Instructions for use

Infinity Acute Care System

WARNING

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

Infinity M540 patient monitor
Software VG2

Typographical conventions

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.

Any text shown on the screen and any labeling on the device are printed in bold and italics, for example, ***Alarms***, or ***Menu***.

The "greater than" symbol **>** indicates the navigation path in a dialog window, for example, ***Menu*** > ***Patient setup*** > ***Admit date***. In this example, ***Menu*** represents the function key, ***Patient setup*** represents a horizontal tab, and ***Admit date*** a menu selection.

Screen images

Schematic renderings of screen images are used, which may differ in appearance or in configuration from the actual screen images.

Trademarks

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Safety information definitions

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.

Definition of target groups

For this product, users, service personnel, and experts are defined as target groups.

These target groups must have received instruction in the use of the product and must have the necessary training and knowledge to use, install, reprocess, maintain, or repair the product.

The product must be used, installed, reprocessed, maintained, or repaired exclusively by defined target groups.

Users

Users are persons who use the product in accordance with its intended use.

Service personnel

Service personnel are persons who are responsible for the maintenance of the product. Service personnel must be trained in the maintenance of medical devices and install, reprocess, and maintain the product.

Experts

Experts are persons who perform repair or complex maintenance work on the product. Experts must have the necessary knowledge and experience with complex maintenance work on the product.

Abbreviations and symbols

For explanations, refer to the sections "Abbreviations" on page 32 and "Device symbols" on page 30.

For your safety and that of your patients

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 Cockpit (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.

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".

Dräger recommends that a service contract is obtained with DrägerService and that all repairs are performed by DrägerService. For maintenance Dräger recommends the use of authentic Dräger repair parts.-

WARNING

Any changes or modifications to the device hardware or software have to be exclusively done by service technicians authorized by Dräger. Any non-authorized change can decrease patient safety, could void the user's authority to operate the equipment and will void the warranty.

Safety checks

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

Accessories

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

CAUTION

Device for use in health care environments only and exclusively by persons as defined in the target groups (see "Maintenance" on page 6).

Restriction of distribution

Federal Law (U.S.) restricts this device to sale by or on the order of a physician.

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 correct functioning 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

CAUTION

Risk of patient injury

Electrical connections to equipment not listed in these instructions for use or the assembly instructions must only be made when approved by each respective manufacturer.

Networking and connection to other devices

When combining Dräger devices with other electrical devices, the owner must ensure that the resulting system meets the requirements of the following standards:

– IEC 60601-1 (EN 60601-1)
  Medical electrical equipment
  Part 1: General requirements for safety
– IEC 60601-1-1 (EN 60601-1-1)
  Medical electrical equipment
  Part 1-1: General requirements for safety
  Collateral standard: Safety requirements for medical electrical systems
– IEC 60601-1-2 (EN 60601-1-2)
  Medical electrical equipment
  Part 1-2: General requirements for safety
  Collateral standard: Electromagnetic compatibility; Requirements and tests
– IEC 60601-1-4 (EN 60601-1-4)
  Medical electrical equipment
  Part 1-4: General requirements for safety
  Collateral standard: Programmable electrical medical systems

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 owner.

Strictly follow the assembly instructions and instructions for use for each connected device.

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. IEC 80001-1 requires manufacturers such as Dräger to make technical documentation in support of such network connections available upon request. Contact your Dräger representative.

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.

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.

General safety information

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.

WARNING

Follow local regulations for safe disposal of batteries. To prevent fire or explosion, never dispose of batteries in fire.

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

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.

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 "Cleaning and disinfection" on page 289 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.

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. 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

The medical device is not approved for use in areas where combustible or explosive gas mixtures are likely to occur.

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

General information on electromagnetic compatibility (EMC) according to international EMC standard IEC 60601-1-2:

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 on page 331.

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

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.

Site of operation

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

WARNING

To avoid interfering with device operation, do not operate devices (monitor, MPod, MCable, and accessories) within 10 m (33 feet) of equipment that emits microwave or other high-frequency emissions.

WARNING

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 radiant 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 panel 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 technical 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.

CAUTION

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

CAUTION

Only defibrillate across the chest.

CAUTION

Using ECG electrodes and cables specified by Dräger protects the device from damage during defibrillation and reduces noise and other interference on the ECG waveform.

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 of transducer (ECG, 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 probe sheaths.

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Contents

Application

Intended use

The Infinity M540 (M540) is intended for the monitoring of multi-parameter, physiologic patient information obtained from connected hardware in environments where patient care is provided by trained health care professionals.The M540 is intended to monitor one patient at a time.

The M540 is also intended for patient transport inside the hospital or outside the hospital in a land ambulance.

For land ambulance transport, the battery-operated M540 patient monitor supports ECG, SpO_2, Temperature, and Mainstream $etCO_2$. Tests were performed in accordance with the following standards: EN1789, EMC (IEC 60601-1-2). EMC and environmental requirements may vary from country to country according to local regulatory standards and directives.

This device is not approved for land ambulance use in the United States and Canada.

The M540 and any connected hardware are not intended for use in the following hospital environments:

– Hyperbaric chambers

– Environments containing MRI equipment

NOTE

The Dräger wireless 802.11 b/g radio card complies with part 15 of the FCC rules. Operation is subject to the following two conditions:

– This device may not cause harmful interference.

– This device must accept any interference received, including interference that may cause undesired operation.

Indications for use

The M540 is capable of monitoring the following parameters:

- Heart rate
- Arrhythmia (adult and pediatric patients only)
- 12-lead ECG monitoring
- TruST monitoring (adult and pediatric patients only)
- ST segment analysis (adult and pediatric patients only)
- 12-lead ST segment analysis (adult and pediatric only)
- Apnea
- Respiration rate – RRi
- Invasive blood pressure – IBP
- Non-invasive blood pressure – NIBP
- Temperature
- Cardiac output – only available when the M540 is docked in an IACS configuration (adult and pediatric patients only)
- Arterial oxygen saturation – SpO_2
- Pulse rate
- Mainstream $etCO_2$
- Perfusion index – PI
- Total hemoglobin – SpHb, (adult and pediatric patients only)
- Total oxygen content – SpOC, (adult and pediatric patients only)
- Carboxyhemoglobin saturation – SpCO
- Methemoglobin saturation – SpMet
- Pleth variability index – PVI

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Overview

Overview of Infinity M540

These instructions for use describe the M540. This monitor is a rugged, light-weight, handheld, transportable patient monitor with a touch screen 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 71).

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

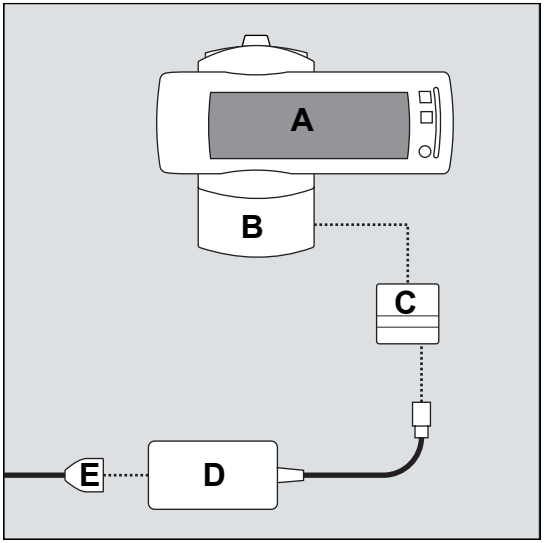
– M540 – refers to the Infinity M540 patient monitor

– 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

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 M540

B M500

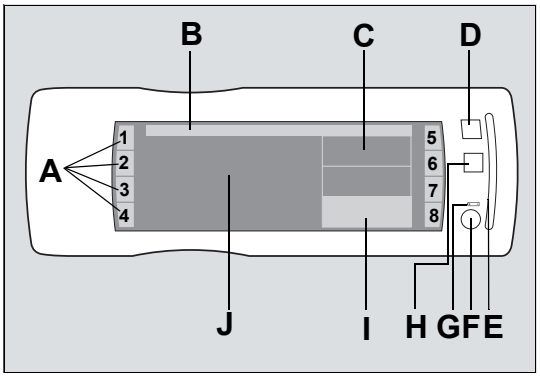
C Y-cable/Y-adapter

D Power supply

E Power cable

M540 front panel

The following illustration shows the elements of the front panel.



A 8 function keys (see page 44)

B Header bar (see page 45)

C Parameter box (see page 46)

D NIBP fixed key

E Alarm bar

F Power on/off fixed key

G Battery LED symbol

H Audio pause fixed key

I Parameter box in alarm

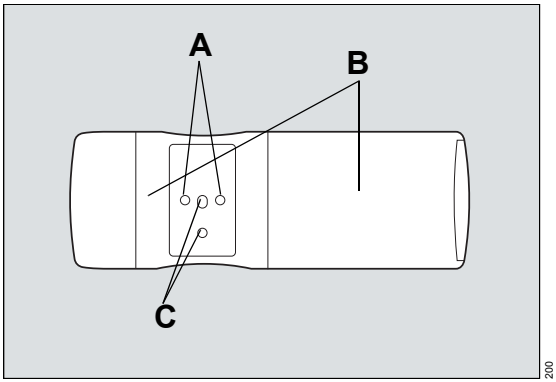
J Waveform area (see page 46)

M540 fixed keys

The M540 has the following fixed keys:

Key/LED	Function
	On/off fixed key Turns the M540 on or off. The button LED flashes when the M540 is undocked; it lights up when the M540 is docked.
	Battery LED symbol 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.
	Audio pause fixed key Pauses acoustic alarm signals for two minutes.
	NIBP start/stop fixed key Starts/stops non-invasive blood pressure measurements.

M540 back panel



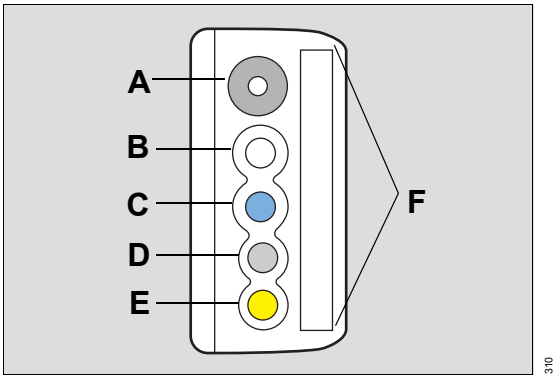
A Charging contact points

B Labels

C Optical ethernet links

CAUTION
Do not affix any labels that cover the optical ethernet links or the charging contact points to the back of the M540.

M540 side panel



A Non-invasive blood pressure connector

B Temp (2) / Aux connector

C SpO_2 connector

D Hemo connector

E CO_2 connector

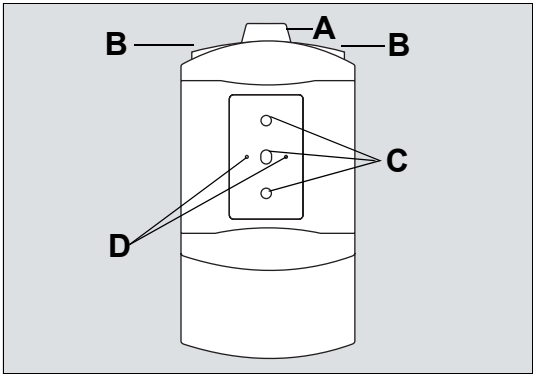
F ECG connector

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 51.

M500 front panel



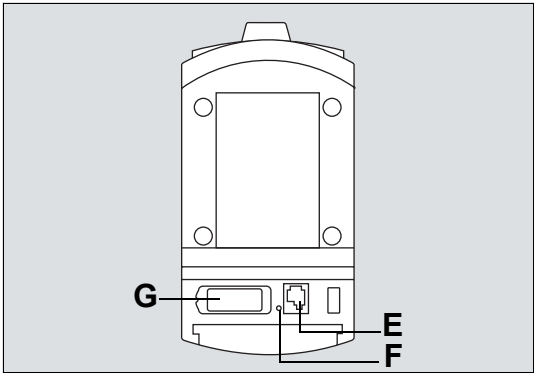
A Locking mechanism – secures the M540 (for more detailed information, see "Locking/unlocking the M540" on page 72)

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

M500 back panel



E Nurse call connector (not available in a standalone configuration)

F Network LED – lights up green when connected to the network

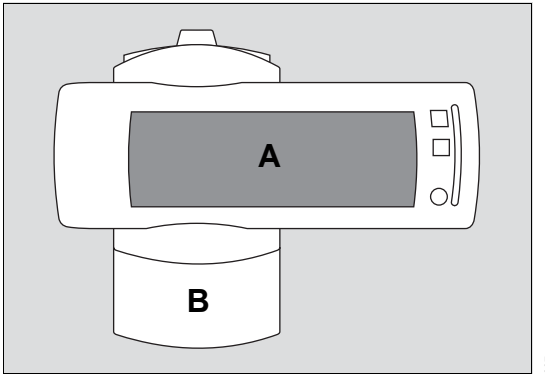
G System cable connector

M540 docked in the M500

The following diagram shows the M540 docked in the M500.

A M540

B M500



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 (%SpO_2) and reports the perfusion index (PI), and the pulse rate (PLS).	Connects directly to the SpO_2 connector of the M540 (see page 168 and page 184).
Infinity MCable – Masimo rainbow SET	Measures the percentage of functional hemoglobin saturated with oxygen (%SpO_2) and reports the perfusion index (PI), and the pulse rate (PLS). In addition, it measures total hemoglobin (SpHb), total oxygen content (SpOC), pleth variability index (PVI), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet)	

Device	Description	Connection
Infinity MCable – Nellcor OxiMax	Measures the percentage of functional hemoglobin saturated with oxygen (%SpO_2) and the pulse rate (PLS).	Connects directly to the SpO_2 connector of the M540 (see page 168 and page 184).
Hemo4 pod Infinity MPod – QuadHemo	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 213).
Hemo2 pod	Measures up to two pressures, cardiac output, core and body surface temperature.	
Infinity MCable – DualHemo	Measures up to two pressures.	
Infinity MCable – Mainstream CO_2	Measures mainstream CO_2.	Connects directly to the CO_2 connector of the M540 (see page 232).
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 ECG 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 192) or to the CO_2 connector with a Y-cable.

Device symbols

	Consult instructions for use		Alarm monitoring deactivated temporarily
	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 tone paused temporarily
	Function/setting is unlocked		Acoustic alarm signal tone 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
IPX4	Degree of protection against liquid ingress		Power on/off
	Lower alarm limits		Non-disposable part
	Upper alarm limits	REF	Device part number and revision
	Autoset alarm limits	SN	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
or the FCC ID			Defibrillation-proof Type CF equipment

Wireless symbols

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

	White wireless symbol indicating the M540 has optimum association with a wireless access point. This symbol also appears on the back of the M540 when the wireless option is activated.		White wireless symbol indicating the M540 has good association with a wireless access point
	White wireless symbol indicating the M540 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.

Abbreviations

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

Abbreviation	Description
ASY	Asystole
AIVR	Accelerated idioventricular rhythm
AHA	American Heart Association
APR	Arterial pulse rate
ARR	Arrhythmia
ART	Arterial pressure
ART D	ART diastolic value
ART M	ART mean value
ART S	ART systolic value
ARTF	Artifact
aVF	ECG lead aVF
aVL	ECG lead aVL
aVR	ECG lead aVR
BGM	Bigeminy
BRADY	Bradycardia
C.O.	Cardiac output
CISPR	International Special Committee on Radio Interference
CO_2	Carbon dioxide
CPP	Cerebral perfusion pressure
CPT	Ventricular couplet
CVP	Central venous pressure
dV1 to dV6	Derived chest leads
ECG	Electrocardiogram
$etCO_2$	end-tidal CO_2
GP1 to GP4	General pressure 1 - 4
GP1 M to GP4 M	General pressure 1 - 4 mean value
GP1 S to GP4 S	General pressure 1 - 4 systolic value
GP1 D to GP4 D	General pressure 1 - 4 diastolic value
HR	Heart rate
I	ECG lead I
IACS	Infinity Acute Care System
IEC	International Electrotechnical Commission
IBP	Invasive blood pressure
ICP	Intracranial pressure
ICS	Infinity CentralStation
II	ECG lead II
III	ECG lead III
ISO	International Organization for Standardization
Iso	Iso-electric point
LA	Left arm electrode (ECG)
LA	Left atrial pressure
LL	Left leg electrode (ECG)
LV	Left ventricular pressure
LV D	Left ventricular diastolic value
LV M	Left ventricular mean value
LV S	Left ventricular systolic value
NIBP	Non-invasive blood pressure
NIBP D	NIBP diastolic value
NIBP M	NIBP mean value
NIBP S	NIBP systolic value
PA	Pulmonary arterial pressure
PA D	PA diastolic value
PA M	PA mean value
PA S	PA systolic value

Abbreviation	Description
PI	Perfusion index (SpO_2)
PLS	Pulse rate from SpO_2
PLS CO-Ox	Pulse CO-Oximetry
PVC/min	Rate of PVC (pre-ventricular contractions) per minute
PVI	Pleth variability index
PWP	Pulmonary wedge pressure
RA	Right arm electrode (ECG)
RA	Right atrial pressure
(L)	Right leg electrode (ECG)
RRc	Respiratory rate (CO_2)
RRi	Respiratory rate (impedance)
RUN	Ventricular run
RV	Right ventricular pressure
RV D	Right ventricular pressure, diastolic
RV M	Right ventricular pressure, mean
RV S	Right ventricular pressure, systolic
SpCO	Carbon monoxide bound to hemoglobin
SpHb	Total hemoglobin levels in arterial or venous blood
SpHbv	Total hemoglobin (venous)
SpMet	Methemoglobin saturation
SpO_2	Pulse oxygen saturation
SpOC	Total oxygen content
STI, STII, STIII, STV, STV1 to STV6	ST deviation leads
STCVM	Change in vector magnitude
STdV1 to STdV6	ST deviation of derived leads (dV1 to dV6)
STVM	ST vector magnitude
SVT	Supraventricular tachycardia

Abbreviation	Description
TACH	Tachycardia
Tblood	Blood temperature
Tinj	Injectate temperature
TruST	Algorithm that provides a TruST-12-lead-ECG (including derived chest leads dV1, dV3, dV4, dV6) using a 6 lead wire set that provides ECG leads I, II, III, aVL, aVR, aVF, V2, V5.
V	Chest lead from a 5 or 6 lead wire set.
V+	Second chest lead from a 6-lead wire set
V1 to V6	ECG chest leads V1 to V6
VESA	Video Electronics Standard Association
VF	Ventricular fibrillation
VTACH	Ventricular tachycardia

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Operating concept

Overview

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 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 or the PS250 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 roll stand, or in a traditional wall mount.

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 253).

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 253.

For information how the M540 behaves in an IACS configuration, see page 39.

Configuration changes while on wireless transport

Any changes to the M540 profile settings while on transport (including remote changes) are maintained when you redock the M540 to the M500 where it was previously docked. However, if you dock 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 63.

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 ***Settings 2*** tab (see page 246).

– The setting ***Transport pulse tone*** determines the pulse tone volume for SpO_2 and heart rate when the M540 is on transport. While on transport, you can adjust the pulse tone volume manually in the parameter-specific SpO_2 or heart rate setup menu.

  You cannot adjust any tone volume setting higher than the ***Transport volume*** setting.

– The ***Transport volume*** determines the speaker volume of the M540 when it undocks for patient transport.

  When used in an IACS configuration, the M540 assumes all audible alarm reporting as soon as it is undocked. The Cockpit no longer issues audible alarms while the M540 is on transport.

  While on transport, you can adjust the ***Transport volume*** setting manually by pressing the ***Alarms*** function key then the ***Speaker 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 63.

Bed label setting

If the ***Keep bed label*** setting on the M500 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 M500 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 window 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.

Contact your technical personnel to configure this setting appropriately. For more information, see page 254.

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

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 38) 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 37.

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). The trend data are available on the network. Trend data are also available for review at the ICS.
– 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 banners: ***All alarms off***, ***All alarms paused*** (with countdown 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 260 for network-related messages.

ICS (Infinity CentralStation) communication

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

WARNING
When the M540 is connected to the Infinity network, make sure that the ICS is equipped with software version VF8.12 or a later version. On earlier versions of the ICS, gaps in the waveform may be displayed in the Full Disclosure application of the ICS after docking or undocking a wireless M540.

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 box 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 boxes. Up to four additional parameter boxes can be allocated to appear along the bottom. The BedView screen is populated with waveforms and parameter boxes from the five available M540 Views. These Views determine how many waveforms and parameter boxes are displayed on the M540.

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

– The top waveform of View 1 of the M540 becomes channel 1 on the ICS BedView.

– No waveform and no parameter box 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 boxes 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 boxes (no waveforms) starting with the right-most parameter box which appears along the bottom of the M540.

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 you dock 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 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

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

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 graph and trend table 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*.

Audio pause feature

The Infinity network supports an audio pause of alarm tones from the ICS (see page 96 for more information).

Network communication 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 alarm error***.

– The alarm tone volume behaves differently for a wireless or a wired M540.

Wireless	Wired
The M540 alarm tone 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 tone volume is automatically set to 100% if the alarm volume was set to ***Off***. 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 tone volume was set to any other setting than ***Off*** when the network interruption occurred, the alarm tone volume remains unchanged.

NOTE

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

When the M540 is connected to the network, but the communication with the ICS is interrupted, the message ***Not monitored by central*** appears in the viewport of the ICS and in the M540 header bar.

Remote view and remote control

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

– IACS Cockpits

– ICS

– Bedside monitors – Delta/Delta XL/Kappa, Vista XL, and Gamma XXL

You can also execute certain remote functions from the above devices for any M540 that is connected to the Infinity network.

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 63).

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.

Remote function	**Remote control from the ICS?**	**Remote control from other bedside 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 you can concentrate on a procedure without being interrupted. Visual alarm signals are still reported for any alarm condition.	Yes	Yes
Requesting continuous/timed recordings for M540 used in an IACS configuration and on wireless transport The recording requests are stored on the M540 and transferred to the Cockpit once the M540 is docked. You can review a stored event at the Cockpit and request a manual recording.	Yes	Yes
Requesting continuous/timed recordings for standalone M540.	No	No
Activate/deactivate the alarm function for a parameter	Yes	No

Remote function	**Remote control from the ICS?**	**Remote control from other bedside monitors?**
Activate/deactivate the alarm ***Archive*** function. The following happens for each setting of the ***Archive*** function: – If the M540 is in an IACS configuration and on wireless transport and a parameter whose ***Archive*** function is set to ***Str/Rec*** or ***Store*** 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. 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 ***Event recall*** dialog window of the M540 (see page 103). – If the M540 is in an IACS configuration and on wireless transport a parameter whose ***Archive*** function is set to ***Record*** 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 you can view it on the alarm history page and request a manual recording. 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 ***Event recall*** dialog window of the M540 (see page 103).	Yes	No
Configuring alarm limits	Yes	No
Auto setting alarm limits	Yes	No
Configuring arrhythmia settings	Yes	No
Configuring ST settings	No	No
Reviewing trend data	Yes	No
Initiate relearning	Yes	No
Change the demographic data of the patient	Yes	No

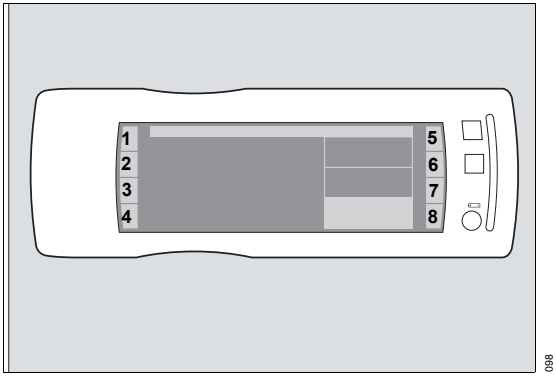
Function keys

A total of eight function keys are located on the front panel 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 45). 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	***Standby*** (default)	Places the M540 into standby mode (see page 66). When the M540 is docked in an IACS configuration, pressing this function key also places the Cockpit in standby mode.
2	***Review*** (function key)	Opens the ***Event recall*** dialog window (see page 103).
3	***Menu*** (function key)	Opens the ***Main*** dialog window. It also closes any open dialog and returns you to the monitoring view.
4	***View 1*** to ***View 5*** (function key)	Scrolls through five pre-configured screen layouts (see page 50).
5	***Code*** (function key)	Invokes the Code function at 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*.
6	***Discharge*** (default)	Discharges the patient (see page 80).
7	***Alarms*** (function key)	Opens the ***Alarm settings*** dialog window.
8	***Record*** (default)	Records an event which can be viewed in the ***Event recall*** dialog window (see page 103). When the M540 is docked in an IACS configuration, pressing the ***Record*** 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.

Alternate function key assignments

Key	Function
Privacy	Places the M540 into privacy mode (see page 66). This mode is only available when the patient is admitted at the ICS.
Mark	Stores an event in the ***Event recall*** dialog window.
Patient	Opens the ***Patient setup*** dialog window (see page 79).
Rest ECG report	Prints a Rest ECG report

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 window.

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.

Monitoring area

The monitoring area of the M540 screen contains a header bar, waveforms, and parameter boxes 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 50).

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 banner field is reserved for one of the following indicators:

  – and the message ***Audio paused*** plus a countdown timer when the ***? Audio paused*** fixed key is pressed

  – and the message ***Audio paused*** when acoustic alarm signals are deactivated

  – the message ***All alarms paused***, and a countdown timer when alarm monitoring is deactivated temporarily

  – and the message ***All alarms off*** when alarm monitoring is deactivated permanently

Parameter boxes

Each parameter box 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 SpO_2 blip
– Countdown 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 box flashes in the color of the alarm grade (see page 87) and a corresponding alarm message appears in the header bar. Each parameter chapter describes the parameter boxes for the corresponding parameter in greater detail.

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

The ***X*** in the upper right corner of any window closes the open dialog window and returns you 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

NOTE

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

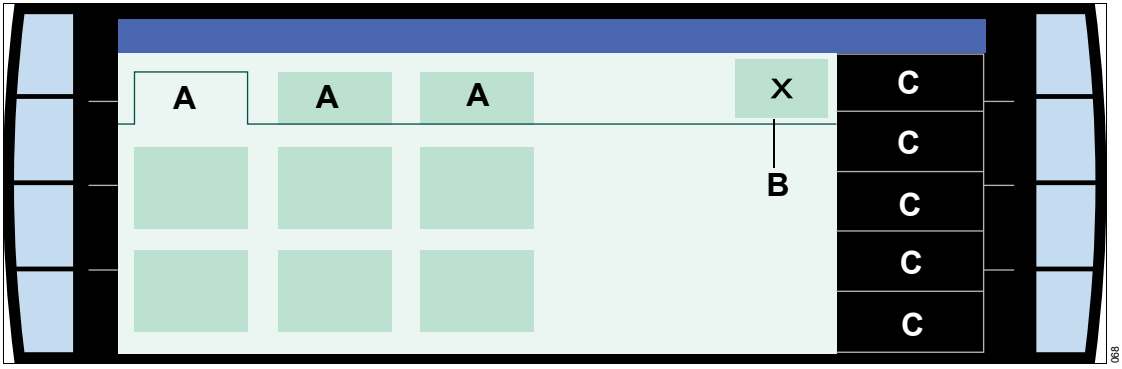
To configure the waveforms

1 Touch the waveform area to open the waveform channel dialog window.
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 window.
4 Touch ***Size*** and then select the desired amplitude.
5 Touch ***X*** to close the dialog window.

Dialog windows

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

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



A Horizontal tabs – the selected tab appears light blue

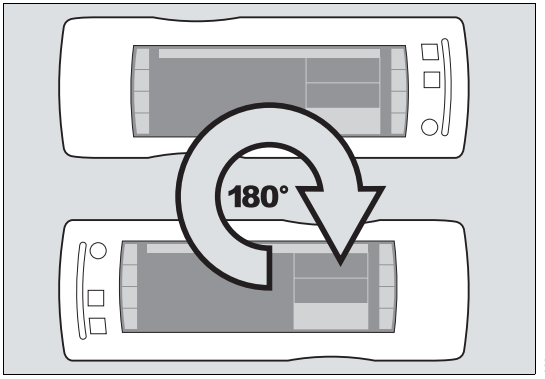
B Button that closes the dialog window

C Parameter boxes 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 touch screen 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 window.

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 you select the button again.

4 Touch ***X*** to close the dialog window.

Calibrating the touch screen

If the touch screen is out of alignment, you can calibrate it at any time.

To calibrate the touch screen

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 fixed keys simultaneously: 

2 Touch each cross appearing successively in each corner of the screen.

Battery power

The M540 automatically switches to battery power when it is undocked or if there is a loss of power to the M500.

When the M540 is docked, the M500 continuously charges the internal battery. The battery charge symbol on the M540 front panel 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.

Battery charging times

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

Capacity	Approximate charging time
70 %	4 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 ECG, SpO_2, and 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 you dock it on an M500 that is receiving power.

Power-saving mode

When the M540 is not docked, the power save mode conserves battery power 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:

– You dock the M540 on the M500

– You touch the screen or any fixed 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

Each M540 supports five pre-configured views, which control the content and the appearance of the screen. You 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, you can change the parameter assignments as needed.

Selected view	Default parameters	Default waveforms
One waveform and three parameter boxes (vital signs display)	HR, SpO_2, and NIBP	ECG lead II
One waveform and four parameter boxes	HR, SpO_2, NIBP, and RRi	ECG lead II
One waveform and seven parameter boxes	HR, SpO_2, RRi, NIBP, GP1, and Temperature. If no IBP sensor is connected the corresponding parameter labels may not be displayed.	ECG lead II
Two waveforms and five parameter boxes	HR, SpO_2, RRi, Temperature, and NIBP	ECG lead II and SpO_2
Three waveforms and three parameter boxes	HR, SpO_2, and RRi	ECG lead II, SpO_2, 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

You 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 window.

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 window.

Profiles

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.

You can save the current profile settings as a default profile and/or restore the default profile under a password-protected menu (see page 250).

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)
Screen views* dialog window** (Press the ***Menu function key > ***Screen setup*** tab > ***Screen views***)			
View 1	x		The view that is active when you save the profiles, will become the designated default view.
View 2	x		
View 3	x		
View 4	x		
View 5	x		
Settings in *Function keys* dialog window (Press the ***Menu*** function key > ***Screen setup*** > ***Function keys***)			
Setup key 1		x	
Setup key 2		x	
Setup key 3		x	
Setup key 4		x	
Alarm profile settings			
The alarm profile settings are configured in the following dialog windows			
Alarm settings* dialog window** (Press the ***Alarms function key)			
Speaker volume		x	
Alarm settings* dialog window** (Press the ***Menu function key ***> System setup > Alarm setup >*** enter password ***> Settings 1***)			
All alarms paused (Time selection)		x	
Alarm validation		x	
SpO_2 alarm delay		x	This selection is only available if the ***SatSeconds*** setting is set to ***Off***.
Alarm group		x	
NIBP/SpO_2 interlock		x	
ASY/VF alarms		x	
Pacer mode	x		
Alarm bar		x	

Setting	Patient default	User default	Comments (if applicable)
Alarm settings* dialog window** (Press the ***Menu function key ***> System setup*** > ***Alarm setup >*** enter password ***> Settings 2***)			
Alarm pattern		x	
Transport volume		x	
Transport pulse tone		x	
SpO2 sensor off dialog window (Masimo) (Press the ***Menu*** function key ***> System setup*** > ***Alarm setup >*** enter password ***> SpO2 sensor off***			
Alarm (alarm priority setting)	x		
Archive	x		
SpO2 check sensor dialog window (Nellcor) (Press the ***Menu*** function key ***> System setup*** > ***Alarm setup >*** enter password ***> SpO2 sensor off***			
Alarm (Alarm priority setting)	x		
Archive	x		
CO2 profile settings			
The CO2 profile settings are configured in the following dialog windows.			
***CO2 limits* dialog window** (Touch the CO2 parameter box)			
Alarm (On/off setting)	x		These settings can be configured separately for each of the following parameters: etCO2, inCO2, RRc
Upper and lower alarm limits	x		
Archive	x		
Settings* dialog window** (Touch the CO2 parameter box ***> Settings > ECG 1)			
Atm. pressure		x	
Gas compens.		x	
RRc apnea time	x		
Apnea archive	x		
Color (Color of the waveform and parameter)	x		
Size [mV/cm] (Size of the waveform)	x		Touch the CO2 waveform to set the scale of the waveform (see page 46).

Setting	Patient default	User default	Comments (if applicable)
Heart rate and arrhythmia profile settings			
The heart rate and arrhythmia profile settings are configured in the following dialog windows			
HR limits* dialog window** (Touch the heart rate parameter box > ***HR limits)			
Alarm (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		
Archive	x		
ARR limits* dialog window** (Touch the heart rate parameter box > ***ARR limits)			
Alarm (Alarm priority setting)	x		The availability of the parameters, depends on the selected arrhythmia mode (see page 139).
Count and ***Rate***	x		
Archive	x		
ECG 1* dialog window** (Touch the heart rate parameter box > ***Settings > ***ECG 1***)			
Tone volume (For pulse tone)	x		
Tone source (For pulse tone)	x		
ECG filter	x		
HR source	x		
Color (Color of the waveform and parameter)	x		This setting affects ECG, ARR, and ST
Size [mV/cm] (Size of the waveform)	x		Touch the heart rate waveform to set the scale of the waveform (see page 46).
ECG 2* dialog window** (Touch the heart rate parameter box > ***Settings > ***ECG 2***)			
Pacer detection	x		This setting is not available when the ESU filter is activated.
QRS sync marker	x		
Cable type	x		
ARR lead 1	x		
ARR lead 2	x		
ARR processing	x		

Setting	Patient default	User default	Comments (if applicable)
ST profile settings			
The ST profile settings are configured in the following dialog windows			
***ST limits* dialog window** (Touch the ST parameter box)			
Alarm (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		
Archive	x		
Settings* dialog window** (Touch the ST parameter box > ***Settings)			
ST lead 1	x		
ST lead 2	x		
ST monitoring	x		
Event duration	x		
TruST	x		This setting is only available with 6-lead cable.
Respiration (RRi) profile settings			
The respiration profile settings are configured in the following dialog windows			
***Resp. limits* dialog window** (Touch the RRi parameter box)			
Alarm (On/off setting)	x		
Upper and lower alarm limits	x		
Archive	x		
Settings* dialog window** (Touch the RRi parameter box > ***Settings)			
Resp. lead	x		
Mode	x		
Marker	x		
Monitoring	x		
Apnea time	x		
Apnea archive	x		
Color (Color of the waveform and parameter)	x		

Setting	Patient default	User default	Comments (if applicable)
Coincidence	x		
Size [mV/cm] (Size of the waveform)	x		Touch the RRi waveform to set the scale of the waveform (see page 46).
SpO_2 (Masimo) profile settings			
The SpO_2 profile settings are configured in the following dialog windows			
***SpO_2 limits* dialog window** (Touch the SpO_2 parameter box)			
Alarm (On/off setting)	x		These settings can be configured separately for SpO_2 and PLS.
Upper and lower alarm limits	x		
Archive	x		
Settings* dialog window** (Touch the SpO_2 parameter box > ***Settings)			
Tone volume	x		
Tone source	x		
Bar graph	x		
Desat alarm	x		This setting is only available in neonatal mode, see page 91.
Averaging time	x		
Sensitivity mode	x		
Fast SAT mode	x		
Color (Color of the waveform and parameter)	x		
Size [mV/cm] (Size of the waveform)	x		Touch the SpO_2 waveform to set the scale of the waveform (see page 46).

Setting	Patient default	User default	Comments (if applicable)
Pulse CO-Ox (Masimo) profile settings			
The Pulse CO-Ox profile settings are configured in the following dialog windows			
Two separate *Pulse CO-Ox limits* dialog window (Touch the Pulse CO-Ox parameter box)			
Alarm (On/off setting)	x		These settings can be configured for the following parameters in two separate ***Pulse CO-Ox limits*** dialog windows: SpHb/SpHbv, SpCO, SpMet, PVI.
Upper and lower alarm limits	x		
Archive	x		
Settings 1* dialog window** (Touch the Pulse CO-Ox parameter box > ***Settings > ***Settings 1***)			
Pulse CO-Ox 1	x		
Pulse CO-Ox 2	x		
Pulse CO-Ox 3	x		
SpHb Averaging	x		
Color (Color of the waveform and parameter)	x		
Settings 2* dialog window** (Touch the Pulse CO-Ox parameter box > ***Settings > ***Settings 2*** > enter password)			
SpHb Cal	x		
PVI Averaging	x		
SpO_2 (Nellcor) profile settings			
The SpO_2 profile settings are configured in the following dialog windows			
***SpO_2 limits* dialog window** (Touch the SpO_2 parameter box)			
Alarm (On/off setting)	x		These settings can be configured separately for SpO_2 and PLS.
Upper and lower alarm limits	x		
Archive	x		
Settings* dialog window** (Touch the SpO_2 parameter box > ***Settings)			
Tone volume	x		
Tone source	x		
Bar graph	x		
Response mode	x		
SatSeconds	x		

Setting	Patient default	User default	Comments (if applicable)
Desat alarm	x		This setting is only available in neonatal mode, see page 91.
Color (Color of the waveform and parameter)	x		
Size [mV/cm] (Size of the waveform)	x		Touch the SpO_2 waveform to set the scale of the waveform (see page 46).
Non-invasive blood pressure profile settings			
The non-invasive blood pressure profile settings are configured in the following dialog windows			
***NIBP limits* dialog window** (Touch the non-invasive blood pressure parameter box)			
Alarm (On/off setting)	x		These settings can be configured separately for NIBP S, NIBP D, and NIBP M.
Upper and lower alarm limits	x		
Archive	x		
Settings* dialog window** (Touch the non-invasive blood pressure parameter box > ***Settings)			
Interval time	x		
Inflation mode	x		
Chime	x		
Color (Color of the waveform and parameter)	x		
Temp profile settings			
The Temp profile settings are configured in the following dialog windows			
***Temp limits* dialog window** (Touch the temperature parameter box)			
Alarm (On/off setting)	x		These settings can be configured separately for Ta, Tb, ΔT, T1a, T1b, ΔT1
Upper and lower alarm limits	x		
Archive	x		
Settings* dialog window** (Touch the temperature parameter box > ***Settings)			
Temp display	x		
Color (Color of the waveform and parameter)	x		

Setting	Patient default	User default	Comments (if applicable)
Invasive blood pressure profile settings			
The invasive blood pressure profile settings are configured in the following dialog windows			
Invasive blood pressure limits dialog window (example: *CVP limits*) (Touch the invasive blood pressure parameter box)			
Alarm (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, RA, LA, RV, CVP, ICP, CPP.
Upper and lower alarm limits	x		
Archive	x		
Settings* dialog window** (Touch the invasive blood pressure parameter box > ***Settings)			
Edit label	x		
Filter	x		
Color (Color of the waveform and parameter)	x		
Size [mV/cm] (Size of the waveform)	x		Touch the invasive blood pressure waveform to set the scale of the waveform (see page 46).

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.

- Fixed key configuration
- ***Speaker volume***
- ***All alarms paused***
- ***Alarm validation***
- ***Alarm pattern***
- ***Alarm bar***
- ***ASY/VF alarms***
- ***SpO_2 alarm delay***
- ***NIBP/SpO_2 interlock***
- ***Pacer mode***
- ***Alarm group***
- Parameter color
- ***HR source***
- ***Tone source*** (ECG and SpO_2)
- ***Tone volume*** (ECG and SpO_2)
- ***Size [mV/cm]*** (ECG and SpO_2 waveform)
- ***ECG filter***
- ***Pacer detection***
- ***QRS sync marker***
- ***ARR processing***
- ***Bar graph*** (SpO_2)
- Desaturation alarm setting for SpO_2
- ***PVI Averaging***
- ***SpHb Cal***
- ***Gas compens.*** (CO_2 compensation)
- Waveform scale (CO_2 and IBP)
- ***Chime*** (non-invasive blood pressure**)**
- ***Filter*** (invasive blood 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 window	Setting
***Screen setup* dialog window (Press the *Menu* function key > *Screen setup*)**	
Screen setup	***Autoflip***
	Power save
***ARR* dialog window (Touch the heart rate parameter box > *Settings* > *ARR*)**	
ARR	***ARR mode***
***Service* dialog windows (Press the *Menu* function key > *System setup* > *Service* > enter password > select dialog window)**	
Service	***ECG baseline***
	Data collection
Network setup	***Network mode***
	Bed label
	Care unit
	Mon. unit
	Hospital
	Mon. unit ID
	IP address
	Net mask
	Default gateway
	RTS / CTS
***Biomed* dialog windows (Press the *Menu* function key > *System setup* > *Biomed* > enter password > select dialog window)**	
Biomed	***Language***
	French NFC
	Line frequency
	Airway adapter
	SpO_2 sensor type
Units	***Temp***
	$etCO_2$
	Pressures
	ST
	SpHb
	Height
	Weight
Docking station	***IP address*** [1]
	Net mask [1]
	Default gateway [1]
	Bed label [1]
	Care unit [1]
	Mon. unit [1]
	Load profile [1]
	Profile settings [1]
Wireless network	***Wireless mode***
	SSID
	Channels
	Encryption
	Keep bed label [1]
	Bed label
Alarm setup	***Central audio pause*** [1]

[1] ***Note:*** 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

You can save the current profile settings as a default device profile (see page 250). 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. You can also request to restore the default profile manually at any time (see page 250).

NOTE
To save a stored profile during a software upgrade, you can copy the profile onto a USB stick by using the import/export feature of an IACS Cockpit. After the upgrade, you can re-import the profile from the USB stick back onto the M540. In addition you can use the same feature to export a profile unto multiple M540 devices. However, this feature is only possible when you are 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

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_2 alarm delay
– Atmospheric pressure value
– IBP labels
– Patient category

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	***Off***	(Not used)	The M540 uses its current profile settings.
	Automatic	***All***	The M540 adopts the profile stored on the M500. See page 52 for a list profile settings.
	Automatic	***Monitor***	The M540 adopts only the monitor settings which are a subset of the profile stored on the M500. See page 60 for a list of monitor settings.
Discharging the M540	***Off***	(Not used)	The profile stored on the M500 is restored.
	Automatic	***All***	The profile stored on the M500 is restored. See page 52 for a list profile settings.
	Automatic	***Monitor***	

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.

NOTE

Contact your technical personnel to make sure the M500 is updated with the latest profile.

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.

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 ***Load profile*** settings are configured to ***Automatic*** and whose ***Profile settings*** feature is set to ***All***.	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

You 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 visual 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 44).

  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 44).

  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 M540 front panel (see page 44) 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 window (see page 103).

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 window of the M540 (see page 79)

– Gender and Race – in the ***Rest ECG setup*** dialog window of the M540 (see page 133)

– 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 44).

  or

1 Press the ***Menu*** function key.

2 Touch the ***Main*** tab, if not already selected.

3 Touch the ***Rest ECG report*** button.

Assembly and preparation

Overview

This section describes the following basic assembly tasks:

– Docking/undocking the M540 from the M500

– Locking/unlocking the M540 into the M500

– Connect/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 your 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.

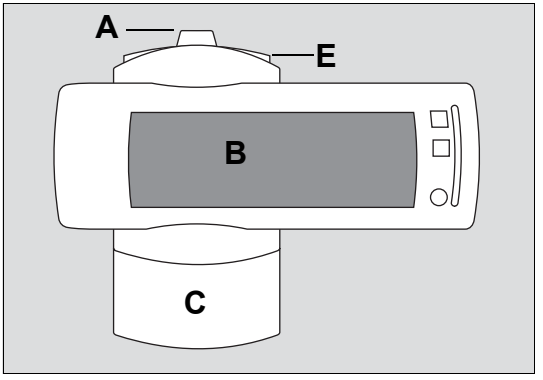
CAUTION

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

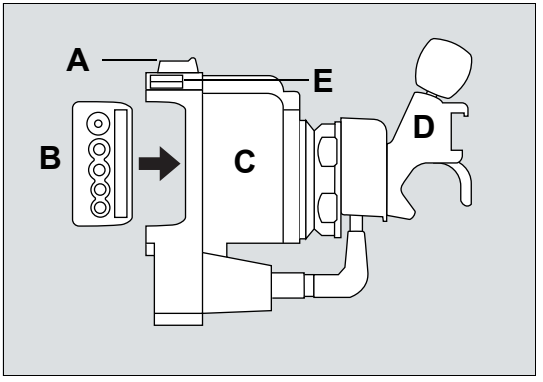
Docking/undocking the M540

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

M500 front view with M540 docked



M500 side view (M540 undocked)



A M500 locking tab

B M540 patient monitor

C M500

D Swivel mount (optional) and mounting clamp

E Release button

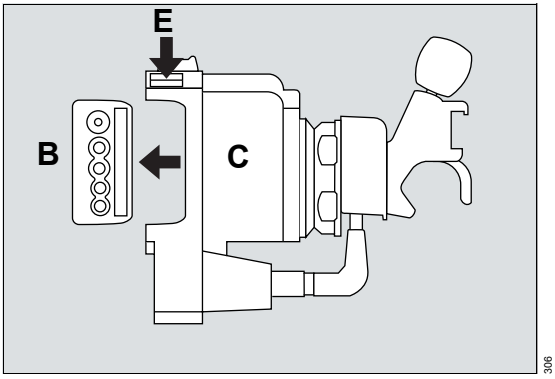
To dock the M540

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 72.

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 72.
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).



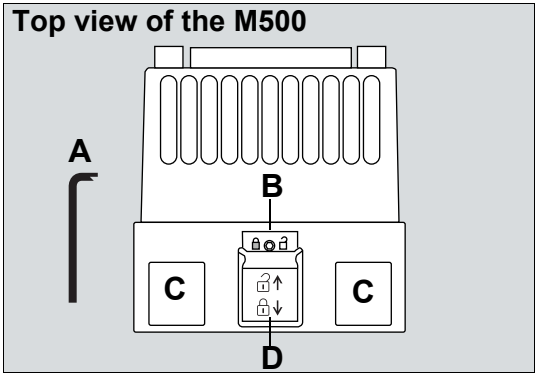
Locking/unlocking the M540

You can lock the M540 permanently 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.



