Customer Reply Form

1. FSN information	
FSN Reference	CRM-SAL-2018-001-C
FSN Date	December 14, 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 *Distributor print name here*		Signature *Distributor sign here*	Date *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

December 14, 2018

URGENT FIELD SAFETY NOTICE

Release of a new software version to maintain therapies in implanted Platinium devices in case of occurrence of the hardware failure described in the Field Safety Notice issued in July 2018

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FSCA identifier:	**CRM-SAL-2018-001-C**
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 deploying a new software version to maintain sensing, pacing and defibrillation functionalities in case of occurrence of the hardware failure described in the Field Safety Notice CRM-SAL-2018-001 issued in July 2018, and updating the 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 Platinium devices potentially affected by the issue described in the Field Safety Notice CRM-SAL-2018-001 issued in July 2018 (provided in **Attachment 1**).

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.

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How did this affect patients?

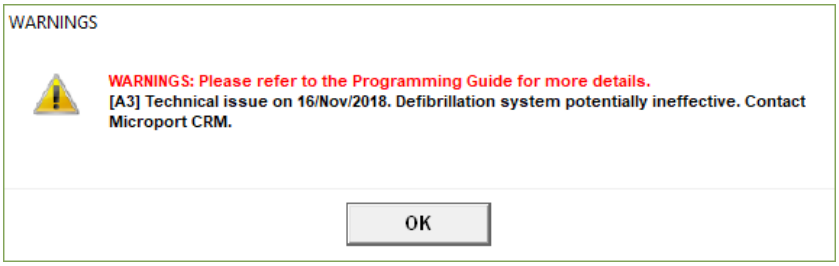
No permanent injury or death has been reported as a result of this issue.
As of December 14th, 2018, no new report has been received since the Field Safety Notice CRM-SAL-2018-001.

Actions taken by MicroPort CRM to address this issue:

MicroPort CRM is releasing a new software version. Your MicroPort CRM representative will inform you as soon as the new programmer software version[1] is available and assist you in upgrading your programmer. All implanted devices interrogated with this new version will then be automatically upgraded.

This software will ensure that pacing and sensing functionalities are preserved if a patient from your population is affected by the hardware failure. As sensing is preserved, the device will be able to identify and treat any tachyarrhythmia that would require a defibrillation shock therapy.

This new software is not able to eliminate the underlying hardware failure. The overconsumption resulting from the failure will not be interrupted. **The warning "Technical issue" will be raised, indicating that overconsumption has been detected. This alert will be sent remotely or observed during in-clinic follow-up. A minimum service period of 45 days after hardware failure is guaranteed.**



Advice on action to be taken by the user:

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.

Your MicroPort CRM representative will assist you in the identification of these products as necessary.

[1] SmartView version 2.60 (and higher) in Europe / 2.60J (and higher) in Japan

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Patient management recommendation:

1. Enroll patients in SmartView™ remote monitoring and verify that the "*RF for Remote Monitoring*" setting is programmed ON. Your MicroPort CRM representative will assist you in this process.

2. Recommendations related to patient in-clinic or remote follow-up remain unchanged. Recommendations 1 to 3 of the Field Safety Notice CRM-SAL-2018-001 still apply (refer to **Attachment 1**):
   i. Perform patient follow-up every three months.
   ii. MicroPort CRM does not recommend rescheduling patient visits, provided that the three-month follow-up periodicity is applied.
   iii. MicroPort CRM recommends physicians check for proper sensing and pacing during each follow-up.

3. Recommendations related to the software upgrade:
   i. Upgrade your programmer with the updated software version[1]. Your MicroPort CRM representative will inform you as soon as the new programmer software version is available and assist you in upgrading your programmer.
   ii. Interrogate Platinium devices with the upgraded programmer during patient in-clinic follow-up. During the first interrogation, the updated software will be loaded in the Platinium devices. **MicroPort CRM recommends that this first interrogation with an upgraded programmer take place as soon as practically possible and not later than three months after your programmer update.**
   iii. **Priority should be given to pacing dependent patients or those with high ventricular arrhythmia burden so that they receive the updated software sooner.**

4. Once the software update has been loaded, and provided that the patient is enrolled in SmartView™ remote monitoring, prophylactic device replacement is no longer recommended.
   If the patient is not enrolled in SmartView™ remote monitoring, the recommendation 6 of the Field Safety Notice CRM-SAL-2018-001 is still applicable:
   "MicroPort CRM does not generally recommend physicians prophylactically replace the Platinium device. However, special consideration should be given in the following circumstances:
   i. 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.
   ii. 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

[1] SmartView version 2.60 (and higher) in Europe / 2.60J (and higher) in Japan

revision), MicroPort CRM recommends physicians prophylactically replace the Platinium device, if subject to this advisory, during the same procedure."

December 14, 2018

5. In case a failure of the integrated circuit arises, the alert "Technical issue" is triggered. There is no audible or vibratory alert on Platinium ICD and CRT-D devices. Without delay, please contact your MicroPort CRM representative, who will confirm if device replacement needs to be scheduled.

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]

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Enclosed:
- Customer Reply Form
- Attachment 1: Field Safety Notice CRM-SAL-2018-001 issued in July 2018

crm.microport.com

Attachment 1:
Field Safety Notice CRM-SAL-2018-001 issued in July 2018

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