Finding Value in Digital Breast Tomosynthesis

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DISCOVER YOUR DEPARTMENT’S UNTAPPED POTENTIAL.

Are you making the most of your CT and MR investments? Unless you’ve connected your Medrad® Smart injectors to a technologically advanced contrast dose management (CDM) solution, you’re probably missing out on greater efficiency and documentation accuracy.

With tools from Bayer in Radiology, you can:
• Track cumulative contrast dose
• Reduce documentation errors and information gaps
• Investigate and tie information to outcomes

NOW AVAILABLE!

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With medical imaging use on the rise, contrast media use is expected to grow as well, according to a May 2016 report from market research firm GlobalData. According to the report, the global market value for contrast injectors was $830 million in 2015, and that number is expected to reach nearly $1.8 billion by 2022 — an increase of nearly $970 million in just seven years. The growth will largely be driven by increasing use of computed tomography (CT), magnetic resonance imaging (MRI) and angiography procedures, as well as increasing disease burdens, according to GlobalData.

In the United States, healthcare reform has been another major driver of innovation. Reform efforts such as the Medicare Access and CHIP Reauthorization Act (MACRA) are poised to alter the way clinicians are reimbursed, providing incentives for them to practice more efficient, value-based care and evaluating their performance based on the quality of care delivered. In the world of contrast injectors, this is spurring increased adoption of technologies like syringeless injectors, which can improve imaging exam efficiency, and contrast dose recording systems, which can serve as a mechanism for measuring quality of care.

Syringeless Injectors
Syringeless power injectors have emerged in recent years as a solution to reduce contrast media waste. The Joint Commission does not allow the reuse of unused doses from single-use syringe injectors, so this option gives facilities the opportunity to use contrast media as efficiently as possible. Syringeless injectors have also been demonstrated to reduce exam times, leading to increased patient throughput. A study published in the Journal of the American College of Radiology in 2012 compared the efficiency of a dual-syringe injector with a syringeless injector in 275 consecutive CT exams. The syringeless injector saved over 2 minutes per exam, resulting in an increased throughput of 2.6 patients per day.

The first syringeless injector on the U.S. market, Bracco’s CT Exprès 3-D, launched at the 2016 Radiological Society of North America (RSNA) annual meeting in November. The multi-dose delivery system is designed for multi-patient use to increase the number of scans clinicians can perform in a day. The system is used in combination with the Isovue Imaging Bulk Package (IBP) and saline (0.9 percent sodium chloride injection USP). IBP was recently defined by the United States Pharmacopeia as the only contrast medium container for multi-dose, multi-patient use directly in the radiology room.

Bracco’s other newest release, launched in February, is SmartInjectCT, which packages the EmpowerCTA+ contrast injection system with the Nexo Contrast Dose monitoring solution. Empower syringeless injectors are able to use every drop of contrast loaded into the system for maximum economy. These syringeless systems use a bulk 500 mL bolus, and the injectors meter out each dose as needed. EmpowerCTA+ launched in March 2015 and is indicated for the vascular administration of contrast and flushing media in conjunction with CT scanning. It allows users to fully customize the injection experience for each patient with real-time variable flow rates, saline advance and saline jump.

Guerbet launched its syringe-free injection system, FlowSens, in March 2014. Composed of a softbag injector and associated disposables, the system uses a hydraulic, syringe-free injector to deliver contrast media. It is compatible with the company’s ScanBag solution and any type of contrast agent available on the market.

Dose Recording Systems
While medical imaging and contrast use are on the rise, several recent studies have raised concerns about potential lingering effects of contrast agents, particularly gadolinium. As a result, several vendors offer their own methods of recording contrast dose and sending the information directly to a picture archiving and communication system (PACS), electronic medical record (EMR) or other data storage system.

Bracco’s EmpowerCTA systems are supported by the Nexo Contrast Dose monitoring solution, which automatically delivers all injection information to a centralized server. This allows for enterprise-wide injector management. According to Bracco, Nexo has the ability to capture four Improvement activity measures under the Merit-based Incentives Payment System (MIPS), one of the two new alternative reimbursement tracks offered under MACRA.

Mallinckrodt launched its own contrast dose monitoring solution, the OptiSync data management system, in the fall of 2014 to complement its OptiVantage dual-head CT contrast delivery system. Operators can access all patient and pharmaceutical information with the scan of a barcode, and injection data — including the patient, drug, dose and administration — is transmitted to HL7-based healthcare systems while patient records are automatically updated. This creates a shared facility database that can help users assess areas where they can reduce errors, increase productivity or improve efficiency.

Other Recent System Releases
In February 2016, Guerbet announced U.S. Food and Drug Administration (FDA) clearance for the OptiOne single-head contrast delivery system. OptiOne is manufactured by Liebel-Flarsheim, one of the companies Guerbet acquired in November 2015 when it purchased Mallinckrodt’s Contrast Media and Delivery Systems (CMDS) business. The entry-level single-head injector is designed for injection of radiopaque CT contrast agents into the vascular system. It uses a motor-driven syringe mechanism with microprocessor control of the flow rate, volume, pressure and timing. All operations are performed on the touch-screen console, and the system has the ability to accommodate prefilled or empty syringes.

Comparison chart compiled by Imaging Technology News
Scranton Gillette Communications assumes no responsibility or liability for any errors or omissions in this chart.
## Contrast Media Injectors

<table>
<thead>
<tr>
<th>Company name</th>
<th>Bayer HealthCare</th>
<th>Bracco SpA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product</strong></td>
<td>Medrad Stellant Dual CT Injection System w/ Certegra Workstation</td>
<td>Medrad Stellant Dual CT Injection System</td>
</tr>
<tr>
<td>FDA cleared, year</td>
<td>Yes 2003 (Launched Certegra Workstation 2012)</td>
<td>Yes 2015</td>
</tr>
<tr>
<td>CE mark, year</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Type (for which imaging modality)</strong></td>
<td>CT</td>
<td>CT</td>
</tr>
<tr>
<td>For cardiac imaging</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Other types of exams</strong></td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>For use in veins or arteries</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Does system record contrast dose used</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>How does this data interface with PACS, CVIS or other reporting software</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>Other software features</strong></td>
<td>Certegra P3T 2.0 software</td>
<td>Certegra P3T 2.0 software</td>
</tr>
<tr>
<td>What differentiates your system from other vendors</td>
<td>Scalable platform that is able to be upgraded with informatics technology that can automate data capture and export to PACS, RIS, SR systems; onsite field service and remote support through VirtualCare</td>
<td>Oncite field service as well as remote support through VirtualCare</td>
</tr>
<tr>
<td>Number of syringes</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td><strong>Drive mechanism</strong></td>
<td>Electromechanical</td>
<td>Electromechanical</td>
</tr>
<tr>
<td><strong>Syringe style</strong></td>
<td>Two</td>
<td>Two</td>
</tr>
<tr>
<td><strong>Syringe capacity, mL</strong></td>
<td>200 contrast, 200 saline</td>
<td>200 contrast, 200 saline</td>
</tr>
<tr>
<td><strong>Disposable</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Prefilled</strong></td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td><strong>Reusable</strong></td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Flow range, mL/sec</td>
<td>0.1-10 mL/sec in 0.1 mL/sec increments</td>
<td>0.1-10 mL/sec in 0.1 mL/sec increments</td>
</tr>
<tr>
<td><strong>User throughput features</strong></td>
<td>Auto fill/prime</td>
<td>Auto fill/prime</td>
</tr>
<tr>
<td>Volume range, mL</td>
<td>1 - 200,1 increments</td>
<td>1 - 200,1 increments</td>
</tr>
<tr>
<td>Delivery pressure range, bar (psi)</td>
<td>50 - 325 psi max</td>
<td>50 - 325 psi max</td>
</tr>
<tr>
<td><strong>Pressure monitoring</strong></td>
<td>Pressure monitored and displayed on real-time pressure monitor graph during injection</td>
<td>Pressure monitored and displayed on real-time pressure monitor graph during injection</td>
</tr>
<tr>
<td>Selectable pressure, increments</td>
<td>50, 100, 150, 200, 250, 300, 325</td>
<td>50, 100, 150, 200, 250, 300, 325</td>
</tr>
<tr>
<td>---------</td>
<td>-----------------------------------------------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>N/S</td>
<td>N/S</td>
<td>N/S</td>
</tr>
<tr>
<td>Yes, 2005</td>
<td>Yes, 2008</td>
<td>Yes, 1998</td>
</tr>
<tr>
<td>MRI</td>
<td>CT</td>
<td>MRI</td>
</tr>
<tr>
<td>N/S</td>
<td>N/S</td>
<td>N/S</td>
</tr>
<tr>
<td>N/S</td>
<td>N/S</td>
<td>N/S</td>
</tr>
<tr>
<td>N/S</td>
<td>N/S</td>
<td>N/S</td>
</tr>
<tr>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>N/S</td>
<td>N/S</td>
<td>N/S</td>
</tr>
<tr>
<td>N/S</td>
<td>N/S</td>
<td>N/S</td>
</tr>
<tr>
<td>N/S</td>
<td>N/S</td>
<td>N/S</td>
</tr>
<tr>
<td>Prefilled contract media syringes, optional RFID and Optibolus bolus-shaping software, fully programable powerhead for scanner-side operation, Patency Check, Timing Bolus and CAN interface</td>
<td>Built-in Patency Check feature, auto home ram, Timing Bolus feature, scanner-side operation</td>
<td>Cardio, angio and CT operating modes</td>
</tr>
<tr>
<td>2 - 100 mL</td>
<td>A and B: 60</td>
<td>150, 200</td>
</tr>
<tr>
<td>N/S</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>No</td>
<td>50, 75, 100, 125; Saline: 125</td>
<td>10, 15, 20, 30; Saline: 50, 125</td>
</tr>
<tr>
<td>No</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>0.1 - 10, real time variable flow rate control increases/ decreases flow rate based on clinical need</td>
<td>0.1 to 10</td>
<td>0.1 - 6 mL/sec</td>
</tr>
<tr>
<td>1 - 100 in 1 increment</td>
<td>1 mL to volume in syringe</td>
<td>1 mL to volume in syringe</td>
</tr>
<tr>
<td>40-100</td>
<td>25 nominal – 325 peak psi</td>
<td>10, 15, 20, 30, 50, 50 mL prefilled syringes at 200 psi; 60 mL empty syringes at 150 psi; 125 mL prefilled at 100 psi</td>
</tr>
<tr>
<td>Yes, remote control</td>
<td>Yes, built in, user programmable pressure limit</td>
<td>Yes, built in, user programmable pressure limit</td>
</tr>
<tr>
<td>1 psi</td>
<td>10 psi</td>
<td>5 psi</td>
</tr>
</tbody>
</table>

**Comparison Chart Compiled by Imaging Technology News**

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**Editor’s Note:** Additional submitted information also appears on our website at www.ITNonline.com.