A Allen key

B Center hole on locking tab for locking/unlocking the M540

C Release buttons for undocking the M540

D Locking tab

To unlock the M540

1 Insert the 2 mm Allen key (A) into the middle hole (B) on the locking tab and turn it counter-clockwise to the unlocked position.

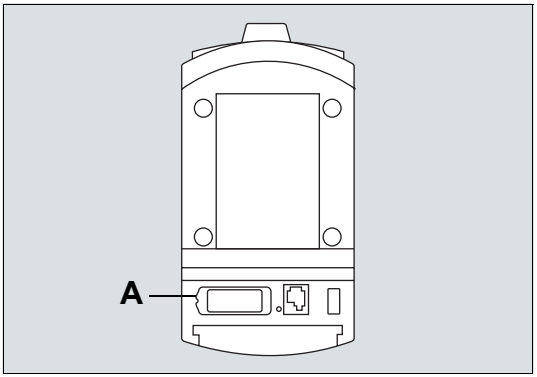
2 Push the locking tab (D) back to unlock the release buttons (C) on the M500 to undock the M540.

Connecting the system cables in an IACS configuration

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

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

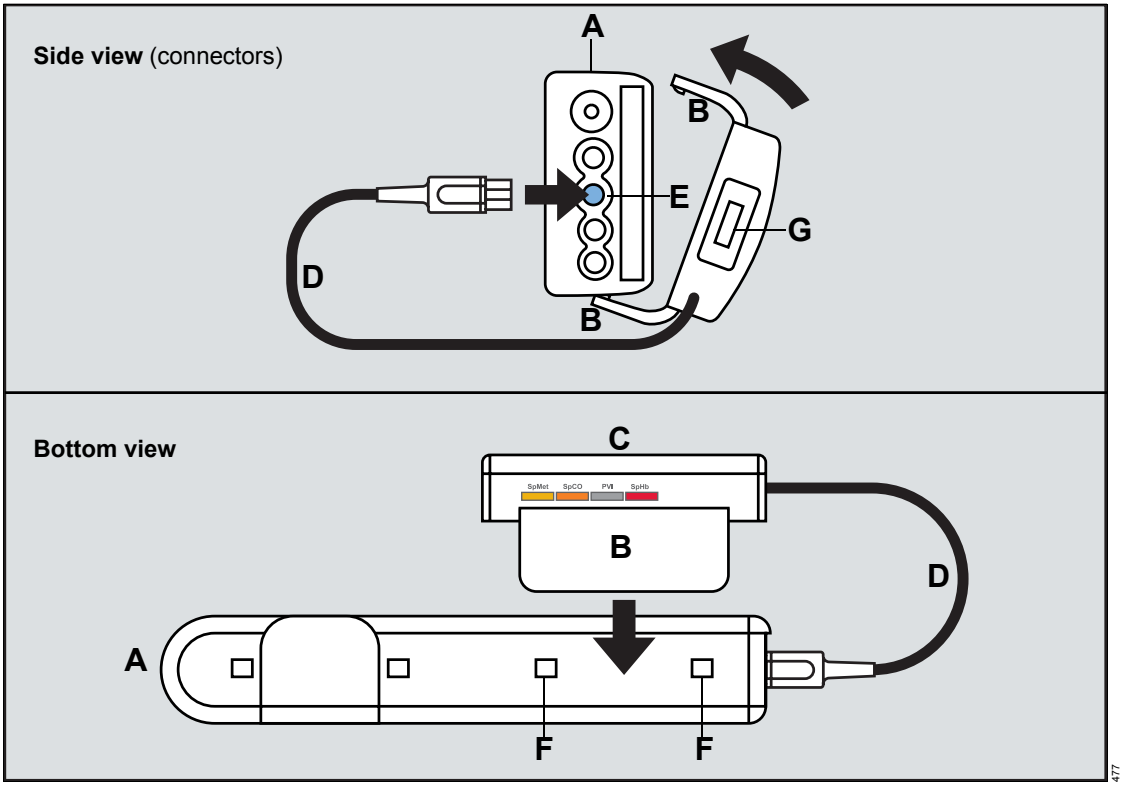


2 Connect the power supply to the M540 system cable.

3 Connect the power cord to the power supply.

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 SpO_2 connector

F Indentations for locking the MCable mount adapter

G Intermediate cable or reusable SpO_2 sensor which connects directly to 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_2 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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Getting started

Overview of monitoring a patient

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

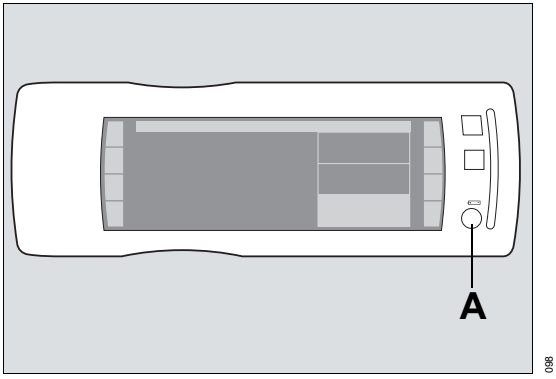
Specifically, this section describes how to:

– 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 key (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 key (A). The ***Power off?*** dialog window appears.

2 Touch ***Shutdown***.

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

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 80.
4. Touch ***OK***. The ***Patient setup*** dialog window closes.
5. Press the ***Menu*** function key.
6. Touch the ***Patient setup*** tab.
7. Touch ***Name*** and use the onscreen keyboard to enter the name (up to 25 characters)
8. Touch ***Confirm***.
9. Touch ***ID*** and use the onscreen 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 onscreen 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 'Get HIS'

You can populate the ***Patient setup*** page automatically, by pulling the demographic data of a patient from the network. 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 patient 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 44).

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***.

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 lbs)	10 to 250 cm (5 to 100 in)
Pediatric	0 to 16 years	0.1 to 350.0 kg (0.1 to 772.0 lbs)	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 45).

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***.

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Alarms

Overview of alarms

The M540 produces acoustic and visual alarm signals to alert you to alarm conditions ranging from alarm limits violations, arrhythmia calls, and battery issues.

Persistent alarms generate acoustic and visual alarm signals that require user intervention to cease. One-shot alarms are only reported once and do not require any user intervention.

Each alarm condition is assigned one of three alarm priorities:

– high (life-threatening)

– medium (serious)

– low (advisory)

Each alarm priority has unique acoustic and visual alarm signals.

In addition to the visual and acoustic alarm signals, alarm messages appear in the alarm message field of the M540. All alarm conditions and associated alarm messages are described in detail in the chapter "Problem solving" on page 259.

The color of an alarm message corresponds to the priority of the associated alarm condition (see "Alarm priorities" on page 84).

The alarm settings for a patient can be set up to store alarms for later event review in the event recall dialog window. A physiological alarm can also activate an external alarm device such as a nurse call system.

When the M540 is docked in an IACS configuration, special monitoring modes (see page 91), such as cardiac bypass mode, affect the regular alarming behavior.

Alarm priorities

Every alarm condition is assigned to one of three priorities: high (life-threatening), medium (serious), or low (advisory). Visual and acoustic alarm signals indicate the level of the alarm priority. For more information on how alarm priorities affect alarm reporting, see "Visual alarm signals" on page 87 and "Acoustic alarm signals" on page 89.

High-priority alarm conditions

All high-priority alarms are physiological alarm conditions that can be life-threatening and require immediate intervention.

An example of a high-priority alarm condition is asystole.

Medium-priority alarm conditions

Most medium-priority alarms report physiological alarm conditions that require prompt attention but may not be life-threatening.

An example of a medium-priority alarm condition is a respiratory rate limit violation.

Low-priority alarm conditions

All low-priority alarms alert you to technical issues that may compromise the ability of the system to monitor the patient.

An example of a low-priority alarm condition is an artifact on the ECG waveform.

Alarm processing

The M540 provides acoustic and visual alarm signals for all parameters except for the following ones:

– Cardiac output (C.O.)

– Injectate temperature (Tinj)

– Pulmonary wedge pressure (PWP)

– Paced beats (%paced)

– Perfusion index (PI) for Masimo SET MCable and Masimo rainbow SET MCable

– Total oxygen content (SpOC) for the Masimo rainbow SET MCable

Latching and non-latching alarm behavior

When an alarm condition no longer exists, the associated acoustic and visual alarm signals behave in one of two ways:

– The alarm signals automatically stop when the alarm condition ceases to exist. This type of alarm is called a non-latching alarm condition.

– The alarm signals continue until you acknowledge the alarm even though the alarm condition has ceased to exists. This type of alarm is called a latching alarm condition.

In general, high-priority alarms are latching alarm conditions while low-priority alarm conditions are non-latching. Exceptions to this alarm behavior are listed on page 91.

The alarm priority of a latching alarm condition determines how the alarm signals behave after the alarm condition ceases to exist:

– A latched alarm condition of high-priority is identified by the standard acoustic and visual alarm signals (see "Visual alarm signals" on page 87).

– A latched alarm condition of medium-priority is downgraded to a status message which appears in the header bar. The background of the alarm message and the parameter box no longer flash in the alarm color, and there are no acoustic alarm signals.

To acknowledge a latched alarm condition

– Press the  key on the M540.

or

1 Select ***All alarms off*** /***All alarms pause*** (the name and function of the button depends on the M540 configuration – see page 257). To access the button, press the ***Alarms*** function key.

2 Change the alarm limits.

The latched alarm signals are cleared and all acoustic and visual latched alarm signals disappear.

Multiple alarm conditions

During multiple alarm conditions, the M540 reports the most recently detected highest-priority alarm condition. When several alarm conditions occur simultaneously, the parameter boxes flash for all alarming parameters. The alarm condition with the highest priority determines which acoustic alarm signal is generated, how the alarm bar and the parameter box appear, and what alarm message appears in the header bar. Messages for active alarms rotate in the header bar.

Activating or deactivating alarm validation

When alarm validation is activated (see page 244), an alarm condition must exist for a certain time before acoustic and visual alarm signals are triggered. This feature reduces nuisance alarms.

When alarm validation is activated, the time between the detection and annunciation of a parameter falling outside the set alarm limits equals the time of detection plus the assigned alarm validation delay. For heart rate, adding the delay time may exceed the maximum of 10 seconds allowed by AAMI EC13 and IEC 60601-2-27.

The following table lists which parameters have an alarm validation time. Parameters that do not appear in the table have no validation times and acoustic and visual alarm signals are triggered almost immediately.

Parameter	Upper alarm limit	Lower alarm limit
ECG/Heart rate (HR)	6 s	6 s
Pulse rate (PLS)	6 s	10 s
ST segment analysis (ST)	off, 15 s to 60 s (in increments of 15 s – selectable) [1]	off, 15 s to 60 s (in increments of 15 s – selectable) [1]
Respiratory rate (RRi)	14 s	14 s
Respiratory rate (RRc)	8 s	10 s
Pulse oximetry (SpO_2) [2]	6 s	10 s
Invasive blood pressure (IBP)	10 s	4 s
Total hemoglobin (SpHb and SpHbv)	6 s	10 s
Carboxyhemoglobin saturation (SpCO)	6 s	10 s
Pleth variability index (PVI)	6 s	10 s
Methemoglobin saturation (SpMet)	6 s	10 s

NOTE

[1] Select the validation period for the ST limit alarm in the ***ST*** dialog window (see page 149).

[2] For Nellcor OxiMax SpO_2: the ***SatSeconds*** alarm time overrides the alarm validation setting (see page 189).

Visual alarm signals

Each alarm priority has its own distinct visual alarm signals.

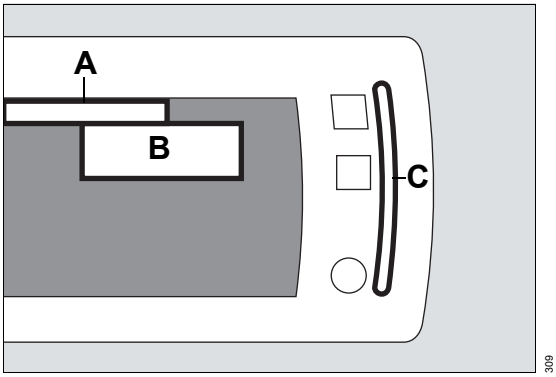
The alarm message in the header bar is the only visual alarm signal if an alarming parameter is not included in the current screen view and the alarm bar is deactivated. For more information on alarm messages, see page 88.

Alarm priority	**Parameter box**	**Alarm message field [1] in header bar**	**Alarm bar (if activated, see page 246)**
High (life-threatening) *(for example, asystole, ventricular fibrillation)*	Flashing red background	Red background	Flashing red
Medium (serious) *(for example, alarm limit violations)*	Flashing yellow background	Yellow background	Flashing yellow
Low (advisory) *(for example, disconnected lead)*	Solid cyan background	Cyan background	No visual signal

NOTE

[1] M540 alarm messages are designed to be legible at arm's length.

Visual alarm indicators on the M540



A Alarm message field in the blue header bar

B Alarming parameter box

C Alarm bar

Alarm bar

The alarm bar on the M540 visually announces high- and medium-priority alarm conditions (see page 84).

However, the alarm bar is inactive when:

– Only low-priority alarm conditions exist

– The alarm bar is deactivated (see page 246)

– Cardiac bypass is activated (see page 93) and the M540 is docked in an IACS configuration

– Privacy mode is activated

– Alarm monitoring is deactivated (see page 99)

Acoustic alarm signals

During an alarm, the M540 provides distinct acoustic alarm signals for each alarm priority in addition to visual alarm signals (see page 87). The specific characteristics of these acoustic alarm signals depend on the selected alarm tone pattern. The available alarm tone patterns are: ***IEC fast***, ***IEC slow***, and ***Infinity***.

When acoustic alarm signals are paused, the alarm bar and the parameter box stop flashing but remain lit up in the respective alarm color.

If multiple alarm conditions exist simultaneously, an acoustic alarm signal sounds for the alarm condition with the highest priority.

NOTE

Normally, in an IACS configuration, acoustic alarm signals only sound at the Cockpit not at the M540. Therefore, all audible alarm signals are transferred automatically from the M540 to the Cockpit once you dock the M540. However, if you want alarms to sound at both devices, select the alarm tone volume at the M540 manually. For more information refer to the *Infinity Acute Care System – Monitoring Applications* instructions for use

Alarm priority	***IEC fast***	***IEC slow***	***Infinity***
High	The following tone sequence is repeated every 4.5 s: Three beeps > one beep > one beep with higher pitch > short pause.	The following tone sequence is repeated every 8 s: Three beeps > one beep > one beep with higher pitch > short pause.	Continuous two-tone sequence
Medium	The following tone sequence is repeated every 7 s: Two beeps > one lower pitched beep	The following tone sequence is repeated every 15 s: Two beeps > one lower pitched beep	Two tones > short pause
Low	Two beeps repeated every 16 s	Two beeps (no repetition)	Low tone repeated every 30 s

Adjusting the alarm tone

The volume of the alarm tone is adjustable. Set the volume of the alarm tone so it can be heard during the noisiest times.

When an M540 is undocked, it uses the speaker volume configured under the ***Transport volume*** setting (see page 246) in the password-protected Service menu to generate audible alarms. The available settings are: 50% to 100% (adjustable in increments of 10%).

When the M540 is docked to the Cockpit, the Cockpit assumes primary alarm annunciation and the M540 speaker is deactivated.

When the M540 is docked to an M500, the profile speaker volume is restored provided the ***Load profile*** setting is activated. If the ***Load profile*** setting was not activated, the previously configured speaker volume setting is maintained.

During patient transport, you can change the alarm tone/speaker volume of the M540.

To adjust the alarm tone volume

1 Press the ***Alarms*** function key.

2 Touch the ***Speaker volume*** button and select the desired volume level (***Off***, 5 %, 10 to 100 % in increments of 10 %).

NOTE

The M540 speaker volume can only be turned off when the M540 is docked in an IACS configuration or when it is connected to the ICS.

The  symbol appears in the M540 header bar when the alarm volume is deactivated.

When the M540 is on wireless transport in an IACS configuration or in standalone mode and it loses its connection to the ICS, the alarm tone volume setting is automatically set to 100 %. The setting ***Off*** is no longer available until the connection to the ICS is restored.

Testing visual and acoustic alarm signals

The alarm bar and the speakers of the M540 are automatically tested during startup. You can also test the visual and acoustic alarm signals by creating an alarm condition (for example, by lowering the upper heart rate alarm limits of the heart rate). To end the test, restore the alarm limits to the previous setting (see page 100).

Special alarm behavior

Activating any of the following features alters the normal alarm annunciation behavior:

- ***ASY/VF alarms***
- ***SpO2 Desat alarm*** feature
- ***NIBP/SpO2 interlock*** feature
- Zeroing invasive blood pressures
- Privacy mode
- ***Cardiac bypass*** mode and OR mode (only available when the M540 is docked in an IACS configuration)
- ***Standby*** mode
- ***French NFC*** mode

Arrhythmia/ventricular fibrillation alarms

You can control the alarming behavior for ventricular fibrillation (VF) and asystole (ASY) alarms.

Alarm signals are not generated for ventricular fibrillation and asystole events when the following conditions are met:

- The ***ASY/VF alarms*** setting is set to ***Always on*** or ***Follow HR*** (see page 245)
- The ***ARR mode*** is set to ***Off***
- The ***HR source*** is set to ***ART*** or ***SpO2*** with ECG available as a heart rate source

To make sure that asystole and ventricular fibrillation alarms are always reported do one of the following:

- Turn arrhythmia monitoring on

  or

- Set the ***HR source*** to ***ECG*** (see page 131) when the ***ARR mode*** setting is set to ***Off*** (see page 142)

The ***HR, ASY, VF off*** banner appears when arrhythmia monitoring is deactivated, the ***ASY/VF alarms*** selection is set to ***Follow HR***, and heart rate alarms are deactivated.

SpO2 desaturation alarm feature

In neonatal mode, the alarm priority is upgraded to high-priority if the SpO2 value falls more than 10% below the lower SpO2 alarm limit. This feature is automatically activated whenever neonatal mode is activated. This function can be activated or deactivated (see page 189). When using the Infinity MCable – Nellcor OxiMax this feature is only available if the ***SatSeconds*** function is set to ***Off*** (see page 189).

NIBP/SpO2 interlock alarm feature

To avoid SpO2 nuisance alarms when the non-invasive blood pressure cuff and the SpO2 sensor are placed on the same limb during an active non-invasive blood pressure measurement, select ***NIBP/SpO2 interlock On*** in the ***Alarm setup*** dialog window (see page 245).

When the feature is activated, all SpO2 alarms are deactivated during an active non-invasive blood pressure measurement. To activate or deactivate this feature, see page 245.

Zeroing invasive blood pressures

Zeroing all invasive blood pressures using the zero key (⇒0⇐) on the hemodynamic pods has the following effects:

– All invasive blood pressure limit alarms and static alarms are suppressed from the time the key is pressed until 30 seconds after the zeroing procedure is completed.

Zeroing an individual invasive blood pressure from the M540 (see page 219) has the following effects:

– The invasive blood pressure limit alarm and static alarm for that parameter are suppressed from the time the button is pressed until 30 seconds after the zeroing procedure is completed.

– If the zeroed parameter is ICP or ART, the CPP limit alarm is also suppressed from the time the button is pressed until 30 seconds after the zeroing procedure is completed.

The following alarm conditions cancel the suppression of alarms caused by zeroing invasive blood pressures:

– Invasive blood pressure parameter is outside of the measuring range (too high/low)

– Invasive blood pressure hardware failures

– Unplugged transducers

– Disconnected hemodynamic pods

– A wedge pressure measurement that ends before the 30-second zeroing period ends, activates the alarm limit for the parameter PA M only

Privacy mode

Privacy mode is available when the M540 is docked in an IACS configuration, on wireless transport, or in standalone mode provided the patient is admitted at the ICS. When privacy mode is activated, the following happens at the M540:

– All patient data are removed from the M540, but continues to display at the ICS

– The alarm bar is deactivated

– Acoustic alarm signals are only provided at the ICS

– The M540 displays ***Privacy, Touch screen to resume monitoring***

You can activate privacy mode only if the patient is also admitted at the ICS. To activate or deactivate this feature, see page 66.

Standby mode

When Standby mode is activated, the following happens at the M540:

– All patient data are removed from the screen

– All monitoring (including acoustic and visual alarm signals) is suppressed

– Active alarms are considered acknowledged by the user

– All recordings are canceled at the Cockpit (provided the M540 is docked in an IACS configuration)

– The M540 displays ***Standby, Touch screen to resume monitoring***

OR mode

OR mode is only available on the M540 when it is docked in an IACS configuration. When OR mode is activated at the Cockpit, alarm messages for medium- and high-priority alarms clear when the alarm condition no longer exists.

Cardiac bypass mode

Cardiac bypass mode is only available when the M540 is docked in an IACS configuration, and the Cockpit is in OR mode. When cardiac bypass mode is activated, the following happens at the M540:

– All alarm monitoring (including arrhythmia alarms), and the alarm bar are deactivated

– The message ***All alarms off: Bypass*** appears in the upper right corner of the screen

Cardiac bypass mode is not available if French NFC mode is activated.

French NFC mode

When French NFC mode is activated, the following happens at the M540:

– Heart rate alarms cannot be deactivated

– The alarm pause period cannot last longer than 3 minutes

– You cannot activate cardiac bypass mode when French NFC mode is activated. If cardiac bypass mode was activated before French NFC mode was turned on, cardiac bypass mode is deactivated.

To activate or deactivate this feature, see page 251.

Pre-silencing alarms

This function allows you to pre-silence (audio pause in advance) potential alarm conditions before they occur. Pre-silencing allows you to concentrate on a procedure without being interrupted by continuous acoustic alarm signals arising from potential alarm conditions. A pre-silence period lasts two minutes.

Pre-silencing alarms has the following effect:

– Any alarm conditions are reported visually by a corresponding alarm message and a blinking parameter box (see page 87).

– A single alarm tone sequence is generated for the first occurrence of an alarm condition of low, medium or high priority.

– The alarm message ***Audio paused*** appears in the far right field of the header bar along with a countdown timer and the following symbol: 

– If multiple alarm conditions arise during an active pre-silence period, the M540 triggers a single alarm tone sequence for the highest-grade alarm event.

Central audio pause feature

The selected ***Central audio pause*** setting of the M540 determines how the ICS reacts when you pre-silence alarms at the M540. This is a password-protected feature. For more details, see page 246.

– If the ***Central audio pause*** setting is set to ***Continue***, the ICS does *not* provide any acoustic alarm tone for any alarm condition of low or medium priority.

  Only an alarm condition of high priority will break through the pre-silence period and is reported acoustically and visually at the ICS.

– If the ***Central audio pause***setting is set to ***Exit***, the ICS announces immediately any alarm visually and acoustically, regardless of its alarm priority.

Initiating a pre-silence period

You can initiate a pre-silence in several ways:

– From an M540 in standalone mode or on wireless transport

– From an ICS

– From the remote view of another Infinity monitor within the same monitoring unit

– From the Cockpit when the M540 is docked in an IACS configuration

To initiate a pre-silence period remotely is only possible when the remote control setting of the remote device is also activated. Refer to the corresponding instructions for use for information on how to activate the remote control feature.

To pre-silence alarms at the M540

- Press the yellow  key on the M540.

The pre-silence state can be cancelled by pressing the same key again that initiated the pre-silence period. All alarm events are again reported as usual.

To pre-silence alarms remotely

- Press the yellow  key on the main menu bar of the ICS to pre-silence alarms for all assigned patients. Press the same button in the viewport area to pause alarm tones for an individual patient. For more information, refer to the ICS instructions for use.
- Refer to the instructions for use of any remote device within the same monitoring unit for instructions on how to initiate an audio pause.

The pre-silence state can be cancelled by pressing the same key again that initiated the pre-silence period. All alarm events are again reported as usual.

Pausing acoustic alarm signals (audio pause)

Active alarms can be paused, or silenced, at the M540 for two minutes.

You can initiate an audio pause in several ways:

– From an M540 in standalone mode or on wireless transport

– From an ICS

– From the remote view of another Infinity monitor within the same monitoring unit

– From the Cockpit when the M540 is docked in an IACS configuration

The central audio pause feature of the ICS provides another unique audio pause behavior which is described in detail below.

Remote control is possible from a remote device provided its remote control feature and that of the M540 (see page 246) are activated. Refer to the instructions for use of the remote device for information on how to activate the remote control feature.

NOTE

If a new alarm condition cancels the current audio pause state and you audio pause the new alarm condition, the audio pause timer is reset to 2 minutes on all devices.

Pausing alarms at the M540

The following happens at the M540 when you pause active alarms:

– All acoustic alarm signals are paused for a maximum of about two minutes.

NOTE

If the condition of the patient remains unchanged after the alarm pause period, the acoustic and visual alarm signals are reactivated. The only exception are one-shot alarms which are only reported once.

– Persistent alarms – the parameter box and the alarm bar stop blinking but appear solid in the alarm color corresponding to the alarm grade (see page 87). The alarm message continues to display in the header bar.

– One-shot alarms – the alarm tone and message are cleared.

– The ***Audio paused*** banner appears in the far right field of the header bar along with a countdown timer and the following symbol: 

If a new alarm conditions occur during an active audio pause period, the following happens at the M540:

– A single alarm tone sequence consisting of several distinct tones sounds in addition to the visual alarm signals for any new alarm condition. Any new alarm condition of equal or lower alarm priority than the paused alarm, does not generate any visual or acoustic alarm signal.

– The parameter box of the new alarming parameter flashes while the parameter box of the previously paused alarm remains highlighted

– All alarm messages for paused and active alarm conditions rotate in the header of the M540

To initiate an audio pause at the M540

- Press the yellow  key on the M540.

Pressing the key again cancels the audio pause period and all alarm events are reported as usual.

To initiate an audio pause remotely

- Press the yellow  key on the main menu bar of the ICS to audio pause alarms for all assigned patients. Press the same button in the viewport area to pause alarm tones for an individual patient. For more information, refer to the instructions for use of the ICS.
- Refer to the instructions for use of any remote device within the same monitoring unit for instructions on how to initiate an audio pause.

Pressing the key again cancels the audio pause period and all alarm events are reported as usual.

Central audio pause feature

The following M540 ***Central audio pause*** settings determine how the ICS handles new alarm conditions when alarms are already paused (see page 246):

– ***Exit*** – Any new alarm condition, regardless of its alarm priority, will break through an already active audio pause state at the ICS. All visual and audible signals are reported fully for any new alarm condition.

– ***Continue*** – Only alarm conditions of high priority will break through an active audio pause state at the ICS. The appropriate parameter box will flash. Alarm conditions of low or medium priority will not break through at the ICS.

The central audio pause feature does not affect how the M540 handles subsequent alarms.

Pausing alarm monitoring temporarily

If the password-protected alarm pause feature is activated (see page 244), you can pause alarm monitoring temporarily. The alarm pause duration is adjustable from 1 minute to 5 minutes.

NOTE
If the French NFC mode is activated (see page 251), you cannot pause alarm monitoring for more than 3 minutes.

The following happens when you pause alarm monitoring:

– Acoustic and visual alarm signals for new alarm conditions are suppressed for all parameters until alarm monitoring begins again
– Alarm signals for any active alarm condition stop immediately
– The alarming parameter box and alarm bar return to the pre-alarm state
– Alarm messages are removed from the alarm message field in the header bar
– The far right field of the header bar turns yellow and displays the alarm message ***All alarms pause***, a countdown timer, and the following symbol: 

To pause alarm monitoring temporarily

1 Press the ***Alarms*** function key.
2 Touch ***All alarms pause***.

As soon as the alarm pause period ends, the M540 generates acoustic and visual alarm signals as needed.

To activate alarm monitoring after pausing

1 Press the ***Alarms*** function key.
2 Touch ***All alarms pause*** before the alarm pause period ends to cancel the alarm pause.

Activating or deactivating alarm monitoring

WARNING

If *No timeout* is assigned to the alarm off period, no counter appears and alarms remain deactivated until you enable them again.

WARNING

Never leave a patient unattended when alarm monitoring is permanently deactivated. Always activate alarm monitoring again as soon as possible.

If the password-protected alarm pause feature is set to ***No timeout*** (see page 244), the following happens when you deactivated alarm monitoring:

– All acoustic and visual alarm signals for new alarm conditions are suppressed for all parameters until alarm monitoring is manually activated again

– Acoustic alarm signals for any active alarm condition stop immediately

– The alarming parameter box and alarm bar return to the pre-alarm state

– Alarm messages are removed from the alarm message field of the header bar

– The far right field of the header bar turns yellow displays a message that all alarms are off and the following symbol: 

To deactivate alarm monitoring

1 Press the ***Alarms*** function key.

2 Touch ***All alarms off***.

To activate alarm monitoring after deactivating

1 Press the ***Alarms*** function key.

2 Touch ***All alarms off***.

The M540 provides acoustic and visual alarm signals again when it detects a new alarm condition.

Configuring a patient's alarm settings

The following section describes the alarm features and settings available for each patient. When setting alarm limits, make sure they are appropriate for the patient's condition.

Each parameter has its own dialog window for configuring parameter-specific alarm functions. For composite parameters such as non-invasive blood pressure, there are alarm settings for each parameter (systolic, diastolic, and mean).

Setting the upper and lower alarm limits

You can configure the upper and lower alarm limits of a parameter manually to trigger acoustic and visual alarm signals if a parameter goes above or below the set limits.

WARNING

Setting alarm limits to extreme values may prevent certain alarm conditions from being detected and from being annunciated with acoustic and visual alarm signals.

To set an individual parameter's alarm settings

1. Touch the parameter box (for example, ***HR***) to access that parameter's dialog window.
2. Touch the tab for configuring the parameter limits (for example, ***HR limits***).
3. Touch the upper or lower alarm limit value.
4. Touch the up or down arrow to change the alarm limit setting.
5. Touch ***OK***.

Using the Auto set function

The Auto set function allows you to adjust alarm limits quickly based on preset percentages listed in the following table.

Parameter	Upper limit	Lower limit
Ta, Tb, T1a, T1b, Tblood	≤107 % of current value	≤93 % of current value
∆T, ∆T1, PVC/min end-tidal CO_2	Not affected	Not affected
SpO_2	Adult/pediatric: 100 % saturation Neonate: 98 % saturation	Current value –((value)*(5 %))
ST	Current value +2.0 mm	Current value –2.0 mm
end-tidal CO_2	Current value +25 %	Current value –20 %
All others	Alarm limit that is closest to but not more than 25 % above the current value of the parameter	Alarm limit that is closest to but not more than 20 % below the current value of the parameter

To use the Auto set function

1 Touch the parameter box of the parameter whose alarm limits you wish to set (for example, ***HR***).

2 Touch the tab for configuring the parameter limits (for example, ***HR limits***).

3 Touch ***Auto set***.

NOTE
If the Auto set function forces the alarm limits of a parameter outside the allowable limit range of the monitor, the alarm limits remain unchanged.

Activating/deactivating alarms

Except for the following parameters, you can activate or deactivate the alarm function for individual parameters:

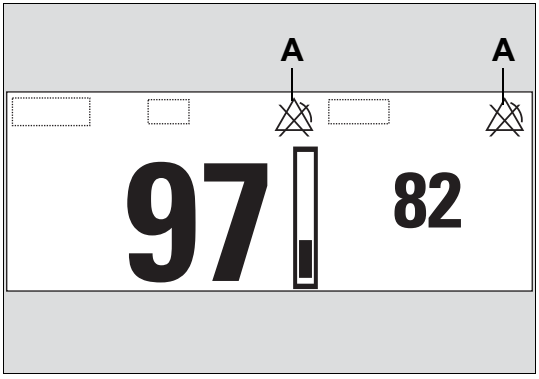
– Asystole and ventricular fibrillation (for these arrhythmia events you cannot deactivated alarms unless the ***ASY/VF alarms*** selection is set to ***Follow HR***, see page 91)

– Pulmonary wedge pressure (PWP)

– Perfusion index (PI)

– Total oxygen content (SpOC) for the Masimo rainbow SET MCable

When you deactivate alarms, no acoustic and visual alarm signals are triggered for that parameter. When alarm monitoring is deactivated, a crossed out triangle (A) appears in the parameter box.



When you activate the alarm function for a parameter, the crossed out triangle disappears.

Archive function

The archive function setting determines what happens in response to an alarm limit violation. The available settings are:

– ***Off*** – no event is stored and no recording is generated.

– ***Store*** – stores the event for later review (see page 103).

– ***Record*** – stores the event for later review (see page 103) when in standalone mode or on wireless transport. Once the M540 is docked, any stored event is transferred to the alarm history of the IACS where you can request a manual recording of the event.

– ***Str/Rec*** – generates a timed recording for an M540 docked in an IACS configuration and stores the event.

  When the M540 is in standalone mode or on wireless transport, this setting stores an event for later review (see page 103). Once the M540 is docked, any stored event is transferred to the alarm history of the IACS where you can request a manual recording of the event.

To configure an individual parameter's archive function

1 Touch the parameter box to access that parameter's dialog window (for example, ***HR***).

2 Touch the tab for configuring the parameter limits (for example, ***HR limits***).

3 Touch ***Archive*** and toggle to one of the following settings: ***Off***, ***Store***, ***Record***, ***Str/Rec***.

4 Touch ***X*** to close the dialog window.

Event recall

The ***Event recall*** dialog window is an electronic record of alarms and events. The ***Event recall*** dialog window records an entry under the following circumstances:

– When an alarm occurs for a parameter (including heart rate and ST) whose alarm feature is activated and archive function is set to ***Store*** or ***Str/Rec*** (see page 102).

  Whenever an arrhythmia event occurs (even when the alarm function is deactivated). For an event to be stored, only the archive function must be set to ***Str/Rec*** or ***Store***, ***Record***.

  In standalone mode, the archive function can be set to ***Record***, ***Str/Rec*** or ***Store*** and an event will be stored.

– When you press the ***Mark*** function key on the front panel of the M540 (see page 44). These alarm events are labelled ***BED TIMED*** and can be viewed in greater detail (see page 105).

– When you press the ***Record*** function key (see page 44) on the M540 when the M540 is either in standalone mode or on transport. These alarm events are labelled ***BED TIMED*** and can be viewed in greater detail (see page 105).

– When the M540 on transport or in standalone mode and an alarm occurs for a parameter whose alarm archive function is set to ***Record***.

The alarm history stores up to 150 events. When the storage capacity of 150 events is reached, new events replace the oldest events.

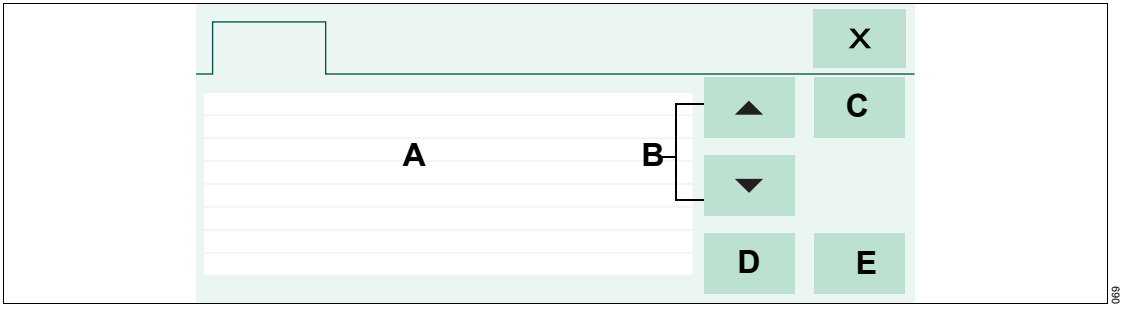
If a higher priority alarm occurs less than 5 seconds from a previous alarm, the higher priority alarm event is stored while the previous one is deleted.

Viewing stored events

The following diagram shows the ***Event recall*** dialog window. When you select any field on the table, a frame highlights the selected row. For information on what conditions prompt an entry to be stored in the ***Event recall*** dialog window, see page 102.

To access stored events

- Select the ***Review*** function key. The following diagram shows the ***Event recall*** dialog window.



A Event list with date, time, and cause of each event.

B Arrow buttons for scrolling through the event list.

C ***View*** button for viewing a single event in greater detail.

D ***Delete*** button for deleting an event.

E ***Lock*** button for locking an event (if the M540 is docked in an IACS configuration, pressing this button has no effect on events at the Cockpit).

Viewing a snapshot of a single event

20 seconds of waveform and parameter data are stored automatically in the ***Event recall*** dialog window under the following circumstances:

– When a parameter whose alarm feature is activated and archive feature is set to ***Store*** or ***Str/Rec*** (see page 102) violates set alarm limits.

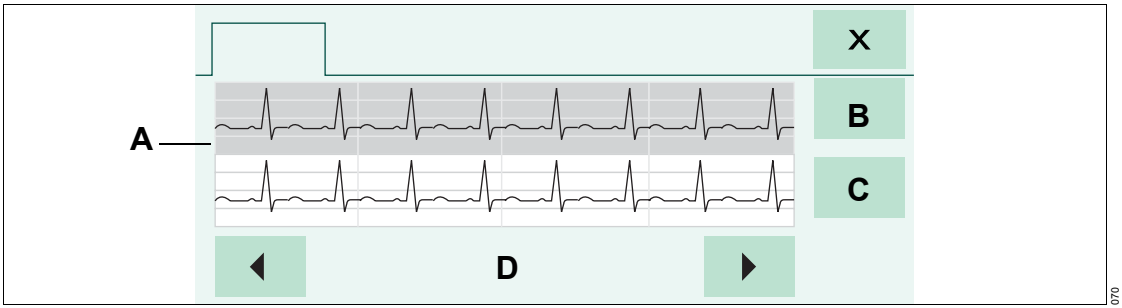
– Whenever an arrhythmia event occurs (even when the alarm function is deactivated). For an event to be stored, only the archive function must be set to ***Str/Rec*** or ***Store***, ***Record***.

– You press the ***Mark*** function key (see page 44).

– When you press the ***Record*** function key (see page 44) on the M540 when the M540 is on transport or in standalone mode.

Events with stored waveform and parameter data are identified in the ***Event recall*** dialog window by the label ***BED TIMED*** for manually stored events or the alarm string (for example, ***HR*** > 120) for a limit violation. Such an event consists of a snapshot of two waveforms at the time of the event. The two waveforms follow the setting for ***Channel 1*** and ***Channel 2*** except in the case of a limit violation where the first waveform is replaced by the alarming parameter waveform. Of the 20-second event capture, 10 seconds were recorded before and 10 seconds were recorded after the event occurred.

The following diagram shows a snapshot of a single event.



A Waveform data

B ***Prev*** button – scrolls to the previous event

C ***Next*** button – scrolls to the next event

D Status bar with date and time stamp the event was stored and arrow buttons for scrolling through 20-second portions of waveform data

To view a snapshot of a stored event

1 Press the ***Review*** function key.

2 Select the event that you wish to view.

3 Touch ***View*** to display the waveforms associated with the event.

Configuring the SpO2 alarm priority

The following two SpO2 alarm messages can be configured for the alarm priority that is most appropriate for your care environment. When the M540 is docked in an IACS configuration, the Cockpit controls these settings.

Depending on which MCable is used, the message reporting the underlying alarm condition differs:

– Masimo: ***SpO2 sensor off***

– Nellcor: ***SpO2 check sensor***

Both settings are saved as part of the patient profile.

Configuring the alarm priority for the Masimo sensor off message

This alarm setting is for configuring the alarm priority and the alarm archiving behavior of certain Masimo SpO2 parameters. The ***SpO2 sensor off*** message appears when the MCable detects that the sensor is no longer attached to the patient. This setting can be configured separately for each patient category. It is available for the following SpO2 cables:

– Masimo rainbow SET MCable

– Masimo SET MCable

For information on how to configure the alarm priority for the setting ***SpO2 sensor off***, see page 247.

The following SpO2 parameters can generate this alarm message according to the selected alarm priority:

Masimo rainbow SET MCable	**Masimo SET MCable**
SpO2	SpO2
PLS	PLS
SpHbv or SpHb	
SpOC	
PVI	
SpMet	

Configuring the alarm condition for the Nellcor check sensor message

This alarm feature is for configuring the alarm priority and the alarm archiving behavior of certain Nellcor SpO2 parameters. The ***SpO2 check sensor*** message appears when the Nellcor OxiMax MCable detects that the sensor is no longer attached to the patient or other technical issues that interfere with the proper functioning of the sensor. This feature can be configured separately for each patient category. For information on how to configure the alarm priority for the setting ***SpO2 check sensor***, see page 247.

The following SpO2 parameters generate an alarm message according to the selected alarm priority:

– SpO2

– PLS

Alarm management setup (password-protected)

The password-protected alarm setup is only accessible to authorized personnel. For details on available setup functions, see page 257.

The *Code* function key

If the M540 is connected to the IACS you can activate a set of monitoring functions at the IACS during emergency care by selecting the ***Code*** function key on the M540. For specific information, refer to the instructions for use *Infinity Acute Care System – Monitoring Applications*.

Alarm groups

You can configure the M540 and other monitors as members of an alarm group. This feature makes sure that any alarms that occur at any of the monitors within the alarm group are broadcast to all other members in the alarm group (see page 245) for remote viewing of alarm conditions.

When the M540 is docked in a IACS configuration, the alarm group of the M540 is adjusted to the alarm group ID set on the Cockpit device.

Alarm ranges and defaults

Parameter	Alarm limit range	Upper limit defaults	Lower limit defaults	Archive default
HR adult *Increment: 5 bpm*	Upper: 25 to 300 bpm Lower: 20 to 295 bpm	– 120 (adult) – 150 (pediatric) – 170 (neonate)	– 45 (adult) – 50 (pediatric) – 80 (neonate)	– ***Str/Rec*** (adult, pediatric) – ***Off*** (neonate)
STVM/STCVM *Increment: 0.1 mm or 0.01 mV*	Upper: 0.1 to 45.0 mm 0.01 to 4.50 mV Lower: 0.0 to 44.9 mm 0.00 to 4.49 mV	1.0 mm (0.1 mV)	0.0 mm (0 mV)	***Off***
ST *Increment: 0.1 mm or 0.01 mV*	Upper: –14.9 to +15.0 mm –1.49 to +1.50 mV Lower: –15.0 to +14.9 mm –1.50 to +1.49 mV	1.0 mm (0.1 mV)	–1.0 mm (–0.1 mV)	***Off***
RRi (adult) *Increment: 1*	Upper: 6 to 100 Lower: 5 to 99 (adult)	30	5	***Off***
RRi pediatric, neonate *Increment: 1*	Upper: 6 to 145 Lower: 5 to 144	80	20	***Off***
PLS *Increment of 5*	Upper: 35 to 235 Lower: 30 to 230	– 120 (adult) – 150 (pediatric) – 180 (neonate)	– 45 (adult) – 50 (pediatric) – 80 (neonate)	***Off***
SpO_2 [1)] *Increment: 1 %*	Upper: 21 to 100 % Lower: 20 to 99 %	– 100 % (adult, pediatric) – 95 % (neonate)	85 %	***On***

NOTE

[1)] If the low alarm limit is set to ≤ the factory default value of 85, the SpO_2 high and low alarm limits are displayed in the SpO_2 parameter box.

