

Instructions for use

# Infinity<sup>®</sup> Acute Care System



## WARNING

To properly use this medical device, read and comply with these instructions for use.

**Infinity<sup>®</sup> M540 patient monitor**  
**Software VG8.0**

# DRAFT

Sections of this IFU have been removed for technical purposes.  
The following sections and pages have been removed.

➤ Alarms.....	105 - 144
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The entire IFU is available from Draeger Medical Systems Inc.

## Information about this document

### Typographical conventions

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- 1 Consecutive numbers indicate steps of action, with the numbering restarting with 1 for each new sequence of actions.
  - Bullet points indicate individual actions or different options for action.
  - Dashes indicate the listing of data, options, or objects.
  - (A) Letters in parentheses refer to elements in the related illustration.
  - A Letters in illustrations denote elements referred to in the text.
- > The greater-than symbol indicates the navigation path in a dialog.  
Bold, italicized text indicates labels on the device and texts that are displayed on the screen.

### Figures

Images of products and screen content in this document may differ from the actual products depending on configuration and design.

### Trademarks

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#### Trademarks owned by Dräger

Trademark
Infinity®
Innovian®
MCable®
Medical Cockpit
MPod®
MonoLead®

The following web page provides a list of the countries in which the trademarks are registered:  
[www.draeger.com/trademarks](http://www.draeger.com/trademarks)

## Trademarks owned by third-party manufacturers

Trademark	Trademark owner
Actichlor	Ecolab
Descogen	Antiseptica
Oxygenon	
SteriMax	Aseptix
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Cleanisept	Dr. Schumacher
neodishermedi-clean	Dr. Weigert
Incidin	Ecolab USA
OxyCide	
Ocivir Excel	Diversey
Masimo	Masimo Corporation
PVI	
Pulse CO-Oximeter Signal Extraction	
SET	
SpCO	
SpHb	
SpMet	
Medtronic	
Nellcor	
OxiMax	
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MicroPod	
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Oridion	
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acryl-des	Schülke & Mayr
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All other brand or product names are trademarks of their respective owners.

## Microstream® MicroPod® External Capnography Module patents

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The capnography component of this product is covered by one or more of the following US patents: 6,437,316; 6,428,483; 6,997,880; 7,488,229; 8,414,488; 8,412,655 and their foreign equivalents. Additional patent applications pending.

## Open-source software

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Dräger devices that use software may use open-source software, depending on their setup. Open-source software may be subject to different terms of license. Additional information regarding

the open-source software used in this device is available at the following web page:  
[www.draeger.com/opensource](http://www.draeger.com/opensource)

## Safety information definitions

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### **WARNING**

**A WARNING statement provides important information about a potentially hazardous situation which, if not avoided, could result in death or serious injury.**

### **CAUTION**

**A CAUTION statement provides important information about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or in damage to the medical device or other property.**

### **NOTE**

**A NOTE provides additional information intended to avoid inconvenience during operation.**

## User group requirements

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The term "user group" describes the personnel responsible who have been assigned by the operating organization to perform a particular task on a product.

Users have medical specialist knowledge in the application of the product.

### Duties of the operating organization

The operating organization must ensure the following:

- Every user group has the required qualifications (e.g., has undergone specialist training or acquired specialist knowledge through experience).
- Every user group has been trained to perform the task.
- Every user group has read and understood the relevant chapters in this document.

### Reprocessing personnel

This user group carries out the necessary activities to reprocess the product.

Reprocessing personnel has specialist knowledge in the reprocessing of medical devices.

### Service personnel

This user group installs the product and performs the service activities.

Service personnel has specialist knowledge in electrical and mechanical engineering and experience in the servicing of medical devices.

Where product-specific knowledge or tools are required, the service activities must be carried out by specialized service personnel. The specialized service personnel was trained by Dräger for these service activities on this product.

## User groups

### Clinical users

This user group operates the product in accordance with the intended use.

## Abbreviations and symbols

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For explanations, refer to the sections "Abbreviations" on page 47 and "Symbols" on page 44.

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## For your safety and that of your patients

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## Mandatory reporting of adverse events

Serious adverse events with this product must be reported to Dräger and the responsible authorities.

## Strictly follow these instructions for use

### NOTE

The Infinity Acute Care System provides the following additional instructions for use:

- *Infinity Acute Care System – Monitoring applications* (describes the Cockpit user interface of the IACS)
- *Infinity Acute Care System – Medical Cockpits* (describes the hardware of the Cockpit)
- *Infinity Acute Care System – Monitoring accessories* (describes all of the IACS accessories).

Please refer to these additional instructions for use for device-specific information.

### WARNING

**Risk of incorrect operation and of incorrect use.**

**Any use of the medical device requires full understanding and strict observation of all sections of these instructions for use. The medical device must only be used for the purpose specified under "Application," and in conjunction with appropriate patient monitoring.**

**Strictly observe all WARNING and CAUTION statements throughout these instructions for use and all statements on medical device labels. Failure to observe these safety information statements constitutes a use of the medical device that is inconsistent with its intended use.**

## Storing the instructions for use

### WARNING

**Risk of incorrect use**

**Instructions for use must be kept accessible for the user.**

## Training

Training for users is available from the responsible Dräger organization, see [www.draeger.com](http://www.draeger.com).

### WARNING

**Risk of incorrect use**

**Use of this device by untrained persons can result in patient harm.**

**Only trained persons shall use this product.**

## Maintenance

### WARNING

**Risk of medical device failure and of patient injury.**

The medical device must be inspected and serviced regularly by service personnel. Repair and complex maintenance carried out on the medical device must be performed by experts.

If the above is not complied with, medical device failure and patient injury may occur. Observe chapter "Maintenance."

A service contract with Dräger is recommended. It is recommended that original Dräger parts are used for repairs and that Dräger performs these repairs.

### WARNING

Any modification of this device or any use different from the one specified in these instructions for use may cause interference with other equipment or result in injury to the patient or the user, including electric shock, burns or death.

## Safety checks

The medical device must be subject to regular safety checks. See chapter "Maintenance".

## Accessories

### WARNING

**Risk of improper operation.**

Use of accessories, transducers and cables other than those specified or provided by Dräger could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Use only accessories, transducers and cables specified or provided by Dräger.

### WARNING

**Risk due to incompatible accessories.**

Dräger has only tested the compatibility of accessories listed in the current list of accessories. If other accessories are used, there is a risk of patient injury due to medical device failure. Dräger recommends that the medical device is only used with accessories listed in the current list of accessories.

## Installing accessories

### CAUTION

Risk of device failure

Install accessories to the basic device in accordance with the instructions for use of the basic device. Make sure that there is a safe connection to the basic device.

Strictly observe instructions for use and assembly instructions.

## Sterile accessories

### CAUTION

Risk of medical device failure and of patient injury.

Do not use sterile-packaged accessories if the packaging has been opened, is damaged, or if there are other signs of non-sterility. Single-use accessories must not be reused, reprocessed, or resterilized.

## Restrictions for use

### WARNING

Risk of medical device failure.

The M540 and any connected hardware, including cables and sensors, are not for use in the magnetic resonance (MR) environment.

Do not place the M540 or connected hardware in an MR environment.

### WARNING

To avoid electric shock, the equipment should only be connected to a power source that is properly grounded (protective earth ground).

### CAUTION

Device for use in healthcare facilities only and exclusively by persons as defined in the user groups (see page 6).

## Connected devices

### WARNING

Risk of electric shock and of device malfunction

Any connected devices or device combinations not complying with the requirements mentioned in these instructions for use can compromise the functional integrity of the medical device and lead to electric shock. Before operating the medical device, strictly comply with the instructions for use of all connected devices and device combinations.

## Safe connection with other electrical equipment

### WARNING

Risk of patient injury

Electrical connections to equipment not listed in these instructions for use should only be made following consultation with the respective manufacturers. Equipment malfunction may result and pose a risk of patient injury.

### WARNING

The leakage current increases when multiple medical devices are connected to a patient. Make sure that the galvanic isolation of each device is suitable for the intended application. Connect only equipment to the analog and digital signal inputs and outputs that is setup and tested according to IEC standards.

To protect the patient from possible injury due to electrical shock, peripheral devices should only be connected to a monitor within the same room. The installer or service provider should verify that the leakage current of the interconnected system meets the electrical safety requirements of IEC 60601-1 and IEC 62353.

## Connection to hospital network

Many medical devices manufactured by Dräger use networks to transmit patient data in real-time and to notify clinical users of alarm conditions. Hospitals should refer to IEC 80001-1 before attempting to connect such medical devices to their IT networks.

## Patient safety

The design of the medical device, the accompanying documentation, and the labeling on the medical device are based on the assumption that the purchase and the use of the medical device are restricted to persons familiar with the most important inherent characteristics of the medical device. Instructions and WARNING and CAUTION statements are therefore largely limited to the specifics of the Dräger medical device.

These instructions for use do not contain any information on the following points:

- Risks that are obvious to users
- Consequences of obvious improper use of the medical device
- Potentially negative effects on patients with different underlying diseases

Medical device modification or misuse can be dangerous.

## General safety information

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The following WARNING and CAUTION statements apply to general operation of the medical device. WARNING and CAUTION statements specific to subsystems or particular features of the medical device appear in the respective sections of these instructions for use or in the instructions for use of another product being used with this medical device.

### CAUTION

Risk of patient injury

Do not make therapeutic decisions based solely on individual measured values and monitoring parameters.

## Patient monitoring

The user of the medical device is responsible for choosing a suitable patient monitoring system that provides appropriate information on medical device performance and patient condition.

Patient safety may be achieved by a wide variety of means ranging from electronic surveillance of medical device performance and patient condition to direct observation of clinical signs.

The responsibility for selecting the best level of patient monitoring lies solely with the user of the medical device.

### WARNING

**Risk of explosion and of chemical burns.**

**Improper handling of batteries can result in explosions and chemical burns.**

**Do not throw batteries into fire. Do not force batteries open.**

**WARNING**

Never use equipment that has been damaged or compromised for patient monitoring.

**WARNING**

To avoid electric shock, inspect all cables before use. Never use cables that appear cracked, worn, or damaged in any way (doing so may compromise performance or put the patient at risk).

**WARNING**

To avoid risk of electric shock, this equipment must only be connected to a main power source with a protective earth ground.

**WARNING**

Do not cover the device with blankets or bed sheets. To prevent burns to the patient, avoid direct contact between external surfaces and the patient.

**WARNING**

To avoid patient injury as the result of a falling monitor when using a rolling trolley, universal bed hook, or handle hook mount, do not apply excessive force to the monitor or mount when entering or exiting elevators, or passing over thresholds or uneven surfaces.

**CAUTION**

To avoid injuring the patient, disconnect all sensors that will not be used during transport, before moving the patient.

**CAUTION**

Read all cleaning instructions (for example, originating from the disinfectant manufacturer and the hospital) carefully *before* cleaning the device. Refer to the chapter entitled "Reprocessing" on page 369 for device-specific cleaning instructions. Moisture may damage the circuits, compromise critical performance and present a safety risk.

**WARNING**

Dräger recommends using the Infinity Acute Care System or the M540 for primary diagnosis and the ICS (Infinity CentralStation) for patient viewing only. Do not use the ICS as the primary monitoring device when making a diagnosis.

**WARNING**

To prevent restriction of air flow to the device and also prevent potential overheating, do not allow the patient to come into direct contact with system components for extended periods of time.

**For countries subject to the EU directive 2002/96/EC**

This device is subject to EU Directive 2002/96/EC (WEEE). In order to comply with its registration according to this directive, this device may not be disposed of at municipal collection points for waste electrical and electronic equipment. Dräger has authorized a company to collect and dispose of this device.

To initiate collection or for further information, visit Dräger on the Internet at [www.draeger.com](http://www.draeger.com). Use the Search function with the keyword "WEEE" to find the relevant information. If access to Dräger's website is not possible, contact the local Dräger organization.

**Not for use in areas of explosion hazard**

**WARNING**

**Risk of fire or explosion**

**This medical device is not approved for use in areas where combustible or explosive gas mixtures are likely to occur or in oxygen-enriched atmospheres.**

**WARNING**

When placing the device, make sure that adequate airflow exists. To prevent overheating, position the device with at least 5 cm (2 in) of space all around.

## Information on electromagnetic compatibility

Medical electrical equipment is subject to special precautionary measures concerning electromagnetic compatibility (EMC) and must be installed and put into operation in accordance with the EMC information provided in "EMC declaration (4th Edition)" on page 425 in the *Technical data* chapter.

Portable and mobile radio frequency communications equipment can affect medical electrical equipment.

Connection to a wired network (hospital LAN) requires shielded LAN cables.

**WARNING**

Do not connect connectors with an ESD warning symbol and do not touch their pins without implementing ESD protective measures. Such protective measures may include antistatic clothing and shoes, touching a potential equalization pin before and during connection of the pins, or using electrically insulating and antistatic gloves. All users concerned must be instructed in these ESD protective measures.

## Operating location

Only use devices (monitor, MPod, MCable, and accessories) in areas that meet the environmental requirements outlined in the technical data section.

**WARNING**

### Risk from adjacent equipment

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

**WARNING**

### Recommended separation distances from RF communications equipment

RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in) to any part of the medical device, including cables specified by the manufacturer. This device has been tested against foreseeable maximum EM phenomena according to IEC 60601-1-2. Nevertheless, locally higher levels may occur, caused by, e.g., metal detectors, RFID emitters, or 5G services. Therefore, it is necessary to monitor the device and increase the distance from interference sources if necessary. Otherwise, degradation of the performance of this equipment could result.

**WARNING**

To avoid interfering with device operation, do not operate devices (monitor, MPod, MCable, and accessories) close to equipment that emits microwave or other high-frequency emissions.

**WARNING**

Periodically make sure that the device is properly mounted and secured to prevent injury. Make sure the requirements for maximum load and slope of floor are met. Consult the documentation of the mounting manufacturer for detailed information.

**WARNING**

To minimize the risk of patient strangulation, carefully position and secure sensor cables. Also position the sensor cables to minimize inductive loops.

**CAUTION**

To prevent overheating, do not place the device in direct sunlight or near heaters.

**CAUTION**

After extended exposure in a cold environment, acclimate the device carefully so that condensation does not form on the electronic parts and damage the device.

**CAUTION**

To avoid damaging the touch-sensitive screen, do not allow sharp instruments to touch the front of the devices.

**CAUTION**

To avoid short-circuiting and otherwise damaging the device, Dräger recommends that no fluids come in contact with the IACS devices when they are connected to a power socket. If fluids are accidentally spilled on the equipment, remove the affected device from service as soon as possible and have service personnel verify that patient safety is not compromised.

## Defibrillator precautions

The M540 and the peripheral devices are protected against high-frequency interference from defibrillators and electrosurgical units and against 50- and 60-Hz power line interference.

**WARNING**

To protect the patient during defibrillation and to ensure accurate ECG information, use only ECG electrodes and cables specified by Dräger. Removal of applied parts that are not rated defibrillation-proof, such as disposable SpO<sub>2</sub> sensors, may be required to prevent sensor breakdown and energy shunting.

**CAUTION**

To prevent burns and electric shock due to the re-routing of electrical current through electrodes, do not position the defibrillator pads near any electrodes or sensors.

**CAUTION**

Only defibrillate across the chest.

## Electrosurgery

Observe the following precautions during electrosurgery to reduce electrosurgical unit (ESU) interference and improve operator and patient safety.

**WARNING**

**For better performance and to reduce the hazard of burns during surgery, always use accessories designed for ESU environments. Do not use skin temperature sensors.**

**WARNING**

**To reduce the hazard of burns during electrosurgery, keep the sensor or transducer (e.g., ECG, SpO<sub>2</sub> pressure) and their associated cables away from the surgical site, the ESU return electrode, and earth ground.**

**NOTE**

Cover internally placed reusable temperature sensors with temperature sensor sheaths.

**WARNING**

**To reduce the hazard of burns during electrosurgery, do not use four-lead extension cables in electrosurgical environments.**

# DRAFT

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## Cybersecurity

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## Overview of cybersecurity

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This chapter describes best practices, recommendations, and guidelines for how to implement cybersecurity protocols in your environment, and how cybersecurity works with IACS devices on the Infinity network.

Hazardous situations that could result from a cybersecurity incident or failure of the network include, but are not limited to, unauthorized access, spread of malware, and unauthorized activation of audio pause or cardiac bypass mode.

### What is cybersecurity?

Cybersecurity is the practice of protecting networks, devices, and data from unauthorized access or criminal use. Cybersecurity helps ensure confidentiality, integrity, and availability of information.

### Cybersecurity terminology

The following table describes the cybersecurity terms used in this instructions for use.

Term	Description
ACS	Application Control Service. ACS is a Dräger-specific network functionality that allows remote control over the network of a patient monitor.
Authentication	Verifying the identity of a user, process, or device, often as a prerequisite to allowing access to resources in an information system.
Cryptographic material (Cryptomaterial)	All material, including documents, devices, or equipment that contains cryptographic information (for example, security credentials) and is essential to the encryption, decryption, or authentication of telecommunications. Invalid cryptomaterial includes missing or expired material, or material not meeting required performance grade.
Data at Rest	Data at rest is data related to IACS that is housed physically on computer data storage in any digital form. Data at rest includes both structured and unstructured data.
Data in motion	Data in motion, also referred to as data in transit and data in flight, is data in route between a source and a destination over an external network. Data in motion does not include internal data buses.
Denial of service	A situation in which intended services or functions cannot be accessed due to unavailable resource. It is usually caused by excess resource consumption.
DSCP	Differentiated Services (DiffServ) value set in an IP packet for classification and management. DSCP is part of a Quality of Service (QoS) implementation.

Term	Description
Legacy mode	A protocol without authenticated and encrypted communication between devices. Legacy mode is a non-preferred security mode in which devices operate without secure communications. When selected, authentication, integrity protection, and encryption will not be used for data in motion between devices on the Infinity network.
MCK	Pre-shared multicast key. An MCK is a shared confidential phrase, code, or key used as a credential to mutually authenticate components in the Infinity system. MCKs are sometimes referred to as security credentials.  Error messages displayed on the device reference PSK, but can apply to either a PSK or MCK. In response to the error messages, service personnel should check both the PSK and MCK to ensure the expiration dates are within a valid range.
Packet storm	An excessive amount of traffic on a computer network. The network congestion can delay or inhibit network communication between devices. A packet storm could cause latency, potentially preventing network communications between devices. It could also cause excessive load on devices as they attempt to manage the adverse condition.
PDS	Patient Data Service. PDS is a Dräger-specific network functionality that allows physiological patient data to be transferred across a network for other entities to consume.
PIN	Personal Identification Number used during initial device configuration.
PSK	Pre-shared unicast key. A PSK is a shared confidential phrase, code, or key used as a credential to mutually authenticate components in the Infinity system. PSKs are sometimes referred to as security credentials.  Error messages displayed on the device reference PSK but can apply to either a PSK or MCK. In response to the error messages, service personnel should check both the PSK and MCK to ensure the expiration dates are within a valid range.
Secure mode	A set of security protocols that enables authenticated and encrypted communication between devices. Secure mode is the preferred security mode in which devices operate with protected communication.  This implementation provides mutual authentication, integrity protection, and encryption for data in motion between devices on the Infinity network.

## Cybersecurity safety information

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The following WARNING and CAUTION statements apply to cybersecurity and security modes.

### WARNING

#### Risk of cybersecurity attacks in Legacy mode

Disabling Secure mode and operating in Legacy mode increases the risk of exposing all network communications to cybersecurity attacks.

Always operate devices in Secure mode when possible.

### WARNING

#### Risk of connection failure due to network security mode mismatch

If the network security mode (Secure or Legacy) does not match between devices on the Infinity network, the devices cannot establish a connection.

Make sure all devices that will communicate on the Infinity network use the same network security mode.

See "Infinity network security" on page 31.

### WARNING

#### Risk of connection failure due to expired PSK/MCK

When using the Secure network security mode, if the PSK/MCK security credentials are not updated before their expiration date, devices on the Infinity network cannot communicate.

Make sure the PSK/MCK are valid and updated promptly when you receive the expiration warnings.

### WARNING

#### Risk of connection failure due to PSK/MCK mismatch

When using the Secure network security mode, devices on the Infinity network must use the same PSK/MCK security credential in order to communicate. If the PSK/MCK security credentials do not match, the devices cannot establish a connection.

Make sure devices that will communicate on the Infinity network use the same PSKs/MCKs.

### WARNING

#### Risk of loss of patient data

Secure mode is not supported on Dräger Delta devices. If the wireless option is activated on an M540 in Secure mode, and a Delta device is on the same wireless network, loss of patient monitoring network data may occur.

Do not use the wireless option on M540 devices in Secure mode on the same wireless network as Delta devices.

### WARNING

#### Risk of delayed response due to packet storms

If a sustained network packet storm occurs:

- Delayed responses may occur during this time, such as delayed responses from the display, keyboard, alarms, patient data, and/or notifications.
- An offline condition may occur and Offline would be displayed in a banner in the screen's header bar.

If the packet storm condition persists, temporarily disconnect the affected monitor from the network, or transfer the patient to a bedside monitor not connected to the network.

**WARNING****Risk of security breach due to external devices**

**Using or allowing the use of an unauthorized external DVD or USB device with IACS poses the risk of a security breach.**

**Do not use or permit the use of an unauthorized external DVD or USB device with IACS.**

**CAUTION****Risk of breach of confidentiality**

Stolen cryptomaterial and unauthorized access to the IT network may lead to a breach of confidentiality and are a potential source of hazardous situations.

Ensure that all precautions outlined in this chapter have been taken to help prevent unauthorized access to the IT network.

**WARNING****Risks due to cybersecurity attack**

**During a cybersecurity attack, data, waveforms, trends, etc., may be altered or unusable. The M540 may experience an offline condition.**

**Ensure that all precautions outlined in this chapter have been taken to help prevent a cybersecurity attack.**

## Cybersecurity information and recommendations

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Dräger recommends always following network cybersecurity best practices, such as:

- Maintaining software and firmware (including Microsoft security patches)
- Updating anti-virus, anti-malware, and anti-spyware tools
- Periodically changing passwords
- Segmenting via firewalls
- Closing unused ports
- Restricting user permissions through use of user levels and passwords. See "User levels" on page 95.
- Limiting third-party access
- Monitoring network activity

Without these measures, there is an increased risk that critical events may go undetected in cases of malicious attack. Undetected critical events could result in patient harm.

**CAUTION**

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

**Product cybersecurity information**

Dräger maintains a product security page with information about cybersecurity threats in the field and possible vulnerabilities in our devices.

Visit <http://static.draeger.com/security/> to:

- Learn more information about cybersecurity threats in the field.

- Learn more information about possible vulnerabilities in Dräger devices.
- Provide information to Dräger via encrypted email about a cybersecurity threat you encountered or security vulnerabilities you identified.

### Cybersecurity incident response

In the event of a cybersecurity incident:

- 1 Isolate the affected M540 unit(s) by disconnecting them from the network.
- 2 Contact your hospital's biomedical and IT departments immediately for support.
- 3 Preserve all M540 logs for investigation. See "Error logs" on page 29 for information on saving an error log file.
- 4 If a cybersecurity threat has been identified, report the specifics following the process on <https://static.draeger.com/security> and send an email to [product-security@draeger.com](mailto:product-security@draeger.com).
- 5 Work with your hospital's IT and/or biomedical department(s) to determine whether it is safe to put the affected M540 units back on to the hospital network.

- Dräger recommends that operating organizations restrict physical access to unused Ethernet, USB, and serial ports on IACS devices.
- When decommissioning an M540, contact DrägerService or specialized service personnel for information on sanitizing the product to remove sensitive, confidential, and proprietary data and software.

### Software and firmware upgrades

Specialized service personnel perform software and firmware installations using the Infinity Installer application. For specific instructions regarding the installation of such software and firmware, contact DrägerService or specialized service personnel.

#### WARNING

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

### Physical security information and recommendations

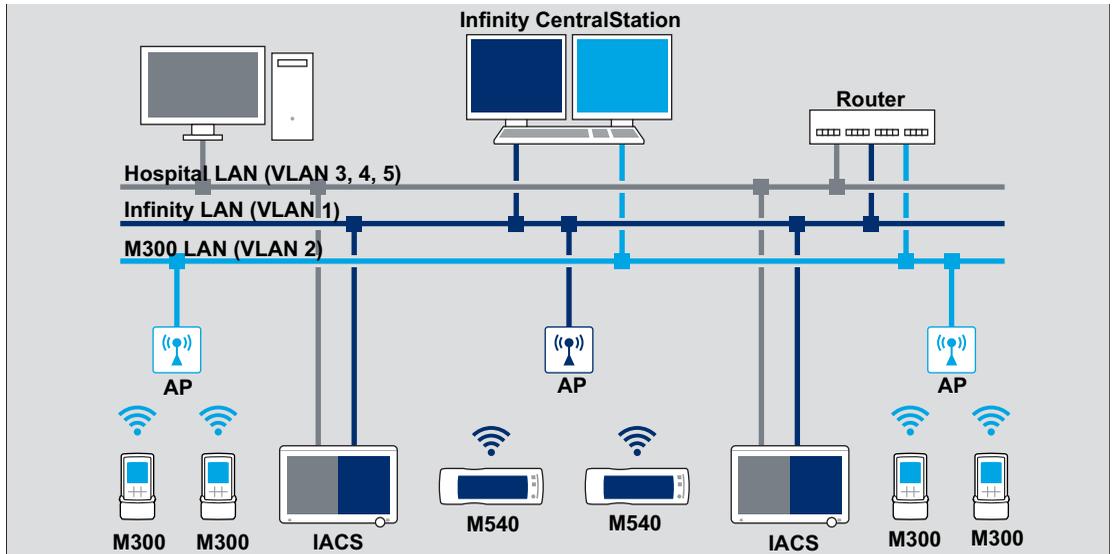
Dräger provides the following physical security information and recommendations:

- 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 using USB memory storage devices that have on-board hardware AES-256 encryption that is FIPS 140-2 Level 3.

## Network traffic and data security

### Infinity network configuration

The following diagram shows an example of the Infinity network configuration.



### Data security recommendations

- Install and operate Infinity monitoring devices only on Dräger segregated IT networks that contain cybersecurity safeguards which protect against sources of malicious attack. For guidance or additional information, contact DrägerService or specialized Dräger service personnel.
- To reduce risk from network security vulnerabilities, Dräger recommends that the responsible organization install and operate Infinity monitoring devices on separate, isolated VLANs. 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.
- Use of QoS at the infrastructure level 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. Undetected critical events could result in patient harm.

## M540 interfaces and network protocols

The M540 device contains the interfaces listed in the following table. The M540 disables unused network 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 (not available in a standalone configuration)
Scio connector	Provides for communication to the respiratory gas module Scio

When an M540 is undocked, patient data is communicated by the M540 to the network via the 802.11 wireless LAN standard.

accept incoming connections inbound from other devices on the network. The M540 disables unused communication protocols.

When docked, it communicates via wired LAN using the following TCP/IP ports. Client ports are used outbound from the device, while server ports

Application Protocol	Transport Protocol	Port Number	Client/Server
SSH/SFTP	TCP	22	Server
Infinity ACS	TCP	1950	Server
Infinity name service	UDP	2150	Client/Server
Infinity remote record	TCP	7100	Server
SNMP	UDP	161	Server
Infinity AGS	UDP	2000	Client/Server
Infinity time service	UDP	2100	Server

## Data integrity and protection

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, both audible and visual notifications alert the user that factory default settings are being restored, as the device assumes that DRAM has failed.

For wireless communication between M540 and 802.11 access points, Dräger recommends the use of WPA2-Personal to provide for increased wireless network security with strong authentication and data protection. 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. Compromised clinical data could result in patient harm.

The responsible organization must perform risk management for their IT network, per IEC 80001-1.

## Excessive network traffic

M540 devices are designed to maintain basic patient monitoring functions during conditions of excessive network traffic. 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 excessive network traffic conditions persist.
- A temporary loss of network communication between the Cockpit and the M540.
- A temporary loss of network communication in wireless mode.

In addition to carrying out high priority tasks, the device ensures that malformed data packets will be discarded, thereby eliminating device reset and maintaining monitoring.

## Error logs

The M540 monitoring device captures network security events in the error log, such as:

- Overload detection
- Malformed control packets
- Software reset
- Presence of multicast and control message storms

### To obtain and save an error log file:

- 1 Connect the M540 to an IACS Cockpit.
- 2 Use the Cockpit's **Export logs** feature to save the M540's log information.

For instructions for using **Export logs**, refer to the *Instructions for use Infinity Acute Care System, Monitoring applications, Software VG8.0*.

Alternatively, contact DrägerService or specialized service personnel for assistance.

## Minimizing excessive network traffic

To minimize excessive network traffic or denial-of-service (DoS) events on the network, perform the following measures when configuring the M540 network:

- Create segmented networks with isolated VLANs to prevent the introduction of malware onto the Infinity network.
- Implement delay and network load guidelines for infrastructure design and provisioning.
- Implement QoS to prioritize patient monitoring traffic.
- Provision storm and rate limiting capabilities of the infrastructure.
- Ensure IP-directed broadcasts are disabled on Layer 3 devices.
- Extend ARP table timeouts.

- Ensure loop-protection protocols, such as STP, are configured to prevent flooding on topology changes.

### Impact of excessive traffic on M540 behavior

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

- A wireless M540 in a stand-alone configuration may experience delays. Audible alarms, visual alarms, parameter box display, header bar, and menus may freeze for up to 10 seconds. This behavior will be repeated every three minutes until the condition is cleared.

A wired M540 in a stand-alone configuration continues monitoring without a delay.

- The M540 may detect a packet storm (an accumulation of traffic) on the network, which hinders the transport and process of normal network traffic. If a network security error or excessive network traffic error is observed, report the condition to the hospital's biomedical and IT departments.

### Potential duplicate IP address

A security mechanism implemented to prevent traffic impersonation may cause the IACS to switch to APIPA (Automatic Private IP Addressing) and generate a Duplicate IP message. If specific ARP (Address Resolution Protocol) traffic is detected, the network behavior will be changed accordingly. This may result in a false positive duplicate IP occurrence and loss of monitoring at the CentralStation.

## Restoring device settings

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In the event of a cybersecurity attack or other configuration error, M540 device settings may be compromised.

### To restore device settings to their previous state:

- 1 Power cycle the unit.
- 2 Select **No** when prompted on the New Patient screen.

### To manually restore device settings to the default patient profile:

- 1 Discharge the patient.
- 2 Re-admit the patient at the M540.
- 3 Adjust parameter settings as appropriate for the patient.

For more information, see "Profiles" on page 77.

### To restore device settings after the device enters a fail state (sustained alarm tone sound):

- 1 Power cycle the unit.
- 2 Re-admit the patient at the monitor.
- 3 Adjust parameter alarms and other settings as appropriate for the patient, as they revert to factory default settings. In a standalone configuration, you can also reload the device settings and default patient profiles from the M500.

## Infinity network security

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There are two security modes available for the Infinity network: Secure mode and Legacy mode. The security mode is set by DrägerService or specialized service personnel.

All devices in the Infinity network intended to communicate must use the same security mode.

Refer to "Cybersecurity safety information" on page 24 for warnings related to security modes.

### To view the M540's security mode:

- 1 Touch the **Menu** function key.
- 2 Touch the **System setup > System information > Security info** tabs.

### Secure mode

Secure mode is an enhancement to the Infinity network suite of protocols that enables authenticated and encrypted communication between devices on the Infinity network. It is the preferred security mode. Secure communication between Infinity devices can be intercepted but not read or altered by an unauthorized device.

Encrypted communication is enabled through use of a set of pre-shared keys, one for unicast communications (PSK) and one for multicast communication (MCK). See "About PSKs and MCKs" on page 31 for more information.

When Secure mode is enabled, M540 and Cockpit devices can establish communication only with Infinity network devices that are also enabled with Secure mode and share the same PSK/MCK. If there is a mode mismatch or PSK/MCK mismatch, a message displays advising users to contact service.

### NOTE

Secure mode is not supported on R50-N recording devices. R50-N devices will not communicate with other devices on a network that uses Secure mode.

### Legacy mode

Legacy mode uses the traditional Infinity protocol suite without the security enhancements available in secure mode. Legacy mode is a non-preferred network security mode in which devices can operate without secure communications. When Legacy mode is selected, authentication, integrity protection, and encryption will not be used for data in motion between devices on the Infinity network.

### About PSKs and MCKs

Pre-shared unicast (PSK) and multicast (MCK) keys are used for device authentication and secure data transfer (encryption) when devices on the Infinity network are set to Secure mode. When operating in Secure mode, all devices that communicate over the Infinity network must share the same PSK/MCK.

PSKs/MCKs are installed and managed by service users, who can optionally assign them an expiration date. The recommended expiration date is 2.5 years from installation. The expiration date, if any, is displayed on the **System setup > System information > Security info** page. If the PSK/MCK expires, devices on the Infinity network that are set to Secure mode can no longer communicate, impacting monitoring functionality.

### NOTE

To communicate in Secure mode, devices on the Infinity network must use the same PSK/MCK.

## Network security error conditions

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The following errors may display on the M540 when secure communication fails or device security credentials will soon expire or have expired.

<b>Message Displayed on the M540</b>	<b>Condition</b>
<b><i>Call service. PSK: &lt;date&gt;</i></b>	The security key (PSK/MCK) used by this device will expire on the date provided in the message. Contact service.
<b><i>Call service. PSK exp.</i></b>	The security key (PSK/MCK) used by this device has expired. Contact service.
<b><i>Call service. Secure comm fail</i></b>	The M540's security key (PSK/MCK) is missing or cannot be read. Contact service.
<b><i>Offline</i></b>	The Cockpit and the M540 are not set to use the same network security mode (Secure or Legacy) and cannot communicate with each other.  The mode can be set only by DrägerService or specialized service personnel. Contact service.

## Application

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## Intended use

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The Infinity M540 (M540) is intended for multi-parameter, physiologic patient monitoring of adult, pediatric, and neonatal patient information in environments where patient care is provided by trained health care professionals.

The M540 obtains physiological data from connection to optional accessory devices. The real-time physiologic and multi-parameter data collected from the M540 is made available on the Infinity network.

The M540 is intended to monitor one patient at a time.

## Indications

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The M540 monitors the following parameters:

- Heart rate
- Arrhythmia (adult and pediatric patients only)
- 12-lead Rest ECG analysis (adult and pediatric patients only)
- ST segment analysis including TruST (adult and pediatric patients only)
- Apnea
- Impedance respiratory rate (RRi)
- Invasive pressure (IP)
- Non-invasive blood pressure (NIBP)
- Temperature
- Cardiac output, only available when the M540 is docked in an IACS configuration (adult and pediatric patients only)
- Carbon dioxide (etCO<sub>2</sub>, inCO<sub>2</sub>, RRc)
- Non-invasive arterial oxygen saturation (SpO<sub>2</sub>), including:
  - Pulse rate
  - Perfusion index (PI)
  - Total hemoglobin (SpHb) (adult and pediatric patients only)
  - Total oxygen content (SpOC) (adult and pediatric patients only)
  - Carboxyhemoglobin saturation (SpCO) (adult and pediatric patients only)
  - Methemoglobin saturation (SpMet)
  - Pleth variability index (PVI)
- Oxygen (O<sub>2</sub>) (adult and pediatric patients only)
- Nitrous oxide (N<sub>2</sub>O) (adult and pediatric patients only)
- Anesthetic agents (Sevoflurane, Desflurane, Isoflurane, Halothane, Enflurane) (adult and pediatric patients only)
- xMAC (adult and pediatric patients only)

## Environments of use

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The device is intended for environments where patient care is provided by trained healthcare professionals, but not in the following environments:

- Hyperbaric chambers
- Environments containing MRI equipment
- Areas where oxygen concentrations above 25 Vol% or combustible or explosive gas mixtures can occur

## Functional safety

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The essential performance of a patient monitor is to provide a clinician with meaningful parameter values and alarm annunciation when the established parameter limits have been exceeded or the ability to provide values is compromised. Risks associated with use of the monitor in light of these essential performance functions have been evaluated and mitigations implemented so that the residual risk is as low as reasonably practicable, provided routine maintenance and service recommendations are followed through the life of the product.

The M540 has the ability to:

- Display physiological measurements (values, waveforms, indicators), with the specified signal quality, accuracy, reproducibility, and conditions.
- Annunciate physiological alarms for critical patient monitoring in a timely manner to the specified conditions.
- Annunciate technical alarms or other notification to user when critical physiological measurements and/or alarms are not available or potentially incorrect.
- Allow alarm and measurement settings to be configured and controlled by clinical user.
- Display the alarm setting, status and other information to user that are required for safe and continuous monitoring.
- Maintain continuous normal operation in specified conditions (e.g., switching from power main to battery).
- Provide protection and recovery of operation against defibrillation, electrosurgery and other interference, in a timely manner with no stored data loss.
- Power down in a controlled manner through notification and safe termination of functionality.
- Ensure real time signal output for defibrillator synchronization if this signal output is provided.
- Initiate automatic calibration/zeroing of Respiratory Gas Monitoring device at proper timing.

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## Overview

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## Overview

These instructions for use describe the M540 patient monitor. This monitor is a rugged, light-weight, hand-held, transportable patient monitor with a touchscreen and independent user interface.

When the M540 is docked in the Infinity M500 and is part of an Infinity Acute Care System (IACS) configuration, the M540 is the signal acquisition and data processing module for the Infinity C500/C700. The M540 can also be used as a standalone monitor docked in an Infinity M500.

The M540 also provides seamless patient monitoring when it is undocked from the M500 for patient transport (see page 92).

The M540 comes with a wireless option that allows it to transmit patient data to the ICS (Infinity CentralStation) during transport.

### NOTE

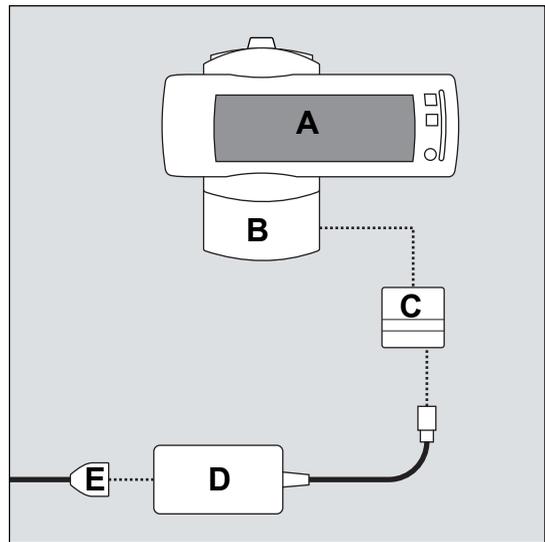
Because the M540 is also part of an IACS configuration, some of the IACS components are also described here. For specific information regarding the IACS, refer to the *Instructions for use Infinity Acute Care System – Monitoring applications*.

Some terms used in these instructions for use:

- Cockpit – refers to the Infinity C700 Medical Cockpit or the Infinity C500 Medical Cockpit which is the display module of the Infinity Acute Care System
- M540 – refers to the Infinity M540 patient monitor
- M500 – refers to the Infinity M500 that secures the M540 and charges the internal battery of the M540
- Docking the M540 – refers to placing the M540 on the M500.
- Patient and user default settings (referred to as profiles) are stored on the M500. For more information, refer to the chapter *Operating Concept* page 59.

