

Dräger 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**
- **Standalone Infinity® M540 patient monitor; software version VG7.0.1**

Important Safety Notice!

The Infinity M540 patient monitor may reboot when the ECG cable plug is not fully connected to the monitor. If the reboot occurs 3 times in 10 minutes or less, the Infinity M540 patient monitor will enter a fail-state.

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:

When the ECG cable plug is not properly connected, the Infinity M540 patient monitor may reboot. If the situation is not corrected and the reboot occurs 3 times in 10 minutes or less, the Infinity M540 patient monitor will enter a fail-state, resulting in a resetting to factory defaults, losing patient settings and locally stored patient data. The reboot and the fail state are indicated by visual and audio alarms.

Based on our information, you are using at least one Infinity Acute Care System or a Standalone Infinity M540 patient monitor that fits into the above criteria.

Interim actions you should take:

To avoid encountering the described situation, please ensure that ECG cable plug is fully connected prior to use. Should you encounter unexpected reboots, please verify that the cable plug is fully connected and if necessary, please ensure proper insertion.

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

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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,



Lloyd Stern
Vice President of Product Management
Dräger Patient Monitoring Systems

cc: Chairman Medical Board and relevant Health of Departments

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Customer Acknowledgement and Response Form

RE: Unexpected reboots with the Infinity Acute Care System (IACS) in conjunction with the use of the ECG cable; software version VG7.0.1

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.