Urgent Field Safety Notice

Potential premature battery depletion in a subset of ICD and CRT-D devices

BIOTRONIK reference: BIO-LQC

Berlin, March 2021

Dear Healthcare Professional,

BIOTRONIK has become aware of an increased likelihood of premature battery depletion in a subset of devices of the following models of Implantable Cardioverter Defibrillators ("ICDs") and Cardiac Resynchronization Therapy Defibrillators ("CRT-Ds").

Idova, Iforia, Ilesto / Inventra, Iperia, Itrevia / Ilivia,
Inlexa, Intica / Ilivia Neo, Intica Neo ICDs and CRT-Ds

These devices have been distributed since 2013. Please note that not all devices of the above models are affected, nor are other ICD or CRT-D families.

We have received no reports of serious injury or death associated with this issue. To date, all reports describe devices that fell short of expected longevity, resulting in an earlier than expected need for device exchange.

Reason for this Communication

The current observed rate of confirmed premature battery depletion events is 0.1% of all devices susceptible to this issue. Since every case of battery depletion may not be reported to BIOTRONIK, the exact number of devices that have experienced this issue is not entirely known. BIOTRONIK estimates the number of active devices which are potentially susceptible to this issue to be approximately 162,000 worldwide.

Analyses of returned devices has revealed the potential for a certain mode of lithium deposition on the anodes of the batteries, known as lithium plating, to occur.

Lithium plating is a very rare phenomenon that may cause a battery drain at a higher rate than under typical use.

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The observed onset for devices experiencing this issue is about 2 years with a failure rate of 0.0012%. The projected failure rate at 5 years after implantation is estimated to be 0.17%.

Risk to Health

There is a very low risk that premature battery depletion could result in sudden loss of high-voltage or pacing therapy. Analyses of returned devices indicate that the risk for loss of high-voltage therapy is 0.0069% and the risk for loss of pacing therapy is 0.0015% on a per month basis.

Due to the identified issue, the interval between the elective replacement indicator ("ERI") being triggered and the loss of ability to provide therapy may be shorter than expected. Our records show, that for impacted devices, the median interval from ERI to loss of high-voltage therapy was 58 days. The median interval until loss of pacing therapy was 6 months.

Early Battery Failure Detection

By design, BIOTRONIK's programmer and Home Monitoring system are equipped with a battery depletion detector. This feature allows a battery depletion, including any premature depletion, to be detected early and displayed by an ERI during in-office follow-up, or via daily remote monitoring using BIOTRONIK Home Monitoring.

Patient Management Recommendations

Following a consultation with our medical advisory board, BIOTRONIK recommends you consider the following management options:

- **Devices in stock:** Do not implant any potentially affected devices. Local BIOTRONIK representatives will replace affected devices in hospital inventory.
- **Continue with the standard patient follow-up schedule.**
    - **During follow-ups:** Verify the status of the device and battery during in-office or Home Monitoring follow-ups. Please note that unresponsive devices or those that are not transmitting data may be experiencing this issue and your BIOTRONIK representative should be informed if you observe any unusual device behavior.
    - **Home Monitoring should be utilized whenever possible as it provides timely ERI warnings to reduce the risk of sudden loss of therapy**. If you do not yet use Home Monitoring, please consider if this option is appropriate for you and your patients. BIOTRONIK will

provide CardioMessenger devices to monitor implants affected by this advisory.

If you would like to register for Home Monitoring, please contact your local BIOTRONIK representative.

- **If there is an unexpected ERI notification** for a device that is subject to this advisory, a timely replacement should be considered based on the patient's underlying conditions:
    - For patients that are not pacemaker dependent, or patients with a primary prevention ICD, device replacement within one week after ERI notification is recommended.
    - For pacemaker dependent patients, replacement of the device is recommended immediately after ERI notification.

In consultation with our medical advisory board, BIOTRONIK does **not recommend prophylactic replacement**. The risk of complications for ICD exchange[1-3] outweighs the risk associated with this issue. We refer to the above patient management recommendations in case an unexpected ERI is observed.

We recognize that individual patients have unique clinical needs. Ultimately, patient care—including the frequency of follow-ups—is determined by the physician's clinical judgement, based on individual patient circumstances.

Further Actions Planned

BIOTRONIK is working on a software update that reduces the probability of batteries developing this form of lithium plating and can therefore mitigate the risk of premature battery depletion. This update is planned to be available with the next programmer software update, which will be released shortly once regulatory approval has been completed.

Additional Information

- If you have any questions or concerns, please contact your local BIOTRONIK representative or the regional BIOTRONIK technical services. Please refer to the table below:

Region	Telephone	Email
Europe, Middle East, Africa	+49 (0) 30 68905 2200	technical.services@biotronik.de
North America	+1 (800) 547 0394	advancedproductsupport@biotronik.com

South & Latin America	+55 11 97663 8135	caio.vinha@biotronik.com
Asia Pacific	+64 21 2809 200	technical.services.ap@biotronik.com

- BIOTRONIK's records show that one or more of your patients may have an affected device. You can determine if a specific device is affected by this corrective action at www.biotronik.com/devicelookup
- Please ensure that all relevant caregivers in your organization are aware of this urgent field safety notice.
- Please note that the United States Food and Drug Administration has been informed about this field safety corrective action.

Patient safety remains our highest priority at BIOTRONIK. We regret any additional strain this may put on you or your patients. We thank you for your continued support and cooperation in this matter.

Yours sincerely,

Stephan Schwerzel
Senior Director Quality Assurance CRM
Medical Device Safety Officer

Roman Borkowski
Senior Vice President Quality Management & Regulatory Affairs CRM

References

1. McCarthy KJ, Locke AH, Coletti M, Young D, Merchant FM, Kramer DB. Outcomes Following Implantable Cardioverter-Defibrillator Generator Replacement in Adults: A Systematic Review. Heart Rhythm. 2020. **[median: 4.57% for complications including reoperation]**
2. Biffi M, Ammendola E, Menardi E, et al. Real-life outcome of implantable cardioverter-defibrillator and cardiac resynchronization defibrillator replacement/upgrade in a contemporary population: Observations from the multicentre DECODE registry. Europace. 2019;21(10):1527-1536. **[4.4 % patients needed at least one surgical action to treat an adverse event following device replacement]**
3. Lewis KB, Stacey D, Carroll SL, Boland L, Sikora L, Birnie D. Estimating the Risks and Benefits of Implantable Cardioverter Defibrillator Generator Replacement: A Systematic Review. Pacing and clinical electrophysiology : PACE. 2016;39(7). **[median rates: 4.0% major complications, 3.5% minor complications]**