Urgent Field Safety Notice

January 2019

Subject: Urgent Field Safety Notice Software Update – Minute Ventilation Sensor Software Update Available for Pacemakers (see previous communication issued in December 2017 with reference 92186345-FA).

Summary Field Safety Notice (FSN)

- New programmer software[1] is now available that eliminates the previously communicated risk of pacing inhibition due to Minute Ventilation (MV) sensor signal oversensing in pacemakers and cardiac resynchronization therapy pacemaker (CRT-P) systems.
- The software includes a Signal Artifact Monitor (SAM) which further expands our proprietary suite of Safety Architecture automatic self-diagnostics.
- Once programmers are upgraded with this software, the SAM is automatically enabled whenever the MV sensor is enabled[2] and continuously monitors electrograms for MV sensor signal artifacts
- If MV artifacts are detected, the SAM either switches to the right ventricular vector or disables the MV sensor in approximately one second thus eliminating the risk of pacing inhibition due to MV sensor signal oversensing.
- Boston Scientific sales professionals are working to upgrade all programmers with the SAM software

Table 1. Affected devices supported by Model 2869 v2.06 software.

VALITUDE™ CRT-P Models U125 and U128	VISIONIST™ CRT-P Models U225, U226, and U228
ACCOLADE™ Pacemakers Models L300, L301, L310, L311, L321, L331	PROPONENT™ Pacemakers Models L200, L201, L209, L210, L211, L221, L231
ESSENTIO™ Pacemakers Models L100, L101, L110, L111, L121, L131	ALTRUA™ 2 Pacemakers Models S701, S702, S722

[1]The Model 2869 v2.06 software for the Model 3120 ZOOM Programmer and Model 3869 software for the Model 3300 LATITUDE Programmer supports the following pacemaker families: ACCOLADE, PROPONENT, ESSENTIO, ALTRUA 2, FORMIO, VITALIO, INGENIO, and ADVANTIO family of pacemakers; and VISIONIST, VALITUDE, INTUA, and INVIVE family of CRT-Ps.

[2]The MV sensor is enabled whenever it is programmed to ON, Passive, or ATR Only

Boston Scientific Software Update for MV Sensor Oversensing

Dear Doctor,

In December 2017, Boston Scientific began notifying physicians about the potential for pacing inhibition due to minute ventilation (MV) sensor signal oversensing in certain Boston Scientific pacemaker and cardiac resynchronization therapy pacemaker systems (pacemakers). At that time, Boston Scientific committed to providing a software update to address this behavior and recommended the MV sensor be disabled for certain types of patients.
Boston Scientific has now received approval for Model 2869 v2.06 software and your local Boston Scientific representative will arrange to upgrade your programmer(s) soon. Once this software upgrade is complete, the MV sensor may be enabled for those patients who are likely to benefit clinically from RightRate™, Respiratory Rate Trend, or AP Scan™.

Description of Software
This software upgrade adds the Signal Artifact Monitor (SAM) to Boston Scientific's proprietary suite of Safety Architecture diagnostics. When enabled, the SAM continuously monitors electrograms (EGMs) for MV sensor signal artifacts and measures MV vector lead impedance values. If artifacts are detected or the MV vector lead impedance is out of range, the monitor either switches to the right ventricular (RV) vector or disables the MV sensor in approximately one second. In this manner, the SAM promptly eliminates the clinical risk of pacing inhibition associated with MV sensor signal oversensing. The monitor will only switch to an RV vector if it is available and the measured RV lead impedance is in range. If the RV vector is not available, the monitor disables the MV sensor.

Appendix A includes additional information on the SAM, for a complete description refer to the pacemaker reference guide[3].

Distribution. Distribute this letter to all physicians and healthcare professionals within your organization who need to be aware of this topic.

