Release Notes
Infinity® Acute Care System

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

Software VG4.2

Contents

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Introduction

This document describes the VG4.2 software version for the Infinity Acute Care System (IACS) patient monitoring platform. The VG4.2 software addresses issues identified in the VG4.1.1/VG4.0.3 release.

Corrected issues

Corrected issues

The VG4.2 software release resolves the following issues:

- A wrong data output scale for the ECG waveform is sent to the Infinity Network from the IACS. This issue does not affect the ECG algorithm. Arrhythmia detection, ST segment changes, and heart rate calculation are not affected.

- The ECG waveform template used by the ECG algorithm for heart rate detection on the M540 can be corrupted by incorrect waveforms during the learning phase. This could lead to incorrectly counting normal heart rate as PVC.

- The ECG Pacer algorithm for asynchronous pacing has new instructions for correct sensing. See the *Supplement* for *Infinity Acute Care System, Software VG4.2*.

- In the case of a power cycle of the M540 during an alarm state, the message **ECG Unplugged** is displayed on the device, but the low grade alarm is not triggered.

- During etCO2 sensor warm up, the M540 will not accept changes on the adapter type (reusable, disposable) leading to incorrect CO2 measurements.

- A duplicate IP functionality error could assign the same IP address to multiple M540s operating on the same network and assigned to different monitoring units.

- A duplicate IP functionality error could assign the same IP address to multiple Cockpits operating on the same network and assigned to different monitoring units.

- Cockpit software not recognizing the alarm manager failure.

- Duplicate IP functionality error could lead to two M540s with the same IP address incorrectly assigned to the CentralStation for 20 seconds.
- M540 does not send the IGMP membership when connecting to different access points while roaming.
- When set to the Neonatal category, under certain conditions the M540 will reboot.
- The IACS produces an unusual amount of Infinity protocol traffic which floods the network. The Infinity CentralStation may go offline and the Infinity Gateway may not be able to connect to different beds as a result.
- The Cockpit may reboot due to queue and timing issues with R50N recorders.
- M540 erroneously indicates it has been assigned to a CentralStation.
- M540 could reboot if another device on the network sends a data package load larger than allowed by the operating system.
- M540 erroneously detects an internal hardware failure and continuously reboots until *Test relay* is pressed on the service menu.
- Desynchronization between the M540 and the Cockpit could occur during an immediate discharge of the patient after docking.
- M540 may reboot when a malformed Infinity network message is sent to the device.
- M540 may reboot under packet storm conditions.
- The export protocol of the IACS Cockpit will not continue sending data after an invalid checksum message is received.
- Invalid code for the patient demographic category is sent over the Infinity network. This could cause priority settings for the arrhythmia alarm to be removed.
- M540 may randomly reboot due to an error in transmitting and reading the header data of files in the memory of the device.
- IACS may accept remote view silence from other devices even if the function is not enabled on the menu.

- NIBP hardware failure alarm is not persistent and may clear the alarm after discharge while the condition is still present.
- When the M540 is coming out of standby and is not connected to the network, the volume of the alarm sound does not revert to 100%.

Change Request

The VG4.2 software release adds the following changes:

- Enables modification of the biomed and service passwords, in addition to clinical password.
- Added security for the FTP connection between M540 and the Cockpit.
- Closing of unused ports and services on network connection to the M540 and the Cockpit.

Known limitations

The VG4.2 software release has the following unresolved issues:

- The following limitations for the Distributed Denial of Service (DDoS) packet storm were found during implementation and validation:
  - An M540 device can be assigned to up to five Infinity CentralStations only.
  - When an M540 joins a wireless network after monitoring outside of the wireless range, the device could trigger the packet storm feature due to the request of trends and data from all the Infinity CentralStations that device is assigned to. This could mean that the M540 disconnects from the network for three minutes and then automatically rejoins.
  - The packet storm feature has significant improvements to maintain monitoring in comparison to the VG4.1.1 software, but in some cases it could still reboot due to the number of

monitoring parameters on demand to the Infinity CentralStation.

- o For a better understanding of the packet storm implementation and overall cybersecurity recommendations, see the *Supplement* for *Infinity Acute Care System, Software VG4.2*.

- M540 may not connect to the Cockpit due to mismatched, inconsistent internal timing between the two devices.

- During conditions of high CPU usage of the Cockpit, when an M540 is docked, the Cockpit may reboot.

- System files are vulnerable to unauthorized access and may be tampered with by a bad actor who has compromised the system.

- M540 reset may clear a previous NIBP hardware failure condition alarm.

- The ECG analog output signal is above 30 milliseconds, which is not compliant with current industry requirements for other devices such as intra-aortic balloon pumps.

- The M540 device could reboot if corrupted messages of the Infinity protocol are found on the network.

- In case of network transfer of a patient, the patient category and gender are not transferred between devices.

- In stand-alone configuration the M540 is capable of monitoring up to 9 parameters at the same time on the same screen. In the unlikely event that the user is monitoring more than 9 parameters at the same time on the same screen, an error could occur and the M540 may send corrupted packets to the network which may cause the ICS to reboot.