N/A = Not applicable    N/S = Not specified
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**OptiStar® Elite**
- MR CONTRAST DELIVERY SYSTEM

**OptiVantage®**
- DUAL-HEAD CT CONTRAST DELIVERY SYSTEM

**Workflow efficiency**
- Perform both single and dual syringe injections, and save up to 40 four-phase protocols.
- Minimize delays with console-enabled injector controls and Auto Retract.
- Color touchscreen features intuitive graphic design.
- Battery-free operation and prefilled compatible.

**Control where you need it**
- Get control where you need it with auto-fill, tilt enable, CAN class 4 and relay interface capabilities, and manual flow knobs calibrated and color-coded for easy use.
- Help safeguard patients with Patency Check® and Auto Purge features.
- Work efficiently with Timing Bolus® feature, multi-phase protocol storage and Auto Home feature.

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- Easy operation with auto-fill, Auto Purge and Auto Home features.
- Adapt to your workflow with multi-purpose functionality, multi-phase programming and multi-phase storage for up to 40 protocols.
- Created for convenience and control, with compact design, disposable or prefilled syringe compatibility and Timing Bolus® feature.

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- Gain flexibility to perform single- or multi-injection procedures, switch operating modes with a single button, and store and recall up to 45 user-defined protocols.
- Support efficiency with LED display that automatically flips as powerhead rotates, and fill control bar featuring one-finger operation.
- Console features easy tilt and rotation, and hand and foot switches for comfortable system operation.
- Optional Air Detection Aid & Warning System (ADAWS) helps reduce the chance of injecting air into patient.

Guerbet
Contrast for Life
<table>
<thead>
<tr>
<th>Company name</th>
<th>Bayer HealthCare</th>
<th>Bracco SpA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adjustable rise time</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Adjustable volume stop type</td>
<td>Electrical</td>
<td>Electrical</td>
</tr>
<tr>
<td>Increments</td>
<td>1 mL</td>
<td>1 mL</td>
</tr>
<tr>
<td>Synchronization with X-ray generator</td>
<td>Triggering interface with CT scanner</td>
<td>N/A</td>
</tr>
<tr>
<td>Console controls</td>
<td>Interactive, color touch screen</td>
<td>Interactive, color touch screen</td>
</tr>
<tr>
<td>Synchronization with ECG</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Ceiling suspension</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Suspension manufac-</td>
<td>Mavig</td>
<td>N/S</td>
</tr>
<tr>
<td>Number of injector head mounting options</td>
<td>Three - ceiling, wall, pedestal</td>
<td>Three - ceiling, wall, pedestal</td>
</tr>
<tr>
<td>Fully integrated, self-contained unit</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Saline injection capabilities</td>
<td>Yes, before and after contrast</td>
<td>Yes, before and after contrast</td>
</tr>
<tr>
<td>Air embolism detector</td>
<td>FluiDots and air expelled indicators</td>
<td>FluiDots and air expelled indicators</td>
</tr>
<tr>
<td>Extravasation detection</td>
<td>Yes, XDS extravasation detector using RF wave technology; minimizing extravasation techniques coincide with ACR guidelines including saline test injection and injection site monitoring: on-site training provided by registered radiologic technologist</td>
<td>Yes, XDS extravasation detector using RF wave technology; minimizing extravasation techniques coincide with ACR guidelines including saline test injection and injection site monitoring: on-site training provided by registered radiologic technologist</td>
</tr>
<tr>
<td>Operator alerts</td>
<td>Yes, armed indicator lights, scan delay, inject delay and injection complete tones</td>
<td>Yes, armed indicator lights, scan delay, inject delay and injection complete tones</td>
</tr>
<tr>
<td>Overpressure protection</td>
<td>Yes, pressure limit: selectable pressure limit; overpressure alert message</td>
<td>Yes, pressure limit: selectable pressure limit; overpressure alert message</td>
</tr>
<tr>
<td>Console size, H x W x D, in.</td>
<td>11.3 x 15.8 x 10.2</td>
<td>11.3 x 15.8 x 10.2</td>
</tr>
<tr>
<td>Weight, lb</td>
<td>17.6 workstation, 31.5 system</td>
<td>19.2 workstation, 100.7 system and power supply</td>
</tr>
<tr>
<td>Voltage, VAC</td>
<td>0.9 head only, 49.1 system, 100-240</td>
<td>0.9 head only, 49.1 system, 100-240</td>
</tr>
<tr>
<td>Warranty</td>
<td>1 year MFG Warranty, which includes VirtualCare connection</td>
<td>1 year MFG Warranty, which includes VirtualCare connection</td>
</tr>
<tr>
<td>Special features, options, additional product information</td>
<td>Informatics ready platform, storage/recall of up to 250 protocols, Certegra P3T 2.0 Software, VirtualCare</td>
<td>Informatics ready platform, storage/recall of up to 250 protocols, Certegra P3T 2.0 Software, VirtualCare</td>
</tr>
<tr>
<td></td>
<td>N/S</td>
<td>N/S</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Guerbet</th>
<th>Nemoto Kyorindo Co., Ltd.</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>No</td>
<td>N/A</td>
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<td>No</td>
<td>N/A</td>
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<tr>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Yes</td>
<td>N/A</td>
</tr>
<tr>
<td>N/S</td>
<td>Mavig</td>
</tr>
<tr>
<td>Floor</td>
<td>Rolling stand and ceiling</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Yes</td>
<td>N/A</td>
</tr>
<tr>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Voice prompts on remote, confirm injection status</td>
<td>Yes</td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Voice prompts on remote, confirm injection status</td>
<td>No</td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Floor</td>
<td>Rolling stand and ceiling</td>
</tr>
<tr>
<td>27.9 x 33 x 10.2 (11 x 13 x 4)</td>
<td>12.3 x 8.5 x 2.5</td>
</tr>
<tr>
<td>4.5</td>
<td>3.5 (2.6)</td>
</tr>
<tr>
<td>100-240</td>
<td>100-120 or 220-240, 50-60 Hz</td>
</tr>
<tr>
<td>1 year, optional 2, 3, and 5 years</td>
<td>1 year parts and labor, extended service plans available</td>
</tr>
</tbody>
</table>

### Additional Information:
- **Battery-free power source, Patency Check feature for extravasation prevention; status indicator line on console, dual syringe w/multiple user defined phases; color coordinated push rods and touchscreen; small footprint ISO 13485, 2003 and TUV certified; FDA cleared; CE marked; UL, cUL and CSA approved**
- **Programmable powerhead touchscreen; Patency Check feature for extravasation prevention; setup for dual-head, simultaneous or single-head protocols; interface for CE; optional optical bolus shaping software; manufacturing ISO 13485, 2003 and TUV certified; FDA cleared; CE marked; UL, cUL and CSA approved**
- **Versatile exam modes; switch between cardiac, angio and CT modes; ceiling, wall, pedestal or table mounts; accommodates Ultraject prefilled syringes; ADAWS optional; manufacturing ISO 13485, 2003 and TUV certified; FDA cleared; CE marked; UL, cUL and CSA approved; Japanese Shonin approved**
- **Capable of utilizing prefilled or empty syringes; fully programmable powerhead touchscreen for scanner side operation, optional Optibolus bolus-shaping software; FDA cleared; CE marked; UL, cUL and CSA approved**
- **Body weight protocol provided as a standard protocol; Footswitch option, table rail mounting option**
Work with quality, in any application.

Our delivery systems are designed to work the way you do.

Our wide range of contrast delivery systems is built upon the key values of quality, flexibility, efficiency and safety, ensuring that medical staff and equipment work together to provide excellent patient care in all imaging modalities.

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Guerbet contrast delivery systems are all part of our Imaging Solutions & Services platform – a family of products intelligently and purposefully designed to help streamline your workflow and optimize confidence in any imaging modality.

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Contrast for Life

Only Liebel-Flarsheim disposable syringes are authorized for use with L-F injectors. These products are medical devices intended for use by medical imaging and diagnostic health professionals. For complete information about precautions and optimal usage conditions, we recommend consulting the user’s manual.

OptiVantage, OptiStar Elite, OptiOne, Angiomat Illumina: Class IIb / Ready Box: Class IIa - CE0123 - Manufacturer: Liebel-Flarsheim Company LLC, 2111 East Galbraith Rd., Cincinnati, Ohio 45237, USA
Deep Learning in Medical Imaging

Artificial intelligence (AI), or deep learning, continues to be an ongoing topic of conversation. According to a new report by Signify Research, an independent supplier of market intelligence and consultancy to the global healthcare information technology industry, this will lead to a $300 million market by 2021.

The report stresses that in most countries there are not enough radiologists to meet the ever-increasing demand for medical imaging, and many radiologists are already working at full capacity. It’s likely the situation will worsen as imaging volumes increase faster than new radiologists can enter the field.

A new breed of image analysis software has emerged that uses deep learning to help alleviate some of the more repetitive and time-consuming tasks routinely performed by radiologists. This growing array of products automates the various stages of the imaging diagnosis workflow.

“Radiology is evolving from a largely descriptive field to a more quantitative discipline. Intelligent software tools that combine quantitative imaging and clinical workflow features will not only enhance radiologist productivity, but also improve diagnostic accuracy,” said Simon Harris, principal analyst at Signify Research and author of the report.

