

Medical Device/Equipment ALERT

Ref.MDEA(NI)2008/065

Issued: 13th August 2008

For:

IMMEDIATE ACTION	
ACTION	
UPDATE	
INFORMATION	✓



HEALTH ESTATES

creating healing environments

	Section			
<p>Medical Device/Equipment: Sonesta 6210 fluoroscopy procedure table manufactured by Stille. <i>It is understood that none of these devices have been supplied to the HSC within Northern Ireland</i></p>	▶ ①			
<p>Problem: The MHRA has received a report of uncontrolled movement of this device caused by a short circuit in the handset. The device has a battery backup and movement cannot be stopped by disconnecting the device from the mains. There is a risk of serious patient injury if this failure occurs during examination with the c-arm.</p>	▶ ②			
<p>Information to: Users of similar devices.</p>	▶ ③			
<p>Action: Until further advice is given by Stille, users of the Sonesta 6210 should:</p> <ul style="list-style-type: none"> consider using an alternative examination table; if use of the table is unavoidable, consider removing/disconnecting the battery backup formulate procedures to remove the patient in case of uncontrolled movement of the table. 	▶ 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 For onward distribution see Section 5</p>	▶ ⑤			
<p>Contacts Details of manufacturer contacts and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥			
<p style="text-align: center;">Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</p> <table border="1" style="width: 100%;"> <tr> <td>Acknowledge Receipt of Alert: 15th Aug 2008</td> <td>Action Under Way: Not applicable</td> <td>Action Complete: Not applicable</td> </tr> </table>	Acknowledge Receipt of Alert: 15 th Aug 2008	Action Under Way: Not applicable	Action Complete: Not applicable	▶ ⑦
Acknowledge Receipt of Alert: 15 th Aug 2008	Action Under Way: Not applicable	Action Complete: Not applicable		

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

1. DEVICE/EQUIPMENT:

The Sonesta 6210 table is intended to be used during video fluoroscopy examinations and procedures.

All movements are mains powered and there is a battery backup facility.

All movements are controlled by a single handset.

It is understood that none of these devices have been supplied to the HSC within Northern Ireland

2. PROBLEM:

The MHRA has received a report of uncontrolled movement of this device caused by a short circuit in the handset. The device has a battery backup and movement cannot be stopped by disconnecting the device from the mains. There is a risk of serious patient injury if this failure occurs during examination with the c-arm.

3. INFORMATION TO:

Users of similar devices.

4. ACTION:

Until further advice is given by Stille, users of the Sonesta 6210 should:

- consider using an alternative examination table; if use of the table is unavoidable, consider removing/disconnecting the battery backup
- formulate procedures to remove the patient in case of uncontrolled movement of the table.

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:

- Biomedical engineering staff
- Biomedical science departments
- EBME departments
- Radiographer superintendents
- Radiographers
- Radiologists
- Radiology directors
- Risk managers
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Cecilia Österkvist
Stille AB, Quality Department
Sundbybergsvägen 1A
SE-171 73 , Solna
Sweden

Tel: +46 8 588 58 029

Fax: +46 8 588 58 005

Cell: +46 730 333 864

E-mail: cecilia.osterkvist@stille.se

Web: www.stille.se

Enquiries to NIAIC should quote reference number MDEA(NI)2008/065 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


Robert Sergeant
NIAIC Operational Manager