Medtronic

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Instructions for Use Update
Medtronic MyCareLink™ Remote Monitors
Models: 24950, 25000

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Dear Physician or Healthcare Professional:

This notification is to provide you with important information regarding an Instructions for Use (IFU) update related to patients monitored on the Medtronic CareLink™ Network with two (2) or more implanted Medtronic heart devices[1]. If a patient has multiple devices, there are potential impacts on the ability to remotely monitor that patient's heart devices as described below. These potential impacts could lead to missed CareAlert™ notifications or device reports.

Medtronic does not recommend the use of remote monitoring for patients with multiple implanted Medtronic heart devices and clinicians should take this into account when implanting an additional Medtronic heart device[1] or preparing a patient for remote monitoring. For example, if a Medtronic pacemaker is implanted in a patient with an existing Reveal LINQ™ Insertable Cardiac Monitor (ICM), you may not be able to monitor either device remotely. In this example, if a physician determines that it is appropriate, removal of the Reveal LINQ ICM will allow for remote monitoring of the Medtronic pacemaker.

It is important to note that in-clinic interrogation of multiple implanted devices via a Medtronic programmer (model 2090 or Encore) can continue to be used to obtain data from each implanted heart device. The inability to reliably communicate with multiple implanted heart devices impacts remote monitoring systems only. In the example above, if the Reveal LINQ ICM and pacemaker remain implanted, in-clinic evaluations using a Medtronic programmer can be used to obtain data from both devices.

Medtronic has released an updated Clinician Instructions for Use for the MyCareLink™ Monitor (model 24950) and MyCareLink Smart™ (model 25000) to include the following information:

- In patients with more than one (1) Medtronic implanted heart device, device data may not be able to transmit from any of the implanted devices to the physician via the Monitor.

- In addition, the patient could potentially transmit device data unintentionally from one of the implanted heart devices when attempting to transmit from another device implanted in the same patient.

- A Medtronic Programmer can be used to obtain data from each implanted heart device.

Medtronic will notify regulatory agencies regarding this communication and obtain approvals for the updated Instructions for Use as required. Until the IFU update is available, clinicians should continue to reference this communication. Medtronic will notify regulatory agencies regarding this communication and obtain approvals for the updated Instructions for Use as required. Clinicians should retain this communication for reference.

1: Medtronic heart devices include Cardiac Resynchronization Therapy (CRTs), Implantable Pulse Generators (IPGs), Implantable Cardioverter Defibrillators (ICDs), Insertable Cardiac Monitors (ICMs) and Transcatheter Pacing Systems (TPSs).

Please share this notification with others in your organization as appropriate. If you have any questions, please contact your Medtronic Field Representative. We appreciate your review of this notification and apologize for the inconvenience that it may cause. Adverse reactions or quality problems experienced with the use of this product may be reported to your Medtronic Field Representative.

Sincerely,

Joo Ee Yap
Business Director
CRHF SEA

Cc: Chairman Medical Board and relevant Head of Department