

Sedation Assessment System for the U.S. Hospital Market



Mike Baltay - CEO

About BrainStem Biometrics

At BrainStem Biometrics we are launching a breakthrough sedation assessment system into the US hospital market to reduce ICU costs and improve patient safety. Our simple, non-invasive and low cost disposable sensor system is cleared by the FDA, backed by patents and validated in 10 clinical studies. Critical care teams use our system to set proper sedation levels for patients who are significantly over-medicated today because there is no feedback loop. Over-sedation in the ICU costs US Healthcare billions. We aim to reduce length of stay, morbidity, mortality and enhance patient safety for ICU directors and hospital administrators.

Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

CEOCFO: Mr. Baltay, what is the concept behind BrainStem Biometrics?

Mr. Baltay: The concept centers on the elimination of a major problem in the intensive care unit, which is that many patients are over medicated with sedatives, and this over-sedation has huge health and economic consequences. The reason that they are over medicated is because today there is no feedback for administering these medications.

CEOCFO: Has it just been decided that a certain amount will be given no matter what?

Mr. Baltay: Yes, each patient requires a certain level of medication, but it is very difficult to administer the appropriate amount so we do it based on height, weight and some guesswork. Our inability to administer the appropriate amount of sedatives means we err on the side of giving them more medicine rather than less. These are our sickest patients and over-medicating them results in 25% longer stays, 10% increases in risk of mortality and many unnecessary health complications.

CEOCFO: What is the challenge in monitoring?

Mr. Baltay: The current standard of care is essentially what we call a stimulus- response mechanism. You provide a verbal command or a physical stimulus and you gage the response of the patient. It is not dissimilar to someone who might be intoxicated after a long night on the town. Do you obtain information when you stimulate or physically touch the patient? Right now, there is a great deal of variation in that practice and it is not well instituted. In particular, that method does not work at all when we get no response. It would be fine if someone says they have had too many drinks and asks to be taken home to bed. But what happens when they do not respond? Now you are concerned for their safety. Do they need to be rushed to the emergency room or do they just need to sleep it off? That is when you have no information, and that is the current situation. When a patient is sedated below the level of responsiveness, we have no idea where they are.

CEOCFO: Have people been looking for a better solution and focusing on it or are they just accepting the status quo?

Mr. Baltay: The industry has been looking for a better solution, but there really is not one. It takes a while for any community to come to consensus, and the first point of consensus about 5-10 years ago was to agree that this is a major problem; it is occurring often and it has a ton of bad effects. The next step is what to do about it. Lacking technology or a medical device or other concrete solution, we have come to solid consensus on several basic practices that all of the experts agree will help. Our system now brings the missing ingredient, a simple way to implement what we have all agreed.

CEOCFO: What have you figured out at BrainStem?

Mr. Baltay: What we have developed is a very simple, low cost feedback system that is a small adhesive patch, like a small Band-Aid or sterile strip, which mounts on the eyelid of an open or closed eye of a patient. It provides much more accurate, better feedback of the status of the patient's brain state all across the entire range, whether they are responsive or completely non-responsive.

CEOCFO: *Why the eyelid or eye?*

Mr. Baltay: The eye itself is fundamentally connected to what is called the brainstem, which is the most basic part of the brain- in evolutionary neuroscience, you would call it the oldest most fundamental part of the brain. The brain stem is directly connected to the eyes through a series of electro muscular systems called the ocular motor system. The first thing that happens when you fall asleep or lose consciousness is your eyes close. Pupillometry is something that has been around for a long time, which is a way of gauging someone's mental state by observing an external physiological phenomenon, which is your eye activity. Your eyes are fundamentally connected to your brain and to your soul. We measure very small movements of the human eye that are directly correlated with your mental state.

CEOCFO: *How did you come about the concept that this was the place to pay attention?*

Mr. Baltay: The idea that there are these eye motions and that they are related to brain state has been known for a long time, since the 1930s, and has been studied on and off since then. What has allowed the advance that we have made has been modern materials and computer processing. These are very small movements of the eye, very small bioelectric signals, and for the most of the history we have not had the ability to make those measurements. When we think about it at a high level, we have a multibillion dollar problem affecting many patients around the world, and the current standard of care is sort of arcane; slap them around and see what they respond to. Now you have new material science and signal processing technologies that allow you to have an objective, state of the art digital sensor which is safe, low-cost and simple to use, yet gives us critical operating information about our most important organ. I say that is a winner.

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CEOCFO: *Where are you in the development and commercialization continuum?*

Mr. Baltay: We are planning to launch our product late this year or next year. We have a few final clinical studies to do and we have redesigned the product to be low cost and reliable. We have already a clearance to market the product from the US Food and Drug Administration, and we have three patents. Over the years, we have completed 10 or 12 clinical studies already showing that this eye motion is an important indicator of many different altered brain states. For example, we have shown that on death brainstem activity is a flat line signal like your heart would be. We have shown that in a coma this signal is severely depressed, and we have demonstrated that in sleep it is altered but in a different way, particularly during rapid eye movement sleep when you are in a very aroused condition. We have shown that in anesthesia for surgery, the signal goes down when you administer drugs and goes back up when you stop administering the drugs. We have also shown that under certain neurological conditions - I do not know if you are familiar or not with Parkinson's disease or MS, but those are neurological conditions that manifest themselves in part with atypical eye motions- we see abnormal eye signals. We know what normal is, and we see deviations from normal on all those different brain states, so we are just doing some final studies mostly around our new low cost product, and then we will address over sedation in the ICU.

