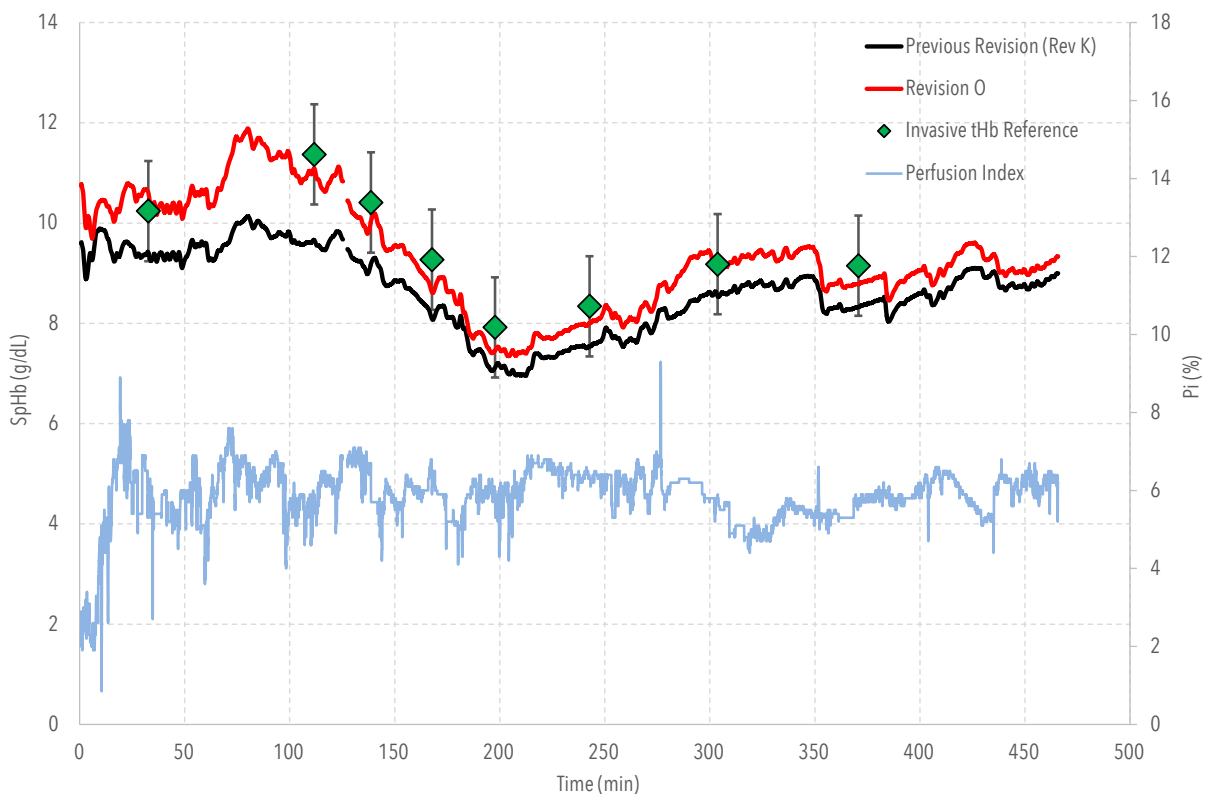


SpHb[®] Revision 0

Featuring improved trending across the SpHb measurement range on rainbow[®] single-patient-use sensors

SpHb is a noninvasive and continuous measurement that provides real-time visibility to changes, or lack of changes, in haemoglobin between invasive blood samples.

