Customer Reply Form

1. FSN information	
FSN Reference	CRM-SAL-2022-001 – Rev. B
FSN Date	*March*, 2024
Device(s)	XFine Leads connected to ALIZEA | BOREA pacemakers
Manufacturer SRN	IT-MF-000029013

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 system.	*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*

Links to provide your Customer Reply Form: https://forms.office.com/r/UWJ7kPDUBH

4. Return acknowledgement to Manufacturer/Supplier/Distributor	
Email	CommercialQA@crm.microport.com
Fax	+33 (0)1 46 01 89 60
Customer Helpline	
Postal Address	Commercial QA, 4 Avenue Reaumur, 92140 Clamart, FRANCE

5. Distributors / Suppliers Only			
☐	I have identified customers that have patients implanted with these devices.	*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 have affected devices.	*Distributor/Supplier to fill in or enter N/A*	
Print Name *Distributor print name here*		Signature *Distributor sign here*	Date *Date here*

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

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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 needed to monitor the progress of the corrective actions.

March, 2024

Update of Urgent Field Safety Notice

Update of the communication issued in August 2022 related to the risk of Minute Ventilation artefact oversensing in patients with a subset of abnormal high polarization XFine passive pacing leads, when connected to ALIZEA / BOREA pacemakers.

FSCA identifier: CRM-SAL-2022-001 – Rev. B

Manufacturer SRN: IT-MF-000029013

FSN Type: Communication Update - Corrective Software release

Attention: Physicians, Healthcare professionals, Healthcare Centers

Affected devices: Subset of MicroPort CRM XFine leads (models XFine TX25D, XFine TX26D, XFine JX24D; XFine JX25D) connected to MicroPort CRM ALIZEA or BOREA pacemakers (models ALIZEA DR 1600, ALIZEA SR model 1300, BOREA DR model 1500, BOREA SR model 1200).

Dear Doctor,

MicroPort CRM has obtained the regulatory approval of a new software version to provide additional solutions on ALIZEA / BOREA pacemakers to facilitate the management of the patients who are implanted with XFine leads listed in the Field Safety Notice CRM-SAL-2022-001 released in August 2022.

This Field Safety Notice pertained to specific XFine lead models (XFine TX25D, XFine TX26D, XFine JX24D, XFine JX25D) identified to potentially exhibit elevated polarization levels. This condition may result in Minute Ventilation (MV) oversensing in narrowly defined programming scenarios, exclusively when interfaced with designated ALIZEA or BOREA pacemaker models (ALIZEA DR 1600, ALIZEA SR 1300, BOREA DR 1500, BOREA SR 1200).

Description of the issue (reminder):

High polarization leads may produce sensing artefacts with MV, potentially leading to oversensing when connected with ALIZEA / BOREA pacemakers.

- In the case of a single chamber device connected to a high polarization lead, MV oversensing may (depending on the programmed sensitivity) lead to inappropriate inhibition of pacing.
- In the case of a dual chamber device connected to a high polarization lead implanted in the atrium, MV oversensing may (depending on the programmed sensitivity) lead to inappropriate Mode Switching.

As of January 25th, 2024, MicroPort CRM has received 10 complaints from HealthCare Professionals on MV oversensing out of approximately 22 000 MicroPort CRM XFine leads distributed worldwide. Extensive analysis performed has revealed that the involved XFine leads suffered from abnormal high polarization at the lead tip. No permanent serious injury or death has been reported.

The risk of Minute Ventilation artefact oversensing is associated with a limited number of XFine leads manufactured before November 2021. Manufacturing changes have been implemented, eliminating the risk of production of high polarization leads.

How does the new software improve the management of the patients affected by the issue?

In the presence of oversensing of MV artefacts:

- the MV oversensing alert is displayed in the programmer and is sent through the remote monitoring system when available;
- the MV sensor will be switched OFF if MV oversensing occurred in the ventricle (the new software does not influence the usage of the G sensor).

Patient management recommendations:

MicroPort CRM provides the following recommendation:

- **Your programmer shall be upgraded with the new programmer software version SmartView version 3.16 (and higher).**

All ALIZEA and BOREA devices interrogated with this new version will then be automatically upgraded during the next scheduled in-clinic follow-up. Your MicroPort CRM representative will assist you in upgrading your programmer.

As long as ALIZEA and BOREA devices have not been interrogated with this new programmer software version, previous recommendations listed in the CRM-SAL-2022-001 communication apply (*cf.* Addendum #1).

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 understood this Field Safety Notice. Returning the Customer Reply Form will also prevent repeated communication of this notice.

