November/December 2017
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Diagnostic and Interventional Cardiology

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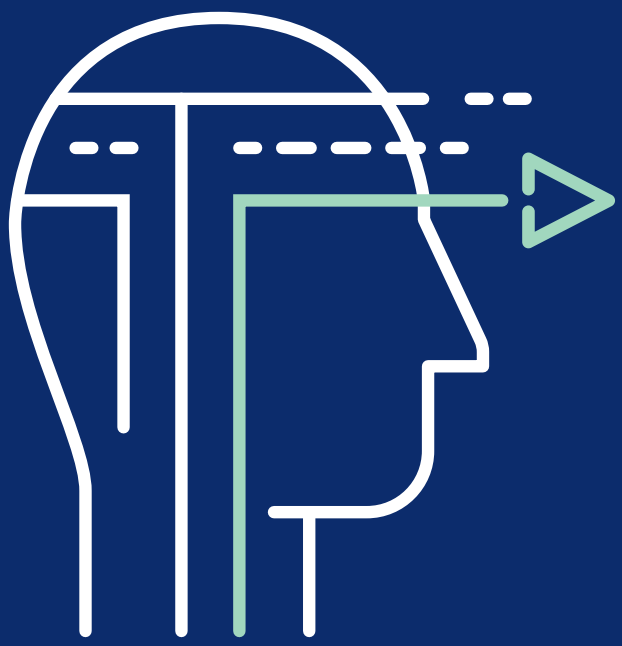

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Consolidation of Cardiology Data and its Integration Into the EMR

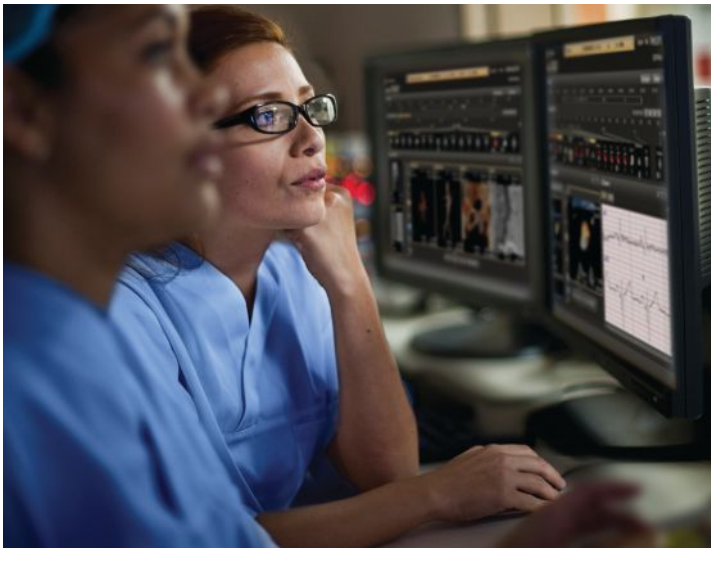
By Dave Fornell

Chonsolidation of data in one location to improve efficiency and enable data analytics, as well as smooth integration with enterprise electronic medical record (EMR) systems are the two main priorities for most hospitals today looking for a new cardiovascular information system (CVIS). CVIS vendors worked over the past several years to create truly vendor-neutral systems that enable a single point of access to patient information from different sources. The newer systems can quickly retrieve a patient's complete cardiology file, generate a report and distribute it, all during one session, even from a remote location.

Cardiac Specialty Reporting Systems Outside the EMR

While most hospital systems are migrating to large, all-encompassing EMRs, the cardiology reporting modules offered by these EMR vendors often lack the depth in reporting that long-time CVIS vendors can offer. Epic has captured a growing share of the EMR market and is billed as a one-stop shop for all of a hospital's information technology needs. However, complaints from various subspecialties including cardiology, radiology, oncology, orthopedics, etc., have been that the Epic specialty reporting modules lack depth, or are missing needed reporting parameters, or do not offer device connectivity to imaging modalities, patient testing or monitoring systems. This can include data integration with electrophysiology (EP) mapping and recording systems, or cath lab hemodynamic systems.

So, while large EMR companies like Epic, Cerner, Allscripts and others have many hospitals using their systems, many cardiology and radiology departments have been successful in maintaining their own speciality reporting systems. However, as health information technology (IT) departments become more



The Philips IntelliSpace is an example of the newer generation of cardiovascular information systems (CVIS) that can consolidate all cardiology department data sources into one location.

Participants

Carestream Health
www.carestream.com/vue-cardiology

Change Healthcare
www.mckesson.com/cardiology

Fujifilm Medical
www.fujifilmusa.com

GE Healthcare
www.gehealthcare.com/cce

Infinitt Healthcare
www.infinittna.com

Konica Minolta
www.konicaminolta.com/medicalusa

Lumedx Corp.
www.lumedx.com

Merge Healthcare
www.merge.com

Novarad
www.novarad.net

Philips Healthcare
www.usa.philips.com/healthcare

Sclmage
www.scimage.com

Siemens Healthineers
www.usa.siemens.com/CVIS

UltraLinq Healthcare
www.ultralinq.com

Scranton Gillette Communications obtained the model specifications from the manufacturers.

deeply involved in all clinical aspects of healthcare operations and gain more oversight in decisions on what software systems are purchased, the need for deep interoperability with the EMR is usually a deciding factor.

This need to play nice with big EMR vendors has led to a change in the market dynamics. In the past decade, former EMR competitors like GE, Siemens, Philips and McKesson-Change Healthcare have moved away from developing their own EMRs to focus solely on their subspecialty reporting systems. This includes complementing and being compatible with the main EMR vendors, rather than competing with them.

An example of this type of integration with Epic are the eight hospitals that make up West Virginia University (WVU)Health System. It adopted SciImage's PICOM365 Enterprise PACS (picture archiving and communication system) to enable cloud-based cardiovascular image management, viewing and reporting capabilities with seamless workflow. This includes connectivity for all cardiology modalities (echocardiography, nuclear cardiology, stress, Holter and ECG) and full integration to Epic.

"The system's agility and scalability allows us to customize our workflow to our specific requirements for reading and interpreting exams, which includes the ability for our physicians to review and report from anywhere," said Partho Sengupta, M.D., director of cardiovascular imaging at the WVU Heart and Vascular Institute. "This innovation supports a new age of caring for patients through automation and speed to provide better and more cost-effective care."

The system also offered the ability for employees to work remotely, said Jim Venturella, chief information officer, WVU Medicine. He said selection criteria was created to evaluate several third-party CVIS vendors. A key area they looked at was the ability of a CVIS to enable remote imaging and remote consultations while still being able to interface with Epic.

Most CVIS vendors now offer web-based platforms operating on increasingly non-proprietary, open standards software. This enables greater connectivity with EMRs, medical devices and imaging systems from various vendors.

Consolidating Cardiovascular Information

Cardiology departments often have multiple legacy software systems and the need to connect medical equipment from numerous vendors. This has led most departments looking to buy a new CVIS to find a solution that can easily integrate all of these devices and data sources into one database.

"We were really looking for an integrated or interfaced product that could manage all of our modalities, no matter what the brand was," said Kathleen Morrow, cardiovascular informatics manager at Memorial Hospital of Gulfport, Miss. The hospital chose Change Healthcare's McKesson Cardiology CVIS to bring together its reporting from across all cardiac imaging, testing and monitoring systems made by GE, Philips and Siemens. Physicians also started using structured reporting to allow more thorough documentation and to pull statistical reports for a range of functions. This has included an interface to registry reporting software to save staff time when sending information to the American College of Cardiology's (ACC) CathPCI Registry. Structured reporting also increases the efficiency and completeness of the data and allows reports to be immediately available after a physician signs off on it.

"We are able to monitor the usage of equipment and practices, and the doctors can more efficiently report," Morrow said. "The doctors can perform more studies per day because they are not spending as much time doing the reports."

Another example of this type of cardiovascular data consolidation is a long-term, multiphase CVIS project Lumedx entered into recently with Baylor Scott and White Health. The Baylor Jack and Jane Hamilton Heart and Vascular Hospital in Dallas implemented the vendor's CVIS to enable comprehensive cardiovascular data management, connecting isolated data sources and integrating with the enterprise EMR to eliminate redundant data collection. It also incorporates business and clinical performance analytics to identify improvement areas.

"The system allows physicians to link acquisition of registry-required data with creation of the procedure-specific report," said Kevin Wheelan, M.D., chief of medical staff, Heart and Vascular Hospital. "This improves the accuracy of the data and the robustness of our internal quality improvement."

At the 2017 ACC annual meeting, Philips showed new features in its IntelliSpace Cardiovascular CVIS. It brings multimodality images and clinical tools together in a single workspace. It seamlessly integrates with Philips' advanced visualization, ECG management and cath lab workflow solutions. It presents patient data in an easy-to-read, chronological format that uses icons for various patient data. This may reduce duplicate studies when all priors are seen on one screen. DAIC

Additional CVIS Resources

Read the article "5 Questions to Ask When Purchasing a CVIS."

http://bit.ly/2yqL5sd

Read the article "How Artificial Intelligence Will Change Medical Imaging."

http://bit.ly/2fTGkA0

Watch the VIDEO "Minneapolis Heart Institute Saves With Analytics Software."

http://bit.ly/2yrsQmu

Comparison Chart Compiled by Diagnostic and Interventional Cardiology

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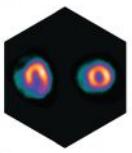
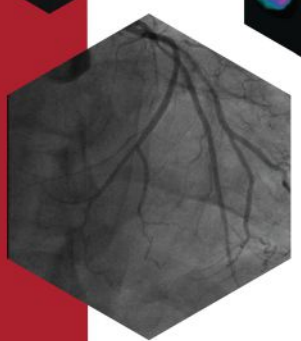


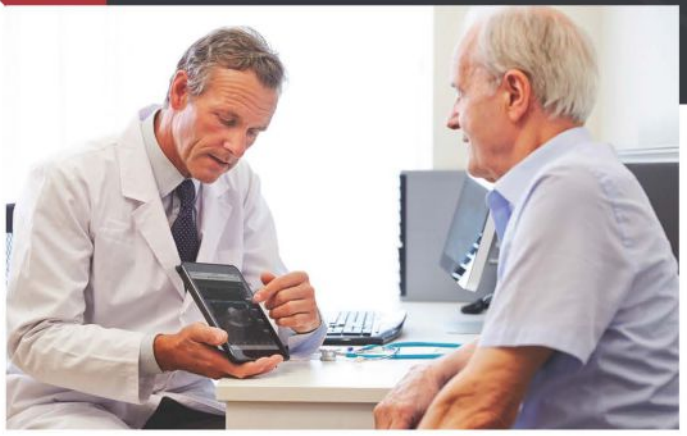


Cardiology requires a unified workflow that supports diagnosis from any location. PICOM365's full post-processing capability, one-click access to integrated tools and industry-leading third-party software applications enable efficient reading and reporting for any image. PICOM365 also features integrated structured reporting for all cardiology disciplines (Cath, Echo, Nuclear, Vascular, Stress, Holter, ECG Management, etc.) in a single platform. PICOM365's flexible architecture gives you fast access to any image, software system or report in an on-premise, Cloud or hybrid solution.

- Quantitative cardiac perfusion and function using SPECT & PET
- Native dual volume MPR, MIP and curved MIP for comparative review
- Evidence-based structured reporting with offline measurements
- Universal web viewer featuring advanced diagnostic measurements

Improving Patient Care
By Combining Humanitarianism With Technology

WVU Medicine Deploys Cloud-Based CVIS to Expand Access throughout West Virginia using PICOM365's Cloud Imaging and Consultation Capabilities



WVU Medicine is Making a Change

West Virginia residents experience disproportionately high instances of cardiovascular disease in comparison to other states, with greater than 40 percent of adults suffering from hypertension and only two out of 10 adults receiving screening for cardiovascular risks. These statistics, coupled with a shortage of healthcare professionals, provide West Virginia with a unique opportunity for innovation and improvement in the detection of latent cardiovascular disease.

"Our goal is to use advanced cardiac visualization and imaging management technologies to detect the early stages of the disease and improve patient care," said Partho Sengupta, MD, Professor and Chief of Cardiology and Chair of Cardiac Innovation at West Virginia University. "ScImage's Cloud-based enterprise imaging solution for cardiology is helping us expand access to high-quality cardiovascular care throughout West Virginia. PICOM365's availability allows remote imaging and consultation so patients can receive services wherever they live."

WVU Medicine has deployed ScImage's PICOM365 Enterprise PACS at the Heart and Vascular Institute for integration throughout the entire WVU Medicine infrastructure which is anchored by a 645-bed academic medical center and includes four community hospitals, three critical-access hospitals and a children's hospital.

ScImage's PICOM365 is a fully-realized Cloud PACS solution offering a resilient computing infrastructure securely accessible from anywhere utilizing high availability technologies with end-to-end redundancy. Far beyond one instance serving one institution, geo-redundant storage systems with multi-petabyte scalability have the power and flexibility to leverage massive bandwidth for maximum data throughput to simultaneously serve thousands of institutions. PICOM365's secure end-to-end imaging and reporting workflow feature real-time advanced threat analytics along with data encryption at rest and in transit. Additionally, full IT and medical device regulatory compliance capability eliminates all barriers to entry, allowing full functionality with ease.

"ScImage has an excellent solution to support our non-invasive cardiology needs for a project of this scale (advanced reporting capabilities, remote work and full integration with Epic, etc.). With PICOM365, we can make a remarkably positive impact on patient care in West Virginia," said Jim Venturella, CIO WVU Medicine.

Partho Sengupta, MD, Professor and Chief of Cardiology and Chair of Cardiac Innovation at West Virginia University
Photo courtesy of the American Medical Association

About ScImage

Founded in 1993, ScImage remains a customer-first, private company with a mission to provide innovative enterprise imaging solutions to the healthcare industry. ScImage's unique single-database PICOM365 enterprise platform delivers end-to-end imaging workflow for Cardiology, Radiology, Women's Health, Orthopedics, Ophthalmology and more. Scalable from a single physician practice to multi-hospital enterprises, PICOM365 is delivered on premises, in the cloud, or as hybrid - based on user choice. The perfect synchrony created between on-site and cloud resources allows PICOM365 to provide secure VPN-less image exchange solutions among legacy silo systems, cloud users, and various EHR systems.

Learn more at www.scimage.com.

About WVU Medicine

WVU Medicine unites the physicians and scientists of the West Virginia University Health Sciences Center with the hospitals, clinics, and health professionals of the West Virginia University Health System. Together, they are a national leader in patient safety and quality, and are unified and driven by an unbridled passion to provide the most advanced healthcare possible to the people of West Virginia and beyond.

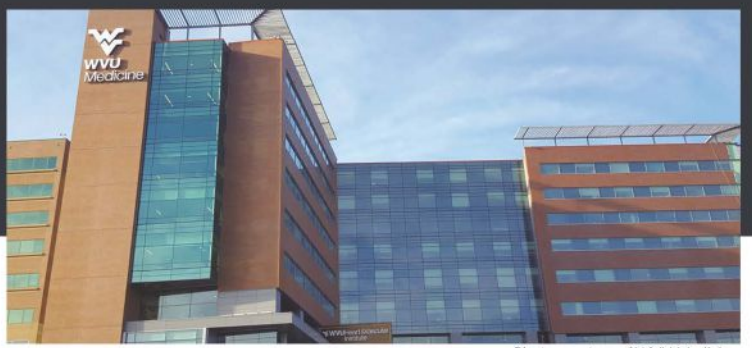


Photo courtesy of WVU Medicine

The Cloud: Disruptive Innovation that Supports a New Age of Caring

PICOM365 delivers secure cardiovascular image management, viewing and reporting capabilities to all cardiology modalities (Cath, Echo, Vascular, Nuclear, Stress, Holter and ECG Management) on a seamless viewing platform, providing WVU Medicine the full benefit of an on-premise solution in a "pure Cloud" offering.