Parameter	Alarm limit range	Upper limit defaults	Lower limit defaults	Archive default
PVI *Increment: 1*	Upper: 1 to 100 Lower: 0 to 99	100	0	***Off***
SpHb / SpHbv *Increment 0.2 g/dL (0.1 mmol/L)*	Upper: 1.2 to 25.0 g/dL (0.7 to 15.5 mmol/L) Lower: 1.0 to 24.8 g/dL (0.6 to 15.4 mmol/L)	17.0 g/dL (10.6 mmol/L)	7.0 g/dL (4.3 mmol/L)	***Off***
SpCO *Increment: 1*	Upper: 1 to 99 Lower: 0 to 98	10	0	***Off***
SpMet *Increment: 0.1*	Upper: 0.1 to 99.9 Lower: 0.0 to 99.8	3.0	0	***Off***
NIBP S adult *Increment: 1 mmHg or 0.1 kPa*	Upper: 11 to 250 mmHg 1.4 to 33.3 kPa Lower: 10 to 249 mmHg 1.3 to 33.2 kPa	160 mmHg (21.3 kPa)	90 mmHg (12.0 kPa)	***On***
NIBP S pediatric *Increment: 1 mmHg or 0.1 kPa*	Upper: 11 to 170 mmHg 1.4 to 22.7 kPa Lower: 10 to 169 mmHg 1.3 to 22.6 kPa	120 mmHg (16 kPa)	50 mmHg (6.7 kPa)	***On***
NIBP S neonate *Increment: 1 mmHg or 0.1 kPa*	Upper: 11 to 130 mmHg 1.4 to 17.3 kPa Lower: 10 to 129 mmHg 1.3 to 17.2 kPa	80 mmHg (10.7 kPa)	50 mmHg (6.7 kPa)	***On***
NIBP D adult *Increment: 1 mmHg or 0.1 kPa*	Upper: 11 to 250 mmHg 1.4 to 33.3 kPa Lower: 10 to 249 mmHg 1.3 to 33.2 kPa	110 mmHg (14.7 kPa)	50 mmHg (6.7 kPa)	***On***
NIBP D pediatric *Increment: 1 mmHg or 0.1 kPa*	Upper: 11 to 170 mmHg 1.4 to 22.7 kPa Lower: 10 to 169 mmHg 1.3 to 22.6 kPa	80 mmHg (10.7 kPa)	35 mmHg (4.7 kPa)	***On***

Parameter	Alarm limit range	Upper limit defaults	Lower limit defaults	Archive default
NIBP D neonate *Increment: 1 mmHg or 0.1 kPa*	Upper: 11 to 130 mmHg 1.4 to 17.3 kPa Lower: 10 to 129 mmHg 1.3 to 17.2 kPa	60 mmHg (8 kPa)	25 mmHg (3.3 kPa)	***On***
NIBP M adult *Increment: 1 mmHg or 0.1 kPa*	Upper: 11 to 250 mmHg 1.4 to 33.3 kPa Lower: 10 to 249 mmHg 1.3 to 33.2 kPa	125 mmHg (16.7 kPa)	60 mmHg (8.0 kPa)	***On***
NIBP M pediatric *Increment: 1 mmHg or 0.1 kPa*	Upper: 11 to 170 mmHg 1.4 to 22.7 kPa Lower: 10 to 169 mmHg 1.3 to 22.6 kPa	85 mmHg (11.3 kPa)	40 mmHg (5.3 kPa)	***On***
NIBP M neonate *Increment: 1 mmHg or 0.1 kPa*	Upper: 11 to 130 mmHg 1.4 to 17.3 kPa Lower: 10 to 129 mmHg 1.3 to 17.2 kPa	70 mmHg (9.3 kPa)	40 mmHg (5.3 kPa)	***On***
ΔT/ ΔT1 *Increment: 0.1 °C or 0.1 $\pm$ 0.2 °F*	Upper: 0.1 to 39.0 °C 0.2 to 70.2 °F Lower: 0.0 to 38.9 °C 0.0 to 70.0 °F	1.0 °C (3.6 °F)	0.0 °C (0.0 °F)	***Off***
Ta/T1a/Tb/T1b *Increment: 0.1 °C or 0.1 °F*	Upper: 0.1 to 50.0 °C 32.2 to 122.0 °F Lower: 0.0 to 49.9 °C 32.0 to 121.8 °F	39.0 °C (102.2 °F)	34.0 °C (93.2 °F)	***Off***

Parameter	Alarm limit range	Upper limit defaults	Lower limit defaults	Archive default
IBP S adult *Increment: 1 mmHg or 0.1 kPa*	Upper: –24 to +300 mmHg –3.2 to +40.0 kPa Lower: –25 to +299 mmHg –3.3 to +39.9 kPa	– 160 mmHg (21.3 kPa) for GP1 S to GP4 S, ART S, LV S – 35 mmHg (4.7 kPa) for PA S, RV S	– 90 mmHg (12.0 kPa) for GP1 S to GP4 S, ART S – 75 mmHg (10.0 kPa) for LV S – 10 mmHg (1.3 kPa) for PA S, RV S	GP1 S to GP4 S, LV S, RV S: ***Off*** PA S, ART S: ***On***
IBP S pediatric/neonate *Increment: 1 mmHg or 0.1 kPa*	Upper: –24 to +300 mmHg –3.2 to +40.0 kPa Lower: –25 to +299 mmHg –3.3 to +39.9 kPa	– 120 mmHg (16.0 kPa) for GP1 S to GP4 S, ART S, LV S – 35 mmHg (4.7 kPa) for PA S, RV S	– 50 mmHg (6.7 kPa) for GP1 S to GP4 S, ART S – 75 mmHg (10.0 kPa) for LV S – 10 mmHg (1.3 kPa) for PA S, RV S	GP1 S to GP4 S, LV S, RV S: ***Off*** ART S, PA S: ***On***
IBP D adult *Increment: 1 mmHg or 0.1 kPa*	Upper: –24 to +300 mmHg –3.2 to +40.0 kPa Lower: –25 to +299 mmHg –3.3 to +39.9 kPa	– 110 mmHg (14.7 kPa) for GP1 D to GP4 D, ART D – 25 mmHg (3.3 kPa) for LV D – 13 mmHg (1.7 kPa) for PA D, RV D	– 50 mmHg (6.7 kPa) for GP1 D to GP4 D, ART D – 2 mmHg (0.3 kPa) for PA D, LV D, RV D	GP1 D to GP4 D, LV D, RV D: ***Off*** ART D, PA D: ***On***

Parameter	Alarm limit range	Upper limit defaults	Lower limit defaults	Archive default
IBP D pediatric *Increment: 1 mmHg or 0.1 kPa*	Upper: –24 to +300 mmHg –3.2 to+ 40.0 kPa Lower: –25 to +299 mmHg –3.3 to +39.9 kPa	– 80 mmHg (10.7 kPa) for GP1 D to GP4 D, ART D – 25 mmHg (3.3 kPa) for LV D – 13 mmHg (1.7 kPa) for PA D, RV	– 30 mmHg (4.0 kPa) for GP1 D to GP4 D, ART D – 2 mmHg (0.3 kPa) for PA D, LV D, RV D	GP1 D to GP4 D, LV D, RV D: ***Off*** ART D, PA D: ***On***
IBP D neonate *Increment: 1 mmHg or 0.1 kPa*	Upper: –24 to +300 mmHg –3.2 to +40.0 kPa Lower: –25 to +299 mmHg –3.3 to +39.9 kPa	– 80 mmHg (10.7 kPa) for GP1 D to GP4 D, PA D – 25 mmHg (3.3 kPa) for LV D – 13 mmHg (1.7 kPa) for PA D, RV D	– 35 mmHg (4.7 kPa) for GP1 D to GP4 D, PA D – 2 mmHg (0.3 kPa) for PA M, LV D, RV D	GP1 D to GP4 D, LV D, RV: ***Off*** PA D, PA M: ***On***
IBP M adult *Increment: 1 mmHg or 0.1 kPa*	Upper: –24 to +300 mmHg –3.2 to +40.0 kPa Lower: –25 to +299 mmHg –3.3 to +39.9 kPa	– 125 mmHg (16.7 kPa) for GP1 M to GP4 M, ART M – 80 mmHg (10.7 kPa) for LV M – 20 mmHg (2.7 kPa) for LA, ICP, CVP – 17 mmHg (2.3 kPa) for PA M, RV M – 12 mmHg (1.6 kPa) for RA	– 60 mmHg (8.0 kPa) for GP1 M to GP4 M, ART M – 40 mmHg (5.3 kPa) for LV M – 7 mmHg (0.9 kPa) for PA M, RV M – 2 mmHg (0.3 kPa) for RA, ICP – 0 mmHg (0.0 kPa) for LA, CVP	***On***

Parameter	Alarm limit range	Upper limit defaults	Lower limit defaults	Archive default
IBP M pediatric *Increment: 1 mmHg or 0.1 kPa*	Upper: –24 to +300 mmHg –3.2 to +40.0 kPa Lower: –25 to +299 mmHg –3.3 to +39.9 kPa	– 80 mmHg (10.7 kPa) for GP1 M to GP4 M, ART M, LV M – 20 mmHg (2.7 kPa) for LA, ICP, CVP – 17 mmHg (2.3 kPa) for PA, RV M – 12 mmHg (1.6 kPa) for RA	– 50 mmHg (6.7 kPa) for GP1 M to GP4 M, ART M – 40 mmHg (5.3 kPa) for LV M – 7 mmHg (0.9 kPa) for PA, RV M – 2 mmHg (0.3 kPa) for RA, ICP – 0 mmHg (0.0 kPa) for LA, CVP	***On***
IBP M neonate *Increment: 1 mmHg or 0.1 kPa*	Upper: –24 to +300 mmHg –3.2 to +40.0 kPa Lower: –25 to +299 mmHg –3.3 to +39.9 kPa	– 85 mmHg (11.3 kPa) for GP1 M to GP4 M, ART M, – 80 mmHg (10.7 kPa) for LV M – 20 mmHg (2.7 kPa) for LA, ICP, CVP – 17 mmHg (2.3 kPa) for PA, RV M – 12 mmHg (1.6 kPa) for RA	– 40 mmHg (5.3 kPa) for GP1 M to GP4 M, ART M, LV M – 7 mmHg (0.9 kPa) for PA, RV M – 2 mmHg (0.3 kPa) for RA, ICP – 0 mmHg (0.0 kPa) for LA, CVP	***On***
CPP *Increment: 1 mmHg or 0.1 kPa*	Upper: –24 to +300 mmHg –3.2 to +40.0 kPa Lower: –25 to +299 mmHg –3.3 to +39.9 kPa	100 mmHg (13.3 kPa)	70 mmHg (9.3 kPa)	***Off***

Parameter	Alarm limit range	Upper limit defaults	Lower limit defaults	Archive default
RRc *Increment of 1 bpm*	Upper: 6 to 150 bpm Lower: 5 to 149 bpm	– 30 bpm (adult) – 60 bpm (pediatric, neonate)	– 5 bpm (adult) – 20 bpm (pediatric, neonate)	***Off***
inCO_2 *Increment of 1 mmHg, 0.1 kPa, or 0.1 %*	Upper: 2 to 10 mmHg 0.3 to 1.3 kPa 0.3 to 1.3 % Lower: not user-selectable	4 mmHg (0.5 kPa, 0.5 %)	Not applicable	***Off***
etCO_2 *Increment of 1 mmHg, 0.1 kPa, or 0.1 %*	Upper: 6 to 100 mmHg 0.8 to 13.3 kPa 0.8 to 13.2 % Lower: 5 to 99 mmHg 0.7 to 13.2 kPa 0.7 to 13.0 %	50 mmHg (6.7 kPa, 6.6 %)	30 mmHg (4.0 kPa, 3.9 %)	***On***
PVC/min *Increment of 1*	Upper: 1 to 50	10	Not applicable	***Off***

Arrhythmia ranges and defaults

Parameter	Alarm grade default	Rate (default)	Count (default)	Alarm archive factory default
ASY	High	Not adjustable	Not adjustable	***Str/Rec***
VF	High	Not adjustable	Not adjustable	***Str/Rec***
VTACH	High	≥100 to 200 (≥120) Increments of 10	≥5 to 15 (≥ 0) Increments of 1	***Str/Rec***
ARTF	Off	Not adjustable	Not adjustable	***Off***
RUN	Medium	not adjustable (Rate = VTACH)	3 to VT count – 1 (3 to 9) changes based on VTACH	***Str/Rec***
AIVR	Medium	Not adjustable = VTACH rate –1 (≤119)	Not adjustable (≥ 3)	***Off***
SVT	Medium	≥120 to 200 (≥150) Increments of 10	≥3 to 10 (≥3) Increments of 1	***Str/Rec***

Parameter	**Alarm grade default**	**Rate (default)**	**Count (default)**	**Alarm archive factory default**
CPT	Low	Not adjustable	Not adjustable	***Str/Rec***
BGM	Low	Not adjustable	Not adjustable	***Str/Rec***
TACH	Off	≥100 to 200 (≥130) Increments of 10	≥5 to 15 (≥8) Increments of 1	***Off***
BRADY	Off	≤30 to 105 (adult ≤ 50; pediatric ≤60) Increment of 5	Not adjustable (≥8)	***Off***
Pause	Off	1 to 3.5 (2.5) Increments of 0.5	Not adjustable	***Off***

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ECG, arrhythmia, and ST segment

Overview of ECG and heart rate monitoring

The M540 calculates and displays the heart rate, identifies paced beats, reports arrhythmia conditions, and measures ST deviations. ECG and heart rate monitoring is for adult, pediatric, and neonatal patients.

3-, 5-, 6-, and 10-lead wire sets are available for adult and pediatric ECG monitoring (including TruST). A neonatal ECG adapter cable is available for connecting individual ECG leads for neonatal monitoring.

Normal ECG monitoring (including 12-lead ECG monitoring) is not of diagnostic quality. The only report of diagnostic quality is an optional Rest ECG report which is generated from a 12-lead ECG. This report can be generated when the required options are activated, and the patient is admitted at the Infinity CentralStation. For more information on how to generate such a report, refer to page 68.

The ECG monitoring functions are configurable in the ECG dialog window (see page 130).

Before performing any monitoring functions, refer to the section "For your safety and that of your patients" on page 5.

ECG signal processing and display

The M540 identifies QRS complexes of certain amplitudes and QRS widths for adult, pediatric, and neonatal patients (see page 317 of the "Technical data" chapter for detailed parameter specifications). It calculates heart rates within a range of 15 beats to 300 beats per minute, using the R-R intervals of the last 10 seconds. This calculation excludes the two longest and two shortest R-R intervals. The M540 averages the remaining intervals and displays the result as the current heart rate in the heart rate parameter box.

During dual-channel processing, a weight is assigned to each channel depending on its level of artifact. The cleaner channel always receives a greater weight. When a channel exceeds a certain level of artifact, it is excluded from the composite signal, and the M540 shifts to single-channel processing. If both channels experience excessive artifact, the message ***ECG artifact*** appears until at least one channel is sufficiently free of artifact.

During artifact, asterisks (* * *) replace the heart rate value. When the artifact clears, QRS processing resumes without initiating a relearning phase.

Arrhythmia monitoring and the selected arrhythmia mode affect the display of the heart rate parameter box. For detailed information, see "Arrhythmia display" on page 141.

Parameter-specific error messages are listed on page 263.

Supported parameters

– ECG: HR ST: STI, STII, STIII, STaVR, STaVL, STaVF, STV, STV+, STV1 to STV6, STVM, STCVM, STdV1, STdV3, STdV4, STdV6

– Arrhythmia: ARR (ASY, VF, ARTF, VTACH, RUN, AIVR, SVT, CPT, BGM, TACH, BRADY, ***PAUSE***; see page 139 for a description of these arrhythmia modes) and PVC/min

ECG precautions

Refer to the following sections for general precautions:

– "Safe connection with other electrical equipment" on page 7

– "Electrosurgery" on page 11

– "Defibrillator precautions" on page 11

WARNING

Do not select TruST leads for ECG signal processing. If the QRS morphology of a TruST lead differs from that of its equivalent conventional lead, always refer to the conventional lead.

WARNING

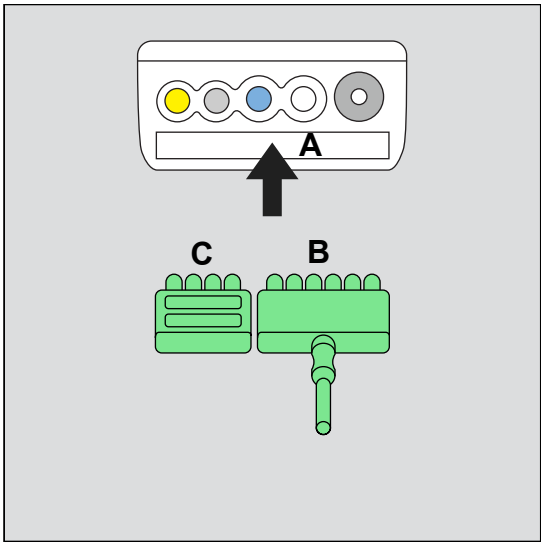
To prevent patient injury, always verify the timing of the QRS synchronization pulse before attempting cardioversion using the Infinity MCable – Analog/Sync.

WARNING

Do not rely solely on the ECG when monitoring seizure-prone patients. Electrical artifacts of non-cardiac origin, such as seizure, may prevent detection of certain arrhythmias.

Connecting the 3-, 5-, 6-lead wire sets for ECG monitoring

The ECG lead wire sets connect directly to the M540:



A M540 ECG connector

B Lead wire set

C Spacer

To connect the ECG lead wire sets

1 Insert the 3-,5-, or 6-lead wire set (B) into the recessed ECG connector (A) on the side of the M540.

Orient the lead wire sets so the exposed pins face toward you as you push them firmly into the channel.

NOTE

An ECG lead wire set can rest in the ECG connector of the M540 without actually being connected. Make sure that all ECG lead wire sets are pushed firmly into the ECG connector of the M540.

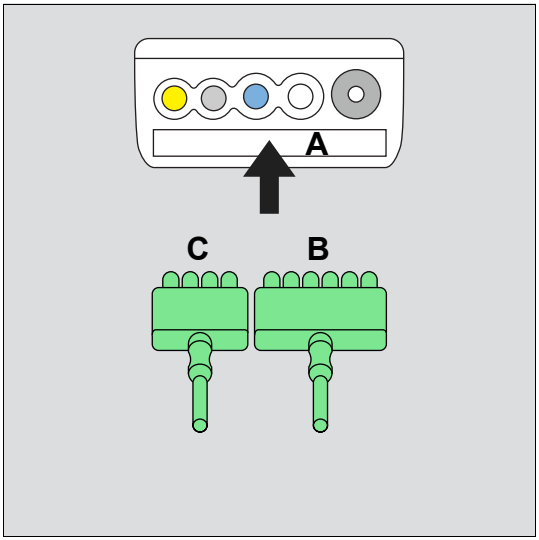
Almost every MonoLead features a number on the lead wire set indicating how many leads connect. When connecting a MonoLead, make sure the number faces in the same direction as the M540 display.

2 Insert the spacer (C) to protect the unused ECG lead pins.

3 Connect the lead wire to the patient. For information on applying the electrodes to the patient, refer to the illustrations starting on page 126.

Connecting the lead wire sets for 12-lead ECG monitoring

The ECG lead wire sets connect directly to the M540:



A M540 ECG connector

B 6-lead wire set

C 4-lead wire set

To connect the ECG lead wire sets

1 Insert the 6-lead wire set (B) and the 4-lead wire set (C) into the recessed ECG connector (A) on the side of the M540.

Orient the lead wire sets so the exposed pins face toward you as you push them firmly into the channel.

NOTE

An ECG lead wire set can rest in the ECG connector of the M540 without actually being connected. Make sure that all ECG lead wire sets are pushed firmly into the ECG connector of the M540.

Almost every MonoLead features a number on the lead wire set indicating how many leads connect. When connecting a MonoLead, make sure the number faces in the same direction as the M540 display.

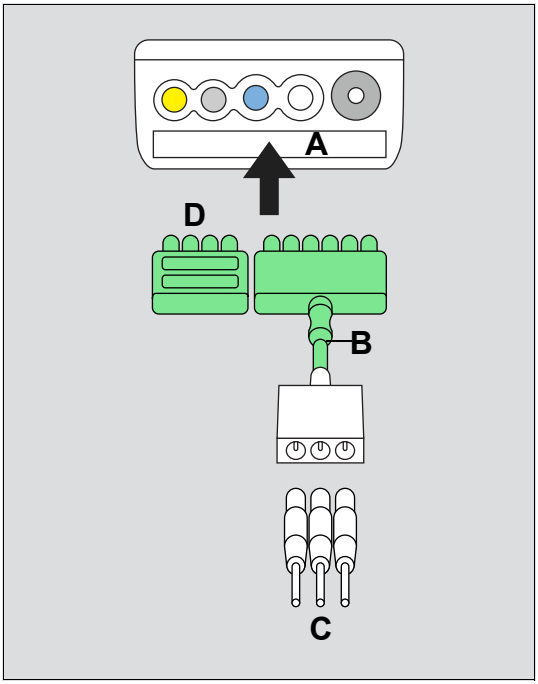
2 Connect the lead wires to the patient. For information on applying the electrodes to the patient, refer to the illustrations starting on page 126.

NOTE

When using a 12-lead ECG wire set where the lead wires are coiled, it is recommended that the 6-lead wire set is wrapped in the same direction as the 4-lead set to prevent artifact. For example, both lead wire sets are either wrapped toward the patient or away from the patient.

Connecting the lead wires for neonatal ECG monitoring

The ECG lead wire sets connect directly to the M540:



A M540 ECG connector

B Neonatal ECG adapter cable

C Neonatal ECG electrodes

D Spacer

To connect the ECG lead wire set

1 Insert the neonatal ECG adapter cable (B) into the recessed ECG connector (A) on the side of the M540.

Orient the neonatal ECG adapter cable (B) so the exposed pins face toward you as you push it firmly into the channel.

NOTE

An ECG lead wire set can rest in the ECG connector of the M540 without actually being connected. Make sure that all ECG lead wire sets are pushed firmly into the ECG connector of the M540.

2 Insert the spacer (D) to protect the unused ECG lead pins on the M540.

3 Connect the individual neonatal ECG electrodes (C) to the neonatal ECG adapter cable (B).

For information on applying the electrodes to the patient, refer to the illustrations starting on page 126.

Patient preparation for ECG monitoring

The following tips provide optimal ECG monitoring results but must never replace hospital-approved practices or manufacturer's recommendations.

Follow hospital procedures for proper skin preparation. Dräger recommends Ag/AgCl disposable electrodes. Never use disposable electrodes after their expiration date and make sure that there is enough gel and that the gel has not dried out.

P- and T-waves with amplitudes exceeding 0.2 mV can be interpreted as QRS complexes. To allow detection of low heart rate conditions under these circumstances, place the lead with the highest R-wave in channel ECG1. If P- and T-waves continue to be misinterpreted, reposition the electrodes or use a pulse oximeter to monitor the pulse rate.

To maintain a clear signal, change electrodes every 24 to 48 hours or more often when the following occurs:

– ECG signal degradation
– Excessive patient perspiration
– Skin irritation

Consider the following when selecting electrode sites:

– Surgery – keep electrodes as far from the surgical site as possible, while maintaining a clinically useful lead configuration. Place the cable and lead wires as far from the ESU as possible and perpendicular to the ESU cables.
– Burn Patients – use sterile electrodes. Clean the equipment thoroughly and follow hospital infection control procedures.

Electrosurgery

Integrated ESU suppression improves the performance of the monitor during electrosurgery, reduces noise on ECG waveforms, and protects the patient from burns.

To minimize interference from the electrosurgical unit

The ESU filter setting can only be activated when the M540 is docked in an IACS configuration.

1 Touch the heart rate parameter box to select the ***ECG*** dialog window directly.

2 Touch the ***Settings*** tab > ***ECG 1*** tab.

3 Touch ***ECG filter*** until it toggles to ***ESU***.

NOTE

12-lead monitoring is not available when the ***ECG filter*** is set to ***ESU***. Likewise, the ***ESU*** filter selection is not available when you are using 12-lead monitoring. If the ***ECG filter*** is set to ***ESU*** and you switch to 12-lead, the filter setting automatically changes to ***Monitor***.

4 Touch ***X*** to close the dialog window.

ECG display

On the M540, the ECG display consists of:

– ECG parameter box

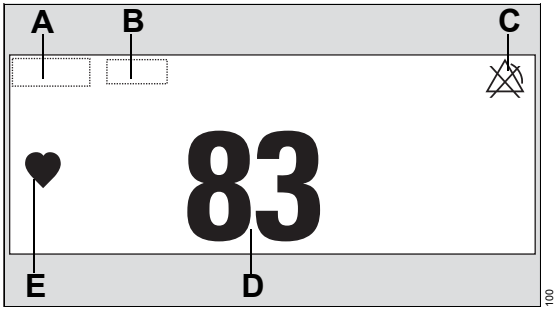
– ECG waveforms

– ***Show all leads*** dialog window containing up to 12 leads

The ECG parameter box appears differently when you activate arrhythmia monitoring. For more detail, see page 141.

ECG parameter box

The ECG parameter box contains the following elements:



A Parameter label

B Unit of measure

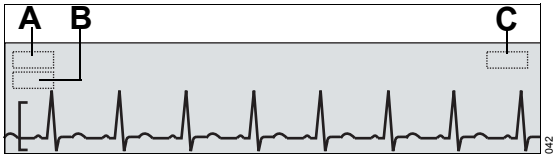
C Crossed triangle symbol when alarms are turned off

D Heart rate value

E Heart blip that flashes with each detected ECG complex (if pacer detection is activated, the symbol appears as P♥ when a paced beat is detected)

ECG waveforms

The ECG waveform contains the following elements:



A Selected waveform scale

B Lead label

C Message field indicating the selected filter and pacer setting. For example, the message ***Pacer off*** appears if you deactivate pacer detection (see page 132).

If pacer detection is activated, blue pacer spikes identify paced beats. Pacer spikes are printed on strip recordings.

Lead wire set	Available ECG leads
Three electrodes	I, II, III
Five electrodes	I, II, III, aVR, aVL, aVF, V [1)]
Six electrodes	Standard: I, II, III, aVR, aVL, aVF, V, V+ [1)] TruST: I, II, III, aVR, aVL, aVF, dV1, V2, dV3, dV4, V5, dV6 [2)]
6 + 4 electrodes	I, II, III, aVR, aVL, aVF, V1 to V6 [3)]

NOTE

[1)] V and V+ are chest leads

[2)] The letter 'd' indicates a derived lead

[3)] Using a 6-lead and a 4-lead wire set provides 12 monitored ECG leads

To select the number of leads and the lead wire set, see page 130.

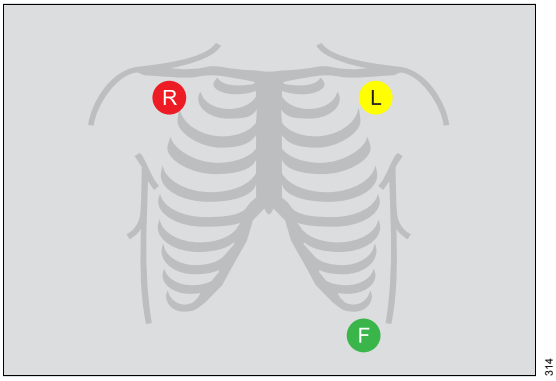
ECG electrode colors

Electrodes are labeled and color-coded according to IEC and AHA as listed in the following table.

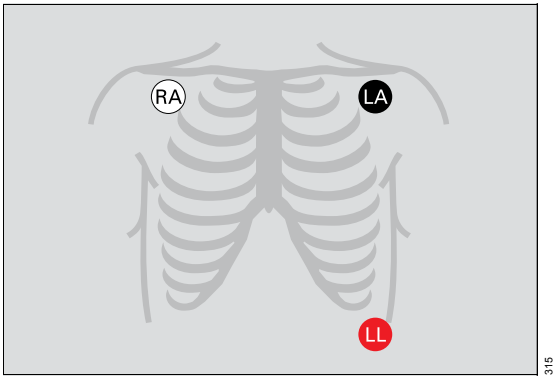
IEC		**AHA/US**	
L	Yellow	LA	Black
F	Green	LL	Red
R	Red	(A)	White
C/C2	White/white and yellow	V/V2	Brown/brown and yellow
N	Black	(L)	Green
C+/C5	Gray and white/white and black	V+/V5	Gray and brown/brown and orange
C6	White and violet	V6	Brown and violet
C4	White and brown	V4	Brown and blue
C3	White and green	V3	Brown and green
C1	White and red	V1	Brown and red

Electrode placement

Standard configuration, three electrodes (IEC/AHA)

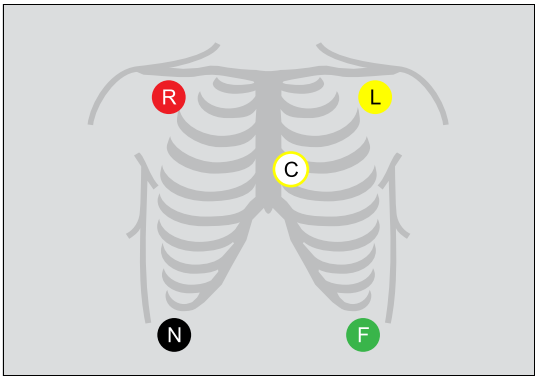


314

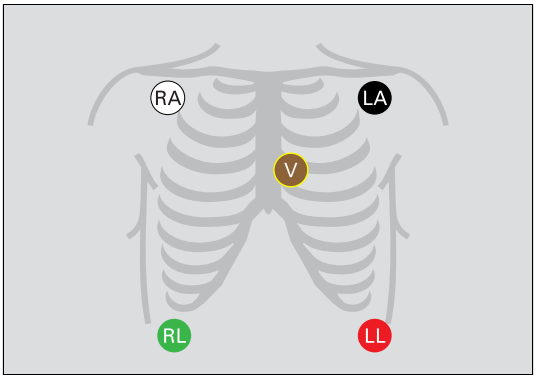


315

Standard configuration, five electrodes (IEC/AHA)

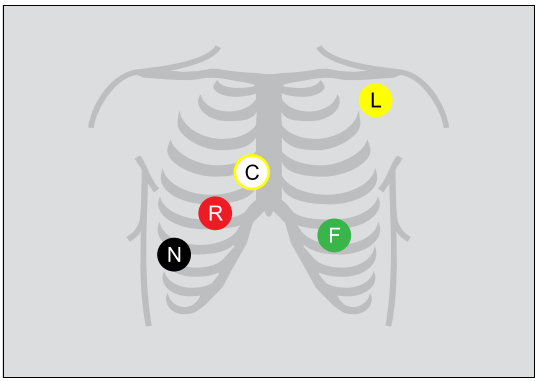


316

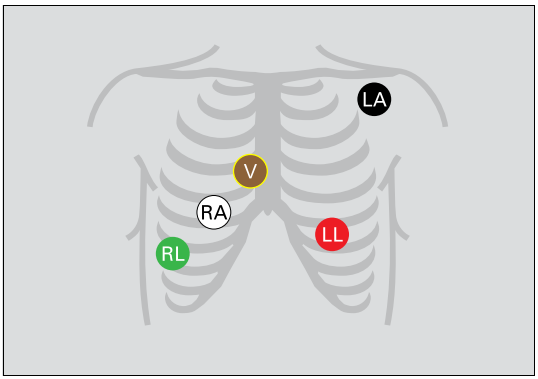


317

Pacer configuration, five electrodes (IEC/AHA)

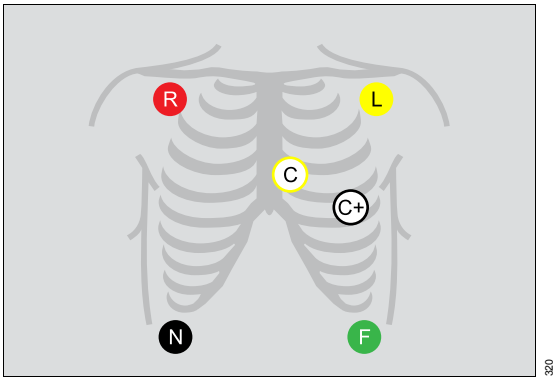


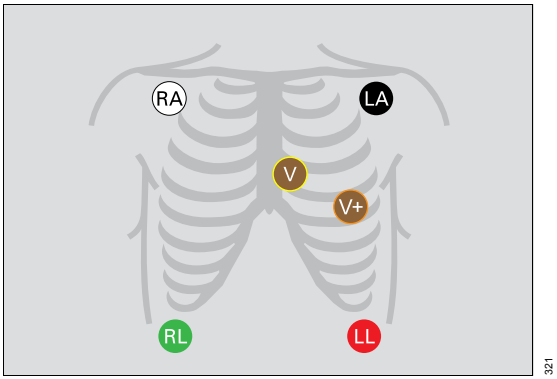
318



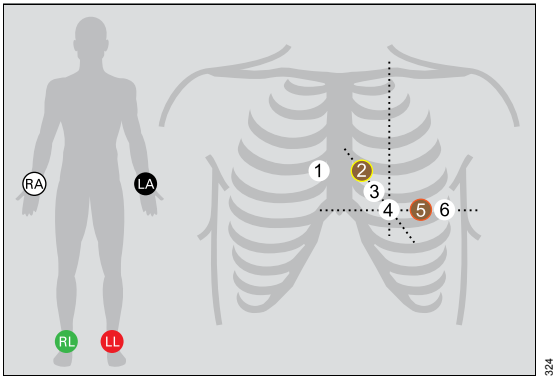
319

Standard configuration, six electrodes (IEC/AHA)

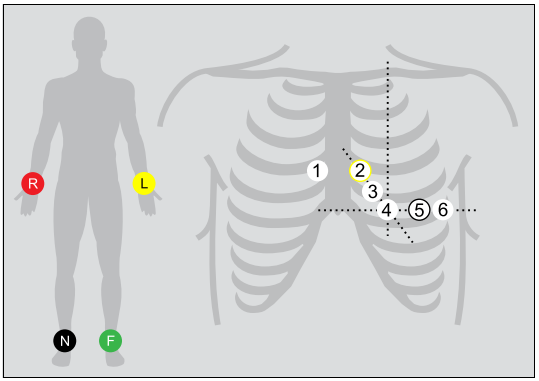




12-Lead configuration, ten electrodes for 12-lead Rest ECG monitoring (AHA)



12-Lead configuration, ten electrodes for 12-Lead Rest ECG monitoring (IEC)



12-lead monitoring

Standard 12-lead monitoring is only available when you use a 6-lead and a 4-lead wire set. 12-lead monitoring using a 10-lead wire set is a locked option that must be purchased separately. Place the chest electrodes in positions V1 through V6 as shown on page 122.

TruST 12-lead monitoring offers real-time assessment of ST segment deviations with only six electrodes. TruST uses the conventional 6-lead standard electrode placement (see page 122), measuring 8 leads and interpolating 4 chest leads. TruST is available in adult and pediatric modes, but not in neonatal mode.

You can view all ECG waveforms, including TruST, on the ***Show all leads*** page (see page 131). For information on how to activate TruST, see page 149.

WARNING

Do not select TruST leads for ECG signal processing. If the QRS morphology of a TruST **lead differs from that of its equivalent conventional lead, always refer to the conventional lead.**

Accessing the ECG dialog window

1 Touch the heart rate parameter box.

2 Touch the ***Settings*** tab.

Or, if the parameter is not displayed

1 Touch any parameter box > ***Settings*** tab > ***Change parameter***.

2 Touch the desired parameter label to display it on the main screen.

3 Touch the parameter box > ***Settings*** tab.

ECG parameter setup functions

All ECG parameter setup functions take place in the ***ECG*** dialog window (see page 130).

The limits dialog window contains the ***Auto set*** and ***Alarm*** buttons for configuring the alarm functions. For detailed alarm setup information, see "Configuring a patient's alarm settings" on page 100.

Selection	Available settings	Description
	Settings – ECG 1 page	
Tone volume [1]	***Off***, 5, 10 (default) to 100 % in increments of 10 %	Selects the volume of the pulse tone. If you dock the M540 in an IACS configuration, this setting is replaced by the pulse tone volume setting of the Cockpit. When you undock the M540, this setting is replaced by the ***Transport pulse tone*** setting configured under the ***Alarm setup*** tab (see page 246).
Tone source [1]	***ECG*** (default), ***SpO2***	Selects the source of the pulse tone.

NOTE

[1] This setting is a patient default which may be unique for each patient category; it is part of the profile.

Selection	Available settings	Description
ECG filter [1]	– ***Off*** – provides the greatest sensitivity to noise or artifact (the message ***Filter off*** appears in the waveform channel) – ***Monitor*** (default) – recommended for standard monitoring; reduces baseline drift, muscle artifact, and power line interference. No message appears in the waveform channel. – ***ESU*** – reduces signal distortion during electrosurgery (the message ***Filter ESU*** appears in the waveform channel). This selection is not available when the M540 is in standalone mode. **NOTE** 12-lead monitoring is not available when the ESU filter is enabled. Likewise, the ESU filter selection is not available when you are using 12-lead monitoring.	Controls the sensitivity to various artifact sources. When the M540 is in OR mode and the filter selection is set to ***Monitoring***, the hardware low pass ESU filter is activated. **NOTE** None of these settings are of diagnostic quality.
HR source [1]	– ***ECG*** (default) – derives the heart rate from the ECG signal. – ***ART*** – derives the heart rate from the arterial pressure signal. The heart rate parameter box label changes to APR and appears in the color of ART. – ***SpO2*** – derives the heart rate from the pulse oximetry signal. The heart rate parameter box label changes to PLS and appears in the color of SpO2. – ***Auto*** – derives the heart rate either from the ECG signal or other available sources. If an ECG signal is not available, the M540 switches to ART, and then to SpO2.	Selects a different source for the heart rate when the ECG channel is unavailable due to artifact resulting from surgical procedures.
Show all leads	None	Shows all ECG waveforms. Press anywhere in the waveform area to access additional ECG waveforms. Press ***Menu*** to close all the ECG waveforms.

NOTE

[1] This setting is a patient default which may be unique for each patient category; it is part of the profile.

Selection	Available settings	Description
Size all ECG [1]	0.25, 0.5, 1 (default), 2, 4, 8 mV/cm	Sets the amplitude of ALL displayed ECG leads.
Color [1]	***Red***, ***White***, ***Yellow***, ***Green*** (default), ***Light blue***, ***Blue***, ***Purple***, ***Orange***	Determines the color of the ECG waveforms, and the arrhythmia/ST parameter labels and values.
Change parameter	A list of currently available parameters.	Changes the parameter box to a different parameter.
Settings – ECG 2 page		
Pacer detection [1] *(Not available in neonatal mode)*	– ***On*** (default) – ***Off*** – the message ***Pacer off*** appears in the waveform channel – ***Fusion*** – the message ***Pacer fusion*** appears in the waveform channel	Determines whether pacer impulses are detected. See "Pacer fusion mode" on page 135 for precautions before you start this mode.
QRS sync marker [1]	– ***On*** – displays QRS synchronization markers – ***Off*** (default)	Determines whether vertical white markers appear on the waveform to identify QRS complexes which helps in determining when it is safe to perform synchronized cardioversion.
Cable type [1] *(TruST is only available with a 6-lead wire set)*	– ***Auto*** (default) **NOTE** When using the ECG extension cable, the system always assumes the cable is a 6-lead wire set. – 3, 5, 6, and 12 leads (if activated)	When set to ***Auto***, it detects the number of connected lead wires automatically. If auto mode does not detect the connected lead wire set, it allows you to select the cable type manually. “12” denotes a combination of a 6-lead and 4-lead wire set for 12-lead monitoring.
ARR lead 1 [1] ***ARR lead 2*** [1]	***ECGI***, ***ECGII*** (arrhythmia lead 1 default), ***ECGIII, ECGaVR, ECGaVL***, ***ECGaVF***, ***ECGV*** (arrhythmia lead 2 default), ***ECGV+***, ***ECGV1*** to ***ECGV6***	Assigns the lead for QRS processing.

NOTE
[1] This setting is a patient default which may be unique for each patient category; it is part of the profile.

Selection	Available settings	Description
ARR processing [1]	***ECG1***, ***ECG1&2*** (default) **NOTE** The ***ECG1&2*** selection is not available if the neonatal patient category is selected.	***ECG1*** setting – arrhythmia processing occurs only on the lead selected as arrhythmia lead 1. ***ECG1&2*** setting – arrhythmia processing occurs on the leads selected as arrhythmia lead 1 and arrhythmia lead 2.
Rest ECG setup page		
Gender	– ***Unknown*** (default) – ***Male*** – ***Female***	
Race	– ***Unknown*** (default) – ***Caucasian*** – ***Asian*** – ***African*** – ***Other***	

Monitoring paced patients

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

– Amplitude (a_p): ±2 to ± 900 mV

– Width (d_p): 0.2 to 2.0 ms

– Rise/Fall times (min): 0.1 d_p, 100 ms

– Overshoot (min): 0.025 a_p, 2 mV

– Recharge time constant: 4 to 100 ms

If a QRS complex occurs within 250 ms of a pacer impulse, it is also considered a paced beat. A paced beat is identified as followed:

– In the heart rate parameter box, the letter 'P' appears next to the flashing heart symbol when a pacer pulse is detected.

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

NOTE

Pacer detection is deactivated automatically in neonatal mode or when the ESU filter is activated.

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

To optimize pacer monitoring, follow the guidelines on page 137.

To turn pacer detection on/off

1 Touch the heart rate parameter box to select the ***ECG*** dialog window directly.

2 Touch the ***Settings*** tab > ***ECG 2*** tab.

3 Touch ***Pacer detection*** until it toggles to ***On*** or ***Fusion*** (see page 245).

4 Touch ***X*** to close the dialog window.

Pacemaker precautions

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

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

– 700 mV pacemaker pulses followed by QRS complexes smaller than 0.5 mV

– Asynchronous pacemaker pulses with overshoot

WARNING

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

WARNING

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

WARNING

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

– Do not assess the patient's condition exclusively from the heart and respiratory rate values the monitor displays and the rate alarms that are generated. Heart rate meters may continue to count the pacemaker rate during cardiac arrest or some arrhythmias.

– Some pacemakers (especially external pacemakers with body surface electrodes) emit pulses with amplitudes far exceeding the 700 mV maximum amplitude specified for the M540. The M540 may incorrectly detect these large pacemaker pulses as valid QRS complexes and may fail to detect cardiac arrest.

WARNING

Impedance respiration and pacemaker detection are inoperative when the ESU filter is selected. Refer to "Electrosurgery" on page 11 for general safety precautions.

Pacer fusion mode

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

WARNING

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

CAUTION

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

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

NOTE

The displayed heart rate may be incorrect if the pacemaker pulse wanders through the ECG waveform (ineffective pacing). During the wandering pacemaker test required by IEC 60601-2-27 and ANSI/AAMI EC13, the displayed heart rate varied between 15 and 30 bpm (rather than consistently being 30 bpm). The displayed heart rate was not affected by the presence of pacemaker pulses during any of those standard's other pacemaker tests.

Device interference with pacemaker monitoring

The following devices can interfere with pacemaker monitoring.

Impedance-derived rate response pacemakers

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

Infusion or roller bypass pumps

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

Line isolation devices

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

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

Transcutaneous Electrical Nerve Stimulators (TENS)

Signals from transcutaneous electrical nerve stimulators (TENS) often resemble pacer signals and can be labeled as such. The M540 can reject valid QRS complexes, which follow misinterpreted TENS signals. If TENS signals continue to register as pacer spikes, turn off pacer detection (see page 132).

Optimizing pacer processing

You can minimize interference and optimize ECG signal acquisition and processing for paced patients.

To optimize pacer processing

1 Touch the heart rate parameter box to select the ECG dialog window directly.

2 Touch the ***Settings*** tab > ***ECG 1*** tab.

3 Touch ***ECG filter*** until it toggles to ***Monitor*** or ***Off*** and determine which setting provides the clearest signal.

4 Touch ***X*** to close the dialog window.

Arrhythmia monitoring overview

WARNING

When heart rate alarm and arrhythmia monitoring are deactivated and the *ASY/VF alarms* setting is set to *Follow HR*, the monitor does not generate ASY/VF alarms. To make sure that ASY/VF alarms are always generated, set the *ASY/VF alarms* setting to *Always on*.

The M540 performs arrhythmia monitoring on adult and pediatric patients. Arrhythmia monitoring is not available for neonates. To make sure that asystole *and* ventricular fibrillation alarms are reported even when the heart rate alarm monitoring and arrhythmia monitoring functions are deactivated, set the ***ASY/VF alarms*** selection in the ***Alarm setup*** dialog window to ***Always on*** (see page 245).

The selected arrhythmia mode (see page 139) controls which arrhythmia parameters are monitored and how they are displayed. Each occurrence of an arrhythmia event is stored in the ***Event recall*** page provided the archive setting is configured (see page 105).

The arrhythmia monitoring functions have configurable parameter-specific setup pages (see page 142).

NOTE

The banner  ***HR Alarms Off*** appears in the right most field in the header bar whenever you turn heart rate alarms off.

The  ***HR, ASY, VF off*** banner appears when arrhythmia monitoring is deactivated, the ***ASY/VF alarms*** feature is set to ***Follow HR***, and heart rate alarms are deactivated.

NOTE

If French NFC mode is activated (see page 251), you cannot deactivate heart rate alarms.

Before performing any monitoring functions, refer to the section "For your safety and that of your patients" starting on 5.

Selecting arrhythmia leads

Appropriate lead selection is essential for accurate arrhythmia monitoring. It is ideal to assign the two best ECG leads as the arrhythmia monitoring leads. The following two options are available:

– ***ECG1*** (single channel selection) – dedicates processing to the lead selected as arrhythmia lead 1.

– ***ECG1&2*** (dual channel selection) – determines the heart rate and arrhythmia based on the leads selected as arrhythmia lead1 and arrhythmia lead 2.

NOTE

When the M540 is docked in an IACS configuration, the top two ECG waveform channels on the Cockpit are arrhythmia lead 1 and arrhythmia lead 2.

When the M540 is in standalone mode or on wireless transport, the selected arrhythmia leads and waveform channel may be different. Make sure that the waveform channel and arrhythmia channels are configured appropriately.

To select arrhythmia leads

1 Touch the heart rate parameter box to select the ***ECG*** dialog window directly.

2 Touch the ***Settings*** tab > ***ECG 2*** tab.

3 Touch the ***ARR lead 1*** or ***ARR lead 2*** tab.

4 Touch the appropriate lead and then touch ***X*** to close dialog window.

Arrhythmia modes

If arrhythmia monitoring is activated, the selected arrhythmia mode (basic or advanced) determines how many events are monitored. When the ASY/VF alarm setting is set to ***Always on*** asystoles and ventricular fibrillation events are always reported, even when arrhythmia monitoring is deactivated.

The following table lists which arrhythmia events are reported with each monitoring mode.

Arrhythmia monitoring off (the following events are detected, if at least one ECG is displayed)		
ASY	Asystole	4 s pass without the detection of a valid QRS complex
VF	Ventricular fibrillation	Sinusoidal waveform with fibrillation characteristics [1]
Basic arrhythmia monitoring mode (the following additional events are detected)		
VTACH	Ventricular Tachycardia	N or more PVCs are detected in a time interval T = (60 * (N - 1)) / R, where N is the VTACH count and R is the VTACH rate [2], [4]
PVC	Premature Ventricular Contraction	PVC alarm limit exceeded. The PVC parameter value represents the number of QRS complexes classified as PVCs over a 1-minute time interval.
ARTF	Artifact	More than 50 % of beats in the last minute were classified as questionable
Advanced arrhythmia monitoring mode (the following additional events are detected)		
BRADY	Bradycardia	Eight or more consecutive normal beats, with an average rate ≤bradycardia rate setting [3]
RUN	Ventricular RUN	Series of 3 to N–1 consecutive PVCs with a beat-to-beat rate ≥ the VTACH rate [2]
AIVR	Accelerated Idioventricular Rhythm	Series of 3 or more PVCs with a rate less than the VTACH rate.
SVT	Supraventricular Tachycardia	N or more consecutive normal beats, with a beat-to-beat rate greater than or equal to the SVT setting [2]
CPT	Ventricular Couplet	Sequence of beats with the pattern: normal, PVC, PVC, normal.

NOTE

[1] Certain ventricular tachycardias have sinusoidal waveforms closely resembling ventricular fibrillation. Because of the similarities between these waveforms, such types of ventricular tachycardia can be classified as ventricular fibrillation, the more serious of the two conditions.

[2] N is the event count set in the count column of the arrhythmia setup table (see page 142).

[3] In neonatal mode, you set alarm limits for BRADY in the alarm setup page. The M540 alarms for this event as a limit violation.

[4] A PVC or another abnormal beat breaks the analysis sequence and restarts analysis.

Advanced arrhythmia monitoring mode (the following additional events are detected)		
BGM	Ventricular bigeminy	Sequence of beats with the pattern: normal, PVC, normal, PVC, normal.
TACH	Tachycardia	N or more consecutive normal beats, with a beat-to-beat rate ≥ TACH rate setting. [2) 4)]
PAUSE	Pause	Sequence of two beats classified as normal or PVC, with an interval ≥ pause rate value in sec (±100 ms).

NOTE

[2)] N is the event count set in the count column of the arrhythmia setup table (see page 142).

[4)] A PVC or another abnormal beat breaks the analysis sequence and restarts analysis.

To select the arrhythmia mode

1 Touch the heart rate parameter box to select the ***ECG*** dialog window directly.

2 Touch the ***Settings*** tab > ***ARR*** tab.

3 Touch ***ARR mode*** and toggle to one of the following modes:

- ***Off***
- ***Basic***
- ***Advanced*** (locked option)

4 Touch ***X*** to close the dialog window.

Arrhythmia display

When arrhythmia monitoring is activated, arrhythmia events appear in the heart rate parameter box.

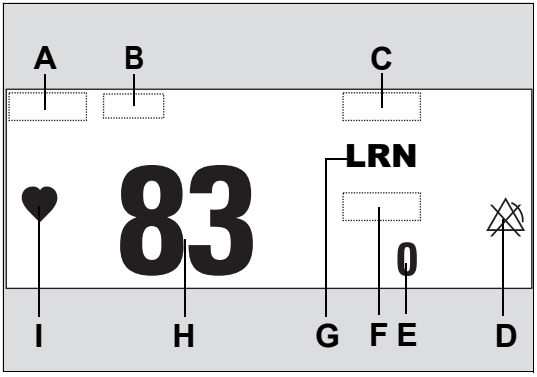
When arrhythmia monitoring is turned off (see page 140) and at least one ECG waveform is displayed, asystole and ventricular fibrillation events are still reported.

NOTE

To make sure that asystole *and* ventricular fibrillation alarms are reported even when heart rate monitoring is turned off, set the ***ASY/VF alarms*** selection in the ***Alarm setup*** dialog window to ***Always on*** (see page 245).

Arrhythmia basic parameter box

If the heart rate parameter box is displayed and arrhythmia monitoring is activated, all arrhythmia values and labels appear in the heart rate parameter box. The arrhythmia parameter box contains the following elements:



A Heart rate parameter label

B Unit of measure

C Arrhythmia label

D Crossed triangle symbol when alarms are turned off

E Number of Premature Ventricular Contractions (PVC) per minute

F PVC label

G ***LRN*** message

H Heart rate

I Heart blip that pulsates with each detected beat (if pacer detection is turned on, the symbol appears as P♥ when a paced beat is detected)

Accessing the arrhythmia dialog window

1 Touch the heart rate parameter box.

2 Touch the ***Settings*** tab.

3 Touch the ***ARR*** tab.

Or, if the parameter is not displayed

1 Touch any parameter box > ***Settings*** tab > ***Change parameter***.

2 Touch the desired parameter label to display it on the main screen.

3 Touch the parameter box > ***Settings*** tab > ***ARR*** tab.

Arrhythmia parameter setup functions

All arrhythmia parameter setup functions take place in the arrhythmia dialog window (see "Accessing the arrhythmia dialog window" on page 142).

The limits dialog window contains the ***Auto set*** and ***Alarm*** buttons for configuring the alarm functions. For detailed alarm setup information, see "Configuring a patient's alarm settings" on page 100.

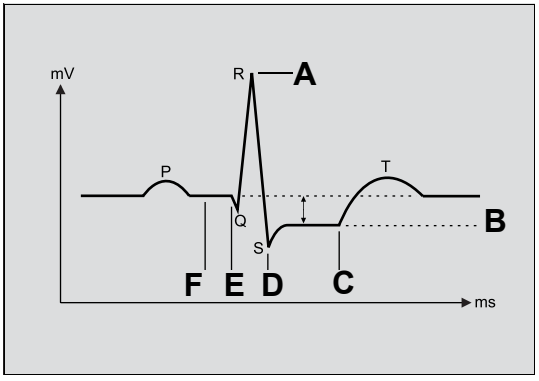
Selection	Available settings	Description
ARR mode	***Off***, ***Basic*** (default), ***Advanced***	Selects which events are reported (see page 139 for more detail).
Relearn	None	Establishes a new QRS templates

Monitoring ST overview

ST analysis examines normal QRS complexes from up to 12 ECG leads. The M540 learns each ST lead, combines the measurements into an average QRS complex, and derives the ST segment deviation. ST monitoring is available for adult and pediatric patients.

The ST segment deviation is defined as the displacement (in mm or mV) above or below the isoelectric level. The deviation measurement compares the isoelectric point to the ST measurement point.

The following illustration identifies the measured elements of a QRS complex.



A Fiducial point

B ST level

C ST measurement point

D QRS offset

E QRS onset

F Isoelectric point

NOTE

ST analysis is always performed using a dedicated filter which ensures diagnostic quality. The ECG filter settings (***ESU***, ***Monitor***, and ***Off***) are not of diagnostic quality, and as a result, the ST segment of the ECG waveform may appear differently from the ST segment of the ST complex.

The ST monitoring functions are configurable parameter-specific setup pages (see page 148).

Before performing any monitoring functions, refer to the section "For your safety and that of your patients" starting on page 5.

Standard ST monitoring

The 6-lead wire set monitors eight ECG leads, of which two are chest leads (V and V+). 12-lead ST analysis provides the most comprehensive view of a patient's condition. However, with optimal placement of the V and V+ leads and using only eight leads, you can achieve an ST analysis that is almost as comprehensive but with fewer electrodes.

TruST 12-lead monitoring

This feature offers real-time assessment of 12 ST segment deviations, with only six electrodes, which provide eight measured ECG leads and four derived chest leads. The derived leads are identified by adding the letter ‘d’ before the lead label. When TruST monitoring is activated, the V-lead defaults to V2 and the V+ lead defaults to V5. Although you can select derived leads for display, they are excluded from arrhythmia and QRS processing.

12-Lead ST monitoring

During 12-lead ST monitoring, the M540 acquires 12 ST leads in addition to the following:

– ST Vector Magnitude (STVM) – the magnitude (mm or mV) of the ST vector. It is a summary vector, combining the ST values from all 12 leads. STVM is trended and has its own alarm limits.

– ST Change in Vector Magnitude (STCVM) – the change of magnitude (mm or mV) between the current ST vector and the ST vector at the time of the last reference. STCVM values also show a change in the location of the ST vector over time.

To activate or deactivate ST monitoring

You can turn ST monitoring on or off at any time.

1 Touch the ST parameter box.

2 Touch the ***Settings*** tab.

3 Touch ***ST monitoring*** until it toggles to ***On*** or ***Off***.

Connecting lead wire sets for ST monitoring

ST monitoring uses the following lead configurations for each available ST monitoring mode:

– Standard ST monitoring – uses the standard 3-5-, and 6-lead wire sets. For more information see the diagrams starting on page 121.

– TruST – provides ST-lead ST monitoring with a 6-lead wire set (see page 144).

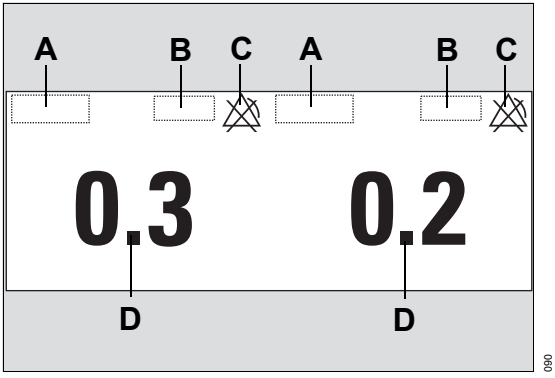
– 12-lead ST monitoring – uses the standard 12-lead ECG configuration with ten electrodes (see page 121).

ST display

When ST alarms are activated, the M540 alarms for all ST leads whether they are displayed or not. In either case, the ST parameter box flashes and the alarming lead is identified in the header bar.

When ST monitoring is activated, current ST values display in a separate parameter box. You can select which two ST leads are displayed in the parameter box.

The ST parameter box contains the following elements:



A Selected ST lead labels

B Unit of measure

C Crossed triangle indicating alarms are off for the selected ST leads

D Selected ST deviation values

ST complex dialog windows

The number of displayed ST complexes depends on the connected lead wire set. You can view all ST complexes or zoom in on a single ST complex to view it in greater detail.

The following functions are available in the single ST complex dialog window:

– Changing the ISO point

– Changing the ST measuring point

To access the general ST complex dialog window

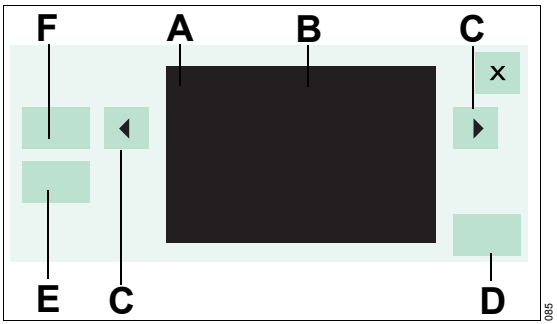
1 Touch the ST parameter box.

2 Touch the ***Settings*** tab.

3 Touch ***ST complex***.

Zooming in on a single ST complex

The following diagram shows a single ST complex when you zoom in on one ST complex.



A ST label (unique for each ST lead)

B Single complex window

C When ***ISO:*** or ***ST:*** button is selected, left and right arrows allow you to move the ISO/ST measuring point

D ***Confirm*** button

E ***ST:*** button

F ***ISO:*** button

To zoom in on a single ST complex

1 Touch the ST parameter box.

2 Touch the ***Settings*** tab.

3 Touch ***ST complex***. The general ST complexes dialog window displays.

4 Touch a single ST complex window.

ST measuring points

You can change the ST measuring points and isoelectric point from the single ST complex dialog window. The setup buttons for changing the measuring points are located on the left side of the screen. Changing the measuring point for one complex adjusts the measuring points for all ST complexes.

Adjusting ST measuring points

Whenever you adjust the isoelectric and ST measuring points, the ST deviation is recomputed.

To change ST measuring points

1. Touch the ST parameter box to access the ST dialog window directly.
2. Touch the ***Settings*** tab.
3. Touch ***ST complex*** to display the general ST complexes dialog window.
4. Touch an individual ST panel to zoom in on a single ST complex.
5. Touch ***ISO:*** and use the arrows to move cursor and adjust ISO point.
6. Touch ***ST:*** and use the arrows to move cursor and adjust ST point.
7. Touch ***Confirm*** to accept the settings and to close the ST complex panel or touch ***X*** to close the ST complex panel without saving changes.

ST reference

You can save ST reference complexes as a reference point for future ST deviation measurement comparisons. The first time you relearn QRS complexes, the current ST data are saved as a reference data. This original ST reference data is updated each time you save ST references.

Saving ST reference

You can save the ST reference from the ***Settings*** tab. Saving the ST reference saves all current ST complexes as the new reference.

To save ST reference complexes

1. Touch the ST parameter box.
2. Touch the ***Settings*** tab.
3. Touch ***Save:***

Accessing the ST dialog window

1 Touch the ST parameter box.

2 Touch the ***Settings*** tab.

Or, if the parameter is not displayed

1 Touch any parameter box > ***Settings*** tab > ***Change parameter***.

2 Touch the desired parameter label to display it on the main screen.

3 Touch the parameter box > ***Settings*** tab.

ST setup functions

All ST parameter setup functions take place in the ST dialog window (see "Accessing the ST dialog window" on page 148).

The limits dialog window contains the ***Auto set*** and ***Alarm*** buttons for configuring the alarm functions. For detailed alarm setup information, see "Configuring a patient's alarm settings" on page 100.

Selection	Available settings	Description
	Settings	
Relearn *(Not available if ECG is not connected, in neonatal mode, or ST monitoring is turned off)*	None	Purges stored average ST complexes, blanks displayed average ST complexes, and learns the arrhythmia and dominant QRS pattern.

Selection	Available settings	Description
ST lead 1 [1]	– Three electrodes: ***STI***, ***STII***, ***STIII***	Selects an ST lead for analysis and display.
ST lead 2 [1]	– Five electrodes: ***STI***, ***STII***, ***STIII***, ***STaVR***, ***STaVL***, ***STaVF***, ***STV***	
	– Six electrodes: ***STI***, ***STII***, ***STIII***, ***STaVR***, ***STaVL***, ***STaVF***, ***STV***, ***STV+***	
	– Six electrodes (with TruST activated): ***STI***, ***STII***, ***STIII***, ***STaVR***, ***STaVL***, ***STaVF***, ***STdV1***, ***STV2***, ***STdV3***, ***STdV4***, ***STV5***, ***STdV6***	
	– Ten electrodes: ***STI***, ***STII***, ***STIII***, ***STaVR***, ***STaVL***, ***STaVF***, ***STV1***, ***STV2***, ***STV3***, ***STV4***, ***STV5***, ***STV6***, ***STCVM***, and ***STVM***	
	– Default for ST lead1: ***STII***	
	– Default for ST lead2: ***STV*** for 5-/6-lead cable, ***STV2*** for TruST or 12-lead cable	
ST monitoring [1]	***Off***, ***On*** (default)	Turns ST monitoring on/off.
ST complex	None	Views ST complexes.
Event duration [1]	***Off***, 15, 30, 45, 60 (default) sec	Defines a period an alarm condition must persist, before alarm signals are generated.
TruST [1] *(TruST is only available with a 6-lead wire set.)*	***On***, ***Off*** (default)	Turns TruST monitoring on or off.
Save:	None	Saves the current ST complexes as references (see page 147).
Change parameter	A list of currently available parameters.	Changes the parameter box to a different parameter.

NOTE

[1] This setting is a patient default which may be unique for each patient category; it is part of the profile.

Learning/relearning QRS pattern

The M540 creates a reference template by learning the dominant QRS pattern of a patient. The reference template is stored for reference and all subsequent beats and rhythms are compared against it and classified either as normal or irregular.

The M540 can only learn the QRS pattern of the leads that are selected for arrhythmia processing. If only one lead is available, the M540 only learns on one lead. If no lead wire set is connected, the M540 cannot perform a learning phase. In this case, an error message is displayed.

The M540 starts a learning phase automatically when:

– Arrhythmia monitoring is turned on
– A different arrhythmia mode is selected
– Different ECG leads are selected for arrhythmia processing
– The cable type is changed
– The M540 is docked in an IACS configuration whose profile has a different ECG lead configuration.
– A standalone M540 is docked on an M500 whose profile has a different ECG lead configuration.

During the learning phase, which lasts approximately 30 to 40 seconds, the message ***ARR relearning*** appears in the message field. In addition, and message ***LRN*** appears in the ECG parameter box.

If ST monitoring is turned on, ST deviations are also recomputed during the learning phase.

Manual relearning

Relearn the QRS pattern of a patient when:

– Leads are reconnected or electrodes are repositioned
– Eight hours have passed since the last learning phase
– Questionable arrhythmia calls appear on the ECG
– Other significant changes appear on the ECG

You can initiate a relearning phase from the arrhythmia and the ST dialog windows.

To relearn from the arrhythmia dialog window

1 Touch the heart rate parameter box to select the ECG dialog window.
2 Touch the ***Settings*** tab > ***ARR*** tab > ***Relearn***.

To relearn from the ST dialog window

1 Touch the ST parameter box to select the ST dialog window.
2 Touch the ***Settings*** tab > ***Relearn***.

Impedance respiration (RRi)

Overview of respiration monitoring

The M540 measures impedance respiration by passing a harmless high-frequency current between two ECG electrodes on the patient's chest. Electrical resistance (impedance) between the electrodes varies with the expansion and contraction of the chest during inspiration and expiration. The M540 displays a respiration waveform and respiratory rate value from these impedance changes.

The M540 uses ECG leads I or II for breath detection regardless of the lead selected for QRS processing.

Respiration monitoring is for adult, pediatric, and neonatal patients. The M540 can use the respiration signal for central apnea monitoring.

The respiration monitoring functions are configurable in the parameter-specific dialog window (see page 159).

Before performing any monitoring functions, refer to the section "For your safety and that of your patients" starting on page 5.

Parameter-specific error messages are listed on page 267.

Supported parameters

RRi – respiration rate measured by impedance (respiration values are not displayed when the ESU filter is activated – see page 131).

RRi precautions

WARNING

The safety and effectiveness of the respiration measurement method in the detection of apnea, particularly the apnea of prematurity and apnea of infancy, has not been established.

WARNING

This device does not monitor obstructive apnea. Patients at risk for respiratory crises should be observed closely.

WARNING

Large amplitude pacemaker pulses (100 mV or greater) may interfere with the monitor's ability to measure or detect respiration.

WARNING

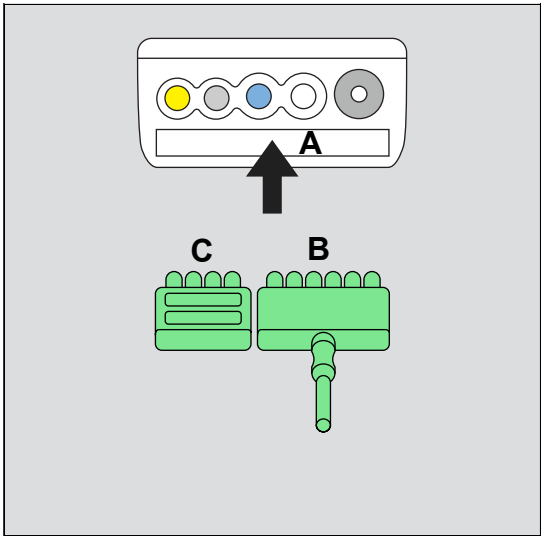
The monitor reports an apneic event when no breaths are detected within the established apnea time period. Therefore, do not rely on impedance respiration monitoring as the sole method for detecting cessation of breathing. Dräger recommends the monitoring of additional parameters that indicate the patient's oxygenation status, such as $etCO_2$ and SpO_2. Heart rate limit alarms should also be enabled and set appropriately.

WARNING

Impedance respiration and pacemaker detection are inoperative when the ESU filter is selected. Refer to "Electrosurgery" on page 11 for general safety precautions.

Connecting the 3-, 5-, 6-lead wire sets for respiration monitoring

The ECG lead wire sets connect directly to the M540:



A M540 ECG connector

B Lead wire set

C Spacer

To connect the ECG lead wire sets

1 Insert the 3-,5-, or 6-lead wire set (B) into the recessed ECG connector (A) on the side of the M540.

Orient the ECG lead wire set (B) so the exposed pins face toward you as you push it firmly into the channel.

NOTE

An ECG lead wire set can rest in the ECG connector of the M540 without actually being connected. Make sure that all ECG lead wire sets are pushed firmly into the ECG connector of the M540.

Almost every MonoLead features a number on the lead wire set indicating how many leads connect. When connecting a MonoLead, make sure the number faces in the same direction as the M540 display.

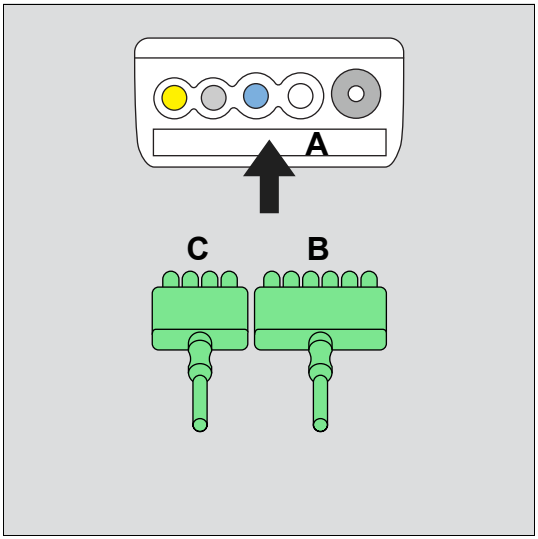
2 Insert the spacer (C) to protect the unused ECG lead pins.

3 Connect the lead wire to the patient.

For information on applying the electrodes to the patient, refer to the illustrations starting on page 156.

Connecting the lead wire sets for 12-lead respiration monitoring

The ECG lead wire sets connect directly to the M540:



A M540 ECG connector

B 6-Lead wire set

C 4-lead wire set

To connect the ECG lead wire sets

1 Insert the 6-lead wire set (B) and the 4-lead wire set (C) into the recessed ECG connector (A) on the side of the M540.

Orient the ECG lead wire sets (B and C) so the exposed pins face toward you as you push it firmly into the channel.

NOTE

An ECG lead wire set can rest in the ECG connector of the M540 without actually being connected. Make sure that all ECG lead wire sets are pushed firmly into the ECG connector of the M540.

Almost every MonoLead features a number on the lead wire set indicating how many leads connect. When connecting a MonoLead, make sure the number faces in the same direction as the M540 display.

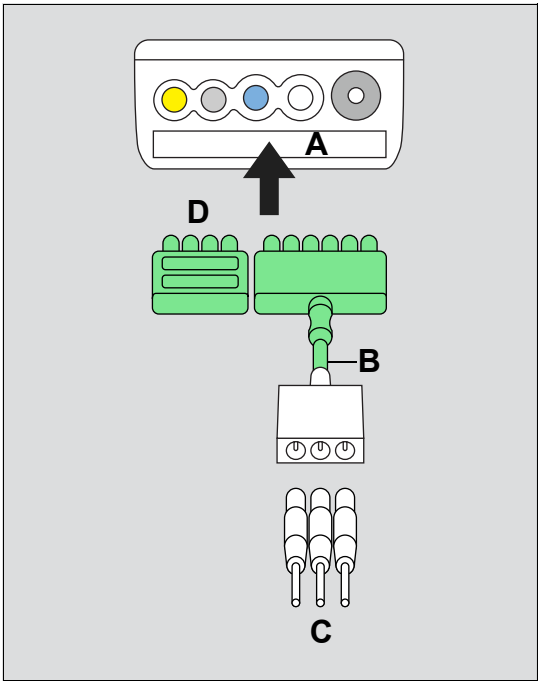
2 Connect the lead wires to the patient. For information on applying the electrodes to the patient, refer to the illustrations starting on page 156.

NOTE

When using a 12-lead ECG wire set where the lead wires are coiled, it is recommended that the 6-lead wire set is wrapped in the same direction as the 4-lead set to prevent artifact. For example, both lead wire sets are either wrapped toward the patient or away from the patient.

Connecting the lead wires for neonatal respiration monitoring

The ECG lead wire sets connect directly to the M540:



A M540 ECG connector

B Neonatal ECG adapter cable

C Neonatal ECG electrodes

D Spacer

To connect the ECG lead wire set

1 Insert the Neonatal ECG adapter cable into the recessed ECG connector (A) on the side of the M540.

Orient the neonatal ECG adapter cable (B) so the exposed pins face toward you as you push it firmly into the channel.

NOTE

An ECG lead wire set can rest in the ECG connector of the M540 without actually being connected. Make sure that all ECG lead wire sets are pushed firmly into the ECG connector of the M540.

2 Insert the spacer (D) to protect the unused ECG lead pins on the M540.

3 Connect the individual neonatal ECG electrodes (C) to the neonatal ECG adapter cable (B).

For information on applying the electrodes to the patient, refer to the illustrations starting on page 156.

Patient preparation for respiration monitoring

The following tips regarding skin preparation and proper electrode placement provide strong signals with minimal artifact but must never replace hospital-approved practices or manufacturer's recommendations. Because ECG electrodes are used for respiration monitoring, see illustrations starting on page 121 for information on electrode placement.

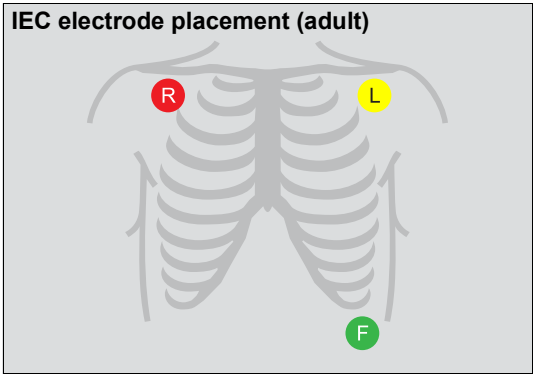
Follow the same precautions for respiratory monitoring as for ECG monitoring (see page 120) and observe the following general recommendations:

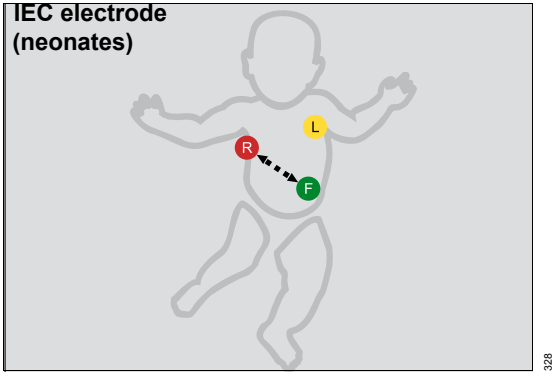
– Place the electrodes so they generate the clearest possible signals with minimal artifact.

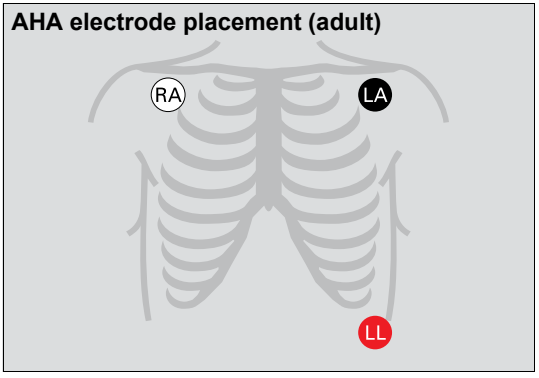
– Electrodes that adhere tightly and have a large conductive area provide the best results. Use a 5-lead wire set to improve the respiration signal (where the N electrode for IEC or RL electrode for AHA is the neutral electrode).

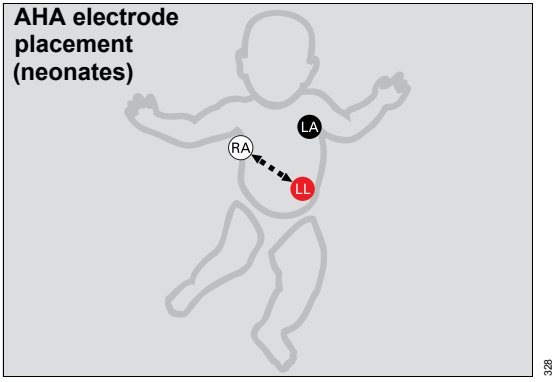
– For adult and pediatric patients, position the electrodes to span the maximum expansion and contraction of the lungs. This is especially important in the case of deep abdominal breathers.

– For neonates, place the (A) and LA electrodes at the midaxillary line. Position the LL electrode below the diaphragm and umbilicus. Avoid the liver area and ventricles of the heart to prevent blood flow artifact.









Respiration display

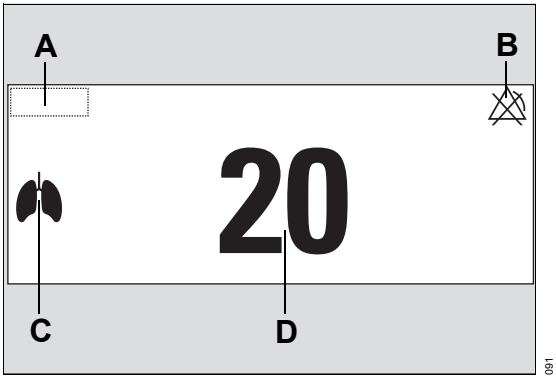
On the M540, the respiration display consists of:

– Respiration parameter box

– Respiration waveform

Respiration parameter box

The respiration parameter box contains the following elements:



A Impedance respiration rate label (RRi)

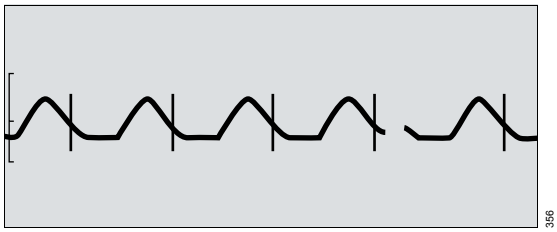
B Crossed triangle symbols if alarms are turned off

C Lung symbol that blinks with each detected breath

D Respiratory rate value

Respiration markers

The following diagram shows how white vertical markers on the respiration waveform can identify each detected breath.



If an M540 is in an IACS configuration, respiration markers are not sent to the Infinity network.

Respiration markers indicate the time of breath detection, not the beginning or end of respiration. If respiration markers also appear during artifact, set the respiration measuring mode to manual and adjust the breath detection threshold so only valid breaths are counted.

To turn the respiration markers on

1 Touch the respiration parameter box to select the Respiration dialog window directly.

2 Touch the ***Settings*** tab.

3 Touch ***Marker*** > ***On***.

Respiration measuring modes

The following respiration measuring modes are available:

– ***Auto*** (default) – appropriate for patients with regular breathing patterns. It uses the optimal breath-detection threshold calculated at the beginning of respiration monitoring.

– ***Manual*** – appropriate for adult or pediatric patients whose breathing patterns show excessive variation, or for neonates with irregular breathing rhythms, whose respiration signals may otherwise not be reliably evaluated. The M540 does not set a breath-detection threshold at the beginning of respiration monitoring. Instead, the adjustments you make to the waveform size (see page 46) alter the breath detection sensitivity of the monitor.

To select the desired respiration mode, see page 160.

WARNING

If the respiration waveform size is set too low in manual mode, shallow breaths may not be counted. If it is set too high, cardiac artifact will be counted as breaths. Therefore, always use the respiration marker to verify breath detection at the desired amplitude.

Accessing the respiration dialog window

1 Touch the respiration parameter box.

2 Touch the ***Settings*** tab.

Or, if the parameter is not displayed

1 Touch any parameter box > ***Settings*** tab > ***Change parameter***.

2 Touch the desired parameter label to display it on the main screen.

3 Touch the parameter box > ***Settings*** tab.

Respiration parameter setup functions

All respiration parameter setup functions take place in the respiration dialog window (see "Accessing the respiration dialog window" on page 159).

The limits dialog window contains the ***Auto set*** and ***Alarm*** buttons for configuring the alarm functions. For detailed alarm setup information, see "Configuring a patient's alarm settings" on page 100.

Selection	Available settings	Description
	Settings	
Resp. lead [1]	I, II (default)	Selects the lead for respiration monitoring.
Relearn	None	Initiates a relearning of the respiration signal.
Mode [1]	***Auto*** (default), ***Manual***	Determines the processing mode for the breath-related impedance change.
Marker [1]	***On***, ***Off*** (default)	Superimposes a vertical line on the respiration waveform when a breath is detected (see page 158).
Monitoring [1]	– ***On*** (default in neonatal mode) – ***Off*** (default in adult/pediatric mode)	Turns respiration monitoring on or off.
Apnea time [1]	***Off***, 10, 15 (default), 20, 25, 30 s	Determines how long an apnea has to last before an alarm is triggered.
Apnea archive [1]	– ***Off*** – ***Str/Rec*** – a recording as well as an event storage is triggered automatically in response to an apnea. – ***Store*** (default) – a waveform segment is stored in response to an apnea. – ***Record*** – a recording is triggered automatically in response to an apnea.	Determines what happens in response to an apnea.

NOTE

[1] This setting is a patient default which may be unique for each patient category; it is part of the profile.

Selection	Available settings	Description
Coincidence [1)]	***On***, ***Off*** (default)	Determines whether you are alerted when the respiratory rate is within 20 % of the heart rate, which is an indication that the M540 is counting heart beats as respiration.
Color [1)]	***Red***, ***White***, ***Yellow***, ***Green***, ***Light blue*** (default), ***Blue***, ***Purple***, ***Orange***	Determines the color of the waveforms, and the parameter labels and values.
Change parameter	A list of currently available parameters.	Changes the parameter box to a different parameter.

NOTE

[1)] This setting is a patient default which may be unique for each patient category; it is part of the profile.

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SpO2 and Pulse CO-Ox monitoring with Masimo SET MCable

Overview of SpO2 monitoring

SpO2 and Pulse CO-Ox monitoring is only possible with the corresponding SpO2 MCable. The following hardware is available for monitoring SpO2 and Pulse CO-Ox parameters:

– Infinity MCable – Masimo SET

– Infinity MCable – Masimo rainbow SET

The values and the waveform are displayed on the M540 and on the Cockpit if the M540 is docked in an IACS configuration.

The Masimo SET MCable and Infinity MCable – Masimo rainbow SET support motion tolerant pulse oximetry using Signal Extraction Technology (SET). This technology enhances the quality of SpO2 monitoring and also measures the percentage of functional hemoglobin saturated with oxygen (%SpO2) in the arterial blood of the patient accurately and effectively.

A sensor applied to the patient measures the absorption levels of red and infrared light. The Masimo SET MCable or Masimo rainbow SET MCable uses the difference between the two measurements to calculate the percentage of saturated hemoglobin (SpO2). Because light absorption varies with blood volume and blood volume varies with pulse rate, both types of Masimo SET MCable can also derive a pulse rate (PLS).

In addition, the Masimo SET MCable also provides a perfusion index (PI) value. PI is the ratio of the pulsatile blood flow to the non-pulsatile blood flow in peripheral tissue. The PI value provides information regarding the perfusion status of the selected application site. This provides a means to select the most optimal site.

The Infinity MCable – Masimo rainbow SET measures additional parameters that continuously and non-invasively measure blood constituents.

SpO2 and Pulse CO-Ox measurements are for adult, pediatric, and neonatal patients (with the following exceptions).

NOTE

The Masimo rainbow SET parameters SpHb and SpOC are not approved for neonatal monitoring.

NOTE

Information about wavelength range may be useful during photodynamic therapy. For details, see the chapter entitled "Technical data" on page 324.

The SpO2 monitoring functions are configurable in the parameter-specific dialog window (see page 174).

Before performing any monitoring functions, refer to the section "For your safety and that of your patients" on page 5.

Parameter-specific error messages are listed on page 269.

NOTE

This device is covered under one or more of the following USA patents: 5,758,644, 6,011,986, 6,699,194, 7,214,986, 7,254,433, 7,530,955 and other applicable patents listed at: www.masimo.com/patents.htm

Supported parameters

The parameters SpO2, PLS, and PI are available and displayed regardless of which Masimo sensor and which Masimo SET MCable is being used.

The availability of additional Masimo rainbow SET parameters depends on the sensor type that is being used and which parameters are activated on the Masimo rainbow SET MCable.

Standard parameter set

The Infinity MCable – Masimo SET and the Infinity MCable – Masimo rainbow SET always support the following parameters:

– Functional oxygen saturation (SpO2). The unit of measure is %.

– Pulse rate (PLS). The unit of measure is beats/min.

– Perfusion index (PI) which indicates the arterial pulse signal strength. The unit of measure is %.

Expanded parameter set

In addition to the above standard parameters, the Masimo rainbow SET MCable provides the following additional optional parameters:

– Total hemoglobin (SpHb) measures the total hemoglobin levels in arterial or venous blood. The unit of measure is selectable (see page 252).

– Total oxygen content (SpOC) measures the total blood oxygen content; this value is calculated from the SpHb and the SpO2 values. The unit of measure is mL/dL.

– Pleth variability index (PVI) measures peripheral perfusion changes secondary to respiration or the PI amplitude over a respiration. PVI may be closely related to intrathoracic pressure changes, circulating blood volume and vascular tone. The unit of measure is %.

– Carboxyhemoglobin saturation (SpCO) measures the amount of carbon monoxide that is bound to hemoglobin. The unit of measure is %.

– Methemoglobin saturation (SpMet) measures the methemoglobin concentration in arterial blood. The unit of measure is %.

Three types of sensors are available for the Masimo rainbow SET MCable. The availability of the parameters depends on the selected sensor type.

Each sensor provides certain parameters which must also be activated on the Masimo rainbow SET MCable.

– CO sensor; this type of sensor provides the following parameters: SpO2, PLS, PI, SpCO, SpMet, PVI.

– M-LNCS sensor; this type of sensor provides the following parameters: SpO2, PLS, PI.

– Hb sensor; this type of sensor provides the following parameters: SpO2, PLS, PI, SpHb, SpOC, SpMet, PVI.

NOTE

A color band on the Masimo rainbow SET MCable indicates which parameters are activated on the MCable. If an MCable does not have a label, the supported parameters are by default SpO2, PLS, and PI.

The following illustration shows the multi-color band which appears on the side of the Masimo rainbow SET MCable (see page 168 for more information).

If you connect a sensor but the parameter is not activated on the MCable, the parameter label appears in the parameter box without a value.

SpO2 and Pulse CO-Ox precautions

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.

WARNING

High oxygen levels may predispose a premature infant to retrolental fibroplasia. If this is a consideration do NOT set the high alarm limit to 100 %, which is equivalent to switching the alarm off. Transcutaneous pO2 monitoring is recommended for premature infants receiving supplemental oxygen.

WARNING

A pulse oximeter should not be used as an apnea monitor.

WARNING

Use only Masimo-specified sensors. Other sensors may not provide adequate protection against defibrillation and may put the patient at risk.

WARNING

A Pulse CO-Oximeter should be considered an early warning device. If a trend toward patient hypoxemia is observed, blood samples should be analyzed by laboratory instruments to completely understand the condition of the patient.

WARNING

The pulsations from an intra-aortic balloon support can elevate the pulse rate. Verify the pulse rate of the patient against the heart rate.

WARNING

Elevated levels of methemoglobin (MetHb) may lead to inaccurate SpO2 and SpCO measurements.

Elevated levels of total bilirubin may lead to inaccurate SpO2, SpMet, SpCO, SpHb, and SpOC measurements.

Motion artifact may lead to inaccurate SpMet, SpCO, SpHb, and SpOC measurements.

Very low arterial oxygen saturation (SaO2) levels may cause inaccurate SpCO and SpMet measurements.

Hemoglobin synthesis disorders may cause erroneous SpHb readings.

WARNING

To reduce the hazard of burns during surgery, keep the sensor or transducer and their associated cables away from the surgical site, the electro-surgical unit return electrode, and earth ground.

WARNING

Inspect the application site every two to three hours to ensure skin quality and correct optical alignment. If the skin quality changes, move the sensor to another site. Change the application site at least every four hours.

CAUTION

Do not immerse the sensor or patient cable in any liquid. Moisture may present a safety risk.

CAUTION

When using the maximum sensitivity setting, the performance of the sensor off detection may be compromised. If the device is in this setting and the sensor becomes dislodged from the patient, false readings may occur due to environmental 'noise' such as light, vibration and excessive air movement. In addition, when a sensor becomes detached from a patient, it will have compromised protection against erroneous pulse rate and arterial saturation readings.

NOTE

A pulse oximeter can be used during defibrillation, but the readings may be inaccurate for up to 20 seconds.

NOTE

Possession or purchase of the Masimo SET MCable or the Masimo rainbow SET MCable does not convey any expressed or implied license to use the device with unauthorized sensors or cables which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

NOTE

Purchase of this device confers no express or implied license under any Masimo patent to use this instrument with any oximetry sensor that is not manufactured or licensed by Masimo. For a list of approved sensors, see the instructions for use *Infinity Acute Care System – Monitoring Accessories*.

NOTE

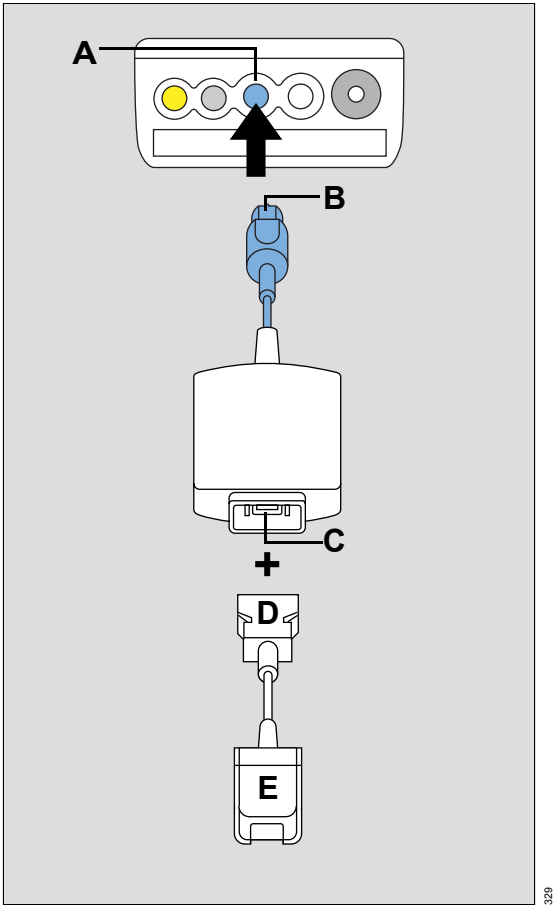
Do not use a functional tester to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor. Since pulse oximeter measurements are statistically distributed, only about two-thirds of those measurements can be expected to fall within ±A rms of a CO-Oximeter's measured value.

NOTE

A functional tester can be used to measure the total error of a pulse oximeter monitor-probe system if a particular calibration curve has been independently demonstrated to be accurate for that system. The functional tester can then measure how accurately a particular pulse oximeter is in reproducing the calibration curve.

Connecting the Masimo SET MCable

The Masimo SET MCable connects directly to the M540. The logo on the MCable identifies if you are using a Masimo rainbow SET or a Masimo SET MCable.



A SpO2 connector on the M540

B MCable connector

C MCable intermediate connector (14-pin connector)

D Intermediate cable connector to MCable

E Intermediate cable connector to sensor

To connect the Masimo SET MCable

1. Attach the Masimo SET MCable connector (B) to the blue SpO2 connector (A) of the M540.
2. Attach the sensor cable (D) to the Masimo SET MCable connector (C).
3. Attach the appropriate Masimo LNCS sensor to the end of the sensor cable (E) – see page 173 for more information.

Connecting the Masimo rainbow SET MCable

The Masimo rainbow SET MCable connects directly to the M540. The logo on the MCable identifies if you are using a Masimo rainbow SET or a Masimo SET MCable.

A color band located on the side of the Masimo rainbow SET MCable indicates which parameters are activated.

478

– Fields appearing in color represent parameters that are already activated
– Fields with the letter 'X' denote parameters that are not activated
– Fields that appear empty denote parameters that might be activated later

A Masimo MCable can be mounted to the back of an M540 (see page 74).

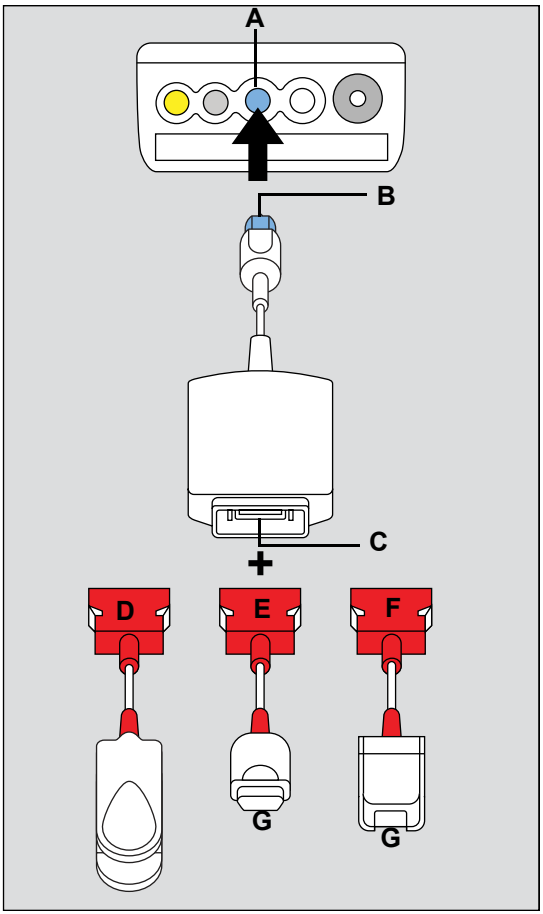
To connect the Masimo rainbow SET MCable

1 Attach the MCable (B) to the blue SpO2 connector (A) of the M540.

2 Attach the intermediate cable (E, F) to the connector of the MCable (C).

The reusable SpCO sensor (D) connects directly to the connector of the MCable (C).

3 Attach the appropriate Masimo sensor to the end of the intermediate cable (G). For detailed information on which sensors support which parameters, refer to the instructions for use *Infinity Acute Care System – Monitoring Accessories*.



481

A SpO2 connector on the M540

B MCable connector

C MCable (20-pin connector)

D Reusable SpCO sensor – connects directly to the connector (C) of the MCable

E Masimo rainbow SET intermediate cable (connector to MCable)

F LNCS intermediate cable (connector to MCable)

G Connector for various sensors

Patient preparation

The following tips provide optimal SpO2 monitoring results but must never replace hospital-approved practices or manufacturer's recommendations.

The accuracy of SpO2 monitoring depends largely on the strength and quality of the SpO2 signal.

If a finger is used as a monitoring site, remove any nail polish. Cut the finger nails of the patient, if necessary.

