Medical Devices Bureau, Ministry of Health Malaysia
Level 5, Block E6, Complex E,
Federal Government Administrative Centre,
62590 Putrajaya, MALAYSIA
Tel: 03-8883 2248/2249/2264
Fax: 03-8888 6184

Medical Device / Equipment ALERT: Field Corrective Action

Date Issued : 5th August 2008 **Ref:MDB/A/2008/011**

IMMEDIATE ACTION	
ACTION	√
UPDATE	
INFORMATION REQUEST	

PRODUCT	**Maximo II VR ICD, DR ICD and CRT-D by Medtronics.**
CLASS	n/a
USE	Implantable Cardioverter Defibrillators and Cardiac Resynchronization Therapy unit.
SOURCE OF MEDICAL DEVICE RECALL / ALERT	Field Corrective Action Letter dated 30th July 2008 from Medtronic International Ltd. - Malaysia Branch.
ALERTING / RECALLING FIRM	**Medtronic International Limited-Malaysia Branch**
REASON	The company is notifying customers that some of the above mentioned models have a configuration issue. The manufacturer has retrieved all the non-implanted Maximo II devices from the customers. ***Please refer to attachment for details.***
SCENARIO IN MALAYSIA	Medtronic representative in Malaysia assured **that 4 units have been implanted to patients** and they have acknowledged the responsible physicians for this Field Corrective Action.
ACTION	***Please refer to attachment for details.***
RECOMMENDATION	Users of the abovementioned device should contact the distributors/supplier of this device (if available) and **inform the Medical Device Bureau, Ministry of**

	Health providing the following information:- a. Name of healthcare centre/hospital/clinic b. Contact person and contact number c. Numbers of units available
CONTACT/ENQUIRIES IN MALAYSIA	**Medtronic International Limited-Malaysia Branch** F-39-7 CREST, 3 Two Square, No. 2, Jalan 19/1, 46300 Petaling Jaya Selangor Darul Ehsan. Tel:- 03-79534800 Fax:- 03- 79582202
REFERENCES	***Please refer to attachment for details.***

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

July 30, 2008.

To:

DIRECTOR OF MEDICAL DEVICE BUREAU
MINISTRY OF HEALTH MALAYSIA
ENGINEERING SERVICES DIVISION,
Level 2-5, Block E6, Parcel E, Precinct 1,
Federal Government Administration Centre,
62590 Putrajaya,
Malaysia.

Dear Sir,

FIELD CORRECTIVE ACTION ON MAXIMO® II DEVICE CONFIGURATION.

Medtronic has identified a Maximo® II VR ICD, DR ICD and CRT-D device configuration issue. Pertaining to this field action, we have retrieved all the non-implanted Maximo II devices from our customers.

Our records indicate that 4 units have been implanted in patients from 2 local hospitals and communication letters has been sent out to the respective physicians. There is no danger to the patients as the device configurations issue does not pose a patient safety risk. Please find the attachment of the Communication Letters for further explanation.

Do consult us should you require additional information.

Thank you and kind regards.

Yours Sincerely,

Debra Anne Anthony Peter
REGULATORY AFFAIRS SPECIALIST
MEDTRONIC INTERNATIONAL, LTD.

Copy: Bay Song Chua, COUNTRY MANAGER.

Medtronic International Ltd. - Malaysia Branch
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July 30th, 2008

Subject: Maximo® II Device Configuration

Dear Doctor,

Medtronic has identified a Maximo® II VR ICD, DR ICD and CRT-D device configuration issue. This issue does not directly pose a patient safety risk. The Capture Management algorithm (Atrial/Right Ventricular/Left Ventricular Capture Management) was inadvertently included in these devices. The Capture Management algorithm monitors daily pacing thresholds and may increase or decrease pacing amplitudes in response to patients' needs. Although the algorithm is operating correctly, it is not accessible to the clinician for reprogramming.

Since this device configuration does not pose a safety risk, no specific patient management actions are recommended. We have received one report of a patient presenting with phrenic nerve stimulation which led to our identification of this issue. Although these symptoms are unlikely to occur in most patients, please contact Jenny Yap @ +6012-2389610 / Fiona Lok @ +852-9035-9434 if you have specific questions regarding managing the care of such patients or how to reprogram the Maximo II devices.

Medtronic is developing an update to the 2090 programmer software that will automatically return the device to the intended configuration. We expect this software to be available in approximately two months, pending regulatory approval. A Medtronic Representative will contact you to make arrangements to update your programmer. Once the 2090 programmer software has been updated, the programmer will automatically reconfigure any impacted Maximo II device at the next regularly scheduled follow-up.

Please collect and hold all non-implanted Maximo II devices for retrieval by a Medtronic Representative. We expect Maximo II products with the correct configuration to be available tentatively by the end of August.

We apologize for any inconvenience this may cause you or your patients.

Sincerely,

CRDM BU Country Leader
Medtronic, Inc.