Release notes

Infinity® CentralStation Wide

WARNING

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

Infinity® CentralStation Wide Software VG5.0

Contents

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Introduction

This document describes the VG5.0 software version for the Infinity® CentralStation (ICS). The VG5.0 software adds cybersecurity enhancements, and addresses limitations identified in preceding software versions.

Enhancements

The VG5.0 release provides the following enhancements.

Cybersecurity enhancements

The VG5.0 release provides secure authentication, integrity, and encryption capability on the Infinity network for the exchange of data between the ICS, IACS and M540, Infinity Gateway, and M300 and M300+ devices.

Security modes of operation

Secure mode is an enhanced Infinity network protocol that includes authentication, integrity, and encryption. Secure communication can be intercepted but not read or altered by an unauthorized device.

For Secure mode, PSKs/MCKs are loaded on all Infinity devices to establish an authorized network connection. All devices must share the same key to communicate. A mismatch, missing or expired key on one or both devices will prevent communication and patient monitoring.

NOTE
PSKs should always be loaded on the ICS first and then the M300/M300+.To operate in Secure mode, all Infinity devices must contain the same pre-shared unicast or multicast key (PSK/MKC).

DrägerService, specialized service personnel, or the hospital's trained biomedical staff loads the PSKs/MCKs to the Infinity devices using the Dräger INST software tool.

Legacy mode is the original Infinity network protocol that exchanges data between the ICS, IACS, M540 and M300/M300+.

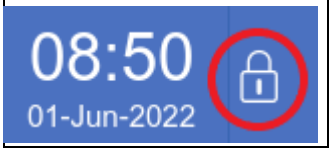
WARNING
Risk of cybersecurity attacks in Legacy mode

Disabling Secure mode and operating in Legacy mode lessens cybersecurity protection of the Infinity network communication. Legacy communication can be intercepted, read, or altered by an unauthorized device connected to the Infinity network, such as a malicious laptop.

Always operate devices in Secure mode when possible.

Secure/Legacy mode symbols

The following symbol displays in the header banner on the ICS when Secure mode is selected:

Symbol	Description
	Secure mode

NOTE

No symbol will be displayed when Legacy mode is selected.

Network security troubleshooting and error conditions

The following errors may display on the ICS and/or M300/M300+ when secure communication is failed. If the device displays the error persistently, the clinician should contact the hospital's biomedical department, DrägerService, or specialized service personnel, or replace the device.

No.	Condition	Action/Condition that caused error	Error message
1	Legacy/Secure mode mismatch between devices	Admit a new patient.	ICS: ***Call service. Secure communication failure %s***[1)] M300/M300+: ***Secure Comm Failure*** and ***Call service***
2	Remote control command or network transfer failure on destination device	PSK/MCK mismatch or expiration.	ICS: ***Call service. Secure communication failure %s***[1)] M300/M300+: ***Secure Comm Failure*** and ***Call service***
3	Remote control command or network transfer failure on originating device	PSK/MCK mismatch or expiration.	ICS: ***%s: remote control failed*** [1)] M300/M300+: ***Secure Comm Failure***
4	Device in Secure mode and device has a missing/bad PSK/MCK	PSK/MCK is missing or mismatched.	ICS: ***Call service. Secure communication failure %s***[1)] M300/M300+: ***Secure Comm Failure*** and ***Call service***

No.	Condition	Action/Condition that caused error	Error message
5	Device in Secure mode and PSK/MCK is expiring	PSK/MCK will expire in 90 days.	ICS: Low-priority alarm ***Call service. Renew PSK: %1*** [1)] M300/M300+: ***Call service*** and ***Service due (renew PSK): %1*** [1)]
6	Device in Secure mode and PSK/MCK is expiring	PSK/MCK will expire in 7 days.	ICS: Medium-priority alarm ***Call service. Renew PSK: %1*** [1)] M300/M300+: Medium-priority alarm ***Call service*** and ***Service due (renew PSK): % 1*** [1)]
7	Device in Secure mode and PSK/MCK is expiring	PSK/MCK will expire in 1 day.	ICS: High-priority alarm ***Call service. Renew PSK: %1*** [1)] M300/M300+: ***Call service*** and ***Service due (renew PSK): %1*** [1)]
8	PSK/MCK is expired	A device has an expired PSK/MCK.	ICS and IACS: ***Call service. PSK exp: %1*** [2)] M300/M300+: ***Call service*** and ***Service due (renew PSK): %1*** [1)]

1) <%s> is the Bed label of destination.
2) %1 is the date (DD-Mon-YYYY) of PSK/MCK expiration

PSK/MCK security credential expiration

The PSK/MCK security credential is valid for 2.5 years by default. The M300/M300+ and ICS will generate an expiration warning when the device is in Secure mode, and the security credential is about to expire.

