MicroPort™ CRM

Customer Reply Form

1. FSN information	
FSN Reference	CRM-SAL-2018-001
FSN Date	July 12, 2018
Device(s)	Platinium ICDs and CRT-Ds

2. Customer Details	
Account Number	
Organization Name	
Organization Address	
Department/Unit	
Shipping address if different from above	
Contact Name	
Telephone number	
Email	

3. Customer action undertaken		
☐	I confirm receipt of the Field Safety Notice. The information and required actions have been brought to the attention of all relevant users.	*Customer to fill in or enter N/A*
☐	I have identified and/or quarantined affected devices - enter number of devices and date complete	*Customer to fill in or enter N/A*
☐	I have returned affected devices - enter number of devices returned and date complete	*Customer to fill in or enter N/A*
☐	I do not have any affected devices	*Customer to fill in or enter N/A*
☐	I have a query please contact me	*Customer to enter contact details if different from above and brief description of query*

Print Name	Signature	Date
Customer print name here	*Customer sign here*	*Date here*

4. Return acknowledgement to Manufacturer/Supplier/Distributor	
Email	*Pre-filled by manufacturer*
Fax	*Pre-filled by manufacturer*
Customer Helpline	*Pre-filled by manufacturer*
Postal Address	*Pre-filled by manufacturer*

5. Distributors / Suppliers Only		
☐	I have checked my stock and quarantined affected inventory	*Distributor/Supplier to enter quantity and date, or enter N/A*
☐	I have identified customers that received or may have received this device and attached a list of customers	*Distributor/Supplier to fill in or enter N/A*
☐	I have attached a list of customers that have confirmed receipt of the FSN	*Distributor/Supplier to fill in or enter N/A*
☐	Neither I nor any of my customers has any affected devices in inventory	*Distributor/Supplier to fill in or enter N/A*

Print Name	Signature	Date
Distributor print name here	*Distributor sign here*	*Date here*

It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organization's reply is the evidence that we need to monitor the progress of the corrective actions.

NAME OF ADDRESSEE
Address line 1
Address line 2
Post Code CITY
COUNTRY

July 12, 2018

URGENT FIELD SAFETY NOTICE

Loss of pacing and sensing following hardware failure, leading to absence of automatic detection of an arrhythmia requiring defibrillation shock therapy

FSCA identifier:	CRM-SAL-2018-001
Affected devices:	Limited subset of Platinium Implantable Cardiac Defibrillator (ICD) and Resynchronization Therapy Defibrillator (CRT-D) models : VR 1210, VR 1240, DR 1510, DR 1540, CRT-D 1711, SonR CRT-D 1811, CRT-D 1741, SonR CRT-D 1841, 4LV CRT-D 1744, 4LV SonR CRT-D 1844
Attention:	Physicians, Medical centers, Healthcare professionals
Reason:	MicroPort CRM is initiating a removal of a limited subset of Platinium ICDs and CRT-Ds that may present with hardware failure and providing recommendations for managing implanted patients

SORIN CRM S.A.S.
A MICROPORT CRM COMPANY
4, AVENUE REAUMUR
92140 CLAMART
FRANCE

CONTACT
T +33 (0)1 46 01 33 33

SHARE CAPITAL 104 825 140 €.
RCS NANTERRE 309 786 481

MICROPORT CRM
HEADQUARTER OFFICES
4, AVENUE RÉAUMUR
92140 CLAMART
FRANCE

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Dear Doctor,

Details on affected devices:

You are receiving this letter because our records indicate that you may have some patients who are implanted with potentially affected Platinium devices and/or your Center or Hospital has in its inventory Platinium devices which may be affected by the issue described below.

Description of the problem:

On a subset of Platinium ICD and CRT-D devices, a specific hardware configuration was identified as potentially defective over time, leading to overconsumption, immediately followed by loss of pacing and sensing capabilities in all cavities. As a result of the loss of sensing capability, the device cannot identify an arrhythmia that would require a defibrillation shock therapy.

