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MAUDE Adverse Event Report

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PHYSIO-CONTROL, INC. LIFEPAK 12 DEFIBRILLATOR/MONITOR SERIES

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Model Number LIFEPAK 12

Event Date 03/19/2008

Event Type Malfunction

Event Description

Physio-control engineering has investigated an occurrence where the mfr of the biphasic to therapy pcb flex cable, designator w20, discovered tin whisker growth which may cause a shorting of the flex cable. Shorting of the flex cable may result in failure to charge or transfer energy. There have been no confirmed failures of distributed devices related to this issue.

Manufacturer Narrative

The physio-control investigation determined the root cause of the reported problem to be the use of rohs compliant material in the manufacturing of the flex cable. It was determined that no field action was warranted. Manufacturing of the flex cable has returned to using non-rohs compliant material, which inhibits the growth of tin whiskers.

Search Alerts/Recalls

New Search | Submit an Adverse Event Report

Brand Name	LIFEPAK 12 DEFIBRILLATOR/MONITOR SERIES
Manufacturer *(Section D)*	PHYSIO-CONTROL, INC. Redmond WA
Manufacturer *(Section G)*	

Manufacturer Contact	Bill Garthe 11811 Willows Rd., N.e. Redmond , WA 98073-9706 (425) 867 -4000
Device Event Key	1269780
MDR Report Key	1058224
Event Key	1016335
Report Number	3015876-2008-00582
Device Sequence Number	1
Product Code	MKJ
Report Source	Manufacturer
Source Type	Other
Reporter Occupation	Other
Type of Report	Initial
Report Date	03/19/2008
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	06/09/2008
Is This An Adverse Event Report?	No
Is This A Product Problem Report?	Yes
Device Operator	Health Professional
Device MODEL Number	LIFEPAK 12
Device Catalogue Number	VLP12-02B
Was Device Available For Evaluation?	Yes
Is The Reporter A Health Professional?	Yes
Event Location	Other
Was The Report Sent To Manufacturer?	No
Date Manufacturer Received	02/29/2008
Was Device Evaluated By Manufacturer?	Yes
Is The Device Single Use?	No
Is this a Reprocessed and Reused Single-Use Device?	No

Is the Device an Implant? No

Is this an Explanted Device?

Type of Device Usage Reuse

Patient TREATMENT DATA

Date Received: 06/09/2008 Patient Sequence Number: 1

#	Treatment	Treatment Date
1,NA		