

September 2018

Subject: Retrieval – LATITUDE™ Programmer model 3300 - Ref.: 92287323-FA

Dear Doctor,

Boston Scientific is retrieving all units of LATITUDE™ Programmers Model 3300 in the field, due to the potential for the Pacing System Analyzer (PSA) to exhibit unintended cross-chamber stimulation. The LATITUDE™ programmer model 3300 is designed to communicate with and program Boston Scientific pacemakers and defibrillators noninvasively. The PSA software application on the LATITUDE™ Programmer model 3300 can be used to assess the electrical performance and placement of cardiac lead systems during implant of the device.

Boston Scientific has received reports of unintended cross-chamber stimulation of the right ventricle (RV) while pacing the right atrium (RA) using the PSA software. The most common clinical outcome is a slightly prolonged procedure to allow for evaluation of the observation. While there is a theoretical potential for life threatening harm due to induced tachyarrhythmia, Boston Scientific has received no reports of patient injury associated with this observation.

This behavior is limited to the PSA software application on the LATITUDE™ programmer model 3300. The table below shows the affected product identification.

Part Number	GTIN	Model	Country / Region
623300-100	00802526585005	3300	US
623300-200	00802526597206	3300	Europe

Actions

1. Segregate all affected product to ensure that it will not be used.
2. Your Boston Scientific sales representative will retrieve any Model 3300 LATITUDE Programmers at your facility.

Further information

The LATITUDE™ programmer model 3300 is in limited commercial release in the US and Europe. Once Boston Scientific completes the retrieval, we will start the process to perform a factory update on these devices.

In lieu of the Model 3300, use the ZOOM Programmer model 3120 to support noninvasive communication and programming of Boston Scientific pacemakers and defibrillators. We recognize the impact of this communication and product retrieval to you and your patients, and want to reassure you that patient safety remains our primary concern. If you have any questions, please contact your local Boston Scientific representative or European Technical Services.

Sincerely,



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