Zacks Small-Cap Research

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CAS Medical Systems Inc. (CASM-NASDAQ)

CASM: FORE-SIGHT Sensor Sales Driving Rapid Revenue Growth, Expanding Margins

Based on EV/S and P/S comps other publicly traded companies in the tissue oximeter, patient monitoring and cardiac surgery industries including BABY, MASI, BRSYF, HPHTY and MDT, CASM should trade near $4/share.

Current Price (08/08/16)	$1.78
Valuation	**$4.00**

OUTLOOK

CASM recently divested two non-core and lower-margin product lines to shift full-focus on their flagship FORE-SIGHT tissue oximetry business. Recently launched next-gen ELITE product has been the main impetus to recent sales growth, helping to push the topline to 24 consecutive quarters of double-digit growth. Plethora of clinical data supporting utility of cerebral oximetry is expanding total market. Clinical studies showing that ELITE outperforms market-share leading cerebral oximeters has been a major catalyst to CASM's growth and has resulted in about one-half of new business coming from customers switching from competing devices. The growing monitor installed base is providing a multiplier effect to sensor (i.e consumables) sales. This, combined with expanding gross margin and growing leverage in OpEx should result in rapid improvement in profitability and cash flow. Based on comp valuation, CASM shares should trade near $4.

SUMMARY DATA

52-Week High	**$2.15**
52-Week Low	**$1.05**
One-Year Return (%)	**60.36**
Beta	**-0.24**
Average Daily Volume (sh)	**87,053**
Shares Outstanding (mil)	**27**
Market Capitalization ($mil)	**$49**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**36**
Insider Ownership (%)	**34**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**0.4**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**N/A**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015					19.5 A
2016	5.5 A	5.5 A	5.7 E	6.1 E	22.8 E
2017					27.6 E
2018					31.1 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015					-$0.40 A
2016	-$0.03 A	-$0.08 A	-$0.07 E	-$0.06 E	-$0.25 E
2017					-$0.15 E
2018					-$0.04 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW…

Q2 Financial Results

CAS Medical reported financial results for the second quarter ending June 30. Results continue to reflect success of the company's transition from a medical capital equipment company to one which primarily provides disposables to an installed base. While the total number of monitor placements in the quarter was moderately lower than what we were expecting, U.S. placements grew by a record 60 systems and facilitated the multiplier effect from continued growth in the installed base and greater per-unit utilization, resulting in record sensor sales and help in pushing gross margin up to the highest level in at least 15 years.

Revenue grew almost 18% yoy with the tissue oximetry and traditional monitoring segments posting 15% and 29% growth, respectively. Ramping sales of FORE-SIGHT coupled with divestitures of product lines within the traditional monitoring segment continues to push up the tissue oximetry segment's contribution of total revenue. The high-growth tissue oximetry (i.e. FORE-SIGHT) segment accounted for 81% of total revenue, up from 78% in Q1 and 79% for all of 2015. And within the tissue oximetry segment, (high margin) FORE-SIGHT sensors continue to account for a greater proportion of total sales. Sensors accounted for 90% of FORE-SIGHT sales and 73% of total revenue in Q2, up from 87% and 68% in Q1 and 85% and 67% for all of 2015.

Results were largely inline with our estimates. While total revenue ($5.5M A vs. $5.5M E) and EPS ($0.08 A vs. $0.08 E) were dead-on with our numbers, there were some positive variances - most significantly of which was gross margin coming in 210 b.p. better (54.7% A vs. 52.6% E) than what we were expecting. Importantly, we expect GM to continue to expand as sensors' continue to grow as a percentage of total revenue.

Sensor sales, particularly in the U.S., is the main impetus driving growth of both revenue and gross margins. Total sensor sales grew 27% in Q2, including 24% in the U.S. - marking the 25th straight quarter of double-digit yoy growth in total sensor revenue and the 10th out of the last 11th quarter with U.S. sensor sales growth of over 20%. Sensor sales remain on a tear internationally as well, posting 48% yoy growth in Q2.

CASM booked sales of 83 monitors in the quarter, down 6% from the 88 sold in the comparable period in 2015 and about 4% lower than our 92 estimate. The strong 60 domestic unit placements represented 25% growth of the U.S. installed base from Q2 2015 and pushed it up to 1,019 units as of the end of Q2 2016. International monitor sales were just 23 in the quarter and represented the miss to our estimate. Importantly management expects international placements to pick up in 2H with an anticipated increase in shipments to Asia. CASM exited the quarter with a total installed base of 1,871 units. With expectations that domestic sales continue their upward trajectory and international monitor sales rebound, management reiterated their guidance of at least 400 monitor sales in 2016 - which implies 237+ units are sold in 2H, 45% more than the 163 sold in 1H 2016.

Our investment thesis hinges in large part to FORE-SIGHT's clinical superiority being able to drive rapid revenue and profitability growth through a combination of expanding the overall market for cerebral oximetry and taking market share from less capable (i.e. lower accuracy) technologies. By all accounts that appears to continue to be the case. Much of the revenue growth continues to be driven by market share gains against competitors as FORE-SIGHT's performance-leading message is resonating with hospitals. Management noted that 35% of U.S. monitor sales over the past 12 months were to customers switching from competitors' technology with the other 65% related to a combination of new customers and additional purchasing from current customers increasing their capacity (i.e. utilization).

One notable recent win, as detailed on the call, was with a hospital in the MedStar Health System (Balt/DC area) which switched to FORE-SIGHT from a competing system after they did a thorough evaluation of four cerebral oximetry systems. Clinical data, including superior accuracy with dark-skinned patients, was cited as the reason the hospital went with FORE-SIGHT.

Outlook

We have made only very minor updates to our model and our outlook remains intact. We continue to look for 17% total revenue growth in 2016 from continuing operations, including 22% growth from the tissue oximetry segment. We have gross margins expanding from 43.6% in 2015 to 54.4% in 2016, facilitated by growth of

the higher margin sensors as a percentage of total sales as well as some efficiency gains. Operating leverage should also continue to improve on growing revenue and productivity gains from the sales force. This is an area that CASM has seen significant benefits and which management believes there is additional room for growth.

We reiterate our $4/share price target.

Refinancing extends maturity, delays principal amortization, providing additional flexibility…
CASM's term loan began principal repayment ($225k for 30 months) in January and had a June 2018 maturity. The amortizing principal and relatively near-term maturity date had been a constraint on the company's ability to reinvest in growth opportunities. But on June 30th they refinanced this (along with their revolver) into a new debt facility which provides them with a significantly longer cash runway. The new facility includes an $8M term loan and up to $2.5M availability (A/R dependent) under a revolver. The term loan is interest only through July 2017 and then repays principal in 36 equal monthly installments of $222k through the July 2020 maturity date. And principal payments can be deferred an additional 6 months if CASM hits a certain revenue target for the 12 months ending June 30, 2017. The longer runway allows for greater flexibility to put the cash to work in areas such as incremental additions to the sales force, which clearly has shown in the past to result in positive revenue growth and ROI.

Cash used in operating and investing activities was $3.0M and $659k, respectively, in the six months ending June 30, 2016. CASM exited Q2 with $7.6M in cash and has $2.1M available under the revolver, which at the current (FCF) burn rate and assuming principal repayment begins August 2017 (i.e. is not deferred an additional 6 months), represents approximately 14 - 15 months worth of operating funds. This likely represents a conservative scenario, however, as we anticipate the burn rate to moderate on revenue growth and improving profitability - it also assumes CASM fails to hit the revenue target to trigger the 6-month interest only extension on the term loan.

BACKGROUND

Tissue Oxygenation Monitoring

Oxygenation refers to the saturation of the tissues, blood or organs with oxygen. Sufficient saturation is required to generate energy in order to maintain the body's functions. The brain, which is constantly consuming energy even when at rest, is the organ that consumes the most oxygen – approximately 20% of the oxygen that enters the bloodstream.