But it is still early in the game for deep learning in medical imaging. Few products are available, and it remains unclear how deep learning will deal with multiple variations in protocols and procedures. And, many radiologists remain skeptical.

Deep learning is a truly transformative technology and the longer-term impact on the radiology market should not be underestimated. It’s more a question of when, not if, machine learning will be routinely used in imaging diagnosis,” Harris concluded. If you want to learn more about the Signify Research study, visit http://bit.ly/2lnCEau.

ITN A Neal Awards Finalist

Also, I’m proud to announce that ITN is again a finalist in the prestigious Neal Awards editorial excellence competition in the category “Best Commentary/Blog” for Greg Freiher’s ongoing Last Read column. (You can read Greg’s latest column on page 34 of this issue.) Now in its 63rd year, the Neal Awards recognize the best in business-to-business editorial across standalone and integrated media channels. Dubbed “the Pulitzer Prize of business media,” the Neal Awards are b-to-b’s most prestigious and sought-after editorial honors.

ITN’s sister publication, Diagnostic and Interventional Cardiology (DAIC), is also a finalist in the category of “Best Use of Social Media.” Winners of all categories will be announced in early April.
Astronauts’ Brains Change Shape During Spaceflight

Magnetic resonance imaging (MRI) exams before and after space missions reveal that astronauts’ brains compress and expand during spaceflight, according to a University of Michigan study.

The findings could have applications for treating other health conditions that affect brain function, said principal investigator Rachael Seidler, U-M professor of kinesiology and psychology.

The study, believed to be the first to examine structural changes that take place in astronauts’ brains during spaceflight, found that the volume of gray matter increased or decreased, and the extent of the alteration depended on the length of time spent in space.

Seidler and colleagues examined structural MRIs in 12 astronauts who spent two weeks as shuttle crew members, and 14 who spent six months on the International Space Station. All experienced increases in gray matter volume decreases, which could be related to redistribution of cerebrospinal fluid in space,” Seidler said. “Gravity is not available to pull fluids down in the body, resulting in so-called puffy face in space. This may result in a shift of brain position or compression.”

The researchers also found increases in gray matter volume in regions that control leg movement and process sensory information from legs, which may reflect changes related to the brain learning how to move in microgravity. These changes were greater in space station astronauts because their brains were learning and adapting 24/7.

“It’s interesting because even if you love something you won’t practice more than an hour a day,” Seidler said. “But the brain changes researchers were observed to be equivalent to someone practicing a new skill round-the-clock.

“They may return to normal, but the way the brain controls the behavior may change,” she said. These results largely parallel findings from a long-term bed rest study that Seidler is leading, in which volunteers spent up to three months in a downward tilted position, and brains shifted up.

The research is supported by a grant from NASA. The study, “Brain structural plasticity with spaceflight,” appeared in the journal Nature Microgravity.
The emerging markets of Asia-Pacific and Latin America will drive the medical imaging market by more than 5 percent by 2021. Globally, medical imaging has transformed the methods of diagnostics and has made the diagnosis and treatment of several medical conditions more effective and efficient in the modern era. Growing awareness about the usage of imaging devices for treatment in the healthcare segment and advancements in technologies is driving the global market for medical imaging worldwide.

The global market for medical imaging was worth $30.05 billion in 2015 and it is expected to reach $40.56 billion in 2021, expanding at a compound annual growth rate (CAGR) of 5.1 percent between 2016 and 2021. Medical imaging equipment can be defined in many ways, but here is mainly categorized as X-ray devices, computed tomography (CT) scanners, magnetic resonance imaging (MRI) scanners, ultrasound devices and nuclear imaging scanners.

**X-ray Devices**

X-ray devices currently dominate the medical imaging market worldwide, while the nuclear imaging market is anticipated to grow at the highest CAGR by 2021. A research report published by Infinium Global Research found that X-ray devices dominated the global medical imaging market, and are expected to continue to do so with a market share of 29.36 percent by 2021. The market size of X-ray devices is projected to grow at a CAGR of 5 percent over the period of 2016 to 2021. X-ray imaging is the oldest form of medical imaging, while it has evolved multifold in order to make diagnosis and treatment more reliable. With advancements in this segment, digital X-ray and 3-D X-ray have become a trend in the recent past. Moreover, advanced X-ray systems help reduce the radiation dose.

**Nuclear Imaging**

With growing demand for radiation devices for the treatment of various types of cancers and neurological medical conditions, the market size of nuclear imaging is expected to grow at the highest CAGR over the forecast period. It is projected to grow at a CAGR of 10 percent between 2016 and 2021. Currently, with an increased number of cancer patients, the demand for nuclear imaging devices is anticipated to experience significant growth. Positron emission tomography (PET) and single-photon emission computed tomography (SPECT) are nuclear imaging instruments used in nuclear imaging. Among the two, SPECT accounted for the largest segment in 2014 and 2015.

**Ultrasound**

According to research conducted for the report, ultrasound imaging accounted for the second largest share — 21 percent — in 2015, while MRI accounted for 19 percent share in the same year. A growing geriatric population and rising number of cancer patients are likely to drive the global market of medical imaging, while high risk of radiation...
exposure is a primary restraining factor. The geriatric population is exposed to a higher threat of cancer and neurological disorders. Moreover, significant environmental changes are likely to create more health concerns for this segment of the population worldwide. Further, technological advancements in diagnostic imaging instruments are expected to escalate the growth in this market by 2021.

One of the main risks associated with medical imaging modalities is high risk of radiation exposure associated with these devices, however it is also an important factor affecting the growth in the medical imaging market over the forecast period. (See Figure 1.) Additionally, stringent regulations pertaining to use of radiation devices in developed markets such as the U.S. and U.K. are anticipated to restrain the growth in this market over the forecast period.

Asia-Pacific Market
The Asia-Pacific market is projected to grow at the highest CAGR after dominating the global market in 2015. The study estimated Asia-Pacific to be the largest market for medical imaging instruments, with the growth in this market driven by emerging markets such India and China, while Japan accounted for the largest market share in the region in 2015. (See Figure 2.) A large consumer base in this region is the primary driving factor that is expected to boost the growth over the forecast period. Emerging markets such as India and China are projected to experience significant growth over the forecast period due to rapid infrastructure development in the healthcare sector in these markets of Asia-Pacific. North America, which was the second largest market for medical imaging devices in 2015, is currently dominated by the U.S. It is the largest market for medical imaging devices among the countries in the world market. Although the U.S. market presents the most stringent laws pertaining to usage of radiation devices, it also presents the most technologically advanced medical imaging modalities in the world.

“The global market for medical imaging was worth $30.05 billion in 2015 and it is expected to reach $40.56 billion in 2021, expanding at a CAGR of 5.1 percent between 2016 and 2021.”

Infinium Global Research is a business consulting and market research firm, a group of experts who cater to fulfilling business and market research needs of leading companies in various industry verticals and business segments. The company also serves government bodies, institutes and non-profit/non-government organizations to meet their knowledge and information needs.
Musculoskeletal Ultrasound Education
Konica Minolta Healthcare Americas Inc. has partnered with 7Dimaging to strengthen its educational resources for musculoskeletal ultrasound (MSK) by offering the mskNAV Education Tool. mskNAV is a portable and user-friendly, tablet-based educational resource that assists users from beginner to advanced in enhancing their ultrasound scanning skills in MSK procedures. The partnership allows Konica Minolta to distribute 7Dimaging’s mskNAV interactive ultrasound training software with its portfolio of ultrasound products. The company will provide on-site training and education in the area of MSK ultrasound, and the tool will complement the educational continuum already offered by Konica Minolta for physicians to perform confident examinations and ultrasound-guided injections.
Konica Minolta Healthcare | www.konicaminolta.com/medicalusa

MRI-compatible IV Infusion Pump
Iradimed Corp. received U.S. Food and Drug Administration (FDA) 510(k) clearance for its MRidium 3860+ magnetic resonance imaging (MRI)-compatible IV infusion pump system, including its Dose Error Reduction System (DEIRS) software feature. The MRidium 3860+ MRI-compatible IV infusion pump system provides a seamless approach that enables accurate, safe and dependable fluid delivery before, during and after an MRI scan. This is important to critically ill patients who cannot be removed from their vital medications, and children and infants who must generally be sedated in order to remain immobile during an MRI scan. The MRidium 3860+ system has been designed with a non-magnetic motor, uniquely designed non-ferrous parts and other special features in order to safely and predictably deliver anesthesia and other IV fluids during various MRI procedures. The system can operate dependably in the presence of 0.2T to 3T magnets and is fully operational up to the 10,000 gauss-line. This means it is highly versatile and can operate virtually anywhere in the MRI scanner room, including close to the MRI scanner.
Iradimed Corp. | www.iradimed.com

App-Based, Pocket-Sized Dual-Probe Ultrasound
Vscan Extend from GE Healthcare is a new generation of pocket-sized, dual-probe ultrasound. From the hospital and ambulance to more rural environments, Vscan Extend uses high image quality and wireless connectivity to help users increase clinical confidence and improve patient care. Vscan Extend offers an intuitive touch screen and weighs just 406 grams. The system offers smooth integration with hospitals’ DICOM systems to complement existing documentation and reporting solutions along with cloud-based image storage and communication. Vscan Extend is GE Healthcare’s first ultrasound system to leverage the GE Marketplace that offers applications with a range of capabilities, such as assessing heart failure patients, measuring bladder volume and offering cloud-based image communication. The system comes with high-level data security standards, ensuring encrypted data both at rest and on the move.
GE Healthcare | www.gehealthcare.com

Medical Imaging Consolidation
Hitachi Ltd. formed a new Americas business group focused on consolidating its various medical imaging offerings while expanding its focus on healthcare innovation and informatics. The company will combine Hitachi Aloka Medical America Inc. into Hitachi Medical Systems America Inc. on April 1, 2017, which will then change its name to Hitachi Healthcare America Corp. The newly formed company will function as the regional headquarters, providing sales and maintenance services while driving an enhanced customer-focused strategy for growing the company’s current medical modality segments. The company will also drive the expansion of its healthcare innovation and strengthen its informatics-related medical businesses in the Americas. Hitachi also announced its intention to integrate its Innovation and Informatics Division, which currently belongs to Hitachi America Ltd. into the new Hitachi Healthcare America Corp. The company will focus on collaborative creation with its Americas-based key partners and customers to realize advanced medical technology and informatics solutions, such as using radiation therapy treatment data and artificial intelligence to support creating better treatment plans.
Hitachi Healthcare America Corp. | www.hitachimed.com