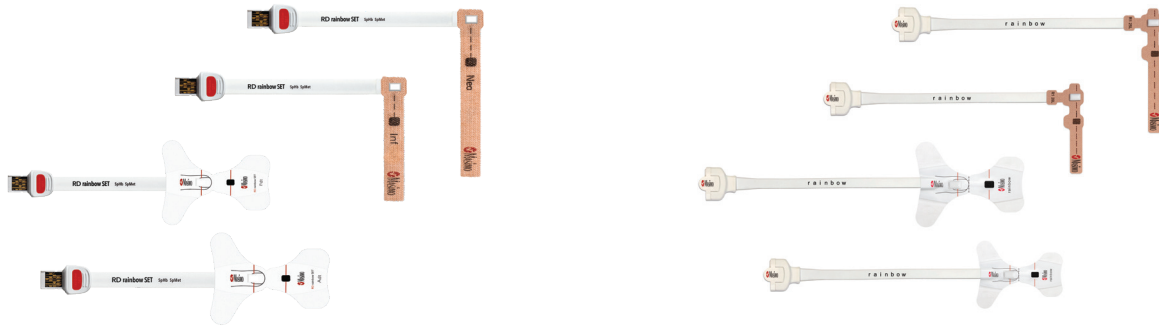
Masimo has continually sought to enhance the SpHb monitoring user experience based on clinician feedback. The latest revision provides improved trending across the SpHb measurement range (8-17 g/dL), as shown below.



Case example from clinical study conducted at hospital. Clinicians were blinded to SpHb data.

rainbow® Single-Patient-Use Sensors

The latest revision of SpHb is available on RD rainbow SET™-2 and rainbow® R1 single-patient-use sensors



Part Number	Description
4026	RD rainbow SET-2 Adt, Adult Sensors
4027	RD rainbow SET-2 Pdt, Paediatric Sensors
4028	RD rainbow SET-2 Inf, Infant Sensors
4029	RD rainbow SET-2 Neo, Adult/Neonatal Sensors

Part Number	Description
3792	rainbow® R1 25, Adult Sensors
3793	rainbow® R1 20, Paediatric Sensors
2415	rainbow® R1 20L, Infant Sensors
2414	rainbow® R1 25L, Adult/Neonatal Sensors

Specifications

ACCURACY – (ARMS)¹

Oxygen Saturation (% SpO ₂) Accuracy Range	70–100%
No Motion Adults/Paediatrics/Infants/Neonates	.2%
Motion Adults/Paediatrics/Infants/Neonates	.3%
Low Perfusion Adults/Paediatrics/Infants/Neonates	.2%
Oxygen Saturation (% SpO ₂) Accuracy Range	60–80%
No Motion Adults/Paediatrics/Infants	.3%
Pulse Rate Accuracy Range	25–240 bpm
No Motion Adults/Paediatrics/Infants/Neonates	.3 bpm
Motion Adults/Paediatrics/Infants/Neonates	.5 bpm
Low Perfusion Adults/Paediatrics/Infants/Neonates	.3 bpm
Total Haemoglobin (SpHb) Accuracy Range	8–17 g/dL
No Motion Adults/Paediatrics/Infants	.1 g/dL
No Motion Neonates	.2 g/dL
SpHb Limits of Agreement (LoA)	
Upper LoA	1.57
Lower LoA	-1.83
Methaemoglobin (SpMet®) Accuracy Range	0–15%
No Motion Adults/Paediatrics/Infants/Neonates	.1%

WEIGHT RANGE

RD rainbow SET-2 Sensors

RD rainbow SET-2 Adt	>30 kg, finger application
RD rainbow SET-2 Pdt	10–50 kg, finger application
RD rainbow SET-2 Inf	3–10 kg, thumb or great toe application
RD rainbow SET-2 Neo (neonatal)	10–30 kg, finger or toe application
RD rainbow SET-2 Neo (adult)	<3 kg, hand or foot application
RD rainbow SET-2 Neo (adult)	>30 kg, finger application

rainbow® R1 Sensors

rainbow® R1 25	>30 kg, finger application
rainbow® R1 20	10–50 kg, finger application
rainbow® R1 20L	3–10 kg, thumb or great toe application
rainbow® R1 20L	10–30 kg, finger or toe application
rainbow® R1 25L (neonatal)	<3 kg, hand or foot application
rainbow® R1 25L (adult)	>30 kg, finger application

¹ ARMS accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within \pm ARMS of the reference measurements in a controlled study.

SpHb monitoring is not intended to replace laboratory blood testing. Blood samples should be analysed by laboratory instruments prior to clinical decision making.

For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, and precautions.

Masimo U.S.
Tel: 1 877 4 Masimo
info-america@masimo.com

Masimo International
Tel: +41 32 720 1111
info-international@masimo.com