The signal may vary due to the following conditions:

– Placement of a sensor that is too tight

– Patient experiences hypotension, severe vasoconstriction, severe anemia, or hypothermia

– Arterial occlusion proximal to the sensor

– Patient is in cardiac arrest or is in shock

– Bright light causing erratic measurement or missing values. Cover the sensor with opaque material if it is likely to be exposed to direct bright light.

– Significant levels of dysfunctional hemoglobins (HbCO or MetHb)

– Intravascular dyes such as indocyanine green or methylene blue

– Excessive patient movement

– Venous pulsations

– Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line

The maximum sensitivity mode for a Masimo MCable is recommended for patients with low perfusion or when the low perfusion or low signal quality message is displayed on the screen in APOD or normal sensitivity mode. This mode is not recommended for care areas where patients are not monitored visually, such as general wards. It is designed to interpret and display data at the measuring site when the signal may be weak due to decreased perfusion.

The message ***SpO2 low perfusion*** appears when the monitor detects low amplitude arterial pulsations. In this case, do the following:

1 Check the patient and treat if necessary.

2 Move the sensor to a site that is more adequately perfused.

3 Select maximum sensitivity mode.

Applying the sensor

NOTE

Only use Masimo sensors with the Masimo SET MCable and the Masimo rainbow SET MCable. Read the instructions provided with the sensor for optimal application techniques and for safety information. Never use damaged sensors.

If you are using a reusable sensor, make sure it is clean before applying it to the patient. Follow the recommendations of the manufacturer.

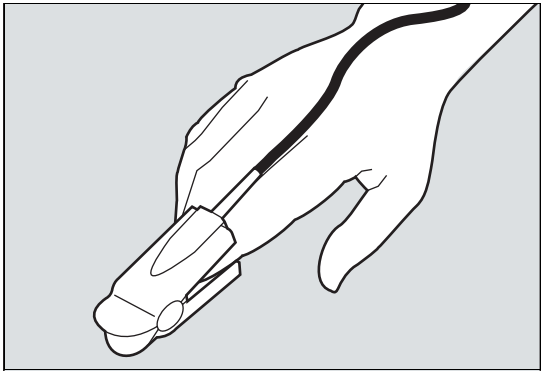
WARNING

Inspect the application site every two to three hours to ensure skin quality and correct optical alignment. If the skin quality changes, move the sensor to another site. Change the application site at least every four hours.

To apply the sensor

1 Select the size and type of sensor that is best suited for your patient. Follow the recommendations of the manufacturer.

2 Position the sensor correctly and attach it to your patient.



3 Connect the sensor to the Masimo SET MCable or the Masimo rainbow SET MCable.

SpO2 and Pulse CO-Ox display

On the M540, the SpO2 display consists of:

– SpO2 parameter box displaying SpO2, PLS, and PI values

– A user-configurable Pulse CO-Ox parameter box when a Masimo rainbow SET MCable with additional parameters is connected. If the Masimo rainbow SET MCable supports only the standard parameter set (SpO2, PLS, PI), the regular parameter box appears instead.

– SpO2 pulse plethysmogram waveform

NOTE

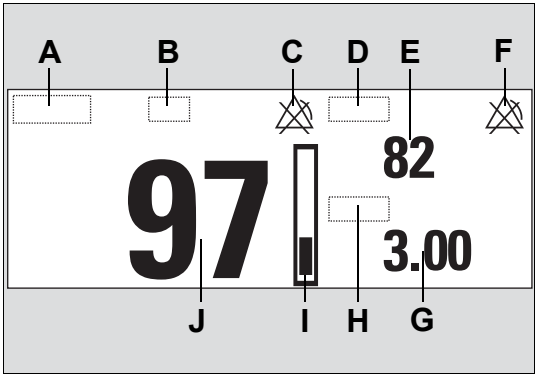
The pulse plethysmogram waveform is directly proportional to the strength of the pulse amplitude.

The following table lists the maximum times the M540 requires to report the parameter values after connecting the sensor to the MCable.

Parameter	Maximum time
SpO2, PLS, PI	up to 35 s
SpMet, PVI, SpCO	up to 60 s
SpHb, SpOC	up to 90 s
PVI	up to 150 s

SpO2 parameter box (Masimo SET MCable)

The SpO2 parameter box contains the following elements:



A SpO2 label

B Units of measure

C Crossed triangle symbol when the SpO2 alarm is turned off.

D PLS (pulse) label

E PLS value

F Crossed triangle symbol when the PLS alarm is turned off.

G PI value

H PI label

I Pulse bar graph — can be turned on/off (see page 174)

J SpO2 saturation value

Pulse CO-Ox parameter box (Masimo rainbow SET MCable)

The Pulse CO-Ox parameter box appears in addition to the regular SpO2 parameter box when a Masimo rainbow SET MCable is connected that supports parameters in addition to the standard parameter set (SpO2, PLS, PI). The parameter content of the parameter box is configurable (see page 177).

The display of Pulse CO-Ox parameters (SpHb/SpHbv, SpOC, SpMet, PVI, SpCO) is affected by the following conditions:

– Blanks appear instead of parameter values if a sensor is connected but the parameter is not activated on the MCable.

– Asterisks (***) replace the parameter values under the following circumstances:

  – A parameter is activated but an incompatible sensor is connected

  – A parameter is activated but no sensor is connected

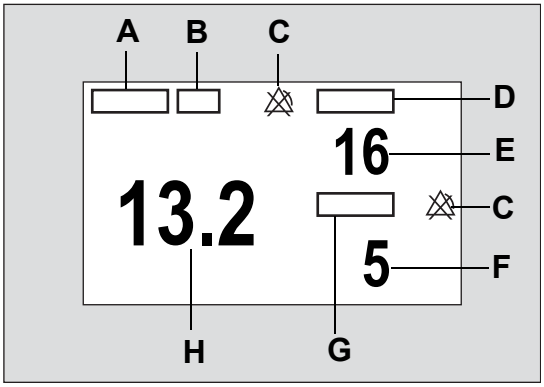
  – A technical failure exists (for example, an unplugged sensor)

NOTE

The parameter SpHb changes to SpHbv (if ***Venous*** was selected for the blood source setting ***SpHb Cal*** – see page 180).

– You can select up to three parameters to be displayed in the parameter box (see page 177). Units of measure appear next to the parameter label if applicable and can be activated/deactivated (see page 252).

The Pulse CO-Ox parameter box contains the following elements.



A Parameter 1 Pulse CO-Ox label

B Parameter 1 unit of measure

C Upper/lower alarm limits or crossed triangle symbols when alarms are deactivated (for the parameters SpOC there are no alarm limits)

D Parameter 2 Pulse CO-Ox label

E Parameter 2 Pulse CO-Ox value

F Parameter 3 Pulse CO-Ox value

G Parameter 3 Pulse CO-Ox label

H Parameter 1 Pulse CO-Ox value

Accessing the SpO2 dialog window

1 Touch the SpO2 parameter box.

2 Touch the ***Settings*** tab.

Or, if the parameter is not displayed

1 Touch any parameter box > ***Settings*** tab > ***Change parameter***.

2 Touch the desired parameter label to display it on the main screen.

3 Touch the parameter box > ***Settings*** tab.

4 Touch the ***Change parameter*** button.

5 Select the desired parameter

6 Repeat steps 1 and 2.

To access the Pulse CO-Ox dialog windows, see page 177.

SpO2 parameter setup functions

All SpO2 parameter setup functions take place in the SpO2 dialog window (see "Accessing the SpO2 dialog window" on page 173).

The limits dialog window contains the ***Auto set*** and ***Alarm*** buttons for configuring the alarm functions. For detailed alarm setup information, see "Configuring a patient's alarm settings" on page 100.

Selection	Available settings	Description
Tone volume [1]	***Off***, 5, 10 (default), 20, 30, 40, 50, 60, 70, 80, 90, 100 %	Adjusts the volume of the pulse tone. If you dock the M540 in an IACS configuration, this setting is replaced by the pulse tone volume setting of the Cockpit. When you undock the M540, this setting is replaced by the ***Transport pulse tone*** setting configured under the ***Alarm setup*** tab (see page 246).
Tone source [1]	– ***ECG*** (default) – the heart blip pulsates with each detected pulse. – ***SpO2***	Selects the source of the pulse tone which affects the ECG and SpO2 parameter box display (see page 171). For the SpO2 selection, the higher the pitch of the tone, the higher the SpO2 saturation percentage.
Bar graph [1]	***On***, ***Off*** (default)	Displays a bar graph that is proportional to the pulse rate and strength.
Desat alarm	***On*** (default), ***Off***	This feature is only available in neonatal mode. The alarm priority is upgraded to high-priority if the SpO2 value falls more than 10 % below the lower SpO2 alarm limit.

NOTE

The password-protected alarm setting ***SpO2 sensor off*** provides additional SpO2 alarm configuration. For more detailed information see page 106.

NOTE

[1] This setting is a patient default which may be unique for each patient category; it is part of the profile.

Selection	Available settings	Description
Averaging time [1]	2 to 4, 4 to 6, 8 (default), 10, 12, 14, 16 s	Determines how quickly the reported SpO2 value responds to changes in the patient's oxygen saturation. **NOTE** A longer averaging time provides a more accurate result. However, in clinical situations where rapid physiological changes have to be monitored, use a shorter averaging time.
Sensitivity mode [1]	– ***Normal*** (default) – standard mode – ***APOD*** (adaptive probe off detection) – the least sensitive mode for detecting a reading on patients with low perfusion. Provides the best detection for detached sensors. This mode is useful for patients at particular risk for sensors becoming detached such as children or patients who are restless. – ***Max.*** – provides maximum sensitivity for poor signals (this mode is recommended for patients with low perfusion or when the low perfusion or low signal quality message is displayed in ***APOD*** or ***Normal*** sensitivity mode. ***Max.*** mode is not recommended for care areas where patients are not monitored visually, such as general wards. It is designed to interpret and display data at the measuring site when the signal may be weak due to decreased perfusion.)	Determines the level of detection sensitivity.
Fast SAT mode [1]	***On***, ***Off*** (default) **NOTE** When the ***Averaging time*** setting is set to 2 to 4 s or 4 to 6 s, the ***Fast SAT mode*** selection is ghosted.	Activates rapid tracking of arterial oxygen saturation changes.

NOTE

[1] This setting is a patient default which may be unique for each patient category; it is part of the profile.

Selection	Available settings	Description
Color [1)]	***Red***, ***White*** (default), ***Yellow***, ***Green***, ***Light blue***, ***Blue***, ***Purple***, ***Orange***	Determines the color of the waveforms, and the parameter labels and values.
Change parameter	A list of currently available parameters.	Changes the parameter box to a different parameter.

NOTE

[1)] This setting is a patient default which may be unique for each patient category; it is part of the profile.

NOTE

The password-protected alarm setting ***SpO2 sensor off*** provides additional SpO2 alarm configuration. For more detailed information see page 106.

Accessing the Pulse CO-Ox dialog window

General Masimo rainbow SET setup functions take place in the SpO2 and Pulse CO-Ox dialog windows.

To access the Pulse CO-Ox dialog window, proceed as follows:

1 Touch the Pulse CO-Ox parameter box if it is displayed on the main screen.

2 Touch the ***Settings*** tab.

Or, if the parameter is not displayed

1 Touch any parameter box > ***Settings*** tab > ***Change parameter***.

2 Touch the desired parameter label to display it on the main screen.

3 Touch the parameter box > ***Settings*** tab.

4 Touch the ***Change parameter*** button.

5 Select the desired parameter

6 Repeat steps 1 and 2.

Pulse CO-Ox parameter setup functions

All Pulse CO-Ox parameter setup functions take place in the Pulse CO-Ox dialog window.

The limits dialog window contains the ***Auto set*** and ***Alarm*** buttons for configuring the alarm functions. For detailed alarm setup information, see "Configuring a patient's alarm settings" on page 100.

Selection	Available settings	Description
Pulse CO-Ox 1 [1]	***SpHb*** [1] (default), ***SpOC***, ***SpMet***, ***SpCO***, ***PVI***	Selects the parameter for the parameter 1 location the Pulse CO-Ox parameter box. The associated parameter label and value have the largest font. With an Hb sensor, the default parameter is SpHb. With a CO-sensor, the default parameter for the parameter 1 location in the parameter box changes automatically to SpCO. **NOTE** Changes to the parameter selection are retained if the same sensor is disconnected and then reconnected. The parameter selection changes to the default selection, if another Masimo rainbow SET sensor type is connected.
Pulse CO-Ox 2 [1]	***SpHb*** [1], ***SpOC*** (default), ***SpMet***, ***SpCO***, ***PVI***	Selects the parameter for the parameter 2 location in the Pulse CO-Ox parameter box. With an Hb sensor, the default parameter is SpOC. With a CO-sensor, the default parameter for the parameter 2 location in the parameter box changes automatically to ***SpMet***. **NOTE** Changes to the parameter selection are retained if the same sensor is disconnected and then reconnected. The parameter selection changes to the default selection, if another Masimo rainbow SET sensor type is connected.

NOTE

[1] This setting is a patient default which may be unique for each patient category; it is part of the profile.

Selection	Available settings	Description
Pulse CO-Ox 3 [1]	***SpHb*** [2], ***SpOC***, ***SpMet***, ***SpCO***, ***PVI*** (default)	Selects the parameter for the parameter 3 location in the Pulse CO-Ox parameter box. ***PVI*** is the default parameter for the parameter 3 location in the parameter box for both CO and Hb sensors. **NOTE** Changes to the parameter selection are retained if the same sensor is disconnected and then reconnected. The parameter selection changes to the default selection, if another Masimo rainbow SET sensor type is connected.
SpHb Averaging [1], [2]	– ***Long*** – approximately 6 minutes – ***Medium*** (default) – approximately 3 minutes – ***Short*** – approximately 1 minute	Determines how responsive the monitor is to rapid physiological changes while tracking blood hemoglobin values. **NOTE** A longer averaging time provides a more accurate result. However, in clinical situations where rapid physiological changes have to be monitored, use a shorter averaging time.
Color [1]	***Red***, ***White*** (default), ***Yellow***, ***Green***, ***Light blue***, ***Blue***, ***Purple***, ***Orange***	Determines the color of the waveforms, and the parameter labels and values.
Change parameter	A list of currently available parameters.	Changes the parameter box to a different parameter.

NOTE

[1] This setting is a patient default which may be unique for each patient category; it is part of the profile.

[2] If the venous blood source was selected for ***SpHb Cal***, the parameter label changes from ***SpHb*** (arterial blood source) to ***SpHbv***.

Password-protected Masimo rainbow SET setup functions

Additional Masimo rainbow SET setup functions take place in the ***Settings 2*** page which is protected by a clinical password.

Selection	Available settings	Description
SpHb Cal [1]	– ***Arterial*** (default) – ***Venous***	Selects the blood sampling source which is used to calculate the SpHb value. The SpHb value changes to SpHbv when the ***SpHb Cal*** setting ***Venous*** is selected.
PVI Averaging [1]	– ***Short*** – ***Long*** (default)	Determines how responsive the monitor is to rapid physiological changes while tracking pleth variability index. **NOTE** A longer averaging time provides a more accurate result. However, in clinical situations where rapid physiological changes have to be monitored, use a shorter averaging time.

NOTE

[1] This setting is a patient default which may be unique for each patient category; it is part of the profile.

SpO2 and pulse rate monitoring with Nellcor OxiMax MCable

Overview of SpO2 monitoring

SpO2 monitoring is only possible with an SpO2 MCable. The M540 uses the Infinity MCable – Nellcor OxiMax (Nellcor OxiMax MCable) to measure the percentage of functional hemoglobin saturated with oxygen (SpO2) and derive a pulse rate (PLS) continuously. The values and waveform display on the M540.

A sensor, applied to the patient, measures the absorption levels of red and infrared light. The Nellcor OxiMax MCable uses the difference between the two measurements to calculate the SpO2. Because light absorption varies with blood volume and blood volume varies with pulse rate, the Nellcor OxiMax MCable can also derive a PLS value.

SpO2 measurements are for adult, pediatric, and neonatal patients.

NOTE

Information about wavelength range may be useful during photodynamic therapy. For details, see the chapter entitled "Technical data" on page 310.

The SpO2 monitoring functions are configurable in the parameter-specific dialog window (see page 188).

Before performing any monitoring functions, refer to the section "For your safety and that of your patients" on page 5.

Parameter-specific error messages are listed on page 269.

Supported parameters

– Saturation (SpO2)

– Pulse rate (PLS)

SpO_2 precautions

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.

WARNING

High oxygen levels may predispose a premature infant to retrolental fibroplasia. If this is a consideration do NOT set the high alarm limit to 100 %, which is equivalent to switching the alarm off. Transcutaneous pO_2 monitoring is recommended for premature infants receiving supplemental oxygen.

WARNING

A pulse oximeter should not be used as an apnea monitor.

WARNING

Use only Nellcor- and Dräger-specified sensors. Other sensors may not provide adequate protection against defibrillation and may put the patient at risk.

WARNING

To reduce the hazard of burns during surgery, keep the sensor or transducer and their associated cables away from the surgical site, the electro-surgical unit return electrode, and earth ground.

WARNING

Inspect the application site every two to three hours to ensure skin quality and correct optical alignment. If the skin quality changes, move the sensor to another site. Change the application site at least every four hours.

CAUTION

Do not immerse the sensor or patient cable in any liquid. Moisture may present a safety risk.

NOTE

A pulse oximeter can be used during defibrillation, but the readings may be inaccurate for up to 20 seconds.

NOTE

Purchase of this instrument confers no express or implied license under any Nellcor patent to use this instrument with any oximetry sensor that is not manufactured or licensed by Nellcor. For a list of approved sensors, see the instructions for use *Infinity Acute Care System – Accessories*.

NOTE

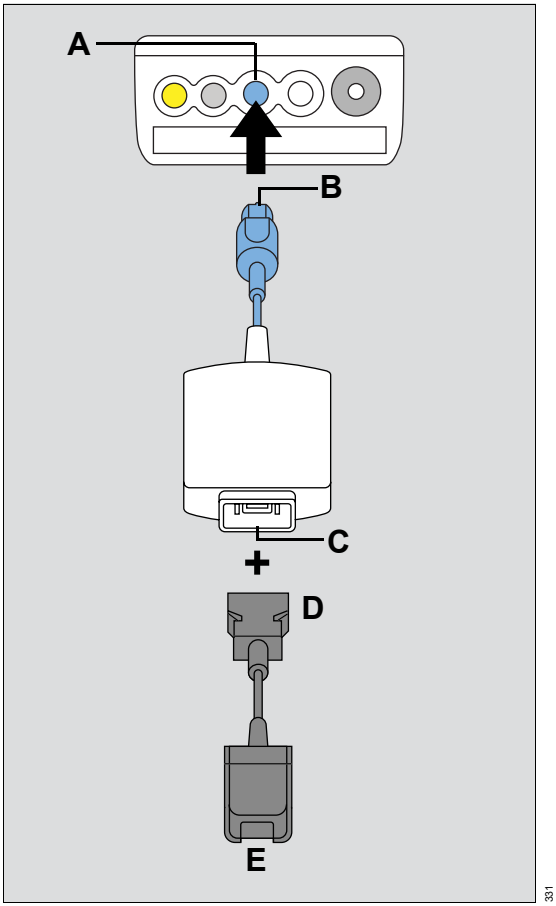
Do not use a functional tester to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor. Since pulse oximeter measurements are statistically distributed, only about two-thirds of those measurements can be expected to fall within $\pm A_{rms}$ of a CO-Oximeter's measured value.

NOTE

A functional tester can be used to measure the total error of a pulse oximeter monitor-probe system if a particular calibration curve has been independently demonstrated to be accurate for that system. The functional tester can then measure how accurately a particular pulse oximeter is in reproducing the calibration curve.

Connecting the Nellcor OxiMax MCable

The Nellcor OxiMax MCable connects directly to the M540.



A SpO_2 connector on the M540

B MCable connector

C MCable intermediate connector (14-pin connector)

D Intermediate cable connector to MCable

E Intermediate cable connector to sensor

To connect the Nellcor OxiMax MCable

Attach the Nellcor OxiMax MCable (B) to the blue SpO_2 connector (A) of the M540.

1 Attach the sensor cable (D) to the Nellcor OxiMax MCable connector (C).

2 Attach the appropriate sensor cable to the end of the SpO_2 cable (E) – see page 187 for more information.

Patient preparation for SpO2 monitoring

The following tips provide optimal SpO2 monitoring results but must never replace hospital-approved practices or manufacturer's recommendations.

The accuracy of SpO2 monitoring depends largely on the strength and quality of the SpO2 signal.

If a finger is used as a monitoring site, remove any nail polish. Cut the finger nails of the patient, if necessary, for better sensor placement.

Pulses may be counted erroneously due to the following conditions:

- Placement of a sensor that is too tight
- Patient experiences hypotension, severe vasoconstriction, severe anemia, or hypothermia
- Arterial occlusion proximal to the sensor
- Patient is in cardiac arrest or is in shock
- Bright light causing erratic measurement or missing values. Cover the sensor with opaque material if it is likely to be exposed to direct bright light.
- Significant levels of dysfunctional hemoglobins (HbCO or MetHb)
- Intravascular dyes such as indocyanine green or methylene blue
- Excessive patient movement
- Venous pulsations
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line

Applying the sensor

If you are using a reusable sensor, make sure it is clean before applying it to the patient. Follow the recommendations of the manufacturer.

WARNING

Inspect the application site every two to three hours to ensure skin quality and correct optical alignment. If the skin quality changes, move the sensor to another site. Change the application site at least every four hours.

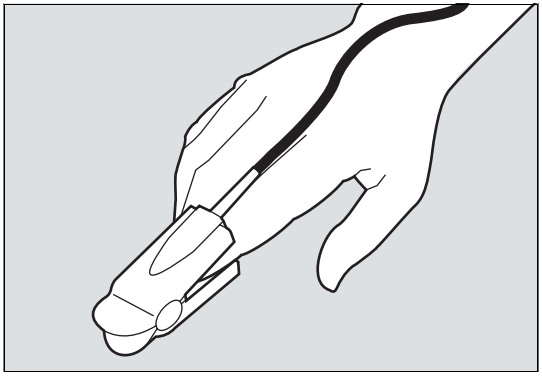
NOTE

Read the instructions provided with the sensor for optimal application techniques and for safety information. Never use damaged sensors. Doing so may compromise performance.

To apply the sensor

1 Select the size and type of sensor that is best suited for your patient. Follow the recommendations of the manufacturer.

2 Position the sensor correctly and attach it to your patient.



3 Connect the sensor to the Nellcor OxiMax MCable.

SpO2 display

On the M540, the SpO2 display consists of:

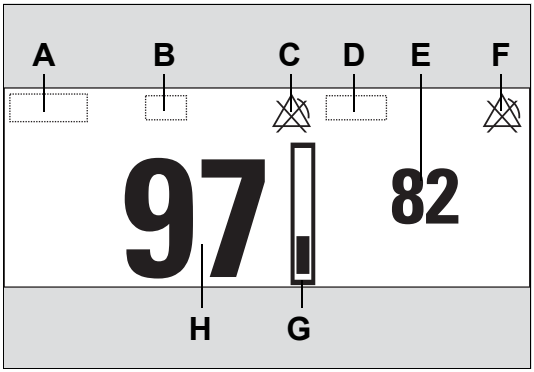
– SpO2 parameter box

– SpO2 pulse plethysmogram waveform

NOTE

The pulse plethysmogram waveform is directly proportional to the strength of the pulse amplitude.

The SpO2 parameter box contains the following elements:



A SpO2 label

B Units of measure

C Crossed triangle symbol when the SpO2 alarm is turned off.

D PLS (pulse) label

E PLS value

F Crossed triangle symbol when the PLS alarm is turned off.

G Pulse bar graph — can be turned on/off, see page 188

H SpO2 saturation value

Accessing the SpO2 dialog window

1 Touch the SpO2 parameter box.

2 Touch the ***Settings*** tab.

Or, if the parameter is not displayed

1 Touch any parameter box > ***Settings*** tab > ***Change parameter***.

2 Touch the desired parameter label to display it on the main screen.

3 Touch the parameter box > ***Settings*** tab.

4 Touch the ***Change parameter*** button.

5 Select the desired parameter

6 Repeat steps 1 and 2.

SpO2 parameter setup functions

All SpO2 parameter setup functions take place in the SpO2 dialog window (see "Accessing the SpO2 dialog window" on page 187).

The limits dialog window contains the ***Auto set*** and ***Alarm*** buttons for configuring the alarm functions. For detailed alarm setup information, see "Configuring a patient's alarm settings" on page 100.

Selection	Available settings	Description
Tone volume [1]	***Off***, 5, 10 (default), 20, 30, 40, 50, 60, 70, 80, 90, 100 %	Sets the volume of the pulse tone. – If you dock the M540 in an IACS configuration, this setting is replaced by the pulse tone volume setting of the Cockpit. – When you undock the M540, this setting is replaced by the ***Transport pulse tone*** setting configured under the ***Alarm setup*** tab (see page 246)
Tone source [1]	– ***ECG*** (default) – the heart rate blip pulsates with each detected pulse. – ***SpO2***	Selects the source of the pulse tone which affects the ECG and SpO2 parameter box display (see page 186). For the SpO2 selection, the higher the pitch of the tone, the higher the SpO2 saturation percentage.
Bar graph [1]	***On***, ***Off*** (default)	Displays a bar graph that is proportional to the pulse rate and strength.
Response mode [1]	– ***Normal*** (default) – 90 % change within 5 to 7 seconds – ***Fast*** – 90 % change within 2 to 4 s	Establishes the frequency the oximeter uses to calculate, record, and display SpO2 saturation levels. – Fast mode responds to changes in blood oxygen saturation levels in 2 to 4 seconds when calculating %SpO2. – Normal mode responds to changes in blood oxygen saturation in 5 to 7 seconds

NOTE

[1] This setting is a patient default which may be unique for each patient category; it is part of the profile.

Selection	Available settings	Description
SatSeconds [1]	***Off*** (default), 10, 25, 50, 100	This function analyzes desaturation events by multiplying their duration (seconds) by the number of percentage points the patient exceeds the alarm limit. **NOTE** This feature eliminates nuisance alarms caused by brief and numerous violations of lower and upper alarm limits. This selection overrides the alarm validation setting (see page 86) and the SpO2 high priority desaturation alarm for neonatal patients.
Desat alarm [1]	– ***On*** (default) – ***Off***	This feature is only available in neonatal mode and only if the ***SatSeconds*** alarm function is set to ***Off***. The alarm priority is upgraded to high-priority if the SpO2 value falls more than 10 % below the lower SpO2 alarm limit. This feature is automatically activated whenever neonatal mode is activated.
Color [1]	***Red***, ***White*** (default), ***Yellow***, ***Green***, ***Light blue***, ***Blue***, ***Purple***, ***Orange***	Determines the color of the waveforms, and the parameter labels and values.
Change parameter	A list of currently available parameters.	Changes the parameter box to a different parameter.

NOTE
[1] This setting is a patient default which may be unique for each patient category; it is part of the profile.

NOTE
The password-protected alarm setting ***SpO2 check sensor*** provides additional SpO2 alarm configuration. For more detailed information see page 106.

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Temperature

Overview of temperature monitoring

The M540 measures and displays the following temperature values:

– Surface body temperature

– Core temperature

Temperature monitoring is intended for adult, pediatric, and neonatal patients.

NOTE

The temperature functions and associated probes should be calibrated every two years by qualified personnel to maintain an accuracy of ±0.1 °C (±0.2 °F).

The temperature monitoring functions are configurable in the parameter-specific dialog window (see page 196).

Before performing any monitoring functions, refer to the section "For your safety and that of your patients" on page 5.

Parameter-specific error messages are listed on page 277.

Supported parameters

– Ta/T1a: absolute temperature values

– Tb/T1b: absolute temperature values

– ΔT/ΔT1: delta temperature values

Connecting the temperature sensors

You can connect temperature sensors directly to the M540 or to one of the following hemodynamic pods:

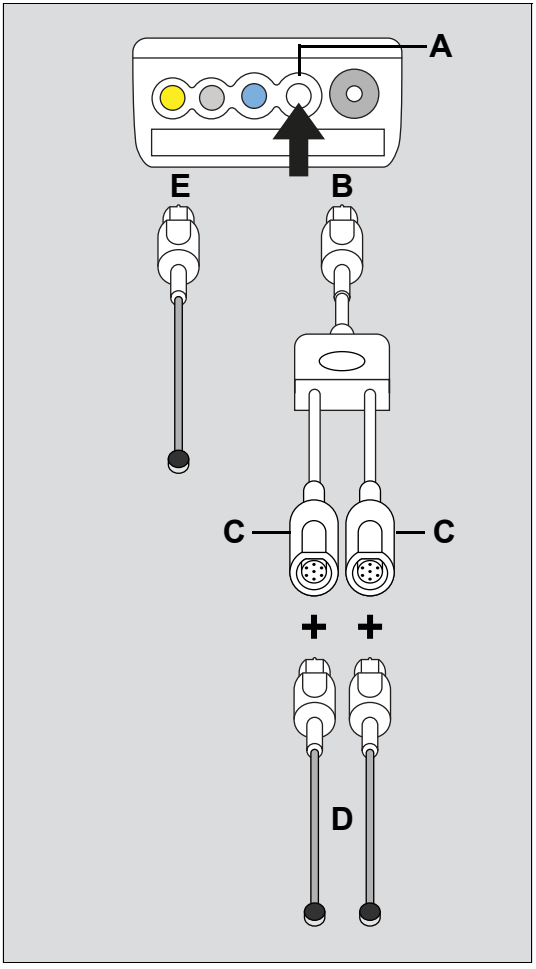
– MPod – QuadHemo

– Hemo4 pod

– Hemo2 pod

Connecting the temperature sensors to the M540

You can connect a single sensor or two sensors to the M540 directly using the dual temperature adapter cable. The dual temperature sensor cable monitors two temperatures simultaneously.



A M540 temperature connector

B Dual temperature adapter cable connector

C Dual temperature adapter sensor connector

D Temperature sensors

E Temperature sensors connecting directly to the M540

To connect two-temperature sensors

1. Connect the temperature sensors (D) to the sensor connectors (C) of the dual temperature adapter cable.
2. Connect the connector (B) of the dual temperature adapter cable to the M540 Temp/Aux connector (A).

To connect a single temperature sensor

- Connect a temperature sensor (E) directly to the M540 Temp/Aux connector (A).

Connecting the temperature sensors to the hemodynamic pods

You can connect a single temperature sensor to the following devices:

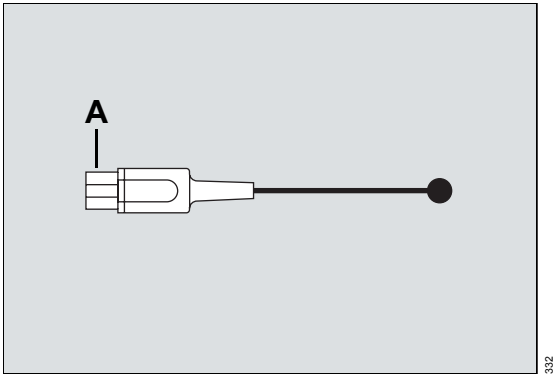
– Hemo4 pod

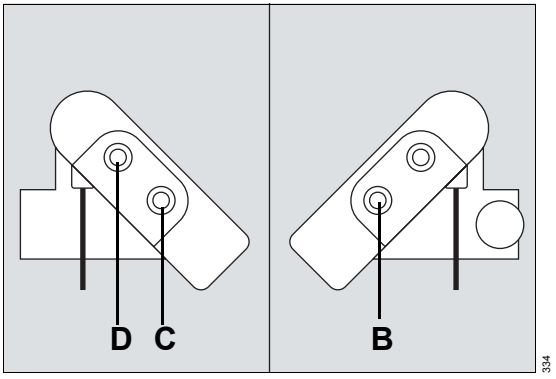
– Hemo2 pod

– MPod – QuadHemo

To connect temperature cables to the MPod – QuadHemo

1 Connect the temperature sensor connector (A) to the MPod – QuadHemo Temp B connector (C) or Temp A connector (D).

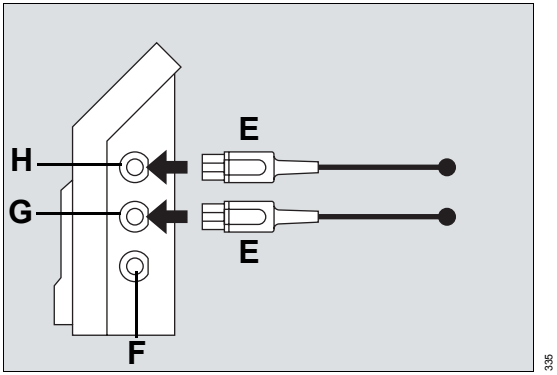




2 Connect the connection cable to the monitor connector (B) of the MPod – QuadHemo and to the gray hemo connector on the M540.

To connect temperature cables to the Hemo2 pod and the Hemo4 pod

1 Connect the temperature sensor connectors (E) to the Temp A connector (H) and/or the Temp B connector (G) of the Hemo4 or the Hemo2 pod.



2 Connect the connection cable to the monitor connector (F) of the Hemo2 or the Hemo4 pod and to the gray hemo connector on the M540 (see page 193).

Temperature display

On the M540, the temperature display consists of a parameter box. You can select which temperature values are displayed in the parameter box (see page 196).

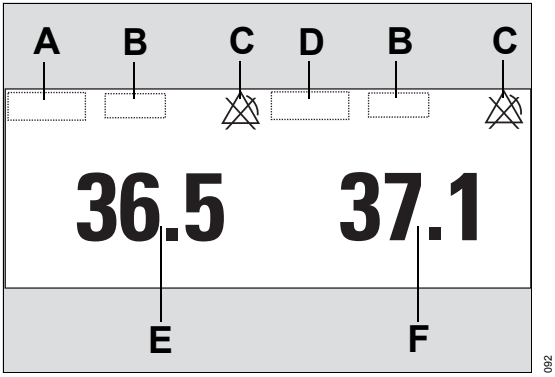
When the dual temperature cable is connected, the parameter box displays either the corresponding temperature values (for example, Ta and Tb) or one direct and one calculated delta value (for example, Ta and ΔT). The symbol ΔT represents the absolute value of the difference between the two direct values.

Any temperature values originating from the MPod – QuadHemo, the Hemo2 pod, or the Hemo4 pod are labelled T1a, T1b, and ΔT1. Any temperature values originating from a single or dual temperature cable that is connected to the M540 temperature connector are labelled Ta, Tb, and ΔT.

When a single temperature sensor is connected, only one temperature value displays. The values for the second temperature appear blank.

Temperature parameter box

The following diagram shows a temperature parameter box.



A Direct temperature label

B Units of measure

C Crossed triangle symbol when the temperature alarms are turned off.

D Delta temperature parameter label or second direct temperature label.

E direct temperature value

F Calculated temperature parameter value or second direct parameter value

Accessing the temperature dialog window

1 Touch the temperature parameter box.

2 Touch the ***Settings*** tab.

Or, if the parameter is not displayed

1 Touch any parameter box > ***Settings*** tab > ***Change parameter***.

2 Touch the desired parameter label to display it on the main screen.

3 Touch the parameter box > ***Settings*** tab.

Temperature parameter setup functions

All temperature parameter setup functions take place in the temperature dialog window (see "Accessing the temperature dialog window" on page 196).

The limits dialog window contains the ***Auto set*** and ***Alarm*** buttons for configuring the alarm functions. For detailed alarm setup information, see "Configuring a patient's alarm settings" on page 100.

Selection	Available settings	Description
	Settings	
Temp display [1]	– ***Tb*** (default) – ***ΔT***	Configures the second temperature value.
Color [1]	***Red***, ***White*** (default), ***Yellow***, ***Green***, ***Light blue***, ***Blue***, ***Purple***, ***Orange***	Determines the color of the parameter labels and values.
Change parameter	A list of currently available parameters.	Changes the parameter box to a different parameter.

NOTE

[1] This setting is a patient default which may be unique for each patient category; it is part of the profile.

Non-invasive blood pressure (NIBP)

Overview of non-invasive blood pressure monitoring

The M540 uses the oscillometric method to acquire and process non-invasive blood pressure (NIBP) signals.

Non-invasive blood pressure measurements are for adult, pediatric, and neonatal patients.

To protect the patient from excessive inflation limits, the blood pressure cuff automatically deflates when:

– A measurement exceeds two minutes in adult and pediatric mode

– A measurement exceeds 90 seconds in neonatal mode

NOTE

The non-invasive blood pressure functionality should be calibrated every two years by technically qualified personnel as described in the Service manual.

The non-invasive blood pressure monitoring functions are configurable in the parameter-specific set-up page (see page 207).

Before performing any monitoring functions, refer to the section "For your safety and that of your patients" on page 5.

Parameter-specific error messages are listed on page 274.

Supported parameters

– NIBP S – non-invasive pressure, systolic value

– NIBP D – non-invasive pressure, diastolic value

– NIBP M – non-invasive pressure, mean value

Non-invasive blood pressure precautions

WARNING

Rapid, prolonged cycling of non-invasive pressure measurements have on occasion been associated with petechia, ischemia, purpura, or neuropathy. Make sure that the cuff is properly attached and check the cuff site regularly to prevent the cuff pressure from impeding the blood flow.

WARNING

Obstructions may cause the cuff to inflate and deflate improperly and result in inaccurate measurement values. Check the hose and cuff for damage and dirt. Do not allow the hose and cuff to come in contact with fluids, and make sure that they are not compressed or kinked.

WARNING

Do not place the cuff on injured or breached skin because cuff compression could further damage the tissue.

WARNING

Do not place the cuff on a limb with either an intra-arterial line or a vascular prothesis because cuff compression will impede perfusion.

WARNING

Accurate non-invasive blood pressure measurements depend on the correct size and type of the blood pressure cuff in relation to the patient's arm circumference. The wrong sized cuff, or cuffs outside the range or size manufactured by Dräger, can cause inaccurate measurements. Use only Dräger approved cuffs and make sure that the correct size is used for each patient.

WARNING

To reduce the possibility of pumping air into the patient's blood vessels, never connect pneumatic connectors to an intravascular system.

WARNING

Before monitoring neonates and infants:

- **Select the correct cuff size and hose.**
- **Select the neonatal or pediatric patient category, if not already selected. This provides the appropriate inflation for neonates, infants, and pediatric patients.**

NOTE

The accuracy of the oscillometric blood pressure signal can decrease (up to loss of measurement) under the following conditions:

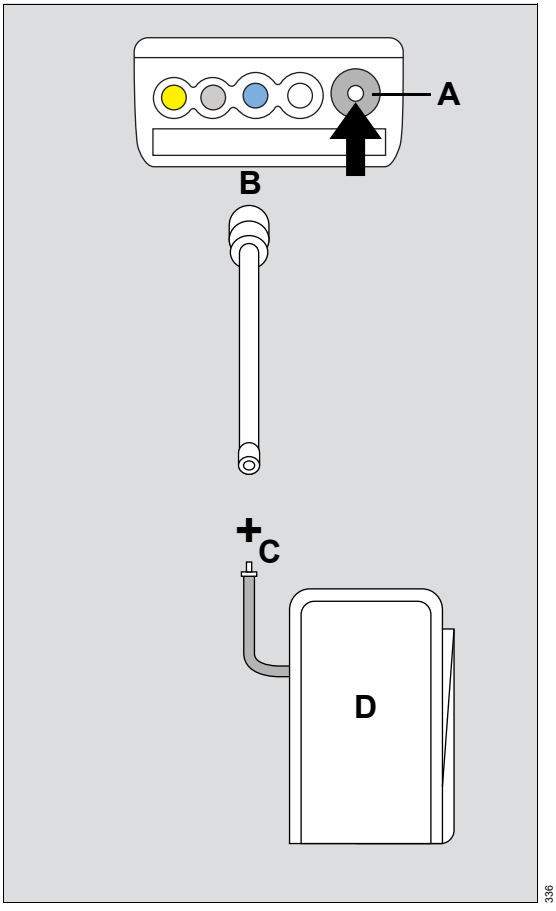
- weak pulses
- irregular pulses
- patient movement artifacts
- tremor artifacts
- respiratory artifacts
- pulses generated from a ventricular assist device

NOTE

A systolic blood pressure higher than the current high inflation limit may trigger a message that the non-invasive blood pressure inflation limit is low. When this message appears, manually check the blood pressure of the patient.

Connecting the non-invasive blood pressure hose and cuff

The following diagram shows where the non-invasive blood pressure hose connects to the non-invasive blood pressure hose connector (A) on the side of the M540.



A Non-invasive blood pressure connector on the M540

B Non-invasive blood pressure hose

C Blood pressure cuff

To connect the non-invasive blood pressure hose and cuff

1. Select a non-invasive blood pressure cuff (D) size that is appropriate for the patient.
2. Connect the non-invasive blood pressure hose (C) to the hose (B).
3. Connect the non-invasive blood pressure hose (B) to the non-invasive blood pressure connector (A) of the M540.

Patient preparation for non-invasive blood pressure monitoring

The following tips provide optimal non-invasive blood pressure monitoring results but must never replace hospital-approved practices or manufacturer's recommendations.

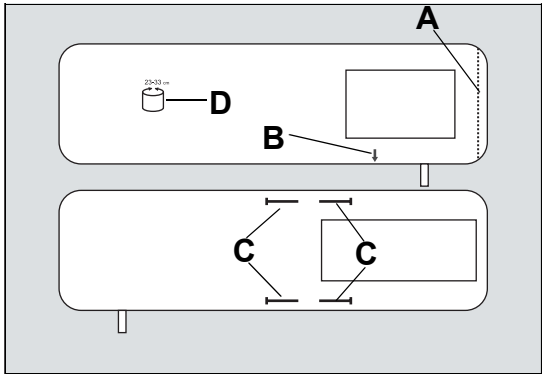
Accurate non-invasive blood pressure measurements depend on the correct size and type of the blood pressure cuff in relation to the arm circumference of the patient. The wrong sized cuffs, or cuffs outside the range or size manufactured by Dräger, can cause inaccurate measurements. Use only Dräger approved cuffs and make sure that the correct size is used for each patient.

Applying the non-invasive blood pressure cuff

Weak or irregular pulses, patient movement, tremors, or respiratory artifacts can affect the accuracy of non-invasive blood pressure measurements and even cause them to fail. Before applying the cuff, read the non-invasive blood pressure precautions.

We recommend that you do not apply the cuff on a limb that is already used for other measurements. Make sure that other patient connections do not interfere with each other.

The following diagram depicts a typical Dräger cuff.



A Index line

B Artery marker

C Range labels

D Size indicator

To apply the non-invasive blood pressure cuff

1. Place the cuff 2 to 5 cm (1 to 2 inches) above the elbow (or around the middle of the thigh). Place the cuff label "this side to patient" against the skin.
2. Place the artery marker (B) over the artery pointing to the hand or the foot. The cuff label 'index' (A) must fall within the range labels (C).
3. Wrap the cuff snug around the limb without impeding blood flow.

Non-invasive blood pressure display

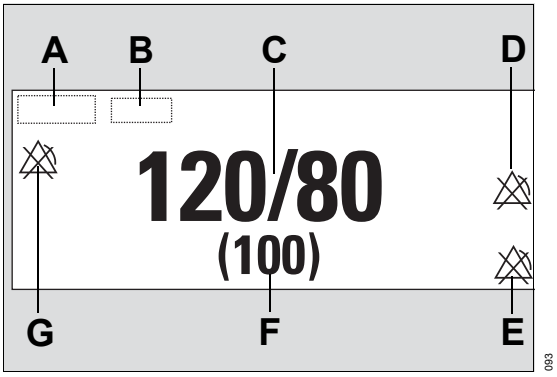
The non-invasive blood pressure parameter box displays the latest readings for mean, systolic, and diastolic pressure (in mmHg or kPa). The appearance of the non-invasive blood pressure parameter box depends on the selected non-invasive blood pressure mode (see page 203). If a measurement is invalid, the non-invasive blood pressure parameter box replaces the non-invasive blood pressure values with asterisks (***).

When a measurement is in progress, the background of the lower part of the parameter box turns white.

During low systolic or diastolic pulse amplitudes or significant motion artifacts, the parameter box may only display a mean value. If the M540 is in venous stasis mode, the cuff pressure appears in the non-invasive blood pressure parameter box.

If you cannot apply the cuff at heart level, adjust the displayed systolic and diastolic non-invasive blood pressure values as follows: add 8 mmHg (1.1 kPa) for each 10 cm (4 in) above the heart; subtract 8 mmHg (1.1 kPa) for each 10 cm (4 in) below the heart.

The non-invasive blood pressure parameter box contains the following elements:



A Non-invasive blood pressure parameter label

B Unit of measure

C Systolic and diastolic pressure value

D Crossed triangle symbol when the NIBP D (diastolic) alarm is turned off.

E Crossed triangle symbol when the NIBP M (mean) alarm is turned off.

F Mean pressure value

G Crossed triangle symbol when the NIBP S (systolic) alarm is turned off.

The inflation pressure value and the label ***Inflation pressure*** appear when a measurement is in progress.

NOTE

An interval timer bar appears in the parameter box between interval measurements.

Non-invasive blood pressure measurement modes

WARNING

Press the NIBP start/stop fixed key to deflate the cuff rapidly if an adverse effect occurs on the patient.

The following non-invasive blood pressure measurement modes are available:

– Single

– Interval

– Continuous

– Venous stasis

The selected mode affects the appearance of the non-invasive blood pressure parameter box (see page 202).

Before taking any non-invasive blood pressure measurements, read the precautions on see page 199.

At the beginning of a measurement, the M540 inflates the cuff to a pressure that is 25 mmHg (3.3 kPa) for adult/pediatric and 30 mmHg (4 kPa) for neonate above the previously detected systolic value. If the M540 cannot obtain a valid measurement, it reinflates the cuff to the maximum inflation pressure provided the measurement cycle has not timed-out. If the M540 cannot obtain a measurement within the measurement cycle, no further attempts are made until the next scheduled interval or until you initiate a single measurement. Error messages identify the cause of failed measurements (see page 274).

The last non-invasive blood pressure measurement value is displayed in the parameter box until the new measurement is completed. New values appear at the end of a measurement at which point a chime sounds if the corresponding function was activated (see page 207).

Single measurement mode

Single measurement mode allows you to start measurements when needed. You can start and stop a single measurement any time.

To start a single measurement

- Press the ***NIBP*** fixed key on M540. Pressing the key again, stops the measurement.

Interval measurements mode

WARNING

Because non-invasive blood pressure measurements occur intermittently, a patient's condition may change between measurements. Therefore, do not rely on non-invasive blood pressure alarms alone to notify you of a patient's changing condition.

In interval mode, the M540 initiates measurements at set intervals. Changing the interval setting during a measurement resets the interval timer. If you select another interval setting after interval mode was deactivated, you must press the ***NIBP*** key on the front of the M540 for interval measurements to start.

NOTE

A safety timer ensures that a cuff remains deflated for at least 30 seconds before the end of a measurement and the beginning of a new one. This precaution avoids prolonged impeded blood flow which could be harmful. The safety timer overrides any interval setting and is of particular importance in the 1 and 2-minute intervals.

You can still take single measurements during an interval cycle.

Interval measurements are not possible during:

– Venous stasis mode – the measurements resume immediately after the cuff deflates.

– Cardiac bypass mode – press the ***NIBP*** key to resume interval measurement after exiting cardiac bypass mode.

– Standby mode – press the ***NIBP*** key to resume interval measurement after exiting standby mode.

– When continuous mode is activated.

To activate or deactivate interval mode

1 Touch the non-invasive blood pressure parameter box.

2 Touch the ***Settings*** tab.

3 Touch the ***Interval time*** button and select the desired time (***Off***, 1, 2, 2.5, 3, 5, 10, 15, 20, 25, 30, 45, 60, 120, or 240 min).

For any interval setting of 5 minutes and up, the following time alignment occurs. After the first measurement is completed, all subsequent measurements align with the next natural time boundary that corresponds to the selected interval. For example, if a 5-minute interval is selected at 10:03, the next interval starts at 10:05, 10:10 and so on. If a 10-minute interval is selected at 10:07, the next interval starts at 10:10, 10:20, and so forth.

4 Touch ***X*** to close the dialog window.

To start interval measurements

- Press the ***NIBP*** key on the M540.

To stop interval measurements

- Press the ***NIBP*** key on the M540.

NOTE

Pressing the ***NIBP*** button longer than two seconds suspends interval mode and sets the ***Interval time*** to ***Off***.

If the M540 is power cycled while in interval mode, you must press the ***NIBP*** button to resume interval measurements.

Continuous measurements

WARNING

When using continuous mode, observe the patient closely and verify limb perfusion clinically. Be extra vigilant when using continuous mode on neonates or hemodynamically compromised patients.

In continuous mode, the M540 continuously initiates the non-invasive blood pressure measurements over a 5-minute period.

A 10 second (±1 second) minimum interval between the end of one measurement and the start of another provides minimal perfusion of the limb.

To activate or deactivate continuous mode

1 Touch the non-invasive blood pressure parameter box.

2 Touch the ***Settings*** tab.

3 Make sure venous stasis is not activated (see page 207).

4 Touch the ***Continuous mode*** button until it toggles to ***On*** or ***Off***.

5 Touch ***X*** to close the dialog window.

NOTE
Continuous mode prevents you from enabling venous stasis.

To stop continuous measurements

Do one of the following:

- Press the ***NIBP*** key on the M540.

  Or

- Touch the non-invasive blood pressure parameter box > ***Settings*** > ***Continuous mode*** button until it toggles to ***Off***.

Venous stasis

By maintaining a constant cuff pressure, the M540 stops the blood flow to the lower extremity of the cuffed limb long enough to cannulate a patient. In this mode, the cuff occludes the limb for about as long as a non-invasive blood pressure measurement takes (approximately two minutes for adults and approximately one minute for neonates).

WARNING
Do not use venous stasis on a limb that is unsuitable for non-invasive blood pressure measurements (for example, an arm with a catheter). If the patient experiences adverse reactions, immediately press the *NIBP* fixed key to deflate the cuff.

During venous stasis the monitor determines the initial and maximum cuff inflation pressure and inflation time based on the patient category.

Inflation	Adult	Pediatric	Neonatal
Initial and maximum inflation pressure (mmHg)	80 ±5	60 ±4	40 ±3
Inflation time (s)	120 ±5	120 ±5	60 ±2.5

Activating or deactivating venous stasis

NOTE

Make sure continuous mode is not enabled (see page 206) because it prevents you from using venous stasis mode.

To activate or deactivate venous stasis

1 Touch the non-invasive blood pressure parameter box.

2 Touch the ***Settings*** tab.

3 Make sure continuous mode is not activated (see page 207).

4 Touch the ***Venous stasis*** button until it toggles to ***On*** or ***Off***.

5 Touch ***X*** to close the dialog window.

NOTE

When the venous stasis mode begins, an attention tone sounds.

Interval measurements are suspended during venous stasis but resume immediately after the cuff deflates.

Accessing the non-invasive blood pressure dialog window

1 Touch the non-invasive blood pressure parameter box.

2 Touch the ***Settings*** tab.

Or, if the parameter is not displayed

1 Touch any parameter box > ***Settings*** tab > ***Change parameter***.

2 Touch the desired parameter label to display it on the main screen.

3 Touch the parameter box > ***Settings*** tab.

Non-invasive blood pressure parameter setup functions

All non-invasive blood pressure parameter setup functions take place in the non-invasive blood pressure dialog window (see "Accessing the non-invasive blood pressure dialog window" on page 206).

The limits dialog window contains the ***Auto set*** and ***Alarm*** buttons for configuring the alarm functions. For detailed alarm setup information, see "Configuring a patient's alarm settings" on page 100.

Selection	Available settings	Description
	Settings	
Interval time [1)] *(Cardiac Bypass mode automatically deactivates interval measurements)*	***Off*** (default), 1 min, 2 min, 2.5 min, 3 min, 5 min, 10 min, 15 min, 20 min, 25 min, 30 min, 45 min, 60 min, 120 min, 240 min	Defines intervals for the non-invasive blood pressure measurements.
Inflation mode	***Adult*** (default), ***Pediatric***, ***Neonate***	Sets a threshold for maximum cuff inflation.
Continuous mode [1)]	***On***, ***Off*** (default)	Initiates successive non-invasive blood pressure measurements for 5 min.
Chime [1)]	***On***, ***Off*** (default)	Determines if a tone sounds at the end of a completed non-invasive blood pressure measurement.
Venous stasis [1)]	***On***, ***Off*** (default)	Stops blood flow to the lower part of the cuffed limb for a fixed time.
Color [1)]	***Red***, ***White*** (default), ***Yellow***, ***Green***, ***Light blue***, ***Blue***, ***Purple***, ***Orange***	Determines the color of the parameter labels and values.
Change parameter	A list of currently available parameters.	Changes the parameter box to a different parameter.

NOTE

[1)] This setting is a patient default which may be unique for each patient category; it is part of the profile.

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Invasive blood pressure (IBP)

Overview of invasive blood pressure monitoring

The M540 acquires, processes, and displays invasive blood pressure signals. Several pods are available for monitoring invasive pressure. Monitoring more than two pressures simultaneously requires the Multi-IBP option.

IBP measurements are for adult, pediatric, and neonatal patients.

The IBP monitoring functions are configurable in the parameter-specific dialog window (see page 222).

Before performing any monitoring functions, refer to the section "For your safety and that of your patients" on page 5.

Parameter-specific error messages are listed on page 278.

Supported parameters

See page 217 for available IBP pressure labels.

– Systolic pressures: GP1 S to GP4 S, ART S PA S, LV S, RV S

– Diastolic pressures: GP1 Dto GP4 D, ART D, PA D, LV D, RV D

– Mean pressures: GP1 Mto GP4 M, ART M PA M, LV M, RV M

– Additional pressures: ICP, CVP, LA, RA

– If both ART and ICP are connected, the algorithm computes the difference between ICP and mean ART and reports it as CPP.

Invasive blood pressure pods

Invasive blood pressure signals originate from the following hemodynamic pods:

– Hemo4 pod

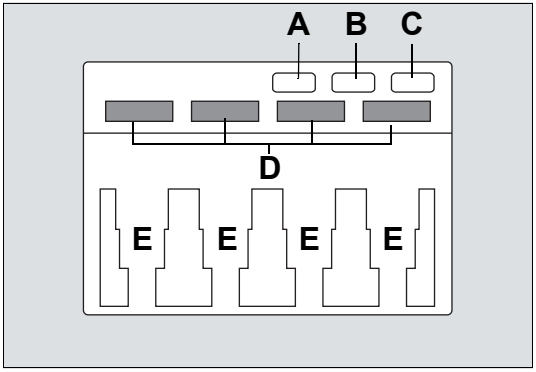
– Hemo2 pod

– Infinity MPod – Quad Hemo (MPod – Quad-Hemo)

– Infinity MCable – Dual Hemo (Dual Hemo MCable)

Hemo4 pod

This pod measures up to four pressures, cardiac output, and temperature.



A Key »0« for zeroing all pressures simultaneously (see page 219)

B Key for starting a cardiac output measurement

C Wedge button for starting wedge pressure measurements

D Pressure label windows

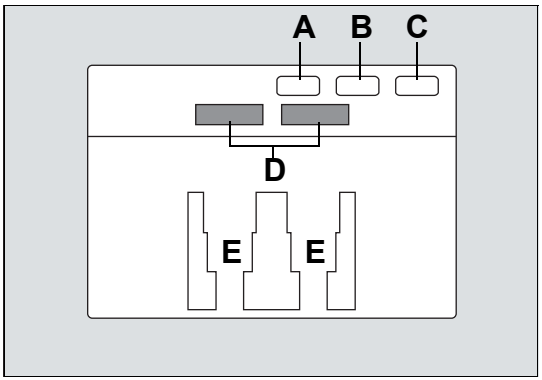
E Transducer slots

NOTE

The connectors for temperature and cardiac output are located on the side panel of the hemodynamic pod.

Hemo2 pod

This pod measures up to two pressures, cardiac output, and temperature.



A Key ⤍0⤎ for zeroing all pressures simultaneously (see page 219)

B Key for starting a cardiac output measurement

C Key button for starting wedge pressure measurements

D Pressure label windows

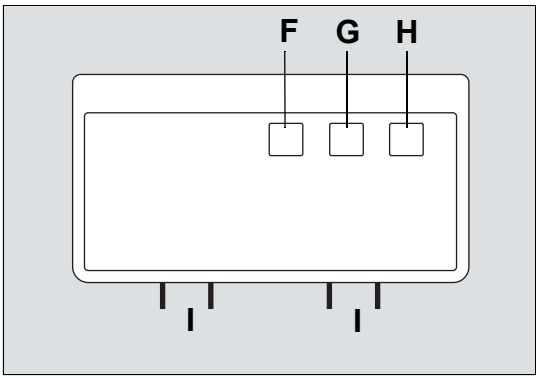
E Transducer slots

NOTE

The connectors for temperature and cardiac output are located on the side panel of the hemodynamic pod.

MPod – QuadHemo

This pod measures up to four pressures, cardiac output, and temperature.



F Key ⤍0⤎ for zeroing all pressures simultaneously (see page 219)

G Key for starting a cardiac output measurement

H Key for starting wedge pressure measurements

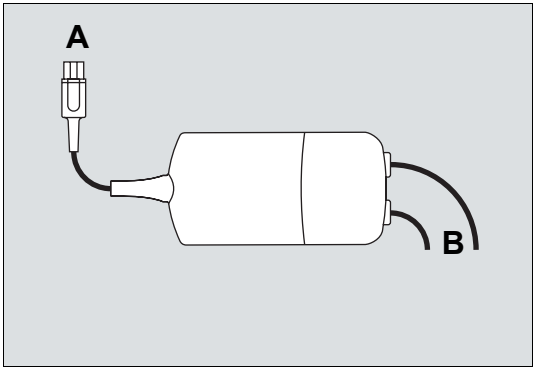
I Intermediate cables for attaching the transducers.

NOTE

The connectors for temperature and cardiac output are located on the side panel of the hemodynamic pod.

Dual Hemo MCable

This Dual Hemo MCable measures up to two pressures.



A Dual Hemo MCable connector that connects to the M540.

B Intermediate cables for attaching the transducers.

Invasive blood pressure precautions

WARNING

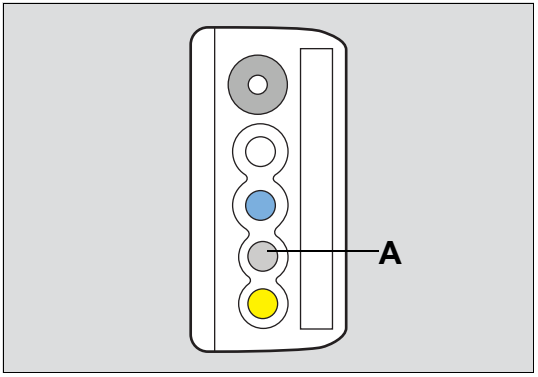
To prevent patient injury, never reuse a single-use transducer.

WARNING

Using the >0< key on the hemodynamic pods zeroes all static invasive blood pressures < 3 mmHg.

Connecting the Hemo4 and Hemo2 pods

The Hemo4 and Hemo2 pods connect directly to the M540. The following diagram shows where the gray hemo connector (A) is located on the side of the M540.



A Invasive blood pressure connector on the M540

B Hemodynamic connector on the pod

C Pod connection cable

D Transducer cable

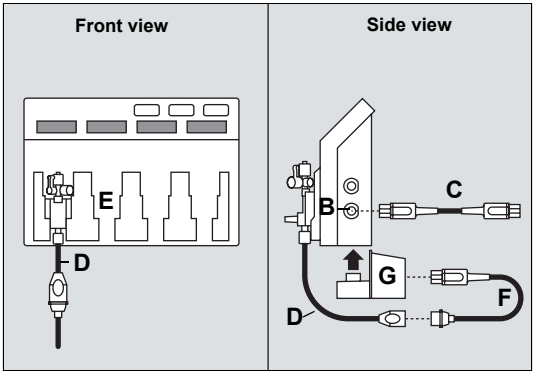
E Transducer slot

F Transducer adapter cable

G Invasive blood pressure adapter block

To connect the Hemo4 and Hemo2 Pod

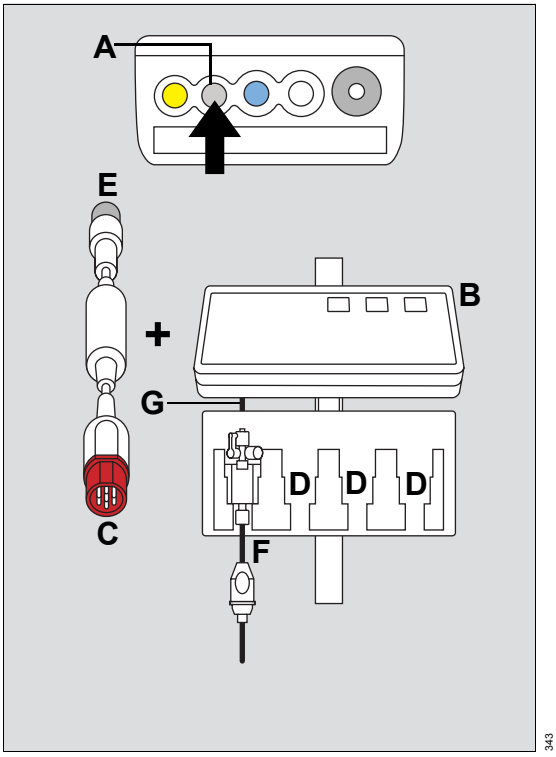
1. Attach the invasive blood pressure adapter (G) to the bottom of the Hemo4/Hemo2 pod.
2. Connect one end of the connection cable (C) to the Hemo4/Hemo2 pod connector (B).



3. Connect the other end of the connection cable (C) to the gray hemo connector of the M540 (A).
4. Attach the transducers to the transducer slot (E).
5. Connect the transducer adapter cables (F) to the transducer cable (D).

Connecting the MPod – QuadHemo

The MPod – QuadHemo connects directly to the M540.



A Invasive blood pressure connector on the M540

B MPod – QuadHemo

C Red pod connection cable connector

D Transducer slot

E Grey pod connection cable connector

F Transducer cable

G Transducer adapter cable

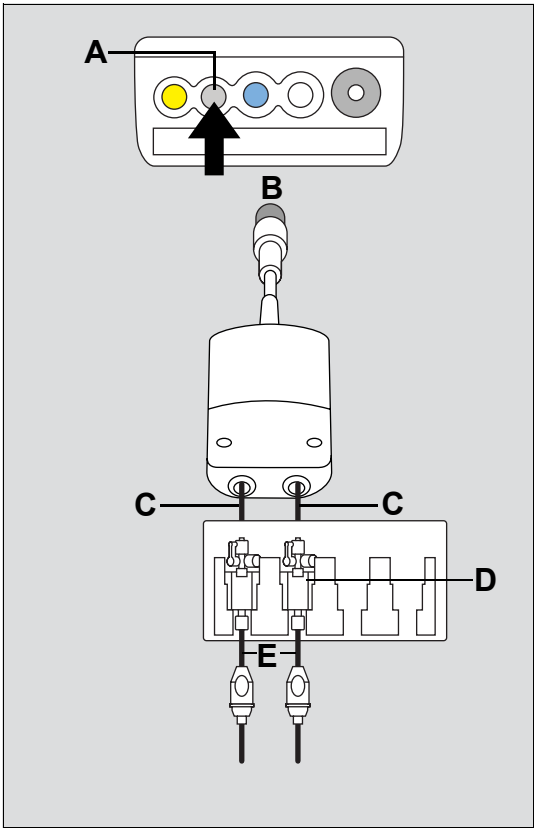
To connect the MPod – QuadHemo

1. Connect one end of connection cable (C) to the connector located on the right side of the MPod – QuadHemo (B).
2. Connect the other end of the connection cable (E) to the gray Hemo connector of the M540 (A).
3. Insert the transducers into the transducer slots (D).
4. Connect the transducer cables (F) to the transducer adapter cable (G).

   The transducer adapter cables are permanently fastened to the back of the MPod – QuadHemo.

Connecting the Dual Hemo MCable

The Dual Hemo MCable connects directly to the M540.



A Invasive blood pressure connector on the M540

B Dual Hemo MCable connector

C Transducer adapter cable

D Transducer

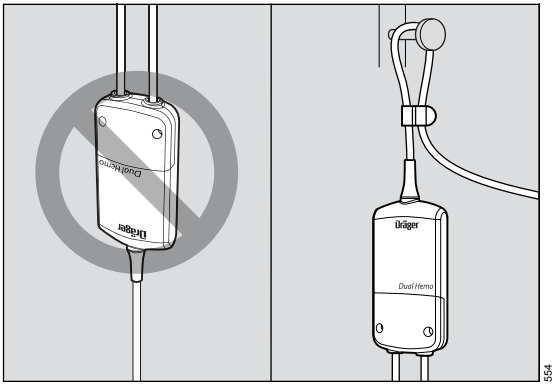
E Transducer cables

To connect the Dual Hemo MCable

1. Attach the transducers (D) to the transducer adapter cables (C). The transducer adapter cables are permanently fastened to the Dual Hemo MCable.
2. Connect the Dual Hemo MCable connector (B) to the gray Hemo connector (A) on the M540.

Preventing fluid ingress

The following illustration shows how to correctly position the Dual Hemo MCable to prevent fluids from entering the ports where the transducer cables are attached. If the Dual Hemo MCable is positioned wrong, fluids may enter and damage the MCable.



Patient preparation for invasive blood pressure monitoring

NOTE

If air bubbles appear in the tubing system, flush the system with the infusion solution again. Air bubbles may lead to wrong pressure measurement values.

The following tips provide optimal invasive blood pressure monitoring results but must never replace hospital-approved practices or manufacturer's recommendations.

– When preparing the patient, make sure there are no air bubbles in the sensor or the stopcock.

– For maximum signal strength, choose the shortest possible length of high-pressure tubing. Shorter tubing reduces signal attenuation but is more susceptible to motion artifacts. High-pressure tubing limits signal dampening.

– Position the transducer so that it is level with the appropriate anatomical reference point for each monitored pressure.

Invasive blood pressure display

On the M540, the invasive blood pressure display consists of:

– Invasive blood pressure parameter box

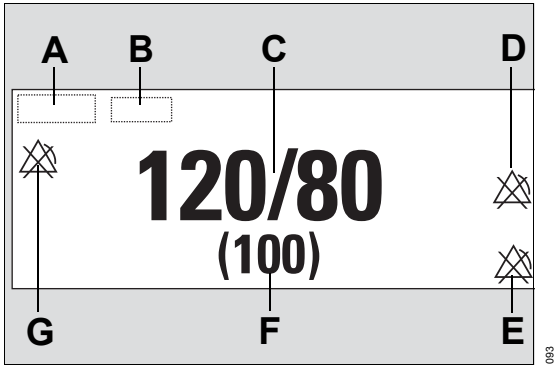
– Invasive blood pressure waveform

Invasive blood pressure parameter box

The content of the invasive blood pressure parameter boxes depends on whether the parameter is pulsatile or non-pulsatile. Parameter boxes for pulsatile pressures (ART, LV, PA, RV, GP1, GP2, GP3, GP4) display systolic, diastolic, and mean pressure values. Parameter boxes for non-pulsatile pressures (LA, RA, CVP, ICP) display only the mean pressure value.

If the M540 detects a static pressure, the algorithm computes only the mean pressure. A static pressure condition occurs when the maximum and minimum values of a pulsatile pressure signal differ by less than 3 mmHg (0.4 kPa).

The invasive blood pressure parameter box contains the following elements:



A Invasive blood pressure parameter label

B Unit of measure

C Systolic/diastolic pressure values

D Crossed triangle symbol when the diastolic invasive blood pressure alarm is turned off.

E Crossed triangle symbol when the mean invasive blood pressure alarm is turned off.

F Mean pressure value

G Crossed triangle symbol when the systolic invasive blood pressure alarm is turned off.

Labeling Invasive blood pressure channels

The invasive blood pressure label determines how a signal is analyzed and reported. The M540 takes the pressure labels from the connected pod or MCable provided the transducers are connected. When a new label is assigned to a pressure channel, the M540 clears the parameters and conditions set for the previous label (including alarms and waveform scales) and replaces them with the settings of the new label.

The following rules apply to labeling pressure channels:

– If no pressure labels are assigned, the labels GP1 to GP4 are automatically assigned depending on how many pressures are connected

NOTE
If the M540 displays the generic pressure labels (GP1, GP2, GP3, GP4), the displays on the Hemo2 and Hemo4 pods are labelled P1a, P1b, P1c, P1d.

– The zero value, the date, and time are associated with the pressure channel remain unchanged even if a new label is assigned

To assign a pressure label manually

1 Touch the invasive blood pressure parameter box.

2 Touch the ***Settings*** tab.

3 Touch ***Edit label***.

4 Touch the appropriate pod label (***Pod 1A label***, ***Pod 1B label***, and so on).

5 Touch the new pressure name (***GP1***, ***ART***, ***PA***, ***CVP***, ***ICP***, ***LV***, ***LA***, ***RA***, ***RV***).

6 Touch ***X*** to close the dialog window.

Or

1 Touch the ***Menu*** function key.

2 Touch ***Label IBP***.

Standard pressure labels

The M540 detects the labels automatically from the hemodynamic pod, provided a transducer is connected. You can also label pressure channels manually.

The following table lists the available invasive blood pressure labels.

Invasive blood pressure labels			
Label	**Pressure type**	**Measured pressures**	**Measurement range**
ART	Arterial pressure	Systolic, diastolic, mean	–50 to +400 mmHg –6.6 to +53.3 kPa
LV	Left ventricular pressure		
PA	Pulmonary arterial pressure		
RV	Right ventricular pressure		
CVP	Central venous pressure	Mean	
CPP [1)]	Cerebral perfusion pressure		
RA	Right atrial pressure		
LA	Left atrial pressure		
ICP	Intracranial pressure		
Generic labels			
GP1 to GP4		Systolic, diastolic, mean	

NOTE

[1)] The CPP value is only calculated when ICP and ART M pressure values are available.

Pressure label conflicts

Each pressure label is assigned to one location. If you try to reuse a label, you must confirm it. The M540 assigns the label to the currently selected parameter box and places an automatic pressure label (GP1 to GP4) in the previous location. When the M540 is docked in an IACS configuration, the pressure labels are saved as part of the M540 profile.

Pod-M540 label conflicts

The hemodynamic pods store pressure labels like the M540. When a pod with previously stored labels is connected, different pressure labels may exist for the same channel, thus causing a conflict.

If a transducer is connected to the pod, the label stored in the pod prevails. The M540 assigns that parameter label to the pressure label list box. If no transducer is connected to the pod, the label stored in the M540 has priority.

Zeroing an invasive blood pressure transducer

To establish accurate invasive blood pressure values, zero the transducer according to the hospital's protocol at least once a day. Perform additional zeroing under the following circumstances:

– After introducing a catheter into the vascular system of the patient

– Before each monitoring session

– Each time you use a new transducer or tubing

– Whenever you connect the transducer cable to the monitor

– If the reported pressure values seem incorrect

– When the message ***check zero*** appears

For zeroing to be successful, a pressure must be stable for at least 3 seconds. Messages report the status of the zeroing process. The time and date of the last successful zero is recorded on the invasive blood pressure page. Check the invasive blood pressure waveform and repeat the zeroing procedure if the zeroing fails because the pressures are not static. If the procedure fails after two attempts, replace the transducer or consult your technical personnel.

Zeroing a specific transducer

This procedure allows you to select a specific transducer for zeroing.

To zero a specific sensor

1 Touch the appropriate invasive blood pressure parameter box.

2 Touch the ***Settings*** tab.

3 Align the transducer to the level of the heart (phlebostatic access point, fifth intercostal space and midaxillary line).

4 Close the transducer stopcock to the patient and open it to air.

5 Touch ***Zero*** on the M540.

If the zeroing of the transducer is successful, the message ***Zero accepted*** appears. If zeroing fails, the message ***did not zero*** appears. In that case, repeat steps three to five.

6 Touch ***X*** to close the dialog window.

Zeroing all pressure transducers

This procedure zeroes all pressure transducers simultaneously.

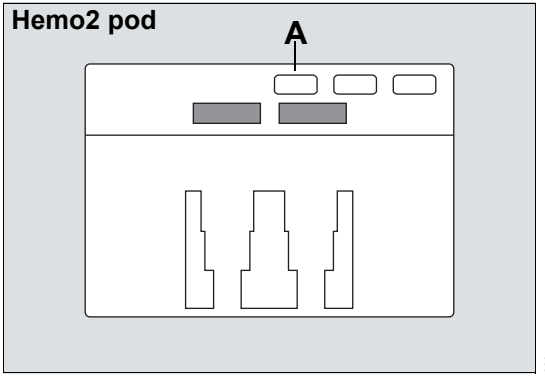
Zeroing all pressures simultaneously from the Hemo4 pod, the Hemo2 pod, and the MPod – QuadHemo automatically zeroes all transducers open to air simultaneously.

To zero all pressure transducers from the hemodynamic pods

1 Align the transducer to the level of the heart (phlebostatic access point, fifth intercostal space and midaxillary line).

2 Close the stopcocks to the patient, and open them to air.

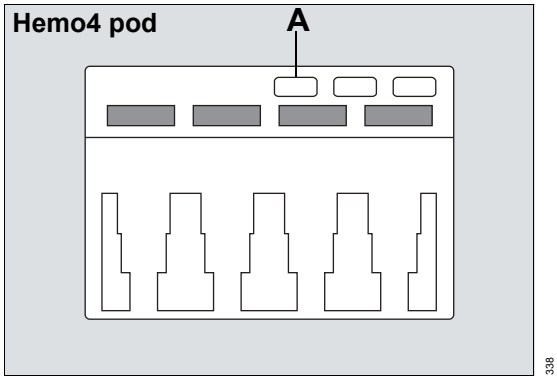
3 Press the ➛0⇽ key (A) on the Hemo4, Hemo2, or the MPod – QuadHemo.

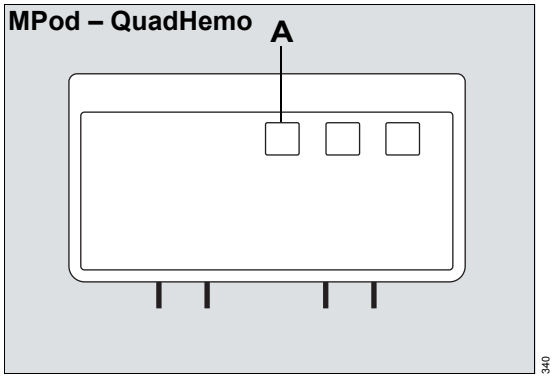


WARNING

Using the ➛0⇽ key on the hemodynamic pods zeroes all static invasive blood pressures < 3 mmHg.

Certain invasive blood pressure alarms are suppressed while pressures are being zeroed. For detailed information, see page 92.





4 Verify that the transducers have been zeroed. If zeroing failed, repeat steps two and three.

Pulmonary wedge pressure

You cannot request pulmonary wedge pressures directly from the M540. For more information on requesting pulmonary wedge pressures when the M540 is part of IACS, refer to the instructions for use *Infinity Acute Care System – Monitoring Applications*.

Accessing the invasive blood pressure dialog window

1 Touch the invasive blood pressure parameter box.

2 Touch the ***Settings*** tab.

Or, if the parameter is not displayed

1 Touch any parameter box > ***Settings*** tab > ***Change parameter***.

2 Touch the desired parameter label to display it on the main screen.

3 Touch the parameter box > ***Settings*** tab.

Invasive blood pressure parameter setup functions

All invasive blood pressure setup functions take place in the invasive blood pressure dialog window (see "Accessing the invasive blood pressure dialog window" on page 221).

The limits dialog window contains the ***Auto set*** and ***Alarm*** buttons for configuring the alarm functions. For detailed alarm setup information, see "Configuring a patient's alarm settings" on page 100.

Selection	Available settings	Description
	Settings	
Zero	None	Zeroes only the pressure indicated on the invasive blood pressure page and displays the time and date of the last zeroing (see page 219).
Edit label [1)]	***ART***, ***PA***, ***CVP***, ***LA***, ***LV***, ***RV***, ***RA***, ***ICP***, ***GP1*** to ***GP4*** The defaults are as follows: – Channel 1: ***GP1*** – Channel 2: ***GP2*** – Channel 3: ***GP3*** – Channel 4: ***GP4***	Allows you to assign a label to each pressure channel.
Filter [1)]	8 and 16 Hz (default)	Selects the filter setting applied to the invasive blood pressure signal.
Color [1)]	***Red***, ***White***, ***Yellow***, ***Green***, ***Light blue***, ***Blue***, ***Purple***, ***Orange*** The various invasive blood pressure parameters have the following defaults: – ART, GP1 to GP4 = ***Red*** – PA, LV = ***Yellow*** – CVP = ***Blue*** – ICP, LA = ***Purple*** – RA, RV = ***Orange***	Determines the color of the waveforms, and the parameter labels and values.
Change parameter	A list of currently available parameters.	Changes the parameter box to a different parameter.

NOTE

[1)] This setting is a patient default which may be unique for each patient category; it is part of the profile.

Cardiac Output (C.O.)

Overview of cardiac output monitoring

The M540 uses the thermodilution method to compute cardiac output (C.O.) for adult and pediatric patients. Cardiac output monitoring is not intended for neonatal patients.

The MPod – QuadHemo, the Hemo4 and Hemo2 pods connect to the M540 and acquire the blood, and the injectate temperatures which are used to compute the cardiac output value.

Although the M540 processes the cardiac output algorithms, you can only view the data and execute cardiac output functions 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*.

Cardiac output measurement method

A solution of known temperature and volume is injected into the blood stream in the right atrium. A thermistor in the catheter tip continuously measures the temperature of the blood as it leaves the heart. The injectate mixes with and cools the surrounding blood. The blood reaches its minimum temperature relatively quickly and then warms up slowly until it returns to the baseline blood temperature. The total drop in blood temperature is inversely related to the cardiac output of the patient. The lower the cardiac output value, the more the injectate cools the blood.

When computing cardiac output, the M540 takes the following factors into account:

– Injectate volume, temperature, density, and specific heat of the fluid that is being injected
– Baseline blood temperature, density, and specific heat
– Temperature changes of the blood injectate mixture
– Area under the temperature curve

Before performing any monitoring functions, refer to the section "For your safety and that of your patients" on page 5.

Parameter-specific error messages are listed on page 280.

Supported parameters

– C.O. – Cardiac output
– Tblood – blood temperature
– Tinj – injectate temperature

Cardiac output precautions

WARNING

An incorrect computation constant may yield incorrect C.O. measurements and put the patient at risk. Confirm that the manually entered computation constant is correct for the catheter you are using.

Connecting the cardiac output hardware

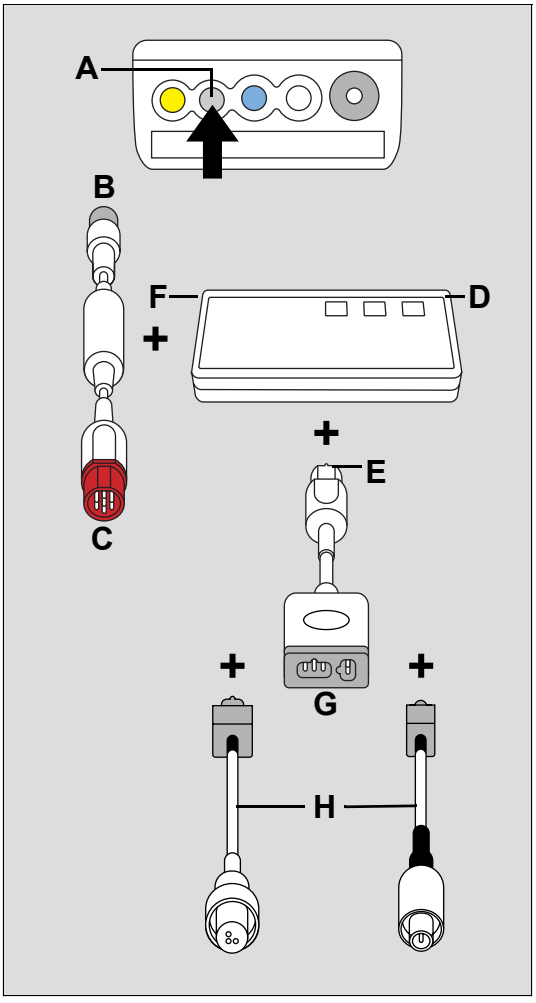
You can connect the hemodynamic cable to one of the following devices:

– MPod – QuadHemo

– Hemo4 pod

– Hemo2 pod

The intermediate cable from any of the above devices connects directly to the M540.



A M540 hemodynamic connector

B Grey intermediate cable connector

C Red intermediate cable connector

D MPod – QuadHemo hemodynamic connector

E Pod connector of the cardiac output intermediate cable

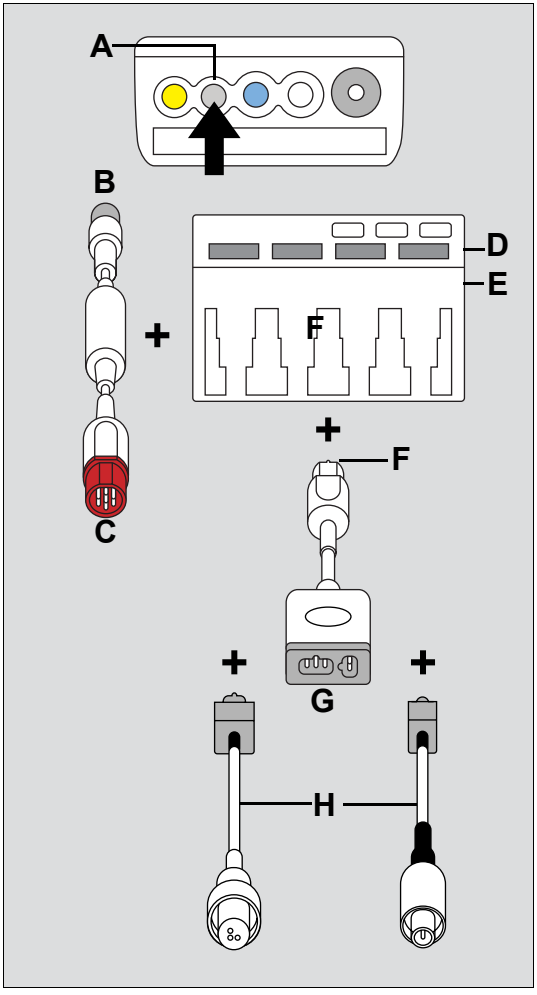
F Cardiac output connector of the MPod – QuadHemo

G Thermistor connector of the cardiac output intermediate cable

H Catheter cable and thermistor cable

To connect the cardiac output hardware to the MPod – QuadHemo

1. Connect the grey connector of the hemodynamic intermediate cable (B) to the hemo connector (A) of the M540.
2. Connect red connector of the hemodynamic intermediate cable (C) to the MPod – QuadHemo connector (D).
3. Connect the pod connector of the cardiac output intermediate cable (E) to the cardiac output connector of the MPod – QuadHemo (F).
4. Connect the catheter and the thermistor cables (H) to the thermistor connector of the cardiac output intermediate cable (G).



A M540 hemodynamic connector

B Grey intermediate cable connector

C Red intermediate cable connector

D Hemodynamic pod connector

E Cardiac output connector

F Pod connector of the cardiac output intermediate cable

G Thermistor connector of the cardiac output intermediate cable

H Thermistor cables

To connect the cardiac output hardware to the Hemo4 and the Hemo2 pods

1. Connect the hemodynamic intermediate cable connector (B) to the grey hemo connector (A) of the M540.
2. Connect the red connector of the hemodynamic intermediate cable (C) to the Hemo4/Hemo2 connector (D).
3. Connect the pod connector of the cardiac output intermediate cable (F) to the cardiac output connector of the Hemo4/Hemo2 pod (E).
4. Connect the catheter and the thermistor cables (H) to the thermistor connector of the cardiac output intermediate cable connector (G).

Patient preparation for cardiac output monitoring

The following tips provide optimal cardiac output monitoring results but must never replace hospital-approved practices or manufacturer's recommendations.

– Follow the recommendations of the manufacturer. Dräger recommends that you place prefilled syringes or the closed injectate delivery system into an ice bath.

– Check the ice bath regularly and add ice to maintain a temperature between 0 °C (32 °F) and 5 °C (41 °F). The accuracy of measurements done with the thermodilution method increases as the temperature of the injectate approaches 0 °C (32 °F).

NOTE

For the most accurate results when using an injectate at room temperature, use a 10 cc injectate volume unless clinically contraindicated, to get the best results.

– Verify the injectate volume.

– Verify the proper selection of catheter type and size or computation constant if ***Other*** is chosen for the catheter type.

– Use an in-line injectate system. Systems that measure the injectate temperature in the ice bath can introduce errors. These errors happen because the injectate temperature changes between its removal from the ice bath and the injection.

– If you fill your syringes manually, fill them with the same volume each time. The recommended amount is 10 cc for adults and 5 cc for pediatric patients. Do not touch the body of the syringe to avoid warming the injectate.

– Inject the entire volume in one swift, continuous motion.

– Perform the injection at the end of expiration. Taking successive cardiac output measurements at different points in the respiratory cycle provides different measurements, especially for patients on mechanical ventilators.

– Discard results that are widely different from the general trend, and results associated with irregularly shaped waveforms.

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Carbon Dioxide Concentrations (CO_2)

Overview of CO_2 monitoring

The M540 provides fast and continuous mainstream measurements of carbon dioxide concentrations (CO_2) in the airway of intubated patients. The M540 acquires signals from a CO_2 sensor (Infinity MCable – Mainstream CO_2) which fits over a mainstream airway adapter. The lightweight, reusable CO_2 mainstream sensor provides sensitive and accurate measurements. It uses non-dispersive infrared technology to measure CO_2 in respiratory gases.

CO_2 monitoring is available for adult, pediatric, and neonatal patients.

As respiration gases flow through the airway adapter, the sensor analyzes the expired and inspired air of the patient by sending a beam of infrared light through transparent ports in the airway adapter while detecting changes in CO_2 absorption levels.

Before performing any monitoring functions, refer to the section "For your safety and that of your patients" on page 5.

Parameter-specific error messages are listed on page 280.

Supported parameters

– etCO_2 – end-tidal CO_2
– inCO_2 – inspired CO_2
– RRc – respiration rate as calculated from capnogram

CO_2 precautions

WARNING
RRc apnea alarms are NOT reported if the setting *RRc apnea time* is set to *Off* in the CO_2 setup page and the RRc alarm feature is deactivated. To generate RRc apnea alarms, activate the RRc alarms and select a RRc apnea time.

WARNING
The safety and effectiveness of the respiration measurement method in the detection of apnea, particularly the apnea of prematurity and apnea of infancy, has not been established.

WARNING
Patient monitors that measure CO_2, anesthetic agents, and/or respiratory mechanics are not intended to be used as an apnea monitor and/or recording device. While these products provide an apnea alarm, that alarm condition is initiated based on the elapsed time since the last breath was detected. Clinical diagnosis of a true apneic event, however, requires multiple physiological signals.

WARNING
CO_2 alarms do not activate until the first breath is detected after turning on the monitor or discharging a patient.

WARNING

The surface temperature of the sensor may rise to 43 °C (109 °F). Prolonged exposure to the patient's skin may result in a burn.

CAUTION

Leaks in the breathing circuit (for example, an uncuffed endotracheal tube or a damaged airway adapter) may significantly affect CO_2 measurement values.

CAUTION

To avoid accidental disconnections, do not apply excessive tension to any sensor cable.

CAUTION

To prevent leakage, make sure the airway adapter is firmly connected to the breathing circuit.

CAUTION

Check the CO_2 mainstream sensor for damage before use. A damaged CO_2 sensor may impair electrical isolation or may introduce debris into the breathing circuit.

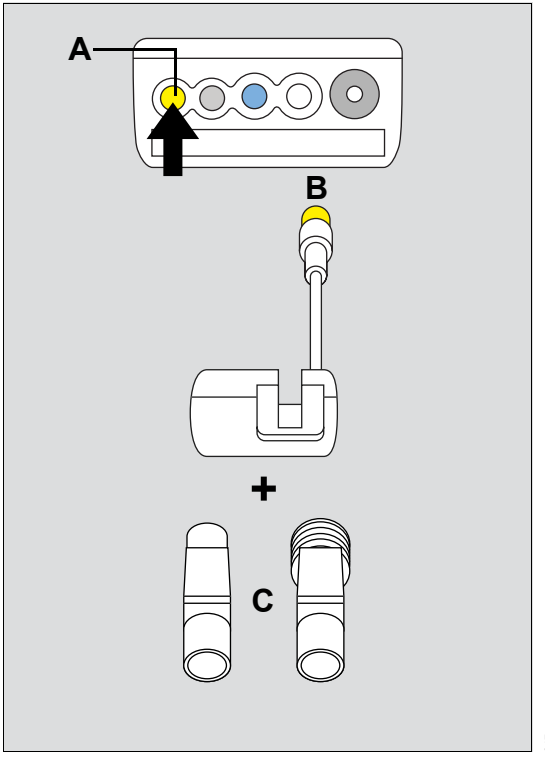
NOTE

Dräger CO_2 accessories that come in contact with the patient do not contain natural rubber latex.

Connecting the CO_2 sensor

Before connecting any CO_2 hardware, make sure the airway adapter that is used, matches the airway adapter setting of the M540 (see page 251). For example, you should not use a disposable airway adapter if the M540 is configured for a reusable airway adapter (and vice versa). Not aligning the adapter with the configuration setting at the M540 compromises the displayed CO_2 value.

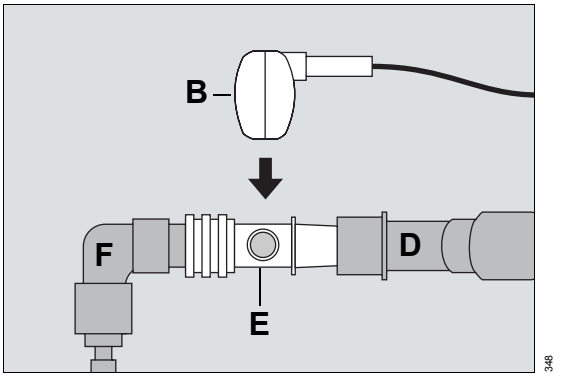
The M540 is only compatible with the CO_2 sensors 6871950 revision 5 or higher. Previous revisions are not compatible.



A CO_2 connector on the M540

B CO_2 sensor cable connector

C Mainstream airway adapter



D Y-piece

E Airway adapter

F Tracheal tube adapter

CAUTION

Always position the sensor windows of the airway adapter vertically to prevent patient secretions from obscuring the adapter windows.

To connect the CO_2 hardware

1. Connect the end of the CO_2 sensor cable (B) to the yellow CO_2 connector (A) on the M540.
2. Select a suitable adult or pediatric mainstream airway adapter (C) whose windows are clean and dry (replace the adapter if necessary).
3. Insert the airway adapter (E) between the endotracheal tube adapter (F) and the ventilator Y-piece (D).
4. Snap the CO_2 mainstream sensor (A) firmly into the airway adapter and make sure that the cable is directed away from the patient.

Patient preparation for CO_2 monitoring

The following tips provide optimal CO_2 monitoring results but must never replace hospital-approved practices or manufacturer's recommendations.

A default O_2 concentration of 21 % (the percentage of oxygen in ambient air) for all CO_2 measurements is assumed. If the patient is receiving supplemental oxygen or N_2O or Heliox, select the gas that is being administered in the CO_2 setup page. Make sure to adjust the atmospheric pressure to the actual measurement value. Failure to compensate for supplemental gases results in inaccurate CO_2 measurement values.

– When you switch adapter types (from reusable to disposable or adult to pediatric, or vice versa) you do not have to rezero a Dräger sensor. If the sensor window is clean and the correct sensor type is selected under the ***Airway adapter*** Biomed setting, you should only zero a Dräger sensor when the measurement value is suspect or when you are prompted to rezero.

CO_2 display

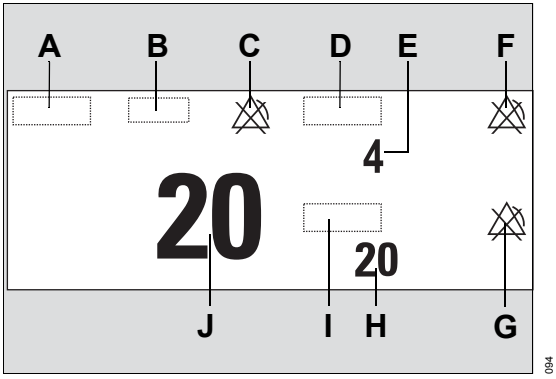
On the M540, the CO_2 display consists of:

– CO_2 parameter box

– CO_2 waveform (capnogram)

CO_2 parameter box

The CO_2 parameter box contains the following elements:



A etCO_2 label

B Unit of measure

C Crossed triangle symbol when the etCO_2 alarm is turned off

D inCO_2 label

E inCO_2 value – the level of CO_2 in the airway during inspiration, taken as the minimum value during the previous measurement interval

F Crossed triangle symbol when inCO_2 alarms are turned off

G Crossed triangle symbol when RRc alarms are turned off

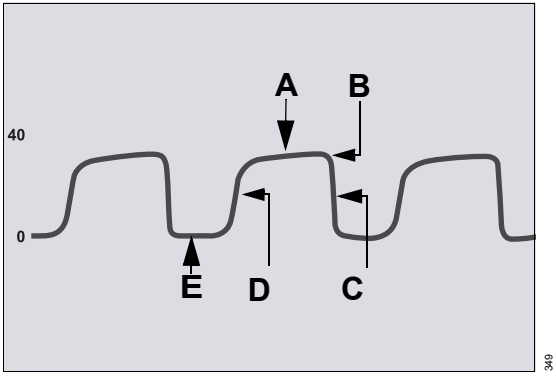
H RRc value – respiratory rate derived from the CO_2 signal

I RRc (respiratory rate) parameter label

J etCO_2 value – highest average CO_2 in the airway during expiratory period

CO_2 waveform (capnogram)

The M540 also displays an instantaneous CO_2 waveform or capnogram.



A Expiratory or alveolar plateau (level of CO_2 in lungs ceases to increase significantly)

B End-tidal concentration point (end of expiration phase, where CO_2 is measured)

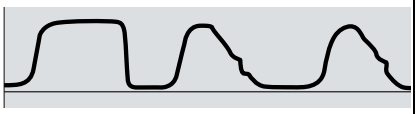
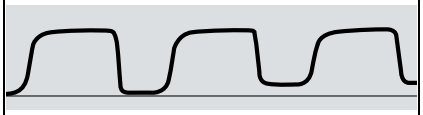
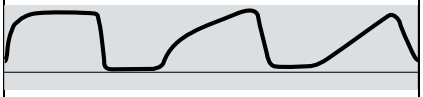
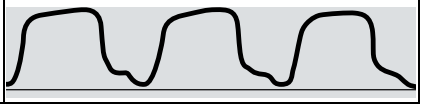
C Onset of inspiration phase

D Onset of expiratory phase

E Baseline during inspiration

Troubleshooting

In addition to evaluating the clinical status of a patient, capnograms can help troubleshoot problems with equipment. The following table shows how capnograms can be used to identify common problems.

Description	Cause	Capnogram
Alveolar plateau showing a downward slope that merges with a descending limb.	– Inadequate seal around the endotracheal tube – Leaky or deflated endotracheal or tracheostomy cuff – Artificial airway that is too small for the patient	
Elevated waveform baseline with corresponding increase in CO_2 level.	Rebreathing due to one of the following causes: – Disposable airway adapter is used although the Cockpit is configured for the reusable adapter type – Contaminated airway adapter (dirty window) – CO_2 zero drift – Insufficient expiratory time – Faulty expiratory valve – Inadequate inspiratory flow – Malfunction of a CO_2 absorber system – Partial rebreathing circuits	
Change in slope of ascending limb. Possible absence of an alveolar plateau.	Obstruction caused by one of the following: – Partial obstruction in expiratory limb of breathing circuit – Foreign body in upper airway – Partially kinked or occluded artificial airway – Herniated endotracheal or tracheostomy tube cuff – Bronchospasm	
Elevated baseline, with pronounced slope on descending limb	– Faulty ventilator circuit valve – Rebreathing (see above)	

Accessing the CO_2 dialog window

1 Touch the CO_2 parameter box.

2 Touch the ***Settings*** tab.

Or, if the parameter is not displayed

1 Touch any parameter box > ***Settings*** tab > ***Change parameter***.

2 Touch the desired parameter label to display it on the main screen.

3 Touch the parameter box > ***Settings*** tab

For the inspired CO_2 parameter, you can only adjust the upper alarm limit. In addition, the ***Auto set*** function does not apply to this parameter.

CO_2 parameter setup functions

All CO_2 parameter setup functions take place in the CO_2 dialog window (see "Accessing the CO_2 dialog window" on page 236).

The limits dialog window contains the ***Auto set*** and ***Alarm*** buttons for configuring the alarm functions. For detailed alarm setup information, see "Configuring a patient's alarm settings" on page 100.

Selection	Available settings	Description
Zero (*only available if a CO_2 device is connected*)	None	Zeroes the CO_2 sensor if necessary. The CO_2 sensor stores a new zero point for CO_2 measurements. **NOTE** The sensor must be removed from the airway adapter before zeroing. The sensor is zeroed in room air. Do not breathe on the airway adapter during zeroing.

Selection	Available settings	Description
Atm. pressure [1]	570 to 800 mmHg Default: 760 mmHg	Determines the atmospheric pressure setting of the sensor and compensates for pressure effects. Failure to compensate for pressure can cause inaccurate measurements.
Gas compens. [1]	***Air*** (default), ***N_2O/O_2***, ***> 50% O_2***, ***HeliOx***	Compensates for supplemental oxygen or N_2O or ***HeliOx***. Failure to compensate for supplemental oxygen can cause inaccurate measurements.
RRc apnea time [2]	***Off*** (default), 10, 15, 20, 25, 30 s	Specifies the time the M540 waits before reporting a cessation of breathing as an apnea event.
Apnea archive [2]	***Off***, ***Store*** (default), ***Str/Rec***, ***Record***	Determines what happens in response to an apnea.
Color [2]	***Red***, ***White***, ***Yellow*** (default), ***Green***, ***Light blue***, ***Blue***, ***Purple***, ***Orange***	Determines the color of the waveforms, and the parameter labels and values.
Change parameter	A list of currently available parameters.	Changes the parameter box to a different parameter.

NOTE

[1] This setting is a user default that is identical for all patient categories and is also part of the profile.

[2] This setting is a patient default which may be unique for each patient category; it is part of the profile.

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System configuration

System configuration overview

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

The ***Menu*** dialog window consists of the following dialog windows:

- ***Main*** (see page 241)
- ***Patient setup*** (see page 242)
- ***System setup*** (see page 243)
  - ***Biomed*** button (see page 250)
  - ***General*** tab (see page 241)
  - ***Alarm setup*** tab (see page 257)
  - ***Service*** tab (see Service Instructions)
  - ***System information*** tab (see page 248)
- ***Screen setup*** (see page 256)
  - ***Settings*** tab (see page 256)
  - ***Screen views*** tab (see page 256)
  - ***Function keys*** tab (see page 256)

Configuring general settings

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

To access the *Main* dialog window

1 Press the ***Menu*** function key.

2 Touch the ***Main*** tab.

***Main* dialog window**		
Selection	**Available settings**	**Description**
All alarms pause or ***All alarms off***	None	When the ***All alarms pause*** 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 ***All alarms off*** 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 241.
Show all leads	None	Displays waveforms for all ECG leads.
Label IBP	Unlabeled pressure labels: ***Pod 1A label***, ***Pod 1B label***, ***Pod 1C label***, ***Pod 1D label*** Pressure labels: ***GP2***, ***ART***, ***LV***, ***LA***, ***PA***, ***CVP***, ***ICP, RA***, ***RV*** Generic labels: ***GP1*** through ***GP4***	Assigns a label name to the IBP labels.
Discharge	– ***Cancel*** – ***Discharge***	Discharges a patient and deletes all the patient's data.
Standby	None	Enters standby mode.
Privacy mode	None	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. For more information, see page 66.

Configuring the patient settings

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

To access the *Patient setup* dialog window

1 Press the ***Menu*** function key.

2 Touch the ***Patient setup*** tab.

***Patient setup* dialog window**		
Selection	**Available settings**	**Description**
Demographics		
Patient category	– ***Adult*** – ***Pediatric*** – ***Neonate***	Selects the type of patient.
Name	Onscreen keyboard	Allows you to enter the name of the patient.
ID	Onscreen keyboard	Allows you to enter the ID number of the patient.
Admit date	– ***Day*** – ***Month*** – ***Year***	Allows you to enter the admit date of the patient.
Birth date	– ***Day*** – ***Month*** – ***Year***	Allows you to enter the birth date of the patient.
Physician	Onscreen keyboard	Allows you to enter the name of the physician of the patient.

Configuring the system settings

This section describes the setup functions of the ***System setup*** dialog window 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 window provides access to password-protected dialog windows and the current system information.

To access the system information

1. Press the ***Menu*** function key.
2. Touch the ***System setup*** tab.
3. Touch the ***Biomed*** tab to access the ***Biomed*** dialog window (see page 250).
4. Enter the password and touch ***OK***.

   or

5. Touch the ***Service*** tab to access the ***Service*** dialog window (refer to the service instructions).
6. Enter the password and touch ***OK***.

   or

7. Touch the ***System information*** tab to access the ***System information*** dialog window (see page 248).

Accessing the *Alarm setup* dialog window

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

To access the *Alarm setup* dialog window

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 ***Settings 1*** or the ***Settings 2*** tabs to access further selections.

Selection	Available settings	Description
***Settings 1* dialog window** (password required)		
All alarms paused [1)] or ***All alarms off***	1, 2 (default), 3, 4, 5 min	Selecting one of these settings changes the alarm button on the ***Main*** dialog window to ***All alarms pause***. When selected, all alarm functions are temporarily suppressed for the selected time. The alarm function is automatically activated when the alarm pause timer times out.
	No timeout	Selecting this setting changes the alarm button on the ***Main*** dialog window to ***All alarms off***. When selected, all alarm functions are suppressed until you select the button again to activate the alarm function again.
	Disable	Selecting this setting deactivates (grays out) the ***All alarms pause/All alarms off*** button (depending on its previous configuration) on the ***Main*** dialog window (see page 241). You cannot temporarily or permanently deactivate alarm monitoring.
Alarm validation [1)]	– ***On*** (default) – ***Off***	When activated, alarm conditions are verified for a certain time before triggering acoustic and visual alarm signals (see page 86). This reduces nuisance alarms.

NOTE

[1)] This setting is a user default that is identical for all patient categories and is also part of the profile.

SpO2 alarm delay [1]	***On*** (default)	An SpO2 lower alarm limit violation must persist for 10 seconds before triggering acoustic and visual alarm signals. This function is not possible if the Nellcor ***SatSeconds*** feature is set to any value other than ***Off*** (see page 189). **NOTE** The alarm validation feature must be activated.
	Off	An SpO2 lower alarm limit violation triggers an alarm immediately.
Alarm group [1]	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.
NIBP/SpO2 interlock [1]	***On***	The SpO2 alarm function is deactivated during non-invasive blood pressure and PLS CO-Ox measurements (for more details, see "NIBP/SpO2 interlock alarm feature" on page 91).
	Off (default)	The SpO2 alarm function is activated during non-invasive blood pressure and PLS CO-Ox measurements.
ASY/VF alarms [1]	***Follow HR***	ASY and VF alarm settings follow the setting of the heart rate alarms. **WARNING** **If you select *Follow HR*, ASY, and VF alarms are not reported if the HR and arrhythmia alarm functions are turned off.**
	Always on (default)	ASY and VF alarm functions are always activated.
Pacer mode [2]	– ***Basic*** (default)	Fusion mode is not selectable.
	– ***Advanced***	Fusion mode is selectable in the ***ECG*** setup page (see page 132).

NOTE

[1] This setting is a user default that is identical for all patient categories and is also part of the profile.

[2] This setting is a patient default which may be unique for each patient category; it is part of the profile.

Alarm bar [1]	– ***On*** (default) – ***Off***	Determines whether the alarm bar flashes during an alarm.
***Settings 2* tab** (clinical password required)		
Alarm pattern	– ***IEC slow*** – ***IEC fast*** – ***Infinity*** (default)	Determines the type of alarm tone pattern in use (for more information, see "Acoustic alarm signals" on page 89). Moved here from Biomed menu.
Transport volume	50% (default), 60%, 70%, 80%, 90%, 100%	Determines the alarm volume of the M540 while it is on patient transport.
Transport pulse tone	– ***Off*** (default) – 5, 10, 20, 30, 40, 50, 60, 70, 80, 90, 100 %	Determines the volume of the heart rate and SpO_2 pulse tone while the M540 is on patient transport.
Central audio pause [1]	– ***Exit*** (default) **NOTE** The ***Central audio pause-*** setting appears greyed out when the M540 is in wireless mode or when it is on transport and the wireless mode is deactivated.	Controls the alarm tone behavior at the ICS or at a remote view monitor. When an audio pause is initiated at the M540, all alarms are paused at the M540 and at the ICS. However, all subsequent alarm conditions of low, medium, and high grade will trigger an alarm tone at the ICS even during an active audio pause state.
	– ***Continue***	When an audio pause is initiated at the M540, all visual alarm signals continue at the ICS. Only a subsequent alarm condition of high priority will be announced acoustically and visually at the ICS.

NOTE

[1] This setting is a user default that is identical for all patient categories and is also part of the profile.

[2] This setting is a patient default which may be unique for each patient category; it is part of the profile.

Accessing the configurable SpO_2 alarm features

The ***Alarm setup*** dialog window provides access to password-protected SpO_2 alarm settings. Depending on the configuration of the M540, one of the following two tabs appears.

– The ***SpO_2 sensor off*** tab when the M540 is configured for Masimo.

– The ***SpO_2 check sensor*** tab when the M540 is configured for Nellcor.

To access the *Alarm setup* dialog window

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_2 sensor off*** tab (Masimo).

or

6 Touch the ***SpO_2 check sensor*** tab (Nellcor)

Selection	Available settings	Description
Alarm	– ***High*** – ***Medium***	Assigns an alarm grade to the sensor alarm or deactivates the sensor alarm. The selected alarm grade affects how the alarm event is reported (see page 106). – 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.
	Low (default)	– 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.
	(off)	– No visual or acoustic alarm signals are triggered.

Selection	Available settings	Description
Archive	***Off*** (default)	Determines what happens when the corresponding alarm occurs: – No event is stored and no recording is generated.
	Store	– Stores the event for later review (see page 103).
	Record	– Generates a timed recording (except for standalone mode)
	Str/Rec	Generates a timed recording and stores the event.

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 window.

NOTE

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

To view the system information

1 Press the ***Menu*** function key.

2 Touch the ***System setup*** tab.

3 Touch the ***System information*** tab. This menu displays general system information.

4 Touch one of the following tabs to view the additional system information: ***Name service***, ***Docking station***, ***Wireless***.

Dialog window	Available information
System information	***Serial number***
	H/W interface
	S/W revision
	S/W checksum
	Boot loader
	FPGA revision
	SpO_2 sensor type

Dialog window	Available information
Name service	***IP address***
	Subnet mask
	Default gateway
	Bed label
	Care unit
	Hospital
	Mon. unit
	Mon. unit ID
Docking station	***DS revision***
	MAC address
Wireless	***WLAN MAC address***
	Signal strength
	BSSID
	SSID
	Encryption
	Channel number
	Regulatory domain

Configuring the biomed settings

This section describes the setup functions of the ***Biomed*** dialog windows.

To access the *Biomed* dialog window

1 Press the ***Menu*** function key.

2 Touch the ***System setup*** tab.

3 Touch the ***Biomed*** button.

4 Enter the password and touch ***OK***.

5 Touch the ***Settings 1*** or the ***Settings 2*** buttons.

***Biomed* dialog windows**		
Biomed > ***Settings 1*** dialog window		
Selection	**Available settings**	**Description**
Language	***English***, ***German***, ***Spanish***, ***French***, ***Italian***, ***Portugese***, ***Port.(Br)***, ***Russian***, ***Japanese, Swedish***, ***Norweg.***, ***Danish***, ***Dutch***, ***Turkish***, ***Polish***, ***Finnish***, ***Greek***, ***Chinese***, ***Hungarian***, ***English (UK)***, ***Czech***	Selects the language of the M540 screen text.
Date	– ***Day*** – ***Month*** – ***Year***	Allows you to enter the date.
Time	– ***Hour,*** – ***Minute***	Allows you to enter the time.
Simulation	– ***Cancel*** – ***OK***	Activates simulation mode. Select the ***Discharge*** function key to exit.
Save profile	– ***Cancel*** – ***OK***	Saves and replaces the profile (including the current views) for the current patient category. **NOTE** Please be aware that saving profiles must be done separately for each patient category.

***Biomed* dialog windows**		
Biomed > ***Settings 1*** dialog window		
Selection	**Available settings**	**Description**
Restore Profile	– ***Cancel*** – ***OK***	Restores the saved profile settings and up to five available views on the M540. In standalone mode, if docked on an M500 that has a saved profile, selecting this button will restore the M500 default profile.
Line frequency	50, 60 Hz (default)	Selects the line frequency.
Biomed > ***Settings 2*** dialog window		
French NFC	– ***Off*** (default) – ***On***	When activated, heart rate alarms cannot be turned off, and the ***All alarms pause*** period cannot exceed 3 minutes.
Airway adapter	– ***Disposable*** – ***Reusable*** (default)	Configures the M540 for a specific type of airway adapter. If the setting does not match the hardware that is being used, the displayed CO_2 value is compromised.
Test pulse	None	Generates 1 mm test pulse.
SpO2 sensor type	– ***Masimo*** (default) – ***Nellcor***	Selects the type of sensor.

Configuring units of measure

To access the *Biomed* dialog window

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.

***Biomed* > *Units* dialog windows**		
Selection	**Available settings**	**Description**
Temp	– ***°C*** (Celsius) default – ***°F*** (Fahrenheit)	Assigns the selected the unit of measure to the parameter. Whenever you change a unit of measure, the M540 discharges the patient.
etCO2	– ***mmHg*** (default) – ***kPa***, ***%***	
Pressures	– ***mmHg*** (default) – ***kPa***	
ST	– ***mm*** (default) – ***mV***	
SpHb (***SpHbv***)	– ***g/dL*** (default) – ***mmol/L***	
Height	– ***cm*** (default) – ***in***	
Weight	– ***lb/oz*** – ***kg/g*** **(default)**	

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 window

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
Network setup dialog window		
IP address	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 ghosted.
Net mask	User selectable; the default setting is: 255.255.0.0	Allows you to configure the subnet mask on the numeric keypad. Once you undock the M540 and it goes wireless, the selection is ghosted.
Default gateway	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 ghosted.
Name service dialog window		
Bed label	User selectable; the default setting is blank	Allows you to enter the bed label on the alphanumeric keypad (limited to 7 characters).
Mon. unit	User selectable; the default setting is blank	Allows you to enter the monitoring unit on the alphanumeric keypad (limited to 7 characters).
Care unit	User selectable; the default setting is blank	Allows you to enter the care unit on the alphanumeric keypad (limited to 7 characters).
Hospital	User selectable; the default setting is blank	Allows you to enter the name of the hospital on the alphanumeric keypad (limited to 7 characters).
Mon. unit ID	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
	Other dialog window	
Load profile **NOTE** The ***Load profile*** button appears greyed out until at least one profile has been saved.	***Off*** (default)	After docking, the M540 does not adopt the profile of the M500 but uses its own settings instead.
	Automatic	After docking, the M540 adopts the profile of the M500.
Profile settings	***All***	Patient and monitor settings are downloaded to the M540.
	Monitor (default)	Only monitor settings are downloaded to the M540.

Configuring the wireless network setup

To access the *Biomed* dialog window

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.

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

Keep bed label	***Yes*** (default)	– 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. – In standalone mode: The M540 retains the bed label configured on the M500.
	No	The M540 retains the bed label configured in the ***Wireless network*** dialog window 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. 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.
Bed label	User selectable; the default setting is blank	Allows you to enter the bed label on the alphanumeric keypad (limited to 7 characters). The ***Keep bed label*** setting determines what happens to the bed label – see above for detailed information.

Configuring the screen setup

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

To access the *Screen setup* dialog window

1 Press the ***Menu*** function key.

2 Touch the ***Screen setup*** tab.

***Screen setup* dialog window**		
Selection	**Available settings**	**Description**
***Settings* dialog window**		
Touch calib.	None	Calibrates the touch screen.
Flip screen	None	Flips the screen 180 degrees.
Autoflip	– ***Yes*** (default) – ***No***	Activates/deactivates automatic flipping of the screen.
Power save	***Off*** (default), 1, 2, 3, 4, 5 min	Selects the amount of time in minutes until the M540 goes into power save mode (see page 50).
***Screen views* dialog window**		
View 1 ***View 2*** ***View 3*** ***View 4*** ***View 5***	– ***1wav 4pbox*** – ***1wav 7pbox*** – ***2wav 5pbox*** – ***3wav 3pbox*** – ***1wav 3pbox*** – ***Off***	Selects a predefined view or deactivates the view by selecting Off (except View 1).
***Function keys* dialog window**		
Setup key 1 ***Setup key 2*** ***Setup key 3*** ***Setup key 4***	***Standby***, ***Code***, ***Discharge***, ***Record***, ***Privacy***, ***Mark***, ***Patient***, ***Rest ECG report***	Assigns a function to the user configurable function keys.

Configuring alarm settings

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

To access the *Alarm settings* dialog window

1 Press the ***Alarms*** function key.

2 Touch the ***Alarm settings*** tab.

***Alarms* dialog window**		
Selection	**Available settings**	**Description**
Alarm settings		
Speaker volume [1]	***Off***, ***5***, ***10***, ***20***, ***30***, ***40***, ***50***, ***60***, ***70***, ***80***, ***90***, ***100 %*** (default)	Sets the overall monitor volume and supersedes alarm tone volume. **NOTE** The setting ***Off*** is not available if there is no connection to the ICS.
All alarms pause or ***All alarms off***	None	When the ***All alarms pause*** 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 ***All alarms off*** 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 241.

NOTE
[1] This setting is a user default that is identical for all patient categories and is also part of the profile.

Options

The M540 supports the following options which are automatically unlocked:

– Full arrhythmia option

– 12 lead monitoring option

– Multi-IBP option for measuring more than two invasive blood pressures

The M540 also supports the wireless (WiFi) locked option which can be unlocked using a passcode. 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 passcode.

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.

Problem solving

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 84 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 table, messages are listed in alphabetical order. This table identifies 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.

Device communication messages / general device messages

Priority	Message	Cause	Remedy
None	***Audio paused by remote***	M540 alarms were paused by a remote device.	Informational message – no action required.
None	***Duplicate address***	The IP address or domain name is already in use.	Assign a unique IP address or domain name.
None	***Network alarm error*** **NOTE** An error tone accompanies this message.	The communication between a wireless M540 and the network is interrupted. The wireless M540 is not assigned to the ICS.	– Check network connections. – Assign the M540 to the ICS.
None	***Network error*** **NOTE** An error tone accompanies this message.	The communication between a docked M540 and the network is interrupted.	Check the connections between the M540, Cockpit, and the M500.

Priority	Message	Cause	Remedy
None	***Not monitored by central***	The communication between the ICS and the M540 is interrupted. A wireless M540 is out of range of the access point.	– Return the M540 within the range of the wireless access point. – Check the network connections. – Make sure the M540 is assigned correctly to an ICS.
None	***Offline***	A wireless M540 is undocked and does not have a bed label assignment. Disconnected network cable.	– Check the network connections. – Assign a bed label to the M540.
None	***Recording stored***	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	***Remote relearn***	The indicated function was initiated from the central station.	Informational message – no action required.
None	***Remote limit change***	The indicated function was initiated from the central station.	Informational message – no action required.
None	***Restore Profile Failed***	The profile could not be restored.	Try to restore the profile again before contacting your technical personnel.
None	***Save profile failed***	The profile could not be saved on the M540 and/or the M500.	Try to save the profile again before contacting your technical personnel.
None	***Profile transfer failed***	The profile failed to load on the M540 upon docking.	Undock and redock the M540 before contacting your technical personnel.

M540 battery messages

Priority	Message	Cause	Remedy
!	***Low battery***	The M540 is undocked and the battery charge has reached 10% of the remaining charge. An advisory tone sounds every 20 seconds.	Return the M540 to the M500 to recharge the battery.
!!	***Recharge battery***	The M540 is undocked and the battery charge has reached 5% of the remaining charge.	

ECG

Priority	Message	Cause	Remedy
!!!	***ASY***	The reported arrhythmia was detected	Check the patient and treat if necessary.
!!!	***Brady*** *(neonatal patient category)*		
!!!	***VF***		
!	***ECG artifact*** [2)]	– Patient movement (shivering, tremors) – Bad electrode contact – Excessive signal noise interference from auxiliary equipment	– Check the electrodes and reapply if necessary. – Make sure that the patient's skin is properly prepped. – Isolate the patient from auxiliary equipment, if possible.
!	***ECG leads off*** [2)]	Lead-off condition detected due to: – Broken cable(s) – Disconnected ECG lead wires – Loose lead wire(s) – Wrong lead selected – Dried out electrode gel	– Replace defective cable(s). – Reapply gel on reusable electrodes and reapply them or replace new disposable electrodes. – Select another ECG lead for processing. – If monitoring augmented leads, verify that the number of selected leads in the ***ECG*** setup page is correct. – Check cable(s) and connection(s) – Replace cable(s) if necessary
!	***ECG unplugged*** [2)]	ECG cable(s) disconnected from the M540.	
!!	***HR >*** (alarm limit) ***HR <*** (alarm limit)	The parameter value is above/below the set upper /lower alarm limits.	– Check the patient and treat if necessary. – Change the alarm limits.

NOTE

[2)] In the parameter box the parameter value is replaced by ***

Priority	Message	Cause	Remedy
!!	***HR out of range high*** [1]	The parameter value is above the measurement range of the monitor.	Check the patient and treat if necessary.
None	xx [3] ***Lead off***	The indicated lead is no longer attached to the patient.	Reattach the electrode to the patient.

NOTE

[1] In the parameter box the parameter value is replaced by +++

[3] xx represents LA, LL, RA, RL, V, V1 to V6, or V+

ST

Priority	Message	Cause	Remedy
!	***Cannot analyze ST*** [3]	The algorithm cannot determine ST values due to artifact, the absence of normal beats, or invalid leads.	– Perform a relearn (see page 150). – Check electrodes; re-apply if necessary. – Make sure the patient's skin is properly prepared. – Isolate the patient from auxiliary equipment if possible. – Inspect and replace defective cable(s) and wire(s). – Reapply gel on reusable electrodes and reapply them or replace new disposable electrodes. – Reapply the electrode(s). Make sure the patient's skin is properly prepared. – If a lead or electrode cannot be replaced, select another ST lead.

NOTE

[3] In the parameter box the parameter value is replaced by ***

Priority	Message	Cause	Remedy
!!	***ST***<label> [4] > (alarm limit) ***ST***<label>[4] < (alarm limit)	The parameter value is above/below the set upper /lower alarm limits.	– Check the patient and treat if necessary. – Change the alarm limits.
!!	***ST***<label> [4] ***out of range high*** [2]	The parameter value is above/below the measurement range of the monitor.	– Check the patient and treat if necessary. – Check the placement of electrodes and change their position if necessary.
!!	***ST***<label> [4] ***out of range low*** [1]		
None	***ST relearning***	ST relearn is in progress	Informational message – no action required.

NOTE

[1] In the parameter box the parameter value is replaced by - - -

[2] In the parameter box the parameter value is replaced by +++

[4] <label> represents I, II, III, aVR, aVL, aVF, V, V1 to V6, or V+

Arrhythmia

Priority	Message	Cause	Remedy
!!!	***ASY***	The indicated arrhythmia was detected.	– Check the patient and treat if necessary. – Some messages only appear when the full arrhythmia option is installed.
!!	***AIVR*** [1)]		
Off	***ARR artifact*** [1)]		
!	***BGM*** [1)]		
Off	***Brady*** [1)]		
!	***CPT*** [1)]		
Off	***Pause*** [1)]		
!!	***RUN*** [1)]		
!!	***SVT*** [1)]		
Off	***TACH*** [1)]		
!!!	***VF***		
!!!	***VTACH*** [1)]		
None	***ARR cannot learn*** (arrhythmia lead)	After 100 beats, the M540 cannot determine the dominant normal complex on any lead selected for QRS processing.	– Check the electrode preparation. – Reapply electrodes if necessary.
None	***ARR relearning***	The M540 is learning the patient's QRS complex to establish a reference template.	Informational message – no action required.
!!	***PVC/min >*** (alarm limit)	PVC value is above the upper alarm limit.	– Check the patient and treat if necessary. – Reapply electrodes if necessary.

NOTE

[1)] 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.

Respiration (RRi)

Priority	Message	Cause	Remedy
!!	***RRi >*** (alarm limit) ***RRi <*** (alarm limit)	The parameter value is above/below the set upper /lower alarm limits.	– Check the patient and treat if necessary. – Check the alarm limits.
!!!	***RRi apnea***	Neonatal apnea condition was detected.	– Check the patient and treat if necessary. – Check the placement of electrodes. Change their position if necessary. – Initiate a relearn or reset breath-detection sensitivity in manual mode.
!!	***RRi apnea***	Adult or pediatric apnea condition was detected.	
!	***RRi artifact*** [2)]	Persistent artifact was detected.	– Check the patient and treat if necessary. – Make sure the patient's skin is prepared properly. – Isolate the patient from any auxiliary equipment, if possible. – Reapply gel on reusable electrodes and reapply them or replace new disposable electrodes. – Inspect and replace defective cables and wires. – If a lead or electrode cannot be replaced, select another lead for processing (in the RRi setup page).
!	***RRi high impedance*** [2)]	A high respiration impedance was detected.	
!	***RRi lead off*** [2)]	The respiration lead has been invalid for 10 seconds.	
!	***RRi lead unavailable*** [2)]	Faulty or disconnected electrodes.	

NOTE

[2)] In the parameter box the parameter value is replaced by ***

Priority	Message	Cause	Remedy
!!	***RRi coincidence***	The heart rate and respiration rate fall within 20 % of each other.	– Check the patient and treat if necessary. – Check and change the electrode placement if you receive a coincidence message until you obtain a clear respiration signal.
!!	***RRi out of range high*** [1)]	The respiration rate is higher than 150 breaths per minute.	– Check the patient and treat if necessary. – Check the placement of electrodes. Change their position if necessary. – Move the electrodes away from the source of interference.
		The M540 may be counting artifacts as valid breaths.	
		The M540 may be counting interference caused by faulty equipment.	
None	***RRi relearning***	Relearn is in progress	Informational message – no action required.

NOTE

[1)] In the parameter box the parameter value is replaced by +++

SpO_2

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	***Learning Pulse CO-Ox*** [3]	The Masimo rainbow SET-specific parameters are being calculated (only the parameters for SpO_2, PLS, and PI are available).	Wait until the Masimo rainbow SET parameters are calculated.
None Any Masimo MCable	***Low SpO_2 SIQ***	MCable detects a low signal quality for the indicated parameter.	– Check the patient and treat if necessary. – Make sure the SpO_2 sensor is attached properly to the patient. – Check all cable connections.
None Masimo rainbow SET only	***Low SpHb SIQ*** ***Low SpHbv SIQ*** ***Low SpOC SIQ*** ***Low SpMet SIQ*** ***Low SpCO SIQ*** ***Low PVI SIQ***		
!!	***PLS >*** (alarm limit) ***PLS <*** (alarm limit)	The pulse rate above/below the set upper/lower alarm limits.	– Check the patient and treat if necessary. – Change the alarm limits.
!!	***PLS out of range high*** [1] ***PLS out of range low*** [2]	The parameter value is above/below the measurement range of the monitor.	– Check the patient and treat if necessary. – Change the alarm limits.

NOTE

[1] In the parameter box the parameter value is replaced by - - -

[2] In the parameter box the parameter value is replaced by +++

[3] In the parameter box the parameter value is replaced by ***

Priority	Message	Cause	Remedy
!!	***SpHb*** > (alarm limit) ***SpHbv*** < (alarm limit) ***PVI*** > (alarm limit) ***PVI*** < (alarm limit) ***SpCO*** > (alarm limit) ***SpCO*** < (alarm limit) ***SpMet*** > (alarm limit) ***SpMet*** < (alarm limit)	The parameter value is above/below the set upper / lower alarm limits.	– Check the patient and treat if necessary. – Change the alarm limits.
!!	***SpO2 >*** (alarm limit) ***SpO2 <*** (alarm limit)	The parameter value is above/below the set upper / lower alarm limits. **NOTE** In neonatal mode, the priority changes to high (!!!) if the SpO2 value falls more than 10 % below the lower limit. This does not occur when using ***SatSeconds*** time with the Nellcor OxiMax MCable.	– Check the patient and treat if necessary. – Change the alarm limits.
! Masimo rainbow SET only	***SpO2 cable failure*** 3)	The Masimo rainbow SET intermediate cable is faulty or has expired.	Replace the intermediate cable.
! Nellcor OxiMax MCable only	***SpO2 check sensor*** 3)	SpO2 sensor is detecting too much ambient light.	– Make sure the SpO2 sensor is attached properly to the patient. – Check all cable connections.
None Masimo rainbow SET only	***SpO2 Sensor Calibrating*** 3)	The sensor is being checked for proper functioning.	– Wait until the message disappears. This message appears right before the message ***SpO2 searching***.

NOTE

3) In the parameter box the parameter value is replaced by ***

Priority	Message	Cause	Remedy
! Any SpO_2 MCable	***SpO_2 H/W failure*** [3]	Masimo SET MCable or Nellcor OxiMax MCable hardware failure.	– Check for defective MCable – Power cycle the M540 to clear the message. – Contact Dräger Technical support.
! Any Masimo MCable	***SpO_2 interference detected*** [3]	Interference such as artifact was detected.	– Make sure the sensor is properly attached. – Make sure that no nail polish or some other substance is blocking the light. – Change the sensor location.
None Any Masimo MCable	***SpO_2 low perfusion***	Arterial pulsations with low amplitudes were detected.	– Check the patient and treat if necessary. – Move the sensor to a site that is more adequately perfused. – Select the maximum sensitivity mode (see page 175)
! Any SpO_2 MCable	***SpO_2 MCable unplugged*** [3] **NOTE** In the parameter box the parameter value is replaced by blanks for the Masimo rainbow SET parameter PI.	The SpO_2 MCable is disconnected from the M540.	Check connections to the M540.

NOTE

[3] In the parameter box the parameter value is replaced by ***

Priority	Message	Cause	Remedy
Masimo rainbow SET only	***SpO2 only mode*** **NOTE** Parameter values are displayed for SpO_2, PLS, and PI; 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 your technical personnel.
None Any SpO_2 MCable	***SpO_2 searching*** [3]	The sensor is searching for valid pulses to compute a measurement value.	Verify proper sensor application.
! Any SpO_2 MCable	***SpO_2 sensor failure*** [3]	The MCable has detected a hardware failure with the SpO_2 sensor.	– Make sure the SpO_2 sensor is properly attached to the patient and all cables are properly connected. – Replace sensor. – Contact Dräger Technical support.
! Any Masimo MCable	***SpO_2 sensor off*** [3]	The Masimo MCable has detected that the SpO_2 sensor is no longer attached to the patient.	Reattach the SpO_2 sensor.
!	***SpO_2 sensor unplugged*** **NOTE** In the parameter box the parameter value is replaced by the following depending on which MCable is used: *** for the parameters SpO_2, PLS, SpHb/SpHbv, PVI, SpCO, SpOC, SpMet; blanks for the parameter PI.	The SpO_2 intermediate cable or sensor is unplugged.	– Verify that the cable and the sensor are properly connected. – Check for defective sensor.

NOTE

[3] In the parameter box the parameter value is replaced by ***

Priority	Message	Cause	Remedy
! Any SpO_2 MCable	***SpO_2 unrecognized sensor*** [3)]	– The MCable does not recognize the connected sensor. – A reusable SpHb sensor is connected to a Masimo rainbow SET MCable that does not support this parameter.	– Connect the right type of sensor. – Contact your technical personnel.

NOTE

[3)] In the parameter box the parameter value is replaced by ***

Non-invasive blood pressure

Priority	Message	Cause	Remedy
!!	***NIBP D >*** (alarm limit) [1)] ***NIBP D <*** (alarm limit) [1)] ***NIBP M >*** (alarm limit) [1)] ***NIBP M <*** (alarm limit) [1)] ***NIBP S >*** (alarm limit) [1)] ***NIBP S <*** (alarm limit) [1)]	The parameter value is above/below the set upper /lower alarm limits.	– Check the patient and treat if necessary. – Change the alarm limits.
!!	***NIBP blocked line*** [1)]	The inflation rate is too high or the time to evacuate residual cuff pressure at the end of the deflation cycle is too short.	– Select a different cuff. – Check the hose and cuff for damage. – Restart the measurement. If the message does not clear, contact Dräger Technical Support.
!	***NIBP cannot measure*** [1)]	The pulse profile is too poor to establish a reliable measurement (usually due to persistent motion artifact)	– Check the patient and treat if necessary. – Move the cuff to a limb with less movement. – Restart the measurement. If the message does not clear, contact your technical personnel or Dräger Technical Support.
!	***NIBP cuff leak*** [1)]	The drop in cuff pressure at the end of the inflation cycle is too great.	– Check the hose and cuff for leaks. Replace if necessary. – Restart the measurement. If the message does not clear, contact Dräger Technical Support.

NOTE

[1)] In the parameter box the parameter value is replaced by ***

Priority	Message	Cause	Remedy
!!	***NIBP H/W failure*** [1]	– Non-invasive blood pressure measurement circuit failure – Non-invasive blood pressure zero out of range or faulty transducer	– Check all hardware, contact Dräger Technical support. – Power cycle the M540 to clear this message.
!!	***NIBP low inflation limit*** [1] [2]	The pressure of the patient is greater than the maximum allowed cuff inflation pressure.	Select the next higher inflation limit setting.
!	***NIBP mean only*** [1] [2]	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.	– Check the patient and treat if necessary. – Check the hose and cuff. – Check the size and the placement of the cuff.
!	***NIBP measurement timeout*** [1]	An non-invasive blood pressure measurement has exceeded time-out limit.	Repeat the measurement.
!	***NIBP open line*** [1]	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.
!!	***NIBP out of range high***	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).
!!	***NIBP out of range low***		
!	***NIBP overpressure*** [1]	The cuff pressure has exceeded the overpressure threshold.	– Check the patient and treat if necessary. – Check the cuff for obstructions. – Repeat the measurement.

NOTE

[1] In the parameter box the parameter value is replaced by ***

[2] In the parameter box the systolic and diastolic parameter values are replaced by ***

Priority	Message	Cause	Remedy
None	***NIBP pneumatic char needed***	Non-invasive blood pressure hardware failure in the M540.	Contact your technical personnel and take the M540 out of service.
None	***NIBP pneumatic char failed***	Technical hardware failure.	Contact your technical personnel and take the M540 out of service.
None	***Venous stasis started***	Message reports the start of venous stasis.	Informational message – no action required).
None	***Venous stasis ended***	Message reports the end of venous stasis.	Informational message – no action required).
None	***Venous stasis ending***	Message reports that venous stasis is ending in less than 10 seconds.	Informational message – no action required).

Cardiac output

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
!	***Cannot derive ΔT*** [3) 4)] ***Cannot derive ΔT1*** ***Cannot derive ΔT2***	One of the cables is either unplugged or defective, or the value is out of range.	– Check the equipment and replace it if necessary. – Connect the second temperature probe.
!!	***T >*** [4)] > (alarm limit) ***T <*** [4)] < (alarm limit)	The parameter value is above/below the set upper/lower alarm limits.	– Check the patient and treat if necessary. – Change the alarm limits.
!	***Tx H/W failure*** [3)]	The hardware reference values do not meet the specified tolerance.	Contact Dräger Technical Support.
!!	***Temp out of range high*** [2)]	The parameter value is above/below the measurement range of the monitor.	– Check the patient and treat if necessary. – Check the equipment and replace, if necessary.
!!	***Temp out of range low*** [1)]		
!	***T unplugged*** [3)]	The temperature probe is unplugged.	Reapply the temperature probe.

NOTE

[1)] In the parameter box the parameter value is replaced by - - -

[2)] In the parameter box the parameter value is replaced by +++

[3)] In the parameter box the parameter value is replaced by ***

[4)] Value can be for Ta/T1a, Tb/T1b, ΔT/ΔT1

Invasive blood pressure

Priority	Message	Cause	Remedy
!!	***CPP >*** (alarm limit)	The parameter value is above/below the set upper/lower alarm limits.	– Check the patient and treat if necessary. – Change the alarm limits.
!!	***CPP <*** (alarm limit)		
!!	***CPP out of range high*** [2)]	The pressure rate falls outside the measuring range of the monitor.	– Check the patient and treat if necessary. – Check the equipment and replace, if necessary.
!!	***CPP out of range low*** [1)]		
!	***HemoPod unplugged*** [3)]	The invasive blood pressure pod is disconnected.	Check the equipment and replace if necessary.
!!	IBP x [4)] > (alarm limit)	The parameter value is above/below the set upper/lower alarm limits.	– Check the patient and treat if necessary. – Change the alarm limits.
!!	IBP x [4)] < (alarm limit)		
!!	IBP x [4)] > ***out of range high***	The pressure signal falls outside the measuring range of the monitor.	– Check the patient and treat if necessary. – Check the equipment and replace, if necessary.
!!	IBP x [4)] < ***out of range low***		
None	<IBP> ***check zero***	The invasive blood pressure zero value stored in the M540 was lost and the transducer requires zeroing.	Zero the transducer.

NOTE

[1)] In the parameter box the parameter value is replaced by - - -

[2)] In the parameter box the parameter value is replaced by +++

[3)] In the parameter box the parameter value is replaced by * * *

[4)] x represents S (systolic), D (diastolic), or M (mean)

Priority	Message	Cause	Remedy
None	<IBP> ***did not zero***	Transducer zeroing failed because of: – excessive signal noise – a non-static waveform	– Keep all tubing motionless, then rezero. – Change the transducer. – Check stopcock, then rezero.
!	***IBP H/W failure*** [3]	Invasive blood pressure hardware failure.	– Check hardware and replace if necessary. – Call your technical personnel or Dräger Technical Support.
!!	<IBP> ***static pressure***	Static pressure detected on a pulsatile signal, due to: – a physiological condition such as an asystole – a transducer that is closed to the patient – a catheter tip that is lodged against a vessel wall – a clot on the catheter tip	– Check the patient and treat if necessary. – Open the system to the patient by turning the stopcock. – Follow hospital procedures for dislodging catheters. – Follow hospital procedures for clotted catheters.
!	***HemoPod unplugged*** [1]	The pressure transducer for the specified parameter is either unplugged or defective.	– During an active pressure: Reconnect or replace the cable. – During an inactive pressure: Turn off alarms.
None	<IBP> ***Zero accepted***	Transducer zeroing was successful.	Informational message – no action required.

NOTE

[1] In the parameter box the parameter value is replaced by - - -

[3] In the parameter box the parameter value is replaced by * * *

CO_2

Priority	Message	Cause	Remedy
!!	***etCO2 >*** (alarm limit) ***etCO2 <*** (alarm limit) (except inCO_2)	The parameter value is above/below the set upper/lower alarm limits.	– Check the patient and treat if necessary. – Change the alarm limits.
!	***CO2 check airway adapter*** [1]	– The mainstream sensor is not properly seated on the adapter – There are secretions in the adapter. – There is sensor zero drift	– Make sure the mainstream sensor is attached properly to the adapter. – If message persists, clean or replace the airway adapter. – If message persists though the airway adapter is clean, zero the sensor.
!	***CO2 H/W failure*** [1]	CO_2 sensor hardware failure.	Contact your technical personnel.
!	***CO2 incompatible sensor*** [1]	– The M540 has detected that the used mainstream sensor is not compatible with the selected sensor type setting (reusable/disposable) – Secretions in the adapter – Sensor zero drift – High inspiratory CO_2 concentration	– Use the airway adapter type the system is configured for or adjust the airway adapter setting (see page 251). – If the message persists, clean or replace the airway adapter. – If the message persists even though the correct airway adapter type is selected and the airway adapter is clean, zero the sensor. – If the message still persists, the inspiratory CO_2 value might not be accurate. Check the patient and ventilation.