Please ensure that all personnel in your organization, involved in the management of patients implanted with ALIZEA and BOREA pacemakers and implanted with potentially impacted XFine leads are promptly made aware of the information and guidelines outlined in this letter.

MicroPort CRM has communicated this information to the relevant Competent Authorities.

We regret any inconvenience caused to your patients and your organization. If you need further information, please contact your local CRM representative.

As always, MicroPort CRM is strongly committed to the safety of all patients.

Sincerely,

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

Addendum #1 – CRM-SAL-2022-001 Patient management recommendations dated August 2022

Patient management recommendations:

MicroPort CRM provides the following recommendation:

- **Potentially impacted XFine leads that are not implanted yet, shall not be used in combination of ALIZEA or BOREA pacemakers.**

- **For patients implanted with potentially impacted XFine leads connected to ALIZEA or BOREA pacemakers:**

1. For pacemaker dependent patients implanted with an SR system, we recommend a prompt in-clinic patient follow-up to **DISABLE MV**. If rate response is required choose "Sensor = G".

2. For non-pacemaker dependent patients implanted with an SR system:

Check remotely or during in clinic patient follow-up for the presence of inappropriate pacing inhibition (oversensing of MV artefacts). If there is evidence of MV oversensing we recommend an in-clinic patient follow-up to:

- Consider reprogramming the sensitivity :
  - If the "Autosensing" value is set as "Auto", first change the Autosensing value to "Monitor";
  - Then change the sensitivity to a higher (less sensitive) value and keep the "Autosensing" value set to "Monitor".
- Alternatively, you may consider switching OFF the MV sensor. In the latter case, if rate response is required choose "Sensor = G".

3. For DR patients with a potentially impacted XFine lead implanted in the atrium:

If MV configuration is activated and set to "A Bipolar" (either for rate response and/or for Sleep Apnea Monitoring), check for the eventual presence of inappropriate Mode Switching either through remote follow-up or during an in-clinic follow-up. In case there is evidence of MV oversensing we recommend an in-clinic patient follow-up to:

- Consider reprogramming the atrial "Sensitivity":
  - If the atrial "Autosensing" value is set as "Auto", first change the atrial "Autosensing" value to "Monitor";
  - Then change the atrial "Sensitivity" to a higher (less sensitive) value and keep the atrial "Autosensing" value set to "Monitor".
- Alternatively, you may consider to switch OFF the MV sensor. In the latter case, if rate response is required choose "Sensor = G".

- In the case of a required pacemaker replacement with ALIZEA / BOREA devices with potentially impacted XFine leads, same recommendations apply.

Addendum #2 – How to check the MV oversensing

How to check the new MV oversensing observation on the programmer overview screen?

At interrogation, when MV oversensing occurred in the ventricle, a pop-up is displayed:

- [A120] MV sensor has been disabled due to RV oversensing suspicion on [date]

