

ForeSight IQ™ Sensor Technology Overview

What is ForeSight IQ™ Sensor?

ForeSight IQ™ Sensor is a next-generation sensor that enables the latest advanced algorithms for tissue oximetry on the HemoSphere Alta™ Platform.

What advanced algorithms are available?

Cerebral Autoregulation Index (CAI)

- A derived parameter that quantifies the dynamic relationship between mean arterial pressure (MAP) and absolute blood oxygen saturation levels (StO₂).
- The CAI value updates every 20 seconds and displays an indexed value from 0-100.
- A high CAI value (CAI ≥ 45) indicates a strong MAP and StO₂ coherence and informs clinicians that an evaluation of the MAP and StO₂ trends may be needed.
- A low CAI value (CAI < 45) indicates a low MAP and StO₂ coherence and does not suggest a clinical action may be needed.

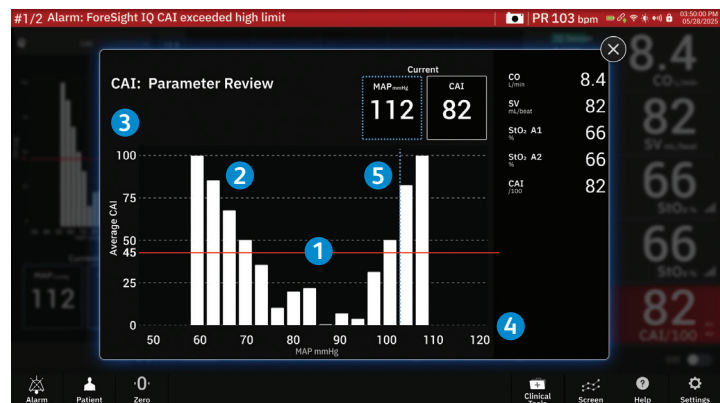
General interpretations and recommended actions for CAI values

CAI Value	General interpretation	Recommended user action
CAI < 45	MAP and StO ₂ are weakly/ moderately associated. Potential changes in MAP are likely not associated with changes in StO ₂ .	None
CAI ≥ 45	MAP and StO ₂ are strongly associated. Potential changes in MAP are likely associated with concomitant changes in StO ₂ .	Review individual MAP and StO ₂ trends. Be aware that potential changes in MAP are likely associated with concomitant changes in StO ₂ (e.g., a drop in MAP may likely be associated with a drop in StO ₂).

HemoSphere Alta™ Monitor CAI Histogram Plot

CAI histogram displays the distribution of CAI values over time, helping visualize the status of cerebral autoregulation over a range of pressures the patient has experienced.

- 1 Threshold:** The CAI threshold of 45 is represented by a red line; values of 45 and above indicate that cerebral autoregulation is likely impaired, while values below 45 suggest that cerebral autoregulation is likely intact.
- 2 Histogram Bars:** CAI histogram continuously updates every 20 seconds with each bar on the histogram showing previous CAI values with corresponding MAP values, providing a cumulative view to assess patient's cerebral autoregulation status.
- 3 Y-axis:** CAI values range from 0 to 100.
- 4 X-axis:** MAP values with each bar representing increments of 5 mmHg.
- 5 MAP:** Blue dotted line represents current MAP value.

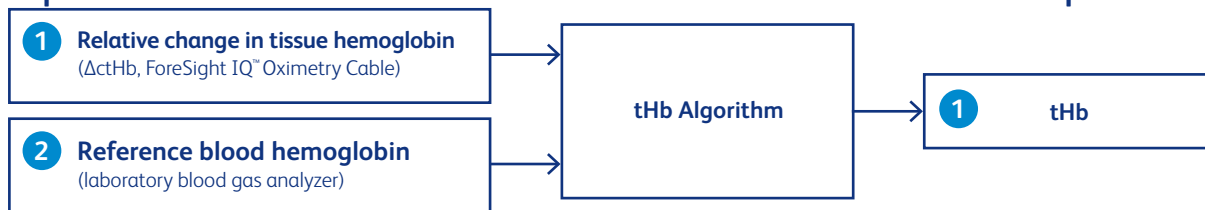


Calibrated Total Hemoglobin (tHb)

- A calibrated parameter that continuously measures the concentration of total hemoglobin in the blood/circulatory system of a patient.
- The calibration uses a reference blood hemoglobin measurement obtained from a laboratory blood gas analyzer and the relative changes in tissue hemoglobin obtained from the ForeSight oximeter cable to display a total blood hemoglobin value in g/dL.
- The accuracy of the tHb parameter is < 1 g/dL and was measured by comparing simultaneous data from ForeSight IQ™ Sensor and reference blood gas measurements.

