Field Safety Notice

Boston Scientific Corporation
Cardiac Rhythm Management
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Subject: **Removal –** Zoom™ LATITUDE™ Programmer model 3120 Reference:92409999-FA

Dear Doctor,

Boston Scientific is retrieving four (4) Model 3120 Zoom LATITUDE Programmers due to an improper software configuration for certain older pulse generator families, which have not been distributed for over 5 years.

The improper software configuration was identified during an internal inspection process. There is no patient risk and no patient harm has been reported to date or is likely to occur.

The table below provides the affected product identification numbers.

Part Number	GTIN	[redacted]	Country / Region
623120-437	00802526602924	[redacted]	Canada
623120-437	00802526602924	[redacted]	Canada
623120-437	00802526606342	[redacted]	Canada
623120-235	00802526602924	[redacted]	Sweden

Boston Scientific is notifying regulatory authorities of this removal as required.

Actions

1. Segregate the product to ensure that it will not be used.
2. Your Boston Scientific sales representative will retrieve these Model 3120 Zoom LATITUDE Programmers at your facility and coordinate a replacement.

Further information

Once Boston Scientific completes the removal, we will start the process to perform a factory update on these programmers. Please know, we recognize the impact of this communication and product removal on you and your patients and want to reassure you that quality, in addition to patient safety, remain our primary concerns.

[redacted]

Renold J. Russie
Vice President, Quality Assurance
Boston Scientific Rhythm Management