How did this affect patients?

No permanent injury or death has been reported as a result of this issue. As of June 30th, 2018, MicroPort CRM has received five (5) reports on Platinium devices about this issue out of the 1637 Platinium devices

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released for distribution that may be subject to the issue (0.31%). MicroPort CRM has not identified a specific time frame during which the problem is more likely to occur. Nevertheless, all five events were detected within the first year after implantation. In only one (1) case, the patient reported feeling weakness. All five devices were replaced.

Actions taken by MicroPort CRM to address this issue:

1. Since June 26th, 2018, MicroPort CRM has stopped releasing Platinium devices having the potentially defective hardware configuration. Platinium devices with unaffected hardware configurations have been made available.

2. MicroPort CRM is initiating a removal of the non implanted Platinium devices that may present with this hardware failure and providing recommendations for managing implanted patients.

Advice on action to be taken by the user:

1. Identify and quarantine affected Platinium devices that are still in your inventory. **Appendix 2** provides the list of the devices subject to this advisory that were shipped to your center. Your MicroPort CRM representative will assist you in the identification of these products as necessary. In addition, if you would like to determine if a device is subject to this advisory, please go and check its serial number on the following website: www.crm.microport.com/platinium-fsn-2018-001.

2. Return Platinium devices that are subject to this advisory to MicroPort CRM by contacting your MicroPort CRM representative or your local Customer Service at [local phone number or email to be inserted] and referencing this communication to initiate a return and credit or replacement of unused product. Your MicroPort CRM representative will assist you in the return of these products as necessary.

Patient management recommendation:

1. Perform patient follow-up every three months. In order to mitigate the potential risks associated with the loss of the device pacing and sensing capabilities, MicroPort CRM recommends physicians follow-up the patients at the periodicity already stated in the implant manual[1] and in the international guidelines[2], especially:
    a. Before the patient is discharged and at each subsequent follow-up, it is advisable to check the battery status and the occurrence of system warnings;

[1] For instance, Implant Manual reference U456C (section 8) in Europe and Australia, U459C (section 17) in the USA, UA069A (section 17) in Canada, available on www.microportmanuals.com.

[2] HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs): Description of Techniques, Indications, Personnel, Frequency and Ethical Considerations - Bruce L. Wilkoff & al. – Europace 2008;10:707-25

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b. It is recommended that a routine follow-up examination be done one month after discharge, and then every three months until the device nears the replacement date.

2. MicroPort CRM does not recommend rescheduling patient visits, provided that the three-month follow-up periodicity is applied.

3. MicroPort CRM recommends physicians check for proper sensing and pacing during each follow-up.

4. If one or more of the items listed below is/are observed during follow-up, then hardware failure may have occurred. Without delay, please contact your MicroPort CRM representative. Refer to the Appendix 1 showing some examples. There is no audible or vibratory alert on Platinium ICD and CRT-D devices.

   a. The warning "Technical issue" indicates that overconsumption was detected. A steep decrease of the battery voltage may be visible on the battery curve.
   b. Warnings on high lead impedances in all cavities.
   c. Loss of sensing capability will result in flat EGMs and 100% pacing in the statistics.

5. Enroll patients in SmartView™ remote monitoring and verify that the "*RF for Remote Monitoring*" setting is programmed ON. System alert checks are automatically performed on a daily basis. Integrity alerts cannot be deactivated, such as the overconsumption alert and the battery depletion alert. Verify that the high lead impedance and continuity alerts are programmed ON. Centers will automatically receive notification of such alerts overnight. On the SmartView website, verify that the "Monitoring Interruption" notification is activated (in the "Clinic Notification Settings" tab), so that the center receives a notification in case of interruption in the communication between the server and the Platinium device for 14 consecutive days. For patients currently enrolled in SmartView™, remind them of the importance of using remote monitoring.

6. MicroPort CRM does not generally recommend physicians prophylactically replace the Platinium device. However, special consideration should be given in the following circumstances:
   a. For pacing dependent patients or those with high ventricular arrhythmia burden the relative risk of device failure versus that associated with device replacement should be assessed on an individual patient basis.
   b. In case of a surgical procedure involving the patient's defibrillation system, already scheduled for other causes than the one related to the Platinium device (*e.g.* lead revision), MicroPort CRM recommends physicians

prophylactically replace the Platinium device, if subject to this advisory, during the same procedure.

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Transmission of this Field Safety Notice:

Please complete and return the Customer Reply Form as soon as possible to acknowledge that you have read and understand this Field Safety Notice. Returning the Customer Reply Form will also prevent repeat notifications of this notice.

Please ensure that all personnel involved in the management of patients implanted with Platinium devices in your organization are aware of the information outlined in this letter.

MicroPort CRM has communicated this information to the Competent Authority of your country.

We regret the inconvenience this could cause you and your patients. If you need further information, please contact your local CRM representative or contact the company at [local phone number to be inserted]. We appreciate your assistance in this matter.

Sincerely,

[Local Company Representative]

Enclosed:
- Customer Reply Form
- Appendix 1: examples of observations resulting from the hardware failure subject to this advisory
- Appendix 2: list of the devices subject to this advisory that were shipped to your center

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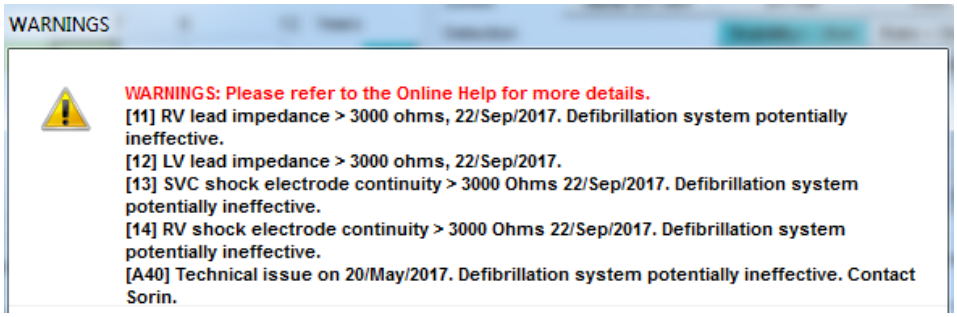
APPENDIX 1

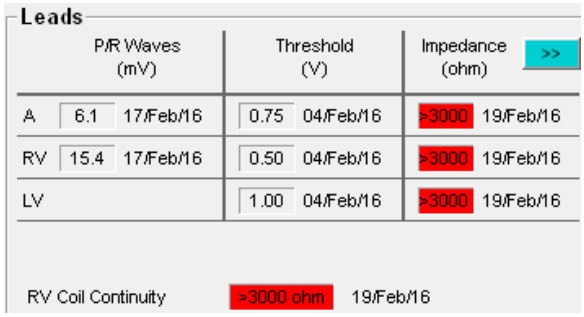
Examples of observations resulting from the hardware failure subject to this advisory