Scenario	Alarm	Action
90-day notification	A 90-day notification will be issued when the security credential is within 90 days of its expiration. The user will receive a single-shot advisory tone, and a persistent low-priority cyan alarm banner in the header bar of the screen.	Contact your hospital's biomedical department, DrägerService, or specialized service personnel.
7-day caution	A 7-day caution will be issued when the security credential is within 7 days of its expiration. The user will receive a single-shot advisory tone, and a persistent medium-priority yellow alarm banner in the header bar of the screen. The user will not be allowed to admit a patient to the M300/M300+. If the M300/M300+ travels out of wireless range while the patient is still admitted during the 7-day warning period, the device will re-connect when returned to the wireless range.	Contact your hospital's biomedical department, DrägerService, or specialized service personnel.
1-day warning	A 1-day warning will be issued when the security credential is within 1 day of its expiration. The user will receive a single-shot advisory tone, and a persistent high-priority red alarm banner in the header bar of the screen. The user will not be allowed to admit a patient on the M300/M300+.	Contact your hospital's biomedical department, DrägerService, or specialized service personnel.
Expired warning	An expired warning will be issued when the security credential has expired. The user will receive a single-shot advisory tone, and a persistent high-priority red alarm banner in the header bar of the screen.	Contact your hospital's biomedical department, DrägerService, or specialized service personnel.

Corrected issues

The VG4.0 software release resolves the following issues:

- Users had unauthorized access to the GRUB (Grand Unified Bootloader).
- If the ICS application repeatedly restarted the full disclosure database may not store patient data. Within the ICS application this can be recognized by a blank ***Biomed*** screen.
- A user with access to the ICS can utilize the USB port to boot the CPU from a USB drive.
- A user can gain local privilege escalation to root using the sms_user account.
- The ICS VG3.0 installer script is not installing the touch screen driver for the 22" Draeger monitors.
- ***Export ECG*** The ECG Export button does not show ***Full disclosure*** report.
- Clicking on ***Alarms*** pages for various M540s results in bad ACS communications from M540 causing the ICS to reset when MSS clamping is in use.
- ***Get data*** “Get data“ ***HIS/CIS demographics*** fails to update the database in rare instances.
- Full disclosure has gaps in data after ICS is restarted.
- Each time the ***ECG views*** screen is accessed a function allocates colors resulting in potential memory leaks.

The VG5.0 software release resolves the following issues:

- When a bedside monitor state changes from online to offline and online again quickly there can be a full disclosure patient record inconsistency. This could result in a missing cursor time in the ***Full disclosure*** tab of the patient Trends/Data record.
- When ***French NFC mode*** is set to ***On*** before the M300 is admitted, the M300 bed view ***Admit/Standby*** page may display lb and in instead of kg and cm.
- When selecting ***Preview reports (On)*** under the ***Trends/DataReports*** button from BedView, selected reports can be previewed, but the printer icon on the preview is missing, thus users cannot print the report from the preview screen.
- If an alarm is currently displayed and the ***Admit/Standby*** screen is selected an alarm artifact for the highest alarm parameter persists on ICS.
- Patient date of birth that was entered may not be printed on reports.
- When users try to set a clinical password in the ***Biomed*** menu, "asdf" will not be recognized by the ICS.
- If an ICS connected only to M300 devices experiences a reboot, the ICS may adapt its BIOS time which may not be synchronous with the local time.
- In four languages (Swedish, Norwegian, Finnish, and Lithuanian), the "-" character (minus sign) is not supported in the pbox on the main screen, impacting negative ST or pressure values.
- Annotations in non-English languages are cropped due to a 25 character limitation.

- If users have a misconfigured wired network (e.g., routing loop), open wireless network, or replay attack, they will observe the defect that the ICS will allow duplicate packets to be displayed on its main screen, the ***Full disclosure***, and reports printed from the ***Full disclosure***.
- The SVV parameter was introduced by the bedside monitor but was not implemented on the ICS, resulting in the ICS not recognizing this parameter and displaying "??" on the ICS interface.
- The ICS displays half blank screen when exiting out of ***System setup*** without entering password.
- Autoscale option on the ICS does not support negative values for pressures and some ventilator parameters.

