

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/022

Issued: 27th March 2008



HEALTH ESTATES

creating healing environments

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	

	Section
Medical Device/Equipment: Hospital beds Eleganza Standard, Smart and Deluxe models supplied by Pegasus.	▶ ①
Problem: The emergency backrest release function on these beds may fail or become stiff and difficult to operate leading to a risk of delay in performing CPR.	▶ ②
Action by: All those using, providing and maintaining hospital beds. In particular bed managers, nurses, care staff, maintenance staff and contractors.	▶ ③
Action: <ul style="list-style-type: none"> Trace all Eleganza Standard, Smart and Deluxe beds that are in use or in storage. From these identify beds that are fitted with Dewert actuators (see page 2). Check that the electrical and manual CPR functions are operating correctly (see page 2). Contact Linet UK to arrange for all Dewert backrest actuators to be exchanged (see contact on page 3). 	▶ ④
Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers Hospices	▶ ⑤
Contacts Details of manufacturer and NIAIC contacts for technical and clinical aspects.	▶ ⑥
Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)	▶ ⑦
Acknowledge Receipt of Alert: 31 st March 2008	Action Under Way: 28 th April 2008
Action Complete: 27 th June 2008	

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

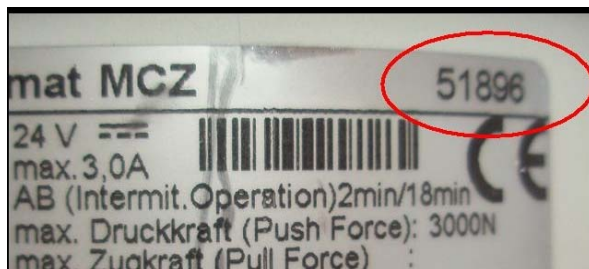
1. DEVICE/EQUIPMENT:

Hospital beds Eleganza Standard, Smart and Deluxe models fitted with Dewert back rest actuators. These beds were manufactured by Linet and supplied in the UK labelled as Pegasus (see appendix for serial numbers).

The beds have an emergency CPR release function on the backrest to provide a level platform for CPR. This function can be operated either electrically by the attendant control panel, or manually using the CPR lever on either side of the backrest frame.

Actuators from various manufacturers were fitted during production but this problem only affects actuators manufactured by Dewert. The labels on these actuators will have the name Dewert and an article number on the top right hand side.

All Dewert actuators in the UK have article numbers 46844 or 51896 (see image below).



A list of the model and serial numbers of beds fitted with Dewert actuators is given in the appendix.

2. PROBLEM:

It has been found that over time a component inside the Dewert backrest actuator can wear and move out of position. This makes the emergency CPR release function difficult to operate or fail completely whilst being operated manually or from the control panel. This may result in a delay in performing CPR.

The manufacturer has now modified the actuators to prevent this problem occurring for new models and is carrying out an exchange programme for those already in the field.

3. ACTION BY:

All those using, providing and maintaining hospital beds. In particular bed managers, nurses, care staff, maintenance staff and contractors.

4. ACTION:

For both the electrical and manual emergency CPR functions:

- check that the backrest operates correctly in the upward and downward directions from both the patient handset and the attendant control panel
- check that the backrest adjusts to a level platform when the electrically operated emergency CPR release function is operated by the attendant control panel
- check that the backrest adjusts to a level platform when the manual emergency CPR release function is operated in accordance with the instructions for use provided with the bed.

Contact Linet UK to pass on the outcome of the checks and to arrange for the replacement of all Dewert actuators (see contact details on page 3).

- Beds with backrests that are inoperative or those with stiff or difficult to operate backrests that may be at risk of an actuator failure in the near future, will be given priority for replacement. Dewert actuators that are operating correctly when checked still need to be replaced to remove the possibility of failure in the future.

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
- All wards
- Day surgery units
- EBME departments
- Equipment stores
- Health and safety managers
- Intensive care units
- Maintenance staff and contractors
- Care management team managers
- Community care staff
- Medical directors
- Nursing executive directors
- Nursing staff
- Outpatient clinics
- Resuscitation officers and trainers
- Risk managers
- Supplies managers
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Natalie York
Linnet UK
Linnet House
17 Murrills Estate
Portchester
Hampshire PO16 9RD

Tel: 02392 322 135
Fax: 02392 389 540

E-mail: nyork@linet.uk.com

Enquiries to NIAIC should quote reference number MDEA(NI)2008/022 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

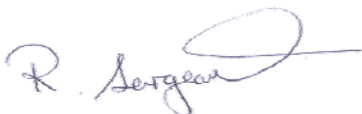
7. FEEDBACK:

Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

Acknowledge Receipt of Alert:
31st March 2008

Action Under Way:
28th April 2008

Action Complete:
27th June 2008



Robert Sergeant
NIAIC Operational Manager

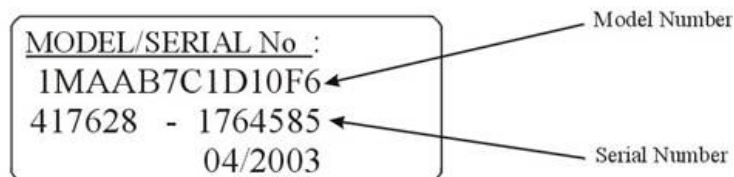
HOW TO REPORT ADVERSE INCIDENTS

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)2007/01. 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 MDEA(NI)2008/022

Below is a table of the model numbers and corresponding serial numbers for beds fitted with the affected Dewert actuators. The label showing the model and serial numbers is located towards the foot end of the base frame of the bed on the left hand side (as viewed from a patient perspective).



Model number	Serial numbers
1GSMA731310600X	01973000 – 01973099, 01973100 – 01973129, 01972974 – 01972999, 02113079 – 02113099, 02113100 – 02113132
1GSMA731110600X	01957256 – 01957299, 01957300 – 01957359, 02113133 – 02113199, 02113200 – 02113294, 02265483 – 02265499, 02265500 – 02265538, 02265595 – 02265599, 02265600 – 02265650, 02265707 – 02265762, 02265819 – 02265830, 02418205
1GLM3G31150600X	02027767 – 02027799, 02027800 – 02027813, 02028100 – 02028149, 02028038 – 02028099, 02127132, 02134414
1GLM3731650600X	02078419 – 02078436
1GSMA73191064X	02128227 – 02128299, 02128300 – 02128394, 02253051 – 02253099, 02253100 – 02253199, 02253200 – 02253218, 02372212 – 02372267, 02372324 – 02372379, 02388403 – 02388458, 02388515 – 02388570, 02390492 – 02390499, 02390500 – 02390547, 02390604 – 02390659, 02474217 – 02474272, 02474144 – 02474160, 02474105 – 02474143, 02468539 – 02468594, 02472269 – 02472299, 02472300 – 02472324, 02472381 – 02472399, 02472400 – 02472436, 02472493 – 02472499, 02472500 – 02472548, 02474329 – 02474384, 02474441 – 02474496, 02474553 – 02474599, 02474600 – 02474608, 02474665 – 02474699, 02474700 – 02474720
1GLM4731650600X	02135057 – 02135099, 02135100 – 02135108, 02243446 – 02243499, 02243500 – 02243535, 02243540 – 02243599, 02243600 – 02243634, 02301770 – 02301795, 02388262 – 02388289, 02418222 – 02418225
1GSN7735320600	02144617 – 02144619, 02255130 – 02255132
1GLM4332650600X	02163280 – 02163299, 02163300 – 02163311, 02189714, 02243760 – 02243761, 02596475
1GLM2632110600X	02189724 – 02189727
1GSM8731110600X	02203325 – 02203371, 02322193 – 02322199, 02322200, 02527372 – 02527374, 02593485 – 02593499, 02593500 – 02593516
1GLN2632310600X	02204308 – 02204333, 02459692 – 02459697
1GLM4731310600X	02204334 – 02204399, 02204400 – 02204422, 02459670 – 02459680
1GSM6132350600X	02227140 – 02227141, 02557101 – 02557106, 20053003592 – 20053003599, 20053003600 – 20053003603
1GSM8731310600X	02230283 – 02230286, 02460009 – 02460032, 02629373 – 02629378
1GSMA731340600X	02251038 – 02251039
1GLM1332310600X	02263023 – 02263026
1GLM3931650689X	02290660 – 02290699, 02290700 – 02290706
1GLM2332310600X	02390136 – 02390139
1GSM8332110600X	02408030 – 02408032