MRI Tools for Multiple Sclerosis
Siemens Healthineers and Biogen will jointly develop magnetic resonance imaging (MRI) applications with the intent of quantifying key markers of multiple sclerosis (MS) disease activity and progression. Biogen is a biotechnology company with a deep focus on neurological and autoimmune conditions. To execute this strategy in the field of neurology, Siemens Healthineers will cooperate with Biogen and contribute its strength in medical imaging. MRI is routinely used to support physicians in diagnosing MS, measuring disease activity and monitoring response to therapy. Clinicians qualitatively evaluate MRIs by comparing the current MRI to the previous MRI. Numerous studies have demonstrated that quantitative MRI measures may provide additional information about disease prognosis and therapeutic effect, but today quantitative measurement techniques with the precision and sensitivity required for MS are typically only available in the research setting. With the development and validation of automated MRI applications to quantify key markers of MS, including new T2 lesions and brain atrophy, patients could benefit from the availability of enhanced data at the point of care.
Siemens Healthineers | www.usa.siemens.com/healthcare
GREAT TO MOVE
COMPACT & POWERFUL

GM85
PREMIUM MOBILE DIGITAL RADIOGRAPHY

EXPERIENCE
A New Healthcare Solution
Samsungmedicalsolution.com
Focused ultrasound (FUS), also called high-intensity focused ultrasound (HIFU), has gained a lot of interest in recent years as noninvasive cancer therapy that does not require radiation, chemotherapy or surgery, resulting in less collateral damage to the patient. FUS is performed as an outpatient procedure, so it can eliminate the usual two weeks of recovery needed from most types of surgery.

In the U.S., the U.S. Food and Drug Administration (FDA) has cleared FUS to treat bone metastases, uterine fibroids, prostate cancer, benign prostatic hyperplasia and essential tremor. Only bone metastases currently has reimbursement. Outside the U.S., there are additional regulatory approvals for breast cancer, kidney cancer, liver cancer, pancreatic cancer, soft tissue tumors, Parkinson's disease, thyroid nodules, back pain, osteoid osteoma, breast fibroadenomas, uterine adenomyosis and neuropathic pain.

Currently, use of FUS is generally considered only if it will have a greater impact on the patient than surgical outcomes, said Pejman Ghanouni, M.D., Ph.D., assistant professor of radiology at the Stanford University Medical Center. He is an expert in FUS and involved in research for the use of FUS in the treatment of various conditions, including essential tremors, soft tissue tumors and localized low-intermediate risk prostate cancer. He spoke on the topic at sessions at the Radiological Society of North America (RSNA) 2016 annual meeting. As more providers begin offering FUS treatment programs, Ghanouni said it is important to have a radiologist champion the project. Patient recruitment from referrals also needs to be considered, so it is important to build relationships with referring physicians. For example, at Stanford he said they have a fibroid center, and one in 10 of the patients with uterine fibroids will qualify for FUS treatment. He said this is how his center primed the pump for initial referrals. He also now works with Stanford's prostate cancer center, radiation therapy and desmoid tumor clinic. He said one of the keys to finding patients has been defining unmet needs and defining how FUS can serve as a niche treatment option.

The Basics of High-intensity Focused Ultrasound

According to the Focused Ultrasound Foundation, the principle of FUS is analogous to using a magnifying glass to focus beams of sunlight on a single point to burn a hole in a leaf. With focused ultrasound, an acoustic lens is used to concentrate multiple intersecting beams of ultrasound on a target deep in the body with extreme precision. Depending on the design of the lens and the ultrasound parameters, the target can be as small as 1 x 1.5 mm or as large as 10 x 16 mm in diameter. Where each of the individual beams passes through the tissue, there is no effect. But, at the focal point where these multiple beams converge, the focused ultrasound energy results in tissue ablation.

FUS uses thermal ablation to denature proteins and cause cell death. The thermal dose required to produce irreversible damage and coagulative necrosis depends on the cell type, temperature...
FUS of Uterine Fibroids, Avoiding Complications

MRI anatomical assessment is used at the start of patient evaluation to determine if the target is reachable by FUS, said Young-Sun Kim, M.D., assistant professor, Department of Radiology and Center for Imaging Science, Samsung Medical Center, Seoul, South Korea. He is an expert in FUS and spoke at RSNA 2016 sessions. In the case of uterine fibroids, he showed an example where the treatment window to access the fibroid might be blocked by cysts in the path of the ultrasound beam. He said thick subcutaneous fat is another ultrasound beam attenuation factor. Edema caused by fluid back up in a fibroid may also lead to poor outcomes with FUS. He also suggests avoiding resistant fibroids.

Additionally, Kim said radiologists need to assess MR imaging along the planned trajectory of the beams to look for foreign bodies, which often present as surgical procedure leftovers like staples. He said these could superheat during the procedure and injure the patient.

MRI offers real-time thermography during the FUS treatment, to ensure healthy tissue is not damaged. Kim said complications from FUS could include skin burns, fat burns, sciatic nerve injury and bowel injury. Like radiation therapy, Kim said the focused ultrasound beams also could cause damage to critical structures, such as nerves and the spine. This is why he suggests using conscious sedation with IV fentanyl so patients can offer feedback during the procedure.

Critical structures like the bowel and spine can often be avoided by manipulating the bladder or bowel. Kim said this can be done by filling or emptying the bladder, or filling the bowel with ultrasound gel to move the bowel out of the way, or to eliminate bowel loops.

Treatment of Bone Tumors, Metastasis

As tumors grow inside bones, they slowly destroy and

“The U.S. Food and Drug Administration (FDA) has cleared FUS to treat bone metastases, uterine fibroids, prostate cancer, benign prostatic hyperplasia and essential tremor. Only bone metastases currently has reimbursement.”

FUS works in conjunction with magnetic resonance imaging (MRI), which is used to identify and target tissue to be treated, for real-time image guidance and control during treatment, and to confirm the effectiveness of the therapy. MRI is used to create a treatment plan similar to radiation therapy. A post-procedure MRI also is performed to confirm the effectiveness of the therapy. MRI is used to identify and target tissue to be treated, for real-time image guidance and control during treatment, and to confirm the effectiveness of the therapy. MRI is used to create a treatment plan similar to radiation therapy. A post-procedure MRI also is performed to confirm the effectiveness of the therapy.

Operators need to watch the real-time MR imaging for the formation of bubbles in the tissue being ablated, which can deflect the FUS beams.

of the treatment. For this reason, hospitals interested in creating FUS programs need staff that is comfortable working in the MRI suite. The close integration with MRI often has lead to the therapy being referred to as magnetic resonance-guided focused ultrasound (MRgFUS).

The treatment plan for FUS uses the anatomical MR imaging with an overlay of the zones of treatment. These are shown as strips, each representing a pass of the FUS beam. These strips are usually stacked on top of each other and the length of each varies to match the contours of the tumor target. Operators need to watch the real-time MR imaging for the formation of bubbles in the tissue being ablated, which can deflect the FUS beams.
Focused Ultrasound Therapy

with the use of microbubbles. Early studies show this breakdown of the barrier only lasts a couple hours before it disappears.

**HIFU to Treat Prostate Cancer**

Napoli said HIFU can be used as a primary treatment for prostate cancer, or as a salvage treatment when there is recurrence after surgery or radiation therapy. He said it is important to target the individual lesions, not to use FUS for whole gland treatment, which can lead to urinary incontinence and erectile dysfunction.

He said a special FUS transrectal transducer has been created so it can be placed against the rectal wall, next to the prostate. This helps focus on the prostate without worry of causing collateral damage to surrounding critical structures.

“The primary argument against targeted treatment for the prostate is that the disease is multifocal,” Napoli explained. He said this often requires the excision of the whole gland. “However, in most cases, a single index or dominant lesion drives prostate cancer risk. The optimal candidates for targeted ablation need to be clearly identified.”

Unlike surgery or brachytherapy, HIFU is significantly less invasive, which may be much more appealing to patients. “It does not require incisions or punctures, it is bloodless, can be carried out on an outpatient basis, and it is repeatable,” Napoli said.

(Editor's note: For more information, see the article “Leading HIFU Expert Begins U.S.-Based Program with Treatment of First Prostate Cancer Patients” at [http://bit.ly/2kzbyp9](http://bit.ly/2kzbyp9)).

**Future Directions for HIFU**

The use of FUS is still relatively new, and there are many preclinical and early stage pilot clinical programs investigating its expanded use for other conditions. Expansion in oncology may include several new cancers in the coming years. Pilot trials have started for pediatric neuroblastoma, melanoma, brain, head and neck, lung, ovarian and cervical cancers.

In neurology there are pilot clinical studies for brain tumors, depression and obsessive-compulsive disorder (OCD). Preclinical studies are underway for Alzheimer’s disease, epilepsy, multiple sclerosis, stroke, traumatic brain injury and trigeminal neuralgia. (Editor's note: For more information, see the article “Pre-Clinical Research Validates Potential for Focused Ultrasound in Alzheimer’s” at [http://bit.ly/2UJYXGo](http://bit.ly/2UJYXGo)).

In cardiovascular medicine, there are pilot trials testing FUS to treat hypertension. There are also numerous preclinical studies looking at the use of FUS to treat arteriovenous malformations, atherosclerosis, atrial fibrillation, deep vein thrombosis, heart block, peripheral artery disease (PAD), septal perforation and heart failure. [Itu](http://www.itononline.com/march-2017/)

References:


Tomotherapy Treatment Planning
RayStation 6, the latest release of RaySearch’s radiation therapy treatment planning system, adds significant new functionality and a wide range of general improvements. Major additions include forthcoming support for Accuray TomoTherapy systems. The new release enables planning for both conventional linacs (linear accelerators) and tomotherapy systems, giving clinics one point of control for all treatment planning needs. All contouring work can be done in one workspace. It is also possible to plan combined treatments and accurately calculate combined dose. Clinical support for tomotherapy systems is pending final validation and will be included in a service pack to be released in the near future. Other highlights include: Monte Carlo dose calculation for proton pencil-beam scanning (PBS); PBS planning with block apertures; simultaneous co-optimization of multiple beamsets; magnetic resonance (MR)-based planning, using MR-image as planning image; and auto-recovery.

