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JULY/AUGUST 2013

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About the Cover

Web-based cardiology PACS allow easier integration with mobile devices, such as tablets and smartphones, as shown here with Carestream’s Vue. See the story and related pull-out comparison chart starting on Page 7.

Web-Exclusive Feature

University of Maryland Launches Genetic-Testing For Cardiac Stent Patients

Patients with coronary artery disease who undergo treatment at the University of Maryland Medical Center now can receive long-term therapy based on information found in their genes. As part of a new personalized medicine initiative, the medical center is offering genetic testing to help doctors determine which medication a patient should take after a stenting procedure in order to prevent blood clots that could lead to serious or fatal heart attacks and strokes.

Read the story at: http://bit.ly/ZjoswL    ALSO USE QR CODE

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Finding ways to lower patient radiation dose from both medical imaging and interventional cardiology has become a major trend. However, when vendors start talking dose, it is important to realize there are no set industry standards agreed upon by manufacturers to calculate dose. For this reason, I call into question vendors’ statistics of how much their technology can lower dose by up to 20, 50 or even 80 percent. While new technologies such as iterative reconstruction, more sensitive detectors and ECG gating do indeed lower dose, quantifying it can be a moving target.

DAIC created a comparison chart for technologies to help lower computed tomography (CT) dose (see Page 34). Vendors were asked, “How does your system calculate estimated dose?” As an example, we asked what they use as a conversion factor to calculate dose in MilliSieverts (mSv) based on dose-length product (DLP) or CT dose index volume (CTDvol) found on a scan’s DICOM header. To our surprise, this central question of how vendors arrive at their dose statistics was not answered by anyone. I wrote back posing this question again and only received responses from GE and Philips — the rest declined to comment. The bottom line is that there are no industry standards agreed upon by manufacturers.

“There have been publications to estimate effective dose from DLP or CTDI through conversion factors and there are organ dose simulations you can calculate using Monte Carlo techniques, however each method has its own level of uncertainty,” said Leslie Lakis, Philips senior public relations manager, imaging systems. “Therefore, physicists are left to use whatever effective dose conversion they prefer until the scientific community formally adopts a standard method for effective dose conversion.”

Ken Denison, global marketing director, CT, global MICT dose leader, GE Healthcare, said each manufacturer takes measurements on 16 and 32 cm water phantoms for a range of parameters (kVp, mA, slice thickness, pitch, etc.) and this allows them to then estimate the exposure using CTDIvol. However, he said GE does not provide an estimate for whole-body effective dose on its systems. “This is because there are different k-factors that may be used to convert DLP to and estimate of whole-body effective dose. Different users may choose which factors to use differently,” he said.

Due to the variability cited, I often wonder if true apples-to-apples comparisons between vendors’ technologies are possible. Also, as more states consider laws requiring providers to record patient dose, what measure is being used? It must be realized that all dose calculations are based on 16 and 32 cm phantoms, which are not real people and most patients are 16 or 32 cm across. In addition, each patient body habitus impacts the individual level of dose, so all dose measures are really a best guess, not an exact science.

We welcome your comments on the topics found in Diagnostic and Interventional Cardiology. Please send your thoughts to dfornell@sgcmail.com
The Evolution of Cardiac Web-Based PACS

Healthcare reforms requiring wider sharing of patient images and records make Web-based systems an attractive solution

By Dave Fornell

Healthcare reform requiring wider access and enterprise sharing of patient images and records are making Web-based cardiology picture archiving and communication systems (PACS) a more attractive solution over traditional thick-client, server-based systems. In just the past few years there has been a departure from thick-client cardiology and radiology PACS to Web-based platforms. There are several reasons for this, including better interoperability, anywhere-anytime access, remote access to data and images, and reduction of IT burdens. Web-based systems also enable easier delivery of many healthcare reform Stage 2 meaningful use (MU) requirements.

The biggest clinical benefit of a Web-based cardiology PACS (also referred to as cardiovascular information systems — CVIS) is the ability for cardiologists and supporting staff to conduct their daily duties from one system instead of several disparate systems, each requiring a separate workstation. The single point-of-entry allows access to all cardiac imaging modalities and related reports, echocardiograms (ECG), procedural reports and prior exams from any computer with Web access.

This consolidation of data allows data mining, which can quickly identify the exact numbers and types of cases seen at a facility, numbers and types of tests ordered, patient demographics, how patients are being triaged and treated, and trends in room or equipment usage.

Web-based, single platform cardiac PACS provide the freedom of anywhere access for physicians, as with GE’s Centricity Cardio Enterprise. Web-based systems allow two-way data transfer so physicians can add notes, complete reports, change drug therapy or order additional tests through computerized physician order entry (CPOE) right at the patient’s bedside. Immediate remote access to images, test results and ECGs also has utility in better addressing emergency situations. Just like the cultural revolution Web-based smartphones have created with people’s personal access to the world via the Internet, social media and e-mail, Web-based PACS untether physicians from their desktop computers and allow them to do their job just as well from a remote clinic or at home.

Editor’s note: This article and accompanying comparison chart serve as an introduction to Web-based cardiac PACS. Due to the expanding complexity of cardiac PACS, this year DAIC has broken its coverage of these systems into two comparison charts. This chart focused on Web-based systems, their remote access capabilities and how they meet Stage 2 meaningful use requirements. A second cardiac PACS chart will appear in the November/December issue, focusing on the modalities supported and reporting functionality of each vendor.
Numerous cardiac PACS vendors released completely re-engineered versions of their systems at American College of Cardiology (ACC) meetings in 2012 and 2013. GE Healthcare, Agfa, Lumedx and Philips launched brand new Web-based platforms. Siemens, McKesson and Infinitt also released several enhancements and new modules for their Web-based systems. Vendors say their new platforms will allow easier integration with both medical device hardware and other software systems by using standards-based architecture with unmodified HL7 and DICOM standards. While partly in response to clinician end-users’ repeated requests for better interoperability over the past decade, the recent improvements and move to Web-based systems is due to the need to meet Stage 2 and eventual Stage 3 MU requirements. Cardiac PACS that do not meet these requirements will eventually face lower reimbursements, and systems that meet the requirements early may qualify for higher reimbursements.

Implementation of Meaningful Use in Cardiology

The latest generation of Web-based cardiovascular PACS offer many cutting-edge technology perks, including software to address Stage 2 meaningful use (MU) requirements. Stage 1 MU requirements were aimed at basic requirements for recording patient data and expanding interoperability of hospital or healthcare system-wide electronic medical records. Stage 2 requirements call for the next level of integration, including specialties such as cardiology and radiology. Stage 2 is designed to expand and leverage IT capabilities to improve efficiency in the U.S. healthcare system.

With the advent of Stage 2, there is an expectation that many hospitals will upgrade or replace their existing cardiovascular PACS to allow better interoperability to meet the new requirements.

While many MU requirements necessitate only small percentages of use in Stage 2, the long-term goal is to expand these capabilities. It is likely that requirements such as CPOE, clinical decision support, remote image and report viewing, physician collaboration, data mining, patient interaction and other requirements will be greatly expanded under Stage 3 requirements in the coming years. Web-based systems will help simplify and facilitate all of the above-mentioned requirements.

Considerations for Web-Based Systems

- Zero-Footprint Access — These systems allow images and data to be accessed anywhere using a Web browser. Some vendors require the download of special software to access the data, while others do not.
- Mobile Devices — There is a growing expectation among physicians to access images and data using their tablet and smart phone devices. By far the largest class of these devices deployed in medicine includes the iPad and iPhone, which use the iOS operating system. Most vendors design access specifically for these devices, but often offer interfaces for other operating systems, such as Android.
- Thick vs. Web-Client — Some systems offer a Web-based and thick-client system, which may differ in functionality.
- Eliminating CDs — A big headache at some facilities is the transfer of files, especially of image datasets on CD between facilities or referring physicians. Burning CDs can be time consuming, and the CDs sometimes cannot be opened or are not compatible with the receiving center’s computers. Web-based systems can help eliminate the need for CDs by allowing direct transfer of the files electronically.
- Creating telecardiology programs may be easier with Web-based systems because outlying clinics and doctors’ offices can more easily transfer images and reports.

Comparison Chart Compiled by Diagnostic & Interventional Cardiology

Scranton Gillette Communications assumes no responsibility or liability for any errors or omissions in this chart.
Perform a 4-D left ventricular function analysis on an echo image, while working on the echo report... from home.

