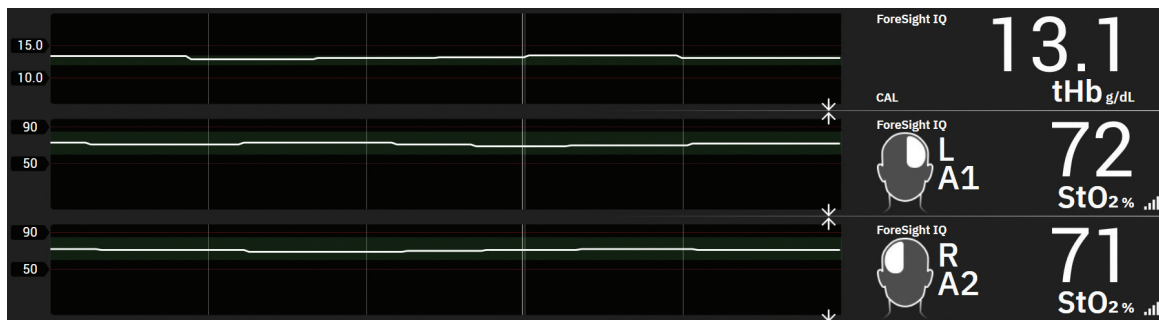


ForeSight IQ™ Sensor Continuous Hemoglobin (tHb)

Smart Algorithm for Continuous Noninvasive tHb Measurement

BD offers continuous hemoglobin (tHb) with ForeSight IQ™ Sensor when used with HemoSphere Alta™ Advanced Monitoring Platform. The algorithm for measurement of blood hemoglobin is intended for continuously monitoring total hemoglobin in the blood. It is derived from the relative changes in tissue hemoglobin (Δ tHb) obtained from one or two of ForeSight IQ™ Sensor(s) placed in the cerebral position and when connected to ForeSight™ Oximeter Cable. An initial calibration is required from a reference hemoglobin measurement obtained from a blood gas measurement.

HemoSphere Alta™ Monitor trend display with StO₂ and tHb from ForeSight IQ™ Sensor



Required equipment



HemoSphere Alta™ Monitor




ForeSight™ Oximeter Cable
(HEMFSM10)



ForeSight IQ™ Sensor(s)
(FSES LIQ)

Calibration

After calibration, the HemoSphere Alta™ Monitor provides tHb values every 2 seconds when connected to the ForeSight IQ™ Sensor. tHb should be recalibrated whenever the calibration icon appears on the tHb parameter display  or when updated HGB laboratory values become available.



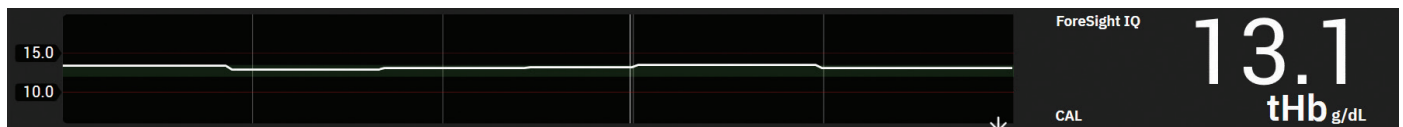
tHb parameter display at the start of monitoring