July 12, 2018

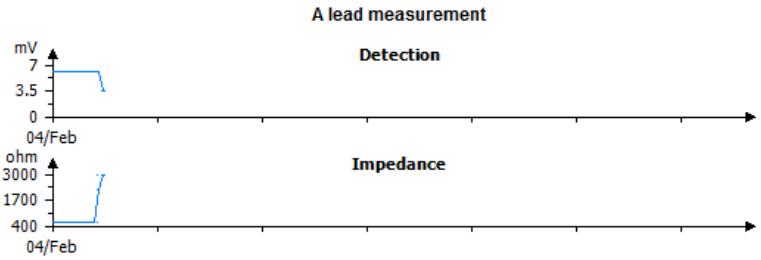


Warnings for high lead impedances and continuities

Warning for overconsumption



Warnings for high lead impedances and continuities



Atrial lead impedance curve showing a sudden increase of the impedance

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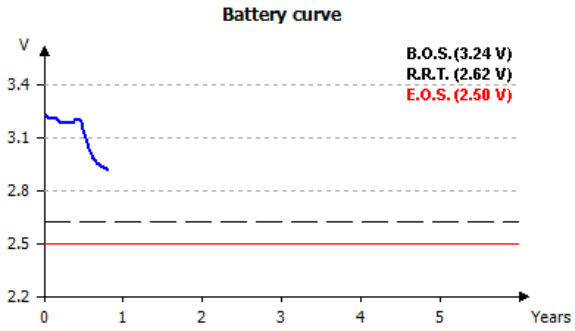

Time to RRT:	5 - 7 Years
Last value measured :	2.91 V - 21/Sep/2017
Last charge to 42J:	05/April/2017
Energy beg./end:	0.1/42.2 J
Charge time:	12.0 s
Last shock:	-
Zone of delivery:	-
Energy stored/delivered:	-/- J
Duration:	-
Charge time:	-
Impedance:	-
Battery reforming date:	-
Total number of charges:	1
Total time of RF transmission:	49min 23s

Battery curve showing a steep decrease of the battery voltage

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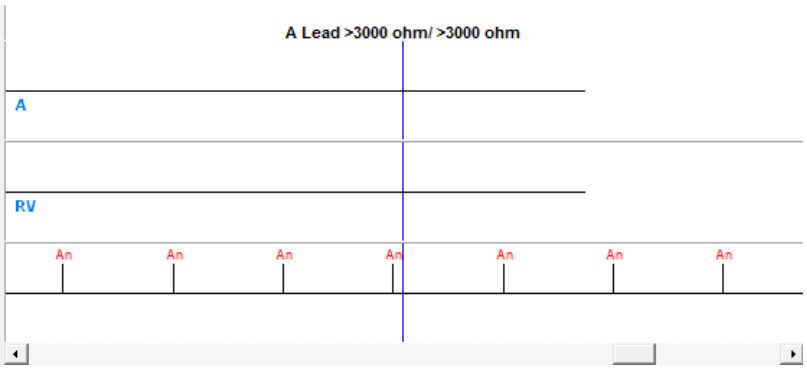

Flat EGMs

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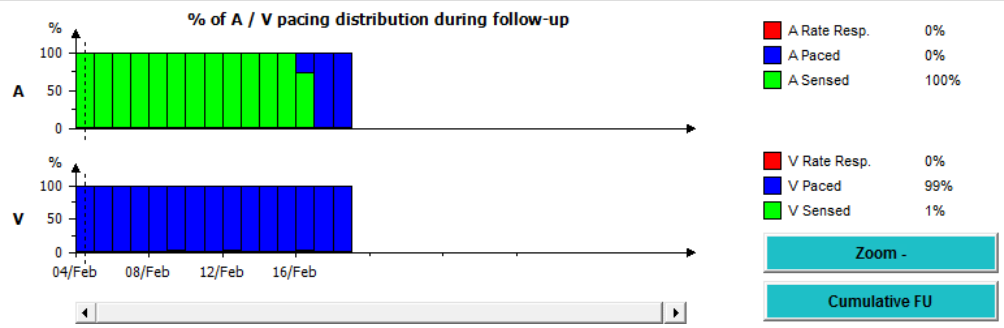

Statistics showing 100% pacing

When the failure described in this Field Safety Notice occurs, the device will no longer pace or sense. Due to the absence of sensing, the algorithm will send a pacing command for 100% of the cardiac cycles. The pacing spikes are not delivered due to the hardware failure, but 100% pacing statistics will be shown.

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APPENDIX 2

List of the devices subject to this advisory that were shipped to your center

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