



Premature battery depletion with St. Jude Medical ICD and CRT-D devices: Indian Heart Rhythm Society Guidelines for physicians[☆]



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1. Introduction

St. Jude Medical (SJM) has recently announced a global medical device advisory that was also communicated by US FDA in a letter dated 11th October 2016.^{1,2} The advisory related to the risk of premature battery depletion in some of the implantable cardioverter-defibrillator (ICD) and Cardiac Resynchronization Therapy – Defibrillator (CRT-D) devices manufactured by SJM prior to 23rd May 2015. The present write up explains the risk in the patients implanted with these devices and suggests measures to mitigate that risk based on the recommendations by SJM, US FDA and Indian Heart Rhythm Society (IHRS) Advisory Committee.

2. Cause of premature battery depletion

The ICDs and CRT-Ds are powered by lithium-based batteries. Sometimes, deposits of lithium technically known as “lithium clusters”, can form within the battery and create abnormal electrical connections leading to rapid battery failure. This can result in premature battery depletion much earlier than the expected longevity and also reduce the usual 3-month lead time for device replacement after elective replacement indicator (ERI). The total battery drain after ERI has happened as early as 24 h in

some cases, though it usually occurs within a few weeks (1–30 days, median of 9 days). If the battery has run out, the ICD or CRT-D device will be incapable of delivering pacing or shock therapy and can potentially result in death of the patient. Hence, pacing dependent patients and those with frequent life-threatening ventricular arrhythmias are particularly at high risk among the recipients of the affected devices.

3. List of affected devices

The high voltages devices (ICDs and CRT-Ds) manufactured by SJM prior to 23rd May 2015 come under the purview of this advisory. These include subset of the devices listed in [Table 1](#).

It should be very clear that low voltage devices (all pacemakers including biventricular pacemakers), all Ellipse family ICDs and high voltage devices manufactured by SJM after 23rd May 2015 are not impacted by this advisory. All new implants of any device also do not fall under the purview of this advisory.

4. Magnitude of the problem and estimate of the risk

The latest available worldwide data indicates that of the 398,740 affected devices sold, 349,852 remain actively implanted and only 841 (0.24%) have been returned for analysis due to premature battery depletion caused by lithium clusters. Two deaths have been associated with devices that could not provide needed shock therapy; 10 patients have reported fainting and another 37 patients have reported dizziness due to lack of pacing by their devices due to premature battery depletion.

Of the 3672 affected devices (ICDs 2312; CRTDs 1360) implanted in India, there has not been any report of premature battery depletion till writing of this document. However, it should

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Table 1

List of devices affected by the advisory.

ICDs	CRT-Ds
Fortify VR and DR	Unify
Fortify ST VR and DR	Unify Quadra
Fortify Assura VR and DR	Quadra Assura
Fortify Assura ST VR and DR	Quadra Assura MP

be remembered that battery depletion may not be always discovered due to lack of reporting to the manufacturer or demise of the patient with no post-mortem interrogation of the device.

5. Suggested measures to reduce health risk

The most important point to be understood by the physicians and that needs to be communicated to the patients is that those patients that have an affected device implanted are at a low but definite health risk due to premature battery depletion. The goal of all measures is to mitigate the risk by detecting the battery depletion (if at all it occurs) at the earliest and then replace the device immediately and at the same time to prevent unnecessary prophylactic device replacements. Although, it is a class I recall; US FDA, SJM and the IHRS advisory committee does not recommend prophylactic replacement of the device in patients with affected device implanted, who do not have any evidence of premature battery depletion because the risk associated with replacement procedure (infection etc.) is estimated to be more than the risk associated with premature battery depletion. The term 'Recall' used by US FDA does not translate to the need for explant or removal or replacement of the device in all patients.

Also, the patients should be reassured that the cost of early detection of premature battery depletion by remote monitoring (Merlin@home) or of the device replacement (both the new device and the procedure cost) if needed will be borne by the SJM and patients need not worry about its financial implications.

The way forward for the physicians and the recommended measures to mitigate the risk due to premature battery depletion have been outlined in [Table 2](#).

The first step to be taken by a physician is to make a list of all the patients in his/her follow up who has the affected device implanted. The local SJM representative will help the physicians in this regard. A patient can also know whether his/her device is under the advisory by entering the model and serial number of the device in the specific web link.³ After excluding those who have died, undergone device explantation for infection or device upgradation or cardiac transplant, the patients should be informed

by phone call and/or letter about the advisory and asked to schedule a follow up.

During out-patient follow up and device interrogation, a note can be added about the advisory in the device and "highlight at every follow up" checked so that whenever the device is interrogated an alert about the advisory is displayed. The device parameters including battery longevity should be checked as also pacemaker dependency of the patient. Also, one should ensure that under the "Trigger Alerts When" section, the "Device at ERI" parameter is ON for ERI, for both "Show on FastPath" and "Notify Patient" selection; although this parameter is nominally ON. The patient can be demonstrated the vibratory alert by giving a test notifier so as to familiarize him/her of the alert and advised to contact the physician immediately if an alert is received. An in-clinic evaluation then needs to be performed to evaluate the reason for the received alert, since many other events can also trigger a vibratory alert.

