Update to Urgent Field Safety Notice

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

BIOTRONIK reference: BIO-LQC

Berlin, November 2026

Dear Healthcare Professional,

BIOTRONIK is issuing this follow-up to the Urgent Field Safety Notice dated March 2021 regarding the potential for premature battery depletion due to lithium plating in a subset of ICD and CRT-D devices. This notice provides updated information on the current observed incidence and expands the affected advisory population to include a subset of Acticor and Rivacor ICDs and CRT-Ds.

The previously communicated patient management recommendations remain unchanged and are summarized in this notice. BIOTRONIK does not recommend prophylactic replacement of affected devices.

Affected devices

In March 2021, a subset of BIOTRONIK ICDs and CRT-Ds was identified to be susceptible to lithium plating that may cause an increase in battery drain leading to premature battery depletion. In addition to this originally communicated advisory population, a subset of Acticor and Rivacor ICDs and CRT-Ds has demonstrated an increased likelihood of being affected by the same failure mode.

The expanded advisory population comprises a subset of the following devices:

Acticor 7 and Rivacor 3/5/7 ICDs and CRT-Ds

The affected subset is limited to early production devices distributed from first market release in September 2018 until March 2022. A total of 59,232 affected devices were distributed worldwide, of which approximately 41,000 are estimated to be currently active. No affected devices remain available for implant.

The following devices of the initial advisory population communicated in March 2021 remain part of this field communication:

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

These devices were distributed between February 2013 and March 2021; not all devices of these models are affected. Approximately 83,700 devices are currently active.

A detailed list of the affected models is provided in the Appendix.

You can check whether a specific device is affected with the device lookup tool on our website[1]. A list of the affected serial numbers for your institution is enclosed.

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Description of the issue

Analyses of returned devices have revealed a certain mode of lithium deposition on the anodes of the batteries, known as lithium plating. Lithium plating is a rare phenomenon that may cause a battery drain at a higher rate than normal. This is the same mechanism identified in 2021 for the original advisory population.

Observed failure rates

The current cumulative observed rate of confirmed premature battery depletion due to lithium plating in the affected Acticor / Rivacor device subset is 0.68%. The earliest observed onset for devices experiencing this issue is 27 months. The table below compares the current data of both advisory populations.

	Acticor / Rivacor subset	Original advisory population
Cumulative observed failure rate	0.68%	2.0%
Earliest onset of failure	27 months	21 months
Cumulative failure probability at 2 years	0%	0.0012%
Cumulative failure probability at 5 years	0.26%	0.57%

Failure probabilities are based on Kaplan-Meier estimates.

Risk to health

Premature battery depletion may result in a loss of shock therapy or pacing therapy if the device is not replaced in time. In the worst case, loss of shock or pacing therapy could result in lack of treatment for cardiac arrest. In most cases, the only consequence is an earlier than expected device replacement.

No serious injuries or deaths have been reported in association with the affected subset of Acticor / Rivacor devices to date. In the original advisory population, one patient death has been reported in connection with premature battery depletion. The patient had been lost to follow-up for two years. No other serious injuries or deaths have been reported.

Availability of therapy functions has been assessed for all confirmed cases to estimate the risk for loss of therapy depending on the service time. The table compares the resulting risk per month for both advisory populations:

Service time	Risk for loss of pacing therapy per month		Risk for loss of shock therapy per month	
	Acticor / Rivacor subset	Original advisory population	Acticor / Rivacor subset	Original advisory population
0 – 24 months	0.00%	< 0.00001%	0.00%	< 0.00001%
24 – 48 months	0.000073%	0.0013%	0.00025%	0.0021%
48 – 72 months	0.0014%	0.0092%	0.0047%	0.0150%

The low risk reflects the comprehensive battery management system for all affected devices. BIOTRONIK ICDs and CRT-Ds feature a battery management system that detects premature battery depletion by monitoring and comparing the battery voltage to expected values for the amount of charge previously consumed. The ERI is displayed promptly with the next daily Home Monitoring transmission or at the next in-office follow-up with the

BIOTRONIK programmer. This enables early detection and timely follow-up in line with standard clinical practice.