"This comprehensive Cloud solution allows seamless integration of imaging and full workflow customization to meet our specific exam interpretation requirements while empowering physicians to review and report from anywhere. This is a disruptive innovation that supports a new age of caring for patients using automation and speed to provide better and more cost-effective care," added Dr. Sengupta.

ScImage and WVU Medicine, leaders in forging predictive solutions to improve patient care and increase physician efficiency, have worked to optimize structured reporting, with advanced ASE-evaluated measurements and sectional reporting among other productivity enhancements. ScImage's inclusion of full Epic integration providing discrete data, image links, encapsulated PDFs and diagnostic view-and-report capability creates a fluid EHR interaction. Added flexibility to control the presentation of the final report, the by-product of the diagnostic procedure, improves the referring clinician experience.

Grace Verzosa, Assistant Director of Cardiovascular Imaging at the Heart and Vascular Institute, stated the ability to customize the workflow was critical. "To enable our physicians to read current and prior studies and report with maximum efficiency, we needed the freedom to develop our workflow recipe, including customizable hanging protocols, tight integration with quantification and visualization software tools in a consistent SR platform across all cardiology disciplines."

ScImage's open SQL database maintains the quality of images and patient data in its native format to access, run reports, pull priors and customize pre-fetching rules. Full reporting capabilities via VR, transcription and Macros enables automated report generation; and, as technologists enter measurements from echo exams, PICOM365 auto-populates preliminary reports using the most current ASE guidelines.

"Not only is the reporting process more efficient, but it also reduces the need for fellows to conduct preliminary reads and has reduced our report turnaround times," said Verzosa. "PICOM365 has also provided many quality enhancements. For example, I can review studies offline at any time and correct inaccurate measurements for the final report. Additionally, the configurable "To-Do List" includes a reporting checklist, which ensures that reports are completely finalized, assuring a more accurate diagnosis and complete billing."

Making a Difference in Population Health

The WVU Heart Center Innovation Lab is known for pursuing new technology and methods to increase population health. Dr. Sengupta noted, "Advanced imaging and visualization tools have made tremendous strides in improving the diagnostic process. However, inequality in access to these tools remains, and that is where the automation and speed of Cloud-based imaging technology are so important; improved access leads to better patient care and, ultimately, better outcomes."

Sai Raya, PhD, founder and CEO of ScImage explained, "as Cloud PACS have become more popular, their true definition has become more dubious. With so many companies offering so many Cloud PACS, differentiating between competitors can be difficult, leading to the misconception that simply moving servers from an on-premise cabinet to a commercial data center is a sufficient solution to storing vital data. This is not a solution; this is a single point of failure." WVU, upon careful consideration of all options, determined a pure Cloud solution to be the most effective pathway to improved health access and outcomes for West Virginians.

"By leveraging Microsoft Azure technologies, ScImage utilizes the industry's most advanced Cloud security and encryption technologies allowing us to focus on providing the best care through remote imaging and consultation without worrying about security. ScImage brings industry-leading technology to the table as well as the positive outlook necessary to move innovation from ideas to real solutions," concluded Dr. Sengupta.

COMPARISON CHART

Cardiovascular Information Systems (CVIS)

Company	Carestream Health	Change Healthcare	Fujifilm Medical Systems	GE Healthcare	Infinitt Healthcare	Konica Minolta
Product name	Carestream Vue Cardio PACS	McKesson Cardiology	Synapse Cardiovascular	CentricityCardio Enterprise (includes Centricity Universal Viewer and Cardio Workflow)	Infinitt Cardiology Suite	Exa
Total number of network systems implemented	>300	>600	Our global installed base is 400 unique customers	This information can be made available with a fully executed non-disclosure agreement	205	80
# of cath labs connected by vendor	>300	>800	>600		74	N/A
# of review stations connected by vendor	Web-based solution, unlimited # of review stations	>2,025 + web access	Over 4,000 non-inclusive of facilities with site licensing structure		Web-based so there is no limit to the number of concurrent users connected	Not finite. Anywhere, all-the-time, no limits access via web
Modalities supported	Angio, cath, echo (cardiac and vascular), nuclear cardiology, ECG/Holter/event monitoring, cardiac CT, cardiac MR, NM, OT, SC, US and IVUS, XA. Can be expanded to include other modalities	CT, ECG (rest, stress, Holter), EP, IVUS, MR, NM, US, XA	Adult, pediatric and fetal echo, ECG, Holter, stress ECG, cardiac rehab, pulmonary function, nuclear cardiology, noninvasive vascular, cardiac catheterization, IVUS, FFR, electrophysiology, invasive peripheral vascular, cardiac CT and cardiac MR	All DICOM modalities	DICOM, XML and HL7 devices: US, XA, ECG, NM, TMT, HT, OT, MR, CT, RF, EEG, EMG, PFT, etc.)	NM, echo, stress echo plus all DICOM supported natively. Many non-DICOM images and files supported either natively, or with third-party integration
Reporting modules for what specialties	Cath (interventional and diagnostic, echo (cardiac and vascular), stress-echo, nuclear medicine, vascular, obstetrics, stress, Holter, ECG. Can be expanded to include other modalities	Cardiac and peripheral cath, cardiac and vascular ultrasound, nuclear, EP, ECG, stress and Holter (supporting adult, congenital, pediatric and fetal patients)	Adult, pediatric and fetal echocardiography (including pediatric and fetal Z-scores) ECG, Holter, stress ECG, nuclear cardiology, noninvasive vascular, cardiac catheterization, electrophysiology, invasive peripheral vascular, cardiac CT and cardiac MR	Diag and interv. cath, EP implants, EP ablations, EP CRM, IPV, NIPV, adult and pediatric echo, ECG, stress, stress echo, nuclear	Offers an extensive library for various reporting template types across cardiology/cardiovascular services: echo, noninvasive vascular, nuclear medicine, cardiac cath, EP, resting ECG, pharmacologic and extercise stress testing, Holter monitor, EEG, EMG, PFT, event monitor, tilt table, etc.	User-customizable structured data entry (SDE or structured reporting), transcription with built-in recorder, and voice-recognition/ user-customizable templates for all modalities. SR auto-population in SDE reports for echocardiography
Does system offer ECG management	Yes, system has native built-in ECG management	Yes, native ECG management system and mobile application	Synapse Cardiovascular integrations with the Epiphany Cardio Server and GE Muse ECG management systems	Yes, with Muse system integration	Yes	No
What format are ECG waveforms saved as	DICOM, XML, PDF	DICOM if received as DICOM from applicable systems, otherwise proprietary XML in the DB	XML, PDF, DICOM	PDF, DICOM PDF	DICOM, XML, .324, PDF, JPEG	No waveform support
Integration with radiology PACS	Integration with Carestream Vue PACS provides an enterprise solution for storing and viewing all cardiology and radiology procedures. Integration with other PACS supported through standard protocols including DICOM and HL7	Integration includes DICOM archive and cross- launch in patient context with McKesson Radiology PACS, Philips iSite, Siemens syngo.via, GE Centricity, Carestream	Single sign on with patient level integration to Fujifilm Synapse PACS and Synapse VNA. Integration with other PACS supported through standard protocols including DICOM and HL7	Yes, Centricity Universal Viewer provides a unified view of cardiology and related radiology exams in a web-based viewer with integrated analysis tools. Centricity Clinical Archive provides an open architecture VNA	Yes, Infinitt Radiology PACS utilizes the same database; also HL7 integration gateway or Infinitt VNA for 3rd-party PACS: Syngo, Horizon Radiology	Yes, Exa is also a radiology PACS
Integration with electronic medical records (EMR/EHR)	Can integrate with all leading HL7 capable systems including Epic, Soarian, Cerner, Meditech, McKesson, NextGen	Yes, such as: Epic, Cerner, MC Clinicals, Paragon, Allscripts, Meditech, Centricity	All major EMRs including Epic, Meditech, Siemens, Cerner, McKesson, Allscripts, NextGen. Supports integration with Epic Cupid Reporting, patient content linking and export of discrete data elements	Yes, multiple vendors including Epic, Cerner, MediTech, ASP, others with non-proprietary HL7 interfaces	Yes, integrates with EMR systems supporting HL7 or direct call by the EMR to the Infinitt Viewer: Epic, Centricity, Soarian, others with non-proprietary HL7 interfaces	Yes
Integration with hospital information systems (HIS)	Supports most HL7 bidirectional communications	Yes, HL7, PDF, allergy, meds, billing, inventory, distributed client/viewer API	Currently integrated with all major EMRs including Epic, Meditech, Siemens, Cerner, McKesson, Allscripts, NextGen, others via HL7, HTML, XML and other proprietary	Yes, with non-proprietary HL7 interfaces	Yes, integrates with HIS systems supporting HL7	Yes
Integration with cath lab hemodynamic systems	Can capture and database procedural, inventory, measurements, etc. via HL7 or XML	Yes, integration with 3rd-party hemo systems. In addition, McKesson offers a McKesson Hemo System integral to the McKesson CVIS	GE Mac-Lab, McKesson Cardiology Hemo, Mennen Horizon, Merge Hemo, Philips Xper/Witt, Siemens Sensis	GE Mac-lab, Philips Xper, Siemens Sensis and Merge Healthcare	Yes, via HL7 or XML: Mac-Lab, Merge Hemo, Xper, McKesson Hemo, Mennen	No

Scranton Gillette Communications obtained the model specifications from the manufacturers.

N/A = Not applicable
N/S = Not specified

Editor's Note: Diagnostic and Interventional Cardiology also offers all submitted product information on our website at www.DIcardiology.com.

Lumedx Corp.	Merge Healthcare, an IBM Company	Novarad	Philips Healthcare	SciImage Inc.	Siemens Healthineers	UltraLinq Healthcare Solutions
HealthView CardioPACS	Merge Cardio	NovaCardio CVIS/PACS	IntelliSpace Cardiovascular / Xcelera	Picom365	syngo Dynamics VA20	UltraLinq
Over 50 PACS implementations	>275	Information upon request	>600	>500	Over 550 production systems, including previous releases	>500
Over 100 cath labs (GE, Siemens, Philips, etc.)	>550	Information upon request	1,500 (actual labs, not sites), majority of them Philips	>300	N/S	>20
Over 500 diagnostic review workstations	>7,700	Information upon request	9,000+ (majority of install base are site licenses)	Unlimited, review stations are virtual	Over 5,500	Cloud PACS, exams viewable via any internet-enabled device
XA, MR, CT, NM, US, RF, IVUS, CR, DR, PET, OCT	US, XA, NM, MR, CT, RF, CR, DF, DX, MG, PT, VI, CF, IVUS, EP, OT, IVOCT	XA, MR, CT, NM, US, RF, IVUS, CR, DR, PET, OCT. All imaging modalities supported	Cath, US, NM, MR, CT, IVUS, ECG, EP	Cath, echo, vascular, angio, nuclear medicine, ECG, CR, CT, DX, ES, MG, MR, OT, PT, RF, SC, US, XA, mammo	XA, US, NM, CT, MR, CR, DX, ECG	Echo, cath, ultrasound (US), IVUS, NM, CT, MRI, angio, ECG, Holter, MSK, ABI, XA, DX
Cath, EP, IR, echo, PVI, PVD, nuclear, CT, MR, stress, Holter, ECG, cardiac surgery, thoracic surgery, pediatric echo, fetal echo	Cath, peripheral arterial/ venous cath, adult/peds echo, noninvasive vascular, EP, nuc med, CTA	Adult and pediatric echo, vascular, nuclear, cath, EP, ECG, CT, MR	US, NM, cath, vascular	Structured reporting for cath, echo, vascular, stress echo, nuclear med, nuclear stress, obstetrics, stress, Holter, ECG	Echocardiography adult and pediatric, cardiac cath adult and pediatric, peripheral vascular intervention, structural heart procedures, EP, vascular ultrasound, maternal fetal medicine, OB/GYN	Echo (adult and pediatric), cardiac cath (adult and pediatric), stress, peripheral vascular intervention, vascular, ultrasound, ECG, Holter, EP, nuclear med, OB/GYN, maternal fetal medicine, EEG, IR
Yes, HealthView ECG Manager	Integrated multi-modality, multi-vendor compatible, pure web-based ECG management system	Yes	Yes. DICOM ECG viewer. Also allows for viewing of finalized ECG reports (PDF)	Native ECG management built-in, PicomECG	Yes, with third-party systems	ECGs can be viewed, stored and reported on in the system, in both DICOM and non-DICOM
XML, PDF	DICOM, PDF	DICOM, PDF, HTML, and can be printed with/without diagnosis or exported	PDF and/or DICOM ECG. WebAPI links to external ECG management systems for report viewing within system	DICOM, XML	DICOM	JPEG or DICOM
Yes, via DICOM Standard	Integrations with many radiology PACS. Depth of integration varies by vendor	Yes	Cardiology images can be stored to a third-party radiology PACS for long-term archiving. Can query/retrieve images from PACS for viewing in system	Picom365 is a true single-database enterprise PACS; can integrate with any other PACS vendor	Any DICOM compliant PACS	Yes
Yes, via HL7 standard and non-HL7 file formats. Epic, Soarian, Centricity, Cerner, Meditech, McKesson	Deep workflow and discrete data integration with Cerner and Epic. Image enabling and HL7 interface with other EHR/EMR vendors	Yes	Can integrate with leading HIS/ EMR vendors via integration engine	Integrates with any HL7 capable system, such as Epic, McKesson, Cerner, NextGen, others with non-proprietary HL7 interfaces	HL7 capable EMRs, e.g. Cerner, Epic, Soarian, Meditech	Yes
Yes, via HL7 standard and non-HL7 file formats	Complete bidirectional HL7 support, including ADT, orders, results, etc.	Yes	Can integrate with leading HIS vendors via integration engine	Supports HL7 bidirectional communications with Epic, McKesson, Cerner, Meditech, others	HL7 capable HIS	Yes
Yes. Mennen, Merge Hemo, Xper, Mac-Lab, CATHCOR/Sensis, McKesson Horizon	Merge Hemo, MacLab IT	Yes, all hemodynamic systems	Can serve as a PACS solution for any vendor's cath lab hemo system	Captures and databases procedural, inventory, measurements, etc. via HL7 or XML, including Mac Lab, Mennen, Merge Hemo, Xper and others	Siemens Sensis, Philips Xper and Witt, GE MacLab and Merge Hemo	Yes

November/December 2017 Comparison Chart Conducted by Scranton Gillette Communications

COMPARISON CHART

Cardiovascular Information Systems (CVIS)