Actions for Software Enhancement
1. Confirm all your center's/clinic's Model 3120 ZOOM programmers are upgraded with Model 2869 v2.06 the software. Appendix B shows how the software model and version number can be identified.
2. Once a programmer is upgraded with Model 2869 v2.06 software:
   a. The programmer performs an upgrade of each pacemaker's firmware in less than one minute.
   b. The MV sensor may now be enabled for those patients, including pacemaker dependent patients, deemed likely to benefit clinically from RightRate, Respiratory Rate Trend, or AP Scan.
   c. When the MV sensor is enabled (programmed to ON, Passive, or ATR Only), the SAM is automatically enabled and the risk of pacing inhibition due to MV sensor signal oversensing is eliminated. Boston Scientific recommends that this monitor remain enabled whenever the MV sensor is enabled.
   Note: If the MV sensor is enabled using a programmer that has NOT been upgraded with this software, the SAM will NOT be enabled.
3. Append the patient's medical record with this letter to maintain awareness of this topic for the remaining service life of their device.

[3]Manuals can be ordered by contacting the phone number on pacemaker's label or online at www.BostonScientific-eLabeling.com

4. If the MV sensor is disabled by the SAM, evaluate lead integrity and lead connection before re-programming the MV vector or programming the MV sensor to ON, Passive, or ATR Only. SAM episode data may assist in determining the source of transient impedance conditions. Contact Technical Services to explore all non-invasive programming options prior to surgical intervention if transient, abrupt changes in impedance measurements, or out-of-range impedance measurements are observed.

Additional Information

Boston Scientific is developing an update to the LATITUDE NXT Remote Patient Management system to view SAM parameters, alerts, and episodes. We recognize the impact of communications on both you and your patients and want to reassure you that patient safety remains our highest priority. If you have additional questions regarding this information or would like to report clinical events, please contact your Boston Scientific representative or Technical Services.

Sincerely,

Renold Russie
Vice President, Quality Assurance

Appendix A – Signal Artifact Monitor Device Diagnostic

The MV sensor in Boston Scientific pacemakers can be used for RightRate™ (rate adaptive pacing), Respiratory Rate Trend, or AP Scan™[4]. When the right atrial (RA) and/or right ventricular (RV) pacing leads and lead terminal connections are operating as intended, the MV sensor signal is appropriately filtered and therefore is not detected by the pacemaker or displayed on EGMs. However, intermittency related to the lead or pacemaker-lead connection[5] has the potential to create a transient high impedance condition. A high impedance condition may subsequently alter the MV sensor signal such that it becomes visible on EGMs and potentially subject to oversensing on the RA or RV channels.

The purpose of the SAM is to detect when MV sensor signal artifacts can result in oversensing, and to prevent oversensing by either changing the vector that the MV sensor signal operates on, or disabling the MV sensor. The monitor responds to detected artifacts in approximately one second thus eliminating the clinical risk of pacing inhibition associated with the MV sensor signal oversensing.

When enabled, the SAM continuously monitors the RA and RV sensing channels for a specific 20 Hz artifact signature that matches the MV sensor signal. When the monitor detects the artifact signature on the primary vector (RA) in a dual chamber pacemaker and the SAM's MV sensor vector is programmed to Auto, the monitor will first attempt to switch to the secondary vector (RV). If the RV vector has an out of range impedance measurement or the monitor detects an MV sensor artifact signal, the MV sensor is disabled. Table 2 describes the SAM response based on MV sensor vector selection and active MV vector.

Table 2. Signal Artifact Monitor response to detection of MV sensor signal artifacts.

If MV Sensor Vector Selection is set to	**And the active vector was**	**Device response to EGM artifact being detected**
Auto Select (dual chamber nominal)	RA	1. SAM episode created 2. Measure MV RV vector's impedance values 3. If in range: Switch the active sensor vector to RV[6] If out of range: Second SAM episode created and MV Sensor Disabled
Auto Select (dual chamber nominal)	RV	SAM episode created and MV Sensor Disabled
A Only	RA	
RV Only	RV	

A disabled MV Sensor will remain in that state until manually reprogrammed. No MV rate-responsive pacing and no respiratory-related trending will occur while the sensor is disabled. At the next programmer interrogation, the user will be notified of any SAM events (see Figure 1) with associated episodes available within the arrhythmia logbook for review. A future LATITUDE NXT Remote Patient Management system release will enable the user to view SAM parameters/episodes and receive a yellow alert if SAM disables the MV sensor.

