# BioWorld MedTech

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MDMA Annual Meeting

## Device makers still using Windows XP despite massive vulnerabilities

*By Mark McCarty, Regulatory Editor*

WASHINGTON – With legislation and an executive order regarding federal cybersecurity either in the works or now in force, the Medical Device Manufacturers Association held a cybersecurity discussion on the second day of its annual meeting. While much of the emphasis of the conversation revolved around cooperative cybersecurity efforts, one of the speakers said some device makers are still using the legacy

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## Inside



FDA/Xavier MedCon 2019

## Experts explain how to prepare for the unknowns of medical device regulations

*By Liz Hollis, Staff Writer*

CINCINNATI – There has been a lot of confusion associated with Unique Device Identifier (UDI) requirements that are part of the medical device regulations (MDR). Three experts at the FDA/Xavier MedCon conference last week aimed to provide some clarifications.

"I think of UDI as a tool that we in industry, and

See UDIs, page 6

## Medtronic wired for action as FDA Attains approval for its left ventricle implant lead

*By David Godkin, Staff Writer*

Medtronic plc won FDA approval for its Attain Stability quad MRI Surescan left heart lead, and the Dublin-based firm described the Attain as "the only active-fixation lead for the left heart" precisely placed during implantation of defibrillators and pacemakers in cardiac resynchronization therapy (CRT) for heart disease. This follows evidence from a recently completed

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## Bioperfectus to list on Shanghai Stock Exchange

*By Elise Mak, Staff Writer*

HONG KONG – Chinese molecular diagnostics firm Jiangsu Bioperfectus Technologies Co. Ltd. has applied this month for listing on the Shanghai Stock Exchange's new Science and Technology Innovation board.

Bioperfectus plans to raise ¥406 million (US$60.3 million) by issuing not more than 14.6 million new shares. The IPO is backed by China Merchants Securities.

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## Axilum now commercializing new transcranial magnetic stimulation robot

*By Bernard Banga, Staff Writer*

PARIS – One month after obtaining CE marking approval for the EU market, and FDA 510(k) clearance for the U.S. market, Axilum Robotics SAS, from Shiltigheim, France, is beginning distribution of its second robotic platform, TMS-Cobot, used for transcranial magnetic stimulation (TMS).

"Our collaborative robot technology improves

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**Patent Highlights**

*BioWorld MedTech* presents Patent Highlights, an excerpt of the most important med-tech patents from this week's Cortellis Patents Gazette. See the attachment at the end of this edition.

**BioWorld MedTech's Neuruology Extra**

Production Editor Andrea Applegate and Senior Science Editor Anette Breindl on one of med-tech's key sectors

Read this week's edition

# Axilum

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accuracy of the procedure whilst sparing the operator a painstaking and time-consuming task, and also reducing pressures on the patient," Michel Berg, CEO of Axilum Robotics, told *BioWorld MedTech*.

## Compensating for patient head movement

TMS is a recent and rapidly growing noninvasive neurostimulation technique used for treating serious depression or chronic drug-resistant neuropathic pain. TMS is often performed by hand or using a fixed arm that holds a coil in place on the patient's scalp. This is connected to a stimulator generating electric pulses, which induce a magnetic field to cause an inverted electric charge within the brain cortex itself.

"However, this procedure does not allow the head position to be tracked in real time and so to compensate for any movement," said Berg. Researchers saw a drop of up to 30% in the magnetic field set initially. A third of the 3,000 centers worldwide providing TMS sessions are equipped with a neuronavigation system to counteract this limitation.

"Robotization is the next step in improving accuracy and repeatability," said Berg.

## A new generation of collaborative robots

Axilum Robotics is a spinoff from the Icube medical robotics team, a laboratory for engineering, computer science and imaging at the Université de Strasbourg. This company was formed in 2011 by three medical robotics research professors, Michel de Mathelin, Bernard Bayle and Pierre Renaud, along with two engineers with doctorates in robotics, Benjamin Maurin and Romuald Ginhoux, and finally Michel Berg, a physician with a degree from the HEC Paris business school. The company has already developed and commercialized a first generation of robots used in transcranial stimulation. The TMS-Robot obtained CE marking approval in 2013. A total of 23 of these first-generation robots have been sold in France, Spain, Denmark, Brazil, Indonesia and China.

The Axilum Robotics engineers specializing in robotics and computer science have been working for three years to develop a second robotic platform based on collaborative technology. This second generation of TMS robot is protected by a patent family covering pressure sensors fixed to the stimulator coil. These allow a constant pressure of up to 200 g per square centimeter to be maintained between the electromagnetic induction coil and the patient's head.

TMS-Cobot, a robotic platform for transcranial magnetic stimulation; Axilum Robotics SAS

## A market worth $500M

Axilum faces international competition in the TMS sector from Neuronetics Inc., The Magstim Company Ltd., Magventure Inc., Neurosoft LLC, and MAG & More GmbH. Axilum said it is the only one using robotic technology for human interaction. In other words, a Cobot. It is targeting the global TMS market for major drug-resistant depression, chronic pain and neuroscience research, worth $500 million and estimated to be growing at 10% a year. The company, which is selling its equipment at $112,000 per unit, or half the price of its first-generation robot, is planning in time to convert 10% of the 300 TMS centers worldwide.

"The U.S. represents 90% of our commercial potential, with medical cover increasing since 2012," said Berg, who has entrusted distribution of his TMS-Cobot to Magventure. "Since 2011, we have been building a partnership with Magventure, who has invested in developing the special coils for our robots," said Berg. Magventure is already distributing a device compatible with the robot from France: its Magventure TMS Therapy. This obtained FDA 510(k) clearance in 2015 and is indicated in the treatment of major drug-resistant depression. The first robot sold by Axilum Robotics in the U.S. was installed at the National Institute of Health in Bethesda at the end of April.

The company has been firmly rooted in the Alsace Biovalley cluster in France since its formation. It has raised $2.8 million from Inserm Transfert Initiative, investment group Sodiv, from the Grand Est region in France, and industrial group LOHR from Alsace. Axilum Robotics, which just about reached break-even at the end of last year, is forecasting EBITDA (earnings before interest, taxes, depreciation and amortization) of several hundred thousand euros this year. "We are getting ready for a funding round of several million dollars in order to boost commercial launch in the U.S. and Europe," said Berg. ♦

> *"Our collaborative robot technology improves accuracy of the procedure whilst sparing the operator a painstaking and time-consuming task, and also reducing pressures on the patient.*
>
> Michel Berg
> CEO, Axilum Robotics SAS