Cerebral hypoxia, which refers to inadequate supply of oxygen to the brain, can result from a variety of conditions including certain diseases (such as heart disease, atherosclerosis or anemia), trauma, heart attack or environmental factors (such as high altitudes) and others. Cerebral desaturation events can also occur during surgery – and at rates that are much higher than previously thought.

Brain cells are highly sensitive to lack of oxygen. Patients undergoing surgery are particularly susceptible to experiencing oxygen deprivation as illness and anesthesia can exacerbate this risk. The proper management of brain oxygenation is one of the principal endpoints of all anesthesia procedures, but the brain remains one of the least monitored organs during clinical anesthesiology[1]. Clinical studies have shown that cerebral desaturation events (CDE) occurring during surgery;

- can result in severe complications including cognitive dysfunction, stroke, coma and even death
- are associated with prolonged hospital stays and related significant additional cost
- happen as often as 60% or more and occur more frequently than previously believed

Traditional Monitoring Does Not Directly Monitor Cerebral Oxygen…

Traditional monitoring uses measurements non-specific to cerebral oxygen with the goal of balancing oxygen supply and demand within the body globally, but not necessarily specifically the brain. The traditional methods used to monitor oxygen status include pulse oximetry, heart rate and blood pressure, capnometry and cardiac output assessment.



SOURCE emsjunkie.com

- **Pulse oximetry**: is similar to cerebral oximetry in that it uses emitted light to estimate oxygen saturation. However, an important difference is that pulse oximeters only measure arterial oxygen saturation, which provides a measure of how well the hemoglobin is oxygenated by the lungs. It does not indicate how much of that oxygenated blood is made available to meet the metabolic demand of particular tissue beds like the brain. This differs from cerebral oximeters which measure the combination of both venous and arterial blood oxygenation. As ~75% of blood volume is venous, and as venous blood oxygenation reflects the end result of oxygen extraction by the tissue, cerebral oximeters allow for a comprehensive understanding of the balance between oxygen demand and oxygen supply of the tissue.


SOURCE wisegeek.com

- **Capnometry**: often used during surgery, a capnometry device is hooked up to a breathing circuit or ventilator to directly monitor the concentration of inhaled and exhaled carbon dioxide. This can provide a measure of the total metabolic function of the body and an indirect gauge of the amount of carbon dioxide expected to be in the blood. While considered more informative than pulse oximetry relative to global cardiorespiratory function and ventilation, similar to pulse oximetry it does not directly measure cerebral oxygen saturation.
- **Cardiac output**: measures the amount of blood pumped by the heart over a given time (e.g. liters per minute). Several methods can be employed to measure cardiac output including in-dwelling catheters and trans-esophageal Doppler Cardiac output, which is useful to measure heart function and overall hemodynamic status but reveals little about end-organ blood perfusion. Other surrogates for cerebral blood flow include Transcranial Doppler (TCD) sonography, in which sound waves are used to estimate blood flow velocity in arteries in the skull. But since it measures velocity, not actual blood flow, which can change during surgery due to factors not associated with flow (such as blood vessel constriction and dilation), its utility in cerebral oxygen monitoring is limited. A study in neonatal aortic arch surgery showed NIRS reliably detected antegrade cerebral flow rates in all (n=10) children at all measurement points while TCD failed to obtain a signal in at least one measurement point in 80% (8/10) of patients[2]. Other drawbacks of TCD include the need for an ultrasound technician and it does not always provide for real-time decision-making. Other types of cardiac output measures are more global and do not specifically measure cerebral blood flow.

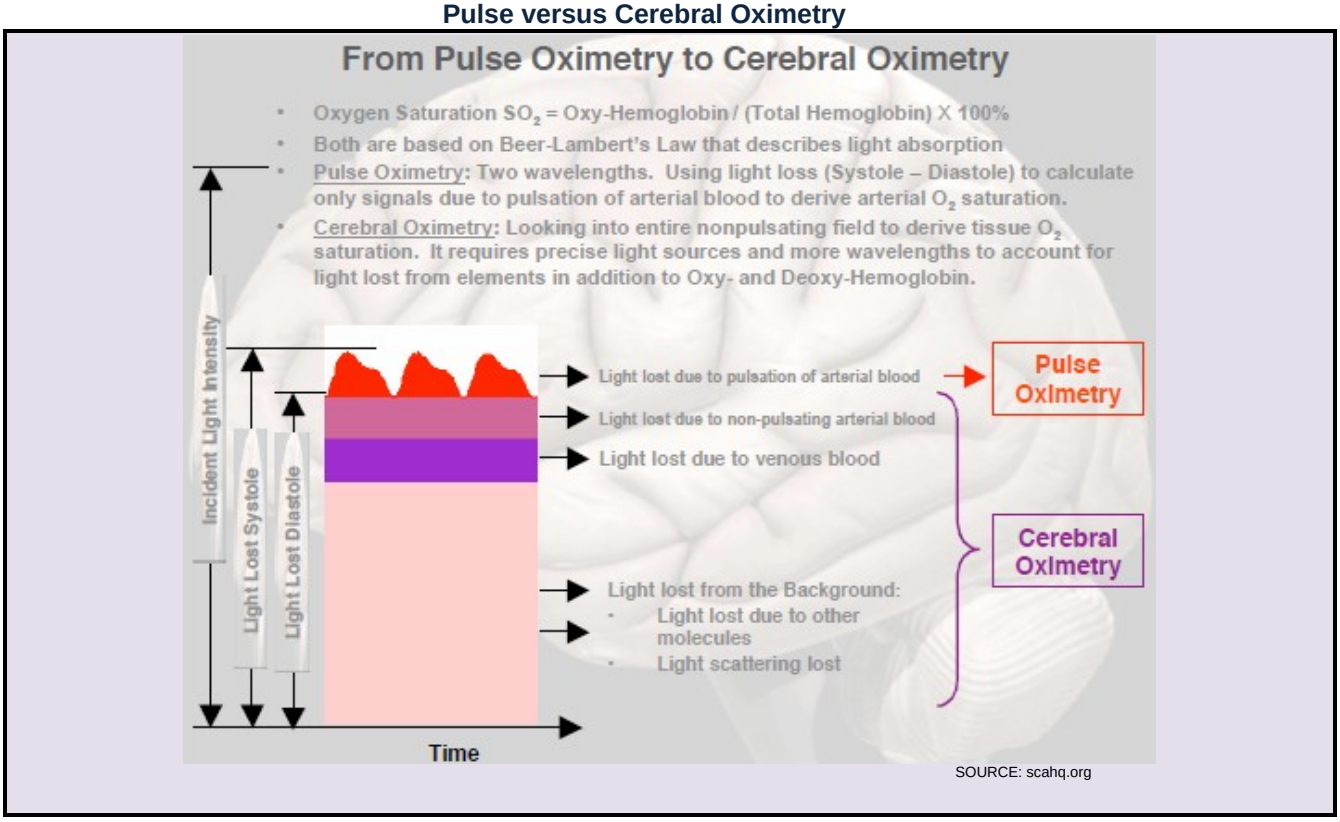
- **Blood pressure**: appropriate systemic blood pressure is a necessary requirement to force blood through the vascular system. Therefore, a drop in blood pressure may suggest less blood flow, and therefore, less oxygen reaching the brain. However, clinical studies have shown that blood pressure is not a reliable indicator of cerebral desaturation events[3,4] and that historically acceptable levels of blood pressure maintained by clinicians may be inadequate to perfuse the brain.