RaySearch | www.raysearchlabs.com

Online Educational Resource for Healthcare Professionals
Varian Medical Systems launched a website for the exchange of clinical information, scientific research and expert opinion around the management of cancers and other conditions, with an emphasis on applications utilizing radiotherapy. The site offers video- and audio-taped symposia that Varian has supported or sponsored in the recent past, including a recent self-assessment continuing medical education (SA-CME) accredited webinar, and a selection of bibliographies organized by disease site. In the future the site will house additional resources including webinars with educational credits, information about sponsored/translational research and clinical trials, case studies and FAQs for the medical professional.

Varian Medical Systems | www.medicalaffairs.varian.com

MR-guided Focused Ultrasound
Insightec Ltd’s Exablate Prostate system received CE mark for treating locally confined prostate cancer with MR-guided focused ultrasound (MRgFUS). One in six men will be diagnosed with prostate cancer during their lifetime. Many patients are diagnosed with locally confined disease with low or intermediate risk for progression. In these cases, patients may choose active surveillance or an intervention. Currently available treatments including prostatectomy, which surgically removes the entire prostate, and radiation therapy, targeting the full prostate, demonstrate good cancer control, however there is high risk of impotency and incontinence. The Exablate Prostate system is based on Insightec’s proprietary MRgFUS. It uses focused ultrasound waves to precisely target and ablate (destroy) the targeted tissue in the prostate, while minimizing damage to adjacent structures. The treatment is done under magnetic resonance imaging (MRI) guidance for high resolution visualization of the patient’s anatomy as well as real-time temperature monitoring. The treatment does not require incisions and is performed in a single session, allowing patients to quickly return to normal activity. The Exablate Prostate system features an endorectal probe integrated into a treatment bed which is compatible with GE 1.5 and 3T MRI. Ultrasound energy is delivered by a high-frequency, 1,000-element phased array transducer which delivers focal therapy under MRI guidance and real-time thermal feedback. This enables the physician to control and personalize the therapy.

Insightec Ltd | www.insightec.com
In the days before picture archiving and communication systems (PACS), collaboration between various hospital departments was extremely difficult, as clinicians could only consult with each other in person. Today, enterprise imaging allows providers to interact from wherever they are with all of the relevant clinical data stored in one place.

ITN Contributing Editor Greg Freiherr spoke with numerous enterprise imaging vendors at the 2016 Radiological Society of North America (RSNA) annual meeting for a feature video, available on itnTV, to find out how they are working together with clinicians to enable this enhanced level of care.

Combing Technology and Clinical Experience
The goal of enterprise imaging is to ensure all members of the patient management team have the information necessary to make the best decisions about patient care. While technology is an important part of any enterprise imaging (EI) strategy, the tools are only helpful if they are wielded with the proper clinical experience.

With Conserus Imaging Fellow, its newest EI offering at RSNA 2016, McKesson looks to assist radiologists with both aspects of their enterprise imaging strategy. “You need to work with each institution to understand how are they going to differentiate on value-based medicine. What is important to them?” said Scott Galbari, McKesson vice president of marketing and portfolio, in the itnTV video.

Conserus Imaging Fellow collects all relevant patient data — including surgical history, medications, lab results and admission/discharge notes — and consolidates it into one easy-to-navigate interface. According to Galbari, the goal is to find “the needle in the haystack” — the information that is most important for the radiologist to make a decision about that patient and that particular clinical disease state.

The system offers full electronic health record (EHR) integration; a vendor neutral design and flexible configuration options allow it to be used in any hospital setting. “They don’t have to search for it, they don’t have to make phone calls to other departments. It’s all right there,” Galbari told Freiherr.

24/7 EHR Integration
The electronic health record provides another common area for all departments to contribute their expertise to patient care by creating a patient-centric view of the information. And with radiology no longer the sole executor of medical imaging, the EHR acts as an archive of its own for all image types.

Sectra believes that clinicians should have access to these repositories anywhere at any time of day or night in order to be the most efficient. “With all our customers growing and the consolidation in the market, having IT systems available 24/7, 365 days a year is of key importance,” said Mats Bjornemo, VP of product management for Sectra. “It’s both for driving efficiency — because if it’s not available, all the other tools you have won’t make a difference — and also for patient safety.” The company prides itself on maintaining high uptime percentages, showing 99-100 percent uptime at five large hospitals in five different countries over a three-year period.

Ultimately, Sectra believes that its PACS can be used to bring together a care team that has previously been fragmented into separate technological silos. “By helping each other out and by divvying up the work across the entire health system,
rather than siloing it like before, you actually get more precise diagnosis,” Anders Osterholm, Sectra VP of sales operations, told Freiherr in the video.

Bridging the Information Gaps
As the U.S. healthcare system shifts focus to patient-centered, value-based care, hospitals have had to get creative to maintain quality care while lowering costs to enhance patient satisfaction — a key metric under the Affordable Care Act and other reform efforts. Imaging can have an impact on all three areas, something radiologists must be aware of. “Radiologists really need to look holistically at the patient and the quality of care for that patient, and not just be so focused on driving transactional reading and revenue volume,” said Frank Pecaitis, senior VP of sales for Agfa Healthcare, in the itnTV video.

Pecaitis told Freiherr that organizations often purchase new technologies, such as vendor neutral archives (VNA) as short-term solutions. “We look at it more as a medical library, and those images are an organizational asset, part of an enterprise imaging platform and strategy,” Pecaitis said. With its Enterprise Imaging Platform, Agfa can help mitigate information gaps for clinicians and develop a cross-enterprise workflow. Customers can opt for a best-of-breed approach or utilize the company’s platform approach to enterprise imaging.

Streamlining Workflow
One of the biggest challenges of coordinating care across multiple departments is that each department often has its own unique workflow, so finding information can be difficult for people outside their own group. An enterprise imaging system can help solve this problem by offering one unified workflow that all-ologies can follow. “When you talk about enterprise imaging, it’s no longer radiology looking out, but rather, coming from a CIO perspective, how is this helping me? How is this integrated into my ecosystem?” Cristine Kao, global marketing and growth operations director for Carestream, told Freiherr in the itnTV video.

Carestream has made this principle the bedrock of all of its enterprise imaging/viewing technologies, powered by what it calls the Unified Core. The zero-footprint technology aims to consolidate all clinical content to a single point of access, supporting four workflow pillars:

- **Acquisition** — Images can be acquired anywhere with any device, including at the point of care with mobile devices.
- **Management** — The Unified Core allows care team members to access relevant information at the point of care or anywhere else via zero-footprint worklists.
- **Archiving** — The system creates an enterprise repository for all clinical images, whether from radiology or visible light photos at the point of care.
- **Viewing** — Zero-footprint technology also allows both providers and patients to quickly and easily access medical records. In addition to medical image viewing, however, solutions like Carestream’s Clinical Collaboration Platform allow clinicians and administrators to take a wider view of performance analytics to ensure they are delivering the highest quality of care. This includes looking at performance from both an operational (e.g., report turnaround times) and a clinical perspective (e.g., ensuring data is gathered and reported accurately).

Adaptive Intelligence in Enterprise Imaging
Artificial intelligence, also known as deep learning and machine learning, was one of the hottest topics at RSNA 2016, with multiple vendors showing off applications in radiology and enterprise imaging. Philips Healthcare has incorporated the technology into its IntelliSpace PACS via a new feature it calls Illumeo. Illumeo employs adaptive intelligence similar to a map application on a smartphone: If the user searches for a restaurant in the map app, the algorithm will
Conserus Imaging Fellow from McKesson collects all relevant patient data — including surgical history, medications, lab results and admission/discharge notes — and consolidates it into one easy-to-navigate interface.

drop a locating pin on the map, and then provide information on the hours and menu in anticipation of what the customer needs. Illumeo behaves similarly, isolating the clinical focus of an image and providing any relevant information the radiologist will need to interpret the image.

“Rather than just opening a study, scrolling through and having to figure out what the radiologist was referring to in the report, we can actually guide them to the right locations and show them what is relevant,” said Eran Rubens, chief technology officer, enterprise imaging, Philips Healthcare IT in the itnTV video.

Lifecycle Management
Philips also introduced the Universal Data Manager for its IntelliSpace PACS that allows differing lifecycle management rules for different types of images (e.g., ordered vs. non-ordered) as they are archived. This can be extremely helpful in a modern environment where newly integrated hospital systems often bring with them different, complex infrastructures and rules for image storage. For example, a hand X-ray may be archived for a year while a pediatric image might have to be held for decades. The Universal Data Manager sits on top of all existing infrastructures to create its own rulesets.

Efficient Data Exchange
As previously discussed, any enterprise imaging system must fit into the workflows of the various departments it serves to best facilitate efficient data exchange. At RSNA 2016, Mach7 Technologies showcased its best-of-breed hybrid approach that combines platform and VNA approaches.

“What is different is how we’ve simplified it, how we’ve made the data workflow behind the scenes much easier to implement and much easier to execute on those standards, and therefore consumable by IT teams and PACS administrators,” said Eric Rice, Mach7 chief technology officer. Recent updates have been driven by considerations like what steps does a wound care physician have to take to associate a picture or video captured at the point of care with an encounter or a patient in the EHR. The goal is to improve workflow so clinicians can access all of the relevant data needed for treatment.

“As much as we are a VNA company, we’re a medical imaging company that delivers a complete solution across workflow to better exchange, manage and share medical imaging data,” Rice told Freiherr.