APPENDIX to MDEA(NI)2008/022

1GMR1112	20053049412 – 20053049499, 20053049500 – 20053049523, 20053052406 – 20053052467, 20053056517 – 20053056572, 20053046857 – 20053046899, 20053057442 – 20053057497, 20053046900 – 20053046912, 20053052356 – 20053052399, 20053054462 – 20053054499, 20053046969 – 20053046999, 20053047000 – 20053047024, 20053054500 – 20053054517, 20053062400 – 20053062405
1GMR1112-5	20060037757 – 20060037781, 20060037349 – 20060037399, 20060037325 – 20060037348, 20060037465 – 20060037499, 20060037400 – 20060037436, 20060037804 – 20060037859, 20060035811 – 20060035845, 20050001185 – 20050001199, 20050001200 – 20050001240, 20060035846 – 20050035864, 20060037500 – 20060037520
1GS1100	20053038869 – 20053038899, 20053064447 – 20053064499, 20053037934 – 20053037989, 20053049539 – 20053049599, 20053049600 – 20053049650, 20060007820 – 20060007874, 20060017396 – 20060017399, 20060017400 – 20060017451, 20053064500 – 20053064502, 20053063571 – 20053063599, 20053082300 – 20053082355, 20060003153 – 20060003199, 20060006358 – 20060006399, 20060006400 – 20060006413, 20053034961 – 20053034977, 20053054703 – 20053054756, 20053034922 – 20053034960, 20053066305 – 20053066360, 20060018376 – 20060018399, 20060018400 – 20060018431, 20053037200 – 20053037225, 20053037170 – 20053037199, 20060032875 – 20060032899, 20060032900 – 20060032930, 20053033538 – 20053033593, 20060001976 – 20060001999, 20060002000 – 20060002031, 20053066700 – 20053066719, 20053038900 – 20053038924, 20060007875, 20053063600 – 20053063626, 20053066664 – 20053066699, 20060003200 – 20060003208
1GMR1112-2	20053066800 – 20053066879, 20053066768 – 20053066799, 20053069035 – 20053069095, 20053068984 – 20053068999, 20053069000 – 20053069034
1GMR1112-3	20053079113 – 20053079132, 20053079133 – 20053079168, 20053077523 – 20053077599, 20053073611 – 20053073666, 20053077827 – 20053077899, 20053077900 – 20053077938, 20053075783 – 20053075799, 20053075800 – 20053075838, 20060002066 – 20060002099, 20060002100 – 20060002111, 20053077600 – 20053077634, 20053074597 – 20053074599, 20053074600 – 20053074652
1GMR1112-1	20053046913 – 20053046968, 20053050520 – 20053050575
1GMR4012-3	20053075840, 20060006844
1GMR4002	20053094354 – 20053094399, 20053088800 – 20053088899, 20053088900 – 20053088969, 20053090557 – 20053090599, 20053087356 – 20053087399, 20053088746 – 20053088799, 20053087400 – 20053087467, 20053098242 – 20053098297, 20053090600 – 20053090612, 20053090500 – 20053090530, 20053090497 – 20053090499, 20053090531 – 20053090552, 20053090031 – 20053090086, 20060002061 – 20060002062, 20053092247 – 20053092278, 20053087328 – 20053087337, 20053098308 – 20053098311, 20053094400 – 20053094465
1GS3321-1	20053066720 – 20053066760, 20053038196 – 20053038197, 20053034894 – 20053034897, 20053066303 – 20053066304, 20053056687 – 20053056698
1GS3313-1	20060005754 – 20060005793, 20060024918 – 20060024920
1GMR1111-61	20060033300 – 20060033399, 20060033289 – 20060033299, 20060033400
1GMR0002	20053085774 – 20053085799, 20053085800 – 20053085829, 20053085679 – 20053085699, 20053085700 – 20053085734, 20053085623 – 20053085678, 20053085832, 20053092233 – 20053092246, 20060001138 – 20060001191
1GSM87319509J8	20053025579 – 20053025599, 20053025600 – 20053025622, 20053021507 – 20053021562
1GS3313-2	20060033436 – 20060033437
1GS1121-9	20053060160 – 20053060183, 20053066300 – 20053066302
1GS3421-2	20053064865 – 20053064866, 20053066643 – 20053066646, 20053066615 – 20053066632
1GS3313	20053058110 – 20053058115
1GLM2632310600	20053013711 – 20053013717
1GL2121-62	20053056681
1GMR1121-58	20060037865 – 20060037899, 20060037900 – 20060037904
1GS3421-3	20053066633 – 20053066642

APPENDIX to MDEA(NI)2008/022

1GL2121-194	20060022118
1GL2221-48	20060035504 – 20060035508, 20060011522
1GS2421-8	20053049535 – 20053049538
1GS3421-4	20053082844 – 20053082845
1GSM6332310600	20053013718 – 20053013727, 20053022251 – 20053022252
1GLM3731116600	20053005857 – 20053005856
1GMR1112-4	20060004660 – 20060004670
1GMR1121-40	20060009986 – 20060009987, 20060030822 – 20060030828
1GMR0021-3	20060037905 – 20060037910
1GL2221-57	20060023923
1GL3521	20053096442
1GMR3311	20060038088
1GL9921	20053064346
1GS2313-39	20053096727
1GL2721	20053082369
1GLM4731310600	20053013728
1GSQ7731350600	20053005845