These methods, along with heart rate, provide indirect information about global oxygen delivery as well as how the respiratory system is functioning. Clinicians can then infer that if these surrogate markers are "acceptable" or if oxygen delivery is satisfactory at a periphery of the body and the respiratory system is functioning correctly, that oxygen delivery in the entire body, including the brain, is satisfactory. But, as clinical studies attest, these indirect methods are not sufficient or reliable to monitor the adequacy of oxygen[5] delivery to the brain. This is part of the reason that there is growing demand for cerebral oximetry.

FORE-SIGHT identifies CDE while traditional monitoring does not…

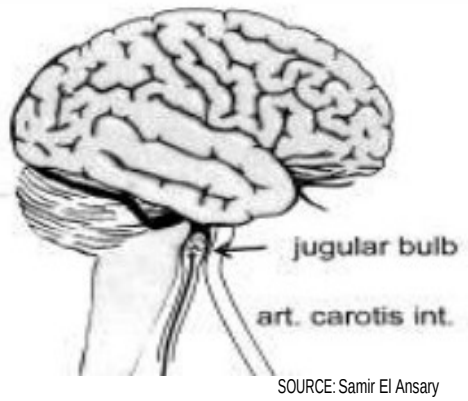
A case report highlights the limitations of traditional monitoring. The beach chair position, where the patient is sat up at an angle during surgery, is preferred by most surgeons for shoulder surgery but several studies have found that the procedure frequently results in CDEs. A case report of a patient undergoing shoulder surgery in the beach chair position showed that FORE-SIGHT detected cerebral desaturation while standard monitoring (including blood pressure, heart rate and pulse oximetry) indicated cerebral oxygen remained at normal (i.e. safe) levels. The author of the report noted that, "This case illustrates that cerebral desaturation can occur during surgical manipulation in the beach chair position without any evident change in other monitored parameters."[6] Broader studies of beach chair shoulder procedures have reported CDE's in up to 80% of patients.[7]

Pulse versus Cerebral Oximetry



Jugular venous bulb oximetry is another method of estimating cerebral oxygenation. It has an advantage over those just discussed in that it is a more direct measure of cerebral oxygenation. But also has a disadvantage in that, unlike the others, it is invasive. Jugular venous bulb oximetry involves insertion of a catheter into the jugular vein with the tip in the jugular venous bulb at the base of the brain from which samples are obtained to measure oxygen saturation of the blood exiting the brain. But while jugular bulb is considered the gold-standard for measuring cerebral oxygen saturation, clinical studies have also cited drawbacks such as that catheter misplacements can result in skewed readings[8]. And in some cases, high jugular bulb saturation values have been correlated to low regional oxygen saturation – suggesting it may not

always recognize brain oxygen desaturations[8]. And while jugular venous bulb oximetry provides a more direct measure of regional cerebral oxygen than the other indirect methods that we described above, it is not continuous and does not allow for measurements at specific areas of the brain (i.e. focal) like NIRS does based on where the sensors are placed. A study which used jugular venous bulb oximetry to monitor cerebral oxygenation in patients with traumatic brain injury suggested that a more sensitive measure should be used[9]. Given its drawbacks and the fact that it is a technically difficult procedure, jugular venous bulb oximetry has fallen out of favor with many clinicians.



SOURCE: Samir El Ansary

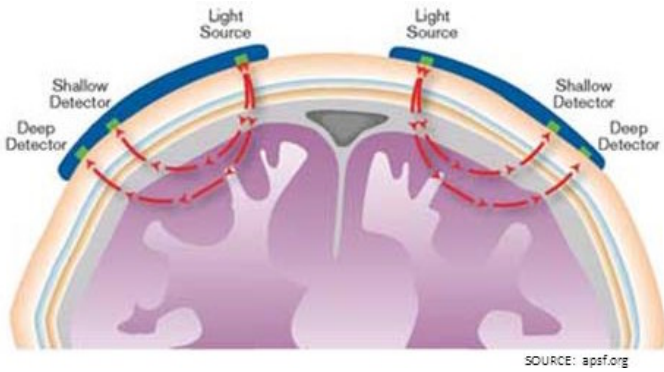
Cerebral Oximetry <u>Does</u> Directly Monitor Cerebral Oxygen…

Near-infrared spectroscopy uses light to identify the concentration of oxygenated and de-oxygenated hemoglobin in the blood. It is based on the Beer-Lambert law which states that the amount of light absorbed by a substance dissolved in a solvent is directly proportional to the concentration of the substance and the path length of the light through the solution.[10] Different substances absorb different amounts of light. Near-infrared light is emitted into a substance and by measuring the amount of light that returns, the specific structure or volume of the substance can be determined.

Near-infrared spectroscopy uses light in the 660 – 900nm spectrum as this easily penetrates skin, tissue and bone but is largely absorbed by hemoglobin. Certain wavelengths within that spectrum are absorbed at different levels by oxygenated hemoglobin and de-oxygenated hemoglobin and therefore, oxygen saturation can be determined. In addition, changes in oxygen levels will change the amount of light that is absorbed. However, many additional substances within that tissue absorb those same wavelengths, so the ability to provide a highly accurate oxygen saturation assessment requires multiple wavelengths of light within that spectrum. The greater number of wavelengths utilized can increase accuracy significantly as it allows the monitor to distinguish between the substances of interest (i.e. oxygenated and de-oxygenated hemoglobin) and substances that can confound that analysis such as melanin and bilirubin. Algorithms within the NIRS device use this absorption information to continuously determine how much oxygen is in the blood in the tissue under the sensor. Oxygen saturation is calculated as oxygenated hemoglobin (HbO_2) divided by [HbO_2+deoxygenated hemoglobin (Hb)].

Cerebral oximetry estimates regional oxygen saturation of the cerebral cortex (i.e. under the forehead), which is the area of the brain that is most sensitive to oxygen deprivation and responsible for many higher cognitive functions. While NIRS technology and cerebral oximetry have been studied and commercially available for several decades, only recently have they been used more extensively in patient monitoring, which is being driven by additional clinical data supporting its use in this application as well as the use of more accurate devices.

Cerebral oximeters consist of adhesive pads that are affixed to the skull and connected to a monitor via cables. The pads include near-infrared light sources (emitters) and light sensors (detectors). As penetration of the light into the tissue is proportional to the distance between the light source and sensors, the distance between the light emitter and the detectors dictates the maximum depth of signal penetration. Also, the use of two separate detectors spaced a distance from the emitter permits the monitor to differentiate between oxygenation of the scalp versus that of the brain tissue. The monitor, using an algorithm that calculates the amount of light that is received by the two detectors in comparison to the amount that the light source emitted, displays the level (or change in level) of cerebral oxygenation.



SOURCE: apsf.org

Studies related to CDE's and patient outcomes…
Results of numerous studies have shown high rates of CDEs during surgery and an association between oxygen desaturation and adverse outcomes. Studies also show that near-infrared spectroscopy (NIRS) is effective in identifying CDEs, providing actionable information for anesthesiologists to immediately restore oxygen saturation (through a variety of techniques which we detail later). Our sampling below, which is categorized by topic (some cited studies have crossover in our categories), is a small portion of the available evidence offering what we believe is ample support for the proposition that NIRS provides accurate, actionable and superior tissue oxygenation monitoring.

