Supplement

Infinity® M300

WARNING

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

Infinity® M300
Software VG2.4

Contents

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Information about this document

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.

Trademarks

Trademarks owned by Dräger

Trademark
Infinity®
MCable®
MonoLead®

The following web page provides a list of the countries in which the trademarks are registered:

https://www.draeger.com/trademarks

Trademarks owned by third-party manufacturers

Trademark	Trademark owner
rainbow®	Masimo Corporation.
Masimo®	
Masimo® SET® (Signal Extraction Technology)	
Capnoline®	Medtronic
Microstream®	
TOFscan®	IDMED

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 equipment or other property.

NOTE

A NOTE provides additional information intended to avoid inconveniences during operation.

Infinity M300 VG2.4

This supplement contains the VG2.4 instructions for use for the Infinity M300.

The IFU that ships with this supplement is the *Infinity CentralStation Wide SW VG 1.n and Infinity M300*.

Infinity M300 Device description

The Infinity M300 is a wireless telemetry, patient-worn device with rechargeable lithium-ion battery which monitors ECG and SpO2 physiological data, features a color display, and local alarm alerts and keypad interface. ECG functions include heart rate, arrhythmia detection and ST segment analysis. SpO2 functions include pulse plethysmogram and pulse rate. Infinity M300 with TruST allows for 12-lead ECG monitoring with a reduced set of electrodes by deriving values for missing leads.

Infinity M300 components

The standard Infinity M300 includes the following:

- Infinity M300 patient-worn device
- Infinity M300 Bedside Charger
- Infinity M300 CentralCharger
- Infinity M300 programming kit

Infinity M300 communications

Infinity M300 connects to the Infinity network via 802.11 wireless communication with hospital access points (AP). From the AP, data is routed over the Infinity network via wired Ethernet for real-time display and annunciation at the Infinity CentralStation Wide (Widescreen) central monitoring workstation. The Infinity CentralStation (ICS) Wide allows for simultaneous central monitoring of up to thirty-two (32) Infinity M300 devices to support wireless telemetry monitoring.

Infinity M300 user interfaces and functions

The Infinity M300 communicates bilaterally with the Infinity CentralStation (ICS) which serves as the primary display, user interface and alarm annunciator for acquired M300 physiological patient data. The Infinity M300 6-button local keypad and display serves as a secondary user interface for clinicians to access local features and functions.

To facilitate patient mobility the M300 can be placed in a disposable or re-usable shower pouch and worn by the patient. When a patient is sedentary (in bed or sitting) the clinician can place the Infinity M300 in the Bedside Charger to provide a slow charge for the device. When the Infinity M300 is not in clinical use, it may be stored and recharged at an accelerated rate in the CentralCharger.

At the ICS clinicians perform the following functions:

- Admit / Discharge patients
- Initiate / Discontinue M300 Standby
- Enter patient demographics
- Assign patient categories
- Assign alarm limits
- Manage M300 audio pause, alarm pause, alarm silence
- Access patient alarm history
- Access patient full disclosure records

At the Infinity M300 clinicians perform the following functions:

- Turn device on and off
- Adjust alarm volume
- Manage alarm pause
- Scroll through waveforms
- Discharge patients
- Initiate strip recordings
- Issue staff alerts

Indications for use/Intended use

The Infinity M300 is intended for use with the ICS to monitor ECG and pulse oximetry on ambulatory and non-ambulatory adult and pediatric patients using wireless communication over the Infinity patient monitoring network.

The Infinity M300 with TruST is intended for 12-Lead ECG monitoring with a reduced set of electrodes. Reconstructed leads are intended for real-time assessment of ST segment changes.

Contraindication

The Infinity M300 is not compatible for use in an MRI magnetic field.

For your safety and that of your patients

Mandatory reporting of adverse events

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

General safety information

The following WARNING and CAUTION statements apply to general operation of the medical device.

Warnings:

WARNING

To properly use the M300 medical device, read and comply with the latest instructions for use and this supplement.

WARNING

Inaccurate SpO2 measurements may result under the following conditions:

- **Elevated levels of methemoglobin**
- **Elevated levels of total bilirubin**
- **Excessive patient motion**
- **Severe anemia**
- **Low arterial perfusion**

WARNING

Risk of electric shock and device malfunction.

Penetrating liquid may cause the following:

- **Damage to the device**
- **Electric shock**
- **Device malfunctions**

Ensure that no liquid penetrates the device.

WARNING

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

Cautions:

CAUTION

Signs of wear, such as cracks, deformation, discoloration, or peeling, may occur with reprocessed products.

Check the products for signs of wear and replace them if necessary.

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.

Environment of Use

The Infinity M300 is intended to be used in an environment where patient care is provided by Healthcare Professionals, i.e. physicians, nurses, and technicians, trained on the use of the device, who determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

Patient Population

The Infinity M300 is intended for use with ambulatory and non-ambulatory adult and pediatric patients, (one patient at a time) excluding infants and neonates, in environments where patient care is provided by healthcare professionals.

NOTE
Clinical judgment must be used to determine when the M300 should be used on a specific pediatric patient. Assigning a specific weight or age to ECG performance is not practical as there are multiple factors to be considered when making a determination for patient care.

Open-source software

Dräger devices that use software may use open-source software, depending on their setup. Open-source software may be subject to different terms of license. Additional information regarding the open-source software used in this device is available at the following web page:

https://www.draeger.com/en_me/Hospital/Online-Services/Open-Source

Network security information and recommendations

Dräger provides the following security information and recommendations:

- Dräger recommends always following network security best practices, such as maintaining software, segmenting via firewalls, closing unused ports, restricting user permissions, limiting third party access, and monitoring network activity.
- M300 device settings may be compromised in the event of a cybersecurity attack or other configuration error. To restore device settings to their previous state, power cycle the unit and select NO when prompted on the New Patient screen. Device settings can be restored manually with patient discharge and re-admit at the M300. In the event of a cybersecurity attack, if the device enters a fail state (sustained alarm tone sound), power cycle the unit. If a device experiences multiple resets and/or fail state behavior, assign each patient to a bedside monitor, isolate the affected devices and immediately contact your hospital's biomedical department and IT department for support. Do not place devices back into service until the situation is resolved.
- Dräger recommends the use of WPA2-Enterprise/EAP-TLS to provide for strong authentication and data protection for wireless communication between M300 and 802.11 access points. With this protection in place, clinical data will be secure in a wireless encrypted tunnel. Customers configuring wireless infrastructures with WPA or WPA+WPA2 will cause the M300 to use the deprecated TKIP cipher which may compromise security. Dräger recommends configuring the network infrastructure to use WPA2 only.