Company	Carestream Health	Change Healthcare	Fujifilm Medical Systems	GE Healthcare	Infinitt Healthcare	Konica Minolta
Integration with EP recording systems	Yes, for report capture	GE Prucka, St. Jude, Boston Scientific	GE Cardiolab	GE Cardiolab recording system	Yes, any images can be stored from DICOM, PDF or JPEG format. Also integrates with any system that outputs HL7 results: GE Prucka, St. Jude EP-WorkMate	No
Does system support charge capture and submission	Supports charge capture via end-of-study billing notification	Yes, McKesson Cardiology Charge Manager supports codes sets for technical and professional charge management. Codes can be sent by HL7 to the hospital billing system	Yes	Yes	Yes, can communicate the status of exams to billing systems	Yes
Business intelligence and clinical data mining (data analytics)	Both administrative and clinical data mining are offered with extensive query and reporting capabilities	McKesson Cardiology Statistical Report Center provides over 100 predefined reports and a flexible tool for custom building ad hoc reports. It supports cross-modality and cross-department reports	Yes	Yes	Yes, statistics can be handled via Infinitt Report Stats, Worklist Queries or through the Infinitt Crystal Package	Business Intelligence, yes. No significant clinical data mining
Can system help automate data for registries – which ones	ACC/NCDR (Cath PCI, ICD, ACTION, IMPACT), STS (adult cardiac surgery, general thoracic surgery, congenital heart surgery), AHA (heart failure) and state registries	Yes, for NCDR, STS and applicable state registries	NCDR (Cath PCI, ACTION, ICD, Atrial-Fib, PVI, IMPACT). STS (adult cardiac surgery, general thoracic surgery, congenital surgery). State (California CORP, Massachusetts Mass-DAC, New Jersey Cath PCI, New Jersey Cardiac Surgery, N.Y. Cardiac Surgery, N.Y. Cath)	ACC NCDR CathPCI Registry, ACC NCDR ICD Registry, ACC NCDR Afib Registry and STS adult surgery	Yes. ACC-NCDR (ACTION, CATH PCI, ICD) ICAEL, ICAVL, ICANL and N.J. state registry	No cardiology registries yet
Web-based access to images, waveforms and reports	Secure web client with full reading and reporting functionality or platform independent zero-footprint viewer using the device's native browser	Yes, full access to DICOM images and ECG waveforms with structured report reading and writing for all modules. Supports single or dual monitor setups. Reading and finalizing ECGs via iPad and iPhone	Synapse Mobility Enterprise Viewer provides secure access to the entire patient imaging record, including DICOM and native non-DICOM images and reports on iPad, iPhone, Android, PC and Mac platforms through a zero-footprint application that requires no code download	Yes, 510(k) cleared for diagnostic image review via a web-based solution	Yes, web-portal with secure login, iPad Integration	Zero-footprint, server-side-rendered access to everything from anywhere all the time
Advanced visualization software capabilities	Integration with popular 3D CT apps; TomTec and QLAB for echo; TomTec for cardiac MR; Pie Medical for LVA and QCA; Cedars for nuc med	CT: TeraRecon (iNtuition) and Vital Images (Vital Connect), US: TomTec. NM: Syntermed, Emory Toolbox, Segami OASIS (Cedars), Invia Corridor4DM	Synapse 3D provides 3D/4D viewers and cardiology toolsets for aortic valve analysis -TAVR planning, cardiac fusion, coronary analysis, CT and calcium scoring. Synapse CV provides integration support for US: GE EchoPAC, Philips QLAB and TomTec. NM: Invia Corridor 4DM	Embedded 4-D tools for advanced visualization via a seamless user experience (AW, EchoPac, TomTec, Medis, Xeleris)	Yes, Xelis Cardiac, LV analysis, quantitative coronary analysis, visual cath report, nuclear med post-processing via Corridor4DM and Cedars Sinai, 3D echo via TomTec and Philips Q-Lab: TeraRecon integration; EVAR, CABG, TAVI planning; CV function quantification; CT stenosis CAD and quantification	Third-party integration for 3D, nuclear medicine and advanced calculations and analysis
Integrated inventory management	Barcoding system optional. Can integrate with HL7 based systems	Inventory tracking and management application integrated into the CVIS hemodynamic. Supports barcode scanning, lot, serial and expiration tracking	No, but we accept direct data input from all major inventory management systems for input into clinical database and use in report templates	Yes, with wireless barcode scanners	N/A	No
Remote access to reports or images by referring physicians	Yes, secure, zero-install, zero-footprint (HTML 5), platform independent access	Yes, browser-based application displaying lossy compressed or DICOM images, and iOS application for ECG waveforms and full access to final reports	Synapse Cardiovascular offers Synapse Webviewer and Synapse Mobility for image review and display of PDF versions of finalized reports	Yes, including zero-footprint viewer (ZFP) for enterprise-wide and community-wide access to images and reports	Yes	Zero-footprint, server-side-rendered access to everything from anywhere all the time

Scranton Gillette Communications obtained the model specifications from the manufacturers.

N/A = Not applicable
N/S = Not specified

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Lumedx Corp.	Merge Healthcare, an IBM Company	Novarad	Philips Healthcare	SciImage Inc.	Siemens Healthineers	UltraLinq Healthcare Solutions
Yes	Limited with GE Prucka (CardioLab), St. Jude, Bard	Yes, GE, St. Jude, Bard	St. Jude EP, GE CardioLab	Integrates for report capture via HL7, DICOM, PDF	Siemens Sensis, GE Prucka	Yes
Yes	System can support charge capture but not submission	Yes	Yes	Supports charge capture via end-of-study billing notification (HL7 ORU/DFT), can include ICD and CPT codes	Supports the ability to submit charges back to a HIS via an HL7 DFT billing interface. For technical billing, order charge codes included in the DFT message. CPT codes sent in HL7 DFT message	No
Yes	Yes, extensive SSRS-based data mining	Yes	Yes	PicomAnalytics option provides extensive business analytics with ad-hoc data query and reporting. The solution leverages a non-propriety SQL database	1. syngo Dynamics has a business analytics module with pre-formatted reporting capabilities. 2. Customers may prefer to build their own data mining and reporting app with SQL Server Reporting Services. 3. To accommodate EMR vendors, can export discrete data to EMR analytics application	Flexible reports can be generated that contain selected or detailed information as needed
Yes. ACC NCDR ACTION, Care, CathPCI, ICD, IMPACT, PVI; STS Adult Cardiac, Thoracic, Congenital; C3PO, PC4 and others	Yes, Merge Hemo and clinical reporting data pre-populates registries. Supports all ACC-NCDR, ICD and STS registries	ACC-NCDR, STS, ICD	Philips offers the Cedaron system for support of registry reporting needs	ACC NCDR, STS, AHA, local registries	Yes, ACC-NCDR, PCI and Impact	N/A
Yes, through web portal with secure data transfer. No iPad integration	Merge Cardio allows for web access to images, as well as the ability to generate, view and confirm clinical report	Yes	Web-based access for viewing multi-modality images, waveforms and reports is possible through zero-footprint (pure HTML5) client, as well as web-based echo reporting	Platform-independent web access using the device's native browser	Web-portal with secure login for PC access; also for iPad/iPhone and Android devices. Diagnostic reading of images with a web browser requires a medical grade monitor using the original quality viewer	Our entire infrastructure is web-native, allowing for unlimited access and functionality
QCA/LVA/BLVA (Pie Medical CAAS Integration), NM/PET/SPECT post processing (INVIA Corridor 4DM Integration), 3D/4D US volumes and quantification (Philips QLAB integration, GE EchoPAC)	Integrated QCA/LVA analysis. Extensive echo measurements module. Real-time image enhancement and DSA functionality. W/L, brightness/contrast/gamma advanced integrations for support of CTA, 4D echo, and nuclear medicine specialty appl	Novarad 3D+; vessel analysis, TDI of 3D MR, 4D imaging, MPR to MIP on the fly, MR flow analysis; nuc med viewer integration; integration with popular 3D CT apps	Echo 2D/3D/4D (via Philips QLAB and/or TomTec); advanced visualization and cardiac analysis for CT, MR, NM; TAVI planning powered by IntelliSpace Portal through IntelliBridge Enterprise	Seamless integration with Qlab, TomTec, Pie Medical, Cedars Cardiac Suite	syngo.via interface to provide access to cardiovascular CTA and MRA reading tools. Ability to launch Corridor 4DM post-processing for nuc med reading and reporting	Via vendor-agnostic integrations with third parties of the customer's choosing
Yes, and barcode management available	Integrated barcode scan based inventory management as well as interfacing to enterprise materials management option via Merge Hemo	Yes, barcode and ability interface with hospital system	Offered with our Xper IM hemodynamic monitoring and reporting solution through IntelliBridge Enterprise	Integrates with HL7-based systems	N/A	N/A
Yes	Referring physicians have remote access to images and reports via the Merge Cardio web client	Yes, as well as optional autofax	Web-based access for viewing multi-modality images, waveforms and reports is possible through zero-footprint (pure HTML5) client	Secure, zero-install, zero-footprint, platform-independent access to images and reports	Portal app allows review of images and edit worksheets and patient reports. syngo Dynamic Mobile, web app available for iPads, iPhones, Android to access study list, perform searches, view images and display PDF versions of reports	Exams can be reviewed, reported on and referred from any device with an internet connection

November/December 2017 Comparison Chart Conducted by Scranton Gillette Communications

COMPARISON CHART

Cardiovascular Information Systems (CVIS)

Company	Carestream Health	Change Healthcare	Fujifilm Medical Systems	GE Healthcare	Infinitt Healthcare	Konica Minolta
Can this solution be integrated into an enterprise imaging system for central access to all patient data and images in one location (ie: EMR, VNA enterprise data repository, etc.)	Yes, it can be integrated into an existing enterprise imaging system or offered as part of Carestream's Clinical Collaboration Platform, which includes Carestream's native VNA repository that provides access to all "ology" images and reports using a zero footprint viewer	Yes, McKesson Cardiology integrates with enterprise imaging systems such as EMRs and VNAs with a variety of interop options and capabilities	Synapse Cardiovascular provides integration with EMRs and VNAs. Synapse CV provides CommonView across all Synapse CV data sources	Yes	Yes	Yes
Main differentiating features of your system	Comprehensive cardiology PACS including imaging, analytics and reporting for cath, echo, nuc med, cardiac CT and MRI, gated SPECT; plus native ECG management, stress test and Holter reporting, all in one outcomes CVIS database	Single database CVIS for all modalities including hemo, EP and ECG that helps connect and coordinate care through mobile access and a single point of connectivity to your EMR. Robust analytics that help to connect quality improvement data to impact cost of procedures, length of stay and re-admission rates. Peer review and critical results management workflows that help prove and improve quality	Powerful data integration capabilities: Ability to accept modality information from a wide variety of clinical devices including hemodynamics, ultrasound, treadmills, noninvasive PV, etc. Automated clinical reporting templates based on the standards that evaluate data and generate clinical statements thus automating workflow yet providing consistent, standardized reporting	510(k) cleared as a web-based diagnostic PACS solution with embedded advanced analysis tools available via web from virtually anywhere there is internet access. Only comprehensive CV imaging and workflow vendor to offer vendor agnostic CRM device programmer data import	Supports the multi-modalities of cardiology and their reports including ECG, Holter, stress and NM all in one system. Reports are customizable for each facility/customer. Infinitt eliminates islands of information with all cardiology modalities in one place	Zero-footprint, server-side-rendered access to everything from anywhere all the time. Single database for all RIS, PACS, mobile service, and other system modules and functions
Hardware	Windows / Intel Server platform	Standard Windows servers and workstations	We support a wide array of hardware including full virtualization	N/A, software only solution	HP/Dell/IBM or other MS Windows server-based hardware. VM environment also supported	True cloud, single-database, server-side-everything application. Very flexible
Architecture	Web server	Client-server based architecture	Specified per customer after evaluation	N-tier web system, SOA (service oriented architecture)	Web-based	True cloud, single-database, server-side-everything app. Very flexible
Communications protocols supported	DICOM, HL7, XML supported. Other communication protocols supported are a function of OS and network appliances	DICOM, HL7, IHE, CCOW, TCPIP, ethernet, ATM, fiber channel, ISDN	TCP/IP, DICOM, HL7, FTP, HTTP, HTTPS SSL	HTTP or HTTPS	HL7, TCP/IP, DICOM, ATM, Ethernet, FDDI, HL7, RS232, token ring, ISDN, SCP/IP, phone line	HL7, DICOM, HTTPS
Web server system security	Login, password, biometric, LDAP	Expansive security package,for example: Windows AD, SSL, FIPS140-2	Support for active directory, password protection, encryption and audit logging	LDAP support	LDAP, HTTPS, passwords, active directory, multiple encryption schemes selectable by end user	SSL
Hardware and software provided	Both, or software only	Both, or software only	We provide either turnkey or software only options	Both or software only if desired	HW and SW or software only	Yes
Image exam access time	Dependent on bandwidth. LAN <5 seconds typical	Less than 2 seconds, varies by image size, network load	Less than 5 sec	Depends on network speed	Typically less than 3 sec	Fewer than 5 seconds
From online to first image, sec, resolution	LAN <5 seconds typical for full native resolution	Less than 2 seconds, varies by image size, network load	Less than 5 sec, any resolution	Depends on network speed	Typically <3 sec	Full resolution and speed within 5 seconds, based on internet speed
Image processing capabilities	Zoom, pan, window/ level, gamma correction, sharpness, invert, DSA, QCA, measurements, etc.	Zoom, pan, windowlevel, brightness, contrast, gamma, DSA, QCA, LCA, invert	Zoom, pan, window level, gamma correction, sharpness, inverse, digital subtraction, brightness, contrast. DSA toolsets	Many options available including 4D, strain, DSA, QCA, LVA	All of the common tools for cardiology with customizable tool bar for each modality	Stress echo comparative stage/ view

Scranton Gillette Communications obtained the model specifications from the manufacturers.