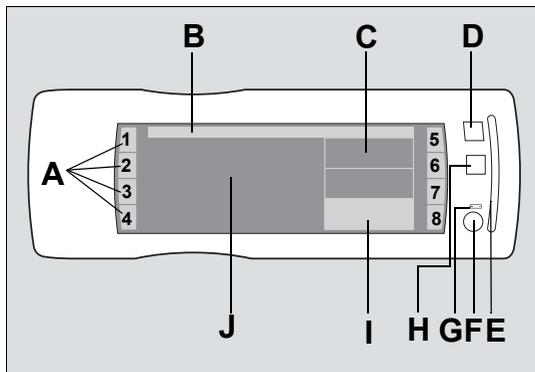
The M540 docked on an M500 can be set up as a stand-alone configuration to charge the battery when the M540 is not part of an IACS configuration.

The following diagram shows an M540 stand-alone configuration. In addition, you can connect various hardware to expand the monitoring capabilities.



- A The M540
- B The M500
- C Y-cable/Y-adaptor
- D Power supply
- E Power cable

## Front view of the M540



**A** 8 function keys (see page 69)

**B** Header bar (see page 70)

**C** Parameter field (see page 72)

**D** NIBP start/stop key

**E** Alarm bar

**F** Power on/off key

**G** Battery LED symbol

**H** Audio pause key

**I** Parameter field in alarm

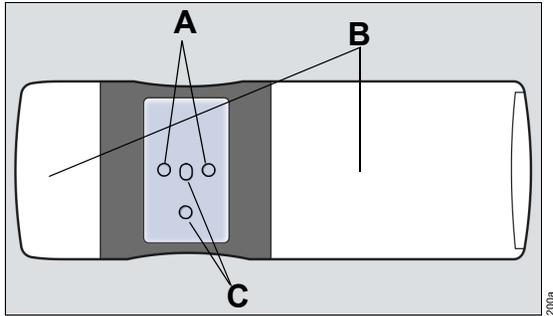
**J** Waveform area (see page 72)

## M540 Keys

The M540 has the following keys:

Key/LED	Function
	<p>On/off key</p> <p>Turns the M540 on or off.</p> <p>The button LED flashes when the M540 is undocked; it lights up when the M540 is docked.</p>
	<p>Battery LED symbol</p> <p>This symbol lights up when the M540 is docked to indicate the battery is being charged; it does not light up when the M540 is undocked.</p>
	<p>Audio pause key</p> <p>Pauses acoustic alarm signals for two minutes.</p>
	<p>NIBP start/stop key</p> <p>Starts/stops non-invasive blood pressure measurements.</p>

**Back view of the M540**

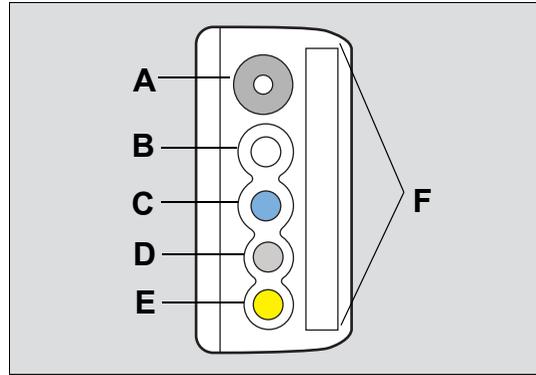


- A** Charging contact points
- B** Labels
- C** Optical ethernet links

**CAUTION**

Do not affix any labels inside the shaded areas of the M540. Doing so may interfere with charging the device or with communicating with the M500. It may also prevent the M540 from physically docking to the M500.

**Side view of the M540**



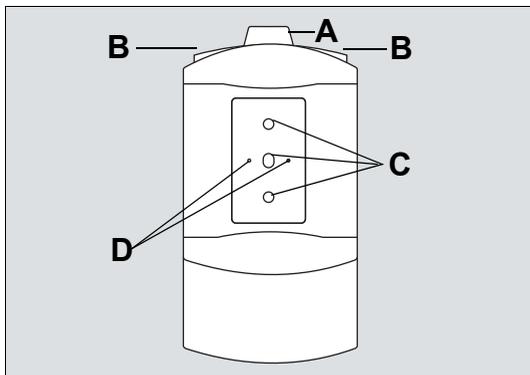
- A** Non-invasive blood pressure connector
- B** Temp (2) / Aux connector
- C** SpO2 connector
- D** Hemo connector
- E** CO2 connector
- F** ECG connector

## M500 docking station

The M500 is the device that mechanically secures and powers the M540. The M500 also charges the battery of the M540. If the M540 is part of an IACS configuration, the M500 controls the communication between the M540 and the Cockpit through an optical Ethernet link.

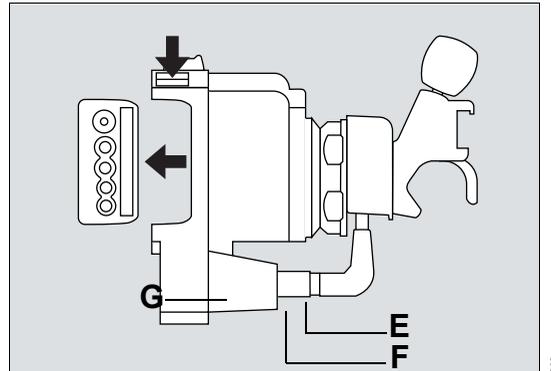
When used in a standalone configuration, the M500 facilitates patient transport by allowing the M540 to be undocked from one M500 and redocked in another M500 while maintaining all patient monitor connections. In addition to powering the M540, the M500 stores network information, connects the M540 to the Infinity network and stores default profile settings that can be adopted upon docking. For detailed information see “Profiles” on page 77.

### Front view of the M500



- A** Locking mechanism – secures the M540 (for more detailed information, see “Locking/unlocking the M540” on page 54)
- B** Release button for undocking the M540 (you only need to press one button to release the M540)
- C** Optical Ethernet links
- D** Pins for charging the M540 battery; the pins also provide power to the M540 when it is docked

### Back view of the M500



- E** Nurse call connector (not available in a stand-alone configuration)
- F** Network LED – lights up green when connected to the network
- G** System cable connector

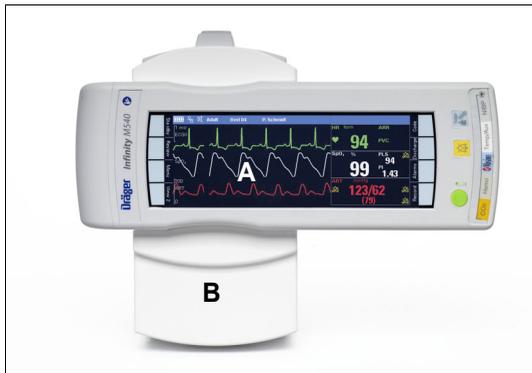
#### NOTE

A cable hook can be attached on the bottom of the M500 docking station. For more information about the hook and other hardware options, refer to the *Instructions for use Infinity Acute Care System – Monitoring accessories*.

## M540 docked in the M500

The following diagram shows the M540 when it is docked in the M500 docking station.

- A M540 patient monitor
- B M500 docking station



## Additional hardware

The following table lists the additional devices that can be connected to the M540.

Device	Description	Connection
Infinity MCable – Masimo SET	Measures the percentage of functional hemoglobin saturated with oxygen ( <b>SpO<sub>2</sub></b> ) and reports the perfusion index ( <b>PI</b> ), and the pulse rate ( <b>PLS</b> ).	Connects directly to the <b>SpO<sub>2</sub></b> connector of the M540 (see page 196 and page 210).
Infinity MCable – Masimo rainbow SET	Measures the percentage of functional hemoglobin saturated with oxygen ( <b>SpO<sub>2</sub></b> ) and reports the perfusion index ( <b>PI</b> ), and the pulse rate ( <b>PLS</b> ). In addition, it measures total hemoglobin ( <b>SpHb</b> ), total oxygen content ( <b>SpOC</b> ), pleth variability index ( <b>PVI</b> ), carboxyhemoglobin saturation ( <b>SpCO</b> ), methemoglobin saturation ( <b>SpMet</b> )	

Device	Description	Connection
Infinity MCable – Nellcor OxiMax	Measures the percentage of functional hemoglobin saturated with oxygen (% <b>SpO<sub>2</sub></b> ) and the pulse rate ( <b>PLS</b> ).	Connects directly to the <b>SpO<sub>2</sub></b> connector of the M540 (see page 196 and page 210).
Infinity MPod – Quad Hemo	Measures up to four pressures, cardiac output, core and body surface temperature.	Connects directly to the Hemo connector of the M540 (see information starting on page 238).
Infinity MCable – DualHemo	Measures up to two pressures.	
Infinity MCable – Mainstream CO <sub>2</sub>	Measures mainstream CO <sub>2</sub> .	Connects directly to the CO <sub>2</sub> connector of the M540 (see page 258).
Infinity MCable – Analog/Sync	Provides a sync pulse to synchronize defibrillators to the heart beat of the patient during cardioversion. The cable's analog out function provides an <b>ECG</b> and arterial blood pressure signal to a device such as intra-aortic balloon pump.	Connects to the Temp/Aux connector of the M540 (see page 217) or to the CO <sub>2</sub> connector with a Y-cable.
Infinity MCable – Microstream CO <sub>2</sub>	Measures Microstream CO <sub>2</sub>	Connects directly to the CO <sub>2</sub> connector of the M540 (see page 272).

Device	Description	Connection
Scio Four	Measures the concentration of CO <sub>2</sub> , N <sub>2</sub> O, and anesthetic agents (Sevoflurane, Desflurane, Isoflurane, Halothane, and Enflurane) in the breathing gas.	Connects directly to the CO <sub>2</sub> connector of the M540 or the M500 docking station (see page 284).
Scio Four Oxi	Measures the concentration of CO <sub>2</sub> , N <sub>2</sub> O, O <sub>2</sub> , and anesthetic agents (Sevoflurane, Desflurane, Isoflurane, Halothane, and Enflurane) in the breathing gas.	
Scio Four plus	Measures the concentration of CO <sub>2</sub> , N <sub>2</sub> O, and anesthetic agents (Sevoflurane, Desflurane, Isoflurane, Halothane, and Enflurane) in the breathing gas.	
Scio Four Oxi plus	Measures the concentration of CO <sub>2</sub> , N <sub>2</sub> O, O <sub>2</sub> , and anesthetic agents (Sevoflurane, Desflurane, Isoflurane, Halothane, and Enflurane) in the breathing gas.	

## Symbols

The following table identifies the symbols that can appear on the M540.

Additional information about the symbols is available on the following web page:  
[www.draeger.com/md-symbols](http://www.draeger.com/md-symbols).

	Keep away from sunlight		Not made with natural rubber latex
	Caution: This product contains natural rubber latex which may cause an allergic reactions		Alarm monitoring deactivated temporarily

	Warning! Strictly follow these instructions for use		Caution! Observe the accompanying documentation!
	Consult instructions for use		Not made with natural rubber latex
	ESD warning		Alarm monitoring deactivated permanently
	Battery status (when the battery is fully charged, all segments in the symbol are filled in)		Acoustic alarm signal paused temporarily
	Function/setting is unlocked		Acoustic alarm signal turned off permanently
	Function/setting is locked		Lung symbol that pulsates with each detected breath
	Manufacturer		Heart blip that flashes with each detected pulse
	Date of manufacture		Pacer detection is activated; the heart symbol flashes with each detected paced pulse
IPXx	Degree of protection against solid particle and liquid ingress, e.g., IPX1, IPX4, etc.		Power on/off
	Lower alarm limits		WEEE - dispose electrical-electronic equipment properly
	Upper alarm limits		Component number and revision
	Autoset alarm limits		Device serial number

	Battery charging LED		Adult patient category
	The speaker is deactivated		Pediatric patient category
	The M540 is docked and connected to the network		Neonatal patient category
	Federal communications commission declaration of conformity number		Japanese radio wave law certification
	Not manufactured with natural rubber latex		Defibrillation-proof Type CF equipment
	Gas in		Defibrillation-proof Type BF equipment
	Gas out		Caution: Federal law restricts this device to sale by or on the order of a physician.
 Do not re-use	Do not re-use, single patient use		China RoHS marking for Control of pollution caused by Electronic Information Products.
Use by:  yyyy-mm-dd	Symbol indicates shelf life. YYYY-mm-dd indicates date by which device needs to be used to remain safe.		Medical device
	European Union Representative		Importer
	Importer		Keep this device outside the MRI scanner room

## Wireless symbols

The following symbols appear in the header bar of the M540 only when it is on wireless transport.

	<p>White wireless symbol indicating the M540 has optimum association with a wireless access point.</p> <p>This symbol also appears on the back of the M540 when the wireless option is activated.</p>		<p>White wireless symbol indicating the M540 has good association with a wireless access point</p>
	<p>White wireless symbol indicating the M540 has adequate association with a wireless access point</p>		<p>The symbol appears white when the M540 is still associated with a wireless access point but no data is transmitted to the ICS.</p> <p>The symbol appears red when the M540 is no longer associated with a wireless access point.</p>

## Abbreviations

The following table lists the abbreviations in these instructions for use and those abbreviations that are displayed on the M540.

Abbreviation	Description
ABD	Abdominal pressure
AHA	American Heart Association
AIVR	Accelerated idioventricular rhythm
AOR	Aortic arterial blood pressure
APP	Abdominal perfusion pressure
ARR	Arrhythmia
ART	Arterial blood pressure
ART D	Diastolic arterial blood pressure
ART M	Mean arterial blood pressure
ART S	Systolic arterial blood pressure
ARTF	Artifact
ASY	Asystole

Abbreviation	Description
AXL	Axillary arterial blood pressure
BDP	Bladder pressure
BGM	Bigeminy
BPP	Bladder perfusion pressure
BRA	Brachial arterial blood pressure
BRADY	Bradycardia
CISPR	International Special Committee on Radio Interference
CO <sub>2</sub>	Carbon dioxide
CPP	Cerebral perfusion pressure
CPP2	Cerebral perfusion pressure 2
CPP3	Cerebral perfusion pressure 3
CPP4	Cerebral perfusion pressure 4
CPT	Ventricular couplet
CVP	Central venous blood pressure

Abbreviation	Description
ECG	Electrocardiogram
ECGaVF, ECGaVL, ECGaVR	ECG leads
ECGdV1 to ECGdV6	Derived chest leads
ECGV	Chest lead from a 5- or 6-wire lead set.
ECGV+	Second chest lead from a 6-wire lead set
ECGV1 to ECGV6	ECG chest leads ECGV1 to ECGV6
ESO	Esophageal pressure
etCO <sub>2</sub>	Endtidal CO <sub>2</sub>
F	Left leg electrode (IEC)
FEM	Femoral arterial blood pressure
FEMV	Femoral venous blood pressure
GPM	Mean general pressure
GP1 D to GP4 D	General pressure 1 to 4, diastolic value
GP1 M to GP4 M	General pressure 1 to 4, mean only value
GP1 S to GP4 S	General pressure 1 to 4, systolic value
GP1 to GP4	General pressure 1 to 4
GP5 to GP8	General pressure 5 to 8
HR	Heart rate
I, II, III	ECG leads
IACS	Infinity Acute Care System
IP	Invasive pressure
ICP	Intracranial pressure
ICP2	Intracranial pressure 2
ICP3	Intracranial pressure 3
ICP4	Intracranial pressure 4
ICS	Infinity CentralStation
IEC	International Electrotechnical Commission

Abbreviation	Description
inCO <sub>2</sub>	Inspiratory CO <sub>2</sub> concentration
ISO	International Organization for Standardization
L	Left arm electrode (IEC)
LA	Left arm electrode (AHA)
LA	Left atrial blood pressure
LL	Left leg electrode (AHA)
LV	Left ventricular blood pressure
LV D	Diastolic left ventricular blood pressure
LV M	Mean left ventricular blood pressure
LV S	Systolic left ventricular blood pressure
N	Right leg electrode (IEC)
NIBP	Non-invasive blood pressure
NIBP D	Diastolic non-invasive blood pressure
NIBP M	Mean non-invasive blood pressure
NIBP S	Systolic non-invasive blood pressure
PA	Pulmonary arterial blood pressure
PA D	Diastolic pulmonary arterial blood pressure
PA M	Mean pulmonary arterial blood pressure
PA S	Systolic pulmonary arterial blood pressure
PI	Perfusion index (SpO <sub>2</sub> )
PLS	Pulse rate from SpO <sub>2</sub>
PLS CO-Ox	Pulse CO-Oximetry
PVC/min	Rate of premature ventricular contractions per minute
PVI	Pleth variability index
R	Right arm electrode (IEC)

Abbreviation	Description
RA	Right arm electrode (AHA)
RA	Right atrial blood pressure
RAD	Radial arterial blood pressure
RL	Right leg electrode (AHA)
RRc	Respiratory rate (CO <sub>2</sub> )
RRi	Respiratory rate (impedance)
RUN	Ventricular run
RV	Right ventricular blood pressure
RV D	Diastolic right ventricular blood pressure
RV M	Mean right ventricular blood pressure
RV S	Systolic right ventricular blood pressure
SpCO	Carbon monoxide bound to hemoglobin
SpHb	Total hemoglobin levels in arterial or venous blood
SpHbv	Total hemoglobin (venous)
SpMet	Methemoglobin saturation
SpO <sub>2</sub>	Pulse oxygen saturation
SpOC	Total oxygen concentration
STCVM	Change in vector magnitude
STdV1 to STdV6	ST-segment deviation of derived leads (ECGdV1 to ECGdV6)
STI, STII, STIII, STV, STV1 to STV6	ST deviation leads
STVM	ST vector magnitude
SVT	Supraventricular tachycardia
TACH	Tachycardia

Abbreviation	Description
TruST	Algorithm that provides a TruST-12-lead-ECG (including derived chest leads ECGdV1, ECGdV3, ECGdV4, ECGdV6) using a 6-wire lead set that provides leads ECGI, ECGII, ECGIII, ECGaVR, ECGaVL, ECGaVF, ECGV2, ECGV5.
UAP	Umbilical arterial blood pressure
UVP	Umbilical venous pressure
VESA	Video Electronics Standards Association
VF	Ventricular fibrillation
VTACH	Ventricular tachycardia

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## Assembly and preparation

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## Overview

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This section describes the following basic assembly tasks:

- Docking/undocking the M540 from the M500
- Locking/unlocking the M540 into the M500
- Connecting/disconnecting the system cables

### Commercially available M500 mounting solutions

Various mounting solutions are available. It is the responsibility of the hospital to install, test, and ensure the proper and safe operation of any mounting solution. Contact a Dräger representative for specific approved mounting solutions.

#### CAUTION

Check the weight ratings of the commercially available mounts to avoid injuring the patient or damaging the device.

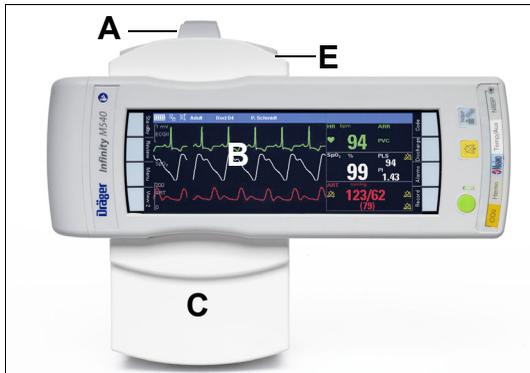
#### CAUTION

Avoid mounting solutions that could impede air flow since the M500 requires adequate airflow to dissipate heat.

## Docking/undocking the M540

The following diagram shows the side and front of the M500 which holds the M540 in place.

### Front view of the M500 with M540 docked



M540\_IFU\_cover1/G

### To dock the M540

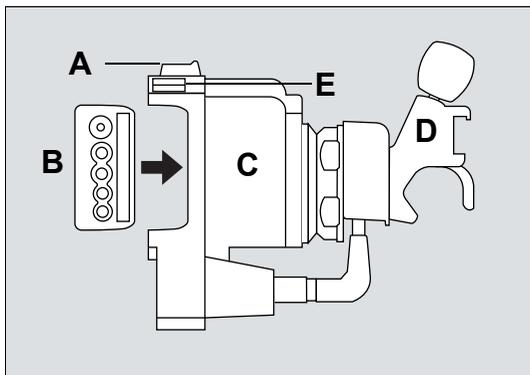
- 1 Align the curved portion of the M540 with the curved portion of the M500.
- 2 Press the M540 (B) into the M500 (C) until it 'clicks' into place.
- 3 Push the locking tab (A) of the M500 toward the front, to the locked position , to fasten the M540 into place.

To lock the M540 into place permanently, see page 54.

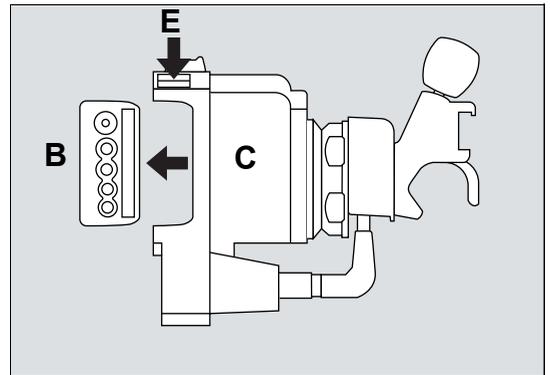
### To undock the M540

- 1 Push the locking tab (A) of the M500 toward the back. If the locking tab does not move, it has been locked. To unlock the M540, see page 54.
- 2 Hold the M540 firmly and press one of the M500 release buttons (E – see arrow).
- 3 Pull the M540 (B) out of the M500 (C).

### Side view of the M500 (M540 undocked)



305



306

- A M500 locking tab
- B M540 patient monitor
- C M500
- D Swivel mount (optional) and mounting clamp
- E Release button

## Locking/unlocking the M540

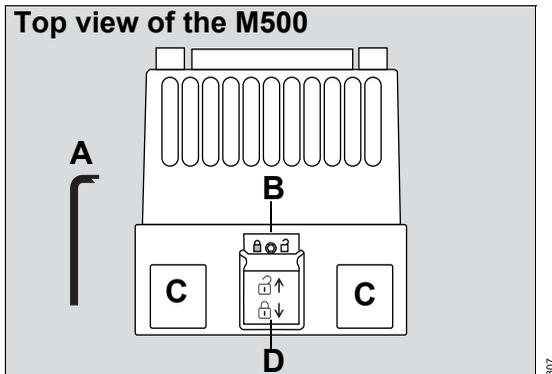
You can lock the M540 in the M500 to prevent anyone from undocking it.

### To lock the M540

- 1 Push the locking tab (D) of the M500 toward the front. This prevents anyone from undocking the M540. Pushing the locking tab back, allows anyone to undock the M540 again.
- 2 Insert the 2 mm Allen key (A) into the middle hole (B) on the locking tab and turn it clockwise to the locked position . The locking tab is now fixed and the M540 cannot be unlocked unless it is first 'unlocked' using the hex wrench tool.

### To unlock the M540

- 1 Insert the 2 mm Allen key (A) into the middle hole (B) on the locking tab and turn it counterclockwise to the unlocked position .
- 2 Push the locking tab (D) back to unlock the release buttons (C) on the M500 to undock the M540.



- A Allen key
- B Center hole on locking tab for locking/unlocking the M540
- C Release buttons for undocking the M540
- D Locking tab

## Connecting the system cables in an IACS configuration

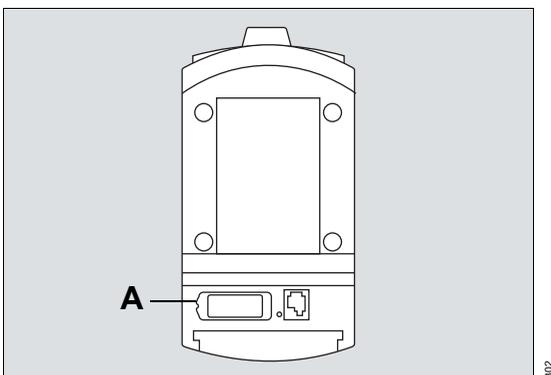
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For details on connecting the IACS system cables, refer to the *Instructions for use Infinity Acute Care System – Monitoring applications*.

## Connecting the system cable in an M540 stand-alone configuration

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- 1 Connect one end of the M540 Y-cable/Y-adapter to the M500 system connector (A).
- 2 Connect the power supply to the M540 system cable.
- 3 Connect the power cable to the power supply.



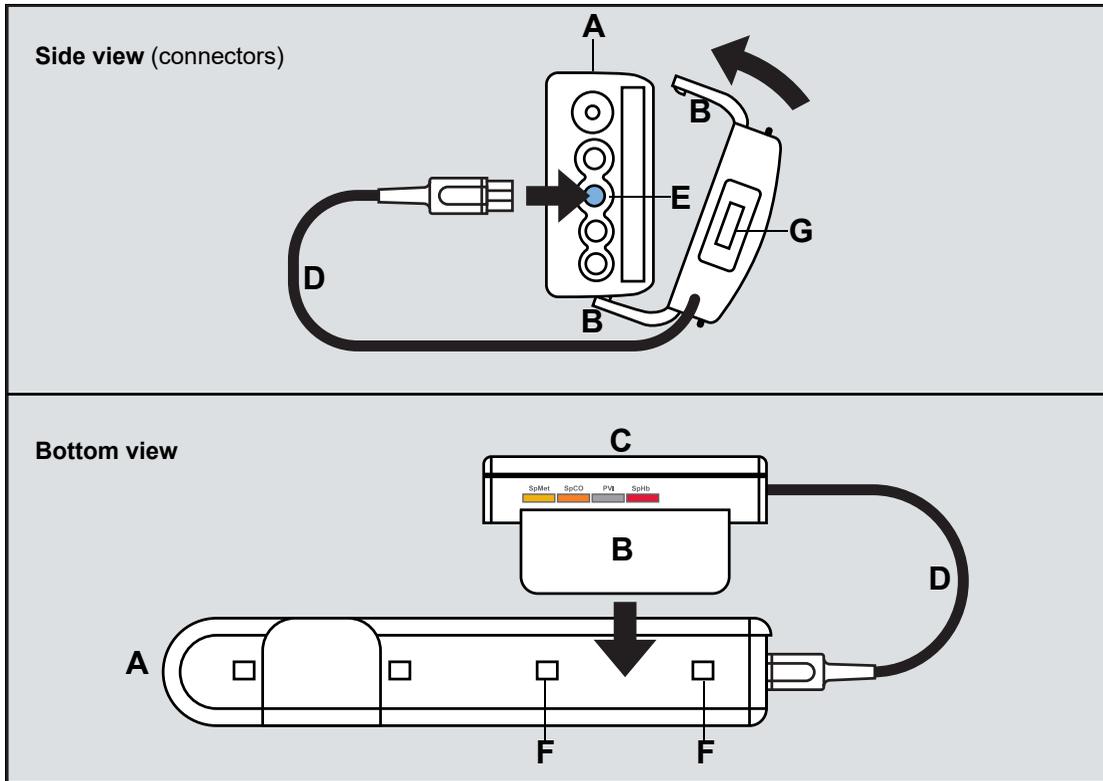
## Additional M540 accessories

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The M540 patient monitor supports a variety of accessories that include transport hardware, clamps, cable hooks, trolleys, and so forth. For more information about these specialized accessories, refer to the *Instructions for use Infinity Acute Care System – Monitoring accessories*.

## Mounting the Infinity MCable – Masimo SET and Masimo rainbow SET/Nellcor OxiMax

The following diagram shows how a Masimo MCable and a Nellcor OxiMax can be mounted to the M540.



- A M540
- B Tabs of the MCable mount adapter that lock into the side of the M540.
- C MCable housing
- D MCable
- E Blue SpO2 connector
- F Indentations for locking the MCable mount adapter
- G Intermediate cable or reusable SpO2 sensor which connects directly to the MCable

**To attach the MCable mount adapter**

Follow these steps to attach the MCable to the M540:

- 1 Make sure the cable end of the MCable (D) mount adapter (C) points in the same direction as the connector side of the M540.
- 2 Align the tabs on the mount adapter (B) with the indentations on the M540 and push firmly until the mount adapter clicks in place.
- 3 Connect the MCable (D) to the blue SpO<sub>2</sub> connector on the M540.

**To remove the MCable mount adapter**

- 1 Insert a flat head screwdriver (or equivalent tool) between the indentations for locking the MCable mount adapter (F).
- 2 Gently lift to unhinge the adapter.

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## Operating concept

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## Overview

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The M540 is a portable patient monitor that accompanies the patient from the bedside to anywhere in the hospital. This small, lightweight, splash-resistant monitor makes transporting less disruptive to the patient, reducing the risks of undetected events, and improving the efficiency of the clinician. The M540 is available in the following configurations:

- As a transport module in an IACS setup. When docked, the M540 communicates with the Infinity network through the Cockpit.
- As a standalone monitor docked in an M500 that is connected to the Infinity network. When docked, the M540 is in wired mode and communicates with the Infinity network through the M500.

If the wireless option is activated and configured, the M540 switches to wireless mode automatically when undocked. If the wireless option is not activated when the M540 is undocked, monitoring continues but the M540 no longer communicates with the network.

### NOTE

The M540 can also be docked to an M500 that is only connected to power and is used for charging the M540 battery.

An M540 standalone configuration consists of the following components:

- M540 patient monitor
- M500 (docking station)
- Y-cable/Y-adapter for power and/or network connection
- Power supply
- MPOD and MCable devices for monitoring specific parameters and associated accessories.

An M540 in an IACS configuration consists of all of the above listed components and the following:

- C500/C700 display module
- P2500 power supply

### NOTE

For detailed information on how the M540 functions in an IACS configuration, refer to the *Instructions for use Infinity Acute Care System – Monitoring applications*.

An M540 can be mounted in an M500 on a trolley, or in a traditional wall mounting.

## M540 in standalone / wireless mode

An M540 standalone monitor communicates with the Infinity network through the M500. For information on configuring the wired option (for example, setting up IP addresses, and so on, see page 317).

When the wireless option is activated and configured, a standalone M540 communicates wirelessly with the Infinity network when undocked. When docked, a wireless M540 transitions back to a wired connection, and the wireless symbol is replaced by the network symbol .

For detailed information on configuring the wireless option (for example, setting up IP addresses, activating and deactivating wireless mode), see page 318.

For information how the M540 behaves in an IACS configuration, see page 62.

### NOTE

Speaker volume reverts to its default after it is power-cycled. Speaker volume can be changed manually.

## Configuration changes while on wireless transport

Any changes to the M540 profile settings while on transport (including remote changes) are maintained when the user redocks the M540 to the M500 where it was previously docked. However, if the user docks the M540 on a different M500, the configuration settings of the M500 determine if the M540 adopts the profile of the M500 or if it retains the transport settings when it is docked.

For detailed information on configuring the profile adoption behavior, see page 91.

### Transport tone volume settings

When an M540 monitor is undocked, the following transport settings are activated. These transport settings are initially configured under the password-protected **Volume/ Tones** tab (see page 307).

- The setting **Transport pulse tone** determines the pulse tone volume for SpO<sub>2</sub> and heart rate when the M540 is undocked. While undocked the user can adjust the pulse tone volume manually in the parameter-specific SpO<sub>2</sub> or heart rate setup menu.

- The transport volume determines the speaker volume of the M540 when it undocks for patient transport.

When used in an IACS configuration, the M540 is responsible for issuing all acoustic alarm signals when it is undocked. The Cockpit no longer issues acoustic alarm signals while the M540 is undocked.

While undocked, the user can adjust the **Transport volume** setting manually by pressing the **Alarms** function key then the **Alarm volume** button. If the M540 docks on an M500 in an IACS configuration, the speaker is deactivated and the Cockpit assumes primary alarm annunciation.

Because these transport settings are part of a profile, the profile adoption setting determines what happens to any changes that occur during transport when the M540 docks to the M500. For more information, see page 91.

## Bed label setting

If the **Keep bed label** setting on the M540 is set to **Yes**, the M540 adopts the bed label that was configured on the previous device (IACS or M500).

If the **Keep bed label** setting on the M540 is set to **No**, the M540 adopts the bed label that was configured on the M540. The other settings that were configured in the **Name service** dialog on the previous device will be maintained (for example: **Mon. unit**).

If the **Keep bed label** setting is set to **No** and the bed label is modified while the M540 is wireless, the bed label is automatically updated on the M540 and the update is transmitted over the network.

If the M540 reports an offline message, the **Keep bed label** setting has not been configured on the M500. In this case the M540 automatically reverts to the default setting **Yes** when it is undocked. For more information about the offline message, see page 328.

Contact specialized service personnel to configure this setting appropriately. For more information, see page 318.

If the wireless mode is disabled, the **Keep bed label** setting appears grayed out.

## Network status symbol

The following table lists the symbols that appear on the M540 header bar to indicate whether the M540 is in wireless mode or not and how robust the wireless connection is.

	The M540 is docked on an M500 and is communicating with the Infinity network through a wired connection.
	The M540 is communicating wirelessly and has optimum association with a wireless access point.
	The M540 is communicating wirelessly and has good association with a wireless access point.
	The M540 is communicating wirelessly and has adequate association with a wireless access point.
	The symbol appears white when the M540 is still associated with a wireless access point but no data is transmitted to the ICS.  The symbol appears red when the M540 is no longer associated with a wireless access point.

## M540 in an IACS configuration

In addition to operating as a standalone device, the M540 can also function as the signal acquisition component for an IACS configuration. When docked on the M500, the M540 remains at the bedside and communicates all patient data to the Infinity Medical Cockpit, the main display component of the IACS. When disconnected ("undocked") from the M500 for patient transport, the M540 continues to monitor the patient.

When the wireless option is activated and configured, the M540 switches to wireless mode automatically within 10 seconds of being undocked from the M500. When the M540 is on wireless transport, the network symbol  is replaced by a wireless symbol (see page 62) until the M540 returns to an M500.

Once redocked on the M500, the M540 transmits the data that was collected during patient transport to the Cockpit. For more detailed information on

how the M540 functions in an IACS configuration, refer to the *Instructions for use Infinity Acute Care System – Monitoring applications*.

### Configuration changes while on wireless transport

Any changes (including remote changes) to the patient profile while the M540 was on wireless transport are reset to the profile settings of the Cockpit once the M540 is docked. For information how the M540 behaves as a standalone device, see page 61.

## Communicating with the Infinity network

An M540 communicates with the Infinity network wirelessly when the wireless option is unlocked and configured. An M540 also communicates with the network when it is docked on an M500 that is connected to the Infinity network. An M540 that communicates with the Infinity network is Infinity OneNet compatible.

The following data are made available to the Infinity network while the M540 is communicating with the Infinity network:

- All real-time parameter and waveform information.
- All alarm information – in case of multiple alarms, the alarm condition with the highest grade alarm is sent to the network.
- M540 trend data (up to 72 hours of trend data for each parameter).
- ST complexes – can be viewed from the ICS and the Symphony application.

- Alarm messages of high, medium, and low priority from devices on the network within the configured monitoring unit and the selected alarm group.
- The following messages:  **All alarms off**,  **All alarms paused** (with timer), **HR Limits Off**, the patient category identifier (adult, pediatric, neonate), **Pacer off**, **Pacer fusion**
- Alarm limits off symbol 
- Patient name

See “Device communication messages / general device messages“ on page 328 for network-related messages.

#### NOTE

If an NIBP measurement was taken more than 24 hours ago, and the M540 is undocked and re-docked to a Cockpit or stand-alone docking station, the data displays on the ClusterView and the ICS BedView without a time stamp.

### Loss of connection to the network

When the M540 loses its connection to the Infinity network and the feature **Offline detection** is activated at the Cockpit, the following happens:

- A single notification alarm of low alarm priority sounds once within 25 seconds of the offline condition. The single notification tone annunciates even if alarms are paused or the alarm volume has been deactivated.

- The alarm volume is automatically adjusted to 100 % until the condition clears. Once the M540 re-establishes communication with the network, the previous alarm volume is restored.
- The message **Offline** appears on cyan background in the network message area until the connection to the network is restored.

The alarm condition clears when communication between the M540 and the network is re-established.

When the setting **Offline detection** is not activated at the Cockpit or at an M540 in a standalone configuration, the above messages and alarm tone behaviors are not supported.

**Offline detection** is a Service setting which is configured by Service personnel.

## ICS (Infinity CentralStation) communication

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Each M540 that is connected to the network can be associated with an ICS.

An M540 is represented on the ICS with a viewport and a BedView. Depending on the layout of the ICS, a viewport may consist of several waveforms and parameters. Regardless of the selected ICS layout, the top M540 waveform and the associated parameter field always appear in the viewport. The parameter data and waveforms appear in the assigned ICS viewport within 40 seconds after the M540 has been undocked from the M500. The wireless symbol  appears next to the bed label in the ICS viewport. The wireless symbol disappears as soon as the M540 is docked on the M500.

Refer to the instructions for use *Infinity CentralStation* for information on how to assign a patient to an ICS.

### ICS BedView waveform/parameter assignment

The ICS also provides a BedView window which displays the content of the M540 in greater detail. A BedView contains up to seven waveforms and associated parameter fields. Up to four additional parameter fields can be allocated to appear along the bottom. The BedView screen is populated with waveforms and parameter fields from the five available M540 Views. These Views determine how many waveforms and parameter fields are displayed on the M540.

Specifically, the ICS uses the following rules to populate the BedView window with waveforms and parameter fields from the M540:

- The top waveform of View 1 of the M540 becomes channel 1 on the ICS BedView.
- No waveform and no parameter field are repeated more than once. Therefore, the next unique waveform becomes channel 2 on the ICS BedView. This waveform could originate from the same View or, if no unique waveform is available, from the next View. For example, if the **ECGII** waveform occupies the top channel in View 1 and the **ECGII** waveform is repeated in View 2, the **ECGII** waveform in View 2 is skipped because it has the same label as the top waveform in View 1 and is therefore not unique.
- The remaining available slots on BedView continue to be populated by other unique waveforms on the M540 in the same way.
- Once the waveforms are assigned to the BedView, the associated parameter fields are assigned next to their respective waveforms.
- Lastly, the four available parameter slots located at the bottom of the BedView are filled with unique parameter fields (no waveforms) starting with the right-most parameter field which appears along the bottom of the M540.

- If you are using PatientWatch, part of the Infinity Gateway product suite, ECG III, ECG aVF, and ECG aVL will not display, but these leads are still available at the patient monitor and the ICS.
- If an NIBP measurement was taken more than 24 hours ago, and the M540 is undocked and re-docked to a Cockpit or stand-alone docking station, then the NIBP measurement data is sent and displayed without a time stamp on the Main screen and the BedView on the ICS.

**NOTE**

When the M540 is placed in standby or discharge mode, ECG and IP waveform scales appear in the viewport. However, waveforms do not appear in the viewport.

**NOTE**

When Bed View 1 is the only view enabled on the M540, the ICS Bed View does not draw correctly.

M540 are made available to the Infinity network and the patient can be manually assigned to an empty viewport at the ICS.

While a M540 is on the Infinity network, any events that occur are sent to the ICS event disclosure data base.

The M540 also supports the full disclosure application on the ICS which stores waveforms continuously.

**NOTE**

PatientWatch does not display ECG III, ECG aVF, and ECG aVL in the ECG show all screen. However, these leads are still available at the patient monitor and at the ICS.