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Now you no longer have to sacrifice functionality and speed for remote access. By developing advanced streaming software, GE Healthcare's Centricity Cardio Enterprise solution is able to optimize network bandwidth to deliver diagnostic image quality at a higher speed. This allows you to perform a 3D or 4D left ventricular function analysis on an echo image while reviewing that patient’s prior CT and working on the echo report, all from the convenience of your office, home, or almost anywhere else you happen to be.

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1 Where there is an internet connection available.
2 Centricity Cardio Enterprise solution is comprised of the Centricity Cardio Imaging and Centricity Cardio Workflow products.
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Advanced quantification tools. In the convenience of a web browser.

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Enhanced productivity isn’t simply about doing more with less. Optimizing technology in new and innovative ways should also help enhance patient care. With Centricity Cardio Enterprise solution¹ you no longer have to sacrifice functionality and speed for remote access. By developing an advanced streaming algorithm, the GE Healthcare Centricity Cardio Enterprise solution delivers diagnostic quality images with quantification measurement tools, virtually anywhere there is an internet connection. Perform a 4-D left ventricular function analysis on an echo image while working on the echo report, all from the convenience of your office, home, or virtually anywhere² you happen to be. All of which means you can focus more on caring for your patients, and less on getting images where and when you need them.

Centricity Cardio Enterprise solution…. the power of web diagnostics (Re) imagined.

For more information about GE Healthcare, visit our website at www.gehealthcare.com

¹Centricity Cardio Enterprise solution is comprised of the Centricity Cardio Imaging and Centricity Cardio Workflow products.
²Where there is an internet connection available.
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ASE Defines Focused Cardiac Ultrasound Exams

Statement due to expanding use of cardiac ultrasound outside of cardiac departments


The recent improvements in portability of cardiovascular ultrasound have had a significant impact on its use in medical practice. This new recommendation defines how focused cardiac ultrasound (FCU) can be used to positively impact patient care. Technological advances have resulted in a growth in cardiac ultrasound by a variety of clinicians in a range of settings, such as outpatient clinics, inpatient wards, critical care units, emergency departments, and remote clinics. With the creation of these recommendations, ASE identifies how practitioners with limited training can appropriately use portable devices to expedite and improve the quality of patient care.

“The development of small, inexpensive, portable ultrasound devices, combined with a growing interest of physicians in many specialties to use ultrasound at the bedside for point-of-care assessment, prompted the ASE to develop this expert consensus document,” said Patricia Pellikka, M.D., FASE, a cardiologist at Mayo Clinic and president of ASE. “This document establishes definitions for focused cardiac ultrasound, describes its appropriate application and discusses issues of training for the user.”

This document encourages additional training in light of the significant role the comprehensive transthoracic echocardiogram (TTE) has in the proper care and treatment of the heart patient. Key information from a TTE is crucial in initiating proper therapies and in the evaluation of abnormalities. FCU is a focused examination performed by a physician as an adjunct to the physical examination to recognize specific signs that represent a narrow list of potential diagnoses. The document distinguishes the emerging field of FCU as a bedside adjunct to the physical examination and echocardiography. Defining the distinctions will allow practitioners to realize the utility of FCU, while maintaining the value of echocardiography.

For more information: www.asecho.org/guidelines

One-year results from St. Jude Medical’s EnligHTN multi-electrode renal denervation system EnligHTN I trial showed safe, rapid and sustained reduction in blood pressure measurements. Presented at EuroPCR 2013, data show an average systolic blood pressure reduction of 27 mmHg points. Eighty percent of patients responded to the therapy, defined as a blood pressure reduction of at least 10 mmHg. The longer-term safety profile for renal denervation was supported by showing no significant changes in kidney function.

Medtronic received CE mark for valve-in-valve (VIV) procedures using the CoreValve transcatheter aortic valve implantation (TAVI) system in degenerated bioprosthetic surgical aortic valves. This is the first regulatory approval for VIV procedures, which provide a minimally invasive treatment option for patients whose surgical aortic valves have degenerated, and who are at extreme or high risk for surgery and would otherwise go untreated.

The Boston Scientific Lotus TAVI device was successfully implanted in all of the first 60 patients in the REPRISE II trial. All patients showed good device performance and low mortality at 30 days. The trial prospectively evaluated the safety and performance of the Lotus in symptomatic patients with severe calcific aortic stenosis considered high risk for surgical valve replacement. The primary endpoint for device performance — mean aortic valve pressure gradient at 30 days compared to a performance goal of 18 mmHg — was met.
St. Jude Medical gained European CE mark approval of its Ilumien Optis stent planning and navigation system. It integrates both fractional flow reserve (FFR) and intravascular optical coherence tomography (OCT) imaging.

Using data from the OCT, it creates real-time 3-D reconstructions, offering a 360-degree panoramic view of vessels, making it easier for physicians to visualize the area they are treating.

Six-month results from the MASTER (MGuard for Acute ST Elevation Reperfusion) trial demonstrating that the MGuard embolic protection stent (EPS) outperformed bare metal stents and drug-eluting stents in all-cause mortality in ST-segment elevation myocardial infarction (STEMI) patients. With its micro-net mesh sleeve, MGuard EPS prevents unstable arterial plaque and thrombus from breaking off and exacerbating damage. The trial achieved its primary endpoint in complete ST-segment resolution at 60 to 90 minutes post-procedure.

Results of a meta-analysis study of the CardioKinetix catheter-based Parachute Ventricular Partitioning Device to treat heart failure substantiated it is a viable treatment. Six-month clinical results from 91 U.S. and European patients demonstrated successful delivery and deployment without the occurrence of major adverse cardiac events (MACE) related to the device in 90 percent of patients. About 89 percent showed improved or maintained New York Heart Association (NYHA) functional class status. Specifically in the NYHA III subgroup, 27 percent improved two classes.

Intermountain Healthcare, a Utah-based nonprofit system of 22 hospitals and 185 clinics, is compiling the cumulative radiation patients receive from about 220,000 higher-dose procedures and imaging exams each year, starting with exams performed in the last quarter of 2012. That information is now readily available to both physicians and patients.

Physicians and other medical personnel can review the cumulative radiation a patient has received through Intermountain’s electronic medical record (EMR) system. Patients can view their own radiation history by signing up for Intermountain’s free “My Health” program, which provides information through a secure password-protected portal on the Internet. In addition to providing the cumulative radiation history, patients and physicians are also given access to educational materials on the risks and benefits of medical radiation.

“With this information, clinicians and staff have reduced radiation, avoided unnecessary treatments and found alternatives which do not involve X-rays,” said Donald Lappé, M.D., medical director of Intermountain’s Cardiovascular Clinical Program.

While a patient’s individual situation typically dictates the imaging procedure needed, knowing a patient’s cumulative radiation exposure can help physicians and medical caregivers determine which type of imaging test is best.

The benefits from a procedure usually outweigh the slightly increased cancer risk from exposure to radiation, but the potential risk of radiation should be considered before these imaging tests are performed. In some cases, equivalent information can be obtained with a medical test that does not use radiation, such as ultrasound or magnetic resonance imaging (MRI) scans.

“Having such information available is especially helpful for children with certain chronic health problems, as they may need to have many tests involving radiation during their lifetime,” said Keith White, M.D., medical director of Intermountain’s Imaging Services. “The cancer risk from an imaging test is lower the older a person gets, and the highest risk is for children.”

For more information: www.intermountainhealthcare.org
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Artis Q and Artis Q.zen. Another example of Sustainable Healthcare Technology—solutions engineered to help improve outcomes while reducing costs through increased efficiencies.

Answers for life.
Advances in Cath Lab Inventory Control Systems

Technology helps track actual procedure costs, find new cost savings

By Dave Fornell

Computerized and semi-automated inventory control system technology offers a more efficient way for cardiovascular departments, especially catheterization and electrophysiology (EP) labs, to track what is on their shelves, when to re-order supplies, their actual costs per procedure and to identify new ways to cut costs.

There are three ways inventory control systems can track items — barcode scanning, radiofrequency identification (RFID) tags and drop-down box selections. Barcode systems require all tracked inventory to be labeled with a sticker bearing a barcode that corresponds with cataloged items in the inventory control system. The items are then scanned with a laser barcode reader, allowing quick, automated data entry into a system. RFID systems utilize stick tags similar to anti-theft RFID security tags that set off alarms at stores. All items are tagged and then stocked into a RFID cabinet, which automatically reads the tags as they enter or leave the cabinet. This enables an accurate count of what is on hand, what was removed, when and by whom.

