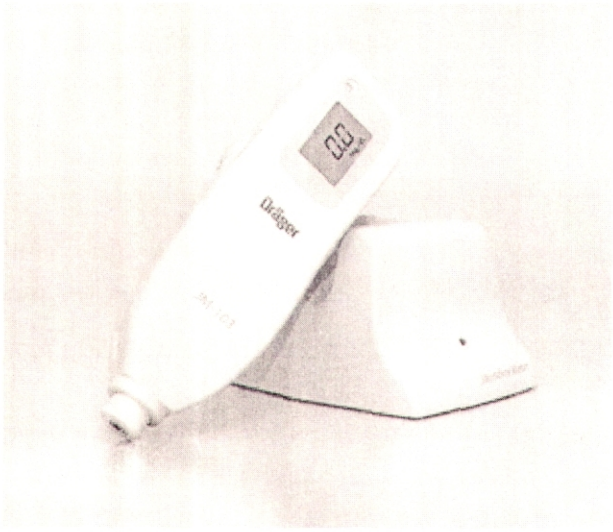
Draeger Medical Systems, Inc. Jaundice Meter JM-103 and Jaundice Meter JM-105 Recalled Due to Misinterpretation of Display Messages for Out of Range Values

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death

Recalled Product:

- Name: Jaundice Meter JM-103 and Jaundice Meter JM-105
- Product code: MQM
- Model numbers: JM-103: MU20606; JM-105: MU20105
- Manufacturing Dates: JM-103 June 2008 to August 2017, JM-105 September 2013 to April 2018
- Distribution Dates: JM-103 July 2008 to September 2017, JM-105 October 2013 to April 2018
- Devices Recalled in the U.S.: JM-103: 2449; JM-105: 2063

Device Use



The JM-103 and JM-105 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.

The JM-105 is a modification of the JM-103 jaundice meter. The basic functionality, including the measuring probe, hardware, and software used to process the measurements, are identical to the JM-103. The display of the JM-105 includes a larger screen and touchscreen, and data storage and transmission functionality.

Reason for Recall

Draeger Medical Systems, Inc. is recalling their Jaundice Meter JM-103 and JM-105 models which are used to measure bilirubin in newborn infants. The meters are being recalled because users have misinterpreted display messages that have resulted in serious injuries. Specifically, the JM-103 Meter displays three blinking dashes (- - -) and the JM-105 Meter displays dash-zero-dash (-0-) when the bilirubin level in the patient is higher than the maximum level of detection (>340µmol or 20mg/dl). Measurement of high bilirubin indicates a need for immediate medical evaluation. Some users have interpreted the two display messages as indicating a "low" or "zero" value instead of high bilirubin levels. When this happens, treatment may be delayed or not offered, which could lead to brain damage and possibly death in some newborns/infants.

The out of range display is visible; however, the interpretation of the reading is not intuitive or clear. Uncertainty about the out of range indication on the Jaundice meter could cause a delay of treatment in a patient with hyperbilirubinemia.

The misuse of display information could increase risk for serious adverse health consequences such as acute and/or chronic brain damage or death.

Who May be Affected

Newborn infants who are being monitored by a physician for hyperbilirubinemia.

What to Do

Draeger Medical issued an Urgent Medical Device Safety Notice to customers with the following instructions:

- Ensure that all JM-105 and JM-103 devices are labeled per the instructions provided by the firm in a timely manner. Draeger provided their users with labels which should be applied directly onto the meter to remind the user of the meaning of the blinking (---) for the JM-103 model, and (-0-) for the JM-105 model. The label has a picture of the out of range display messages as they appear on the meter with three blinking (---) for JM-103 or (-0-) for JM-105: and the interpretation of the messages stating "Measurement out of range >340µmol/L/20mg/dL."

- Provide training to all users in the clinical environment on how to use the equipment, and ensure that they understand that this is a screening device not to be used as a standalone diagnostic device.
- Perform a blood test if they obtain a bilirubin measurement that is above the device maximum value of 20mg/dL or 340µmol.
- Complete and return the Customer Reply card sent by the firm.
- Look for a separate communication letter from Draeger which notifies those using JM-105 about the availability of upgraded software and provides instructions for sending the device to the firm if they choose to have the upgrade implemented.

Contact Information

Draeger Medical Systems, Inc.
3135 Quarry Road, Telford Pennsylvania
USA 18969-1042

Full List of Affected Devices

- Draeger Jaundice Meter JM-103 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=164039)
- Draeger Jaundice Meter JM-105 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=164040)

Date Recall Initiated

May 21, 2018

Additional Resources

- Draeger Medical's Urgent Safety Recall Notice (https://www.bfarm.de/SharedDocs/Kundeninfos/EN/10/2018/04434-18_kundeninfo_en.pdf;jsessionid=4926FF8DF37F6F80BF99A68A7993B69A.2_cid344?__blob=publicationFile&v=1)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/)** either online, by regular mail or by FAX to 1-800-FDA-0178.

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2018 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm590900.htm)

2017 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)