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MAUDE Adverse Event Report: PHILIPS MEDICAL SYSTEMS AVALON FM30 FETAL MONITOR



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PHILIPS MEDICAL SYSTEMS AVALON FM30 FETAL MONITOR

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Model Number M2703A

Event Date 02/03/2019

Event Type Death

Manufacturer Narrative

A follow up report will be submitted once the investigation is complete. Serial number not provided at time of report.

Event Description

The customer reported the death of a newborn after an emergency c-section and 19 minutes of attempted resuscitation. According to the customer (biomedical engineer) and caregivers, artifacts between the mother's pulse and the fetus' pulse rate were identified. But they think the device worked properly.

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Brand NameAVALON FM30 FETAL MONITOR
Type of DeviceFETAL MONITOR
Manufacturer (Section D)PHILIPS MEDICAL SYSTEMS
Hewlett-Packard Str.2
Boeblingen 71034
GERMANY 71034
Manufacturer (Section G)PHILIPS MEDICAL SYSTEMS
3000 Minuteman Road
Andover MA 01810
Manufacturer ContactBetty Harris
Hewlett-Packard Str.2
Boeblingen 71034
GERMANY 71034
MDR Report Key8331468
Report Number9610816-2019-00044
Device Sequence Number1
Product Code

[HGM](#)²⁴**Report Source**Manufacturer**Source Type**FOREIGN,USER FACILITY**Reporter Occupation**BIOMEDICAL ENGINEER**Type of Report**Initial**Report Date**02/05/2019**1 Device Was Involved in the Event****1 Patient Was Involved in the Event****Date FDA Received**02/12/2019**Is This An Adverse Event Report?**Yes**Is This A Product Problem Report?**Yes**Device Operator**HEALTH PROFESSIONAL**Device MODEL Number**M2703A**Device Catalogue Number**862199**Was Device Available For Evaluation?**Yes**Is The Reporter A Health Professional?**Yes**Was the Report Sent to FDA?**No**Event Location**No Information**Date Manufacturer Received**02/05/2019**Was Device Evaluated By Manufacturer?**No**Date Device Manufactured**04/10/2017**Is The Device Single Use?**No**Is this a Reprocessed and Reused Single-Use Device?**No**Type of Device Usage**Reuse**Patient TREATMENT DATA****Date Received: 02/12/2019 Patient Sequence Number: 1**

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Page Last Updated: 03/31/2019

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