“Inventory systems will cost money on the front end, but you will save money on the back end,” said Marcia Deeb, CVIS coordinator, Washington Hospital, Washington, Penn. “We really know what is on our shelves, and we only have our re-orders set based in minimum and maximum numbers of what is on hand. We can now see what we are actually using and what it really costs to do a right cath compared to a peripheral cath.”

Over the past year, Washington Hospital has implemented McKesson Cardiology Inventory to track items in the cath lab. It is now phasing it in for the cardiac care unit (CCU). Deeb said the barcode-based system has fit well into the nurses’ workflow, scanning the item as it is used. Previously, nurses used a paper and sticker system to record what they used, but everything had to be manually entered and tracked. She said many times they just eyeballed items on the shelves to decide if they needed to order more items. The new system automatically tracks everything and sends a report to the inventory clerk to reorder supplies that are running low. The system also allows queries to compare costs and supplies used for various procedures.

The McKesson system is tied into billing, which charges patients as items are scanned. Users can also set up one-click order sets, so numerous items can be bundled for a procedure.

Florida Hospital, Adventist Health System, adopted the Lumedx Apollo Advance Inventory Module in 2001 to better manage its stocks of cath and electrophysiology (EP) lab supplies. It is a barcode-based system that allows all supplies to be scanned as they are used or pulled for a procedure. It also uses drop-down boxes to for common disposables. “It has worked very, very well. Lumedx has really stepped up to the plate and it most certainly has allowed us to be more efficient,” said Barry Egolf, RN, nurse manager, invasive cardiovascular services.

In addition, four years ago the hospital installed Wavemark RFID cabinets for high-ticket cath and EP lab supplies, such as stents, balloons and implantable devices. Since implementation of both inventory tracking systems, Egolf said Florida Hospital has saved millions by better tracking expiration dates, usage,

Many CVIS-based inventory control systems use barcode readers to automatically track inventory, as shown here with McKesson’s cardiology inventory control system.
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For more information about McKesson Cardiology or to schedule a demo, visit us at AllAboutCVIS.com.
Interventional Inventory Control Systems

theft prevention, billing capture and knowing exactly what is used for better contract negotiations with vendors.

Florida Hospital has 17 cath labs using the system, including six cardiac, five EP, two interventional radiology, two interventional neurology, one vascular lab and a pediatric hybrid OR. The primary use of these systems is in the cath labs, where real-time inventory tracking data offers a clear picture of the types and volume of procedures being done and what supplies they require. He said this enables the hospital to reliably predict what supplies are needed on hand at all times and at what level supplies should be reordered. Egolf said this helps Florida Hospital maintain a much leaner inventory.

“Most vendors sell on consignment, so it is free until you use an item, but it does not mean we have the real estate to store everything,” Egolf said.

WakeMed Health and Hospitals in Raleigh, N.C., uses GE Healthcare’s Centricity Cardiology with the barcode-based DMS inventory control system in their cath and EP labs. The system currently manages about 3,500 items in this inventory.

The system categorizes inventory into two types — perpetual or periodical. Items that are perpetual will automatically get ordered when the number on hand gets below a certain number and periodicals are ordered by shelf utilization. Wake Med also interfaced its inventory system with Lawson (a hospital-wide materials management system), so all ordering, purchase order generations and receiving are performed in Lawson.

Cutting Costs

The main cost savings from inventory systems are found in streamlining the number of items in stock. At Washington Hospital, the McKesson system helped identify the use of 12 different types of wires in stock, ordered by several physicians, which was reduced down to just three types of wires.

The tracking systems can help with loss prevention, making it much easier to track when items go missing, such as theft of high-ticket items, both Deeb and Egolf said.

Since inventory tracking systems offer a clear picture of what a cath lab uses, a hospital knows exactly what it needs and this can greatly help when negotiating volume discounts.

“Understanding what volume you are using is really important when negotiating contracts with vendors,” Egolf said.

“It helps with contract negotiations,” Deeb continued. “If a vendor asks you to use their product in 70 percent of your cases, you can see your actual usage of the products. This makes contract negotiations easier.”

Several companies also offer no-cross guarantees, so if their balloon does not cross a lesion, but another brand does, the vendor will replace their product at no charge. Because of this system, Egolf has been able to achieve savings of tens of thousands of dollars per month in wasted devices. The Lumedx system also adds a layer of data integrity for vendors because it ties the inventory items to how they were clinically utilized.

Another way these systems help cut costs is through better tracking of expiration dates. Manual tracking of various expiration dates on a large number of items can be very complex and tedious, but Egolf said automated systems greatly simplify this process and can help avoid disposing of unused expired stock.

Tracking Costs

Inventory tracking can help better manage the bottom line by breaking down costs to see what the actual cost is by procedure, by disease state and even by physician.

“The one thing we really, really like is the statistical data we can get back out of the system,” Deeb said. “If I want to know the cost per case, or how to create a set of items, or what vendors we are working with, I can find all that in the system.”

In the current era of cutting costs due to lower reimbursements, inventory systems can help show physician efficiency. In most cases, Egolf said physicians are very good at keeping costs down and not using unnecessary supplies.

“That has pretty much been an eye-opener when we used the system’s analytics,” he explained. “This gives the physicians the opportunity to have their practice defended,” he said. “Today everything is about best practices and this affords physicians the justification for what they are doing.”

Hospitals looking to purchase one of these systems should ensure it can easily be used to data mine.

“You have got to be able to mine the data from the inventory tracking system information or else you are not taking full advantage of the technology,” Egolf said. It also needs to be easy to query the system for specific items, doctors, types of procedures, etc. If a system requires IT to get involved to find the information, he said it makes the system more difficult to use and less likely inquires will be made.

WakeMed configured its administrative reports to run automatically for different time frames (daily, weekly, monthly, periodically and annually) to provide insights on their stock level, utilization and costs. Among the reports they created are daily usage, shelf counts, utilization by physician and cost per case.

IT Considerations

He said one of key things to keep in mind when reviewing systems for purchase is their ease of use. Not only should it be easy to access, use and query information, but also it is essential for new products to easily be added. In the case of barcoded items, most hospitals use their own specific identification numbers, which need to be combined with vendors’ barcodes so it can be scanned in properly. The more difficult this is to do, the less user-friendly the system, Egolf said.

“As an administrator, you need the system to be malleable to meet the needs of your unique hospital,” Egolf explained.

Another requirement is easy interfaces via HL7 with other key systems, such as admission, discharge and transfer (ADT), hospital information systems (HIS) and the cardiac PACS.
Balloon Catheters

Interventional

Percutaneous transluminal coronary angioplasty (PTCA) balloon catheters were the first devices used in the field of interventional cardiology. The growth of the stent market, which is the largest segment for interventional cardiology devices, has helped to fuel the sales of PTCA balloons. In addition, this market is driven by U.S. Food and Drug Administration (FDA) policy, pre-/post-stent dilations and plaque debulking.

PTCA and Cutting Balloon Catheters Market

The total U.S. market for PTCA and cutting balloon catheters was valued at $293.5 million in 2012. The PTCA balloon segment accounted for close to 90 percent of the total coronary balloon catheter market, with cutting balloons accounting for the remaining portion. The PTCA balloon catheter market is expected to increase over the next few years, and the cutting balloon market is expected to experience a slight decrease. The number of percutaneous coronary intervention (PCI) procedures is the primary market driver as a moderate decrease in the average selling price of devices is expected. There are several market drivers.

Changes in FDA Policy

In 2010, the FDA downgraded standard balloon-tipped angioplasty catheters from Class III medical devices to Class II devices with special controls. This means that companies can now bring balloon catheters to market through the 510(k) clearance process rather than the premarket approval (PMA) process. A 510(k) device only needs to prove that it is similar enough to a previously approved device in order to receive FDA approval. The PMA process requires either a clinical trial or additional laboratory studies in order to receive FDA approval and is a much longer process than 510(k). This influences the market such that companies will be able to receive clearance for their devices faster and will be more likely to attempt to enter this market because of the shorter, less expensive approval time. This change in policy has the potential to significantly alter the competitive landscape and drive product innovation through increased competition.

Pre-/Post-Stent Dilations

The majority of PTCA balloon catheters are used to dilate a vessel before inserting a stent. Concerns about late-stent thrombosis have also had a positive effect on the number of pre-stent
Interventional Balloon Catheters

The AngioScore Angiosculpt PTA scoring balloon uses wires on the edge of the balloon to score and crack heavily calcified lesions.

dilation procedures performed. Additionally, PTCA balloon catheters may be used for confirming proper deployment and placement of self-expanding stents, and their increased use during those procedures is also having a positive effect on unit growth.