**NOTE**

An alarming M540 wireless parameter is only stored in the ICS Event Disclosure database if the parameter appears on the BedView of the ICS.

**Wireless M540 and the ICS**

If the **Keep bed label** setting on the M540 is set to **Yes**, the patient data of a wireless M540 continue to display in the same viewport of the ICS even after it is undocked.

If the **Keep bed label** setting is set to **No**, the M540 uses the bed label configured in the M540 wireless menu when it undocks. In this case the patient data are removed from the ICS viewport. A message appears in the viewport that the M540 is disconnected because the ICS no longer recognizes the patient due to the new bed label. To display the patient data on the ICS, the patient must be admitted again at the ICS. If not readmitted, the patient will no longer appear in the ClusterView of the ICS.

If the user docks a different M540 on an M500, the data of the original wireless M540 continues to be displayed in the same ICS viewport. In addition, the ICS alarm surveillance function monitors the new patient if configured to do so. The data of the new

### Trend data

After docking/undocking the M540, one minute of trend data collected during this transition period may not be displayed at the ICS equipped with software version VG1. However, these trends are visible at the Cockpit.

The ICS also displays trend data for a M540 that is on the Infinity network. The trend history and tabular trend windows on the ICS only display parameters that have trend data available. Parameters with no trend data do not appear at the ICS. %Paced values originating from the M540 do not appear in the trends of an ICS equipped with software version VG1. These values do appear when the M540 is docked in an IACS configuration.

For more detailed information regarding the windows and functions on the ICS, refer to the instructions for use *Infinity CentralStation*.

Wireless	Wired
The M540 alarm volume is automatically set to 100 % and you can no longer deactivate the volume setting. Once the communication between the M540 and the ICS is restored, the previous alarm volume setting is restored.	The M540 alarm volume is automatically set to 100 % if the alarm volume was set to <b>Off</b> . You can no longer deactivate the volume setting. Once the communication between the M540 and the ICS is restored, the previous alarm volume setting is restored.  If the alarm volume was set to any other setting than <b>Off</b> when the network interruption occurred, the alarm volume remains unchanged.

### Audio pause feature

The Infinity network supports an audio pause of alarm tones from the ICS (see "Pausing acoustic alarm signals (audio pause)" on page 118 for more information).

**WARNING**  
**Interruptions to network communication can limit parameter information and alarm annunciation to the bedside. Respond to network alarm errors immediately to ensure continued monitoring from areas remote to the bedside.**

### Network communication interruptions

#### Wireless interruptions

If the communication between a wireless M540 and the ICS is interrupted because the M540 is outside the range of the wireless access points, the following happens:

- The wireless symbol  appears red in the M540 header bar.
- A message indicating that the M540 is offline appears at the ICS in the viewport of the patient.
- The M540 sounds an error tone and displays the message **Network error**.
- The alarm volume behaves differently for a wireless or a wired M540.

**NOTE**  
 For detailed information about the configuration and operation of wireless components in the Infinity network, contact your Dräger representative.

#### Network interruptions

When the M540 is connected to the network, but the communication with the ICS is interrupted, the following occurs:

- The message **Not monitored by central** appears in the viewport of the ICS and in the M540 header bar.
- The privacy mode is canceled.

- A single notification alarm of low alarm priority sounds once within 25 seconds of the start of the offline condition. The single notification tone annunciates even if alarms are paused or the alarm volume has been deactivated.
- The alarm volume is automatically adjusted to 100 %. Once the M540 re-establishes communication with the ICS, the previous alarm volume is restored.

## Network data transfer

The IACS network supports the transfer of patient data from a source device, such as an Infinity Delta, Delta XL/Kappa (software version VF10.1; not supported when the M540 is set to Secure mode),

or an IACS Cockpit, to another Cockpit. For more information about how to transfer data, refer to the *Instructions for use Infinity Acute Care System – Monitoring applications*.

During a network transfer, the M540 displays the message **Transferring data...**

### CAUTION

Do not touch the screen or undock the M540 during the data transfer. Doing so can cause a network failure and result in an incomplete transfer.

After a successful transfer the M540 returns to the last monitoring screen before the transfer started. A message appears at the Cockpit to confirm that the transfer is complete.

## Remote view and remote control

The user can remotely view the data of any M540 that is connected to the Infinity network from the following devices:

- IACS Cockpits
- ICS
- Patient monitors – Delta/Delta XL/Kappa (not supported when the M540 is set to Secure mode)

The user can also execute certain remote functions from the above devices for any M540 that is connected to the Infinity network provided the **Remote control** and **Remote silence** settings are enabled. These settings are located in the **Service** menu. For more information, contact specialized service personnel.

If the M540 is on wireless transport, any remote changes to the patient profile are reset to the profile settings of the Cockpit once the M540 is docked.

When the M540 is in a standalone configuration, the profile adoption setting determines if remote changes that affect profile settings are reset to the

default profile of the M500 or not (see "Profile behavior in a standalone configuration" on page 91).

If multiple devices try to execute a remote function simultaneously, the M540 always accepts the latest remote request.

The following table lists which functions can be performed remotely for an M540.

### NOTE

When viewing the patient monitor in Remote View, the HR label displays instead of the PLS label. The value reported is the PLS value.

### NOTE

To communicate, all devices must use the same security mode. See "Infinity network security" on page 31 for information on security modes.

Remote function	Remote control from the ICS?	Remote control from other patient monitors?
Pausing the alarm tone for 2 minutes	Yes	Yes
Pre-silencing alarms for 2 minutes. This function suppresses acoustic alarm signals for possible alarm conditions so that the user can concentrate on a procedure without being interrupted. Optical alarm signals are still reported for any alarm condition.	Yes	Yes
<p>Requesting continuous/timed recordings for M540 used in an IACS configuration and on wireless transport.</p> <p>The recording requests are stored on the M540 and transferred to the Cockpit once the M540 is docked. The user can review a stored event at the Cockpit and request a manual recording.</p>	Yes	Yes
Requesting continuous/timed recordings for standalone M540.	No	No
Activate/deactivate the alarm function for a parameter.	Yes	No
<p>Activate/deactivate the alarm <b>Archive</b> function. The following happens for each setting of the <b>Archive</b> function:</p> <ul style="list-style-type: none"> <li>– If the M540 is in an IACS configuration and on wireless transport and a parameter whose <b>Archive</b> function is set to <b>Str/Rec</b> or <b>Store</b> goes into alarm, that event is stored at the M540 and in the Event Disclosure database of the ICS. Once the M540 is docked, the event is transferred to the Cockpit where you can view it on the alarm history page and request a manual recording.</li> </ul> <p>If the M540 is in standalone mode, the alarming parameter causes an event to be stored in the Event Disclosure database of the ICS and in the <b>Event recall</b> dialog of the M540 (see "Event recall" on page 125).</p> <ul style="list-style-type: none"> <li>– If the M540 is in an IACS configuration and on wireless transport a parameter whose <b>Archive</b> function is set to <b>Record</b> goes into alarm, the recording request is stored at the M540 but no recording is generated. Once the M540 is docked, the request is transferred to the Cockpit where the user can view it on the alarm history page and request a manual recording.</li> </ul> <p>If the M540 is in standalone mode, the alarming parameter causes an event to be stored in the Event Disclosure database of the ICS and in the <b>Event recall</b> dialog of the M540 (see "Event recall" on page 125).</p>	Yes	No
Configuring alarm limits	Yes	No
Auto setting alarm limits	Yes	No

Remote function	Remote control from the ICS?	Remote control from other patient monitors?
Configuring arrhythmia settings	Yes	No
Configuring <b>ST</b> settings	No	No
Reviewing trend data	Yes	No
Initiate relearning	Yes	No
Change the demographic data of the patient	Yes	No

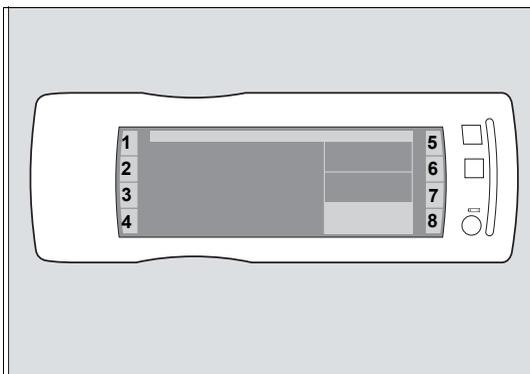
## Function keys

A total of eight function keys are located on the front of the M540 (4 on the right and 4 on the left side).

The function keys in positions 2, 3, 4 and 7 are permanently assigned to the functions **Review**, **Menu** (Main), **View 1**, and **Alarms**.

The function keys in positions 1, 5, 6 and 8 carry default assignments, but they can be reprogrammed (see page 70). The current function key assignments (key names) are displayed next to the function keys.

The following diagram shows where the function keys are located on the M540.



## Default function key assignments

	Function Key	Function
1	<b>Standby</b> (default)	Places the M540 into standby mode (see page 93). When the M540 is docked in an IACS configuration, pressing this function key also places the Cockpit in standby mode.
2	<b>Review</b>	Opens the <b>Event recall</b> dialog (see <i>Event recall</i> in the Alarms chapter).
3	<b>Menu</b>	Opens the <b>Main</b> dialog. It also closes any open dialog and returns the user to the monitoring view.
4	<b>View 1</b> to <b>View 5</b>	Scrolls through five pre-configured screen layouts (see page 76).
5	<b>Code</b> (default)	Invokes the Code function at the Cockpit when the M540 is docked in an IACS configuration. For more information, refer to the <i>Instructions for use Infinity Acute Care System – Monitoring applications</i> .

	Function Key	Function
6	<b>Discharge</b> (default)	Discharges the patient (see page 102).
7	<b>Alarms</b>	Opens the <b>Alarm settings</b> dialog.
8	<b>Mark</b> (default)	Stores an event in the <b>Event recall</b> dialog.

### To program a function key

- 1 Touch the **Menu** function key.
- 2 Touch the **Screen setup** tab > **Function keys** tab.
- 3 Touch one of the programmable setup keys (**Setup key 1**, **Setup key 2**, **Setup key 3**, or **Setup key 4**) and then touch the desired function.
- 4 Touch **X** to close the dialog.

The new key assignment is retained until manually reset to the factory default or until another key is assigned as described above. Because the function key assignments are also part of the profile, the position of these keys might change if the M540 is docked on an M500 with a profile whose stored function key setup is different.

### Alternate function key assignments

Key	Function
<b>Privacy</b>	Places the M540 into privacy mode (see page 93). This mode is only available when the patient is admitted at the ICS.
<b>Record</b>	Records an event which can be viewed in the <b>Event recall</b> dialog.  When the M540 is docked in an IACS configuration, pressing the <b>Record</b> function key notifies the Cockpit to start/stop a timed recording.  Press and hold the function key for two seconds to start a continuous recording.
<b>Patient</b>	Opens the <b>Patient setup</b> dialog (see page 101).
<b>Rest ECG report</b>	Prints a Rest ECG report

## Monitoring area

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The monitoring area of the M540 screen contains a header bar, waveforms, and parameter fields that report the current vital signs of the patient. The appearance of the monitoring area depends on the selected view, which controls the layout and content of the screen (see page 76).

### Header bar

The blue header bar appears along the top of the screen. It is always visible and displays the following information:

- Remaining battery charge symbol  (when the battery is fully charged, all segments in the symbol are filled in; the segments appear empty as the battery charge is depleting)
- Network connection symbol  when the M540 is connected to the network
- Patient category (adult, pediatric, neonate)
- Bed label
- Patient name and alarm message field
- Current time
- Wireless symbol  appears when the M540 is on wireless transport.
- The alarm message symbol, when applicable.

## The alarm status field

The following are some examples of alarm-related symbols and messages that can appear in the alarm status field.

Symbol	Label	Description
	<b>Audio paused</b>	Appears with a timer and disappears when the user presses the yellow key on the front of the M540 patient monitor.
	<b>Audio off</b>	Indicates that the alarm volume is set to off.
	<b>All alarms paused</b>	Indicates that all alarms have been paused for the amount of time specified in the <b>Alarms</b> menu.
	<b>Alarms</b>	Indicates that all alarms have been set to off.

For a complete list of supported messages see page 327.

For more detailed information on alarm monitoring see "Alarms" on page 105.

## Parameter fields

Each parameter field contains real-time values of a parameter and a combination of the following information:

- Parameter labels (including dynamic pressure labels)
- Crossed triangle symbols  when alarms are turned off
- Units of measure
- ECG heart blip (and pacer blip for paced pulses), RRi blip, and SpO2 blip
- Timers for non-invasive blood pressure
- Special source labels (for example, PLS for heart rate signal source for pulse oximetry)

When a parameter is in alarm, the parameter field flashes in the color of the alarm priority (see *Alarm priorities* in the Alarms chapter), and a corresponding alarm message appears in the header bar. Each parameter chapter describes the parameter fields for the corresponding parameter in greater detail.

When a dialog is open, the parameter fields appear along the right side of the screen. This display behavior prevents the vital signs from being obscured while the user is performing setup tasks.

The **X** in the upper right corner of any window closes the open dialog and returns the user to the main screen.

## Waveforms

The main screen of the M540 displays up to three waveforms simultaneously. Waveforms are drawn from left to right and can contain the following information:

- Signal scales
- Units of measure
- Parameter labels
- Pacer spikes
- QRS synchronization markers
- Respiration waveform markers to indicate breath detection

### To configure the waveforms

- 1 Touch the waveform area to open the waveform channel dialog.
- 2 Touch the **Channel 1**, **Channel 2**, or **Channel 3** tab to configure the desired channel.
- 3 Touch **Waveform** and select the desired parameter in the **Waveform** dialog.
- 4 Touch **Size** and then select the desired amplitude.
- 5 Touch **X** to close the dialog.

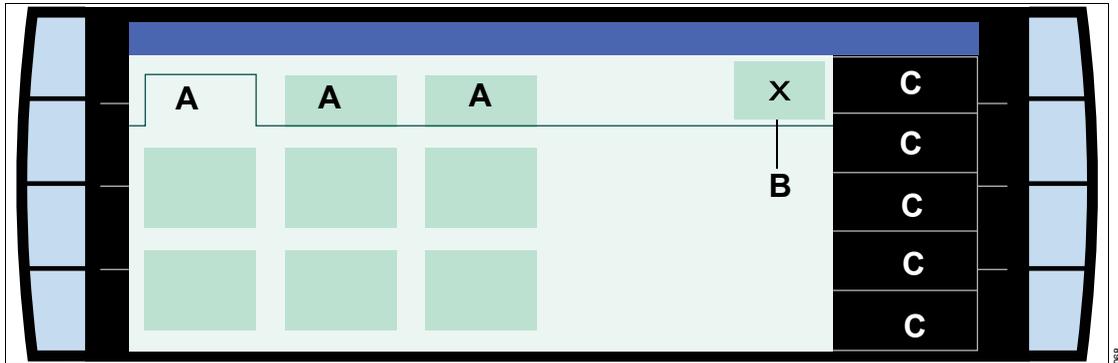
### NOTE

If the acquired signal does not fit in the waveform channel, the top of the waveform may appear clipped.

## Dialogs

The following diagram shows how the monitoring area appears when accessing a dialog. The left side is reserved for the dialog while the right side displays the parameter fields. A dialog contains horizontal and vertical tabs that open additional dialogs.

To access dialogs, touch the function keys on the front of the M540. To access parameter-specific setup pages directly, touch the corresponding parameter fields on the main screen.



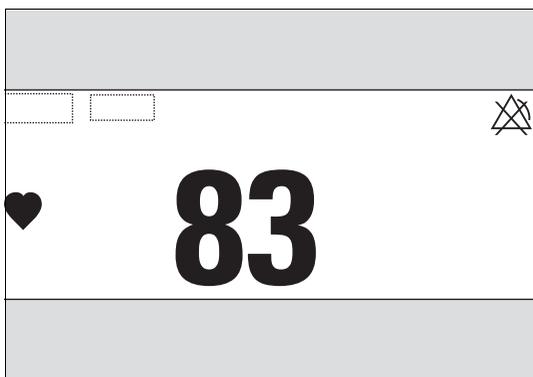
- A** Horizontal tabs – the selected tab appears light blue
- B** Button that closes the dialog
- C** Parameter fields displaying real-time values

## Adjusting the display

If the orientation of the device changes during patient transport, the Auto flip function allows the screen to flip by 180°. This feature can be turned on or off.

### NOTE

Operate the touchscreen with finger presses only. Do not use sharp objects.



### To turn the auto flip function on/off

- 1 Touch the **Menu** function key.
- 2 Touch the **Screen setup** tab > **Settings** tab.
- 3 Touch **Autoflip** until the desired choice is selected (**Yes** or **No**).
- 4 Touch **X** to close the dialog.

### To flip the screen manually

- 1 Touch the **Menu** function key.
- 2 Touch the **Screen setup** tab > **Settings** tab.
- 3 Touch **Flip screen**. The screen flips automatically and flips back if the user selects the button again.
- 4 Touch **X** to close the dialog.

### Calibrating the touchscreen

If the touchscreen is out of alignment, the user can calibrate it at any time.

### To calibrate the touchscreen

- 1 Touch the **Menu** function key.
  - 2 Touch the **Screen setup** tab > **Settings** tab > **Touch calib**.
  - 3 Touch each cross appearing successively in each corner of the screen.
- or
- 1 Push and hold the following two keys simultaneously:  
  - 2 Touch each cross appearing successively in each corner of the screen.

## Battery power

The M540 automatically switches to battery power for up to 3 hours when it is undocked or if there is a loss of power to the M500. The M540 displays low battery messages as applicable and then performs a safe shutdown that preserves the integrity of the patient data and the user settings. A shutdown is accompanied by an audible tone. When the M540 is docked, the M500 continuously charges the internal battery. The battery charge symbol  on the front of the M540 lights up green when the battery is being charged.

To continue monitoring during a loss of power or during patient transport, the battery of the M540 should be fully charged at all times. The battery charge indicator  in the header bar indicates the remaining battery charge.

### Charging times

The following table indicates the required time to charge a depleted battery:

Capacity	Approximate charging time
70 %	4 hours
90 %	5.5 hours
100 %	6.5 hours

### Battery operating times

The following table lists the operating times of a fully charged internal battery powering an M540 that is monitoring with ECG, SpO<sub>2</sub>, Temp continuously, and NIBP in 15-minute interval mode.

Mode	Approximate operating time
Regular bedside mode	3 hours
Power save	4 hours

#### NOTE

Connecting any additional parameters other than the configuration specified in the instructions for use, may diminish the battery life of the M540.

### Low battery conditions

When the message **Low battery** appears, 10 minutes of battery runtime remains before the M540 shuts down automatically. The message remains on display for 5 minutes and is accompanied by an acoustic alarm signal of low priority. The battery charge indicator  in the header bar appears red.

After the 5-minute period, the message **Recharge battery** appears in the message area of the header bar indicating that 5 minutes of battery life remain. This message is accompanied by an acoustic alarm signal of medium priority. The battery charge indicator  in the header bar appears red.

When the battery of an M540 is depleted, it can still monitor a patient as soon as the user docks it on an M500 that is receiving power.

#### WARNING

**When the M540 shuts down due to a depleted battery, M540 configured settings are preserved for up to 60 hours. To avoid the loss of configured settings, Dräger recommends docking the M540 back into the M500 prior to 60 hours.**

## Power-saving mode

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When the M540 is not docked, the power save mode conserves battery charge while continuing to monitor a patient.

When power save mode is activated, the display of the M540 is turned off. The display of the M540 automatically turns back on when:

- The user docks the M540 on the M500
- The user touches the screen or any key
- The M540 detects an alarm condition of medium- or high-priority

### To activate/deactivate power save mode

- 1 Touch the **Menu** function key.
- 2 Touch the **Screen setup** tab > **Settings** tab.
- 3 Touch **Power save** until the desired choice is selected (**Off**, 1, 2, 3, 4, 5 min).
- 4 Touch **X** to close the dialog window.

## Views

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Each M540 supports five pre-configured views, which control the content and the appearance of the screen. The user can switch to a different view to adjust the screen layout to the needs of the current monitoring session.

### Selecting a view

The following table lists the pre-configured views and the associated defaults. Once selected, the user can change the parameter assignments as needed.

Selected view	Default parameters	Default waveforms
One waveform and three parameter fields (vital signs display)	HR, SpO <sub>2</sub> , and NIBP	ECG lead II
One waveform and four parameter fields	HR, SpO <sub>2</sub> , NIBP, and RRi	ECG lead II
One waveform and seven parameter fields	HR, SpO <sub>2</sub> , RRi, NIBP, GP1, GP2 and Temperature. If no IP sensor is connected the corresponding parameter labels may not be displayed.	ECG lead II
Two waveforms and five parameter fields	HR, SpO <sub>2</sub> , RRi, Temperature, and NIBP	ECG lead II and SpO <sub>2</sub>
Three waveforms and three parameter fields	HR, SpO <sub>2</sub> , and RRi	ECG lead II, SpO <sub>2</sub> , and RRi

**To select a view**

- Touch the currently selected function key several times (for example, **View 5**) to scroll through the available view labels.

**To deactivate a view**

The user can deactivate up to four views.

- 1 Touch the **Menu** function key.
- 2 Touch the **Screen setup** tab > **Screen views** tab.
- 3 Touch **View 1**, **View 2**, **View 3**, **View 4**, or **View 5**, > **Off**.
- 4 Touch **X** to close the dialog.

**To assign a pre-configured view to a view key**

- 1 Touch the **Menu** function key.
- 2 Touch the **Screen setup** tab > **Screen views** tab.
- 3 Touch **View 1**, **View 2**, **View 3**, **View 4**, or **View 5** and then touch the desired configuration.
- 4 Touch **X** to close the dialog.

## Profiles

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A profile consists of pre-defined settings. Profiles eliminate time-consuming setup tasks that would otherwise have to be repeated for each monitoring session.

A profile includes patient and user defaults. Patient defaults can be customized for each patient category separately. User defaults are the same across all patient categories.

The user can save the current profile settings as a default profile and/or restore the default profile under a password-protected menu (see page 315).

The following sections describe which settings are included in a profile and which are not and how profiles behave in an IACS configuration and in standalone mode.

## Settings included in a profile

The following table illustrates which settings are included in a profile. The table also identifies which settings are patient defaults and which are user defaults.

Setting	Patient default	User default	Comments (if applicable)
<b>Screen views dialog</b> (Press the <i>Menu</i> function key > <i>Screen setup</i> tab > <i>Screen views</i> )			
<b>View 1</b>	x		The view that is active when the user saves the profiles, will become the designated default view.
<b>View 2</b>	x		
<b>View 3</b>	x		
<b>View 4</b>	x		
<b>View 5</b>	x		
<b>Settings in <i>Function keys</i> dialog</b> (Press the <i>Menu</i> function key > <i>Screen setup</i> > <i>Function keys</i> )			
<b>Setup key 1</b>		x	
<b>Setup key 2</b>		x	
<b>Setup key 3</b>		x	
<b>Setup key 4</b>		x	
<b>Alarm profile settings</b>			
The alarm profile settings are configured in the following dialogs			
<b>Alarm settings dialog</b> (Press the <i>Alarms</i> function key)			
<b>Speaker volume</b>		x	
<b>Alarm settings dialog</b> (Press the <i>Menu</i> function key > <i>System setup</i> > <i>Alarm setup</i> > enter password > <i>Alarm setup</i> )			
<b>All alarms paused</b> (Time selection)		x	
<b>Alarm validation</b>		x	
<b>SpO<sub>2</sub> alarm delay</b>		x	This selection is only available if the <b>SatSeconds</b> setting is set to <b>Off</b> .
<b>Alarm group</b>		x	
<b>NIBP/SpO<sub>2</sub> interlock</b>		x	
<b>ASY/VF alarms</b>		x	
<b>Pacer mode</b>	x		
<b>Alarm bar</b>		x	
<b>Battery alarm</b>		x	

Setting	Patient default	User default	Comments (if applicable)
<b>Pressures paused</b>	x		
<b>Pressures off</b>	x		
<b>Alarm settings dialog</b> (Press the <b>Menu</b> function key > <b>System setup</b> > <b>Alarm setup</b> > enter password > <b>Volume/ Tones</b> )			
<b>Minimum alarm vol.</b>		x	
<b>Transport volume</b>		x	
<b>Transport pulse tone</b>		x	
<b>Alarm pattern</b>		x	
<b>Reminder: all alarms off</b>		x	
<b>Reminder: audio off</b>		x	
<b>SpO2 sensor off dialog (Masimo)</b> (Press the <b>Menu</b> function key > <b>System setup</b> > <b>Alarm setup</b> > enter password > <b>SpO2 sensor off</b> )			
<b>Alarm</b> (alarm priority setting)	x		
<b>Archive</b>	x		
<b>SpO2 check sensor dialog (Nellcor)</b> (Press the <b>Menu</b> function key > <b>System setup</b> > <b>Alarm setup</b> > enter password > <b>SpO2 sensor off</b> )			
<b>Alarm</b> (Alarm priority setting)	x		
<b>Archive</b>	x		
<b>CO2 profile settings</b>			
The CO2 profile settings are configured in the following dialogs.			
<b>CO2 limits dialog</b> (Touch the CO2 parameter field)			
<b>Alarm</b> (On/off setting)	x		These settings can be configured separately for each of the following parameters: etCO <sub>2</sub> , inCO <sub>2</sub> , RRc.
Upper and lower alarm limits	x		
<b>Archive</b>	x		
<b>Mainstream dialog</b> (Touch the CO2 parameter field > <b>Mainstream</b> )			
<b>RRc apnea time</b>	x		
<b>Apnea archive</b>	x		
<b>Size [mV/cm]</b> (size of the waveform)	x		Touch the CO <sub>2</sub> waveform to set the scale of the waveform.
<b>Atm. pressure</b>		x	
<b>Gas compenss.</b>		x	

Setting	Patient default	User default	Comments (if applicable)
<b>Airway adapter</b>		x	
<b>Color</b> (Color of the waveform and parameter)	x		
<b>Microstream dialog</b> (Touch the CO <sub>2</sub> parameter field > <i>Microstream</i> )			
<b>RRc apnea time</b>	x		
<b>Apnea archive</b>	x		
<b>Size [mV/cm]</b> (size of the waveform)	x		Touch the CO <sub>2</sub> waveform to set the scale of the waveform (see page 72).
<b>Averaging</b>	x		
<b>Color</b> (color of the waveform and parameter)	x		
<b>Scio dialog</b> (Touch the CO <sub>2</sub> parameter field > <i>Scio</i> )			
<b>RRc apnea time</b>	x		
<b>Apnea archive</b>	x		
<b>Size [mV/cm]</b> (size of the waveform)	x		Touch the CO <sub>2</sub> waveform to set the scale of the waveform (see page 72).
<b>Color</b> (color of the waveform and parameter)	x		
<b>Scio profile settings</b>			
The Scio profile settings are configured in the following dialogs. For CO <sub>2</sub> settings, see <i>CO<sub>2</sub> profile settings</i> in this table.			
<b>O<sub>2</sub> limits dialog</b> (Touch the O <sub>2</sub> parameter field > <i>Scio</i> )			
<b>Alarm</b> (On/off setting)	x		These settings can be configured separately for each of the following parameters: FiO <sub>2</sub> , etCO <sub>2</sub>
Upper and lower alarm limits	x		
<b>Archive</b>	x		

Setting	Patient default	User default	Comments (if applicable)
<b>Agents limits dialog</b> (Touch the Agent parameter field > Scio)			
<b>Alarm</b> (On/off setting)	x		These settings can be configured separately for each of the following parameters: FiO2, etCO2
Upper and lower alarm limits	x		
<b>Archive</b>	x		
<b>Agent settings</b>			
<b>Agent</b> Touch <b>Prim. agent</b> parameter field OR Touch <b>Sec. agent</b> parameter field			
<b>Sec. agent alarm</b>	x		These settings can be configured separately for each of the following parameters: inSev, etSev, inDes, etDes, inlso, etlso, inHal, etHal, inEnf, etEnf
<b>Agent</b>	x		
<b>xMAC archive</b>	x		
<b>Heart rate and arrhythmia profile settings</b>			
The heart rate and arrhythmia profile settings are configured in the following dialogs			
<b>HR limits dialog</b> (Touch the heart rate parameter field > HR limits)			
<b>Alarm</b> (On/off setting)	x		These settings can be configured separately for each of the following parameters: HR, Brady (only in neonatal mode); PVC (only in adult and pediatric mode).
Upper and lower alarm limits	x		
<b>Archive</b>	x		
<b>ARR limits dialog</b> (Touch the heart rate parameter field > ARR limits)			
<b>Alarm</b> (Alarm priority setting)	x		The availability of the parameters, depends on the selected arrhythmia mode (see page 171).
<b>Count and Rate</b>	x		
<b>Archive</b>	x		
<b>ECG 1 dialog</b> (Touch the heart rate parameter field > Settings > ECG 1)			
<b>Tone volume</b> (For pulse tone)	x		

Setting	Patient default	User default	Comments (if applicable)
<b>Tone source</b> (For pulse tone)	x		
<b>ECG filter</b>	x		
<b>HR source</b>	x		
<b>Color</b> (Color of the waveform and parameter)	x		This setting affects ECG, ARR, and ST
<b>Size [mV/cm]</b> (Size of the waveform)	x		Touch the heart rate waveform to set the scale of the waveform (see page 72).
<b>ECG 2 dialog</b> (Touch the heart rate parameter field > <b>Settings</b> > <b>ECG 2</b> )			
<b>Pacer detection</b>	x		This setting is not available when the ESU filter is activated.
<b>QRS sync marker</b>	x		
<b>Cable type</b>	x		
<b>ARR lead 1</b>	x		
<b>ARR lead 2</b>	x		
<b>ARR processing</b>	x		
<b>ST profile settings</b>			
The ST profile settings are configured in the following dialogs			
<b>ST limits dialog</b> (Touch the ST parameter field)			
<b>Alarm</b> (On/off setting)	x		These settings can be changed for all ST parameters (STI, STII, STIII, STaVR, STaVL, STaVF, STV, STV+, STV1, STV2, STV3, STV4, STV5, STV6, STVM, STCVM, STdV1, STdV3, STdV4, STdV6).
Upper and lower alarm limits	x		
<b>Archive</b>	x		
<b>Settings dialog</b> (Touch the ST parameter field > <b>Settings</b> )			
<b>ST lead 1</b>	x		
<b>ST lead 2</b>	x		
<b>ST monitoring</b>	x		
<b>Event duration</b>	x		
<b>STV1</b>	x		This setting is only available with 6-lead cable.

Setting	Patient default	User default	Comments (if applicable)
<b>Respiration (RRi) profile settings</b>			
The respiration profile settings are configured in the following dialogs			
<b>Resp. limits dialog</b> (Touch the RRi parameter field)			
<b>Alarm</b> (On/off setting)	x		
Upper and lower alarm limits	x		
<b>Archive</b>	x		
<b>Settings dialog</b> (Touch the RRi parameter field > <b>Settings</b> )			
<b>Resp. lead</b>	x		
<b>Mode</b>	x		
<b>Marker</b>	x		
<b>Monitoring</b>	x		
<b>Apnea time</b>	x		
<b>Apnea archive</b>	x		
<b>Color</b> (Color of the waveform and parameter)	x		
<b>Coincidence</b>	x		
<b>Size [mV/cm]</b> (Size of the waveform)	x		Touch the <b>RRi</b> waveform to set the scale of the waveform (see page 72).
<b>SpO2 (Masimo) profile settings</b>			
The SpO2 profile settings are configured in the following dialog			
<b>SpO2 limits dialog</b> (Touch the SpO2 parameter field)			
<b>Alarm</b> (On/off setting)	x		These settings can be configured separately for <b>SpO2</b> , <b>Desat.</b> , and <b>PLS</b> .
Upper and lower alarm limits	x		
<b>Archive</b>	x		

Setting	Patient default	User default	Comments (if applicable)
<b>Settings dialog</b> (Touch the <b>SpO<sub>2</sub></b> parameter field > <b>Settings</b> )			
<b>Tone volume</b>	x		
<b>Tone source</b>	x		
<b>Bar graph</b>	x		
<b>Averaging time</b>	x		
<b>Sensitivity mode</b>	x		
<b>Fast SAT mode</b>	x		
<b>Color</b> (Color of the waveform and parameter)	x		
<b>Size [mV/cm]</b> (Size of the waveform)	x		Touch the <b>SpO<sub>2</sub></b> waveform to set the scale of the waveform (see page 72).
<b>Pulse CO-Ox (Masimo) profile settings</b>			
<b>The Pulse CO-Ox profile settings are configured in the following dialogs</b>			
<b>Two separate Pulse CO-Ox limits dialog window</b> (Touch the Pulse CO-Ox parameter field)			
<b>Alarm</b> (On/off setting)	x		These settings can be configured for the following parameters in two separate <b>Pulse CO-Ox limits</b> dialogs: SpHb/SpHbv, SpCO, SpMet, PVI.
Upper and lower alarm limits	x		
<b>Archive</b>	x		
<b>Settings 1 dialog</b> (Touch the Pulse CO-Ox parameter field > <b>Settings</b> > <b>Settings 1</b> )			
<b>Pulse CO-Ox 1</b>	x		
<b>Pulse CO-Ox 2</b>	x		
<b>Pulse CO-Ox 3</b>	x		
<b>SpHb Averaging</b>	x		
<b>Color</b> (Color of the waveform and parameter)	x		

Setting	Patient default	User default	Comments (if applicable)
<b>Settings 2 dialog</b> (Touch the Pulse CO-Ox parameter field > <b>Settings</b> > <b>Settings 2</b> > enter password)			
<b>SpHb Cal</b>	x		
<b>PVI Averaging</b>	x		
<b>SpO2 (Nellcor) profile settings</b>			
The SpO2 profile settings are configured in the following dialogs			
<b>SpO2 limits dialog</b> (Touch the <b>SpO2</b> parameter field)			
<b>Alarm</b> (On/off setting)	x		These settings can be configured separately for <b>SpO2</b> , <b>Desat.</b> , and <b>PLS</b> .
Upper and lower alarm limits	x		
<b>Archive</b>	x		
<b>Settings dialog</b> (Touch the <b>SpO2</b> parameter field > <b>Settings</b> )			
<b>Tone volume</b>	x		
<b>Tone source</b>	x		
<b>Bar graph</b>	x		
<b>Response mode</b>	x		
<b>SatSeconds</b>	x		
<b>Color</b> (Color of the waveform and parameter)	x		
<b>Size [mV/cm]</b> (Size of the waveform)	x		Touch the <b>SpO2</b> waveform to set the scale of the waveform (see page 72).
<b>Non-invasive blood pressure profile settings</b>			
The non-invasive blood pressure profile settings are configured in the following dialogs			
<b>NIBP limits dialog</b> (Touch the non-invasive blood pressure parameter field)			
<b>Alarm</b> (On/off setting)	x		These settings can be configured separately for NIBP S, NIBP D, and NIBP M.
Upper and lower alarm limits	x		
<b>Archive</b>	x		

Setting	Patient default	User default	Comments (if applicable)
<b>Settings dialog</b> (Touch the non-invasive blood pressure parameter field > <b>Settings</b> )			
<b>Interval time</b>	x		
<b>Inflation mode</b>	x		
<b>Chime</b>	x		
<b>Color</b> (Color of the waveform and parameter)	x		
<b>Temperature profile settings</b>			
<b>The temperature profile settings are configured in the following dialogs</b>			
<b>Temp limits dialog</b> (Touch the temperature parameter field)			
<b>Alarm</b> (On/off setting)	x		These settings can be configured separately for Ta, Tb, $\Delta T$ , T1a, T1b, $\Delta T1$
Upper and lower alarm limits	x		
<b>Archive</b>	x		
<b>Settings dialog</b> (Touch the temperature parameter field > <b>Settings</b> )			
<b>Color</b> (Color of the waveform and parameter)	x		
<b>Ta label</b>	x		Parameter labels can be changed to <b>TOral, TEso, TNasal, TRect, TBlad, Tcore, TBld1, TBlnkt, TSkin, TR, TL</b>
<b>Tb label</b>	x		
<b>T1a label</b>	x		Parameter labels can be changed to: <b>T1Oral, T1Eso, T1Nasal, T1Rect, T1Blad, T1core, T1Bld1, T1Blnkt, T1Skin, T1R, T1L</b>  NOTE: These selections are available only when using an MPod – Quad Hemo.
<b>T1b label</b>	x		

Setting	Patient default	User default	Comments (if applicable)
<b>Invasive pressure profile settings</b>			
The invasive pressure profile settings are configured in the following dialogs			
<b>Invasive pressure limits dialog (example: CVP limits)</b> (Touch the invasive pressure parameter field)			
<b>Alarm</b> (On/off setting)	x		These settings can be configured separately for ART D, ART M, ART S, PA D, PA M, PA S, LV D, LV M, LV S, GP1 D, GP1 M, GP1 S, GP2 D, GP2 M, GP2 S, GP3 D, GP3 M, GP3 S, GP4 D, GP4 M, GP4 S, GP5, GP6, GP7, GP8, RA, LA, RV, CVP, ICP, CPP, AXL, BRA, FEM, FEMV, AOR, RAD, UAP, ABD, BDP, BPP, ESO, UVP, GPM, ICP2, ICP3, CPP3, ICP4, CPP4.
Upper and lower alarm limits	x		
<b>Archive</b>	x		
<b>Settings dialog</b> (Touch the invasive pressure parameter field > <b>Settings</b> )			
<b>Edit label</b>	x		
<b>Filter</b>	x		
<b>Color</b> (Color of the waveform and parameter)	x		
<b>Size [mV/cm]</b> (Size of the waveform)	x		Touch the invasive pressure waveform to set the scale of the waveform (see page 72).
<b>Edit label</b> (For <b>Pod 1A label</b> through <b>Pod 1D label</b> and <b>Pod 2A label</b> through <b>Pod 2D label</b> )	x		Parameter labels can be changed to: <b>GP1 to GP8, ART, LV, LA, PA, CVP, ICP, ICP2 to ICP4, RA, RV, AXL, BRA, FEM, RAD, AOR, UAP, ABD, BDP, ESO, FEMV, UVP, GPM</b>

## Monitor settings

The following list contains the monitor settings which are a subset of the profile settings. When the **Profile settings** is set to **Monitor**, only these settings are adopted when the M540 is docked.

- Key configuration
- **Alarm volume**
- **All alarms paused**
- **Alarm validation**
- **Alarm pattern**
- **Alarm bar**
- **ASY/VF alarms**
- **SpO2 alarm delay**
- **NIBP/SpO2 interlock**
- **Pacer mode**
- **Alarm group**
- **Parameter colors**
- **HR source**
- **Tone source (ECG and SpO2)**
- **Tone volume (ECG and SpO2)**
- **Size [mV/cm] (ECG and SpO2 waveform)**
- **ECG filter**
- **Pacer detection**
- **QRS sync marker**
- **ARR processing**
- **Bar graph (SpO2)**
- **PVI Averaging**
- **SpHb Cal**
- **Gas compens.** (CO2 compensation)
- Waveform scale (CO2, O2, and IP)
- Scio anesthetic agent selection
- **Chime** (non-invasive blood pressure)
- **Filter** (invasive pressure)
- **Transport volume**
- **Transport pulse tone**

## Settings not included in a profile

The following settings are not included in a profile and must be configured separately. These settings remain unchanged until they are manually changed again by the user.

