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European Competent Authorities

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Field Safety Corrective Action regarding the JM-105 Jaundice Meter June 14, 2018

Dear Sir or Madam,

herewith we would like to inform you as Competent Authority about the current status of the Dräger JM-105. We are aware that this case has been discussed between the national Competent Authorities responsible for medical device regulation in the EU. There is also various information appearing on the Internet. In order to assure the same level of information we ask you to take note of our information.

In particular, we would like to prevent any false impression by our decision to appeal against a decision by the Medical Product Agency.

Background

The case concerns the JM-105, a screening device to measure bilirubin in neonates in order to detect risks for jaundice.

Manufacturer of the device is the Draeger Medical Systems Inc. situated in Telford, USA. The European Representative is Drägerwerk AG & Co KGaA, having its principal offices at Moislinger Allee 53-55, 23558 Lübeck, Germany, Commercial register: Amtsgericht/Local court Lübeck HRB 7903 HL.

The device has the following Intended Use:

> The Jaundice Meter is a non-invasive transcutaneous bilirubinometer. It measures yellowness of subcutaneous tissue in newborn infants. The unit provides a visual digital measurement that has been shown to correlate with serum bilirubin in newborn infants.
>
> The device is intended for use in hospitals or doctors offices under a physician's supervision, or at their direction. It helps clinicians to monitor newborn infants. The device is not intended as a standalone screening device for diagnosis of hyperbilirubinemia. It is used as a screening device with other clinical signs and laboratory measurements.
>
> Newborn infants whose Jaundice Meter test results are indicative of hyperbilirubinemia should be evaluated by their physicians for appropriate patient management. Specific neonatal patient bilirubin levels should be confirmed by other methods, such as serum bilirubin, before treatment determinations.
>
> The Jaundice Meter is not intended for home use.
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> The JM-105 is a prescription medical device.
>
> The JM-105 may only be used at the sternum measurement site for Physician's office applications.

The JM-105 has been sold since 2013. Approx. 7000 JM-105 devices are in use worldwide. Further, identical devices are sold under the Konica Minolta brand in Japan.

If the measured Bilirubin exceeds the measurement range of 0,0 mg/dL to 20,0 mg/dL (0 µmol/L to 340 µmol/L) then the display shows a blinking "-O-".

Three reported adverse events were received by us in 2017, where misinterpretation of the display information may have contributed to a delay in treatment. One of the cases was in Sweden (event on 06.01.2017, incident referens No. Dnr 8.1.1-41509/2017-6 Hospital name: Centralsjukhuset i Karlstad), others in Switzerland and the UK.

The Swedish incident was subject to an inquiry of the Swedish Health and Social Care Inspectorate (Inspektionen för Vård och Omsorg, IVO). This inquiry identified other factors than the device display as the main factors contributing to the incident. The report concluded:

(JM 105 incident referens No. Dnr 8.1.1-41509/2017-6 Hospital name: Centralsjukhuset i Karlstad, page 6, our translation)

"... Underlying causes leading to the incident as related by the caregiver:

The caregiver has identified the following underlying factors as having bearing on the cause of the incident in question: lack of competence, deficiency in reporting and documentation, deficiency in routines for interpretation of test results, failure to follow governing routines and the medical technical device…"

In the same report it is written
"…IVO has noted that the formidable complication of kernicterus is now reoccurring in Sweden. IVO estimates that early hospital discharge of mother and child presents and contributes to the risk to this complication of hyperbilirubinemia. Increased meticulousness and strictness compliance with routines is called for in the detection and treatment of hyperbilirubinaemia in newborns.
IVO sees deficiencies in fastidiousness and compliance with current procedures as integral and underlying factors to the cause of this incident…"

The incidents made us aware about deficiencies in the actual handling of the device by the users. We have therefore initiated a Field Safety Corrective Action (FSCA). Nonetheless, we follow the reasoning of the Swedish inquiry that the actual risk contributing factors lie elsewhere and that the product, if used according to the Instruction for Use (IfU), is a safe product suitable to increase the chance of detecting hyperbilirubinemia by the physician.

Current Status of the Field Safety Action

Dräger has implemented measures to prevent a false use of the device resulting in patient damage. Users have been informed via FSN the about the significance of the "-O-" display notification and the importance to follow the IfU. They are provided with an additional label to be labelled onto the product to remind the Operator what the meters displays when the measurement is out of range.

Furthermore, a firmware update is being developed. With that update the device can be set to show ">340" instead of "-o-" (or ">20" depending on the choice of unit). This firmware update will be made available to all users of the JM-105. Dräger decided to make this available free of charge for all users, even though the German jurisdiction is more limited in that regard - you may be

aware of the so called "Pflegebetten" decision of the German Federal Civil Court (BGH, 16.12.2008 - VI ZR 170/07).
We updated our Report Form for the Field Safety Corrective Action and this will be supplied to you together with this letter.

Current proceedings at the Swedish Medical Product Agency (Lakemedelsverket, MPA)

The incident in Sweden lead to proceedings at the MPA. Dräger worked closely with the MPA and reported regularly how Dräger intended to proceed in the matter. However, there developed the impression that despite the results of the IVO investigation it was attempted to depict the device as sole risk resulting in the incident.

While other authorities, whom we cooperated with, generally accepted the measures taken up by Dräger the MPA passed in May 2018 a formal decision with a three week period of appeal. The decision contains specific orders that we consider as not consistent with the law. To prevent an administrative finality of orders we consider wrong and harming our company, we at Dräger decided to appeal the decision of the MPA.

Kind regards,
Sonja Hillmer
Head of Post Market Surveillance