MAUDE Adverse Event Report

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.
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

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