CEOCFO: *Is there interpretation or is it clear-cut?*

Mr. Baltay: Nothing is clear cut in medicine. You always have to use the judgment of physicians, but our system does two things. It provides an entire new level of objectivity. In other words, it is much higher quality of new information on which a physician can base a decision. It also allows much better communication between the nurse, who in a critical care unit is the one administering medication, and the physician who may not be there and is the one prescribing the medication. Right now, there is sub-optimal communication between those two because there is no specific objective measure or reliable information.

CEOCFO: *Is the segment of the medical community that will potentially make use aware yet? Is it too early before you launch for people to know?*

Mr. Baltay: I think the timing is right. They are not so much aware of this technology, although just recently with the announcement of several awards and our partnership with Johnson & Johnson there has been a whole new state of awareness. Over the last year as we have developed it, we have had thousands of hits on our website. We have also enrolled a number of top physicians who have had many conversations amongst the physician community. There is a growing awareness, and there is also a huge awareness that this problem is not being solved with the current methods today. You are seeing a number of major companies coming out with very important statements about the need for better technologies, and that has raised additional interest in companies like ours.

CEOCFO: *Would you tell us about the arrangement with Johnson & Johnson?*

Mr. Baltay: I can only say what is publicly available, which is that we have come to an agreement with Johnson & Johnson Ethicon Endo-Surgery in a deal that was facilitated by Johnson & Johnson Innovation company. Part of the work we will be doing together are these additional studies that I mentioned. Johnson & Johnson is very interested in several different potential market applications. They have technical depth in neuroscience and other areas and the ability to see how important a basic parameter like this could be. Many people think that this is another vital sign. Right now, the four existing vital signs are entirely centered on heart, lung and skin, like respiratory rate, and body temperature. Those are important organs, but in our monitoring industry less than one percent of the emphasis is on the brain, arguably the most important organ of all. J&J sees the potential of this technology to be essentially the fifth vital sign, and that is an extremely important advancement for medicine. Johnson & Johnson is the kind of bold company that is capable of seeing that and exploiting it early.

CEOCFO: *What have you learned from previous ventures that has been most helpful?*

Mr. Baltay: One of the most critical things is to know where the money is and to target fund raising efforts. Each venture and business opportunity is of different interest to different investors, and the key is to find the right match. What is very interesting to me in this particular one is the fairly strong shift going on in the investment community for medical devices. Traditionally, you could get money much more easily from traditional venture capital firms. They are shifting in two directions away from early stage medical devices. They are shifting to later stage companies that have revenues already, and they are shifting more of their investment into health IT or big data health care or health care informatics, all of which are general names for the intersection between information technology (where venture capitalists have a lot of experience) and health care where information is becoming critical going forward to managing large patient populations at the lowest cost with best outcomes. Health care IT is less regulated and more capital efficient than drugs or devices, especially for risk-averse investors. So this contraction in traditional device venture capital is being filled by wise companies like Johnson & Johnson and large hospital systems like Partners here in Boston, Kaiser or Ascension Health. The companies and the health care systems need new innovations to continue to advance medicine and lower the cost. You are seeing a rise in funding from non-traditional sources. It is either corporate investing, which is where we secured funds, or venturing groups that are now emerging out of large hospital systems. They collectively are saying that if the VC community is not going to provide a pipeline of new innovations then somebody has to do it. That is probably the single most important thing for us and for any venture, which is where are you getting your money? There are increasing opportunities for higher numbers of investors to invest smaller amounts, moving toward crowd sourcing as well as federal and state government programs.

CEOCFO: *How do you deal with the frustration of knowing you have something that could really make a difference and having it be such a long, arduous process?*

Mr. Baltay: I do not get too frustrated by it because I understand adoption cycles and the different behaviors that need to occur in different organizations of people in order for it to happen. For me, it is a question of: are we progressing equal to or better than our guess as to how that would unfold. These entrepreneurs who think they have a new product, a physician and FDA clearance, and therefore they are going to make a lot of money, that kind of an approach can make you very frustrated, and you realize that the product itself is only 15 percent of the game. In particular, this over-sedation and brain state monitoring area has a very big unmet market and medical need, and we are filling it. I am actually surprised. I was not anticipating engaging with a corporation like J&J quite so early in the game here. That said, there is no question that the health care system is pretty screwed up. That is very frustrating. Very large organizations, government and private and many hospitals of non-profit all have their own incentives that are associated with their own economics. Those are not always aligned. As a matter of fact, they are out of alignment many times. When that happens, we all suffer, and that is frustrating to me at a high level. We need to be much more bold at all levels.

CEOCFO: *Put it all together for our readers. There are many companies in your industry to take a look at. Why pay attention to BrainStem Biometrics?*

Mr. Baltay: We are about to reduce the cost of health care significantly in an area where there is significant traction already. Critical care is 15 percent of the hospital or the US expenditure, and we have an opportunity to knock that back significantly. We have a significant opportunity to take out real cost with little to no incremental investment. Even more importantly than saving billions of dollars, there have been recent studies showing that when you over medicate patients in the ICU, it results in a ten percent increase of risk of mortality. That is not acceptable, so I do not know about you, but saving a ton of money and reducing unnecessary mortality gets my eyes to open. It is also a really cool product.

CEOCFO: *Final thoughts?*

Mr. Baltay: The key thing we do is reduce the length of the stay in the ICU. That is what effects the mortality and that is what effects the costs in the ICU and more so in reduced follow-on care for the payers.

BIO: Mike has over 20 years experience with new ventures and marketing in healthcare and medical technology and is the founder of two successful small businesses. As founder of Spin-In Ventures, he successfully raised capital and developed a portfolio of three ventures. He was also a partner at healthcare consultancies Arthur D. Little and Monitor Group. Mike has extensive industry and team management experience in medical technology, therapeutics, diagnostics, institutional and outpatient channels and hospital distribution (GPO). He holds a M.S. Management from Stanford University and a B.S. Mechanical Engineering from Union College.



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