



Customer Reply Form

1. FSN information	
FSN Reference	CRM-SAL-2018-001
FSN Date	July 12, 2018
Device(s)	Platinum 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		
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice. The information and required actions have been brought to the attention of all relevant users.	<i>Customer to fill in or enter N/A</i>
<input type="checkbox"/>	I have identified and/or quarantined affected devices - enter number of devices and date complete	<i>Customer to fill in or enter N/A</i>
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete	<i>Customer to fill in or enter N/A</i>
<input type="checkbox"/>	I do not have any affected devices	<i>Customer to fill in or enter N/A</i>
<input type="checkbox"/>	I have a query please contact me	<i>Customer to enter contact details if different from above and brief description of query</i>
Print Name	Signature	Date
<i>Customer print name here</i>	<i>Customer sign here</i>	<i>Date here</i>



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

5. Distributors / Suppliers Only		
<input type="checkbox"/>	I have checked my stock and quarantined affected inventory	<i>Distributor/Supplier to enter quantity and date, or enter N/A</i>
<input type="checkbox"/>	I have identified customers that received or may have received this device and attached a list of customers	<i>Distributor/Supplier to fill in or enter N/A</i>
<input type="checkbox"/>	I have attached a list of customers that have confirmed receipt of the FSN	<i>Distributor/Supplier to fill in or enter N/A</i>
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices in inventory	<i>Distributor/Supplier to fill in or enter N/A</i>
Print Name	Signature	Date
<i>Distributor print name here</i>	<i>Distributor sign here</i>	<i>Date here</i>

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

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

FSCA identifier: CRM-SAL-2018-001

Affected devices: Limited subset of Platinum 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 Platinum ICDs and CRT-Ds that may present with hardware failure and providing recommendations for managing implanted patients

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 Platinum devices and/or your Center or Hospital has in its inventory Platinum devices which may be affected by the issue described below.

Description of the problem:

On a subset of Platinum 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.

crm.microport.com

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 Platinum devices about this issue out of the 1637 Platinum devices

July 12, 2018

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 Platinum devices having the potentially defective hardware configuration. Platinum devices with unaffected hardware configurations have been made available.
2. MicroPort CRM is initiating a removal of the non implanted Platinum devices that may present with this 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

Advice on action to be taken by the user:

1. Identify and quarantine affected Platinum 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/platinum-fsn-2018-001.
2. Return Platinum 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 manual¹ and in the international guidelines², 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;

crm.microport.com

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



- 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.

July 12, 2018

- 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 Platinum ICD and CRT-D devices.

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 REAUMUR
92140 CLAMART
FRANCE

crm.microport.com

- 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 Platinum 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 Platinum 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 Platinum device (e.g. lead revision), MicroPort CRM recommends physicians



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

July 12, 2018

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 Platinum devices in your organization are aware of the information outlined in this letter.

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

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

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

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.

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

Sincerely,

[Local Company Representative]

MICROPORT CRM
HEADQUARTER OFFICES
4, AVENUE REAUMUR
92140 CLAMART
FRANCE

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

crm.microport.com

APPENDIX 1

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

July 12, 2018

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

crm.microport.com

WARNINGS



WARNINGS: Please refer to the Online Help for more details.

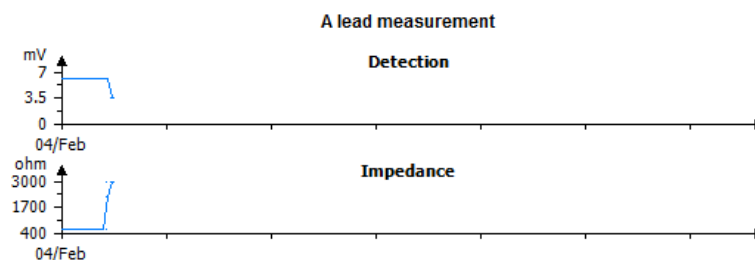
- [11] RV lead impedance > 3000 ohms, 22/Sep/2017. Defibrillation system potentially ineffective.
- [12] LV lead impedance > 3000 ohms, 22/Sep/2017.
- [13] SVC shock electrode continuity > 3000 Ohms 22/Sep/2017. Defibrillation system potentially ineffective.
- [14] RV shock electrode continuity > 3000 Ohms 22/Sep/2017. Defibrillation system potentially ineffective.
- [A40] Technical issue on 20/May/2017. Defibrillation system potentially ineffective. Contact Sorin.