Expanding the Enterprise Reach
Among El vendors at RSNA 2016, Lexmark is one of the newest, having entered the market less than three years ago via acquisition of VNA companies and others focused on the capture and sharing of photos and videos. Most recently, Lexmark purchased Clarion Technology, adding the NilRead viewer to its product portfolio. Since then, Lexmark has expanded the viewer’s capabilities, enabling it to perform both image-enabled EHR functionality and a fully diagnostic workflow — a rarity, according to Lexmark Chief Technology Officer Claudio Gatti, who told Freiherr that most zero-footprint solutions are only capable of basic viewing functionality.

“We started with radiology, and we can now essentially perform all the functions of a traditional PACS in a zero-footprint manner. Then as a strategy we started specializing in other specialties,” Gatti said in the itnTV video.

This year, according to Gatti, NilRead’s capabilities expanded to include digital pathology and light-based specialties. The digital pathology functionality has been cleared for use in Europe, and the company hopes to have U.S. clearance within the next 12 months.

For light-based imaging, such as surgery and gastroenterology, Lexmark added video functionality, and clinicians can even select smaller portions of a larger video to be archived into the EHR.

“The goal of enterprise imaging is to ensure all members of the patient management team have all of the information necessary to make the best decisions about patient care.”

If there was a common theme among enterprise imaging vendors at RSNA 2016, it was that medical practices must break out of their individual silos to form truly collaborative patient management teams. Enterprise imaging has the potential to break these patterns, change the decision-making environment and may even change the way decisions are made. In

Medical Imaging Monitor
LG Electronics USA Business Solutions is introducing clinical and surgical monitors, marking its entry into the growing global medical imaging devices market. The LG 8 MP Clinical Review Monitor is a 27-inch IPS monitor driving 3,840 x 2,160 pixels, specifically designed to increase hospital staff efficiency by enabling streamlined workflows and multitasking. In addition to enhanced brightness levels, this monitor provides healthcare professionals with wide viewing angles, minimal color shift and accurate images. The monitor is Digital Imaging and Communications in Medicine (DICOM)-compliant, which means that grayscale tones are corrected to maintain image accuracy. Finely calibrated to ensure consistency across multiple devices, the monitor is equipped with backlight stabilization technology to guarantee stable luminance levels. Dynamic Sync Mode reduces input lag, while Flicker Safe and Reader Mode settings help reduce eye strain experienced by doctors and nurses working long shifts.
LG Electronics | www.lg.com/us

Medical Image Sharing
NexGenic LLC, the developer of the image sharing solution ImageInbox, announced that its latest release includes cloud-based features for clinical specialists and hospital customers to provide comprehensive image tele-consultation services, which can be rapidly integrated into existing clinical operations and workflows. The latest version also includes options for cloud image viewing and supports EEG and non-DICOM image formats. Developed for more than a decade in support of millions of diagnostic image transfers, ImageInbox provides a turnkey image capture and utilization platform for individual physicians, healthcare organizations, clinical trial sponsors and patients that need to send essential images securely at a moment’s notice.
NexGenic | www.nexgenic.com

4-D Advanced Vis MRI Software
Arterys received 510(k) clearance from the FDA for its Arterys Software in November, paving the way for use in clinical settings for the quantification of cardiac flow. This includes 4-D Flow and 2-D Phase Contrast workflows, and cardiac function measurements. Arterys plans on launching the product in the United States through a partnership with GE Healthcare’s ViosWorks product. Powered by the Arterys software, ViosWorks will be the first clinically available cardiovascular solution that delivers cloud-based, real-time processing of images with resolutions previously unattainable, according to the company.
Arterys | www.arterys.com

Expanded Clinical Guidelines
National Decision Support Company (NDSC) recently announced expanded CareSelect solutions that cover a wide variety of care settings and healthcare services including the ABIM Foundation’s Choosing Wisely Campaign. NDSC’s CareSelect helps to accurately render clinical guidelines for electronic medical record (EMR) delivery, leveraging existing clinical documentation and creating a seamless user experience within the EMR workflow. The expanded solution now includes clinical and business logic covering medication, lab and blood management, as well as a complete set of advisories based on the Choosing Wisely Campaign. The CareSelect platform exchanges data with the EMR in real time to perform clinical calculations against evidence-based guidelines and pathways. This enables the caregiver to choose alternate tests or clinical pathways based on the guideline. This advanced functionality can be coupled with the CareSelect benchmarking and reporting tools to ensure success.
National Decision Support Company | www.nationaldecisionsupport.com

Enterprise Viewing Platform
Calgary Scientific Inc. announced version 6.0 of its enterprise image-viewing platform, ResolutionMD. The platform continues to expand interoperability capability across the healthcare enterprise, offering institutions a better way to connect clinicians and patients to each other and their data. ResolutionMD provides a scalable pathway and seamless integration between picture archiving and communication systems (PACS), vendor neutral archives (VNAs), cloud archives, electronic medical records (EMRs), patient portals and hospital-developed apps. The new version includes multi-monitor support, expanded DICOM modalities in departments outside radiology, extended image sharing with third-party providers, FHIR data integration, expanded HTML5 capabilities and mobile measurements. Scalability improvements include both virtualized and physical server deployments with CPU or GPU options.
Calgary Scientific | www.calgaryscientific.com
While patient welfare has always been the guiding principle of the healthcare system, patient satisfaction has only become a priority recently. Reform efforts of the last several years have focused on fixing aspects of the system that have been headaches for patients — namely high costs and care process inefficiencies. As the healthcare system continues to change, the importance of patient satisfaction will continue being a guiding metric for progress — a reality that could have a major impact on healthcare providers.

Those at the leading edge of change have stressed the importance of practicing patient-centered care. What this means and how it is done are driving discussions, including during the 2016 annual meeting of the Radiological Society of North America (RSNA) last November in Chicago. Several presenters there addressed why patient satisfaction is important, how the system is changing to accommodate it and what it means for the future of radiology.

Why Patient Satisfaction is Important

At first thought, one might believe patient satisfaction and patient welfare are interchangeable concepts, as improved health is the primary reason patients seek out medical care. The reality, however, is that patient health is just one part of a larger picture. Practicing patient-centered care and prioritizing patient satisfaction requires providers to look beyond health outcomes and other clinical benchmarks to the overall patient experience.

“Imagine you don’t know anything about healthcare; how would you want to interact with the healthcare system? Would you want to be 50th in a queue at the on-call center to schedule a radiology test?” said Ella Kazerooni, M.D., professor of radiology, associate chair for clinical affairs and director of cardiothoracic radiology, University of Michigan Health System, to an audience of healthcare professionals at RSNA 2016.

This traditional radiology experience (dubbed “Radiology 1.0” by Kazerooni), from scheduling an exam all the way through to results communication and billing, has placed little emphasis on patient involvement, with patients being shepherded from one place to the next with little to no explanation. This has slowly given way to what Kazerooni calls “Radiology 2.0,” where more patients are coming into the radiology department via referrals from other physicians. Patient portals emerged in this era, allowing online scheduling of appointments, and viewing of imaging and lab results.

Through both phases of the radiology experience there have been various metrics to measure performance and guide improvement efforts. Kazerooni pointed out, however, that the majority of these metrics have focused on clinical quality.

“We’ve always thought quality was a CT with the lowest radiation exposure for the question being asked, or the fastest report turnaround time and access to a test this afternoon,” she said. “But in the value world, you see that quality as perceived by the patient includes a lot of the patient experience. This disconnect is very real.”

Financial Incentives for Quality

Bridging this divide has been one of the driving forces in the transformation of the healthcare industry the last several years from a volume-based culture to a value-based one. Perhaps the most significant legislation in this arena has been the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), which will provide financial incentive for hospitals and healthcare providers to practice quality and value in medicine.

Under the guidelines of MACRA, the Centers for
Medicare and Medicaid Services (CMS) announced in 2016 it would be creating a Quality Payment Program to develop new incentives to focus on quality care and patient satisfaction. One of the primary mechanisms of the program will be the Merit-Based Incentive Payment System (MIPS), which will provide financial incentives for Medicare physicians based on four performance categories: Quality, Advancing Care Information, Clinical Practice Improvement Activities and Cost. There will be an option for physicians to include patient experience data in their annual reporting for additional incentive pay. While MIPS reimbursements are not scheduled to begin until 2019, performance evaluation under the new criteria does begin this year.

Reaching Radiology 3.0

With MACRA, MIPS and other changes yet unknown in the future, radiology is poised to enter yet another phase, which Kazerooni calls Radiology 3.0. This next evolution will center on the healthcare “team,” on which patients will play an integral role. “People demand a lot and radiology costs a lot, so we need to reassociate with our patient base,” she said.

To establish a philosophy of patient- and family-centered care, Kazerooni told the audience there are four core concepts that must be practiced:

• Respect and dignity;
• Information sharing;
• Participation; and
• Collaboration.

Most importantly, these tenets must be integrated throughout all parts of the patient experience. For example, if a department wants to optimize its CT operations, the project team should start by speaking to the patient check-in desk and ask questions about those procedures — i.e., are the exam request processes easy to access, understand and navigate? Do the people working the call center have good customer service skills?

Kazerooni emphasized that it is important to collect data — be it through surveys, patient satisfaction scores or other metrics — throughout the process. Then, as changes are implemented, the same metrics should be used to remeasure the effects of the changes.

Remembering the difference between professionally centered metrics and patient-centered metrics is key. For example, a provider may believe that if a patient needs multiple tests, it would be best to schedule them all in one day so the patient does not have to come back multiple times. This type of schedule can be exhausting for patients, though, and they may actually prefer to come back and do one test at a time.

Five Keys to Quality Improvement Success

While the idea of a quality improvement project as described may be exciting, it is important for the project team and its leaders to come in with a solid plan, said David B. Larson, M.D., MBA, associate professor of radiology and associate chair of the department of radiology, at Stanford University School of Medicine. “If you’ve made no preparations and you just start into it, you’re probably going to fail,” Larson told his RSNA audience, “and that’s OK. You can learn from that failure and move on.”

To minimize the chances of failure, however, Larson noted that every successful quality improvement (QI) project considers five factors:

1. **Leadership:** In order for change to fully set in, the team must understand the leadership hierarchy of their organization to know who is best suited to help facilitate the changes. The leader’s role is not to solve the problem, Larson stressed, but rather enable their team to solve the problem.

