Medtronic

Urgent Field Safety Notice

Disabling of TriageHF™ CareAlerts CareLink™ Network

Customer Notification

CareLink Feature	Model/
TriageHF™ CareAlerts	5242

April 2020

Medtronic Reference: FA914

Dear Healthcare Professional/Clinician,

Medtronic is writing to notify you of a change being made to one of the features you may have recently used while accessing CareLink data to assess the clinical status of patients implanted with a Medtronic OptiVol™-enabled implantable cardioverter defibrillator (ICD) or a cardiac resynchronization therapy device (CRT-Defibrillator or CRT-Pacemaker). Specifically, this notice is to inform you of a status change on the availability of TriageHF™ CareAlerts.

Medtronic enabled a new CareAlert for your CareLink account known as TriageHF™ CareAlerts. This feature was enabled prior to obtaining the necessary regulatory approval within your geography. To ensure compliance with regulatory requirements, Medtronic disabled access to TriageHF™ CareAlerts from your account on March 10, 2020. Note, TriageHF™ CareAlerts are associated with the Heart Failure Risk Status diagnostic. Only the CareAlert has been disabled; the Heart Failure Risk Status will continue to be available on CareLink for patients implanted with one of the applicable devices.

Please contact your Medtronic Representative at <XXXX> if you have questions about this letter.

The Competent Authority of your country has been notified of this action. Please share this notification with others in your organization as appropriate.

We regret any confusion this may have caused. Thank you for continuing to use the Medtronic CareLink™ Network. Medtronic will continue to work to ensure we meet your needs and those of your patients.

Sincerely,

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