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BUSINESS NEWS FOR MEDICAL IMAGING
"THE STORY BEHIND THE ANNOUNCEMENT"

BUSINESS BRIEFS WEEK IN REVIEW

Growth of MR procedures slows as cost containment and market maturation dampen product sales.

- Fujifilm plans direct digital detector for FFDM
- GE unveils images from its new ultra-premium CT
- Visage sells direct to open door for OEM sales
- Bacteria gene shows potential as cellular tag for MR
- TeraRecon uses 'thin' technology to democratize imaging
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The use of MRI in the U.S. has slowed from an average annualized rate of greater than 15% at the beginning of the decade to about 3% from 2003 to 2007, according to market research firm IMV. The Des Plaines, IL-based firm estimates that 27.5 million MRI procedures were performed at 7195 U.S. sites last year. This represents a 14% increase from 24.2 million in 2003, or an average annualized rate of 3% per year. The number of MRI procedures was growing at more than five times that rate between 1999 and 2003, according to the IMV census.

The slowdown may be due to several factors, including the Deficit Reduction Act of 2005, precertification requirements from health insurers, and the relative maturity of the MRI market, according to IMV. This is translating into fewer MR sales. The research firm noted that virtually all of the hospitals with more than 200 beds in the census now have at least one MR device, which cuts into the expansion of MR sites. Also, the replacement cycle for the devices is getting longer.

Fujifilm Europe has a new answer to an old problem—a CD viewer for providers who do not have PACS. AXON Omnivor, a

Fujifilm plans direct digital detector for FFDM

Amorphous selenium detector would complement phosphor-based CR

Fujifilm of Tokyo will break from its dependence on computed radiography plates, if efforts to develop a direct-capture detector for mammography pan out.

The company has begun work on an amorphous selenium detector composed of two selenium substrate layers. The first will convert x-rays into electrical signals, which will be read in the second layer through the use of an optical switch.

Last year, the company earned FDA approval to sell a CR-based mammography system in the U.S., after offering the system worldwide for several years. This is the first indication that the Japanese company plans to offer a mammography system that is not based on CR.

"We believe that, when the [direct digital] detector is available, we will be the first vendor to be able to offer CR and DR for mammography," said Robert E. Cooke, vice president of network business management for Fujifilm Medical Systems.

The two technologies are complementary, Cooke said, and the company will pursue a strategy that uses each to address different segments of the market.

"Both of these products can work together because our customers have diverse needs," he said. "Given the global audience for this technology, we will find a mix of customers who want to remain with existing gantries as well as those who require new systems and flexibly meet their needs."

Implementing this strategy may be a while off, however. The company currently has no plans to commercialize a full-field digital mammography system based on the direct digital detector, Cooke said.

Any plans that develop could be helped by a regulatory change now being considered by the FDA. Earlier this month, regulators announced their intention to move FFDM systems from class 3 to class 2. This would make it easier for vendors to navigate the regulatory process needed to sell these products in the U.S.

"Our estimate is that the final guidance will be issued in mid-2009," Cooke said.

Just as the change in policy would help Fujifilm enter the marketplace with another FFDM, it would also help its competitors. Cooke put

GE unveils images from its new ultra-premium CT

Clinical images began flowing at the end of May from GE Healthcare's first installed LightSpeed CT750 HD, located at Froedtert Hospital in Milwaukee. This volume-rendered image of an abdominal aortic aneurysm shows stents and spinal hardware, as well as nearby vasculature. With FDA clearance obtained earlier in the month, GE began marketing the ultra-premium CT scanner, highlighting claims of markedly improved resolution and reduced x-ray dose to the patient. See the *DI SCAN* exclusive story on the launch of the CT scanner in our May 13 issue.

(Provided by GE Healthcare)

multifunctional DICOM image viewer whose software runs on an Apple iMac, can handle a wide variety of CD formats, according to the company. The basic software package can manage, for example, multiplanar reconstruction of CT and MR data, as well as the real-time representation of cardio sequences with simultaneous ECG display. The software module for 3D imaging, however, is offered separately. A variation of this product, FCR AXON, is available in the U.S. for nonhospital use.

StructuRad has paid Amirsys an undisclosed amount of cash to settle a copyright infringement lawsuit. In addition to the payment, on June 2, U.S. District Judge Dee Benson entered a permanent injunction against StructuRad and Drs. Richard Gray and Gerald Berman, holding Amirsys' copyrights valid and enforceable. The court order prohibits the defendants from infringing works copyrighted by Amirsys, according to the provider of imaging informatics.

A compact proton linear accelerator is slated to begin producing PET radioisotopes in the coming weeks. The facility, located in Kennewick, WA, and operated by Advanced Medical Isotope, received May 14 its radioactive materials license, awarded by the State of Washington. It has already produced fluorine-18, the first in a series of isotopes that Advanced Medical plans to manufacture.