Patient management recommendations

Following consultation with our medical advisory board, BIOTRONIK recommends the following:

- **Devices in stock:** No affected devices remain available for implantation. No action is required.
- **Follow-up:** Continue with the standard patient follow-up schedule. During in-office or Home Monitoring follow-ups, verify the status of the device and battery. Devices that are unresponsive or no longer transmit data may be affected by this issue; please inform your BIOTRONIK representative if you observe any unusual device behavior.
- **Home Monitoring:** Use Home Monitoring when possible. It provides timely ERI notifications and has reduced the probability of loss of shock therapy by 57% and loss of pacing therapy by 82% in confirmed cases. BIOTRONIK will provide CardioMessenger devices free of charge to monitor implants affected by this advisory.

  To register for Home Monitoring, please contact your local BIOTRONIK representative or visit our website[2].
- **Unexpected ERI notification:** For a device subject to this advisory, a timely replacement should be considered based on the patient's underlying condition:
  - For patients who 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, device replacement is recommended as soon as possible after ERI notification.

BIOTRONIK does **not recommend prophylactic replacement**. The procedure-related risks of an ICD or CRT-D generator replacement, such as reoperation in 4.57% and major complications in about 4% of procedures[3,4], clearly outweigh the risk associated with this issue.

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

Additional information

- If you have any questions or concerns, please contact your local BIOTRONIK representative or the regional BIOTRONIK technical service:

Region	Telephone	Email
Europe, Middle East, Africa	+49 (0) 30 68905 2200	technical.services@biotronik.de
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South & Latin America	+55 11 3372 8900	qualidade@biotronik.com
Asia Pacific	+61 2 8551 2291	technical.services.ap@biotronik.com

- BIOTRONIK's records show that one or more of your patients may have an affected device. You can determine whether a specific device is affected with the device lookup tool on our website[1].
- Please ensure that all relevant clinicians in your organization are aware of this Field Safety Notice.
- The Competent Authority in your country has been informed about this field safety corrective action.
- Please complete the Customer Acknowledgement Form provided with this communication and return it as instructed on the form. This is required for us to comply with regulatory requirements.

At BIOTRONIK, quality remains a top priority, and we will continue to rigorously monitor our products to support the care you provide for your patients.

Yours sincerely,

Arite Wildau
Director, Patient Safety

Stephan Schwerzel
Vice President, Quality Management CRM

References
1. BIOTRONIK. Device Lookup Tool. Available at: digital.biotronik.com/devicelookup
2. BIOTRONIK. BIOTRONIK Home Monitoring. Available at: https://www.biotronik.com/en-int/products/cardiac-rhythm-management/remote-patient-monitoring-systems/biotronik-home-monitoring
3. 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;17(6):1036-1042.
4. Poole JE, Gleva MJ, Mela T, et al. Complication rates associated with pacemaker or implantable cardioverter-defibrillator generator replacements and upgrade procedures: results from the REPLACE registry. Circulation. 2010;122(16):1553-1561.

Appendix: Affected models

The following models are affected by this advisory. Not all devices of the listed models are affected.

Model name	Model number	UDI-DI
Acticor 7 HF-T QP DF4 IS4 ProMRI	429522	04035479156671
Acticor 7 HF-T DF4 IS-1 ProMRI	429523	04035479156688
Acticor 7 DR-T DF4 ProMRI	429524	04035479156695
Acticor 7 VR-T DX DF4 ProMRI	429525	04035479156701
Acticor 7 VR-T DF4 ProMRI	429526	04035479156718
Rivacor 7 HF-T QP DF4 IS4 ProMRI	429532	04035479156770
Rivacor 7 HF-T DF4 IS-1 ProMRI	429533	04035479156787
Rivacor 7 DR-T DF4 ProMRI	429534	04035479156794
Rivacor 7 VR-T DX DF4 ProMRI	429535	04035479156800
Rivacor 7 VR-T DF4 ProMRI	429536	04035479156817
Rivacor 5 HF-T QP DF4 IS4 ProMRI	429561	04035479156879
Rivacor 5 HF-T DF4 IS-1 ProMRI	429562	04035479156886
Rivacor 5 DR-T DF4 ProMRI	429563	04035479156893
Rivacor 5 VR-T DX DF4 ProMRI	429564	04035479156909
Rivacor 5 VR-T DF4 ProMRI	429565	04035479156916
Rivacor 3 HF-T QP DF4 IS4 ProMRI	429571	04035479156978
Rivacor 3 HF-T DF4 IS-1 ProMRI	429572	04035479156985
Rivacor 3 DR-T DF4 ProMRI	429573	04035479156992
Rivacor 3 VR-T DF4 ProMRI	429574	04035479157005