

Battery Performance Alert

A TOOL FOR IMPROVED PATIENT
MANAGEMENT FOR DEVICES UNDER
BATTERY ADVISORY

VERSION 2.0



Abstract

BACKGROUND:

In October 2016, St. Jude Medical (now Abbott) issued an advisory on a family of ICD and CRT-D devices that may develop Lithium deposits within the battery leading to a short circuit and result in premature and potentially rapid battery depletion. We have developed and evaluated a battery performance algorithm to detect and alert to abnormal battery behavior associated with devices that are likely to experience premature battery depletion due to this mechanism prior to reaching the Elective Replacement Indicator (ERI).

METHODS

A software algorithm for the Merlin.net™ PCN system and Merlin™ PCS programmer systems was developed to monitor battery performance and alert the clinician when anomalous behavior is present. The alert generated by this algorithm is referred to as the Battery Performance Alert (BPA). The Battery Performance Alert (BPA) algorithm analyzes the daily battery voltage measurements and identifies deviations from the expected voltage behavior that may be indicative of abnormal battery performance. The ability of the BPA to detect and trigger an alert to abnormal battery performance was evaluated on advisory devices returned for premature battery depletion and returned devices that were performing normally. Metrics of sensitivity, specificity, and time from alert to End of Service (EOS) were determined. The algorithm was further augmented by development of an ICD/CRT-D device based alert that allows for continuous monitoring with upgraded device firmware. Please refer to Appendix A for more information and the performance data associated with the device based alert.

RESULTS

The algorithm sensitivity, defined as the ability of the BPA algorithm to detect abnormal battery performance prior to ERI, was 97.8% with a 95% lower confidence bound of 95.4%. The specificity, defined as accurately not alerting when a battery was performing normally, was 99.8% with a 95% lower confidence limit of 99.5%. The time to react to an alert is increased six times with the addition of the BPA. In the test data set, the median time from alert to EOS without BPA (i.e. ERI to EOS, including cases where an ERI alert was not generated prior to EOS) was 2 days (interquartile range [IQR] 0 – 4 days). Using the exact same devices, with BPA, the median time from alert to EOS was 12 days (IQR 8 – 17.25 days). Without the BPA, the probability of a patient with an advisory device reaching EOS with ≤ 1 day warning is 0.18%. With the addition of the BPA alert, the overall probability of a device with a battery subject to the advisory reaching EOS with ≤ 1 day warning is 0.004%.

CONCLUSION

The study suggested that the BPA algorithm is a highly sensitive and specific tool that increases time from alert to EOS on devices subject to the October 2016 advisory. It accurately and reliably alerts to abnormal battery performance in these devices and has a high specificity demonstrating a low probability of a false alert in a normally functioning battery. Most importantly, the study demonstrated that BPA provides notification of an abnormally functioning battery earlier than the existing alert which is triggered by the battery voltage reaching a certain level (i.e., ERI), thus providing more time for identification and management of patients with advisory devices.

Introduction

In October 2016, St. Jude Medical (now Abbott) issued a global medical device advisory to notify physicians that the batteries in a subset of implantable cardiac defibrillator (ICD) and cardiac resynchronization therapy defibrillator (CRT-D) devices may have the potential to experience premature battery depletion (PBD). The batteries in these devices were determined to be susceptible to the formation of Lithium (Li) deposits near the anode and cathode of the battery that could cause a short circuit and result in premature and/or rapid depletion of the battery. As of data through November 30, 2017, the worldwide incidence of PBD was 0.35%.¹

At the time of the advisory, the Elective Replacement Interval (ERI) alert was the only notification to patients (vibratory alert) and physicians (via Merlin.net™ Patient Care Network [PCN] remote monitoring or an in-clinic Merlin™ Patient Care System [PCS] programmer alert message) that a device would need to be replaced. The ERI alert is generated when the battery voltage measured by the device is consistently below a specified voltage threshold. Initial investigation indicated that if a short circuit occurs, battery depletion from ERI detection to the End of Service (EOS) voltage or below could potentially occur within a day, but typically within weeks. The time from ERI alert to EOS was ≤ 1 day (including some with no alert at all) in approximately 20% of devices returned for PBD.¹ This is the primary clinical concern for patients with devices impacted by the battery advisory as they may suddenly, with little notice, no longer be able to receive device therapy.

