

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/19

Issued: 15<sup>th</sup> February 2007

For:

<b>IMMEDIATE ACTION</b>	✓
ACTION	
UPDATE	
INFORMATION	



**HEALTH ESTATES**

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	Section
<p><b>Medical Device/Equipment:</b> Patient vital signs monitor: Draeger Infinity monitor with Infinity docking station (IDS).</p>	▶ ①
<p><b>Problem:</b> The Infinity docking station mechanism may fail on all models of Infinity monitors. This can result in the monitor falling from its mounting.</p>	▶ ②
<p><b>Action by:</b> Anaesthetists, operating theatre practitioners, intensive care, A&amp;E and technical staff responsible for maintenance.</p>	▶ ③
<p><b>Action:</b></p> <ul style="list-style-type: none"> <li>Identify units that were made or repaired between 15 November 2004 and 08 November 2006.</li> <li>Contact Draeger immediately if the IDS mounting is loose or unsteady.</li> <li>Ensure all users are aware of this problem and that they follow the advice overleaf and in the Draeger notice (see appendix) regarding their continued use until the inspection has been made.</li> </ul>	▶ ④
<p><b>Distributed by NIAIC to:</b> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers <b>For onward distribution see Section 5</b></p>	▶ ⑤
<p><b>Contacts</b> Details of manufacturer contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥
<p><b>Feedback Requirements to NIAIC</b> In accordance with PEL(06)17 acknowledgment of assurance should be given:-</p>	▶ ⑦

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

## **1. DEVICE/EQUIPMENT:**

All models of Infinity docking stations (IDS) that were distributed or repaired between 15 November 2004 and 08 November 2006.

## **2. PROBLEM:**

Draeger has received reports of the IDS top cover assembly separating, which could have been caused by the monitor being docked/undocked from the IDS, or being moved/repositioned, pulled or pushed while on the IDS. This can result in the monitor falling onto the patient or user.

Because affected docking stations cannot easily be identified, units distributed or repaired between the dates above will be inspected by Draeger during the next scheduled service or you will be contacted by Draeger directly. Affected IDSs will be repaired free of charge.

Users who have not been contacted by Draeger should contact the manufacturer to arrange an inspection.

## **3. ACTION BY:**

Anaesthetists, operating theatre practitioners, intensive care, A&E and technical staff responsible for maintenance.

## **4. ACTION:**

If you continue to use an affected IDS unit until it is upgraded, Draeger recommends taking the following precautions (extracted from the appendix):

- consider the patient location relative to the position of the monitor
- adjust the tilt angle of the monitor mount to horizontal to minimise the stress on the IDS
- avoid heavy contact during static and transfer use and during docking and undocking procedures
- do not use undue force to dock/undock the monitor onto/from the IDS.

## **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:

- A&E departments
- Adult intensive care units
- Anaesthetists
- Coronary care departments
- Day surgery units
- EBME departments
- Equipment stores
- High dependency units
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA
- In-house maintenance staff
- Intensive care units
- Maternity units
- Outpatient theatre managers
- Risk managers
- Special care baby units
- Theatre managers

## 6. CONTACTS:

Enquires to the manufacturer should be addressed to:

Mr D Sims  
Quality Manager  
Draeger UK Limited  
The Willows Mark Road  
Hemel Hempstead  
Hertfordshire HP2 7BW

Tel: 01442 213 542

Fax: 01442 240 327

E-mail: [doug.sims@draeger.co.uk](mailto:doug.sims@draeger.co.uk)

Enquires to NIAIC should quote reference number MDEA(NI)2007/19 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](mailto:NIAIC@dhsspsni.gov.uk)

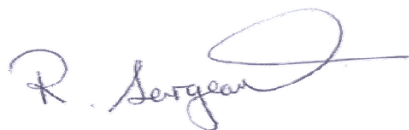
## 7. FEEDBACK:

In accordance with PEL(06)17 the following acknowledgment of assurance should be given:-

**Deadline (Email received) : 16 February 2007**

**Deadline (action underway) : 02 March 2007**

**Deadline (action complete) : 16 March 2007**



Robert Sergeant  
NIAIC Operational 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)2006/01. 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](http://www.dhsspsni.gov.uk/niaic)

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

## APPENDIX to MDEA(NI)2007/019

To all EBME Managers/Risk Managers – NHS Trusts and Hospitals  
Listed on our Installed Database Infinity Docking Stations.

