



Hospital Based Artificial Pancreas System Could Save Lives and Healthcare Resources



Leon DeJournett, MD
CEO

Ideal Medical Technologies
www.idealmedtech.com

Contact:
leondej@idealmedtech.com

Interview conducted by:
Lynn Fosse, Senior Editor
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"By utilizing our system, the total cost of care will go down, not up. Death rates will go down, complication rates will go down and nursing efficiency will improve." Leon DeJournett, MD

CEOCFO: Dr. DeJournett, what is the concept behind Ideal Medical Technologies?

Dr. DeJournett: Ideal Medical Technologies is creating an artificial pancreas system for use in the hospital setting. Specifically, we are going to start with the ICU setting. It turns out that good glucose control in the ICU setting is important for lowering mortality rates, shortening hospital lengths of stay, decreasing cost of care, and improving nursing efficiency. In fact, it is a dramatic effect. Good glucose control can lower mortality rates by at least thirty percent and decrease the overall length of stay by one to two days.

The nurses spend one to two hours per patient per day on glucose control with the current methods. Our artificial pancreas system will decrease the time spent on glucose control to ten minutes per patient per day, while producing net cost savings of at least \$1,500 per ICU patient. The current method is an open loop system, whereby the nurse has to manually check the patients glucose level, enter the glucose level into insulin dosing software, and then manually adjust the IV pump infusing insulin into the ICU patient. Our system is fully autonomous, meaning it will run with almost no input from the nursing staff.

CEOCFO: What led you to create the FUSION artificial pancreas system?

Dr. DeJournett: I have been an ICU doctor for thirty years and I got involved in glucose control in 2007 when I realized that the methods that were being utilized, at the time, would not be able to keep up with the very non-linear glucose versus time curve. ICU patient's glucose levels are kind of going all over the place; it is going low, high, with extreme variability. A good explanation that I use for people to explain the current method of glucose control is to imagine you are in a boat on a

narrow winding lake and you are asked to keep the boat in the middle of the lake, but are restricted to turning the steering wheel every one to four hours. However, in order to keep the boat in the middle of that narrow winding lake, you actually have to turn the steering wheel every five to ten minutes.

Our FUSION artificial pancreas system will adjust the infusion rates of the insulin and/or glucose infusing into the ICU patients every five to ten minutes, whereas the current method makes adjustments every one to four hours. I knew that the current method, with the slow reaction time and adjustments of insulin infusion rates every one to four hours, would never be able to achieve good glucose control. I thought that I could develop a system that could mimic the way that the human body works and achieve safe and effective glucose control.

CEO CFO: What is physically happening? What is the equipment? How does it attach? What is FUSION measuring?

Dr. DeJournett: An artificial pancreas system has three main components. It has the glucose sensor that transmits the glucose signal to the glucose control software. The glucose control software controls the output rates of the intravenous pumps that are infusing insulin and/or glucose into the patient. The glucose sensor that we are going to utilize has already been CE Marked for use in ICU patients, so it is available for use in Europe. In addition, our system will also work with Bluetooth enabled continuous glucose monitors worn by diabetic patients, such as the Dexcom G6®.

Our FUSION systems ability to use multiple different types of continuous glucose monitors will allow us to eventually bring glucose control to both ICU patients and diabetic patients in a non-ICU setting. Our glucose control software is artificial intelligence based and uses biomimicry, which means it mimics how the native pancreas and the liver work together in controlling blood glucose levels. The current intravenous pumps that are available on the market are accurate and reliable enough to control blood glucose levels in ICU patients.

CEO CFO: Would you tell us about the recent FDA designation and your next steps?

Dr. DeJournett: In 2019 the FDA designated our FUSION closed loop glucose control system as a Breakthrough Medical Device, which means they acknowledged that our pre-clinical testing demonstrated the proof of concept, both in our simulation work and our animal work. Also, it is an acknowledgment that there are currently no approved closed loop glucose control systems available for use in the ICU setting in the U.S, and that our FUSION artificial pancreas system would be a breakthrough device. We have been working with the FDA for more than a year now, thus they are aware of our work. Our plans had been to do a series of clinical studies and try to bring our system to the market at the end of 2021. However, with the COVID pandemic, our plans have actually changed. We are trying to accelerate our timeline.