Investigation of the daily battery voltage measurements in devices returned due to PBD indicated that there were observable changes in the battery voltage measurements occurred days to months prior to the device reaching the ERI voltage. This led to the research and development effort of creating an algorithm, with the goal of providing a reliable and timely alert to the clinician in the instance of PBD.

Methods

A software algorithm for the Merlin.net™ PCN system and Merlin™ PCS programmer systems was developed to monitor battery performance and alert the clinician when anomalous behavior is present. The alert generated by this algorithm is referred to as the Battery Performance Alert (BPA). Development of this

algorithm was performed using the following steps. First, device battery voltage information was extracted from out of service devices under the battery field advisory. Second, the battery voltage trends of these devices were analyzed for patterns of normal versus abnormal battery behavior. Using this information, the software algorithm was developed to detect abnormal battery behavior and, in turn, device PBD. The algorithm performance was then validated with adjudicated device battery trends from actual devices.

BATTERY VOLTAGE DATA

Battery voltage trend data from devices subject to the October 2016 battery advisory was used to develop and test the algorithm. Data was obtained from the following devices:

- Explanted and returned due to complaint of PBD associated with Li deposit formation
- Out of service, no complaint (including those explanted prophylactically).

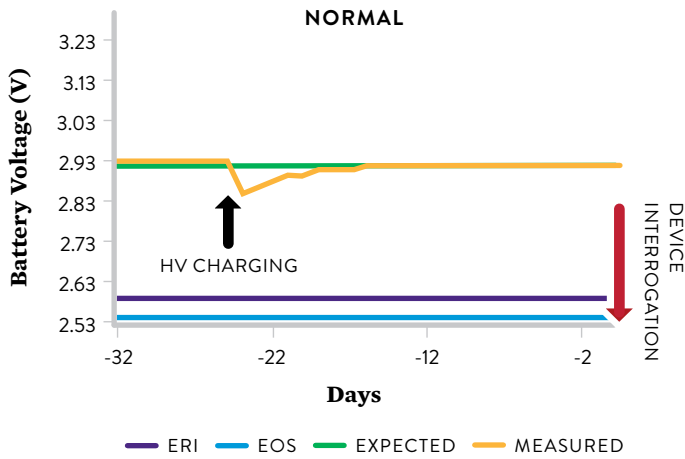
All available Merlin.net PCN and returned product data was extracted for these devices. The data was split into two sets. Battery voltage data from a total of 3,719 unique devices was used to develop and optimize the algorithm for detection of abnormal battery voltage (development set). Data from a total of 2,293 unique devices was used for validation of the algorithm performance (validation set).

ALGORITHM DEVELOPMENT

Abbott ICDs and CRT-Ds maintain a running log of the most recent 32 daily battery voltage measurements. Along with the measured values, an expected battery curve is calculated based on the expected battery use. Battery voltage measurements in a normally functioning device will closely track the expected battery curve. Expected deviations may be noted for known transient events of heavy battery use such as high voltage charging. Figure 1 shows a 32 day battery voltage trend of both expected (green line) and measured battery voltage (yellow line) for a device with a battery that is performing normally.

Premature battery depletion was defined as the device battery voltage dropping suddenly or more rapidly than expected. Rules to quantify the discrimination of PBD from normal battery operation were derived based on the development data.

Figure 1



Three specific types of patterns were identified in the battery voltage trends that indicate that the battery is not performing as expected. The BPA algorithm was developed to trigger if these specific patterns are noted when comparing the measured battery voltage to the expected battery voltage.

- These patterns are:
- Sudden Drop
 - Deviated Voltage
 - Delayed Recovery

Figure 1: A 32 day battery voltage (BV) trend for a normally functioning battery. The device is interrogated on the right hand edge of the graph and the voltages are from the thirty two prior days. High voltage charging (and other heavy transient usage, e.g. extended RF telemetry) results in a sudden drop in battery voltage that recovers over the course of approximately 10 days. This is reflected in the Measured BV trend, but not the Expected trend. The algorithm accounts for this normal behavior.