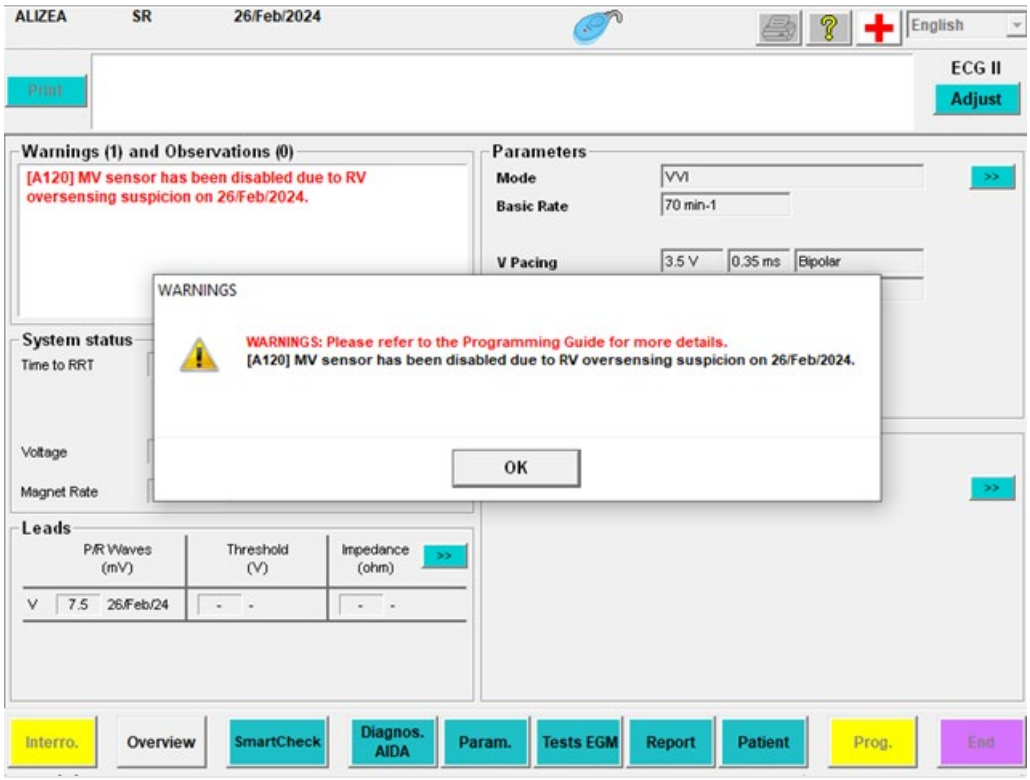

Figure 1: Warning for the deactivation of the MV sensor due to MV oversensing

When MV oversensing occurred in the atrium, a pop-up is displayed at interrogation:

- [A110] RA oversensing suspicion due to MV sensor on [date].

How to check the presence of MV oversensing in the stored EGM episodes?

MV oversensing might be visible in episodes stored in the device memory, as:

- “A Burst” or “V Burst” episodes for SR pacemakers;
- “A Burst” or “Mode Switch” episodes for DR pacemakers.

After interrogation of ALIZEA or BOREA pacemakers with Orchestra Plus or SmartTouch programmers:

1. Select the “Diagnos. AIDA” tab in the menu bar at the bottom of the screen;
2. Select the “Arrhythmias” tab;
3. Check recorded episodes individually to identify the presence of MV oversensing.

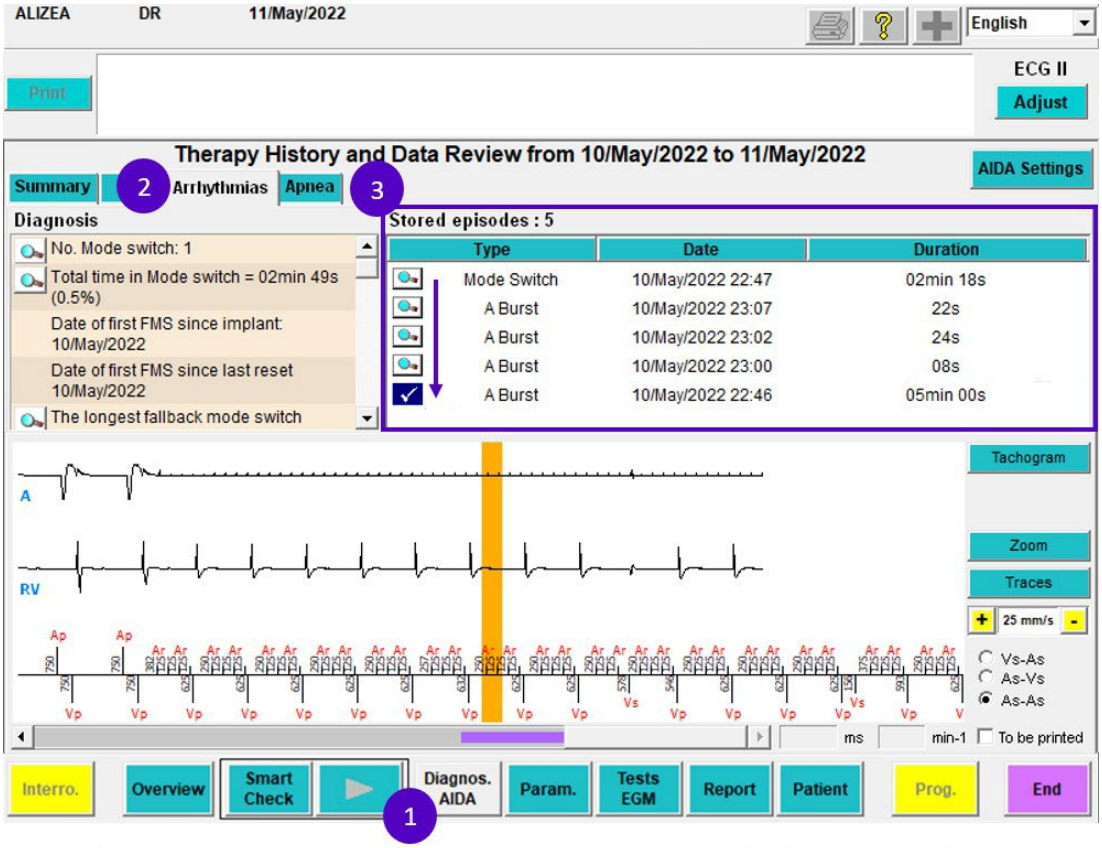

Figure 2: Sequence for checking the presence of MV oversensing in recorded episodes

MV noise oversensing is characterized by the presence of repetitive 125ms or 250ms cycles (as illustrated below), visible in:

- The atrial or ventricular channel for SR pacemakers;
- On the atrial channel for DR pacemakers.

