

Release notes

Infinity[®] M300



WARNING

To properly use this medical device, read and comply with the Instructions for Use, all supplements, and these release notes.

Software VG2.4

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Introduction

This document describes the VG2.4 software version for the Infinity M300. Software VG2.4 adds software enhancements, performance enhancements, and addresses limitations identified in preceding software versions.

Software enhancements

The VG2.4 software release provides the following software enhancements:

- Patient discharge
- Battery alarms
- ECG/Arrhythmia enhancements
 - QRS detection enhancements
 - QRS double counting detection
 - QRS detection threshold enhancements
 - QRS detection threshold enhancements (two-lead mode)
 - Arrhythmia enhancements
 - Alarm processing and hierarchy
 - Brady arrhythmia definition
- QRS threshold
- QoS (Quality of Service)

Patient discharge

Discharge can be performed from the M300 device and the Infinity CentralStation.

Battery alarms

Reported visually and acoustically at both the ICS and M300.

Low battery - Low alarm indicates battery charge is low with approximately 30 minutes of remaining charge.

Recharge battery - Critical battery alarm indicates battery charge is critically low with approximately 15 minutes of remaining charge.

ECG/Arrhythmia enhancements

VG2.4 offers the latest Dräger ECG and Arrhythmia algorithms described below.

QRS detection enhancements

Addresses QRS complex over-sensing and under-sensing to reduce false positive alarms and enhance heart rate and arrhythmia detection accuracy.

QRS double counting detection

Detects obvious double-counting by assessing morphology and strength differences in individual leads.

QRS Detection Threshold Enhancements

- *Lower minimum QRS threshold* – Expands the lower limits for QRS threshold detection for detection sensitivity of current cleared patient populations and requires additional criteria to prevent detection of P-waves as QRS complexes and prevent valid QRS complexes from being rejected as P- and T-waves.
- *'Normal' vs 'Low' setting* – Decouples user adjustment of waveform scale and QRS threshold amplitude and allows default selection per patient category to enhance user control and visibility of settings.
- *Rhythm change adjustment* – Detects and responds quicker to rhythm changes to prevent under-sensing of QRS complexes at the onset of VTach/VFib conditions.
- *Dynamic QRS detection threshold calculation* – Corrects logic error by capping the average candidate value used in dynamic adjustment of QRS detection threshold.

QRS Detection Enhancements (two-lead mode)

- *Signal Strength Estimate* – Faster reaction to noisy signals to reduce false positive alarms and enhance PVC count and arrhythmia detection accuracy.
- *Signal Quality Analysis* – Identifies which of two user-selected leads has a higher quality signal for arrhythmia detection.

Arrhythmia Enhancements

Implements corrections to improve existing arrhythmia algorithm features.

- Alarm processing and hierarchy – Correction to ensure all arrhythmia conditions are reported and displayed based on user priority.
- Brady arrhythmia definition – Defined as eight consecutive beats that have a slow rate.

QRS threshold

For ICS version VG2.1.1 or later connected with an M300 version VG2.4 or later, QRS threshold is set by a menu selection, either *Normal* or *Low*.

Note: If ICS is VG2.1 or earlier, or the M300 is VG2.3.1 or earlier, the QRS threshold is still linked to the ECG gain and the QRS threshold buttons are greyed out.

- Setting the gain to 1, 2, 4, or 8 mV/cm automatically sets the QRS threshold to *Normal*.
- Setting the gain to 0.5 or 0.25 mV/cm automatically sets the QRS threshold to *Low*.

QoS (Quality of service)

QoS to provide M300 with network priority configuration capability is implemented in VG2.4. This configuration option allows the user to adjust the DSCP (Differentiated Services Code Point) value via the service menu.

Corrected issues

The VG2.4 software release addresses the following issues currently observed with the M300:

- M300 unit LED blinking when it is docked to the Central Charger.
- M300 display not always turning off after docking to the Central Charger.
- Weight UOM toggling each time the patient category is changed at the ICS demographics screen.
- M300 unit resetting during a security port scan (now will go into Offline condition).

Software compatibility and labeling

Software compatibility

Infinity M300 VG2.4 has been validated with the following devices.