tHb parameter recalibration warning

tHb Display

- tHb value g/dL
- High / low alarms
- Target zone





tHb parameter display on HemoSphere Alta monitor – example

tHb Specifications

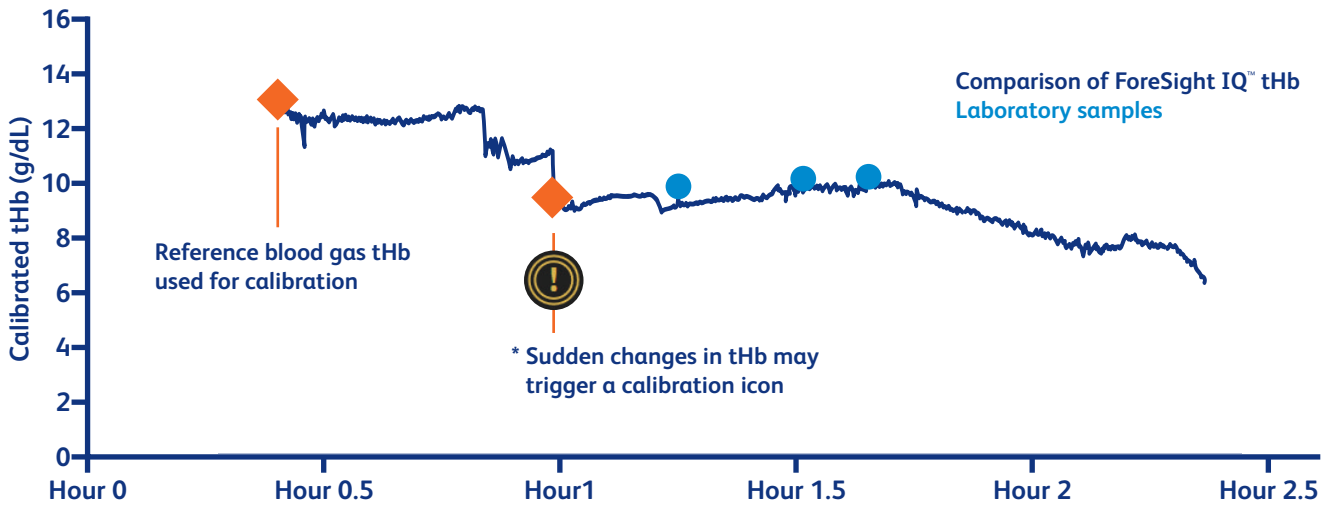
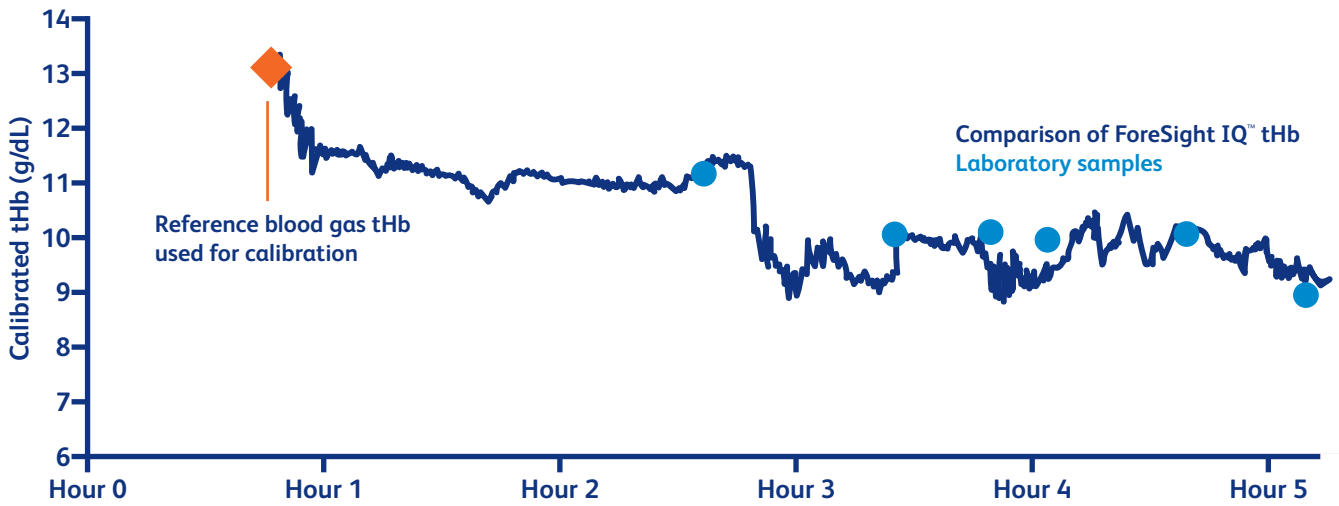
Parameter	Specification	
tHb	Units	g/dL
	Update rate	2 seconds
	Accuracy*	$A_{RMS} < 1$ g/dL
	Display range	4.0 to 20.0 g/dL