N/A = Not applicable
N/S = Not specified

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Lumedx Corp.	Merge Healthcare, an IBM Company	Novarad	Philips Healthcare	ScImage Inc.	Siemens Healthineers	UltraLinq Healthcare Solutions
Yes	Yes, deep integration with all major EMR vendors, common archive, improved notifications and bi-directional QC with EA, ability to view complete cardiology reports in iConnect Access, providing single-point access to a patient's complete cardiovascular record	Yes	Can be integrated with supporting system via DICOM and HL7 for patient data exchange	ScImage has a proven record of providing interoperability solutions and specializes in providing solutions for the entire order-driven PACS workflow, specifically referring to a closed loop workflow with many EHR vendors, or specific components of the data entry process as required to improve workflow	Yes, using an API as well as DICOM and HL7 standards	Yes
CVIS available client-server or web-based; SaaS analytics and integrated data intelligence	Merge Cardio has deep bidirectional integration with the leading EMR vendors creating a truly complete cardiology patient record. Extensive support for all cardiac modalities and subspecialties and complete integration with the iConnect suite of interoperability products providing a true enterprise imaging solution	Comprehensive, flexible system. Team of full-time cardiologists to work with you. Access system in facility or remotely across all cardiology areas	Structured reporting, zero-footprint viewer and echo reporting, HTML reporting, customizable UI, IT flexibility, linking of measurements to images while reporting (for Philips echo), and integration of third-party APIs and web APIs	Comprehensive enterprise PACS including imaging, business analytics and reporting for all cardiology disciplines (including nuc med and ECG management); clinical outcomes for study specific data including diagnosis and measurements and radiology imaging and reporting; a single database platform for all modalities. The solution can be implemented on-premise, in the cloud or both	Patient centric, multimodality, bidirectional nterface with Sensis, interfaced advanced visualization, portals for clinical and business metrics/analytics. Result consistencies and data accuracy checks decision support for reporting includes checking for valid range of input and optional data consistency check of numerical values in reports, e.g., consistency of EF% measured with NM and echo. Boston z-scores	510(k) cleared Class II medical device. HIPAA-compliant, cloud-based medical image management solution. Includes anytime, anywhere access. Vendor-agnostic. Offers personalizable worksheets, unlimited users. Pay-per-exam (SaaS) model enables cost-effective workflow optimization
32/64 bit processor(s)	Turnkey solution with off-the-shelf hardware or SW only	Dell, or customer-provided hardware to spec	Customer provided hardware; supports VMWare, Server (Windows 2012), clients (Windows 10 and Windows 7)	Any Windows-based hardware or VM platform meeting hardware specs is acceptable	3 server levels: 1, 2 or 4 Intel Xeon multi-core processors, depending on user requirements	N/A, software-only solution
Windows, imaging, DB, web servers. All-in-one enterprise	Client server, web	.net	Server-client architecture	Client-server and web-based	Client-server, web-enabled	AWS n-tier web architecture
HL7, DICOM, TCP/IP, HTTP, HTTPS, TCP-TLS. Any TCP/IP network topology	DICOM, TCP/IP, HL7, VPN	TCP/IP, FTPS, HL7, DICOM, DICOM SR	TCP/IP, DICOM, HL7	DICOM, HL7, TCP/IP, HTTPS, others	DICOM, HL7, TCP/IP, XML	DICOM, HL7, TCP/IP, FTP, HTTP, HTTPS SSL
TLS, SSL, HTTPS, encryption 128/256 bit, LDAP, SSO, ACL	Windows authentication	HTTPS SSL encryption or VPN over web. Strong passwords req, auto-logout after set time	Active directory, TLS	LDAP, TLS, SSL, HTTPS, 256/1024 bit AES	Supports Microsoft active directory. User ID and password, HIPAA enabled	HTTPS, TLS, SSL, 256 bit AES
Software only	Turnkey or SW only	Both, or software only. Functionalities from the standalone client available	Offered as software-only; solution utilizes customer provided hardware	Software only or both	User ID and password, HIPAA enabled	Software only
As fast as network allows. Exams vary in size	<1 sec	<2 sec., any resolution	Network infrastructure dependent	Less than 2 seconds, dependent on network speed	Depends on network and client hardware	2-5 sec average, dependent on network speed
Within 5 sec based on network speed and exam size	Immediate, all resolutions	Depends on exam size	Immediate (resolution as acquired)	Less than 2 seconds, dependent on network speed	Depends on network and client hardware	Depends on network, full res
2D, Doppler, M-mode measurement tools natively plus 3rd-party post processing integrations	Zoom/pan, W/L or brightness/contrast/gamma, real-time edge enhancement, invert, DSA image review	Zoom, pan, window level, local contrast and edge enhance, invert, color filters, annotations, measures, MIP/MPR	Zoom, pan, grayscale, edge enhancement, measurements, annotations	Standard imaging tools, such as: zoom, pan, window-level; advanced tools such as DSA, QCA, enhanced rendering	Zoom, window/level, invert, magnification, auto-dimming, frame speed, measurements, study comparison, etc.	Brightness/contrast, inversion, window level (W/L), zoom/pan

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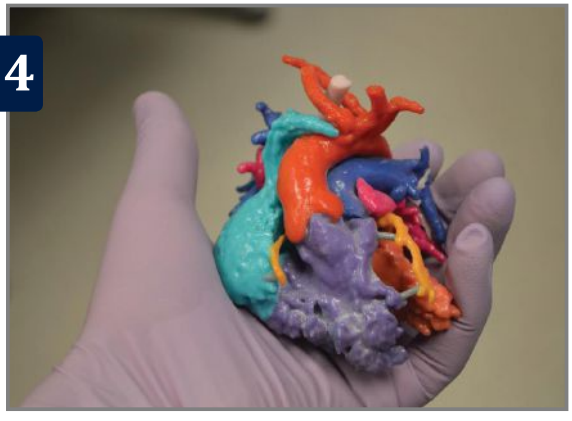

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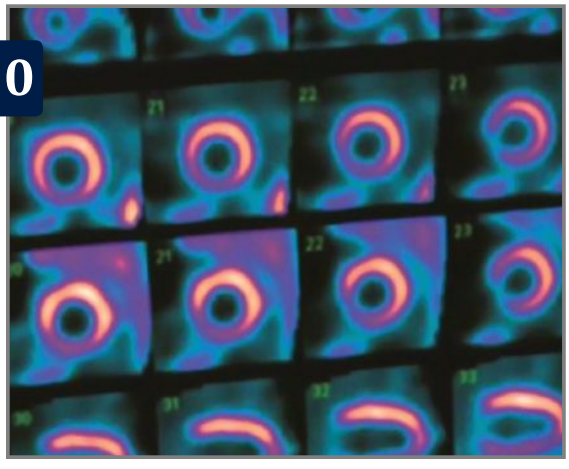

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About the Cover

The cover shows GE Healthcare's Centricity Cardio Enterprise cardiovascular information system (CVIS). It is an example of the newest generation of CVIS that can integrate all data sources in the cardiology department into a single point of access for patient information. Read the CVIS trends article and see the CVIS pull-out comparison chart starting on Page 3.

For more on Centricity Cardio Enterprise, visit the digital interactive guide at: *http://bit.ly/2gwkuPX*

Late-breaking Clinical Trial Presentations at ESC and VIVA 2017

Here are quick summaries for all the key late-breaking clinical trials presented at VIVA 2017 in September and the European Society of Cardiology (ESC) Congress 2017 in August. Both articles offer article links or summaries from each trial.

- VIVA 2017 Late-breaking Clinical Trial Presentations
  http://bit.ly/2wyG1S8

- Late-breaking Trial Presentations at ESC 2017
  http://bit.ly/2fASgTV

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ADVERTISING
Publisher
Sean Reilly
847.954.7960 F: 847.390.0408 • sreilly@sgcmail.com

Integrated Media Consultant (West/Midwest)
Stephanie A. Ellis
847.954.7959 F: 847.390.0408 • sellis@sgcmail.com

Integrated Media Consultant (East/Southeast)
Louise Clemens
216.342.4012 F: 847.390.0408 • lclemens@sgcmail.com

Advertising Coordinator
Karen Teeter • kteeter@sgcmail.com

MARKETING CREATIVE SERVICES
Marketing Director
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Dara Rubin • drubin@sgcmail.com

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BPA WORLDWIDE

Abbott Ends Sale of **Absorb Bioresorbable Stent**

Abbott Vascular ended its commercial sales of the Absorb bioresorbable vascular scaffold in all countries as of Sept. 14, 2017. The company said low sales of the bioabsorbable stent led to the decision to stop offering the product. However, this will not be the end of bioresorbable stents.

While the Absorb had some advantages over metallic stents, these were not enough to persuade interventional cardiologists to increase their usage.

Abbott said it believes the bioresorbable technology offers patients the possibility of life without permanent metallic implants. For this reason the company said it is continuing work on a next-generation bioresorbable device. This new device will need to overcome some of the key issues preventing widespread adoption of the Absorb.

As use of the stent expanded and new trial data was revealed, it was found the scaffold had several limitations compared to metallic stents. These include delivery issues due to the thicker struts, stent recoil, the limited ability to over expand without breaking struts, the need for very precise sizing, and poor outcomes if the Absorb is used in coronary vessels 2.5 mm or smaller. Perhaps the biggest barrier to wider adoption was the much higher price tag for Absorb over traditional metallic drug-eluting stents (DES).

"First-generation products often go through iterations as experience is gained using them," said Abbott spokesman Jonathon Hamilton. "Absorb is a highly innovative ground-breaking device, and we're incorporating learnings into a second-generation product."

The company plans to continue follow-up for ongoing Absorb clinical trials to assess long-term outcomes after the scaffold has dissolved. Abbott said trial centers can continue to use their existing Absorb inventory, but will not continue to supply the product.

While sales of the Absorb did not do well, interest in its bioresorbable technology has not wained. Three of the key late-breaking trials presented at the 2017 Transcatheter Cardiovascular Therapeutics (TCT) meeting were for ongoing Absorb trials. These included ABSORB IV 30-day outcomes, ABSORB III three-year outcomes and ABSORB II four-year outcomes.

The company said its metallic Xience drug-eluting stent (DES) will continue to be the cornerstone of Abbott's stent portfolio. The vendor also stated it will focus efforts on a next-generation metallic DES, the Xience Sierra, which will offer improved deliverability and expanded sizes.

Watch the VIDEO "Bioresorbable Stent Comparable to Xience at Two Years, With Concerns," with Stephen Ellis, M.D., director of interventional cardiology at Cleveland Clinic — *http://bit.ly/2wGUJl9*

Read the article "Questions Remain on Future of Bioresorbable Stents" at *http://bit.ly/2xfhelO*

Dave Fornell

We welcome your comments on the topics found in *Diagnostic and Interventional Cardiology.* Please send your thoughts to dfornell@sgcmail.com

STAFF
Editor
Dave Fornell | 847.954.7962
dfornell@sgcmail.com

Editorial Director
Melinda Taschetta-Millane | 847.954.7961
mtaschetta-millane@sgcmail.com

Associate Editor
Jeff Zagoudis

Designer
Kimberly Pellikan

SCRANTON GILLETTE COMMUNICATIONS
3030 W. Salt Creek Lane, Suite 201
Arlington Heights, IL 60005-5025
Ph: 847.391.1000 F: 847.390.0408

Oxygen Does Not Improve Survival in AMI

DETO2X-AMI study shows room air equal

Oxygen therapy does not improve survival in patients with heart attack symptoms, according to late-breaking research from the DETO2X-AMI Study presented in a Hot Line session at the European Society of Cardiology (ESC) Congress in August.

Giving oxygen to patients suffering a heart attack is not beneficial, according to the DETO2X-AMI study presented at ESC 2017.

"The DETO2X-AMI study questions the current practice of routine oxygen therapy for all patients with suspected myocardial infarction," said first author Robin Hofmann, a cardiologist from the Karolinska Institutet at Södersjukhuset, Stockholm, Sweden.

This prospective, randomized, open-label trial enrolled 6,229 patients with suspected heart attack from 35 hospitals across Sweden. Half of the patients were assigned to oxygen given through an open face mask and the other half to room air without a mask.

The primary outcome, the mortality rate one year after randomization, was not statistically different between the two groups (5 percent in the oxygen group versus 5.1 percent in the air group). Similarly, there was no significant difference between the two groups for secondary endpoints, including the risk of a new heart attack or heart muscle injury.

Even in patients at high risk, such as smokers, older patients, patients with diabetes or patients with previous heart disease, the results were similar concerning mortality within one year.

ESC guidelines on treatment of patients with ST-segment elevation myocardial infarction (STEMI) recommend oxygen (by mask or nasal prongs) for patients who are breathless, hypoxic or have heart failure. They add that the systematic use of oxygen in patients without heart failure or dyspnoea "is at best uncertain."

"ESC guidelines have gradually shifted toward more restrictive use of oxygen," said author Prof. Stefan James, a cardiologist at Uppsala University, Uppsala, Sweden. "While the current recommendations were based on expert opinion only, we can now add substantial new data from our large clinical trial. The study results will likely have an immediate impact on clinical practice and future guidelines. Our findings do not support the routine use of oxygen therapy in all patients with symptoms of a heart attack. The general use of oxygen in these cases is still widespread in the world but can now be adjusted." DAIC

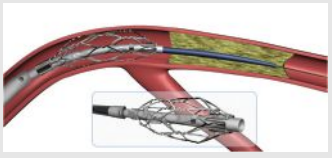
News Briefs

■ Abbott/St. Jude Medical said it has resolved its cybersecurity and battery depletion issues with its electrophysiology devices. In late August, the U.S. Food and Drug Administration (FDA) approved a firmware update to reduce the risk of patient harm due to potential exploitation of cybersecurity vulnerabilities involving certain Abbott pacemakers and implantable cardioverter defibrillators (ICDs). This updated software is intended to address a recall of these devices and an FDA corrective action involving these devices. The new device updates include a battery performance alert for the company's ICDs that provides physicians with earlier warning of the potential for premature battery depletion. Another update to pacemaker firmware is designed to reduce the risk of unauthorized access to patients' pacemakers.

■ Medtronic announced its intent to move forward with a new renal denervation pivotal trial following positive first results from a sham-controlled study in patients with high blood pressure. Investigators of the SPYRAL HTN-OFF MED Study found statistically significant and clinically important blood pressure reductions in the patients treated with renal denervation (RDN) across both office and ambulatory systolic and diastolic measurements. The data on the first 80 patients enrolled in the study at three months were presented in a late-breaking clinical trial session at the ESC meeting in August.

■ Philips Healthcare and HeartFlow Inc. entered into a collaboration agreement to co-develop angiography image-based fractional flow reserve (FFR) technology. This would allow table side imaging in the cath lab to evaluate coronary segments without the need for FFR catheters. The agreement improves access to diagnostic and planning tools for interventional

cardiologists evaluating and treating patients with suspected coronary artery disease. Philips will promote the use of HeartFlow's FFR-CT analysis in conjunction with its advanced catheters for imaging and assessing measurements in the coronaries.



■ Roxwood Medical Inc. entered into an exclusive agreement with Abbott for distribution of Roxwood products in the United States. This includes Roxwood's anchoring catheters (CenterCross Ultra, MultiCross) and microcatheters (MicroCross) that offer minimally invasive platforms for physicians to percutaneously treat patients with chronic blockages by facilitating guidewire access across the blockage, often times averting an invasive bypass procedure.

■ Rambam Hospital in Haifa, Israel, recently became the first to use the CORolla device from Israeli start-up company CorAssist in a 72-year-old diastolic heart failure patient. It uses an elastic device that is implanted inside the left ventricle of the heart by a minimally invasive procedure on a beating heart. The device can improve cardiac diastolic function by applying direct expansion force on the ventricle wall to help the heart fill with blood.

■ The first European patient was treated using the NaviGate Cardiac Structures Inc. catheter-guided tricuspid atrioventricular valved stent. It was implanted through the jugular vein into a patient's transplanted heart that was failing due to severe tricuspid valve insufficiency at the Policlinico of the University of Padua, Italy. Two months post-procedure, the patient continued to demonstrate clinical improvement and excellent valvular function.

Biotronik's Stent Outperforms Xience

Data demonstrates statistically significant lower event rates with Orsiro

The Biotronik Orsiro stent showed 6.2 versus 9.6 percent 12-month target lesion failure over the Abbott Xience stent.

Data from the BIOFLOW-V randomized trial comparing Biotronik Orsiro and Abbott Xience drug-eluting stents (DES) with 12-month target lesion failure (TLF) as the primary endpoint proving non-inferiority. Results were presented at the European Society of Cardiology (ESC) 2017 congress in August. Data show 6.2 versus 9.6 percent 12-month TLF rate, demonstrating statistically significant improved clinical outcomes with Orsiro.

This pivotal U.S. investigational device exemption (IDE) trial included a large, complex patient population and was designed in collaboration with the U.S. Food and Drug Administration (FDA) to support an upcoming premarket approval submission.

Highlights of the BIOFLOW-V study include the following 12-month data points comparing Orsiro to Xience:

- 6.2 percent versus 9.6 percent TLF rate (p=0.04);
- 4.7 percent versus 8.3 percent target vessel myocardial infarction (MI) rate (p=0.02);
- 2 percent versus 2.4 percent clinically driven target lesion revascularization (cd-TLR) rate; and
- 0.5 percent versus 0.7 percent Academic Research Consortium (ARC) definite/probable stent thrombosis rate.

