

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

**To our customers and users of the:**

- **The Infinity<sup>®</sup> Acute Care System<sup>™</sup> (IACS); software version VG7.0**
- **Standalone Infinity<sup>®</sup> M540 patient monitor; software version VG7.0**

**Important Safety Notice!**

When the operator changes a patient category, and then an NIBP measurement is taken, the NIBP inflation limits that are applied may not correlate to the patient category chosen.

The Infinity M540 patient monitor reboots when NIBP measurement violates the set alarm limit. If the reboot occurs 3 times in 10 minutes or less, the Infinity M540 patient monitor will go into fail-state.

**March 2018**

Dear Madam or Sir,

1. When the operator changes a patient category, and then an NIBP measurement is taken, the NIBP inflation limits that are applied may not correlate to the patient category chosen. For example, if the operator switches the patient category from "Adult" to "Pediatric," the "Adult" inflation limits will be applied, instead of the desired "Pediatric" setting. The visual indicator on the screen will correspond to the desired selection. This may lead to higher pressure and longer application times in neonatal and pediatric patients.
2. When the alarm validation timer is turned ON, and the NIBP measurements are taken, the Infinity M540 patient monitor will reboot whenever the NIBP measurement violates the set alarm limit. If the reboot occurs 3 times in 10 minutes or less, the Infinity M540 patient monitor will go into fail-state, resulting in a resetting to factory defaults, losing patient settings and stored patient data. When the M540 patient monitor enters a fail-state, a continuous tone is annunciated from the device. If the M540 patient monitor is connected to the Central Station, then the Central Station will annunciate a medium alarm tone, along with an "Offline" message.

Condition 1 will occur when a non-generic blood pressure label is configured for either a Quad Hemo MPod or Dual Hemo MCable, and the hemodynamic pod is not connected; a subsequent change of patient category may not be processed by the Digital Signal Processor on the M540 patient monitor and therefore the change will not be accepted although the main screen will display patient category per the operator's request.

Condition 2 is related to the setting of the Alarm Validation feature, which is intended to be applied only to continuously monitored parameters and not to discrete measurements, such as NIBP. In software version VG7.0 the Alarm Validation feature is applied to NIBP.

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

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.

## **Containment:**

To avoid encountering the described situation, Dräger is offering the following options:

- a) If you are using the system with Neonate or Pediatric patient mode, Dräger will downgrade your systems to the previous software version.
- b) If you are using the system with Adult patient mode only, you may choose to:
  - Downgrade your systems to the previous version of software or;
  - Continue to use the VG7.0 software version. If you chose this option, your Dräger service representative will schedule a visit to label all your systems indicating that the systems are not for use in Neonate or Pediatric patient mode and will set the Alarm Validation setting to OFF to prevent condition 2 from occurring.

*Caution: Until the systems are labeled, it is important to ensure that the systems are not used in Pediatric or Neonatal mode.*

## **Correction:**

We are in the process of resolving these product issues and will provide you with an updated software version (VG7.0.1) 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.

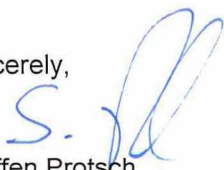
Please distribute this Safety Information to all potential users and system administrators within your facility.

We regret any inconvenience this may cause. We consider it a necessary preventive measure to increase patient safety and product reliability. We thank you for completing the attached 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,



Steffen Protsch  
Head of Segment and Product Management  
Medical Systems  
Dräger Medical Systems Inc.

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

**Medical Device Safety Notice**

**Customer Response Form**

RE: NIBP functionality with the Infinity Acute Care System (IACS); software version VG7.0

Customer Name/Address:

---

---

---

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

Please indicate whether you use your system in **Neonate or Pediatric** patient mode

Yes, downgrade my system to the previous software version

Please indicate whether you use your system only with **Adult** patient mode and whether or not you wish to downgrade your system to the previous software version

Yes, downgrade my system to the previous software version

No, I wish to continue to use the VG7.0 software. I confirm that I have been advised of the risks of using the system in Neonate and Pediatric patient mode and I agree to only use the system in Adult mode. Please label and update the settings of my system(s).

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 remove the software or update and label the systems as indicated in this notice.