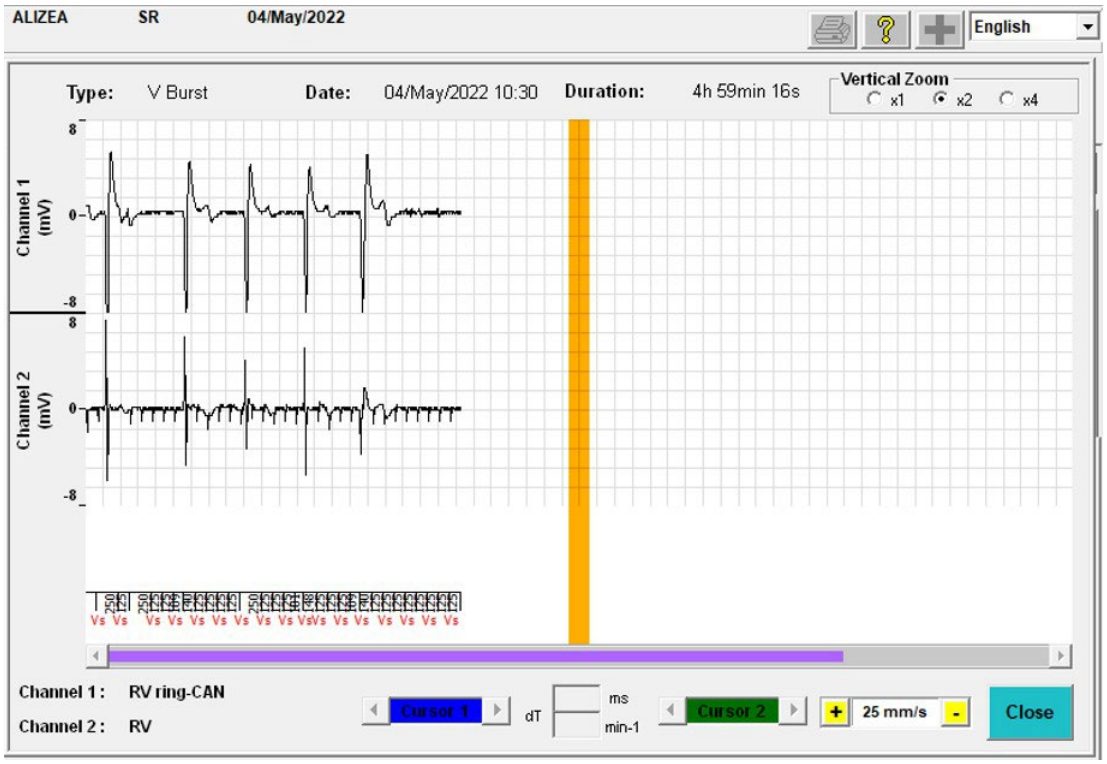

Figure 3: Illustration of "V Burst" episode due to MV noise oversensing on an SR pacemaker

Figure 4: Illustration of "Mode Switch" episode due to MV noise oversensing on a DR pacemaker

Addendum #3 - List of impacted XFine leads that have been distributed to your site.

Serial Number	Item Code	Commercial Name	Comment
“SN1”	“IC1”	“Description1”	
“SN2”	“IC2”	“Description2”	
“SN3”	“IC3”	“Description3”	
“SN4”	“IC4”	“Description4”	
“SN5”	“IC5”	“Description5”	
“SN6”	“IC6”	“Description6”	
“SN7”	“IC7”	“Description7”	
“SN8”	“IC8”	“Description8”	
“SN9”	“IC9”	“Description9”	
“SN10”	“IC10”	“Description10”	
“SN11”	“IC11”	“Description11”	
“SN12”	“IC12”	“Description12”	
“SN13”	“IC13”	“Description13”	
“SN14”	“IC14”	“Description14”	
“SN15”	“IC15”	“Description15”	
“SN16”	“IC16”	“Description16”	
“SN17”	“IC17”	“Description17”	
“SN18”	“IC18”	“Description18”	
“SN19”	“IC19”	“Description19”	
“SN20”	“IC20”	“Description20”	
“SN21”	“IC21”	“Description21”	
“SN22”	“IC22”	“Description22”	
“SN23”	“IC23”	“Description23”	
“SN24”	“IC24”	“Description24”	
“SN25”	“IC25”	“Description25”	

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