

To our customers and users of the:

- **The Infinity® Acute Care System™ (IACS); software version VG7.1**
- **Standalone Infinity® M540 patient monitor; software version VG7.1**

Important Safety Notice!

October 2020

Dear Madam or Sir,

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

1. 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.
2. The IACS Cockpit may lose the ability to send commands to the M540 patient monitor. This could lead to desynchronization of commands and alarm changes between the Cockpit and the M540. Please verify that alarm configuration settings match from the Cockpit to the M540. To recover from this issue, it is necessary to undock/dock the M540, or to power cycle the devices. Real-time patient monitoring is not affected at the M540.
3. The IACS patient monitor may exhibit a loss of configuration of the patient and system profile due to disconnection from the internal database after power up of the Cockpit. If this problem is present, it will impact patient category, patient name, patient bed name, network settings, trends, and the units of measure. Most noticeable is that the device will revert to English language. If this problem is present, the user will have to restore the configuration they had previously and readmit the patient to restore patient monitoring.

These issues were observed in the scope of our post market activities. There were no reported cases of patient impairment.

Correction:

We will provide you with an updated software version VG 7.1.1 to resolve these product issues. Your Dräger service representative will contact you regarding upgrade options for your affected Infinity Acute Care Systems.

In the meantime, you can still use the systems by paying special attention to the above described situations. 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.

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

Thank you for your continued support.

Sincerely,

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