Dialog	Setting
<b>Screen setup dialog</b> (Press the <i>Menu</i> function key > <i>Screen setup</i> )	
<b>Screen setup</b>	<b>Autoflip</b>
	<b>Power save</b>
<b>ARR dialog</b> (Touch the heart rate parameter field > <i>Settings</i> > <i>ARR</i> )	
<b>ARR</b>	<b>ARR mode</b>

Dialog	Setting
<b>Service dialogs</b> (Press the <i>Menu</i> function key > <i>System setup</i> > <i>Service</i> > enter password > select dialog)	
<b>Service</b>	<b>ECG baseline</b>
	<b>Data collection</b>

Dialog	Setting
<b>Network setup</b>	<b>Network mode</b>
	<b>Bed label</b>
	<b>Care unit</b>
	<b>Mon. unit</b>
	<b>Hospital</b>
	<b>Mon. unit ID</b>
	<b>IP address</b>
	<b>Net mask</b>
	<b>Default gateway</b>
	<b>Duplicate IP check</b>
	<b>IP check interval [s]</b>
<b>Biomed dialogs</b> (Press the <i>Menu</i> function key > <i>System setup</i> > <i>Biomed</i> > enter password > select dialog)	
<b>Biomed</b>	<b>Language</b>
	<b>French NFC</b>
	<b>Line frequency</b>
	<b>SpO<sub>2</sub> sensor type</b>
<b>Units</b>	<b>Temp</b>
	<b>etCO<sub>2</sub></b>
	<b>Pressures</b>
	<b>ST</b>
	<b>SpHb</b>
	<b>Height</b>
	<b>Weight</b>
<b>Docking station</b>	<b>IP address <sup>1)</sup></b>
	<b>Net mask <sup>1)</sup></b>
	<b>Default gateway <sup>1)</sup></b>
	<b>Bed label <sup>1)</sup></b>
	<b>Care unit <sup>1)</sup></b>
	<b>Mon. unit <sup>1)</sup></b>
	<b>Load profile <sup>1)</sup></b>
	<b>Profile settings <sup>1)</sup></b>

Dialog	Setting
<b>Wireless network</b>	<b>Wireless mode</b>
	<b>SSID</b>
	<b>Channels</b>
	<b>Encryption</b>
	<b>Keep bed label <sup>1)</sup></b>
	<b>Bed label</b>
<b>Alarm setup</b>	<b>Quiet mode <sup>1)</sup></b>
<sup>1)</sup> <b>Note:</b> These M500 configuration settings are not part of the profile and must be configured separately on each M500. They are automatically adopted by the M540 regardless of the profile adoption setting.	

## Saving a profile

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The user can save the current profile settings as a default device profile (see page 315). In a standalone configuration, the profile is saved on the M540 and on the M500. If the profile cannot be saved, the message **Save profile failed** appears.

### CAUTION

If the profile save function fails, the previously stored profile on the M500 is deleted. Therefore, if the message **Save profile failed** appears, save the profile again.

Whenever a patient is discharged, units of measure are changed, or a new patient is admitted, the user-configurable profile is restored automatically. The user can also request to restore the default profile manually at any time (see page 315).

### NOTE

To save a stored profile during a software upgrade, the user can copy the profile onto a USB flash drive by using the import/export feature of an IACS Cockpit. After the upgrade, the user can re-import the profile from the USB flash drive back onto the M540. In addition, the user can use the same feature to export a profile to multiple M540 devices. However, this feature is only possible when the M540 is docked on an M500 in an IACS configuration. For detailed information, refer to the *Instructions for use Infinity Acute Care System – Monitoring applications*.

## Profile behavior in an IACS configuration

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When the M540 is docked in an IACS configuration, the profile of the connected Cockpit overwrites any profile settings of the M540. The M540 itself provides the following profile settings to the Cockpit:

- ECG cable type
- Heart rate source
- **SpO<sub>2</sub>** alarm delay, **SpO<sub>2</sub>** sensitivity mode for Masimo, **SpO<sub>2</sub>** sensitivity mode for Nellcor
- Ambient pressure value
- IP labels
- Patient category (adult, pediatric, neonatal)

After a patient discharge, all patient data are deleted and the default profile of the Cockpit is restored.

## Profile behavior in a standalone configuration

The ability to store the profile settings on the M500 in a standalone configuration allows the M540 to accompany the patient to different care areas of the hospital. By uploading the default profile from the M500 at the new care area, the monitor adapts to its new clinical environment (OR, ICU, CCU, and so on) while retaining the patient data.

How profiles are handled when an M540 is docked, depends on the configuration settings of the M540 and the M500. The **Load profile** setting of the M500 determines if the M540 adopts the M500 profile or if it uses its current profile settings.

The **Profile settings** feature determines if the entire profile is adopted (patient and user settings) or only a subset (monitor settings only).

### Profile adoption

The configuration of the M500 determines whether or not the M540 adopts the profile settings stored on the M500.

The following table illustrates how the profiles are managed under different circumstances.

Action	M500 Load profile settings:	M500 Profile settings:	Result
Docking the M540	<b>Off</b>	(Not used)	The M540 uses its current profile settings.
	<b>Automatic</b>	<b>All</b>	The M540 adopts the profile stored on the M500. See page 78 for a list profile settings.
	<b>Automatic</b>	<b>Monitor</b>	The M540 adopts only the monitor settings which are a subset of the profile stored on the M500. See page 88 for a list of monitor settings.
Discharging the M540	<b>Off</b>	(Not used)	The profile stored on the M500 is restored.
	<b>Automatic</b>	<b>All</b>	The profile stored on the M500 is restored. See page 78 for a list profile settings.
	<b>Automatic</b>	<b>Monitor</b>	The profile stored on the M500 is restored. See page 78 for a list profile settings.

## Different profile configurations

The following happens when an M540 with a newer software version and newer profile settings docks on an M500 with an outdated profile:

- If the **Load profile** settings on the M500 is set to **Automatic**, the M540 adopts the settings stored on the M500.
- Any M540 settings that are not part of the profile setup stored on the M500, remain unchanged on the M540.

The following happens when an M540 with an older software version that does not support new settings docks on an M500 with an updated profile:

- If the **Load profile** settings on the M500 is set to **Automatic**, the M540 adopts the recognized settings stored on the M500.
- Any M500 profile settings that are not supported on the M540 are ignored.

### NOTE

Contact specialized service personnel to make sure the M500 is updated with the latest profile.

## Use-case scenario

The following scenario describes how profiles are handled when the patient is moved to different clinical areas:

Step	Action	Result
1	The M540 is docked to the ICU M500 whose <b>Load profile</b> settings are configured to <b>Automatic</b> and whose <b>Profile settings</b> feature is set to <b>All</b> .	The M540 adopts the profile settings defined for the ICU that are stored on the M500.
2	The M540 is undocked for transport.	The M540 continues to use the adopted ICU profile settings.
3	During transport, the alarm limits are changed on the M540.	The M540 continues to use the adopted ICU profile settings with the modified alarm limits.
4	The M540 is docked to the same M500 in the ICU.	The M540 does not readopt the profile but continues to use the ICU profile settings with the modified alarm limits.
5	The M540 is undocked and accompanies the patient to the OR where it is docked to an M500.	The M540 adopts the profile settings defined for the OR that are stored on the M500.
6	The M540 is undocked from the OR M500.	The M540 continues to use the adopted OR profile settings.
7	The M540 is redocked to the same ICU M500.	The M540 adopts the profile settings defined for the ICU that are stored on the M500.

## Standby mode

---

The user can temporarily interrupt patient monitoring by placing the M540 in standby mode.

Standby mode has the following effect:

- All patient data are removed from the screen
- All monitoring (including acoustic and optical alarm signals) is suppressed
- Active alarms are considered acknowledged by the user
- All recordings are canceled
- The M540 displays **Standby, Touch screen to resume monitoring**

When the M540 is docked in an IACS configuration, selecting standby mode automatically activates standby mode on the Cockpit and vice versa. For more information, refer to *Instructions for use Infinity Acute Care System – Monitoring applications*.

### To place the M540 in standby mode

- Press the **Standby** function key (if available for display, see page 69).

or

- 1 Press the **Menu** function key.
- 2 Touch the **Main** tab, if not already selected.
- 3 Touch **Standby**.

The message **Standby**, appears in the center of the M540 screen.

### To take the M540 out of standby mode

- Touch the screen to resume monitoring.

## Privacy mode

---

Privacy mode is available when the M540 is docked in an IACS or a standalone configuration provided the patient is admitted at the Infinity CentralStation (ICS). In privacy mode, patient monitoring continues but the patient data are removed from the screen and appear only at the ICS BedView.

When the M540 is part of an IACS configuration, selecting privacy mode on the M540 automatically activates privacy mode on the Cockpit and vice versa. Likewise, taking a patient out of privacy mode on the M540 does the same on the Cockpit. Privacy mode is canceled when the connection to the Infinity network is disrupted.

Activating privacy mode has the following effect:

- All patient data are removed from the display of the M540, but continue to display at the ICS in BedView mode.
- The alarm bar is deactivated
- Acoustic alarm signals are only provided at the ICS
- The M540 displays **Privacy, Touch screen to resume monitoring**

### To place the M540 into privacy mode

- Press the **Privacy** function key (if available for display, see page 69).  
or
- 1 Press the **Menu** function key.
- 2 Touch the **Main** tab, if not already selected.
- 3 Touch **Privacy mode**.

The message **Privacy, Touch screen to resume monitoring** appears in the center of the M540 screen.

### To take the M540 out of privacy mode

- Touch the screen to resume monitoring.

## Recordings/reports

---

The following recordings and reports can be requested from an M540.

### Timed, continuous, and stored recordings

The **Record** function key located on the front of the M540 (see page 69) executes different commands:

- In an IACS configuration – pressing the **Record** function key notifies the Cockpit to start/stop a timed recording on the assigned network recorder.  
  
Press and hold the same function key for at least two seconds to start a continuous recording.
- On wireless transport or in standalone mode – pressing the **Record** function key stores an event which can be viewed in the **Event recall** dialog (see "*Event recall*" on page 125).

#### NOTE

In standalone mode, the M540 does not support timed or continuous recordings.

## Rest ECG reports

A diagnostic 12-lead Rest ECG report can only be requested from the M540 when the patient is also admitted at the ICS and the 12-lead locked option is unlocked on the M540 and on the ICS. If either of those two pre-requisites are not met, the function key is not available for requesting this report.

### NOTE

Rest ECG report is only available for adult and pediatric patients.

To obtain an optimal automatic diagnostic interpretation of an Rest ECG report, make sure the following settings are configured appropriately for the patient before the report is generated:

- Birth date – in the **Patient setup** dialog of the M540 (see page 101)

- Gender and Race – in the **Rest ECG setup** dialog of the M540 (see page 162)
- Height, weight – these settings must be entered at the Cockpit when the M540 is docked in an IACS configuration. If the M540 is in standalone mode, the same settings must be entered at the ICS.

### To generate a Rest ECG report

- Press the **Rest ECG report** function key (if available for display, see page 69).  
or
- 1 Press the **Menu** function key.
- 2 Touch the **Main** tab, if not already selected.
- 3 Touch the **Rest ECG report** button.

## User levels

---

Some monitoring functions are designed for users with specific training. Access to these functions is controlled through password-protected menus. Options on protected menus are available only to users who have been given the password for those menus.

Based on their need to access specific password-protected menus, users are assigned to user levels. Users are given the password for their user level, and they can then access menus appropriate for their level.

There are four user levels:

- **Primary users.** Access to primary clinical features, such as waveforms, parameters, alarms, and settings that are required to monitor a patient, does not require a password. This allows the Primary user to focus on patient treatment without needing to enter a password.
- **Clinical users.** Access to advanced clinical features requires a password. Once the password is authenticated, users have access to password-protected configuration pages, in addition to all features available to Primary users.
- **Biomedical users,** such as Biomedical engineers. Access to biomedical functionality requires a password. Once the password is authenticated, users have access to biomedical menus in addition to all features available to Primary and Clinical users. This user level is responsible for routine inspection and maintenance of clinical devices. Biomedical tasks can be performed without product-specific skills or tools.

- **Service users** (DrägerService or specialized service personnel). Access to service functionality requires a password. This user level is responsible for mechanical installation, software upload, certificate upload, configuration of technical system settings, and basic and extended inspection, maintenance and repair. Service users have permissions to select the network security mode and set expiration dates for passwords.

To request that a user's access be changed to a different user level, contact biomedical or specialized service personnel.

## Security passwords

Access to password-protected menus requires password authentication.

All users in each user level share the same password, which consists of eight numerical characters.

When attempting to access a password-protected menu, if the user enters an incorrect password six times within two minutes the system will prohibit the user from accessing password-protected menus for two minutes. Users with a higher user level password can still access password-protected menus.

While viewing a password-protected menu, if the user is inactive for more than two minutes the system stops displaying the password-protected menu.

When an M540 is docked to a Cockpit, the M540 adopts the Cockpit user level passwords and password expiration settings.

If any user level password has not been set, a message displays when the Cockpit or M540 starts. Access is blocked for that user level until a password has been set.

## Changing passwords

Passwords are initially set by the Service user during system initialization. Biomedical users can change the Biomedical or Clinician passwords after successfully entering the current password. Once changed, the new password must be used by all users in that user level.

Passwords can also be changed by docking to a Cockpit. The M540 will adopt the Cockpit's passwords and password settings.

Remotely connected Service users can reset the Clinical, Biomed, and Service user passwords.

### To change a password

- 1 Touch the **Menu** function key.
  - 2 Touch the **System setup** tab.
  - 3 Touch **Biomed**.
  - 4 Enter the Biomed password and touch **OK**.
  - 5 Touch **Settings 2**.
  - 6 Touch **Change clinical password** or **Change biomedical password**.
  - 7 Enter the new password and press **Enter**.  
Passwords must consist of eight non-sequential numerical characters that are not all the same. The new password cannot be the same as the previous password.
- If the new password does not meet the password complexity requirements, the system displays the message that the password is incorrect and the existing password is not changed.
- 8 If the new password meets the password complexity requirements, a confirmation screen displays. Re-enter the new password and press **Enter**.
  - 9 Touch **OK**.

### **Password expiration**

Passwords can be configured with or without an expiration date.

When a user enters a password, if the password will expire within two weeks a message displays informing the user of the expiration date. Once the expiration date passes, that password is no longer valid. A message displays advising the user to contact biomedical or specialized service personnel.

Password expiration dates, if any, are displayed on the **System setup > System information > Security info** tab. They can be changed by specialized service personnel only.

# DRAFT

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## Getting started

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## Overview of monitoring a patient

---

This chapter describes the necessary steps to start monitoring a patient on the M540.

Specifically, this section describes how to:

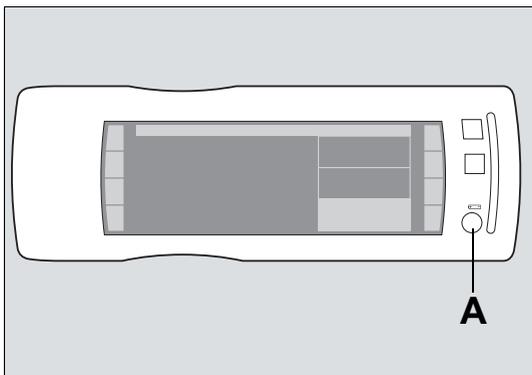
- Turn the M540 on/off
- Admit/discharge a patient on the M540
- Change the patient category

## Turning the M540 on/off

---

### To turn the M540 on

- Press the on/off switch (A) of the M540.



The M540 emits a high-pitched tone followed by two power-up tones, performs a self-test, and displays the **New patient?** prompt. Touch **Discharge** to delete the patient data or **Cancel** to continue monitoring the patient and append the new data to the previous data set. The main screen appears.

### To turn the M540 off

- 1 Press and hold the on/off switch  (A). A dialog appears and asks if you want to shut down the monitor.
- 2 Touch **Shutdown**. The M540 emits a high-pitched tone and shuts down.

## Admitting a patient

You can admit a patient at the M540 manually by entering the demographic data in the **Patient setup** tab.

You can also admit a patient over the network by pulling the data from an HL7/ADT interface. This is either possible if the M540 is part of an IACS configuration that is connected to the Infinity network, the patient data can be retrieved over the network and transferred to the M540.

### WARNING

**Monitors in a care area may seem identical but may use different default alarm settings because of different profile assignments. After admitting a patient, always verify that the set alarm limits are appropriate for the patient.**

### To admit the patient manually

#### NOTE

Avoid using dashes in patient identification numbers, as the monitor could cut off part of the number.

- 1 Press the **Menu** function key.
- 2 Touch the **Patient setup** tab.
- 3 Touch **Patient category** and then touch the appropriate category (**Adult**, **Pediatric**, **Neonate**). The message **Changing category will change alarm settings and algorithmic processing** appears. For more details on the categories, see page 103.
- 4 Touch **OK**. The **Patient setup** dialog closes.
- 5 Press the **Menu** function key.
- 6 Touch the **Patient setup** tab.
- 7 Touch **Name** and use the keyboard to enter the name (up to 25 characters)
- 8 Touch **Confirm**.

- 9 Touch **ID** and use the keyboard to enter the ID number (up to 12 characters) and then touch **Confirm**.

- 10 Touch **Admit date**, then touch each of the following: **Day**, **Month**, and **Year** to enter the appropriate date.

- 11 Touch **OK** to confirm the data entry.

Use the arrows to scroll up or down to change the data. To scroll faster through the data (for example, the year), touch and hold the arrow.

- 12 Touch **Birth date**, then touch each of the following: **Day**, **Month**, and **Year** to enter the appropriate date.

Use the arrows to scroll up or down to change the data. To scroll faster through the data (for example, the year), touch and hold the arrow.

- 13 Touch **OK** to confirm the data entry.

- 14 Touch **Physician** and use the keyboard for entering the name of the physician (up to 12 characters).

- 15 Touch **Confirm** to confirm the data entry.

#### NOTE

The height and weight of the patient must be entered at the Cockpit when the M540 is docked in an IACS configuration. When the M540 is on wireless transport or in standalone mode, the height and weight can be entered at the ICS.

## Admitting a patient using the hospital information system

You can populate the **Patient setup** page automatically, by pulling the demographic data of a patient from the network. The prerequisite for this network data transfer is the Infinity gateway with an

interface to the hospital Admit, Discharge, Transfer (ADT) system. The Hospital Information System (HIS) searches the database for the demographic data of the patient by using the patient ID.

## Discharging a patient

---

A patient discharge has the following effect at the M540:

- All demographic data are removed from the screen
- Any active recordings are canceled at the Cockpit if the M540 is docked in an IACS configuration
- Factory or user default limit settings are restored
- The message **Discharged, Touch screen to resume monitoring** appears

### To discharge a patient

Press the **Discharge** function key (if available for display, see page 69).

or

- 1 Press the **Menu** function key.
- 2 Touch the **Main** tab.
- 3 Touch **Discharge**. The message **Caution discharge will delete patient data** appears.
- 4 Touch **Discharge**.

#### WARNING

**Risk: Mixing of patient data**

**Before monitoring a patient, always press the function key *Discharge* to make sure that any previous patient data does not get appended to the new patient data.**

#### WARNING

**Pressing the *Discharge* function key unintentionally could lead to loss of data.**

#### NOTE

When docking an M540 to a Cockpit, the **Discharge** function key on both the M540 and on the Cockpit is temporarily unavailable until the connection to the Cockpit is complete.

## Patient categories

---

Each patient category has a specific profile associated with it. Profiles are a set of patient and user settings that have been pre-configured by the factory or the hospital. The M540 supports the following patient categories:

Patient category	Typical age range	Weight	Height
Adult	12 to 140 years	0.1 to 350.0 kg (0.1 to 772.0 lb)	10 to 250 cm (5 to 100 in)
Pediatric	0 to 16 years	0.1 to 350.0 kg (0.1 to 772.0 lb)	10 to 250 cm (5 to 100 in)
Neonate	0 to 2 years	1 to 10,000 g (0 oz to 351 oz)	10 to 250 cm (5 to 100 in)

### Selecting a new patient category

After selecting the patient category, the new patient category label appears in the header bar (see page 70).

A patient category change does not affect the following settings: the patient and physician names, patient ID, birth date, admit date, height, and weight.

### To select a new patient category

- 1 Press the **Menu** function key.
- 2 Touch the **Patient setup** tab.
- 3 Touch **Patient category** and then select the appropriate category (**Adult**, **Pediatric**, **Neonate**). The message **Changing category will change alarm settings and algorithmic processing** appears.
- 4 Touch **OK**.

# DRAFT

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# DRAFT

Sections of this IFU have been removed for technical purposes.  
The following sections and pages have been removed.

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➤ ECG, arrhythmia, and ST segment.....	145 - 180
➤ Impedance respiration (RRi).....	181 - 190
➤ SpO2 and Pulse CO-Ox monitoring with Masimo SET MCable.....	191 - 206
➤ SpO2 abd pulse rate monitoring with Nellcor OxiMax MCable.....	207 - 214
➤ Temperature.....	215 - 222
➤ Non-invasive blood pressure (NIBP).....	223 - 234
➤ Invasive pressures (IP).....	235 - 250
➤ Cardiac output.....	251 - 254
➤ Mainstream CO2 monitoring.....	255 - 266
➤ Microstream CO2 monitoring.....	267 - 280
➤ Scio Monitoring.....	281 - 300

The entire IFU is available from Draeger Medical Systems Inc.

## System configuration

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## Overview

---

This chapter describes the **Menu** and **Alarm settings** dialogs. The **Menu** dialog consists of several dialogs for configuring the M540. Some of these dialogs are password-protected and are only accessible to authorized personnel.

### Service tab

The Service tab is password-protected and includes features such as factory defaults, service and test modes. It also includes remote control settings which enables the M540 to be controlled by the Infinity CentralStation. For more information about service-related features, refer to the repair instructions.

The **Menu** dialog consists of the following dialogs:

- **Main** (see page 303)
- **Patient setup** (see page 305)
- **System setup** (see page 306)
  - **Biomed** button (see page 314)
  - **Service** tab
  - **System information** tab (see page 312)
  - **Alarm setup** tab (see page 321)
- **Screen setup** (see page 320)
  - **Settings** tab (see page 320)
  - **Screen views** tab (see page 320)
  - **Function keys** tab (see page 320)

## Configuring general settings

---

This section describes the setup functions of the **Main** dialog.

### To access the **Main** dialog

- 1 Press the **Menu** function key.
- 2 Touch the **Main** tab.

<b>Main dialog</b>		
<b>Selection</b>	<b>Available settings</b>	<b>Description</b>
<b>All alarms pause</b> or <b>All alarms off</b>	None	When the <b>All alarms pause</b> button is selected, all alarm functions are temporarily suppressed for a selected time. The alarm function is automatically activated when the alarm pause timer times out.  When the <b>All alarms off</b> button is selected, all alarm functions are suppressed until you select the button again to activate the alarm function.  To configure this button, see page 303.
<b>Show all leads</b>	None	Displays waveforms for all ECG leads.
<b>Label IP</b>	Available channels: <b>Pod 1A label, Pod 1B label, Pod 1C label, Pod 1D label, Pod 2A label, Pod 2B label, Pod 2C label, Pod 2D label</b>  Pressure labels: <b>GP2, ART, LV, LA, PA, CVP, ICP, RA, RV, AXL, BRA, FEM, RAD, AOR, UAP, ABD, BDP, ESO, FEMV, UVP, GPM</b>  Generic labels: <b>GP1 through GP8</b>	Assigns a label name to the IP labels.

**Main dialog**

<b>Selection</b>	<b>Available settings</b>	<b>Description</b>
<b>Rest ECG report</b>	None	<p>Prints a 12-lead Rest ECG report for an adult or pediatric patient during 10-wire, 12-lead monitoring. You request 12-lead Rest ECG report printing either from the M540 in wireless mode or when docked in an M500 and in standalone mode.</p> <p>When the M540 is docked in an M500 which is connected to the Infinity network via a Cockpit, you must request printing the 12-lead Rest ECG report from that Cockpit.</p> <p>When access to the Infinity network is interrupted or unavailable, printing 12-lead Rest ECG reports is disabled.</p> <p>The report can be configured to include the following demographic data (refer to page 305):</p> <ul style="list-style-type: none"> <li>– <b>Gender</b></li> <li>– <b>Race</b></li> </ul> <p>If the <b>ECG filter</b> is set to <b>ESU</b>, the report cannot be generated.</p>
<b>Standby</b>	None	Enters standby mode.
<b>Privacy mode</b>	None	<p>Enters privacy mode. This mode is only available when the M540 is docked in an IACS configuration or when it is on wireless transport and the patient is admitted at the ICS.</p> <p>If the patient is not admitted at the ICS, the button is displayed but it is not activated. For more information, see page 93.</p>
<b>Discharge</b>	<ul style="list-style-type: none"> <li>– <b>Cancel</b></li> <li>– <b>Discharge</b></li> </ul>	Discharges a patient and deletes all the patient's data.
<b>M540 Audio</b>	<ul style="list-style-type: none"> <li>– <b>On</b></li> <li>– <b>Off</b> (default)</li> </ul>	<p>When the M540 is initially docked to a Cockpit, the <b>M540 Audio</b> setting is <b>Off</b> and the speaker off symbol displays. This setting can be turned <b>On</b> and if needed, the alarm volume and pulse tone volume can also be adjusted.</p> <p>When the M540 is on transport, in wireless mode or in standalone configurations, this setting is always activated.</p>

## Configuring the patient settings

---

This section describes the setup functions of the **Patient setup** dialog. The dialog configures the M540 for the patient.

### To access the **Patient setup** dialog

- 1 Press the **Menu** function key.
- 2 Touch the **Patient setup** tab.

<b>Patient setup dialog</b>		
<b>Selection</b>	<b>Available settings</b>	<b>Description</b>
<b>Demographic Data</b>		
<b>Patient category</b>	<ul style="list-style-type: none"> <li>– <b>Adult</b></li> <li>– <b>Pediatric</b></li> <li>– <b>Neonate</b></li> </ul>	Selects the type of patient.
<b>Name</b>	Keyboard	Allows you to enter the name of the patient.
<b>ID</b>	Keyboard	Allows you to enter the ID number of the patient.
<b>Admit date</b>	<ul style="list-style-type: none"> <li>– <b>Day</b></li> <li>– <b>Month</b></li> <li>– <b>Year</b></li> </ul>	Allows you to enter the admit date of the patient.
<b>Birth date</b>	<ul style="list-style-type: none"> <li>– <b>Day</b></li> <li>– <b>Month</b></li> <li>– <b>Year</b></li> </ul>	Allows you to enter the birth date of the patient.
<b>Physician</b>	Keyboard	Allows you to enter the name of the physician of the patient.
<b>Race</b>	<ul style="list-style-type: none"> <li>– <b>Unknown</b></li> <li>– <b>Caucasian</b></li> <li>– <b>Asian</b></li> <li>– <b>African</b></li> <li>– <b>Other</b></li> </ul>	Allows you to enter a race for the patient.
<b>Gender</b>	<ul style="list-style-type: none"> <li>– <b>Unknown</b></li> <li>– <b>Male</b></li> <li>– <b>Female</b></li> </ul>	Allows you to enter a gender for the patient.

## Configuring the system settings

---

This section describes the setup functions of the **System setup** dialog from where you can access biomed and service settings and system information. In addition the **Alarm setup** tab provides access to various alarm settings.

### Accessing the system information

The **System setup** dialog provides access to password-protected dialog and the current system information.

**WARNING**

Do not service the M540 while monitoring a patient.

### To access the system information

- 1 Press the **Menu** function key.
- 2 Touch the **System setup** tab.
- 3 Select one of the following actions:
  - Touch the **Biomed** button to access the **Biomed** dialog (see page 314).
  - or
  - Touch the **Service** button to access the **Service** dialog (refer to the service instructions).
  - or
  - Touch the **System information** button to access the **System information** dialog (see page 312).
  - or
  - Touch the **Alarm setup** button to access the **Alarm setup** tab (see page 307).
- 4 Enter the password and touch **OK**.

## Accessing the Alarm setup dialog

The **Alarm setup** dialog provides access to password-protected alarm settings.

**WARNING**

**Risk of patient harm**

**Unauthorized changes to alarm configuration could result in patient harm.**

**Ensure that only authorized users have access to alarm setup pages.**

To access the **Alarm setup** dialog

- 1 Press the **Menu** function key.
- 2 Touch the **System setup** tab.
- 3 Touch the **Alarm setup** or the **Volume/ Tones** tab.
- 4 Enter the required password and touch **OK**.

Refer to the following table for available selections:

Selection	Available settings	Description
<b>Alarm setup tab</b> (password required)		
<b>All alarms paused</b> <sup>1)</sup> or <b>All alarms off</b>	1, 2 (default), 3, 4, 5 min	Selecting one of these settings changes the alarm button on the <b>Main</b> dialog to <b>All alarms paused</b> .  When selected: <ul style="list-style-type: none"> <li>– All alarm functions are temporarily suppressed for the selected time.</li> <li>– The alarm function is automatically activated when the alarm pause timer times out.</li> <li>– The message <b>All alarms paused</b> with the remaining time and the symbol  appears on the M540.</li> </ul>
	<b>No timeout</b>	Selecting this setting changes the alarm button on the <b>Main</b> dialog to <b>All alarms off</b> .  When selected: <ul style="list-style-type: none"> <li>– All alarm functions are suppressed until you select the button again to activate the alarm function again.</li> <li>– The message <b>All alarms off</b> and the symbol  appears on the M540.</li> </ul>
	<b>Disable</b>	Selecting this setting deactivates (grays out) the <b>All alarms off</b> button (depending on its previous configuration) on the <b>Main</b> dialog (see page 303). You cannot temporarily or permanently deactivate alarm monitoring.

<sup>1)</sup> This setting is a user default that is identical for all patient categories and is also part of the profile.

Selection	Available settings	Description
<b>Alarm validation</b> <sup>1)</sup>	<ul style="list-style-type: none"> <li>– <b>On</b></li> <li>– <b>Off</b> (default)</li> </ul>	When activated, alarm conditions are verified for a certain time before triggering acoustic and optical alarm signals (see "Activating or deactivating alarm validation" on page 108). This reduces nuisance alarms.
<b>SpO2 alarm delay</b> <sup>1)</sup>	<b>On</b> (default)	<p>An SpO2 lower alarm limit violation must persist for 10 seconds before triggering acoustic and optical alarm signals.</p> <p>This function is not possible if the Nellcor <b>SatSeconds</b> feature is set to any value other than <b>Off</b> (see page 214).</p> <p>The alarm validation feature must be activated.</p>
	<b>Off</b>	An SpO2 lower alarm limit violation triggers an alarm immediately.
<b>Alarm group</b> <sup>1)</sup>	0 (default) to 255	You can configure the M540 and other monitors as members of an alarm group. This feature allows each member of an alarm group to view each other's alarm conditions remotely.
<b>NIBP/SpO2 interlock</b> <sup>1)</sup>	<b>On</b>	The SpO2, Desaturation, PLS and Rainbow parameters, and the Nellcor "check sensor" alarm when configured as non-latching, are deactivated during an active non-invasive blood pressure and PLS CO-Ox measurements (for more details, see "NIBP/SpO2 interlock alarm feature" on page 113).
	<b>Off</b> (default)	The SpO2, Desaturation, PLS and Rainbow parameters, and the Nellcor "check sensor" alarm when configured as non-latching, are activated during non-invasive blood pressure and PLS CO-Ox measurements.

<sup>1)</sup> This setting is a user default that is identical for all patient categories and is also part of the profile.

Selection	Available settings	Description
<b>ASY/VF alarms</b> <sup>1)</sup>	<b>Follow HR</b>	ASY and VF alarm settings follow the setting of the heart rate alarms.  <b>WARNING: If you select <i>Follow HR</i>, ASY, and VF alarms are not reported if the heart rate and arrhythmia alarm functions are turned off.</b>
	<b>Always on</b> (default)	ASY and VF alarm functions are always activated.
<b>Pacer mode</b> <sup>2)</sup>	– <b>Basic</b> (default)	Fusion mode is not selectable.
	– <b>Advanced</b>	Fusion mode is selectable in the <b>ECG</b> setup page (see page 166).
<b>Alarm bar</b> <sup>1)</sup>	– <b>On</b> (default)	Determines whether the alarm bar flashes during an alarm.
	– <b>Off</b>	
<b>Battery alarm</b>	See "Configuring the battery alarm" on page 324.	
<b>Volume/ Tones tab</b> (clinical password required)		
<b>Minimum alarm vol.</b>	<ul style="list-style-type: none"> <li>– <b>Off</b> (not available if connection to the ICS is unavailable)</li> <li>– 5, 10, 20, 30, 40, 50 (default), 60, 70, 80, 90, 100 %</li> </ul>	Determines which alarm volume settings are available under the <b>Alarm volume</b> button. This setting does not affect the volume of the attention or the pulse tone.
<b>Transport volume</b>	50 % (default), 60 %, 70 %, 80 %, 90 %, 100 %	Determines the alarm volume of the M540 while it is on patient transport.
<b>Transport pulse tone</b>	<ul style="list-style-type: none"> <li>– <b>Off</b> (default)</li> <li>– 5, 10, 20, 30, 40, 50, 60, 70, 80, 90, 100 %</li> </ul>	Determines the volume of the heart rate and the SpO2 pulse tone while the M540 is on patient transport.
<b>Alarm pattern</b>	<ul style="list-style-type: none"> <li>– <b>IEC slow</b></li> <li>– <b>IEC fast</b> (default)</li> <li>– <b>Infinity</b></li> <li>– <b>Hybrid</b></li> </ul>	Determines the type of alarm tone pattern in use (for more information, see "Acoustic alarm signals" on page 110).
<p><sup>1)</sup> This setting is a user default that is identical for all patient categories and is also part of the profile.</p> <p><sup>2)</sup> This setting is a patient default which may be unique for each patient category; it is part of the profile.</p>		

Selection	Available settings	Description
<b>Quiet mode</b>	<ul style="list-style-type: none"> <li>– <b>On</b></li> <li>– <b>Off</b> (default)</li> </ul>	<ul style="list-style-type: none"> <li>– <b>On</b> – Only alarm conditions of higher priority override an active audio pause. The appropriate parameter field flashes. Alarm conditions of equal or lower alarm priority will not be reported with an alarm tone.</li> <li>– <b>Off</b> – Any new alarm condition, regardless of its alarm priority, overrides an already active audio pause state at the Cockpit and at the ICS if the patient is admitted there. All optical and acoustic signals are reported fully for any new alarm condition.</li> </ul> <p>For detailed information how quiet mode affects the audio pause behavior, see "Quiet mode" on page 118.</p>
<b>Reminder: audio off</b>	<ul style="list-style-type: none"> <li>– <b>On</b> (default)</li> <li>– <b>Off</b></li> </ul>	<p>Sounds an alarm tone every 30 seconds at the M540 to remind you that the alarm tone is deactivated during an active alarm condition. This alarm tone is suppressed if you initiate an audio pause.</p> <p>When the M540 is set to OR alarms, the volume of the alarm tone corresponds to the <b>Alarm volume</b> setting of 10 %. When OR alarms are not activated, the volume equals to 50 %.</p> <ul style="list-style-type: none"> <li>– <b>On</b> – a truncated acoustic alarm signal sounds every 30 seconds for an alarm condition of medium priority or high priority. Low-priority alarms tones are not truncated.</li> </ul> <p>During multiple alarm conditions, the reminder tone adjusts itself to always report the alarm condition with the highest alarm priority.</p> <ul style="list-style-type: none"> <li>– <b>Off</b> – No alarm tone sounds when the alarm volume is deactivated and an alarm occurs.</li> </ul> <p><b>Reminder: audio off</b> is not supported on the ICS or any other such device in remote view mode.</p>

## Accessing the configurable SpO<sub>2</sub> alarm features

The **Alarm setup** dialog provides access to password-protected SpO<sub>2</sub> alarm settings. Depending on the configuration of the M540, one of the following two tabs appears.

- The **SpO<sub>2</sub> sensor off** tab when the M540 is configured for Masimo.
- The **SpO<sub>2</sub> check sensor** tab when the M540 is configured for Nellcor.

### To access the Alarm setup dialog

- 1 Press the **Menu** function key.
  - 2 Touch the **System setup** tab.
  - 3 Touch the **Alarm setup** tab.
  - 4 Enter the required password and touch **OK**.
  - 5 Touch the **SpO<sub>2</sub> sensor off** tab (Masimo).
- or
- 6 Touch the **SpO<sub>2</sub> check sensor** tab (Nellcor)

Selection	Available settings	Description
<b>Alarm</b>	<ul style="list-style-type: none"> <li>– <b>High</b></li> <li>– <b>Medium</b></li> </ul>	<p>Assigns an alarm priority to the sensor alarm or deactivates the sensor alarm. The selected alarm priority affects how the alarm event is reported.</p> <p>The event is treated as a persistent alarm. The message appears in the header bar of the M540 until the condition disappears. The acoustic alarm signal can be audio paused but will resume if the condition persists beyond the two minute audio pause time.</p>
	<b>Low</b> (default)	<p>The event is treated as a one-shot alarm. The message appears briefly in the header bar. Once you acknowledge the alarm by pressing the yellow audio pause key, the message disappears and the acoustic alarm signal stops.</p>
	 (off)	<p>No visual or acoustic alarm signals are triggered.</p>
<b>Archive</b>	<b>Off</b> (default)	<p>Determines what happens when the corresponding alarm occurs:</p> <ul style="list-style-type: none"> <li>– No event is stored and no recording is generated.</li> </ul>
	<b>Store</b>	<ul style="list-style-type: none"> <li>– Stores the event for later review.</li> </ul>
	<b>Record</b>	<ul style="list-style-type: none"> <li>– Generates a timed recording (except for standalone mode).</li> </ul>
	<b>Str/Rec</b>	<p>Generates a timed recording and stores the event.</p>

## Viewing the system information

---

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

### 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**.

#### NOTE

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

Dialog	Available information
<b>System information</b>	
<b>Info 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>SpO2 sensor type</b>
	<b>Wireless bootloader</b>
	<b>Wireless Firmware</b>
<b>Info 2</b>	<b>Boot loader</b>
	<b>NTIM revision</b>
	<b>OBM revision</b>
<b>Security info</b>	<b>Security mode</b>
	<b>TLS PSK expiry</b>
	<b>Multicast PSK expiry</b>
	<b>Clinical pwd expiry</b>
	<b>Biomed pwd expiry</b>
	<b>Service pwd expiry</b>
	<b>SSH pin</b>

<b>Dialog</b>	<b>Available information</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. **5** Touch the **Settings 1** or the **Settings 2** button.

