

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/13

Issued: 7 February 2007

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
<p>Medical Device/Equipment: Lucas external cardiac compressor, manufactured by Jolife AB and distributed by Medtronic Ltd.</p>	▶ ①
<p>Problem: The MHRA has received reports of:</p> <ul style="list-style-type: none"> • inadequate ventilation in non-intubated patients • thoracic cage and lung damage • raised levels of atmospheric oxygen in ambulances where the device is powered by an oxygen supply. 	▶ ②
<p>Action by: First responders, ambulance staff, A&E staff, cardiology staff and cardiothoracic surgical staff.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> • Ensure that all users of this device are aware of the ventilation update to the instructions for use (IfU) from Jolife AB, appended to this Alert. • If the device is powered by oxygen always ensure there is an adequate oxygen supply for both the Lucas device and the patient's respiratory requirements. 	▶ 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</p>	▶ ⑤
<p>Contacts Details of manufacturer/supplier contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC None Required</p>	▶ ⑦

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

1. DEVICE/EQUIPMENT:

The Lucas external cardiac compressor is used for external cardiac chest compressions on adult patients who have acute circulatory arrest. The manufacturer defines this as the absence of spontaneous breathing, no pulse and the loss of consciousness. This device is only intended for temporary use where manual resuscitation would otherwise be used.

The model of device presently used in the UK, with serial numbers up to and including 14063999, is powered by either oxygen or medical air from the wall outlets of hospitals and ambulances, or from cylinders. This model was manufactured up to May 2006 and uses IfU 100081-00 Rev B. Copies of the device's instructions for use and its ventilation update, are available from the manufacturer's website www.lucascpr.com/lucas.php?sid=9

Device users should ensure they use the appropriate instructions for their device, as there is a new model with serial numbers from 14064000 which is powered by medical air only.

2. PROBLEM:

The MHRA has received reports of:

- inadequate ventilation in non-intubated patients
- thoracic cage and lung damage
- raised levels of atmospheric oxygen in ambulances where the device is powered by an oxygen supply.

3. ACTION BY:

First responders, ambulance staff, A&E staff, cardiology staff and cardiothoracic surgical staff.

4. ACTION:

- Ensure that all users of this device are aware of the ventilation update to the instructions for use from Jolife AB, appended to this Alert. This now states that when used in non-intubated patients the device can be safely stopped to allow intermittent manual ventilation.
- Ensure the device is placed correctly, according to its instructions for use (IfU).
- If the device is powered by oxygen and used in confined spaces (e.g. ambulances) ensure there is adequate ventilation. In ambulances always run the ventilation at the highest capacity and do not recirculate the air.
- If the device is powered by oxygen always ensure there is an adequate oxygen supply for both the Lucas device and the patient's respiratory requirements.

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 consultants
- A&E departments
- A&E directors
- A&E nurses
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic nursing staff
- Anaesthetists
- Cardiac laboratory technicians
- Cardiac pacing technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic nurses
- Cardiothoracic surgeons
- Cardiothoracic surgery, directors of
- Clinical governance leads
- Coronary care departments
- Coronary care nurses
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA
- Medical directors
- Nurse executive directors
- Paramedics
- Resuscitation officers and trainers
- Risk managers

6. CONTACTS:

Enquires to manufacturer or supplier should be addressed to:

Manufacturer:

Jolife AB
Ingmar Malm, Quality Manager
Ideon
22370 LUND
Sweden

Tel: 0046 46 286 5011

Fax: 0046 46 286 5010

E-mail: ingmar.malm@jolife.com

Supplier:

Medtronic Ltd
Dr David Dunham,
Suite One
Sherbourne House
Croxley Business Centre
Watford WD18 8WW

Tel: 01923 212 213

E-mail: david.dunham@medtronic.com

Enquires to NIAIC should quote reference number MDEA(NI)2007/13 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)

Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

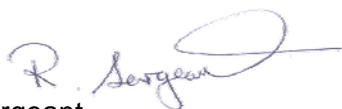
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None required



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



PLEASE NOTE,

Amendment to the Instruction for Use for LUCAS with serial numbers less than 1406 4000 regarding ventilation during LUCAS compressions.

Ventilation with LUCAS in a non intubated patient

When LUCAS is used on a non intubated patient the device can safely be stopped allowing intermittent manual ventilation. Switch off the device by turning the ON/OFF knob to the **Lock** position, ventilate and turn the ON/OFF knob back to the **Active** position again.

Ventilation with LUCAS in an intubated patient (advanced airway)

When using LUCAS on an intubated patient, there is no need to interrupt LUCAS chest compressions for ventilation. Ventilate according to guidelines for advanced life support.