Dräger, Andover, MA / Telford, PA

To all customers of the JM-103
Jaundice Meters

Important Safety Notice!!! March 2018
Dräger Jaundice Meter JM-103 Out of Range Indication

Dear Ladies and Gentlemen,

Our continuous post market surveillance has shown that some users have concerns about the method used by the JM-103 to indicate that a taken measurement is out of range (higher than the measuring range of the device). As described in the instructions for use and in the device's training materials, the JM-103 displays a blinking "- - -" when the measurement is out of range. The measuring range is defined to 340 µmol/L / 20 mg/dl.

We have decided to proactively add a label to the device in order to remind the user of the meaning of the blinking "- - -".

Our records indicate that your hospital owns one or more JM-103 devices. Please refer to the label instruction how to apply the label onto your device/s. Please make sure that all devices in your hospital will be labeled according to the instructions in a timely manner. If you have any questions, please feel free to contact Dräger Service.

We would like to underline that the JM-103 is not intended to be used as a standalone screening device for diagnosis of hyperbilirubinemia. The devices are intended to be used as a screening device in conjunction with other clinical signs and laboratory measurements by trained clinical

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personal. We recommend using the TcB Nomogram by Maisels (see attached Sample Usage Protocol Template) in combination with the risk factors in order to decide whether a blood test has to be performed or not.

Please make sure that in your clinical environment the users are trained in the use of the equipment and the clinical workflow is set up in a way that the device is not used as diagnostic device. In case of any uncertainty (e.g. risk factors cannot be evaluated), a blood test needs to be performed. The risk factors according to the Guideline of American Academy of Pediatrics are summarized in the attached Sample Usage Protocol Template as well as the recommended method to use the device as intended in a clinical environment.

In case you have further questions regarding the intended use of the devices or if you need further training, please feel free to contact your local Dräger application specialist.
Dräger is committed to customer satisfaction and patient safety. We apologize for any inconvenience this action may cause and appreciate your patience and cooperation.

Kind regards,

Philip Moehring
Head of Product Management
Product Management Life Support Systems
Thermoregulation

Bryan Overton
Director, Quality Assurance & Compliance
Processes, Quality, & Regulatory

Attachment:
- Sample Usage Protocol Template: Sample Usage Protocol for Drager Jaundice Meter JM-103

Dräger

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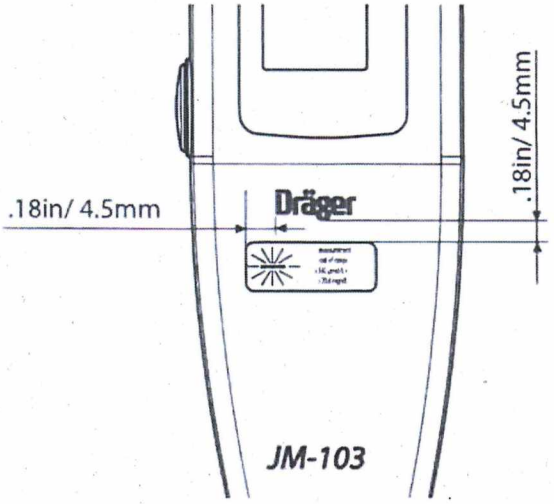
Label placement instruction

Ensure that the device is cleaned prior to application of the label in accordance to instructions for use.



Label placement as shown in picture (reference only).

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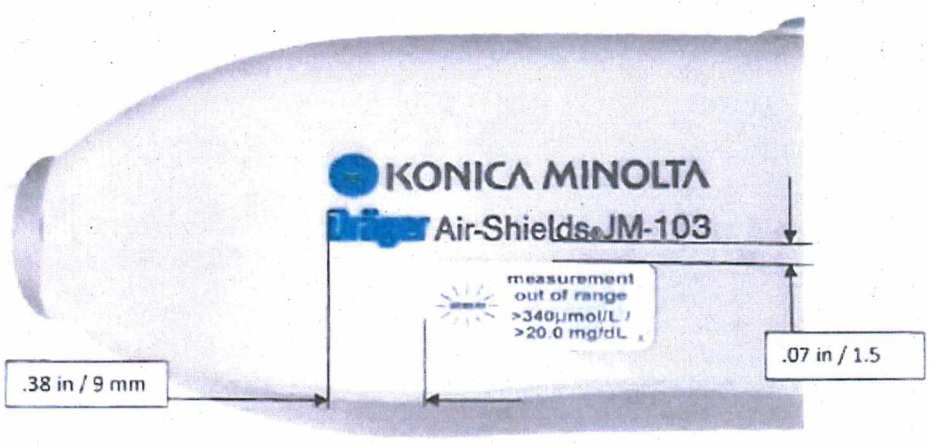
JM-103 - Konica Minolta/Air-Shields



Dimensional Tolerance REF ONLY for label placement.

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