

To our customers and users of the:

- **Infinity® CentralStation, software versions VG3.0.1 and lower**
- **Infinity® M300/M300+, software versions VG 2.4 and lower**

Important Safety Notice

March 2023

Dear Customer,

During our global market surveillance activities, we have become aware of cases in which the software on the Infinity® CentralStation drops peaks on narrow waveforms causing the Infinity® M300 to fail clauses 201.12.1.101 and 201.12.1.101.8 within IEC 60601-2-27 Frequency and Impulse Response requirements. In this condition, ECG waveforms with unusually narrow and/or high frequency QRS may be displayed or printed with QRS amplitudes intermittently lower than actual.

There is no impact on calculated heart rate, arrhythmia calls, or ST analysis. Additionally, stored ECG waveforms do not represent diagnostic quality ECG nor real-time waveform data. If such examples are observed, check the ECG directly on the source patient monitor, or generate a diagnostic quality 12-lead report using the Rest ECG function if available to confirm the validity of the signal. The Rest ECG 12-lead report is not impacted by this issue.

Identification of the affected medical devices:

- Infinity® CentralStation devices running VG3.0.1 or lower (UDI DI: MS26800)
- Infinity® M300/M300+ devices running VG2.4 or lower (UDI DI: MS18501 / MS33950)

Actions to be taken:

Please confirm the current installed software version and notify Draeger Service to arrange for a software upgrade to schedule an upgrade when it becomes available.

Please ensure that all users of the affected products listed above and other people within your organization are made aware of this Important Safety Notice. If you have provided the products to third parties, please forward a copy of this information to them.

We are currently working on releasing updated software which fixes the real-time ECG waveforms to show accurate QRS amplitude for the Infinity® CentralStation and Infinity® M300/M300+ which will be provided to you at no charge.

Please keep this information at least until the software update has been completed.

We regret any inconvenience this may cause. We consider this notice a necessary preventive measure to increase your satisfaction with our products.

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

Contact:

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

Sincerely,



Lloyd Stern
Vice President of Product Management
Draeger Patient Monitoring Systems

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