In a pooled analysis with prior Orsiro randomized control trials versus Xience, BIOFLOW-II and BIOFLOW-IV, it demonstrated statistically significant improved outcomes and clear non-inferiority. Mean estimates of TLF at 12 months are 6.3 percent with Orsiro versus 8.9 percent with Xience, resulting in a mean difference of -2.6 percent.

"Orsiro's rate of TLF shows an unprecedented improvement in DES outcomes compared with a control stent that has served as a standard in interventional cardiology," said David Kandzari, M.D., Piedmont Heart Institute, Atlanta, U.S. principal investigator. "Orsiro also notably has exceptional deliverability that is essential for PCI procedures. We believe Orsiro's ultrathin 60 micron struts, bioresorbable polymer and proven antiproliferative drug are the key elements to its superior performance."

This is the first large trial to show improved outcomes of any DES over Xience. The international study included 1,334 patients. DAIC

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The Future of Cardiology

A List of 17 Technologies to Watch

Cardiac departments planning for the future should consider these

By Dave Fornell

A cardiovascular service line manager reader of *DAIC* recently e-mailed me and asked if I had a list of the top technologies that will likely change cardiology in the next few years. He wanted this information for a capital improvement planning for the next decade. I did not have this compilation handy, so I wrote the following list of 17 technology trends I feel will change how cardiology is practiced over the next 10 years, based on my industry observations. These items are not listed in any particular order of importance:

1. Expanding catheter-based interventions for all areas of the body. This will boost interventional radiology and cardiac cath lab volumes and lead to declines in open surgical procedures. As coronary interventions have plateaued, many of the new innovations in the coming years will be for heart failure and structural heart interventions. In the cardiac/vascular lab, new expansion areas will be in peripheral artery disease (PAD), critical limb ischemia (CLI), transcatheter valve repair and replacement technologies for all four heart valve positions, and interventional heart failure devices.

2. Closer integration of computed tomography (CT) and echo imaging to provide better pre-procedural planning and peri-procedural guidance.

3. Analytics software, combined with artificial intelligence, will see rapid uptake to look at big data across healthcare systems. This will enable new ways to manage healthcare, including identification of bottlenecks and inefficiencies within departments or processes. Analysis of big data will also enable population health initiatives to identify high-risk patients for screening programs and proactive outreach for checkup appointments. This can also help assess the readmission or infection risks a specific patient likely poses to help target limited hospital resources. Big data also offers a new way to conduct retrospective clinical studies. This might include analysis of the best protocols for treating patient subgroups that have a specific mix of various diseases. Or, it can highlight long-term outcomes or late complications for patients who are prescribed specific drugs or who received specific implantable devices.

4. We will see greater efforts and several new technologies to reduce radiation dose in both CT and cath lab angiography imaging systems. This includes increasing use of ultrasound and transesophageal echo (TEE) during procedures to cut or eliminate use of angiographic X-ray. There also will be increased use of 3-D navigation aids using 3-D echo, pre-procedural CT or rotational angiography to reduce procedure times. A handful of centers will build out interventional magnetic resonance imaging (MRI) suites to eliminate radiation entirely for long procedures, such as electrophysiology (EP) ablations.

5. There will be greater emphasis on reducing staff radiation dose and related orthopedic problems due to wearing heavy lead aprons all day. This includes adopting new technologies in the lab to better protect staff, including real-time dose monitoring systems, use of new, lightweight aprons, and possibly robotics to remove the physician from the X-ray field.

"There is a trend toward the 'Uberization' of healthcare, where traditional office hours and care models will rapidly change to better match the digital interface and delivery of service models pioneered by Amazon, Uber and others."

6. I predict wide adoption of virtual fractional flow reserve (FFR) technologies in the next decade if computer processing times can be reduced to minutes rather than hours. Current FFR combined with noninvasive CT angiography (FFR-CT) and advances like CT perfusion imaging will likely eliminate the need for nuclear myocardial perfusion imaging. In the cath lab, tableside FFR-angio now in development may replace the need for the current gold standard of catheter-based FFR.

7. Transcatheter aortic valve replacement (TAVR) will likely replace the majority of open-heart surgical valve replacements in select patient populations. If clinical trial data

Small, leadless, wireless pacemakers like Abbott's Nanostim will likely replace larger, conventional pacemakers in select patients.

continues the very positive trends for TAVR, it will gain more procedural volume than surgical valve replacements. It is a very good possibility this trend will be duplicated in transcatheter mitral and tricuspid valve repair and replacement technologies in the next few years.

8. Catheter ablation for atrial fibrillation will greatly improve from 60 percent procedural success rates to 80-90 percent in the coming years with the use of more accurate electro-anatomical mapping systems and improved ablation catheter technologies that reduce intra-operator variability. Both of these technologies are also helping reduce the time it takes to map and treat patients, which will allow for greater patient throughput and higher volumes in the EP lab. Improved accuracy and more complete abations also will reduce the number of repeat procedures.

9. EP implantable devices will become much smaller and wireless. This will enable catheter-based implant procedures, eliminating need for surgical pockets and venous leads for pacemakers. These technologies also will reduce the number of leads required for ICDs.

10. All EP device follow-up and 24-7 monitoring will be conducted via the web through remote monitoring. Artificial intelligence will be used to help track patient data and identify patients who need office follow-up, device reprogramming and other issues requiring human interventions.

11. Simple, small wearable patient monitors will largely replace traditional Holter monitors. Consumer-grade patient monitors may offer new data to monitor patient health, including watching if a patient's health is declining or improving based on activity due to lifestyle changes, new drugs, etc. This data will need to be accessible for review and storage in patient electronic medical records. This may be automated as part of the larger trend of the Internet of things (IoT), and artificial intelligence will likely play a role in monitoring this data and alerting providers and patients of closely monitored, higher-risk patients.

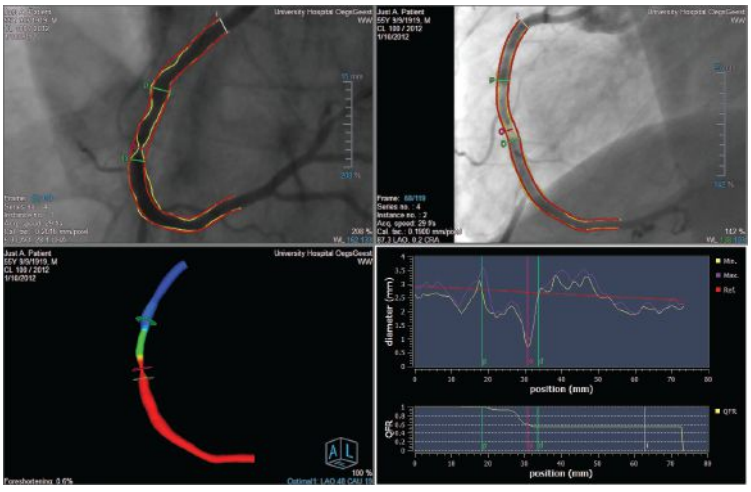
12. Wearable or implantable technology will also play a big role in better monitoring heart failure patients to prevent hospitalizations or readmissions.

13. However, with the new wireless connectivity of wearables and implantable devices, a new factor **physicians may need to discuss with patients is cybersecurity risk**. The U.S. Food and Drug Administration (FDA) is taking this very seriously and is working on new rules to better regulate cybersecurity management of these devices. Cybersecurity issues will also increase across healthcare with the further digitization of the industry and patient data.

14. There is a trend toward the "Uberization" of healthcare, where traditional office hours and care models will rapidly change to better match the digital interface and delivery of service models pioneered by Amazon, Uber and others. Like Amazon and Facebook, consumers today expect immediate results and access to their patient data, images, labs, etc. They do not want to wait a week for a radiology or lab report, or have to take time off work for a blood draw, imaging or to review test results with a nurse. Digital patient portals that integrate into the electronic medical record (EMR) and other reporting systems like the cardiovascular information system (CVIS), radiology picture archiving and communication systems (PACS) and laboratory reporting systems will play a key role in patient satisfaction. Telemedicine and patients using their own smartphone diagnostic tools will also likely play a big role in this in the future. This will start with medical care kiosks and move to web-based care for better provider access after normal business hours, weekends and late at night.

15. Across cardiac imaging, there will be greater use of 3-D advanced visualization. This includes fully automated

Wearable electronics, including consumer-grade devices, will increasingly be used to remotely monitor patients and increase patient engagement in managing their health.



Noninvasive imaging-based fractional flow reserve (FFR) technologies will see increasing use to better diagnose patients and justify treatments for patients with coronary artery blockages. This example shows an angiography imaging-derived FFR assessment from Medis, which eliminates the need for FFR catheters and offers a 3-D reconstruction of the coronary vessel that can be used for procedural guidance.

reconstructions to improve efficiency and increase 3-D usage. This and other advanced visualization tools and image analysis will be immediately available at all staff workstations, not just dedicated computers. Some of this imaging capability will also be available for patients via their patient portals, and referring physicians via remote image viewing systems integrated with the EMR, PACS and/or CVIS. Advanced visualization in really complex cases will see a rapid increase in 3-D printed models from medical images. Holographic and true 3-D imaging will also see increasing use in radiology, cardiology and other specialities to better understand complex anatomy and for procedural planning.

16. CVIS, PACS and all other clinical data systems will be upgraded to systems that easily interface into enterprise-wide EMR systems. Some will be based around the hospital system's EMR as the main digital data access point. Others will be based around a vendor-neutral archive (VNA) that provides enterprise-wide access to the data using content management software to sort the data from all clinical systems and the EMR. Information technology (IT) departments will have a much greater say over what IT reporting systems are purchased and how departments and hospitals are wired, and will be the overall agents to interconnect all departments together into unified, enterprise systems.

17. Healthcare reforms to convert the current fee-for-service model to a fee-for-value model will continue because the payment system is inefficient, costly and is not sustainable for Medicare. While the pace of these reforms is slowing because of Trump administration policies, there is still a need to contain costs over the long term. Among these reforms will be movements toward bundled payments and the adoption of clinical decision support (CDS) software to determine if an order is appropriate for the specific patient. Both of these reforms were slated for 2017, but are now in question. The CDS for cardiac imaging (CT, MRI and nuclear) component is now pushed back to start in January 2018. The goal for both of these reforms is to reduce costs by making hospitals look at ways to reduce their use of testing and become more efficient to enable profitability under bundled payments. The CDS component is designed to double-check orders to ensure they are appropriate according to the standards of care set in guidelines by various cardiac and imaging societies. This includes imaging, procedures, drugs, etc. The systems are supposed to red flag any orders that do not match appropriate use guidelines, match previous orders already entered to reduce duplication, or highlight procedures, drugs etc. that may cause harm to a patient based on their specific data. These systems will likely incorporate an artificial intelligence component (such as IBM Watson). DAIC

Additional Business Resources

Watch the VIDEO "Current State of Leadless Pacemaker Technology."

http://bit.ly/2svjLEZ

Read the article "Predicting the Cath Lab of the Future," ideas from Martin Leon, M.D.

http://bit.ly/2xbzXuc

Read the article "Understanding How Big Data Will Change Healthcare."

http://bit.ly/2fFDZVs

Read the article "How Smartphones and Apps May Change the Face of Healthcare."

http://bit.ly/2hH48aD

Read the article
"The Uberization of Healthcare."

http://bit.ly/2xPHJvQ

The Use of 3-D Printing in **Structural Heart Procedures**

Applications include planning, guidance in complex procedures and in speeding development of new transcatheter technologies

By Dave Fornell

Three-dimensional (3-D) printed anatomic models created from a patient's computed tomography (CT), magnetic resonance imaging (MRI) or 3-D ultrasound imaging datasets are seeing increasing use for procedural planning and hands-on clinical education. Some cardiovascular centers have created their own 3-D printing labs enabling on-demand printing of complex anatomy not only for planning and device sizing, but also to practice dry runs and aid procedural navigation. An emerging trend is the use of new 3-D computer modeling software to enable virtual device implantations for improved patient selection, to reduce complications, and enable faster development of new transcatheter devices and techniques.

Building a Cardiac 3-D Printing Program

For centers thinking of creating a 3-D printing program, cardiologists need to ask what they plan to use the models for to determine what they need in terms of printer quality and types of media to make the models, said Vijay Iyer, M.D., Ph.D., director of the complex valve clinic and structural heart interventions at the Gates Vascular Institute (GVI) and Buffalo General Medical Center (BGMC). Iyer helped create a 3-D printing lab at Gates. If the printed models are for educational purposes, these can be printed out of a single color and material. But, if the model will be used for pre-procedural planning, he said a higher-end printer will be needed that can print multiple materials to simulate the actual anatomy. This includes flexible materials for soft tissues and hard plastics for calcified valves.

"The ability to do multi-material printing is very important if you are using the models for procedural planning and dry runs," Iyer said. "We print the entire structure, including the valves, aortic arch and the femoral access points to see the impact of the angulations and vessel tortuosity. If you only print the heart, you don't have all the anatomy that plays a role in the delivery of the device."

To start a 3-D printing program, Iyer said a hospital needs physicians who will champion the project and invest time. There also needs to be buy-in from the other physicians so the lab will be used. "It's not just a shiny new toy, they have to understand its applications and actually use it," he stressed. He said the biggest value in 3-D printing is being able to see things in a new way to better prepare physicians for procedures and to understand potential complications.

"For someone to really understand the anatomy — even for an experienced cardiologist — they do not always appreciate the complexities by looking at 2-D images from ultrasound, CT scans or angiography," Iyer explained. "In congenital heart cases, 3-D printing is invaluable. We find it most beneficial in the areas of pre-surgical planning, transcatheter structural heart procedural planning, and education and training." This includes use for planning, device sizing, and procedural guidance for novel devices and techniques, such as mitral or pulmonic transcatheter valve-in-valve procedures.

"We try to anticipate problems with dry runs using the 3-D printed anatomy," Iyer said. "We want to answer questions like is a 23 mm valve

Participants

EchoPixel
www.echopixeltech.com

Stratasys
www.stratasys.com

TeraRecon
www.terarecon.com

Vital Images
www.vitalimages.com

WhiteClouds
www.whiteclouds.com

Materialise did not respond to our request to submit specifications by deadline.

Scranton Gillette Communications obtained the model specifications from the manufacturers.

Dee Dee Wang, M.D., runs Henry Ford Hospital's 3-D printing lab that supports its complex structural heart program.

better than a 26 mm valve, or what are the delivery issues we will likely run into."

Gates Vascular Institute often prints 3-D models of patients' left atrial appendage (LAA) prior to Watchman transcatheter occlusions. Iyer said the shape of the LAA varies tremendously between patients, so careful patient selection is important to prevent embolization. The models help determine the best deployment landing zones and help evaluate the actual 3-D shape, depth and ostium of the LAA, which all play a role in the success of LAA occluder implantations.

Iyer said physicians at the institute have been creative to think of new applications for 3-D printing. One use that was not thought of originally is to print the vasculature of the brain in complex neuro-interventional procedures. This way operators can see if devices fit the anatomy and if they can be successfully navigated through very tortuous anatomy. Physicians also have discussed using 3-D printed coronary vessels with known fractional flow reserve (FFR) readings to bench-test use of various device therapies to see the impact on hemodynamics.