Philips Healthcare and Skytron are partnering to deliver hybrid operating rooms for minimally invasive cardiovascular surgical procedures. Under the alliance, the two companies will combine Philips' cardiovascular x-ray systems with Skytron's advanced operating room communications control, surgical lighting, and boom technologies.

QUICK HITS

Merge Healthcare is changing its name and its leadership, amid plans to cut about 20% of its global workforce. Under the reorganization, Merge Healthcare North America becomes Merge Fusion and its Canadian

a positive spin on both possibilities.

"Having more access to more FFDM technologies will only enhance the quality of the experience for patients," he said. "And we are certainly up to the competition."

Fujifilm will produce the new selenium-based detectors in its own manufacturing plants. A novel procedure for selenium vacuum storage, developed in-house, generates extremely pure selenium layers with an even and consistent thickness across each layer, according to the company.

Preliminary experience indicates that the detector may be able to produce a spatial resolution of 50 microns and improved signal-to-noise ratio over current detectors, Cooke said.

Using the new detector for digital mammography may enable the operator to lower patient radiation dose while improving diagnostic confidence and efficiency of the examination, according to the company. The detector will be built into systems for mammography applications in both screening and diagnosis.

Fujifilm is already a major player in the digital mammography marketplace with thousands of FFDM systems in use outside the U.S. About 500 are operating at U.S. installations. All are built around the company's CR, the underlying technology of which was introduced 25 years ago. Fujifilm's development of a direct digital detector signals a major change in direction for the company in terms of technology, but not philosophy, Cooke said.

"Our goal is to use technologies to enhance patient quality of life, to make digital mammography more accessible to a wide range of populations over many geographies," he said. "Development of a direct digital detector is consistent with that."

Visage sells direct to open door for OEM sales

Thin-client visualization boosts existing PACS, say execs

Visage Imaging wants to "turbo-charge" PACS through the addition of advanced visualization tools. But rather than selling only to OEMs, the company is also selling directly to end users. The reason for the direct sales, however, is to simply catch the attention of PACS companies.

"We want to prove to them that we can integrate with their products and that we have something that the market needs," said Colin T. Murphy, vice president of sales and marketing at Visage. "It opens up some broader opportunities."

Visage is a subsidiary of Mercury Computer Systems, a long-time supplier to imaging OEMs of computing accelerators and other electronic components built into CT and MR scanners. Although substantial, Mercury revenues gained from medical imaging sales historically have been dwarfed by those from defense electronics.

About four years ago, the company began looking for ways to expand its reach in the medical imaging industry, choosing PACS and IT as the means to gain ground. Three years ago, Mercury purchased a German software development firm Sohard, which supplies PACS through OEMs, as well as through distributors and dealers.

Mercury soon began providing both software only and software-hardware combinations designed to perform critical functions in diagnostic and interventional products, as well as PACS. Company strategists added pieces to the corporate puzzle to acquire various technological and engineering capabilities. One example was Echotek, in 2005, for board-level electronics. They also expanded the company's market reach through partnerships, often with small PACS companies such as Brit Systems.

Last year, the transformation became complete with the creation of Visage. The company is positioning its advanced visualization tools as the means for making expensive CTs and MRs cost effective. They do so, according to Murphy, by getting rid of the data bottlenecks and improving access as an adjunct to existing PACS. The thin-client Visage CS makes quick work of volumetric data sets, just as it allows access to the images across the enterprise and beyond.

"Building it as a thin client gives us the infrastructure to add more and more functionality and to make it completely transparent to the user," Murphy said.

This functionality is not limited by the location of the user, according to Murphy, who said the system can support a wide area network with remote access using a 2-megabit bandwidth.

"This is enough to take a 3D, 4000-slice data set remotely to a radiologist's home to do a full diagnostic read," he said.

Visage CS integrates tightly with Visage PACS as well as PACS sold by other ven-

dors. This integration is the key to the company's marketing approach. It can and does provide turnkey solutions for end users by offering a complete package of advanced visualization and PACS—but it would rather focus on the postprocessing side, which is its strength.

"We don't want to be a PACS company," said Visage president Marcelo Lima. "We want to help users boost their PACS."

The company is framing its advanced visualization tools—its Visage CS—as an appliance akin to a PACS archive or display. The thin-client server can be purchased separately to extend the ability of the core PACS, which remains otherwise unchanged.

Ideally, the company would like to sell Visage CS through OEMs. The investment needed to become a full-blown PACS company is too much. Its direct sales are really just to prove a point, Murphy said.

"In selling to hospitals, we demonstrate that this is something that is needed, and that we can integrate with them," he said.

