URGENT Field Safety Notice

LUCAS™ 2 Chest Compression System
Medical Device Correction

February 2011

Medtronic Reference: FA508

RE: LUCAS™ 2 Chest Compression System

Dear Customer,

What is the issue?
Jolife AB, with the servicing support assistance of Physio-Control, a division of Medtronic, Inc., is conducting a voluntary upgrade of the LUCAS 2 Chest Compression System. Specific LUCAS 2 devices manufactured in April 2009 through December 2010 have been experiencing device malfunctions resulting from the failure of a hood probe on the device that connects to the battery. If the device malfunctions it will stop in fail safe mode and the LEDs will start flickering or the device will switch off. No adverse patient events have been reported related to this issue.

Am I affected by this issue?
Your facility has been identified as having received a LUCAS 2 System shipped between April 2009 and December 2010 within the affected serial number range of 30090016 through 30101932. Devices shipped in 2011, beginning with serial number 30101933, incorporated the improved hood probe and are excluded from this correction. The serial number label is located on the inside of the leg of the device.

What should I do?
Keep LUCAS 2 in service and continue to use it in accordance with the Instructions For Use, described below:
Section 3.8 - Safety Precautions. WARNING – MALFUNCTION.
If there are interruptions, or the compressions are not sufficient or something unusual occurs during operation: Push ON/OFF for 1 second to stop LUCAS and remove the device. Start manual chest compressions.

Serial numbers starting with 30101200 and higher have been observed to be more likely to experience this issue and servicing devices in this serial number range will be prioritized. For serial numbers outside of this range, the connector board will be replaced within 12 months or as part of your next scheduled preventative maintenance if this occurs earlier.

Your local Physio-Control service representative will contact you within 60 days to schedule a service call to replace the affected connector board. If your device exhibits any problems prior to your scheduled servicing, please call your local area service support center.

What if I don't have the affected device any longer or the device location has changed?

If you no longer own a LUCAS 2 Chest Compression System, please contact Physio-Control Technical Support as soon as possible to ensure accurate updating of your account.

The Competent Authority of your country has been notified of this action.

If you have any questions regarding this action, please visit the Physio-Control website at www.physio-control-notices.com/LUCAS2 or call your local area service support center.

Thank you for your cooperation.

Sincerely,

[Country Manager Name]