

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

To our customers and users of the:

- **The Infinity® M300+**

Important Safety Notice Update!

This letter contains important information relating to the M300+ telemetry monitoring device, and the swappable battery pack.

The battery pack may unintentionally disengage during use.

April 2019

Dear Madam or Sir,

Last year, we informed you of a potential issue with the battery used with your M300+ telemetry monitoring device.

The M300+ telemetry monitoring device is equipped with a swappable battery pack that is held in place by two tabs. When the tab release points are simultaneously pressed, the battery pack can be removed and replaced with another battery pack. It has come to our attention that in some instances the battery pack may disengage during use; for example if the patient inadvertently lays on top of the device, or leans on the device against a hard surface, such as a table edge.

The detachment of the battery pack from the device will result in an Offline condition and annunciation of audio and visual alarms at the Infinity CentralStation. The "Offline" message will continue to be displayed until the battery pack is reconnected. The M300+ will retain clinical data and alarm settings for up to two minutes after the battery pack is disengaged.

We thank you for following our instructions provided in the original notices. We have resolved the issue and the solution is now fully validated and released. The solution is a battery retainer that fits over your device's battery tabs and when properly installed, will keep the battery safely in place. Each device is provided with two (2) retainers.

Please install the battery retainers on all of your devices per the instruction card provided in the kit that you are receiving. Please confirm the receipt and installation with the attached Customer Response Form. The instruction card should be kept with your battery charger for future reference.

Please distribute this information and the retainer kit to all potential users within your facility.

Dräger is committed to our customers. We apologize and regret any inconvenience this issue may had caused you and thank you for taking the steps described above to ensure effective performance of the device.

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

Thank you for your continued support.

Sincerely,

Lida Reed 
Director Quality Assurance
Draeger Medical Systems

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

Enclosure: Customer response form

Medical Device Safety Notice Update
Customer Response Form

The Infinity® M300+

Customer Name/Address:

I acknowledge the receipt of Retainer kit(s)

The retainers were installed on all Infinity M300+ devices and users were instructed on proper use.

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.