**Calcified Plaque Busting**

Cutting and scoring balloons are used as an auxiliary method for plaque debulking. These devices have small blades or abrasive surfaces attached to the balloon in order to aid in the dissection of calcified lesions. While cutting balloons are predicted to gradually represent less of the total coronary balloon catheter market over the next few years, they have expanded the number of cases that can benefit from their use, which has had a positive effect on unit sales.

**Competitor Analysis**

In 2012, Boston Scientific was the leading competitor in the total PTCA and cutting balloon catheter market, with more than half of the market share. The company continues to dominate the cutting balloon catheter market with its Flexor product. It has leveraged its leading position in the drug-eluting stent market in order to negotiate combined contracts with hospitals and group purchasing organizations (GPOs). Other competitors include Abbott Laboratories, Medtronic, AngioScore, Cordis, Atrium Medical and Volcano Corp.

Editor’s note: The information contained in this article is derived from a detailed and comprehensive report published by iData Research titled “U.S. Interventional Cardiology Devices Market.” This is part of a series of publications by the same title for Japan and 15 European countries. For more information, visit idataresearch.com.
Interventional Technology | Products

Aortic Valvuloplasty For Use in Stand-Alone BAV, TAVR Pre-Dilation

The new V8 Aortic Valvuloplasty Balloon Catheter is designed to be used in stand-alone balloon aortic valvuloplasty (BAV), and pre-dilation during transcatheter aortic valve replacement (TAVR) procedures.

The balloon catheter features a figure-eight shape balloon that enables the bulbs at either end of the balloon to “lock” into either side of the aortic annulus. This design has the potential to reduce the risk of balloon movement during dilatation, thereby reducing procedure and ischemic time. The non-compliant material maintains the figure-eight shape throughout inflation, which allows for leaflet hyperextension to create maximum valve area opening, without increasing the risk of over stretching the annulus. Lastly, the catheter is designed to inflate and deflate rapidly to reduce the duration of bloodflow obstruction.

GE Healthcare | www.gehealthcare.com

Aortic Valvuloplasty For Use in Stand-Alone BAV, TAVR Pre-Dilation

Aortic Valvuloplasty For Use in Stand-Alone BAV, TAVR Pre-Dilation

Additional Sizes of Cordis Sleek OTW Platform

Cordis Corp. is offering additional sizes of its Sleek OTW (over-the-wire) platform, a 0.014-inch ultra-low profile percutaneous transluminal angioplasty (PTA) dilatation catheter. The Cordis Sleek OTW PTA dilatation catheter is a highly deliverable balloon catheter designed to treat patients undergoing peripheral angioplasty procedures below the knee.

Cordis now offers additional lengths of 20 mm and 280 mm for most of its current diameters. The new 280 mm length will enable physicians to treat diffuse disease with fewer inflations.

Cordis | www.cordis.com

DoseMap Monitors Patient Angiographic Dose to Avoid Skin Burns

DoseMap alerts interventional cardiologists to patient radiation exposure during longer procedures. DoseMap is available on the GE Innova IGS 5x0 platform. This dose feature allows the operator to display local cumulative patient dose levels all along the examination and offers the operator the chance to change the local dose delivery by modifying the dose setting and/or gantry angulation when reaching given thresholds of a procedure. The expected benefit is to help the operator avoid potentially exceeding the local dose threshold and help clinicians better monitor dose levels.

GE Healthcare | www.gehealthcare.com

Software Provides Precise Information About Coronary Blockages

A new solution enables seamless access to Infraredx’s true vessel characterization (TVC) Imaging System via Philips’ Allura Xper angiography systems. It ensures compatibility between the two systems and allows clinicians to quickly and easily connect the TVC to the Allura Xper when intravascular imaging is required.

The new solution is the result of a joint product development agreement announced by Infraredx and Philips in October 2012 that aims to improve the integrated functioning of the cath lab with the TVC Imaging System’s near-infrared spectroscopy (NIRS) and intravascular ultrasound (IVUS) technologies.

Infraredx | www.infraredx.com

Terumo Expands Radial-Specific Family of Heartrail III Coronary Guiding Catheters

Terumo Interventional Systems expanded its family of Heartrail III Coronary Guiding Catheters to include a smaller profile 5 French Ikari shape, specifically designed to provide backup support and access to target coronary lesions during transradial catheterizations. The smaller 5 French Heartrail is designed to help physicians achieve access to the coronary arteries using a smaller-diameter catheter platform, and proprietary Ikari tip shapes, while providing the backup support and body of a traditionally larger French size catheter. The smaller size enhances the guiding catheter portfolio by providing various options in response.

Terumo | www.terumois.com
PET vs. SPECT
Will PET Dominate Over the Next Decade?
New radiotracers and technology are improving both technologies

By Dave Fornell

Just when positron emission tomography (PET) appears to be eclipsing single photon emission computed tomography (SPECT) for cardiac imaging, new advances make SPECT more attractive. Both modalities also have suffered setbacks with radiopharmaceutical supply problems in recent years and both modalities have their pros and cons. Looking toward the future, the question of which modality will dominate remains unanswered. PET shows major promise with exciting new tracers, while new SPECT scanner technology introduced at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) 2013 meeting may herald a rebirth for SPECT with previously unseen image quality enhancements.

At SNMMI, Siemens introduced innovative new technologies for both PET and SPECT. The vendor introduced what it calls xSPECT on its 510(k)-pending Symbia Intevo SPECT/CT. In traditional SPECT/CT imaging, the SPECT image has always been reconstructed at a low-resolution matrix — much lower than the CT portion of the exam. As a result, the CT resolution must be downgraded dramatically to the level of SPECT to enable mechanical fusion of the two modalities. xSPECT combines the images into a new, completely integrated single dataset for vastly higher resolution and quantitative images.

Aimed at the oncology market to start, an example displayed at SNMMI showed a traditional SPECT/CT spinal image with hot spots, but the low resolution makes it unclear if the areas of enhancement are tumors or inflammation. The combined xSPECT image greatly enhanced resolution to show the hot spots were actually inflammation caused by clearly defined spinal compression fractures. The clear, fused image also eliminates the alignment artifacts common with hybrid imaging, where the SPECT and CT images do not exactly match anatomical boundaries. The vendor says centers using the system in trials are reading the xSPECT image rather than going back and forth between the usual collage of three images showing the SPECT, CT and combined overlay image.

SPECT has traditionally been dubbed “unclear” instead of “nuclear” imaging due to its low image quality, said Mike Rittman, senior manager, product marketing, Siemens molecular imaging. He explained xSPECT offers a way to greatly clarify the image with CT-like quality. Instead of an incremental technology advance, Rittman said this is a major step forward for SPECT, involving 10 years of development and 32 pounds worth of paperwork submitted to the U.S. Food and Drug Administration (FDA) for the approval process.

Siemens also introduced the FDA-cleared Biograph mCT Flow PET/CT system, which is the first to offer continuous motion scans, rather than step-and-shoot acquisitions. It uses a magnetically levitated bed that moves the patient smoothly through the system’s gantry. A standard PET/CT scan can last 25 to 30 minutes, with the patient frequently falling asleep while the system acquires a bed position. When the bed shifts to the next scanning position, the patient is often startled, resulting in an image that is marred by motion artifacts. The patient also can feel anxiety during the lengthy scanning process, perceiving no progress until the bed shifts to a new scanning position. Siemens had to develop new ways to process the continuous flow of massive amounts of data from the scanner.

The mCT Flow also removes the limits of the standard 16 cm scan area, which often requires image overlap for stitching and scanning additional areas that are not required. Rittman said this can lower radiation doses considerably, since the scan length can be set by the operator instead of using 16 cm increments.

“While there is buzz around new PET agents in neurology for detecting beta amyloid plaques associated with Alzheimer’s disease, it is cardiology that presents some of the most exciting opportunities for PET.”

PET vs. SPECT Technology
The future success of PET may be grounded in its inherently better image resolution. In cardiac scanning, it has generally been reported that PET offers a resolution of 5 to 7 mm, compared with
a cardiac SPECT resolution of 12 to 15 mm. Better performance has allowed data to emerge suggesting that as many as one in 10 scans interpreted as normal on SPECT would have been abnormal if done on PET due to the presence of unseen microvascular, triple-vessel disease. PET’s superior diagnostic capability is achieved partly through advances in hardware, particularly quantification, which leverages numerical precision to identify global perfusion defects in the heart that otherwise might be hidden from qualitative SPECT scans.

