

Infinity® MCable®-Masimo rainbow SET®

Bring the advantages of Masimo's rainbow Signal Extraction Technology (SET®) to the Infinity® M540 monitor – both at the bedside and on transport in the hospital.



In addition to the Masimo SET gold standard* motion and low perfusion tolerant pulse oximetry, the Infinity MCable also provides the first and only technology to continuously and noninvasively measure blood constituents and fluid responsiveness that previously required invasive procedures, such as SpHb®, PVI®, SpCO®, SpMet® and SpOC® with the same MCable.

The Infinity MCable-Masimo rainbow SET connects the Dräger Infinity M540 patient monitor to Masimo rainbow SET sensors and provides continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂), pulse rate and perfusion index.

Masimo's rainbow SET, which reads through motion and performs even in low perfusion conditions, provides accurate and reliable pulse oximetry in virtually all clinical conditions. Additionally, optional measurements include SpHb (total hemoglobin), SpOC (total oxygen content), SpCO (carboxyhemoglobin saturation), SpMet (methemoglobin), and PVI (Pleth Variability Index) in combination or separately using one cable.

*As documented in Masimo's peer-reviewed studies found at www.masimo.com.

FEATURES

- Continuous monitoring of SET SpO₂, pulse rate and PI with motion tolerance to perform even during low perfusion conditions in adult, pediatric and neonatal patients
- Can be configured with optional SpMet, SpCO, PVI, SpHb, and SpOC
- One cable for all measurements to reduce clutter and maximize flexibility
- Part of the accessory portfolio of Infinity® Acute Care System monitoring solution

TECHNICAL DATA

Measuring Capabilities

Measured parameters	Saturation – fraction of oxyhemoglobin to functional hemoglobin (SpO ₂) Pulse rate (PLS) Perfusion index (PI) Methemoglobin (SpMet®) Carboxyhemoglobin (SpCO®) Pleth Variability Index (PVI®) Total hemoglobin (SpHb®) Total oxygen content (SpOC®)
Measuring method	Absorption spectrophotometry



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CONTINUING TECHNICAL DATA

Parameter display	SpO ₂ PLS PI SpMet® SpCO® PVI® SpHb® SpOC®
Measurement range	SpO ₂ : 1 to 100% PLS: 26–239 bpm PI: 0.02–20% SpMet: 0 to 99.9% SpCO®: 0 to 99% PVI®: 0 to 100% SpHb®: 0.0 to 25.0 g/dL (0.0 to 15.5 mmol/L) SpOC®: 0 to 35 ml of O ₂ /dL of blood
Resolution	SpO ₂ : 1% PLS: 1 bpm PI: 0.01% SpMet: 0.1% SpCO®: 1% PVI®: 1% SpHb/SpHb®: 0.1 g/dL (0.1 mmol/L) SpOC®: 1 ml of O ₂ /dL of blood
Maximum update interval	30 sec

Measuring Accuracy

SpO ₂ ^{1,2} with no motion (adult, pediatric)	0 to 69% not specified 70 to 100% – LNCS DCI, LNCS DCIP, LNCS TF-I, LNCS YI (patient weight > 3 kg), LNCS Amtx, LNCS Pmtx, LNCS Neo (on finger ⁶) ±2% LNCS TC-I ±3.5%
SpO ₂ ^{1,2,3} with no motion (neonatal)	0 to 69% not specified 70 to 100% LNCS Neo (foot ⁶), LNCS NeoPt, LNCS YI (patient weight 1–3 kg, foot ⁷) ±3% LNCS Inf, LNCS Neo ±2%
PLS ⁴ with no motion	±3 bpm
SpO ₂ ^{1,2,5} with motion (adult, pediatric)	0 to 69% not specified 70 to 100% – LNCS DCI, LNCS DCIP, LNCS YI, LNCS Amtx, LNCS Pmtx ±3%
SpO ₂ ^{1,2,3,5} with motion (neonatal)	0 to 69% not specified 70 to 100% – LNCS Inf, LNCS Neo, LNCS NeoPt ±3%
PLS ⁴ with motion	±5 bpm
Low perfusion ^{1,2} (adult, pediatric)	LNCS DCI, LNCS DCIP, LNCS TF-I, LNCS Amtx, LNCS Pmtx ±2% LNCS TC-I ±3.5%
Low perfusion ^{1,2,3} LNCS (neonatal)	Neo (foot ⁶), LNCS NeoPt ±3% LNCS Inf, LNCS Neo (finger ⁶) ±2%
Low perfusion PLS	±3 bpm
SpMet	1 to 15%: ±1%
SpCO	1 to 40%: ±3%
SpHb	8 to 17 g/dL: ±1 g/dL

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. 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

¹ Since pulse oximeter measurements are statistically distributed, only about two-thirds of those measurements can be expected to fall within ± 1 Arms 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 70–100% SpO₂ against a laboratory co-oximeter and ECG monitor. This variation equals ± 1 Arms of the value measured by a co-oximeter.

