

Dräger, Andover, MA / Telford, PA

Update of FSCA Dräger Jaundice Meter JM-105 high value indication

Jaundice Meter JM-105 Firmware Upgrade

November 2018

Dear Ladies and Gentlemen,

As already mentioned in the Safety Notice sent in April 2018, we have implemented a firmware change to the JM-105 for how it indicates a high bilirubin measurement. We offer this change for all JM-105 devices. The new firmware version 1.20 changes the display for an out of range measurement. The new indication for an out of range measurement is ">340 µmol/L" / ">20 mg/dl" (depending on the selected units of measure).

Our records indicate that your hospital owns one or more Dräger Jaundice Meter JM-105 devices that are affected by the firmware update. Please note that the devices have to be sent to a Repair Center for the firmware change (as for calibration).

Please contact your local Dräger Service organization within the next month to schedule the change and to decrease the downtime of your device to a minimum.

As a matter of course, this quality improvement activity is free of charge for you. We apologize for any inconveniences resulting from this action. If you have further questions, please feel free to contact your local Dräger representative.

Kind regards,

Inken Schroeter

Product Manager

Product Management Life Support Systems

ven Schroeter

Thermoregulation