20, 2012	Last clinic follow-up: Jul 1, 2013



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Status report - Oct 11, 2013

To: Service Télécardiologie

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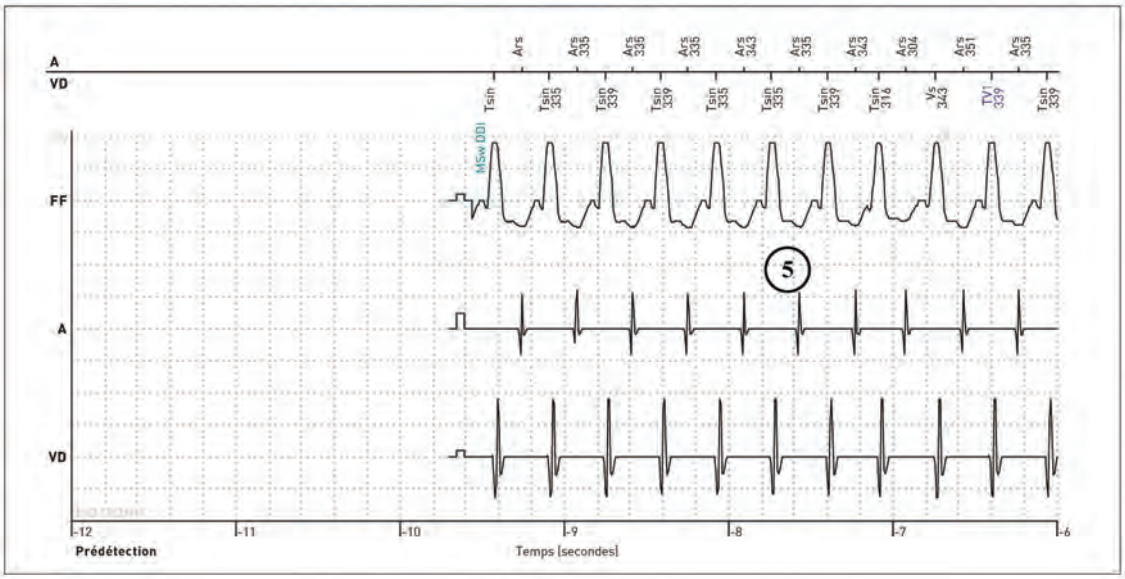
Name:	DOB:	Lumax 740 DR-T	Last message: Oct 11, 2013
Patient ID:	Phone:	ICD implanted Nov 20, 2012	Last clinic follow-up: Jul 1, 2013

Enregistrements - Episode 10:

Généralités	
Numéro d'épisode	10
Type d'épisode	TSV
Classification	2 déc. 2012 01:07:29
Fin	---
Durée	---
Réglages n°	4
Classification	
PP moyen lors de classification initiale [ms]	332
RR moyen lors de classification initiale [ms]	336
Début [%]	18
Stabilité [ms]	8
Redétection	---

Traitement	
ATP délivrée en TV/FV	0
ATP One Shot délivrées	NON
Choc(s) délivré(s)	0
Chocs annulés	0
Energie maximale [J]	---
Fin	
PP moyen en fin d'épisode [ms]	en cours
RR moyen en fin d'épisode [ms]	en cours
Remarque	
Classification	Tachycardie sinusale (PP = RR, PP et RR stables, démarrage non satisfait)



Status report - Oct 11, 2013

To: Service Télécardiologie

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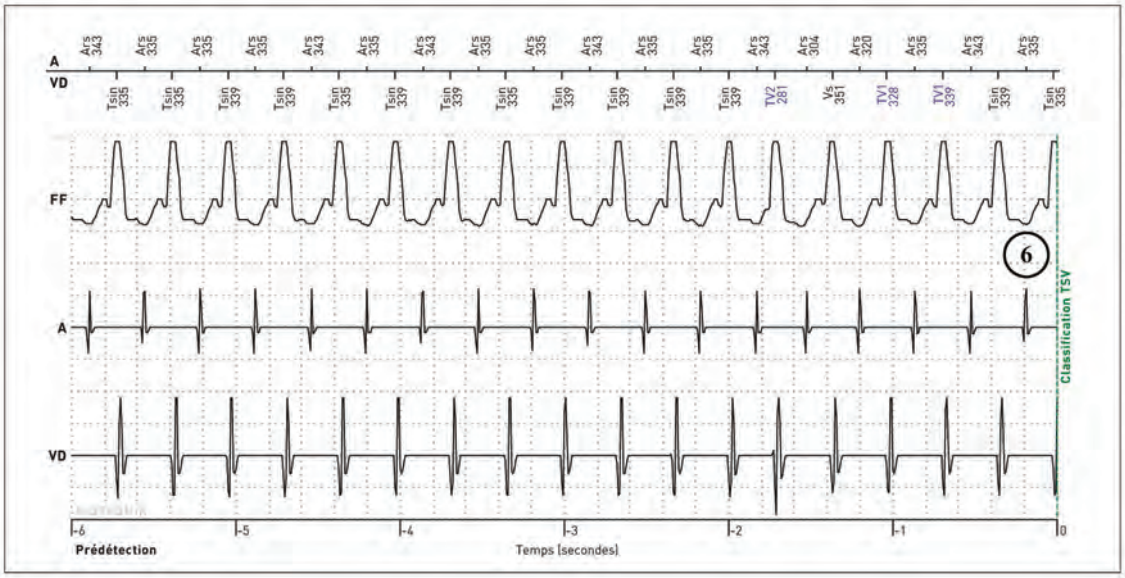
Name:	DOB:	Lumax 740 DR-T	Last message: Oct 11, 2013
Patient ID:	Phone:	ICD implanted Nov 20, 2012	Last clinic follow-up: Jul 1, 2013