Warnings for high lead impedances and continuities

Warning for overconsumption

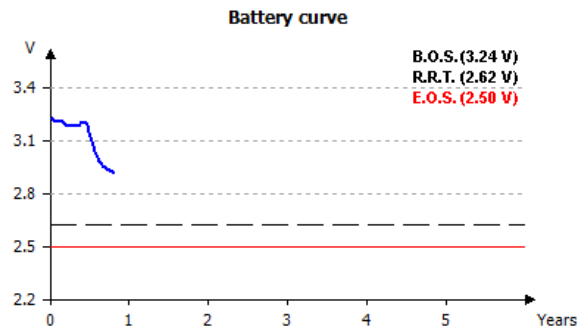
Leads			PR Waves (mV)	Threshold (V)	Impedance (ohm)
A	6.1	17/Feb/16	0.75	04/Feb/16	>3000 19/Feb/16
RV	15.4	17/Feb/16	0.50	04/Feb/16	>3000 19/Feb/16
LV			1.00	04/Feb/16	>3000 19/Feb/16
RV Coil Continuity			>3000 ohm		19/Feb/16

Warnings for high lead impedances and continuities



Atrial lead impedance curve showing a sudden increase of the impedance

July 12, 2018



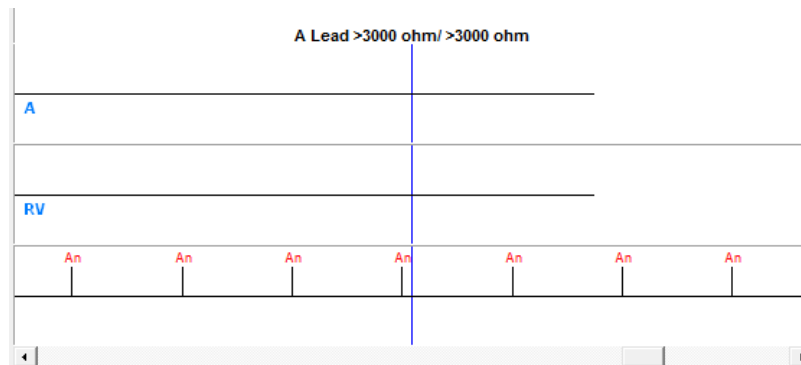
Time to RRT: 5 - 7 Years
 Last value measured : 2.91 V - 21/Sep/2017
 Last charge to 42J: 05/April/2017
 Energy beg./end: 0.1/42.2 J
 Charge time: 12.0 s
 Last shock: -
 Zone of delivery: -
 Energy stored/delivered: -/- J
 Duration: -
 Charge time: -
 Impedance: -
 Battery reforming date: -
 Total number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

Battery curve showing a steep decrease of the battery voltage

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

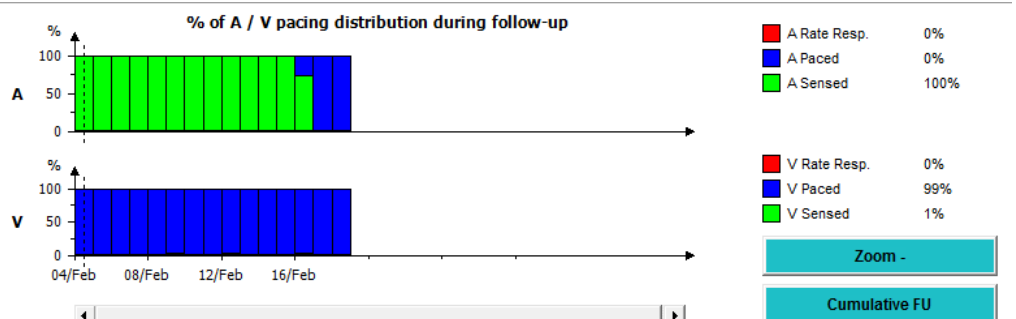
CONTACT
 T +33 (0)1 46 01 33 33

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



Flat EGMs

MICROPORT CRM
 HEADQUARTER OFFICES
 4, AVENUE REAUMUR
 92140 CLAMART
 FRANCE



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.



APPENDIX 2

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

July 12, 2018

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

crm.microport.com