### 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**.

<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>Biomed dialogs</b>		
<b>Biomed &gt; Settings 1 dialog</b>		
<b>Selection</b>	<b>Available settings</b>	<b>Description</b>
<b>Restore Profile</b>	<ul style="list-style-type: none"> <li>– <b>Cancel</b></li> <li>– <b>OK</b></li> </ul>	<p>Restores the saved profile settings and up to five available views on the M540.</p> <p>In standalone mode, if docked on an M500 that has a saved profile, selecting this button will restore the M500 default profile.</p>
<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>SpO2 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>	<p>Use the keypad to enter the new password (up to eight non-sequential numerical characters that are not all the same. The new password cannot be the same as the previous password.)</p> <p><b>CAUTION: Be sure to record the new password because it cannot be retrieved once it is lost. For further assistance, contact specialized service personnel.</b></p>	<p>Configures a new password for access to password-protected menus on the M540.</p> <p>When an M540 docks to a Cockpit, the Cockpit passwords override the M540 passwords.</p>
<b>Change biomedical password</b>		

## Configuring units of measure

### 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 **Units** tab.

Changing the units of measure discharges the patient.

<b>Biomed &gt; Units dialogs</b>		
<b>Selection</b>	<b>Available settings</b>	<b>Description</b>
<b>Temp</b>	<ul style="list-style-type: none"> <li>– °C (Celsius) default</li> <li>– °F (Fahrenheit)</li> </ul>	Assigns the selected unit of measurement to the parameter. Whenever you change a unit of measurement, the M540 discharges the patient.
<b>CO<sub>2</sub></b>	<ul style="list-style-type: none"> <li>– <b>mmHg</b> (default)</li> <li>– <b>kPa</b></li> <li>– %</li> </ul>	
<b>Pressures</b>	<ul style="list-style-type: none"> <li>– <b>mmHg</b> (default)</li> <li>– <b>kPa</b></li> </ul>	
<b>ST</b>	<ul style="list-style-type: none"> <li>– <b>mm</b> (default)</li> <li>– <b>mV</b></li> </ul>	
<b>SpHb (SpHbv)</b>	<ul style="list-style-type: none"> <li>– <b>g/dL</b> (default)</li> <li>– <b>mmol/L</b></li> </ul>	
<b>Height</b>	<ul style="list-style-type: none"> <li>– <b>cm</b> (default)</li> <li>– <b>in</b></li> </ul>	
<b>Weight</b>	<ul style="list-style-type: none"> <li>– <b>lb/oz</b></li> <li>– <b>kg/g</b> (default)</li> </ul>	
<b>Agent</b>	<ul style="list-style-type: none"> <li>– <b>kPa</b></li> <li>– %</li> </ul>	

## Configuring the M500 setup

The following setup features are intended for a wired M500. These settings are stored on the M500 and are adopted by an M540 when it is docked.

### NOTE

When the wireless option is activated on the M540 or the M540 is used in an IACS configuration, the **Docking station** tab is grayed out and no configuration is possible.

### 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 **Docking station** tab.
- 6 Touch the following tabs: **Network setup**, **Name service**, **Other**.

Selection	Available settings	Description
<b>Network setup</b> dialog		
<b>IP address</b>	User selectable; the default setting is: 0.0.0.0	Allows you to configure the IP address on the numeric keypad. Once you undock the M540 and it goes wireless, the selection is grayed out.
<b>Net mask</b>	User selectable; the default setting is: 255.255.0.0 NOTE: The Net mask cannot be 255.255.255.128.	Allows you to configure the subnet mask on the numeric keypad. Once you undock the M540 and it goes wireless, the selection is grayed out.
<b>Default gateway</b>	User selectable; the default setting is: 0.0.0.0	Allows you to configure the default gateway on the numeric keypad. Once you undock the M540 and it goes wireless, the selection is grayed out.
<b>Name service</b> dialog		
<b>Bed label</b>	User selectable; the default setting is blank	Allows you to enter the bed label on the alphanumeric keypad (limited to 7 characters).
<b>Mon. unit</b>	User selectable; the default setting is blank	Allows you to enter the monitoring unit on the alphanumeric keypad (limited to 7 characters).
<b>Care unit</b>	User selectable; the default setting is blank	Allows you to enter the care unit on the alphanumeric keypad (limited to 7 characters).
<b>Hospital</b>	User selectable; the default setting is blank	Allows you to enter the name of the hospital on the alphanumeric keypad (limited to 7 characters).
<b>Mon. unit ID</b>	User selectable from 1 – 255; the default setting is: 1	Allows you to enter the monitoring unit ID on the alphanumeric keypad (limited to 7 characters).

Selection	Available settings	Description
<b>Other dialog</b>		
<b>Load profile</b> <b>NOTE:</b> The <b>Load profile</b> button appears grayed out until at least one profile has been saved.	<b>Off</b> (default)	After docking, the M540 does not adopt the profile of the M500 but uses its own settings instead.
	<b>Automatic</b>	After docking, the M540 adopts the profile of the M500.
<b>Profile settings</b>	<b>All</b>	Patient and monitor settings are downloaded to the M540.
	<b>Monitor</b> (default)	Only monitor settings are downloaded to the M540.

## Configuring the wireless network setup

### 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 **Wireless network** tab.

### NOTE

When the wireless option is not installed, the **Wireless network** tab is grayed out and the information is not available.

<b>Biomed &gt; Wireless network dialogs</b>		
Selection	Available settings	Description
<b>Wireless mode</b>	– <b>On</b> – <b>Off</b> (default)	Activates/deactivates the wireless option.
<b>SSID</b>	Keyboard for entering a passphrase with alphanumeric values	This selection is only available when you choose <b>WPA2-PSK</b> for the <b>Encryption</b> menu selection.
<b>Channels</b>	1 to 13	The available channel selections are determined by the regulatory domain.
<b>Encryption</b>	– <b>None</b> (default) – <b>WPA2-PSK</b>	Activates/deactivates wireless encryption. If <b>None</b> is selected, the <b>SSID</b> setting changes to <b>SSID</b> .

<b>Keep bed label</b>	<b>Yes</b> (default)	<ul style="list-style-type: none"> <li>– In an IACS configuration: The M540 retains the bed label of the Cockpit when it undocks. Any changes to the M540 bed label do not have any effect. If the patient is also monitored by the ICS, the data continue to display in the same viewport when the M540 is undocked.</li> <li>– In standalone mode: The M540 retains the bed label configured on the M500.</li> </ul>
	<b>No</b>	<p>The M540 retains the bed label configured in the <b>Wireless network</b> dialog when it is undocked. If the wireless bed label is changed while wireless, the bed label is automatically updated at the M540 and over the network.</p> <p>If the patient is monitored by the ICS, the data are removed from the viewport. A message appears in the viewport that the M540 is disconnected. An offline message appears if the wireless bed label has not been configured.</p>
<b>Bed label</b>	User selectable; the default setting is blank	<p>Allows you to enter the bed label on the alphanumeric keypad (limited to 7 characters).</p> <p>The <b>Keep bed label</b> setting determines what happens to the bed label – see above for detailed information.</p>

## Configuring the screen layout

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This section describes the setup functions of the **Screen setup** dialog.

### To access the **Screen setup** dialog

- 1 Press the **Menu** function key.
- 2 Touch the **Screen setup** tab.

<b>Screen setup dialog</b>		
<b>Selection</b>	<b>Available settings</b>	<b>Description</b>
<b>Settings dialog</b>		
<b>Touch calib.</b>	<b>None</b>	Calibrates the touchscreen.
<b>Flip screen</b>	<b>None</b>	Flips the screen 180 degrees.
<b>Autoflip</b>	<ul style="list-style-type: none"> <li>– <b>Yes</b> (default)</li> <li>– <b>No</b></li> </ul>	Activates/deactivates automatic flipping of the screen.
<b>Power save</b>	<b>Off</b> (default), 1, 2, 3, 4, 5 min	Selects the amount of time in minutes until the M540 goes into power save mode (see page 76).
<b>Screen views dialog</b>		
<b>View 1</b>	– <b>1wav 4pbox</b>	Selects a predefined view or deactivates the view by selecting <b>Off</b> (except View 1).
<b>View 2</b>	– <b>1wav 7pbox</b>	
<b>View 3</b>	– <b>2wav 5pbox</b>	
<b>View 4</b>	– <b>3wav 3pbox</b>	
<b>View 5</b>	<ul style="list-style-type: none"> <li>– <b>1wav 3pbox</b></li> <li>– <b>Off</b></li> </ul>	
<b>Function keys dialog</b>		
<b>Setup key 1</b>	<b>Standby, Code, Discharge, Record, Privacy, Mark, Patient, Rest ECG report</b>	Assigns a function to the user configurable function keys.
<b>Setup key 2</b>		
<b>Setup key 3</b>		
<b>Setup key 4</b>		

## Configuring alarm settings

This section describes the setup functions of the **Alarms** dialog.

### WARNING

Auditory alarm signal sound pressure levels that are less than ambient levels can impede operator recognition of alarm conditions.

To access the **Alarm settings** dialog

- 1 Press the **Alarms** function key.
- 2 Touch the **Alarm settings** tab.

<b>Alarms dialog</b>		
<b>Selection</b>	<b>Available settings</b>	<b>Description</b>
<b>Alarm settings</b>		
<b>Alarm volume</b> <sup>1)</sup>	<b>Off, 5, 10, 20, 30, 40, 50, 60, 70, 80, 90, 100 %</b> (default)	Sets the overall monitor volume and supersedes alarm volume.  The setting <b>Off</b> is not available if there is no connection to the <b>ICS</b> .  While the M540 is in transport, the full range of volume settings are available.
<b>All alarms pause</b> or <b>All alarms off</b>	<b>None</b>	When the <b>All alarms pause</b> button is selected, all alarm functions are temporarily suppressed for a selected time. The alarm function is automatically activated once the alarm pause timer times out.  When the <b>All alarms off</b> button is selected, all alarm functions are suppressed until you select the button again to activate the alarm function.  To configure this button, see page 303.
<b>Pressures pause</b>	<b>1 min, 2 min, (default), 3 min, 4 min, 5 min, Disabled</b>	Determines the duration and availability of the <b>Pressures pause</b> function.
<b>Pressures off</b>	<b>Enabled, Disabled</b>	Determines the availability of the <b>Pressures off</b> function.
<sup>1)</sup> This setting is a user default that is identical for all patient categories and is also part of the profile.		

**Alarms dialog**

Selection	Available settings	Description
<b>Config. alarms</b> window		
<b>SpO2 sensor off</b>	<ul style="list-style-type: none"> <li>– <b>High</b></li> <li>– <b>Medium</b></li> <li>– <b>Low</b> (default for Nellcor)</li> <li>– <b>One-shot</b></li> <li>–  (off) – default for Masimo</li> </ul>	<p>Assigns an alarm priority to the sensor alarm or deactivates the sensor alarm.</p> <ul style="list-style-type: none"> <li>– <b>High:</b> The event is treated as a high-priority alarm.</li> <li>– <b>Medium:</b> The event is treated as a medium-priority alarm.</li> <li>– <b>Low:</b> The event is treated as a persistent low-priority alarm.</li> <li>– <b>One-shot:</b> The event is treated as a low-priority, single notification alarm.</li> <li>– : No visual or acoustic alarm signals are triggered; however, if the sensor is no longer attached to the patient, a corresponding message appears in the SpO2 parameter field.</li> </ul>
<b>ECG leads off</b>	<ul style="list-style-type: none"> <li>– <b>High</b></li> <li>– <b>Medium</b></li> <li>– <b>Low</b> (default)</li> <li>– <b>One-shot</b></li> <li>–  (off)</li> </ul>	<p>Determines what happens when the corresponding alarm occurs. The selected alarm priority affects how the alarm event is reported visually and acoustically – generates a timed recording and stores the event.</p> <ul style="list-style-type: none"> <li>– <b>High:</b> The event is treated as a latching alarm.</li> <li>– <b>Medium:</b> The event is treated as a medium-priority alarm.</li> <li>– <b>Low:</b> The event is treated as a persistent low alarm.</li> <li>– <b>One-shot:</b> The event is treated as a low grade, single notification. The message <b>ECG leads off</b> appears briefly in the header bar until the user acknowledges the condition or the condition disappears.</li> <li>– : No visual or acoustic alarm signals are triggered.</li> </ul>

<b>Alarms dialog</b>		
<b>Selection</b>	<b>Available settings</b>	<b>Description</b>
<b><i>RRi lead off</i></b>	<ul style="list-style-type: none"> <li>– <b>High</b></li> <li>– <b>Medium</b></li> <li>– <b>Low</b> (default)</li> <li>– <b>One-shot</b></li> <li>–  (off)</li> </ul>	<p>Assigns an alarm priority to the RRi lead-off alarm or deactivates it. The selected alarm priority affects how the alarm event is reported visually and acoustically.</p> <ul style="list-style-type: none"> <li>– <b>High:</b> The event is treated as a high-priority alarm.</li> <li>– <b>Medium:</b> The event is treated as a medium-priority alarm.</li> <li>– <b>Low:</b> The event is treated as a persistent low-priority alarm.</li> <li>– <b>One-shot:</b> The event is treated as a low-priority, single notification alarm. The message <b>RRi lead off</b> appears briefly in the header bar until the user acknowledges the condition or the condition disappears.</li> <li>– : No visual or acoustic alarm signals are triggered.</li> </ul>
<b><i>ART cath. disconnected?</i></b>	<ul style="list-style-type: none"> <li>– <b>High</b> (default)</li> <li>–  (off)</li> </ul>	<p>Assigns an alarm priority to the <b>ART cath. disconnected?</b> alarm or deactivates it. The selected alarm priority affects how the alarm event is reported visually and acoustically.</p> <ul style="list-style-type: none"> <li>– <b>High:</b> The event is treated as a high-priority alarm condition.</li> <li>– : No visual or acoustic alarm signals are triggered.</li> </ul>

## Configuring the battery alarm

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A battery alarm alerts you to a low battery charge when the M540 is undocked. The priority of the accompanying battery alarm tone is configurable.

### To configure the battery alarm

- 1 Press the **Menu** function key.
- 2 Touch the **System setup** tab.
- 3 Touch the **Alarm setup** tab.
- 4 Enter the password.
- 5 Select one of the following settings:
  - **Medium** (default) – a persistent tone of medium priority sounds when the battery has approximately 5-10 minutes of the remaining charge left.
  - **High** – a tone of high priority sounds when the battery has approximately 5 minutes of the remaining charge left. Also, the message **Recharge battery** appears in the alarm area. Refer to "Alarm priorities" on page 106.

## Options

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The M540 supports the following options which are automatically unlocked:

- Full arrhythmia option
- 12-lead monitoring option
- Multi-IP option for measuring more than two invasive blood pressures

The M540 also supports the wireless (WiFi) locked option which can be unlocked using a password. The **Wireless** tab under **System information** tab and the **Biomed** menu is available when the wireless option is unlocked. The wireless tabs do not appear when the wireless option is locked.

### To unlock the wireless option

- 1 Press the **Menu** function key.
- 2 Touch the **System setup** tab.
- 3 Touch the **Service** button.
- 4 Enter the password > **OK**.
- 5 Touch the **Locked options** tab.
- 6 Touch the **Wireless** button.
- 7 Enter the password.

The label inside the **Wireless** button changes to **Unlocked**.

Once unlocked, options remain activated even under the following circumstances:

- When the M540 is turned on or off
- When software is downloaded
- When factory defaults are restored
- When another language is selected

**To lock the wireless option**

- 1 Press the **Menu** function key.
- 2 Touch the **System setup** tab.
- 3 Touch the **Service** button.
- 4 Enter the password > **OK**.
- 5 Touch the **Locked options** tab.
- 6 Touch the **Wireless** button. A dialog box with the following message appears:

***Disabling this option disables wireless functionality. A passcode is required to re-enable the option.***

- 7 Touch the **Lock** button. The label inside the **Wireless** button changes to **Locked**.

**Temporary options**

Temporary options make it possible for an M540 in an IACS configuration to perform the intended functions together with the Cockpit when the devices do not share the same option setup. For example, when an M540 with permanent options docks to an IACS Cockpit that does not have the same options activated, the M540 options temporarily loans these options to the Cockpit. Temporary options are deactivated when a patient is discharged. However, they are retained if you turn the Cockpit or the M540 off and on.

# DRAFT

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## Troubleshooting

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## Overview

Multiple alarm messages cycle in the alarm message field of the header bar.

For example, if two faults are detected simultaneously, the more urgent of the two is displayed.

The exclamation marks in the following tables indicate the priority level of the alarm messages (see page 106 for definitions). The exclamation marks are not in the actual alarm messages.

Warning = !!! Message of high priority

Caution = !! Message of medium priority

Advisory = ! Message of low priority

If no priority level is assigned, the message is informational and no action is required.

In the following tables, messages are listed in alphabetical order. These tables identify possible alarm causes and provides corrective action. The various causes and remedies should be worked through in the order listed until the problem has been resolved.

### NOTE

If the M540 speakers fail, all alarm patterns are generated by the M540's power-up/power-down alert tone mechanism. Contact specialized service personnel.

## Device communication messages / general device messages

Priority	Message	Cause	Remedy
None	<b>Audio paused by remote</b>	M540 alarms were paused by a remote device.	Informational message – no action required.
None	<b>Check IP 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 device name</b>	The domain name is already in use (i.e., a duplicate monitoring unit label, care unit label, device label, and hospital name).	Assign a unique domain name.
None	<b>Not monitored by central</b>	The communication between the ICS and the M540 is interrupted.	<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>
		A wireless M540 is out of range of the access point.	

Priority	Message	Cause	Remedy
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 Infinity CentralStation.	Informational message – no action required.
None	<b>Remote limit change</b>	The indicated function was initiated from the Infinity CentralStation.	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 specialized service 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 specialized service personnel.
None	<b>Profile transfer failed</b>	The profile failed to load on the M540 upon docking.	Undock and redock the M540 before contacting specialized service personnel.

## M540 battery messages

Priority	Message	Cause	Remedy
!	<b>Low battery</b>	The M540 is undocked and the battery charge has ten minutes of run time remaining.  An advisory tone sounds every 20 seconds.	Return the M540 to the M500 to recharge the battery.
!!	<b>Recharge battery</b>	The M540 is undocked and the battery charge has five minutes of run time remaining.	For information on how to configure the priority of the alarm tone that accompanies this message, see page 324.

## Messages

Priority	Message	Cause	Remedy
!!!	<b>All alarms off</b>	The <b>All alarms off</b> function is set to <b>No timeout</b> (see page 321) and you select the <b>All alarms off</b> button.	Select the <b>All alarms off</b> button again to remove the message.
!!!	<b>All alarms paused</b> with timer	The <b>All alarms paused</b> function is set to a time (see page 321) and you select the <b>All alarms paused</b> button.	Select the <b>All alarms paused</b> button again to remove the message.
None	<b>All alarms paused</b> with timer	The yellow All alarms paused key was pressed.	Press the key again to remove the message.
!	<b>2nd HemoPod unplugged</b> <sup>1)</sup>	The second invasive pressure device is disconnected.	Check the equipment and replace if necessary.
None	<b>HemoPod incompatible</b>	An incompatible invasive pressure device has been connected.	Remove the incompatible invasive pressure pod.
<sup>1)</sup> In the parameter field the parameter value is replaced by * * *			

Priority	Message	Cause	Remedy
!!	<b>Audio off</b>	This message appears in the alarm message field when the alarm volume is deactivated on a standalone M540 and the patient is also admitted at the ICS.  When the M540 is in an IACS configuration, this message appears when the alarm volume of the Cockpit is deactivated.	Activate the alarm volume.
!!!	<b>All alarms off: Bypass</b>	This message appears in the alarm message field when you activate cardiac bypass mode (see page 321).	Deactivate the feature to remove the message.
None	<b>Discharged</b> <b>Touch screen to resume monitoring</b>	This message appears in the center of the M540 screen when the patient has been discharged (see page 102).	Touch the screen to resume monitoring and admit a new patient.
!	<b>Duplicate IP address</b>	This message appears in the alarm message field when a duplicate IP address is detected anywhere on the Infinity network.  The M540 goes offline within 10 seconds of a <b>Duplicate IP address</b> alarm condition.	<ul style="list-style-type: none"> <li>– Configure a new IP address</li> <li>– Power-cycle the M540</li> <li>– Re-dock the M540</li> </ul> <p>The M540 then immediately tries to rejoin the Infinity network. If the address is already used, the same steps provided above will repeat.</p>
None	<b>Filter ESU</b>	This message appears above the ECG waveform when set to <b>Filter off</b> (see page 160).	Select another filter setting to change or remove the message.
None	<b>Filter off</b>	This message appears above the ECG waveform when set to <b>Filter off</b> (see page 160).	Activate the function to remove the message.

ECG

Priority	Message	Cause	Remedy
!!!	<b>ASY</b>	The reported arrhythmia was detected.	Check the patient and treat if necessary.
!!!	<b>Brady</b> ( <i>neonatal patient category</i> )		
!!!	<b>VF</b>		
!!!	<b>ASY, VF off</b>	<p>This message appears in the alarm message field under the following circumstances:</p> <ul style="list-style-type: none"> <li>– Heart rate alarms are activated.</li> <li>– <b>HR source</b> is set to <b>Arterial</b> or <b>SpO<sub>2</sub></b>.</li> <li>– <b>ARR mode</b> (arrhythmia) is deactivated.</li> </ul>	<p>The message disappears under the following circumstances:</p> <ul style="list-style-type: none"> <li>– The <b>HR source</b> is changed to <b>ECG</b>, or</li> <li>– The <b>ARR mode</b> is changed to <b>Basic</b> or <b>Advanced</b>.</li> </ul>
!!!	<b>HR, ASY, VF off</b>	<p>This message appears in the alarm message field when specific settings are configured as follows:</p> <ul style="list-style-type: none"> <li>– Heart rate alarms are deactivated.</li> <li>– <b>ASY/VF alarms</b> feature is set to <b>Follow HR</b> (see page 309).</li> <li>– Arrhythmia monitoring is deactivated.</li> </ul> <p>The same message also appears under the following circumstances:</p> <ul style="list-style-type: none"> <li>– Heart rate alarms are deactivated.</li> <li>– <b>ASY/VF alarms</b> feature is set to <b>Always on</b> (see page 309).</li> <li>– Arrhythmia monitoring is deactivated.</li> <li>– The selected <b>HR source</b> is activated and is either <b>SpO<sub>2</sub></b> or <b>Arterial</b> (which automatically selects ART, AOR, FEM, AXL, RAD, UAP, or BRA).</li> </ul>	Reconfigure the setting to remove the message.

Priority	Message	Cause	Remedy
!!	<b>HR alarms off</b>	<p>This message appears in the alarm message field under the following circumstances.</p> <ul style="list-style-type: none"> <li>– When the alarm limits for heart rate are deactivated and the <b>ASY/VF alarms</b> function is set to <b>Always on</b> (see page 309).</li> <li>– When the alarm limits for heart rate are deactivated, the basic arrhythmia function is activated and the <b>ASY/VF alarms</b> function is set to <b>Follow HR</b> (see page 309).</li> </ul>	
!	<b>ECG artifact</b> <sup>2)</sup>	<ul style="list-style-type: none"> <li>– Patient movement (shivering, tremors)</li> <li>– Bad electrode contact</li> <li>– Excessive signal noise interference from auxiliary equipment</li> </ul>	<ul style="list-style-type: none"> <li>– Check the electrodes and reapply if necessary.</li> <li>– Make sure that the patient's skin is properly prepped.</li> <li>– Isolate the patient from auxiliary equipment, if possible.</li> </ul>
!	<b>ECG leads off</b> <sup>2)</sup>	<p>Lead-off condition detected due to:</p> <ul style="list-style-type: none"> <li>– Broken cable(s)</li> <li>– Disconnected ECG lead wires</li> <li>– Loose lead wire(s)</li> <li>– Wrong lead selected</li> <li>– Dried out electrode gel</li> </ul>	<ul style="list-style-type: none"> <li>– Replace faulty cable(s).</li> <li>– Reapply gel on reusable electrodes and reapply them or replace new disposable electrodes.</li> </ul>
!	<b>ECG unplugged</b> <sup>2)</sup>	<p>ECG cable(s) disconnected from the M540.</p>	<ul style="list-style-type: none"> <li>– Select another ECG lead for processing.</li> <li>– If monitoring augmented leads, verify that the number of selected leads in the <b>ECG</b> setup page is correct.</li> <li>– Check cable(s) and connection(s).</li> <li>– Replace cable(s) if necessary.</li> </ul>

<sup>2)</sup> In the parameter field the parameter value is replaced by \*\*\*

Priority	Message	Cause	Remedy
!!	<b>HR &gt;</b> (alarm limit) <b>HR &lt;</b> (alarm limit)	The parameter value is above/below the set upper /lower alarm limits.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Change the alarm limits.</li> </ul>
!!	<b>HR out of range high</b> <sup>1)</sup>	The parameter value is above the measurement range of the monitor.	Check the patient and treat if necessary.
None	xx <sup>3)</sup> <b>Lead off</b>	The indicated lead wire is no longer attached to the patient.	Reattach the electrode to the patient.
<sup>1)</sup> In the parameter field the parameter value is replaced by +++ <sup>3)</sup> xx represents LA, LL, RA, RL, V, V1 to V6, or V+			

**NOTE**

**RRi** and 12-lead ECG monitoring are unavailable when the M540 is set to OR alarms and the ECG filter is set to **Monitor**.

## ST

Priority	Message	Cause	Remedy
!	<b>Cannot analyze ST</b> <sup>3)</sup>	The algorithm cannot determine ST values due to artifact, the absence of normal beats, or invalid leads.  or,  HR greater than 180 bpm +/- 5 bpm  or,  Lead with QRS amplitude less than 200 uV	<ul style="list-style-type: none"> <li>– Perform a relearn.</li> <li>– Check electrodes; re-apply if necessary.</li> <li>– Make sure the patient's skin is properly prepared.</li> <li>– Isolate the patient from auxiliary equipment if possible.</li> <li>– Inspect and replace faulty lead sets.</li> <li>– Reapply gel on reusable electrodes and reapply them or replace new disposable electrodes.</li> <li>– Reapply the electrode(s). Make sure the patient's skin is properly prepared.</li> <li>– If a lead wire or electrode cannot be replaced, select another ST lead.</li> </ul>
!!	<b>ST</b> <label> <sup>4)</sup> > (alarm limit) <b>ST</b> <label> <sup>4)</sup> < (alarm limit)	The parameter value is above/below the set upper /lower alarm limits.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Change the alarm limits.</li> </ul>
!!	<b>ST</b> <label> <sup>4)</sup> <b>out of range high</b> <sup>2)</sup>	The parameter value is above/below the measurement range of the monitor.	– Check the patient and treat if necessary.
!!	<b>ST</b> <label> <sup>4)</sup> <b>out of range low</b> <sup>1)</sup>		– Check the placement of electrodes and change their position if necessary.
None	<b>ST relearning</b>	ST relearn is in progress	Informational message – no action required.
<p><sup>1)</sup> In the parameter field the parameter value is replaced by - - -</p> <p><sup>2)</sup> In the parameter field the parameter value is replaced by + + +</p> <p><sup>3)</sup> In the parameter field the parameter value is replaced by * * *</p> <p><sup>4)</sup> &lt;label&gt; represents I, II, III, aVR, aVL, aVF, V, V1 to V6, or V+</p>			

## Arrhythmia

Priority	Message	Cause	Remedy
!!!	<b>ASY</b> Asystole	The indicated arrhythmia was detected.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Some messages only appear when the full arrhythmia option is installed.</li> </ul>
!!!	<b>VF</b> Ventricular fibrillation		
!!!	<b>VTACH</b> <sup>1)</sup> Ventricular Tachycardia		
!!	<b>RUN</b> <sup>1)</sup> Ventricular RUN		
!!	<b>AIVR</b> <sup>1)</sup> Accelerated Idioventricular Rhythm		
!!	<b>SVT</b> <sup>1)</sup> Supraventricular Tachycardia		
!	<b>CPT</b> <sup>1)</sup> Ventricular Couplet		
!	<b>BGM</b> <sup>1)</sup> bigeminy		
Off	<b>TACH</b> <sup>1)</sup> Tachycardia		
Off	<b>Brady</b> <sup>1)</sup> Bradycardia		
Off	<b>Pause</b> <sup>1)</sup> user selectable interval		
Off	<b>ARTF</b> <sup>1)</sup> artifact, background rhythm		
None	<b>ARR cannot learn</b> (arrhythmia lead)	After 100 beats, the M540 cannot determine the dominant normal complex on any lead selected for QRS processing.	<ul style="list-style-type: none"> <li>– Check the electrode preparation.</li> <li>– Reapply electrodes if necessary.</li> </ul>
None	<b>ARR relearning</b>	The M540 is learning the patient's QRS complex to establish a reference template.	Informational message – no action required.
!!	<b>PVC/min &gt;</b> (alarm limit)	PVC value is above the upper alarm limit.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Reapply electrodes if necessary.</li> </ul>
<p><sup>1)</sup> These arrhythmia events can have one of three alarm priorities assigned (high, medium, or low.) or is turned off. The priority listed in this table is the default. For these arrhythmia events, you can disable alarms.</p>			

## Respiration (RRi)

Priority	Message	Cause	Remedy
!!	<b>RRi &gt;</b> (alarm limit) <b>RRi &lt;</b> (alarm limit)	The parameter value is above/below the set upper /lower alarm limits.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Check the alarm limits.</li> </ul>
!!!	<b>RRi apnea</b>	Neonatal apnea condition was detected.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> </ul>
!!	<b>RRi apnea</b>	Adult or pediatric apnea condition was detected.	<ul style="list-style-type: none"> <li>– Check the placement of electrodes. Change their position if necessary.</li> <li>– Initiate a relearn or reset breath-detection sensitivity in manual mode.</li> </ul>
!	<b>RRi artifact</b> <sup>2)</sup>	Persistent artifact was detected.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> </ul>
!	<b>RRi high impedance</b> <sup>2)</sup>	A high respiration impedance was detected.	<ul style="list-style-type: none"> <li>– Make sure the patient's skin is prepared properly.</li> </ul>
!	<b>RRi lead off</b> <sup>2)</sup>	The respiration lead has been invalid for 10 seconds.	<ul style="list-style-type: none"> <li>– Isolate the patient from any auxiliary equipment, if possible.</li> </ul>
!	<b>RRi lead unavailable</b> <sup>2)</sup>	Faulty or disconnected electrodes.	<ul style="list-style-type: none"> <li>– Reapply gel on reusable electrodes and reapply them or replace new disposable electrodes.</li> <li>– Inspect and replace faulty lead sets.</li> <li>– If a lead wire or electrode cannot be replaced, select another lead for processing (in the RRi setup page).</li> </ul>
!!	<b>RRi coincidence</b>	The heart rate and respiratory rate fall within 20 % of each other.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Check and change the electrode placement if you receive a coincidence message until you obtain a clear respiration signal.</li> </ul>

<sup>2)</sup> In the parameter field the parameter value is replaced by \*\*\*

Priority	Message	Cause	Remedy
!!	<b>RRi out of range high</b> <sup>1)</sup>	The respiratory rate is higher than 150 breaths per minute.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Check the placement of electrodes. Change their position if necessary.</li> <li>– Move the electrodes away from the source of interference.</li> </ul>
		The M540 may be counting artifacts as valid breaths.	
		The M540 may be counting interference caused by faulty equipment.	
None	<b>RRi relearning</b>	Relearn is in progress.	Informational message – no action required.
<sup>1)</sup> In the parameter field the parameter value is replaced by +++			

**NOTE**

**RRi** and 12-lead ECG monitoring are unavailable when the M540 is set to OR alarms and the ECG filter is set to **Monitor**.

## SpO2

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The following messages originate from three different hardware devices (Masimo SET, Masimo rainbow SET, and Nellcor OxiMax).

Priority	Message	Cause	Remedy
None Masimo rainbow SET only	<b>Learning Pulse CO-Ox</b> <sup>3)</sup>	The Masimo rainbow SET-specific parameters are being calculated (only the parameters for SpO2, PLS, and PI are available).	Wait until the Masimo rainbow SET parameters are calculated.
<sup>3)</sup> In the parameter field the parameter value is replaced by ***			

Priority	Message	Cause	Remedy
None Any Masimo MCable	<b>Low SpO<sub>2</sub> SIQ</b>	MCable detects a low signal quality for the indicated parameter.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Make sure the SpO<sub>2</sub> sensor is attached properly to the patient.</li> <li>– Check all cable connections.</li> </ul>
None Masimo rainbow SET only	<b>Low SpHb SIQ</b> <b>Low SpHbv SIQ</b> <b>Low SpOC SIQ</b> <b>Low SpMet SIQ</b> <b>Low SpCO SIQ</b> <b>Low PVI SIQ</b>		
!!	<b>PLS &gt;</b> (alarm limit) <b>PLS &lt;</b> (alarm limit)	The pulse rate above/below the set upper/lower alarm limits.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Change the alarm limits.</li> </ul>
!!	<b>PLS out of range high</b> <sup>1)</sup> <b>PLS out of range low</b> <sup>2)</sup>	The parameter value is above/below the measurement range of the monitor.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Change the alarm limits.</li> </ul>
!!	<b>SpHb &gt;</b> (alarm limit) <b>SpHbv &lt;</b> (alarm limit) <b>PVI &gt;</b> (alarm limit) <b>PVI &lt;</b> (alarm limit) <b>SpCO &gt;</b> (alarm limit) <b>SpCO &lt;</b> (alarm limit) <b>SpMet &gt;</b> (alarm limit) <b>SpMet &lt;</b> (alarm limit)	The parameter value is above/below the set upper / lower alarm limits.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Change the alarm limits.</li> </ul>
<sup>1)</sup> In the parameter field the parameter value is replaced by - - - <sup>2)</sup> In the parameter field the parameter value is replaced by + + +			

Priority	Message	Cause	Remedy
!!	<b>SpO<sub>2</sub> &gt;</b> (alarm limit) <b>SpO<sub>2</sub> &lt;</b> (alarm limit)	The parameter value is above/below the set upper / lower alarm limits.  The priority changes to high (!!!) if the SpO <sub>2</sub> value falls more than 10 % below the lower limit. This does not occur when using <b>SatSeconds</b> time with the Nellcor OxiMax MCable.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Change the alarm limits.</li> </ul>
! Any Masimo MCable	<b>SpO<sub>2</sub> cable expired</b> <sup>3)</sup>	Cable expired.	Replace the cable.
! Any Masimo MCable	<b>SpO<sub>2</sub> cable expires soon</b>	Cable near expiration.	Replace the cable.
! Masimo rainbow SET only	<b>SpO<sub>2</sub> cable failure</b> <sup>3)</sup>	The Masimo rainbow SET intermediate cable is faulty or has expired.	Replace the intermediate cable.
! Nellcor OxiMax MCable only	<b>SpO<sub>2</sub> check sensor</b> <sup>3)</sup>	SpO <sub>2</sub> sensor is detecting too much ambient light.	<ul style="list-style-type: none"> <li>– Make sure the SpO<sub>2</sub> sensor is attached properly to the patient.</li> <li>– Check all cable connections.</li> </ul>
None Masimo rainbow SET only	<b>SpO<sub>2</sub> Sensor Calibrating</b> <sup>3)</sup>	The sensor is being checked for functional integrity.	<ul style="list-style-type: none"> <li>– Wait until the message disappears.</li> </ul> <p>This message appears right before the message <b>SpO<sub>2</sub> searching</b>.</p>
!!! AnySpO <sub>2</sub> MCable	<b>Desat. &lt;</b> (alarm limit)	The parameter value is below the set lower alarm limit.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Change the alarm limit.</li> </ul>
<sup>3)</sup> In the parameter field the parameter value is replaced by ***			

Priority	Message	Cause	Remedy
! Any SpO <sub>2</sub> MCable	<b>SpO<sub>2</sub> H/W failure</b> <sup>3)</sup>	Masimo SET MCable or Nellcor OxiMax MCable hardware failure.	<ul style="list-style-type: none"> <li>– Check for a faulty MCable.</li> <li>– Power cycle the M540 to clear the message.</li> <li>– Contact specialized service personnel.</li> </ul>
! Any Masimo MCable	<b>SpO<sub>2</sub> interference detected</b> <sup>3)</sup>	Interference such as artifact was detected.	<ul style="list-style-type: none"> <li>– Make sure the sensor is properly attached.</li> <li>– Make sure that no nail polish or some other substance is blocking the light.</li> <li>– Change the sensor location.</li> </ul>
None Any Masimo MCable	<b>SpO<sub>2</sub> low perfusion</b>	Arterial pulsations with low amplitudes were detected.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Move the sensor to a site that is more adequately perfused.</li> <li>– Select the maximum sensitivity mode (see page 203).</li> </ul>
! Any SpO <sub>2</sub> MCable	<b>SpO<sub>2</sub> MCable unplugged</b> <sup>3)</sup> In the parameter field the parameter value is replaced by blanks for the Masimo rainbow SET parameter PI.	The SpO <sub>2</sub> MCable is disconnected from the M540.	Check connections to the M540.
None Masimo rainbow SET only	<b>SpO<sub>2</sub> only mode</b> Parameter values are displayed for <b>SpO<sub>2</sub></b> , <b>PLS</b> , and <b>PI</b> ; the Masimo rainbow SET parameter values are replaced by ***	The device cannot calibrate the Masimo rainbow SET parameters and is attempting to display the standard Masimo parameters.	Remove and reapply the sensor. If the problem persists, contact specialized service personnel.
<sup>3)</sup> In the parameter field the parameter value is replaced by ***			

Priority	Message	Cause	Remedy
! Any Masimo MCable	<b>SpO2 replace cable next pt.</b>	Cable expired.	Replace the cable.
! Any Masimo MCable	<b>SpO2 replace sensor next pt.</b>	<ul style="list-style-type: none"> <li>– SpO2 sensor expired</li> <li>– Adhesive sensor expired</li> </ul>	Replace the sensor.
None Any SpO2 MCable	<b>SpO2 searching</b> <sup>3)</sup>	The sensor is searching for valid pulses to compute a measurement value.	Verify proper sensor application.
! Any Masimo MCable	<b>SpO2 sensor expired</b> <sup>3)</sup>	<ul style="list-style-type: none"> <li>– SpO2 sensor expired</li> <li>– Adhesive sensor expired</li> </ul>	Replace the sensor.
! Any Masimo MCable	<b>SpO2 sensor expires soon</b>	<ul style="list-style-type: none"> <li>– SpO2 sensor near expiration</li> <li>– Adhesive sensor near expiration</li> </ul>	Replace the sensor.
! Any SpO2 MCable	<b>SpO2 sensor failure</b> <sup>3)</sup>	The MCable has detected a hardware failure with the SpO2 sensor.	<ul style="list-style-type: none"> <li>– Make sure the SpO2 sensor is properly attached to the patient and all cables are properly connected.</li> <li>– Replace sensor.</li> <li>– Contact specialized service personnel.</li> </ul>
! Any Masimo MCable	<b>SpO2 sensor off</b> <sup>3)</sup>	The Masimo MCable has detected that the SpO2 sensor is no longer attached to the patient.	Reattach the SpO2 sensor.
! Any Masimo MCable	<b>SpO2 sensor unplugged</b>  In the parameter field the parameter value is replaced by the following depending on which MCable is used: *** for the parameters SpO2, PLS, SpHb/SpHbv, PVI, SpCO, SpOC, SpMet; blanks for the parameter PI.	The SpO2 intermediate cable or sensor is unplugged.	<ul style="list-style-type: none"> <li>– Verify that the cable and the sensor are properly connected.</li> <li>– Check for faulty sensor.</li> </ul>
<sup>3)</sup> In the parameter field the parameter value is replaced by ***			

Priority	Message	Cause	Remedy
! Any Masimo MCable	<b>SpO2 unrecognized cable</b> <sup>3)</sup>	An incompatible Masimo MCable is connected.	<ul style="list-style-type: none"> <li>– Connect the right type of cable.</li> <li>– Contact specialized service personnel.</li> </ul>
! Any SpO2 MCable	<b>SpO2 unrecognized sensor</b> <sup>3)</sup>	<ul style="list-style-type: none"> <li>– The MCable does not recognize the connected sensor.</li> <li>– A reusable SpHb sensor is connected to a Masimo rainbow SET MCable that does not support this parameter.</li> </ul>	<ul style="list-style-type: none"> <li>– Connect the right type of sensor.</li> <li>– Contact specialized service personnel.</li> </ul>
<sup>3)</sup> In the parameter field the parameter value is replaced by - - -			

## Non-invasive blood pressure

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Priority	Message	Cause	Remedy
!!	<b>NIBP D &gt;</b> (alarm limit) <sup>1)</sup> <b>NIBP D &lt;</b> (alarm limit) <sup>1)</sup> <b>NIBP M &gt;</b> (alarm limit) <sup>1)</sup> <b>NIBP M &lt;</b> (alarm limit) <sup>1)</sup> <b>NIBP S &gt;</b> (alarm limit) <sup>1)</sup> <b>NIBP S &lt;</b> (alarm limit) <sup>1)</sup>	The parameter value is above/below the set upper /lower alarm limits.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Change the alarm limits.</li> </ul>
!!	<b>NIBP blocked line</b> <sup>1)</sup>	The inflation rate is too high or the time to evacuate residual cuff pressure at the end of the deflation cycle is too short.	<ul style="list-style-type: none"> <li>– Select a different cuff.</li> <li>– Check the hose and cuff for damage.</li> <li>– Restart the measurement. If the message does not clear, contact specialized service personnel.</li> </ul>
<sup>1)</sup> In the parameter field the parameter value is replaced by ***			

Priority	Message	Cause	Remedy
!	<b>NIBP cannot measure</b> <sup>1)</sup>	The pulse profile is too poor to establish a reliable measurement (usually due to persistent motion artifact)	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Move the cuff to a limb with less movement.</li> <li>– Restart the measurement. If the message does not clear, contact specialized service personnel.</li> </ul>
!	<b>NIBP cuff leak</b> <sup>1)</sup>	The drop in cuff pressure at the end of the inflation cycle is too great.	<ul style="list-style-type: none"> <li>– Check the hose and cuff for leaks. Replace if necessary.</li> <li>– Restart the measurement. If the message does not clear, contact specialized service personnel.</li> </ul>
!!	<b>NIBP H/W failure</b> <sup>1)</sup>	<ul style="list-style-type: none"> <li>– Non-invasive blood pressure measurement circuit failure</li> <li>– Non-invasive blood pressure zero out of range or faulty transducer</li> </ul>	<ul style="list-style-type: none"> <li>– Check all hardware, and contact specialized service personnel.</li> <li>– Power cycle the M540 to clear this message.</li> </ul>
!!	<b>NIBP low inflation limit</b> <sup>1)</sup>	The pressure of the patient is greater than the maximum allowed cuff inflation pressure.	Select the next higher inflation limit setting.
!	<b>NIBP mean only</b> <sup>1)2)</sup>	The pulse amplitude is too small or too high for the M540 to derive systolic and diastolic pressure values but sufficient to report a mean pressure value.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Check the hose and cuff.</li> <li>– Check the size and the placement of the cuff.</li> </ul>

<sup>1)</sup> In the parameter field the parameter value is replaced by \*\*\*

<sup>2)</sup> In the parameter field the systolic and diastolic parameter values are replaced by \*\*\*

Priority	Message	Cause	Remedy
!	<b><i>NIBP measurement timeout</i></b> <sup>1)</sup>	An non-invasive blood pressure measurement has exceeded time-out limit.	Repeat the measurement.
!	<b><i>NIBP open line</i></b> <sup>1)</sup>	There was no significant increase in cuff pressure during the inflation cycle.	Make sure that the hose and cuff are properly connected to the monitor.
!!	<b><i>NIBP out of range high</i></b>	The parameter value is above/below the measurement range of the monitor.	Check the non-invasive blood pressure inflation limits and adjust them if necessary (for example, if the wrong patient category is selected).
!!	<b><i>NIBP out of range low</i></b>		
!	<b><i>NIBP overpressure</i></b> <sup>1)</sup>	The cuff pressure has exceeded the overpressure threshold.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Check the cuff for obstructions.</li> <li>– Repeat the measurement.</li> </ul>
None	<b><i>NIBP pneumatic char needed</i></b>	Non-invasive blood pressure hardware failure in the M540.	Contact specialized service personnel and take the M540 out of service.
None	<b><i>NIBP pneumatic char failed</i></b>	Technical hardware failure.	Contact specialized service personnel and take the M540 out of service.
None	<b><i>Venous stasis started</i></b>	Message reports the start of venous stasis.	Informational message – no action required.
None	<b><i>Venous stasis ended</i></b>	Message reports the end of venous stasis.	Informational message – no action required.
None	<b><i>Venous stasis ending</i></b>	Message reports that venous stasis is ending in less than 10 seconds.	Informational message – no action required.
1) In the parameter field the parameter value is replaced by ***			

## Cardiac output

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Although the M540 processes the cardiac output algorithm, you can only view the messages on the Cockpit, when the M540 is docked in an IACS configuration. For more information, refer to the *Instructions for use Infinity Acute Care System – Monitoring applications*.