- Adverse patient outcomes;
    - **Yao FS, et al**.[11]: showed that cerebral oxygen desaturation occurring during cardiac surgery is associated with neuropsychological dysfunction as measured by the mini-mental state examination (MMSE) and antisaccade eye movement test (ASEM)
    - **Slater, et al**.[12]**:** showed that intraoperative cerebral oxygen desaturation is significantly associated with an increased risk of cognitive decline and prolonged hospital stay after coronary artery bypass grafting
    - **Fischer GD, et al**.[13]: 30 subjects undergoing aortic arch surgery with oxygen saturation measured by CASM's FORE-SIGHT. Showed statistically significant association between accumulated duration of decreased cerebral oxygen saturation and severe adverse outcomes which included death, stroke with persistent neurological deficits, new heart problems, respiratory failure, sever infection, delirium, new kidney failure, GI complications and severe fluid retention. Additionally, oxygen desaturation was correlated to longer stay in the ICU and hospital and additional related cost of $8,300
    - **Murkin JM, et al**.[14]: landmark study showing significantly higher rates of death and major organ morbidity among patients with cerebral desaturation. 200 coronary bypass patients randomized to either cerebral oxygen saturation monitoring and treatment intervention (n=100) or blinded monitoring (n=100). Significantly more patients in control group (i.e. sham monitoring) experienced prolonged oxygen desaturation and in addition to having higher rates of death and major organ morbidity, these patients also had longer stay in the ICU and post-surgery hospitalization. Study concluded that cerebral oxygen monitoring in coronary artery bypass patients avoids profound cerebral desaturation and is associated with significantly fewer incidences of major organ dysfunction
    - **de Tournay-Jetté E, et al**.[15]: 61 elderly (mean age 70+) patients monitored for cerebral oxygen saturation during coronary bypass grafting (CABG) surgery and evaluated for postoperative neurocognitive dysfunction (POCD). Follow up occurred 4 – 7 days and 1 month after surgery. 81% developed early POCD and 38% late POCD. Patients which had cerebral oxygen saturation fall below 50% experienced more POCD 4 – 7 days after surgery and a decrease of more than 30% from baseline was associated with POCE 1 month following surgery
    - **Kazan R, et al**.[16]: Assessed postoperative complications in 50 patients undergoing thoracic surgery with single-lung ventilation. 82% of patients had regional cerebral oxygen saturation decrease of > 15% and 10% of patients had decrease of 45% - 55%. Lower cerebral oxygen saturation values were associated with non-respiratory organ failure and higher rates of pos-operative complications according to the Clavien score
    - **Greenberg SB, et al**.[17]: 53 patients undergoing cardiac surgery monitored for cerebral oximetry. Was found that 53% (28/53) of patients experienced early post-operative CDEs and 64% of these lasted for more than one hour. 18% (5/28) that experienced early post-operative CDEs died while none of the patients without early post-operative CDEs died

- High rates of CDEs;
    - **Edmonds HL Jr**.[18]**:** found that there were imbalances in cerebral perfusion and oxygenation in 59% of CABG surgeries
    - **Austin EH, et al**.[19]: showed that 70% (176/250) of pediatric patients undergoing cardiac surgery experienced deficiencies in cerebral perfusion or oxygenation as detected by NIRS and other methods. 74% (130/176) of these patients showed neurophysiologic changes and required intervention to correct deficiencies in cerebral perfusion or oxygenation
    - **Casati A, et al**.[20]: 122 elderly patients undergoing major abdominal surgery were randomized to either monitoring of cerebral oxygen saturation (rSO2) which were maintained at a rSO2 level of

≥ 75% (n=56) or blinded monitor and routine anesthesia management (n=66). Results showed 20% of treatment (i.e. monitored) and 23% of control patients experienced oxygen desaturation

- **Murphy GS, et al**.[21]: compared rates of cerebral oxygen desaturation of patients undergoing shoulder surgery (n=124) using the beach chair position (BCP, n=61) versus the lateral decubitus position (LDP, n=63). Incidence of CDE's were 80% in the BCP group and 0% in the LDP group and cerebral oxygen saturation values were lower in the BCP group throughout the surgery
- **Greenberg SB, et al**.[17]: 53 patients undergoing cardiac surgery monitored for cerebral oximetry. Was found that 53% of patients experienced early post-operative CDEs and 64% of these lasted for more than one hour. Patients with post-operative CDEs were more likely to have intraoperative CDEs

- Benefits of monitoring:
  - **Austin EH, et al**.[19]**:** showed that intervention to correct deficiencies in cerebral perfusion or oxygenation as detected by NIRS and other methods during pediatric cardiac surgery, decreases the incidence of post-operative neurologic complications and reduces the length (and cost) of hospital stays
  - **Goldman S, et al**.[22]: compared incidence of stroke among two sets of cardiac surgery patients; those which had cerebral oxygen monitored and optimized during surgery (n=1,034) and those that did not (n=1,245). Both groups followed for 18 months post-surgery. Results showed the oxygen monitored/optimized group had significantly less strokes, fewer patients in this group required prolonged ventilation and length of hospital stay was shorter as compared to the unmonitored group
  - **Casati A, et al**.[20]: 122 elderly patients undergoing major abdominal surgery were randomized to either monitoring of cerebral oxygen saturation (rSO2) which were maintained at a rSO2 level of ≥ 75% (n=56) or blinded monitor and routine anesthesia management (n=66). Results showed average rSO2 levels in treatment group were higher than those of control. And of the patients experiencing desaturation events (20% of treatment, 23% of control), there was a correlation between oxygen level and postoperative decrease in neuropsychological dysfunction. Patients in control group which experienced intraoperative desaturation also had longer hospital stay compare to those in the treatment group. Authors concluded that using rSO2 monitoring to manage anesthesia in elderly patients undergoing major abdominal surgery reduces the potential exposure of the brain to hypoxia; this might be associated with decreased effects on cognitive function and shorter PACU and hospital stay

Studies related to utility of NIRS

- **Putnam B, et al**.[23]: compared regional tissue oxygenation saturation (STO2) as measured by NIRS to traditional monitoring (including arterial pressure, cardiac output, oxygen delivery, arterial blood gases and lactate) in 40 patients undergoing cardiopulmonary bypass. Showed that with initiation of surgery STO2 value declined sooner than lactate levels increased (i.e. NIRS showed faster response) and minimum STO2 value preceded the maximum lactate level by an average of ~94 minutes. Authors concluded that STO2 (NIRS) is a reliable monitor which correlates well with oxygen delivery and identifies perfusion deficits earlier than lactate or base deficit
- **Taillefer MC, Denault AY**[24]: review of NIRS in adult heart surgery published in 2005 in Canadian Journal of Anesthesia. Included 48 papers and 5,931 cardiac surgery patients. Found NIRS monitoring appears to detect brain desaturation episodes encountered during surgery. Authors noted several study limitations, however, including methodological limitations and a low level of evidence.
- **Daubeney PE et al**.[8]: compared NIRS to jugular bulb oximetry in measuring cerebral oxygenation in 40 children undergoing cardiac surgery. Concluded that near-infrared spectroscopy may be a useful tool for assessing intravascular cerebral oxygenation during pediatric cardiac operations.
- **Orihashi K, et al**.[25]: Fifty-nine patients undergoing aortic surgery with selective cerebral perfusion monitored with NIRS. Concluded that a sustained drop in regional oxygen saturation during aortic surgery is closely related to the occurrence of neurological events following surgery.
- **Plachky J, et al**.[26]: Sixteen patients undergoing orthotopic liver transplantation monitored with NIRS. Found decrease in regional cerebral oxygen saturation was correlated significantly with post-operative increases in markers indicative of cerebral disturbances due to hypoxia/ischemia. Concluded that monitoring with NIRS may be useful during orthotopic liver transplantation.

