Dräger Jaundice Meter JM-105 and JM-103 out-of-range indication

Vizient Patient Safety Organization Safety Alert

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Situation

Dräger Jaundice Meter JM-105 “out of range” indication may be misinterpreted as normal and not acted upon with the potential to cause serious harm to newborn infants. The U.S. Food and Drug Administration (FDA) has identified this as a Class 1 recall, the most serious type of recall.[1]

Background

Jaundice—a yellowing of the skin or whites of the eyes caused by excess bilirubin in the blood—is a common condition in newborns, particularly in preterm and breast fed babies. Bilirubin is the pigment released during the normal breakdown of red blood cells. Newborns produce and break down red blood cells faster in the first few days of life, and their immature liver may not remove bilirubin quickly enough. Jaundice can also be caused by other underlying medical conditions or diseases such as infection, incompatibility between the mother and baby’s blood, or liver malfunction. If bilirubin levels in babies remain high for too long, brain damage can occur.[2]

The JM-103 and JM-105 Dräger jaundice meters are non-invasive transcutaneous bilirubinometers, which measure yellowness of subcutaneous tissue in newborn infants. The unit provides a visual digital measurement that has been shown to correlate with blood levels of bilirubin in newborn infants. High levels of bilirubin (hyperbilirubinemia) may indicate jaundice or other conditions which require medical attention. The device is intended for use in hospitals or doctors' offices under a physician's supervision or at their direction to assist clinicians in monitoring newborn infants. The device is not intended as a standalone screening device for diagnosis of hyperbilirubinemia. It is used as a screening device along with other clinical assessments and laboratory measurements.[1,3]

Assessment

A safety issue was brought to our attention regarding the Dräger jaundice meter:

> The Dräger Jaundice Meter JM-105 displays a blinking -0- and JM-103 displays three blinking dashes (- - -) to indicate that the measurement is is higher than the maximum level of detection—above 340 µmol/L or 20 mg/dl.[3]

After taking this concern to the manufacturer, Vizient PSO learned that misinterpretation of the meter indication blinking -0- also resulted in cases of delays in treatment in newborns with hyperbilirubinemia in other countries. The indication gets misinterpreted by users as a zero value and within normal range instead of an high, out-of-range level warranting further urgent laboratory testing.[3]

Recommendations

- Determine if your organization uses these meters or other meters that may have a similar issue. Review the safety notice and take appropriate steps to address the identified safety issues.
- Review the Draeger Medical's Urgent Safety Recall Notice and FDA safety notice of the Class 1 recall of Jaundice Meter JM-103 and Jaundice Meter JM-105.[1,3]
- Ensure that the labels developed to inform users how to interpret the out of range display are applied directly to JM-105 and JM-103 meters per the instructions of the manufacturer.[1,3]
- Look for a separate communication from Draeger about the availability of a firmware update to modify the indication for the high, out-of-range bilirubin measurement to a specific display message (>340 µmol/L / >20 mg/dl) and the actions organizations should take to implement the update.[1,3]
- Train all users and ensure staff who use the equipment demonstrate competency in the proper use.[1]
- Design the clinical workflow so that the meter is not used by itself for the diagnosis of hyperbilirubinemia but in conjunction with clinical signs and symptoms and laboratory tests. In case of any uncertainty (e.g., risk factors cannot be evaluated), establish policies with criteria for when a blood test should be ordered and completed by clinical laboratory staff.[1,3]
- Review American Academy of Pediatrics Risk Factors and Guidelines summarized in the Sample Usage Protocol.[3]
- Follow manufacturer's recommendations and obtain the product manual which includes a description of the out of range indication.
- Disseminate this safety issue and recommendations to those involved in the use of these products.

For more information, contact Tammy Williams or Ellen Flynn.

References

1. U.S. Food and Federal Drug Administration website. Draeger Medical Systems, Inc. Jaundice Meter JM-103 and Jaundice Meter JM-105 Recalled Due to Misinterpretation of Display Messages for Out of Range Values. Available at https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm611564.htm. Accessed January 3, 2019.
2. Infant Jaundice: Symptoms and causes. Available at https://www.mayoclinic.org/diseases-conditions/infant-jaundice/symptoms-causes/syc-20373865. Accessed January 3, 2019.
3. Draeger Medical's Urgent Safety Recall Notice. Available at https://www.bfarm.de/SharedDocs/Kundeninfos/EN/10/2018/04434-18_kundeninfo_en.pdf;jsessionid=4926FF8DF37F6F80BF99A68A7993B69A.2_cid344?__blob=publicationFile&v=1. Accessed January 3, 2019.