Canadian Heart Rhythm Society
Société canadienne de rythmologie

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CHRS Device Advisory Committee
Advisory Notification

Boston Scientific S-ICD in-clinic programmer:
Risk of RF interference causing inappropriate in-clinic programming

This is a notification of the possibility of radiofrequency interference during a programmer session with the Boston Scientific Model 3200 S-ICD programmer causing unintended programming during the programming session. This can result in changed settings including disabling therapies or triggering induction of therapies during the programming session.

Nature of the issue: There is the potential for radiofrequency interference from unidentified sources to interfere with the wireless communication between the programmer and the S-ICD only during an active in-clinic programming session. This interference can alter programming, which could affect the permanently programmed settings within the device. This can happen only in the device and may not be reflected in the programmer display. This has caused an inappropriate induction of a ventricular arrhythmia during the programming session in at least one case, and has altered programming in other cases. The source of the RF interference has not been identified in cases where this has occurred.

This interference can only occur during in-clinic visits and is not seen with remote monitoring sessions. The interference risk can be minimized by making sure the programming head is very close to the S-ICD during the programming session, and that potential sources of stray RF energy be removed from the area if possible. Programming sessions should not be left open with the patient unattended, and should be closed when programming is complete. At the end of a clinic visit, it is recommended to close the session and then perform a re-interrogation to confirm settings to ensure no unintended programming changes had occurred.

Scope of the issue: This issue has been observed 10 times in S-ICD sessions – 7 times with EMBLEM S-ICDs and 3 times with the SQ-RX S-ICD. The estimated risk of serious adverse consequence is 1 in 25,000 at 5 years for the EMBLEM devices, and 1 in 200,000 at 5 years in the SQ-RX devices.

CHRS DAC Recommendations:

1. This is not an advisory of the S-ICD device, but is rather an advisory of possible issues with the programmer during in-clinic sessions. Thus, there is no need for patient notification at this time, and no need to change patient follow-up.

2. As this issue is not seen with remote follow-up, it underscores the general recommendation of having CIED patients on remote follow-up when possible and utilizing this method of patient management when possible.
3. During programming sessions the wand should be as close to the device as possible, and sources of possible RF interference should be removed if possible.
4. Programming sessions should be kept short, and the programming session should not be left open with the patient unattended.
5. As the unintended programming may not be shown on the programmer screens, at the end of a patient clinic visit, the programming session should be closed and then a re-interrogation of the device should be done to ensure that no inadvertent programming changes occurred during the session.

Further information regarding the management of this possible anomaly has been communicated directly to centers following these patients. This information should be reviewed by all clinic personnel who are involved in the in-clinic programming sessions with these patients.

Sincerely,

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