

Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/52

Issued: 13 September 2004

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	✓
INFORMATION REQUEST	



HEALTH ESTATES

**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
<p>Medical Device/Equipment: Medtronic implantable cardioverter defibrillator (ICD) models GEM[®] DR 7271 and Micro Jewel[®] II 7223Cx.</p>	▶ ①
<p>Problem: Extended charge times and inability to deliver therapy at battery voltages close to Elective Replacement Indicator (ERI) for a subset of the above devices.</p>	▶ ②
<p>Action by: All clinicians and cardiac technicians managing patients implanted with GEM[®] DR 7271 or Micro Jewel[®] II 7223Cx implantable cardioverter defibrillators.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Note that the recommendations in this update supersede the advice given in Pacemaker Technical Note (PTN) No. 80 issued by the Medical Devices Agency in October 1999. Identify patients affected by referring to the serial numbers listed in Appendix 2. Follow the detailed instructions given in Medtronic's Advisory Notice (see Appendix 1). 	▶ ④
<p>Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p>	▶ ⑤
<p>Contacts Details of manufacturer contacts, and NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC Report all instances in which a device has failed to deliver therapy (with a note of the battery voltage and charge time) to NIAIC and Medtronic. Report explants to the National Pacing and ICD database, PO Box 9205, Bridge of Weir, Strathclyde PA11 3DZ, telephone 01505 612 829.</p>	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

Medtronic GEM[®] DR and Micro Jewel[®] II ICDs manufactured with suspect capacitors and having serial numbers as indicated in Appendix 2.

2. PROBLEM:

Since 1999 Medtronic has issued a series of advisory notices concerning the performance of some GEM[®] DR and Micro Jewel[®] II ICDs.

Medtronic's most recent Advisory Notice is appended to this alert and updates previous follow-up recommendations for affected GEM[®] DR and Micro Jewel[®] II ICDs. This most recent advisory notice followed receipt of reports in which appropriate therapy had not been delivered during cardiac arrhythmias. Medtronic was concerned that these devices may not be capable of delivering adequate high voltage defibrillation therapy at or near the specified ERI at 4.91V, or during the following period to end of life (EOL), specified at 4.57V. NIAIC is publishing this Medical Device Alert in line with MHRA advice to reiterate the recommendations made by Medtronic, and to update and replace advice previously issued by the Medical Devices Agency in PTN No. 80.

3. ACTION BY:

All clinicians and cardiac technicians managing patients implanted with GEM[®] DR 7271 or Micro Jewel[®] II 7223Cx implantable cardioverter defibrillators.

4. ACTION:

Carry out the following actions for all affected patients (refer to list of serial numbers):

1. Verify the ICD's battery voltage and capacitor charge time.
2. Schedule replacement for any device if **either** of the following conditions occur:
 - battery voltage of **5.16 V or less**,
 - charge time of **18 seconds or greater**.
3. If the battery voltage is greater than 5.16 volts and the charge time is greater than 14 seconds, program the Automatic Capacitor Formation interval to one month.
4. If the battery voltage is greater than 5.16 volts and the charge time is less than 14 seconds, or if the Automatic Capacitor Formation is already programmed to one month, no additional reprogramming is required.
5. Continue to monitor battery voltage and charge times at intervals of not greater than **three months**.

Trust managers should ensure that measures to implement the actions specified above are planned and completed within the following SABS deadlines:

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Medical Directors
- Cardiac Pacemaker/ICD Technicians
- Cardiologists in Pacing and Electrophysiology

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

David G Dunham BSc PhD
Regulatory Affairs Manager – UK & Ireland
Cardiac Rhythm Management
Medtronic (UK) Ltd
Suite One

Sherbourne House
Croxley Business Centre
Watford
WD18 8WW

Tel: 01923 212 213

E-mail: david.dunham@medtronic.com

Enquires to NIAIC should quote reference number MDEA(NI)2004/52 and be addressed to:
Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

Report all instances in which a device has failed to deliver therapy (with a note of the battery voltage and charge time) to NIAIC and Medtronic. Report explants to the National Pacing and ICD database, PO Box 9205, Bridge of Weir, Strathclyde PA11 3DZ, telephone 01505 612 829



Brian Godfrey
NIAIC Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2004/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety

APPENDIX 1 to MDEA(NI)2004/52 – Medtronic's Advisory Notice



Medtronic

Medtronic Limited

Suite One
Sherbourne House
Croxley Business Centre
Watford, Herts WD18 8WW
Telephone: 01923 212213
Facsimile: 01923 241004

7th April 2004

Dear Doctor

IMPORTANT PATIENT SAFETY INFORMATION

Medtronic is providing an update to previous advisory notices for **GEM® DR Model 7271 and Micro Jewel® II Model 7223Cx ICDs**. This update replaces recommendations made for the GEM DR Model 7271 in December 1999, and for the Micro Jewel II Model 7223Cx provided in August 1999 and November 2000 about suspect capacitors in identified populations. This notification is consistent with our commitment to provide you with ongoing performance updates.