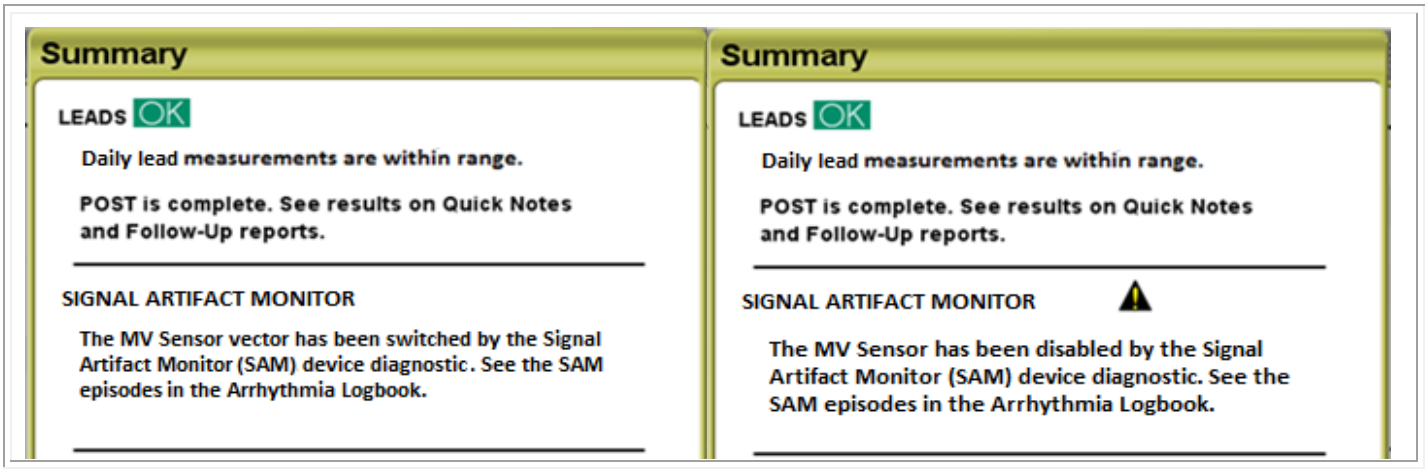
[4]AP Scan is not available in Pacemakers or CRT-Ps in all countries.

[5]Such as lead conductor fracture, under-insertion of the lead terminal, or axial/radial motion of the lead terminal's ring electrode within the pacemaker header

[6]If a MV Sensor vector switch occurs, an automatic 6-hour calibration will occur (no MV rate responsive pacing during the 6-hour calibration period).

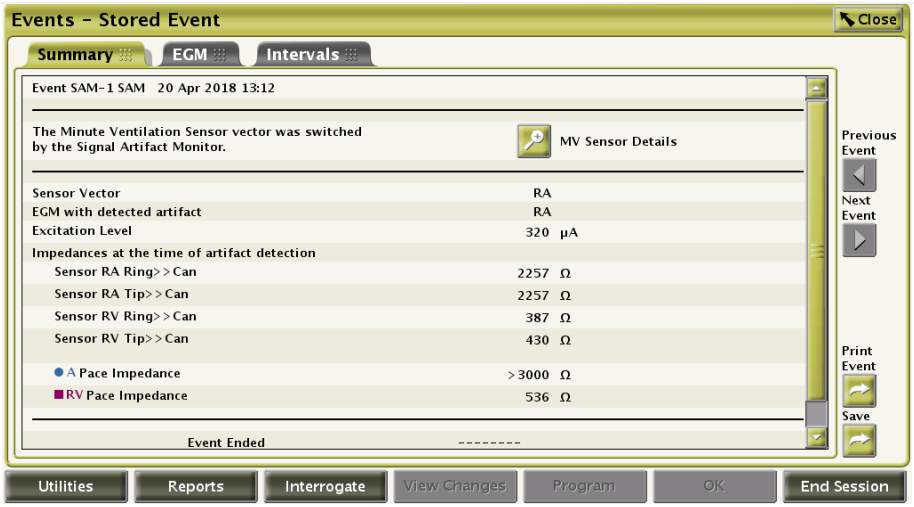
Appendix B – Identification of Programmer Software

Figure 1. Summary dialogue presented at the next programmer interrogation after the MV sensor vector has been switched or MV disabled by the Signal Artifact Monitor.



