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

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

June 2023

Dear Customer,

During the Verification Phase of the unreleased VG4 software of Infinity Central Station (ICS), Draeger Engineering discovered an issue of inconsistent QRS complex amplitudes being observed real time on the ICS display coming from the M300/M300+. This defect causes the Infinity® M300/M300+ to fail to meet clauses 201.12.1.101 and 201.12.1.101.8 within IEC 60601-2-27 Frequency and Impulse Response requirements. In this condition, real time narrow and tall QRS complexes may be intermittently displayed or printed with amplitudes lower than actual.

NOTE: All heartrate, ST calculations, arrythmia detection and alarms are not impacted and will continue to annunciate.

This issue is due to a software defect. This only affects the Infinity® CentralStation when used with the Infinity® M300/M300+ (pediatric and adult patients).

There have been no reports of this defect being observed in the field. There are no complaints and no reports of adverse patient impact.

Risk to Patient Health
This defect only affects the Infinity® CentralStation when used with the Infinity® M300/M300+ (pediatric and adult patients). The neonate population is not impacted as the M300/M300+ is not intended for the neonate population.

This defect impacts real time, narrow and tall QRS complexes by displaying/printing them intermittently lower than actual (may be incorrectly observed by the clinician as a low QRS). These complexes are identified as having a QRS width of 20ms. QRS complexes that have a width of 20ms are rare among the intended use populations indicated for M300/M300+ (pediatric and adult patients).

While such complexes with a width of 20ms are rare, they can be a characteristic of rare cardiac conditions, worst case scenario being posterior myocardial infarctions that present with narrow and tall QRS complexes.

When the defect occurs, you may observe some QRS complexes to be lower than the other ones which are normal and not affected.

The hazardous situation created by this defect is the clinicians may inaccurately interpret the impacted complexes, leading to the potential of misdiagnosis and life-threatening situations.

NOTE: All heartrate, ST calculations, arrythmia detection and alarms are not impacted and will continue to annunciate.

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Identification of the affected medical devices:
According to our records, you have Infinity® CentralStation devices running software versions VG3.0.1 or lower and/or Infinity® M300/M300+ devices running software versions VG 2.4 or lower. See Attachment for Part Number and UDI information.

Actions to be taken:
Until the corrected software is available and installed, clinicians should utilize the Draeger ICS/M300/M300+ Instructions For Use while applying any additional means of standard clinical practices for assessment of patients with unusually narrow and tall QRS complexes. All heartrate, ST calculations, arrythmia detection and alarms are not impacted and will continue to annunciate. Clinicians should combine this information with physical assessment of the patient and follow standard clinical practice.

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.

Actions being taken by the Company:
We are currently working on releasing updated software (ICS VG4/M300 VG3) to resolve the issue which will be provided to you at no charge; targeted for third quarter of 2023. Your local Drager Service representative will contact you to arrange a date for the software update to be performed once the software is available.

Please keep this information at least until the software update has been completed. Please also complete and return the Customer Acknowledgment Card provided to confirm to us that you have received this information.

We regret any inconvenience this may cause. We consider this notice a necessary measure to increase patient safety. We thank you for your support.

Contact:
If you have any questions regarding the operation of the Product, please contact your local Draeger representative.

Sincerely,

Anne-Severine Lima Pimenta
Sr Director, Product Management
Draeger Patient Monitoring Systems

ESRN: US-MF-000020721
List of affected medical devices including their UDI

Product name	Part Number	Unique Device Identifier (UDI)
Infinity® CentralStation	MS26800	04049098001878
Infinity® M300	MS18501	04049098004183
Infinity® M300+	MS33950	04049098095730