MAUDE Adverse Event Report: PHILIPS MEDICAL SYSTEMS SERIES 50 XM FETAL/MATERNAL MONITOR

PHILIPS MEDICAL SYSTEMS SERIES 50 XM FETAL/MATERNAL MONITOR

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Model Number M1350B
Event Date 08/03/2011
Event Type Death
Event Description

The customer reported that a fetus was stillborn during monitoring of a philips device.

Manufacturer Narrative

(b)(4). The customer reported that a fetus was stillborn during monitoring of a philips series 50 xm fetal/maternal monitor. The available info states that although the fetus was dead, the device showed toco values and printed a toco diagram. Also a fmp has been recorded. After a few minutes the physician decided to do a c-section because the recorded heart rate did not change during a contraction. The fetus was found to be dead. It could be determined that the fetus was stillborn before the mother arrived at the hospital. A 3rd party contractor has been onsite to collect all data from the incident on (b)(6) 2011, and has tested the device. The initial analysis of the provided data and testing revealed that there was no device malfunction during use in this incident. Additional training with the customer in regards to the procedures for use with the philips series 50 xm fetal/maternal monitor to prevent incidents in the future has been arranged. There is no indication of any malfunction of the philips series 50 xm fetal/maternal monitor. Note that the users had failed to verify fetal viability before commencing monitoring as specified in the device labeling (instructions for use). Instructions for use: obstetrical care, series (b)(4), fetal/maternal monitors, part number (b)(4). Page iv: the monitor should only be used by, or under the direct supervision of, a licensed physician or other health care practitioner who is trained in the use of fetal and maternal heart rate monitors and in the interpretation of fetal and maternal heart rate traces. Page 49: be aware that fmp annotations on a fetal trace alone may not always indicate that the fetus is alive. For example, fmp annotations in the absence of fetal life may be a result of: movement of the deceased fetus during or following maternal movement. Movement of the deceased fetus during or following manual palpation of fetal movement (especially if the pressure applied is too forceful). Movement of the ultrasound transducer. Philips is in the process of obtaining additional info regarding this incident and the complaint is still under investigation. A final report will be submitted once the investigation is completed.

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Brand Name SERIES 50 XM FETAL/MATERNAL MONITOR
Manufacturer *(Section D)* PHILIPS MEDICAL SYSTEMS
3000 Minuteman Road
Andover MA 01810
Manufacturer Contact Nancy Ataide

3000 Minuteman Road
Andover , MA 01810
9786597429

MDR Report Key 2212882
Report Number 9610816-2011-00473
Device Sequence Number 1
Product Code HGM[24]
Report Source Manufacturer
Source Type Health Professional,User facility,Company Representative
Reporter Occupation
Type of Report Initial
Report Date 08/03/2011
***1* Device Was Involved in the Event**
***0* PatientS WERE Involved in the Event:**
Date FDA Received 08/09/2011
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator HEALTH PROFESSIONAL
Device MODEL Number M1350B
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? Yes
Date Manufacturer Received 08/03/2011
Was Device Evaluated By Manufacturer? No
Is The Device Single Use? No
Is this a Reprocessed and Reused Single-Use Device? No
Type of Device Usage Reuse

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