CEO CFO: What has been the feeling from medical people who have looked at the system? What has been the reaction from people who know about it?

Dr. DeJournett: Anyone who has heard about it is extremely excited, because it is very difficult to achieve safe and effective glucose control with the current open loop method. You really cannot keep up. The nursing staff, who are the clinicians that will be utilizing the system, love the concept and cannot wait to use it! The doctors who are responsible for caring for the patient, those being the ICU doctors, cardiac surgeons and so on, are very excited for the possibility of a safe and effective system to control the blood glucose levels of their patients. The endocrinologists who care for diabetic patients in a non-ICU setting would also like to have a safe and effective system to lock in the glucose levels of their patients. Overwhelmingly, the response is very positive. We will have to prove to the clinicians that it is safe and effective, but once we do, we believe we will have rapid adoption of the system.

CEOCFO: *Where does cost of the system come into play? It should not when it is a breakthrough, but we know it often does.*

Dr. DeJournett: Certainly! We project that it will cost approximately five hundred dollars per patient to use the system. However, that will be offset by a total savings of at least two thousand dollars per patient, mainly through shortening the length of hospital stay and decreasing the complication rates. This should produce net cost savings of at least fifteen hundred dollars per patient.

By utilizing our system, the total cost of care will go down, not up. Death rates will go down, complication rates will go down and nursing efficiency will improve. Therefore, we feel that the Value Analysis Committee's that decide whether or not to bring a new device into the hospital will love our system, because we check all the boxes as far as improving patient outcome, improving staff efficiency, producing net cost savings, and enhancing patient throughput.

CEOCFO: *You are looking to raise money at this point. How will you use it? What has been the reaction from potential investors so far?*

Dr. DeJournett: We just started our Series A money raising round. We are looking to raise ten million dollars and this money will be used to fully develop a commercial grade device and to do our initial clinical studies, including our pivotal study, prior to bringing the device to market. However, I mentioned earlier the COVID-19 pandemic, and I would like to expound on that. A large U.S. study has shown that hyperglycemia, or elevated glucose levels in COVID-19 patients, increases their mortality rate by at least four hundred percent.

We feel that our system could significantly lower mortality rates in COVID-19 patients. Therefore, the money that we raise will be utilized to bring an early version of the system to market, hopefully by the end of this year or Q1 of 2021. Our plan is to utilize the money raised to build out a more simplified version of our system and to seek an Emergency Use Authorization from the FDA, given that we feel that we can have a positive impact on COVID-19 mortality rates.

CEOCFO: *Are you assuming that COVID is going to be around for a long time?*

Dr. DeJournett: There is a group out in Minnesota that are pandemic experts and they project at least two years for this pandemic. Our system is not COVID specific, but we think it will help with COVID. In addition, it will help long after COVID is gone for ICU patients and the diabetic patients on the floor. We just feel we can help with this pandemic, but it is going to help in general for all hospitalized patients who would benefit from a safe and effective glucose control.

CEOCFO: *Since your FUSION system is something that would be useful for COVID, will it help in attracting attention or are people so diverted from everything other than COVID that it may get lost in the shuffle?*

Dr. DeJournett: I hope it does not get lost in the shuffle! Everyone is focused on vaccines and antivirals, but it may not be just antivirals that lower COVID-19 mortality rates. Vaccines are very difficult to develop, usually taking at least 3 years to get them ready for widespread use. They are hoping to shorten this timeline to twelve to eighteen months with this virus. We know the virus has already mutated a lot. You could develop a vaccine against the current strain and when you go to utilize the vaccine in twelve months the virus is going to be mutated such that the vaccine is not completely effective. Therefore, it is hard to really bank on a future vaccine being 100% effective.