- **Hofer, et al**.[2]: Ten neonates undergoing aortic arch surgery. NIRS was able to detect antegrade cerebral flow rates in all (n=10) children at all measurement points while Doppler failed to obtain a signal in at least one measurement point in 80% (8/10) of patient. Authors concluded that near infrared spectroscopy reliably detects flow alterations during ACP with profound hypothermia.
- **Olsson C, Thelin S**.[27]: Assessed cerebral tissue oxygen saturation using NIRS of 46 patients during selective antegrade cerebral perfusion. Concluded that NIRS allows detection of clinically important cerebral desaturation. It can help predict perioperative neurologic sequelae. Its performance as a diagnostic instrument is satisfying and supports its use as a noninvasive trend monitor of cerebral saturation

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Cerebral Oximeters, not all are created equal…

There are two general types of cerebral oximeters; those that are;

- **Trend-based:** focus on the change in oxygenation from a pre-established baseline. Trend-based oximeters rely on the percentage change in cerebral oxygen from a measurement taken prior to initiation of surgery to define intervention thresholds for clinicians. These monitors are susceptible to providing flawed feedback, however, as they rely on the assumption that the baseline oxygen measurement is not already compromised by factors such as illness (e.g. existing cardiovascular disease or heart failure), generally weak health, anesthesia, medications and therapy (such as supplemental oxygen) and other variables. So if baseline is already compromised, clinicians must assess whether to intervene (or not) even if a standard decrement in the reading has not occurred.
- **Absolute oximeters**: such as FORE-SIGHT, focus on the absolute level of oxygen and how that compares to clinically meaningful reference ranges. Measurement of the actual oxygen level, as opposed to the change from baseline, provides more actionable and accurate information to clinicians which can be used to intervene if oxygen saturation falls below a pre-determined trigger level. As such, direct oxygen measurement via absolute oximeter readings, as opposed to trend-based measurements, is the protocol which could provide clinicians more confidence in identifying CDEs and when intervention is necessary.

FORE-SIGHT Absolute Oximeter

FORE-SIGHT provides absolute oxygen saturation measurements. It consists of a monitor and two sensors, which are placed on the left and right side of the forehead. It can also be used to measure non-cerebral tissue oxygenation such as that of the calf during cannulated surgeries, or on the flank or gut for children. 14 U.S. patents, 15 non-U.S. patents and multiple patents pending cover the FORE-SIGHT technology.

The original FORE-SIGHT device received FDA 510(k) clearance in late 2005. The second-generation model, FORE-SIGHT ELITE received FDA clearance in April 2013 and launched in September of that same year. It is indicated for use to monitor the brain as well skeletal muscle with adults, children and neonates. ELITE provides greater accuracy than the first generation model as it emits five wavelengths of light instead of just four, providing for greater level of signal acquisition (i.e. minimizes what would otherwise be confounding variables) and allows for monitoring of four channels (instead of just two) of patient data. Additional channels allow for the monitoring of both cerebral and somatic (i.e. body) tissue oxygenation. In addition, ELITE has a larger viewing screen touch-screen controls and has been designed as to have lower manufacturing and servicing costs.

FORE-SIGHT ELITE



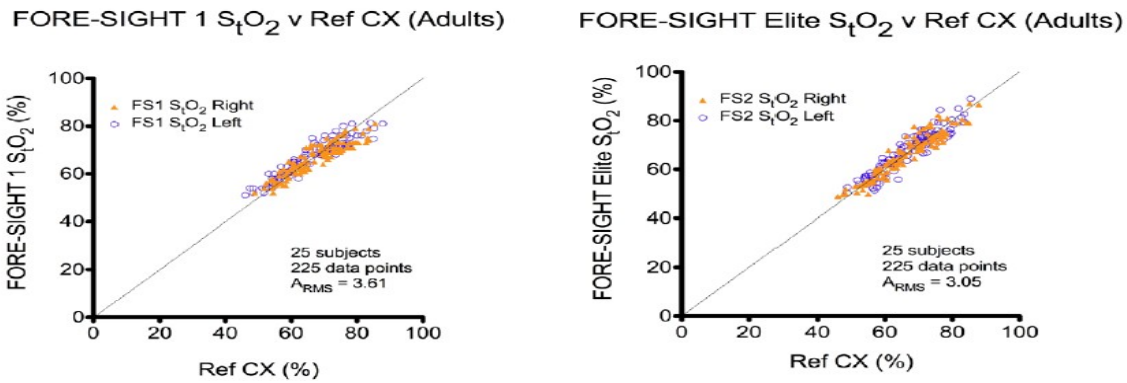
SOURCE: CAS Medical

ELITE outperforms first-generation model…

In a head-to-head study conducted by Duke University ELITE demonstrated greater accuracy than the legacy model, data from which was presented at the Annual Meeting of the Society for Cardiac Anesthesiologists in 2013. The study compared cerebral oxygen saturation as measured by ELITE (F2) and legacy (F1). A F2 sensor was placed on one side of the forehead and a F1 sensor on the other side of 25 healthy subjects which were intentionally desaturated in a controlled manner. Arterial oxygen concentrations as measured by pulse oximetry were varied between 70% and 100% in 5% increments and blood samples were taken at each step (via jugular bulb and arterial catheters) and analyzed with a blood gas analyzer. These blood results reflecting the biological condition were compared to readings of the two oximeters – precision and bias were measured.

Results showed that F2 (i.e. ELITE) had less bias and greater precision than F1 (i.e. the legacy model). Investigators concluded that ELITE demonstrated a high level of accuracy for measuring cerebral tissue oxygen saturation with greater accuracy than the FORE-SIGHT first generation model.

ELITE (F2) More Accurate Than Legacy (F1)



ELITE has been the major impetus to the 37% and 24% revenue growth of CASM's tissue oximetry segment in 2014 and 2015, respectively. FORE-SIGHT ELITE neonatal and pediatric sensors were launched in September 2015 which are expected to further steepen the revenue curve. CASM divested their vital signs monitoring products in late-2015 and their non-FORE-SIGHT neonatal products in March 2016 as they continue to shift more of their focus to the FORE-SIGHT product line and the tissue oximetry segment in general.

Competition

Other cerebral oximeters on the market include INVOS (Medtronic plc), Equanox/SenSmart (Nonin Medical), CerOx (Ornim Medical) and NIRO (Hamamatsu Photonics). FORE-SIGHT ELITE is the only oximeter with five wavelengths, has a greater depth of signal penetration and has a unique proprietary and patented algorithm, all of which CASM believes provides for greater accuracy. There have been no formal large randomized, controlled head-to-head studies between the different devices. In addition, there is no set industry or clinical standard for what is considered 'normal' cerebral oxygen saturation, which instead is inferred from the plethora of clinical data supporting the use of cerebral oximeters. This leaves the market and adoption-curve for these devices wide open. We provide a brief background on the different manufacturers and their devices as well as a general comparison to FORE-SIGHT.

Somanetics introduced the first adult cerebral oximeter, in 1996, and the first pediatric cerebral oximeter, in 2000. Somanetics was purchased by Covidien plc in 2010 (for $291M, net of $37M in acquired cash) which was subsequently acquired by Medtronic plc, in early 2015. According to Millennium Research Group, their **INVOS** device is the most widely used cerebral oximeter in the world.[28] INVOS 5100 C, the current model, uses just two wavelengths of light. Medtronic notes that INVOS is "backed by an unmatched level of quality clinical data". INVOS is FDA-cleared for adult, pediatric and neonatal use. While we have not been able to find current usage or installed base figures, a 2011 product brochure[29] notes that they had 6k INVOS units placed worldwide and it was being used in 250k procedures annually. This compares to FORE-SIGHT's installed base of 1,708 units as of December 31, 2015.

Minnesota-based Nonin (a play on 'noninvasive') Medical claims to have invented the first finger pulse oximeter. The company offers a catalog of monitoring devices including pulse and cerebral oximeters, capnographs and others. Their cerebral oximeters, which use up to four wavelengths, includes their **Equanox 7600 model**, a stand-alone cerebral oximeter, as well as **SenSmart X-100**, a combination pulse and cerebral oximeter. Nonin's monitors are FDA-cleared for neonatal, pediatric and adult use. Nonin is privately held with no publicly available sales or unit placement/installed base information.

