Class 2 Device Recall Physio Control LIFEPAK 1000 Defibrillator

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Class 2 Recall
Physio Control LIFEPAK 1000
Defibrillator

See Related Information[21]

Date Posted	May 23, 2014
Recall Status[1]	Open
Recall Number	Z-1660-2014
Recall Event ID	67963[22]
Premarket Notification 510(K) Number	K042404[23]
Product Classification	Automated External Defibrillators (Non-Wearable)[24] - **Product Code** MKJ[25]
Product	LIFEPAK 1000 defibrillator. The LP1000 (in AED mode) is indicated for use on patients in cardiac arrest.
Code Information	Affected Part Numbers: 320371500XXX
Recalling Firm/ Manufacturer	Physio-Control, Inc. 11811 Willows Rd Ne Redmond, Washington 98052-2003
For Additional Information Contact	Physio Control 425-867-4000
Manufacturer Reason for Recall	Physio-Control has become aware of incidents where customers have attempted to use their LIFEPAK 1000 defibrillator and the device has shut down unexpectedly due to a very low battery. A defibrillator in this scenario has the potential to fail to deliver a shock, with the potential result that therapy is not delivered and a patient is not resuscitated. A software malfunction in the LIFEPAK 100
FDA Determined Cause [2]	PRODUCTION CONTROLS: Software Manufacturing/Software Deployment
Action	On May 9, 2014 Physio-Control sent an Urgent Medical Device Recall Letter (dated May 2014) to all affected customers. The letter identified the product, the problem and the action needed to be taken by the customer. The customer notification letter will provide new instructions on how to check the functional and power readiness of the device and advise the customer on the actions to take based on the symbol displayed. Customers are asked to record the readiness indicator(s) shown on each device and fax the confirmation sheet back to Physio-Control at 1-866-448-9567. Customers are also directed to contact Physio-Control at 1-800-442-1142 to obtain replacement batteries, if needed. Customers are provided a Device Readiness Guide for use in interpreting the Readiness Display on the device, and are directed to refer to the Operating Instructions which were provided upon purchase. In addition to notifying Physio-Control of any potential quality problems or adverse reactions or events experienced associated to the use of these products, Physio-Control asks customers to report directly to the FDA through the MedWatch Adverse Reporting Program online, by regular mail or by fax. Physio-Control reminds customers that it is critically important in understanding what the device and battery indicators mean on your defibrillator and what actions you need to take as a result. At any time the battery charge can be verified by following the instruction provided on page 2-5 of the Operating Instructions. It is also important that you always carry a spare fully-charged battery, as stated in the Operating Instructions. Customers are directed to call Physio-Control at 1-800-442-1142, 6:00 a.m. to 4:00p.m. (Pacific), Monday - Friday for any further questions.

Quantity in Commerce	96,261 total; 40,818 within the US and 55,281 outside US.
Distribution	Worldwide Distribution-USA (nationwide) and the countries of Canada, Albania, Lebanon, Austria, Libya, Bahrain, Lithuania, Bangladesh, Barcedonia, Belgium, Maldives, Bosnia/Herzegovina, Malta, Canary Islands, Morocco, Croatia, Namibia, Cyprus, Netherlands, Czech Republic, Niger, Denmark, Norway, Egypt, Oman, Faroe Islands, Pakistan, Finland, Poland, France, Portugal, Gabon, Qatar, Georgia, Reunion, Germany, Romania, Greece, Russian Federation, Hungary, San Marino, Iceland, Saudi Arabia, India, Serbia, Iran, Slovakia, Iraq, Slovenia, Ireland, South Africa, Israel, Spain, Italy, Sweden, Ivory Coast, Switzerland, Jordan, Tunisia, Kazakhstan, Turkey, Kenya, Turkmenistan, Kuwait, Ukraine, Latvia, UAE, UK, Zambia, Asia Pacific: Australia, Korea, Brunei, Malaysia, Cambodia, Myanmar, China, New Caledonia, French Polynesia, New Zealand, Hong Kong, Philippines, Indonesia, Singapore, Sri Lanka, Taiwan, Thailand, Japan, Latin America: Argentina, Curacao, Barbados, Ecuador, Bolivia, French Guiana, Brazil, Guatemala, Cayman Islands, Honduras, Chile, Mexico, Colombia, Panama, Costa Rica, Peru, Suriname, and Uruguay.
Total Product Life Cycle	TPLC Device Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database	510(K)s with Product Code = MKJ and Original Applicant = MEDTRONIC EMERGENCY RESPONSE SYSTEMS, INC.[28]

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
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4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfRL/rl.cfm
9. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
10. /scripts/cdrh/cfdocs/cfRES/res.cfm
11. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
12. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
13. /scripts/cdrh/cfdocs/cfStandards/search.cfm
14. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
15. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
16. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
17. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
18. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
19. /scripts/cdrh/cfdocs/cfClia/Search.cfm
20. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
21. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
22. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=67963
23. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K042404
24. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=MKJ
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=MKJ