Bacteria gene shows potential as cellular tag for MR

Iron oxide outlines cells after insertion of single gene

Mammalian cells produce nanometer-sized magnetic clumps of iron oxide after the addition of a single bacteria gene, scientists have found. Now researchers at Emory University and Georgia Institute of Technology are exploring whether this gene, MagA, could be used to track cell movement in the body using MR.

"We have found a very simple way to make mammalian cells have a magnetic signature," said Xiaoping Hu, Ph.D., director of Emory's Biomedical Imaging Technology Center and a Georgia Research Alliance Eminent Scholar.

Results from preliminary studies of this potential appeared in the June issue of *Magnetic Resonance in Medicine*.

MagA allows magnetotactic bacteria to "sense" the Earth's magnetic field by encoding the production of a protein that transports dissolved iron across cell membranes. When inserted into animal cells, MagA triggers the accumulation of clumps of magnetite, also called iron oxide. Only a few nanometers wide, this magnetite makes the cells visible under MRI.

The MagA technique appears to be nontoxic, according to Hu, but early applications will likely be limited to preclinical studies. Although Hu's team tested MagA's effects in human kidney cells, he says the technique will probably be most useful in transgenic animals.

"MagA can be thought of as the equivalent of green fluorescent protein, but for magnetic resonance imaging," he said.

Scientists currently use green fluorescent protein, found in jellyfish, to map the connections of the nervous system or follow the migration of stem cells through the body. This process requires illumination of the protein by light, typically from a laser or an LED.

MagA has the potential to serve the same applications as fluorescent protein in a way that is easier to track.

TeraRecon uses 'thin' technology to democratize imaging

Advanced visualization tools work within tight bandwidth

TeraRecon wants to spread advanced visualization beyond the traditional bounds of healthcare practices—to referring physicians and the homes of radiologists—where access is constrained by bandwidth. At the Society for Imaging Informatics in Medicine meeting, the company framed its Aquarius-WEB viewer as the solution. The browser-based viewer uses JavaScript to deliver images through a URL. Images can be viewed on desktops, laptops, or even PDAs.

"You can click on a link and have access to the 3D image," said Robert Taylor, Ph.D., TeraRecon president and COO. "There is no installation and you don't have to call an IT guy. It's so obvious, anyone can use it."

The thinner the technology the better, according to Taylor. TeraRecon's pursuit of this axiom has progressed over the last decade from a workstation for limited numbers of physicians to handle multislice CT to its current campaign to democratize today's most sophisticated postprocessing tools.

"These days, advanced visualization is becoming a standard of care," he said. "It's needed by referring physicians and by the surgeon in the OR who is dealing with a ruptured aortic aneurysm."

Whatever these physicians use to access these capabilities has to be small and enter-

operating division Cedara turns into Merge OEM. The top leadership of the company is out (see People) along with 60 other employees, reducing worldwide headcount to 300.

Hitachi Medical Systems America has upgraded its installed base of Echelon 1.5T users with a noncontrast MR angiography sequence and a new fast spin-echo capability as part of an overall software update. The MRA sequence, VASC, provides an alternative to MRA that uses bolus infusions of gadolinium-based contrast. The prime FSE feature enables high-quality imaging in patients with prostheses or implants.

Software developer **Acuo Technologies** has integrated its data management middleware into IBM's Grid Medical Archive Solution. The company also has added **IBM** to its Elite Partner Program, thereby certifying IBM to deliver Acuo Technologies' intelligent medical image management product suite.

Axsun Technologies will supply **LightLab Imaging** with advanced tunable lasers for its next generation of optical coherence tomography systems for use during minimally invasive cardiac applications. The company will provide the lasers under a multiyear exclusive agreement. The Westford, MA-based LightLab Imaging, a wholly owned subsidiary of the Japanese firm Goodman Company, has exclusive license to a broad range of OCT applications from MIT and other groups.

For the next 31 months, Philips will provide PACS discounts to members of **Premier Purchasing Partners** under a contract that went into effect April 1. Specifically covered are Philips iSite PACS for Radiology and Xcelera PACS.

Infrared Sciences, the manufacturer of the Sentinel BreastScan breast cancer detection system, is exploring strategic alternatives for its business, including possible sale of the company. Its major asset is the Sentinel BreastScan infrared breast scanner, which has been cleared by the FDA and bears a CE Mark.

Medicsight has cut a deal to work exclusively with two luminaries in CT colonography, Drs. Perry Pickhardt and David Kim, both from the University of Wisconsin Medical School. In 2004, the two physicians established a third-party reimbursed colorectal cancer screening program based on CTC.

The FDA has cleared Norway-based **NordicNeuroLab** to begin marketing its nordicAktiva. The software streamlines and simplifies functional MRI through ready-to-use clinical paradigms, and step-by-step guidance in preparation and stimulus presentation. It integrates with the company's fMRI hardware and automated data analysis.