## Temperature

Priority	Message	Cause	Remedy
!	<b>Cannot derive <math>\Delta T</math></b> <sup>3) 4)</sup> <b>Cannot derive <math>\Delta T1</math></b> <b>Cannot derive <math>\Delta T2</math></b>	One of the cables is either unplugged or faulty, or the value is out of range.	<ul style="list-style-type: none"> <li>– Check the equipment and replace it if necessary.</li> <li>– Connect the second temperature sensor.</li> </ul>
!!	<b><math>T &gt;</math></b> <sup>4)</sup> > (alarm limit) <b><math>T &lt;</math></b> <sup>4)</sup> < (alarm limit)	The parameter value is above/below the set upper/lower alarm limits.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Change the alarm limits.</li> </ul>
!	<b><math>T</math> H/W Failure</b> <sup>3)</sup> <b><math>T1</math> H/W Failure</b> <sup>3)</sup> <b><math>T2</math> H/W Failure</b> <sup>3)</sup>	The hardware reference values do not meet the specified tolerance.	Contact specialized service personnel.
!!	<b>Temp out of range high</b> <sup>2)</sup>	The parameter value is above/below the measurement range of the monitor.	– Check the patient and treat if necessary.
!!	<b>Temp out of range low</b> <sup>1)</sup>		– Check the equipment and replace, if necessary.
!	<b><math>T</math> unplugged</b> <sup>3)</sup>	The temperature sensor is unplugged.	Reapply the temperature sensor.
<p>1) In the parameter field the parameter value is replaced by - - -</p> <p>2) In the parameter field the parameter value is replaced by +++</p> <p>3) In the parameter field the parameter value is replaced by ***</p> <p>4) Value can be for <b><math>Ta/T1a</math>, <math>Tb/T1b</math>, <math>\Delta T/\Delta T1</math></b></p>			

## Invasive pressure

Priority	Message	Cause	Remedy
!!!	<b>ART cath. disconnected?</b>	The arterial catheter could be dislodged, or there could be a leak in the tubing.	<ul style="list-style-type: none"> <li>– Assess the catheter insertion site.</li> <li>– Inspect the tubing for leaks or the presence of blood.</li> </ul> <p>Check the patient and treat, if necessary.</p>
!!	<b>transducer failure</b>	Hardware failure in the pressure transducer.	Check the transducer and replace, if necessary.
!!	<b>CPP &gt;</b> (alarm limit) <b>CPP2 &gt;</b> (alarm limit) <b>CPP3 &gt;</b> (alarm limit) <b>CPP4 &gt;</b> (alarm limit) <b>APP &gt;</b> (alarm limit) <b>BPP &gt;</b> (alarm limit)	The parameter value is above/below the set upper/lower alarm limits.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Change the alarm limits.</li> </ul>
!!	<b>CPP &lt;</b> (alarm limit) <b>CPP2 &lt;</b> (alarm limit) <b>CPP3 &lt;</b> (alarm limit) <b>CPP4 &lt;</b> (alarm limit) <b>APP &lt;</b> (alarm limit) <b>BPP &lt;</b> (alarm limit)		

Priority	Message	Cause	Remedy
!!	<b>CPP out of range high</b> <sup>2)</sup> <b>CPP2 out of range high</b> <sup>2)</sup> <b>CPP3 out of range high</b> <sup>2)</sup> <b>CPP4 out of range high</b> <sup>2)</sup> <b>APP out of range high</b> <sup>2)</sup> <b>BPP out of range high</b> <sup>2)</sup>	The pressure rate falls outside the measuring range of the monitor.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Check the equipment and replace, if necessary.</li> </ul>
!!	<b>CPP out of range low</b> <sup>1)</sup> <b>CPP2 out of range low</b> <sup>1)</sup> <b>CPP3 out of range low</b> <sup>1)</sup> <b>CPP4 out of range low</b> <sup>1)</sup> <b>APP out of range low</b> <sup>1)</sup> <b>BPP out of range low</b> <sup>1)</sup>		
!	<b>HemoPod unplugged</b> <sup>3)</sup>	The hemodynamic pod is disconnected.	Check the equipment and replace if necessary.
!	<b>2nd HemoPod unplugged</b> <sup>3)</sup>	The second invasive pressure device is disconnected.	<ul style="list-style-type: none"> <li>– Check the equipment and replace if necessary.</li> </ul>
None	<b>HemoPod incompatible</b>	An incompatible invasive pressure device has been connected.	<ul style="list-style-type: none"> <li>– Remove the incompatible invasive pressure pod.</li> </ul>
!!	<b>IP x</b> <sup>4)</sup> > (alarm limit)	The parameter value is above/below the set upper/lower alarm limits.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Change the alarm limits.</li> </ul>
!!	<b>IP x</b> <sup>4)</sup> < (alarm limit)		
!!	<b>IP x</b> <sup>4)</sup> > <b>out of range high</b>	The pressure signal falls outside the measuring range of the monitor.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Check the equipment and replace, if necessary.</li> </ul>
!!	<b>IP x</b> <sup>4)</sup> < <b>out of range low</b>		
None	<b>&lt;IP&gt; check zero</b>	The invasive pressure zero value stored in the M540 was lost and the transducer requires zeroing.	Zero the transducer.

<sup>1)</sup> In the parameter field the parameter value is replaced by - - -

<sup>2)</sup> In the parameter field the parameter value is replaced by +++

<sup>3)</sup> In the parameter field the parameter value is replaced by \* \* \*

<sup>4)</sup> x represents S (systolic), D (diastolic), or M (mean)

Priority	Message	Cause	Remedy
None	<b>&lt;IP&gt; did not zero</b>	Transducer zeroing failed because of: <ul style="list-style-type: none"> <li>– excessive signal noise</li> <li>– a non-static wave-form</li> </ul>	<ul style="list-style-type: none"> <li>– Keep all tubing motionless, then rezero.</li> <li>– Change the transducer.</li> <li>– Check stopcock, then rezero.</li> </ul>
!	<b>HemoPod H/W failure</b> <sup>3)</sup>	Invasive pressure hardware failure.	<ul style="list-style-type: none"> <li>– Check hardware and replace if necessary.</li> <li>– Call specialized service personnel.</li> </ul>
!!	<b>&lt;IP&gt; static pressure</b>	Static pressure detected on a pulsatile signal, due to: <ul style="list-style-type: none"> <li>– a physiological condition such as an asystole</li> <li>– a transducer that is closed to the patient</li> <li>– a catheter tip that is lodged against a vessel wall</li> <li>– a clot on the catheter tip</li> </ul>	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Open the system to the patient by turning the stopcock.</li> <li>– Follow hospital procedures for dislodging catheters.</li> <li>– Follow hospital procedures for clotted catheters.</li> </ul>
!	<b>HemoPod unplugged</b> <sup>1)</sup>	The pressure transducer for the specified parameter is either unplugged or faulty.	<ul style="list-style-type: none"> <li>– During an active pressure: Reconnect or replace the cable.</li> <li>– During an inactive pressure: Turn off alarms.</li> </ul>
None	<b>&lt;IP&gt; Zero accepted</b>	Transducer zeroing was successful.	Informational message – no action required.
<sup>1)</sup> In the parameter field the parameter value is replaced by - - - <sup>3)</sup> In the parameter field the parameter value is replaced by * * *			

## Mainstream CO<sub>2</sub>

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Priority	Message	Cause	Remedy
None	<b>CO<sub>2</sub> calibration check failed</b>	The mainstream sensor calibration procedure failed.	<ul style="list-style-type: none"> <li>– Ensure that the filter and sensor are clean.</li> <li>– If failure persists, contact specialized service personnel.</li> </ul>
None	<b>CO<sub>2</sub> calibration check successful</b>	The mainstream sensor calibration procedure was successful.	Informational message – no action required.
None	<b>%0 calibration in progress</b>	The mainstream sensor calibration procedure is in progress.	Informational message – no action required.
!	<b>CO<sub>2</sub> check airway adapter <sup>1)</sup></b>	<ul style="list-style-type: none"> <li>– The mainstream sensor is not properly seated on the adapter</li> <li>– There are secretions in the adapter</li> <li>– There is sensor zero drift</li> </ul>	<ul style="list-style-type: none"> <li>– Make sure the mainstream sensor is attached properly to the adapter.</li> <li>– If message persists, clean or replace the airway adapter.</li> <li>– If message persists though the airway adapter is clean, zero the sensor.</li> </ul>
!	<b>CO<sub>2</sub> MCable failure <sup>1)</sup></b>	CO <sub>2</sub> sensor hardware failure.	Contact specialized service personnel.
<sup>1)</sup> In the parameter field the parameter value is replaced by ***			

Priority	Message	Cause	Remedy
!	<b>CO<sub>2</sub> incompatible sensor</b> <sup>1)</sup>	<ul style="list-style-type: none"> <li>– The M540 has detected that the used mainstream sensor is not compatible with the selected sensor type setting (reusable/disposable)</li> <li>– Secretions in the adapter</li> <li>– Sensor zero drift</li> <li>– High inspiratory CO<sub>2</sub> concentration</li> </ul>	<ul style="list-style-type: none"> <li>– Use the airway adapter type the system is configured for or adjust the airway adapter setting (see page 263).</li> <li>– If the message persists, clean or replace the airway adapter.</li> <li>– If the message persists even though the correct airway adapter type is selected and the airway adapter is clean, zero the sensor.</li> <li>– If the message persists, the inspiratory CO<sub>2</sub> value might not be accurate. Check the patient and ventilation.</li> </ul>
!!	<b>CO<sub>2</sub> out of range high</b> <sup>1)</sup>	The parameter signal is outside the measuring range of the monitor.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Check the equipment and replace if necessary.</li> </ul>
None	<b>CO<sub>2</sub> please zero</b>	Instructional message for the mainstream sensor only.	Zero the mainstream sensor.
!	<b>CO<sub>2</sub> sensor too warm</b> <sup>1)</sup>	The CO <sub>2</sub> mainstream sensor is too warm due to ambient temperature.	<ul style="list-style-type: none"> <li>– Unspecified accuracy at ambient temperatures above 40 °C (104 °F).</li> <li>– The sensor will return to normal operation at ambient temperatures below 40 °C (104 °F). If not, replace the sensor and contact specialized service personnel.</li> </ul>
!	<b>CO<sub>2</sub> MCable unplugged</b> <sup>1)</sup>	The CO <sub>2</sub> sensor is disconnected.	Check the CO <sub>2</sub> connections.
<sup>1)</sup> In the parameter field the parameter value is replaced by ***			

Priority	Message	Cause	Remedy
!	<b>CO<sub>2</sub> MCable failure</b>	The CO <sub>2</sub> sensor hardware failed due to a corrupt EPROM (erasable programmable read-only memory) chip.	Contact specialized service personnel.
!!	<b>CO<sub>2</sub> warming up</b>	The CO <sub>2</sub> sensor is completing its warm-up cycle.	<ul style="list-style-type: none"> <li>– Wait for the CO<sub>2</sub> sensor to warm up. During warm-up, the accuracy is reduced.</li> <li>– If the message persists longer than 15 min. after the sensor has warmed up, and the ambient temperature is above 10 °C (50 °F), contact specialized service personnel.</li> <li>– You cannot zero the sensor while this message is displayed and the ambient temperature is above 10 °C (50 °F).</li> <li>– When the ambient temperature is below 10 °C (50 °F), the message can display longer than 15 minutes. In this case, it is possible to zero the sensor after the message has been displayed for at least 10 minutes.</li> </ul>
None	<b>CO<sub>2</sub> zeroing failed</b>	Zeroing of the sensor has failed or the sensor is faulty.	<ul style="list-style-type: none"> <li>– Try to zero the sensor again making sure not to breathe on the sensor and that the sensor is not blocked.</li> <li>– If zeroing fails again, replace the sensor and contact specialized service personnel.</li> </ul>
None	<b>CO<sub>2</sub> zeroing in progress</b>	The CO <sub>2</sub> zeroing is in progress	Informational message – no action required.
!!	<b>etCO<sub>2</sub> &gt; (alarm limit)</b> <b>etCO<sub>2</sub> &lt; (alarm limit)</b> (except inCO <sub>2</sub> )	The parameter value is above/below the set upper/lower alarm limits.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Change the alarm limits.</li> </ul>

Priority	Message	Cause	Remedy
!!	<b><i>RRc out of range high</i></b>	The parameter signal is outside the measuring range of the monitor.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Check the equipment and replace if necessary.</li> </ul>
!!	<b><i>RRc apnea</i></b>	Apnea was detected	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Check the placement of sensor.</li> </ul>

## Microstream CO<sub>2</sub>

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### Calibration and maintenance

Priority	Message	Cause	Remedy
None	<b><i>CO<sub>2</sub> calibration check failed</i></b>	The Microstream MCable calibration procedure failed.	Contact specialized service personnel.
None	<b><i>CO<sub>2</sub> calibration check successful</i></b>	The Microstream MCable calibration procedure was successful.	Informational message – no action required.
None	<b><i>%O<sub>2</sub> calibration in progress</i></b>	The Microstream MCable calibration procedure is in progress.	Informational message – no action required.
None	<b><i>CO<sub>2</sub> calibration required</i></b>	The Microstream MCable calibration procedure is due.	Contact specialized service personnel.
None	<b><i>CO<sub>2</sub> MCable: Maintenance is due</i></b>	Maintenance for Microstream MCable is due.	Contact specialized service personnel.
None	<b><i>CO<sub>2</sub> zeroing failed</i></b>	Resetting the Microstream MCable to zero has failed the standard three attempts.	Contact specialized service personnel.
None	<b><i>CO<sub>2</sub> zeroing in progress</i></b>	The Microstream MCable is being reset to zero.	Informational message – no action required.

CO<sub>2</sub> monitoring

Priority	Message	Cause	Remedy
!!	<b>CO<sub>2</sub> out of range high</b> <sup>1)</sup>	The parameter signal is outside the measuring range of the monitor.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Check the equipment and replace if necessary.</li> </ul>
!	<b>CO<sub>2</sub> sensor unplugged</b> <sup>1)</sup>	The Microstream MCable is disconnected.	Check the CO <sub>2</sub> connections.
!	<b>CO<sub>2</sub> MCable unplugged</b>	The Microstream MCable is disconnected from the monitor.	Reconnect the Microstream MCable to the monitor.
!	<b>CO<sub>2</sub> MCable failure</b>	<p>The Microstream MCable hardware has failed due to an internal issue including:</p> <ul style="list-style-type: none"> <li>– a corrupt EPROM (erasable programmable read-only memory) chip</li> <li>– a compromised flow rate that caused the auto-zero procedure to fail.</li> </ul>	Contact specialized service personnel.
!	<b>CO<sub>2</sub> MCable: Gas outlet blocked</b>	The Microstream MCable gas outlet is blocked.	<ul style="list-style-type: none"> <li>– Ensure that the gas outlet is not blocked.</li> <li>– Contact specialized service personnel.</li> </ul>

<sup>1)</sup> In the parameter field the parameter value is replaced by \*\*\*

Priority	Message	Cause	Remedy
!!	<b>CO<sub>2</sub> warming up</b>	The Microstream MCable is completing its warm-up cycle.	<ul style="list-style-type: none"> <li>– Wait for the Microstream MCable to warm up. During warm-up, the accuracy is reduced.</li> <li>– If the message persists longer than 15 min. after the sensor has warmed up, and the ambient temperature is above 10 °C (50 °F), contact specialized service personnel.</li> <li>– You cannot zero the sensor while this message is displayed and the ambient temperature is above 10 °C (50 °F).</li> <li>– When the ambient temperature is below 10 °C (50 °F), the message can display longer than 15 minutes. In this case, it is possible to zero the sensor after the message has been displayed for at least 10 minutes.</li> </ul>
None	<b>CO<sub>2</sub> zeroing in progress</b>	The Microstream MCable is being reset to zero.	Informational message – no action required.
!!	<b>etCO<sub>2</sub> &gt;</b> (alarm limit) <b>etCO<sub>2</sub> &lt;</b> (alarm limit) (except inCO <sub>2</sub> )	The parameter value is above/below the set upper/lower alarm limits.	<ul style="list-style-type: none"> <li>– Check the patient and treat, if necessary.</li> <li>– Change the alarm limits.</li> </ul>
!!!	<b>RRc apnea</b>	Apnea was detected.	<ul style="list-style-type: none"> <li>– Check the patient and treat, if necessary.</li> <li>– Check the placement of sensor.</li> </ul>
!!	<b>RRc out of range high</b>	The parameter signal is outside the measuring range of the monitor.	<ul style="list-style-type: none"> <li>– Check the patient and treat if necessary.</li> <li>– Check the equipment and replace if necessary.</li> </ul>

**Sample line**

<b>Priority</b>	<b>Message</b>	<b>Cause</b>	<b>Remedy</b>
!	<b><i>Sample line is being cleared</i></b>	A sample line blockage occurred and the Microstream MCable is attempting to clear the sample line.	Informational message – no action required.
!	<b><i>Sample line blocked</i></b>	The sample line is blocked during the purging process.	Replace the sample line.
!	<b><i>Sample line disconnected</i></b>	The sample line is disconnected from the Microstream MCable.	Securely connect the sample line to the Microstream MCable.

## Scio

### CAUTION

Risk due to gas measurement failure

If gas measurement fails, the patient can no longer be adequately monitored.

- Ensure corresponding substitute monitoring.
- Check sample line and water trap for damage or blockage and resolve these as needed.
- Observe the prescribed exchange intervals.

### Alarm - Cause - Remedy

If an alarm occurs, the table helps to quickly identify causes and remedies. The possible causes and remedial measures should be consulted in the order in which they are listed until the alarm is resolved.

The following table lists the alarm messages in alphabetical order.

Alarm Priority	Alarm	Cause	Remedy
Medium	<b>[agent] out of range high</b>	Agent concentration has exceeded the Scio upper limit of the measurement range.	Check vaporizer, fresh-gas settings, and ventilation
Low	<b>Agent reduced accuracy</b>	<p>Accuracy of the Agent sensor cannot currently be guaranteed.</p> <p><b>NOTE</b></p> <p>This alarm occurs only on gas analyzers with manual agent identification.</p>	<ul style="list-style-type: none"> <li>– Ensure clean ambient air</li> <li>– Check water trap and sample line.</li> <li>– Change the water trap or sample line if necessary.</li> <li>– Wait for automatic zeroing.</li> <li>– Power cycle the gas analyzer.</li> <li>– Call specialized service personnel.</li> </ul>
Low	<b>Agent sensor failure</b>	<p>The Agent sensor measurement has failed due to:</p> <ul style="list-style-type: none"> <li>– Sample line occlusion.</li> <li>– Electrical disturbance.</li> <li>– Internal failure.</li> </ul>	<ul style="list-style-type: none"> <li>– Check sample line.</li> <li>– Remove radiating devices (e.g., telephone).</li> <li>– Use alternative agent measurement system.</li> <li>– Call specialized service personnel.</li> </ul>

Alarm Priority	Alarm	Cause	Remedy
Low	<b>Agent value temporarily unavail.</b>	Agent parameter has unknown accuracy or automatic identification is taking more time than usual, possibly due to: <ul style="list-style-type: none"> <li>– Zeroing failure</li> <li>– Polluted ambient air during zeroing.</li> <li>– Electromagnetic disturbances.</li> <li>– Overheating.</li> </ul>	<ul style="list-style-type: none"> <li>– Ensure clean ambient air.</li> <li>– Remove radiating devices (e.g., telephone).</li> <li>– Check ambient temperature.</li> <li>– Change the water trap or sample line if necessary.</li> <li>– Power cycle Scio.</li> <li>– Change vaporizer settings.</li> <li>– Call specialized service personnel.</li> </ul>
Low	<b>Check water trap/sample line</b>	<ul style="list-style-type: none"> <li>– Sample line is blocked or not connected.</li> <li>– Water trap is full or not installed.</li> </ul>	<ul style="list-style-type: none"> <li>– Check sample line.</li> <li>– Check water trap.</li> </ul>
Medium	<b>CO<sub>2</sub> out of range high</b>	CO <sub>2</sub> concentration has exceeded the Scio upper limit of the measurement range.	Check vaporizer, fresh-gas settings and ventilation.
Low	<b>CO<sub>2</sub> reduced accuracy</b>	Accuracy of the CO <sub>2</sub> sensor cannot currently be guaranteed.	<ul style="list-style-type: none"> <li>– Ensure clean ambient air</li> <li>– Check water trap and sample line.</li> <li>– Change the water trap or sample line if necessary.</li> <li>– Wait for automatic zeroing.</li> <li>– Power cycle the gas analyzer.</li> <li>– Call specialized service personnel.</li> </ul>

Alarm Priority	Alarm	Cause	Remedy
Low	<b>CO<sub>2</sub> sensor failure</b>	The CO <sub>2</sub> sensor in patient gas measurement module has failed due to: <ul style="list-style-type: none"> <li>– Sample line occlusion.</li> <li>– Electrical disturbance.</li> <li>– Internal failure.</li> </ul>	<ul style="list-style-type: none"> <li>– Check sample line.</li> <li>– Remove radiating devices (e.g., telephone).</li> <li>– Use alternative CO<sub>2</sub> measurement system.</li> <li>– Call specialized service personnel.</li> </ul>
Low	<b>et[agent] &lt; #</b> <b>NOTE</b> This alarm occurs only for the primary agent.	<ul style="list-style-type: none"> <li>– Expiratory anesthetic gas concentration has fallen below the lower alarm limit for more than 15 seconds.</li> <li>– Soda lime is dried out.</li> </ul>	<ul style="list-style-type: none"> <li>– Check vaporizer and fresh-gas settings.</li> <li>– Check breathing system for large leaks.</li> <li>– Exchange soda lime.</li> </ul>
Medium	<b>et[agent] &gt; #</b> <b>NOTE</b> This alarm occurs only for the primary agent.	Expiratory anesthetic gas concentration has exceeded the upper alarm limit for more than 15 seconds.	Check vaporizer and fresh-gas settings
Medium	<b>etCO<sub>2</sub> &lt; #</b>	Expiratory CO <sub>2</sub> has fallen below the limit for more than 15 seconds.	Check ventilation.
Medium	<b>etCO<sub>2</sub> &gt; #</b>	Expiratory CO <sub>2</sub> has exceeded the limit for more than 15 seconds.	Check ventilation.
Medium	<b>etO<sub>2</sub> &lt; #</b>	Expiratory O <sub>2</sub> concentration has fallen below the lower alarm limit for more than 15 seconds.	<ul style="list-style-type: none"> <li>– Check O<sub>2</sub> concentration and fresh-gas settings</li> <li>– Check breathing system for large leaks.</li> <li>– Check O<sub>2</sub> supply.</li> </ul>
Medium	<b>etO<sub>2</sub> &gt; #</b>	Expiratory O <sub>2</sub> concentration has exceeded the upper alarm limit for more than 15 seconds.	Check O <sub>2</sub> concentration and fresh-gas settings.

Alarm Priority	Alarm	Cause	Remedy
High	<b><i>FiO<sub>2</sub> &lt; #</i></b>	Inspiratory O <sub>2</sub> concentration has fallen below the lower alarm limit: <ul style="list-style-type: none"> <li>– At least 15 seconds (with respiratory phases).</li> <li>– At least 30 seconds (without respiratory phases).</li> </ul>	<ul style="list-style-type: none"> <li>– Check O<sub>2</sub> concentration and fresh-gas settings</li> <li>– Check breathing system for large leaks.</li> <li>– Check O<sub>2</sub> supply.</li> </ul>
Medium	<b><i>FiO<sub>2</sub> &gt; #</i></b>	Inspiratory O <sub>2</sub> concentration has exceeded the upper alarm limit for more than 15 seconds.	Check O <sub>2</sub> concentration and fresh-gas settings.
Medium	<b><i>Gas sensor failure</i></b>	The patient-gas measurement has failed due to: <ul style="list-style-type: none"> <li>– Sample line occlusion.</li> <li>– Electrical disturbance.</li> <li>– Internal failure.</li> </ul>	<ul style="list-style-type: none"> <li>– Check sample line.</li> <li>– Remove radiating devices (e.g., telephone).</li> <li>– Use alternative gas measurement system.</li> <li>– Call specialized service personnel.</li> </ul>
Low	<b><i>Gas sensor reduced accuracy</i></b>	Accuracy of the gas measurements cannot be guaranteed.	<ul style="list-style-type: none"> <li>– Ensure clean ambient air</li> <li>– Check water trap and sample line.</li> <li>– Change the water trap or sample line if necessary.</li> <li>– Wait for automatic zeroing.</li> <li>– Power cycle the gas analyzer.</li> <li>– Call specialized service personnel.</li> </ul>

Alarm Priority	Alarm	Cause	Remedy
Low	<p><b><i>in[agent] &lt; #</i></b></p> <p><b>NOTE</b> This alarm occurs only for the primary agent.</p>	<ul style="list-style-type: none"> <li>– Inspiratory anesthetic gas concentration has fallen below the lower alarm limit for more than 15 seconds.</li> <li>– Soda lime is dried out.</li> </ul>	<ul style="list-style-type: none"> <li>– Check vaporizer and fresh-gas settings.</li> <li>– Check breathing system for large leaks.</li> <li>– Exchange soda lime.</li> </ul>
Medium	<p><b><i>in[agent] &gt; #</i></b></p> <p><b>NOTES</b> This alarm occurs only for the primary agent.</p>	<p>Inspiratory anesthetic gas concentration has exceeded the upper alarm limit:</p> <ul style="list-style-type: none"> <li>– At least 15 seconds (with respiratory phases).</li> <li>– At least 30 seconds (without respiratory phases).</li> </ul>	<p>Check vaporizer and fresh-gas settings.</p>
Medium	<p><b><i>inN<sub>2</sub>O &gt; 82</i></b></p> <p><b>NOTE</b> This alarm is suppressed if any of the following alarms is active:</p> <ul style="list-style-type: none"> <li>– <b><i>Scio is not connected</i></b></li> <li>– <b><i>Gas sensor failure</i></b></li> <li>– <b><i>N<sub>2</sub>O sensor failure</i></b></li> <li>– <b><i>Sample line blocked</i></b></li> </ul>	<p>Inspired N<sub>2</sub>O is less than 82 %:</p> <ul style="list-style-type: none"> <li>– At least 15 seconds (with respiratory phases).</li> <li>– At least 30 seconds (without respiratory phases).</li> </ul>	<p>Check fresh-gas composition.</p>

Alarm Priority	Alarm	Cause	Remedy
Medium	<b>inCO<sub>2</sub> &gt; #</b>	<p>Inspired CO<sub>2</sub> has exceeded the limit for more than 15 seconds possibly due to one of the following:</p> <ul style="list-style-type: none"> <li>– Soda lime is depleted.</li> <li>– Leakage in breathing system.</li> <li>– Gas measurement is inaccurate due to high respiratory rate.</li> <li>– Large dead space.</li> </ul>	<ul style="list-style-type: none"> <li>– Check soda lime.</li> <li>– Increase fresh-gas flow.</li> <li>– Check fresh-gas settings.</li> <li>– Replace the breathing system.</li> <li>– Adjust alarm limits if necessary.</li> <li>– Check ventilation settings.</li> </ul>
Medium	<b><i>Inspiratory xMAC high</i></b>	<ul style="list-style-type: none"> <li>– The inspiratory anesthetic gas concentration has exceeded 5 xMAC</li> </ul> <p>or, while the patient is breathing:</p> <ul style="list-style-type: none"> <li>– The inspiratory anesthetic gas concentration has exceeded 3 xMAC for more than 30 seconds,</li> <li>– The expiratory anesthetic gas concentration has exceeded 2.5 xMAC for more than 30 seconds.</li> </ul>	Check vaporizer and fresh-gas settings.
High	<b><i>Inspiratory xMAC high</i></b>	<ul style="list-style-type: none"> <li>– The inspiratory anesthetic gas concentration has exceeded 3 xMAC for more than 30 seconds,</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>– while the patient is breathing, the expiratory anesthetic gas concentration has exceeded 2.5 xMAC for more than 30 seconds.</li> </ul> <p>or</p> <ul style="list-style-type: none"> <li>– The inspiratory anesthetic gas concentration has exceeded 5 xMAC.</li> </ul>	Check vaporizer and fresh-gas settings.

Alarm Priority	Alarm	Cause	Remedy
Medium	<b><i>N<sub>2</sub>O out of range high</i></b>	N <sub>2</sub> O concentration has exceeded the Scio upper limit of the measurement range.	Check vaporizer, fresh-gas settings and ventilation.
Low	<b><i>N<sub>2</sub>O reduced accuracy</i></b>	Accuracy of the N <sub>2</sub> O sensor cannot currently be guaranteed.	<ul style="list-style-type: none"> <li>– Ensure clean ambient air</li> <li>– Check water trap and sample line.</li> <li>– Change the water trap or sample line if necessary.</li> <li>– Wait for automatic zeroing.</li> <li>– Power cycle the gas analyzer.</li> <li>– Call specialized service personnel.</li> </ul>
Low	<b><i>N<sub>2</sub>O sensor failure</i></b>	<p>The N<sub>2</sub>O sensor in the patient-gas measurement module has failed due to:</p> <ul style="list-style-type: none"> <li>– Sample line occlusion.</li> <li>– Electrical disturbance.</li> <li>– Internal failure.</li> </ul>	<ul style="list-style-type: none"> <li>– Check sample line.</li> <li>– Remove radiating devices (e.g., telephone).</li> <li>– Use alternative N<sub>2</sub>O measurement system.</li> <li>– Call specialized service personnel.</li> </ul>

Alarm Priority	Alarm	Cause	Remedy
Low	<b><i>N<sub>2</sub>O value temporarily unavail.</i></b>	<p>N<sub>2</sub>O parameter has unknown accuracy possibly due to:</p> <ul style="list-style-type: none"> <li>– Zeroing failure.</li> <li>– Polluted ambient air during zeroing.</li> <li>– Electromagnetic disturbances.</li> <li>– Overheating.</li> </ul>	<ul style="list-style-type: none"> <li>– Ensure clean ambient air.</li> <li>– Remove radiating devices (e.g., telephone).</li> <li>– Check ambient temperature.</li> <li>– Check water trap and sample line.</li> <li>– Change the water trap or sample line if necessary.</li> <li>– Power cycle the gas analyzer.</li> <li>– Call specialized service personnel.</li> </ul>
Medium	<b><i>O<sub>2</sub> out of range high</i></b>	O <sub>2</sub> concentration has exceeded the Scio upper limit of the measurement range.	Check vaporizer, fresh-gas settings and ventilation.
Low	<b><i>O<sub>2</sub> reduced accuracy</i></b>	Accuracy of the O <sub>2</sub> sensor cannot currently be guaranteed.	<ul style="list-style-type: none"> <li>– Ensure clean ambient air</li> <li>– Check water trap and sample line.</li> <li>– Change the water trap or sample line if necessary.</li> <li>– Wait for automatic zeroing.</li> <li>– Power cycle the gas analyzer.</li> <li>– Call specialized service personnel.</li> </ul>

Alarm Priority	Alarm	Cause	Remedy
Medium	<b><i>O<sub>2</sub> sensor failure</i></b>	The O <sub>2</sub> sensor in the patient-gas measurement module has failed due to: <ul style="list-style-type: none"> <li>– Sample line occlusion.</li> <li>– Electrical disturbance.</li> <li>– Internal failure.</li> </ul>	<ul style="list-style-type: none"> <li>– Use alternative O<sub>2</sub> measurement system.</li> <li>– Call specialized service personnel.</li> </ul>
Low	<b><i>O<sub>2</sub> value temporarily unavail.</i></b>	O <sub>2</sub> parameter has unknown accuracy, possibly due to: <ul style="list-style-type: none"> <li>– Polluted ambient air during zeroing.</li> <li>– Electromagnetic disturbances.</li> <li>– Overheating.</li> </ul>	<ul style="list-style-type: none"> <li>– Ensure clean ambient air.</li> <li>– Remove radiating devices (e.g., telephone).</li> <li>– Check ambient temperature.</li> <li>– Check water trap and sample line.</li> <li>– Change the water trap or sample line if necessary.</li> <li>– Wait for auto zeroing to complete.</li> <li>– Power cycle the gas analyzer.</li> <li>– Change vaporizer settings.</li> <li>– Call specialized service personnel.</li> </ul>
Medium	<b><i>RRc &gt; #</i></b>	Respiratory rate has exceeded the limit.	Check ventilation.
Medium	<b><i>RRc &lt; #</i></b>	Respiratory rate is below the limit.	Check ventilation.