Moving From Static Models to Dynamic Simulations

Henry Ford Hospital in Detroit, Mich., was a pioneer in the use of a 3-D printing lab as part of its renowned structural heart program. "We get a lot of high-risk patients who are turned down by other institutions and because of our heart team and the transcatheter procedures we offer," said Dee Dee Wang, M.D., FACC, FASE, FSCCT, director of structural heart imaging, medical director 3-D printing, Henry Ford Innovations Institute. Many patients referred to her center are too frail, old or sick to be surgical candidates and they come to Henry Ford as a last resort. For this reason, precision is important, so 3-D printing was adopted to review complex anatomies and new procedures.

"There is added value of 3-D printing during procedures, but what we quickly learned was that the real value of 3-D printed anatomy is in the physical shape," Wang said. However, it was not as impactful in adult structural heart interventions as hoped.

She said the problem with 3-D models is that it freezes the motion of the heart in a static position and cannot predict the exact impact on the cardiac anatomy or function.

CT imaging can determine what device size to put into a patient, Wang said. "What we were missing is computer-aided design (CAD), because then you have the technology to see depth, angulation, diameters and anatomical constrains," she explained. For this reason, Henry Ford has been an early adopter of the Mimics inPrint CAD software from Materialise. This medical-grade software creates dynamic, digital 3-D models where virtual devices can be placed to look at their impact on hemodynamics, or how the movement of the heart is impacted.

Mitral valve regurgitation (MR) is the No. 1 valvular heart disease. As the U.S. population ages, the patient population for MR and surgical valve procedures is expected to rise rapidly. "However, it is the most high-risk procedure that can cause death on the table," Wang said. "This is where transcatheter interventions are moving to, and 3-D modeling has two critical roles, which are sizing and identifying LVOT (left ventricle outflow tract) obstruction. This helps us see what we fear. If we undersize a valve it embolizes. If we oversize, it causes LVOT obstruction. We also can have annular disruption, which can tear apart the heart.

"The value in 3-D for us is actually in the computed-aided design," Wang continued. "We learned we can size the valves using the CAD software. We can overlay a valve and see how it fits. We can take the patient's CT scan and use computer modeling to try implanting the valves in various positions to find out what valve size we are going to use, and find out what the impact will be on LVOT. We calculate a baseline LVOT surface area to see what level of blood flow they live with, and then we model a valve inside and see what remainder of the LVOT they have left, and we can set a cutoff perimeter. We have done enough of these patients where we now have a curve. Our data is pretty good and we know where the cutoff curve for procedures should be, so we know when to send a patient to hospice and not try to put a valve in them."

This ability to do computer modeling also is impacting the development of new devices and techniques.

"The real-world impact with CAD-specific modeling, we can now find alternative ways to innovate new technologies," Wang said. This includes the use of alcohol spatial ablations to make the LVOT bigger, so patients who would have died a year ago during this procedure can now survive. DAIC

Comparison Chart Compiled by Diagnostic and Interventional Cardiology

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COMPARISON CHART

3-D Printing and Printing Services

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

Company name	EchoPixel Inc.	Stratasys	
Product name	True 3D Viewer	Stratasys J750 3D Printer	Objet260 Connex3
Is this a printer or a 3-D printing service	3-D printing software, VR, create STL files	Printer	Printer
Year first sold	2015	2016	2014
Number of sites installed or using software	15	N/S	N/S
System or service summary	Software platform allows interaction with patient-specific organs and tissue as if they were real physical objects in an open 3-D space emanating from the display. Allows a physician to load CT, MRI or ultrasound images and see anatomy within that 3-D space. Users can walk around it and see around it, use a pointing device, reach in and touch the virtual patient tissue and create crosssections in any direction they would like. Or if they see a tumor, pull it and take it out. True 3-D enables physicians to immediately identify, evaluate and dissect clinically significant structures	3-D printer that can replicate any anatomy, such as hearts, liver, bones and more to support any surgical specialty. Use patient-specific models to plan, practice and determine surgical approach. Enhance communication with the surgical team and patient	3-D printer that can replicate any anatomy, such as hearts, liver, bones and more to support any surgical specialty. Use patient-specific models to plan, practice and determine surgical approach. Enhance communication with the surgical team and patient
What differentiates your printer or service from other vendors	Enables visualization and interaction with medical images of specific organs and tissue as if they were real, physical objects. It is an FDA-cleared solution that uses existing medical image datasets to give physicians an interactive, 3-D solution that can make reading medical images more intuitive, help physicians reach a diagnosis, assist in complex surgical planning applications and facilitate 3-D printing	Only six-material 3-D printer available. Create high resolution (down to 16 microns) models out of more than 340,000 material combinations in a full color spectrum. Combine soft, flexible materials with rigid. Operates safely in a hospital environment. Plug and play system	Small footprint, high resolution 3-D printer combines up to three materials at once with properties ranging from flexible to rigid in a multi-color single print. Operates safely in a hospital environment. Plug and play system
3-D PRINTING SERVICES SPECIFICATIONS			
Service model (single projects, monthly subscription service, etc.)	3-D printing support, generation of STL files is part of regular services offered through existing software	N/A	N/A
Does the service support local printers, or this a 100% outsourced solution	N/S	N/A	N/A
Does the service require the user to download additional software	Yes, printer software	N/A	N/A
Is the segmentation software 510(k) compliant as a medical device	Software is 510(k) compliant	N/A	N/A
Is the software cloud vs. locally installed	Locally installed	N/A	N/A
What is the file output from the segmentation software	STL, PLY, OBJ	N/A	N/A
What file formats need to be exported for printing	STL, PLY, OBJ	N/A	N/A
Can a DICOM print-ready file be used	Yes	N/A	N/A
Is there a size limit to files	No	N/A	N/A
How are files uploaded	PACS	N/A	N/A
Is technical assistance offered	Yes	N/A	N/A
Average turnaround time for model	3 minutes	N/A	N/A
How is pricing of a model calculated	N/A	N/A	N/A
Is there a verification process for the file	Yes, registered to DICOM data	N/A	N/A
3-D PRINTER SPECIFICATIONS			
Printing technology used	N/A	PolyJet technology	PolyJet technology
Z axis resolution (microns)	N/A	1,600 DPI	1,600 DPI
Layer resolution/thickness (microns)	N/A	14 microns	16 microns (.0006 in.)
How fast a printer can print a one-inch cube	N/A	50 minutes	50 minutes
Build volume (L x W x H), inches	N/A	490 x 390 x 200 mm (19.3 x 15.35 x 7.9 in.)	255 x 252 x 200 mm (10.0 x 9.9 x 7.9 in.)
Typical accuracy	N/A	Up to 200 microns for full model size (for rigid materials only, depending on geometry, build parameters and model orientation)	
Can software and printer reproduce precise and repeatable geometry	Yes	Versatile geometric freedom to print complex and delicate features and small cavities in transparent, flexible and even colorful materials with repeatable, precision accuracy	
Materials that can be printed	N/A	Photopolymer	Photopolymer
Able to print multiple colors, multiple textures	N/A	Yes	Yes
Can system print transparent materials	N/A	Yes	Yes
Supported file types	STL, PLY, OBJ	STL, OBJZF, OBJTF, PRINT and range of native CAD	STL, OBJZF, OBJTF
Systems size, inches (L x W x H)	N/A	1,400 x 1,260 x 1,100 mm (55.1 x 49.6 x 43.4 in.)	87 x 120 x 73.5 cm (34.2 x 47.2 x 29 in.)
Weight, lbs.	N/A	430 kg (948 lbs.)	264 kg (581 lbs.)

Comparison Chart Compiled by *Diagnostic and Interventional Cardiology*

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N/A = Not applicable
N/S = Not specified

	TeraRecon powered by WhiteClouds	Vital Images	WhiteClouds	
	3D Print Pack portal and iNtuition for segmentation	Vitrea Advanced Visualization	Full-color Sandstone models, 3DyourSCAN	Transparent or Rubber-like models, 3DyourSCAN MJP
	Service	Software	Service	Service
	2017	2015	2015	2015
	1	N/S	N/S	N/S
	Terarecon has leveraged the top rated iNtuition software suite that was designed from the ground up as an advanced medical viewer and segmentation software. The tool enables the user to segment their DICOM data with a 'What you see is what you get' approach for 3-D printing segmentation. This data can then be exported to either a cloud 3-D Print Pack portal for outsourcing of the prints, or can locally site the Print Pack Portal to convert segmented DICOM studies for local printing. The same platform can be extended to support holography as well	Vitrea software provides expert segmentation tools incorporated with the ability to export stereolithography (STL) files for 3-D modeling	Offers complete DICOM to 3-D print solution including the 3-D segementation service for the region of interest. Includes the often overlooked engineering and functionality design to ensure the print will have the proper support, pegging, slicing, presentation, etc. Knowing that speed of delivery is critical for pre-surgery planning, WhiteClouds has built the largest-capacity full-color printing facility in the world. Full-color Sandstone is an attractive model for any medical print. It is rigid, heavy and has vibrant colors	Offers complete DICOM to 3-D print solution including the 3-D segementation service for the region of interest. Includes the often overlooked engineering and functionality design to ensure the print will have the proper support, pegging, slicing, presentation, etc. Knowing that speed of delivery is critical for pre-surgery planning, WhiteClouds has multiple MJP printers used to manufacture these special parts. MJP uses a UV-cured resin to make the model
	Service can print full-color sandstone, transparent or rubber-like materials. Segmentation and 3-D printing capabilities are seamlessly integrated with advanced visualization software suite, iNtuition. Can adapt to customer's need, offer turn-key cloud solutions that allows 100 percent outsource as well as locally sited options to support local customer owned printers. Also offers the capability to convert DICOM to a print ready format	Segmentation tools and STL creation are 510(k) approved and optimized for speed and accuracy, significantly reducing the time needed to create a 3-D model	WhiteClouds provides a full service end-to-end solution from DICOM to 3-D print in your hands within a few days. Vendor differentiates itself with quality, accuracy and speed of delivery. Models are detailed with color and anatomical accuracy. After segmenation, vendor performs an engineering and functionality design to ensure the highest presentation and usability for the medical team and patient	
	Offers 3-D printing solutions as a monthly subscription. It is easily accessible by existing TeraRecon users or by new users via cloud access	Software available through direct purchase or subscription. Printing quoted per project	Single-project	Single-project
	Can do both	Vitrea can export for local printing and send files to Stratasys Direct printing services	100 percent outsourced, just submit and wait for model to arrive	100 percent outsourced, just submit and wait for model to arrive
	Can use a zero-footprint cloud approach or a locally hosted software deployment	Sending files to Stratasys Direct printing services may req an additional download	No	No
	Yes to both. Software specifically designed for -D advance post-processing used across the globe and are 510(k) compliant	Yes, segmentation tools and STL creation are 510(k) cleared and optimized	N/A	N/A
	Can do both	Locally	Cloud	Cloud
	DICOM	DICOM and STL	N/A	N/A
	Can export the segmented/ready to print file as OBJ, STL, ZPR, 3MF, FBX	STL	DICOM or STL, OBJ, VRML, WRL, FBX, PLY, 3MF	DICOM or STL, OBJ, VRML, WRL, FBX, PLY, 3MF
	Yes	Depends on the printer	Yes	Yes
	Our platform has no limit to file size, some printers require maximum file size	No	No	No
	iNtuition users subscribed to this service can use rt click menu option to save fully segmented dataset and export to the configured DICOM node to print	Secure web transmission used for connecting to Stratasys Direct	Drag-and-drop to a secure webpage	Drag-and-drop to a secure webpage
	Yes	Yes	Yes	Yes
	Physical model is in your hands within 72 hrs	Offers rush and standard service. Rush can be shipped in three days	Physical model is in your hands within 72 hrs	Physical model is in your hands within 120 hrs
	Purchase print credits, which are consumed by the physical size of the model	Based on volume, material and finish	Pricing based on the physical size of the model	Pricing based on the physical size of the model
	Customer designates checkpoints for verification of the print object	Yes	Yes	Yes
	Sandstone, binder jetting full-color gypsum. Transparent or rubber uses material jetting UV-cured resin	N/A	Binder-jetting full-color gypsum	Material jetting UV-cured resin
	N/A	N/A	N/A	N/A
	100 microns sandstone. 16 microns transparent or rubber-like	N/A	100 microns	16 microns
	1 hr sandstone. 2 hrs ransparent or rubber-like	N/A	1 hr	2 hrs
	Sandstone 20 x 15 x 9. Transparent or rubber-like 19 x 15 x 8	N/A	20 x 15 x 9 inches	19 x 15 x 8 inches
	Sandstone 0.005 inch per 2 inches. Transparent or rubber-like models 200 microns per 5 inches	N/A	0.005 inch per 2 inches	200 microns per 5 inches
	Slight variation in color and geometry is possible from print-to-print for sandstone. Very repeatable for transparent or rubber-like models	N/A	Slight variation in color is possible from print-to-print	Very repeatable
	Gypsum for sandstone. Plastic, digital ABS, rubber-like, polypropylene-like for transparent or rubber-like models	N/A	Gypsum	Plastic, digital ABS, rubber-like, polypropylene-like
	Both on sandstone. Simple colors on transparent or rubber-like models	Yes	Both	Simple colors
	Yes	Yes	No	Yes
	STL, OBJ, VRML, WRL, FBX, PLY, 3MF	STL	STL, OBJ, VRML, WRL, FBX, PLY, 3MF	STL, OBJ, VRML, WRL, FBX, PLY, 3MF
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CASE STUDY

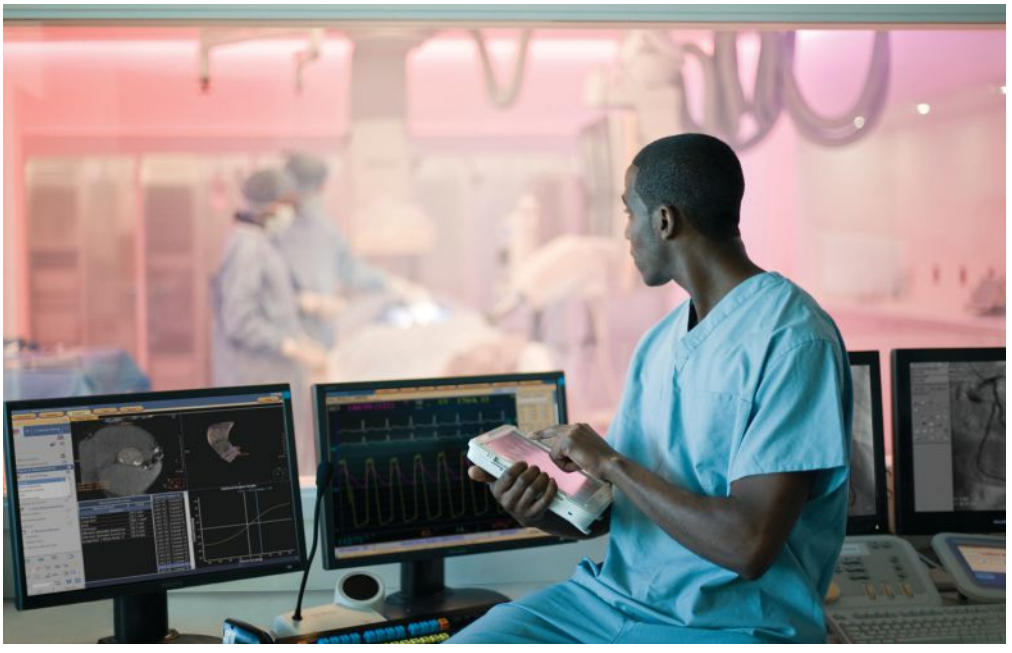
Sponsored by Philips Healthcare

TAVI Planning Goes High-tech to Boost Workflow at Amery Medical Academy

As medicine and technology evolve, results emerge. Such is the case with an innovative software application that offers comprehensive solutions for addressing both the common and complex challenges faced by radiologists, interventional cardiologists and cardiologists. A team of experts at Amery Medical Academy is working with Philips Healthcare to help physicians maximize the IntelliSpace Portal 9.0 software's functionality and improve patient care. From the interventional suite to the C-suite, the collaboration between developers, trainers and users of the technology is boosting operational, clinical and financial efficiencies for Amery.