- Dräger recommends that the responsible organization install and operate Infinity monitoring devices on separate, isolated, VLANs to reduce risk from network security vulnerabilities. Use of QoS with M300 is required to ensure optimal network data transmission. Without these measures there is an increased risk that critical events may go undetected in cases of malicious attack, which could result in patient harm.
- Dräger maintains a product security page for continued visibility into cybersecurity threats in the field and possible vulnerabilities in our devices. In the event you encounter a cybersecurity threat or identify a security vulnerability in one of our products, visit the following website to find instructions on how to provide this information to Dräger via encrypted e-mail: https://static.draeger.com/security/.
- The M300 device provides logging of software resets and presence of multicast. M300 error logs may be obtained using the device webpage or via connection to a serial programming cable and appropriate terminal software. If errors are observed, report the condition to the hospital's Biomed and IT departments.
- To maintain the M300 logs for investigatory purposes, isolate the affected M300 unit(s), place the devices in a bedside charger, and contact Dräger service personnel for support and troubleshooting. Do not place the M300 in the CentralCharger as this will discharge the patient deleting useful data.
- The device configurations can be recovered by one of the following methods:
  - Programming cable with password
  - Manually discharge patient, re-admit and configure settings
  - Manually configure settings at the M300
- The M300 device contains the following interfaces:

Type	Purpose
Display	Visualize various clinical parameters and device configuration settings
Keypad	Provide for modest level of user interaction, such as startup/shutdown of device; alarm silence; and local discharge
Wireless Network	Provides for communication with other Infinity network devices and some diagnostic tools via 802.11
Serial Console	Provides access to service menu to allow for configuration and maintenance of device

The M300 device communicates via the 802.11 wireless LAN standard. Client ports are used outbound from the device, while server ports accept incoming connections inbound from other devices on the network:

Application Protocol	Transport Protocol	Port Number	Client/Server
FTP	TCP	21	Server
HTTP	TCP	80	Server
Infinity ACS	TCP	1950	Server
Infinity PDS	TCP	2050	Client
Infinity NameService	TCP	2150	Client

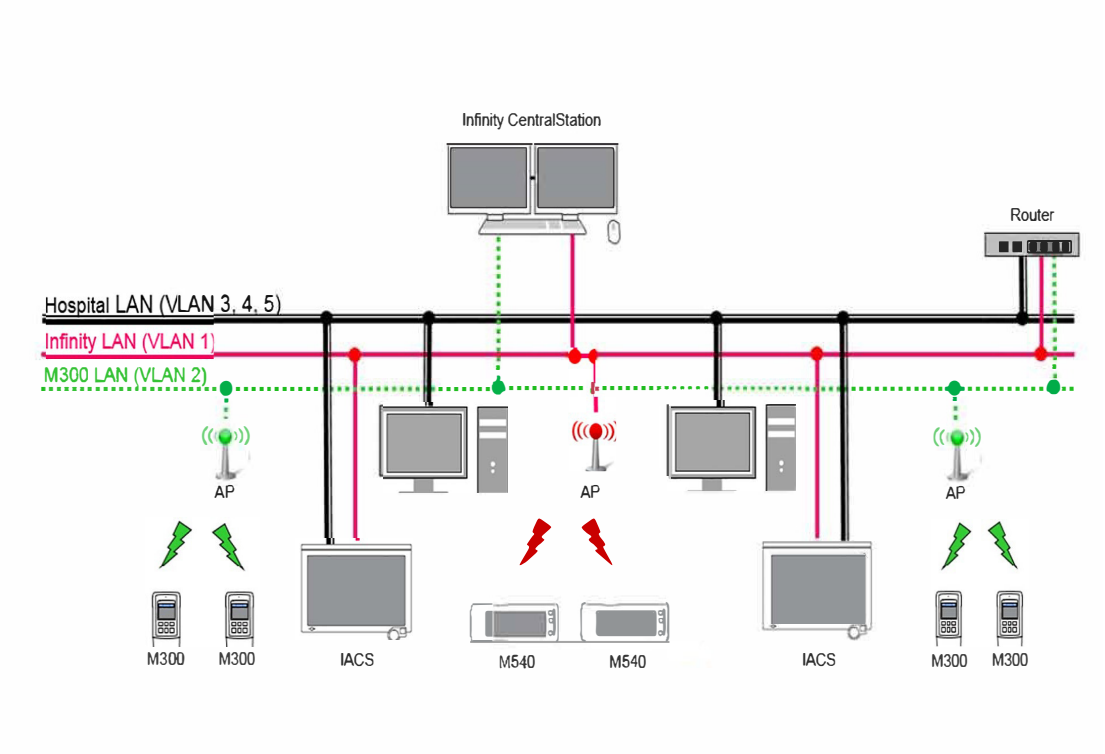
Application Protocol	Transport Protocol	Port Number	Client/Server
Infinity Recorder	TCP	6000	Client
Infinity Recorder	TCP	6050	Client
Infinity RemoteRecord	TCP	7100	Server
Infinity LocalDischarge	TCP	9200	Client
Infinity LLIP	TCP	18000	Client

- In the presence of multicast network traffic, ‘Network Config Error’ will be annunciated on the M300 display and will be captured in the error log. M300 error logs may be obtained using the device webpage or via connection to a serial programming cable and appropriate terminal software. If this error is observed, report the condition to the hospital's Biomed and IT departments. If a device experiences multiple resets the unit may enter a fail state and issue a sustained audible alarm. If your facility experiences multiple M300 device resets and/or fail state behavior, assign each patient to a bedside monitor, isolate the affected devices and immediately contact your hospital’s biomedical department and IT department for support. Do not place devices back into service until the situation is resolved.
- To enhance network and device security, restrict physical access to the Infinity network, monitoring devices and accessories to hospital personnel according to job function and classification. Restrict physical access to unused ethernet ports, and unused USB and serial ports.
- Modifications to the Infinity network after initial installation could result in degraded performance and/or security risks. Contact Dräger Service personnel to ensure optimal network performance for any planned network modification. Unauthorized modifications to network settings could degrade network performance and could result in patient harm due to delayed assessment or intervention.

NOTE

M300 is an embedded code device that verifies sensitive data integrity (i.e., code space, stored configuration data, and DRAM content) at startup and during operation. If the stored settings are corrupt, the device assumes that DRAM has failed and restores its factory default settings with audible and visual notification to users.

Infinity Network Diagram Example Configuration



M300 message

The following message may display on the M300:

Priority	Message	Description	Action
None	Network config error	Multicast traffic is detected on the VLAN.	Contact your hospital biomedical department and IT department for support.

Device symbols

The following table lists the new hardware device symbols displayed on various Dräger hardware.

Symbol	Description
 Do not re-use	Do not re-use, single patient use
	Not made with natural rubber latex
 Not made with natural rubber latex	Not made with natural rubber latex
	Medical Device
For USA: **Rx only**	Caution: Federal law restricts this device to sale by or on the order of a physician.

Refer to the IFU, *Infinity CentralStation Wide SW VG 1.n and Infinity M300,* that ships with this supplement for additional device symbols.

Infinity M300 Features for VG2.4

This section contains the Infinity M300 features for the VG2.4 release.

QRS Threshold

Depending on the software versions running on the ICS and the M300 devices, the procedure you follow to set the QRS threshold on the M300 will differ:

- If ICS is VG2.1.1 or later, and the M300 is VG 2.4 or later, you set the QRS threshold by a menu selection, either ***Normal*** or ***Low***
- If ICS is VG2.1 or earlier, or the M300 is VG2.3 or earlier, the QRS threshold is linked to the ECG gain and the QRS threshold buttons are greyed out. The following relationships apply:
  - Setting the gain to 1, 2, 4, or 8 mV/cm, automatically sets to the QRS threshold to ***Normal***.
  - Setting the gain to 0.5 or 0.25 mV/cm, automatically sets the QRS threshold to ***Low.***

NOTE

Patient admitted on M300 VG2.4:
Changes to QRS/ARR processing leads and gain settings do not change QRS threshold settings**.**

Patient admitted on M300 VG2.3 and earlier:
– Changes to QRS/ARR processing leads and gain settings will alter the QRS threshold settings between ***Normal*** and ***Low***.
– When selecting one or two QRS/ARR processing leads, a gain setting of < 1mv on either lead, sets the ICS QRS threshold to ***Low***.
– When selecting one or two QRS/ARR processing leads, a gain setting of > 1mv on all leads, sets the ICS QRS threshold to ***Normal***.

