

GE-Philips Health Equipment Market Opens as Smartphones Win FDA Nod: Tech

By Olga Kharif - Sep 29, 2011

When Brian Froelke joined emergency responders in tornado-ravaged Joplin, <u>Missouri</u>, in May, the physician brought along a <u>Toshiba Corp.</u> (6502) smartphone with a hairbrush-size gadget attached.

The device, made by Redmond, Washington-based startup Mobisante Inc., converts a phone into a pocket ultrasound machine. Froelke used it to examine a pregnant woman who came to a temporary hospital complaining of stomach pain.

"It was helpful to reassure the mom that the baby didn't have any obvious problems," Froelke says.

Mobisante's device, which goes on sale in October, is part of a wave of new smartphone applications and attachments in the nascent mobile health market, Bloomberg Businessweek reports in its Oct. 3 issue. In the past eight months, products that turn a phone into a blood-pressure monitoring cuff, a CT-scan viewer and other health-care gadgets have received U.S. Food and Drug Administration clearance.

The market is predicted to grow: By 2015, 30 percent of the world's smartphone users will be using mobile health products, up from 5 percent now, estimates Research2guidance, a mobile- market consulting firm in Berlin.

"Health care will be fundamentally different than it used to be," says Bakul Patel, a policy adviser at the FDA.

And potentially less expensive. One of the promises of mobile health products is that, by building on existing products such as <u>Apple Inc. (AAPL)</u>'s iPhone, they can perform the same function as high-end hospital gear for a fraction of the price.

'Bang for Buck'

Mobisante's ultrasound attachment, for example, costs \$7,495. Though the images aren't the highest quality available, a top-of-the-line ultrasound machine costs as much as \$100,000, and Mobisante's device is "easily the best bang for your buck," says Jason C. Wagner, an emergency department doctor in St. Louis, who reviewed it for Emergency Physicians Monthly.

By reducing costs for insurers and medical providers, mobile health-focused startups hope to snag a slice of the \$273 billion medical equipment and supplies market, currently dominated by large companies such as General Electric Co. (GE) and Royal Philips Electronics NV.

"Big companies of tomorrow are the small companies of today," says Cedric Hutchings, chief executive officer of Withings, a company in the Paris suburb of Issy-les-Moulineaux that makes a \$129 blood-pressure monitoring cuff that attaches to iPhones.

Although smartphones have been on the market for years, the long process for obtaining FDA clearance means health-related apps and attachments are only now starting to appear in significant numbers.

'New for Them'

MIM Software Inc. sells an iPhone and iPad app for physicians to view CT, MRI and PET images on their mobile devices. Mark Cain, the Cleveland-based company's chief technology officer, says MIM built a prototype of the app in a week, then spent 2 1/2 years and more than \$150,000 getting FDA clearance, which came through in February.

"It was new for them, it was new for us," Cain says.

The cost and approval time may shrink in 2012, when the FDA is expected to issue <u>detailed guidelines</u> about which mobile health devices and apps fall under its jurisdiction, and how it will regulate them. That will help potential customers like hospitals and medical practices decide which devices to buy and "will probably help accelerate this area," says the FDA's Patel.

The pioneers have already done some of the legwork: Mobisante, for instance, had to prove to the FDA that smartphones' digital screens were comparable to the screens on existing ultrasound machines, work that future applicants may not have to replicate.

Retail Opportunity

Mobile health products could get another boost next year, when AT&T Inc. plans to start carrying some in their retail stores, according to Glenn Lurie, president of emerging devices at the company.

Mobisante says it's in talks with several potential big purchasers, including the U.S. Army, which is interested in using the portable ultrasound device to diagnose wounded soldiers in the field. In June, Health Care Service Corp., a Chicago-based insurer with 13 million customers, began testing a wireless service from Baltimore-based startup WellDoc Inc. that helps Type 2 diabetics manage their disease.

Investors and potential acquirers already are eyeing the market. In September, Sandy Spring, Maryland-based venture capital firm Hickory Ridge Group started a \$50 million fund focused on new health technologies, including mobile products.

"We are looking very closely at some of these startups," says Paul Coss, a director for wireless technologies at Philips Healthcare. "There's some clever innovation happening there."