MAUDE Adverse Event Report: WIPRO GE HEALTHCARE PRIVATE LTD COROMETRICS MONITOR PERINATAL MONITORING SYSTEM

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Model Number 259 CX-C
Event Date 08/05/2012
Event Type Death
Event Description

Ge healthcare has received notification of a death of a fetus.

Manufacturer Narrative

The legal complaint that general electric company received alleges the following: "the corometrics monitor made it appear to the healthcare providers that the fetal heart rate was being monitored throughout labor and was normal. " "however, at some point hours before delivery, his fetal heart rate became distressed. Instead of picking up this distress, the corometrics fetal heart monitor made a smooth transition to the maternal heart rate, confusing the healthcare providers into believing the baby's heart was fine. " ge healthcare's investigation is ongoing. A follow up report will be submitted once the investigation has been completed.

Manufacturer Narrative

No information has been provided to ge healthcare by the hospital on the status of the unit. At this time, it is not known if the unit was taken out of service or if it continues to be used with patients. No further details about the alleged device or the event have been provided to ge healthcare. There are no service records for the device in the ge healthcare database. Therefore, without sufficient information about the event, or the evaluation of the alleged device, it is not possible to determine the root cause of the alleged issue.

Manufacturer Narrative

The following information was obtained by ge healthcare through the legal proceedings related to this case. Multiple clinical signs presented that indicated fetal distress during the monitoring session to which the ob team did not take appropriate actions: low fetal heart rate variability- a healthy fetus has high heart rate variability. Maternal heart rate was very close to fetal heart rate; the strip chart indicated the maternal heart rate and fetal heart rate actually overlapped 5 times during the monitoring session, as shown by the hbc indication- a healthy fetal heart rate is typically higher than the maternal heart rate. Fetal heart rate accelerated during contractions- a healthy fetus would have heart rate decelerations during maternal contractions. Multiple maternal parameters to indicate the mother was at high risk for a complicated birthing process, i. E. She was overweight, tachycardic, and feverish. The ob team attempted to use a fetal scalp electrode (fse) to obtain a fetal heart rate directly on four occasions with two different electrodes. They observed no good signal from the fse attempts and concluded the electrodes were defective, instead of concluding there was a problem with the fetus. One of the obstetricians communicated they do not look at the monitor strip chart at all. Another member of the ob team communicated they didn't know about overlapping heartrates and, therefore, did not understand the indications. The obstetricians communicated they did not read the monitor user's manual and did not understand heartbeat coincidence. The obstetricians applied, removed, and then applied spo2 again. When spo2 was applied and indicated a

maternal heart rate that was overlapping with the fetal heart rate, appropriate actions were not taken. The obstetricians did not consider the two heart beats were both from the mother and that the fetal heart beat was not being detected. Ge healthcare provided training on the device which was attended by hospital staff several months prior to the incident. The hospital is responsible for ensuring their clinicians are properly trained on the device through personnel turnover cycles, etc. The ge training was provided one time only and was not purchased again for new clinicians that did not receive the original training. It was concluded that the root cause was user error interpreting the clinical situation of the mother and the fetus.

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Brand Name	COROMETRICS MONITOR
Type of Device	PERINATAL MONITORING SYSTEM
Manufacturer *(Section D)*	WIPRO GE HEALTHCARE PRIVATE LTD Bangalore INDIA
Manufacturer *(Section G)*	WIPRO GE HEALTHCARE PRIVATE LTD. Bangalore INDIA
Manufacturer Contact	Joy Sonsalla 3000 N. Grandview Blvd. Waukesha , WI 53188 2625482661
MDR Report Key	3369763
Report Number	9617277-2013-00001
Device Sequence Number	1
Product Code	HGM[24]
Report Source	Manufacturer
Source Type	Other
Reporter Occupation	
Type of Report	Initial
Report Date	08/20/2013
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	09/18/2013
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	HEALTH PROFESSIONAL
Device MODEL Number	259 CX-C
Device Catalogue Number	2036400-005
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Date Manufacturer Received	08/20/2013
Was Device Evaluated By Manufacturer?	No
Date Device Manufactured	10/01/2011
Is The Device Single Use?	No
Is this a Reprocessed and Reused Single-Use Device?	No

Type of Device Usage Unkown

Patient TREATMENT DATA
Date Received: 09/18/2013 Patient Sequence Number: 1

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