A brachytherapy planning product developed by **Nucletron** has cleared the FDA. Oncentra Brachy, a comprehensive volume-based treatment planning solution, will be marketed as the world's first fully DICOM-compatible treatment planning system for brachytherapy.

Imaging Biometrics is FDA-cleared to begin marketing its new MR perfusion software, IB Neuro. It provides information about brain tumor biology and vasculature, using algorithms that correct for the leakage of MR contrast agents. The company claims that most of the postprocessing software tools now on the market for this purpose do not correct for leakage and, therefore, produce widely varying results.

PEOPLE

Justin C. Dearborn, most recently managing director and general counsel of Merrick Ventures, replaces **Kenneth Rardin** as chief executive officer at Merge Healthcare North America, recently renamed Merge Fusion. **Steven M. Oreskovich,** most recently Merge vice president of internal audit, steps in for **Steven Norton** as chief financial officer. **Nancy J. Koenig,** formerly CEO of Merrick Healthcare Solutions, a Merrick Ventures company, is president of Merge Fusion, replacing **Gary Bowers. Antonia Wells,** formerly Merge vice president of customer operations, is president of the Canadian division, formerly Cedara, now called Merge OEM. Wells replaces **Loris Sartor.**

prise-friendly, Taylor said. And it has to be easy to operate so that extensive training is not required.

The AquariusWEB viewer can be applied as part of the company's new IT platform, iNtuition, through which it delivers workstation-class applications to PCs. Over the past several months, TeraRecon has installed iNtuition at more than 30 sites, according to Taylor. The company's long-standing AquariusNET thin-client server provides the foundation for this platform, allowing TeraRecon's installed base of AquariusNET users to easily upgrade to iNtuition.

Some IT firms are looking into the use of asynchronous JavaScript and XML (AJAX) as the means to build image viewers that can handle large data sets while operating within web browsers.

In contrast, TeraRecon's browser-based technology uses the simplest version of JavaScript. In so doing, TeraRecon ensures that any PC will be compatible with iNtuition and its AquariusWEB viewer.

"If you want to go into the IT enterprise, you want to keep it very simple, very rudimentary," Taylor said.

The company may eventually embrace AJAX, but only if and when the technology has taken root in the PC environment. This process will take several years and will depend partly on the phasing out of technologies now in place.

"The PACS now in place will be here for the next five years or so," Taylor said. "Whatever we put in place in the meantime will have to be compatible so that everybody can use it."

COMMENTARY

PUTTING A FACE ON IMAGING

BY GREG FREIHERR

Last week federal legislators came face to face with the benefits of medical imaging. Their meeting was part of an ad campaign orchestrated by the Medical Imaging and Technology Alliance with support from a baker's dozen of patient advocacy groups.

MITA and its allies, including women's health and cancer advocacy groups, are running ads in publications that target Capitol Hill, such as *Roll Call* and the *Congressional Quarterly.* The ads are not in response to pending legislation but are meant to demonstrate the importance of imaging in an environment of cost constraint.

"We want to drive home that medical imaging is there to treat real disease states—cancer, heart disease, stroke, and osteoporosis," said MITA vice president Andrew Whitman.

The ad campaign is designed by MITA to put imaging's best foot forward on Capitol Hill. The current ad sports the tagline, "You are looking at the power of medical imaging." It features a group portrait of children and teenagers, and young, middle-aged, and elderly adults, who represent the range of patients helped daily by medical imaging.

The photo is not of actual patients. MITA is looking for real ones with real stories but finding them in this age of HIPAA and patient privacy is easier said than done. In the meantime, stock photos in this MITA ad and future ones will help humanize imaging technology to lawmakers. While it's necessary to show the clinical value of medical imaging and its cost-effectiveness, there's more to the ad than that.

Emphasized in the copy is the human value of imaging: "You can't tell who had the MRI that caught her breast cancer; the coronary angioplasty that helped treat his heart disease; the ultrasound scan that diagnosed his aortic aneurysm; the imaging agent that helped determine if she had Alzheimer's; or the PET scan that showed her leukemia in remission. But you can see the results."

Other ads will follow and will be aimed at legislators as well, at least for the time being. MITA is focusing its early efforts where they will have the greatest political impact—inside the Beltway. Whitman said MITA may expand its efforts to other audiences, however, if the need arises to help one of its partners.

Thirteen patient advocacy groups are standing shoulder-to-shoulder with MITA, including the American Brain Tumor Association, the Breast Cancer Network of Strength (formerly Y-Me), the National Ovarian Cancer Coalition, and the National Stroke Association.

This coalition has potential to develop a long-term and mutually beneficial relationship as it addresses the grassroots appeal of imaging. It is exactly what medical imaging needs if it is to meet its potential to help the American public.