Hardware, software compatibility, and labeling

Software compatibility

The VG5.0 software has been validated with the following devices and software versions:

- ICS CPU 4th Generation (Legacy/Secure mode)
- Infinity CentralStation (ICS) VG4.0 (Legacy mode)
- Infinity CentralStation (ICS) VG5.0 (Secure mode)
- M300 VG3.0 (Legacy/Secure mode)
- Delta VF10.1 (Legacy mode)
- Infinity Acute Care System (IACS) including M540 VG4.n (Legacy mode only)
- Infinity Gateway VF9.0.n (Legacy mode only)
- Infinity Gateway VF9.1.n (Legacy/Secure mode)

Known limitations

The VG5.0 software release has the following unresolved issues:

- When the language in ICS is set to Serbian, the date text is incorrectly shown in Cyrillic.
- Evita XL ventilator alarm messages will not be displayed on the BedView if the Delta experiences a reset while the device has an active alarm. The alarm tone will still annunciate from the ICS and ventilator.
- The waveform scale does not update to customized settings when ***Follow ICS*** is selected. The waveform scale will retain the bed settings.

- Relabeled temperature parameters are not displayed on the main screen when using Customized layouts.
- The Customized layout is retained when a bed is removed and reassigned.
- The ***Paw*** parameter box is not displayed when using the Customized layout.
- Within the ***Trends graph***, the lower scale value of the temperature graph does not auto scale correctly in some instances.
- The M540 wireless icon is not displayed when viewing an M540 in Surveillance mode. BedView will display the wireless icon.
- The respiration markers from bedside monitor are not displayed on the ICS respiration (RRi) waveform.
- The SpO2 units for Infinity M540SA do not display in the ICS Main screen parameter box. To view the units of measure open the ICS BedView of the device.
- The ICS may continue to show ***HR*** and ***ST*** parameters as default trends when viewed in ***VentCentral***, even though users have chosen other parameters in the ***Setup*** screen as default. Users will have to re-select desired parameters to display trends as a workaround.
- Users may experience that sub dialogs in the ***VentCentral Trends*** setup are not displayed when performing electronic rounds (switching between patients, one after the other for clinical review). Re-opening the BedView for the current patient (under review) will resolve the issue.
- When users transition from using 3 leads to 6 leads or switch ***TruST 12-lead On*** and ***Off***, users may observe a total of 14 leads instead of the expected 12 leads in the ***Full disclosure*** window. Additionally, they may observe a blank screen when they scroll the visual band back and forth. Re-launching the ***Full disclosure*** window will remove the additional leads (V and V+) to display the expected 12 leads and make data appear when scrolling the visual band back and forth.
- The ICS may show inconsistent ECG amplitude peaks on the ***Full disclosure*** screens as well as on ***Full disclosure*** printed reports. The real-time ECG waveform is not impacted by this anomaly. Hence, there is no impact on calculated heart rate, arrhythmia calls, ST analysis, any associated alarms and any reports based on real time waveforms. Storage of ECG waveforms with particularly narrow and/or high frequency QRS complexes may be displayed or printed with QRS amplitudes intermittently lower than they actually are. If such examples are observed, check the ECG displayed directly on the source patient monitor and/or generate a diagnostic quality 12-lead report (using the Rest ECG function if available), to confirm the validity of the signal.
- The 12L Rest ECG report, prints time as HH:MM (hours and minutes) without seconds.
- Users may observe lowest pressure on ICS main screen to display 0mmHg even if the scale is negative on the bedside monitor. This is because negative scale is not selectable on the ICS.
- ***Scheduled reports*** may print additional reports if ALL patients are selected.This can be avoided by manually selecting only currently active patients. Desired/requested data still appears on the reports.

- Analog speaker: An R19UMKII speaker set to analog mode (green LED) will switch to USB mode (red LED) if a) a speaker in use temporarily loses power or b) analog cable is connected to speaker rear AUX jack before speaker is initially powered up.
  This can be corrected by unplugging and then re-plugging the analog cable into the speaker rear AUX jack.
  USB speakers: An R19U or R19UMKII speaker set to USB mode (red LED) may switch to analog mode (green LED) if a cable is connected to the speaker rear AUX jack.
  This is prevented by ensuring a cable is NOT connected to speaker rear AUX jack for speaker set to USB.

Training recommendations

The VG5.0 Instructions for use can be downloaded from ServiceConnect. Dräger, the manufacturer of Infinity CentralStation, requires 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.

Dräger recommends the responsible organization personnel refer to the ***Cybersecurity information and recommendations*** in the Instructions for use for all network security guidance.

Contact DrägerService, or specialized service personnel for assistance with all installation requirements.

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

Trademarks

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These release notes only apply to
Infinity® CentralStation Wide VG5.0
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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