To set the QRS Threshold using ICS VG2.1.1 and M300 VG2.4

From the Main ICS screen:

1 Click ***System setup*** on the ICS.

2 Click ***Layouts***.

3 Click one of the following:

- ***Normal*** to detect QRS complexes of normal amplitude.
- ***Low*** to detect QRS complexes of low amplitude.

To set the QRS Threshold using earlier ICS and M300 versions

For ICS 2.1 or earlier, or M300 VG2.3 or earlier, from the Main ICS screen:

1 Click ***System setup*** on the ICS.

2 Click ***Layouts***.

3 Click the dropdown arrow of the appropriate ***Gain/Scale*** channel.

4 Select the appropriate Gain value:

- Select a value of 1,2,4 or 8 mV/cm to set the QRS threshold to ***Normal***.
- Select a value of 0.5 or 0.25 mV/cm to set the QRS threshold to ***Low***.

QRS detection amplitude

QRS detection amplitude: 0.5 to 5.0 mVp-v RTI

QRS threshold detection duration:

Adult: 70 to 120 ms

Pediatric: 40 to 120 ms

Configuring the QRS threshold to ***Low*** may extend the QRS detection amplitude to as low as 0.17 mVp-v RTI.

WARNING
Risk of inaccurate HR value. If the QRS setting is set to *Low* in the presence of HR artifact, the associated HR value may be inaccurate.

To avoid an inaccurate HR value, it is recommended to set the QRS threshold setting to *Normal*.

ECG QRS processing settings

Gain/Scale column	mV/cm	Detection threshold
For all ECG waveforms: 0.25, 0.5, 1 (default), 2, 4, 8 mV/cm The M300 uses an AAMI-compliant regular QRS threshold when you select a scale of 1, 2, 4, or 8 mV/cm. If you select a scale of 0.25 or 0.5 mV/cm, the M300 lowers the detection threshold, and the AAMI requirement is not met.	8	≥0.35 mV
	4	≥0.35 mV
	2	≥0.35 mV
	1	≥0.35 mV
	0.5	≥0.17 mV
	0.25	≥0.17 mV

M300 Arrhythmia processing

Arrhythmias are identified using an internal detection process. This process does the following:

– Filters out ECG signal artifacts
– Detects the beat pattern
– Classifies the beat pattern
– Detects the rhythm

When arrhythmia analysis is enabled, multiple alarm conditions may occur simultaneously. Announcing all the alarm conditions would cause alarm fatigue and prevent the clinician from addressing the most serious condition. For this reason, the arrhythmia conditions are prioritized and only the highest priority alarm event shall annunciate. The priority order of the arrhythmia events is based on the default priority defined in the algorithm and the alarm grade configured by the user.

Based on this detection process, arrhythmias and other associated events are reported in the following order of severity:

1 ***ASY*** (asystole)
2 ***VF*** (ventricular fibrillation)
3 ***VTACH*** (ventricular tachycardia)
4 ***RUN*** (ventricular run)
5 ***AIVR*** (accelerated idioventricular rhythm)
6 ***SVT*** (supraventricular tachycardia)
7 ***CPT*** (ventricular couplet)
8 ***BGM*** (bigeminy)
9 ***TACH*** (tachycardia)
10 ***Brady*** (bradycardia)
11 ***Pause*** (sinus pause)
12 ***ARR artifact***

In addition to storage as events, the two high priority alarms, ***ASY*** and ***VF***, are also stored and displayed in the trends of the ICS.

An arrhythmia with a high grade alarm configuration has a higher priority than an arrhythmia with a medium, low or disabled alarm grade configuration. An arrhythmia with a medium grade alarm configuration has a higher priority than an arrhythmia with a low or disabled alarm grade configuration. An arrhythmia with a low grade alarm configuration has a higher priority than an arrhythmia with a disabled alarm configuration.

The priority for arrhythmia events configured with the same alarm grade follows the arrhythmia hierarchy list. When arrhythmia artifact is present (ARTF) at 100% artifact level, no arrhythmia events are recognized except for bradycardia and ventricular fibrillation. If sinus tachycardia and ventricular tachycardia are configured at the same alarm grade, a ventricular tachycardia will take priority if the rate is high enough and the beats are classified as ventricular beats.

ECG signal processing and display

The M300 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 M300 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 channel with less artifact always receives the greater weight. When a channel exceeds a certain level of artifact, it is excluded from the composite signal, and the M300 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.

NOTE

For heart rates of 300 bpm and greater, the monitor may display ***VF*** and not the expected +++ as the parameter value.

Patient preparation for ECG monitoring

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

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.

If QRS detection threshold is configured to ***Low***, P- and T-waves with amplitudes exceeding 0.17 mV may be interpreted as QRS complexes. P- and T-waves with amplitudes exceeding 0.35 mV when QRS detection threshold is configured to ***Normal***, may be interpreted as QRS complexes. The algorithm has implemented safeguards to reduce the occurrence of P- and T-wave detection as QRS complexes, however additional steps can be taken to prevent and/or troubleshoot occurrence:

– To allow detection of low heart rate conditions under these circumstances, place the lead with the highest R-wave in ECG ***Channel number*** 1.

– If P- and T-waves are misinterpreted, confirm that the lead with highest R-wave is in ECG ***Channel number*** 1 and set QRS detection threshold to ***Normal***.

– 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:

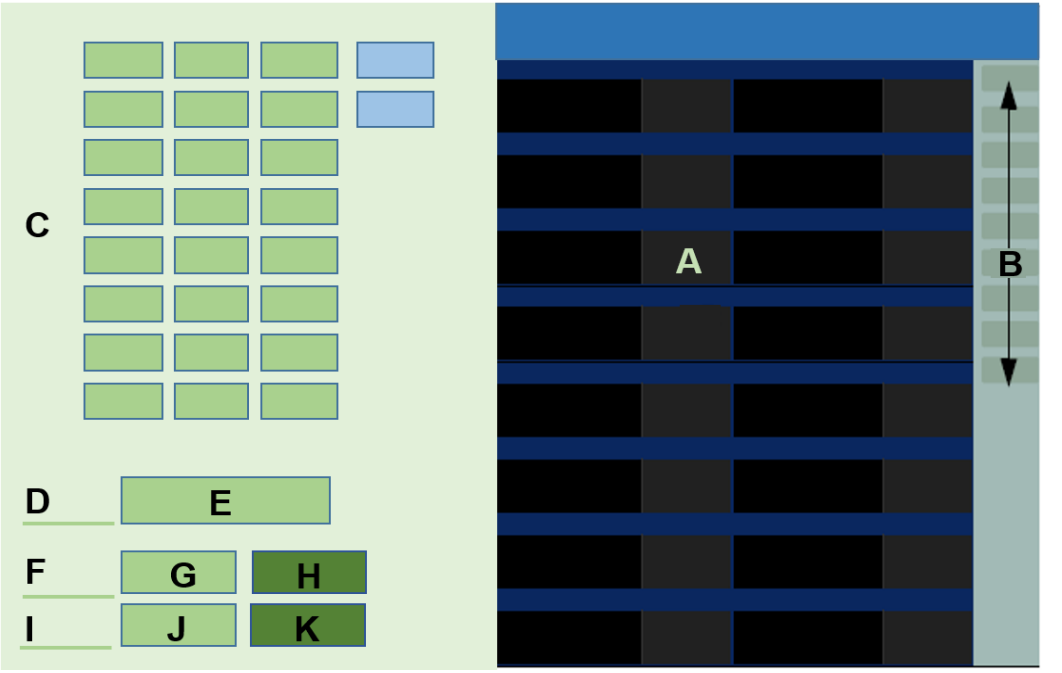
– **Surgery** – keep electrodes as far from the surgical site as possible, while maintaining a clinically useful lead configuration.
– **Burn patients** – use sterile electrodes. Clean the equipment thoroughly and follow hospital infection control procedures.

ECG precautions

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.

ICS Telemetry defaults screen

To set the ***Adult QRS threshold*** or ***Pediatric QRS threshold***, navigate to the Telemetry defaults screen and select the ***Layout/Parameters*** tab, then the ***Layout*** tab.

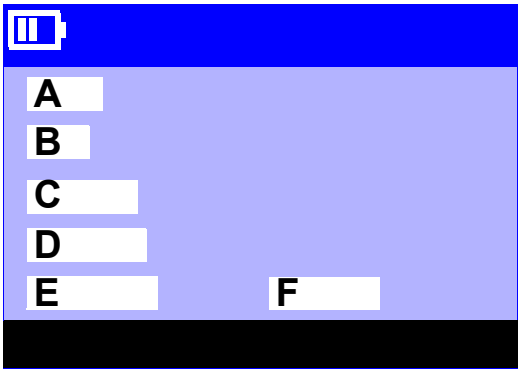


A	Reduced Main screen showing vital signs in real time
B	Main menu bar
C	Telemetry Layout Tab page
D	***QRS/ARR processing***
E	***QRS/ARR processing*** channels
F	***Adult QRS threshold***
G	***Normal***
H	***Low***
I	***Pediatric QRS threshold***
J	***Normal***
K	***Low***

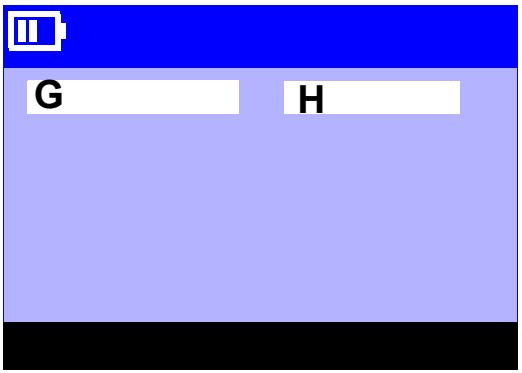
Refer to the IFU, *Infinity CentralStation Wide SW VG 1.n and Infinity M300,* for additional screen descriptions of the ICS interface.

M300 Demographic screens

The Infinity M300 two Demographic screens display patient demographic information. All patient demographic information is received from the ICS. Use the Up/Down arrows to jump from screen to screen.



Screen 1	
A	***Name***
B	***ID***
C	***Bed label***
D	***Care unit***
E	***Patient category***
F	***Adult / Pediatric***



Screen 2	
G	***QRS threshold***
H	***Normal/Low***

NOTE
To display Biomed page from page 2, press the down arrow three times.

Alarm settings

Low battery alarm

When the battery power level has reached approximately 30 minutes of remaining charge, a ***Low battery*** message is reported visually and acoustically at both the ICS and M300 to indicate that the battery is low. The M300 displays the ***Low battery*** status once every three minutes, plus or minus five seconds.

Critical battery alarm

Displays a critical battery alarm message, ***Recharge battery***, to indicate a low battery when the M300 power level has reached approximately 15 minutes of remaining charge. The alarm is reported visually and acoustically at both the M300 and the ICS. After the user acknowledges the alarm, the message will rotate through any other displayed M300 messages.

Alarm validation times for the M300

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

M300 Parameter	Upper alarm limit	Lower alarm limit
ECG/Heart rate (HR)	6 s	6 s
Pulse rate (PLS)	6 s	10 s
Pulse oximetry (SpO2)	6 s	10 s
ST segment analysis (ST)	55-61 seconds	55-61 seconds

For information about alarm validation times for a bedside monitor, refer to the instructions for use of the specific bedside monitor.

CAUTION

Failure to discharge previous patient information can result in the mixing of patient archive data at ICS when admitting a new patient using the ICS or the M300.

Discharging a Patient

Patient discharge occurs from the ICS as well as from the M300. To discharge a patient from the M300 screen, do the following:

1 On the M300 keypad, press the ***Staff alert*** setting key  and the ***Alarm pause*** setting key  simultaneously for 3 seconds.

A confirmation screen appears asking to ***Confirm discharge*** of the patient or to ***Cancel*** and not discharge the patient.

2 To discharge the patient, use the up and down arrows on the keypad and select ***Discharge***.

3 Press the ***Views*** key  to confirm that the patient was discharged.

Refer to the IFU, *Infinity CentralStation Wide SW VG1.n and Infinity M300* for the steps to admit a patient using the M300.

Technical specifications

Infinity M300 (MS25755)

Environmental requirements	
Temperature	Operating: 0 to 40 °C (32 to 104 °F) Storage: –20 to 60 °C (–4 to 140 °F)
Humidity (non-condensing)	Operating: 10 % to 95 % Storage: 5 % to 95 %
Atmospheric pressure	Operating: 64.7 to 106 kPa Storage: 50 to 106 kPa
Protection against ingress of water	IPX7, temporary immersion

Infinity M300 Central Charger (MS25699)

Infinity M300 Central Charger	
Physical specifications	
Size, H x W x D	230 x 525 x 190 mm (9.0 x 20.7 x 7.5 in)
Weight	6.8 kg (15 lb)
Cooling	Convection
Connections	Up to ten (10) Infinity M300 devices
Electrical specifications	
Input Voltage	100 to 240 VAC
Input frequency (Hz)	50/60 Hz
Protection Class	Class 1
Mode of Operation	Continuous
Environmental requirements	
Temperature	Operating: 0 to +35 °C (32 to 95 °F) Storage: –20 to +60 °C (–4 to +140 °F)
Humidity (non-condensing)	Operating: 10 % to 95 % Storage: 10 % to 95 %
Atmospheric Pressure	Operating: 64.7 to 106 kPa Storage: 50 to 106 kPa
Protection against ingress of water	IPX1 (dripping) per IEC 60529
Standards/compliance	
Standards	UL 60601-1, IEC 60601-1, and IEC 60601-1-2

Infinity M300 Bedside Charger (MS18620)

Infinity M300 Bedside Charger	
Physical specifications	
Size, H x W x D	45.7 x 162.5 x 99.1 mm (1.8 x 6.4 x 3.9 in)
Weight	224.0 g (7.9 oz)
Cooling	Convection
Connections	One (1) Infinity M300
Electrical specifications	
Input voltage	92 to 264 VAC, 50/60 Hz (±5 %)
Protection class	Class 2
Mode of operation	Continuous
Environmental requirements	
Temperature	Operating: 0 to 40 °C (32 to 104 °F) Storage: –20 to +60 °C (–4 to +140 °F)
Humidity (non condensing)	Operating: 10 % to 95 % Storage: 5 % to 95 %
Atmospheric pressure	Operating: 64.7 to 106 kPa Storage: 50 to 106 kPa
Protection against ingress of water (cradle only)	IPX4, splashing water
Standards/compliance	
Standards	IEC 60601-1 and IEC 60601-1-2

Infinity M300 Bedside Charger (MS29558)

Infinity M300 Bedside Charger	
Physical specifications	
Size, H x W x D	45.7 x 162.5 x 99.1 mm (1.8 x 6.4 x 3.9 in)
Weight	375 g (13.2 oz) to 447 g (15.8 oz) depending on plug style
Cooling	Convection
Connections	One (1) Infinity M300
Electrical specifications	
Input voltage	92 to 264 VAC, 50/60 Hz (±5 %)
Protection class	Class 1
Mode of operation	Continuous
Environmental requirements	
Temperature	Operating: 0 to 40 °C (32 to 104 °F) Storage: –20 to +60 °C (–4 to +140 °F)
Humidity (non condensing)	Operating: 10 % to 95 % Storage: 5 % to 95 %
Atmospheric pressure	Operating: 64.7 to 106 kPa Storage: 50 to 106 kPa
Protection against ingress of water (cradle only)	IPX4, splashing water
Standards/compliance	
Standards	IEC 60601-1 and IEC 60601-1-2

M300 Performance data

The following disclosures related to algorithm performance using certain waveforms are added or updated to the monitoring specifications:

M300 ECG/Arrhythmia/ST Supplemental information	
Time to alarm for tachycardia	Ventricular tachycardia 1mVpp, 206 bpm Gain 0.5, range 3.0 to 3.5 seconds, average 3.3 seconds Gain 1.0, range 2.9 to 3.3 seconds, average 3.2 seconds Gain 2.0, range 2.8 to 3.5 seconds, average 3.0 seconds
	Ventricular tachycardia 2 mVpp, 195 bpm Gain 0.5, range 2.2 to 4.0 seconds, average 3.0 seconds Gain 1.0, range 1.9 to 2.5 seconds, average 2.3 seconds Gain 2.0, range 2.0 to 2.9 seconds, average 2.5 seconds
Tall T wave rejection capability	1.20 mV T wave amplitude
Heart rate averaging method	Heart rate is normally based on the average R-R interval calculated over the last 10 seconds.
Response time of heart rate meter to change in heart rate	HR change from 80 to 120 bpm: Range: < 13 seconds HR change from 80 to 40 bpm: Range: < 13 seconds
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	Methods A, B, C, and D from IEC 60601-2-27 were used to establish overall system error and frequency response.
Lead-off sensing applied current	Lead-off sensing applied current < 0.1 µ ampere

M300 User Interface	
Time from alarm condition to representation	System alarm delay: < 1/s

M300 accessories overview

Pulse Oximetry (SpO_2) monitoring with Masimo (for M300)

The following components are for the M300. Contact your Dräger representative for additional information.

NOTE

- For Masimo sensors, there are unique part numbers for Global, USA, and Japanese location references.
- Always refer to the Directions for Use accompanying the Masimo patient accessories.
- LNCS intermediate cables are designed to last approximately 17,000 hours while actively monitoring SpO2 (for example 4 years if monitoring occurs 12 hours a day). This duration is monitored by a chip inside the cable.

LNCS Adhesive SpO_2 Sensors

Global Part Number	USA Part Number	Japanese Part Number	Description
MP00790	MP03011	MP03089	Masimo SpO_2-Sen.LNCS Adtx.Bx20
MP00793	MP03012	MP03090	Masimo SpO_2-Sen.LNCS Pdtx.Bx20

LNCS Reusable SpO_2 Sensors

Global Part Number	USA Part Number	Japanese Part Number	Description
MP00796	MP03019	MP03097	Masimo SpO_2-Sensor LNCS DC-I
MP00795	MP03020	MP03098	Masimo SpO_2-Sensor LNCS DC-IP
MP00788	MP03021	MP03099	SpO_2 Masimo Sen LNCS-TC-I Ear
MP00799	MP03022	MP03101	SpO_2 Masimo Sen LNCS-TF-I
MP00789	MP03023	MP03102	SpO_2 Masimo Sen LNCS-YI Multi
MP02993	MP03024	MP03103	SpO_2 Masimo Sen LNCS DBI Adult **NOTE**: Masimo does not make any claims regarding motion for this sensor.

NOTE

To use Masimo M-LNCS and RD-SET sensors, an additional intermediate cable is required.

M-LNCS Adapter Cables

Global Part Number	USA Part Number	Japanese Part Number	Description
MP02994	MP03028	MP03107	Adapter Cable M-LNCS to LNC

M-LNCS Adhesive SpO_2 Sensors

Global Part Number	USA Part Number	Japanese Part Number	Description
MP02976	MP03071	MP03173	SpO_2 Masimo M-LNCS Adtx-3, 20p
MP02977	MP03072	MP03174	SpO_2 Masimo M-LNCS Pdtx-3, 20p

M-LNCS Reusable SpO_2 Sensors

Global Part Number	USA Part Number	Japanese Part Number	Description
MP02981	MP03080	MP03182	SpO_2 Masimo M-LNCS DCI Adult
MP02982	MP03081	MP03183	SpO_2 Masimo M-LNCS DCIP Pedi
MP02983	MP03082	MP03184	SpO_2 Masimo M-LNCS TC-I Ear
MP02985	MP03083	MP03185	SpO_2 Masimo M-LNCS TF-I Adult
MP02984	MP03084	MP03186	SpO_2 Masimo M-LNCS YI Multis.
MP03207	MP03085	MP03187	SpO_2 Masimo M-LNCS DBI Adult **NOTE**: Masimo does not make any claims regarding motion for this sensor.

Masimo RD-SET SpO2 Sensors

Global Part Number	USA Part Number	Japanese Part Number	Description
MS33726	MS33745	MS33764	Masimo SpO_2 RD-SET Adt
MS33727	MS33746	MS33765	Masimo SpO_2 RD-SET Pdt
MS33740	MS33759	MS33778	Masimo SpO_2-Sen. RD-SET DC-I
MS33741	MS33760	MS33779	Masimo SpO_2-Sen RD-SET DCIP

Masimo RD-SET Adapters

Global Part Number	USA Part Number	Japanese Part Number	Description
MS33731	MS33750	MS33769	RD to LNOP adapter
MS33732	MS33751	MS33770	RD to LNCS adapter
MS33734	MS33753	MS33772	RD to M-LNCs adapter

RD-SET intermediate cables

MS34436	SpO_2 intermediate cable Masimo RD-SET, 1.2 m
MS34437	SpO_2 intermediate cable Masimo RD-SET, 3 m

Electromagnetic compatibility (EMC)

EMC third edition

The Infinity M300 device (MS25755) revisions 19 and below, which are hardware revision 3, meet EMC 3rd edition requirements as described in this section.

The Infinity M300 has been designed and tested for compliance with current regulatory standards as to its capacity to limit electromagnetic emissions (EMI), and also as to its ability to block the effects of EMI from external sources. The Infinity M300 is designed to comply with the EMI/EMC standard, IEC 60601-1-2.

The separation distances are written regarding the Infinity M300. The numbers provided will not guarantee faultless operation. This information may not be applicable to other medical electrical equipment, and older equipment may be particularly susceptible to interference.

Reducing EMI

To reduce possible problems caused by electromagnetic interference, Dräger recommends the following:

– Use only Dräger-approved, accessories, otherwise the correct functioning of the device may be compromised. Contact your local Dräger representative for a list of approved accessories.

– Ensure that other products used in areas where patient monitoring and/or life-support products are used comply to accepted emissions standards (CISPR 11).

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

– Strictly limit access to portable radio-frequency sources, e.g., cellular phones, and radio transmitters. Be aware that portable phones may periodically transmit even when in *Standby* mode.

– Maintain good cable management. Try not to route cable over electrical equipment. Do not intertwine cables.

– Be sure that all electrical maintenance is performed by trained personnel.

General notes

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.

Cables and accessories not specified within the instructions for use are not authorized. 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 next 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.

When using wireless networking, be aware that the system operates at the 2.4 to 2.4835 GHz ISM band. Other equipment, even if compliant with CISPR emission requirements, could interfere with reception of wireless data. When selecting new wireless systems (e.g. cell phones, pager systems, cordless phones, Bluetooth, etc.) for use in installations where wireless networking is used, care should always be used to insure that operating frequencies are compatible. For example, selecting cordless phones that operate at 2.4 GHz will likely cause difficulty with the phones and networking components.

NOTE

Detailed radio frequency characteristics: 2.4 to 2.4835 GHz ISM band, IEEE 802.11b/g compatible, limited to 100 mW. Applicable to both access points and client adapters. See the documentation that accompanies the wireless products for further details.

Low-level signals such as ECG are potentially 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 Infinity CentralStation and Infinity M300 are intended for use in the electromagnetic environments specified below. The user of this equipment should assure that is used in an environment meeting these specifications.

Electromagnetic emissions		
Emissions	**Compliance according to...**	**Electromagnetic environment**
RF emissions (CISPR 11) Infinity CentralStation and Infinity M300	Group 1 Class B	The Infinity M300 must emit electromagnetic energy to perform its intended function. Nearby electronic equipment may be affected.

Electromagnetic immunity			
Immunity against...	**IEC 60601-1-2 3rd edition test level**	**Compliance level (of this device)**	**Electromagnetic environment**
Electrostatic discharge, ESD (IEC 61000-4-2)	Contact discharge: ±6 kV	*±6 kV*	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be kept at levels to reduce electrostatic charge to suitable levels.
	Air discharge: ±8 kV	*±8 kV*	
Electrical fast transients / bursts (IEC 61000-4-4)	Power supply lines: ± 2 kV	*±2 kV*	Mains power quality should be that of a typical commercial or hospital environment.
	Longer input / output lines: ±1 kV	*±1 kV*	
Surges on AC mains lines (IEC 61000-4-5)	Common mode: ±2 kV	*±2 kV*	Mains power quality should be that of a typical commercial or hospital environment.
	Differential mode: ±1 kV	*±1 kV*	
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	>95 %, 0.5 periods	Mains power should be that of a typical commercial or hospital environment. If user requires continued operation during power mains interruptions insure that batteries are installed and charged. Make sure that battery life exceeds longest anticipated power outages or provide and additional uninterruptible power source.
	Dip 60 %, 5 periods	60 %, 5 periods	
	Dip 30 %, 25 periods	30 %, 25 periods	
	Dip >95 %, 5 seconds	>95 %, 5 seconds	

Electromagnetic immunity			
Immunity against...	**IEC 60601-1-2 3rd edition test level**	**Compliance level (of this device)**	**Electromagnetic environment**
Conducted RF RF coupled into lines (IEC 61000-4-6)	150 kHz to 80 MHz:	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter as below. Recommended separation distance: d = 1.2√P 150 kHz to 80 MHz d = 1.2√P 80 MHz to 800 MHz d = 2.3√P 800 MHz to 2.5 GHz *where 'P' is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and 'd' is the recommended separation distance in meters.* Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[1], should be less than the compliance level in each frequency range[2]. Interference may occur in the vicinity of equipment marked with the following wireless symbol: 
Radiated RF (IEC 61000-4-3)	80 MHz to 2.5 GHz	3 V/m	

Electromagnetic immunity			
Immunity against...	**IEC 60601-1-2 3rd edition test level**	**Compliance level (of this device)**	**Electromagnetic environment**

[1] 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.

[2] If the frequency range is 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the equipment			
Rated maximum output power of transmitter (watts)	**Separation distance according to frequency of transmitter (meters)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed, the recommended separation distance ‘d’ *(*in meters) can be estimated using the equation applicable to the frequency of the transmitter, where ‘P’ is the maximum output power rating of the transmitter (in watts) according to the transmitter manufacturer.

NOTE

– At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

– These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Infinity M300 Radio emissions statement

NOTE

This device was developed and produced in a manner that the emission limits for RF (Radio Frequency Energy), defined by the FCC (Federal Communication Commission), by RSS (Radio Standards Specification) and by ETSI, IEC 60601-1-2, will not be exceeded. These limits are part of international safety standards and defined by international committees.

NOTE

The Infinity M300 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.

EMC fourth edition

The Infinity M300 device (MS25755) revisions 20 and above, which are hardware revision 4, meet EMC 4th edition requirements as described in this section.

Medical electrical equipment is subject to special precautionary measures concerning electromagnetic compatibility. During installation and before initial operation, follow the information in section: "EMC declaration for M300" (page 39).

This device can be affected by other electrical devices.

WARNING

Risk due to electrostatic discharge

Malfunctions that endanger the patient may occur if no protective measures against electrostatic discharge are employed in the following situations:

– When touching the pins of connectors that carry the ESD warning symbol.

– When establishing connections with these connectors.

To prevent malfunctions, observe the following measures and train the relevant personnel:

– Observe the ESD protective measures. Such measures may include wearing antistatic clothing and shoes, touching a potential equalization pin before and while making the connection, or using electrically insulating and antistatic gloves.

– Observe the requirements for the electromagnetic environment. Observe the following section: "Electromagnetic environment" (page 39).

WARNING

Risk due to electromagnetic disturbance

Wireless communication devices (e.g., cellular phones) and medical electrical equipment (e.g., defibrillators, electrosurgical devices) emit electromagnetic radiation. When such devices are operated too close to this device or its cables, the functional integrity of this device may be compromised by electromagnetic disturbances. As a result, the patient could be put at risk.

Maintain a distance of at least 0.3 m (1.0 ft) between this device and wireless communication devices, to ensure that the essential performance of this device is fulfilled.

Maintain an adequate distance between this device and other medical electrical equipment.

EMC declaration for M300

General information

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

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

Electromagnetic environment

This device may only be used in environments specified in section "Infinity M300 Device description" on page 7.

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

NOTE

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

Immunity against IEC 60601-1-2 4th edition	**Test level and required electromagnetic environment**
Electrostatic discharge (ESD) (IEC 61000-4-2)	Contact discharge: ±8 kV
	Air discharge: ±15 kV
Magnetic fields at mains frequency (IEC 61000-4-8)	30 A/m
Radiated high-frequency disturbances (IEC 61000-4-3)	80 MHz to 2.7 GHz: 3 V/m
Conducted high-frequency disturbances (IEC 61000-4-6)	150 kHz to 80 MHz: 3 V_{RMS}, ISM bands: 6 V_{RMS}
Electromagnetic fields in the vicinity of wireless communication devices	Various frequencies from 385 MHz to 5785 MHz: 9 V/m to 28 V/m, with various pulse modulations and immunity test levels.

Recommended separation distances from wireless communication devices

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

Additional information

ECG, arrhythmia, and ST segment monitoring with M300

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

NOTE

ST analysis is always performed using a dedicated filter which ensures diagnostic quality. ST segment of the ECG waveform may appear differently from the ST segment of the ST complex. An ECG report is not of diagnostic quality. Therefore, the ST segment of the ECG waveform on the report may appear differently from the ST segment of the ST complex. The only report of ECG diagnostic quality is a Rest ECG report.

NOTE

When monitoring in dual-lead mode, ECG signal processing uses pre-determined logic to assess signal quality and determine which lead to use for analysis. If the first lead's signal quality is poor but the second lead's signal quality is good, the algorithm puts more weight on the good lead for monitoring the patient's condition

Monitoring paced patients

When pacer detection is enabled, the M300 uses the following specifications to identify a pulse as a pacer pulse:

Amplitude: ±2 to ±700 mV
Width: 0.2 to 2.0 ms
Rise/Fall times (min.): 0.1 d_p, ≤100 µs
Overshoot (min.): 0.025, ≤2 mV
Recharge time constant: 4 to 100 ms

If a pacer pulse is within 250 ms by a QRS complex, the QRS is classified a paced beat. A paced beat is identified as follows:

– 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, vertical spikes appear to identify pacer spikes.

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

Pacemaker precautions

WARNING

Risk of pacer-induced artifacts on M300 waveform

The M300 has been tested for pacemaker pulse detection. However, it is impossible to anticipate every clinically possible waveform characteristic. For paced patients, the M300 could therefore miscount heart rates and misinterpret rate-dependent arrhythmias.

– Dräger recommends closely monitoring the heart rate of paced patients.

Pacemaker considerations

The M300 is tested in accordance with 60601-2-27 201.12.1.101.13 Rejection of pacemaker pulses. All pacemaker pulses within this defined range are effectively rejected with the exception of the following:

- False low-rate alarms can result under the following conditions:
  – Fused beats and asynchronous pacemakers, when coupling intervals are in the range of +10 ms to –90 ms
  – Presence of large pacemaker pulses 2.0 ms wide with amplitude 500 mV or greater
  – Asynchronous pacemaker pulses with overshoot
  – Asynchronous pacemaker with large amplitude pace pulses with no overshoot and at low heart rate (30 bpm)
  – Paced pulses of 0.2 – 0.5ms and amplitude voltage from -2.0 – 700 mV with overshoot greater than 0.3% may result in missed valid heart beats, contributing to a lower than actual heart rate.

  Dräger recommends closely monitoring paced patients.

- False high-rate alarms can result under the following conditions:
  – Asynchronous pacemaker with large pace pulse tails and at low heart rate (30 bpm)
  – Pace pulses above 200 - 700 mV, such as when an external pacemaker is used, may cause an electrical overshoot which can mimic a QRS complex, which may affect the accuracy of ECG beat classification.

    Dräger recommends monitoring transcutaneous paced patients in accordance with your hospital's policy.
  – With lower pace pulses of -2.0 - 2.0 mV an electrical overshoot can occur, and mimic a QRS complex, which may affect the accuracy of ECG beat classification.
  – Large atrial pacemaker pulse followed by a large ventricular pacemaker pulse (both having identical amplitude and durations)

  Dräger recommends closely monitoring paced patients.

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 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 M300. The M300 may incorrectly detect these large pacemaker pulses as valid QRS complexes and may fail to detect cardiac arrest.**

Operating concept

To transfer data from an M300 to another M300:

The following caution is added:

CAUTION

Do not select the same M300 as the source and the destination for data transfer. This action results in discharging patient data on the M300.

M300 offline recordings

While the M300 is offline or the R50N recorder is not available, the last five recordings (automatic or manual) are stored on the M300. When the connection is restored, those recordings are sent to the R50N recorder.

Known issues

Continuous pacer spikes on M300

CAUTION

Continuous pacer spikes can appear on the ECG waveform if the M300 is docked on the bedside charger and the electrode impedances are not balanced. Continuous pacer spikes can also appear as a result of electromagnetic interference generated by other devices in the patient's immediate vicinity. False pacer spikes may affect the accuracy of ECG beat classification.

To resolve this issue:

– Be sure to use new electrodes.

– Temporarily remove the Infinity M300 from the bedside charger until the electrode impedance normalizes.

– Turn pacer detection off, if appropriate.

Reviewing stored ST complexes at Symphony

When reviewing the M300 stored ST complexes at Symphony, the three augmented leads (aVR, aVL, aVF) are displayed in the ST complexes view only when the M300 has 12-leads available (i.e., M300 6-wire with TruST enabled).

ECG lead wires setting

NOTE

In TruST 12-lead mode (ECG Lead Wires = 6 wires and TruST 12-Lead = On), leads III, aVL, and aVF are not displayed on a remote view from a network device.

To resolve this issue, TruST 12-lead mode must be disabled, as follows:

Set TruST 12-Lead = Off,
or set ECG Lead Wires = 5.

ICS VG1 incorrectly displays ***% Paced*** and the alarm off symbol (IEC alarm off) in the heart rate parameter field.

The alarm off symbol should not display because there are no alarms associated with ***% Paced***.

Reprocessing

This section provides information for the reprocessing of M300 device-specific components and accessories. Keep this supplement with the instructions for use.

Safety Information

WARNING

Risk due to inappropriately reprocessed products

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

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

CAUTION

Risk due to faulty products

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

Information on reprocessing

Follow the national infection prevention policies and reprocessing regulations.

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

Classification for reprocessing

Classification of medical devices

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

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

Classification of device-specific components

The following classification is a recommendation from Dräger.

Non-critical

Device Components:

– M300 Telemetry Device

Chargers:

– M300 Central Charger

– M300 Bedside Charger

Before reprocessing

Observe before disassembly

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

1 Turn off the M300 Telemetry Device:

a. Simultaneously press and hold both arrow keys.

b. Select the up arrow to highlight **Yes**.

c. Press the **Menu** button and confirm the shutdown.

2 Unplug the M300 Bedside and Central Charger:

a. If docked, remove the M300 telemetry device.

b. Disconnect the power plug.

Patient-specific accessories and consumables

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

Reusable products:

- If the reusable product has its own instructions for use, perform reprocessing in accordance with the separate instructions for use. Further information can be found in the list of accessories.
- If no separate instructions for use are available for the reusable product, perform reprocessing in accordance with the instructions in this supplement (see "Reprocessing of patient-specific accessories" on page 52).