Alarm Priority	Alarm	Cause	Remedy
Medium	<b>RRc apnea</b>	No breathing or ventilation.	<ul style="list-style-type: none"> <li>– Start manual ventilation.</li> <li>– Check ventilation settings.</li> <li>– Check spontaneous breathing ability of the patient</li> </ul>
		Sample line is not connected.	Connect sample line to breathing circuit.
Medium	<b>RRc out of range high</b>	RRc has exceeded the upper limit of the measurement range of the Scio.	Check vaporizer, fresh-gas settings and ventilation.
Low	<b>Sample line blocked</b>	Sample line or patient-side filter is occluded.	Check sample line, water trap, and patient-side filter.
Medium	<b>Scio is not connected</b>	Scio module disconnected or turned off.	Connect the Scio module or turn it on.
Low	<b>Scio unavailable for neonates</b>	<ul style="list-style-type: none"> <li>– Scio is plugged in while the M540 is already in neonate mode.</li> <li>– M540 is switched to neonate mode while Scio is already plugged in.</li> </ul>	<ul style="list-style-type: none"> <li>– Connect an alternate CO2 monitor (e.g., Mainstream or Microstream) if CO2 monitoring is desired in neonate mode.</li> <li>– Switch the M540 out of neonate mode in order to continue Scio monitoring.</li> </ul>
Low	<b>Scio warming up: Accur. low</b>	Accuracy is not guaranteed while Scio is warming up.	Wait for the Scio module to warm up.
Low	<b>Second agent detected</b>  <b>NOTE</b> This alarm occurs only on gas analyzers with automatic agent identification.	A second anesthetic agent has been detected.  <b>NOTE</b> This alarm could be an expected clinical behavior if the clinician regularly uses two agents as part of the process.	<ul style="list-style-type: none"> <li>– Wait for the transition phase to end after changing anesthetic agents.</li> <li>– Flush the system if necessary.</li> <li>– Check fresh-gas settings.</li> </ul>

Alarm Priority	Alarm	Cause	Remedy
Medium	<p><b>Third agent detected</b></p> <p><b>NOTE</b> This alarm occurs only on gas analyzers with automatic agent identification.</p>	<p>A mixture of three or more anesthetic agents has been detected, possibly as a result of:</p> <ul style="list-style-type: none"> <li>– A change of the anesthetic agent during monitoring</li> <li>– Electromagnetic interference</li> <li>– The use of inhalants or sprays (e.g., albuterol)</li> </ul>	<ul style="list-style-type: none"> <li>– Wait for the transition phase to end after changing anesthetic agents.</li> <li>– Flush the system if necessary.</li> <li>– Check fresh-gas settings.</li> <li>– Check for electromagnetic radiation in the vicinity.</li> </ul>
Low	<p><b>Water trap is full</b></p>	<ul style="list-style-type: none"> <li>– Water trap is full.</li> <li>– Sample line is occluded.</li> </ul>	<ul style="list-style-type: none"> <li>– Check water trap.</li> <li>– Check sample line, water trap, and patient-side filter.</li> </ul>
Medium	<p><b>xMAC out of range high</b></p>	<p>Indicates that the expiratory xMAC is out of range high when:</p> <ul style="list-style-type: none"> <li>– Primary agent, secondary agent, and/or N2O are out of range high.</li> </ul> <p>or</p> <ul style="list-style-type: none"> <li>– Expiratory xMAC exceeds 10.</li> </ul>	<p>Check vaporizer, fresh-gas settings, and ventilation.</p>

**Status Messages**

Message	Condition	Suggested action
<p><b>Scio zeroing is in progress</b></p>	<p>Zeroing cycle in progress.</p>	<p>Wait for zeroing cycle to complete.</p>

## Reprocessing

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## Reprocessing

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This chapter provides information for the reprocessing of M540 device-specific components and accessories.

For cleaning instructions regarding devices that connect to the IACS, refer to the instructions for use entitled *Infinity Acute Care System – Monitoring applications* (Software VG8.0).

For specific cleaning instructions regarding the Infinity Medical Cockpits, refer to the instructions for use entitled *Infinity Acute Care System – Infinity Medical Cockpits*.

## Safety Information

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### WARNING

**Risk due to inappropriately reprocessed products**

**Reusable products must be reprocessed, otherwise there is an increased risk of infection.**

- **Follow the infection prevention policies and reprocessing regulations of the health-care facility.**
- **Follow the national infection prevention policies and reprocessing regulations.**
- **Use validated procedures for reprocessing.**
- **Reprocess reusable products after every use.**
- **Follow the manufacturer's instructions for cleaning agents, disinfectants, and reprocessing devices.**

### CAUTION

Risk due to faulty products

- Signs of wear, e.g., cracks, deformation, discoloration, or peeling, may occur with reprocessed products.
- Check the products for signs of wear and replace them if necessary.

## Information on reprocessing

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Follow the national infection prevention policies and reprocessing regulations.

Follow the infection prevention policies and reprocessing regulations of the health-care facility (e.g., concerning the reprocessing cycles).

## Classification for reprocessing

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### Classification of medical devices

The classification depends on the intended use of the medical device. The risk of infection transmission through the application of the product to the patient without proper reprocessing is the basis of the Spaulding classification.

Classification	Explanation
Non-critical	Components that come only into contact with skin that is intact
Semi-critical	Components that carry breathing gas or come into contact with mucous membranes or pathologically altered skin
Critical	Components that penetrate skin or mucous membranes or come into contact with blood

### Classification of device-specific components

The following classification is a recommendation from Dräger.

#### Non-critical

- Device surface
- Mounting and holders
- Modules
- Removable parts of the main device

#### Semi-critical

- None

#### Critical

- None

## Before reprocessing

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### WARNING

**A risk of an electric shock might occur due to penetrating liquid. Follow the instructions below to disconnect power before reprocessing.**

### Observe before disassembly

- 1 Switch off the device and all devices connected to it.
- 2 To turn the monitor off, press and hold the power key for two seconds.

The power indicator light turns dark, and the monitor emits a power-down tone.

- 3 Disconnect all power plugs, modules, or other devices.
- 4 Remove cables and patient-specific accessories for cleaning.
- 5 Un-dock the monitor from the mount for cleaning.

### Patient-specific accessories and consumables

The patient-specific accessories and consumables must be removed from the device and, if necessary, disassembled.

#### Reusable products:

- If the reusable product has its own instructions for use, perform reprocessing in accordance with the separate instructions for use. Further information can be found in the list of accessories.
- If no separate instructions for use are available for the reusable product, perform reprocessing in accordance with these instructions for use (see "Reprocessing of patient-specific accessories" on page 377).

#### Disposable products:

- Dispose of the disposable products.

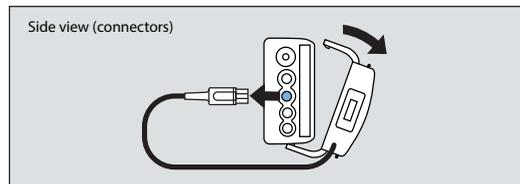
#### WARNING

**Disposable accessories (such as disposable electrodes) are for single-use only. Do not reuse disposable accessories.**

#### Removing the accessories

- MCable

The following diagram shows how a SpO2 MCable can be removed from the M540.



## Validated reprocessing procedures

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### Overview of the reprocessing procedures of the components

Components	Surface Disinfection with cleaning	Manual cleaning followed by disinfection by immersion	Machine cleaning with thermal disinfection	Steam sterilization	Description of the procedure
Device surface	Yes	N/A	N/A	N/A	See "Surface disinfection with cleaning" on page 373.
Mounting and holders	Yes	N/A	N/A	N/A	
Modules	Yes	N/A	N/A	N/A	
Removable parts of the main device	Yes	N/A	N/A	N/A	

### Surface disinfection with cleaning

#### Components:

- Device surface
- Mounting and holders
- Modules
- Removable parts of the main device

Surface disinfectant	Manufacturer	Concentration	Contact time
Dismozon plus	BODE Chemie	1.6 %	15 min
Oxycide	Ecolab USA	2.3 %	5 min

**Prerequisites:**

- The surface disinfectant has been prepared in accordance with the manufacturer's instructions.
- The manufacturer's instructions, e.g., regarding shelf life or application conditions, are observed.
- An uncontaminated, lint-free cloth soaked in surface disinfectant is used for the cleaning surface disinfection.

**WARNING**

**Risk of electric shock and device malfunction.**

**Penetrating liquid may cause the following:**

- Damage to the device
- Electric shock
- Device malfunctions

**Ensure that no liquid penetrates the device.**

**WARNING**

**Do not immerse or rinse the device and its peripherals. If you spill liquid on the device (including the battery or accessories), or accidentally immerse it in liquid, allow contacts to thoroughly dry.**

**CAUTION**

Do not use excessive pressure when cleaning the device and accessories. Excessive pressure can damage the components.

**CAUTION**

Do not steam autoclave, gas sterilize, or immerse the components in liquid or cleaning solutions. Do not subject the components to intense vacuum.

**WARNING**

**Risk of cross contamination:**

**Perform every step of the instructions below for each of the components:**

- Device surface
- Mounting and holders
- Modules
- Removable parts of the main device

**Failure to do so can lead to infection.**

**Cleaning**

- 1 Wipe off obvious soiling with a disposable cloth soaked in surface disinfectant.
- 2 Dispose of the cloth.
- 3 Thoroughly clean all surfaces with a new disposable cloth soaked in surface disinfectant. Inspect the product for any remaining visible soiling. If soiling is present, repeat the cleaning steps.

**Surface disinfection**

- 4 Take a new disposable cloth soaked in surface disinfectant. Wipe cleaned surfaces again until all surfaces to be disinfected are visibly wet.
- 5 Wait for the surface disinfectant contact time.
- 6 At the end of the contact time, moisten a new, uncontaminated and lint-free cloth with water (at least drinking water quality).
- 7 Wipe all surfaces until no remains of the surface disinfectant, such as foam residues or streaks, are visible.
- 8 Wait until the surfaces are dry.
- 9 Check the surfaces for visible damage and, if necessary, replace the product.

## Storage and transport

After reprocessing, there are no special requirements for the storage and transport of the product. However, the following must be observed:

- Store dry and free of dust.
- Avoid recontamination and damage during transport.

All further information on storage and transport included in the accompanying documents must be observed.

## Other agents and reprocessing procedures

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### Disinfectants

Use nationally approved disinfectants suitable for the respective reprocessing process and the intended application.

### Surface disinfectants

Follow the manufacturer's instructions for surface disinfectants.

The following surface disinfectants were compatible with the material at the time of testing:

Class of active ingredient	Surface disinfectant	Manufacturer	Listing
Chlorine-releasing agents	Clorox Professional Disinfecting Bleach Cleaner	Clorox Professional Products Company	EPA <sup>1)</sup>
	Dispatch Hospital Cleaner Disinfectant Towels with Bleach		
	Actichlor plus	Ecolab	–
	Chlor-Clean Tablets	helix Solution	–
	Chloricide +	Sky Chemicals	–
	Chlorine Disinfectant Wipes	Medipal	–
	Lierkang type II disinfection effervescent tablet	Lircon	–
	JIANZHISU disinfection effervescent tablets	JIANZHISU	–

Class of active ingredient	Surface disinfectant	Manufacturer	Listing
Oxygen-releasing agents	Descogen Liquid	Antiseptica	CE
	Descogen Liquid r.f.u.		
	Oxygenon Liquid		
	Oxygenon r.f.u.		
	Dismozon plus	BODE Chemie	CE
	Oxycide	Ecolab US	EPA
	Perform	Schülke +	CE
	SteriMax Wipes	Aseptix (Ecolab)	CE
	Incidin OxyWipe	Ecolab	CE
	Incidin OxyWipe XL		
	Rubysta	Kyroin (Japan)	–
	Rely+On Virkon	LANXESS Corporation	EPA
	Perisept 62	Triple S	EPA
	Accel PREvention RTU	Diversey	DIN <sup>2)</sup>
	Accel PREvention Wipes		
Oxivir Excel Wipes	Diversey	ARTG <sup>3)</sup>	
Quaternary ammonium compounds	acryl-des	Schülke +	CE
	mikrozid alcohol free liquid		
	mikrozid alcohol free wipes		
	mikrozid sensitive liquid		
	mikrozid sensitive wipes		
	Cleanisept Wipes "Maxi"	Dr. Schumacher	CE
	Surfa'Safe Premium	Laboratoires ANIOS	CE
	WIP' ANIOS EXCEL		
	Tuffie 5	Vernacare	–
	Medizar Hospital Grade Surface Disinfectant Wipes	Ainsworth Medical	–
Premier Disinfectant Wipes	Reynard	–	

1) United States Environmental Protection Agency

2) Drug Identification Number

3) Australian Register of Therapeutic Goods (classified as class IIb)

Dräger states that oxygen-releasing agents and chlorine-releasing agents may cause color change in some materials. Color change does not indicate

that the product is not functioning correctly.

Other surface disinfectants are used at one's own risk.

Dräger makes no statement about the effectiveness or the current approval status of these products

## Reprocessing of patient-specific accessories

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### Categorization of accessories

Category	Classification	Description of the procedure
ECG lead wires	Non-Critical	See "Surface disinfection with cleaning" on page 377.
SpO2 intermediate cables and sensor	Non-Critical	
Temperature cable and probes	Non-Critical	
IBP cables and adapters	Non-Critical	
Cardiac Output cables	Non-Critical	
NIBP blood pressure cuffs and hoses	Non-Critical	
Microstream CO2 sensor	Non-Critical	
Hemodynamic pods	Non-Critical	
Miscellaneous adapters	Non-Critical	
System cables	Non-Critical	

For part numbers associated with each accessory, see the instructions for use entitled *Infinity Acute Care System - Monitoring accessories*.

**Reprocessing of the categories ECG lead wires, SpO2 intermediate cables and sensor, Temperature cable and probes, IBP cables and adapters, Cardiac output cables, NIBP cuffs and hoses, CO2 sensors and airway adapters, Hemodynamic pods, Adapters, System cables**

### Surface disinfection with cleaning

Surface disinfectant	Manufacturer	Concentration	Contact time
Dismozon plus	BODE Chemie	1.6 %	15 min
Oxycide	Ecolab USA	2.3 %	5 min

#### Prerequisites:

- The surface disinfectant has been prepared in accordance with the manufacturer's instructions.
- The manufacturer's instructions, e.g., regarding shelf life or application conditions, are observed.

- An uncontaminated, lint-free cloth soaked in surface disinfectant is used for the cleaning surface disinfection.

**WARNING**

**Risk due to penetrating liquid.**

**WARNING**

**Risk of electric shock and device malfunction.**

**Penetrating liquid may cause the following:**

- Damage to the device
- Electric shock
- Device malfunctions

**Ensure that no liquid penetrates the device.**

**CAUTION**

To avoid damaging the device, do not use sharp tools or abrasives. Never immerse electrical connectors in water or other liquids.

**CAUTION**

Do not autoclave accessories.

**CAUTION**

Do not use excessive pressure or flex patient cables unnecessarily when cleaning. Excessive pressure can damage the patient cables.

**Cleaning**

- 1 Wipe off obvious soiling with a disposable cloth soaked in surface disinfectant.
- 2 Dispose of the cloth.
- 3 Thoroughly clean all surfaces with a new disposable cloth soaked in surface disinfectant. Inspect the product for any remaining visible soiling. If soiling is present, repeat the cleaning steps.

**Surface disinfection**

- 4 Take a new disposable cloth soaked in surface disinfectant. Wipe cleaned surfaces again until all surfaces to be disinfected are visibly wet.
- 5 Wait for the surface disinfectant contact time.

- 6 At the end of the contact time, moisten a new, uncontaminated and lint-free cloth with water (at least drinking water quality).
- 7 Wipe all surfaces until no remains of the surface disinfectant, such as foam residues or streaks, are visible.
- 8 Wait until the surfaces are dry.
- 9 Check the surfaces for visible damage and, if necessary, replace the product.

**Storage and transport**

After reprocessing, there are no special requirements for the storage and transport of the product. However, the following must be observed:

- Store dry and free of dust.
- Avoid recontamination and damage during transport.

All further information on storage and transport included in the accompanying documents must be observed.

**Other agents and reprocessing procedures****Disinfectants**

Use nationally approved disinfectants suitable for the respective reprocessing process and the intended application.

**Surface disinfectants**

Follow the manufacturer's instructions for surface disinfectants.

The following surface disinfectants were compatible with the material at the time of testing:

<b>Class of active ingredient</b>	<b>Surface disinfectant</b>	<b>Manufacturer</b>	<b>Listing</b>
Chlorine-releasing agents	Clorox Professional Disinfecting Bleach Cleaner	Clorox Professional Products Company	EPA <sup>1)</sup>
	Dispatch Hospital Cleaner Disinfectant Towels with Bleach		
	Actichlor plus	Ecolab	–
	Chlor-Clean Tablets	helix Solution	–
	Chloricide +	Sky Chemicals	–
	Chlorine Disinfectant Wipes	Medipal	–
	Lierkang type II disinfection effervescent tablets	Lircon	–
	JIANZHISU disinfection effervescent tablets	JIANZHISU	–
Oxygen-releasing agents	Descogen Liquid	Antiseptica	CE
	Descogen Liquid r.f.u.		
	Oxygenon Liquid		
	Oxygenon r.f.u.		
	Dismozon plus	BODE Chemie	CE
	Oxycide	Ecolab US	EPA
	Perform	Schülke +	CE
	SteriMax Wipes	Aseptix (Ecolab)	CE
	Incidin OxyWipe	Ecolab	CE
	Incidin OxyWipe XL		
	Rubysta	Kyroin (Japan)	–
	Rely+On Virkon	LANXESS Corporation	EPA
	Perisept 62	Triple S	EPA
	Accel PREvention RTU	Diversey	DIN <sup>2)</sup>
	Accel PREvention Wipes		
Oxivir Excel Wipes	Diversey	ARTG <sup>3)</sup>	

Class of active ingredient	Surface disinfectant	Manufacturer	Listing
Quaternary ammonium compounds	acryl-des	Schülke +	CE
	mikrozid alcohol free liquid		
	mikrozid alcohol free wipes		
	mikrozid sensitive liquid		
	mikrozid sensitive wipes		
	Cleanisept Wipes "Maxi"	Dr. Schumacher	CE
	Surfa'Safe Premium	Laboratoires ANIOS	CE
	WIP'ANIOS EXCELI		
	Tuffie 5	Vernacare	–
	Medizar Hospital Grade Surface Disinfectant Wipes	Ainsworth Medical	–
Premier Disinfectant Wipes	Reynard	–	

- 1) United States Environmental Protection Agency
- 2) Drug Identification Number
- 3) Australain Register of THerapeutic Goods (classifiedas class IIb)

Dräger states that oxygen-releasing agents and chlorine-releasing agents may cause color change in some materials. Color change does not indicate that the product is not functioning correctly.

Other surface disinfectants are used at one's own risk.

Dräger makes no statement about the effectiveness or the current approval status of these products.

## After reprocessing

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### Assembling and fitting device-specific components

#### Prerequisite:

- All components have been reprocessed and dried.

After the equipment is cleaned, inspect it and ensure that the monitor is in good working condition. To do this, follow the guidelines below:

- Make sure that the environment and power supply meet specifications.

- Inspect all power cords for damage, and make sure that the insulation is in good condition.
- Inspect the equipment and its accessories for mechanical damage. In case of any damage or abnormality, do not use the equipment. Contact the hospital's biomedical engineers or your service personnel immediately.
- Turn on the monitor and reconnect it to the AC power.

- Make sure that only specified accessories are applied: NIBP air hose and cuff, Massimo SpO2 cable or Nellcor SpO2 cable, and ECG cable. For the part numbers, refer to the instructions for use entitled *Infinity Acute Care System - Monitoring accessories*.

## Preparation before next use of device

### Assembling and fitting patient-specific accessories and consumables

- Make sure that the battery meets the performance requirements. In case of battery performance issues contact the hospital's biomedical engineers or your service personnel immediately.

### Checking the operational readiness

#### Prerequisite:

- The device has been assembled and prepared so that it is ready for operation.

#### Procedure:

- Check the operational readiness. For more information, see "Getting started" on page 99.

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## Disposal

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## EU Directive 2002/96/EC (WEEE)

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This device is subject to EU Directive 2002/96/EC (WEEE). It is not registered for use in private households, and may not be disposed of at municipal collection points for waste of electrical and electronic equipment. Dräger has authorized a firm to dispose of this device in the proper manner. For more detailed information, please contact your local Dräger organization.

### **M540 and M500**

All materials must be disposed of or recycled properly and in accordance with local regulations. There are no known special disposal requirements for any accessories.

### **Disposal of Accessories**

When disposing accessories, observe the hospital infection prevention guidelines and the respective instructions for use.

## Secure decommissioning

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Before disposing of an M540, contact DrägerService or specialized service personnel for information on sanitizing the product to remove sensitive, confidential, and proprietary data and software.

## Maintenance

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## Overview

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This chapter describes the maintenance measures required to maintain the functional integrity of the medical device. Maintenance measures must be performed by the responsible personnel.

### WARNING

#### Risk of infection

**Users and service personnel can become infected with pathogens.**

**Disinfect and clean the device or the components before any maintenance measures and also before returning the medical device for repair.**

### WARNING

#### Risk of electric shock

**Current-carrying components are located under the cover.**

- **Do not remove the cover.**
- **Maintenance measures must be performed by the responsible personnel. Dräger recommends specialized service personnel performs these measures.**

### WARNING

**If the device is mechanically damaged, or if it is not working properly, do not use it. Contact your hospital's service personnel.**

### WARNING

**Any modification of this device or any use different from the one specified in these instructions for use may cause interference with other equipment. It may also result in injury to the patient or the user, including electric shock, burns or death.**

### CAUTION

This device must be inspected and serviced at regular intervals. A record must be kept on this preventive maintenance. We recommend obtaining a service contract with specialized service personnel through your vendor. For repairs we recommend that you contact specialized service personnel.

### CAUTION

When servicing devices from Dräger, always use spare parts that are qualified to Dräger standards. Dräger cannot warrant or endorse the safe performance of third-party spare parts for use with the devices.

### CAUTION

If you spill liquid on the equipment, battery or accessories or immerse these components in liquid, allow them to dry completely for at least 24 hours to 48 hours. Contact your hospital's service personnel to test any such component is fully operational before putting it back in clinical use.

### NOTE

Perform maintenance measures only when no patient is connected to the device.

## Definition of maintenance concepts

Concept	Definition
Maintenance	All measures (inspection, preventive maintenance, repair) intended to maintain and restore the functional integrity of a medical device.
Inspection	Measures intended to determine and assess the actual state of a medical device.
Preventive maintenance	Recurrent specified measures intended to maintain the functional integrity of a medical device.
Repair	Measures intended to restore the functional integrity of a medical device after a device malfunction.

## Inspection

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Perform inspections of the system and all accessories at regular intervals and observe the following specifications to ensure safe operation of each device.

Checks	Interval	Personnel responsible
Inspection/safety checks	Every 2 years	Expert
Metrological checks	Every 2 years	Expert

## Visual inspection

---

Perform a visual inspection before every use and in accordance with your hospital's policy.

- 1 Make sure that the housing is not cracked or broken and there are no signs of spilled liquids or damage.
- 2 Inspect all accessories (for example, sensors and cables). Do not use if there are any signs of damage.
- 3 Turn the monitor on and make sure the backlight is bright enough.
- 4 Examine all system cables, power plugs and discontinue use if there are any signs of damage.
- 5 Inspect all patient cables, lead wires and strain reliefs for general condition. Make sure the connectors are properly engaged at each end.

## Inspection / safety checks

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Inspection and safety checks of devices must be performed according to the suggested intervals specified in the table on page 387.

### Scope of inspection/safety checks for the M540

Safety checks are no substitute for preventive maintenance measures (including preventive replacement of wearing parts) as identified by the manufacturer.

#### WARNING

##### Risk of medical device failure

**If safety checks are not performed on a regular basis, the proper operation of the medical device can be compromised.**

**Perform safety checks at the indicated intervals.**

- 1 Check accompanying documents:
  - Instructions for use are available.
- 2 Perform a functional test of the following features according to the instructions for use:
  - Verify the LEDs.
  - Perform a functional test of the internal battery
  - Perform system tests (for example, communication with the IACS and functional integrity of buttons, alarm bar, and monitored parameters).
- 3 Check that the device combination is in good condition:
  - All labels are complete and legible
  - There is no visible damage
  - Fuses which are accessible from the outside are in compliance with the specified values
- 4 Check the electrical safety requirements according to IEC 62353 every two years by qualified DrägerService personnel.
- 5 Check the following safety features:
  - The power LED and the battery indicator LED function properly.
  - Check the functional integrity of the Infinity MCable – Nurse call.
  - Functional integrity of the visual and acoustic alarm signals.
  - Functional integrity of the  button located on the front of the device.
  - Functional integrity of the non-invasive blood pressure overpressure sensor (including the valves and the pump).
- 6 The battery should be replaced every two years and checked annually to ensure that the M540 runs on battery charge without fail for one minute as follows:
  - Undock the M540 from the M500.
  - Turn on the M540.
  - Wait for one minute and observe the M540.

If the battery fails, trained personnel must replace it.

### Metrological checks

If required by applicable regulations, the following measurement functions must be checked every two years by specialized service personnel:

- Body temperature
- Non-invasive blood pressure

## Preventive maintenance

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### WARNING

#### Risk of faulty components

Device failure is possible due to wear or material fatigue of the components.

To maintain proper operation of all components, this device must undergo inspection and preventive maintenance at specified intervals.

### WARNING

#### Risk of electric shock

Before performing any maintenance work, disconnect all electrical connectors from the power supply.

The following table shows the preventive maintenance intervals.

Following maintenance, confirm that attached devices meet IEC 60601-1 patient vicinity leakage current requirements.

Component	Interval	Measure	Personnel responsible
Two non-invasive blood pressure air inlet filters of the M540  If the non-invasive blood pressure air inlet filter seems dirty or damaged, replace it before the recommended two years. The air inlet filter should be replaced, if the M540 was exposed to liquid. See <i>"Exchanging the ambient air filter"</i> in the Technical documentation which is available from Dräger.	Every two years	Replace	Expert
Internal M540 battery  <b>NOTE:</b> For devices that have high transport or battery use, the battery must be checked more often.	Annually	Check	Hospital personnel
Internal M540 battery	Every two years	Replace	Trained personnel

Technical documentation is available on request by contacting the Dräger representative.

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## Technical data

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## Overview

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This chapter contains the technical data for the following devices of the Infinity Acute Care System:

- M540
- Infinity M500 MDock
- Power supply
- MPod and MCable

- Parameter specifications

For technical data regarding the C500/C700, refer to the Instructions for use entitled *Infinity Acute Care System – Infinity Medical Cockpits*.

## Device combinations

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This device can be operated in combination with other Dräger devices or with devices from other manufacturers. Observe the accompanying documents of the individual devices.

If a device combination is not approved by Dräger, the safety and the functional integrity of the individual devices can be compromised. The operating organization must ensure that the device combination complies with the applicable editions of the relevant standards for medical devices. Device combinations approved by Dräger meet the requirements of the following standards:

- IEC 60601-1, 3rd edition (general requirements for safety, device combinations, software-controlled functions)
- IEC 60601-1-2 (electromagnetic compatibility)
- IEC 60601-1-8 (alarm systems)

If a device combination is not approved by Dräger, proper operation of the devices can be compromised.

The operating organization must ensure that the device combination meets the applicable standards.

Strictly observe Instructions for use and assembly instructions of all connected devices.

### CAUTION

Combinations of Dräger devices and third-party devices that are not approved by Dräger may adversely affect operation of those devices and may put the patient at greater risk of injury.

### CAUTION

The medical device must only be used with software tested and approved by Dräger. Any modifications of the operating system settings can impair operating safety. Responsibility for any such modifications lies with the operating organization.

## Infinity M540

<b>Physical specifications</b>	
Dimensions (W x H x D)	259 x 89 x 43 mm (10.2 x 3.5 x 1.7 in)
Weight	916 g (2.0 lb)
Cooling	Conduction (docked), Convection (undocked)
Materials	Enclosure: PC-ABS/TPU Lenses: polyamide Internal plastic: polyamide (PA) Printed circuits: glass/epoxy, lead/tin solder, copper etch Battery: lithium ion Heatsink: magnesium Non-invasive blood pressure assembly: plastic, stainless steel, copper wire Packing: corrugated cardboard, urethane foam
User interface	Touchscreen plus 3 keys
<b>Connectors</b>	
Input/output ports	<ul style="list-style-type: none"> <li>– ECG</li> <li>– NIBP</li> <li>– Temperature/Auxillary</li> <li>– SpO<sub>2</sub></li> <li>– Hemo CO<sub>2</sub></li> <li>– CO<sub>2</sub></li> </ul>
<b>Display attributes</b>	
Display type	Color Liquid Crystal Display (LCD), advanced touchscreen
Display size	158.2 mm (6.2 in) diagonal
Viewing size	148.8 x 53.8 mm (5.9 x 2.1 in)
Resolution (pixels)	640 x 240 (1/2 VGA)
Luminance	80 cd/m <sup>2</sup> minimum during battery operation 110 cd/m <sup>2</sup> minimum when powered by M500
Alarm bar	Integrated on the side of the front bezel; blinks red for high priority and yellow for medium-priority alarm conditions; does not blink for low-priority alarm conditions.

<b>Acoustic attributes</b>	
Minimum acoustic tone	45 dB(A)
Alarms	Alarm levels: high priority, medium priority, low priority
System alarm delay	<3 s
<b>Electrical specifications</b>	
Power source	Internal lithium-ion battery or external power from the M500, 24 V
Battery pack	Lithium: 7.2 V DC, 3200 mAh
Protection class	Internally powered (per IEC 60601-1)
Battery operating time	Normal operation: approximately 3 hours Power save mode: approximately 4 hours <b>NOTE:</b> Battery operating time varies with device configuration. The battery operating times specified above are under the following load conditions: wireless enabled; invasive pressure (IP) via the MPod Quad Hemo (4 invasive pressures); continuous 6-lead ECG; SpO <sub>2</sub> with Nellcor MCable or Masimo SET MCable; two continuous temperature probes; non-invasive blood pressure (NIBP) with 15-minute interval mode enabled.
Battery recharging time	100 % capacity: approximately 6.5 hours for a completely discharged battery 90 % capacity: approximately 5.5 hours for a completely discharged battery 70 % capacity: approximately 4 hours for completely discharged battery
Mode of operation	Continuous (with power coupling through the M500)
<b>Environment</b>	
Humidity (non condensing)	Operating: 10 % to 95 % Storage: 5 % to 95 %
Temperature	Operating: 0 °C to 40 °C (32 °F 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 symbol still indicates the actual battery charge. Storage: -20 °C to 60 °C (-4 °F to 140 °F)
Atmospheric pressure	Operating: 485 to 795 mmHg (647 to 1060 hPa) Storage: 375 to 795 mmHg (500 to 1060 hPa)

Drop	IEC 60068-2-31: 2008 Procedure 1 Drop once on each of six surfaces from a height of 1 m (3.2 ft)
Shock and vibration	Shock test in accordance with IEC 60068-2-27:2008  Test type: Type 2: – peak acceleration: 300 m/s <sup>2</sup> (30g); – duration: 6 ms; – pulse shape: half sine; – number of shocks: 3 shocks per direction per axis (18 total)  Broad-band random vibration in accordance with IEC 60068-2-64:2008 using the following conditions:  Acceleration amplitude: – 10 Hz to 100 Hz: 1,0 (m/s <sup>2</sup> ) 2/Hz; – 100 Hz to 200 Hz: –3 db/octave; – 200 Hz to 2,000 Hz: 0,5 (m/s <sup>2</sup> ) 2/Hz;  Duration: 30 min per each perpendicular axis (3 total).
Transportation	Per International Safe Transit Association (ISTA)
Protection against liquid ingress	IPX4 (protected against splashing water) per IEC 60529
<b>Communications</b>	
Wired network	802.3 100BaseT Ethernet when connected to the M500. Optically isolated connection between the M540 and M500.
Wireless network	Complies with IEEE 802.11b/g/n WLAN standards (2.4GHz). Supports WPA2 security.
Radio power output	30mW (2.4 GHz)

## Sound pressure

Sound pressure levels can be adjusted from 5 % to 100 % volume setting, ranging between 42 dB(A) and 75 dB(A) for high, medium and low priority alarms, measured at a distance as specified per IEC 60601-1-8.

On each M540, the sound pressure level of a high priority alarm is no less than the sound pressure level of a medium priority alarm, which is no less than the sound pressure level of a low priority alarm.

## Infinity M500

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<b>Physical specifications</b>	
Dimensions (W x H x D)	102 x 195 x 107 mm (4.0 x 7.7 x 4.2 in)
Weight	1200 g (2.6 lb)
Cooling	Convection
Materials	Enclosure: polyamide (PA) and ABS
Mounting	VESA 75
<b>Connectors</b>	
Input/output ports	<ul style="list-style-type: none"> <li>– System cable connector</li> <li>– Nurse call connector (not available in a standalone configuration)</li> <li>– CO2 connector</li> </ul>
<b>Electrical specifications</b>	
DC input	24 V DC nominal, 1.5 A (18 to 30 V DC)
Protection class	For use with specified Class I power supply
Mode of operation	Continuous
Power output	26 W nominal

<b>Environment</b>	
Humidity (non condensing)	Operating: 10 % to 95 % Storage: 5 % to 95 %
Temperature	Operating: 0 °C to 40 °C (32 °F to 104 °F) Storage: -20 °C to 60 °C (-4 °F to 140 °F)
Atmospheric pressure	Operating: 485 to 795 mmHg (647 to 1060 hPa) Storage: 375 to 795 mmHg (500 to 1060 hPa)
<b>Risk management</b>	
Protection against liquid ingress	IPX1 (protected against vertically falling water drops) per IEC 60529
<b>Communications</b>	
Internal network (M540)	802.3 100BaseT Ethernet (optically isolated)

## 120 Watt desktop power supply (PS120)

The following power supply is for use with the M540 patient monitor.

### CAUTION

Always use a power cable with a hospital-grade plug and connect it to a hospital-grade or grounded receptacle as required by local regulation.

<b>Physical specifications</b>	
Connections	ODU Medi-Snap (3 pins)
Cooling	Convection -- non-vented case
Size (W x D x H)	174 x 82 x 40 mm (6.85 x 3.2 x 1.6 in)
Weight	684 grams (24 ounces) excluding the cord
<b>Environment</b>	
Temperature	Operating: 0 to 40 °C (32 to 104 °F) Storage: -20 to 85 °C (-4 to 185 °F)
Relative humidity	5 to 95 % non-condensing
Height above sea level	0 to 3000m (10,000 feet)
Ambient pressure	70 to 106 kPa (10.15 to 15.37 psi)

<b>Electrical specifications</b>	
Input voltage	100 V AC to 240 V AC ( $\pm 10\%$ )
Input frequency	47 to 63 Hz
Input current	2 A max at 90 V AC input
Inrush current	30A at 115 V AC or 60A at 230 V AC
Leakage current	Less than 0.6 mA in fault condition (264 V/50 Hz)
Output voltage	24.5 V
Maximum output power	120W
Protection class	Class I
Mode of operation	Continuous
<b>Standard compliance</b>	
Protection against liquid ingress	IP41 (protected against vertically falling water drops and ingress of e.g. wires or screws) per IEC 60529.

## Infinity MCable – Mainstream CO<sub>2</sub>

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For technical specifications for Mainstream CO<sub>2</sub> sensors, refer to the *Dräger CO<sub>2</sub> Mainstream Sensor Instructions for Use*.

## Infinity MCable – Microstream CO<sub>2</sub>

<b>Physical specifications</b>	
Infinity MCable Microstream	92 mm (height) x 70 mm (width) x 49 mm (depth)
Infinity MCable Microstream weight	240 grams (0.52 pounds)
MCable holder	105.8 mm (height) x 87.3 mm (width) x 69.9 (depth)
MCable holder weight	100 grams (3.52 ounces)
<b>Storage</b>	
Ambient pressure	88 mmHg to 795 mmHg
Height above sea level	–381 m to 15,240 m (–1,250 feet to 50,000 feet)
Temperature	–40 to 70 °C (–40 to 158 °F)
Humidity	10 to 95 %
<b>During operation</b>	
Height above sea level	–1,250 to 15,000 feet
Height above sea level change rate	500 feet/min maximum or ambient pressure change of 12.4 mmHg/min max.
Ambient CO <sub>2</sub> levels	0 to 700 ppm
Ambient pressure	430 to 795 mmHg
Humidity	10 to 95 % non-condensing
Maximum tolerable change rate of the units of ambient temperature	0.5 °C/min
Operating pressure from a ventilation system	Over pressure: +100 cmH <sub>2</sub> O Under pressure: –20 cmH <sub>2</sub> O
Temperature	0 to 40 °C (32 to 104 °F)
<b>Electrical specifications</b>	
Power source	Powered directly from the M540
Mode of operation	Continuous
<b>Risk management</b>	
Protection against electrical shock	Type BF
Protection against liquid ingress	IPX2
Defibrillator protection	Yes

## Infinity MCable – Masimo SET and Infinity MCable – Masimo rainbow SET

<b>Physical specifications</b>	
Size (W x H x D)	61 x 20 x 130 mm (2.4 x 0.8 x 5.1 in)
Weight	0.12 kg (0.26 lb)
Cable length	300 mm (11.8 in)
Connections	Single cable connecting to the M540 Masimo cable connector for sensor cable
<b>Environment</b>	
Humidity (non-condensing)	Operating: 10 to 95 % Storage: 10 to 95 %
Temperature	Operating: 0 to 45 °C (32 to 113 °F) Storage: -40 to +70 °C (-40 to +158 °F)
Atmospheric pressure	Operating: 480 to 795 mmHg (64 to 106 kPa) Storage: 375 to 795 mmHg (50 to 106 kPa)
<b>Electrical specifications</b>	
Power source	Powered directly from the M540
Input voltage	5 V nominal
Maximum power consumption	500 mW / 1 W
Mode of operation	Continuous
<b>Risk management</b>	
Protection against electrical shock	Type CF
Protection against liquid ingress	IPX2 (protected against vertically falling water drops with enclosure tilted up to 15°) per IEC 60529
Defibrillator protection	Yes

## Infinity MCable – Nellcor OxiMax

<b>Physical specifications</b>	
Size (W x H x D)	61 x 21 x 130 mm (2.4 x 0.8 x 5.1 in)
Weight	0.12 kg (0.26 lb)
Cable length	300 mm (11.8 in)
Connections	Single cable connecting to the M540 Nellcor cable connector for sensor cable
<b>Environment</b>	
Humidity (non-condensing)	Operating: 10 to 95 % Storage: 10 to 95 %
Temperature	Operating: 0 to 45 °C (32 to 113 °F) Storage: -40 to +70 °C (-40 to +158 °F)
Atmospheric pressure	Operating: 480 to 795 mmHg (64 to 106 kPa) Storage: 375 to 795 mmHg (50 to 106 kPa)
<b>Electrical specifications</b>	
Power source	Powered directly from the M540
Input voltage	5 V nominal
Maximum power consumption	500 mW
Mode of operation	Continuous
<b>Risk management</b>	
Protection against electrical shock	Type CF
Protection against liquid ingress	IPX2 (protected against vertically falling water drops with enclosure tilted up to 15°) per IEC 60529
Defibrillator protection	Yes

## Infinity MPod – Quad Hemo

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<b>Physical specifications</b>	
Size (W x H x D)	205 x 110 x 80 mm (8.1 x 4.3 x 3.2 in)
Weight	0.48 kg (1.1 lb) <b>NOTE:</b> Weight includes four transducer cables but excludes the mounting clamp and rod.
Connections	Four invasive pressure channels, two temperatures, and C.O. Single cable connecting to the M540
<b>Environment</b>	
Humidity (non-condensing)	Operating: 10 to 95 % Storage: 10 to 95 %
Temperature	Operating: 0 to 45 °C (32 to 113 °F) Storage: –40 to 70 °C (–40 to 158 °F)
Atmospheric pressure	Operating: 480 to 795 mmHg (64 to 106 kPa) Storage: 375 to 795 mmHg (50 to 106 kPa)
<b>Electrical specifications</b>	
Power source	Powered directly from the M540
Input voltage	10 V nominal
Maximum power consumption	500 mW for a single pod with connected pressure probes
Mode of operation	Continuous
<b>Risk management</b>	
Protection against electrical shock	Type CF
Protection against liquid ingress	IPX2 (protected against vertically falling water drops with enclosure tilted up to 15°) per IEC 60529
Defibrillator protection	Yes

## Infinity MCable – Dual Hemo

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<b>Physical specifications</b>	
Size (W x H x D)	61 x 25 x 125 mm (2.4 x 1.0 x 5.0 in)
Weight	0.20 kg (0.44 lb)
Cable length	2500 mm (98.4 in)
Connections	Two invasive pressure channels Single cable connecting to the M540
<b>Environment</b>	
Humidity (non-condensing)	Operating: 10 to 95 % Storage: 10 to 95 %
Temperature	Operating: 0 to 45 °C (32 to 113 °F) Storage: -40 to 70 °C (-40 to 158 °F)
Atmospheric pressure	Operating: 480 to 795 mmHg (64 to 106 kPa) Storage: 375 to 795 mmHg (50 to 106 kPa)
<b>Electrical specifications</b>	
Power source	Powered directly from the M540
Input voltage	10 V nominal
Maximum power consumption	300 mW
Mode of operation	Continuous
<b>Risk management</b>	
Protection against electrical shock	Type CF
Protection against liquid ingress	IPX4 (protected against vertically falling water drops) per IEC 60529
Defibrillator protection	Yes

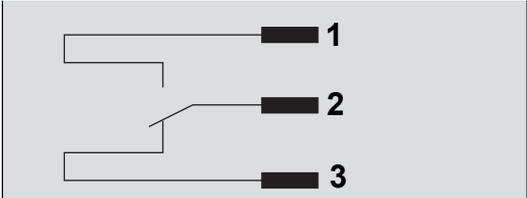
## Infinity MCable – Analog/Sync

<b>Physical specifications</b>	
Size (W x H x D)	66 x 31 x 110 mm (2.6 x 1.3 x 4.4 in)
Weight	0.19 kg (0.42 lb)
Cable length	500 mm (19.7 in)
Connections	Two connectors; one for analog output and one for QRS sync pulse cable Single cable connecting to the M540
<b>Environment</b>	
Humidity (non-condensing)	Operating: 10 to 95 % Storage: 10 to 95 %
Temperature	Operating: 0 to 45 °C (32 to 113 °F) Storage: -40 to 70 °C (-40 to 158 °F)
Atmospheric pressure	Operating: 480 to 795 mmHg (64 to 106 kPa) Storage: 375 to 795 mmHg (50 to 106 kPa)
<b>Analog output</b>	
Signals	ECG, arterial blood pressure
Maximum delay	≤ 25 ms
Output range	±4.95 V ±5 %
Signal gain	ECG: 1000 (1 V/mV) Arterial pressure: 10 mV/mmHg
Accuracy	ECG: ±100 mV or ±10 % Arterial pressure: ±40 mV or ±4 %
ECG bandwidth	0.5 to 40 Hz
Invasive pressure bandwidth	DC to 50 Hz
Pacemaker pulses	Amplitude: 5 V (nominal) Duration: 4 ms
Maximum pressure offset	±10 mV
Pressure range	-50 to +400 mmHg (1 V/100 mmHg) -6.6 to +53.3 kPa (1 V/13.3 kPa)
Output impedance	200 Ω ±5 %
Data rate	250 per second

<b>QRS sync pulse output</b>	
Delay	≤35 ms
Output high (QRS detected):	Amplitude: 10 V ±5 %
	Duration: 50 ms
	Output impedance: 5000 Ω
Output low (no QRS)	<0.8 V
Pacemaker pulses	Not included
<b>Electrical specifications</b>	
Source	Powered directly from the M540
Input voltage	5 V nominal
Maximum power consumption	≤325 mW under fault condition
	≤250 mW during normal operation
Mode of operation	Continuous
<b>Risk management</b>	
Protection against liquid ingress	IPX1 (protected against vertically falling water drops) per IEC 60529

## Infinity MCable – Nurse call

The Nurse Call connector is supported only when the M540 is connected to a Cockpit. It is not available in a standalone configuration.