Because of the concern that these ICDs with suspect capacitors may not be consistently capable of providing high voltage energy delivery near or at ERI (4.91 V) and continuing through EOL (4.57 V), we are issuing the following revised recommendations:

- **If the patient's last follow-up was within the previous three months, and records are available, verify the recorded battery voltage and capacitor charge time as below.**
- **For all others, schedule follow-up as soon as possible, and verify the charge time and battery voltages below.**
- **Schedule replacement for any device with:**
 - **battery voltage of 5.16 V or less, (NEW RECOMMENDATION)**
 - **OR charge time of 18 seconds or greater.**
- **If the battery voltage is greater than 5.16 volts, verify the charge time:**
 - **If less than 18 seconds but greater than 14 seconds, program the Automatic Capacitor Formation Interval to one month.**
 - **No additional reprogramming is required if verified charge time is less than 14 seconds, or if capacitor formation is already set to one month.**
- **Continue to follow these patients at least at three monthly intervals.**

These recommendations relate only to the Micro Jewel II and Gem DR ICDs identified by serial number on the attached list. **No other Micro Jewel II Model 7223Cx or GEM DR Model 7271 devices are affected.**

This update supercedes earlier Micro Jewel II letters (August 1999 and November 2000) and a GEM DR letter (December 1999) regarding this same previously identified population of devices with capacitors from specific component lots. Those communications focused on managing performance of affected devices through the Automatic Capacitor Formation Interval and replacing devices with charge times of 18 seconds or greater.

Worldwide, we have now seen thirty (30) Micro Jewel II devices with suspect capacitors that have experienced unexpected performance of the charge circuit at battery voltages near ERI. Six (6) of these occurred during cardiac arrhythmias, resulting in therapy not being delivered.

Although all field reports to date have involved Micro Jewel II devices, it is possible that some GEM DR devices with suspect capacitors could exhibit similar behavior. Therefore, this recommendation applies to both Micro Jewel II (~1386 active units worldwide) and GEM DR (~435 active units worldwide) with suspect capacitors. These devices were implanted in 1997 and 1998.

We sincerely apologise for any inconvenience this has caused to you and your patients. If you have questions, or would like information about our supplemental warranty for these devices, please contact your Medtronic Sales Representative or myself at the Medtronic UK Office on 01923 212213.

The Medicines and Healthcare products Regulatory Agency (MHRA) have been consulted in respect to this notification.

Your sincerely

A handwritten signature in black ink that reads "D. G. Dunham". The signature is written in a cursive style with a small flourish at the end.

David G. Dunham BSc (Hon). PhD.
Clinical, Technical & Education Manager
Cardiac Rhythm Management

APPENDIX 2 to MDEA/2004/52 – Affected Serial Numbers

Serial No	Catalog No
PFR100285K	7223CX25
PFR100296K	7223CX25
PFR100297K	7223CX25
PFR100369K	7223CX25
PFR100375K	7223CX25
PFR100390K	7223CX25
PFR100405K	7223CX25
PFR100416K	7223CX25
PFR100431K	7223CX25
PFR100444K	7223CX25
PFR100447K	7223CX25
PFR100518K	7223CX25
PFR100538K	7223CX25
PFR100543K	7223CX25
PFR100547K	7223CX25
PFR100548K	7223CX25
PFR100551K	7223CX25
PFR100586K	7223CX25
PFR100615K	7223CX25
PFR100673K	7223CX25
PFR100707K	7223CX25
PFR100713K	7223CX25
PFR100728K	7223CX25
PFR100774K	7223CX25
PFR100788K	7223CX25
PFR100816K	7223CX25
PFR100818K	7223CX25
PFR100823K	7223CX25
PFR100826K	7223CX25
PFR100857K	7223CX25
PFR100861K	7223CX25
PFR100957K	7223CX25
PFR100960K	7223CX25
PFR100979K	7223CX25
PFR101140K	7223CX25
PFR101179K	7223CX25
PFR101185K	7223CX25
PFR101198K	7223CX25
PFR101202K	7223CX25

Serial No	Catalog No
PFR101206K	7223CX25
PFR101213K	7223CX25
PFR101216K	7223CX25
PFR101222K	7223CX37
PFR101258K	7223CX25
PFR101260K	7223CX25
PFR101271K	7223CX25
PFR101289K	7223CX25
PFR101382K	7223CX36
PFR101426K	7223CX36
PFR101458K	7223CX25
PFR101462K	7223CX25
PFR101463K	7223CX25
PFR101496K	7223CX25
PFR101573K	7223CX36
PFR101592K	7223CX36
PFR101594K	7223CX37
PFR101596K	7223CX36
PFR101597K	7223CX37
PFR101598K	7223CX37
PFR101754K	7223CX36
PFR101808K	7223CX37
PFR102002K	7223CX37
PFR102003K	7223CX37
PFR102004K	7223CX37
PFR102016K	7223CX37
PFR102020K	7223CX37
PFR102023K	7223CX37
PFR102025K	7223CX37
PFR102046K	7223CX37
PFR102057K	7223CX37
PFR102080K	7223CX37
PFR102104K	7223CX36
PFR102146K	7223CX36
PFR102148K	7223CX36
PFR102154K	7223CX37
PFR200020K	7223CX237
PFR200021K	7223CX237
PFR200040K	7223CX237

