**Medtronic International Ltd.** - Malaysia Branch
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46300 Petaling Jaya,
Selangor Darul Ehsan, Malaysia.
Tel: 603-7953 4800 (10 lines) Fax: 603-7958 2202

October 15, 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:**
**Model 5388 Dual-Chamber External Temporary Pulse Generator.**

This letter is to inform you of an important medical device correction being carried out by Medtronic, Inc., on a subset of approximately 6,000 out of 36,000 Model 5388 Dual-Chamber External Temporary Pulse Generators.

The scope of this field action impacts on the local market, with 50 units distributed. We have located all the 50 units and are notifying the relevant customers 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

**IMPORTANT MEDICAL DEVICE CORRECTION**
Model 5388 Dual-Chamber External Temporary Pulse Generator

October 2010

Dear Customer:

Medtronic has determined that a subset of approximately 6,000 out of 36,000 Model 5388 Dual-Chamber External Temporary Pulse Generators worldwide may be unable to power up or may power down unexpectedly. The root cause has been identified as a high resistance contact on the electronic circuit board. Medtronic has developed a design upgrade that will eliminate this issue. There have been no patient injuries reported as a result of this issue. Medtronic is communicating this information to the appropriate regulatory agencies.

When this issue occurs, it presents in one of two ways.

First, during startup, and prior to initiating patient therapy, the instrument may power down in 1-2 seconds. As of October 4, 2010, Medtronic has received 114 reports of this device behavior (approximately 2% of affected instruments).

Second, the instrument may power up correctly, but power down at a later time while in use. As of October 4, 2010, Medtronic has received 2 reports of this device behavior (approximately 0.04% of affected instruments).

As indicated in the technical manual, if loss of control of rate, output, sensitivity or power occurs, and it is not due to a low battery, disconnect the device and return it to Medtronic for service.

5388
Dual Chamber Temporary Pulse Generator

Medtronic will contact you to return affected units for servicing. In the interim, you should continue to use normally functioning devices.

Medtronic is committed to ensuring our products meet the highest quality standards and that our customers are fully supported. If you have any questions regarding this action, please call your local technical service.

Sincerely,

Shamik Dasgupta

Business Director
Cardiac Rhythm Disease Management
South Asia and ASEAN