

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/79

Issued: 18th September 2007

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
<p>Medical Device/Equipment: Electrosurgery bipolar unit: model TDB 60 manufactured by Eschmann Ltd (serial numbers with the last six digits from 5D-1201 to 7D-1273 inclusive are affected - see appendix for full list of serial numbers).</p>	▶ ①
<p>Problem: Failure of a component in the main control board may lead to the power output being up to four times that displayed on the front panel. As a precautionary measure, Eschmann are changing the main control board of affected units.</p>	▶ ②
<p>Action by: Surgeons, theatre managers, operating theatre staff and all those who maintain and service these devices.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> • Locate and check TDB 60 units against the list of serial numbers (see appendix). • If you have an affected unit, check that the manufacturer has changed the main control board. If not, contact Eschmann to arrange fitting. • Ensure that users of affected devices are aware of this potential problem. 	▶ 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 aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC 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:

Electrosurgery bipolar unit: model TDB 60 manufactured by Eschmann Ltd (serial numbers with the last six digits from 5D-1201 to 7D-1273 inclusive are affected - see appendix for full list of serial numbers).

2. PROBLEM:

There have been no reported incidents of this problem occurring during clinical use. The manufacturer has indicated that the likelihood of failure is low. Patient injury is also unlikely but in exceptional circumstances localised serious tissue damage may occur. The manufacturer has indicated that the units may continue to be used whilst awaiting the upgrade.

3. ACTION BY:

Surgeons, theatre managers, operating theatre staff and all those who maintain and service these devices.

4. ACTION:

- Locate and check TDB 60 units against the list of serial numbers (see appendix).
- If you have an affected unit, check that the manufacturer has changed the main control board. If not, contact Eschmann to arrange fitting.
- Ensure that users of affected devices are aware of this potential problem.

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:

- Clinical governance leads
- EBME departments
- Health and safety managers
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA
- Medical directors
- Medical physics departments
- Nursing executive directors
- Operating department practitioners
- Outpatient theatre managers
- Outpatient theatre nurses
- Purchasing managers
- Risk managers
- Supplies managers
- Surgeons
- Theatre managers
- Theatre nurses
- Theatres

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Quality Affairs Department
Eschmann Equipment
Eschmann House
Peter Road
Lancing
West Sussex
BN15 8TJ

Tel: 01903 753 322

Fax: 01903 875 710

E-mail: quality_affairs@eschmann.co.uk

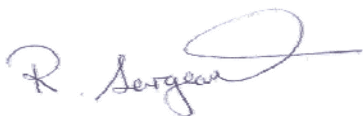
Enquiries to NIAIC should quote reference number MDEA(NI)2007/79 and be addressed to:
Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868
Fax: 028 9052 3900
Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

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

Deadline (Email received)	: 21st Sept 2007
Deadline (action underway)	: 26th Sept 2007
Deadline (action complete)	: 9th Oct 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

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

Appendix to MEDA(NI)2007/79

List of serial numbers of affected TDB 60 units

5D-1201 5D-1202 5D-1204 5D-1205 5D-1206 5D-1207 5D-1208 5D-1209
5D-1211 5D-1210 5D-1212 5D-1213 5D-1214 5D-1215 6F-1247 5G-1216
5G-1217 5G-1219 6A-1239 5G-1220 5G-1221 5G-1222 5G-1223 5G-1224
5G-1225 5I-1226 5I-1229 5L-1230 5L-1231 5L-1233 5L-1234 6AF-1235
6A-1236 6A-1237 6A-1238 6E-1240 6E-1243 6E-1244 6F-1245 6F-1246
6F-1248 6F-1249 6F-1250 6F-1251 6F-1252 6F-1253 6K-1255 6K-1256
6E-1242 6K-1257 6K-1258 6K-1259 6K-1260 6K-1261 6K-1262 6K-1263
6K-1264 7C-1265 7C-1266 7C-1267 7C-1268 7C-1269 7C-1270 7D-1271
7D-1272 7D-1273