

To our customers and users of the:

- **Infinity® Acute Care System™ (IACS) and Standalone Infinity® M540 patient monitor; M540 Revision Indexes 24-29**

Important Safety Notice!

December 2020

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:

The Infinity M540 patient monitor may randomly reboot due to an error to correctly transmit and read the header data of files in the memory of the device. Under this situation, the device will try to reboot to mitigate the error. The device will be available again for use within 30 seconds. If this error continues and reboots three times in a time span of 10 minutes, it will enter a fail-state. A fail-state will announce itself with a continuous sound to alert the user. The M540 will reset to factory default and the user can manually configure and readmit the patient to continue patient monitoring.

This issue was observed in the scope of our post market activities. There were no reported cases of patient impairment.

Our records indicate that your facility is using at least one IACS device that is affected by this notice.

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.

In the meantime, you can still use the systems by paying special attention to the above described situation. Please distribute this Safety Notice to all potential users within your facility.

We regret any inconvenience this may cause. We consider it is 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.



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

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

Customer Acknowledgement and Response Form

**RE: Infinity® Acute Care System™ and the standalone Infinity® M540 patient monitor, M540
Revision Indexes 24-29**

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. A Dräger representative will call you to schedule a visit to update the software once the revised software becomes available.