³ The saturation accuracy of the neonatal sensors were validated on adult volunteers and 1% was added to account for the properties of fetal hemoglobin.

⁴ The pulse rate accuracy has been validated on healthy adult volunteers during induced hypoxia studies in the range of 70–100% SpO₂ against a laboratory co-oximeter and ECG monitor. This variation equals ± 1 Arms 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 1–2 cm and continuous random frequency motion between 1–5 Hz at amplitude of 2–3 cm.

⁶ Sensor accuracy depends on the weight of the patient. If the weight is less than 3 kg, the accuracy is $\pm 3\%$. For weights above 40 kg, the accuracy is $\pm 2\%$.

⁷ Sensor accuracy depends on the weight of the neonate. If the weight exceeds 3 kg, the accuracy is $\pm 2\%$. For weights between 1 and 3 kg, the accuracy is $\pm 3\%$ (if the sensor is applied on the foot).

The Infinity® MCable®-Masimo SET® with LNCS-Adt sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70–100% SpO₂ against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation.

The Infinity® MCable®-Masimo SET® with LNCS-Adt sensors has been validated for motion accuracy in human blood studies on healthy adult volunteers while performing rubbing and tapping motions at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm "in induced hypoxia studies", in the range of 70–100% SpO₂ against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation.

The Infinity® MCable®-Masimo SET® with LNCS-Neo and Neo Pt sensors has been validated for motion and no motion accuracy in human blood studies on healthy adult volunteers while performing rubbing and tapping motions at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm "in induced hypoxia studies", in the range of 70–100% SpO₂ against a laboratory co-oximeter and ECG monitor. 1% has been added to the results to account for the effects of fetal hemoglobin.

Nominal wavelength	All LNCS sensors except tip clips: Red: 660 nm / IR: 905 nm All LNCS tip clip sensors: Red: 653 nm / IR: 880 nm LNCS TF-I: Red: 660 nm / IR: 880 nm
Radiant power at 50 mA pulsed	≤ 15 mW

User-Selectable Settings

SpO ₂ Sensitivity	Normal, APOD, Max
SpO ₂ Averaging	2–4, 4–6, 8 (default), 10, 12, 14, 16 sec
SpO ₂ FastSat Mode	On, Off
Pulse CO-Ox 1	SpHb (default), SpOC, SpMet, SpCO, PVI
Pulse CO-Ox 2	SpHb, SpOC (default), SpMet, SpCO, PVI
Pulse CO-Ox 3	SpHb, SpOC, SpMet, SpCO, PVI (default)
Note: if the venous blood source was selected for SpHb Cal, the parameter label changes from SpHb® (arterial blood source) to SpHbv.	
SpHb® Averaging	Long – approximately 6 minutes Medium (default) – approximately 3 minutes Short – approximately 1 minute
SpHb® Cal	Arterial (default), Venous
PVI® Averaging	Short, Long (default)

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

Physical Specifications

Size (H × W × D)	20 × 61 × 130 mm (0.8 × 2.4 × 5.1 in)
Weight	0.12 kg (0.26 lbs)
Cable length	300 mm (11.8 in)
Monitor connector	7-pin connector
Connectors	Intermediate cable for sensor connection
Protection against ingress of water	IPX2 (per IEC 60529)
Protection against electrical shock	Type CF
Defibrillator protection	Yes

CONTINUING TECHNICAL DATA**Environmental Requirements****Temperature range**

Operating	0 to 45°C (32 to 113°F)
Storage	-40 to 70°C (-40 to 158°F)

Relative humidity

Operating	10% to 95%
Storage	10% to 95%, with packaging

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

Standards

IEC 60601-1:2005 + A1:2012 and applicable particular and collateral standards,
IEC 60601-1-2:2007: Electromagnetic compatibility,
ISO 80601-2-61:2011: Pulse oximeter equipment
The Infinity® MCable®-Masimo® rainbow® SET® complies with the Medical Device Directive (MDD) 93/42/EEC and bears the CE mark.

ORDERING INFORMATION

Infinity® MCable®-Masimo rainbow SET® MS27003
Order via MS25510 or MS25520

For information on Masimo rainbow SET® sensors, contact your local Dräger representative.

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This product may not be approved for Market Clearance in all countries.

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