Based in Irvine, Calif., with courses offered on both coasts, Amery Medical Academy is a comprehensive Level 1, 2 and 3 cardiac computed tomography (CT) training course, considered one of the most intensive in the country and endorsed by the Society of Cardiovascular Computed Tomography (SCCT). Among its team of qualified coronary and peripheral vascular CT instructors is Matthew J. Budoff, M.D., FACC, FAHA, FSCCT, who serves as Amery Medical's advisory board chairman. Budoff is a professor of medicine at the David Geffen School of Medicine at UCLA, and director of cardiac CT angiography (CTA) at the Los Angeles Biomedical Research Center at Harbor-UCLA Medical Center. In his practice and through his work at Amery Medical Academy, Budoff has been utilizing IntelliSpace for the past several years and instructed hundreds of physicians on its use.

"For us, this application has provided a robust solution for a vast array of cardiac imaging demands," said Budoff. Physicians rely on it for quality interpretation and its many diagnostic advantages, he added, and they appreciate its usefulness as a remote portal, allowing physicians to access the images from virtually anywhere and be able to interpret those studies.



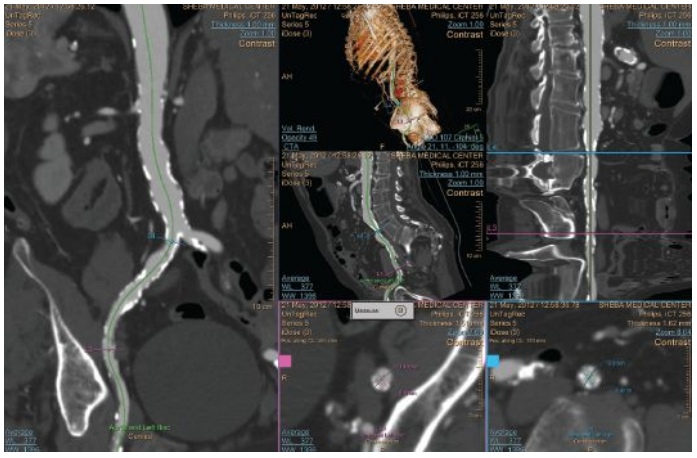
Amery Medical Academy worked with Philips to develop its CT transcatheter aortic valve planning software.

Clinical and Workflow Benefits of Application

The intuitive, comprehensive IntelliSpace Portal workstation helps clinicians visualize, diagnose, measure disease state and communicate across modalities with one automated and guided workflow. The noninvasive, post-processing application provides a 3-D model-based automatic segmentation of the aortic valve and aortic arch. Physicians trained on IntelliSpace Portal at Amery Medical have experienced a range of benefits in cardiac care. Chief among them are its flexibility, easy access to data and dramatic time savings. Data can be accessed from anywhere, and the portal allows physicians to save bookmarks and share results with referring physicians and interventional cardiologists; turnaround time is reduced when compared to manual measurements. The software also offers faster scanning-to-reporting time, improved reproducibility and greater specificity in measurements.

When asked to address the portal's diagnostic benefits, Budoff said he uses it for a large number of different clinical applications, including aortic valve replacement surgery, coronary and cardiac CTA, aortic imaging, and more. "From a cardiovascular standpoint, we find it to be quite robust. Everything from perfusion imaging to valve replacement, ejection fraction analysis, it's a one-stop shop for all of our CT-related needs," said Budoff. "The software loads the images quickly, allows for great image quality and easy access, and we can quickly get our 3-D reconstructions done to analyze the images."

The CT TAVR Planning offers measurements of relevant heart structures for TAVR (transcatheter aortic valve replacement) device sizing. It also provides a reasonable starting angle for C-arm position in the cath lab for the interventional team performing the procedure. Amery Medical appreciates the precision analysis and workflow efficiency tools, and being able to turn almost any PC that meets minimal requirements into a workstation. "We find [it] quite impactful," Budoff said. "We have, with our interactions with structural heart disease colleagues, appreciated the images and analyses — fast reconstruction times, adjustments to measurements and angles in the cardiac environment."



CT angiography plays a key role in TAVR, so Philips has integrated its planning and procedural guidance software.

Broad-Based Advantages to Use

The training on IntelliSpace Portal at Amery Medical brings about numerous advantages that span the cardiac landscape for physicians. "When we think about the utility of a better applications package and platform for shared images, this is most useful in the more advanced, challenging cases," said Budoff.

> "This application has provided a robust solution for a vast array of cardiac imaging demands."
>
> — *Matt Budoff, M.D., FACC, FAHA, FSCCT*

"This includes perfusion, TAVR and other structural heart cases and coronary arteries."

Whether physicians are looking at more advanced cardiovascular cases or serial studies to identify subtle changes over time, the robust programming offered by IntelliSpace enables them to do measurements, comparisons and further analyses. "It really presents a broad application. So when we want to collaborate with other doctors or get second opinions on certain challenging cases, or share our results with our referring doctors, it's quite easy. We can bring up our saved states and be able to show our clinical cases at that point, making it quite valuable in improving patient care," said Budoff.

According to Mike Allen, CEO of Amery Medical Academy, the CT TAVR Planning application is most beneficial in complex cases of aortic stenosis requiring surgical valve replacement. These complex cases often consume disproportionate amounts of time and expense for the physicians, hospitals and patients. As such, the time saved with easy access across departments is a critical advantage appreciated by clinicians, executives and patients.

Allen was an early believer in the vision enabled by IntelliSpace Portal. "First and foremost, what we teach in the classroom is completely applicable to the real-world cardiac environment," said Allen. Beyond clinical value for the team and patient, Allen said the cardiac package offers wide-ranging and positive impact at all levels, including addressing key concerns for the C-suite. "Bottom line is that this application allows for a highly efficient tool to run metrics, company performance indicators and equipment utilization to help executives make day-to-day decisions," he said.

"When we speak of CT TAVR planning and heart disease projects, we are getting positive feedback that it helps improve patient care," added George Jurdak, Philips Healthcare's senior marketing manager for enterprise imaging Informatics in North America. "Working with the Amery Medical Academy team and Dr. Budoff has been a pleasure, and this is an example of the collaboration physicians can appreciate when integrating technology and teamwork for patient benefit.

At the intersection of technology and cardiac care, collaboration is key. According to Budoff, Amery Medical Academy looks forward to expanding its training and conducting clinical studies with the IntelliSpace Portal 9.0 workstation and CT TAVR Planning application. "Going forward, we are hoping to be able to quantify some of the metrics, showing the cost and time savings, the accuracy of the different measurements, so that doctors are confident that the benefits of the portal can be validated in a definitive way," he said.

With an eye toward further strengthening clinical integration and improving clinical outcomes, the training offered by Amery is a critical cog in the wheel that is driving new technologies into clinical use.

For more information:
www.philips.com/intellispaceportal

Recent Advances in Cardiac Nuclear Imaging Technology

CZT SPECT cameras, new stress-only protocols and emphasis on lowering dose top the list

By Dave Fornell

Cardiac nuclear myocardial perfusion imaging (MPI) has been a mature area of imaging for years, but recently has started a transformation with new technologies, protocols and applications. This is partly due to the availability of technologies, concerns about dose, competition, reimbursement and unease over isotope availability.

"We have been practicing nuclear cardiology since the late 1970s, so people think of it as a stable and well-established modality, but if you look at the past five years, there has been a tremendous amount of advance in nuclear cardiological techniques," said Prem Soman, M.D., director of nuclear cardiology at the Heart and Vascular Institute, University of Pittsburgh, and president of the American Society of Nuclear Cardiology (ASNC). "We have a whole new generation of SPECT cameras, we are expanding our imaging applications, we have made great strides in reducing our radiation dose, and PET is becoming more widely used, so I am very excited about the future of cardiac nuclear imaging."

"If you look at the past five years, there has been a tremendous amount of advance in nuclear cardiological techniques."

— Prem Soman, M.D., director of nuclear cardiology, Heart and Vascular Institute, University of Pittsburgh

He said there have been advances in both imaging modalities used for nuclear cardiology, positron emission tomography (PET) and single photon emission computed tomography (SPECT). This includes new, more sensitive SPECT detector technology, new imaging systems and new ways to use the imaging to better quantify perfusion.

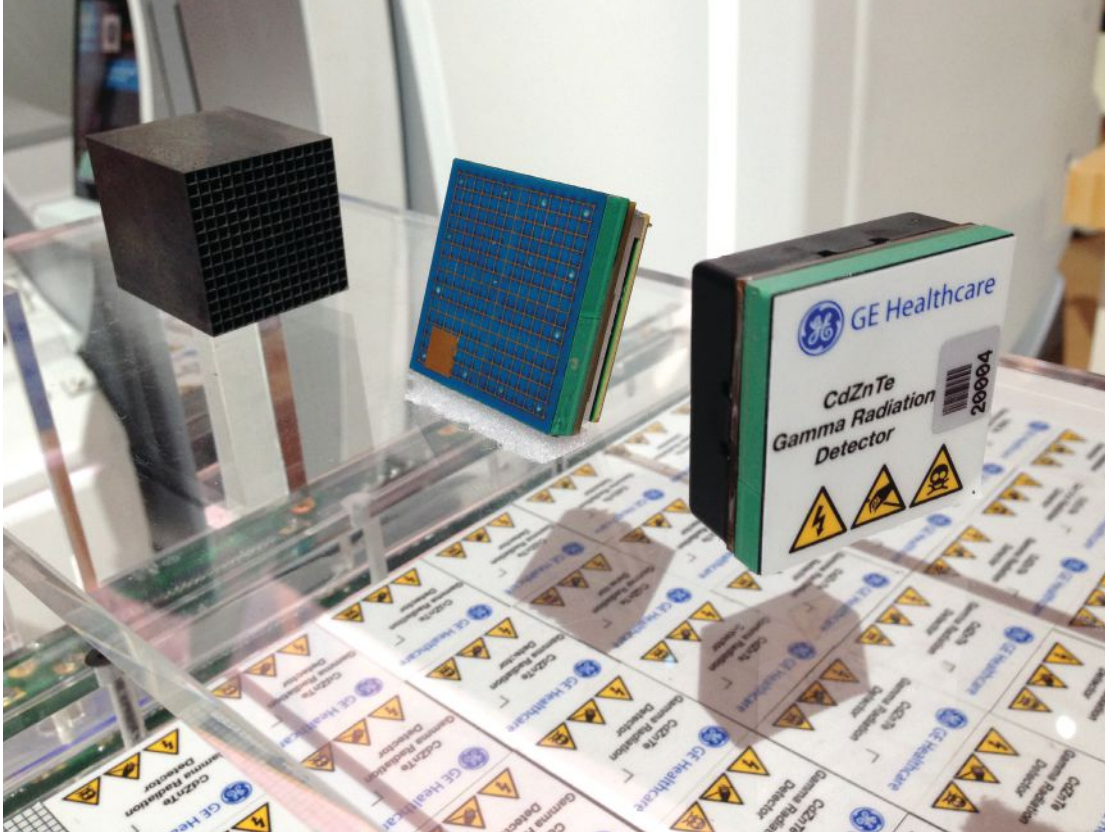
New SPECT Cameras Can Lower Dose, Speed Imaging

The traditional analog SPECT gamma cameras use sodium-iodide scintillation crystals, and the new cadmium zinc telluride (CZT) SPECT detectors are based on solid state technology. The new CZT detectors allow for a much smaller footprint for the imaging system, including for office-based imaging or very small imaging suites, Soman explained. The CZT cameras also do not have to rotate around the patient, which makes imaging much easier and efficient than the older technology. The design of the collimators on the newer cameras also offers greater sensitivity. These advantages allow SPECT to be used in new ways, including shorter exams, lower radiation doses or for new techniques like absolute blood flow quantification.

CZT detectors can enable either lower dose or faster imaging speeds. Using normal radioisotope doses, these cameras can image much faster than conventional cameras, reducing scan times or the radioisotope dose exposure, explained Randy Thompson, M.D., attending cardiologist, St. Luke's Mid-America Heart Institute, Kansas City. However, he said some centers might not be able to take full advantage of the efficiency for faster scans because there are other steps involved in the imaging process that usually cause bottlenecks. "The camera imaging is not really rate limiting to that level," he explained.

Thompson said St. Luke's Mid-America Heart Institute uses the radiation dose reduction aspect of the newer cameras. "We have embraced a very low-dose protocol," he said. "Sometimes it means imaging longer or even repeating images, but radiation dose reduction has been dramatic."

ASNC recommends half of all patients scanned using SPECT should have a dose of 9 mSv or less of radiation. Thompson



A display of CZT SPECT gamma camera detectors at RSNA 2016. These detectors are more sensitive than those used in older cameras, allowing for faster scans or lower radiation dose.

said for comparison, 11 mSv is a more standard dose for SPECT. "We now have it down where half of our patients have a median dose of under 3 mSv," he said.

To achieve these lower doses, most patients receive stress-only, low-dose exams. "Some of the patients we image this way have a tenth of the dose previously used in the standard approach," Thompson explained. "If you have enough of those patients in your laboratory, of course the average/median dose comes down a lot. Our average dose in 2009 was about 18 mSv, and now our median dose is around 7.5 mSv, and our mean dose is under 3 mSv."

However, Thompson said low-dose protocols do not work for all patients. He explained it is difficult to get good image quality with obese patients at lower doses. Some patients might also be better served with faster imaging, including those who cannot hold still for long periods of time because of back problems.

Soman said the old standard dose for SPECT was about 8-10 millicurie (mCi) of Technetium (Tc-99m) for a resting study and about 24-30 mCi for a stress study. Today, he explained his lab uses a 5 mCi rest and a 15 mCi stress study, resulting in a total body dose of about 6 mSv of radiation. He explained the new ASNC guidelines calling for 9 mSv or less of dose is easily achievable using the new CZT cameras. "You can go down much lower, and there are studies looking at stress-first imaging with only 3-5 mCi of dose. We use that protocol sometimes and the average dose is less than 2 mSv," he said.

Thompson pointed out lower dose protocols will take time to see wide adoption. The proliferation of the new CZT camera technology into the field also takes time and money, as centers slowly replace older equipment over the course of several years.

"The CZT images do look a little different, and there is a learning curve in reading them," Soman said. "But, it is not prohibitive and anyone can learn how to read on a CZT system."

Any centers thinking of replacing older SPECT cameras should consider CZT systems, Soman said. "The efficiencies of the camera, the image quality and the ability to do other things in the future like flow qualification are very good reasons to go with CZT detector technology."

