

# Medical Device Alert

## Action

Ref: MDA/2010/070 Issued: 09 September 2010 at 14:00

### Device

LIFEPAK 20/20e defibrillator/monitor.

Manufactured by Medtronic/Physio-Control.

Specific serial numbers are affected.



### Problem

Due to component failures, which affect AC (mains) and/or DC (battery) operating power, there is a risk that the defibrillator will not deliver therapy.

The corrective action programme initiated by the manufacturer will take approximately two years to complete.

### Action by

All those involved in the use and maintenance of these devices.

### CAS deadlines

Action underway: 23 September 2010

Action complete: 07 October 2010

### Action

1. Assess the need for a back-up or alternative device whilst awaiting corrective action.
2. All users should ensure that:
  - they are aware of manufacturer's [Field Safety Notice](#).
  - the manufacturer's recommended daily inspection and testing as per the operator's checklist are performed.
  - where possible, devices are connected to AC mains power and the DC battery kept continuously on charge.
3. The manufacturer has contacted all affected customers. However, if you wish to check if your device is affected, refer to the [Field Safety Notice](#).

### Contact

#### Manufacturer

Lezlie Bridge  
Medtronic Ltd

Tel: 01923 212 213

Email: [lezlie.j.bridge@medtronic.com](mailto:lezlie.j.bridge@medtronic.com)

## Device

This is an acute cardiac care device used in clinical and hospital settings. It has a dual power supply system and is designed to operate on AC (mains) power or DC (battery) power.

Devices with specific serial numbers, manufactured from 31 July 2002 to 9 February 2009 inclusive, are affected. See the manufacturer's [Field Safety Notice](#) for a list of the relevant serial numbers.

## Problem

### **Problem 1: No DC (battery) operating power**

Current leakage can prevent operation when using DC battery power. Failure of DC power can result in an inability to deliver defibrillation therapy, if no AC power is available.

The global failure rate is 0.9% to date.

### **Problem 2: No AC (mains) operating power**

A component failure prevents AC power operation and prevents battery charging capability. Failure of AC power can result in an inability to deliver defibrillation therapy if DC power is depleted.

The global failure rate is 0.7% to date.

### **Solution:**

Affected devices may have problem 1, or problem 2, or both problems. The following phased corrective actions to replace the power supply board have been initiated:

- Phase 1 DC power – identifies devices at a higher risk that accounts for 92% of all DC power failures. The manufacturer expects to complete this phase in 9 to 12 months.
- Phase 2 AC power – identifies the remaining lower risk devices that will be updated upon completion of phase 1. The manufacturer expects phase 2 to take an additional 9-12 months to complete.

## Action

- Be aware of the two year timeline for completion of the corrective action. Assess the need for a back-up or alternative device during this period.
- If your device exhibits either or both problems, report the failure of the device to the manufacturer and to the MHRA. Arrange for repair of the device with the manufacturer.

## Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)

### **Onward distribution**

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

#### **Trusts to:**

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units
- All clinical departments
- All staff
- All wards
- Anaesthesia, directors of

- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Biomedical engineering staff
- Cardiac laboratory technicians
- Cardiac pacing technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Clinical governance leads
- Coronary care departments
- Coronary care nurses
- EBME departments
- Equipment stores
- Health and safety managers
- Intensive care units
- Intensive care, directors of
- Medical directors
- Medical libraries
- Midwifery staff
- MRI units, directors of
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- Outpatient theatre managers
- Paediatric intensive care units
- Patient transport managers
- Resuscitation officers and trainers
- Risk managers
- Theatre managers

**Care Quality Commission (CQC) (England only) to:**

The MHRA considers this information to be important to:

- Care homes providing nursing care (adults)
- Clinics
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

**Primary care trusts to:**

CAS liaison officers for onward distribution to all relevant staff including:

- Community defibrillation officers
- Community hospitals
- Community nurses
- Equipment libraries and stores
- General practitioners
- Minor injury units
- NHS walk-in centres

## Contacts

**Manufacturer**

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Senior Regulatory Affairs Specialist - UK & Ireland  
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Fax: 01923 202 550

Email: [lezlie.j.bridge@medtronic.com](mailto:lezlie.j.bridge@medtronic.com)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/070** or **2010/006/003/081/021**

### Technical aspects

Enitan Taiwo or Nicole Small  
Medicines & Healthcare products Regulatory Agency  
Market Towers  
1 Nine Elms Lane  
London SW8 5NQ

Tel: 020 7084 3122 / 3310

Fax: 020 7084 3209

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### Clinical aspects

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Medicines & Healthcare products Regulatory Agency  
Market Towers  
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### How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>

Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

## Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre  
Health Estates Investment Group  
Room 17  
Annex 6  
Castle Buildings  
Stormont Estate  
Dundonald BT4 3SQ

Tel: 02890 523 704

Fax: 02890 523 900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

### How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

## Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

Health Facilities Scotland

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

## Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

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