

«Hospital_Name»
«Users_Name»
«Department»
«Customer_Address»
«Zip_Code» «City»
«Country_name»

<Reference: 92659146C-FA>

19 February 2021

Dear «Users_Name»,

Earlier this month, Boston Scientific distributed 4G LATITUDE™ MIMIC Cell Adapters that were configured incorrectly by the manufacturer. The original configuration error was resolved and 1,845 replacement cell adapters were distributed. Unexpectedly these cell adapters were also unable to transmit data. Further investigation identified a second root cause. Boston Scientific is working to resolve this additional root cause. The enclosed letter describes an expansion of the original Field Safety Notice and includes the complete list of all affected cell adapters. Our recommendation to dispose (scrap) of affected units locally is unchanged.

If you have further questions, please contact your local Boston Scientific representative or your local LATITUDE Customer Support.

Yours sincerely,



Alexandra Naughton
Vice President, Quality Assurance
Boston Scientific International S.A.

Attachment: Acknowledgement Form

Field Safety Notice

Subject: 4G LATITUDE™ MIMIC Cell Adapters. Disposal of a subset of 4G LATITUDE MIMIC Cell Adapters configured incorrectly, Reference 92659146C-FA.

Dear «Users_Name»,

This letter provides important information about the 4G LATITUDE MIMIC Cell Adapter (Cell Adapter), a telecommunications tool, that may be used to facilitate transmission of data from a patient's in-home LATITUDE Communicator (Communicator) to the LATITUDE NXT Patient Management System (LATITUDE System).

Boston Scientific has recently learned that up to 5,258 of these Cell Adapters distributed in some countries in Europe were configured incorrectly by the manufacturer and will not successfully allow the LATITUDE System to connect to a 4G cellular network. This Cell Adapter behavior does not affect data security and does not affect the integrity of the Communicator. Boston Scientific has informed applicable National Competent Authorities of this action.

Clinical Impact

The in-home Communicator collects data from a patient's Boston Scientific cardiac implantable electronic device (CIED) at intervals specified by their HCP. The Communicator is designed to transmit the data either over phone lines, via local area network (LAN) using an ethernet adapter, mobile hotspot, or cellular network to the LATITUDE System for review by a patient's HCP.

The Cell Adapter supports a cellular connection. If an incorrectly configured Cell Adapter is connected to a Communicator, the Communicator will not connect to the LATITUDE System, however, the Communicator is designed to notify patients and clinicians when data is not transmitted.

- If a Communicator configured to the patient's CIED is unable to successfully transmit data, the communicator will display one yellow sending wave (see Figure 3 top image).
- If an CIED red alert condition was not transmitted, the Communicator will prompt the patient within 24 hours to call their HCP via the Red Call Doctor icon on the Communicator (see Figure 3 bottom image).
- If the Communicator is unable to transmit data to the LATITUDE System, the HCP will be informed via LATITUDE after 14 days.

Given the above system design, the likelihood of severe patient harm due to a CIED alert condition not being transmitted via LATITUDE to an HCP is remote (less than 1 in 6,000,000) and has not been reported.

Affected Cell Adapters

Table 1 describes the affected Cell Adapters and Figures 1 and 2 include images of the product and label.

Universal Part Number	BSC Model	Description	Serial Number	GTIN	Supplier Model
666227-100	6227	4G LATITUDE MIMIC Cell Adapter	Appendix A	00802526615207	TD191

Table 1. Affected 4G LATITUDE MIMIC Cell Adapter descriptive information



Figure 1. Front/Back images of the 4G LATITUDE MIMIC Cell Adapter, the CID label includes the serial number.



Figure 2. Package label of the 4G LATITUDE MIMIC Cell Adapter, the Boston Scientific (BSC) Model is 6227.



Figure 3. Top: If data transmission is unsuccessful connecting to the LATITUDE System, the Communicator will display one yellow sending wave. Bottom: If a CIED alert condition is not transmitted, the Communicator will display a Red Call Doctor icon.

Action:

- 1- Distribute this letter to all other physicians and HCPs within your organization who need to be aware of this topic.
- 2- Immediately segregate all affected 4G LATITUDE MIMIC Cell Adapters in your inventory (see Table 1 and Appendix A) and dispose of (scrap) them locally (there are no special disposal requirements).
- 3- Contact patients that have received a 4G LATITUDE MIMIC Cell Adapters and instruct them to dispose affected Cell Adapters.
- 4- Complete the enclosed Acknowledgement Form and send it back to Boston Scientific for the attention of «**Customer_Service_Fax_Number**» on or before **8 March 2021**.

Please continue to report any complaints relating to the Cell Adapter to Boston Scientific.

Although Boston Scientific is not physically recalling any product, your Competent Authority is being notified of this Field Safety Notice.

Additional Information

Boston Scientific recognizes the impact of these types of communications on both you and your patients. We are committed to transparent communication with HCPs to ensure you have timely, relevant information for managing your patients.

If you have further questions, please contact your local Boston Scientific representative or your local LATITUDE Customer Support.

Yours sincerely,



Alexandra Naughton
Vice President, Quality Assurance
Boston Scientific International S.A.

Attachment: Acknowledgement Form

Please complete the form & Send it to: «Customer_Service_Fax_Number»

**Acknowledgement Form –
Expanded Field Safety Notice
4G LATITUDE™ MIMIC Cell Adapters
92659146C-FA**

1- We acknowledge receipt of the Boston Scientific Field Safety Notice dated 19 February 2021.

2- **Boston Scientific records indicate you have received the following affected product** (*additionally please check inventory against complete list of affected product provided*)

Material N° (UPN)	Lot / Batch / Serial N°	Customer PO	Qty Sent

3- We confirm that all areas where affected product could be located have been checked.

4- **TICK ONE OF THESE STATEMENTS***, **SIGN THIS FORM** and send it to «Customer_Service_Fax_Number»

- We do not have any affected product.
- We have found affected product and they have been disposed.

NAME* _____ **Title** _____

Telephone _____ Email _____

Customer' **SIGNATURE*** _____ **DATE*** _____

* Required field

dd/mm/yyyy