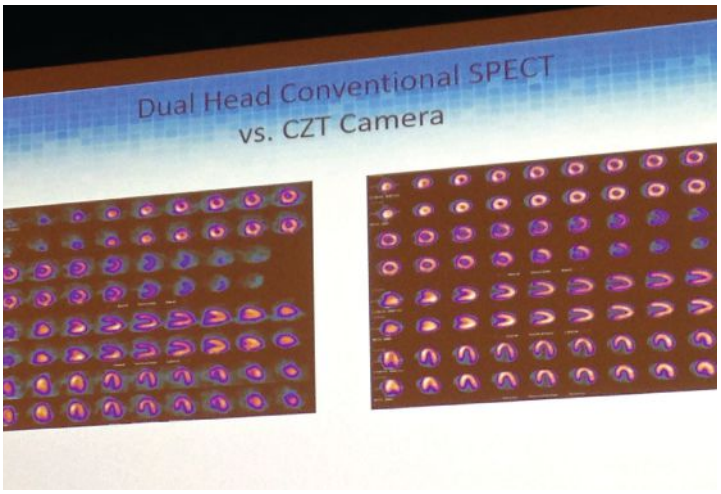
While the newer CZT scanners offer advantages, Thompson said there are some advantages of the older SPECT scanner technology. This includes the ability to fit extremely obese patients, which may not fit into the smaller confines of the CZT scanners. These cameras also are less expensive. He said a refurbished SPECT scanner may cost half as much as a new CZT scanner, which will allow some smaller centers to still offer nuclear perfusion imaging at an affordable price. However, he said the future of SPECT will be with the newer CZT cameras.

New CZT SPECT detectors have had a big impact on cardiac nuclear imaging, said David Wolinsky, M.D., director of nuclear cardiology at Cleveland Clinic Florida and ASNC past-president. He said CZT can offer faster cameras, better photon counts and better images. "For older patients you can't lie down for a long time, you can image them much quicker, and for the younger patients where you don't want to give them a lot of radiation dose, you can given them a lower dose," he said.

PET vs. SPECT

"You always want to exercise people on a treadmill if you can and then they can go under a SPECT camera," Wolinsky said. "You also can get very good adjunct information from an exercise stress test." With PET, the half-life of the radioisotopes used is very short, so PET imaging only allows for pharmacological stress test imaging, which he said is not ideal. But, for less optimal patients who have issues exercising or who may be high risk, pharmacologic stress is fine to use and they may be better suited to PET.

There are also reimbursement issues regarding PET that play a big role in medical decision-making. He said SPECT is universally reimbursable and it is a lot harder to get a PET scan done. "SPECT commands more than 90 percent of the nuclear cardiology market," Wolinsky said. "So to be able to add better SPECT



A comparison of image quality between traditional SPECT (left) and new CZT SPECT detector imaging (right).

cameras to allow us to do the same thing we have always done but get better results is really very important."

For larger institutions and research centers that are imaging larger numbers of high-risk patients, or if they want to image for sarcoid or inflammation, Wolinsky said PET offers a good option.

He said there have been concerns about SPECT radioisotope availability in the past. This prompted new protocols to image using less isotope, which also reduced patient radiation exposure. This includes stress-first or stress-only imaging.

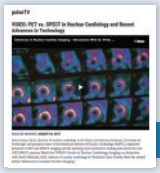
Unlike SPECT, PET does offer some new ways to use nuclear imaging beyond MPI. Soman said this includes a big push with PET to diagnose sarcoidosis, amyloidosis, inflammation and dyssynchrony assessment.

Thompson said some of the newer PET assessments are gaining momentum. He cited a new category III CPT code for a PET myocardial perfusion imaging add-on for absolute quantitation of myocardial blood flow. This goes into effect Jan. 1, 2018. The assessment can help reduce the possibility of false negative exams and improve the accuracy of PET MPI studies. A category III code does not mean it will be reimbursed, but is seen as a first step. Thompson said it allows providers to speak with payors to see if the code can be made reimbursable.

Reasons PET Has Not Replaced SPECT

There was a lot of discussion more than 10 years ago when positron emission tomography (PET) first entered the market that it might replace SPECT as the dominant cardiac nuclear imaging technology. However, despite several advantages of PET over SPECT, including improved image quality, PET technology uptake has been very slow. In the intervening years, SPECT technologies have also improved. This includes use of both CZT detectors and iterative reconstruction software to help enhance images and reduce dose.

Additional Cardiac Imaging Resources



Watch the VIDEO PET vs. SPECT in Nuclear Cardiology and Recent Advances in Technology with Prem Soman, M.D.

http://bit.ly/2xRwfu0

Watch the VIDEO Implementing CZT SPECT Cardiac Protocols to Reduce Radiation Dose with Randy Thompson, M.D.

http://bit.ly/2yyCwaO

Watch the VIDEO Trends in Nuclear Cardiology Imaging with David Wolinsky, M.D.

http://bit.ly/2ydPq22

"PET has some very distinct advantages, but SPECT is much more widely available," Soman said. "But, there are some big differences in the delivery of the tracer."

For PET centers that use ammonia as a tracer, the cyclotron that produces the isotope needs to be very close to where the imaging is done due to its very short half-life. With rubidium, an Rb-82 generator is used to create a 75-second half-life tracer in the imaging room. With SPECT, Soman said imaging centers can get a unit dose with much longer half-lives delivered from a remote production facility very easily.

"I think this is one of the reasons why PET technology has taken longer than we expected to implement," Soman explained. "But, there has been a rapid increase over the past few years for centers doing cardiac PET."

Combined PET-CT and SPECT-CT Scanners

Much of nuclear imaging is done on smaller SPECT cameras, but the large medical imaging system vendors have pushed the adoption of newer hybrid imaging systems that combine nuclear imaging with a computed tomography (CT) scanner in one gantry. This combination allows for CT attenuation correct on the nuclear images to produce more accurate scans. It also adds CT anatomical image overlays to better visualize the coronary anatomy and better pinpoint where blockages causing perfusion defects are located. Lastly, the CT offers the ability to perform a CT calcium scoring exam of the coronary arteries.

"I think CT adds a lot," Wolinsky said. "The ability to add calcium scoring is an important piece of information, it adds tremendous value. It is very good for primary prevention and risk identification and adds to the prognostic value of nuclear scans, whether they are PET or SPECT. Also, knowing the calcium score helps you interpret the nuclear scan and helps add prognosis value to the imaging. I think if anybody had a choice, they would want to get a SPECT-CT or a PET-CT." DAIC

HeartWare HVAD System Approved for Destination Therapy

Medtronic received FDA clearance for its HeartWare HVAD System as a destination therapy for patients with advanced heart failure who are not candidates for heart transplants. The left ventricular assist device (LVAD) helps the heart pump and increases the amount of blood that flows through the body. The ENDURANCE trials of nearly 1,000 patients supported the safety and effectiveness in patients with advanced, refractory LV heart failure as a bridge to transplantation, or myocardial recovery, or as destination therapy (DT) in patients for whom subsequent transplantation is not planned.

Medtronic | www.medtronic.com

FDA Clears Impella RP for Right Heart Failure

Abiomed Inc. received U.S. Food and Drug Administration (FDA) pre-market approval (PMA) for the Impella RP heart pump. The device is the only percutaneous temporary ventricular support device for right heart failure. It is is indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area ≥1.5 m^2, who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant or open-heart surgery.

Abiomed | www.abiomed.com

New Hemodynamic Monitoring System Enters U.S. Market

Fysicon was granted FDA 510(k) clearance for its QMAPP hemodynamic monitoring system. The QMAPP amplifier is the size of a ream of A4 paper, features all available vital patient monitoring parameters and has up to 32 bipolar intra-cardiac channels for electrophysiology procedures. The system is fanless, which minimizes the risk of cross-contamination. The hardware design ensures a high level of usability. The unit is connected via one single cable to the floor base of the X-ray table and with a clamp mounted to the DIN-Rail. The acquired vitals and reporting entries can easily be exchanged with any electronic medical record (EMR) system using standard protocols like DICOM and HL7.

Fysicon | www.fysicon.com

TrueFusion Structural Heart Feature Integrates Echo, Angio

Siemens Healthineers gained FDA clearance for TrueFusion, which integrates ultrasound and angiography to guide cardiac teams when administering treatment for structural heart disease. Available on the new Release 5.0 of the Acuson SC2000 cardiovascular ultrasound system, it is designed to maximize not only interventional cardiology procedures, but also routine diagnosis and follow-up of patients with structural heart disease, offering real-time echo and fluoroscopy imaging in one view.

Siemens | www.usa.healthcare.siemens.com

HeartMate 3 Left Ventricular Assist System Enters Market

Abbott launched its Full MagLev HeartMate 3 Left Ventricular Assist System. The system provides a new option for physicians managing advanced heart failure patients in need of short-term hemodynamic support (bridge-to-transplant or bridge to myocardial recovery). The system also provides patients living with their device new benefits that embody the evolution of left ventricular assist device (LVAD) therapy, such as improved blood flow in a pump that uses full magnetic levitation to reduce trauma to blood passing through the system.

Abbott | www.abbott.com

Marijuana Has Three-Fold Risk of **Death From Hypertension**

Study also found that hypertension death risk increased with each additional year of marijuana use

Marijuana use is associated with a three-fold risk of death from hypertension, according to research published recently in the *European Journal of Preventive Cardiology*.

"Steps are being taken toward legalization and decriminalization of marijuana in the United States, and rates of recreational marijuana use may increase substantially as a result," said lead author Barbara A. Yankey, a Ph.D. student in the School of Public Health, Georgia State University, Atlanta. "However, there is little research on the impact of marijuana use on cardiovascular and cerebrovascular mortality."

In the absence of longitudinal data on marijuana use, the researchers designed a retrospective follow-up study of NHANES (National Health and Nutrition Examination Survey) participants aged 20 and above. In 2005–2006, participants were asked if they had ever used marijuana. Those who answered "yes" were considered marijuana users. Participants reported the age when they first tried marijuana and this was subtracted from their current age to calculate the duration of use.

Information on marijuana use was merged with mortality data in 2011 from the National Center for Health Statistics. The researchers estimated the associations of marijuana use, and duration of use, with death from hypertension, heart disease and cerebrovascular disease, controlling for cigarette use and demographic variables including sex, age and ethnicity. Death from hypertension included multiple causes such as primary hypertension and hypertensive renal disease.

Among a total of 1,213 participants, 34 percent used neither marijuana nor cigarettes, 21 percent used only marijuana, 20 percent used marijuana and smoked cigarettes, 16 percent used marijuana and were former smokers, 5 percent were former smokers and 4 percent only smoked cigarettes. The average duration of marijuana use was 11.5 years.

Marijuana users had a higher risk of dying from hypertension. Compared to nonusers, marijuana users had a 3.42-times higher risk of death from hypertension and a 1.04 times greater risk for each year of use. There was no association between marijuana use and death from heart disease or cerebrovascular disease.

A new study found marijuana users had a greater than three-fold risk of death from hypertension and the risk increased with each additional year of use.

"We found that marijuana users had a greater than threefold risk of death from hypertension and the risk increased with each additional year of use," Yankey said. He pointed out that there were limitations to the way marijuana use was estimated. For example, it cannot be certain that participants used marijuana continuously since they first tried it.

"Our results suggest a possible risk of hypertension mortality from marijuana use," she said. "This is not surprising since marijuana is known to have a number of effects on the cardiovascular system. Marijuana stimulates the sympathetic nervous system, leading to increases in heart rate, blood pressure and oxygen demand. Emergency rooms have reported cases of angina and heart attacks after marijuana use."

The authors stated that the cardiovascular risk associated with marijuana use may be greater than the cardiovascular risk already established for cigarette smoking. DAIC

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References
1. Abiomed Data on File, PROTECT II **2.** O'Neill W, et al. Circulation. 2012 Oct 2;126(14):1717-27

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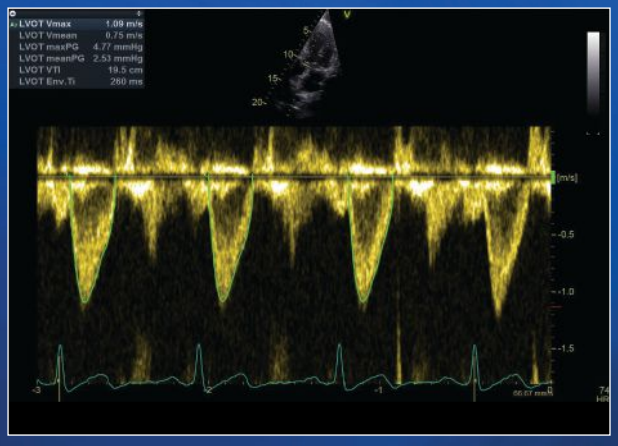
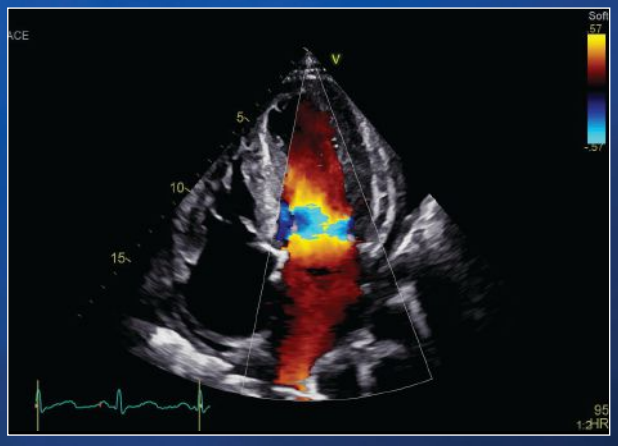


Achieve fast, consistent measurements: Cardiac Auto Doppler



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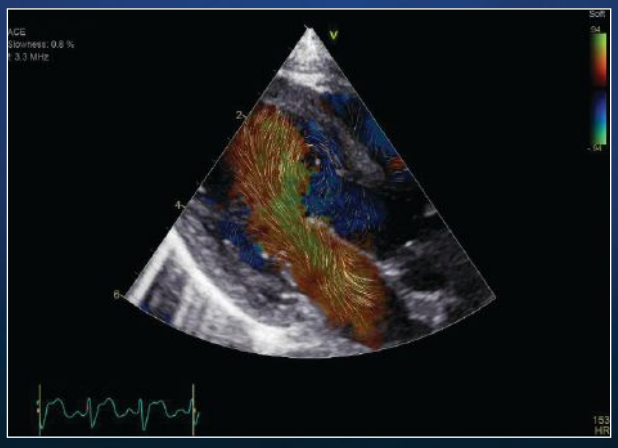
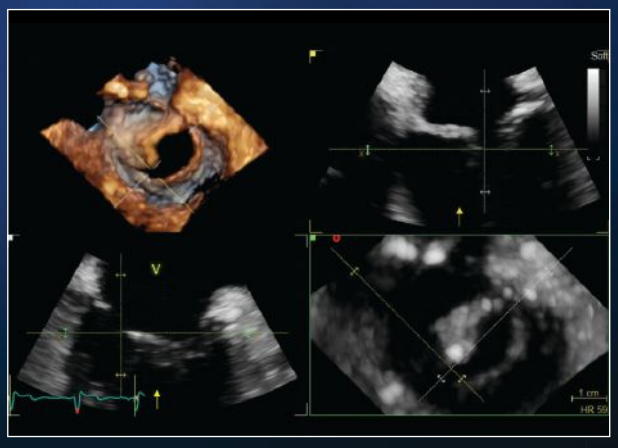


Quickly understand complex blood flow issues: Blood Speckle Imaging (BSI)



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