MAUDE Adverse Event Report: MASIMO CORPORATION ADULT SPO2 REUSABLE TRANSFLECTANCE SENSOR OXIMETER

MASIMO CORPORATION ADULT SPO2 REUSABLE TRANSFLECTANCE SENSOR OXIMETER

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Catalog Number LNOP TF-1
Event Date 11/20/2013
Event Type Malfunction
Event Description

Situation: patients have developed pressure ulcers/burns related to the forehead pulse oximetry probe. Background: last fall, user facility changed vendors for pulse oximetry equipment to masimo. With this equipment change, patients, particularly critically ill patients who have low perfusion states, have developed forehead pressure ulcers/burns in the shape of the forehead probe. Assessment: nursing staff in several adult intensive care units have provided feedback regarding the masimo forehead probe. It is rigid and requires the headband to be tightened in order to get an accurate reading which causes the probe to put pressure on the skin. The probes provided were designed by masimo for assessment during short-term procedures. Examples of the pressure ulcer descriptions include: 1. Patient has a 2. 5 cm x 1. 25 cm area of non-blanchable dark purple skin above her right eye. This appears to be a deep tissue injury and likely to be a result of pressure from the forehead pulse oximeter probe (consistent with size and location). 2. Nursing had placed the new masimo adult spo2 reusable transfectance forehead sensor on patient. When performing a skin assessment, rn identified that the sensor had caused a suspected deep tissue injury (sdti) vs burn. Upon review of skin alteration today it appears to be a burn. 3. Despite every 2 hour repositioning and every hour assessment, tissue injury has occurred to patient above right eyebrow. Equipment: masimo headband adult forehead sensor. Recommendation: the following action is being taken to minimize the potential for this incident to reoccur. A high priority shipment order has been placed with masimo to increase the amount of ear clips. When this shipment arrives, the forehead probes will be removed from distribution in the icus. Ear clips will be used in those patients who have a low perfusion state in which the finger probes are not accurate until the disposable forehead probes are available. Manufacturer response for adult spo2 reusable transflectance sensor, adult spo2 reusable transflectance sensor (per site reporter). ========== manufacturer referred user facility to produce "directions for use. ".

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Brand Name	ADULT SPO2 REUSABLE TRANSFLECTANCE SENSOR
Type of Device	OXIMETER
Manufacturer *(Section D)*	MASIMO CORPORATION 40, 50 & 60 Parker Irvine CA 92618
MDR Report Key	3636451
Report Number	3636451
Device Sequence Number	1
Product Code	DQA[24]
Report Source	User Facility
Reporter Occupation	Other
Type of Report	Initial
Report Date	01/16/2014
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	01/17/2014
Is This An Adverse Event Report?	No
Is This A Product Problem Report?	Yes
Device Operator	Invalid Data
Device Catalogue Number	LNOP TF-1

Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? No Answer Provided
Was the Report Sent to FDA? Yes
Date Report Sent to FDA 01/17/2014
Event Location Hospital
Date Report TO Manufacturer 02/20/2014
Is this a Reprocessed and Reused Single-Use Device? No

Patient TREATMENT DATA
Date Received: 01/17/2014 Patient Sequence Number: 1
Treatment
DEVICE DESIGN CAUSED PRESSURE ULCER

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