MAUDE Adverse Event Report: PHILIPS MEDICAL SYSTEMS ULTRASOUND TRANSDUCER FOR USE WITH FM20/FM30 AVALON

PHILIPS MEDICAL SYSTEMS ULTRASOUND TRANSDUCER FOR USE WITH FM20/FM30 AVALON

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Model Number M2736A
Event Date 10/12/2018
Event Type Death

Manufacturer Narrative

A follow-up report will be submitted upon completion of the investigation. The device was in use on a patient at the time of the reported event. No further details regarding the baby had been made available at the time of the reporting decision. Philips is in the process of obtaining additional information regarding the reported event.

Event Description

It was reported that there was a "wrong ecg trace issue. The users reported that the ultrasound transducer didn't give the right ecg trace, the ecg trace was shown for a healthy baby's heartbeat, but the baby was born dead".

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Brand Name	ULTRASOUND TRANSDUCER FOR USE WITH FM20/FM30 AVALON
Type of Device	ULTRASOUND TRANSDUCER
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 Contact	Robert Corning Hewlett-Packard Str.2 Boeblingen 71034 GERMANY 71034
MDR Report Key	8032345
Report Number	9610816-2018-00303

Device Sequence Number 1
Product Code HGM[24]
Report Source Manufacturer
Source Type FOREIGN,HEALTH PROFESSIONAL,U
Reporter Occupation BIOMEDICAL ENGINEER
Type of Report Initial
Report Date 10/24/2018
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 11/02/2018
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? Yes
Device Operator HEALTH PROFESSIONAL
Device MODEL Number M2736A
Device Catalogue Number 989803143691
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 10/24/2018
Was Device Evaluated By Manufacturer? No
Date Device Manufactured 09/29/2016
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: 11/02/2018 Patient Sequence Number: 1

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Page Last Updated: 03/31/2019

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