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Urgent Field Safety Notice

Model 5388 Dual-Chamber External Temporary Pulse Generator
Medical Device Correction

October 2010

Medtronic ref.: FA490

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 behaviour (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 behaviour (approximately 0.04% of affected instruments).


5388
Dual Chamber Temporary Pulse Generator

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.

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

The Irish Medicines Board has been notified of this action. This notice needs to be passed to all those who need to be aware within your organization.

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 Medtronic Directo Technical Services on 01 511 1400.

Yours sincerely

D. G. Dunham.

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