We would like to lower the mortality rate for patients who are sick and hospitalized right now, and we feel our system can do that. We are hoping that people will want to help bring the FUSION system to market, given its potential to have an immediate impact on COVID-19 mortality rates.

CEOCFO: *What have you learned through the development process that was surprising?*

Dr. DeJournett: It takes a long time, number one! If you are thinking you are going to develop such a system in a year to two, it is probably not going to happen. You have to be in for the long haul. In my case, it is actually close to fifteen years since I started the process. You have to persevere. You have to be ready to be told "no" a lot, because that is pretty much all you hear; "no, no, no." However, eventually if you persist and do not quit and you believe in your idea, and your idea works, you can persevere.

I think we have shown perseverance through our ability to publish peer-reviewed journal articles pertaining to both our simulation and animal studies, and the fact that these positive results led to our working with the FDA to achieve Breakthrough Medical Device status. We feel that perseverance and drive will carry the day when we go to seek Emergency Use Authorization from the FDA. Therefore, if you have a great idea that is going to really make a positive impact on people's lives, you just have to stick with it. You owe it to society to not quit.

CEOCFO: *Have similar ideas in this arena been tried before?*

Dr. DeJournett: People have used different control methods, so yes. People, just a couple of times, have used a control method called model predictive control. They use a mathematical model of the ICU patient's glucose-insulin system, and then adjust the model on a real time basis to

try to achieve safe and effective glucose control. While there has been some limited success with this method, we feel it will not hold up well during the extreme edge cases often seen in the ICU setting (e.g., wildly fluctuating insulin sensitivity levels).

Our system is basically an exact mimicker of the native system and we feel that our ability to rapidly adjust our infusion rates of insulin and glucose will allow us to keep up with any scenario. For instance, if you have a patient in the ICU and they have a high dextrose parenteral nutrition bag infusing, if that bag runs out because the nurse is busy with another critically ill patient, what will happen is the patient will experience a sudden fall in their glucose level because they will no longer be getting a continuous infusion of glucose. Our system will recognize the rapid fall in the glucose level and will automatically increase our systems rate of glucose infusion to counteract this scenario. Therefore, we feel that our system can basically handle any scenario in a much better fashion than the other glucose control systems under development. By the way, there are currently no approved glucose control systems available for use in the hospital setting in either the U.S. or EU.

CEOCFO: Why should both the healthcare community and investors look at Ideal Medical Technologies right now?

Dr. DeJournett: We are trying to impact a large percent of hospitalized patients. In the U.S. alone, we spend \$1.3 trillion on healthcare for hospitalized patients annually. Approximately forty percent of that amount is on the combination of ICU patients and diabetics in a non-ICU setting. The United States spends \$500 billion a year in caring for patients who will be positively impacted by an artificial pancreas system. We feel we can decrease the cost of care for these patients by up to five percent, which would equate to a \$25 billion saving for the U.S. healthcare system. That is in addition to lowering mortality rates, complication rates, shortening the overall length of stay, and improving nursing efficiency and patient throughput.

We feel that this is really a good, disruptive system that will dramatically improve patient outcomes, not just ICU patients, but also diabetics admitted to the hospital in a non-ICU setting. It will also increase bed capacity because of the shorter length of stay. This means hospitals may not have to spend as much money on building out new facilities. The other thing we know is that, with our demographics, we are going to have a surge of ICU patients, because most of the patients in the adult ICU settings are greater than sixty-five years of age. The United States is an aging country. The proportion of our population that is age greater than sixty-five is going to expand in the decades ahead. In addition, Type 2 diabetes is a huge problem and that population is also going to dramatically expand in this country in the coming decades. Therefore, there is going to be a need for increased bed capacity to handle the surge of both ICU and diabetic patients in the next 20 years. Our FUSION system can help with that, because it will shorten the hospital length of stay of these patients and decrease the need for the expansion of beds. This means we will have a dramatic impact across the hospital setting.