PET may have an ace in the hole in its ability to quantify results. Quantification is now being built into PET/CTs sold into mainstream medical practices. SPECT scanners lack the resolution of PET/CTs and SPECT vendors have yet to commercialize systems capable of quantification.

A big difference between the two technologies is the half-life of the isotope that each radiopharmaceutical tracer uses. SPECT tracers have a relatively long half-life (technetium-99m has a half-life of six hours), whereas rubidium-82 is only 75 seconds. This short half-life is a limitation of the current front-line cardiac PET radiotracer, which does not leave much room for error when imaging and presents the inability to do exercise stress testing.

New iterative reconstruction (IR) software such as UltraSPECT is improving SPECT image quality by boosting the signal-to-noise ratio. Just as in CT scans, IR can also help reduce dose by enhancing lower-quality scans.

**Advances in Radiotracers**

The next generation of PET imaging agents might herald an age when PET will eclipse SPECT as the “go to” modality for molecular imaging, according to Thijs Spoor, chairman, CEO and president of FluoroPharma, a company developing new PET radiotracers. He explained PET will do so by enabling personalized medicine through precision diagnostics, the ability to be delivered cost-effectively in a manner with less radiation to patients, by leveraging hardware advances already being commercialized. PET also is taking advantage of the extra throughput capacity present in the U.S. installed base of PET/CT scanners.

Fluorodeoxyglucose (FDG) created the oncology business for PET, and its growth was explosive, Spoor said. But while FDG is clinically very good, he says it is not perfect. It does not work on all cancers and only provides a look at the basic metabolism. This is opening the door for the next generation of oncology agents that are specific to cancers not well-characterized by FDG.

“While there is buzz around new PET agents in neurology for detecting beta amyloid plaques associated with Alzheimer’s disease, it is cardiology that presents some of the most exciting opportunities for PET,” Spoor said. “New cardiac PET agents promise robust, reproducible and dependable results in everyday cardiology practices and the need for these agents is mind-boggling.”

Cardiovascular disease is the single largest cause of global mortality, causing more than 17 million deaths each year, exacting an annual financial cost around the globe of a staggering $863 billion. In the United States alone, 729,000 people die from cardiovascular disease annually. Annual U.S. health costs are estimated to be $280 billion, rising to $800 billion by 2030.

**New PET Radiotracers**

Rubidium-82 technology has established benchmarks in the assessment of myocardial perfusion against which the next generation of cardiac agents can be measured for sensitivity and specificity. It also is producing data that should demonstrate the cost-effectiveness of cardiac PET over SPECT, and has pioneered the way for cardiac PET through the issuance of CPT codes and reimbursement policy by third-party payers for PET myocardial perfusion. But rubidium-82 has drawbacks that may limit its sustained clinical adoption as seen in recent publications. These limitations include supply chain issues, economics, its short half-life and potential safety issues as presented in the black box warning in the package insert. These issues should be resolved by the coming wave of new fluorinated cardiac PET radiopharmaceuticals.

Fluorinated positron emitters that compose the next generation of PET radiopharmaceuticals offer benefits over rubidium, including a longer half life of about 109 minutes. They also offer some clinical possibilities in the diagnosis and monitoring of cardiovascular disease beyond myocardial perfusion. Expected advantages of these new agents over SPECT radiopharmaceuticals are improved diagnostic accuracy, image clarity and lower radiation exposure to patients.

Lantheus Medical Imaging’s Flurpiridaz F-18 myocardial perfusion imaging agent is currently being evaluated in Phase III clinical studies. The agent can be used with exercise stress (PET is currently limited by its short half-life agent to pharmacologically
induced stress), and has a high extraction rate of up to 90 percent by the myocardium, which can help reduce the amount of agent and the radiation dose to the patient. Also, F-18 tracers are already being produced and have an established distribution network.

FluoroPharma’s BFPET, a fluorinated myocardial perfusion agent, exemplifies how the next generation of cardiac PET technology might boost diagnostic performance. In a study patient, BFPET indicated that the patient did not have a perfusion defect, as was suspected on the basis of SPECT, but rather suffered from apical thinning. Cardiovascular disease was confirmed through CT angiography — as was the absence of a perfusion defect.

BFPET has the potential to establish a new standard for measuring cardiovascular blood flow. The agent is being developed for use in combination with stress testing in patients with presumptive chronic coronary artery disease (CAD), as a replacement for SPECT in institutions with PET capability.

Healthcare reform emphasizes cost-effective care, so it is increasingly important to minimize the number of tests performed. The significance of getting it right the first time rises when considering the danger of cumulative radiation exposure to the patient, where the best diagnostic test done first might eliminate the need for subsequent invasive, expensive or unnecessary tests.

Several next-generation cardiac PET agents are designed to address unmet clinical needs. Whereas BFPET promises increased diagnostic accuracy compared with thallium and technetium-based SPECT agents, as well as advantages that go beyond the PET agent rubidium-82, CardioPET transcends even that, Spoor said. This agent, another in FluoroPharma’s pipeline, accesses a novel metabolic pathway, one that involves fatty acids, the primary source of energy for the cardiac muscle.

“Our studies indicate that imaging with CardioPET can potentially be used to accurately gauge fatty acid uptake by the myocardium. This uptake can be visualized and quantified using PET scanners that are becoming more available at price points within the grasp of routine practitioners,” Spoor explained.

Preliminary data indicates that the agent is especially suited for the diagnosis of acute coronary syndrome and chronic coronary artery disease in patients who cannot undergo stress testing.

By obtaining list-mode data on modern scanners, CardioPET may allow measurements of perfusion during the first five minutes of administration while scans done 40 to 60 minutes later may indicate tissue viability. These two clinical capabilities suggest the potential utility of CardioPET as a way to assess patients after they have complained of chest pain in the emergency department.

PET may offer an imaging option to detect heart failure and the risk of sudden cardiac death by imaging the sympathetic nervous system using the cardiac neuronal agent LMI 1195. Lantheus has this agent in a Phase I trial.

Research is ongoing for use of FDG F-18 agents to image cardiac sarcoid to identify patients at risk for sudden death. “We see huge promise to inject these patients with FDG to check for sarcoid, and if they have it, we can get them treated with an ICD [implantable cardioverter defibrillator] before they end up in a fatal situation,” said April Mann, CNMT, NCT, FSNMMI-TS, manager of noninvasive cardiology, Hartford Hospital, during a presentation at SNMMI 2013.

Another exciting area of research mentioned by several SNMMI presenters is the use of coronary flow reserve as a way to quantify the severity of coronary lesions, similar to fractional flow reserve (FFR) measurements made invasively in the cath lab. F-18 agents may offer the best imaging agent for this type of quantification due to its high myocardial uptake and eliminate the need for diagnostic catheterizations.

**New SPECT Radiotracers**

On the SPECT front, FDA in March approved a new indication for GE Healthcare’s agent AdreView (iobenguane I-123) as the first agent to link nerve function in the heart to a patient’s mortality risk. AdreView is approved for the scintigraphic assessment of myocardial sympathetic innervation (cardiac nerve activity) to assist in the evaluation of patients with New York Heart Association (NYHA) Class II or Class III heart failure and left ventricular ejection fraction (LVEF) ≤ 35 percent. Increased myocardial sympathetic activity is a prominent feature of heart failure and is often associated with decline in LV function, worsening heart failure symptoms and sudden cardiac death. This increase leads to a depletion of norepinephrine (NE) storage and uptake. AdreView provides a means for assessing the neuronal capacity for uptake of NE.

In January, Lantheus began shipments of its new LEU Technetium generator, which is the first technetium-99m (Tc-99m) generator in the United States that contains molybdenum-99 (Mo-99) produced from at least 95 percent low-enriched uranium (LEU). Through its supply chain diversification strategy, Lantheus plans to eventually eliminate the use of highly enriched uranium (HEU)-sourced Mo-99 from its supply chain. This is also in part due to its high myocardial uptake and eliminate the need for diagnostic catheterizations.
to a federal effort to eventually reduce the availability of HEU to aid interventional efforts to stop nuclear weapons proliferation.

Imaging Vulnerable Plaques

VasoPET, a next-generation positron biortracer being developed by FluoroPharma, is designed to address the unmet clinical need of identifying vulnerable plaques. These plaques are likely to rupture and cause a stroke or heart attack. Preclinical tests show that this fluorine-bearing radiopharmaceutical is taken up by inflammatory cells not found in stable plaque.

