

**MAY 10, 2023**

# Medtronic Statement: Implantable Cardioverter Defibrillators, Cardiac Resynchronization Therapy Defibrillators

Medtronic is informing physicians of a potential for reduced-energy or no-energy high-voltage therapy in its implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) manufactured after July 2017.

We are instructing physicians to contact patients to non-invasively reprogram these devices to reduce the risk for this issue. Medtronic is aware of 27 devices out of ~816,000 distributed worldwide (as of April 10, 2023) that have experienced a reduced- or no-energy high-voltage therapy. There have been no deaths due to this issue in this population.

In consultation with an Independent Physician Quality Panel, we are providing physicians with comprehensive patient management recommendations. Prophylactic device replacement is not recommended, as the risk of complications associated with device replacement is greater than the risk of the issue occurring when programmed according to the recommendations.

Devices in scope of this communication can be identified by serial number look-up at <http://productperformance.medtronic.com> and were manufactured with a specific (glassed) feedthrough under the brand names: Cobalt™ XT ICDs and CRT-Ds; Cobalt™ ICDs and CRT-Ds; Crome™ ICDs and CRT-Ds; and a subset of Claria MRI™, Amplia MRI™, Compia MRI™, Viva™ and Brava™ CRT-Ds; and a subset of Visia AF™, Visia AF MRI™, Evera™, Evera MRI™, Primo MRI™, and Mirro MRI™ ICDs.

We are committed to product quality, patient safety, and public reporting on the reliability of our products, all of which are vital to delivering on our Mission to alleviate pain, restore health and extend life.

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<https://news.medtronic.com/Medtronic-Statement-Implantable-Cardioverter-Defibrillators.-Cardiac-Resynchronization-Therapy-Defibrillators>