A SAM episode includes an EGM and the associated sensor vector and lead impedance values. The RA/RV ring>>can and tip>>can impedances are new diagnostic data that along with the pace lead impedances may be helpful in identifying whether there is a compromise in lead integrity or lead connection (see Table 3).

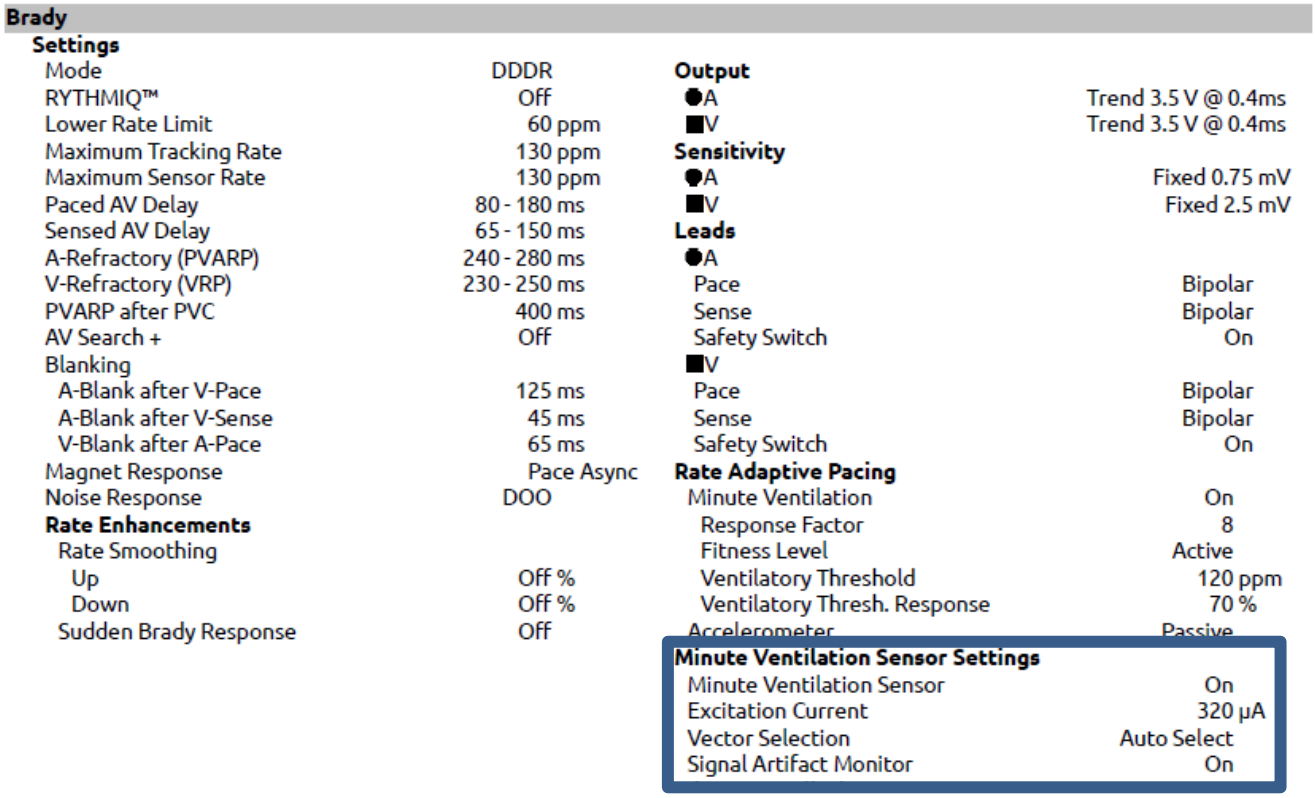
Table 3. Example of Signal Artifact Monitor episode with associated vector and lead impedance values.

In this example the RA Tip/Ring>>Can and A Pace Impedance are out of range. Note: The normal range for: • Sensor RA/RV Ring >>Can is 100-1500Ω • Sensor RA/RV Tip>>Can is 200-2000Ω.	 A summary of stored SAM events may be accessed through the Arrhythmia Logbook

Boston Scientific recommends the SAM be programmed ON whenever the MV sensor is enabled (programmed to ON, Passive, or ATR Only). The programmers' device settings report describes the parameter values for the SAM (see Figure 2).