Ornim Medical is an Israeli company which sells tissue and cerebral blood flow monitors in the U.S. Their lead product is a bedside cerebral monitor called c-FLOW, which is intended to be used to continuously monitor microcirculatory blood flow in the body. They also have **CerOx**, with three wavelengths, which measures both blood flow and oxygen saturation. CerOx is FDA-cleared for use in monitoring newborns through adults, although the product is no longer promoted by the company. Ornim is privately held with no publicly available sales or unit placement information.

Japanese company Hamamatsu Photonics is the world's leader of optoelectronics components with a major emphasis on medical devices. Their systems division develops and manufactures systems that utilize optic sensors. Their **NIRO-200NX** tissue oximeter, which measures three wavelengths, received FDA clearance in July 2015 for monitoring of blood oxygen of the brain and other tissue under the probes. It had been available in Europe and Japan for more than four years prior to FDA clearance.

FORE-SIGHT Versus the Competition

There are no large head-to-head, randomized clinical trials comparing the different cerebral oximeters that we are aware of. However, smaller studies comparing FORE-SIGHT to the market leader, INVOS, as well as devices from Nonin and Hamamatsu, have suggested superior accuracy of CASM's oximeters. And, noteworthy is the fact the first generation model of FORE-SIGHT was used in these studies. Had ELITE been used instead, which showed even better accuracy than the original model, results of these competitor studies would likely have been even more favorable to FORE-SIGHT.

FORE-SIGHT vs. Three Competing Devices…

CASM sponsored a clinical study comparing FORE-SIGHT (first-generation model) to the current models of INVOS, Nonin and Hamamatsu. An abstract of the results titled, *Direct Performance Comparison of Cerebral Oximeter Devices*, was first presented at the 2011 Annual Meeting of the American Society of Anesthesiologists and later published in the peer-reviewed journal, Anesthesia & Analgesia. The study compared oxygen saturation values as measured by four cerebral oximeters (FORE-SIGHT first-generation, INVOS 5100C, Equanox 7600 with both Advance and Classic sensors, and NIRO-200NX) during controlled oxygen desaturation to that of simultaneous blood gas readings from blood taken via jugular bulb and arterial catheters. Sensors from the different manufacturers were randomly placed on alternating sides of each of the 23 healthy subject's foreheads. Subjects were administered oxygen/carbon dioxide mixture to adjust arterial oxygen concentrations from 98% down to ~68% in equal increments. Oxygen values from blood samples were compared to cerebral oximetry values of each device.

Results showed that FORE-SIGHT measured cerebral oxygen with the greatest precision (3.90%) and accuracy (A_{rms} 4.26%), compared with (lower is better on both measures) precision and accuracy of INVOS of 9.72% / 9.69%, NIRO-200NX of 9.64% / 9.68%, Equanox (Classic sensor) of 8.12% / 8.47% and Equanox (Advance sensor) of 6.27% / 6.86%. The values among all four of the monitors was also generally consistent with several earlier studies.

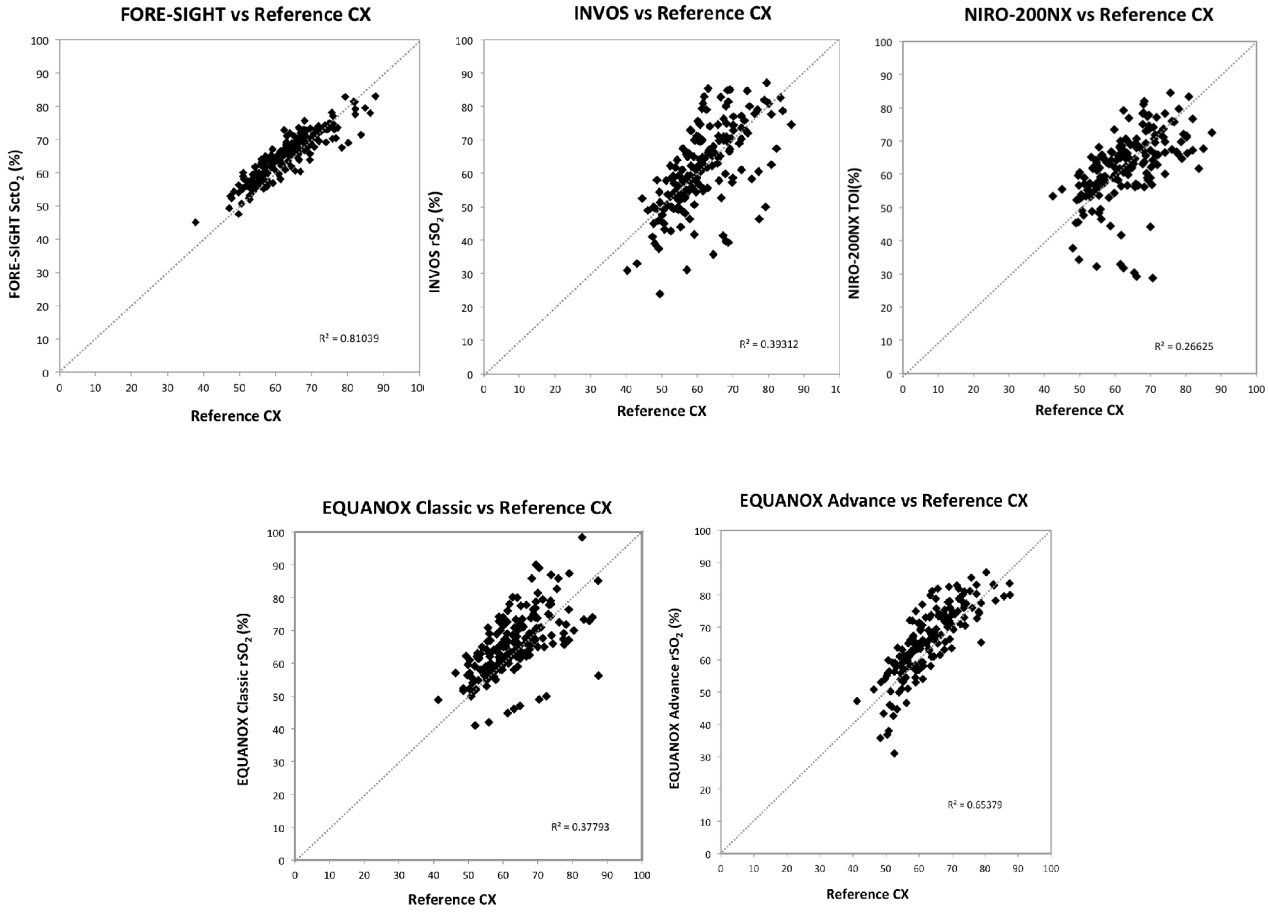
Greater Precision and Accuracy of FORE-SIGHT[30]

	FORE-SIGHT	INVOS	NIRO-200NX	EQUANOX Classic	EQUANOX Advance
Prec (±1SD)	3.90	9.72	9.64	8.12	6.27
Bias	-1.73	-0.05	1.23	-2.48	-2.84
A_{rms}	4.26	9.69	9.68	8.47	6.86

Table 1: Precision, Bias, and A_{rms} of different manufacturer's device. Bias is presented as [Reference CX - Measured Value].