Figure 2

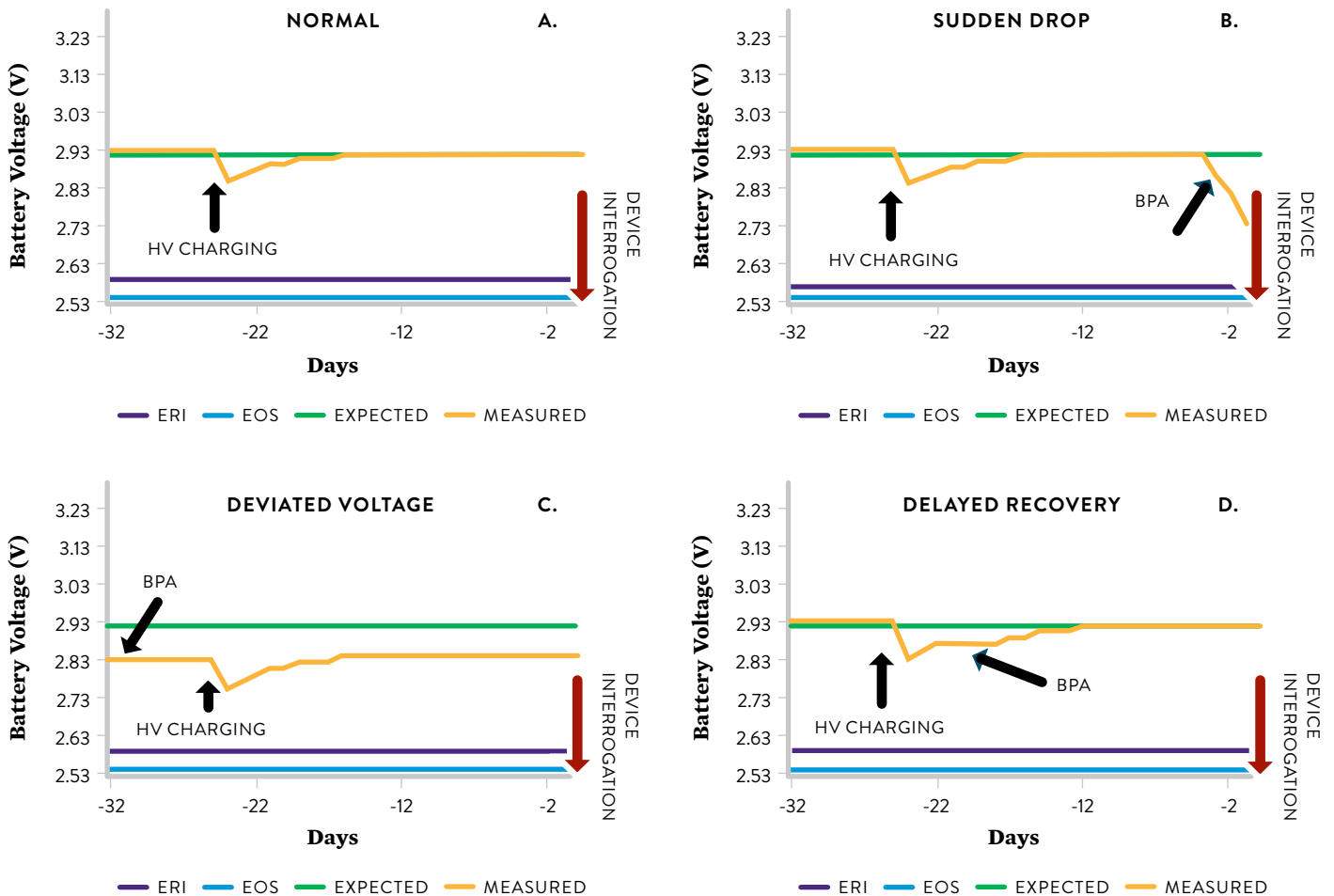


Figure 2: Examples of a normal BV trend (Panel 2a) and each of the patterns that the BPA will detect. The BPA arrow indicates the earliest detection point in each case.

Figure 2 contains graphical examples of each of the patterns that the BPA detects along with an example of a normal battery performance curve. The Sudden Drop rule (Figure 2b) looks for a sudden decrease in measured battery voltage not associated with a high battery usage event. The Sudden Drop rule will trigger an alert in one to three days, depending on the magnitude of the voltage drop. A large drop will be detected within one day, whereas it may take 3 days if there are a series of small drops. This is the primary rule that protects against the case of a complete short resulting in a battery voltage going from normal to EOS in a matter of days. The Deviated Voltage rule (Figure 2c) detects the case where the battery voltage drops from the expected level and then resumes predictable battery consumption but at a baseline level significantly lower than expected based on historical device usage. This case is likely due to a transient short. The third pattern is referred to as Delayed Recovery (Figure 2d). In this case, the battery voltage takes a longer time to recover to baseline than expected after a heavy battery usage event.

