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Working together to improve the diagnosis, treatment and quality of life for all those affected by arrhythmias

This summary is not intended to replace or contradict Boston Scientific's ***Urgent Field Safety Notice: "Boston Scientific High Battery Impedance May Initiate Safety Mode in a subset of ACCOLADE™ Family of Pacemakers and CRT-Ps"***, published 24 December 2024. It is an interpretation to aid clinical decision making.

Pacemakers Affected

Boston Scientific has found that a subset of the ACCOLADE™ family of pacemakers and CRT-Ps may prematurely develop abnormal function of the pacemakers' battery. ***Note that the manufacturers have determined that pacemakers in this group are only susceptible to this malfunction in the last four years of the pacemakers' battery life.*** The pacemakers affected were all manufactured before September 2018 and approximately 13% of those devices may be affected. At risk devices can be identified by consulting this link:

www.BostonScientific.com/lookup.

Enter your language, as well as the model and serial numbers of the device.

Abnormal Pacemaker Function

In "at risk devices" a manufacturing process, prior to September 2018, can result in a high battery impedance which may cause a device to exhibit transient voltage decreases in the last 4 years' life of the battery. When the pacemaker's battery is stressed, for example during telemetry operations or during other normal high power device operations such as automatic radio frequency telemetry circuit enablement and automatic memory checks, then the battery voltage may drop below a minimum threshold (that is during a high-power state). The pacemaker's software then triggers an automatic system reset such that the conditions of the high-power state are interrupted. Further system resets may occur with further high battery impedance high-power states. **If 3 such resets occur during a 48hour period** the pacemaker's software causes it to **enter safety pacing mode,** intended to maintain basic pacing functionality in the context of reducing battery capability.

Safety Mode Pacing

Safety mode pacing is intended to provide basic pacing treatment for 3 months, but this cannot be relied upon in the context of a high battery impedance, and neither is it as sophisticated as normal pacemaker function. It is only intended to be a bridge to pacemaker replacement. Pacing can be stopped altogether by external electrical factors (for example: pacemaker interrogation, myopotential inhibition, diathermy).

Thus, patients who are pacing-dependent are at risk of asystole and collapse. There have been two patients' deaths in the affected population in such circumstances.

Importantly during box change, the safety mode's non-programmable sensitivity setting, and unipolar pacing configuration, make the system susceptible to pacing inhibition during electrocautery and removal of the device from the pocket such that a temporary pacing wire may be required to cover the procedure in pacing-dependent patients.

Who Should Have a Pacemaker Box Change Because of this Problem?

The manufacturer is not recommending prophylactic pacemaker replacement in all patients with pacemakers that fall into the advisory population. However, many patients with affected devices may initially seek pacemaker replacement. Thus, the risk of pacing malfunction needs to be balanced against procedural risks (e.g., infection, lead damage etc.). This will always be a matter of **individual clinical judgement** but in summary and as a guide to the decision process:

If your patient has one of the affected pacemakers
and
If your patient's pacemaker is in the last 4 years of its battery life
and
If your patient is "pacemaker-dependent"
then
prophylactic replacement should be considered, because should their pacemaker have 3 resets in 48 hours, they will go into safety pacing mode and will be at risk of asystole and collapse.

OR

If your patient has one of the affected pacemakers
and
If their device has already gone into **safety mode pacing** mode and is therefore not providing optimal pacing for your condition
then
the pacemaker should be promptly replaced, and urgently so if the patient is pacing-dependent.

OR

If your patient has one of the affected pacemakers
and
If their pacemaker is in the last 4 years of its battery life
and
If you consider your patient to have another condition that you consider puts them at high risk, should they go into **safety pacing mode**
then
consider prompt prophylactic replacement.

An interpretation to aid clinical decision making.
Medical Executive Committee
ARRHYTHMIA ALLIANCE