Medical device recall – defibrillator

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We have been passed a recall notice, copied below, put out by Laerdal Medical Ltd regarding its Heartstart 3000 and 3000QR defibrillators.

URGENT: MEDICAL DEVICE RECALL	Laerdal
AFFECTED PRODUCT	**Product:** Laerdal Heartstart 3000 and Heartstart 3000QR Semi-Automatic Defibrillator **Manufactured by:** Laerdal Medical As, PO Box 377, N-4001 Stavanger, Norway
REASON FOR RECALL	Affected Laerdal Heartstart 3000 and Heartstart 3000QR Defibrillator may cease operation and display *Service Mandatory NO 9 Transistor Voltage* during charging period due to failure of a component on the High Voltage Board. The instance occurs when the unit is subjected to the combination of high humidity and high temperature. There is no early indication or warning that the fault has or will occur before the charging for shock delivery. Laerdal Medical AS have confirmed 6 such failures among approximately 1400 devices shipped since 1998. All these failures have been in one country, namely Japan, during conditions of both high humidity and high temperature: no such failure has been reported from any other country. Nevertheless, although this number of failures is low and restricted to one country, we are taking this action because there is a potential for additional failures.
HAZARD INVOLVED	• The clinician would be unable to get the device to function • The patient would be prevented from receiving therapy
HOW TO IDENTIFY	• Laedal Heartstart 3000 and Heartstart 3000QR • Serial Numbers: 19230-21718
REQUIRED ACTION	• You will be receiving a call from a Laedal Medical representative within the next 4 to 6 weeks to schedule a repair. We have identified the correction and are in the process of providing new components. • If an effected unit is likely to be used during conditions of both high humidity and high temperature, we recommend the affected unit is tested in similar conditions by giving a series of three shocks into a tester or other appropriate device. • If you have questions about this recall notice, please call your local Laerdal Medical company or Laerdal Medical dealer.