January 2007

Dear EBME Manager/Risk Manager

**Re: Corrective Measures on Draeger Infinity Docking Station**

Please find enclosed details of an Important Safety Notice regarding the Infinity Docking Station. We would be grateful if you could circulate this information to the relevant Clinical Users within your Trust Group, please include any other department you feel may benefit from this notice.

To enable us to monitor the effectiveness of the circulation of the information, we request you confirm receipt of this letter and the enclosed customer information by returning the form titled 'Confirmation of Receipt'.

Please confirm receipt by – 28<sup>th</sup> February 2007.

Draeger remain dedicated to the provision of quality medical devices and a quality customer service, if however you have any further questions or queries regarding our corrective action, please do not hesitate to contact our Quality Department on 01442 213542 or e-mail to [quality@draeger.co.uk](mailto:quality@draeger.co.uk)

Yours sincerely

Quality Department  
**Draeger Medical UK Ltd**

Confirmation of Receipt.

# 1 **FAO: Quality Department**

As EBME Manager/Risk Manager of **Hospital** I would like to confirm I have read and understood the important safety information concerning the Infinity Docking Stations.

Signature:.....

Name:.....

Date:.....

Please return this form by post, email or fax:

Address:  
Quality Department  
Draeger Medical UK Ltd  
The Willows  
Mark Road  
Hemel Hempstead  
Hertfordshire  
HP2 7BW

Email: [qsreturns@draeger.co.uk](mailto:qsreturns@draeger.co.uk)

Fax: 01442 240327

01 Feb 2007

To all customers and users of Draeger Infinity Docking Stations.

**Important Safety Notice!**  
**Corrective measures on the Draeger Infinity Docking Station.**

Dear Sir/Madam,

As part of our world wide post-market surveillance activities, we have learned about events involving Infinity Monitors which are mounted on Infinity Docking Stations (IDS).

The reported events involve the IDS top cover assembly separating. This could be caused by the Monitor being undocked/redocked from/to the IDS. The separation may also occur through the Monitor being moved or repositioned, including being pulled or pushed, whilst on the IDS. This situation can result in the Monitor falling from the IDS, which could result in injury to staff or patients.

Investigation with our supplier has revealed that affected Docking Stations cannot be easily identified. Therefore, it is necessary to perform an inspection of all IDS models distributed or repaired within a specific time frame - between 15<sup>th</sup> November 2004 and 8<sup>th</sup> November 2006. The potentially affected world wide installed base is 23,345 units. We have reports of seven events occurring in this population. The relevant competent authority has been informed about this action.

Our records indicate that potentially affected IDS' are installed at your facility. A Draeger Service Representative will inspect these devices during the next scheduled service visit, or you will be contacted directly to schedule an inspection. Should an IDS at your facility be affected, it will be repaired free of charge.

Meanwhile, your IDS' may continue to be used, but we suggest that you take the following precautionary measures:

- Inform all users of Patient Monitors/IDS' within your organisation of this situation.
- Consider the patient location relative to the position of the Patient Monitor/IDS.
- Adjust the tilt angle of the Patient Monitor mount to horizontal, to minimise stress on the IDS.
  
- Be aware of user contact with the Patient Monitor/IDS during both static and transfer use.
- Be aware of user contact with the Patient Monitor/IDS during docking/undocking procedures.
- Do not use undue force to dock/undock the Patient Monitor to/from the IDS.

Should you notice that any of your IDS' appear loose or unsteady, please contact your Draeger Service Representative immediately.

Draeger Medical Inc. is committed to customer satisfaction. We apologise for any inconvenience this action may cause and appreciate your patience and co-operation.

If you have any questions or comments, please contact your Draeger Service Representative.

Sincerely,

Draeger Medical Inc.