Draeger Medical Systems, Inc., Telford, PA 18969-1042 USA

To our customers of the:
Infinity® Acute Care System (IACS) and Infinity M540 standalone configuration

April 2024

Important Safety Notice

Infinity Acute Care System - Infinity M500 Docking Station is not in full compliance to type CF requirements
Affected devices: Infinity M500 Docking Station, MS20407 Rev. 20, 21, and 23

Dear Customer,

Draeger Medical Systems, Inc. (DMSI) has become aware during testing in conjunction with our global market surveillance activities that Infinity M500 Docking Station is not in full compliance to type CF requirements of IEC 60601-1 and IEC 60601-2-34 standards. The awareness of the non-compliance to the standards was detected through bench testing and not during clinical use.

Infinity M500 Docking station is a part of Infinity Acute Care System. The M500 is the device that mechanically secures and powers the M540 patient monitor. The M500 also charges the battery of the M540 and the M500 controls the communication between M540/Cockpit or Infinity Network if in a standalone configuration.

The only ports that could be affected are: Hemo port (gray color), SpO2 port (blue color), and Temp port (white color) on M540 (refer to **Attachment 1**). The specific accessories which can be connected to these ports and may be affected are the Dual Hemo MCable, SpO2 MCables, and temperature probes, respectively.

Because of non-compliance to the above-mentioned standards, there is a potential risk of electric shock, which might carry corresponding health consequence, to a patient connected to an M540 docked into an affected M500 ONLY if mechanical insulation of the accessories connected to the M540 is damaged AND if there is unintended electrical potential delivered to the patient from an external source.

IMPORTANT: Please note that the IACS system can continue to be used safely. Users should take the added precaution to inspect the patient cables and probes and to discard damaged or compromised accessories as stated in the Instructions for Use.

Actions to be taken:
Ensure all accessories are in proper working order and do not have frayed wires or are not otherwise compromised as required in the patient monitor Instructions for Use. Accessories must only be used in accordance with the Instructions for Use.

Please ensure that all users of the above-mentioned product and other people within your organization are made aware of this Important Safety Notice. Please complete and return the attached reply card to confirm this. Please also notify us if you have already taken your device out of service. If you have provided the affected M500 units to third parties, please forward a copy of this information to the third party.

Please keep this information at least until the corrective measure has been completed. You will be contacted by one of our Draeger Service staff or your service partner to arrange for modification of the affected M500 units to be carried out free of charge as soon as the material for modification is available.

Identification of the affected medical devices:
According to our records, you have received at least one affected M500 (MS20407 Rev.20, 21, or 23) manufactured by Draeger Medical Systems, Inc (European Single Registration Number: US-MF-000020721, UDI: 04049098054447) that may be affected by this issue. It can be identified on the underside product label of the M500 (see **Attachment 2**).

Contact:
If you have any further questions, please do not hesitate to contact your local representative. The responsible authorities have been notified of this action. We regret any inconvenience this may cause.

We thank you for your support.

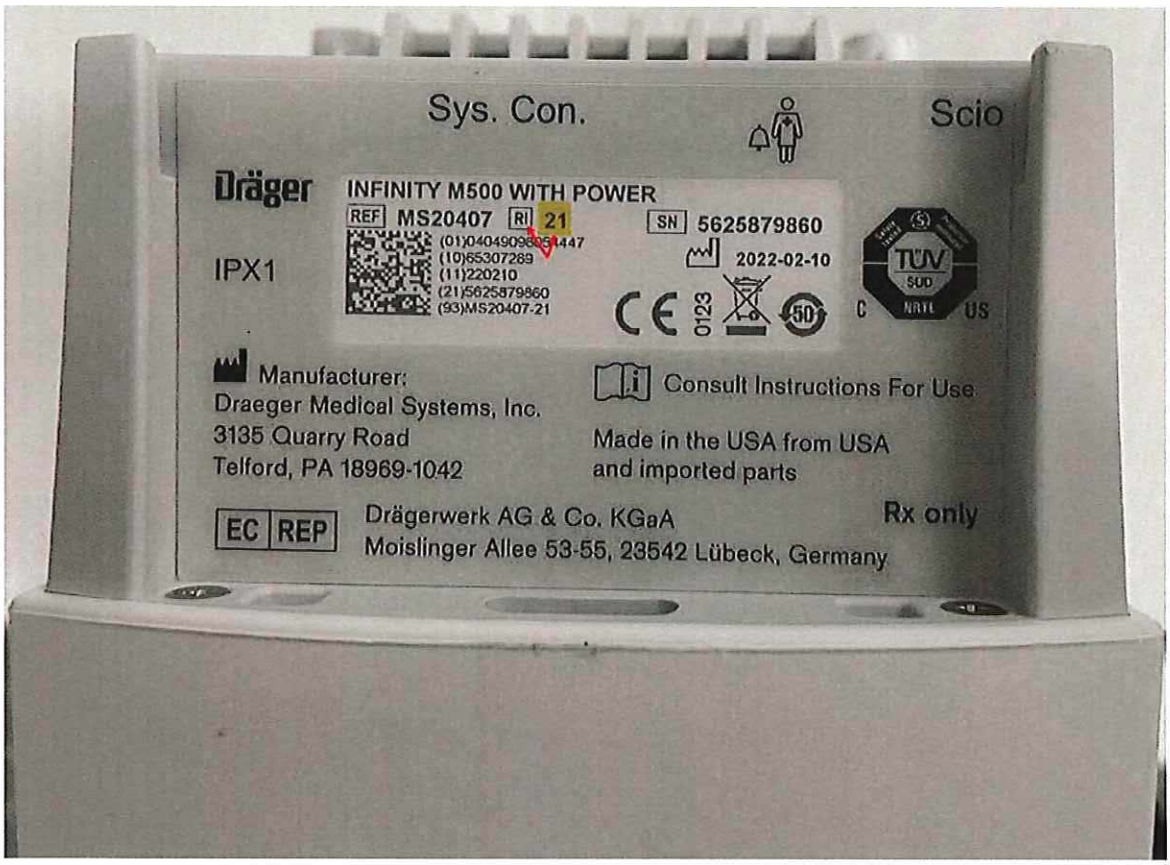
With kind regards

Rafael Zuaznabar
Lead Product Manager
Business Unit Patient Monitoring
Draeger Medical Systems, Inc.,

Attachments

Attachment 1: Affected Ports on the M540

Attachment 2: Identification of the affected medical devices



Red Arrow in picture above identifies revision (RI) of the device (MS20407 – Infinity M500 Docking Station). This label can be found on the underside of the device.

Dräger

Draeger Medical Systems, Inc., Telford, PA 18969-1042 USA

Customer Reply Card
Please fax or e-mail this form to your Dräger representative!

DRÄGER

To: < To be completed by relevant subsidiaries/dealers >

Department:

Dräger Representative:

Fax:

Phone:

E-mail:

Re: **Safety notice on Infinity M500 Docking Station, MS20407 rev. 20, 21, and 23**

(Please complete)

CUSTOMER DATA

Hospital:

Customer name:

Phone: Fax:

E-mail:

Address:

Address 2:

Town/city: Country:

Quantity of affected units: _____

☐ We acknowledge receipt of the safety notice and that the information contained therein has been brought to the attention of all affected users.

☐ We confirm that the devices in our hospital have now been taken out of service.

Please include the device serial numbers relating to the above items in an attachment if possible.

(Please complete and sign)

Title/position:

Name: (Please print in capitals)

Signature: Date: