

**Supplement**

# **Infinity Acute Care System**

**WARNING**

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

## **Infinity Acute Care System Software VG7.n**

## Trademarks

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<b>Trademark</b>	<b>Trademark owner</b>
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Mikrozid®	
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Dismozon®	Bode Chemie
Klorsept®	Medentech
Infinity®	Dräger
Tcore®	
Oxycide®	Ecolab USA
Virkon®	DuPont

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## Introduction

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### Content of this document

This supplement contains updates to the instructions for use (IFU) for the Infinity Acute Care System VG7.n. Combine this supplement with the following documents to form the complete set of IFUs:

- *Instructions for use Infinity Acute Care System Monitoring Applications Software VG7.n*
- *Instructions for use Infinity Acute Care System Monitoring accessories Software VG7.n*
- *Instructions for use Infinity Acute Care System Infinity M540 patient monitor Software VG7.n*

### Structure of this document

This supplement is structured to follow the organization of the IFUs for which they are intended. The main headings in this document reflect the chapter names in the IFUs. Sub-headings reflect the sections of the chapters to which the information applies.

## Invasive Pressures (IP)

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### Connecting a second Infinity MPod — Quad Hemo

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**NOTE**

If two MPod — Quad Hemos are “daisy-chained”, then the second MPod — Quad Hemo’s temperature ports will not provide a temperature reading.

**NOTE**

Cardiac Output (C.O.) is not supported on the second MPod — Quad Hemo.

**NOTE**

Unplugging the second MPod — Quad Hemo will automatically power-cycle the first MPod — Quad Hemo. This erases the zero reference for all existing invasive pressure channels.

After unplugging the second MPod — Quad Hemo:

- Please re-zero all existing invasive pressure channels.
- If you are using the arterial invasive pressure signal with the analog synch MCable, please re-zero the arterial invasive pressure channel.

See **Connecting a second MPod — Quad Hemo** in the *Instructions for use Infinity Acute Care System Infinity M540 patient monitor VG 7.n*

## Invasive pressure (M540)

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The invasive pressure message table in the **Troubleshooting** section of the *Instructions for use Infinity Acute Care System Infinity M540 patient monitor Software VG7.n* contains two new messages:

- **2nd HemoPod unplugged**
- **HemoPod incompatible**

Priority	Message	Cause	Remedy
!	<b>2nd HemoPod unplugged</b> <sup>3)</sup>	The second invasive pressure device is disconnected.	– Check the equipment and replace if necessary.
None	<b>HemoPod incompatible</b>	An incompatible invasive pressure device has been connected.	– Remove the incompatible invasive pressure pod.

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

## Configuring the alarm priority for a disconnected Masimo sensor

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When the Masimo rainbow SET MCable or Masimo SET MCable is used, the alarm message is:

### **SpO2 sensor off**

On the Cockpit and the M540, 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
SpHb or SpHbv	
SpCO	
PVI	
SpMet	
SpOC	
PI	

## Parameter Monitoring Specifications

### Pulse Oximetry (SpO<sub>2</sub>) Infinity MCable-Masimo SET, Infinity MCable-Masimo rainbow SET

Adult and pediatric sensors	<p>LNCS DCI, LNCS DCIP, LNCS TC-I, LNCS TF-I, LNCS YI, LNCS Adtx, LNCS Pdtx, LNCS Adtx-3, LNCS Pdtx-3, LNCS-DBI Adtx, LNCS Inf, LNCS Inf-3, Trauma LNCS Adtx, Trauma LNCS Inf/Pdtx</p> <p>RD-SET Adt, RD-SET Pdt, RD-SET Inf, RD-SET DC-I Adt, RD-SET DCIP Pdtx</p> <p>M-LNCS DCI Adtx, M-LNCS DCIP Pdtx, M-LNCS TC-I, M-LNCS TF-I Adtx, M-LNCS YI multi-site, M-LNCS DBI Adtx, M-LNCS Adtx-3, M-LNCS Pdtx-3, M-LNCS Adtx-3, M-LNCS Inf-3, Trauma M-LNCS Adtx, Trauma M-LNCS Inf/Pdtx</p> <p>R2-25a, R2-20a, R2-25, R2-20, R2-25r, R2-20r, R25-L, R20-L, R25, R20, rainbow DCI Adtx, rainbow DCIP Pdtx</p>
Neonatal sensors	<p>LNCS Inf, LNCS Inf-3, LNCS Neo, LNCS Neo-3, LNCS NeoPt-3, LNCS NeoPt, LNCS YI, LNCS SofTouch, Neo-Pt-500m, Trauma LNCS Neo</p> <p>RD-SET Neo, RD-SET NeoPt</p> <p>M-LNCS NeoPt-3, M-LNCS Neo-3, Trauma M-LNCS Neo</p>
Parameter display	<p>Percentage of functional, for example, oxygen-saturated hemoglobin.</p> <p>Masimo SET MCable: Pulse oximetry (SpO<sub>2</sub>), pulse rate (PLS), perfusion index (PI))</p> <p>Masimo rainbow SET MCable: Pulse oximetry (SpO<sub>2</sub>), pulse rate (PLS), perfusion index (PI), SpHb (total hemoglobin), SpOC (total oxygen saturation), SpCO (carbon monoxide in hemoglobin), SpMet (methemoglobin saturation), PVI (pleth variability index)</p>
Measuring method	Absorption-spectrophotometry

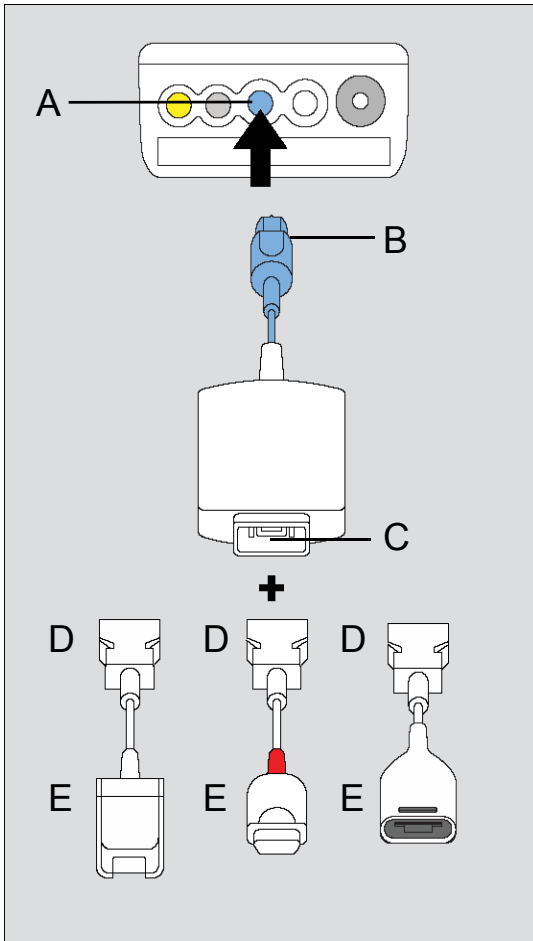
*Parameter Monitoring Specifications*

<b>Measurement range</b> (Infinity MCable – Masimo SET)	SpO <sub>2</sub> : 1 to 100% PLS: 26 to 239 bpm PI: 0.00 to 20%
<b>Measurement range</b> (Infinity MCable – Masimo rainbow SET)	SpHb/SpHbv: 0.0 to 25.0 g/dL (0.0 to 15.5 mmol/L) SpOC: 0 to 35 mL/dL PVI: 0 to 100% SpCO: 0 to 99% SpMet: 0 to 99.9%
<b>Resolution</b> (Infinity MCable – Masimo SET)	SpO <sub>2</sub> : 1% PLS: 1 bpm PI: 0.01%
<b>Resolution</b> (Infinity MCable – Masimo rainbow SET)	SpHb/SpHbv: 0.1 g/dL (0.1 mmol/L) SpOC: 1 mL/dL PVI: 1% SpCO: 1% SpMet: 0.1%
<b>Maximum update interval</b>	30 s
<b>Accuracy</b> (Infinity MCable – Masimo rainbow SET)	SpHb/SpHbv for 8 to 17 g/dL: ±1 g/dL SpCO accuracy for 1 to 40%: ±3% SpMet accuracy for 1 to 15%: ±1%
<b>PI accuracy</b>	±10%



## 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 SpO<sub>2</sub> port on the M540
- B MCable connector
- C MCable 14-pin connector
- D Intermediate cable connector to MCable
- E Connector for various sensors (3 options)

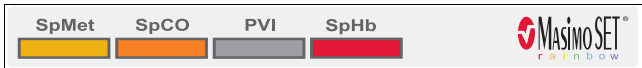
### To connect the Masimo SET MCable

- 1 Attach the Masimo SET MCable connector (B) to the blue SpO<sub>2</sub> port (A) of the M540.
- 2 Attach the sensor intermediate cable (D) to the Masimo SET MCable 14-pin connector (C).
- 3 Attach the appropriate Masimo sensor to the end of the sensor cable (E).

## Connecting the Masimo rainbow SET MCable

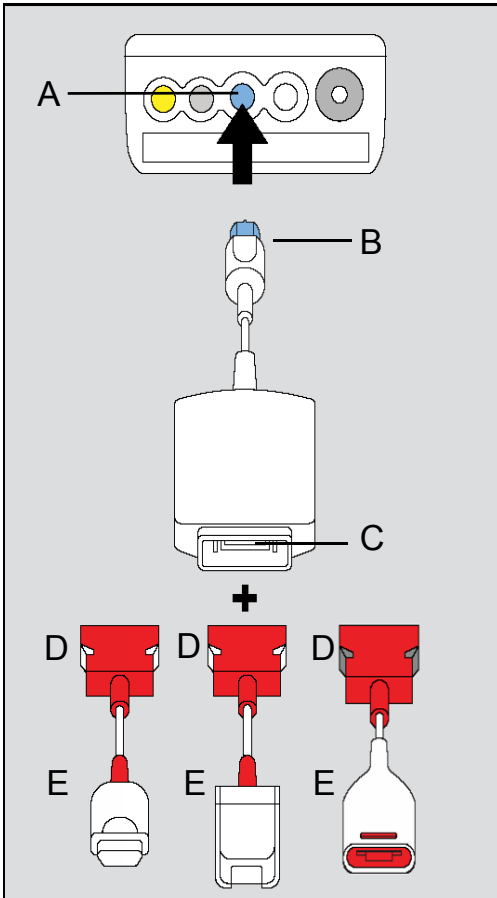
The Masimo rainbow SET MCable connects directly to the M540. The logo on the MCable identifies it as a Masimo rainbow SET or a Masimo SET MCable.

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



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

A Masimo MCable can be mounted to the back of an M540.



- A SpO<sub>2</sub> port on the M540
- B MCable connector
- C MCable 20-pin connector
- D Masimo rainbow SET intermediate cable connector to MCable
- E Connector for various sensors (3 options)

### To connect the Masimo rainbow SET MCable

- 1 Attach the MCable connector (B) to the blue SpO<sub>2</sub> port (A) of the M540.
- 2 Attach the intermediate cable (D) to the 20-pin connector of the MCable (C).
- 3 Attach the appropriate Masimo sensor to the end of the intermediate cable (E).

## List of Accessories

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### Device interface kits

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The following device interface cables are available for the Infinity Acute Care System and are used to connect to the corresponding devices.

Device	Part No. (cable)
Edwards EV1000/Vigi.II/Vigileo	MS34114
Dräger Evita 2D/4/XL ventilator	
Dräger Savina 300 ventilator	
Dräger Carina ventilator	
Bis Vista monitor	MS34115
Dräger Primus/IE/Apollo	
Dräger Fabius Family	
Masimo SpO <sub>2</sub>	
Nellcor SpO <sub>2</sub>	MS34239
Dräger V500 ventilator	MS34116
Dräger Babylog VN500	
Dräger V300 ventilator	
Dräger Oxylog 3000+ ventilator	
Dräger Perseus A500	
Dräger Zeus IE	
Maquet Servo-I ventilator	MS34117
TOFscan monitor	MS34118
TOF-Watch SX	N/A

## Temperature

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### Temperature parameter setup functions

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On the M540, changing the color of one temperature parameter changes the color of all the temperature parameters.