This agent is still in preclinical development, so it remains a speculative technology. The prospect is extraordinarily appealing for an agent that might be used in high-risk patients, particularly those being readied for cardiac catheterization.

“This technology could help the interventional cardiologist identify blood vessel segments that have vulnerable plaques to avoid them and the possibility of creating emboli in the vessel. In the future, this imaging might be used to preventively identify and treat these lesions. An imaging agent such as VasoPET would also be helpful in the development of therapeutics being tested for their ability to dissolve vulnerable plaques,” Spoor said.

Other modalities, including CT and MRI, cannot readily differentiate inflamed from stable plaques.

The challenge facing all these agents is whether they can deliver clinically significant results in the hands of routine practitioners and not just once in a while. Their results must be consistent and reproducible, rendering diagnostic and prognostic conclusions regardless of practitioner skill.

Serious Issues With Isotope Supply

Technetium, which fuels the majority of SPECT procedures in cardiology, has suffered several disruptions in supply over the past decade. A reactor at Chalk River Laboratories in Ontario, Canada, normally supplies about half of the world’s molybdenum, which serves as a generator of technetium. The vast majority of the technetium generators are used in the United States. Canada plans to permanently shut down the reactor in 2016 due to its age and safety concerns. Thus far, no other North American sources of molybdenum have surfaced to make up for this deficit.

In the past, supply disruptions have seriously impacted the nuclear medicine community. When a radioactive leak sidelined the reactor in 2009, extreme shortages of technetium resulted over the 15 months the reactor was out of service. Because molybdenum has a half-life of 66 hours, shipments from overseas reactors to the United States caused significant logistical headaches.

Some physicians turned to the PET tracer rubidium-82 to fill in until news broke last year that improper daily monitoring of the generator was resulting in strontium breakthroughs that left radioactive material in the patient long after a perfusion exam. While crossing the border between the United States and Canada in July 2011, two patients who had recently undergone rubidium-82 PET scans set off radiation alarms. It was learned that these patients had been inadvertently exposed to large doses of strontium contaminant, the parent isotope used in the generation of rubidium. Rubidium-82 was voluntarily taken off the market by Bracco pending review by the FDA and did not return to market until nine months later, after the FDA traced the fault to improper handling of the generator, not its manufacture. The incident has had lasting effects, however, on the molecular imaging community. Today, those using rubidium-82 must undergo special training and are subject to daily reporting requirements.

Currently, the U.S. Department of Energy (DOE) is the only domestic supplier of the isotope strontium-82 used in rubidium-82 generators. Positron Corp. is working with the FDA for certification so it can begin its own production of strontium-82, through its subsidiary Manhattan Isotope Technology, to provide a second source for the PET cardiac perfusion isotope.

Fluorinated positron emitters could be produced with relative ease in the United States, and the methodology for handling the fluorine-18 radioisotope has been vetted by decades of use and millions of procedures involving FDG without mishap, said Spoor. Fluorine-18 has a lower dose profile than SPECT radioisotopes, reducing the overall radiation burden placed on the patient. Dual isotope SPECT scans may expose the patient to between 25 and 30 mSv of radiation. SPECT rest-stress with technetium exposes the patient to between 8 and 10 mSv. In contrast, exposure from fluorine-18 scans range from 4 to 8 mSv, Spoor explained.

To the benefit of the molecular imaging community and the future growth of this modality, the widespread use of FDG with its utility in oncology led to a rapid expansion of the installed base of PET/CT scanners and establishment of an extensive and nationwide FDG distribution network. About 1,800 PET/CTs are operating in the United States and are served by about 100 commercial FDG production sites. Many of these scanners are running at only about half capacity. Consequently, early adopters of the next generation of PET radiopharmaceuticals will have ready access to the needed hardware to perform scans.

“It makes sense when performing medical imaging procedures to go with the modality that delivers the best image quality at the lowest dose, one that renders reproducible results regardless of the skill of the practitioner and is not vulnerable to supply-line disruptions. The case is that much stronger when this modality gains access to specialized radiopharmaceuticals that promise cost-effective and clinically significant testing that will expand the capability of routine healthcare practitioners in neurology, oncology and cardiology,” Spoor said.

Editor’s note: Thijs Spoor, FluoroPharma chairman, CEO and president, contributed to this article. He has more than 15 years medical industry experience. He is a former securities analyst at J.P. Morgan and Credit Suisse, covering the medical device industry. Before joining FluoroPharma, he led the nuclear cardiology portfolio and PET new product opportunity portfolio at Amersham/GE Healthcare.
Radiation exposure from multidetector computed tomography (CT) has become a pressing public health concern in both lay and medical publications. Implementation of iterative reconstruction offers the ability to minimize radiation exposure while preserving and, in some cases, improving image quality. However, in order to evaluate iterative reconstruction software, one must first understand the basics of how it works.

CT images are created from data and a computer uses software to reconstruct this data into a diagnostic-quality image. When CT was developed by Godfrey Hounsfield in the 1970s, the original reconstruction algorithm he used was iterative reconstruction (IR), where the software builds an image and then revises it with scores of reiterations to enhance image quality. However, computer speeds in the 1970s were so slow it took about 45 minutes to reconstruct a single slice using this method. A less intense computer power algorithm called filtered back projection (FBP) was adopted that could process slices in 30 seconds. This software has been the backbone of CT imaging for more than 30 years with only incremental improvements.

“You can get a fast answer to the problem of how to take all those inputs into the detector and create an image from them. The problem with filtered back projection is that it tends to have relatively high noise and relatively high dose,” said Jeffrey B. Mendel, M.D., staff radiologist, radiation safety officer, Parkland Medical Center, Derry, N.H., and assistant professor of radiology, Tufts University School of Medicine. He said FBP either offers high spatial resolution or high contrast resolution, but it cannot do both at the same time. However, IR does offer this ability and at lower doses.

As computing power and speeds rose exponentially in the 1990s and 2000s, IR saw a revival, especially in its ability to enhance image quality for lower dose scans. Lowering CT dose became a major issue in recent years after mass media reports of patients receiving radiation burns from newer CT scanners.

“Here’s the bottom line: radiation is scary and it is certainly very scary to the general public,” Mendel said. “The big driver to adopt iterative reconstruction is that we can reduce dose.”

With IR, the data is processed in a continuous loop where calculations are performed to create the different images; projection data is then processed and compared to assumed ideal models over and over to improve the image voxel-by-voxel.

“Iterative reconstruction solves the equation for each voxel in...
the image,” Mendel said. “It’s a slow, complex calculation, but it offers both low noise and dose, and the ability to do both high spatial and contrast resolution together.”

He explained iterative reconstruction times in the 1970s were terrible, and even with modern computers it is still very time-consuming. In addition, full iterative reconstruction images have a different appearance that radiologists are not used to seeing. The technique also creates its own set of image artifacts. Images can appear plastic because of the absence of noise, edges are artificially sharper and the tissue appears to be smudged or smoothed. IR can also cause blotchy pattern artifacts inside the borders of organs. To reduce the time required to reconstruct IR images and to reduce these artifacts, all current IR software programs use a blend of FBP and IR techniques. Only a percentage of IR is used and it can be adjusted up or down based on the radiologist’s preference. This mixed approach shortens the time to create an image and all IR systems, except one, can do this in about the same amount of time as FBP, Mendel said.

“I think everyone is uncomfortable when they move from something they know to something new,” he explained, saying the new look of IR CT images often causes apprehension about the technology because they are not used to seeing images in this way. “Noise is inherent to filtered back projection images, and what we are dealing with here is a perception that when we look at CT images, we expect it to have noise.”

In response to radiologists not being comfortable with the appearance of IR images, vendors developed advanced iterative methods (AIM) that reproduce the look of full-dose FBP scans using low-dose scan data. This is accomplished through how image noise is filtered, which is evaluated by frequency and then adjusted equally across the image so it does not shift the frequency spectrum. The end result is an image that looks more like traditional FBP. For example, compared to first-generation IR software, which had a 30 percent shift in the noise frequency spectrum, Philips’ current iDose4 AIM only has an 8-10 percent shift. “That is a remarkable difference in the visual appearance of the image,” Mendel explained. “It’s much more comfortable for us radiologists; they look like FBP and they are very easy for us to deal with.”

