

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

To our customers and users of the:

Infinity® CentralStation, software version VG3.0 only

Important Safety Notice

December 2022

Dear Customer,

During our global market surveillance activities, we have become aware of cases in which the watchdog software in VG3.0 does not initiate thereby not triggering a system restart to fix hang up issues. As a result, should Infinity® CentralStation freeze, it may continue to remain in that state and refrain from restarting. During this time the bedside monitors will not be monitored at the central station. In this condition, the alarms may not annunciate at the central station and the user will not be aware of the problem.

There have been no reports of any adverse impact to the health of any patients.

Actions to be taken:

Confirm current installed version of software. If the installed version of software is VG3.0, please notify Draeger Service and arrange for a software upgrade to at least VG3.0.1. Alternatively, the software upgrade can be performed by internal, trained personnel.

Please ensure that all users of the above-mentioned products and other persons 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.

Identification of the affected medical devices:

According to our records, you have Infinity® CentralStation devices running VG3.0 manufactured by Draeger Medical Systems, Inc. that may be affected by this issue.

Please keep this information at least until the measure 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.

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

Herd A.