ALGORITHM VALIDATION

To validate the performance of the BPA, battery voltage trends were adjudicated by trained professionals, trends were processed through the algorithm, and results of adjudication versus algorithm determination were compared.

Battery voltage trends of the available data were created for each of the 2,293 devices used for validation of the BPA. The duration of these trends contained as many measurements as available for each of the devices, a minimum of 30 and up to a max of 365 days prior to the final available measurement. These trends were adjudicated as normal or abnormal by a minimum of two independent, blinded, trained adjudicators. The battery voltage trends were adjudicated as normal if the measured battery voltage tracked the expected battery voltage for the duration of the data. Conversely, trends were adjudicated as abnormal if there were significant deviations from the expected battery voltage. Disagreements were resolved by consensus. The battery voltage trends were then processed through the algorithm in 32 day windows (one device session at a time) to determine if and when the algorithm detected an anomaly. This process simulated the performance of the algorithm as would occur with daily Merlin.net™ PCN remote follow-up.

PERFORMANCE ANALYSIS

The following analysis was performed to assess the performance of the Battery Performance Alert.

Sensitivity

BPA algorithm sensitivity was calculated as:

$$\text{Sensitivity} = \frac{\text{Number of BV trends adjudicated as abnormal with BPA detection prior to ERI}}{\text{Total number of BV trends adjudicated as abnormal}} \times 100$$

Specificity

BPA algorithm specificity was calculated as:

$$\text{Specificity} = \frac{\text{Number of BV trends adjudicated as normal without BPA detection}}{\text{Total number of BV trends adjudicated as normal}} \times 100$$

TIME FROM ERI TO EOS

To further understand the current field experience, the time from ERI detection to EOS was determined for all of the devices that were adjudicated as abnormal and had reached the EOS voltage in the available data.

TIME FROM BPA DETECTION TO EOS

To assess the improvement in time from alert to EOS, the time from triggering of BPA to EOS was also calculated for all of the devices that were adjudicated as abnormal and had reached the EOS voltage in the available data.

Results

ADJUDICATION AND DATA SUMMARY:

There were 2,293 devices included in the validation data set. Of those, 224 devices were adjudicated as abnormal and the remaining 2,069 were adjudicated as normal. There was 95% agreement between the adjudicators with the majority of disagreements relating to devices exhibiting the delayed recovery pattern. Of the abnormal devices that had reached EOS (n=52), 46.2% (n=24), had ≤ 1 day from ERI detection to EOS.

SENSITIVITY AND SPECIFICITY

The sensitivity was defined as the ability of the BPA to detect and alert to abnormal battery performance prior to detection and alert of ERI. Among the 224 devices that were adjudicated as abnormal, a BPA was triggered prior to ERI in 219 devices. Therefore, the sensitivity is 97.8% (219/224) with a 95% lower confidence bound of 95.4%. The five devices that were adjudicated as abnormal but were not detected as abnormal by the BPA were all well above the ERI voltage. Thus it is likely that the BPA would have triggered prior to the device reaching the ERI voltage, however, the data is not available to confirm. The BPA triggered an alert at least one day prior to ERI in 100% of the 110 devices where the battery reached the ERI voltage.

Specificity was defined as BPA correctly not alerting for devices with normally functioning batteries. Among 2,069 devices that were adjudicated as normal, 2,064 devices did not have BPA detection. Therefore, the specificity is 99.8% (2064/2069) with a 95% lower confidence bound of 99.5%.

TIME FROM ALERT TO EOS

As the time from alert to EOS is critical in timely management of advisory patients, the ability of BPA to reliably increase this time is a key metric. In the validation data set, fifty-two of the devices adjudicated as having abnormal battery performance reached EOS. Of those, 46% of devices (n=24) had ≤ 1 day between ERI detection and EOS. With ERI detection as the only method of notification to a failing battery (i.e. without BPA), the median time from alert to EOS was 2 days (interquartile range [IQR] 0 – 4 days). Using the exact

same devices, with the BPA, the median time from alert (i.e., BPA) to EOS was 12 days (IQR 8 – 17.25 days); this represents a sixfold increase in time to react. The time from alert to EOS analysis was limited to devices that actually reached EOS.