- M540 SA (standalone)
- M540
- ICS CPU 3rd Generation
- ICS CPU 4th Generation
- IACS
- Delta XL
- Delta

Known limitations

Note: These are unresolved software issues.

- Pressing the Record button does not stop an alarm recording in process from printing as expected.
- Cyrillic numerical characters are not supported in the heart rate parameter box.
- Russian characters do not display on strip recordings.
- When a fault in processing a recording occurs, recording start/finish messages are not displayed in the Infinity CentralStation message area as expected.
- When special characters are entered in a patient name field on the Infinity CentralStation for Polish, Czech and Hungarian languages the characters may be displayed as a question mark.
- ECG print strip recordings may be clipped when the amplitude is greater than 1.3mv and negative peaks with a sinusoidal signal input are present.
- When a patient transfer is done from one M300 to another M300, the "Type of implant" demographics data is omitted.
- ST and PVC/min values are expected to be displayed as "LRN" in tabular and graphical trend when ECG Learn is manually selected, but no parameter values or "LRN" will be shown.
- When two M300s assigned to an Infinity CentralStation have the same IP address, one M300 will go offline and an alarm notification will annunciate at 100%.
- The Intel® Centrino® Advanced-N 6205 chipset may interfere with the M300 network communication under heavy data load. This interference may cause the M300 to go offline until the interference is eliminated.
- The pulse alarms will annunciate earlier than specified in the IFU, but do not delay clinical treatment.
- When pediatric monitoring is selected, and the heart rate is set to 325 BPM or greater, the M300 will sometimes display values lower than 300 while the expected result is +++ or VF.
- When the patient profile is changed (e.g. Adult to Pediatric), the patient data will be recorded under a new instance. The Infinity CentralStation will maintain two separate sessions for before and after the patient profile change. All full disclosure, events and alarm histories are viewable under either of these instances.
- While configured with WPA2-Enterprise, if the M300 tries to reconfigure/reauthenticate, a gap of approximately 20 seconds is observed on the real-time waveform and full disclosure. Events that occur during this time are backfilled on the Infinity CentralStation after successful reauthentication of M300.
- In the event of an M300 reset, the clinician will immediately be alerted with a visual and audible "Offline" alarm at the Infinity CentralStation.
- Configuring wireless infrastructures with WPA or WPA+WPA2 will cause the M300 to use the deprecated TKIP cipher which may compromise security. Dräger recommends configuring the network infrastructure to use WPA2 only.

Dräger coordinated disclosure statement

At Dräger we develop technology for life which is why patient safety and medical device security are our top priorities. We endeavor to make our products as secure as possible against vulnerabilities that could affect the functioning of the products and the security, integrity and privacy of the electronic information and data used. We are committed to continuously improving the cyber security posture of our products and, as part of this effort and in line with our Coordinated Disclosure Policy, we have proactively issued an advisory to make you aware of some potential cyber security risks with our Infinity M300 patient monitors (software versions VG2.4 and earlier).

Dräger has identified that, although unlikely, an unauthorized person who has the skills and the access to the hospital network could potentially cause the Infinity M300 device to reboot, lose alarm functionality, and/or lose communication with the Infinity network.

Details of these vulnerabilities are published at the following Dräger Product Security Advisory link:

<https://static.draeger.com/security/>

Important note: Dräger has received no reports of patient harm or successful exploits associated with these vulnerabilities.

Training recommendations

The VG2.4 Instructions for use can be downloaded from Service Connect. Dräger, the manufacturer of Infinity M300, recommends that clinicians as well as those responsible for setting up and servicing devices read all Instructions for use manuals prior to employing the system in the care of patients.

Dräger recommends the responsible organization personnel see **Network security information and recommendations** in the IFU supplement for all network security guidance.

Contact your Dräger service representative for assistance with all installation requirements.

Dräger will provide product training specific to the software enhancements and upgrades referenced in these release notes, enabling your organization to fulfill the requirements of local regulations. Contact your Dräger representative for details.

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These release notes only apply to
Infinity® M300 VG2.4
with the Serial No.:
If no Serial No. has been filled in by Dräger,
these release notes are provided for general
information only and are not intended for use
with any specific machine or unit.



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Dräger reserves the right to make modifications
to the device without prior notice.