- When physically transferring the M540, Rest ECG demographic data is not transferred with the device and is restored to default after docking. The user must reenter the specific Rest ECG report demographic data.

- If a Rest ECG report is requested within 2 minutes after an M540 docks to an IACS, the M540 may disconnect. While disconnected, the M540 continues collecting information. The M540 resumes connection on its own.

- If the Cockpit screen is configured in manual display mode, it displays the configured parameter boxes even if they do not have any measurements or data. If the user selects one of the parameter boxes which does not have any measured value, the device could show a menu for a different parameter other than the one selected.

- The source for arterial pressure heart rate should not be selected if the patient heart rate has rapid changes due to the patient's conditions, as it could trigger unnecessary bradycardia alarms. The user should select ECG or SpO2 source instead.

- When adjusting the alarm threshold for temperatures, the adjustment precision must be within 0.1 ºF of the desired temperature threshold to trigger the necessary alarms.

- If the Drug Calculations function is used, be aware that for small doses (i.e., microgram) the calculation on the titration table may show different values for the rate due to the dose precision.

Hardware and software compatibility, and labeling

Hardware components and corresponding software versions for Cockpit VG4.2 / M540 VG4.2.

- Infinity C500/C700 Cockpit   VG4.2

  (1st generation Advantage Cockpit).

- Infinity C500/C700 Cockpit   VG4.2

  (2rd generation Kontron Cockpit)

- Infinity M540 patient monitor   VG4.2
- Infinity PS250/P2500   1.49/1.15
- Infinity M500   4.0

Minimum software versions for Dräger Infinity patient monitoring devices, basic compatibility with Cockpit VG4.2 / M540 VG4.2:

- Infinity Delta/Delta XL/Kappa series   VF9.0 and higher
- Infinity OMEGA/OMEGA S series   VF9.0 and higher
- Infinity CentralStation   VG1.1.2 and higher
- Infinity M300 telemetry monitor   VG2.2 and higher
- Infinity Gateway   VF6.0 and higher

Cockpit VG4.2 / M540 VG4.2 software IS NOT COMPATIBLE with the following Dräger systems:

- Infinity MVWS CentralStation   Not compatible
- Infinity MVVS View Station   Not compatible

-	Infinity Kappa XLT	Not compatible
-	Infinity Central Station VF	Not compatible

Compatible Dräger systems and corresponding minimum requirement software versions:

-	Dräger Evita 2 Dura ventilator	1.00
-	Dräger Evita 4 ventilator	1.00
-	Dräger Evita XL ventilator	5.00
-	Dräger V500 ventilator	2.51
-	Dräger V300 ventilator	2.42
-	Dräger VN500 ventilator	2.51
-	Dräger Carina ventilator	3.21
-	Dräger Savina ventilator	4.21
-	Dräger Oxylog ventilator 3000+	1.06
-	Dräger Perseus A500 anesthesia machine	2.01
-	Dräger Atlan A300/A350 anesthesia machine	1.01
-	Dräger Primus anesthesia machine family	4.53
-	Dräger Apollo anesthesia machine	4.53
-	Dräger Zeus IE anesthesia machine	2.0
-	Dräger Fabius anesthesia machine family	3.35b

Compatible systems from other manufacturers and corresponding minimum requirement software versions:

-	Maquet SERVO-i	7.0
-	Edwards Vigilance II	All software versions
-	Edwards EV1000	Software version 1.5
-	Covidien BIS Complete	Software version 3.0
-	IDMed ToFScan	Software version 1.5.8 and higher
-	Citrix ICA	Citrix XenApp server (versions 5, 6 and 6.5)

Training recommendations

The VG4.2 Instructions for use can be downloaded from Service Connect. Dräger, the manufacturer of Infinity Acute Care System recommends that clinicians as well as those responsible for setting up and servicing devices read all Instructions for use manuals and supplements prior to employing the system in the care of patients.

As part of the continuous efforts of Dräger to improve the cybersecurity of the device, we recommend to hospitals and those responsible for setting up and servicing the devices to head warnings in the Instructions for use and the Technical Installation Guides. Doing so can further decrease the risk of exposure or potential of occurrence from frequent to occasional. These changes can be reasonably implemented and would be beneficial to any other medical device within the hospital networks

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 regulation. Contact your Dräger representative for details.

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These release notes only apply to Infinity® Acute
Care System SW VG4.2
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.

CE 0123

Manufacturer

Draeger Medical Systems, Inc.
3135 Quarry Road
Telford, PA 18969-1042
U.S.A.
(215) 721-5400
(800) 4DRAGER
(800 437-2437)
FAX (215) 723-5935
http://www.draeger.com

EC│REP in Europe, Middle East, Africa, Latin
America, Asia Pacific distributed by
Drägerwerk AG & Co. KGaA
Moislinger Allee 53 – 55
D-23542 Lübeck
Germany
+49 451 8 82-0

FAX +49 451 8 82-20 80
http://www.draeger.com

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