While the images now look similar to FBP, dose can be severely slashed. He said excellent coronary CT angiography (CCTA) images can be rendered from scans at just 0.25 or 0.8 mSv, instead of scans of 10 or more mSv.

**Understanding Differences in Software**

Mendel said each vendor offers its own version of IR software — ASIR, iDose4, AIDR, SAFIRE, Veo, IMR, IRIS and Intelli IP — and while all of them basically do the same thing, each has slightly different strengths and limitations. As a user, he said it is important to know these points to maximize the software’s utility.

It is helpful to know how each vendor’s software functions.

Some software applies IR after an initial FBP image has been created, others apply IR using the original projection data, and some perform two stages of IR on the original projection data and the final rendered version of the image.

As an example, a strength of a system that creates an FBP image first is speed, but if there is heavy noise or artifact in an area of the image, IR will not be able to completely clarify the anatomy unless it uses the original projection data. Another example is how common shoulder artifacts at the lung apexes are corrected automatically by some versions of IR software using the original projection data.

**Reducing Artifacts**

Beyond dose reduction, IR software can help reduce streaking, metal and blooming artifacts, increase the contrast-to-noise ratio in bariatric imaging and increase iodine opacification to help reduce contrast dose.

FBP causes artifacts because of low photon count areas (caused by metal, bone, wide body parts, calcified lesions and so on) that lead to high statistical error and are amplified by the Hounsfield unit bias introduced by the processing algorithm. First-generation IR greatly reduced streak and bias artifacts and AIM can nearly eliminate these artifacts in most scans.

In bariatric patients, where higher doses are used, sometimes image quality is limited by the scanner’s X-ray tube power. IR has the ability to improve image quality on these scans by better filtering noise than FBP. Mendel said a scanner tube that is maxed out at 60 kW can have its images enhanced with IR to the same level as a scanner with a 120 kW tube limit, effectively doubling the tube power for a scanner.

Mendel said the best way to understand the capabilities of IR software in various situations is to render images using the different techniques and compare them. “Iterative reconstruction is just like getting a brand new set of high-performance tires for your car, and you need to take your CT scanner out and see what you can do,” he concluded.

**Comparison Chart Compiled by Diagnostic and Interventional Cardiology**

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

### CT Dose Reduction

All submitted information appears on our website at www.DIcardiology.com.

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<td>Angular modulation</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>Iterative reconstruction technique</td>
<td>Yes</td>
<td>Yes</td>
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<td>Perfusion</td>
<td>ASIR, low kVp, axial shuttle</td>
<td>ASIR, low kVp, axial shuttle</td>
<td>ASIR, low kVp</td>
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<tr>
<td>Cardiac spiral phase modulation</td>
<td>Yes</td>
<td>Yes</td>
<td>N/A</td>
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<tr>
<td>Cardiac prospective acq</td>
<td>Yes</td>
<td>Yes</td>
<td>N/A</td>
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<tr>
<td>Methods used to reduce rescan of cardiac exam</td>
<td>HR monitoring prior to scan; ECG editing tools following scan; early beat avoidance in prospective mode</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Chest prospective acq</td>
<td>Yes</td>
<td>Yes</td>
<td>N/A</td>
</tr>
<tr>
<td>Maximum possible pitch with full image quality</td>
<td>1.375</td>
<td>1.375</td>
<td>1.75:1</td>
</tr>
<tr>
<td>Advanced processing to reduce dose</td>
<td>3-D filters, ASIR or Vio</td>
<td>VISR 3-D image filters or ASIR</td>
<td>3-D image filters or ASIR</td>
</tr>
<tr>
<td>Warning messages</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>DOSE PROTECTION / WARNING</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose notice window</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Can dose thresholds be set for exams or patient types to prompt operator if threshold crossed</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>PROTOCOLS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pediatric protocols</td>
<td>Color-coded for kids</td>
<td>Yes, included</td>
<td>Yes, included</td>
</tr>
<tr>
<td>Large patient protocols</td>
<td>User-defined</td>
<td>User-defined</td>
<td>User-defined</td>
</tr>
<tr>
<td>Enables different levels of dose reduction by protocol</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Protocols password protect</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>DOSE REPORTING</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tabular results</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Export / extraction</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Tracking / registry</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Dose on report/DICOM file</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Data available in reports</td>
<td>Dose SR provides the following modules: radiation dose, accumulated dose, irradiation event, scanning length, dose check details</td>
<td>CTDiVol, DLP, scan region, scan type, status comment, mA, KV, description</td>
<td>N/A</td>
</tr>
<tr>
<td>Supports IHE REM profile</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Encodes dose in DICOM radiation dose structured reports (RDSR)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Supports NEMA XR 25, 26, 29, other CT dose stds</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Perform dose QA analysis</td>
<td>Dose Check monitors and notifies user when prescribed dose levels exceed AV/NV thresholds</td>
<td>N/S</td>
<td>N/S</td>
</tr>
<tr>
<td>Can system submit dose reports to registries</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Other dose reporting or dose controls</td>
<td>Dose audit tool and report show users what changed in the system when someone modifies the AV/NV thresholds</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>
## Comparison Chart Compiled by Diagnostic and Interventional Cardiology

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

### Philips Healthcare

<table>
<thead>
<tr>
<th>iCT Family</th>
<th>Ingenuity Family</th>
<th>Brilliance CT</th>
<th>Definition Flash</th>
<th>Definition AS/AS+</th>
<th>Definition Edge</th>
<th>Somatom Emotion</th>
<th>Somatom Perspective</th>
<th>Aquilion One</th>
<th>Aquilion One</th>
<th>Aquilion Premium</th>
<th>Aquilion Prime</th>
<th>Aquilion RXL</th>
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### Siemens

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### Toshiba

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<tr>
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</table>

### Additional Features

- DoseRight
- Dose4 Premium Package, iDose4
- Heartmon, beat-to-beat variable-delay algorithm, ECG editing
- Flash spiral/flash cardio sequence
- Adaptive ECG pulsing and sequence
- ECG gating
- Adaptive ECG pulsing and sequence
- Arrhythmia rejection
- Heart-rate monitoring, beat-to-beat variable-delay algorithm, ECG editing
- 4-D noise reduction, neuro best contrast
- Age/weight-based
- Exposure record, DICOM RDSR
- Adaptive collimation

- Philips Healthcare
- Siemens
- Toshiba

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Dicardiology.com

July/August 2013 DAIC 35
**Toshiba Launches New Cardiac Ultrasound Systems**

Toshiba’s Aplio 500 and Aplio 300 CV (cardiovascular) ultrasound systems help clinicians more accurately and efficiently diagnose cardiovascular disease. Both offer premium 2-D cardiac exams and feature 2-D wall motion tracking technology, which provides visualization and quantitative analysis of myocardial wall motion with accuracy and reproducibility. With on-board quantification measurements in all directions (radial, circumferential, 2-D rotation and longitudinal), the systems are designed to get the most comprehensive information. Additional cardiac-specific technologies include tissue enhancement, advanced dynamic flow, lateral gain controls, tissue Doppler, stress echo, Flex-M mode and auto IMT. Both systems are easy to use, with superior ergonomics and a smaller footprint.

Toshiba | [www.medical.toshiba.com](http://www.medical.toshiba.com)

**FDA Expands MultiHance for Magnetic Resonance Angiography**

The FDA approved the use of MultiHance (gadobenate dimeglumine) injection, 529 mg/mL, in magnetic resonance angiography (MRA) to evaluate adults with known or suspected renal or aorto-ilio-femoral occlusive vascular disease. Bracco’s MultiHance was already the highest relaxivity gadolinium-based contrast agent available for intravenous use in MRI of the central nervous system.

Bracco | [www.multihanceusa.com](http://www.multihanceusa.com)

**UltraSPECT Partners with PharmaLogic to Offer Dose Reduction Solution**

UltraSPECT announced its distribution agreement with PharmaLogic for the sale of UltraSPECT’s cardiac and bone imaging applications. The agreement enables PharmaLogic to provide its hospitals and imaging centers with access to UltraSPECT’s Xpress line of products for lower radiation dose with no diminished image quality. Through the use of UltraSPECT’s Wide-Beam Reconstruction (WBR) technology, the products in the company’s portfolio can significantly reduce the standard radiopharmaceutical dose requirements for cardiac and bone nuclear medicine imaging exams, and/or cut the imaging procedure time in half while maintaining the image quality the facility is accustomed to. Many times they even enhance the image resolution. The company’s Xpress3.Cardiac solution provides benefits — enabling nuclear exams to be performed with 50 percent reduction in both dose and procedure time. UltraSPECT’s WBR technology is compatible with most major manufacturers’ nuclear medicine (NM) systems.