SOURCE: CAS Medical

Tighter Scatterplot of FORE-SIGHT Highlights Greater Accuracy

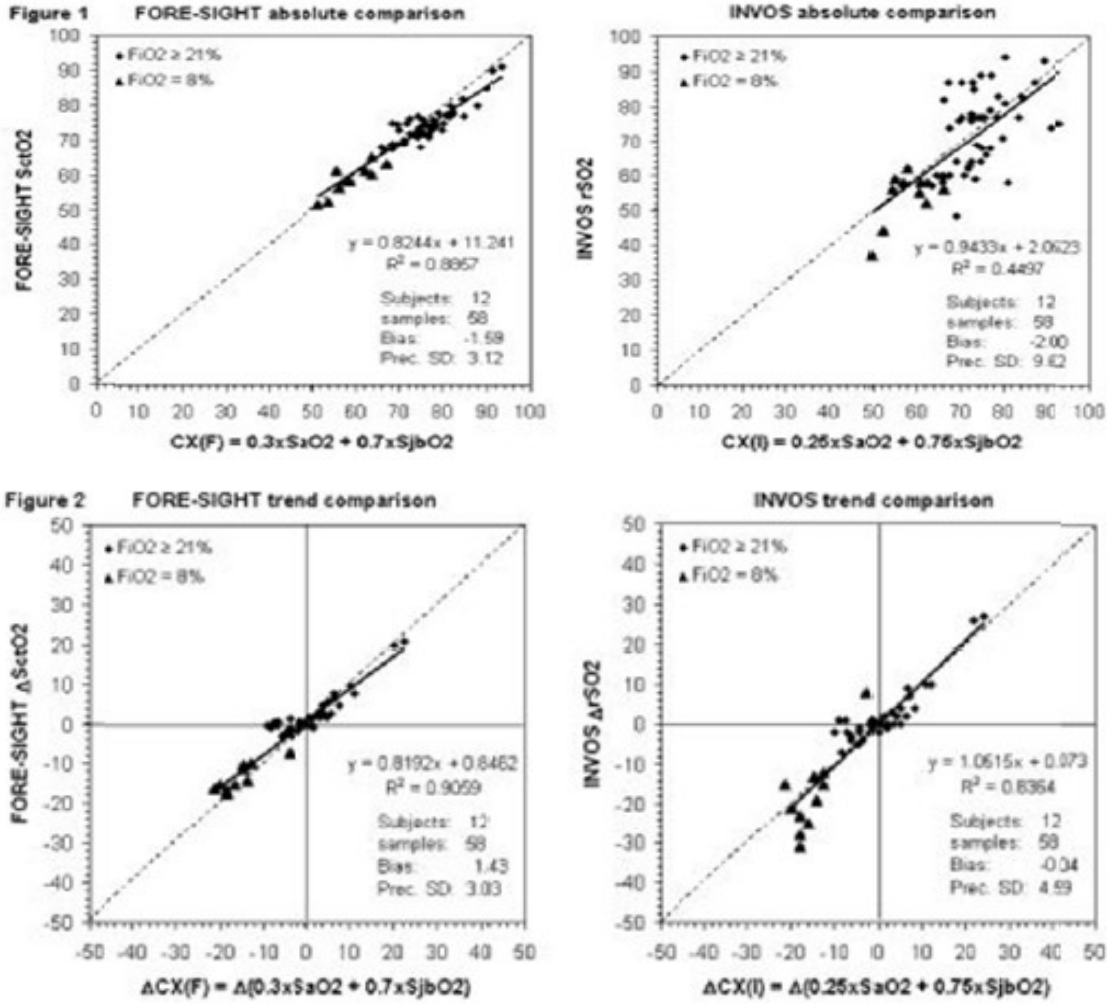


FORE-SIGHT vs. INVOS…

Below we detail small head-to-head studies comparing FORE-SIGHT to INVOS 5100C which also suggests superior accuracy of CASM's device.

- **MacLeod David B, et al.**[31]: Conducted by Duke University and presented at 2009 Annual Meeting of the American Society of Anesthesiologists. Comparison of FORE-SIGHT (1st gen) and INVOS 5100C to co-oximetry jugular bulb and arterial oxygen saturation (i.e. reference) in 12 healthy subjects. FORE-SIGHT and INVOS sensors were placed on the right and left forehead of each subject. Sequential gas delivery delivered step changes of inspired oxygen at five minute intervals from room air to 21% to 8% to 21% and then 50%. A total of 58 samples were taken. Oxygen saturation was kept at >70% as measured at the finger. Results showed baseline room air reference values for FORE-SIGHT and INVOS were in the ranges of 69.7% - 80% and 67.6% - 78.7%, respectively. This compared to measured ranges of 68% - 76% for FORE-SIGHT and 48% - 89% for INVOS. The tighter range of FORE-SIGHT as compared to reference demonstrated much greater accuracy as compared to INVOS in measuring both absolute and trend changes in cerebral oxygen saturation. Standard deviation of FORE-SIGHT was much lower than that of INVOS (3.12% vs. 9.16%), implying FORE-SIGHT is 3x more accurate than INVOS. In addition, for two of the twelve subjects INVOS measured a change from baseline that exceeded the change in reference value by two standard deviations during a sudden change in oxygen mixture, inaccurately indicating cerebral oxygen saturation was falling faster than it was.

Tighter (more accurate) Regression Plots of FORE-SGHT in Measuring Absolute and Trend Changes

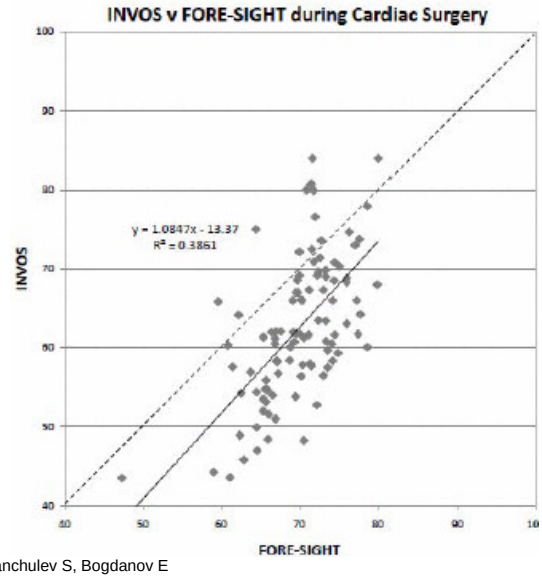


- **Ianchulev S, Bogdanov E[32].:** Conducted by anesthesiologists from Tufts Medical Center and Weill Cornell Medical Center and presented at the Society of Cardiovascular Anesthesiologists Annual Update on Cardiopulmonary Bypass in 2012. Comparison of FORE-SIGHT (1st gen) and INVOS 5100 during cardiac surgery in 11 patients (7 CABG, 4 open chamber surgery). One sensor from each device was placed on the left and right side of the forehead. Oxygen saturation values were recorded with each device and intervention was initiated when values fell below 55% or decreased by more than 20% from baseline. These pre-set intervention trigger points are the established standard treatment protocol for the investigators' institution. Results showed correlation, albeit weak (R^2 = 0.386), between the measurements of the two devices but significant (p<0.00001) differences in absolute values with INVOS showing lower values. INVOS showed values below the 55% trigger point more often than FORE-SIGHT including an average of 47 more minutes on the left side of the forehead and 110 more minutes on the right side which, per the study investigators, "consistently prompt[ed] treatment often without expected results." They further noted that, "Given the treatment protocol used we can assume that treating of false positive values can lead to possible injury, neurological deficit and an increase in morbidity and mortality."

Higher False Positive Rates for INVOS?

