MAUDE Adverse Event Report: HUNTLEIGH HEALTHCARE LTD. DIAGNOSTICS SONICAID

HUNTLEIGH HEALTHCARE LTD. DIAGNOSTICS SONICAID

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Model Number FM830ENCORE
Device Problem Adverse Event Without Identified Device or Use Problem
Event Date 08/29/2014
Event Type Death
Event Description

The monitor was recording traces for an intra uterine fetal death.

Manufacturer Narrative

Arjohuntleigh, inc is submitting the report on behalf of huntleigh healthcare ltd. Exemption no. (b)(4). Having reviewed the limited information provided (pdf of trace provided dated (b)(6) 2014), the following points summarise the investigation: this would appear to have been a known high risk pregnancy, as indicated by the "g12p0" or more likely "g2p0" annotation (difficult to read) whether it's g12 or g2 it indicates that at least one, and possibly as many as 11, previous pregnancy(s) failed for some reason, making this pregnancy a high risk one by default. We would expect a high risk pregnancy to be more closely managed than a low risk pregnancy and for the user to be more alert to any possible problems a well-known, and well documented, limitation of all fetal monitors is that, in the absence of a fetal heart signal, the monitor can pick up on a maternal signal. Best practice, as specified in a number of national safety notices on this subject is to always check the maternal heart rate (pulse) at the start of the trace and record this on the trace. This should be repeated at regular intervals throughout the trace, ensuring that the maternal rate is different from the printed fhr trace and will alert users to the possibility that the fetus may be dead. It is also recommended that a pinard or fetal doppler is used before starting a trace to confirm fetal life and position. As a back-up to this best practice, use of the spo2 sensor (or bp or mecg) will allow the trace to print the maternal heart rate on the same scale as the fetal heart rate trace, making it very obvious if they are the same. It is noted from the trace print out that the spo2 sensor was actually plugged into the monitor during this trace but the absence of either spo2 values or maternal heart rate suggests that it was not actually applied to the patient. If this sensor had been used, the monitor would have alerted the user to the rates being the same. Before the start of the trace, there are a number of hand written annotations on the trace. One is "bp 116/72", clearly the maternal blood pressure. Below this is an annotation which cannot be read clearly. It is probable that, in line with the above stated best practice, they did check the maternal rate and this was recorded as 92bpm. This being the case, this is within the range of the recorded fetal heart rate trace and could have alerted the clinician to the trace being maternal in origin. There is nothing in this trace to indicate that there is any fault with the fetal monitor. The conclusion based on the limited information provided is that this fetus may have been dead before the trace was started and that the printed trace represents that of the mother. Use of the spo2 sensor would have made this both visually obvious and would have triggered the monitor's cross channel alert risk management file has been reviewed and concluded that the mitigation of the associated risks are appropriate, have been adequately documented and are acceptable, i. E. , warnings have been included in relevant areas. However, we cannot state the problem will not reoccur as further mitigation of these risks is outside our direct control, being driven by local & national guidelines, protocols, training and individual clinician's practices. Similar issue has been reported and this was also concluded as above. Corrective i preventative actions, including field safety corrective actions - none required.

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Brand Name	SONICAID
Manufacturer *(Section D)*	HUNTLEIGH HEALTHCARE LTD. DIAGNOSTICS 35 Portmanmoor Rd. Cardiff
Manufacturer *(Section G)*	HUNTLEIGH HEALTHCARE LTD. DIAGNOSTICS 35 Portmanmoor Rd. Cardiff
Manufacturer Contact	Pamela Wright 12625 Wetmore Ste 308 San Antonia , TX 78247 2102787040
MDR Report Key	4131195
Report Number	1000589001-2014-00004
Device Sequence Number	1
Product Code	HGM[24]
Report Source	Manufacturer
Source Type	Foreign
Reporter Occupation	
Type of Report	Initial
Report Date	09/10/2014,09/01/2014
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	09/12/2014
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	HEALTH PROFESSIONAL
Device MODEL Number	FM830ENCORE
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	Yes
Date Report Sent to FDA	09/10/2014
Distributor Facility Aware Date	09/01/2014
Device Age	1 yr
Event Location	Hospital
Date Report TO Manufacturer	09/10/2014
Date Manufacturer Received	09/01/2014
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Date Device Manufactured	11/01/2013
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: 09/12/2014 Patient Sequence Number: 1

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