UltraSPECT | [www.ultraspect.com](http://www.ultraspect.com)

**Siemens Offers New MR Breath-Holding Software**

The U.S. Food and Drug Administration (FDA) cleared the CAIPIRINHA (Controlled Aliasing in Volumetric Parallel Imaging Results IN Higher Acceleration) software as part of Siemens’ syngo MR D13A software package for parallel magnetic resonance imaging (MRI). The MRI software helps enable patients with breath-holding difficulties to reduce the amount of time they hold their breath by up to 50 percent without sacrificing imaging resolution or contrast.

The software enables acquisition of higher-quality 3-D volumetric interpolated breath-hold sequence (VIBE) T1 images through higher acceleration factors.

www.siemens.com/healthcare

**CX50 xMATRIX Offers TEE, ICE, Diagnostic Features**

CX50 xMatrix now offers 2-D intracardiac echo (ICE) capability. The system has been the only ultrasound system with the flexibility of a portable system together with Live 3-DTEE capability. Now it integrates with the St. Jude Medical ViewFlex Xtra ICE catheter, a new, 2-D catheter featuring four-way steering and the unique benefit of single-handed control. The CX50 xMatrix is an all-in-one imaging solution for cardiac cath labs, EP labs and hybrid operating rooms. With both ICE and Live 3-DTEE available on a single system, hospitals will not need to rely on scheduling two separate ultrasound systems for various procedures.

Philips | [www.philips.com](http://www.philips.com)
Emory Toolbox 4.0 Launches SmartReport, Cardiac Imaging Decision Support System

Syntermed Inc. gained 510(k) clearance for Emory Cardiac Toolbox version 4.0. It offers SmartReport, the first cloud-based nuclear cardiology reporting tool using decision support. The decision support system that powers SmartReport is called Syntermed IDS and will allow diagnosticians to perform faster, more accurate nuclear cardiology reports from SPECT and PET heart scans. Emory Toolbox 4.0 was totally rebuilt on a progressive .NET framework to maximize the computer and network technologies, but it still has the same familiar user-guide. Designed to increase lab workflow and efficiency, it has a more intuitive user interface that supports a dynamic Windows manager and a new 3-D display, and it offers simplified packaging. The system is Internet based.

Syntermed | www.syntermed.com

MIM Offers Single Platform Viewing Solution for PET, CT, MRI and Nuclear

A new version of MIM Encore provides a single platform for viewing positron emission tomography (PET), computed tomography (CT), magnetic resonance imaging (MRI) and nuclear medicine exams. Users will benefit from having all of the imaging data they need available on one workstation. Additionally, integrated quantitative analysis solutions are available for both cardiac and neuro PET and single photon emission computed tomography (SPECT) providing an all-in-one solution for nuclear medicine departments.

MIM Software Inc. offers solutions for PC and Mac workstations, as well as mobile iOS and cloud-based platforms.

MIM Software | www.mimsoftware.com

Preventice Offers Remote Patient Monitoring

Preventice’s mobile health solutions for remote patient monitoring, the BodyGuardian Remote Monitoring System (RMS), includes a small, wearable body sensor that collects important physiological data from patients with cardiac arrhythmias. The company received FDA clearance for this solution in September 2012. It was developed in collaboration with Mayo Clinic and STMicroelectronics.

Preventice | www.preventice.com

Schiller Offers MS-2015 Touch Screen ECG

The Schiller 12-Lead ECG MS-2015 unites precision, performance and a sophisticated but simplified user interface. The system operates by touching the large, 15-inch, high-resolution, color display. Clinicians can quickly record, select and print high-quality 12-lead ECG’s. Since MS-2015 exports ECG’s in XML, PDF and DICOM format, users can transmit recordings to any system that supports these industry standards.

Schiller | www.schilleramerica.com

Welch Allyn Single-Use Blood Pressure Cuff Aids Infection Control

Welch Allyn’s FlexiPort EcoCuff blood pressure cuff and EarlySense Vitals surveillance system both enable improvements in patient safety and clinical decision-making. It is a single-patient-use blood pressure cuff that helps fight cross-contamination and rising costs while also having less environmental impact than other disposable blood pressure cuffs. EcoCuff is designed to remain with one patient for the duration of the hospital stay and then disposed of upon release.

As part of the FlexiPort line of disposable blood pressure cuffs, EcoCuff utilizes the FlexiPort single-point connection standardization system, making the EcoCuff compatible with virtually every device throughout the hospital.

Welch Allyn | www.welchallyn.com

MIM Offers Single Platform Viewing Solution for PET, CT, MRI and Nuclear

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MIM Software Inc. offers solutions for PC and Mac workstations, as well as mobile iOS and cloud-based platforms.

MIM Software | www.mimsoftware.com
Cleansing your mouth and cleaning your arteries could be as simple as a once-a-day oral rinse if additional clinical studies confirm preliminary findings about a new product. The Biomedical Development Corp. (BDC) presented data in April to the American Academy of Oral Medicine showing that its oral rinse was safe and effective at fighting gingivitis in a recent clinical trial. But the most surprising finding of the study was that users of the oral rinse showed significantly lower LDL cholesterol levels than the placebo group.

“We didn’t expect to see any difference in LDL cholesterol,” said Charles Gauntt, the study’s principal investigator. “We expected to see improvements in oral health, and we did. But we also monitored a number of biological markers for inflammation. The results showed the oral rinse had no adverse effects and users exhibited lower levels of LDL, or what many people know as bad cholesterol. This definitely merits further study.”

The three-month, phase II trial was funded by the National Heart, Lung and Blood Institute (NHLBI). The trial was preceded by a phase I clinical trial for safety and a phase II pilot efficacy clinical trial. Another, longer phase II trial is now under way and will evaluate gingivitis patients over a six-month period. This new trial, conducted by the Center for Oral Health Research at the University of Kentucky, will monitor gingivitis and LDL cholesterol levels as the previous trial did. The NHLBI is funding the research, which is also supported by the Kentucky SBIR/STTR Matching Funds Program.

BDC’s product is designed as a once-daily, 30-second oral rinse. The active ingredient is a proprietary formula based on iodine. The National Institutes of Health (NIH) Office of Dietary Supplements fact sheet on iodine addresses a variety of important roles for iodine in the human body, from helping the thyroid function properly to appearing to play a part in the body’s immune response system. About 40 percent of the world’s population is thought to be at risk of iodine deficiency.

Gauntt also notes that iodine is known to be effective in inactivating viruses, bacteria and fungi. He is intrigued by recent clinical studies showing what appears to be a closer link between oral health and cardiovascular health. Although scientists cannot yet fully explain how the two are connected, there is ample statistical evidence to suggest that gum disease and heart disease are closely related. According to the American Academy of Periodontology, people with periodontal disease (gum disease) are almost twice as likely to have coronary artery disease. The academy also notes that one study showed stroke victims were more likely than the general population to also have oral infections.

Gauntt believes that future research might make it much clearer that a healthy mouth, free of gum disease and its associated toxins and bacteria, is critical to a healthy cardiovascular system. Although further study is required, he believes BDC’s oral rinse may eventually prove to be an important tool in keeping both mouths and cardiovascular systems healthy, in addition to proper nutrition and exercise.

Phyllis Siegel, CEO of BDC, said that while results of its ongoing clinical trials are pending, a specific formulation of the product called iClean Mouths, designed for general mouth cleaning, will soon be available.

The iClean Mouths mouth rinse retails online for $30 for an 8-ounce bottle.

The company anticipates additional scientific studies on the ability of the wash to reduce oral inflammation and may look to the private sector for funding of cholesterol-related research.
tct 25

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When time is tight, efficiency is everything. So we’ve worked closely with clinicians to develop the Vivid* E9 Breakthrough 2012, featuring our 4D TEE transducer that delivers excellent image quality. Exceptional ease of use. And breakthrough workflow efficiency—from acquisition to navigation to quantification.

Vivid E9 helps clinicians to assess the anatomy, quantify heart function and quantify valve structure in the echo lab, cath lab and OR. User-friendly navigation tools enable efficient image-guided procedures—such as ASD, VSD, or PFO closures, aortic valve replacements, TAVR procedures, and mitral valve repair—in the cath lab, OR or Hybrid OR.

Contact your GE rep for information on the Vivid E9 Breakthrough 2012 with the 4D TEE transducer.

When time is critical...