<b>Physical specifications</b>	
Size (W x H x D)	65 x 32 x 161 mm (2.6 x 1.36 x 6.3 in)
Cable length	4500 mm (177.2 in)
Connections	Single cable connection to the M500
Cable signals during non-alarm state	 <p>Cable 1 (NO normally open): white                      Cable 2 (COM common): brown                      Cable 3 (NC normally closed): green</p>
<b>Environment</b>	
Humidity (non-condensing)	Operating: 10 to 95 % Storage: 10 to 95 %
Temperature	Operating: 0 to 45 °C (32 to 113 °F) Storage: -20 to +60 °C (-4 to +140 °F)
Atmospheric pressure	Operating: 480 to 795 mmHg (64 to 106 kPa) Storage: 375 to 795 mmHg (50 to 106 kPa)
<b>Electrical requirements</b>	
Input voltage	24 V ±25 %
Relay contact	1 A DC, 24 V DC, 15 W maximum
Mode of operation	Continuous
Isolation voltage	1.5 k V AC

## Parameter monitoring specifications

### NOTE

The following parameters are not monitored in neonatal mode: Arrhythmia, Cardiac Output, and ST segment analysis.

### ECG

Display	Up to 12 leads
Available leads	<p>3-wire lead set: ECGI, ECGII, ECGIII (user-selectable)</p> <p>5-wire lead set: ECGI, ECGII, ECGIII, ECGaVR, ECGaVL, ECGaVF, ECGV</p> <p>6-wire lead set: ECGI, ECGII, ECGIII, ECGaVR, ECGaVL, ECGaVF, ECGV, ECGV+</p> <p>Optional 12-lead monitoring with 6-wire lead set and 4-wire lead set: ECGI, ECGII, ECGIII, ECGaVR, ECGaVL, ECGaVF, ECGV1 to ECGV6</p> <p>TruST on: ECGI, ECGII, ECGIII, ECGaVR, ECGaVL, ECGaVF, ECGdV1, ECGV2, ECGdV3, ECGdV4, ECGV5, ECGdV6 ("d" prefix identifies derived lead)</p>
Measurement range	<p>15 bpm to 300 bpm (beats/min)</p> <p><b>NOTE:</b> For heart rates of 300 bpm and greater, the monitor may display VF and not the expected +++ as the parameter value.</p>
Accuracy	$\pm 2$ bpm or $\pm 1$ % (whichever is greater)
Resolution	1 bpm
Sweep speed	25 mm/s $\pm 2$ %
QRS detection	0.5 mV - 5.0 mV detected, $\leq 0.15$ mV not detected, per IEC 60601-2-27.
Frequency band	<p>Monitor filter: 0.5 to 40 Hz (0.5 to 40 Hz in OR alarms)</p> <p>Diagnostic filter: 0.05 to 150 Hz</p> <p>ESU filter: 0.5 to 40 Hz (pacer detection deactivated)</p> <p>Filter OFF: 0.05 to 40 Hz (M540 display is limited to 40 Hz)</p>
ECG isoelectric line recovery	$\leq 3$ s after the termination of the transient interference from a defibrillator or ESU device

Common mode rejection ratio (CMRR)	Diagnostic mode: >90 dB (with a 51 kΩ/47 nF imbalance) Filter mode: >110 dB (with a 51 kΩ/47 nF imbalance)
Degree of protection against electric shock	Type CF
Defibrillation protection	Yes
<b>Unit will detect pacers with the following characteristics:</b>	
Pacer detection (adult/pediatric only)	Amplitude (a <sub>p</sub> ): ±2 to ±700 mV Width (d <sub>p</sub> ): 0.2 to 2.0 ms
Rise/fall times (min)	0.1 d <sub>p</sub> , ≤100 μs
Overshoot (min)	0.025 to 0.25 a <sub>p</sub> , <2 mV
Recharge time constant	4 to 100 ms

### ECG/Arrhythmia/ST supplemental information

QRS isoelectric components (Rest ECG report only)	Isoelectric components between the overall QRS onset and an individual lead onset are not included in a Q or R duration
Sample Frequency	Use of the Rest ECG report is required for an ECG signal quality that is compliant with the diagnostic high frequency specification of 500 Hz sampling rate in IEC 60601-2-25
Amplitude quantisation	2.5 μV/LSB
Respiration excitation waveform	Square wave signal, 50 μA, 39.896 kHz
Auxiliary current (leads off detection)	Active electrode: <100 nA Reference electrode: <900 nA
Noise suppression	Not applicable
Maximum alarm delay	<10 s according to ANSI/AAMI/IEC 60601-2-27
Time to alarm for tachycardia	Ventricular tachycardia 1 mV pp, 206 bpm Gain: 0.5, range: 3.0 to 3.5 s, average: 3.3 s Gain: 1.0, range: 2.9 to 3.3 s, average: 3.2 s Gain: 2.0, range: 2.8 to 3.5 s, average: 3.0 s
	Ventricular tachycardia 2 mV pp, 195 bpm Gain: 0.5, range: 2.2 to 4.0 s, average: 3.0 s Gain: 1.0, range: 1.9 to 2.5 s, average: 2.3 s Gain: 2.0, range: 2.0 to 2.9 s, average: 2.5 s
Tall T wave rejection capability	1.3 mV

Heart rate averaging method	Heart rate is normally based on the average R-R interval calculated over the last 10 seconds, however it updates more quickly to reflect changes to the patient's underlying rate.
Response time of heart rate meter to change in heart rate	Heart rate change from 80 to 120 bpm Range: 3.4 to 7.1 s average: 5.3 s Heart rate change from 80 bpm to 40 bpm: Range: 6.3 to 8.6 s average: 7.4 s
Heart rate meter accuracy and response to irregular rhythm	Ventricular bigeminy: 80 bpm Slow alternating ventricular bigeminy: 60 bpm Rapid alternating ventricular bigeminy: 120 bpm Bidirectional systoles: 90 bpm

### Arrhythmia (ARR)

Basic arrhythmia detection	Asystole, ventricular fibrillation, artifact, ventricular tachycardia <sup>1)</sup>
Full arrhythmia detection	Adds the following calls on to basic arrhythmia: ventricular run, accelerated idioventricular rhythm, supraventricular tachycardia, couplet, bigeminy, tachycardia, bradycardia, pause, and PVC/min
PVC/min measurement range	0 to 300 bpm
PVC/min resolution	1 bpm
PVC/min accuracy	$\pm 5$ or $\pm 10$ % of the rate (whichever is greater)
PVC/min response time	$\leq 4$ s
<sup>1)</sup> Artifact and ventricular tachycardia are not available for neonates. Bradycardia is available as a low heart rate alarm for neonates.	

## ST segment analysis

Sensing leads	<p>3-wire lead set: ECGI, ECGII, ECGIII (user-selectable)</p> <p>5-wire lead set: (choice of 2 leads for display) ECGI, ECGII, ECGIII, ECGaVR, ECGaVL, ECGaVF, ECGV</p> <p>6-wire lead set: (choice of 2 leads for display) ECGI, ECGII, ECGIII, ECGaVR, ECGaVL, ECGaVF, ECGV, ECGV+</p> <p>Optional 12-lead monitoring with 6-wire lead set and 4-wire lead set: (choice of 2 leads for display) ECGI, ECGII, ECGIII, ECGaVR, ECGaVL, ECGaVF, ECGV1 to ECGV6, STCVM, STVM</p> <p>TruST on: ECGI, ECGII, ECGIII, ECGaVR, ECGaVL, ECGaVF, ECGdV1, ECGV2, ECGdV3, ECGdV4, ECGV5, ECGdV6 ("d" prefix identifies derived lead)</p>
ST complex	Length: 828 ms (–260 to +568 ms from the fiducial point)
Isoelectric point	<p>Setting range: start of ECG complex to fiducial point</p> <p>Default: QRS onset –28 ms</p>
ST measurement point	<p>Setting range: fiducial point to end of ECG complex</p> <p>Default: J point +80 ms</p>
ST update interval	15 s ± 1 s, 1 normal beat required
ST input accuracy	<p>±0.5mm (0.05mV) 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>±3.2 mm (0.32 mV) for STVM and STCVM</p> <p><b>CAUTION</b> ST accuracy may be impacted if ECG double-counting occurs or with highly irregular heart rates.</p> <p><b>NOTE</b> In an unlikely scenario where the heart rate is low (e.g., 30 bpm, 45 bpm), and ST-segment deviation is high (≥ ± 13 mm), the claimed ST accuracy might not be met on one or two leads.</p>
ST measuring range	–15.0 to +15.0 mm (–1.5 to +1.5 mV)
ST resolution	±0.1 mm (0.01 mV)

**Respiration (RRi)**

Sensing leads	I or II (user-selectable)
Measuring method	Impedance pneumography
Auxiliary current	<10 $\mu$ A for any active electrode
Respiration excitation waveform	Square wave signal, 50 $\mu$ A, 39.896 kHz
Bandwidth (–3dB)	0.25 to 3.5 Hz
Detection threshold	Manual mode: 0.20 to 3.5 $\Omega$ Auto mode: Minimum 0.25 $\Omega$
Measurement range	0 to 150 bpm
Resolution	1 bpm
Measuring accuracy	The accuracy of respiration rate is: @ 0-100 breaths/minute: +/- 2 breaths/minute or +/- 2 % of the rate value (whichever is greater) @ 101-150 breaths/minute: +/- 3 breaths/minute or +/- 3 % of the rate value (whichever is greater)
Apnea detection intervals	Off, 10, 15, 20, 25, and 30 s

**NOTE**

Under very specific conditions, respiration rates may be underestimated when outside the range of 20-120 breaths per minute. The conditions and corresponding troubleshooting tips are described in the following table.

Mode	Respiration amplitude	Respiration rate	Troubleshooting tips
Automatic mode	Near the minimum threshold of 0.18 $\Omega$	0-19 breaths per minute 121-150 breaths per minute	Enable respiration markers and if breaths are not being detected, implement the following troubleshooting tips: <ul style="list-style-type: none"> <li>– Adjust ECG electrodes for leads I and II to acquire a signal with increased amplitudes. (See "Connecting the 3-, 5-, 6-wire lead sets for respiration monitoring" on page 183.)</li> <li>– Confirm the electrodes are not placed over bony prominences and are free of debris or hair.</li> <li>– Follow hospital procedures for proper skin preparation. (See "Patient preparation for respiration monitoring" on page 186.)</li> </ul>
Manual mode	Near the configured threshold	0-19 breaths per minute 121-150 breaths per minute	Enable respiration markers and if breaths are not being detected, implement the following troubleshooting tips: <ul style="list-style-type: none"> <li>– Adjust ECG electrodes for leads I and II to acquire a signal with increased amplitudes. (See "Connecting the 3-, 5-, 6-wire lead sets for respiration monitoring" on page 183.)</li> <li>– Increase the respiration waveform gain to reduce threshold. (See the instructions for manual mode in "Respiration measuring modes" on page 188.)</li> <li>– Confirm the electrodes are not placed over bony prominences and are free of debris or hair.</li> <li>– Follow hospital procedures for proper skin preparation. (See "Patient preparation for respiration monitoring" on page 186.)</li> </ul>

**Invasive pressure (IP)**

Measuring method	Resistive strain gauge transducer
Resolution	1 mmHg (0.1 kPa)
Measurement range	–50 to 400 mmHg (–6.6 to +53.3 kPa) GP1 to 8, arterial pressures, PA, wedge pressure, CVP, LA, LV, RV, RA, ICP, ABD, BDP, ESO, FEMV, UVP, GPM
Dynamic range	Before zeroing: –250 to +600 mmHg (–33.3 to +79.9 kPa) After zeroing: –50 to +400 mmHg (–6.6 to +53.3 kPa)
Zero balance range	±200 mmHg (±26.6 kPa)
Filter settings	User selectable DC to 8 Hz, DC to 16 Hz
Accuracy	±1 mmHg or ±3 % (whichever is greater) excluding the transducer
IP update interval	4 s
Response time (at 90 % of pressure change)	14 beats + 2 s (arterial pressures, LV, GP1 to GP8) 8 beats + 2 s (PA, RV) 16 s (CVP, ABD, BDP, ESO, FEMV, UVP, GPM, RA, LA, ICP)
Transducer specifications	Transducers with a resistance of 200 Ω to 3000 Ω and an equivalent pressure sensitivity of 5 μV/V/mmHg ±10 %

## Non-invasive blood pressure (NIBP)

Accuracy validation	<p>Reference method: intra-arterial.</p> <p>Adult: the femoral artery                      Pediatric: the umbilical, brachial, radial or femoral arteries                      Neonate: the umbilical, brachial, radial or femoral arteries</p> <p>The associated NIBP readings were taken on the same limb.</p> <p>The Sphygmomanometer was clinically investigated according to the requirements of ISO's 81060-2:2013.</p>
Parameter display	Systolic, diastolic, mean values
Measuring method	Oscillometric through step-deflation. The cuff inflates to occlude blood flow through the patient's limb, and then the cuff is deflated in a controlled manner. As the cuff pressure decreases, the oscillations increase in amplitude and then decrease as blood returns to normal flow. From this change in amplitude, the mean arterial blood pressure can be directly determined and systolic (S) and diastolic (D) blood pressures derived.
Modes of operation	Manual (single measurement), interval, continuous, or venous stasis
Interval times	Off, 1, 2, 2.5, 3, 5, 10, 15, 20, 25, 30, 45, 60, 120, and 240 min
Adult measurement range	Heart rate: 30 to 240 bpm Systolic: 30 to 250 mmHg (4 to 33.3 kPa) Mean: 30 to 230 mmHg (4 to 30.6 kPa) Diastolic: 10 to 210 mmHg (1.3 to 28 kPa)
Pediatric measurement range	Heart rate: 30 to 240 bpm Systolic: 30 to 170 mmHg (4 to 22.6 kPa) Mean: 30 to 150 mmHg (4 to 20 kPa) Diastolic: 10 to 130 mmHg (1.3 to 17.3 kPa)
Neonatal measurement range	Heart rate: 30 to 240 bpm Systolic: 30 to 130 mmHg (4 to 17.3 kPa) Mean: 30 to 110 mmHg (4 to 14.7 kPa) Diastolic: 10 to 100 mmHg (1.3 to 13.3 kPa)
Connector	Quick-release connector with single airway
Maximum inflation pressure	Adult: 265 mmHg, $\pm 5$ mmHg (35.3 kPa, $\pm 0.66$ kPa) Pediatric: 180 mmHg, $\pm 5$ mmHg (24 kPa, $\pm 0.66$ kPa) Neonate: 140 mmHg, $\pm 5$ mmHg (18.7 kPa, $\pm 0.66$ kPa)
Minimum inflation pressure	Adult: 110 mmHg, $\pm 5$ mmHg (14.7 kPa, $\pm 0.66$ kPa) Pediatric: 90 mmHg, $\pm 5$ mmHg (12 kPa, $\pm 0.66$ kPa) Neonate: 80 mmHg, $\pm 5$ mmHg (10.7 kPa, $\pm 0.66$ kPa)

Default inflation pressure	Adult: 160 mmHg, $\pm 5$ mmHg (21.3 kPa, $\pm 0.66$ kPa) Pediatric: 130 mmHg, $\pm 5$ mmHg (17.3 kPa, $\pm 0.66$ kPa) Neonate: 110 mmHg, $\pm 5$ mmHg (14.7 kPa, $\pm 0.66$ kPa)
Inflation pressure after a valid measurement	Adult: last systolic value plus 25 mmHg, $\pm 5$ mmHg (3.3 kPa, $\pm 0.66$ kPa) Pediatric: last systolic value plus 25 mmHg, $\pm 5$ mmHg (3.3 kPa, $\pm 0.66$ kPa) Neonate: last systolic value plus 30 mmHg, $\pm 5$ mmHg (4 kPa, $\pm 0.66$ kPa)
Inflation pressure after a technical alarm	Adult: 160 mmHg, $\pm 5$ mmHg (21.3 kPa, $\pm 0.66$ kPa) Pediatric: 130 mmHg, $\pm 5$ mmHg (17.3 kPa, $\pm 0.66$ kPa) Neonate: 110 mmHg, $\pm 5$ mmHg (14.7 kPa, $\pm 0.66$ kPa)
Maximum measurement time	Adult: 2 min, $\pm 3$ s Pediatric: 2 min, $\pm 3$ s Neonate 90 s, $\pm 1$ s
Maximum measurement time including a retry	Adult: 3 min Pediatric: 2 min Neonate: 90 s
Software safety cut-off SWh = value in specified range that last for at least 15 s SWi = instantaneous limit value	Adult (SWh): 265, to 290 mmHg (35.3, to 38.6 kPa) Pediatric (SWh): 185 to 215 mmHg (24.6 to 28.6 kPa) Neonate (SWh): 125 to 145 mmHg (16.6 to 19.3 kPa)  Adult (SWi): $>290$ mmHg (38.6 kPa) Pediatric (SWi): $>215$ mmHg (28.6 kPa) Neonate (SWi): $>145$ mmHg (19.3 kPa)
Redundant safety cut-off	Adult: 300 mmHg (40 kPa) Pediatric: 300 mmHg (40 kPa) Neonate: 150 mmHg (20 kPa)
Static cuff accuracy	$\pm 3$ mmHg ( $\pm 0.4$ kPa)
Calibration check range	0 to 260 mmHg, $\pm 3$ mmHg (0 to 34.6 kPa, $\pm 0.4$ kPa)
Resolution	1 mmHg (0.13 kPa)
Measurement accuracy	Maximum Standard Deviation: 8 mmHg (1.1 kPa) Maximum Mean Error: $\pm 5$ mmHg ( $\pm 0.7$ kPa)

**Cardiac Output**

Parameter display	Cardiac output, blood temperature, injectate temperature
Measuring method	Thermodilution
Measurement range	Cardiac output: 0.5 to 20 L/min Blood temperature: 25 to 43 °C (77 to 109 °F) Injectate temperature: -5 to +35 °C (23 to +95 °F)
Accuracy	Cardiac output: ±5 % or 0.1 L/min, whichever is greater Blood temperature: ±0.2 °C (±0.36 °F) not including probe errors Injectate temperature: ±0.3 °C (±0.54 °F) not including probe errors)
Resolution	Cardiac output: 0.1 L/min Blood temperature: 0.1 °C (0.1 °F) Injectate temperature: 0.1 °C (0.1 °F)
Response time	Blood temperature: ≤3 s Injectate temperature: ≤3 s

**Pulse Oximetry (SpO<sub>2</sub>) Infinity MCable – Masimo SET and Infinity MCable – Masimo rainbow SET**

Adult and pediatric sensors	LNCS DCI, LNCS DCIP, LNCS TC-I, LNCS TF-I, LNCS YI, LNCS Amtx, LNCS Pmtx, LNCS Amtx-3, LNCS Pmtx-3, LNCS-DBI Amtx, LNCS Inf, LNCS Inf-3, Trauma LNCS Amtx, Trauma LNCS Inf/Pmtx  RD-SET Adt, RD-SET Pdt, RD-SET Inf, RD-SET DC-I Adt, RD-SET DCIP Pmtx  R2-25a, R2-20a, R2-25, R2-20, R2-25r, R2-20r, R25-L, R20-L, R25, R20, rainbow DCI Amtx, rainbow DCIP Pmtx
Neonatal sensors	LNCS Inf, LNCS Inf-3, LNCS Neo, LNCS Neo-3, LNCS NeoPt-3, LNCS NeoPt, LNCS YI, LNCS SofTouch, Neo-Pt-500m, Trauma LNCS Neo  RD-SET Neo, RD-SET NeoPt

Parameter display	Masimo SET MCable: Pulse oximetry (SpO <sub>2</sub> ), pulse rate (PLS), perfusion index (PI)  Masimo rainbow SET MCable: Pulse oximetry (SpO <sub>2</sub> ), pulse rate (PLS), perfusion index (PI), SpHb (total hemoglobin), SpOC (total oxygen saturation), SpCO (carbon monoxide in hemoglobin), SpMet (methemoglobin saturation), PVI (pleth variability index)
Measuring method	Absorption-spectrophotometry
Measurement range (Infinity MCable – Masimo SET)	SpO <sub>2</sub> : 1 to 100 % PLS: 26 to 239 bpm PI: 0.00 to 20 %
Measurement range (Infinity MCable – Masimo rainbow SET)	SpHb/SpHbv: 0.0 to 25.0 g/dL (0.0 to 15.5 mmol/L) SpOC: 0 to 35 mL/dL PVI: 0 to 100 % SpCO: 0 to 99 % SpMet: 0 to 99.9 %
Resolution (Infinity MCable – Masimo SET)	SpO <sub>2</sub> : 1 % PLS: 1 bpm PI: 0.01 %
Resolution (Infinity MCable – Masimo rainbow SET)	SpHb/SpHbv: 0.1 g/dL (0.1 mmol/L) SpOC: 1 mL/dL PVI: 1 % SpCO: 1 % SpMet: 0.1 %
Maximum update interval	30 s
Accuracy (Infinity MCable – Masimo rainbow SET)	SpHb/SpHbv for 8 to 17 g/dL: ±1 g/dL SpCO accuracy for 1 to 40 %: ±3 % SpMet accuracy for 1 to 15 %: ±1 %
PI accuracy	±10 %
SpO <sub>2</sub> accuracy with no motion adult, pediatric <sup>1) 2)</sup>	0 to 69 % not specified 70 to 100 %  ±2 % for: LNCS DCI, LNCS DCIP LNCS TF-I, LNCS YI, LNCS Actx, LNCS Pctx, LNCS Neo (finger) <sup>6)</sup>  ±3.5 % for: LNCS TC-I
SpO <sub>2</sub> accuracy with no motion neonatal <sup>1) 2) 3)</sup>	0 to 69 % not specified 70 to 100 %  ±2 % for: LNCS Inf  ±3 % for: LNCS Neo (foot) <sup>6)</sup> , LNCS NeoPt, LNCS YI <sup>7)</sup>
PLS accuracy with no motion <sup>4)</sup>	±3 bpm

SpO <sub>2</sub> accuracy with motion adult, pediatric <sup>1) 2) 3)</sup>	0 to 69 % not specified 70 to 100 %, ±3 % for: LNCS DCI, LNCS DCIP, LNCS YI, LNCS Amtx, LNCS Pmtx		
SpO <sub>2</sub> accuracy with motion neonatal <sup>1) 2) 3) 5)</sup>	0 to 69 % not specified 70 to 100 %, ±3 % for: LNCS Inf, LNCS Neo, LNCS NeoPt		
PLS accuracy with motion <sup>4)</sup>	±5 bpm		
SpO <sub>2</sub> low perfusion accuracy adult, pediatric <sup>1) 2) 8)</sup>	±2 % for: LNCS DCI, LNCS DCIP, LNCS TF-I, LNCS Amtx, LNCS Pmtx ±3.5 % for: LNCS TC-I		
SpO <sub>2</sub> low perfusion accuracy neonatal <sup>1) 2) 3) 8)</sup>	±2 % for: LNCS Inf, LNCS Neo (finger) <sup>6)</sup> ±3 % for: LNCS Neo (foot) <sup>6)</sup> , LNCS NeoPt		
PLS low perfusion accuracy <sup>4)</sup>	±3 bpm		
Interfering substances	Carboxyhemoglobin may erroneously increase measurement values. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes that change arterial pigmentation, may cause erroneous measurement values.		
Nominal wavelength LNCS sensors	Tip clip	Tip clip	All others
	Red: 653 nm	653 nm	660 nm
	IR: 880 nm	880 nm	905 nm
Radiant flux at 50 mA pulsed	≤15 mW		

**NOTE**

- 1) Since SpO<sub>2</sub> sensor measurements are statistically distributed, only about two-thirds of those measurements can be expected to fall within  $\pm 1 A_{rms}$  of the value measured by a co-oximeter.
- 2) The Infinity MCable – Masimo SET SpO<sub>2</sub> sensor with adult sensors has been validated in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70 % to 100 % SpO<sub>2</sub> against a laboratory co-oximeter and ECG monitor. This variation equals  $\pm 1 A_{rms}$  of the value measured by a co-oximeter. Subjects were male (63 %) and female (37 %) between the ages of 18 and 38, with skin pigmentation ranging from light to dark.
- 3) Accuracy of saturation measurements on neonates is decreased by  $\pm 1$  digit as compared to accuracy on adult patients to account for the theoretical effect on oximeter measurements of fetal hemoglobin in neonatal blood.
- 4) The pulse rate accuracy has been validated on healthy adult volunteers during induced hypoxia studies in the range of 70 to 100 % SpO<sub>2</sub> against a laboratory co-oximeter and ECG monitor. This variation equals  $\pm 1 A_{rms}$  of the pulse rate value measured by the ECG monitor.
- 5) The Masimo sensors have been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100 % SpO<sub>2</sub> against a laboratory CO-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68 % of the population.
- 6) Sensor accuracy depends on the weight of the patient. If the weight is less than 3 kg, the accuracy is  $\pm 3$  %. For weights above 40 kg, the accuracy is  $\pm 2$  %.
- 7) Sensor accuracy depends on the weight of the neonate. If the weight exceeds 3 kg, the accuracy is  $\pm 2$  %. For weights between 1 and 3 kg, the accuracy is  $\pm 3$  % (if the sensor is applied on the foot).
- 8) The Masimo SET Technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02 % and transmission of greater than 5 % for saturations ranging from 70 to 100 %. 1 % has been added to the saturation accuracy for neonatal sensors to account for the effects of fetal hemoglobin. This variation equals plus or minus one standard deviation which encompasses 68 % of the population.

**Pulse oximetry (SpO<sub>2</sub>) Infinity MCable – Nellcor OxiMax**

Adult and pediatric sensors	OxiMax MaxA, OxiMax MaxAL, OxiMax MaxA, OxiMax MaxP, OxiMax MaxN, OxiMax MaxI, OxiMax MaxR, OxiMax MaxFast, SoftCare SC-A, OxiCliq A, OxiCliq P, OxiBandOXI-A/N, OxiBandOXI-P/I, Durasensor DS-100A, Dura-Y D-Ys
Neonatal sensors	OxiMax MaxN, OxiMax MaxI, SoftCare SC-NEO, SoftCare SC-PR, OxiCliq I, OxiCliq N, Oxi-A/N, Oxi-P/I
Parameter display	Pulse oximetry (SpO <sub>2</sub> ), pulse rate (PLS)
Measuring method	Absorption-spectrophotometry
Measurement range	SpO <sub>2</sub> : 1 to 100 % PLS: 26 to 239 bpm
Resolution	SpO <sub>2</sub> : 1 % PLS: 1 bpm
Update interval	2 s, ±0.5 s
Maximum update interval	30 s
SpO <sub>2</sub> measuring accuracy adult, pediatric <sup>1)2)</sup>	<p>0 to 60 % not specified</p> <p>60 to 80 % not specified: SoftCare SC-A, OxiMax MaxR, OxiCliq A, OxiCliq P, OxiCliq N, OxiCliq I, D-Ys, DS100A, Oxi-A/N, Oxi-P/I</p> <p>60 to 80 %, ±3 % for: OxiMax MaxA, OxiMax MaxAL, OxiMax MaxP, OxiMax MaxN, OxiMax MaxI, OxiMax MaxFast</p> <p>70 to 100 %</p> <p>±2 % for: OxiMax MaxA, OxiMax MaxAL, OxiMax MaxP, OxiMax MaxN, OxiMax MaxI, OxiMax MaxFast, SoftCare SC-A</p> <p>±2.5 % for: OxiCliq A, OxiCliq P, OxiCliq N, OxiCliq I</p> <p>±3 % for: D-Ys, DS100A, Oxi-A/N, Oxi-P/I</p> <p>±3.5 % for: D-Ys with D-YSE Ear Clip or D-YSPD Spot Clip</p> <p>80 to 100 %, ±3.5 % for: OxiMax MaxR</p>

SpO <sub>2</sub> measuring accuracy neonatal <sup>1) 2) 3)</sup>	0 to 60 % not specified 60 to 80 % not specified: SoftCare SC-PR, SoftCare SC-NEO, OxiCliq N, D-YS, Oxi-A/N 60 to 80 %, $\pm 3$ % for: OxiMax MaxN 70 to 100 % $\pm 2$ % for: OxiMax MaxN, SoftCare SC-PR, SoftCare SC-NEO $\pm 3.5$ % for: OxiCliq N $\pm 4$ % for: D-YS, Oxi-A/N
PLS measuring accuracy <sup>4)</sup>	PLS: $\pm 3$ bpm or $\pm 3$ % (whichever is greater)
SpO <sub>2</sub> /PLS response time	Normal mode: 90 % change within 5 to 7 s Fast mode: 90 % change within 2 to 4 s
Nominal wavelength	Red: 660 nm IR: 910 nm
Radiant flux	$\leq 15$ mW

**NOTE**

- 1) Since SpO<sub>2</sub> sensor measurements are statistically distributed, only about two-thirds of those measurements can be expected to fall within  $\pm 1$  Arms of the value measured by a co-oximeter.
- 2) The Infinity MCable – Nellcor OxiMax SpO<sub>2</sub> sensor with adult sensors has been validated in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70 to 100 % SpO<sub>2</sub> against a laboratory co-oximeter and ECG monitor. This variation equals  $\pm 1$  Arms of the value measured by a co-oximeter. Subjects were male (45 %) and female (55 %) between the ages of 19 and 48, with skin pigmentation ranging from light to dark.
- 3) Accuracy of saturation measurements on neonates is decreased by  $\pm 1$  digit as compared to accuracy on adult patients to account for the theoretical effect on oximeter measurements of fetal hemoglobin in neonatal blood.
- 4) The pulse rate accuracy has been validated on healthy adult volunteers during induced hypoxia studies in the range of 70 to 100 % SpO<sub>2</sub> against a laboratory co-oximeter and ECG monitor. This variation equals  $\pm 1$  Arms of the pulse rate value measured by the ECG monitor.

**Microstream carbon dioxide concentrations (CO<sub>2</sub>)**

CO <sub>2</sub> units	mmHg or kPa or Vol % (as relevant to Microstream capnography)
etCO <sub>2</sub> , inCO <sub>2</sub> range	0–99 mmHg (as relevant to the Microstream capnography)
CO <sub>2</sub> waveform resolution	0.1 mmHg
etCO <sub>2</sub> , inCO <sub>2</sub> resolution	1 mmHg
CO <sub>2</sub> partial pressure accuracy	– 0 to 38 mmHg ± 2 mmHg <sup>1) 2) 3)</sup> 39 to 99 mmHg ± [5 % of expected reading + 0.08 x (expected reading in mmHg - 39mmHg)] <sup>1) 2) 3)</sup>
Accuracy in presence of interfering gases as required by ISO 80601-2-55	The accuracy in presence of interfering gases is within 4 % of the accuracy values above; therefore: – 0 to 38 mmHg: ± (2 mmHg + 4 % of expected reading in mmHg) – 39-99 mmHg: ± [9 % of expected reading in mmHg + 0.08 x (expected reading in mmHg – 39 mmHg)] – 0 to 38 mmHg ± (2 mmHg + 4 % of expected reading in mmHg) in the presence of up to 80 % helium with up to 15 % oxygen 39-99 mmHg: ± [9 % of expected reading in mmHg + 0.08 x (expected reading in mmHg – 39 mmHg)] in the presence of up to 80 % helium with up to 15 % oxygen
Waveform sampling	20 samples/s
Respiratory rate range	0 to 150 breaths per minute
Respiratory rate accuracy	– 0 to 70 breaths per minute ± 1 breaths per minute – 71 to 120 breaths per minute ± 2 breaths per minute – 121 to 150 breaths per minute ± 3 breaths per minute
Flow rate	50 mL per minute (tolerance –7.5, +15), flow measured by volume
Leakage rate	Less than 40 mbar per minute when a 30 % vacuum is invoked on the flow system.
<b>System Response</b>	
Rise time	<190 ms.
Delay time	<2.7 sec.  After the system warm up and during steady state Microstream MCable use: the maximum delay time between patient breath and its report on the CO <sub>2</sub> waveform is 2.9 sec.

Warm-up period	Includes power-up time (10 seconds maximum) and initialization time (180 seconds). Total warm-up time 1 minute and 30 seconds maximum.
Compression	BTPS is the standard correction used by Microstream capnography during all measurement procedures for body, temperature, pressure, and saturation.

**NOTE**

- 1) Applies for respiratory rates up to 80 breaths per minute.
- 2) For respiratory rates above 80 breaths per minute, accuracy is 4 mmHg or  $\pm 12\%$  of reading, whichever is greater, for etCO<sub>2</sub> values exceeding 18 mmHg.
- 3) For respiratory rates above 60 breaths/minute, the Microstream FilterLine H Set for Infant/Neonatal is required.

## Temperature

Parameter display	Temperatures: Ta, Tb, $\Delta T$ , T1a, T1b, $\Delta T1$ (or assigned labels)
Measurement range	Ta, Tb, T1a, T1b: 0 to 50 °C (32 to 122 °F) $\Delta T$ , $\Delta T1$ : 0 to 50 °C (32 to 122 °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: 75 s – disposable GP probes: 35 s – reusable and disposable skin temperature sensors: 15 s
Degree of protection against electric shock	Type CF
Defibrillation protection	Yes

## Scio

For Scio Four/Scio Four Oxi/Scio Four plus/Scio Four Oxi plus modules, refer to the Technical Data appendix in the gas analyzer supplement for further information regarding gas analyzer accuracy.

## EMC declaration (4th Edition)

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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

Immunity against	Test level and required electromagnetic environment
Magnetic fields at mains frequency (IEC 61000-4-8)	30 A/m
Voltage dips (IEC 61000-4-11)	0 % $U_T$ ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0 % $U_T$ ; 1 cycle and 70 % $U_T$ ; 25/30 cycles Single phase: at 0°
Voltage interruptions (IEC 61000-4-11)	0 % $U_T$ ; 250/300 cycle
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 V <sub>rms</sub> , ISM bands: 6 V <sub>rms</sub>
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
Proximity to magnetic fields (IEC 61000-4-39)	Test frequency: 30 kHz Modulation: CW Immunity Test Level (A/m): 8  Test frequency: 134,2 kHz Modulation: Pulse modulation, 2,1 kHz Immunity Test Level (A/m): 65  Test frequency: 13,56 MHz Modulation: Pulse modulation, 50 kHz Immunity Test Level (A/m): 7,5

### 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 30 cm (12 in) between this device and wireless communication devices.

**NOTE**

Avoid exposure to known sources of EMI (electromagnetic interference) with medical devices such as magnetic resonance imaging MRI systems, diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as metal detectors. Note that the presence of RFID devices may not be obvious.

## Radiation exposure statement

This equipment must be installed and operated in accordance with provided instructions and the antenna(s) used for this transmitter must be installed to provide a separation distance of at least 11 mm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.

This equipment should be installed and operated with minimum distance 11mm between the radiator & your body.

The Infinity M540 patient monitor uses a certified wireless module.

Contains FCC ID: URA-MS40251

Contains IC ID: 5895B-MS40251

## ISED

This equipment complies with IC radiation exposure limits set forth for an uncontrolled environment.

## Operating characteristics

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### Classification

Classification Medical Device Europe

Class IIb

# DRAFT

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These instructions for use only apply to  
**Infinity® Acute Care System –  
Infinity M540 – VG8.0**

with the Serial No.:

If no Serial No. has been filled in by Dräger,  
these instructions for use are provided for general  
information only and are not intended for use  
with any specific machine or unit.

DRAFT



The radio equipment in the Infinity M540 patient  
monitor complies with the Radio Equipment  
Directive (2014/53/EU). A copy of the  
Declaration of Conformity is available at the  
following Internet address:  
[www.draeger.com/doc-radio](http://www.draeger.com/doc-radio)

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Dräger reserves the right to make modifications  
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