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Tracing 23: accurate discrimination of atrial fibrillation

Patient

This 61-year-old man received a Lumax 340 HF-T triple chamber defibrillator for primary prevention indication in the context of a dilated cardiomyopathy with left bundle branch block. An event report (yellow color) was issued in the context of a classified SVT.

Main programmed settings

- VF zone (260 ms limit), VT2 zone (330 ms limit), VT1 zone (370 ms limit)
- 12/16 cycles in the VF zone, 16 cycles in the VT2 zone and 26 cycles in the VT1 zone were needed for the diagnosis
- Maximum sensitivity programmed at 0.8 mV
- VF zone: ATP one shot, followed by 8 shocks of maximum strength (40 J); VT2 zone: 3 bursts of ATP, followed by a single 20-J shock, followed by 7 shocks of maximum strength; VT1 zone: 4 bursts of ATP, followed by 3 ramps, followed by a single 7-J shock, followed by a single 12-J shock, followed by 6 shocks of maximum strength;
- Effective discrimination in the VT2 and VT1 zones (SMART discrimination)
- Pacing mode: biventricular DDD at 50 bpm

Telecardiology tracing

The 4 channels available are 1) the markers with the time intervals, 2) the atrial (A) sensing channel, 3) the right ventricular (RV) sensing channel, and 4) the left ventricular (LV) sensing channel;

1: mode switch for atrial arrhythmia (MSw DDI);

2: fast and irregular atrial rhythm with rapid and irregular atrioventricular conduction, consistent with atrial fibrillation. On the atrial channel, the cycles are classified As or Ars; on the ventricular channel, Vs markers indicate the cycles outside the VT1 zone (370 ms limit) and markers FibA indicate the shorter cycles;

3: classification of SVT episode in the PP<RR arm. On several occasions, the ventricular cycles are irregular and the RR cycles are unstable. Consequently, the device classified the episode as atrial fibrillation and no therapy was delivered.

Status report - Oct 11, 2013

To: Service Télécardiologie

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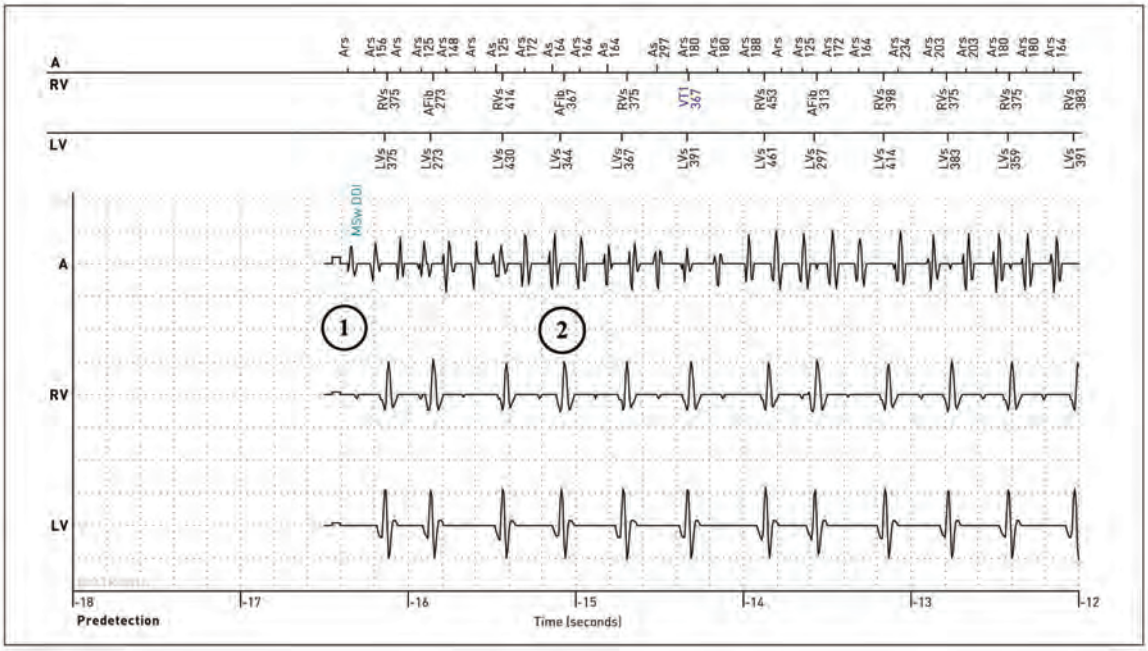
Name:	DOB:	Lumax 340 HF-T	Last message: Oct 11, 2013
Patient ID:	Phone: -	CRT-D implanted May 31, 2010	Last clinic follow-up: Sep 17, 2013

