

DEVICE OFFERS SHAREABLE DATA

Cellnovo files 510(k) for new wearable diabetes management system

By Melody Watson, Contributing Writer

Throw away your diabetes journal! No more having to tediously record data about what you're eating and your physical activity level is, let alone work out how much insulin you need to administer. A new wearable diabetes management system has just made it easier for patients to record lifestyle data, monitor their glucose levels and administer the optimal amount of insulin needed.

Recently, Cellnovo CLNV, based in Paris, and Bridgend, U.K., filed for 510(k) approval with the U.S. FDA for marketing clearance of their diabetes management system, with the process being expected to last for several months. In the meantime, Cellnovo will continue to prepare for launch of the system in the U.S. The device has already been awarded the CE mark and is being marketed in France and the U.K.

Cellnovo claims its diabetes management system is the first mobile, connected, all-in-one system, letting patients enjoy extensive freedom of movement while providing optimal management of insulin injections. The compact tubeless system consists of an intuitive touchscreen controller with an integrated blood-glucose meter. Data is automatically transmitted, enabling the patient's diabetes to be monitored in real time by family members and health care professionals. This is particularly important in a health care setting as this data can help with diabetes management decisions for the patient.

A key feature of the Cellnovo diabetes management system is its ability to share a patient's data, not only enabling doctors to understand their patients daily lives but also letting caregivers or the patients see how the "big three" (exercise, insulin and blood sugar) affect their diabetes management. Data is transmitted to a centralized server via the mobile handset, which monitors blood glucose levels, controls the insulin pump, including calculating boluses with the on board food application, and logs important data. The centralized server then sends the data to a web-based platform or transmits it as a text message to a mobile phone.

Another one of the interesting features of the Cellnovo is its pump. Unlike traditional insulin pumps which use a motor to push insulin out of an enormous barrel (ranging from 180 to 300 units), Cellnovo's pump uses something called a wax actuator

which moves insulin from a larger reservoir into a smaller chamber which is then sealed and the insulin delivered. This system enables the pump to administer the insulin with a much higher accuracy than more traditional systems. Most wearable insulin pump systems deliver insulin with a ± 20 percent accuracy rate (so the dose administered could be 20 percent higher or lower than the target dose) whereas the Cellnovo pump drops the error margin down to about 1-2 percent.

In terms of logging physical activity, the Cellnovo pump has a tiny sensor which can track and record movement. It then sends the data wirelessly to the remote handset.

SUPERIOR DELIVERY OF INSULIN DEMONSTRATED

In a recent peer-reviewed study published in the journal European Endocrinology, pulse accuracy of the Cellnovo management system was compared with the Escrik, U.K.-based Ypsomed Ltd.'s Omnipod diabetes management system. The proportion of single pulses outside the accuracy level of ± 5 percent, ± 10 percent, ± 15 percent, ± 20 percent, ± 25 percent, and ± 30 percent were as follows: 79.6 percent, 55.6 percent, 35.0 percent, 19.9 percent, 9.7 percent and 4.3 percent, respectively. For the Omnipod system, the respective values were 86.2 percent, 71.6 percent, 57.4 percent, 45.5 percent, 35.2 percent and 25.4 percent. Cellnovo's system showed greater accuracy across the board.

DIABETES DEVICE MARKET FORECAST

Currently the diabetes market is booming and is expected to reach \$35.5 billion by 2024, according to a new report by Grand View Research Inc. The main drivers of this increase include the growing number of new type II diabetes diagnoses due to sedentary lifestyles and unhealthy diets, as well as government initiatives to support better diabetes management and growing awareness of diabetes devices in the diabetic population. Propelling the market growth of products is the demand for affordable monitoring devices, both in developed and developing countries. In particular, the increasing popularity of compact easy-to-wear monitoring devices, such as Cellnovo's management system, is expected to drive the market growth at

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a highly profitable rate. Additionally, most of the major markets, such as the U.S. and Europe, generally have smooth product approval procedures that are also expected to boost growth. The main challenge for the overall growth of this market is the disparity in reimbursement policies across these countries.

KEY MARKETS AND PLAYERS

In 2015, North America captured the largest market share, at a whopping 32 percent, and is expected to continue to dominate the market with a compound annual growth rate of 5.9 percent, according to the Grand View Research report. The Asia Pacific region is currently the fastest growing market segment, with countries such as India and China predicted to experience swift growth due to the increasing prevalence of diabetes, the growing disposable income in these countries, and the growing awareness of devices on the market. Major players

in the diabetes devices market include Bayer Healthcare AG, Abbott Laboratories Inc., F.Hoffman La-Roche Ltd., Medtronic Inc., Sanofi, Novo Nordisk A/S and Becton Dickinson.

Cellnovo CEO Sophie Barratte told *Medical Device Daily* that "The U.S. market values innovation and patients have already shown their attraction towards a wearable patch pump for insulin delivery. Our system will position itself nicely in this space, with key additional features, such as its unique safety features, its best in class accuracy of delivery and its ability to send data to an online platform in real time." She added, "The Cellnovo system' characteristics will provide unique benefits to future U.S. users, adding peace of mind and comfort of use to the freedom of movement, and discreetness. Parents, in particular, will be delighted to use our e-health feature to control the insulin delivered to their child in real time, without intruding in the child's life." //