Figure 3

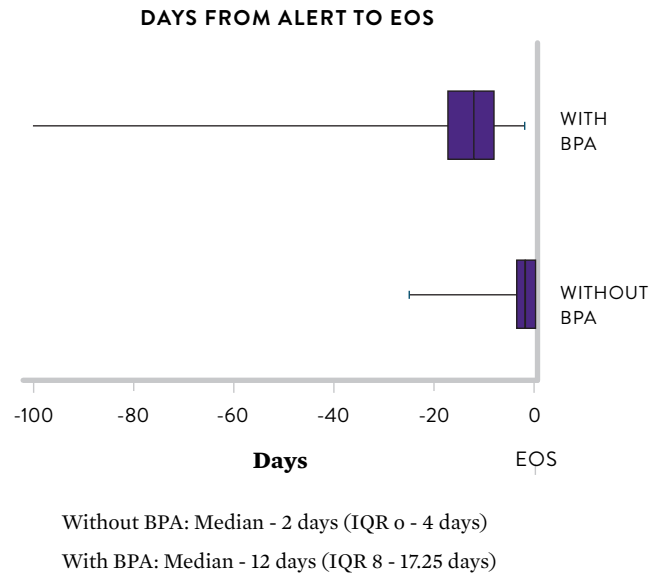


Figure 3: Summary of time from Alert to EOS, with and without BPA. Analysis limited to devices that reached EOS (52 out of 224 abnormal devices)

Table 1

TIME FROM ALERT TO EOS		
Time from alert to EOS	Without BPA (ERI to EOS)	With BPA (BPA to EOS)
≥ 2 days	54%	100%
≥ 1 week	12%	89%
≥ 4 weeks	0%	10%

Discussion

The primary clinical concern for patients with devices impacted by the battery advisory is sudden battery depletion that may leave the device unable to deliver necessary therapy without a timely notification. Prior to BPA, ERI detection was the only warning of a battery that was failing, and in some incidences, ERI alert was generated less than 1 day before the device reached EOS or not even delivered at all. With the introduction of BPA, a timely management of those advisory devices is feasible with an earlier detection and notification of abnormal battery performance. Our analysis demonstrated that the BPA correctly detected abnormal battery performance in 97.8% of the devices adjudicated as abnormal and detected abnormal performance at least one day prior to ERI in 100% of the devices that had reached ERI. Further, the BPA indicated abnormal battery performance in only 0.2% of battery data adjudicated as normal. As shown in Table 1, there was at least two days between BPA and EOS in 100% of the 52 devices that had reached EOS, and 89% of the devices had at least 1 week from alert to EOS with BPA.

The limitation of this analysis is that it was performed retrospectively using data collected from devices that were already out of service and a full set of data was not available for all devices. However, all of the data is from devices that are part of the advisory population and includes devices that had been returned for premature battery depletion and had evidence of Li clusters. Further, data was available to directly compare the expected improvement with the addition of the BPA alert. Based on the estimated six year combined Kaplan-Meier (KM) survival curve, the freedom from premature battery depletion associated with Li deposits in the affected device population is 99.089%.¹ Without the BPA algorithm, the probability of a patient having a device reach EOS with ≤ 1 day is 0.18%. With the addition of the BPA alert, the overall probability of having a device reach EOS without prior warning is 0.004%.

Conclusion

The BPA provides a reliable tool for management of patients that have devices with batteries at risk of premature depletion due to unexpected shorts. The validation testing demonstrated that the BPA detects and alerts to abnormal battery performance earlier than the existing alert mechanisms and has a high specificity, demonstrating a low probability of a false alert in a normally functioning battery.

Appendix A

The earlier battery performance alert (BPA) algorithm was primarily based on daily monitoring via the Merlin.net™ PCN system. Battery information from the implanted device was uploaded automatically each night to Merlin.net™ PCN system, and analyzed to determine if an anomalous battery voltage trend was observed. Once a BPA was triggered, notification would be provided to physicians through the Merlin.net™ PCN system. For patients not followed remotely with Merlin.net™ PCN system, the status of their device's battery and whether the BPA algorithm had triggered an alert could only be determined during an in-person interrogation using the Merlin™ programmer.