#### NOTE

Do not connect a Tcore<sup>®</sup> sensor to the Cardiac Output (C.O.) Tb port on an MPod — Quad Hemo.

## Reprocessing

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### Disinfectants

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Use disinfectants that are nationally approved and are suitable for the particular reprocessing procedure.

### Surface disinfectant

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At the time of the test, the surface disinfectants listed in the following table showed good material compatibility. They can be used in addition to the surface disinfectants listed in "Validated reprocessing procedures".

The manufacturers of the surface disinfectants have verified at least the following spectra of activity:

- Bactericidal
- Yeasticidal
- Virucidal or virucidal against enveloped viruses

Observe the specifications of the surface disinfectant manufacturers.

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

<b>Class of active ingredient</b>	<b>Surface disinfectant</b>	<b>Manufacturer</b>
Chlorine-releasing agents	Actichlor plus	Ecolab
	BruTab 6S	Brulin
	Clorox Professional Disinfecting Bleach Cleaner	Clorox
	Dispatch Hospital Cleaner Disinfectant Towels with Bleach	
	Klorsept 17	Medentech
Oxygen-releasing agents	Descogen Liquid	Antiseptica
	Descogen Liquid r.f.u.	
	Dismozon plus	Bode Chemie
	Dismozon pur	
	Oxycide	Ecolab USA
	Perform	Schülke & Mayr
	Virkon	DuPont
Quaternary ammonium compounds	Mikrozyd sensitive liquid <sup>1)</sup>	Schülke & Mayr
	Mikrozyd sensitive wipes <sup>1)</sup>	
	Mikrozyd alcohol free liquid <sup>1)</sup>	
	Mikrozyd alcohol free wipes <sup>1)</sup>	
	Acryl-des <sup>1)</sup>	
Aldehydes	Buraton 10 F	Schülke & Mayr

1) Virucidal against enveloped viruses

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 procedures

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### Validated reprocessing procedures

At the time of product-specific validation, the following reprocessing procedures showed good material compatibility and effectiveness:

Procedure	Agent	Manufacturer	Concentration	Contact time	Temperature
Surface disinfection with cleaning	Buraton 10 F	Shülke & Mayr	1%	30 min	N/A
	Dismozon	BODE Chemie	1.5%	15 min	N/A

The effectiveness of the listed reprocessing procedures has been validated by independent laboratories that are certified to the standard ISO 17025.

### Surface disinfection with cleaning

**WARNING**

**Risk due to penetrating liquid.**

**Penetrating liquid may cause the following:**

- Damage to the device
- Electric shock
- Device malfunctions

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

- 1 Remove soiling immediately. Use a cloth dampened with disinfectant to remove soiling.
- 2 Perform surface disinfection.
- 3 After the product has been exposed to the disinfectant for the specified contact time, remove residual disinfectant.
- 4 Wipe with a cloth dampened with water (preferably drinking-water quality). Allow the product to dry.
- 5 Check the product for visible soiling. Repeat steps 1 to 5 if necessary.
- 6 Check the product for visible damage and replace if necessary.

## After reprocessing

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### Preparations before re-use

- 1 Assemble and prepare the device so that it is ready for use, see "Assembly and preparation" in the appropriate IFU:
  - *Instructions for use Infinity Acute Care System Monitoring Applications Software VG7.n*
  - *Instructions for use Infinity Acute Care System Infinity M540 patient monitor Software VG7.n*
- 2 To check the operational readiness, see "Getting started" in the appropriate IFU.

This Instructions for use only applies to **Infinity Acute Care System Monitoring Applications and M540 Patient Monitoring Software VG7.n** 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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