Recordings

Recordings - Episode 30:

General	
Episode number	30
Episode type	SVT
Detection	Dec 14, 2010 12:58:33 PM
Termination	Dec 14, 2010 12:59:28 PM
Duration	55s
Device settings no.	50
Detection	
Mean PP at initial detection [ms]	360
Mean RR at initial detection [ms]	361
Onset [%]	21
Stability [ms]	13
Redetection	---

Therapy	
ATP in VT/VF delivered	0
ATP One Shot delivered	NO
Shocks delivered	0
Shocks aborted	0
Maximum energy [J]	---
Termination	
Mean PP at termination [ms]	201
Mean RR at termination [ms]	383
Remark	
Detection	Atrial fibrillation (PP < RR, RR unstable)



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Status report - Oct 11, 2013

To: Service Télécardiologie

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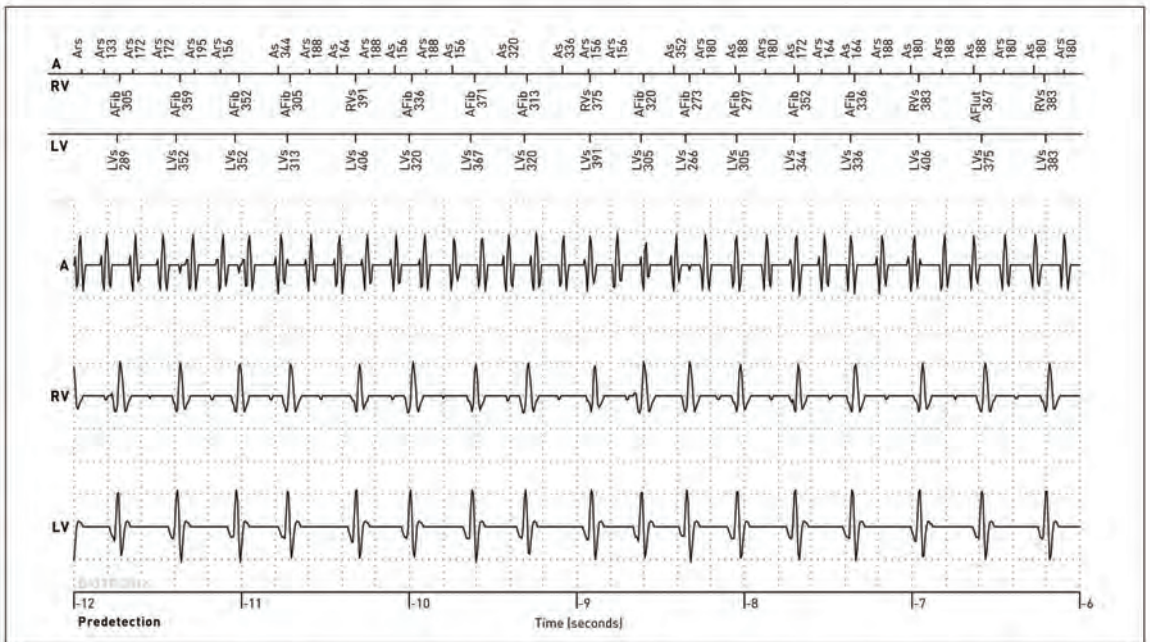
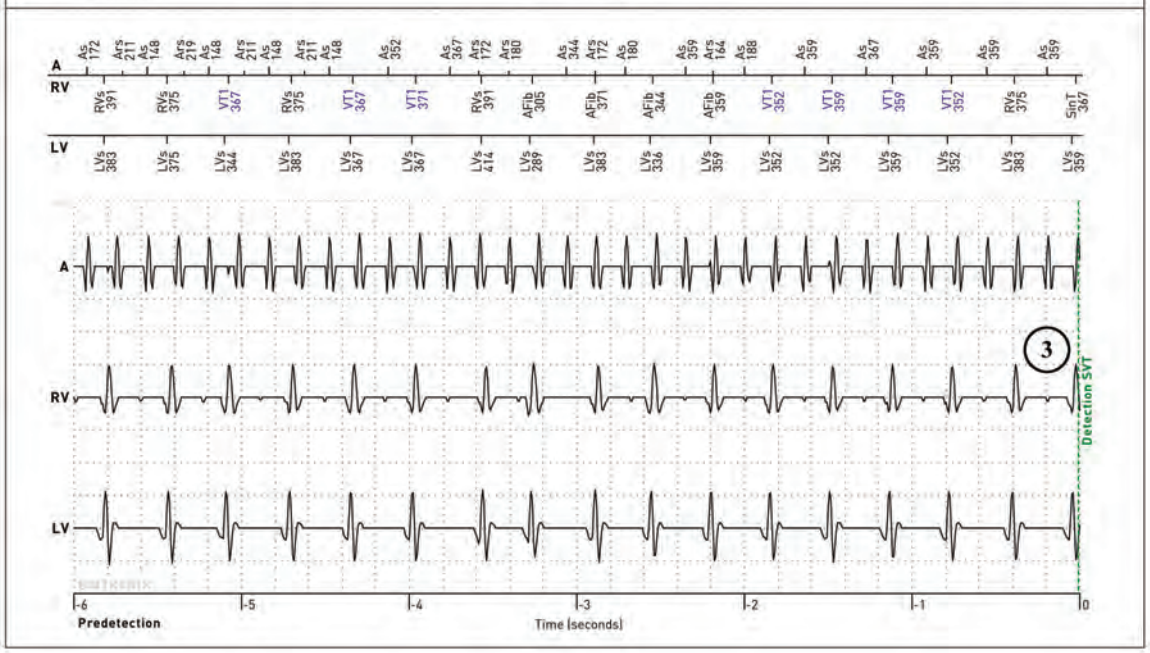
Name:	DOB:	Lumax 340 HF-T	Last message: Oct 11, 2013
Patient ID:	Phone: -	CRT-D implanted May 31, 2010	Last clinic follow-up: Sep 17, 2013