Patient	Time under threshold 55%, min			
	$SctO_2$ L	$SctO_2$ R	rSO_2 L	rSO_2 R
1	0.0	0.0	0.0	2.2
2	0.0	15.9	32.7	172.0
3	0.0	0.0	0.0	0.9
4	0.0	0.0	48.2	284.4
5	9.6	23.0	14.7	75.9
6	0.0	0.0	24.1	6.2
7	0.0	0.0	1.0	46.4
8	0.0	0.0	306.4	115.0
9	0.0	0.0	0.3	213.9
10	0.0	0.0	66.2	105.9
11	0.0	0.0	27.1	220.5
average	0.9	3.5	47.3	113.0
maximum	9.6	23.0	306.4	284.4

FORE-SIGHT / INVOS Weak Correlation



SOURCE: Ianchulev S, Bogdanov E

OUTLOOK / VALUATION

We think the performance advantages of FORE-SIGHT compared to competing systems, most notably market-leading INVOS, coupled with increasing adoption of cerebral oximetry in surgical and other applications sets the stage for deeper and wider market penetration of FORE-SIGHT. Shedding of the 740 vital signs and neonatal disposables product lines has allowed CASM to dedicate more resources and focus on that goal. Sales force expansion, improved productivity and the pediatric/neonatal indications should further facilitate growth of the installed base and, most importantly, increase utilization and related sensor sales. The transition to a disposables company is already well underway, the benefits of which we think will accelerate and result in continued double-digit growth of the tissue oximetry business, widening of gross margin and more rapid improvement towards reaching profitability.

Valuation

We value CASM using comparable EV/S and P/S ratios of other publicly traded companies in the tissue oximeter, patient monitoring and cardiac surgery industries including direct competitors Masimo Corporation (MASI), Hamamatsu Photonics (HPHTY) and Medtronic (MDT). As the other tissue oximetry competitors are not publicly traded, we have rounded out our comparable cohort with companies which have similar exposure to CASM's end markets including Brainsway (BRSYF), a manufacturer non-invasive brain stimulation devices and Natus Medical (BABY), which makes monitoring and detection devices for neonatal neurological disorders.

Both EV/S and P/S value CASM at approximately $4/share, indicating the market is substantially undervaluing the stock.

	Sales Estimate (M)							
	2016	2017	EV	EV/2016	EV/2017	MC	P/S '16	P/S '17
BABY	$389	$407	$1,170	3.0	2.9	$1,260	3.2	3.1
MASI	$683	$727	$2,820	4.1	3.9	$2,740	4.0	3.8
BRSYF	$8	$10	$38	4.8	4.0	$50	6.3	5.3
HPHTY	$1,121	$1,234	$3,820	3.4	3.1	$4,500	4.0	3.6
MDT	$29,930	$31,440	$140,130	4.7	4.5	$121,470	4.1	3.9
Avg.				**4.0**	**3.7**		**4.3**	**3.9**

CASM Valuation Based On:					
Comparable EV/Sales			Comparable Price/Sales		
	EV	Implied Share Value		MC	Implied Share Value
2016 S	$91	$3.52	2016 S	$98	$3.68
2017 S	$100	$3.85	2017 S	$107	$4.01
Average		**$3.68**	**Average**		**$3.85**

FINANCIAL MODEL

CAS Medical Systems Inc. (figures in 000s of $)

	Q1 A	Q2 A	Q3 E	Q4 E	2016 E	2017 E	2018 E
FORE-SIGHT Sensors	$3,734.0	$4,051.0	$4,134.3	$4,387.1	$16,306.4	$21,165.2	$24,907.0
yoy growth	*27.7%*	*26.7%*	*21.6%*	*25.2%*	*25.2%*	*29.8%*	*17.7%*
% of total oximetry sales	87.3%	90.4%	86.5%	84.8%	87.2%	88.7%	89.6%
FORE-SIGHT Monitors & Access.	$543.0	$431.0	$642.7	$786.4	$2,403.2	$2,694.7	$2,886.7
yoy growth	*54.3%*	*-37.5%*	*19.5%*	*-1.1%*	*1.2%*	*12.1%*	*7.1%*
% of total oximetry sales	12.7%	9.6%	13.5%	15.2%	12.8%	11.3%	10.4%
Tissue Oximetry Total Sales	**$4,277.0**	**$4,482.0**	**$4,777.0**	**$5,173.6**	**$18,709.6**	**$23,860.0**	**$27,793.7**
yoy growth	*30.6%*	*15.3%*	*21.3%*	*20.3%*	*21.5%*	*27.5%*	*16.5%*
% of total revenue	**78.4%**	**80.9%**	**83.2%**	**85.1%**	**82.0%**	**86.6%**	**89.3%**
Traditional Mntrng Total Sales	**$1,179.0**	**$1,057.0**	**$963.0**	**$907.0**	**$4,106.0**	**$3,695.4**	**$3,325.9**
yoy growth	*-5.4%*	*28.7%*	*-9.0%*	*-11.0%*	*-34.2%*	*-10.0%*	*-10.0%*
% of total revenue	**21.6%**	**19.1%**	**16.8%**	**14.9%**	**18.0%**	**13.4%**	**10.7%**
Total Revenues	$5,455.5	$5,539.0	$5,740.0	$6,080.6	$22,815.1	$27,555.4	$31,119.5
YOY Growth	*20.7%*	*17.7%*			*17.1%*	*20.8%*	*12.9%*
Cost of Revenues	$2,574.9	$2,510.1	$2,617.4	$2,705.9	$10,408.3	$12,262.15	$13,474.8
Gross Income	$2,880.7	$3,028.9	$3,122.6	$3,374.7	$12,406.8	$15,293.2	$17,644.8
Gross Margin	*52.8%*	*54.7%*	*54.4%*	*55.5%*	*54.4%*	*55.5%*	*56.7%*
R&D	$955.4	$867.2	$928.0	$935.0	$3,685.6	$3,244.0	$3,150.0
% R&D	*17.5%*	*15.7%*	*16.2%*	*15.4%*	*16.2%*	*11.8%*	*10.1%*
SG&A	$3,367.9	$3,491.3	$3,558.8	$3,709.2	$14,127.1	$15,017.7	$15,528.7
% SG&A	*61.7%*	*63.0%*	*62.0%*	*61.0%*	*61.9%*	*54.5%*	*49.9%*
Operating Income	($1,442.6)	($1,329.6)	($1,364.2)	($1,269.4)	($5,405.9)	($2,968.4)	($1,033.9)
Operating Margin	*-26.4%*	*-24.0%*	*-23.8%*	*-20.9%*	*-23.7%*	*-10.8%*	*-3.3%*
Interest Income, net	($199.2)	($322.1)	($212.3)	($212.3)	($946.0)	($871.5)	($643.9)
Other income	$4.9	$2.0	$0.0	$0.0	$6.9	$0.0	$0.0
Pre-Tax Income	($1,637.0)	($1,649.7)	($1,576.5)	($1,481.7)	($6,345.0)	($3,839.9)	($1,677.8)
Taxes	($1,091.2)	$30.3	$0.0	$0.0	($1,060.9)	$0.0	$0.0
Tax Rate	*66.7%*	*0.0%*	*0.0%*	*0.0%*	*16.7%*	*0.0%*	*0.0%*
Income (loss) from discont. ops	$2,026.6	($86.7)	$65.0	$30.0	$2,034.9	$0.0	$0.0
Net Income (cont ops)	($906.8)	($2,047.4)	($1,950.4)	($1,862.1)	($6,766.8)	($5,426.9)	($1,677.8)
YOY Growth	*-53.4%*	*-13.5%*	*-2.8%*	*-17.4%*	*-34.9%*	*-19.8%*	*-69.1%*
Net Margin	-	-	-	-	-	-	-
EPS (cont ops)	($0.03)	($0.08)	($0.07)	($0.07)	($0.25)	($0.15)	($0.04)
YOY Growth	*-60.4%*	*-14.2%*	*-5.8%*	*-20.8%*	*-38.6%*	*-39.3%*	*-72.2%*
Diluted Shares O/S	26,800	26,824	27,500	27,900	27,256	36,000	40,000

Brian Marckx, CFA

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