Appendix B – Identification of Programmer Software

Figure 2. Sample device settings report showing MV Sensor and Signal Artifact Monitor settings.



Brady

Settings

Mode	DDDR
RYTHMIQ™	Off
Lower Rate Limit	60 ppm
Maximum Tracking Rate	130 ppm
Maximum Sensor Rate	130 ppm
Paced AV Delay	80 - 180 ms
Sensed AV Delay	65 - 150 ms
A-Refractory (PVARP)	240 - 280 ms
V-Refractory (VRP)	230 - 250 ms
PVARP after PVC	400 ms
AV Search +	Off
Blanking	
A-Blank after V-Pace	125 ms
A-Blank after V-Sense	45 ms
V-Blank after A-Pace	65 ms
Magnet Response	Pace Async
Noise Response	DOO
Rate Enhancements	
Rate Smoothing	
Up	Off %
Down	Off %
Sudden Brady Response	Off

Output

●A	Trend 3.5 V @ 0.4ms
■V	Trend 3.5 V @ 0.4ms

Sensitivity

●A	Fixed 0.75 mV
■V	Fixed 2.5 mV

Leads

●A	
Pace	Bipolar
Sense	Bipolar
Safety Switch	On
■V	
Pace	Bipolar
Sense	Bipolar
Safety Switch	On

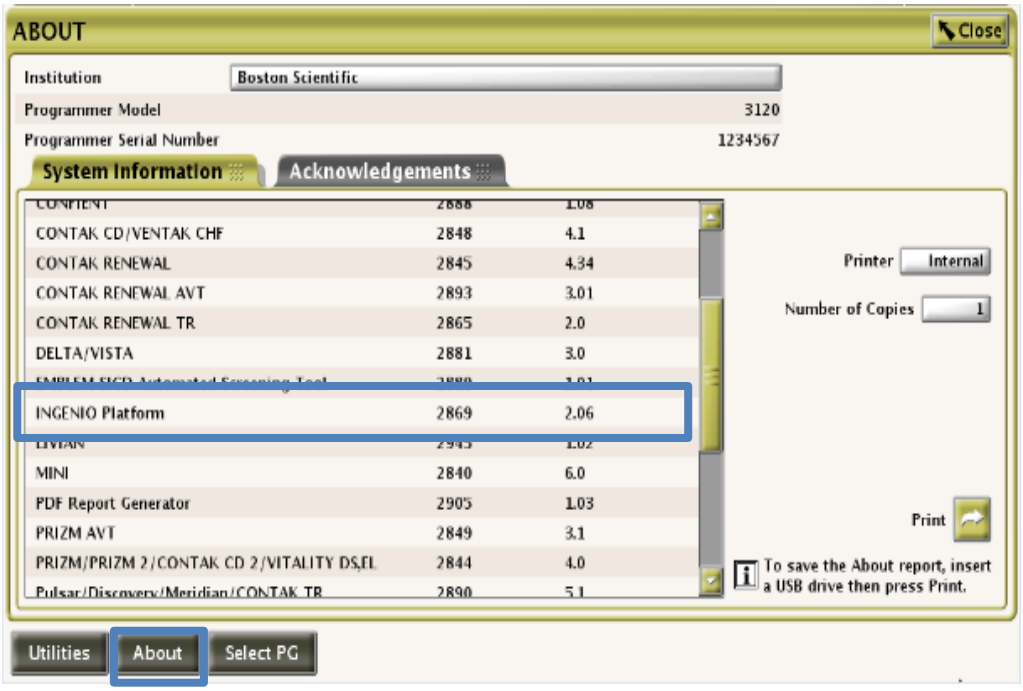
Rate Adaptive Pacing

Minute Ventilation	On
Response Factor	8
Fitness Level	Active
Ventilatory Threshold	120 ppm
Ventilatory Thresh. Response	70 %
Accelerometer	Passive

Minute Ventilation Sensor Settings

Minute Ventilation Sensor	On
Excitation Current	320 µA
Vector Selection	Auto Select
Signal Artifact Monitor	On

Appendix B – Identification of Programmer Software

Confirm software upgrade	**Model 3120 ZOOM™ Programmer** 
Select About button and Confirm Software Model and Version	 Confirm Model 2869 v2.06 is installed on the About Screen