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Status report - Oct 11, 2013

To: Service TélécArdiologie

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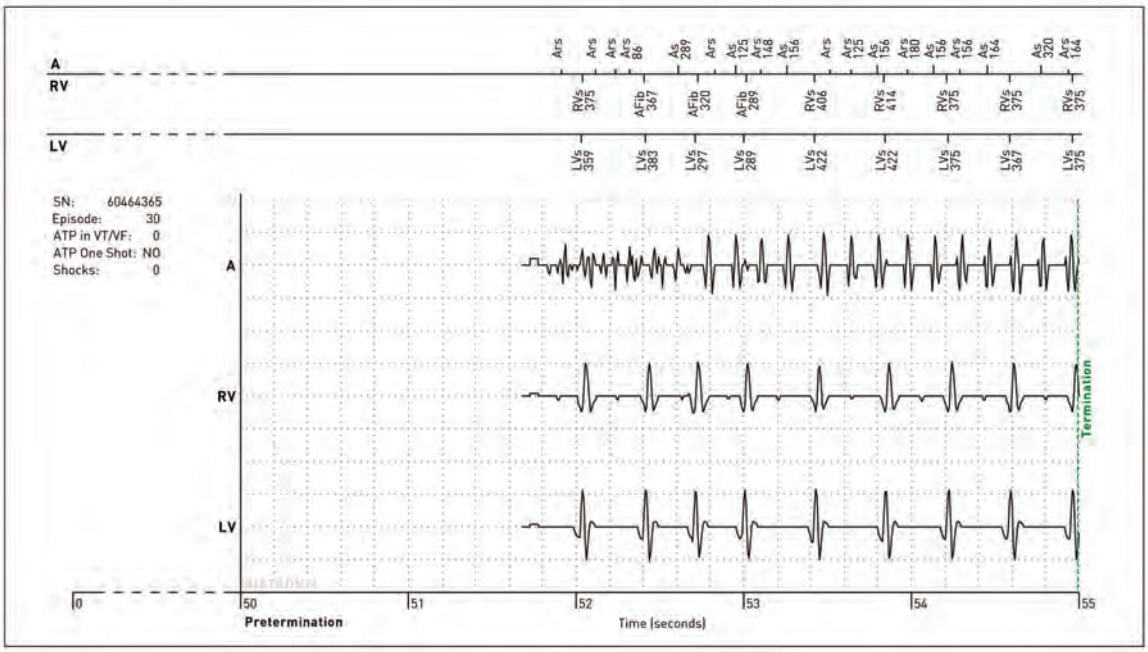
Name:	DOB:	Lumax 340 HF-T	Last message: Oct 11, 2013
Patient ID:	Phone: -	CRT-D implanted May 31, 2010	Last clinic follow-up: Sep 17, 2013



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