MicroPort

Customer Reply Form

1. FSN information	
FSN Reference	CRM-CLA-2021-001
FSN Date	April 1, 2021
Device(s)	Symphony, Rhapsody pacemakers

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

4. Return acknowledgement to Manufacturer/Supplier/Distributor	
Email	ludovic.flahaut@crm.microport.com
Fax	-
Customer Helpline	-
Postal Address	-

5. Distributors / Suppliers Only		
☐	I have identified customers that have patients implanted with these devices 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*
☐	None of my customers has affected devices	*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 organisation'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

April 1, 2021

Urgent Field Safety Notice

Risk of inappropriate patient management due to the delayed follow-up of patient implanted with a previous generation of ELA Medical branded pacemakers. Overall device longevity is not affected.

FSCA identifier: CRM-CLA-2021-001

Affected devices: Symphony family pacemaker (models Symphony DR 2550, SR 2250, D 2450, VDR 2350, Rhapsody DR + 2530, DR 2510, SR 2210, D 2410, S 2130)

FSN Type: New

Attention: Physicians, Healthcare professionals, Healthcare Centres

Reason for notice: MicroPort CRM is issuing this Field Safety Notice to provide recommendations for managing the follow-up of patients implanted with a previous generation of ELA Medical branded pacemakers (Symphony and Rhapsody) as listed above, with battery impedance above 4 kΩ towards Recommended Replacement Time (RRT[1]).

Dear Doctor,

The COVID-19 pandemic has created many unexpected and unavoidable situations all around the world, including some deviations in the regular processes of pacemaker follow-up. Many patients and physicians have therefore taken the decision to cancel or reschedule their routine pacemaker follow-up appointments in order to mitigate exposure to the virus. This novel situation has created an unexpected risk for patients implanted with specific ELA Medical branded pacemaker models, which have been in function for many years. The affected models are Symphony and Rhapsody, which were commercialised between 2002 and 2012.

Based on the projected maximum longevity per model, as of March 31, 2021, it is expected that of the 203168 devices distributed worldwide, less than 10% approximately remain actively implanted. When also taking into account the reported mean life expectancy of the recipient patients[2], it is estimated

[1] Recommended Replacement Time, previously known as ERI (Elective Replacement Indicator)
[2] From Brunner M, Olschewski M, Geibel A, Bode C, Zehender M. Long-term survival after pacemaker implantation. Prognostic importance of gender and baseline patient characteristics. Eur Heart J. 2004;25:88-95

that a few dozen devices may reach the RRT or the EOS[3] level during the unusually long period between two controls.

As per the implantation manual[4] and in line with published international guidelines[5], it is "advisable to follow up the patient every 6 months when the battery impedance becomes greater than or equal to 5 kΩ, especially for pacemaker-dependent patients".

Indeed, whilst these devices are continuing to perform well in terms of overall predicted longevity from implant to RRT, there have been a number of documented incidences whereby the recommended follow-up interval has not been applied in the mid-late phase of the device's lifetime (battery impedance greater than 4kΩ). This longer interval period risks exposing pacing-dependent patients to unexpectedly reach RRT or EOS between follow-up visits. This risk is only observed for Symphony and Rhapsody devices, for which the residual longevity displayed by the programmer is overestimated. All other legacy models and current MicroPort CRM devices are not affected by this risk.

The aim of this letter is to provide you with important information with regard to the management of patients who are still implanted with the aforementioned devices.

How does this affect patients?

As of January 31, 2021, 222 events (0.1%) of pacemakers reaching RRT or EOS between follow-up visits have been reported. Among these, patient symptoms (*e.g.* syncope) were reported in 33 cases.

No incidence of total loss of pacing functionality leading to death has been observed.

Patient management recommendation:

Further to the existing guidance stipulated in the implantation manual and published international guidelines, MicroPort CRM recommends the following actions **for Symphony and Rhapsody pacemakers only**:

- The predicted longevity displayed by the programmer **should be disregarded unless this value is indicating less than six months.**
- Follow-up frequency should be increased to six-monthly once the battery impedance reaches 4 kΩ (if this is not already your standard clinical practice).

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 communications of this notice.

Please ensure that all personnel involved in the management of patients implanted with Symphony and Rhapsody pacemakers in your organisation are aware of the information outlined in this letter.

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

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[3] End Of Service

[4] For instance, Implant Manual reference N998D (section "Patient follow-up") in Europe, N999E (section 15.5.1) in the USA.

[5] 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

We regret any inconvenience caused by the unprecedented COVID-19 situation to your patients and you. If you need further information, please contact your local CRM representative or Ludovic FLAHAUT (ludovic.flahaut@crm.microport.com), Commercial Quality Manager, Europe. We appreciate your assistance in this matter.

As always, MicroPort CRM is strongly committed to the safety of all patients and to helping you face the challenges presented by this pandemic.

Sincerely,

MicroPort CRM S.r.l.
Andrea VINCON
VP, Quality Assurance