HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Jaundice Meters
JM-103, JM-105

Priority 2 – Warning

HPRA Safety Notice: SN2018(12) **Issue Date: 3rd May 2018**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Draeger Medical Systems, Inc.	V35600

ISSUE

Draeger has been notified of concerns regarding the method used by the JM-103 and JM-105 jaundice meters to indicate that a 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. Draeger will be requesting meter owners to add a label to the JM-103 devices to remind users of the meaning of the blinking "- - -".

As described in the instructions for use and in the device's training materials, the **JM-105** displays a blinking "-O-" when the measurement is out of range. The measuring range is defined to 340 µmol/L / 20 mg/dl. Draeger will be requesting meter owners to add a label to the JM-105 devices to remind users of the meaning of a blinking "-O-". Draeger is also implementing a firmware change for indication of a high bilirubin measurement

for the JM-105 meter. The firmware change allows the user to set the out of range indication as "-O-", ">340 µmol/L "or ">20 mg/dl" (depending on the selected unit of measure).

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1. Refer to the two accompanying Field Safety Notices (FSNs) and follow the instructions provided.
2. Acknowledge receipt of the FSNs if you have not already done so.
3. Liaise with Draeger to arrange for all of your devices to be labelled and for JM-105 devices to receive the firmware upgrade.
4. Forward a copy of this safety notice and the FSNs to all relevant personnel within your organisation and to any other organisations/persons to which/whom these devices have been transferred.
5. Report any concerns regarding these devices and this issue to the manufacturer and the HPRA.

TARGET GROUPS

Clinical Directors	Neonatal intensive care units
Hospital Managers / CEOs	Nursing Managers
Intensive care units	Paediatricians
Maternity hospitals CEOs	Paediatric hospitals / CEOs
Midwives	Public health nurses
Neonatologists	Risk Managers

BACKGROUND

Draeger has identified through post market surveillance that in one case in Sweden and one case in the UK, the uncertainty about high value indication may have been a factor in the delay of treatment of patients with hyperbilirubinemia.

Draeger is also reminding users that the JM-103 and JM-105 jaundice meters are not intended to be used as standalone screening devices for diagnosis of hyperbilirubinemia. The devices are intended to be used in conjunction with other clinical signs and laboratory measurements by trained clinical personnel.

If you have further questions regarding the intended use of the devices or if you need further training, please contact your local Draeger application specialist.

MANUFACTURER INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Draeger Medical UK Ltd
The Willows, Mark Road
Hemel Hempstead
Hertfordshire HP2 7BW
UK

Telephone: +44-1442-213542
E-mail: Helen.Glass@draeger.com

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie