

## Supplement

### **WARNING**

For a full understanding of the performance characteristics of this device, the user should carefully read this supplement and the related instructions for use before use of the device.

## **Infinity® Acute Care System VG4.2**



## Supplement for Infinity Acute Care System VG4.2

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This document supplements the instructions for use of Infinity Acute Care System (IACS) Monitoring Applications Software VG4.2, and Infinity M540 patient monitor Software VG4.2.

### Intended use

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For information about the Intended use, see the:

- *Instructions for use Infinity Acute Care System, Infinity M540 patient monitor, Software VG4.n*
- *Instructions for use Infinity Acute Care System, Monitoring applications, Software VG4.n*

### Indications for use

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For information about the Indications for use, see the:

- *Instructions for use Infinity Acute Care System, Infinity M540 patient monitor, Software VG4.n*
- *Instructions for use Infinity Acute Care System, Monitoring applications, Software VG4.n*

### Security information and recommendations

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Dräger provides the following security information and recommendations:

- Physical security of the patient monitors is recommended and is the responsibility of the operating organization.
- Physical security of the telecommunications closet is recommended and is the responsibility of the operating organization.
- Dräger recommends that operating organizations restrict physical access to unused Ethernet ports on the IACS.
- Dräger recommends that operating organizations restrict physical access to unused USB and serial ports on the IACS.
- Dräger relies on the medical device isolation mechanism of the VLANs and the proper configuration, implementation, and use of the operating organization's security measures to prevent the introduction of malware onto the Infinity network.

### CAUTION

Dräger recommends that all documents opened for viewing within a hospital LAN must come from a secure source.

## Software and firmware upgrades

Dräger-authorized service technicians perform software and firmware installations using the Infinity Installer application. For specific instructions regarding the installation of such software and firmware, contact Dräger-authorized service technicians.

### WARNING

**Any changes or modifications to the device hardware or software must be performed exclusively by service technicians authorized by Dräger. Any unauthorized change can decrease patient safety, void the user's authority to operate the equipment, and void the warranty.**

## Cybersecurity information and recommendations for M540

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- Dräger recommends always following network security best practices, such as maintaining software, updating anti-virus/anti-malware tools, segmenting via firewalls, closing unused ports, restricting user permissions, limiting third party access, and monitoring network activity. Without these measures, there is an increased risk that critical events may go undetected in cases of malicious attack, which could result in patient harm.
- Only install and operate Infinity monitoring devices on Dräger segregated IT networks which contain cybersecurity safeguards against sources of malicious attack. For guidance or additional information, contact Dräger-authorized service personnel.
- M540 device settings may be compromised in the event of a cybersecurity attack or other configuration error. To restore device settings to their previous state, power cycle the unit and select **No** when prompted on the New Patient screen. Device settings can be restored manually with patient discharge and re-admit at the M540. In the event of a cybersecurity attack, if the device enters a fail state (sustained alarm tone sound), power cycle the unit, re-admit the patient at the IACS and adjust parameter alarms as appropriate for the patient as they revert to unit defaults.
- M540 devices are designed to maintain basic patient monitoring functions during conditions of network overload. The device ensures that high priority tasks are carried out by the real-time operating system. This situation may result in:
  - A delay in alarm generation and a delay in updates of measured parameters while the system checks if the network overflow conditions persist.
  - A temporary loss of network communication between the IACS and the M540.
  - A temporary loss of network communication in wireless mode.

In addition, the device ensures that malformed data packets will be discarded, thereby eliminating device reset and maintaining monitoring.

- M540 is an embedded code device that verifies sensitive data integrity (i.e., code space, stored configuration data, and DRAM content) at startup and during operation. If the stored settings are corrupt, the device assumes that DRAM has failed and restores its factory default settings with audible and visual notification to users.
- Dräger recommends the use of WPA2-Personal to provide for strong authentication and data protection for wireless communication between M540 and 802.11 access points. With this protection in place, clinical data will be secure in a wireless encrypted tunnel. Use of lower levels of security or no security may allow clinical data to be compromised which could result in patient harm.
- Dräger recommends that the responsible organization install and operate Infinity monitoring devices on separate, isolated, VLANs to reduce risk from network security vulnerabilities. For increased wireless network security, configure Dräger devices with WPA2-Personal authentication. Use of QoS with M540 is required to ensure optimal network data transmission. Without these measures, there is an increased risk that critical events may go undetected in cases of malicious attack, which could result in patient harm.
- Dräger recommends, when installing and operating Dräger medical devices, to periodically change the device password as appropriate for the hospital environment.
- The M540 device contains the following interfaces:

Type	Purpose
<b>M540 interfaces</b>	
Display	Visualize various clinical and device configuration parameters
Hard keys	Provides for a modest level of user interaction, such as: startup/shutdown of the device, alarm silence, and NIBP start/stop measurement
Wireless network	Provides for communication with other Infinity network devices and some diagnostic tools via 802.11
Patient cable and accessory connectors	Provides for connection to patient monitoring cables such as: ECG, SpO2, NIBP, IBP, Temp/Aux, etCO2
Optical Ethernet link	Provides for communication to the M500 docking station
<b>M500 interfaces</b>	
Optical Ethernet link	Provides for communication to the M540 monitoring device
System cable connector	Provides for power supply and communication to other components of the system or Ethernet connection to other Infinity devices
Nurse Call connector	Provides for remote notification of medium- and high-priority alarms
Scio connector	Provides for communication to the respiratory gas module Scio

The M540 device communicates via the 802.11 wireless LAN standard during transport and via wired LAN when docked using the following TCP/IPs. Client ports are used outbound from the device, while server ports accept incoming connections inbound from other devices on the network:

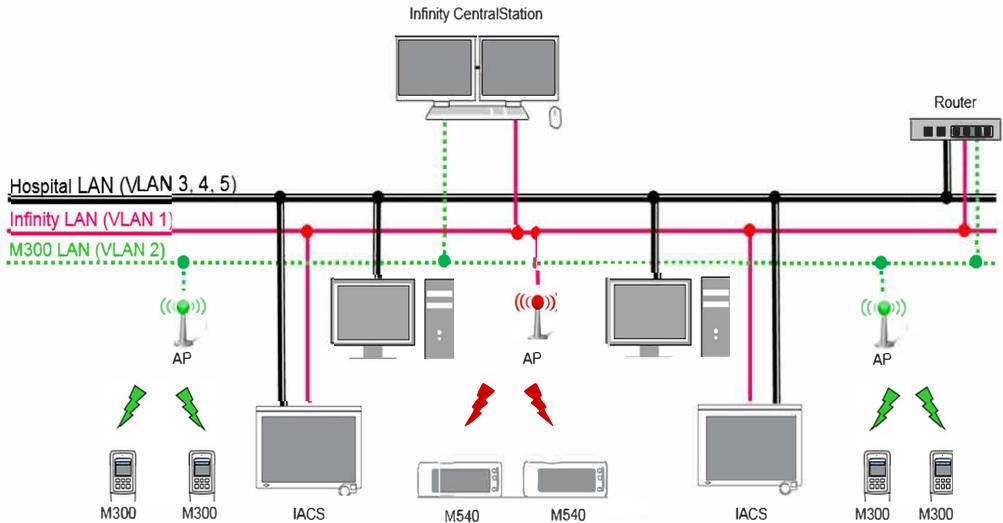
Application Protocol	Transport Protocol	Port Number	Client/Server
FTP	TCP	21	Server
HTTP	TCP	80	Server
Infinity ACS	TCP	1950	Server
Infinity PDS	UDP	2050	Client
Infinity name service	UDP	2150	Client/Server
Infinity recorder	TCP	6000	Client
Infinity recorder	TCP	6050	Client
Infinity remote record	TCP	7100	Server
Infinity ACS tunnel	TCP	32001	Server
SNMP	UDP	161	Server
Infinity AGS	UDP	2000	Client/Server
Infinity time service	UDP	2100	Server

- If excessive network traffic is encountered a message indicating a packet storm has been detected is captured in the error log. Additionally, **Offline** or **Not monitored by central** may be displayed in the status bar of the M540.

M540 error logs can be obtained using the device webpage, or via connection to a USB flash drive when connected to an IACS. If the excessive network traffic error is observed, report the condition to the hospital's biomedical and IT departments.

When excessive network traffic is encountered, you may notice the following behaviors on the M540 device:

- The M540 will continue to monitor, audibly alarm, and display patient data. However, the flashing alarm on the M540 display, including header bar and parameter box, may freeze for up to 8 seconds during the confirmation of the excessive network traffic. This behavior will be repeated every 3 minutes until the condition is cleared.
- The M540 connection to the C500/C700 and/or to the wireless or standalone network may be temporarily lost. The message **Disconnected from M540** will display on the Cockpit. When the excessive network traffic is no longer encountered, the M540 will resume normal operation on the network. The C500/C700 will reconnect to the M540 within 20 seconds.
- The M540 monitoring device provides logging of network security events, such as: overload detection, malformed control packets, software reset, and presence of multicast and control message storms. M540 error logs may be obtained and saved using a USB flash drive when part of an Infinity Acute Care System, or by contacting Dräger-authorized service personnel. If this error is observed, report the condition to the hospital's biomedical and IT departments.



- Dräger maintains a product security page for continued visibility into cybersecurity threats in the field and possible vulnerabilities in our devices. In the event you encounter a cybersecurity threat or identify a security vulnerability in one of our products, please visit the following website for instructions on how to provide this information to Dräger via encrypted e-mail: <http://static.draeger.com/security/>.
- In the event of a cybersecurity incident, maintain the M540 logs for investigatory purposes. Isolate the affected M540 unit(s). Contact your hospital's biomedical department immediately.
- The M540 device configurations can be recovered by one of the following methods:
  - Manually discharge patient, re-admit patient and configure settings. For more information, see *Operating Concept > Profiles* in the *Instructions for use Infinity Acute Care System, Infinity M540 patient monitor, Software VG4.n*.
  - Load the profile from the M500. For more information, see *Operating Concept > Profile behavior in a standalone configuration* in the *Instructions for use Infinity Acute Care System, Infinity M540 patient monitor, Software VG4.n*.

## Cybersecurity information and recommendations for IACS

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- Dräger recommends always following network security best practices, such as maintaining software updates, using anti-virus/anti-malware tools, segmenting via firewalls, closing unused ports, restricting user permissions, limiting third party access, and monitoring network activity. Without these measures, there is an increased risk that critical events may go undetected in cases of malicious attack, which could result in patient harm.
- Only install and operate Infinity monitoring devices on Dräger segregated IT networks which contain cybersecurity safeguards against sources of malicious attack. For guidance or additional information, contact Dräger-authorized service personnel.
- IACS device settings may be compromised in the event of a cybersecurity attack or other configuration error. To restore device settings to their previous state, power cycle the unit and select **No** when prompted on the New Patient screen. Device settings can be restored manually with patient discharge and re-admit at the Cockpit. In the event of a cybersecurity attack, if the device enters a fail state (sustained alarm tone sound), power cycle the unit, re-admit the patient at the IACS and adjust parameter alarms as appropriate for the patient as they revert to unit defaults.
- M540 devices are designed to maintain basic patient monitoring functions during conditions of network overload. The device ensures that high priority tasks are carried out by the real-time operating system. This situation may result in:
  - A delay in alarm generation and a delay in updates of measured parameters while the system checks if the network overflow conditions persist.
  - A temporary loss of network communication between the IACS and the M540.
  - A temporary loss of network communication in wireless mode.

In addition, the device ensures that malformed data packets will be discarded, thereby eliminating device reset and maintaining monitoring.

- M540 is an embedded code device that verifies sensitive data integrity (i.e., code space, stored configuration data, and DRAM content) at startup and during operation. If the stored settings are corrupt, the device assumes that DRAM has failed and restores its factory default settings with audible and visual notification to users.
- Dräger recommends that the responsible organization install and operate Infinity monitoring devices on separate, isolated, VLANs to reduce risk from network security vulnerabilities. For increased wireless network security, configure Dräger M540 devices with WPA2-Personal authentication. Use of QoS with IACS is required to ensure optimal network data transmission. Without these measures, there is an increased risk that critical events may go undetected in cases of malicious attack, which could result in patient harm.
- Dräger recommends, when installing and operating Dräger medical devices, to periodically change the device password as appropriate for the hospital environment.

The IACS device contains the following interfaces:

Type	Purpose
<b>M540 interfaces</b>	
Display	Visualize various clinical and device configuration parameters
Hard keys	Provides for a modest level of user interaction, such as: startup/shutdown of the device, alarm silence, and NIBP start/stop measurement
Wireless network	Provides for communication with other Infinity network devices and some diagnostic tools via 802.11
Patient cable and accessory connectors	Provides for connection to patient monitoring cables such as: ECG, SpO2, NIBP, IBP, Temp/Aux, etCO2
Optical Ethernet link	Provides for communication to the M500 docking station
<b>M500 interfaces</b>	
Optical Ethernet link	Provides for communication to the M540 monitoring device
System cable connector	Provides for power supply and communication to other components of the system or Ethernet connection to other Infinity devices
Nurse Call connector	Provides for remote notification of medium- and high-priority alarms through a relay connector
Scio connector	Provides for communication to the respiratory gas module Scio
<b>Cockpit interfaces</b>	
Display	Visualize various clinical and device configuration parameters
Hard keys and rotary knob	Provides for a modest level of user interaction, such as: startup/shutdown of the device, alarm silence, and use of the rotary knob
Wired network (hospital LAN)	Provides wired communication with the hospital information network
External display connector	Provides the ability to clone the screens to other displays
Serial data connection-RS-232	Provides communication to other medical devices approved by Dräger. For additional information, see the main instructions for use <i>Infinity Acute Care System – Monitoring Applications</i>
Serial data connection-USB	Provides communication to other user interfaces such as the mouse and keyboard
System cable connectors	Provides for power supply and communication to other components of the system
<b>P2500 interfaces</b>	
System cable connectors	Provides for power supply and communication to other components of the system
Wired network (Infinity LAN)	Provides wired communication with other Infinity network devices

Type	Purpose
Nurse Call connector	Provides remote notification of medium- and high-priority alarms through a relay connector
Export protocol connector	Allows sharing data over Dräger and third-party devices such as clinical information systems, anesthesia record systems, and data loggers

The IACS devices communicate via the 802.11 wireless LAN standard during M540 transport and via wired network connection when docked using the following TCP/IP network ports. Client ports are used outbound from the device, while server ports accept incoming connections inbound from other devices on the network:

### Hospital

The following inbound ports are open on the hospital network connection.

Port	Protocol	Service
68	UDP	DHCP client
161	UDP	SNMP
20000	TCP	S14 network manager test

All other inbound connections are disallowed. All outbound connections are allowed.

### Infinity

The following inbound ports are open on the Infinity network connection.

Port	Protocol	Service
1950	TCP	ACS
2000	UDP	AGS
2050	UDP	PDS
2100	UDP	Time service
2150	UDP	Name service
7100	TCP	ACS recorder manager
20000	TCP	S14 network manager test
20010	TCP	S14 physical transfer
20011	TCP	S14 profile transfer
20012	TCP	S14 message transfer
32002	TCP	ACS tunnel service

All other inbound connections are disallowed. All outbound connections are allowed.

## Aux

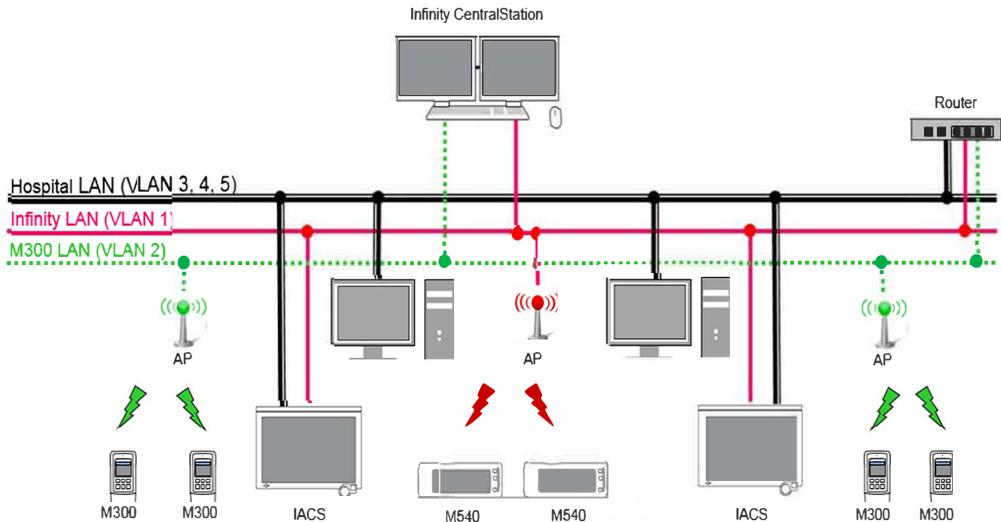
The Aux connection is disabled.

- If excessive network traffic is encountered, a message indicating a packet storm has been detected is captured in the error log. Additionally, **Offline** or **Not monitored by central** may be displayed in the status bar of the M540.

Monitoring application error logs can be obtained using a USB flash drive. If the excessive network traffic error is observed, report the condition to the hospital's biomedical and IT departments.

When excessive network traffic is encountered, you may notice the following behaviors on the IACS devices:

- The M540 will continue to monitor, audibly alarm, and display patient data. However, the flashing alarm on the M540 display, including header bar and parameter box, may freeze for up to 8 seconds during the confirmation of the excessive network traffic. This behavior will be repeated every 3 minutes until the condition is cleared.
- The M540 connection to the C500/C700 and/or to the wireless or standalone network may be temporarily lost. The message **Disconnected from M540** will display on the Cockpit. When the excessive network traffic is no longer encountered, the M540 will resume normal operation on the network. The C500/C700 will reconnect to the M540 within 20 seconds.



- Dräger maintains a product security page for continued visibility into cybersecurity threats in the field and possible vulnerabilities in our devices. In the event you encounter a cybersecurity threat or identify a security vulnerability in one of our products, please visit the following website for instructions on how to provide this information to Dräger via encrypted e-mail: <http://static.draeger.com/security/>.

- In the event of a cybersecurity incident, maintain the IACS logs for investigatory purposes. Isolate the affected IACS unit(s). Contact your hospital's biomedical department immediately.
- The IACS device configurations can be recovered by one of the following methods:
  - Manually discharge patient, re-admit patient at the Cockpit or M540 and configure settings
  - Load the profile from the M500. For more information, see *Profile behavior in standalone configuration* in the *Infinity M540 patient monitor* instructions for use.
- Dräger recommends that all documents opened for viewing within a hospital LAN must come from a secure source.

## Technical data

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### Temperature

Parameter display	Temperatures: Ta, Tb, $\Delta T$ , T1a, T1b, $\Delta T1$
Measurement range	Ta, Tb, T1a, T1b: 0 to 50 °C (32 to 122 °F) $\Delta T$ , $\Delta T1$ : 0 to 50 °C (0 to 90 °F)
Resolution	0.1 °C (0.1 °F)
Accuracy (exclusive of probe)	Ta, Tb, T1a, T1b: $\pm 0.1$ °C ( $\pm 0.2$ °F) $\Delta T$ , $\Delta T1$ : $\pm 0.2$ °C ( $\pm 0.4$ °F)
Probe accuracy	Reusable probe: $\pm 0.1$ °C ( $\pm 0.2$ °F) at 0 °C to 50 °C (32 to 122 °F) Disposable probes: $\pm 0.1$ °C ( $\pm 0.2$ °F) at 25 °C to 45 °C (77 to 113 °F) $\pm 0.2$ °C ( $\pm 0.4$ °F) at 0 to 25 °C (32 to 77 °F)
Average update time	<2.5 s
Response time	23 to 44 °C (73.4 to 111.2 °F) $\pm 0.2$ °C ( $\pm 0.4$ °F) within 150 s 2 °C (°F) temperature change (approximately): – reusable GP probes with cover: 60 s – disposable GP probes: 30 s – reusable and disposable skin probes: 15 s
Degree of protection against electric shock	Type CF
Defibrillation protection	Yes

## Environment

Humidity (non condensing)	Operating: 10 to 95% Storage: 5 to 95%
Temperature	Operating: 0 to 40 °C (32 to 104 °F) <b>NOTE:</b> At ambient temperatures above 35 °C (95 °F) the battery may not be charging even while it is docked in the M500; however, the battery icon still indicates the actual battery charge. Storage: -20 to +60 °C (-4 to +140 °F)
Atmospheric pressure	Operating: 485 to 795 mmHg (647 to 1060 hPa) Storage: 375 to 795 mmHg (500 to 1060 hPa)

## Compatible Medibus.X devices

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The Cockpit device connectivity interface allows data from various standalone devices to display parameters, settings, and waveforms on the Cockpit.

The following table lists which devices and corresponding software versions are supported with Medibus.X version 1.0.3.

Supported device	Supported software version
<b>Ventilators</b>	
Dräger Evita V500	2.31
Dräger Babylog VN500	2.31
Savina 300	4.02
Carina	3.21
Dräger Evita V300	2.31
Oxylog 3000+	1.04
<b>Anesthesia machines</b>	
Atlan A350/A300	1.01
Primus family, Apollo	4.5
Infinity Perseus A500	1.11
Zeus IE	1.04
Fabius family	3.35

## ST monitoring specifications

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In the ST segment analysis table, the updated ST input accuracy is as follows:

### ST segment analysis

ST input accuracy	<p><math>\pm 0.5</math> mm (0.05 mV) or 15% of the measured value is valid for STI, STII, STIII, aVR, aVL, aVF, V, V+, V1 to V6, dV1, dV3, dV4 and dV6.</p> <p><math>\pm 3.2</math> mm (0.32 mV) for STVM and STCVM.</p> <p><b>CAUTION</b></p> <p><b>ST accuracy may be impacted if ECG double-counting occurs or with highly irregular heart rates.</b></p> <p><b>NOTE</b></p> <p>In an unlikely scenario where the heart rate is low (e.g., 30 bpm, 45 bpm), and ST-segment deviation is high (<math>\geq \pm 13</math> mm), the claimed ST accuracy might not be met on one or two leads.</p>
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### NOTE

The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes needs to be determined by a clinician.

## Monitoring paced patients

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When pacer detection is activated, the M540 uses the following specifications to identify a pulse as a pacer pulse:

- Amplitude ( $a_p$ ):  $\pm 2$  to  $\pm 700$  mV
- Width ( $d_p$ ): 0.2 to 2.0 ms

A paced beat is identified in the heart rate parameter field by the letter P that appears next to the flashing heart symbol when a pacer pulse is detected.

On the ECG waveform, blue spikes appear to identify pacer spikes.

**NOTE**

In adult and pediatric mode, pacer detection is deactivated automatically when the M540 is docked or when the ESU filter is activated. In adult and pediatric mode, the M540 automatically activates the pacer detection when undocked. In neonatal mode pacer detection is disabled.

When pacer detection is deactivated in adult or pediatric mode, the message **Pacer off**, appears in the top **ECG** channel.

**To activate/deactivate pacer detection**

- Select the heart rate parameter field to select the **ECG** page directly.
- or
- 1 Select **Sensor parameters...** from the main menu bar.
- 2 Select the **ECG** tab to access the **ECG** page.
- 3 Select the **Settings 2** tab.
- 4 Select **On** next to **Pacer detection**.

**Pacemaker precautions**

The M540 has been tested for pacemaker pulse detection. However, it is impossible to anticipate every clinically possible waveform characteristic. For paced patients, the M540 could therefore miscount heart rates and misinterpret rate-dependent arrhythmias. False low-rate alarms can result under the following conditions:

- 700-mV pacer pulses followed by QRS complexes smaller than 0.5 mV
- Asynchronous pacemaker pulses with overshoot
- Asynchronous pacemaker with large amplitude pace pulses with no overshoot and at low heart rate (30 bpm)
- Large atrial pacemaker pulse preceded by a large ventricular pacemaker pulse with overshoot (both having identical amplitude and durations)

False low-rate and asystole alarms can result in the following conditions:

- Fused beats and asynchronous pacemakers, when coupling intervals are in the range of +10 to –90 ms

As well, false high-rate alarms can result under the following condition:

- Asynchronous pacemaker with large pace pulse tails and at low heart rate (30 bpm)

- Pace pulses above 500 - 700 mV, such as when an external pacemaker is used, may cause an electrical overshoot which can mimic a QRS complex, which may affect the accuracy of ECG beat classification.  
  
Dräger recommends closely monitoring paced patients.
- Large atrial pacemaker pulse preceded by a large ventricular pacemaker pulse (both having identical amplitude and durations)

**WARNING**

Impedance respiration and pacemaker detection are inoperative when the ESU filter is selected. See *For your safety and that of your patients > General safety information > Electrosurgery in:*

- *Instructions for use Infinity Acute Care System, Infinity M540 patient monitor, Software VG4.n*
- *Instructions for use Infinity Acute Care System, Monitoring applications, Software VG4.n*

**WARNING**

Make sure pacer detection is deactivated for patients without pacemakers. Make sure it is activated for patients with pacemakers. Deactivating pacer detection for paced patients may result in pacemaker pulses being counted as regular QRS complexes, which could prevent an asystole alarm from being detected. Always verify that the pacer detection status is correct for the patient. Be aware that setting the ECG filter option to ESU deactivates pacemaker detection automatically.

**WARNING**

Interference from a monitor may cause some rate-adaptive implantable pacemakers to pace at unnecessarily high rates. Be extra vigilant with patients when using these types of pacemakers.

**WARNING**

Always keep pacemaker patients under close surveillance and monitor their vital signs carefully.

- Do not assess the patient's condition exclusively from the heart and respiratory rate values the monitor displays and the rate alarms that are generated. Heart rate meters may continue to count the pacemaker rate during cardiac arrest or some arrhythmias.
- Some pacemakers (especially external pacemakers with body surface electrodes) emit pulses with amplitudes far exceeding the 700 mV maximum amplitude specified for the M540. The M540 may incorrectly detect these large pacemaker pulses as valid QRS complexes and may fail to detect cardiac arrest.

**NOTE**

Full arrhythmia processing does not occur on detected paced beats.

## Pacer fusion mode

Pacer fusion mode offers increased detection sensitivity to fused paced beats, thereby reducing false asystole and low heart rate alarms.

### WARNING

**Pay close attention to pacemaker patients being monitored in Fusion mode because this mode may increase the risk of falsely counting pacemaker spikes as QRS complexes, thus failing to detect cardiac arrest.**

### CAUTION

**Fusion** mode pacer detection is not intended for use with large-signal, unipolar pacemakers. It is intended for use only with bipolar pacemakers. Observe the following:

- Select **Fusion** mode only in situations where it becomes necessary to suppress repeated false asystole and/or false low heart rate alarms.
- Before selecting **Fusion** mode, be certain that the patient has a bipolar pacemaker (external or implanted) and that it is accurately programmed as appropriate for that patient.
- Do not use **Fusion** mode if you are uncertain as to what type of pacemaker is being used.

### NOTE

The displayed heart rate may be incorrect if the pacemaker pulse wanders through the ECG waveform (ineffective pacing). During the wandering pacemaker test required by AAMI/ANSI/IEC 60601-2-27, the displayed heart rate varied between 15 and 30 bpm (rather than consistently being 30 bpm).

## Device interference with pacemaker monitoring

The following devices can interfere with pacemaker monitoring.

### Impedance-derived rate response pacemakers

These pacemakers emit pulses that adjust the pacemaker rate to the respiratory rate. These pulses could be falsely interpreted as pacer pulses. For impedance-derived rate response pacemakers, modify the electrode placement until the blue spikes on the waveform disappear since they are not related to real pacer impulses.

### Infusion or roller bypass pumps

Interference from these devices can cause pacer spikes to appear on the waveform although the ECG appears normal. To determine if the pump is the cause of the artifact, turn it off, if possible. To minimize the artifact, choose the lead with the best signal or replace the electrodes. Rerouting pressure tubing away from the infusion tubing can also improve the ECG signals.

### Line isolation devices

To minimize the effect of line isolation devices, which can cause temporary disturbances in the ECG signal, follow these precautions:

- Choose the lead with the best signal for ECG monitoring.
- Check the ECG electrodes; replace them, if necessary.

**Transcutaneous electrical nerve stimulators**

Signals from transcutaneous electrical nerve stimulators (TENS) often resemble pacemaker signals and can be labeled as such. The M540 can reject valid QRS complexes, which follow misinterpreted TENS signals. If TENS signals continue to register as pacemaker spikes, deactivate pacemaker detection.

## EMC declaration

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### General information

This device was tested for electromagnetic compatibility using accessories from the list of accessories. Other accessories may only be used if they do not compromise the electromagnetic compatibility. The use of non-compliant accessories may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device.

This device may be used in the direct vicinity of other devices only if Dräger has approved this device arrangement. If no approval has been given by Dräger, it must be ensured that this device functions correctly in the desired arrangement before use. The instructions for use for the other devices must be followed.

### Electromagnetic environment

Emissions	Compliance
Radiated emissions	Class A, group 1 (30 MHz to 1 GHz)
Conducted emissions	Class A, group 1 (150 kHz to 30 MHz)

#### NOTE

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Immunity against	Test level and required electromagnetic environment
Electrostatic discharge (ESD) (IEC 61000-4-2)	Contact discharge: $\pm 8$ kV
	Air discharge: $\pm 15$ kV
Fast transient electrical disturbances (bursts) (IEC 61000-4-4)	Power cable: $\pm 2$ kV
	Longer signal input lines/output lines: $\pm 1$ kV
Impulse voltages (surges) (IEC 61000-4-5)	Voltage, external conductor – external conductor: $\pm 1$ kV
	Voltage, external conductor – protective ground conductor: $\pm 2$ kV
Magnetic fields at mains frequency (IEC 61000-4-8)	30 A/m

Immunity against	Test level and required electromagnetic environment
Voltage dips and short interruptions in the supply voltage (IEC 61000-4-11)	100 % drop, 0.5 period 100 % dip, 1 period 30 % dip, 25/30 periods  Voltage interruptions: 100 % drop, 5 seconds
Radiated high-frequency disturbances (IEC 61000-4-3)	80 MHz to 2.7 GHz: 3 V/m
Conducted high-frequency disturbances (IEC 61000-4-6)	150 kHz to 80 MHz: 3 Vrms, ISM bands: 6 Vrms
Electromagnetic fields in the vicinity of wireless communication devices	Various frequencies from 385 MHz to 5785 MHz: 9 V/m to 28 V/m, with various pulse modulations

## Recommended separation distances from wireless communication devices

To ensure that the functional integrity of this device is maintained, there must be a separation distance of at least 1.0 m (3.3 ft) between this device and wireless communication devices.

## Viewing the system information

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This section describes how to review the various system information which is located in different menus under the **System information** dialog.

### NOTE

When the wireless option is not installed, the **Wireless** tab does not appear and the information is not available.

### To view the system information

- 1 Press the **Menu** function key.
- 2 Touch the **System setup** tab.
- 3 Touch the **System information** button. This menu displays general system information.
- 4 Touch one of the following tabs to view the additional system information: **Name service**, **Docking station**, **Wireless**.

<b>Dialog</b>	<b>Available information</b>
<b>System information (tab 1)</b>	<b>Serial number</b>
	<b>H/W interface</b>
	<b>S/W revision</b>
	<b>S/W checksum</b>
	<b>FPGA revision</b>
	<b>SpO<sub>2</sub> sensor type</b>
	<b>Wireless firmware</b>
<b>System information (tab 2)</b>	<b>Boot loader</b>
	<b>NTIM revision</b>
	<b>OBM revision</b>
<b>Name service</b>	<b>IP address</b>
	<b>Subnet mask</b>
	<b>Default gateway</b>
	<b>Bed label</b>
	<b>Care unit</b>
	<b>Hospital</b>
	<b>Mon. unit</b>
	<b>Mon. unit ID</b>
<b>Docking station</b>	<b>DS revision</b>
	<b>MAC address</b>
<b>Wireless</b>	<b>WLAN MAC address</b>
	<b>Multicast address</b>
	<b>Signal strength</b>
	<b>BSSID</b>
	<b>SSID</b>
	<b>Encryption</b>
	<b>Channel number</b>
	<b>Regulatory domain</b>

## Configuring the biomed settings

This section describes the setup functions of the **Biomed** dialogs.

### To access the **Biomed** dialog

- 1 Press the **Menu** function key.
- 2 Touch the **System setup** tab.
- 3 Touch the **Biomed** button.
- 4 Enter the password and touch **OK**.
- 5 Touch the **Settings 1** or the **Settings 2** button.

<b>Biomed dialogs</b>		
<b>Biomed &gt; Settings 1 dialog</b>		
<b>Selection</b>	<b>Available settings</b>	<b>Description</b>
<b>Language</b>	<b>English, German, Spanish, French, Italian, Port.(Br), Port (EU), Russian, Japanese, Swedish, Norweg., Danish, Dutch, Turkish, Polish, Finnish, Greek, Chinese, Hungarian, Czech</b>	Selects the language of the M540 screen text.
<b>Date</b>	– <b>Day</b> – <b>Month</b> – <b>Year</b>	Allows you to enter the date.
<b>Time</b>	– <b>Hour</b> – <b>Minute</b>	Allows you to enter the time.
<b>Simulation</b>	– <b>Cancel</b> – <b>OK</b>	Activates simulation mode. Select the <b>Discharge</b> function key to exit.
<b>Save profile</b>	– <b>Cancel</b> – <b>OK</b>	Saves and replaces the profile (including the current views) for the current patient category.  Be aware that saving profiles must be done separately for each patient category.
<b>Restore Profile</b>	– <b>Cancel</b> – <b>OK</b>	Restores the saved profile settings and up to five available views on the M540.  In standalone mode, if docked on an M500 that has a saved profile, selecting this button will restore the M500 default profile.

<b>Biomed dialogs</b>		
<b>Biomed &gt; Settings 1 dialog</b>		
<b>Selection</b>	<b>Available settings</b>	<b>Description</b>
<b>Line frequency</b>	50, 60 Hz (default)	Selects the line frequency.
<b>Biomed &gt; Settings 2 dialog</b>		
<b>French NFC</b>	<ul style="list-style-type: none"> <li>– <b>Off</b> (default)</li> <li>– <b>On</b></li> </ul>	When activated, heart rate alarms cannot be turned off, and the <b>All alarms pause</b> period cannot exceed 3 minutes.
<b>Test pulse</b>	None	Generates 1 mm test pulse.
<b>SpO<sub>2</sub> sensor type</b>	<ul style="list-style-type: none"> <li>– <b>Masimo</b> (default)</li> <li>– <b>Nellcor</b></li> </ul>	Selects the type of sensor.
<b>Change clinical password</b>	Use the keypad to enter the new password (up to 4 numbers)	Configures a new password for the M540.  When an M540 whose password has been changed docks to a Cockpit with a different password, the Cockpit password overrides the M540 password.  <b>CAUTION</b>  <b>Be sure to record the new password because it cannot be retrieved once it is lost. For further assistance, contact specialized service personnel.</b>
<b>Change biomedical password</b>		

## Biomed setup – network setup

The following table lists the available settings for configuring the Infinity and the hospital network settings in the **Infinity** and the **Hospital** pages. To access the pages, see "Biomed setup" on page 25. After making the desired changes, select the **Apply** button to activate them.

Selection	Available settings	Description
<b>DHCP</b>	<ul style="list-style-type: none"> <li>– <b>Disabled</b> (default)</li> <li>– <b>Enabled</b></li> </ul>	<p>Applies to the hospital network.</p> <p>When the Dynamic Host Configuration Protocol (DHCP) is activated, the settings for <b>IP address</b>, <b>Subnet mask</b>, <b>Gateway</b>, and <b>Primary DNS</b> are pulled automatically from the server.</p>
<b>IP address</b>	User selectable	Allows you to select an IP address manually (the <b>DHCP</b> setting has to be set to <b>Disabled</b> ).
<b>Subnet mask</b>	User selectable	Allows you to set up a subnet mask (the <b>DHCP</b> setting has to be set to <b>Disabled</b> ).
<b>Gateway</b>	User selectable	Allows you to set up a gateway (the <b>DHCP</b> setting has to be set to <b>Disabled</b> ).
<b>Primary DNS</b>	User selectable	Allows you to set up the primary Domain Name System (DNS) – set the <b>DHCP</b> setting to <b>Disabled</b> .
<b>Offline detection</b>	<ul style="list-style-type: none"> <li>– <b>On</b> (default)</li> <li>– <b>Off</b></li> </ul>	<p>Determines if the Cockpit issues an alarm tone and a message when it loses its connection to the Infinity network. See <i>Operating Concept &gt; Communicating with the Infinity Network</i> in:</p> <ul style="list-style-type: none"> <li>– <i>Instructions for use Infinity Acute Care System, Infinity M540 patient monitor, Software VG4.n</i></li> <li>– <i>Instructions for use Infinity Acute Care System, Monitoring applications, Software VG4.n</i></li> </ul>

## Biomed setup

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This section describes several pages accessible only to authorized personnel. All Biomed pages are password protected.

**WARNING**

**Do not service the Cockpit while monitoring a patient.**

### To access the biomed pages

- 1 Select **System setup...** on the main menu bar.
- 2 Select the **Biomed** tab.
- 3 Enter the password and select **Enter**.
- 4 Select one of the following tabs:
  - **Country**
  - **Units of measure**
  - **Patient monitor**
  - **Name service**
  - **Network setup** (select either the **Infinity** or **Hospital** tab)
  - **Printer setup**
  - **Recorder setup**
  - **Service**
  - **IT setup** (select the desired tab such as **Web browser**, and so on).

## Device communication messages / general device messages

Priority	Message	Cause	Remedy
None	<b>Duplicate address</b>	Duplicate PDS or Multicast address.	Ensure the fourth octet of the IP address is unique within the monitoring unit.
None	<b>Duplicate IP address</b>	The IP address is already in use.	Assign a unique IP address.
None	<b>Duplicate domain name</b>	Duplicate domain.	Assign a unique IP address.
None	<b>Audio paused by remote</b>	M540 alarms were paused by a remote device.	Informational message – no action required.
None	<b>Not monitored by central</b>	The communication between the ICS and the M540 is interrupted. A wireless M540 is out of range of the access point. This page intentionally left blank.	<ul style="list-style-type: none"> <li>– Return the M540 within the range of the wireless access point.</li> <li>– Check the network connections.</li> <li>– Make sure the M540 is assigned correctly to an ICS.</li> </ul>
None	<b>Offline</b>	A wireless M540 is undocked and does not have a bed label assignment. Disconnected network cable.	<ul style="list-style-type: none"> <li>– Check the network connections.</li> <li>– Assign a bed label to the M540.</li> </ul>
None	<b>Recording stored</b>	A recording was requested but no recorder is available for printing the recording.	Dock the M540 to an the M500 in an IACS configuration so the recording request can be processed by the Cockpit.
None	<b>Remote relearn</b>	The indicated function was initiated from the central station.	Informational message – no action required.
None	<b>Remote limit change</b>	The indicated function was initiated from the central station.	Informational message – no action required.
None	<b>Restore Profile Failed</b>	The profile could not be restored.	Try to restore the profile again before contacting your technical personnel.
None	<b>Save profile failed</b>	The profile could not be saved on the M540 and/or the M500.	Try to save the profile again before contacting your technical personnel.
None	<b>Profile transfer failed</b>	The profile failed to load on the M540 upon docking.	Undock and redock the M540 before contacting your technical personnel.



These Instructions for Use only apply to  
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Directive 93/42/EEC  
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