Some patients especially with CRT-D and a few with ICDs who were implanted the device for primary prevention of sudden death indication and have now shown improvement in left ventricular function, may be out of indication of ICD and hence are at a much lower risk from premature battery depletion. On the other hand, some patients with CRT-D who are pacing dependent, especially those who received the device as an upgrade from a pacemaker, are at a much higher risk from premature battery depletion.

All these interrogation data, absence or presence of pacing dependency, current ejection fraction and that the patient has been informed about the advisory and suggested measures to reduce risk should be documented legibly in the out-patient card and a copy kept in clinic or hospital records.

All patients implanted with the affected device as per the advisory should be encouraged to avail of the home-monitoring system. Especially those who live far away from the physician's clinic or healthcare facility should be enrolled (if not already enrolled) in the remote (home) monitoring system known as Merlin@home or Merlin.net. With this system, the physician can get notified if the device in the patient reaches ERI so as to enable prompt detection of battery depletion even if the patient has ignored or failed to notice the delivered vibratory alert. SJM will provide this facility at no cost to the patient if recommended by his/her physician, in those who have the device affected by the advisory. [Table 3](#) lists the recommendations for utilizing the remote monitoring facility. The physician along with the SJM representative should ensure that the Merlin settings are adjusted such that physician or any of his/her assistants should get notified if the patient's device reaches ERI via a text message or email.

Table 2

Measures to mitigate risk due to premature battery depletion.

1. Preparation and communication

- a Make a list of patients with affected devices with phone number, address, type of device and date of implant
- b Exclude patients from the list that have known to have expired, or who have undergone cardiac transplant, or device explantation due to infection or other reasons

2. Out-patient follow up

- a Add "note" and check "highlight at every follow up" (on the device)
- b Interrogation including battery longevity
- c Assess pacing dependency (ICD and CRT-D) and percentage pacing in ICDs
- d Ensure vibratory alert is ON for ERI
- e Demonstrate and familiarize the patient to the Vibratory Alert
- f Assess present ICD indication in patients with primary prevention ICD indication
- g Request for a 3-month follow-up in those without remote monitoring

3. Remote monitoring – Merlin.net for all/selected patients (see [Table 3](#))

4. Consider prophylactic device replacement for highly selected patients (see [Table 4](#))

5. Notification to IHRS if a patient with premature battery depletion with or without any adverse event/s is seen

Table 3

Recommendations for the use of Remote monitoring (Merlin.net).

1. Patient residing at far-off location and difficult to reach at an implanting centre at short notice (physician decision or patient's preference or both)
2. Patient not able to comprehend the vibratory alert (patient's decision)
3. Pacing dependant patient with high right ventricular threshold (≥ 2.5 V)
4. Pacemaker dependant patients (physician decision/patient's preference)
5. Patient recovered from ventricular tachycardia storm or appropriate ventricular fibrillation therapy in last 3 months

Table 4

Recommendations for Device Replacement.

1. Evidence of battery depletion – ERI/vibratory alert for battery depletion – as an emergency
2. Prophylactic device replacement in a pacing dependent patient if
 - a has high (≥ 2.5 V) right ventricular threshold
 - b unwilling for remote monitoring
 - c cannot/unwilling to follow-up every 3 months (for those without home monitoring)
 - d physician perceives risk-benefit in favour of replacement (many appropriate ICD therapies)
 - e patient desires and accepts risk of replacement procedure
 - f patient travelling abroad for an extended period of time with follow-up being uncertain
 - g expected longevity of the device < 1 year

It should be emphasized that prophylactic device replacement is not recommended because the risk of complications following replacement such as infection has been reported to occur at a higher rate than the rate of harm associated with premature battery depletion.^{4–6} However, if the physician (or the patient after consultation with the physician) decides to proactively replace the device in an individual patient due to some high-risk factors like pacemaker dependency or patient's home far away from health-care facility; device replacement can be done and SJM will bear the cost of the new device and procedure. To avail free Prophylactic Replacement from SJM, the same needs to be done within 180 days from the date of advisory i.e., 11th October 2016. The physicians can contact their local SJM representative for further details and support. After this six-month period of notification, the decision and support to replace the device will be done on a case to case basis understanding the reason for delay. Table 4 lists the recommendations for replacement of the device affected by the advisory.

Finally, it is requested to all physicians and implanters that any adverse events detected due to premature battery depletion in the affected patients or instances of premature battery depletion should be informed to IHRS so as to enable a compiled database of all adverse events related to this advisory in India.

Conflicts of interest

None.

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