The introduction of a device based alert allows patients to be continuously monitored through the ICD/CRT-D device firmware without interrogation by a programmer or Merlin.net PCN and analyze the battery trend within the device. Once a device based BPA is triggered, a vibratory patient notifier is immediately delivered to the patient. Notification will also be provided to the physician through an automatic Merlin.net™ PCN system alert transmission or at the next in-clinic interrogation using the Merlin™ programmer. The performance of the device based BPA algorithm was evaluated using the validation data set (2,293 devices) that was previously used for validation of the software algorithm for the Merlin.net™ PCN system and Merlin™ PCS programmer system. Metrics of sensitivity, specificity, and time from alert to End of Service (EOS) were determined.

SENSITIVITY AND SPECIFICITY:

The sensitivity was defined as the ability of the device-based BPA to detect and alert to abnormal battery performance prior to detection and alert of ERI. In the validation data set, 224 devices were adjudicated as abnormal. Among them, 218 had device-based BPA detection prior to ERI. Therefore, the sensitivity is 97.3% (218/224) with a 95% lower confidence bound of 94.8%. This is equivalent to the performance of the software algorithm; however one device was detected by the software algorithm that was not detected by the device-based algorithm. This device was not detected due to an approximation in the expected battery curve necessitated by the limited processing capacity of the device.

Specificity was defined as the device-based BPA correctly not alerting for devices with normally functioning batteries and normal battery trends. There were 2,069 battery voltage trends adjudicated as normal. Among them, 2,064 did not have a device-based BPA detection. Therefore, the specificity is 99.8% (2064/2069) with a 95% lower confidence bound of 99.5%. This is identical to the performance of the software algorithm.

TIME FROM ALERT TO EOS

Analysis of the software algorithm for the Merlin™ PNC system and the Merlin™ PCS programmer systems demonstrated a sixfold increase in the time to notification. Analysis of the device-based algorithm demonstrated identical performance, with a median time from BPA to EOS of 12 days. A comparison summary can be found below.

References

1. Medical SJ. ICD Premature Battery Depletion Advisory Update - January 2018. 2018. <https://www.sjm.com/en/professionals/resources-and-reimbursement/technical-resources/product-advisories-archive> (accessed February 14 2018).

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St. Jude Medical is now Abbott.

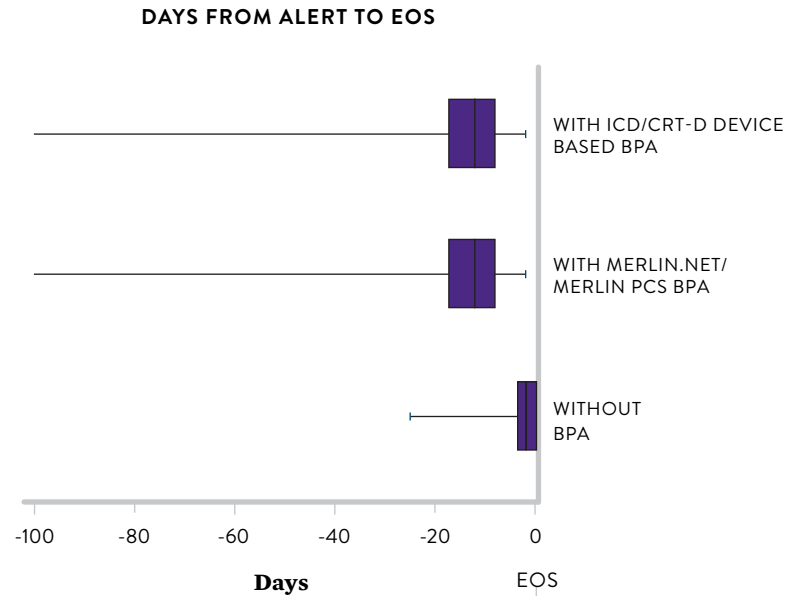
Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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Figure 4



Without BPA: Median - 2 days (IQR 0 - 4 days)
With Software BPA: Median - 12 days (IQR 8 - 17.25 days)
With Device-Based BPA: Median - 12 days (IQR 8 - 17.25 days)

Figure 4: Summary of time from Alert to EOS, with and without device-based BPA or software BPA. Analysis limited to devices that reached EOS (52 out of 224 abnormal devices)

Table 2

TIME FROM ALERT TO EOS			
Time from alert to EOS	Without BPA (ERI to EOS)	With Merlin.net/Merlin PCS BPA (BPA to EOS)	With ICD/CRT-D Device Based BPA (BPA to EOS)
≥ 2 days	54%	100%	100%
≥ 1 week	12%	89%	89%
≥ 4 weeks	0%	10%	10%