2. **Method:** Knowing how the team is going to approach the project is critical to ensure everyone is on the same page. While those with a healthcare/science background may be more familiar with the scientific method (centered on answering a question), Larson said QI projects are more suited to an engineering-design approach (centered on solving a problem). “You should be developing solutions to a problem and refining them as you go,” he told the audience.

3. **Resources:** The project team must have a strong knowledge of all of the resources at their disposal before they begin, or they will be unable to overcome obstacles along the way. Larson gave the example of calling a team meeting, but attendance is sparse because people are unable to break away from their other work. “Ask leadership up front, ‘What resources are we going to have available to us? ’ and ‘If we need more personnel/equipment/other resources along the way, are you willing to make that commitment?’ ” he said.

4. **Culture:** Every organization has its own unique culture — the way people interact, what informal procedures are in place and who talks to whom. “You have to ask yourself: Who will be impacted by the change and is everyone who will be impacted included in the process?” Larson said.

5. **Execution:** Ultimately, the project team must have the ability, desire and perseverance to execute the improvement plan. The key, according to Larson, is choosing the projects and project roles wisely.

The Future of Quality in Radiology

As healthcare reform continues forward in the future, providers must ask themselves, “How can we think more like patients, what information will they want to know, and what measures can we use?” said James Duncan, M.D, Ph.D., professor of radiology in the Division of Interventional Radiology at Washington University School of Medicine in St. Louis. Duncan wrapped up the RSNA session by considering these questions and offering two predictions:

1. Patients will want “more” and “better” from all aspects of healthcare. Maintaining patient satisfaction, in Duncan’s mind, will require more predictable processes and outcomes throughout the healthcare system — as well as more transparency on pricing and expertise. The ultimate goal, he said, should be better integration across the system and care better tailored to individual patient needs.

2. Providers will be working with more data. In order to provide the level of care patients will expect, Duncan warned providers will need to rely on traditional sources — speaking with and observing patients — as well as newer ones like patient monitors and patient-entered data. “Other industries have figured out how to get around it and maybe we should too,” Duncan said of allowing patients to contribute their own information.

The ultimate goal will be to use all of this data and information to reduce uncertainty in the process of patient care. Duncan said patients are more aware of how much data is collected but that they are often frustrated with how it does not seem to be used. By prioritizing patient satisfaction throughout their entire experience, providers can begin to build the relationships that will be key to successful outcomes moving forward. It is
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gehealthcare.com/mammography

Finding Value in Digital Breast Tomosynthesis

By Melinda Taschetta-Millane

New research presented by Stephen Rose, M.D., chief medical officer of Solis Mammography and president of Rose Imaging Physicians Group, Houston, at the 2016 Radiological Society of North America (RSNA) annual meeting found recall rates, cancer detection and invasive cancer detection for women under age 50 were significantly improved with the addition of digital breast tomosynthesis (DBT) to mammography.1

However in January 2016, the U.S. Preventive Services Task Force (USPSTF) sparked controversy when it changed its recommendations, advising women to start their mammograms at age 50. This reversed the previous standard set by the American Cancer Society (ACS) in October 2015 in its “Breast Cancer Screening for Women at Average Risk: 2015 Guideline Update” that advised women to be screened by age 45 and then every two years after age 50 when diagnosed. In addition, women under the age of 50 tend to be more likely to have dense breast tissue, “said Rose in a statement released by RSNA.

New to the market is Fujifilm Medical Systems U.S.A. Inc.’s DBT software upgrade for its Aspire Cristalle full field digital mammography system with DBT combines Fujifilm’s hexagonal close pattern (HCP) detector design, advanced image processing and image acquisition workflow to optimize patient dose while maximizing image quality.

Looming on the horizon is the Planned Clarity 3-D DBT system, which is FDA-pending and has received the CE mark and is currently available for sale in the European Union and other countries where the CE mark applies. Planned’s new method is said to significantly improve image accuracy and allows even the smallest details to be captured with great precision.

Coverage Issues

A recent report from market intelligence firm Infiniti Research discussed the growth of DBT in the United States, highlighting the benefits and acknowledging the barriers to continued adoption. The report states that despite all of the benefits of this technology, many have been unable to take advantage of them. In the United States, numerous health insurance companies will not cover procedures that use this new technology, despite its effectiveness. While Medicare and Medicaid do cover it, private insurers do not, forcing patients to settle for a 2-D mammogram even when it is not the best option.

Some states are fighting this, however. According to Infiniti Research, Connecticut has brought in a new law this year that requires insurers to cover 3-D mammograms if the patient asks for them. “While the state’s Insurance Department argues that this will be very costly to implement, supporters of the law disagree. Although the initial cost of acquiring new equipment will be high, the accuracy of these tests will eliminate the need for many 2-D tests. The costs should also fall as the equipment and tests become more prevalent,” according to the report.  

Comparison chart compiled by Imaging Technology News

Scranton Gillette Communications assumes no responsibility or liability for any errors or omissions in this chart.

References:


## Breast Tomosynthesis Systems

### Comparision Chart

<table>
<thead>
<tr>
<th>Company Name</th>
<th>Fujifilm Medical Systems U.S.A., Inc.</th>
<th>GE Healthcare</th>
<th>Hologic</th>
<th>Siemens Healthcare</th>
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</thead>
<tbody>
<tr>
<td>Product name</td>
<td>Fujifilm Essential Senographe Essential with SimFrac</td>
<td>Senographe Pristina</td>
<td>Senographe Pristina</td>
<td>Senographe Pristina</td>
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<tr>
<td>FD detector</td>
<td>Fujifilm Essential Senographe Essential with SimFrac</td>
<td>Senographe Pristina</td>
<td>Senographe Pristina</td>
<td>Senographe Pristina</td>
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<tr>
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<tr>
<td>FD indication of equivalent/superior to FFDM</td>
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<td>N/S</td>
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<td>N/S</td>
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<tr>
<td>GE, year released</td>
<td>2013</td>
<td>2017</td>
<td>2008</td>
<td>2005</td>
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</table>

### What differentiates your product from competitors:

- Innovative hexagonal close pattern (HCP) detector provides more uniform coverage vs. conventional square pixels, resulting in better patient dose, AEI intelligent unit recognition of differentiating tissues, mass, and requires for optimal exposure conditions.
- GE Digital’s Breast Tomosynthesis delivers superior diagnostic accuracy of the same class as 2-D FFDM, the breast patient dose of all FFDM approved DMS systems, AEC, DQE, a high-performance cone-beam reconstruction algorithm that allows for a more comprehensive breast examination and may help reduce costs (breast density, confidence for technologies), fully integrated digital platform and thoughtful ergonomic design enhancing tube head and patient positioning, next to the patient, allowing for easier handling and setup.
- Hologic AEC detector is designed to go off-line to reduce the mammography exposure fluence for comfort, improving the overall mammography experience with an imaging appearance and unique features such as the nearest detector edge and the path down to allow for a more comprehensive breast examination and may help reduce costs (breast density, confidence for technologies), fully integrated digital platform and thoughtful ergonomic design enhancing tube head and patient positioning, next to the patient, allowing for easier handling and setup.
- Siemens’ Tomosynthesis systems deliver superior diagnostic accuracy of the same class as 2-D FFDM, the breast patient dose of all FFDM approved DMS systems, AEC, DQE, a high-performance cone-beam reconstruction algorithm that allows for a more comprehensive breast examination and may help reduce costs (breast density, confidence for technologies), fully integrated digital platform and thoughtful ergonomic design enhancing tube head and patient positioning, next to the patient, allowing for easier handling and setup.

### N/A

- Number of mm at the wafer (compressor)
- Standard size, cm
- High-resolution size
- Spatial resolution
- Digital Detector
- Dose software
- Radiation therapy
- 3-D/tomo mammography systems

**Note:** The table above provides a comprehensive comparison of the mentioned breast tomosynthesis systems, including hardware specifications, imaging modalities, and additional features. Each system offers unique benefits, such as improved diagnostic accuracy, reduced patient dose, and enhanced user experience, which are crucial in the field of mammography. The comparison chart helps healthcare providers make informed decisions based on the specific needs of their institutions.
### Warranty

<table>
<thead>
<tr>
<th>Warranty</th>
<th>Fujifilm Medical Systems U.S.A., Inc.</th>
<th>GE Healthcare</th>
<th>Siemens Healthcare</th>
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<tbody>
<tr>
<td></td>
<td>1 year</td>
<td>1 year system warranty</td>
<td>1 year system warranty</td>
</tr>
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</table>

### Weight, kg (lb)

| Weight, kg (lb) | Acquisition station: 217 kg; gantry: 420 kg; generator: 160 kg | Gantry: 394 kg; control station without monitors: 198 kg | Gantry: 400 kg (882 lbs); AWS: 209 kg (460 lbs) |

### Power Requirements

| Power requirements | Acquisition station: 217 kg; gantry: 420 kg; generator: 160 kg | Gantry: 394 kg; control station without monitors: 198 kg | Gantry: 400 kg (882 lbs); AWS: 209 kg (460 lbs) |

### Additional Features

#### Connectivity features: customizable Katapult to move to GE system

#### Sensitive to Patient: same as the above

#### Mammography image processing step: user

#### GE: service for mammography diagnostically capable

### Review Workstation

<table>
<thead>
<tr>
<th>Review Workstation</th>
<th>Fujifilm Departmental PACS</th>
<th>Departmental PACS</th>
<th>Departmental PACS</th>
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<tbody>
<tr>
<td></td>
<td>N/A</td>
<td>N/S</td>
<td>N/S</td>
</tr>
</tbody>
</table>