NOTE

[1] In the parameter box the parameter value is replaced by ***

Priority	Message	Cause	Remedy
!!	***CO_2 out of range*** [1]	The parameter signal is outside the measuring range of the monitor.	– Check the patient and treat if necessary. – Check the equipment and replace if necessary.
None	***CO_2 please zero***	Instructional message for the mainstream sensor only.	Zero the mainstream sensor.
!	***CO_2 sensor too warm*** [1]	The CO_2 mainstream sensor is too warm due to ambient temperature.	– Unspecified accuracy at ambient temperatures above 40 °C (104 °F). – The sensor will return to normal operation at ambient temperatures below 40 °C (104 °F). If not, replace the sensor and contact Dräger Technical Support.
!	***CO_2 unplugged*** [1]	The CO_2 sensor is disconnected.	Check the CO_2 connections.
None	***CO_2 zero failed***	Zeroing of the sensor has failed or the sensor is defective.	– Try to zero the sensor again making sure not to breathe on the sensor. – If zeroing fails again, replace the sensor and contact Dräger Technical Support, if the message persists.

NOTE

[1] In the parameter box the parameter value is replaced by ***

Priority	Message	Cause	Remedy
None	***CO_2 warming up***	The mainstream sensor is going through the warm-up cycle.	– Wait for the mainstream sensor to warm up. During warm-up, the accuracy is reduced. – 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 Dräger Technical Support. **NOTE** You cannot zero the sensor when this message is displayed and the ambient temperature is above 10 °C (50 °F). When the ambient temperature is below 10 °C (50 °F), the message can persist 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.
None	***CO_2 zero in progress***	The CO_2 zeroing is in progress	Informational message – no action required.
!!	***RRc apnea***	Apnea was detected	– Check the patient and treat if necessary. – Check the placement of sensor.

NOTE

[1] In the parameter box the parameter value is replaced by ***

Maintenance

Overview

This chapter describes the maintenance measures required to maintain the proper functioning 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 pathogenic germs.

Disinfect and clean the device or the device parts 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 DrägerService to perform these measures.**

WARNING

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

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 DrägerService through your vendor. For repairs we recommend that you contact DrägerService.

CAUTION

When servicing devices from Dräger, always use replacement parts that are qualified to Dräger standards. Dräger cannot warrant or endorse the safe performance of third-party replacement 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 technical personnel to test any such component is fully operational before putting it back in clinical use.

Definition of maintenance concepts

Concept	Definition
Maintenance	All measures (inspection, preventive maintenance, repair) intended to maintain and restore the functional condition 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 condition of a medical device.
Repair	Measures intended to restore the functional condition of a medical device after a device malfunction.

Inspection

Perform inspections at regular intervals and observe the following specifications.

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, leads and strain reliefs for general condition. Make sure the connectors are properly engaged at each end.

Inspection / safety checks

Inspection and safety checks of devices must be performed according to the suggested intervals specified in the table on page 285.

Scope of inspection/safety checks for the M540

Safety checks are no substitute for preventive maintenance measures (including preventive replacement of wear 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 device checks (for example, communication with the IACS, front panel buttons, alarm bar, and correct functioning of 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 IEC62353 every two years by qualified Dräger service personnel.

5 Check the following safety features:

- The power LED and the battery indicator LED function properly.
- Check the correct functioning of the Infinity MCable – Nurse call.
- Correct functioning of the visual and acoustic alarm signals
- Correct functioning of the  button located on the front panel of the device
- Correct functioning of the non-invasive blood pressure overpressure sensor (including the valves and the pump)

6 Check the battery every two years and make sure the M540 runs on battery power 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 qualified DrägerService personnel:

- Body temperature
- Non-invasive blood pressure

Preventive maintenance

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:

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

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Cleaning and disinfection

Overview of cleaning and disinfecting the M540 and its accessories

Clean and disinfect the device or device parts before each maintenance step – and also when returning for repair.

Continuous exposure to moisture can damage the M540 and its peripheral devices. Please read the following instructions carefully before cleaning any device.

- Do not spray cleaning agents on the M540 or peripheral devices. Wipe them with a cloth moistened with soapy water.
- Disinfect the surfaces with a gauze moistened with one of the approved agents (see page 291).
- Dry thoroughly with a lint-free cloth.

Before cleaning any device, read the general safety precautions under "General safety information" on page 9.

Cleaning and disinfecting precautions

WARNING

Because of the danger of electric shock, never remove the cover of any device while it is in operation or connected to power.

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, disconnect the device from the power source and allow it to dry completely for at least 24 to 48 hours. Contact your technical personnel regarding the continued safety of the device and its peripherals before placing it back in operation.

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

Never immerse electrical connectors or the NIBP connector.

Approved cleaning agents

Clean and disinfect the device or device parts per hospital approved protocol. Agents tested by Dräger and shown to have no harmful effect at the time of testing on the materials utilized in the device include:

– Isopropyl alcohol 40 %

CAUTION
If using alcohol, it should only be a 40 % diluted solution. Higher concentrations could damage the device.

– Compliance (not for use on touch screen); this cleaning agent may discolor soft plastic material
– Sporox II (not for use on touch screen)
– Dismozun pur
– Amonia-based glass cleaner (M540 touch screen only)
– Isopropyl alcohol (40 % solution)

Dräger makes no claims regarding the efficacy of the listed chemicals, their methods as a means for disinfecting, the ability of the agents to control infection, their environmental impact, safe handling, or any related precautions in their use. Refer to the information provided by the manufacturer of the cleaning solution for more information in these areas.

Cleaning and disinfecting the M540, M500, and power supply

Use only the approved cleaning agents listed on page 291, unless otherwise specified.

M540, M500, and power supply precaution

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, disconnect the device from the power source and allow it to dry completely for at least 24 to 48 hours. Contact your technical personnel regarding the continued safety of the device and its peripherals before placing it back in operation.

To clean the M540 and M500

1 Clean the M540/M500 with a gauze pad moistened with soapy water or with an approved cleaning agent.

2 Dry thoroughly with a lint-free cloth.

To disinfect the M540 and M500

1 Disinfect the M540/M500 with a gauze pad moistened with diluted alcohol.

2 Dry thoroughly with a lint-free cloth.

CAUTION

Do not steam autoclave, gas sterilize, or immerse the M540 in liquid or cleaning solutions. Do not subject the M540 to intense vacuum.

To clean the power supply

Clean the outside enclosure of the power supply PS50 with a cloth dampened with diluted alcohol.

Cleaning and disinfecting an MCable and MPod

Use only the approved cleaning agents listed on page 291, unless otherwise specified.

MCable precautions

CAUTION
Do not sterilize by irradiation, steam, heat, or ethylene oxide.

CAUTION
Do not use sharp tools or abrasives to clean the MCables.

To clean an MCable and MPod

1 Disconnect the MCable from the M540.

2 Clean the MCable with a gauze pad moistened with soapy water or with an approved cleaning agent.

3 Dry thoroughly with a lint-free cloth.

To disinfect an MCable and MPod

1 Disconnect the MCable from the M540.

2 Disinfect the MCable with a gauze pad moistened with diluted alcohol.

3 Dry thoroughly with a lint-free cloth.

CAUTION
Do not immerse a SpO_2 sensor or an MCable in water, organic solvents, or cleaning solutions. Make sure that NO liquid enters an MCable.

To clean and disinfect a reusable SpO_2 sensor

- Refer to the cleaning instructions and recommendations provided with the sensor.

Cleaning and disinfecting patient cables

Use only the approved cleaning agents listed on page 291, unless otherwise specified. The following procedures apply to all patient cables.

Patient cable precautions

CAUTION
Do not immerse the patient cables in any liquid.

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

To clean patient cables

1. Disconnect the patient cable from the M540.
2. Clean the patient cables with a gauze pad moistened with soapy water or with an approved cleaning agent.
3. Dry thoroughly with a lint-free cloth.

To disinfect patient cables

1. Disconnect the patient cable from the M540.
2. Disinfect patient cables with a gauze pad moistened with diluted alcohol.
3. Dry thoroughly with a lint-free cloth.

Cleaning and disinfecting reusable ECG lead wires

Use only the approved cleaning agents listed on page 291, unless otherwise specified.

To clean ECG lead wire

1. Disconnect the lead wires from the M540.
2. Clean the reusable ECG electrodes. regularly with a toothbrush and water to remove any gel residue.
3. Wipe the ECG lead wires with a gauze pad moistened with soapy water or with an approved cleaning agent.
4. Dry thoroughly with a lint-free cloth.

To disinfect ECG lead wire

1. Disconnect the ECG lead wires from the M540.
2. Disinfect the ECG lead wires with a gauze pad moistened with diluted alcohol.
3. Dry thoroughly with a lint-free cloth.

Cleaning and disinfecting temperature sensors and cables

Use only the approved cleaning agents listed on page 291, unless otherwise specified.

Temperature probe and cable precautions

CAUTION
Do not immerse the patient cables in any liquid.

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

CAUTION
Never boil or autoclave the cable. Vinyl can withstand temperatures up to 100 °C (212 °F) but begins to soften around 90 °C (194 °F). Handle gently when hot and wipe away from the tip, toward the cables.

To clean temperature cables

1. Disconnect the temperature cable from the M540.
2. Clean the temperature cables with a gauze pad moistened with soapy water or with an approved cleaning agent.
3. Dry thoroughly with a lint-free cloth.

To clean temperature sensors

1. Clean the temperature sensors with a gauze pad moistened with a 30 % hydrogen peroxide or 40 % alcohol solution.
2. Dry thoroughly with a lint-free cloth.

To disinfect temperature cables

1. Disconnect the temperature cable from the M540.
2. Disinfect temperature cables with a gauze pad moistened with diluted alcohol.
3. Dry thoroughly with a lint-free cloth.

To disinfect temperature probes

- Refer to the recommendations provided with the probes.

Cleaning non-invasive blood pressure cuffs

Non-invasive blood pressure precaution

CAUTION
The non-invasive blood pressure cuff can be immersed in cleaning solution, but do not allow the solution to enter the non-invasive blood pressure hose. The warranty is void if cleaning solution is allowed to enter the hose or the cuff.

To clean non-invasive blood pressure cuffs

1 Disconnect the non-invasive blood pressure hose from the M540.

2 Wipe the non-invasive blood pressure cuff with a cloth moistened with soapy water or a sodium hypochlorite solution (1:10), alcohol, or phenol.

3 Dry thoroughly with a lint-free cloth.

Cleaning and disinfecting invasive blood pressure transducers and hemodynamic pods

Transducers

Always handle transducers and other pressure accessories with great care. Do not apply excessive pressure to a transducer diaphragm.

CAUTION
Do not allow liquids to enter the connector.

To clean and sterilize transducers

Refer to the cleaning instructions and recommendations provided with the transducer.

To clean transducer plates

1 Remove the transducer mounting plate from the front of the hemodynamic pod.

2 Wash the plate with hot soapy water.

To clean hemodynamic pods

1 Disconnect the hemodynamic pod from the M540.

2 Wipe the hemodynamic pod with a gauze pad moistened with an enzymatic detergent or a solution of green tinctured soapy water.

NOTE
Do not spray cleaning agents on the hemodynamic pod.

3 Dry thoroughly with a lint-free cloth.

To disinfect hemodynamic pods

1 Disinfect the surfaces with a gauze pad moistened with diluted alcohol.

2 Dry thoroughly with a lint-free cloth.

Cleaning and disinfecting mainstream CO_2 sensors and airway adapters

Use only the approved cleaning agents listed on page 291, unless otherwise specified.

Mainstream sensors and airway adapters precaution

WARNING

To reduce the risk of infection, remember that the disposable airway adapters are for single patient use only and cannot be sterilized.

To clean mainstream sensors

1. Disconnect the sensor cable from the M540 and then disconnect the airway adapter from the sensor cable.
2. Wipe the sensor, particularly the sensor windows, with a cotton swab to remove dirt.
3. Dry thoroughly with a lint-free cloth.

To disinfect mainstream sensors

1. Disconnect the airway adapter cable from the M540 and then disconnect the sensor from the sensor cable.
2. Wipe the sensor with a cotton swab moistened with diluted alcohol.
3. Dry thoroughly with a lint-free cloth.

To clean reusable airway adapters

1. Disconnect the sensor from the airway adapter.
2. Wipe the airway adapter with a cotton swab to remove dirt.
3. Rinse the airway adapter in warm soapy water, then soak it in an approved cleaning agent.
4. Dry thoroughly with a lint-free cloth, making sure that the adapter windows are dry and free of any residue before they are used.

To disinfect reusable airway adapters

Refer to the recommendations provided with the airway adapters.

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Disposal

EU Directive 2002/96/EC (WEEE)

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, M500 and instructions for use

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.

Technical data

Overview

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 Cockpit*.

System compatibility

An M540 is compatible with the following devices and applications.

Device/Application	**Compatible software version**
ICS	VF8 or higher
Display module	VG2
Innovian	VF6 or higher
Symphony	VF7 or higher
Gateway	VF6 or higher

Infinity M540

Physical specifications	
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 lbs)
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	Touch screen plus 3 fixed keys

Connectors	
Input/output ports	– ECG – NIBP – Temperature/Auxillary – SpO_2 – Hemo CO_2 – CO_2
Display attributes	
Display type	Color Liquid Crystal Display (LCD), Advanced Touch Screen
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^2 minimum during battery operation 110 cd/m^2 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.
Acoustic attributes	
Minimum acoustic tone	45 dB(A); full volume >70 dB(A)
Alarms	Alarm levels: high priority, medium priority, low priority
System alarm delay	≤3 s
Electrical specifications	
Power source	Internal lithium-ion battery or external power from the M500, 24 V
Battery pack	Lithium: 7.5 VDC, 2400 mAh
Protection class	Internally powered (per IEC 60601-1)
Battery operating time	Normal operation: approximately 3 hours Power save mode: approximately 4 hours **NOTE** The battery life depends on the monitoring configuration. The specified battery charge is for the following load conditions: 12-Lead ECG, SpO_2, temperature probes, non-invasive blood pressure in 15 min interval mode, and LCD at transport (battery operation). Power save mode disables the LCD.
Battery recharging time	100 % capacity: approximately 6.5 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)
Environmental specifications	
Humidity (non condensing)	Operating: 20 to 95 % Storage: 20 to 95 %
Temperature	Operating: 0 to 40 °C (32 to 104 °F) **NOTE** At ambient temperatures above 35 °C (95 °F) the battery may not be charging even while it is docked in the M500; however, the battery icon still indicates the actual battery charge. Storage: –20 to +60 °C (–4 to +140 °F)
Atmospheric pressure	Operating: 485 to 795 mmHg (64.7 to 106 kPa) Storage: 375 to 795 mmHg (50 to 106 kPa)
Drop IEC 60068-2-32: 1975 +A1: 1982, +A2: 1990, Procedure 1	Drop once on each of six surfaces from a height of 1 m (3.2 ft)
Transportation	Per International Safe Transit Association (ISTA)
Risk management	
Fire protection	IEC 60601-1: 1988, clause 43
Protection against liquid ingress	IPX4 (protected against splashing water) per IEC 60529
Communications	
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 WLAN standards. Supports WPA2 security.

Infinity M500

Physical specifications	
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 lbs)
Cooling	Convection
Materials	Enclosure: polyamide (PA) and ABS
Mounting	VESA 75
Connectors	
Input/output ports	– System cable connector – Nurse call connector
Electrical specifications	
DC input	24 VDC nominal, 1.5 A (18 to 30 VDC)
Protection class	Internally powered (per IEC 60601-1) for use with specified Class I power supply
Mode of operation	Continuous
Power output	26 W nominal
Humidity (non condensing)	Operating: 20 to 95 % Storage: 20 to 95 %
Temperature	Operating: 0 to 35 °C (32 to 95 °F) Storage: –20 to +60 °C (–4 to +140 °F)
Atmospheric pressure	Operating: 485 to 795 mmHg (64.7 to 106 kPa) Storage: 375 to 795 mmHg (50 to 106.0 kPa)
Transportation	Per International Safe Transit Association (ISTA)
Risk management	
Protection against liquid ingress	IPX1 (protected against vertically falling water drops) per IEC 60529
Communications	
Internal network (M540)	802.3 100BaseT Ethernet (optically isolated)

Power supply (PS50)

Physical specifications	
Dimensions (W x H x D)	76 x 146 x 43 mm (2.99 x 5.75 x 1.69 in)
Weight	400 to 550 g (0.88 to 1.2 lbs)
Cable length (from power supply to DC output connector)	1.82 m (71.7 in)
Display attributes	
LED	Power (green)
Humidity (non-condensing)	Operating: 5 to 95 % Storage: 5 to 95 %
Temperature	Operating: 0 to 70 °C (32 to 158 °F) Storage: –40 to +85 °C (–40 to +185 °F)
Atmospheric pressure	Operating: 485 to 795 mmHg (64.7 to 106 kPa) Storage: 375 to 795 mmHg (50 to 106 kPa)
Electrical specifications	
Input voltage	100 VAC to 240 VAC (±10 %)
Input frequency	50 to 60 Hz (±5 %)
Input current	1.35 A max at 115 VAC 0.7 A max at 230 VAC
Inrush current	15 A at 115 VAC or 30 A at 230 VAC at 25 °C (77 °F) cold start
Leakage current	0.1 mA max at 230 VAC, 50 Hz
Output voltage	24 V
Maximum output power	50 W
Total regulation	±5 % maximum at full load, includes tolerance Line and load regulation
Risk management	
Classification	Meets conducted and radiated limits of CISPR11 Class B and EN55011 Class B

Infinity MCable – Mainstream CO_2

Physical specifications	
Size (W x H x D)	30 x 50 x 20 mm (1.18 x 1.97 x 0.79 in)
Weight (without cable)	30 g or less (0.066 lb or less)
Cable length	2.5 m (98.4 in)
Connections	Single cable connecting to the M540
Environmental specifications	
Humidity (non-condensing)	Operating: 5 to 95 % Storage: 5 to 95 %
Temperature	Operating: 10 to 40 °C (50 to 104 °F) Storage: –40 to 75 °C (–40 to +167 °F)
Atmospheric pressure	Operating: 428 to 825 mmHg (57 to 110 kPa) Storage: 86 to 825 mmHg (11.5 to 110 kPa)
Electrical specifications	
Power source	Powered directly from the M540
Mode of operation	Continuous
Risk management	
Protection against electrical shock	Type BF
Protection against liquid ingress	IPX4 (protected against splashing water) per IEC 60529

Infinity MCable – Masimo SET and Infinity MCable – Masimo rainbow SET

Physical specifications	
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
Environmental specifications	
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)
Electrical specifications	
Power source	Powered directly from the M540
Input voltage	5 V nominal
Maximum power consumption	500 mW / 1 W
Mode of operation	Continuous
Risk management	
Protection against electrical shock	Type CF
Protection against liquid ingress	Masimo SET: IPX1 (protected against vertically falling water drops) per IEC 60529 Masimo rainbow SET: IPX2 (protected against vertically falling water drops with enclosure tilted up to 15°) per IEC 60529
Defibrillator protection	Per IEC60601-1

Infinity MCable – Nellcor OxiMax

Physical specifications	
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 lbs)
Cable length	300 mm (11.8 in)
Connections	Single cable connecting to the M540 Nellcor cable connector for sensor cable
Environmental specifications	
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)
Electrical specifications	
Power source	Powered directly from the M540
Input voltage	5 V nominal
Maximum power consumption	500 mW
Mode of operation	Continuous
Risk management	
Protection against electrical shock	Type CF
Protection against liquid ingress	IPX1 (protected against vertically falling water drops) per IEC 60529
Defibrillator protection	Per IEC60601-1

Infinity Hemo2 and Hemo4 pods

Physical specifications	
Size (W x H x D)	205 x 140 x 60 mm (8.1 x 5.5 x 2.3 in)
Weight	Hemo2: 0.7 kg (1.6 lbs) Hemo4: 0.9 kg (1.9 lbs) **NOTE** Weight includes one (Hemo2) or two (Hemo4) transducer adapter block(s) and excludes mounting clamp.
Connectors	
Input/output ports	Two (Hemo2) or four (Hemo4) invasive pressure channels (IBP), two temperatures, and C.O. Single cable connecting to the M540
Display attributes	
User controls	Fixed keys (C.O. Start, IBP zero, Wedge)
Displays	Two (Hemo2) or four (Hemo4) four-character LCDs
Environmental specifications	
Humidity (non-condensing)	Operating: 20 to 90 % Storage: 10 to 95 %
Temperature	Operating: 10 to 40 °C (50 to 104 °F) Storage: –20 to +50 °C (–4 to +122 °F)
Atmospheric pressure	Operating: 525 to 795 mmHg (70 to 106 kPa) Storage: 375 to 795 mmHg (50 to 106 kPa)
Electrical specifications	
Power source	Powered directly from the M540
Input voltage	10 V nominal
Maximum power consumption	1 W for a single pod with connected pressure probes
Patient leakage current	≤0.05 mA
Mode of operation	Continuous
Risk management	
Protection against electrical shock	Type CF
Protection against liquid ingress	IPX0 (not protected against water ingress) per IEC 60529
Defibrillator protection	Per IEC 60601-2-34

Infinity MPod – Quad Hemo

Physical specifications	
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 lbs) **NOTE** 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
Environmental specifications	
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)
Electrical specifications	
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
Patient leakage current	≤0.05 mA
Mode of operation	Continuous
Risk management	
Protection against electrical shock	Type CF
Protection against liquid ingress	IPX1 (protected against vertically falling water drops) per IEC 60529
Defibrillator protection	Per IEC 60601-2-34

Infinity MCable – Dual Hemo

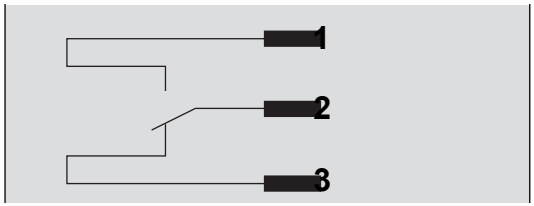
Physical specifications	
Size (W x H x D)	61 x 25 x 125 mm (2.4 x 1.0 x 5.0 in)
Weight	0.20 kg (0.44 lb)
Cable length	2500 mm (98.4 in)
Connections	Two invasive pressure channels Single cable connecting to the M540
Environmental specifications	
Humidity (non-condensing)	Operating: 10 to 95 % Storage: 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)
Electrical specifications	
Power source	Powered directly from the M540
Input voltage	10 V nominal
Maximum power consumption	300 mW
Patient leakage current	+0.05 mA
Mode of operation	Continuous
Risk management	
Protection against electrical shock	Type CF
Protection against liquid ingress	IPX1 (protected against vertically falling water drops) per IEC 60529
Defibrillator protection	Per IEC 60601-2-34

Infinity MCable – Analog/Sync

Physical specifications	
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
Environmental specifications	
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)
Analog output	
Signals	ECG, arterial blood pressure (ART)
Maximum delay	≤30 ms
Output range	±4.95 V ±5 %
Signal gain	ECG: 1000 (1 V/mV)
	ART: 10 mV/mmHg
	±20 mV or ±2 %
ECG bandwidth	0.5 to 40 Hz
Invasive blood pressure bandwidth	DC to 16 Hz
Pacemaker pulses	Amplitude: 5 V (nominal)
	Duration: 4 ms
Maximum pressure offset	±10 mV
Pressure range	–500 to +500 mmHg (1 V/100 mmHg) –66.6 to +66.6 kPa (1 V/13.3 kPa)
Output impedance	200 Ω ±5 %
Data rate	250 sps

QRS sync pulse output	
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
Electrical specifications	
Power 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
Risk management	
Protection against electrical shock	Type CF
Protection against liquid ingress	IPX1 (protected against vertically falling water drops) per IEC 60529
Defibrillator protection	IEC 60601-1: 1988

Infinity MCable – Nurse call

Physical specifications	
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	 Cable 1 (NO normally open): white Cable 2 (COM common): brown Cable 3 (NC normally closed): green
Environmental requirements	
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)
Electrical requirements	
Input voltage	24 V ±25 %
Relay contact	1 A DC, 24 VDC, 15 W maximum
Mode of operation	Continuous
Isolation voltage	1.5 k VAC

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	3-lead wire set: I, II, III (user-selectable) 5-lead wire set: I, II, III, aVR, aVL, aVF, V 6-lead wire set: I, II, III, aVR, aVL, aVF, V, V+ Optional 12-lead monitoring with 6-lead wire set and 4-lead wire set: I, II, III, aVR, aVL, aVF, V1 to V6 TruST on: I, II, III, aVR, aVL, aVF, dV1, V2, dV3, dV4, V5, dV6 ("d" prefix identifies derived lead)
Measurement range	15 bpm to 300 bpm (beats/min)
Accuracy	±2 bpm or ±1 % (whichever is greater)
Resolution	1 bpm
Sweep speed	25 mm/s ±2 %
QRS detection	Amplitude: 0.5 to 5 mV p-v RTI Duration: Adult: 70 to 120 ms Pediatric/neonate: 40 to 120 ms
Frequency ranges	Monitor filter: 0.5 to 40 Hz (0.5 to 20 Hz in OR mode) ESU filter: 0.5 to 20 Hz (pacer detection deactivated) Filter OFF: 0.05 to 40 Hz (M540 display is limited to 40 Hz)
ECG baseline recovery	≤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	In accordance with IEC 60601-2-27, ANSI/AAMI EC11 and ANSI/AAMI EC13

Unit will detect pacers with the following characteristics:	
Pacer detection (adult/pediatric only)	Amplitude (a_p): ±2 to ±900 mV Width (d_p): 0.2 to 2.0 ms
Rise/fall times (min)	0.1 d_p, ≤100 µs
Overshoot (min)	0.025 to 0.25 a_p, <2 mV
Recharge time constant	4 to 100 ms

ECG/Arrhythmia/ST supplemental information required by ANSI/AAMI EC13:2002 and IEC 60601-2-27:2005

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 IEC 60601-2-27:2005 and ANSI/AAMI EC13:2002
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	Exceeds minimum 1.2 mV T-Wave amplitude required by ANSI/AAMI EC 13 section 4.1.2.1(c) and IEC 60601-2-27 section 6.8.2 bb) 2).
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
Accuracy of input signal reproduction	Methods A, B, C and D from ANSI/AAMI EC11:2001 were used to establish overall system error and frequency response.

Arrhythmia (ARR)

Basic arrhythmia detection	Asystole, ventricular fibrillation, artifact, ventricular tachycardia [1)]
Full arrhythmia detection	Adds the following calls on to basic arrhythmia: ventricular run, accelerated idioventricular rhythm, supra-ventricular tachycardia, couplet, bigeminy, tachycardia, bradycardia, pause, and PVC/min
PVC/min measurement range	0 to 300 bpm
PVC/min display resolution	1 bpm
PVC/min accuracy	±5 or ±10 % of the rate (whichever is greater)
PVC/min response time	≤4 s

NOTE

[1)] Bradycardia is available as a low heart rate alarm for neonates.

ST segment analysis

Sensing leads	3-lead wire set: I, II, III (user-selectable) 5-lead wire set: (choice of 2 leads for display) I, II, III, aVR, aVL, aVF, V 6-lead wire set: (choice of 2 leads for display) I, II, III, aVR, aVL, aVF, V, V+ Optional 12-lead monitoring with 6-lead wire set and 4-lead wire set: (choice of 2 leads for display) I, II, III, aVR, aVL, aVF, V1 to V6, CVM, VM TruST on: I, II, III, aVR, aVL, aVF, dV1, V2, dV3, dV4, V5, dV6 ("d" prefix identifies derived lead)
ST complex	Length: 828 ms (–260 to +568 ms from the fiducial point)

ISO point	Adjustment range: start of QRS complex to fiducial point (–260 to +40 ms) Default: QRS onset –28 ms
ST measurement point	Adjustment range: fiducial point to end of QRS complex (–28 to +568 ms) Default: QRS offset +80 ms
ST update interval	15 s ±1 s, 1 normal beat required
ST input accuracy	±0.1 mm (±0.01 mV)
ST measuring range	–15.0 to +15.0 mm –1.50 to +1.50 mV

Respiration (RRi)

Sensing leads	I or II (user-selectable)
Measuring method	Impedance pneumography
Auxiliary current	<10 μA for any active electrode
Respiration excitation waveform	Square wave signal, 50 μA, 39.896 KHz
Bandwidth (–3dB)	0.25 to 3.5 Hz
Detection threshold	Manual mode: 0.15 to 2.0 Ω Auto mode: 0.2 to 1.5 Ω
Measurement range	0 to 155 bpm
Resolution	1 bpm
Measuring accuracy	±1 or 2 % of rate (whichever is greater)
Apnea detection intervals	Off, 10, 15, 20, 25, and 30 s

Invasive blood pressure (IBP)

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 4, ART, PA, PWP, CVP, LA, LV, RV, RA, ICP)

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)
Display output	User selectable DC to 8 Hz, DC to 16 Hz
Accuracy	±1 mmHg or ±3 % (whichever is greater) excluding the transducer
IBP update interval	4 s
Response time (at 90 % of pressure change)	14 beats + 2 s (ART, LV, GP1, GP2, GP3, GP4) 8 beats + 2 s (PA, RV) 16 s (CVP, RA, LA, ICP)
Transducer specifications	Dräger-approved 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)

Parameter display	Systolic, diastolic, mean values
Measuring method	Oscillometric through step-deflation
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, ±5 mmHg (35.3 kPa, ±0.66 kPa) Pediatric: 180 mmHg, ±5 mmHg (24 kPa, ±0.66 kPa) Neonate: 140 mmHg, ±5 mmHg (18.7 kPa, ±0.66 kPa)
Minimum Inflation Pressure	Adult: 110 mmHg, ±5 mmHg (14.7 kPa, ±0.66 kPa) Pediatric: 90 mmHg, ±5 mmHg (12 kPa, ±0.66 kPa) Neonate: 80 mmHg, ±5 mmHg (10.7 kPa, ±0.66 kPa)
Default inflation pressure	Adult: 160 mmHg, ±5 mmHg (21.3 kPa, ±0.66 kPa) Pediatric: 130 mmHg, ±5 mmHg (17.3 kPa, ±0.66 kPa) Neonate: 110 mmHg, ±5 mmHg (14.7 kPa, ±0.66 kPa)
Inflation pressure after a valid measurement	Adult: last systolic value plus 25 mmHg, ±5 mmHg (3.3 kPa, ±0.66 kPa) Pediatric: last systolic value plus 25 mmHg, ±5 mmHg (3.3 kPa, ±0.66 kPa) Neonate: last systolic value plus 30 mmHg, ±5 mmHg (4 kPa, ±0.66 kPa)
Inflation pressure after a technical alarm	Adult: 160 mmHg, ±5 mmHg (21.3 kPa, ±0.66 kPa) Pediatric: 130 mmHg, ±5 mmHg (17.3 kPa, ±0.66 kPa) Neonatal: 110 mmHg, ±5 mmHg (14.7 kPa, ±0.66 kPa)
Maximum measurement time	Adult: 2 min, ±3 s Pediatric: 2 min, ±3 s Neonatal: 90 s, ±1 s
Maximum measurement time including a retry	Adult: 3 min Pediatric: 2 min Neonatal: 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) Neonatal (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) Neonatal (SWi): >145 mmHg (19.3 kPa)
Redundant safety cut-off	Adult: 300 mmHg (40 kPa) Pediatric: 300 mmHg (40 kPa) Neonatal: 150 mmHg (20 kPa)
Static cuff accuracy	±3 mmHg (±0.4 kPa)
Calibration check range	0 to 260 mmHg, ±3 mmHg (0 to 34.6 kPa, ±0.4 kPa)
Resolution	1 mmHg (0.13 kPa)

Standards compliance	– IEC 60601-2-30:1999 Medical Electrical Equipment – Part 2-30 Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment – EN 1060-1:1995 Specification for Non-invasive sphygmomanometers – part 1; general requirements – EN 1060-3:1997 Non-invasive sphygmomanometers Part 3; supplementary requirements for electro-mechanical blood pressure measuring systems – Blood pressure measurements are determined by the oscillometric method and are equivalent to those obtained by intra-arterial methods, within the limits prescribed by the Association for Advancement of Medical Instrumentation, Electronic Automated Sphygmomanometers (AAMI/ANSI SP-10).

Cardiac Output (C.O.)

Parameter display	Cardiac output (C.O.), blood temperature (Tblood) injectate temperature (Tinj)
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 % Blood temperature: ±0.15 °C (±0.3 °F) not including probe errors Injectate temperature: ±0.25 °C (±0.45 °F) not including probe errors)
Resolution	Cardiac output: 0.1 L/min Blood temperature: 0.1 °C (0.2 °F) Injectate temperature: 0.1 °C (0.2 °F)
Response time	Blood temperature: 3 s Injectate temperature: 3 s

Pulse Oximetry (SpO_2) 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 Adtx, LNCS Pdtx, LNCS Adtx-3, LNCS Pdtx-3
Neonatal sensors	LNCS Inf, LNCS Inf-3, LNCS Neo, LNCS Neo-3, LNCS NeoPt-3, LNCS NeoPt, LNCS YI, LNCS SofTouch, Neo-Pt-500
Parameter display	Masimo SET MCable: Pulse oximetry (SpO_2), pulse rate (PLS), perfusion index (PI) Masimo rainbow SET MCable: Pulse oximetry (SpO_2), 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_2: 1 to 100 % PLS: 26 to 239 bpm PI: 0.00 to 20 %
Measurement range (Infinity MCable – Masimo SET rainbow)	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_2: 1 % PLS: 1 bpm PI: 0.01 %
Resolution (Infinity MCable – Masimo SET rainbow)	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 SET rainbow)	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_2 accuracy with no motion adult, pediatric [1) 2)]	0 to 69 % not specified 70 to 100% ±2 % for: LNCS DCI, LNCS DCIP LNCS TF-I, LNCS YI, LNCS Adtx, LNCS Pdtx, LNCS Neo (finger) [6)] ±3.5 % for: LNCS TC-I
SpO_2 accuracy with no motion neonata l [1) 2) 3)]	0 to 69 % not specified 70 to 100 % ±2 % for: LNCS Inf ±3 % for: LNCS Neo (foot) [6)], LNCS NeoPt, LNCS YI [7)]
PLS accuracy with no motion [4)]	±3 bpm
SpO_2 accuracy with motion adult, pediatric [1) 2) 3)]	0 to 69 % not specified 70 to 100 %, ±3 % for: LNCS DCI, LNCS DCIP, LNCS YI, LNCS Adtx, LNCS Pdtx
SpO_2 accuracy with motion neonatal [1) 2) 3) 5)]	0 to 69 % not specified 70 to 100 %, ±3 % for: LNCS Inf, LNCS Neo, LNCS NeoPt
PLS accuracy with motion [4)]	±5 bpm
SpO_2 low perfusion accuracy adult, pediatric [1) 2)]	±2 % for: LNCS DCI, LNCS DCIP, LNCS TF-I, LNCS Adtx, LNCS Pdtx ±3.5 % for: LNCS TC-I
SpO_2 low perfusion accuracy neonatal [1) 2) 3)]	±2 % for: LNCS Inf, LNCS Neo (finger) [6)] ±3 % for: LNCS Neo (foot) [6)], LNCS NeoPt
PLS low perfusion accuracy [4)]	±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 power at 50 mA pulsed	≤15 mW

NOTE

1) Since pulse oximeter measurements are statistically distributed, only about two-thirds of those measurements can be expected to fall within ±1 A_{rms} of the value measured by a co-oximeter.

2) The Infinity MCable – Masimo SET pulse oximeter with adult sensors has been validated in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70 % to100 % SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals ±1 A_{rms} of the value measured by a co-oximeter.

3) Accuracy of saturation measurements on neonates is decreased by ±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 to100 % SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals ±1 A_{rms} of the pulse rate value measured by the ECG monitor.

5) Motion defined as continuous rubbing and tapping motions at 2-4 Hz at amplitude of 1 cm to 2 cm and continuous random frequency motion between 1 to 5 Hz at amplitude of 2 to 3 cm.

6) Sensor accuracy depends on the weight of the patient. If the weight is less than 3 kg, the accuracy is ±3 %. For weights above 40 kg, the accuracy is ±2 %.

7) Sensor accuracy depends on the weight of the neonate. If the weight exceeds 3 kg, the accuracy is ±2 %. For weights between 1 and 3 kg, the accuracy is ±3 % (if the sensor is applied on the foot).

Pulse oximetry (SpO_2) 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_2), pulse rate (PLS)
Measuring method	Absorption-spectrophotometry
Measurement range	SpO_2: 1 to 100 % PLS: 26 to 239 bpm
Resolution	SpO_2: 1 % PLS: 1 bpm
Update interval	2 s, ±0.5 s
Maximum update interval	30 s
SpO_2 measuring accuracy adult, pediatric [1) 2)]	0 to 60 % not specified 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 60 to 80%, ±3 % for: OxiMax MaxA, OxiMax MaxAL, OxiMax MaxP, OxiMax MaxN, OxiMax MaxI, OxiMax MaxFast 70 to 100 % ±2 % for: OxiMax MaxA, OxiMax MaxAL, OxiMax MaxP, OxiMax MaxN, OxiMax MaxI, OxiMax MaxFast, SoftCare SC-A ±2.5 % for: OxiCliq A, OxiCliq P, OxiCliq N, OxiCliq I ±3 % for: D-YS, DS100A, Oxi-A/N, Oxi-P/I ±3.5 % for: D-YS with D-YSE Ear Clip or D-YSPD Spot Clip 80 to 100 %, ±3.5 % for: OxiMax MaxR

SpO_2 measuring accuracy neonatal [1) 2) 3)]	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 %, ±3 % for: OxiMax MaxN 70 to 100 % ±2 % for: OxiMax MaxN, SoftCare SC-PR, SoftCare SC-NEO ±3.5 % for: OxiCliq N ±4 % for: D-YS, Oxi-A/N
PLS measuring accuracy [4)]	PLS:±3 bpm or ±3 % (whichever is greater)
SpO_2/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

NOTE

1) Since pulse oximeter measurements are statistically distributed, only about two-thirds of those measurements can be expected to fall within ±1 A_{rms} of the value measured by a co-oximeter.

2) The Infinity MCable – Nellcor OxiMax pulse oximeter with adult sensors has been validated in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70 to100 % SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals ±1 A_{rms} of the value measured by a co-oximeter.

3) Accuracy of saturation measurements on neonates is decreased by ±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 to100 % SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals ±1 A_{rms} of the pulse rate value measured by the ECG monitor.

Carbon dioxide concentrations (CO_2)

Measurement range	etCO_2 and inCO_2: 0 to 100 mmHg (0 to 13.3 kPa or 0 to 13.2 vol % at sea level) RRc: 0 to 150 bpm
Measurement accuracy	Reporting range –5 to 120 mmHg (–0.6 to +16 kPa) Bias ±2 mmHg (0.26 kPa) absolute or 5 % of reading, whichever is greater
Resolution	etCO_2 and inCO_2: 0.1 mmHg (0.01 kPa or 0.1 %) RRc: 1 bpm
Warm up time needed to reach full operating specifications	At 20 to 40 °C (68 to 104 °F), approximately 2 min At 10 °C (50 °F), approximately 10 min
Total system response time	25 ms (rise time is 25 ms)
Measurement accuracy drift	Over 6 hours is less than 0.02 Vol. % at 5 Vol. % CO_2, drift of precision (noise).
How humidity/condensate affect performance	The airway adapter windows are indirectly heated through the sensor to prevent moisture condensation. Water droplets and other window contamination may slightly influence measurement bias, up to 0.3 Vol. % at 5 Vol. % CO_2 at worst (normally much less). If measurement light is blocked so the noise of the reading gets too high, an error message is sent by the CO_2 sensor indicating that the airway adapter has to be checked (cleaned or replaced) and such message is displayed by the host.
Adverse effects on performance of cyclical pressures up to 10 kpa (100 cmH_2O)	No other effects than with static pressure. See “How barometric pressure affects performance“.
How barometric pressure affects performance	When the system provides total gas pressure (for example, ambient or barometric pressure) to the mainstream CO_2 sensor, the sensor automatically compensates for pressure effects. The remaining bias error is less than 2 % of reading (that is 2 % relative) for ambient pressures between 570 and 1100 mbar, which error includes imperfection of foreign gas compensation (O_2, N_2O, He, Xe).

How interfering gases and vapors affect performance	N_2O 100 Vol.%: reading 0.00 Vol.% CO_2 Halothane 5 Vol.%: reading 0.02 Vol.% CO_2 Enflurane 5 Vol.%: reading 0.03 Vol.% CO_2 Isoflurane 5 Vol.%: reading 0.02 Vol.% CO_2 Sevoflurane 5 Vol.%: reading 0.02 Vol.% CO_2 Desflurane 20 Vol.%: reading 0.00 Vol.% CO_2 Ethanol 4 vol.%: reading 0.00 Vol.% CO_2 Isopropanol 1 Vol.%: reading 0.00 Vol.% CO_2 Acetone 1 Vol.%: reading 0.00 vol.% CO_2 Methane 3 Vol.%: reading less than 0.02 Vol.% CO_2 NO 100 ppm: reading 0.01 Vol.% CO_2 CO 4 Vol.%: reading 0.00 Vol.% CO_2 Freon R21 100 Vol.%: reading 0.07 Vol.% CO_2 Freon R134a 100 Vol.%: reading 0.19 Vol.% CO_2 Water vapour 37 °C saturated: reading 0.01 Vol.% CO_2

NOTE
Given readings are pure interfering gas effects, balance N_2 (if applicable, without CO_2 content). CO_2 reading of mixtures (for example, CO_2, N_2O, O_2, anesthetic agent or CO_2, O_2, N_2, water vapor) is within specified tolerance.

Temperature

Parameter display	Temperatures: Ta, Tb, ΔT, T1a, T1b, ΔT1
Measurement range	Ta, Tb, T1a, T1b: 0 to 50 °C (32 to 122 °F) ΔT, ΔT1: 0 to 50 °C (32 to 122 °F)
Resolution	0.1 °C (0.1 °F)
Accuracy (exclusive of probe)	Ta, Tb, T1a, T1b: ±0.1 °C (±0.2 °F) ΔT, ΔT1: ±0.2 °C (±0.4 °F)
Probe accuracy	±0.1 °C (± 0.2 °F)
Average update time	<2.5 s
Response time	23 to 44 °C (73.4 to 111.2 °F) ±0.2 °C (±0.4 °F) within 150 s

Degree of protection against electric shock	Type CF
Defibrillation protection	In accordance with IEC 60601-1

Electromagnetic compatibility

The separation distances are written with regard to the M540. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment, and older equipment may be particularly susceptible to interference.

General notes

The M540 patient monitor and its radio are designed and manufactured in a way that ensures that the emission limits for RF (Radio Frequency) energy, as defined by the FCC (Federal Communications Commission), the RSS (Radio Standards Specifications), by ETSI and by IEC/EN 60601-1-2, will not be exceeded. These limits are part of international safety standards that are defined by international committees.

The radio in the M540 patient monitor complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this manual.

Portable and mobile RF communications equipment can affect medical electrical equipment.

Cables and accessories not specified within the instructions for use are not recommended. Using other cables and/or accessories may adversely impact safety, performance and electromagnetic compatibility (increased emission and decreased immunity).

The equipment should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is inevitable, the equipment should be observed to verify normal operation in the configuration in which it will be used.

Low level signals such as ECG are particularly susceptible to interference from electromagnetic energy. While the equipment meets the testing described below, it is not a guarantee of perfect operation, the 'quieter' the electrical environment the better. In general, increasing the distance between electrical devices decreases the likelihood of interference.

NOTE

The equipment is intended for use in the electromagnetic environments specified below. The user of this equipment should assure that is used in such an environment.

Electromagnetic emissions		
Emissions	**Compliance according to...**	**Electromagnetic environment**
RF emissions (CISPR 11)	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
CISPR emissions classification	Class B	The equipment is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power network that supplies buildings used for domestic purposes.
Harmonic emissions (IEC 61000-3-2)	Class A	
Voltage fluctuations / flicker (IEC 61000-3-3)	Complies	

Electromagnetic immunity			
Immunity against...	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment**
Electrostatic discharge, ESD (IEC 61000-4-2)	contact discharge: ±6 kV air discharge: ±8 kV	±6 kV ±8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transients/bursts (IEC 61000-4-4)	AC power lines: ±2 kV input / output lines: ±1 kV	±2 kV ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surges on AC mains lines (IEC 61000-4-5)	Common mode: ±2 kV differential mode: ±1 kV	±2 kV ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.

Electromagnetic immunity			
Immunity against...	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment**
Power frequency magnetic field 50/60 Hz (IEC 61000-4-8)	3 A/m	3 A/m	Equipment which emits high levels of power line magnetic fields (in excess of 3A/m) should be kept at a distance to reduce the likelihood of interference.
Voltage dips and short interruptions on AC mains input lines (IEC 61000-4-11)	dip >95 %, 0.5 periods dip 60 %, 5 periods dip 30 %, 25 periods dip >95 %, 5 s	>95 %, 0.5 periods 60 %, 5 periods 30 %, 25 periods >95 %, 5 s	Mains power should be that of a typical commercial or hospital environment. If user requires continued operation during power mains interruptions ensure that batteries are installed and charged. Ensure that battery life exceeds longest anticipated power outages or provide an additional uninterruptible power source.

Electromagnetic immunity			
Immunity against...	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment**
Conducted RF rf coupled into lines (IEC 61000-4-6) radiated rf (IEC 61000-4-3)	150 kHz to 80 MHz: 80 MHz to 2.5 GHz	3 Vrms 3 V/m [*V*1] V [*E*1] V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter as below. Recommended separation distance $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Electromagnetic immunity			
Immunity against...	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment**

NOTE

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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Numerics

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These instructions for use only apply to
Infinity Acute Care System VG2
with the Serial No.:
If no Serial No. has been filled in by Dräger Medical, these instructions for use are provided for general information only and are not intended for use with any specific machine or device.
This document is provided for customer information only, and will not be updated or exchanged without customer request.

CE 0123
Directive 93/42/EEC
concerning Medical Devices

CE
The Infinity Acute Care System - Infinity M540 complies with the Radio Equipment and Telecommunications Terminal Equipment Directive (99/5/EC). For a copy of the Declaration of Conformity please contact the local sales representative.

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