

Draeger Medical Systems, Inc., Andover, MA 01810 USA

To our customers and users of the:

- **The Infinity® Acute Care System™ (IACS); software version VG7.0.1, VG7.0.2**
- **Standalone Infinity® M540 patient monitor; software version VG7.0.1, VG7.0.2**

Important Safety Notice!

Possible loss of communication between the cockpit and the M540 patient monitor after discharge of patient immediately after docking the monitor to the docking station.

March 2019

Dear Madam or Sir,

The purpose of this letter is to advise you that Dräger is issuing a voluntary field correction to address the following situation:

immediately after the monitor has been docked to the M500 docking station and a user discharges a patient from the M540 patient monitor, there is a possibility that the communication between the IACS cockpit and the M540 patient monitor is not established.

If the communication is not established, the IACS cockpit will not be able to send any commands to the M540 patient monitor with the exception of the "audio pause". Changes made on the IACS cockpit will not be transferred to the M540 patient monitor, though the changes will be reflected on the IACS cockpit.

This lack of communication may occur:

- when the discharge is performed within 10 seconds after docking the M540 patient monitor to the M500 docking station, and
- it occurs only with the first patient admitted to the M540 monitor/IACS cockpit any time after the above action has been performed.

This lack of communication would not be obvious to the user.

After another discharge action is performed while the M540 patient monitor remains docked to the M500 docking station, the M540 patient monitor and the IACS cockpit resume normal communication.

Based on our information, you are using at least one Infinity Acute Care System that fits into the above criteria.

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Interim actions you should take:

To avoid encountering the described situation, please use the following workflow:

If you dock the M540 and need to perform a discharge, please wait at least 10 seconds prior to pressing the Discharge button.

Correction:

We are in the process of resolving this product issue and will provide you with an updated software version as soon as it becomes available. At that time, your Dräger service representative will schedule a visit to upgrade all affected Infinity Acute Care Systems.

Please distribute this Safety Information to all potential users within your facility.

We regret any inconvenience this may cause. We consider it a necessary preventive measure to increase patient safety and product reliability. We thank you in advance for completing the attached Customer Acknowledgement and Response form and returning the completed form to your Dräger representative per instructions provided.

If you have any further questions, please contact your local Dräger representative.

Thank you for your continued support.

Sincerely yours,



Lloyd Stern
Vice President of Product Management
Dräger Patient Monitoring Systems

cc: Chairman Medical Board and relevant Head of Departments

Customer Acknowledgement and Response Form

RE: Possible loss of communication between the cockpit and the M540 patient monitor after discharge of patient immediately after docking the monitor to the docking station.

Customer Name/Address:

☐ I acknowledge the receipt of the information in the safety notice and confirm that the information has been brought to the attention of all users.

Completed By:

Print Name:

Signature/Date:

Thank you for sending the completed acknowledgement form to our attention per the instructions provided by your Dräger representative. Dräger representative will call you to schedule a visit to update the software once the revised software becomes available.