

Customer Reply Form

1. FSN information	
FSN Reference	CRM-SAL-2022-001
FSN Date	August 30, 2022
Device(s)	XFine Leads connected to ALIZEA BOREA 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		
<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 do not have any affected system.	<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	
Fax	
Customer Helpline	
Postal Address	

5. Distributors / Suppliers Only		
<input type="checkbox"/>	I have identified customers that have patients implanted with these devices.	<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"/>	None of my customers have affected devices.	<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 organisation's reply is the evidence needed to monitor the progress of the corrective actions.



Attn:

August 30, 2022

Urgent Field Safety Notice

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

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).

FSN Type: New

Attention: Physicians, Healthcare professionals, Healthcare Centers

Dear Doctor,

MicroPort CRM is providing information related to a subset of XFine leads (models XFine TX25D, XFine TX26D, XFine JX24D; XFine JX25D) that may be at risk of high polarization and could lead to Minute Ventilation (MV) oversensing under very specific programming conditions when connected to ALIZEA or BOREA pacemakers (models ALIZEA DR 1600, ALIZEA SR model 1300, BOREA DR model 1500, BOREA SR model 1200).

As of July 25th, 2022, MicroPort CRM has confirmed 7 complaints 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.

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.

When can the issue occur?

The issue can be observed only after the activation of the MV function and under specific low sensitivity programming values for rate response and/or for sleep apnea monitoring and/or “Rest Rate”.

How does this affect patients?

Dizziness has been reported in one (1) VVI pacemaker patient during a follow-up session when sensitivity was temporarily set at a value detecting artefacts. No permanent serious injury or death has been reported as a result of the confirmed malfunction.

Root cause investigation

Recent investigations revealed that the risk of Minute Ventilation artefact oversensing is associated with a limited number of XFine leads manufactured before November 2021, where high polarization was undetected by incorrect application of the polarization test method. Manufacturing changes have been implemented, eliminating the risk of production of high polarization leads. XFine leads currently distributed are exempt from this risk.

Furthermore, MicroPort CRM is actively working towards additional solutions on ALIZEA / BOREA pacemakers to facilitate patient management. MicroPort CRM will inform you as soon as a solution is available. In the meantime, the below patient management recommendations should be applied.

Patient management recommendations:

MicroPort CRM provides the following recommendations:

- 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.

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 – Guidance on device reprogramming

How to check the presence of MV oversensing?

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.



The screenshot shows the 'Therapy History and Data Review' screen for a device on 11/May/2022. The 'Diagnosis' tab is selected, and the 'Arrhythmias' sub-tab is active. A table titled 'Stored episodes : 5' is displayed, showing the following data:

Type	Date	Duration
Mode Switch	10/May/2022 22:47	02min 18s
A Burst	10/May/2022 23:07	22s
A Burst	10/May/2022 23:02	24s
A Burst	10/May/2022 23:00	08s
A Burst	10/May/2022 22:46	05min 00s

The ECG trace below the table shows a series of heartbeats with a vertical yellow line highlighting a specific episode. The trace is labeled 'A' and 'RV'. The bottom of the screen shows a menu bar with the 'Diagnos. AIDA' tab selected.

Figure 1: 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.