Serial No	Catalog No
PFR200041K	7223CX237
PFR200061K	7223CX236
PFR200067K	7223CX237
PFR200077K	7223CX237
PFR200125K	7223CX237
PFR200126K	7223CX237
PFR200127K	7223CX237
PFR200128K	7223CX237
PFR200129K	7223CX237
PFR200130K	7223CX237
PFR200133K	7223CX237
PFR200140K	7223CX237
PFR200161K	7223CX237
PFR200178K	7223CX237
PFR200209K	7223CX237
PFR200213K	7223CX237
PFR200229K	7223CX236
PFR200234K	7223CX236
PFR200236K	7223CX236
PFR200238K	7223CX236
PFR200243K	7223CX236
PFR200244K	7223CX236
PFR200245K	7223CX236
PFR200246K	7223CX236
PFR200256K	7223CX236
PFR200258K	7223CX236
PFR200310K	7223CX236
PFR200346K	7223CX236
PFR200348K	7223CX236
PFR200401K	7223CX237
PFR200424K	7223CX236
PFR200432K	7223CX237
PFR200447K	7223CX236
PFR200455K	7223CX237
PFR200468K	7223CX236
PFR200476K	7223CX236
PFR200502K	7223CX237
PFR200513K	7223CX237
PFR200516K	7223CX237

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Serial No	Catalog No
PFR200529K	7223CX237
PFR200534K	7223CX237
PFR200535K	7223CX237
PFR200536K	7223CX237
PFR200537K	7223CX237
PFR200599K	7223CX237
PFR200626K	7223CX236
PFR200635K	7223CX236
PFR200637K	7223CX237
PFR200654K	7223CX236
PFR200675K	7223CX237
PFR200684K	7223CX236
PFR200685K	7223CX236
PFR200691K	7223CX237
PFR200745K	7223CX237
PFR200764K	7223CX237
PFR200768K	7223CX237
PFR200769K	7223CX237
PFR200782K	7223CX236
PFR200795K	7223CX236
PFR200809K	7223CX236
PFR200812K	7223CX236
PFR200841K	7223CX236
PFR200871K	7223CX237
PFR200884K	7223CX236
PFR200894K	7223CX237
PFR200942K	7223CX237
PFR200952K	7223CX236
PFR200955K	7223CX236
PFR200956K	7223CX236
PFR201010K	7223CX236
PFR201050K	7223CX236
PFR201088K	7223CX236
PFR201094K	7223CX236
PFR201109K	7223CX237
PFR201149K	7223CX236
PFR201150K	7223CX236
PFR201159K	7223CX236
PFR201181K	7223CX236

Serial No	Catalog No
PFR201181K	7223CX236
PFR201191K	7223CX236
PFR201192K	7223CX236
PFR201197K	7223CX236
PFR201207K	7223CX237
PFR201248K	7223CX237
PFR201286K	7223CX236
PFR201287K	7223CX236
PFR201291K	7223CX236
PFR201297K	7223CX236
PFR201360K	7223CX236
PFR201364K	7223CX237
PFR201365K	7223CX237
PFR201370K	7223CX236
PFR201387K	7223CX236
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PFR201458K	7223CX236
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PFR201486K	7223CX237
PFR201491K	7223CX237
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PFR201541K	7223CX236
PFR201544K	7223CX236
PFR201554K	7223CX236
PFR201595K	7223CX236
PFR201596K	7223CX236
PFR201598K	7223CX236
PFR201617K	7223CX236
PFR201634K	7223CX236
PFR201635K	7223CX236
PFR201638K	7223CX236
PFR201643K	7223CX236
PFR201691K	7223CX236
PFR201696K	7223CX236
PFR201697K	7223CX236
PFR201698K	7223CX236

Serial No	Catalog No
PFR201702K	7223CX236
PFR201724K	7223CX236
PFR201726K	7223CX236
PFR201766K	7223CX236
PFR201800K	7223CX236
PFR201823K	7223CX236
PFR201825K	7223CX236
PFR201827K	7223CX236
PFR201829K	7223CX236
PFR201843K	7223CX236
PFR201846K	7223CX236
PFR201847K	7223CX236
PFR201849K	7223CX236
PFR201911K	7223CX236
PFR201920K	7223CX236
PFR201951K	7223CX236
PFR201957K	7223CX236
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PFR201993K	7223CX236
PFR202021K	7223CX236
PFR202044K	7223CX236
PFR202047K	7223CX236
PIM100679R	7271AF
PIM100692R	7271AF
PIM200155R	7271AF
PIM200232R	7271AF
PIM300181R	727136
PIM300182R	727136
PIM300206R	727136
PIM300271R	727136
PIM300486R	727136
PIM300487R	727136
PIM300523R	727136
PIM300616R	727136
PIM300643R	727136
PIM300680R	727136
PIM300707R	727136
PIM300716R	727136