* Accuracy validated for 6.0 g/dL < tHb < 14.9 g/dL.
See Performance Verification Results in the HemoSphere Alta™ Operator's Manual.

tHb calibration, recalibration troubleshooting messages

Message/Icon	Possible causes	Suggested actions
	Total blood hemoglobin (tHb) has not been calibrated	Calibration needed to view total blood hemoglobin (tHb)
	A significant change in Δ tHb monitored by ForeSight™ Oximeter Cable detected	Recalibrate tHb to continue accurate monitoring of total blood hemoglobin (tHb)
tHb – Do Not Calibrate	Poor signal quality Calibration is unavailable	Verify patient HGB levels per hospital standard of care Wait for improved signal quality

Continuous calibrated tHb trends with laboratory hemoglobin



* Patient going on cardiopulmonary bypass.

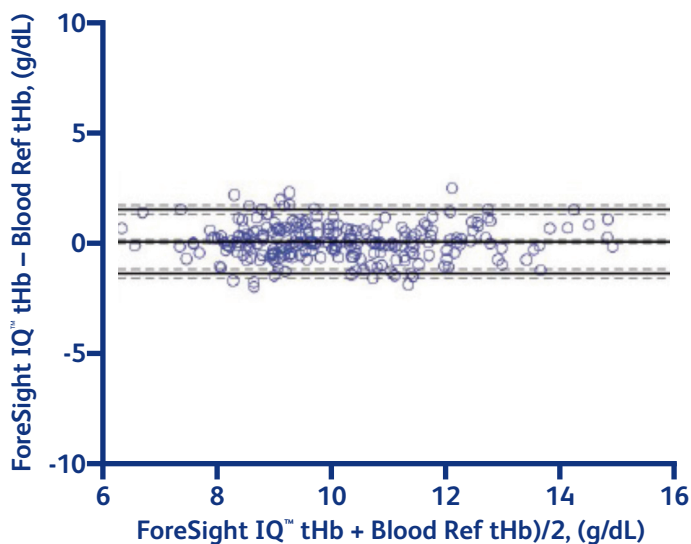
Accuracy

The accuracy of the continuous tHb parameter when compared to reference hemoglobin measurement is < 1g/dL. The reference hemoglobin ranged from 6.0 to 14.9.

tHb Specifications				
Parameter	Number of patients	RMSE, g/dL	Bias, g/dL	Precision, g/dL
The algorithm for tHb vs. laboratory blood gas analyzer	83	0.77 [0.69, 0.85]	0.07 [-0.03, 0.16]	0.73 [0.66, 0.81]

RMSE and Bland-Altman analysis results comparing tHb and Δ tHb with reference blood gas analyzer measurements.

Bland-Altman plots of tHb algorithm vs. blood gas analyzer for tHb



Note: The accuracy of tHb measurements may be compromised by conditions impacting local blood flow hemodynamics intermittently such as asymmetric carotid stenosis and occurrence of undiagnosed focal stroke during monitoring.

Indocyanine green dye and methylene blue may lead to inaccurate or erroneous measurements. Recalibration is recommended after use of these products. Elevation of carboxyhemoglobin (COHb) or Methemoglobin (MetHb) or dyshemoglobins may lead to inaccurate or erroneous measurements. Other factors that may affect measurement accuracy include conditions such as myoglobin hemoglobinopathies, anemia, sickle cell anemia, pooled blood beneath the skin, bilirubinemia, birthmarks, externally applied coloring and high Hb or Hct levels.

Summary

ForeSight IQ™ Sensor, when used with HemoSphere Alta™ Monitor, allows for continuous calibrated tHb values every 2 seconds. This may allow for proactive interventions as compared to reactive interventions from static laboratory values. Moreover, continuous assessments may give you the ability to detect unseen or internal bleeding both intra- and postoperatively.

Medical device for professional use. For a listing of indications, contraindications, precautions, warnings and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

BD, Eysins, Vaud, Switzerland

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