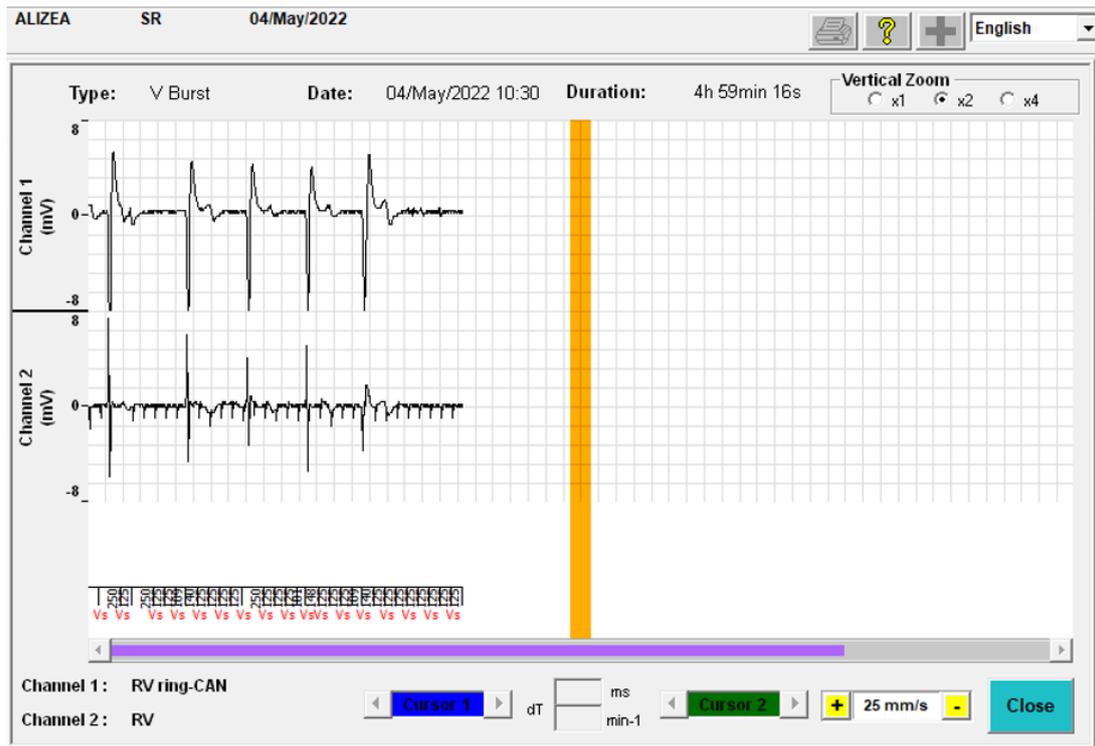


Figure 2: Illustration of “V Burst” episode due to MV noise oversensing on an SR pacemaker



Figure 3: Illustration of “Mode Switch” episode due to MV noise oversensing on a DR pacemaker

How to disable the “MV sensor”?

The “MV sensor” can be deactivated by the programmer during an in-clinic visit.

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

1. Select the “Param.” tab in the menu bar at the bottom of the screen;
2. Select the “Brady” tab;
3. Check the status of the “Sensor” parameter in the “Rate response” zone;
4. Deactivate the “MV Sensor” parameter by selecting “G” and then press “Prog”. The parameter value will be then changed to G only.

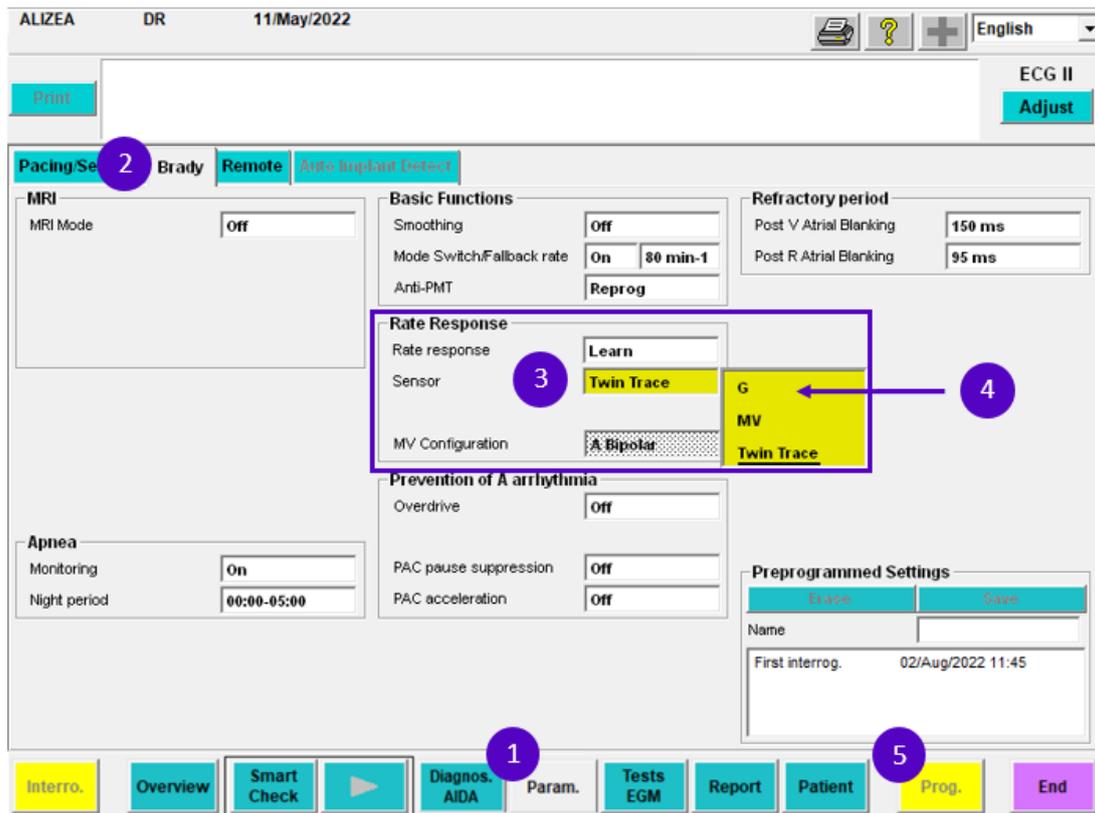


Figure 4: Sequence for disabling the MV sensor functionality

How to modify the “Autosensing” functionality?

The “Autosensing” functionality can be deactivated by the programmer during an in-clinic visit.

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

1. Select the “Param.” tab in the menu bar at the bottom of the screen;
2. Select the “Pacing/Sensing” tab;
3. Check the value of the “Autosensing” parameter in the “Pacing/Sensing” area;
4. Deactivate the “Autosensing” parameter by selecting “Monitor” and then press “Prog”.

ALIZEA DR 11/May/2022 English

Print ECG II Adjust

2 Pacing/Sensing **Brady** Remote Auto Inhibit Detect

Basic Parameters

Mode:

Basic Rate:

Rest Rate:

Max Rate:

Hysteresis:

AVD Rest/Exer:

AVD Paced/Sensed Offset:

Accel. /AVD short:

Pacing/Sensing

	A	V
Sensitivity	2.0 mV	2.0 mV
Sensing Polarity	Bipolar	Bipolar
Autosensing 3	Monitor	Auto
Amplitude	3.5 V	Monitor 4
Width	0.35 ms	0.35 ms
Paced Polarity	Bipolar	Bipolar
Autothreshold	Off	Off

Preprogrammed Settings

Name:

First Interrog.: 02/Aug/2022 11:42

Lead Polarity Switch:

1 **5**

Figure 5: Sequence for deactivating the Autosensing functionality



Addendum #2 - List of impacted devices that have been shipped to your site.

Serial Number	Item Code	Commercial Name	In Stock (Yes/No)
"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"	

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.

You can also complete the form by using the URL link or scanning the QR Code here below.

Links to provide your Customer Reply Form:



<https://forms.office.com/r/UkC6kuSHHw>

MATERIAL	CODE	SERIAL NUMBER
XFine TX26D MRI	TLD055C	TTX639113
XFine TX26D MRI	TLD055C	TTX639348
XFine TX26D MRI	TLD055C	TTX640002
XFine TX26D MRI	TLD055C	TTX640023
XFine TX26D MRI	TLD055C	TTX640561
XFine TX26D MRI	TLD055C	TTX640586
XFine TX26D MRI	TLD055C	TTX640653
XFine TX26D MRI	TLD055C	TTX641330
XFine TX26D MRI	TLD055C	TTX641537
XFine TX26D MRI	TLD055C	TTX641616
XFine TX26D MRI	TLD055C	TTX641621
XFine TX26D MRI	TLD055C	TTX641692
XFine TX26D MRI	TLD055C	TTX641859
XFine TX26D MRI	TLD055C	TTX642129
XFine TX26D MRI	TLD055C	TTX642414
XFine TX26D MRI	TLD055C	TTX642578
XFine TX26D MRI	TLD055C	TTX642820
XFine TX26D MRI	TLD055C	TTX642876
XFine TX26D MRI	TLD055C	TTX643262
XFine TX26D MRI	TLD055C	TTX643330
XFine TX26D MRI	TLD055C	TTX643419
XFine TX26D MRI	TLD055C	TTX643828
XFine TX26D MRI	TLD055C	TTX644074
XFine TX26D MRI	TLD055C	TTX644180
XFine TX26D MRI	TLD055C	TTX644212
XFine TX26D MRI	TLD055C	TTX644213
XFine TX26D MRI	TLD055C	TTX644224
XFine TX26D MRI	TLD055C	TTX644485
XFine TX26D MRI	TLD055C	TTX644657
XFine TX26D MRI	TLD055C	TTX645811
XFine TX26D MRI	TLD055C	TTX645813
XFine TX26D MRI	TLD055C	TTX646020
XFine TX26D MRI	TLD055C	TTX646256
XFine TX26D MRI	TLD055C	TTX646282
XFine TX26D MRI	TLD055C	TTX646782
XFine TX26D MRI	TLD055C	TTX646812
XFine TX26D MRI	TLD055C	TTX646847
XFine TX26D MRI	TLD055C	TTX646928
XFine TX26D MRI	TLD055C	TTX647381
XFine TX26D MRI	TLD055C	TTX647382
XFine TX26D MRI	TLD055C	TTX647401
XFine TX26D MRI	TLD055C	TTX647547
XFine TX26D MRI	TLD055C	TTX647972
XFine TX26D MRI	TLD055C	TTX648356
XFine TX26D MRI	TLD055C	TTX648428
XFine TX26D MRI	TLD055C	TTX648431
XFine TX26D MRI	TLD055C	TTX649192
XFine TX26D MRI	TLD055C	TTX649669
XFine TX26D MRI	TLD055C	TTX649988

XFine TX26D MRI	TLD055C	TTX650182
XFine TX26D MRI	TLD055C	TTX650620
XFine TX26D MRI	TLD055C	TTX651041
XFine TX26D MRI	TLD055C	TTX651042
XFine TX26D MRI	TLD055C	TTX651064
XFine TX26D MRI	TLD055C	TTX651196
XFine TX26D MRI	TLD055C	TTX651277
XFine TX26D MRI	TLD055C	TTX651711
XFine TX26D MRI	TLD055C	TTX652605
XFine TX26D MRI	TLD055C	TTX652998
XFine TX26D MRI	TLD055C	TTX653000
XFine TX26D MRI	TLD055C	TTX653292
XFine TX26D MRI	TLD055C	TTX653360
XFine TX26D MRI	TLD055C	TTX653926
XFine TX26D MRI	TLD055C	TTX654247
XFine TX26D MRI	TLD055C	TTX654317
XFine TX26D MRI	TLD055C	TTX654320
XFine TX26D MRI	TLD055C	TTX654482