Disposable products:

- Dispose of the disposable products.

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

Removing the accessories

- ECG lead wire
- SpO2 intermediate cable
- Pouch M300 components

Validated reprocessing procedures

Overview of the reprocessing procedures of the components

Components	Surface disinfection with cleaning	Manual cleaning followed by disinfection by immersion	Machine cleaning with thermal disinfection	Steam sterilization	Description of the procedure
M300 telemetry device	Yes	N/A	N/A	N/A	See Surface disinfection with cleaning on pages 52 - 54.
Charger(s)	Yes	N/A	N/A	N/A	

Surface disinfection with cleaning

Components:
- M300/Telemetry Device
- Charger(s)

Surface disinfectant	Manufacturer	Concentration	Contact time
Oxycide	Ecolab USA	2.3%	5 min

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

WARNING

Risk of electric shock and device malfunction.

Penetrating liquid may cause the following:
- **Damage to the device**
- **Electric shock**
- **Device malfunctions**

Ensure that no liquid penetrates the device.

WARNING

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

CAUTION

Do not use excessive pressure when cleaning the charging contacts. Excessive pressure can damage the contacts.

CAUTION

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

WARNING

Risk of cross contamination:

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

– M300 Telemetry Device

– Charger(s)

Failure to do so can lead to infection.

Cleaning

1 Wipe off obvious soiling with a disposable cloth soaked in surface disinfectant.

2 Dispose of the cloth.

3 Wipe all surfaces with a new disposable cloth soaked in surface disinfectant. After that, there must no longer be any soiling visible.

Surface disinfection

4 Take a new disposable cloth soaked in surface disinfectant. Wipe cleaned surfaces again until all surfaces to be disinfected are visibly wet.

5 Wait 15 minutes for the surface disinfectant contact time.

6 At the end of the contact time, moisten a new, uncontaminated and lint-free cloth with water (at least drinking water quality).

7 Wipe all surfaces until no remains of the surface disinfectant, such as foam residues or streaks, are visible.

8 Wait until the surfaces are dry.

9 Check the surfaces for visible damage and, if necessary, replace the product.

Supplementary information

Storage and transport

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

– Store dry and free of dust.

– Avoid recontamination and damage during transport.

All other information in the instructions for use regarding storage and transport continues to apply. In addition, the requirements that prevent contamination or damage to the product must be met. These include, for example, dry and dust-free storage and avoiding damage during transport to the operating location.

Other agents and reprocessing procedures

Disinfectants

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

Surface disinfectants

The manufacturers of the surface disinfectants have verified at least the following spectra of activity:
– Bactericidal
– Yeasticidal
– Virucidal or virucidal against enveloped viruses

Follow the manufacturer's instructions for surface disinfectants.

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

Class of active ingredient	**Surface disinfectant**	**Manufacturer**	**Listing**
Chlorine-releasing agents	BruTab 6S	Brulin	EPA[1)]
	Clorox Professional Disinfecting Bleach Cleaner	Clorox	EPA
	Dispatch Hospital Cleaner Disinfectant Towels with Bleach		
	Klorsept 17	Medentech	EPA
	Actichlor plus	Ecolab USA	EPA
Oxygen-releasing agents	Oxycide	Ecolab USA	EPA

1) United States Environmental Protection Agency

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

Reprocessing of patient-specific accessories

Categorization of accessories

Category	Classification	Part number	Description of the procedure
ECG monolead	Non-Critical	MS14555 MS14556 MS14559 MS14560 MS14683 MS14682	See Surface disinfection with cleaning on pages 57 - 59.
SpO2 intermediate cable	Non-Critical	MS18683 MS17330	
SpO2 sensor	Non-Critical	MS13235	
Pouch M300 waterproof new tag	Non-Critical	MS32401	
Tele transmitter pouch disposable 100 pcs	Non-Critical	MS22905	

Reprocessing of the categories ECG monolead, SpO2 intermediate cable and SpO2 sensor

Surface disinfection with cleaning

Surface disinfectant	Manufacturer	Concentration	Contact time
Oxycide	Ecolab USA	2.3%	5 min

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

WARNING
Risk due to penetrating liquid.

WARNING

Risk of electric shock and device malfunction.

Penetrating liquid may cause the following:
- **Damage to the device**
- **Electric shock**
- **Device malfunctions**

Ensure that no liquid penetrates the device.

CAUTION

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

CAUTION

Do not autoclave accessories.

CAUTION

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

Cleaning

1. Wipe off obvious soiling with a disposable cloth soaked in surface disinfectant.
2. Dispose of the cloth.
3. Wipe all surfaces with a new disposable cloth soaked in surface disinfectant. After that, there must no longer be any soiling visible.

Surface disinfection

4 Take a new disposable cloth soaked in surface disinfectant. Wipe cleaned surfaces again until all surfaces to be disinfected are visibly wet.

5 Wait 15 minutes for the surface disinfectant contact time.

6 At the end of the contact time, moisten a new, uncontaminated and lint-free cloth with water (at least drinking water quality).

7 Wipe all surfaces until no remains of the surface disinfectant, such as foam residues or streaks, are visible.

8 Wait until the surfaces are dry.

9 Check the surfaces for visible damage and, if necessary, replace the product.

Reprocessing of the category Pouch

The non-disposable transmitter pouch can be cleaned using mild soap and water on a damp cloth. Air dry. Laundering and solvents are not recommended.

Storage and transport

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

– Store dry and free of dust.

– Avoid recontamination and damage during transport.

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

Other agents and reprocessing procedures

Disinfectants

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

Surface disinfectants

The manufacturers of the surface disinfectants have verified at least the following spectra of activity:
– Bactericidal
– Yeasticidal
– Virucidal or virucidal against enveloped viruses

Follow the manufacturer's instructions for surface disinfectants.

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

Class of active ingredient	**Surface disinfectant**	**Manufacturer**	**Listing**
Chlorine-releasing agents	BruTab 6S	Brulin	EPA[1)]
	Clorox Professional Disinfecting Bleach Cleaner	Clorox	EPA
	Dispatch Hospital Cleaner Disinfectant Towels with Bleach		
	Klorsept 17	Medentech	EPA
	Actichlor plus	Ecolab USA	EPA
Oxygen-releasing agents	Oxycide	Ecolab USA	EPA

1) United States Environmental Protection Agency

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

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

After reprocessing

Assembling and attaching device-specific components

Prerequisite:

– All components have been reprocessed and are dry.

Preparation before next use of device

Assembling and fitting patient-specific accessories and consumables

Assemble the ECG lead wire and SpO2 intermediate cable

Checking the operational readiness

Prerequisite:

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

Check the operational readiness (see the instructions for use, chapter “Getting started“in the IFU, *Infinity CentralStation Wide SW VG 1.n and Infinity M300*).

This supplement only applies to
Infinity® M300 VG2.4
with the Serial No.:
If no Serial No. has been filled in by Dräger, these Instructions for Use are provided for general information only and are not intended for use with any specific machine or unit.
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The radio equipment in the Infinity M300 patient monitor complies with the Radio Equipment Directive (2014/53/EU). A copy of the Declaration of Conformity is available at the following Internet address:
www.draeger.com/doc-radio

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

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