Medtronic International Ltd. - Malaysia Branch
(993966-P)
F-39-7, CREST,
3 Two Square,
No. 2, Jalan 19/1,
46300 Petaling Jaya,
Selangor Darul Ehsan, Malaysia.
Tel: 603-7953 4800 (10 lines) Fax: 603-7958 2202

May 06, 2010.

To:
DIRECTOR OF MEDICAL DEVICE BUREAU
MINISTRY OF HEALTH MALAYSIA
Level 5, No. 26, Boulevard Plot 3C4,
Precinct 3,
Federal Government Administration Centre,
62675 Putrajaya,
Malaysia

Dear Sir,

MEDICAL DEVICE CORRECTION:
Consulta® CRT-D, Secura® DR/VR, Concerto® II CRT-D, Virtuoso® II DR/VR, Maximo® II CRT-D, Maximo® II DR/VR.

This letter is to inform you that Medtronic, Inc., is conducting a voluntary correction for the ICD and CRT-D device models listed above, due to a rare device software issue.

The scope of this field action impacts on the local market, and we are notifying the relevant physicians on this field action.

Please find the attached copy of the communication letter to provide further insights into this field action.

Do consult us should you require additional information.

Yours Sincerely,

Debra Anne Anthony Peter
Regulatory Affairs Specialist
MEDTRONIC INTERNATIONAL, LTD.

Encl: Customer Communication Letter

Medtronic

IMPORTANT: MEDICAL DEVICE CORRECTION

Consulta® CRT-D, Secura® DR/VR, Concerto® II CRT-D, Virtuoso® II DR/VR, Maximo® II CRT-D, Maximo® II DR/VR

May 2010

Dear Doctor,

Medtronic is informing you of a rare device software issue in the ICD and CRT-D device models listed above. A software update will be available to correct this issue.

As of April 19, 2010, Medtronic has received 5 confirmed reports out of approximately 144,000 devices worldwide. No patient injuries or deaths have been reported as a result of this issue. Medtronic has identified the root cause to be a rare and specific sequence of events that must occur within a few milliseconds of each other:

- High voltage capacitors reach programmed energy (charge end)
- Battery voltage measurement in-process at charge end
- VT/VF rhythm self-terminates and therapy is aborted

In the unlikely event that this sequence occurs, all subsequent high voltage therapies will experience prolonged charge time or loss of high voltage therapy (due to a charge circuit timeout). Device alerts are nominally ON and will notify patients to seek medical attention should either of these alert conditions occur.

If the software update is not implemented, Medtronic estimates the rate of occurrence of this specific sequence of events in an ambulatory setting is 1 in 27,000 devices per year (0.000037 per year). The projected probability that a patient would need life sustaining therapy prior to a device alert being triggered for a charge circuit timeout is projected to be 1 in 291,000 per year (0.0000034 per year).

Your local Medtronic representative will assist you with installing the software on your programmer. Your patients' devices will receive the update automatically upon their next in-clinic interrogation and their devices will be corrected.

Summary
Medtronic has identified a rare device software issue in the ICD and CRT-D device models listed above. Your Medtronic Representative will update your programmer with software Model 9995 Version 7.3. Upon their next in-clinic interrogation, patients' devices will receive the update automatically and their devices will be corrected. Attached are the specific model and serial numbers of affected devices you are following according to our device registration records. We regret any difficulties this may cause you and your patients. If you have any questions, or if we can be of assistance, please contact your local Medtronic Representative or Medtronic Technical Services.

Sincerely,

dasgus1
2010.05.06
08:56:01 +05'30'

Shamik Dasgupta
Business Director
Cardiac Rhythm Disease Management
South Asia and ASEAN