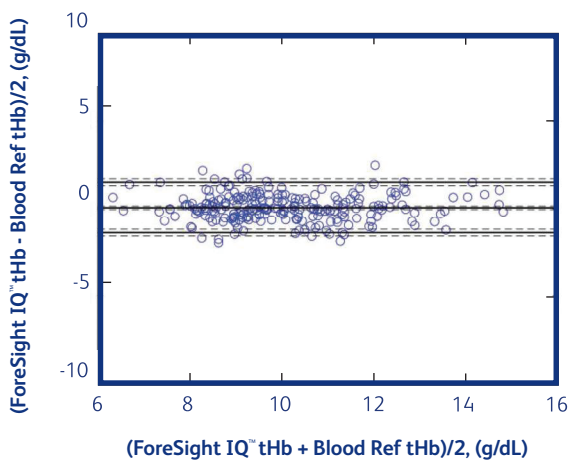
Block diagram of the algorithm for measurement of blood hemoglobin (tHb algorithm)

Inputs



Outputs

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



CAI and tHb Validation Studies

Cerebral Autoregulation Index Clinical Validation

Site	Number of patients	Age (years)	Gender	Height (cm)	Weight (kg)	Surgery type
Northwestern University, Chicago, USA	18	66±10	4 females 14 males	173±13	89±30	Cardiac surgery (N = 12) General surgery (N=6)
UC Davis, Sacramento, USA	9	61±17	4 females 5 males	169±9	79±20	General surgery
Amsterdam UMC, Amsterdam, The Netherlands	23	58±16	7 females 16 males	180±11	83±15	Cardiac surgery (N = 16) General surgery (N=7)

Calibrated Total Hemoglobin Clinical Validation

Site	Number of patients	Age (years)	Gender	Height (cm)	Weight (kg)	Surgery type	Race / ethnicity	Reference device used*
Amsterdam UMC, Amsterdam, The Netherlands	27	68.7±8	6 females 21 males	175.6±9.4	80.5±14	Heart valve replacement (10) Heart valve repair (2) Bentall procedure (2) CABG (12) Other cardiac (1)	Hindustani (1) White (11) Not available (15)	RAPID Point 500 - Siemens Healthcare Diagnostics
Hospital Universitario Marques de Valdecilla Santander, Spain	8	61.5±14	5 females 3 males	163.0±6.7	72.8±12	Heart valve replacement (5) Heart valve repair (2) Other cardiac (1)	Not available (8)	ABL800 flex - Radiometer
Greenville Memorial Hospital, North Carolina, USA	18	60.6±15	4 females 14 males	176.5±10.0	90.7±22	Heart valve repair (1) Coronary artery disease (6) CABG (8) Open chest heart valve repair (3)	Black or African American (9) White (9)	iSTAT 1 - Abbott
Northwestern University, Chicago, USA	19	58.4±12	5 females 14 males	173.7±10.0	84.8±18	Other cardiac (19)	Asian (1) Black or African American (1) Not available (1) Hispanic/Latino (1) White (15)	GEM Premier 5000
UC Davis, Sacramento, USA	11	66.6±12	5 females 6 males	168.7±7.2	86.4±25	Vascular (3) Orthopedic (2) Other cardiac (1) Other/ general surgery (5)	Asian (1) Black (1) Hispanic/Latino (1) White (8)	ABL90 - Radiometer

* All reference devices used are FDA cleared for laboratory use and as such, must comply with Clinical Laboratory Improvement Amendments (CLIA) requirements.



Medical device for professional use. See instructions for use. CE marked medical device.

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