### Additional submitted information also appears on our website at www.ITNonline.com.
Breast Tomo Monitor
Eizo Inc’s RadiForce GX550 is a 21.3-inch, 5 megapixel monitor for viewing detailed digital breast tomosynthesis and mammography images. It is the successor model to the RadiForce GX540 and features superior imaging capability and ease-of-use. The RadiForce GX550 features Eizo’s Sharpness Recovery technology, with which the decrease in sharpness (MTF) is restored. This allows healthcare professionals to display an image safely on the monitor that is true to the original source data, even at high brightness levels. The monitor’s new design features thinner, black front bezels, making it easier to focus on images in dark reading rooms, while the original white stripe design around the sides of the monitor presents a fresh, clean aesthetic to promote a comfortable, user-friendly environment. For keeping the workspace efficient, the monitor’s width, height and depth were reduced by 21 mm, 36 mm and 45.5 mm respectively – a 28 percent difference compared to its predecessor. The width of the side bezels was reduced by approximately half to 13.5 mm – the thinnest in the industry for 5 megapixel monitors, according to Eizo. This allows users to comfortably view two monitors side by side to compare images. The company has received U.S. Food and Drug Administration (FDA) 510(k) clearance for digital breast tomosynthesis and digital mammography for the RadiForce GX550.
Eizo | www.eizo.com

Breast Imaging Workstation
Three Palm Software released version 1.8.2 of its breast imaging workstation, WorkstationOne. It is a total integration of imaging and informatics for breast imaging, which provides native functionality to generate diagnostics reports and patient letters. This mechanism is integrated into the reading workflow, so that reporting information is captured as the case is read, and is transparently used to populate customizable templates. The reports are saved in a variety of formats, including DICOM standard mechanisms that can be archived to any picture archiving and communication system (PACS) and accompany the studies for reference in future years. Generated DICOM formats include secondary capture, encapsulated PDF and structured reports. The 1.8.2 release of WorkstationOne builds on its existing comprehensive support for mammography, which includes seamless integration of tomosynthesis and breast projection images from any vendor into the workflow; display of mammography computer-aided detection (CAD) reports (including 3-D tomosynthesis CAD reports with enhanced workflow); and simultaneous display of related modalities and reports. WorkstationOne was also shown in a number of partner booths at RSNA, including PACS and full-field digital mammography (FFDM) vendors, as well as the major vendors of high-resolution mammography monitors.
Three Palm Software | www.threepalmsoft.com

TMIST Tomosynthesis Trial
Researchers from The Ottawa Hospital Breast Health Centre and the Ottawa Integrative Cancer Centre (OICC) have opened the Ottawa site of the Lead-In to the Tomosynthesis Mammographic Imaging Screening Trial (TMIST). The Breast Health Centre is one of three clinical trial sites to launch the Lead-In in Canada. It is expected that shortly this trial will be integrated into a larger U.S./Canada TMIST, managed by the ECOG-ACRIN Cooperative Clinical Trials Group. TMIST is the first large randomized, multi-centre study to assess whether a novel 3-D digital tomosynthesis technology combined with 2-D digital mammography may be more effective at reducing the incidence of advanced breast cancers than conventional 2-D mammography alone. Previous smaller studies suggest that this new kind of mammography can increase breast cancer detection and reduce the rate of false positives and recalls for women who do not have cancer. If successful, implementation of this technology would provide greater assurance of an effective test, reduce patient stress and anxiety, and ultimately reduce costs to the healthcare system. The current Lead-In study aims to enroll 6,300 women in Canada, including 2,000 from Ottawa. Women attending mammographic screening at the Breast Health Centre may be approached to participate.
Canadian Cancer Trials | www.canadiancancertrials.ca

Personalized Compression
Sigmascreening’s Sensitive Sigma Paddle enables personalized compression for better quality mammograms without unnecessary discomfort for patients. The patented Sensitive Sigma Paddle has multiple sensors that measure each breast to optimize compression for each breast. Based on breast size and tissue stiffness, the device calculates the pressure to achieve an optimal compression of 75 mmHg and allows for a highly reproducible procedure. Investigational in the United States, the device is CE-marked and is actively being used at breast screening centers and hospitals in England, Germany, Sweden, The Netherlands, Belgium and Switzerland since receiving CE-mark last year.
Sigmascreening | www.sigmascreening.com
Breast Screening Software
VolparaEnterprise 2.0 software helps breast imaging providers deliver high-quality, personalized breast screening. It delivers key performance indicators (KPIs) for hundreds of performance and quality metrics, including positioning, compression and equipment utilization. The Microsoft Azure–based solution provides continuous quality assurance and performance monitoring through dynamic, interactive dashboards. Updated with every mammography or tomosynthesis exam, the VolparaEnterprise ConstantQuality metrics may help facilities comply with the U.S. Food and Drug Administration’s (FDA’s) new EQUIP inspection program. Designed to support large or small enterprises, VolparaEnterprise software enables breast imaging providers to provide objective evidence to demonstrate compliance and quality of care. Users can perform rapid quality control checks to optimize the productivity and efficiency of imaging resources, to help reduce costs through the reduction of retakes, and to increase staff effectiveness.

Volpara | www.volparasolutions.com

Breast Density Category Assessment Software
The FDA has granted 510(k) clearance to Statlife’s DenSeeMammo, a software solution for breast density category assessment. DenSeeMammo provides a standardized and automatic breast density evaluation that mimics radiologists’ visual assessment according to the BI-RADS 5th Edition guidelines. The images from the mammography equipment are compared to a database of images that were previously quoted by a consensus of Mammography Quality Standards Act (MQSA) radiologists specialized in breast imaging. The DenSeeMammo software can be combined with Statlife’s MammoRisk software for breast cancer risk assessment; it provides a breast density category assessment, a risk evaluation, and a patient report with a personalized screening program. DenSeeMammo is a software application intended for use with digital mammography systems. DenSeeMammo estimates BI-RADS breast density value by analyzing digitally processed 2-D mammograms using a fully automated comparison procedure. It provides a BI-RADS breast density 5th Edition category to aid radiologists in the assessment of breast density. DenSeeMammo is compatible with images obtained from GE Senographe Essentials systems.

Statlife | www.mammorisk.com/us

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slam against radiology is probably the last thing anybody would expect to see in fallout coming from the new U.S. president. And so far there has been nothing. In literally thousands of Trump tweets over the last several years, radiology has not been mentioned once. And that is exactly why radiology needs to be on the lookout. Big time!

It’s not what the tweets say but the effect they have — how Trump tweets distract and how they might provide cover for the gorilla that could be coming for radiology. To see this, we first must consider the phenomenon of “Trump tweeting.” In early December, the President-elect took aim at Boeing for “out of control costs” on a new Air Force One — “more than $4 billion. Cancel order!” he tweeted.

Never mind that the Air Force, according to Reuters, had previously said it planned to spend $1.65 billion for two of the jets. Never mind that the initial contract of $25.8 million had been awarded to reduce risk and lower the cost of the program, according to the Pentagon’s daily digest of arms deals.

A big company with lots of military contracts, booming sales of commercial planes and a soaring stock price, Boeing was an irresistible target for the soon to be Commander in Chief. And world media from CNBC to the BBC, The Guardian to WirtschaftsWoche quickly scrambled to report the “news.”

The tweetfest continued after Mr. Trump moved into the White House. And it wasn’t all about Boeing. In the three weeks since inaugural day (Jan. 20 to Feb. 10), more than 130 Presidential tweets were sent, according to a search on Trump Twitter Archive. Those tweets gripped the nation’s attention, appearing daily on websites and in newspapers, nightly on network news, distracting the public from the substance of what was going on.

To understand the significance of this for radiology, we must consider the phenomenon of the “invisible gorilla.” But first we must look at the economic barrage that radiology has struggled against in recent years.

**Hard Times**

More than a decade ago, as editor of the newsletter DI SCAN, I suggested in a series of commentaries that radiology launch a public awareness campaign. Radiology, I warned, was not properly appreciated by the public. And, because radiologists are “doctors’ docs,” it has no grassroots support among patients, making it an easy target for politicians wanting to “do something” about spiraling healthcare costs.

From 2006 to 2013, the Centers for Medicare and Medicaid (CMS) repeatedly cut radiology payments. The bundling of reimbursement codes for computed tomography (CT) of the abdomen and pelvis led to a 29 percent drop in payments in 2011, according to a study by Thomas Jefferson University researchers. In 2012 and 2013, the volume of CT procedures dropped 5.5 percent annually, according to the IMV Medical Information Division.

In 2013 the Protecting Access to Medicare Act of 2014 (PAMA) directed CMS to develop an appropriate use criteria (AUC) program for advanced diagnostic imaging services, singling out magnetic resonance (MR), CT and molecular imaging. It is no coincidence that the highest profile modalities — the ones with the costliest machines and the highest charges — continue to be lightning rods for politicians. And that brings us to the gorilla and the presidential tweets that could make it invisible.

Cognitive psychologists call this phenomenon of invisibility “inattentional blindness.” (It is also known as perceptual blindness and change blindness.) It happens when observers see only what they are looking for, even when other options are right in front of them.

This phenomenon was most famously demonstrated in a study that asked volunteers to count the times players passed a basketball. Absorbed in the counting, the volunteers did not notice a person in a gorilla suit walking right through the players.

**Enter the Gorilla**

Radiologists are not immune. In a study at Brigham and Women’s Hospital in Boston, 24 radiologists were asked to detect lung nodules. “A gorilla, 48 times the size of the average nodule, was inserted in the last case … 83 percent of the radiologists did not see the gorilla,” the researchers wrote, even though the majority, as revealed by eye tracking, looked directly at it.

Will radiology fail to see the approaching gorilla of reimbursement cuts, if and when it comes again? There are plenty of reasons to be alert.

In his bid for the Presidency, Mr. Trump attacked ObamaCare relentlessly as Republicans voted repeatedly — and unsuccessfully — to repeal it. Both had cited this program as the cause of rising insurance premiums. Hoping to leverage the seismic shift in Washington that occurred last November, Mr. Trump and Congressional Republicans are trying to come up with a “replace/repair” plan for ObamaCare.

Assuming they succeed in the ouster of ObamaCare, if insurance premiums (or healthcare costs) rise, Congressional Republicans and Mr. Trump will want a scapegoat, something the President can tweet about with impunity. What branch of medicine will it likely be? (Hint: Which lacks grassroots support? Which depends on costly machines and high charges?)

Maybe it isn’t a bad idea for radiology to keep an eye out for gorillas.

Greg Freiherr has reported on developments in radiology since 1983. He runs the consulting service, The Freiherr Group. Read more of his views on his blog at www.itnonline.com.
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