



Cardiac Arrhythmias and Heart Failure
15900 Valley View Court
Sylmar, CA 91342
USA

URGENT MEDICAL DEVICE CORRECTION

Confirm Rx DM3500

November 20, 2018

Dear Physician,

On November 19, 2018 Abbott began voluntarily recalling a small number (33 total devices) of Confirm Rx DM3500 Insertable Cardiac Monitors (ICM) subject to a communication issue resulting in the inability to pair the implanted device with the mobile phone app.

Description of the Issue

The Confirm Rx ICM's Bluetooth technology pairs with a mobile phone app to make patient data available to clinicians via Abbott's Merlin.net servers. For the affected Confirm Rx devices, the pairing process with the mobile phone app will not complete. Importantly, only communication between the implanted device and the mobile phone app is affected by the inability to pair. Confirm Rx diagnostic data is collected as intended, and continues to be accessible via the Merlin PCS programmer during in-office follow-up. However, patient-initiated recording functionality is not available since there is no connection between the mobile phone and the implanted ICM.

Safety Impact

We have currently received nineteen (19) complaints related to this issue. Investigation has shown that there are a total of twenty-one (21) affected devices currently implanted. The primary patient impact of the inability to pair is inconvenience, but one (1) device explant has been reported. All remaining affected shelf inventory has been removed from hospitals and distribution channels.

Status of Correction and Action Requested

By November 22, 2018, a Merlin.net solution will be implemented allowing affected devices to successfully pair to each patient's mobile phone. Device explant is not necessary.

To support your implanted patients, the following actions are requested from you:

- Verify that the communication issue is resolved for your implanted patients listed at the end of this letter by establishing a connection between the implanted Confirm Rx and a mobile phone.
- Report any remaining communication issues to Abbott.
- Return the attached acknowledgment form to your sales representative.

A copy of this letter is available on www.sjm.com/notices. Should you have questions about patient management or this issue, please contact your local Abbott Representative or Abbott Support at **1-800-727-7846 (Opt3) (U.S.)**, 8:30am - 5:30pm Central Time Monday thru Friday.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. To submit your report:

- Complete the voluntary Form FDA 3500 online
- Call 1-800-FDA-1088 to report by telephone
- [Download form](#) from FDA.gov or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 (Send only page 1 plus any continuation pages - do not send instruction pages).

Abbott is committed to providing the highest quality products and support. We apologize for any inconvenience this action may cause you, and we appreciate your understanding as we take action to ensure patient safety and customer satisfaction.

Thank you for your continued support.

Sincerely,

A handwritten signature in black ink that reads "Robert Blunt". The signature is written in a cursive style with a horizontal line at the end.

Robert Blunt
Divisional Vice President, Quality
Cardiac Rhythm Management